House of Commons

Health Committee

The Electronic Patient Record

Written evidence

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Evidence submitted by the Department of Health (EPR 01)

Executive Summary

The National Programme for IT in the NHS is already providing essential services to support patient care and the smooth running of the NHS, without which it could not now properly function. Installation of a modern, high speed, secure infrastructure and national network has been completed ahead of schedule and is daily supporting millions of business transactions in the NHS. Key systems have been successfully deployed on time and are benefiting patient care. Widespread coverage of Community Patient Administration Systems has been achieved where nothing existed before. Over half of hospitals now have digital X-rays and scans. At the heart of the National Programme is the NHS Care Records Service which will in due course provide a lifelong electronic personal health record for NHS patients in England.

The Summary Care Record will go live in early adopter sites in Spring 2007. Development of the more detailed care record continues. Safeguards for patients have been built in to protect confidential information, including controls they can choose to exercise themselves and advanced technological standards. The safeguards were designed following substantial research and consultation with patients and the public as well as the NHS and other interested parties.

Benefits will accrue to patients and the NHS from the introduction of modern IT systems and the supporting national network, enabling clinicians to share information about patients and with patients. Medical errors and harm to patients arising from inadequate information will be reduced; inefficiency and waste will be curbed and better information will be available to improve the understanding of health outcomes and needs.

We are developing electronic records with continuous input from patients/carers/citizens. We are taking great care to ensure that the public will be properly informed at key stages of what is happening to their personal health information and the choices they have to control access to it.

Full transformation to a digital NHS will be achieved in the next few years.

Patients have already begun to see the benefits provided by the NPfIT implementations:

- Patients are now able to choose an appointment at a time and location convenient to them.
- Patients benefit from a reduction in booking time which means their GP can focus on providing better care.
- Patients will no longer need to visit their GP to collect repeat prescriptions and can have them sent electronically to their chosen pharmacy.
- Doctors are able to make a quicker more efficient patient diagnosis using digital images and x-rays.
- Patients will no longer need to wait extended periods of time to receive their results and start treatment which is especially critical for conditions like cancer.
- There will be a reduction in safety incidents where the patient was allergic to the treatment given as a result of a missing or illegible referral letter.
- An increase in the accuracy of patient records meaning correspondence letters are sent to the right address.
- GPs will be able to begin diagnosis immediately as they will have the patient's historical medical record to hand.
- All parents of new born babies can be confident that their baby's personal information is available at the touch of a button anywhere ensuring doctors can provide the best care possible.
- By removing some of the unnecessary delays to patient care, the programme will offer patients a quicker discharge from hospital and better, safer overall care.

Managing Information About Patients

1. In a typical week, over six million people visit their GPs, 800,000 people are treated in hospital clinics, and thousands of operations are performed. This corresponds to around 3 million critical processes per day that need accurate patient and clinical information to be immediately available. The National Programme for IT is developing and implementing an overarching, secure information system, using multiple new and existing IT components, to enable important patient related information to be accessible where and when it is needed in the NHS Care Records Service (NHS CRS).

2. When supported fully by a single electronic records system, these 3 million critical processes will result in approximately 30 million transactions per day over a cohesive, robust and resilient infrastructure. An effective national information technology system is a central plank of NHS modernisation, essential to the Government's vision of plurality of provision within the NHS. The deployment of modern IT is essential to deliver the Government's vision of reform in the NHS and bring about greater quality, safety and

efficiency of patient care; the Choice agenda, and greater empowerment of patients, can only be fully realised with the adoption of nationally integrated systems. Today the NHS could not function without the systems which have been delivered by the National Programme for Information Technology since 2004.

3. A key part of the system which underpins the NHS Care Records Service (NHS CRS) is the National Network (N3) for the NHS. The Network (N3) is now integral to the daily running of the NHS, with the data equivalent of 24,000 copies of the Encyclopaedia Britannica sent over the high speed, secure network every day. Over 18,500 locations are now connected, providing the infrastructure to allow clinicians to securely access information on patients, including scans and images from any location, at any time. The network is the largest Virtual Private Network (VPN) in Europe and once completely deployed will be the largest in the world.

4. On a typical day in March 2007, the National Programme for IT already enables:

- 100,000 prescriptions to be transmitted electronically, reducing errors and inefficiencies. This represents around 10% of the total and is set to rise steeply in the coming months.
- 16,000 Choose and Book electronic bookings to be made, putting patients in charge of their care. 90% of GPs have made electronic bookings and 37% of all bookings are being made electronically.
- 1,200,000 queries to be processed on the patient demographic system, enabling letters to be posted to the correct address and patient information to be handled more efficiently.
- 540 new users to be registered for access to the NHS Care Record Service.
- 50,000 unique authenticated users to access the NHS Care Records Service.
- 200 new NHS secure email users to be registered.
- 109,000 NHSMail users, each of whom has an email address for life, to send 1 million secure emails, one third of which contain confidential patient information.
- 10 New National Network (N3) secure broadband connections to be installed.
- 8,800 GP practices (33,000 GPs) to use the Quality Management Analysis System to deliver better care to patients under the new GP contract.
- 1 million records to be added to the Secondary Uses Service.

In an organisation as large and diverse as the NHS, it is neither feasible nor affordable to undertake a wholesale replacement of existing IT systems. This puts a greater emphasis on standards, integration and compliance to enable interoperability between multiple IT systems. There have been 102 existing systems accredited for connection to NPfIT services to date, which are operating across over 10,000 locations with tens of thousands of users handling millions of transactions a week. The total cost of accreditation is estimated to be £6.3 million since 2004 of which £5.1 million has been allocated to Suppliers' resource costs. A Common Assurance Process (CAP) will be extended to cover all systems and improve their quality so that they may be connected. The first phase of CAP is already underway to support the Early Adopter sites. The National Programme is designed to promote the secure availability of information across the NHS to support patient care efficiently and safely.

The Case for an Electronic Patient Record

5. "People will, increasingly, expect an integrated system that looks after patients' needs providing an efficient hassle free service. Innovations such as the Electronic Health Record will fuel such expectations; patients are likely to be less accepting of requests for repetitive information or communication weaknesses"—Wanless interim report http://www.hm-treasury.gov.uk/media/44F/3F/wanless_chapters_7to8.pdf

Preventing medical error and harm to patients

6. There is hard evidence of the problems of using traditional paper records. The root cause of 27% of medication errors is poor information availability. 1,200 people die each year in England and Wales as a result of medication errors—*almost a third of the number killed on the roads in the same period*—costing the NHS £500 million a year.

7. There are many examples of medical error and the harm resulting to patients where traditional record keeping is at fault. Examples include:

- During the calendar year 2006 almost 1,700 patient safety incidents were reported to the National Patient Safety Agency where the patient was allergic to treatment given, over 900 where the patient suffered an adverse drug reaction, and over 800 where the primary cause was put down to a missing, inadequate or illegible referral letter, with around 29,000 where this was a factor. The introduction of the NHS Care Records Service (NHS CRS) will help reduce these errors and prevent harm to patients.
- Up to 5,000 patient procedures are cancelled each year due to lost X-rays and patients are often subjected to harmful repeat X-rays as a result. The introduction of Picture Archiving and Communications Systems (PACS) under the National Programme for IT in the NHS will help to substantially reduce this.

— Similarly, when fully implemented and integrated with the Summary Care Record, the Electronic Prescriptions Service (EPS) should enable up to 3,000 adverse drug reactions to be avoided, with a saving of some 1,000 lives and around 25,000 bed days each year.

8. Currently, electronic records range from a detailed general record capturing clinical detail at the primary care surgery, through specialist clinical databases for particular areas of care, to the more general patient administration record created and held at the acute and secondary care hospital. In the main, the various classes of electronic health records are maintained separately and with no electronic linkage between them. The NHS did not until recently have a single, reliable, definitive means of recording and sharing up to date patient demographic information.

9. Instead of having individual health records in all the different places patients receive care, NHS organisations which normally work together will in future be able to share a Detailed Care Record for each patient. Detailed Care Records will be developed over several years and patients will also have a Summary Care Record, available to those treating the patient anywhere in England. At first, the Summary Care Record will contain basic information such as allergies, adverse reactions to medications, and current prescriptions. In due course more information will be added, and discussions are ongoing about the content of these records.

10. The absence of up to date information about patients can have damaging consequences. "*Providing clinicians with simultaneous access to accurate patient records, quality-assured knowledge and details of local care pathways is key to ensuring safe and effective healthcare in the future. With changes in patterns of work and increased patient mobility . . . the Electronic Health Record, has much to offer patients in a healthcare system in which they may be the only constant. (CMO July 2006 report." "Good doctors, safer patients").* Some examples are provided below (see paragraphs 8–11).

Shared care needs shared information

11. Modern healthcare is delivered by teams of healthcare professionals who need to share essential information to provide safe, effective care. Locally held records depend on local filing, archiving and retrieval processes, all of which are subject to human error and can prevent appropriate and timely sharing of information. Locally held records can be lost or inaccessible when they are needed, and cannot easily reflect different confidentiality ratings for different parts of the record to meet individual patient's wishes. Lost medical notes, missing information about appointments and concerns about lack of information at times of medical emergency are frequently cited as a problem (source: BMA discussion paper 2005 "Confidentiality as part of a bigger picture"). Typically patients have different medical records in existence in different institutions that are difficult to coordinate, and often are not shared. Patients are often repeatedly asked for the same information.

12. Shared record systems, such as those being delivered by the National Programme, provide more complete data and lead to the delivery of better patient care. Evidence from environments where they are already routinely available and used shows that the number of failed appointments falls because hospitals have accurate and up-to-date addresses for patients. The number of duplicate diagnostic procedures and tests reduces so that patients do not have to undergo repeat X-rays, reducing their risk of excess radiation. Importantly, patients benefit from knowing their records are up-to-date.

13. Continuing changes to the ways in which care is provided in the NHS—the restructuring of evening and weekend arrangements in primary care, and the growing contribution of the private and voluntary sector—will only underline the shortcomings of traditional approaches to records keeping and management. Staff will increasingly work as members of a multi-disciplinary team. The traditional divisions between primary and secondary care and specialty based practice are being challenged. Joint working between health and social care providers will continue. The future is likely to see professionals delivering care to specific patient groups rather than in specific health care settings. All this will have a striking impact on the premium placed on the availability of reliable information at the point of contact with the patient, irrespective of time, place, or care setting.

Reducing inefficiency and waste

14. The risk to life and wellbeing is compounded by inefficiency and waste resulting from the reliance on traditional record systems. Up to 10% of appointments are currently not attended, leading to re-scheduling. Similarly, traditional local records for patients are manually maintained and stored, costing the NHS £120 million per year to create, maintain and store. Fragmented and partially integrated systems are the norm—over 8,500 different systems exist, none of which is secure enough to transfer patient information.

15. Major examples of areas in which the introduction of modern IT systems and support can help reduce inefficiency and waste include:

— In 2005–06 the NHS Litigation Authority paid out some £560 million in settlement of clinical negligence claims, much of it, as in previous years, on an uncontested basis because records that might have made it possible to defend claims could not be produced locally.

— The introduction of Picture Archiving and Communications Systems (PACS) can help a typical hospital save tens of thousands of staff hours a year previously required to locate and move films around the site and elsewhere in the NHS, and hundreds of thousands of pounds on the cost of X-ray films and processing, and by releasing storage space for better alternative uses. There is also significant potential for much greater savings arising from service redesign, reduced waiting times, and better, faster diagnosis.

— The Electronic Prescriptions Service (EPS) will eliminate the need for the prescription details to be typed manually from hand-written prescriptions by the dispenser, allowing them more time with patients. It will also eliminate the 2 million per year prescriptions which are returned to pharmacies for reimbursement queries, and the need for patients to visit a GP for a repeat prescription. As 70% of all prescriptions are repeat prescriptions, this could result in a reduction of up to 1 million patient visits a year.

Empowering patients

16. The creation of the Care Record Service will put control of care records into people's own hands. Patients will be able to view and review their summary record via HealthSpace. It will enable patient choice of treatment or clinician and provide access to Choose and Book. It will allow patients to record their preferences for care and to identify errors in their record. It will enable them to choose how their records are shared.We continually involve patients/carers/citizens in the development of the NHS Care Record Service to ensure it meets their needs. They are involved through research and consultation. They sit on project boards and reference panels. They form advisory committees and attend workshops. They read and comment on materials we produce for the public.

Improved understanding of health outcomes and needs

17. Information is essential for providing care but is also important for public health, research, and to improve the quality of care processes and management. Data can be retrospectively examined to identify practice patterns, incidence of disease or complications, and the like. It can also be used to target specific practitioner behaviours where there is scope for improvement.

18. The NHS Care Records Service (NHS CRS) also provides information for these "secondary" purposes as part of a coherent strategy to improve the quality of healthcare delivered by the NHS in England. The current approach to supporting these secondary purposes is fragmented, variable and historically dependent upon access to confidential identifiable patient information, a situation which the Department of Health has been working with the Patient Information Advisory Group to improve. The NHS CRS will provide access to rich but anonymised or coded information and unprecedented tools for utilising this information to analyse outcomes, trends and performance to support improved future care.

Specific Issues Raised by the Committee

Question 1. *What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems*

Clinical Information

19. The recording of clinical information is a matter for professional regulation and will also depend in part on policies and protocols in local NHS organisations. Doctors are required by the General Medical Council to keep clear, accurate, legible and contemporaneous patient records which report the relevant clinical findings, the decisions made, the information given to patients, and any drugs or other treatment prescribed, and which serve to keep colleagues well informed when sharing the care of patients. Other health professionals have similar obligations.

Demographic Information

20. Patients' demographic details are already held in the Personal Demographics Service (PDS), a key component of the NHS Care Records Service. It is estimated that in the region of 3.5 million patients per annum change GP Practices and for an increasingly mobile population, and with an ever more diverse range of NHS healthcare providers, the PDS provides a consistent accurate source of demographic information. This includes items such as:

— name
— address
— date of birth
— NHS number
— current GP.

21. Currently, in a typical week, 6.5 million messages are processed by the demographics service which is accessed on a typical NHS day by 50,000 authenticated unique users. The total number of queries to date now exceeds 230 million. As a result of the central personal demographics database some three quarters of a million letters per year are now correctly addressed. The introduction of the Personal Demographic Service (PDS) at University Hospital Birmingham has seen a reduction from 3% of misdirected letters down to 0.44%, improving overall accuracy rates for patient correspondence to 99.56%.

22. Access to the Personal Demographics Service (PDS) will reduce clinical risks arising from a failure to match patients with their clinical record, and help minimise cases of correspondence and documents being misdirected. Currently, some trusts send tens of thousands of misdirected items of mail a year, and nationally the figure runs into millions of items. Early evidence from one trust has shown a six-fold reduction in misdirected mail addressed using data held in the Personal Demographics Service (PDS), with a saving in postal and staff-related costs that would translate into many millions of pounds nationally per year.

23. People registered with the NHS will not be able to prevent their basic demographic and contact details from being held within the NHS CRS. The NHS has maintained registers of its service users from the earliest days of its existence and for a variety of reasons to support the delivery of healthcare. Regulations require the NHS to keep a record of which GP practice each person is registered with and reasons of efficiency and probity require this to be held centrally (eg to prevent multiple GPs from being paid for the same patient and to ensure that the correct commissioning body meets the cost of care provided). A register is also needed to enable the Secretary of State to meet legal obligations to provide healthcare, free at the point of contact, for those patients who are ordinarily resident in England.

24. However, whilst it is not practicable to give patients choice about whether their demographic details will be held in the system, safeguards have been built into the PDS which allow an individual's contact details to be hidden from NHS staff if they request this level of protection. Access to the Personal Demographics Service (PDS) by NHS staff is restricted to those issued with a smartcard and an appropriate role.

Summary Care Record

25. The Summary Care Record forms the national element of the NHS Care Record Service and will provide authorised healthcare professionals with access to key clinical information about a patient anywhere at any time. Piloting of the Summary Care Record, part of the NHS Care Records Service (NHS CRS), in "early adopter sites" will begin from Spring 2007. The ready availability of information about patients in the Summary Care Record will help prevent medication errors which cause 1200 unnecessary deaths a year in England and Wales—*almost a third of the number killed on the roads in the same period*—and a human tragedy costing the NHS £500 million a year. It will also help reduce unnecessary admissions to hospital particularly of older people The Summary Care Record will be created by copying data currently held within GP systems with the agreement of the GP Practices concerned. At first, the Summary Care Record will contain only basic information such as known allergies, known adverse reactions to medications and other substances (eg, peanuts) acute prescriptions in the past six months and repeat prescriptions that are not more than six months beyond their review date.

26. In due course more information will be added about current health conditions and treatment. "Adverse drug reactions (ADRs) continue to represent a considerable burden on the NHS, accounting for one in 16 hospital admissions and 4% of the hospital bed capacity. Most ADRs were predictable from the known pharmacology of the drugs and many represented known interactions and are therefore likely to be preventable. Over 2% of patients admitted with an adverse drug reaction died, suggesting that adverse effects may be responsible for the death of 0.15% of all patients admitted" (Source: BMJ abstract of research at two general hospitals in Merseyside—BMJ 2004; 329:15–19). Discussions are under way with representatives of the medical professions, patients and the public about the final scope and implementation of the Summary Care Record. Experience in the early adopter sites will be thoroughly evaluated before wider roll-out of the Summary Care Record.

27. Individuals who have concerns can choose not to have a Summary Care Record created for them. They will be advised to inform their GP of their views and to request that a note be made of their concerns and the choice they have made. The GP practice may ask the patient to sign a form indicating that they understand and accept that it may not be possible for the NHS to provide them with the same care as others receive in circumstances where the Summary Care Record will enable improved care. They can alternatively choose to have a Summary Care created but not accessible to anyone but themselves. They will be able to access it anytime using a secure internet site called HealthSpace. Patients will of course be able to change their mind and request a Summary Care Record at any point.

Detailed Care Record

28. Records containing information about a patient's medical care exist currently in a variety of places, for example, at their GP surgery or at hospitals where they have received treatment but at present they cannot easily be shared. Over the next few years, as the NHS Care Records Service (NHS CRS) develops, NHS organisations such as hospitals, clinics and GPs will be able to share their electronic records where appropriate. This may vary from area to area depending on the physical infrastructure. A patient who has attended NHS organisations in different areas may have more than one set of shared detailed records.

29. The detailed care record component of the NHS Care Records Service (NHS CRS) will support the care process and will typically contain:

— Name, address, date of birth and NHS Number.
— Past and current health conditions, allergies.
— Assessment, investigations and diagnosis including test result and digital images.
— Care plans and reminders.
— Treatments including operations and medications.
— Care reviews and discharge information.

30. Individuals may ask those who are providing care for them whether or not it is possible to withhold information from the new IT systems but in many cases this will be impracticable. Some forms of care, X-rays, laboratory tests etc will generate records within the new systems automatically and the only way to prevent this is to choose not to have that particular care or treatment. Where clinicians feel that they can keep adequate records outside of the new systems there will need to be robust arrangements for clinical audit in order to assure the quality of care and protect patient safety. The Department of Health is to conduct a consultation on processes for managing patient requests of this sort. However, even where information has to be held within the new systems, patients have considerable control over who may access that information as described below. Alternatively, people can choose to have their information held electronically but not accessible to anyone outside the organisation that created it—thereby recreating an electronic version of the *status quo.*

Question 2. *Who will have access to locally and nationally held information and under what circumstances*

31. Only the duly authorised staff of organisations that are involved in providing care will have access to confidential medical information held within the NHS Care Records Service (NHS CRS). Such staff will need to have a "legitimate relationship" (see paragraph 37) to access the information in an individual patient's record. Organisations that are not involved in providing or supporting the delivery of health and social care, will not have direct access to any confidential medical data. Exceptionally, disclosure outside a health context may be considered in cases of serious crime or where there are significant risks to other people, but public interest rules for disclosure to the police or other agencies are not changed by the introduction of the NHS Care Records Service (NHS CRS). This is exactly the same as what happens now with paper records and non-linked computer systems.

32. Arrangements known as "role based access controls" will limit what a member of staff can do within the system and consequently which parts of a record he or she can see and amend. Access to record content will therefore be controlled by a member of staff's professional relationship with the patient, and by what they need to see to do their jobs. Senior clinicians within an organisation will also be able to see patient records when assuring the quality of care provided by their staff, but other access will only be authorised when required or permitted by law.

Question 3. *Whether patient confidentiality can be adequately protected*

33. The benefits of the NHS Care Records System (NHS CRS) for both patients and NHS staff depend on safeguarding sensitive patient information from inappropriate disclosure. The NHS Care Record System provides a set of technical access controls and audit facilities that, along with the professional standards of staff in the NHS, safeguard sensitive patient information from inappropriate disclosure. They provide much more rigorous controls than exist now for either paper records or existing electronically held records.

34. The Department of Health sets stringent standards for patient confidentiality and has taken the lead in government in developing a comprehensive privacy statement in the form of the NHS Care Record Guarantee, articulating in plain language precisely what NHS organisations must do to meet legal and policy requirements. The Department is also strongly supporting the Information Commissioner in seeking stronger penalties for breaches.

35. International security standards are applied across all system implementations. These include the use of encryption to communication links between systems, and to user interfaces with systems. The security of data centres is assured using both international and British standards, and all suppliers to the National Programme are contractually bound to auditing their adherence to these.

36. The NHS Care Records Service (NHS CRS) incorporates stringent security controls and safeguards to prevent unauthorised access to personal information and to detect potential abuse. These controls are complex to implement and there is a trade-off between usability and ease of access to data and questions relating to security and patient safety. The Department is therefore proceeding cautiously and consultatively and is providing the NHS with a set of security tools to deliver centrally determined standards.

37. The Department is aware that some patients will not be reassured by NHS security controls and is therefore providing patients with choice about participation in many of the new developments. Uniquely, the Department is also providing security controls that are set at the direction of patients. This provides unprecedented confidentiality management for patients of the NHS in England.

38. The Department of Health is establishing a National Information Governance Board answerable to the Secretary of State for Health, to provide a single authoritative source of monitoring, oversight and advice on the use of information in health and social care. The NIGB will review compliance with the NHS Care Record Guarantee and report annually to the Secretary of State. It will subsume the roles of a number of existing Department of Health Committees. With increased availability of patient information, it is important to safeguard access and to retain the confidence of the public. The NIGB will prevent complacency by adapting and maintaining high standards and by being ever watchful and in touch with public perception.

Security Controls Managed by the NHS

39. Users (healthcare professionals) are vetted and sponsored by their local organisations for specific access appropriate to their job role and area of work. There is a strong registration process compliant with the government standard eGif level 3 which means the user has to initially appear in person to prove their identity before access is assigned by the "Registration Authority" governed by NHS Connecting for Health. On successful completion of the registration process, a user is issued a smartcard—a secure token that, together with a passcode, confirms the identity of a user at the time of access. The registration process assigns them a role profile consistent with their area of work and responsibilities and establishes a unique electronic footprint when used to access systems. These records can be analysed to identify suspect behaviours. Where suspect behaviour is identified, local trusts will follow their procedures for investigating staff.

40. No system functionality will be available to an individual who does not possess a smartcard and know the associated pass code. The role profile that has been assigned to an individual through the registration process determines which system functions, and consequently which parts of a record, an individual who has logged on to the system can access.

41. A central record is also maintained within the systems of which patients each staff team—workgroup—are currently caring for. A GP Practice, an A&E Department or a clinic would be typical workgroups. This relationship, termed a "legitimate relationship" (LR) is a prerequisite of access to a specific patient's record. Without such a relationship access is prevented.

42. Full audit trails of who has done what, made possible by the unique identity associated with each smartcard, are maintained within systems and it is intended that these will be available to patients on request, as well as to staff charged with checking for system misuse by authorised staff. This is a considerable advance on what exists now with either paper or electronically held records.

43. NHS organisations must undertake to observe strict conditions to ensure the NHS CRS is used appropriately, and users are required to sign up to a set of conditions for use of the smartcard. These obligations and conditions are complemented by the various existing codes of conduct and professional responsibilities by which all NHS staff are bound. Actions which do not conform to them, which includes the sharing of smartcards, are dealt with locally. Sharing of information between members of a team has happened routinely prior to the introduction of smartcards, but we recognise that the sharing of smartcards could undermine the assurance that patient confidentiality will always be appropriately respected. Staff who breach patient confidentiality are subject to professional disciplinary measures. Offending doctors and nurses will be reported to their professional regulatory bodies and may face additional disciplinary action, including losing their licence to practice.

Options and Controls Available to Patients

44. Patients have a number of options. They were developed following extensive research and consultation with patients/carers/citizens and the NHS:

(i) Not to have a Summary Care Record (SCR) by requesting this through the GP Practice where they are registered. Individuals who opt-out of having a SCR may change their minds at any point in the future. Electronic prescriptions and electronic bookings are also optional.

(ii) To direct that controls are set to prevent data sharing. In this case the SCR can only be viewed with the individual's express permission or in accordance with the exceptions to English common law confidentiality obligations. Local sharing of Detailed care records across organisational boundaries will also be prevented—essentially recreating the pre-NCRS situation.

(iii) To have their address and contact numbers hidden so that they are not available to NHS staff. Whilst the NHS is legally required to hold non-clinical patient contact details for all patients where these can be obtained, this option has been provided so that even the most concerned individuals can still receive care and have joined-up records.

In time, patients will also be able to have an SCR but to designate some data items as sensitive so that they cannot be viewed outside of the team that recorded the information without the individual's express permission. This type of control is referred to as a "sealed envelope".

Question 4: *How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research*

45. The primary purpose of the NHS Care Records Service (NHS CRS) is to support the delivery of care to patients. However, as a by-product of collecting information for operational patient care, the introduction of the NHS Care Records Service (NHS CRS) represents a major opportunity for supporting the secondary analysis and reporting of information for a variety of purposes. The architecture of the NHS Care Records Service (NHS CRS) provides the opportunity to rationalise data abstraction, data flows, data management, analysis and reporting. This supports management and clinical purposes other than direct patient care, such as healthcare planning, commissioning, public health, clinical audit, benchmarking, performance improvement, research and clinical governance. The system by which this is done is called the Secondary Uses Service (SUS).

46. Wherever possible, data will extracted automatically as a by-product of NHS services supporting direct patient care, including the NHS Care Records Service (NHS CRS), Choose and Book and Electronic Transmission of Prescriptions. Initial Secondary Uses Service (SUS) content will cover the NHS in England and will be patient-specific. It will build on operational information already being shared by the NHS such as commissioning of healthcare services (eg diagnosis and procedures), cancer waiting times, clinical audit and supporting demographic data. Data will in due course cover all care settings (primary, community and acute) and all NHS-commissioned activity, including services provided for the NHS by the independent sector.

47. The aim is for this data to be made available either in aggregate form or, where detailed information is provided, in anonymised or pseudonymised form. This process removes patient identifiable information and allocates a consistent "pseudonym" so that individual cases can still be tracked, but only with explicit approval.

48. Access to identifiable information is available only where patient consent has been given, or where specific permissions apply. Permission is required from an expert group called the Patient Information Advisory Group (PIAG), set up under the Health and Social Care Act (2001). This group assesses each application to test that the use of patient information is justified, taking into account issues of confidentiality and consent.

49. Access to the Secondary Uses Service requires each user to be formally registered and to use individual smart card access, just as for other systems in the National Programme for IT in the NHS. Each user is allocated a role which determines the functions (ie what reports they can access) and the coverage (eg the organisation or geography of data which may be accessed). Key user activities, eg, logon and performing an extract, are logged.

50. In January 2006, the new national health research strategy *Best Research for Best Health* announced that the Department of Health would ensure the capability exists within the national NHS IT system to facilitate, strictly within the bounds of patient confidentiality, the recruitment of patients to clinical trials and the gathering of data to support work on the health of the population and the effectiveness of health interventions. The UK Clinical Research Collaboration established an expert group under Professor Ian Diamond, Chief Executive of the Economic and Social Research Council, to advise NHS Connecting for Health on maximising the use of the NHS Care Record for research. It has simulated how clinical trials and large observational studies could draw on the NHS infrastructure, and will report shortly.

51. The Secondary Uses Group set up by the Care Record Development Board to advise on the ethical use of patient data and how the potential for research, statistics and management can be realised without compromising confidentiality or security is due to report shortly.

Question 5. *Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule*

Current Progress on Development

52. Growth in volumes of activity on National Programme Systems is rising dramatically with the increase in functionality across the NHS Care Records Service (NHS CRS) and continuing roll out of the various elements of the system. Already the spine is the world's biggest structured healthcare messaging system. It is significantly larger than the entire Reuters global network used to distribute financial data in real time. The processing power of the spine environments would put it in the top 100 supercomputers ever built. Over 300 terabytes of storage is held on the spine which is roughly equivalent to a 3,000km long book shelf. The national PACS programme will ensure that all acute trusts will have the technology in place by the end of 2007, with the South having already achieved this target and London on target to achieve this by the end of March 2007. By the end of 2007, every GP and community pharmacy in England will have access to the Electronic Prescription Service (EPS).

53. Alongside progress in delivering the technology have come measurable patient benefits:

— The Picture Archiving and Communications Systems (PACS) means images can be accessed remotely in any place and at any time by consultants, making care better, more attentive and diagnosis quicker than before. Patients will be assessed and treated more quickly in emergency care

situations, and consultants can conduct more thorough examinations with the ability to manipulate images onscreen resulting in the best possible diagnosis. Lost or deteriorated images will no longer be an issue, saving money and time wasted due to cancelled or inadequate consultations. Space currently used for the physical storage of images will be reduced in this near-filmless process, with all the flexibility of digital systems.

— Virtually all GPs maintain electronic health records for their patients. GP systems are connected to a fast modern and secure national network over which are transmitted, electronic bookings and prescription scripts all using a central register of demographic data to ensure safety and available across the NHS 24/7. Comparative performance and quality measures of the services provided by GP practices are available to the public and healthcare planners.

— Electronic prescriptions have improved accuracy in prescribing. As well as saving lives by reducing prescribing errors, the electronic prescription service improves efficiency.

— Choose and Book is delivering patient choice, but also saving nursing and clinical time by reducing "Did Not Attends" by around a half, whilst most bookings are made in under a minute.

— Payment by Results and the Quality Outcomes Framework (QOF) has incentivised performance.

— The Quality Management Analysis System (QMAS), collects data on the Quality and Outcomes Framework (QOF) component of the new General Medical Services contract for general practices. The aim is to improve care standards by assessing and benchmarking quality of care. The QOF rewards practices for the provision of quality care, and helps to fund further improvements in the delivery of clinical care. QMAS represents a valuable source of information for healthcare managers or researchers responsible for the planning and delivery of primary care services and resource allocation, either within organisations or nationally in respect of specific disease areas. This unique quality-of-service information is available to the public to look up information on how well their local surgery performs. Other searches will compare local GP practice scores against other GP practices in the local area and the national score across England. QOF data provides, for the first time, easy access to comprehensive information on the pattern of the most common chronic diseases such as asthma, diabetes and cancer, from over 8,400 GP practices with just over 53 million registered patients in England. QOF helps doctors to compare the delivery and quality of care. By providing this world-leading intelligence on the spread of illnesses such as diabetes, heart conditions and cancers, GPs and other health professionals can make improvements in managing these chronic diseases.

— The Personal Demographics System is reducing the very significant numbers—some three-quarters of a million a year—of letters sent to the wrong address.

— The GP2GP records transfer system, which provides a secure way for GPs to pass the records of a patient who has changed GPs to the new GP quickly and safely. GP2GP makes a process that can take months to complete using paper records into one which is effectively instantaneous.

Delivery of the New Systems

54. There has been substantial progress with many systems fully deployed and daily supporting critical NHS business. The NHS could not now function normally without the Quality Management and Analysis System (QMAS), the N3 broadband network, the Personal Demographics Service, Picture Archiving and Communications System (PACS) or Payment by Results. Other programmes, such as Choose and Book and Electronic Prescriptions, have seen the software delivered to time and budget but take-up has been slower than expected. In both cases, roll-out has been dependent on the goodwill of existing system suppliers to achieve compliance and to undertake the work to install the upgrade.

55. Although much of the NHS Care Record Service was delivered on time and to budget, including the Personal Demographics System, Security and Authentication Systems and Messaging Systems, the national Summary Care Record containing the clinical record has been delayed by around two years against the original plan. This is partly due to its complexity and partly because of the need to secure consensus from the medical profession on its contents. The medical profession has been divided, with GPs typically favouring less or no clinical information to be placed in the national summary record and hospital doctors wishing there to be more information. Consensus was achieved by the Ministerial Taskforce on the Summary Care Record. The software is now on track for deployment at the end of March 2007.

56. Significant progress has been made at a local NHS level by the installation of community and child health systems into Trusts that have not had any previous IT support and where managers and clinicians have praised the transformation.

57. The deployment of new IT systems into acute hospitals with existing Patient Administration Systems, non-standard LANS, WANS and firewalls and multiple interfaces to a myriad of Departmental systems is up to two years behind the original schedule. Unlike the successful PACS deployment which has effectively been into greenfield sites, the patient and clinical systems implementations are into acute hospitals with existing legacy systems. Rather than providing a standard, repeatable deployment, the individual requirements, particularly for reporting at the local Trust, has required greater effort and has taken longer.

58. As at 12 March 2007, the position across major elements of the programme is as follows:

Picture Archiving and Communications Systems

— two Picture Archiving and Communications Systems going live almost every week (only five per year before the programme);

— over 178 millions digital images now stored;

— 5.4 million images are typically added each week;

— c 40,000 patient studies per day.

Picture Archiving and Communications Systems capture, store, distribute and display static or moving digital images, including X-rays and scans. Over 178 million digital images have already been stored. Currently there are 79 live deployments and we are digitising around two hospitals each week. The Picture Archiving and Communications Systems Business Case shows £1 billion net benefit, both cash and non-cash, to the NHS over 10 years. Trusts with Picture Archiving and Communications Systems are more efficient—a typical medium hospital can save 100,000 staff hours, equivalent to 50 staff. Picture Archiving and Communications Systems enables earlier diagnosis and more prompt treatment—providing digital transfer of images as required. Before Picture Archiving and Communications Systems, 5,000 patient procedures per annum were cancelled due to lost X-ray films.

NHS Care Record Service

— 332,029 registered users;

— now contains national patient demographic information for over 50 million patients in England;

— patient confidentiality protected by a Care Record Guarantee and system controls; and

— over 1.2 million patient records are successfully retrieved from the Personal Demographics Service every day, helping to correctly identify patients.

The NHS Care Record Service is creating an electronic record for each of England's 50 million patients, replacing four existing national systems. There are already 333,029 registered users and over 550 million activity records have been submitted to Secondary Uses Services. The NHS Care Record Service will bring process efficiencies and improvements to patient safety, care and experience, helping to reduce deaths through adverse drug reactions, of which there were 570 in 2001–02, as well as reducing the cost of litigation by reducing the number of avoidable adverse incidents. The summary clinical record is now ready for launch in April 2007.

Choose and Book

— over 2.9 million Choose and Book bookings made to date;

— over 16,000 bookings made in a typical day;

— now available to 97% of GP practices; and

— software delivered to time and budget.

http://www.chooseandbook.nhs.uk/

GPs and other care staff are booking initial hospital appointments at a convenient date, time and place for patients. Currently, there are over 16,000 bookings made per day and a total in excess of 2.9 million total bookings have been made to date. 97% GP practices are able to make electronic bookings.Choose and Book has been shown to halve the number of "did not attends" by giving the patient choice and placing them in control of their booking. Choose and Book will save the NHS approximately £69 million per year or 100,000 days per year of nursing and clinical time. "Did not Attend" rates are 5% for Choose and Book compared to 9% for non-Choose and Book bookings. Most bookings are made in 44 seconds.

Electronic Prescription Service

— software delivered to time and budget; and

— over 14 million prescription messages issued.

The Electronic Prescription Service will allow prescriptions generated by GPs to be transferred electronically from their surgeries to their local pharmacies. Over 14 million prescriptions have been transmitted to date and over 550,000 prescriptions are issued per week. 1,669 GP practices have transmitted prescriptions. The Electronic Prescription Service more than halves keying time, by both the pharmacy and the Business Services Authority, equating to £13M savings or 700 staff equivalents. The Electronic Prescription Service will save an estimated eleven lives per week and will free up 3,920 hospital beds per week by reducing prescribing errors. The Electronic Prescription Service brings more choice in access to medication including home delivery and involves less time for GPs administering repeat prescriptions by 70%. Electronic Prescription Service data will be used to populate the patient summary care record.

National Network for the NHS (N3)

— target achieved two months ahead of schedule with over 18,000 connections delivered.

N3 is providing reliable supporting IT infrastructure, world class networking services, sufficient, secure connectivity and broadband capacity potential to meet current and future NHS IT needs. There are 18,664 secure connections of which 10,717 are GP connections. Approximately 1,000,000 NHS employees use N3 services. All GP sites and branch practices get at least 512Kbps N3 service. For every £1 spent on N3 the NHS would have spent £2.25 on the legacy NHSnet. By using N3 to monitor four ambulance trusts, Yorkshire Air Ambulance has reduced scramble time from seven to two minutes. N3 transfers 96.5 terabytes of data per month which is equal to the Encyclopaedia Britannica every four seconds. There are connections to all sites where healthcare is offered.

NHSmail

— over 236,000 registered users; and

— around one million emails a day, one-third of which are clinical information.

NHSmail is a centrally managed, secure, clinical email and directory service provided free of charge to the NHS organisation in England. Currently there are 236,652 registered users. Over 205 million emails have been transmitted to date, 30% for secure transfer of patient identifiable data. University City Hospital Leicester estimates £1 million saving over four years equivalent to an extra ten nurses per year. All users have one email account, contact details and diary that can be shared across multiple organisations. NHSmail will save £185 million over the life of the contract. NHSMail is a secure service with the highest level of encryption available.

The Quality Management and Analysis System (QMAS)

QMAS is a new single, national IT system, which gives GP practices and PCTs objective evidence and feedback on the quality of care delivered to patients. As general practices are now rewarded financially according to the quality of care they provide, it is essential that the payment rules that underpin the GMS Contract are implemented consistently across all systems and all practices in England. QMAS ensures that this is achieved. The system shows how well each practice is doing, measured against defined national achievement targets.

Overall Position

59. The technology to support most aspects of the National Programme for Information Technology has already been delivered and the remaining challenge is to utilise these systems fully at local level.

Conclusion

60. Having access to comprehensive and secure electronic health records has been shown to improve quality of care and patient safety and facilitate appropriate treatment of patients in providing health professionals with a better knowledge of the patient's history and of previous interventions by other colleagues. A longstanding commitment by the Department of Health to give patients access to information about their health and care will become a reality. The National Programme for IT and the NHS Care Records Service (NHS CRS) have the potential to transform and save lives. They will enable better informed patients to work in partnership with the NHS.

61. Currently, the NHS operates with disparate paper-based and fragmented national IT systems. Many of these inefficiencies are being removed and better services for patients are available as a result across the NHS. Modern IT Systems and the Services described here will support access to care when and where it is convenient, reducing the numbers of failed appointments, improving the accuracy and handling of prescriptions and facilitating the capture, storage and transmission of X-rays and digital images so they are available to clinicians when and where needed. The implementation of a secure broadband network will improve the communication and availability of information to clinicians and managers; patients too will be able to view the information held about them, putting them in control for the first time and offering meaningful choice. They will also have unprecedented control over who sees their information. Crucially, the NHS Care Record Service (NHS CRS) will provide a single integrated national system for all NHS clinical applications, with consequent improvements in efficiency and patient safety, care and experience.

62. The transformation from paper to digital information will take place gradually up to 2010 and beyond. The NHS will move from being an organisation with fragmented, partially integrated national systems, with physical processing and storage of records on paper which are often unavailable when required or incomplete to a position where national systems are fully integrated, record keeping is digital and patients have unprecedented access to their personal health records. There will be a move from existing paper-based systems to modern IT based flows of information at every level in a careful progression from the Summary Care Record to the full NHS Care Records Service (NHS CRS), supported by a universal, secure physical IT infrastructure. We have in the past and continue to involve patients/carers/citizens in the development of electronic records.

63. Information about the National programme for IT in the NHS can be found on the following web site—http://www.connectingforhealth.nhs.uk/

Department of Health

March 2007

Evidence submitted by the Academy of Medical Sciences (EPR 34)

The Independent Academy of Medical Sciences promotes advances in medical science and campaigns to ensure these are translated as quickly as ossible into benefits for society. The Academy's 800 Fellows are the United Kingdom's leading medical scientists from hospitals, academia, industry and the public service.

Introduction

1. The Academy of Medical Sciences welcomes the opportunity to respond to the House of Commons Health Committee Inquiry into the Electronic Patient Record and its use. The Academy's core objectives are to promote advances in medical science and ensure that these are converted as quickly as possible into healthcare benefits for society. Our focus is therefore on the research aspects of the Committee's Inquiry and our submission will concentrate on the fourth area of the terms of reference: *"How data held on the new systems can and should be used for purposes other than the delivery of care, eg clinical research".*

2. The use of patient health records in research was the subject of a recent major study by the Academy, chaired by Professor Robert Souhami CBE FMedSci and involving a working group of senior researchers and clinicians.[1] The study culminated in the publication of a report, *Personal data for public good: using health information in medical research,* which is enclosed with this submission.[2] Publication was followed in June 2006 by a symposium involving senior members of the legal profession, including barristers, solicitors, academics and members of the judiciary, the report of which is also enclosed.[3]

3. *Personal data for public good* describes in detail how information contained in patient records provides much of the evidence on which improvements in healthcare are based. This kind of "secondary research" has identified important causes of disease, led to effective measures for control of epidemics, demonstrated the long-term effects of treatment, and shown how the health of the population can be improved by better services. The late Sir Richard Doll OBE FRS FMedSci put it thus: *"Much of the research on the effects of ionising radiation and the use of oral contraceptives, leave alone smoking, would have been impossible without the facility of obtaining unbiased access to medical records".*

Opportunities and Challenges

4. The UK already has an outstanding record in population-based research and epidemiology. The development of the National Programme for IT (NPfIT) and the Electronic Patient Record offer unparalleled opportunities for research that could have a real and significant impact on future health in the UK. In 2005, the Chancellor of the Exchequer, Gordon Brown, and the Health Secretary, Patricia Hewitt, stated a new commitment to develop the capability within NPfIT to facilitate *"the gathering of data to support groundbreaking work on the health of the population and the effectiveness of health interventions".*[4] This was reflected in Sir David Cooksey's Review of UK Health Research, which identified an essential need *"to ensure that research is fully embedded in and integral to the NHS IT programme, and prioritised on a par with other service uses for the system."*[5]

5. However, the Academy is concerned that a number of factors, including confusing legislation and professional guidance, bureaucracy of process and an undue emphasis of privacy and autonomy, are having a detrimental effect on UK research activity in this area. The report *Personal data for public good* describes how disproportionate constraints on the use of health information can compromise the quality and validity of research results, leading to potentially misleading claims, or even costing lives. The UK must avoid mistakes made elsewhere, for instance the decision by the Hyogo prefecture in Japan to halt cancer registration on the basis of privacy concerns, which led to delays in the detection of a significant cluster of asbestos-related mesothelioma cases.

6. There is no doubt that information held in electronic health records can be extremely sensitive; inappropriate use or disclosure of such information has the potential to cause embarrassment or distress. Experience or fear of inappropriate disclosure might induce patients to withhold information from a health professional or even avoid treatment altogether. We also note that the introduction of more pervasive

[1] For further details see http://www.acmedsci.ac.uk/p48prid5.html

[2] Further copies can be downloaded from http://www.acmedsci.ac.uk/images/project/Personal.pdf

[3] Further copies can be downloaded from http://www.acmedsci.ac.uk/images/project/1170326729.pdf

[4] http://www.hm-treasury.gov.uk/newsroom—and—speeches/press/2005/press—100—05.cfm

[5] Sir David Cooksey (2006) *A review of UK health research funding*. The Stationery Office, London http://www.acmedsci.ac.uk/images/project/1170326729.pdf

CCTV, aggressive use of data for commercial marketing purposes and the national debate over identify cards have all influenced the climate in which issues related to research using health information are discussed.

7. Policies that emphasise choice within healthcare focus on the value of individual autonomy. But this emphasis presents challenges for activities such as medical research, which are performed for public, rather than individual, benefit. It could be maintained that a patient has the right to say "use my data to treat me, but not to improve care for others".[6] Or more starkly, "use evidence from other people's data to treat me, but don't use my data to help them."

8. In the following sections, we outline some of the considerations around consent, confidentiality and anonymisation that should be taken into account during the development of systems supporting the Electronic Patient Record. We also share our hopes and concerns for the Secondary Uses Service and Care Record Development Board, before discussing ways forward and the need for public engagement.

Using Patient Records in Research: Consent

9. Consent is quite rightly the cornerstone of all interventional research involving human subjects, including clinical trials and invasive investigations. However, the nature of records-based research can make obtaining consent unfeasible or impracticable. For instance, the hypothesis that adverse conditions in pregnancy might increase the likelihood of cardiovascular disease in later life was developed and tested by Professor Barker using over 15,000 birth records collected in Hertfordshire from 1911 onwards.[7] 3,000 of the patients had died and the population had dispersed, making obtaining consent impractical is most cases and impossible in some. The results of Professor Barker's research have linked low birth weight with risk of hypertension, type II diabetes and other disorders in adult life.

10. Seeking consent can also bias a dataset, leading to misleading results. For example, until 2001 there was a great deal of controversy over whether termination of pregnancy increased the risk of breast cancer. A potential bias was that women who had developed breast cancer might be more likely to disclose information about termination than women without cancer. It was only when a data linkage study was done on records accessed without consent that the absence of risk was demonstrated conclusively.[8]

Using Patient Records in Research: Confidentiality and Anonymisation

11. All patient records must be handled in a manner that reflects obligations and expectations of confidentiality, namely that:

- Effective procedures are in place to prevent the unintentional disclosure of sensitive data.
- Data are only used for authorised purposes.
- Those handling data understand and respect patients' interests.

12. Many guidance documents now emphasise anonymisation of data (ie stripping the data of any identifiers) as the preferred approach for records-based research. However, we emphasise that anonymising data is only one component in protecting confidentiality and can sometimes compromise the integrity of the research.

13. There may be several reasons why constructing a research dataset would require access to identifiable information:

- **To assess/avoid double counting.** For example, congenital anomaly registers were set up in response to the thalidomide tragedy and are essential in identifying teratogenic exposure in pregnancy. Many of the anomalies only come to light later in life so data must be collected from paediatricians, midwives, genetic counselling services and many other sources. In many instances, notification of the same individual will be received from several sources and matching reliable personal information is the only way to identify duplicates and avoid double counting.[9]
- **For longitudinal research.** Without long-term research based on large, complete datasets the risks of occupational, environmental or social factors would not be known with certainty. This is exemplified by studies on the health of coal miners,[10] fluoridation of water[11] and social distribution

[6] Detmer D (2000) *Your privacy or your health—will medical privacy legislation stop quality health care?* International Journal for Quality in Healthcare 12, 1–3.

[7] Barker D (2003) *The midwife, the coincidence and the hypothesis.* British Medical Journal, 327, 1428–9.

[8] Goldacre M J, Kurina L M, Seagroatt V & Yeates D (2001) *Abortion and breast cancer: a case[en rule]control records linkage study.* Journal of Epidemiology and Community Health, 55, 336–7.

[9] Richards I D, Bentley H B & Glenny A M (1999) *A local congenital anomalies register: monitoring preventive interventions.* Journal of Public Health Medicine, 21, 37–40.

[10] Fox A J, Goldblatt P & Kinlen I J (1981) *A study of mortality of Cornish tin miners.* British Journal of Industrial Medicine, 38, 378–80.

[11] Kinlen L & Doll R (1981) *Fluoridation of water supplies and cancer mortality.III: A re-examination of mortality in cities in the USA.* Journal of Epidemiology and Community Health, 35, 239–44.

of cancer.[12] Understanding how exposure to a risk factor influences later health requires that information on an individual be updated over time. This is impossible if data are irreversibly anonymised.

— **For validation.** The quality of the data contained in health records can vary significantly, and the ability to test the validity of a sample of records is essential. This is generally done by taking a random sample and retrieving the original records to confirm that data subject x really is data subject x. This can only be achieved using identifiers to match the records.

— **Identifiers contain useful information.** Many of the identifiers that might be stripped from data during anonymisation are useful to research.[13] For instance, postcode, date of birth, date of death and occupation are all routinely used as important factors in analysing population health data, but are stripped out when data are anonymised.

14. This final point illustrates that "anonymised" and "identifiable" are not distinct categories of data. There is no consensus guidance on the identifiers that should be stripped from a dataset to render it anonymised, and, as illustrated above, removing potential identifiers can leave the data unusable for research purposes.

Secondary Uses Service and Care Record Development Board

15. The Secondary Uses Service (SUS), which is being delivered as part of NPfIT through NHS Connecting for Health, is *"a system designed to provide timely, pseudonymised, patient-based data and information for management and clinical purposes other than direct patient care"*. The plan is for information from SUS to be available in pseudonimysed form to researchers.[14] It will also provide results of standard and bespoke analyses, as well as extract anonymised data sets on behalf of researchers and other users.

16. One aim of SUS is to reduce the overall burden on local NHS servces of data collection, abstraction and submission by centralising and automating these processes. However, the Academy seriously doubts whether SUS will be able to provide the flexible access needed to allow existing research methods to be applied to the new datasets. The plan relies on SUS undertaking much of the work currently done by research groups, such as linkage, validation and additional data collection from patients. Although this is theoretically possible, we doubt that it will be a high priority among the other calls on the resources of SUS, not least the implementation of "Payment by Results". Researchers have also expressed concern that the different IT systems being developed in England and the devolved nations will not be sufficiently compatible and integrated to allow UK-wide research.

17. Given these concerns, the Academy welcomes the formation of the UK Clinical Research Collaboration (UKCRC) R&D Advisory Group to Connecting for Health, which followed an explicit recommendation in our 2006 report.[15] The Advisory Group, which is chaired by Professor Ian Diamond, is tasked with *"obtaining and presenting evidence to help prioritise the research agenda in future development commissioning of the NHS Care Records Service"*. The Group is now completing a series of simulations designed to interrogate the NHS Care Records Service (including the Secondary Uses Service) for its suitability to support research. These simulations cover research applications in observational epidemiology, clinical trials, surveillance and prospective tracking of a cohort (longitudinal research). We look forward with interest to the publication of the results of these simulations in March, which we hope will address concerns around data quality (completeness, validity and reliability), removal of identifiers and data linkage, as well as issues of information governance. We urge careful examination of the Research Simulation Report by the Health Committee and on the part of all those involved.

18. We are also aware of a forthcoming report from the Care Record Development Board Working Group on the Secondary Uses of Patient Information. The date of publication is to be confirmed, but might be in April 2007. This is likely to make a number of recommendations on governance issues arround researchers' access to information in the Secondary Uses System, which we hope will take into consideration issues of consent and anonymisation raised in the Academy's 2006 report and summarised above.

The Care Record Guarantee

19. The Academy has previously expressed significant concerns about the Care Record Guarantee, which has been drawn up and published by the Care Record Development Board (CRDB).[16] The Guarantee sets out for the public the rules that will govern information held in the NHS Care Records Service (CRS) and will be the basis for an information campaign intended to reassure the public about the confidentiality of the system.

[12] Kinlen L J (1988) *The longitudinal study and the social distribution of cancer.* British Medical Journal, 297, 1070.

[13] Ohno-Machado L, Silveira P S & Vinterbo S (2004) *Protecting patient privacy by quantifiable control of disclosures in disseminated databases*. International Journal of Medical Information, 73, 599–606.

[14] In this context pseudonymised data cannot be used by the holder of the data to indentify an individual. However, the original provider of the data (in this case SUS) retains a means of identifying individuals. This will often be achieved by attached codes or other unique references to information so that the data should only be identifiable to those with access to the code or key.

[15] See http://www.ukcrc.org/activities/infrastructureinthenhs/nhsitprogrammes/advisorygroup.aspx

[16] See http://www.connectingforhealth.nhs.uk/crdb/docs/nhscrgenglish.pdf

20. We are concerned that the current version of the Guarantee seems to be based on the assumption that all work with identifiable data will be accomplished within SUS and that research and public health users will be only supplied with anonymised output from SUS. It includes statements that seem to preclude any use of CRS data outside the NHS for research purposes. We welcome the mention in the document that data might be used to "*help with research*". However, we are concerned about the explicit pledge that the new IT system will "*allow only those involved in your care to have access to records about you from which you can be identified*". A public statement of this kind invalidates the legal basis on which public health professionals and clinical researchers currently access identifiable data for research and is therefore of grave concern.

21. We have previously recommended that the current wording of the Guarantee should be revised to make a clear distinction between *bone fide* researchers acting in the public interest and "third parties" who should not be permitted access to records (eg employers, insurers, the press and other members of the public). We strongly urge the promotion of the benefits of research during the Care Record Guarantee public engagement campaign.

The Way Forward: Engaging The Public

22. The public, patients and researchers have a common interest in ensuring that research involving patient records is conducted efficiently and to the highest standards. NPfIT and the Electronic Patient Record offer an exceptional opportunity to allow research to inform all aspects of healthcare. However, the Academy is concerned that research needs are not being integrated into the development of these programmes.

23. The basis for accessing and using the Electronic Patient Record for research depends upon public expectations of what is involved. The public is largely unaware of the regulation that underpins research of this kind, including the role of ethics committees, NHS data controllers and Caldicott Guardians, as well as the Patient Information Advisory Group. Evidence of public attitudes towards the use of health information in research is largely absent, forcing regulatory bodies to make assumptions about what the public might find acceptable. There are two large studies—by Shickle *et al*[17] and Barrett *et al*[18]—which are noteworthy because of the rigorousness of the methodology and the focus of the questions. We also warmly welcome recent studies undertaken by the Wellcome Trust and Medical Research Research Council to investigate public perspectives in this area. We look forward to the publication of the outcomes of this work in April.

24. Urgent work is needed to increase public engagement about the value of research using healthcare records and the arrangements under which records are held and accessed. The introduction of NPfIT, the Electronic Patient Record and the Care Record Guarantee will provide valuable opportunities for such engagement. The research mission of the NHS is seldom mentioned in literature given to patients—in striking contrast to its role in teaching nurses, medical students and other staff. In the development of the Electronic Patient Record, the Department of Health understandably does not want the primacy of confidentiality to be undermined in gaining public acceptance. However, in our discussions with patient representatives there was strong support for research using health data. There was great concern that a vocal minority, loudly proclaiming the right of privacy, might override the unexpressed desire of many people to contribute to the public good. The Academy recommends that a long-term programme of public engagement concerning research uses should be established. We consider that the benefit for health will strengthen the perceived value of the Electronic Patient Record in the opinion of the public.

The Academy of Medical Sciences

16 March 2007

Evidence submitted by Alliance Boots (EPR 27)

Introduction and Executive Summary

Alliance Boots is Europe's largest pharmacy-led health and beauty group, created following the merger in 2006 of Alliance UniChem and Boots Group. We operate 2,300 pharmacies across the UK, through our Boots The Chemists and Alliance Pharmacy stores.

We believe pharmacists' access to patient care records is important for the benefit of patients; to enhance patient safety; to benefit other health professionals; for pharmacists to fulfill their responsibilities under the new contract; and for pharmacists to reach the full potential of their professional role. This memorandum

[17] School of Health and Related Research (2002) *Patient Electronic Record: Information and Consent (PERIC) Public attitudes to protection and use of personal health information*. School of Health and Related Research, University of Sheffield.

[18] Barrett G *et al* (2006) *National survey of British Public's views on use of identifiable medical data by the National Cancer Registry*. BMJ, 332: 1068–72

explains why pharmacists require access to certain data, how this access will enhance joint working with GPs and benefit patients, and how we envisage the system will work, including protection of patient data and secure access.

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems

1. The new NHS community pharmacy contractual framework is enabling pharmacy to develop beyond its traditional role of dispensing medicines into a more service-orientated role. The development of new health services in pharmacies is highly beneficial for patients and the NHS, and it is clear that pharmacists require access to sufficient data to enable them to provide a safe and effective service to the patients under their care.

2. While local computer systems already provide a full and comprehensive record of the service that an organisation has provided to the patient, or Patient Medication Record (PMR), there is most likely to be relevant information held within other healthcare providers' systems that would be of benefit in providing effective care to the patient. Conversely, information about the service that we provide to a patient would benefit other healthcare providers (eg GP or hospital) and so should be uploaded onto the summary care record.

3. The record needs to include all information about medication that has been prescribed and dispensed to a patient both in primary and secondary care. It should also include details of any allergies, active clinical conditions and any previous adverse reaction information. The care record could also include information regarding the supplies of selected prescription only and non-prescription lines supplied from a pharmacy, for example under a Patient Group Direction.

4. Having access to the full patient medication history would enable pharmacists to perform a full drug interaction check with all medicines prescribed and dispensed for a patient and thus improve the overall safety of the patient. If access to basic clinical condition information were included, this would further improve safety by allowing the pharmacist to check that the dosage was appropriate for the condition being treated.

5. A practitioner will not be in a position to provide treatment to a patient without access to relevant information but patients should be entitled to prevent their information being shared with other healthcare providers or restrict it to a limited number of individuals through use of controlled access rights and sealed envelopes. If a patient chooses to limit the sharing of their information, the implications of doing so should be made clear to them. Likewise, patients should be made aware of their responsibility to provide any relevant information at the point of care.

6. Many members of the public already volunteer personal data, regarding lifestyle, body weight and health-related purchases, as part of our company initiatives. For example, over 1.5 million people are signed up to the Boots "HealthClub" and there are 15 million Boots Advantage Card users. High take-up for initiatives such as these suggests broad public acceptance of data holding in a patient's own interest.

Who will have access to locally and nationally held information and under what circumstances?

7. The NHS care record should incorporate the patient's medical record, accessible to the healthcare provider, at the point of care and whenever required. Within community pharmacy, all pharmacists must have access to a core set of clinical information as detailed above. This must include a full record of the patient's medication history and any adverse drug reactions, to support the pharmacist in conducting a Medicines Use Review (MUR). In addition, certain pharmacists such as independent prescribers or pharmacists providing a specific service to a patient, such as Chlamydia screening, should have access to a fuller data set to include relevant information, for example laboratory test results. In pharmacies there will be role-related access, so that healthcare assistants will only be able to access a patient's records if this is a necessary part of their job.

8. When providing a repeat dispensing service to a patient, it is the duty of the responsible pharmacist to ensure that nothing about the patient has changed since the last time they made a supply. Having access to the care record would facilitate the pharmacist carrying out this check rather than relying solely on information provided verbally by the patient.

Whether patient confidentiality can be adequately protected

9. This information needs to be stored and accessed securely to protect the confidentiality of the patient. Pharmacy contractors and pharmacy systems are already subject to the controls of the Data Protection Act. Existing security measures (physical and technical) ensure the security of any patient information held locally on these systems.

10. Pharmacists already have NHS Smartcards and PIN numbers to enable them to access the Electronic Prescription Service (EPS). These same Smartcards can be used to enable access to the NHS care record and provide a full audit trail of who is accessing and updating confidential patient information.

11. Should a patient not want their information shared, he or she must have the ability to limit who sees what information or to authorize the user to view the information during a face to face consultation for that one time only.

How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research

12. Unable to comment on this.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule

13. Unable to comment on this.

Alliance Boots

March 2007

Evidence submitted by the Association of the British Pharmaceutical Industry (EPR 39)

EXECUTIVE SUMMARY

1. Safety and the increased health of the nation are of paramount importance. Significant safety and research improvements are now possible through the effective use of the detailed electronic patient record. Procedures such as record coding promote patient confidentiality whilst allowing vital healthcare data to be collected and analysed. Patient confidentiality should remain totally protected and patient consent via continuation of the current opt out arrangements is preferred. Industry's commitment to patient health and safety is demonstrated by active partnership in the UK Clinical Research Collaboration (UKCRC) vision for the benefit of UK integrated health research data.

1.1 We believe that Connecting for Health (CfH) has run into cost and time over-runs and so we consider that it is important that the right specification for increased safety and research effectiveness while different from that currently being put in place, does not necessarily drive up costs or raise additional security issues. Indeed the only requirement would be access to the detailed electronic patient record.

1.2 Whilst CfH is a very considerable undertaking, it should be recognised that there is an international race for benefit and competitive advantage in research where the UK could have a significant Unique Selling Point (USP), if research interests are given priority. This is not the case currently so radical changes are necessary for the UK not to lose out as a centre for R&D in competition with other countries. The implementation of the research programme envisaged in the recent Cooksey review[19] and by the UKCRC whilst making use of the full electronic patient record will provide substantial benefits to patients, the NHS and the economy.

SAFETY AND THE INCREASED HEALTH OF THE NATION ARE OF PARAMOUNT IMPORTANCE

2. ABPI members' interests related to the electronic patient record are to increase patient safety through the active monitoring of safety and efficacy of new and existing medicines and to provide additional health benefits from research. These aims cannot be achieved without access to the detailed electronic patient record. This will not be provided by CfH in the proposed centrally-held Summary Care Record.

SAFETY IMPROVEMENTS ARE NOW POSSIBLE

3. There is strong interest from several parties to improve patient safety through better pharmacovigilance as highlighted in previous reports from the Health Select Committee (HSC),[20] the BMA[21] and the NHS R&D Directorate.[22] Future improvement to keep up with US and other European safety conscious countries will require up to date detailed and complete patient data of good quality, accessible to the regulator (The Medicines and Healthcare products Regulatory Agency (MHRA)). Safety systems would then need to be able to send alerts to GPs about specific patients without their identity being known at a central level.

DETAILED RECORD ACCESS FOR SAFETY AND BEST HEALTH THROUGH RESEARCH

4. It is our understanding from CfH that the proposed central Summary Care Record will be only a small subset of the complete patient record held on the current GP systems and will not contain specific data to be of much use to improve safety and to enhance clinical research.

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[19] A review of UK health research funding December 2006.
[20] House of Commons Health Committee Report "The Influence of the Pharmaceutical Industry Session 2004–05.
[21] Reporting Adverse Drug Reactions: A guide for healthcare professionals May 2006.
[22] Best Research for Best Health. January 2006 published by DH.

4.1 The Summary Care Record will be an abstract from the existing detailed primary care record, together with abstracts from hospital care patient records which will be provided through the National Care Records Service (NCRS). Over 95% of the UK population already has an electronic record through their GP's system.

4.2 We are unaware of any significant changes being proposed to local patient record systems. Initiatives such as GP Systems of Choice (GPSoC) may be moving to a more standardised and accessible record. Such moves could potentially offer greater patient safety, pharmacovigilance and research quality.

Patient Confidentiality Should Remain Protected

5. Mechanisms to promote patient confidentiality during pharmaceutical research are well-established. For example, only coded-data is supplied to the researcher who has no direct access to the patient or identifying details such as name, address etc. It is therefore essential that confidentiality is maintained in any future electronic system.

5.1 Additionally, the ABPI has recently developed comprehensive guidelines for the secondary use of data for medical research purposes, providing guidance to its members (Appendix). There is also a body of opinion suggesting that electronic data will allow greater security than paper-based systems.

Patient Consent via Continued Opt Out Arrangements Preferred

6. As with current international research practice today in the use of existing databases, future systems should support use of patient level data via an opt out patient consent protocol. Patient identification at GP level to enhance pharmacovigilance will be vital, a topic that has previously been identified for action by the HSC. The Cooksey recommendations and those of Best Research for Best Health will not be delivered without access to patient level data being fully optimised in terms of data quality and speed of access.

Industry Commitment to Patient Health and Safety

7. Industry is actively engaged with UKCRC and DH to identify the future vision for enhanced patient safety and more effective clinical research use of patient data in work sponsored by Professor Sally Davies, the Director of the National Institute for Health Research and Richard Jeavons. A fully integrated detailed patient record for research use would be a major USP for the UK in competition with other countries as a centre for clinical research to advance the health of the nation. As noted above, patient confidentiality and privacy will be promoted through the existing research mechanisms of data coding effectively providing an anonymised patient record to the end user.

A Vision for the Benefit of UK Integrated Health Research Data

8. We consider that the provision of internationally competitive research services would require the creation of a secure network and regulated services provision, building on initiatives such as the NCRS, as well as those in Scotland, Wales and at the primary care level, databases such as the General Practice Research Database (GPRD). A possible model is shown below.

The Right Specification does not Necessarily Drive Up Costs or Raise Security Issues

9. Industry is interested primarily in the actual detailed patient record, not the Summary Care Record held on the SPINE. Research needs will therefore not add to the costs or specification of central records but research does need access to specific fields held in local records in order to make advances in clinical care and medicines for patient benefit. Provision of this data will support much more of that research taking place in the UK.

The International Race for Benefit and Competitive Advantage in Research

10. Nobody should underestimate the complexity of what CfH have set out to do and, when all the systems are in place, the potential is for considerable benefits to healthcare. It is for this reason that parallel initiatives are well advanced in many countries around the world, driven by the wish to enhance patient health through the advancement of research, and to attract the best international research to their respective country. The UK has a real opportunity to attract more of the best research projects through the use of UK integrated health data.

Dr Richard Tiner
The Association of the British Pharmaceutical Industry

16 March 2007

Evidence submitted by the Association of British Dispensing Opticians (ABDO), the Association of Optometrists (AOP), the College of Optometrists and the Federation of Ophthalmic and Dispensing Opticians (FODO) (EPR 44)

1. Overview

1.1 ABDO, AOP, the College and FODO together represent the 10,000 optometrists and over 5,000 dispensing opticians who provide high quality and accessible eye care services to the whole population across the UK. There are over 6,900 opticians' premises in the UK, ranging from large stores with multiple consulting rooms to small practices in local shopping centres or in the high street as well as domiciliary eye care services who provide care to those confined to their home.

1.2 Overall we support the introduction of a national NHS-wide IT system which will enable healthcare information to be shared between clinicians. We believe the potential benefits to improve patient care and safety are important goals. However we do have a number of concerns about the development and timescale of the IT system. Optical practices must be linked to the national data spine and be fully integrated on the NHS Care Records Services.

1.3 Solutions for connecting optical practices need to be found which do not conflict with existing practice software infrastructure. At present, when PCTs occasionally try to connect to optical practices, they usually insist on a separate stand alone PC isolated from the practice network. This solution is NOT part of an integrated network and requires re-typing of all information, with the associated potential for error. Better and more workable security solutions will need to be found to integrate practices into the Care Records Services.

1.4 In the short term, optical practices should be given access (with specific patient consent at the time of access) to the summary care record. This should be piloted as soon as possible.

2. *What patient information will be held on the new Local and National Electronic Record Systems, including whether patients may prevent their personal data being placed on systems*

2.1 Patient information held by optical practices should in due course be recorded on the NHS Care Records Service. Increasingly optometrists co-manage patients with GPs and ophthalmologists and therefore an electronic system of sharing information will ensure all those involved in the care of a patient are fully informed and have access to the most up to date information.

2.2 The government recently consulted on proposals to give optometrists independent prescribing rights. All the optical bodies submitted their views on behalf of the profession, calling on the government to adopt prescribing rights for optometrists. Once optometrists have prescribing rights it will be imperative that they have access to information including repeat prescriptions, acute prescriptions, significant and recent diagnoses, as well as any adverse and allergic reactions to medication.

2.3 We believe that patients should agree to information being shared between professionals, although any potential problems should be explained to the patient, e.g. if there are any adverse implications from withholding information about medications. Patients should have clear information about the electronic sharing of health information.

3. *Who will have access to locally and nationally held information and under what circumstances?*

3.1 All optical practices should be included in the Connecting for Health IT programme—whether they provide NHS or private services—to ensure the same level of care for all patients. Many patients who are paying privately for eye care will be NHS patients for other healthcare services such as when they visit their GP. As mentioned above, once optometrists have prescribing rights it will become increasingly important for them to have access to a patient's medical history. Optometrists should have access to relevant sections of the patient's electronic record (subject to informed consent) and NHS electronic GP and hospital referral systems and "choose and book" systems. This should be centrally funded through the Connecting for Health programme in the same way as for other sectors.

3.2 Providers of domiciliary eye care services must also be included. Visiting optometrist and dispensing opticians provide a vital service to vulnerable people in their own homes who are often suffering from multiple health problems.

4. *Whether patient confidentiality can be adequately protected*

4.1 We believe it is imperative that adequate measures are put in place to maintain patient confidentiality. Optical practices already obtain and process confidential data in patient records and have a long history of maintaining confidential information securely. Currently in most practices this is in written form but we believe that any issues arising from a transfer to an electronic record can easily be addressed.

5. *How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research*

5.1 We support the plans for information to be used anonymously for clinical research, public health, strategic planning, commissioning and clinical audit. As long as the information is strictly anonymised and only used for the purposes outlined above, we believe this could provide a very beneficial and useful service for the whole of the NHS.

6. *Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule*

6.1 Optical practices are due to be included in the NHS Care Records Service, however there has been no commitment to an agreed timetable for this to happen. In a written answer on 16 June 2006, Health Minister Caroline Flint confirmed that the national programme was designed to "support all the clinical services in and around the national health service, including dentists and opticians" but no date has yet been set. The Minister added that "The national programme is on target to achieve full integration of health and social care systems in England by 2010", but we do not believe this is achievable given that optical practices have not been notified when they will be integrated. (*Hansard* 16 June 2006, Column 1561W)

6.2 We believe that the NHS Care Records Service must be properly piloted and we strongly believe that a pilot system for integrating optical practices must commence as a matter of urgency if the deadline of 2010 is to be met.

7. Additional Points

7.1 A further long-standing issue has been that—unlike dentists and pharmacists—there is no centralised electronic claims and payment system for optical practices.

7.2 The main problem for optical practices is that PCTs have different cut-off dates for submitting claims and many are very slow when making payments. Some PCTs hold up whole batches of payments which can severely affect cash-flow particularly for smaller practices. Payments, and hence cash-flow, are also subject to the vagaries of PCT staff absences, half-term and computer breakdowns at local level. All these additional costs have of course ultimately to be passed on to the patient or the NHS.

7.3 Far better all round would be for a national system with standardised methodologies which ensured that optical practices received payments regularly and on time and which, as a by-product, generated useful data for PCTs so that they could concentrate on their core strategic function of service planning rather than data processing.

7.4 The optical bodies very much welcome the government's commitment to carry out a feasibility study to improve the streamlining and standardisation of the claims and payments system. We look forward to participating fully in the optional appraisal and hope very much it will lead to a national, centralised system for the beneficial reasons for patients, practices and the NHS, as outlined above.

Heather Marshall
Association of Optometrists

16 March 2007

Evidence submitted by the Association of Directors of Social Services (ADSS) and the Association of Directors of Children's Services (ADCS) (EPR 21)

1. Executive Summary

1.1 The Electronic Patient Record must be understood in the context of the Government's programme, firstly, for the modernisation of public services and, secondly, the vision to place the citizen and the citizen's needs at the centre of public service delivery.

1.2 The strategy is set out in the Cabinet Office publication, "Transformational Government—Enabled by Technology" (Cabinet Office 2005). The aim is to use information systems and technology as a key means of meeting "each of the three major challenges which globalisation is setting modern governments—economic productivity, social justice and public service reform" (Transformational Government, Cabinet Office 2005 p 2).

1.3 A patient-centred health service requires joint working between health and social care. This must be supported by the capacity to share information across traditional organisational boundaries. The vision is set out in the White Paper, "Our Health, Our Care, Our Say: a new direction for community services" (published Department of Health 2006).

1.4 The Government's target is that by 2008 "we would expect everyone with both long-term health and social care needs to have an integrated care plan if they want one. By 2010 we would expect everyone with a long-term condition to be offered a care plan" through joint health and social care teams supported by "an information system that supports a shared health and social care record" (Our Health, Our Care, Our Say).

1.5 These targets are achievable within the timescales set out in the Government's strategy. However, progress in meeting these targets is constrained by a lack of co-ordination between those Government departments which are responsible for the development of personal electronic care records.

1.6 In some respects, the NHS has made most progress in establishing the necessary infrastructure by establishing a Care Record Guarantee. Furthermore, the NHS, through Connecting for Health, has established standards for confidentiality, for authorisation and verification of NHS staff who are entitled to access to confidential patient information. The NHS Information Standards Board ensures consistency of data definition and information standards across the NHS. These standards are essential to ensure data has the same meaning across the organisation.

1.7 However, there is not an equal commitment from the Department of Health and the Department for Education and Skills to ensure consistency of standards and of the structure of electronic care records between the NHS, adult social care and children's information systems. Nor is there a co-ordinating framework to ensure consistency within these cross-Departmental programmes. Consequently, this is a threat to the successful implementation of the electronic patient and social care records.

1.8 To promote effective implementation of the Electronic Patient Record, within the context of the requirements of "Our Health, Our Care, Our Say" and the Transformational Government strategy, it is recommended that:

1.8.1 Government establish a cross-Departmental Board with authority to ensure consistency in the development of personal care record systems across the NHS, adult and children's social care services.

1.8.2 That this Board be responsible for the consistent implementation of personal care record standards, confidentiality guarantees and quality systems relating to personal electronic records.

1.8.3 The implementation of the Electronic Patient Record be promoted by the Department of Health by giving a greater emphasis to the implementation of integrated health and social care systems and, in particular, to promote national implementation of the Single Assessment Process and Common Assessment Framework, which are care components of the Electronic Patient Record and Electronic Social Care Record.

2. Submission from the Association of Directors of Social Services (ADSS) and the Association of Directors of Children's Services (ADCS)

2.1 The members of ADSS are responsible for the management of social care services for adults throughout Local Government. The members of ADCS are responsible for the management of all children's services within Local Government.

2.2 Increasingly, social care services are provided in partnership with the NHS.

2.3 The submission has been drafted on behalf of ADSS and ADCS by the social care representative on the NPfIT National Board who is also chair person of the Department of Health & Electronic Social Care Implementation Board. He is also chair person of the ADSS committee which has responsibility for information systems and standards, and chairs a forum of independent social care systems suppliers.

3. *What patient information will be held on the new Local and National Electronic Records Systems, including whether patients may prevent their personal data being placed on systems*

3.1 The Government's vision is for citizen-centred public services designed around the needs of the individual. One of the key strategies to achieve this transformation is through improved information systems and electronic records. The citizen or patient should not have to repeatedly provide information to a range of different people about their care needs. There should be a single, electronic care record which provides the information needed to deliver effective and efficient health and social care systems. Therefore, essential information required within an electronic patient record is:

3.1.1 standard demographic data about the individual;

3.1.2 information about those organisations and professionals involved in his or her care;

3.1.3 information about the individual's needs;

3.1.4 the treatment provided to meet those needs, and

3.1.5 finally, the record should contain information about outcomes of that treatment programme.

The care record must be linear over time so that past history can be examined and it must also contain current need and treatment plans from all of those involved in that individual's care programme.

3.2 Consistent with the vision to break down barriers between traditional organisations, the electronic patient record must contain full and comprehensive health care information and have the capacity to interface with social care systems. This requirement is set out in the National Service Framework for Older People which established the requirement to provide a Single Assessment Process. This expectation for older people is being carried across to other adults through the development of a Common Assessment Framework for all adults, which is one of the requirements of objectives set out in the Department of Health White Paper "Our Health, Our Care, Our Say : a new direction for community services".

4. *Who will have access to Locally and Nationally-held Information and under what circumstances?*

4.1 Person-centred care will, in most circumstances, be multi agency and multi-disciplinary. The White Paper "Our Health, Our Care, Our Say" sets the target that "everyone with both long-term health and social care needs to have an integrated care plan" by 2008 and that these integrated care plans will be provided through "an information system that supports a shared health and social care record". The White Paper envisages such care to be provided by "joint health and social care teams". There is an increasing body of evidence of the effectiveness of such integrated teams in terms of reducing unplanned hospital admissions, reducing prescribing costs and demands made on general practice. Supporting people in the community through integrated care teams places more responsibility and authority on the patient and carer to manage their own health care needs with demonstrable beneficial outcomes for patients.

Therefore, the people who need to have access to the health and social care records are the members of the multi-disciplinary team. What needs to be determined is who are the designated members of the multi-disciplinary team. This might vary according to each case, and also be dependent upon the views of the patient as to who is entitled to have access to their confidential care record. A simple guide to multi-disciplinary team membership is that if a member is authorised to carry out assessment of the individual's health and/or social care needs. If so, then that individual would require access to the patient's health and social care record insofar as he or she had a "need to know". There will be some information which is within a "confidentiality envelope" where access is restricted to certain team members either because of the nature of the information or because of the restriction on access to that information imposed by the patient.

4.2 There would need to be agreement between the NHS, the Department of Health with its social care responsibilities and DfES in relation to children's information systems as to the level of electronic care record assessment which would be deemed to come within the restrictions of a multi-disciplinary team approach. The DfES approach to development of children's information systems takes a universal approach to electronic records with a very broad accessibility to those records by a range of different organisations. This introduces complexities for information sharing where more detailed, confidential information is held on an individual. This could be managed by setting the level of multi-disciplinary working at the Integrated Children's System rather than in the children's Index or Common Assessment Framework which are more universal in their concept.

5. *Whether patient confidentiality can be adequately protected*

5.1 The key to protecting patient confidentiality is to be specific about the level of electronic record which is subject to the terms of the Care Record Guarantee. The Guarantee can be applied to those electronic care records which are selective, not universal in their nature; which are undertaken by accredited professionals who have been vetted, authorised and appropriately trained in the details of confidentiality and information sharing; who are members of accredited teams and are individually authorised to have access, on a need-to-know basis and subject to the approval of the patient.Health The information systems must be capable of monitoring who has had access to an individual's care record and when. This level of protection and guarantee of confidentiality is in excess of that which exists currently in practice in relation to paper-based records.

6. *How data held on the new systems can and should be used for purposes other than the delivery of care, eg clinical research*

6.1 Data which is held in electronic care records can be anonymised and aggregated for the purposes of clinical research. It is possible to do this using standard techniques such that an individual would not be identified.

6.2 There is considerable capacity within electronic records to undertake epidemiological studies which would contribute significantly to shifting the focus of the NHS away from an acute treatment mode into more positive, more effective programmes of promoting health and well-being and managing health care problems within the community.

6.3 For example, people with chronic health problems who experience ill health on a long-term basis are estimated to account for between 30 and 40% of unplanned hospital admissions. Treatment of long-term conditions takes up a significant amount of NHS and primary care resources. Research evidence demonstrates that long-term conditions can be better managed in the community, that the patient and carer are capable of taking an active role in health management and that, as a consequence, there is a reduction

in unplanned hospital admissions, take up of acute hospital beds and a reduction in demands on prescription and GP time. Having person-centred electronic care records would enable health and social care services to target programmes aimed at more effective management of long-term conditions within the community and, at the same time, provide a basis for anonymised comparison using random control groups. Strategic approaches such as this were envisaged in the Wanless Report "Securing our Future Health : Taking a long-term view" (HM Treasury 2002).

7. *Current progress on the development of the NHS Care Record Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule*

7.1 It is not within my area of expertise to comment on aspects of the Care Record Service or National Data Spine being behind schedule. However, with reference to the introduction of a comprehensive Electronic Patient Record it is my understanding that the target date for the introduction of this record and its capacity to interface with social care systems is between 2008 and 2010. These are also the dates set out in the White Paper for the introduction of integrated teams to support long-term conditions management. The tools have already been developed which can deliver these objectives within the time frame 2008-2010. These are the Single Assessment Process, elements of the Electronic Patient Record and the Electronic Social Care Record.

7.2 The Single Assessment Process is a core module of the Electronic Patient Record and of the Electronic Social Care Record. Implementation of the electronic Single Assessment Process so that it feeds into the Electronic Patient Record and the Electronic Social Care Record without dual entry by health and social care professionals and enabling real time access to the electronic care record by accredited professionals will deliver a very high proportion of the requirement to provide electronic care records across health and social care. An electronic Single Assessment Process could be implemented nationally within this timescale. Connecting for Health has undertaken a review of the strengths and weaknesses of the electronic Single Assessment Process nationally and has made recommendations for its consistent implementation across the country.

7.3 There are, however, several constraints in delivering this achievable goal.The first constraint is that there must be a consistency in the design and architecture of electronic care records between the NHS, adult social care and children's information systems. This requires the NHS, DH and DfES to work collaboratively to ensure consistency of system architecture and consistent standards across health, adult social care and children's information systems. There is no co-ordinating framework to ensure that the necessary consistency is achieved across these systems. Underneath the strategic co-ordinating framework, there needs to be a means to ensure consistency of information standards, structure and definition of data, etc. Within the NHS, there is a robust structure led by the NHS Information Standards Board but there is not an equivalent body across children's and adults' social care services to ensure an equivalent consistency. The NHS programme, being implemented by Connecting for Health, is constrained, therefore, in the extent to which it can safely integrate the Electronic Patient Record with the Electronic Social Care Record and the Integrated Children's System.

7.4 In the absence of such a co-ordinating framework, it acts as a constraint on the development of the Electronic Patient Record within the context of the Government's strategy for the transformation of public services so that they are person-centred and support flexible working across organisational boundaries. Furthermore, in the absence of such a co-ordinating framework, it is difficult to see that the targets set out in the White Paper "Our Health, Our Care, Our Say" for the better management of health and social care services through integrated teams and supported by shared information systems will be achieved.

7.5 Considering the enormous investment in information systems and technology being directed into health and social care systems, this lack of co-ordination is running the risk of "losing the ship for a ha'p'orth of tar".

David Johnstone
Devon County Council
On behalf of the ADSS and the ADCS

March 2007

Evidence submitted by the Association of Independent Multiple Pharmacies, the Company Chemists Association, the National Pharmacy Association and the Pharmaceutical Services Negotiating Committee (EPR 22)

EXECUTIVE SUMMARY

— Providing community pharmacists with appropriate role-based read and write access to both detailed and summary care records has the potential to greatly improve patient safety, support the development of new services for patients, improve interdisciplinary working and increase the quality and continuity of care provided to patients.

— To maximise patient safety, community pharmacists must have access to a pre-determined core data-set, for example the medication profile, active clinical conditions, allergies and previous adverse reactions. It would be beneficial for patients, the NHS and pharmacists if supplementary information, such as access to laboratory test results, is also available to pharmacists to use where appropriate and with patient consent, to support a particular role they are undertaking, for example, the provision of an anticoagulation monitoring service.

— All community pharmacies have robust systems in place for handling patient confidential information and are subject to a wide range of legal, ethical and professional requirements. We welcome the proposed additional safeguards to protect patient confidentiality including role-based access controls and the ability for patients to choose to dissent from their information being shared.

— We believe that community pharmacists should be involved at an early stage in the implementation of the NHS Care Records Service to study the benefits and challenges that arise in joining-up care and to provide learning to support the wider roll-out of the Service to other professionals and organisations within the NHS.

1. Introduction

1.1 Since the first announcement of the development of the NHS Care Records Service, pharmacists and their representative bodies have been calling for community pharmacists to be provided with appropriate role-based access to patients' Care Records.

1.2 Providing community pharmacists with appropriate read and write access to both the detailed and summary care records has the potential to greatly improve patient safety, support the development of new services for patients, improve interdisciplinary working and increase the quality and continuity of care provided to patients.

1.3 To maximise patient safety, we believe that community pharmacists must have access to a pre-determined core data-set, for example the medication profile, active clinical conditions, allergies and previous adverse reactions. This should be agreed in full consultation with the profession. It would be beneficial for patients, the NHS and pharmacists if supplementary information, such as access to laboratory test results, is also available to pharmacists to use, with patient consent, to support a particular role they are undertaking, for example, the provision of an anticoagulation monitoring service for the secondary prevention of stroke.

1.4 More than one third of pharmacies in England are already able to operate the Electronic Prescription Service and we anticipate that the overwhelming majority of pharmacies will be connected to the NHS network by the end of 2007. This will provide the basic infrastructure for pharmacy connectivity to other national functionality, as it becomes available, including the NHS Care Records Service.

1.5 In the Department of Health publication "A Vision for Pharmacy in the New NHS", (2003) the Government signalled that it would consult on the elements of patient information that community pharmacists may need to deliver appropriate healthcare services as part of the NHS pharmacy contract. This was reiterated in the 2006 Department of Health Annual Report. It is of great concern that this consultation has not taken place and consequently the uncertainty over when community pharmacists will be granted appropriate role-based access continues.

1.6 It is unfortunate that community pharmacies have not been invited to participate in the pilot of the Summary Care Record at this key learning stage. The information that will be shared during the initial implementation will be limited to prescription information which pharmacies currently have access to, as well as information on adverse and allergic reactions to medication. This information is unlikely to be considered sensitive by the public and could greatly improve the safety of the provision of medicines to patients.

1.7 To study the benefits and challenges that arise in joining-up care and to provide learning to support the wider roll-out of the Service to other professionals and organisations within the NHS, we believe that community pharmacists should be involved at an early stage in the implementation of the Service.

1.8 In this paper, we outline the key benefits to patients, pharmacists and other health professionals, of community pharmacists being provided appropriate role-based access to the NHS Care Records Service. We also detail the structures currently in place to safeguard confidential patient information available to pharmacists.

2. Improving Patient Safety

2.1 Appropriate access to the patient's summary records is necessary for many reasons. In a recent observational study,[23] 6.5% of admissions to the medical admissions unit in a teaching hospital in Nottingham were judged to be drug related with 67% of these judged to be preventable. Providing community pharmacists with access to a patient's full medication profile and information on current clinical

[23] Investigation into the reasons for preventable drug related admissions to a medical admissions unit: observational study; *Quality Safe Health Care* 2003;12:280-285.

conditions improves the safety of prescribing, for example, by allowing pharmacists to check that newly prescribed medication is not contraindicated by a coexisting disease or by ensuring that medication does not interact.

2.2 Some medicines, such as tricyclic antidepressants, can be used in different ways to treat different conditions. A pharmacist would only be able to confirm the medication is appropriate and the dose adequate if the clinical condition being treated is known. Such information is currently available only by asking the patient who may not be able to accurately provide the necessary information or by contacting the prescriber directly which is a time-consuming and disruptive operation for both parties.

2.3 It is important, for patient safety reasons for pharmacists to have access to information on allergies and previous adverse reactions, so that a check on the suitability of the prescribed product can be carried out at the point of dispensing. The pharmacist's detailed knowledge of side effects and potential interactions is relied on by many GPs.

2.4 Providing community pharmacists with a baseline data-set which includes the full medication record, active clinical conditions, allergies and adverse reactions would support pharmacists in helping the Government meet its target of reducing by 40%[24] the number of serious errors in the use of prescribed drugs and help reduce the human and financial cost of prescribing errors.

3. Supporting the Development of New Services to Patients

3.1 Community pharmacy is changing. In April 2005, the community pharmacy profession entered into a new contractual framework with the Government for the provision of pharmaceutical services. The framework allows pharmacies to play a more central role in patient care, with more scope for making clinical interventions and better integration of pharmacists within the primary health care team. As part of the new arrangements, community pharmacists undertake Medicines Use Reviews, conduct public health campaigns and advise patients on self care and the treatment of minor ailments. Many pharmacists are also involved in providing other locally commissioned services to meet the needs of patients in their locality, for example diagnostic testing, substance misuse services and services to care homes.

3.2 In addition to the basic dataset for community pharmacists, required for the above reasons, pharmacists should also be provided with additional role based read and write access to specific types of information required to support that role. For example, supplementary and independent prescribing can only be effectively carried out in the community pharmacy setting with electronic access to appropriate patient information such as laboratory results and patient care plans.

3.3 The development of Practitioners with a Special Interest was proposed by the NHS plan to improve access and convenience. In September 2006, the Department of Health published a framework[25] which acknowledged that "Pharmacists with a Special Interest" can contribute to a broad range of service objectives including: improving patient access, reducing waiting times, increasing capacity in primary care, reducing demand on secondary care and delivering value for money. The success of this programme is dependent on community pharmacists having appropriate role based access to care records.

3.4 One example of a service provided by a small number of pharmacies is an anticoagulant monitoring clinic. Patients receiving warfarin can attend a community pharmacy for their regular blood test and dosage adjustment. This offers convenience to patients as community pharmacies are more easily accessible and have longer opening hours than secondary care clinics. This service could be more effective if pharmacists had appropriate read and write access to appropriate information about the patients they were monitoring. For example, access to previous test results and the ability to record electronically results they obtain, to allow other health professionals involved in the care of the patient to access this information.

3.5 Access to care records would also support the role of pharmacists in providing urgent care. Pharmacy opening hours are much longer than those of GP surgeries—with routine evening and weekend opening—and full integration of pharmacies within the provision of urgent care will relieve the pressure on A + E departments and out-of-hours providers.

4. Improving the Level and Continuity of Care Offered to Patients

4.1 Patients sometimes forget to ask their doctor questions or misunderstand the information they are given during a consultation. If pharmacists have access to records they can reinforce important health messages and correct misunderstandings—this realises the benefits of an integrated health care system, the *raison d'etre* of Connecting for Health.

4.2 Pharmacists, like other service providers, must make reasonable adjustments to their service under the Disability Discrimination Act 1995, so that people with disabilities are able to access the service. Healthcare professionals, including community pharmacists, who identify patients whom they believe

[24] Aim first set out in the Chief Medical Officer's Report, An Organisation with a Memory, Department of Health, 2000.

[25] Implementing care closer to home—providing convenient quality care for patients: A national framework for Pharmacists with Special Interests; Department of Health. 2006.

require support could, with patient consent, make an appropriate entry on the NHS Care Record so that other healthcare professionals are aware of the nature of the disability, and can make adjustments to the services they provide.

5. Improving Interdisciplinary Working in Primary Care

5.1 Pharmacists based in hospitals and GP surgeries have demonstrated the value that they bring to clinical teams when they have access to clinical information about patients. However, the value of community pharmacists has, to date, not been fully utilised, as they have access only to clinical information gathered from the prescription form or through discussion with the patient. Providing community pharmacists with appropriate role-based access to patient information would enable pharmacists to work more closely and efficiently with the other members of the primary healthcare team and improve the level of pharmaceutical care provided.

5.2 Under the new pharmacy contractual framework pharmacies are required to maintain patient medication records which include details of drugs supplied to patients and advice given where the information is clinically significant. At present, other health professionals, including other community pharmacists, are unable to access and therefore cannot benefit from these records.

5.3 As patients have the freedom to use any pharmacy this means that community pharmacists will generally not have a comprehensive medication history for each patient. By joining up the information held in pharmacy records through the NHS Care Records Service, pharmacies will be able to provide improved continuity and quality of care.

5.4 The NHS Plan[26] committed the Government to making a wider range of medicines available over the counter. In recent years, products such as the cholesterol lowering drug, simvastatin; the antibiotic used in the treatment of conjunctivitis, chloramphenicol, and omeprazole which is used in the treatment of gastro-oesophageal reflux disease have been reclassified to allow sale through pharmacies without prescription. This facilitates patient access to medicines, reduced health inequalities and supports self-care, which was highlighted in the NHS Plan as one of the key building blocks for a patient-centred health service. Providing pharmacists with appropriate write-access to the Care Records Service will ensure that the patient's general practitioner can access clinically significant information when products have been provided to patients over the counter, ensuring these products are considered at the point of prescribing.

5.5 Looking to the future, products such as oral contraceptives[27]may be available for sale without prescription through pharmacies. Access to relevant information about the patient would improve patient safety and help ensure joined up care.

5.6 Securely sharing information amongst appropriate health professionals would also help improve the efficiency of some existing services. For example, the NHS Medicines Use Review service could be developed to the benefit of patients both through allowing pharmacists access to appropriate information about the patient and allowing a summary of the review to be made available electronically to other health professionals involved in the care of the patient.

5.7 Under the repeat dispensing service, patients with stable long term conditions can collect their medicine from a pharmacy at regular intervals for up to a year without the need to return for repeat prescriptions from their prescriber. When dispensing medication, the pharmacist has a duty to check if the patient's circumstances have changed. Appropriate read access to the patient's record would support pharmacists in carrying out this check and appropriate write access for clinically significant interventions would support the continued care by the patient's GP.

5.8 There are also instances where patients choose not to collect medicines prescribed for them. Allowing pharmacists to write to the record would highlight these instances and improve the medication record by logging medicines prescribed and received rather than simply prescribed.

6. Improving Communication at the Primary and Secondary Care Interface

6.1 Appropriate role based access to the NHS Care Records Service could support the seamless transfer of care between primary and secondary care.

6.2 There are risks[28] inherent in the discharge of patients from secondary care and in the general transfer of care. Research has demonstrated that discharge medication summaries provided to the patient, GP and the patient's nominated community pharmacist help reduce re-admissions[29 30].

[26] The NHS Plan: A Plan for Investment A Plan for Reform; Department of Health; 2000.

[27] *Pharmaceutical Journal*; Vol 278; No 7438; p 153.

[28] Moving patients medicines safely: Guidance on Discharge and Transfer Planning; RPSGB, GHP, PSNC and PCPA Joint Publication; 2005.

[29] Al-Rashed S, Wright D, Roebuck N, Sunter W, Chrystyn H. Inpatient pharmaceutical inputs to facilitate seamless care. Pharm J 2000; **265(7114)**: R60.

[30] Brookes K, Scott MG, McConnell JB. The benefits of a hospital based community services liaison pharmacist. Pharm World Sci 2000; **22(2)**: 33-38.

6.3 Providing community pharmacists with relevant role-based access to patient information will greatly improve patient safety at the primary and secondary care interface with the potential for pharmacists to have up-to-date information and the medication prescribed to patients. If a patient's medication therapy has been changed in hospital, it can result in patient misunderstandings or problems with duplicated medicines which community pharmacists can help resolve if they have access to appropriate information.

7. Health and safety of patients and staff

7.1 The Government has indicated[31] that it is serious about tackling violence and the threat of violence against community pharmacists and many positive steps have been taken to tackle this problem.

7.2 It is proposed that a "violent warning marker" may be included on the NHS Care Records Service. At present some trusts operate paper based systems to alert staff about patients who have previously assaulted NHS staff and continue to pose a potential risk. This information necessary for the protection of pharmacists is currently not accessible. We believe that appropriate role-based access should be available, particularly if the pharmacist is undertaking a service that involves visiting the patient in their home.

8. Support for Community Pharmacy Access

8.1 It is also worth noting that it is not just the profession that believes that access to the NHS CRS is necessary for the full potential of pharmacy to be realised. In their recent written submission to the All Party Pharmacy Group inquiry into the future of pharmacy, *Which?* stated: "*Consumers want and expect continuity of care and all healthcare professionals (including pharmacists) involved in their care to have access to their medical record. Without this, how can care be patient centred?"*

9. Confidentiality

9.1 We are aware that as community pharmacies are readily accessible to the public, pharmacy must be able to demonstrate that confidential information will be stored securely. All community pharmacies already have robust systems in place for handling patient confidential information and are subject to a wide range of legal, ethical and professional requirements.

9.2 Pharmacy contractors are required to comply with the legal obligations of the Data Protection Act 1998, Human Rights Act 1998 and the common law duty of confidence and under the NHS community pharmacy contract, pharmacy contractors and their employees must also conform with the NHS code of practice on confidentiality. The clinical governance framework assures compliance by including polices for ensuring staff are appropriately trained and that all staff contracts include clauses on patient confidentiality.

9.3 Pharmacists are also bound by the Royal Pharmaceutical Society of Great Britain's (RPSGB) professional "Code of Ethics and Standards" and can be held accountable for breaches. Disciplinary action that can be taken may include the pharmacist being removed from the professional register and therefore being prevented form working as a pharmacist.

9.4 Pharmacists and their staff have worked within these regulatory frameworks for many years. However we welcome the additional safeguards that are being introduced into the NHS Care Records Service to safeguard information. This includes the use of smart cards to control access with PCT Registration Authorities providing external control on the granting of individuals' access rights, legitimate relationships, sealed envelopes and the ability for patients to choose to dissent from their information being shared. We believe that PCTs should be supported by national guidelines to ensure consistency in permitting additional access to Connecting for Health.

Lindsay McClure
On behalf of the Association of Independent Multiple Pharmacies, the Company Chemists' Association, the National Pharmacy Association and the Pharmaceutical Services Negotiating Committee

15 March 2007

Evidence submitted by the Association for Clinical Biochemistry (EPR 36)

Executive Summary

The Association for Clinical Biochemistry (ACB), founded in 1953, is a professional body dedicated to the practise and promotion of clinical science and laboratory medicine and has medical and non-medical members in all major UK healthcare laboratories, many university departments and several commercial companies. It was instrumental in establishing accreditation for clinical scientists in all disciplines and plays a significant role in the training of Clinical Scientists in the discipline of Clinical Biochemistry.

[31] The Pharmaceutical Journal; Vol 274 No 7339 p 261.

Laboratory investigations play a significant role in some 70% of all clinical diagnoses and in the management of treatment for patients. The results of such investigations are therefore an essential element of the electronic patient record and will represent the bulk of the information stored in it.

The Association recognises that the accuracy, reliability and repeatability of this information is essential for the safe and efficient use of electronic patient records. It also recognises the need for appropriate security mechanisms to protect the confidentiality and accuracy of any information stored in such records.

The Association's evidence reflects those concerns. The evidence is generic in its nature in that it is relevant to all the scientific disciplines within clinical science and laboratory medicine that will contribute to the electronic record.

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems

From the perspective of Clinical Science and Laboratory Medicine the information stored needs to include:

- Sufficient patient demographic information safely to identify a specific patient.
- The results of investigations undertaken on that patient.
- Relevant interpretive and diagnostic information.
- Information identifying when, where and with what techniques any treatments and investigations were undertaken on the patient and with what outcomes.

If the information is to be of value, and to avoid impairing patient safety, the information stored must be accurate, timely, consistent and reproducible. The information must be the full record. That is, ALL interventions and investigations, regardless of where they are carried out, must be included.

Who will have access to locally and nationally held information and under what circumstances

Access to the information must be related to the sensitivity of the particular item as well as the role and responsibilities of the professionals being given access to it. This must take account of the need for Clinical Scientists to have access to sensitive data in order safely to supply interpretive information.

Whether patient confidentiality can be adequately protected

A system of identifiers and passwords with sufficient flexibility to identify the roles and responsibilities of staff and the categories of information to which they should have access is required.

How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research

A separate database for research could be established containing information derived from the electronic patient record but anonymised in such a way as to protect the confidentiality of the individual patients.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to twoars behind schedule

A variety of factors may have contributed to this. Careful attention needs to be paid to the management of the project, in particular with respect to the operational requirements, assumptions and interdependencies, and the effects of central policy changes.

The team managing the development and implementation needs adequate resources, including skills and experience commensurate with those available to the contractors.

Introduction

1. The Association for Clinical Biochemistry (ACB), founded in 1953, is a professional body dedicated to the practise and promotion of clinical science and laboratory medicine and has medical and non-medical members in all major UK healthcare laboratories, many university departments and several commercial companies. It has a relationship with the clinical diagnostics industry through links with its Corporate Members. The Association liaises with, and is consulted by, many national and international organisations on issues relating to Clinical Biochemistry. It was instrumental in establishing accreditation for clinical scientists in all disciplines. It also plays a significant role in the training of Clinical Scientists in the discipline of Clinical Biochemistry and its training framework is used by other disciplines.

2. The Association has long recognised and had experience of the value of electronic information management both in the support of the efficient operation of clinical laboratories and in the wider sense as an important tool for efficient, safe and secure storage of patient records as "electronic patient records". The added benefit of the ability rapidly to share electronic patient records across hospital and even national boundaries presents significant opportunities that may enhance patient treatment and care.

3. Our experience has been that the opportunities can only be exploited if surrounding issues are addressed, including:

- Maintaining the accuracy of the information stored in the records.
- Protecting confidentiality.
- Ensuring that there is consistency in the structure of the information stored.
- Ensuring that related types of information (such as test results) are comparable, regardless of where the investigations were carried out for both numerical and textual data.
- Integrating information by recording all relevant observations regardless of where they are made; this would include clinical examinations as well as laboratory tests, physiological tests, imaging etc. Some diagnostic tests may be conducted outside the hospital and possibly outside health services premises (eg high street pharmacies, the patient's home, private laboratories, and so on.)
- Ensuring completeness of the information stored. The value will be lost if the records are incomplete. Indeed, there is the risk of mistakes being made in the management of a patient if an element of information (such as episodes of care taking place in a hospital or laboratory not connected to the electronic record) is missing.

4. The results of clinical scientific investigations, such as laboratory tests, together with interpretive comments made by clinical scientists and laboratory doctors, make a significant contribution to some 70% or more of diagnostic and treatment decisions. They therefore play a vital role in the efficiency and cost effectiveness of the healthcare system and represent the bulk of the information stored in an electronic patient record.

5. The interpretive comments often include guidance on the appropriateness of testing which is important both in the avoidance of expenditure on unnecessary tests and recommending tests that identify when a particular treatment would be ineffective. The electronic record facilitates such guidance by bringing all the relevant information relating to a patient together.

6. Comprising as it does the majority of doctors and clinical scientists active in the clinical biochemistry discipline of laboratory medicine in the United Kingdom the Association is well placed to comment on those aspects of the electronic patient record.

7. The Association's evidence in this context is generic, in that it applies to other clinical science disciplines.

8. The assumption has been made in compiling this evidence that the inquiry relates to the UK "Connecting for Health" initiative and the Clinical Spine Application of that initiative in particular. The evidence is applicable throughout the UK.

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems

9. There are many aspects of information relating to patients that might be included in an electronic patient record but are not of direct relevance to the test results derived from laboratory investigations. There are some items of patient information that need to be stored if the test results that are stored are to be used effectively and safely to manage patient care. These include:

- Sufficient demographic information uniquely to identify a particular patient across all healthcare settings.
- Chronological information between and within the episodes of care and investigations undergone by the patient.
- Therapeutic (such as medications administered) and diagnostic (such as imaging) interventions made on the patient, and clinical diagnoses of conditions affecting the patient, as these may affect the results of laboratory investigations and their interpretation.

10. The question as to whether or not a patient should have the power to prevent personal data being included on electronic systems is one of ethics and personal freedom. But it must be borne in mind that if the elements of information referred to in paragraph 9 above are omitted from a record this would adversely affect the safety with which test results could be interpreted and may lead healthcare professionals to incorrect conclusions and inappropriate action.

Who will have access to locally and nationally held information and under what circumstances

11. Clinical Scientists require access to a level commensurate with interpreting a result leading to a diagnosis, advising on therapy etc. We need access to demographic data so that, for example, out of hours results that require urgent intervention can be more readily acted upon if the patient's telephone number is accessible.

12. While the Association recognises that patients must have the ability to restrict access to sensitive personal and diagnostic information it recognises equally that a Clinical Scientist must have the ability to gain access (through a suitably regulated and audited process) to gain access to such information where the safety of the patient demands it.

Whether patient confidentiality can be adequately protected

13. It may be argued that patient confidentiality can be better protected by electronic records than by paper records.

14. Appropriate identifiers for staff and levels of security are necessary. These need to be sufficiently flexible to allow specialist laboratory staff engaged in diagnostic and interpretive work to have access to sensitive information that would not be required by staff undertaking solely analytical work. The electronic record must also recognise that some laboratory data such as HIV status, pregnancy tests and drug abuse screens are highly sensitive.

How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research

15. The new systems will contain a wealth of information in a highly accessible and usable form. The information has the potential to be a valuable source of material for epidemiological and other studies that could be valuable for future treatment and planning of services for patients.

16. The Association would therefore encourage the harvesting of anonymised data to be made available for authorised research purposes, with the following two provisos:

— Such use must not breach the security or confidentiality of individual patient information.

— The quality (consistency, accuracy, repeatability and so on) of the information from all sources contributing to the electronic records must be assured. Otherwise there would be a significant danger of inaccurate predictions being made, or conclusions drawn, during research making use of the information.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule

17. The Association's observations on this include.

18. There has been some question of the requirements of practitioners within the Health Service having been inadequately canvassed and reviewed at the outset leading to delays as unanticipated requirements come to light.

19. The scale of the initiative is such that requirements can change throughout the period of design and implementation. The changes may occur due to developments in technology, treatment and care. They may also result from changes in policy regarding the delivery and scope of health care and the organisational structures responsible for delivery.

20. There is a perception that delivery and implementation have been poorly planned, notably in the area of "Anglicisation" of software originating from outside the UK NHS healthcare context, that have consumed considerable time from practitioners. Better preparation centrally could eliminate such delays at the point of delivery.

21. The skills, quality and experience of the internal representatives managing the development and implementation need to match those of the external contractors.

22. Interdependencies and assumptions need to be carefully managed. The Carter Report,[32] for example, makes the assumption that the developments in "Connecting for Health" will facilitate the proposed "network" approach to delivery of pathology services. It is not clear how such a requirement will be conveyed to the connecting for health implementation.

[32] Report of the Review of Pathology Services in England chaired by Lord Carter of Coles. August 2006.

23. Engagement of coal-face clinical practitioners in detailed design and functionality that they need to "work smarter" and the willingness of providers to recognise their issues has been very variable across CfH Clusters. If that approach continues it will inevitably compromise the clinical, operational and financial cost-benefits realisation.

The Association for Clinical Biochemistry

March 2007

Evidence submitted by Breakthrough Breast Cancer (EPR 32)

1. Introduction

1.1 Breakthrough welcomes this inquiry into the electronic patient record and its use. Our memorandum focuses on the kind of patient information that should be held on the electronic record systems; who should have access to such electronic information; patient confidentiality; and how the data held on the systems should be used for purposes other than the delivery of care.

2. Executive Summary (Recommendations for Action)

2.1 Breakthrough broadly welcomes the development of any system that will enhance breast cancer services and treatment, improve the breast cancer patient experience and augment breast cancer research. It is important that if an electronic records system is developed, it must be of value for individual health care and public health. However, the Department of Health should ensure that patients are not denied the right to decide who may access particularly sensitive information.

2.2 PCTs and all NHS staff should be supported by the Department of Health in creating and maintaining systems to ensure that information held on electronic patent records is both accurate and up-to-date. Such accuracy is essential to both safe and effective treatment, and to the validity of research based on the information stored, and therefore also benefits both the individual patient and public health as a whole.

2.3 The Department of Health should ensure that all staff are fully trained in data security and patient confidentiality, and that all and any access to data takes place only in specified circumstances. It is important that only healthcare professionals directly responsible for a patient's care should have access to the full contents of electronic records, with support and other staff being granted only access appropriate to their role.

2.4 The Department of Health should ensure that any electronic records system established is protected by the most thorough and up-to-date security hardware and software available, accompanied by effective systems to both limit the damage caused by and inform patients of any breaches.

2.5 The Department of Health should permit the use of anonymised electronic patient data in research, as a valuable resource that presents no risk to patients. The use of selected identifiable data should also be permitted, in both circumstances where express consent has been obtained from the patient, and where despite every effort such consent cannot be obtained, but approval by ethics and other regulatory bodies has been granted.

3. About Breakthrough Breast Cancer

3.1 Breakthrough Breast Cancer is the UKs leading breast cancer charity and is committed to fighting breast cancer through research, campaigning and education. Breakthrough has established the UK's first dedicated breast cancer research centre, in order to realise our vision: *a future free from the fear of breast cancer*. Breakthrough campaigns for policies that support breast cancer research and improved services, as well as promoting breast cancer education and awareness amongst the general public, policy makers, health professionals and the media.

3.2 Breakthrough works closely with healthcare professionals, patient advocates, and researchers. Our memorandum incorporates the views of Breakthrough and members of its Campaigns & Advocacy Network (Breakthrough CAN)—which is made up of over 800 individuals and organisations. Many members of Breakthrough CAN have personal experience of breast cancer as well as being involved in and working alongside their local NHS to try to deliver better treatments and services for people affected by breast cancer and their families. Breakthrough consulted Breakthrough CAN members, healthcare professionals and breast cancer researchers in the development of this memorandum and their views are reflected in its content.

4. *What Patient information should be held on the new local and national electronic record systems, and should patients be able to prevent their personal data being placed on these systems?*

4.1 Breakthrough broadly welcomes the development of any system that will enhance breast cancer services and treatment, improve the breast cancer patient experience and augment breast cancer research.

> "*I am all in favour of electronic patient records as it could help save lives.*" Breakthrough CAN member, Lancashire.

> "*. . . when patients are being treated in hospital the experts need all the necessary information to give the best diagnosis and treatment. Ideally 100% security of records is needed. [I] hope that electronic records lead to more accurate and efficient diagnosis, treatment and research.*" Breakthrough CAN member, East Sussex.

> "*For the most part I would support the notion of electronic patient records in that [they] provide (a) greater continuity of care with all members of the multidisciplinary care team able to communicate with each other and have instant access to decisions made by other carers regarding individual patients. This is particularly important when hospitals are split over several sites, or where radiotherapy or chemotherapy is held at a regional centre but the local unit is responsible for local care; (b) it avoids the issue of notes getting lost in transit between sites.*" Consultant breast care nurse, Hampshire.

4.2 Although we understand that the initial patient electronic record, or Summary Care Record, will contain basic information (such as details of allergies, current prescriptions and reactions to medicines), it is important that the eventual complete electronic patient record includes all clinically useful information. For example, past and current medication, significant past medical problems, diagnostic test results, allergies, general health and lifestyle information (such as height, weight, smoking, alcohol consumption) and demographic information, including ethnicity. Details of any information prescriptions or signposting to further information and advice that a patient has received should also be included in their electronic records once this information scheme has been rolled out.

4.3 It will be important to ensure that the data held on any patient record is up-to-date and accurate:

> "*The disadvantage of allowing [electronic] data to be more widely available is that the information is more likely to be relied upon in, for example, emergency situations. At present a GP would be contacted directly and the contents of the records confirmed or verified. With electronic patient records this is unlikely to happen."* GP, London.

4.4 A balance must be reached when determining the level of control a patient has over the content of his/her electronic patient record. Some patients would ideally like to have the right to prevent their personal information being placed on an electronic patient records system, although there is recognition that this could lead to delays in accessing records and treating such patients. However, it is also important that if an electronic records system is developed, it must be of value for individual health care and public health:

> "*My personal view would be in general to favour [individual health care and public health] provided there is no harm done to the patient. The more that individuals can prevent their data entering, the more the whole system becomes unusable, particularly for public health, but also for individual patient care. Thus, I would be in favour of at least some data being present for everybody, even if there are degrees of detail that individuals could prevent."* Epidemiologist, Surrey

4.5 Breast cancer patients would also like to see the provision of a "sealed envelope" so that every patient can determine who should access sensitive information contained within their electronic record:

> "*If a patient has medical conditions or treatments that [they] do not want others to know about they should be able to have that information kept private and not kept on the electronic record.*" Breakthrough CAN member, Lancashire.

> "*I . . . have some concerns regarding delicate information being included—such as in-depth psychological assessment, sexual health etc. But in terms of general diagnostic information and care necessary for treating the patient in a multidisciplinary way I support [electronic patient records]."* Consultant breast care nurse, Hampshire.

5. *Who should have access to electronic patient information and under what circumstances?*

5.1 Health care professionals directly responsible for a patient's care should have access to the relevant electronic health care records. Other staff needing access to a patient's data, for example medical secretaries or GP receptionists, should have levels of access appropriate to their role. It is important that all health care professionals receive adequate training in data security and patient confidentiality.

5.2 There is concern that the electronic records will be accessible to parties that do not have an interest in patient care:

> "*GPs and hospital doctors only [should have access]. Not insurance companies, police (without court order), social services or any other party without express consent."* GP, London.
>
> "*No relatives, friends or acquaintances of patients should have access without prior consent by the patient."* Breakthrough CAN member, Lancashire.
>
> "*There needs to be prevention, however, of outside individuals walking up to hospital computers and being able to look at other people's records."* Epidemiologist, Surrey.

It is therefore important that electronic patient records can only be accessed by appropriate parties, under specified circumstances.

5.3 Breakthrough CAN members and health care professionals have told us that they would prefer a simple system where all patient data (apart from that in the "sealed envelope") can be shared by relevant clinical staff, unless a patient chooses not to have an electronic record. A system that requires patient consent each time an electronic record is shared is likely to be complex and cumbersome:

> ". . . *this would seem impractical and could lead to mistakes. I think patients do not need to have the right to choose who has access to information if it is only [clinical] staff with that right."* Breakthrough CAN member, East Sussex.
>
> ". . . *the administration of this might be impossibly complicated and if that is the case it would be better to have a simple opt in or opt out system only.*" GP, London
>
> "*With regard to whether patients should be able to control who has access to [their record], I think that clinically it would be too complex if each record had different access provisions . . . so there should be reasonable . . . provisions that allow access by relevant clinical care staff."* Epidemiologist, Surrey

6. *Will patient confidentiality be adequately protected?*

6.1 No computer system is entirely immune to hacking and both Breakthrough CAN members and health care professionals are extremely concerned that an electronic patient records system will be vulnerable to security breaches:

> "*Confidentiality will probably not be as good as when all records were paper and locked in the records office. But hopefully the benefits of clearer and quicker to access records will outweigh this potential disadvantage.*" Breakthrough CAN member, East Sussex.
>
> "*I feel that there is a potential of people's medical history being cloned and false identities being easily created.*" Breakthrough CAN member, Hampshire.
>
> "*I think the NHS electronic record system is open to widespread breaches of confidentiality. The system is in no way secure and there are far too many people with the potential to access records far too easily.*" GP, London.
>
> "*The only concerns I have are in relation to confidentiality and access . . . mechanisms should be in place to protect individuals from potential invasion of privacy."* Consultant breast care nurse, Hampshire.

6.2 If an electronic records system is established, it is essential that it is protected by the most rigorous security software and hardware possible. All security measures must be kept up-to-date and provisions must be in place inform patients and their clinicians if the security system is breached and to limit any potential harm this may cause the patient.

7. *How should data held on the new system be used for purposes other than the delivery of care?*

7.1 Breakthrough CAN members have told Breakthrough that they support valid research to enhance breast cancer services and treatments, improve patients' quality of life and investigate the causes of breast cancer. Some health care professionals and Breakthrough CAN members feel that if the electronic data is to be used in research without the express consent of the patient, all identifying information should be removed:

> ". . . *as far a[s] cancer is concerned all research is good and therefore information should be available for medical research . . . without the patient being identified."* Breakthrough CAN member, East Sussex.

7.2 Health care professionals and scientists that undertake breast cancer research agree that anonymised patient data is an extremely valuable resource:

> "*Provided no harm is done to the individual, I favour the Scandinavian assumption that individuals owe it to society to some extent to allow their data to be used for a public health benefit . . . For anonymised data there is no possible harm to the individuals, so I think individuals should not have to consent [to] anonymised uses.*" Epidemiologist, Surrey.

7.3 However, in some research studies it may be necessary to include selected identifiable patient data and it may not always be possible to obtain the express consent of every patient involved, especially in large scale studies. While Breakthrough believes that every effort should be made to obtain patient consent for such research, if this is not possible and the research is deemed suitably important, identifiable patient data should be used without consent as long as the research has the approval of an ethics committee, the relevant Caldicott Guardians[33] and bodies such as PIAG[34]:

> "*Your information will go to the cancer registry without your permission. Relatives cannot change what goes in the death certificate.*
>
> *Research is done in all these areas, and some has been very beneficial to the health of the nation."*
> Genetic oncologist, London.
>
> *"If active consent was required, then large scale research would become very difficult, and potentially selected and hence biased, which would seriously damage the validity and hence value of doing the studies . . . For identifiable data, I think ethics committees should decide whether there could potentially be harm, and whether, on a case-by-case basis, individual consent is required.*"
> Epidemiologist, Surrey.

Vicki Nash
Breakthrough Breast Cancer

15 March 2007

Evidence submitted by the British Association for Community Child Health (EPR 16)

The British Association for Community Child Health (BACCH) is the largest paediatric subspecialty in the UK; we represent about 1,200 career grade paediatricians working in many settings such as health centres, clinics, schools and social care venues as well as traditional hospitals. We work closely with colleagues in other agencies, particularly education and social care and with other health colleagues including general practitioners and community nurses such as health visitors and school nurses. Our referral base is extremely broad and the spectrum of our work covers physical illness, learning problems, emotional health as well as psychosocial problems such as safeguarding and children in special circumstances. We seek to reverse the inverse care law by specifically targeting vulnerable children, carry out holistic assessments of health needs and help establish a multiagency network around the child and family. Many of the children we see have multiple problems NOT requiring admission to hospitals and better managed close to the child's home and school. We would like the Electronic Health Record to support our attempts at reducing health inequalities for our patients, whose manifold health problems are often compounded by economic adversity.

The British Association for Community Child Health (BACCH) would like to make the following points specifically with regards to the needs of children and young people (CYP):

1. There must be adequate safeguards for confidentiality; this is primarily a technical design issue although staff training will be required. Where there are genuine safety concerns for example in the context of a partner fleeing form domestic violence, safeguards about revealing the address and location of the family can be increased without the health data needing to be hidden.
2. Regardless of the complexity of information being held on the system, it cannot be in the interests of CYP for their data to be withheld from the system; indeed if parents are able to prevent their children's data from being entered onto the system, it is likely that the planned information sharing index (ISA) supporting the concept of Every Child Matters cannot be developed. Most parents can see the benefit of health information being shared and it is, unfortunately, likely that it would be the parents of the most vulnerable children, wishing to disengage from services who would be asking for their children's data to be withheld. This would worsen the existing inverse care law and make, in particular, safeguarding children even more difficult.
3. Access to named patient data should be role based and justifiable on the basis of need to know (in order to deliver health care). There should be a clear audit trail and regular audits.
4. Basic demographic data (name, date of birth, sex, address, GP and educational establishment) will be need to be transferred from the national spine to set up the Information Sharing Index, which will also carry the name of involved professionals (barring some specified exempt services such as sexual health services) and indicate whether a common assessment framework (CAF) has been carried out. Detailed specifications for the ISA and CAF will be available from the DfES.
5. We assume that the term "delivery of care" includes secondary uses of data such as commissioning and auditing services and the use of data for public health purposes; this should include monitoring

[33] Since 1999, each NHS Trust has had to appoint a senior member of staff to act as a Caldicott Guardian, responsible for overseeing the use of personal health data and ensuring that patients' rights to confidentiality are respected.

[34] Patient Information Advisory Group (PIAG). This body was established by the Health and Social Care Act 2001 (England and Wales) to advise the Secretary of State for Health about when patient consent can be set aside and under what circumstances.

of selected key outcome and process measurements, eg immunisation coverages, waiting times for treatment of disabled children, time scales and results of looked after children's health assessments and age at identification of severe hearing loss (among many others needed to cover all the modules of the National Service Framework for children). The data should be available ,subject to confidentiality agreements, to agreed research projects; in some cases it may not be possible to obtain retrospective subject consent but if no harm is deemed likely by an appropriate ethical committee (eg for statistical analyses), the research should still go ahead for the benefit of the entire population.

6. A comprehensive record available instantly throughout England is a dream worth working for but is beginning to look like a mirage with an ever receding completion date. It may be more realistic and useful to concentrate on developing an agreed summary electronic health record covering, for children, the child health promotion programme and the domains of the common assessment framework (CAF) as well as current health problems and medication and ensuring immediate transmissibility of such a summary; further details can be then requested; for example it is useful to know a child has had an operation for squint but not so useful to know the blow by blow account of the operation.

7. In our view the delays in the delivery of the system are due to:

   (i) Poor communication between IT specialists and clinicians.

   (ii) Disregard for work that may have already been done in many clinical departments on their information needs.

   (iii) a failure to grasp the complexity of the delivery of health care, specially for vulnerable groups such as children, patients with mental health and learning disability, where social care and education are intimately involved. Referral sources and onward referrals for children cover a wide range of professionals in several agencies (health, social services, education, police, voluntary organisations) and are often multiple for the most vulnerable children, in order to set up a multiagency network and team around the child and family.

   (iv) an unrealistic pace: clinicians cannot set aside seven whole days in the next two months (the current request for clinical involvement for Lorenzo) to develop IT systems in the face of their current workload. Seconding clinicians to CFH is only partly the answer as the clinicians still on the ground are reduced in numbers and still need to become involved.

   (v) an unrealistic aim: whereas transmitting X-rays is, informatically, simple, transmitting complex clinical information and clinical judgements is more difficult; in our view transmitting summaries in an agreed format, developed nationally for each subspecialty would ensure the availability of essential data anytime, anywhere.

Therefore, in our view, work should concentrate on developing the summary templates and their messaging as the fist step for all clinical services. In fact the only real success story of CFH so far is PACS; sending X-rays pictures relied upon a summary of the information in an agreed format (pixels for pictures plus a report) being messaged instantly across the entire network to recipients in distant places. The development of the clinical record for children is seen as a major priority particularly after the Lamming report. The potential for timely and accurate information exchange could potentially save lives by alerting professionals to abnormal or atypical patterns of care access by parents (eg repeated non attendance at health appointments and no access visits) and deficiencies in care delivery by professionals (eg adverse incidents). On a more positive note, there is high interest amongst paediatricians to develop this quickly and in a standardised way. The commercial interests of developers can potentially slow this development unless appropriate sharing of intellectual property rights of NHS staff is facilitated. It cannot be right that private informatics firms should seek to garner for their shareholders only the benefit they have obtained from the thinking processes of many NHS staff paid for by the tax payer.

The DH and DFES need to have a much closer liaison in the development of a holistic care record that takes advantage of the developments such as ISA and CAF. Currently the CFH programme is heavily skewed towards so called "pure" hospital inpatient based health measures and this is particularly disadvantageous for vulnerable children where maintenance/improvement in health status is based upon interagency work usually occurring outside acute care units.

Dr Fawzia Rahman
Consultant Paediatrician, Derby City Primary Care Trust,

Dr Mitch Blair
Chair BACCH Informatics Working Group
on behalf the British Association for Community Child Health

Evidence submitted by the British Computer Society (EPR 66)

Introduction

The BCS is delighted to have been invited by the House of Commons Select Committee to comment on its Inquiry into Electronic Patient Record and it's use.

The British Computer Society (BCS) is the industry body for IT professionals and a chartered engineering institution for information technology (IT). With members in over 100 countries, the BCS is the leading professional and learned society in the field of computers and information systems.

In the limited time available we have consulted members of our Health Informatics Forum (BCSHIF). Members of the Forum are from a wide range of interested parties, representing clinicians, managers and informatics experts. We are therefore confident that the views expressed represent those from a much larger body of IT professionals in the health sector.

Executive Summary

1.1 BCSHIF comprises groups containing clinicians, managers and informatics experts working directly and indirectly for the NHS: in the design, development, implementation and use of current and future NHS information systems. For their credentials, see www.bcshif.org. . Supplementary evidence is attached in the form of the BCSHIF Statement of the Way Forward for NHS Health Informatics, available also from www.bcshif.org .

1.2 BCSHIF supports the concept that successful implementation of appropriate electronic patient records systems is essential to providing safer and more appropriate patient care and to the viability of the NHS and its constituent organisations.

1.3 Patient information held must be fit for purpose, be only held for as long as necessary and for use by authorised professionals with a need to know as required by the Data Protection Act and other relevant legal requirements.

1.4 Access should be for explicit purposes agreed by the individual record subject; both for direct patient care and for secondary uses, except where there is an emergency requirement or an over-riding need to know for the public good.

1.5 We suggest that patient confidentiality can be best ensured with three levels of patient data confidentiality deployed within a distributed record with access mechanisms that balance patient rights with wider public benefits. Informed patient consent to access should be paramount.

1.6 Patient data can and should be used for other purposes beyond personal care and treatment, predominantly in anonymised/pseudoanonymised form. Secondary uses requiring personally-identifiable information should continue to require explicit patient consent for information use. No other uses of the patient record should be permitted.

1.7 Progress in developing the National Care Records Service (NCRS) varies depending on the mix of application solutions in each geographic area, the current state of readiness of the organisations and the fitness for purpose of those solutions. There are fundamental questions of structure, content, confidentiality and security that require resolution before further implementation of the NCRS.

1.8 BCSHIF seeks to work with the relevant agencies in resolving the issues it has identified. We would be pleased to expand on analysis and recommendations contained in this report if the Health Select Committee so wishes.

Introduction

1.9 Sharing patient information with those making decisions about the care of the patient (professional and non-professional) is vital to ensure safe and appropriate care. Patient information may be shared by "push" (where someone gives unsolicited information to someone else, as in a referral or discharge message or email containing a test result), or "pull" (where someone makes an enquiry of a person or Electronic Patient Record (EPR). Previously, sharing between care providers has predominantly been via messaging and personal enquiry. Sharing record(s) per se has largely been restricted to staff caring for the patient within a care provider organisation acting as the EPR(s) "owner".

1.10 NHS Connecting for Health (NHS CFH) is proposing to change the balance between the various methods, so that sharing the patient's EPR(s) assumes a more important role. This change is non-trivial. Ensuring that the author's meaning is transferred to the enquirer is a real challenge. Enquirers will also need to selectively filter EPR contents to suit their needs and avoid information overload. There is therefore an onus on content authors to make their record entries as comprehensive, contemporaneous and consistently understandable as is practicable. It is also relevant to note here that NHS EPRs exist outside NHS CFH.

2. *What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems*

2.1 The information held must meet legal requirements and tried and tested standards. The primary purpose of the EPR is to support direct patient care and treatment. For this, extensive detailed personal and clinical data about the patient is necessary. These include demographic details (name address date of birth, ethnicity, etc), details of the past and current state of the patient (including diagnoses), investigation results, treatments, family history, and relevant social details (including information about third parties). Only the patient and those involved in their care and treatment should have access to this personally-identifiable data and this access should be governed by their role in that care.

2.2 Patients' requirements are central to any EPR records developments. Patients' reluctance to opt in to having their information stored and shared have led to delays which will not be resolved until their concerns are addressed (see "Big Opt Out", http://www.nhsconfidentiality.org/).

2.3 Unless patients are confident that their data is secure and only used for health-related purposes, they will not allow selected significant information to be recorded or may withhold their entire record. In either case, their care may suffer. We support a patient's right to withhold personally-identifiable data, given that they are informed of any possible effect on their care. Patient withholding of data will be minimized by restricting uses of personally-identified information and ensuring security, and respecting their concerns about confidentiality.

2.4 Most sharing of personally-identifiable patient data, takes place during episodes of care in a local health economy, and the data should be retained for legal and clinical purposes at that level. There are other legitimate needs to share patient data more widely during treatment. These include patients moving between the UK home countries, or NHS and private care, or choosing to use alternative facilities, or accessing national specialist units or receiving shared care with social services. In such circumstances appropriate patient information needs to accompany the patient on their journey through care. What is shared and how it is shared depends on the intended use, and requires further consultation to confirm.

2.5 There is a case for a simple EPR summary to support emergency care, similar to Scottish Emergency Care Summary (ECS). It currently contains safety-related patient data. Scottish patients must provide consent before it is used (if possible), and may opt out of having an ECS. The BMA has approved these arrangements, unlike those for the NHS CFH Summary Care Record.

2.6 If a distributed (virtual) record architecture is adopted for the NHS Care Record Service (NCRS), then minimal patient information needs to be held at national level (see 5.5)

3. *Who will have access to locally and nationally held information and under what circumstances*

3.1 Who has access to a specific record depends on the agreed purposes for using that data. In line with current practice and guidance, use of patient-identifiable information for anything other than direct patient care should only be with the explicit informed consent of the patient; unless there is an over-riding public interest or legal requirement. See 6 for more on secondary uses.

3.2 Those involved in the direct care and treatment of a patient should have access to all information necessary to provide those services effectively, subject to their role and any patient-derived restrictions (see 5.2). Accessors should include the patient, and if they so wish, their non-professional carers.

3.3 Delivery of care increasingly requires cross-organisational, multi-disciplinary team working (eg in clinical pathway management, mental health care programmes, single assessment processes and complex multi-agency scheduling) and related information sharing. Sound interoperable systems must reflect the complex supply chains involved in delivering healthcare, and securely and sensitively handle information linkage across organisational boundaries.

3.4 Future extensions to remote patient record sharing means that increasingly substantial patient-identifiable data will be in the custody of organisations other than those that collected it and that are not clinical in nature. Patient trust in such organisations is significantly less than in the clinical professions, and such organisations should not be the data controllers. Confidentiality procedures that meet concerns already expressed by patients will be challenging, but must be put in place in addition to consent given at or prior to time of use.

3.5 Nationally, data quality is critical to realising benefits from raised investment in IT and to ensuring patient confidence in the sharing of their data (reference the Helen Wilkinson case, http://society.guardian.co.uk/e-public/story/0,,1937302,00.html). Enabling patients to access their records, add to them and initiate corrections will significantly assist this. It will also encourage patients &/or their carers to become "primus inter pares" of their care teams, and to assume greater responsibility for their health and healthcare, a key element of current healthcare policy (for current work see http://recordaccess.icmcc.org/). Patient custodianship of their EPR(s) should be seriously considered.

3.6 Information governance requires establishing generic requirements for information sharing; to improve the quality of individual patient care and the efficiency of care provision. .Any arrangements to use EPR content, at local or national level, must support the trust that is crucial to clinician-patient relationship,

and technical issues should not be allowed to unduly dominate the discussions. This work goes beyond the boundaries of NHS CFH, but the results will form the foundation for revisiting the National Care Records Service (see 7).

3.7 Transferring EPR data between systems where the user does not explicitly initiate that transfer, raises difficult technical issues and concepts such as "role-based access controls", "legitimate relationships" and "sealed envelope" mechanisms. These are not yet acceptable to clinicians and the public.

4. *Whether patient confidentiality can be adequately protected*

4.1 Privacy issues will escalate as multi-agency sharing of care—and therefore patient data—becomes more prevalent. The nature of the EPR requires a high degree of confidentiality and other privacy mechanisms to restrict access only for agreed purposes and to authorised professionals with a recognised need to know, subject to any restrictions that the patient wishes to place on the sharing of their data (in whole or part).

4.2 Research, suggests that patients see their data as having one of three levels of confidentiality:

(a) available wherever required by those providing personal care to the patient (the vast majority of patient records and their contents). Such data could be shared as need for the purpose of personal care;

(b) available to all clinicians caring for the patient within a specific provider organisation, eg hospital or practice (common now where individual provider organisations hold their own EPRs). Such data would not leave the custody of the organisation without explicit patient consent; and

(c) availability restricted to the original recipient only (applying to very limited parts of EPR for a small minority of patients). Such data would not be viewable by any other person without explicit patient consent.

There are also information environments, such as community pharmacies, with which patients feel less comfortable sharing their information. However implementation of these constraints is feasible, and offer a more acceptable alternative to the "sealed envelope" mechanism proposed by NHSCFH.

4.3 From the record user's point of view, NHSCFH assume that the complex technological and policy challenges are answered by restricting access to patient records to those having an appropriate role (eg NHS hospital consultant) and relationship with the patient (eg GP registered with). In practice these mechanisms have sometimes proved cumbersome to use, and manual workarounds have been deployed which enable inappropriate access to patient data. Accessors can also override the software's controls, although this is reported after the event to the organisation's information governance monitor—the Caldicott guardian. The mechanisms also depend on near real-time updating of roles and legitimate relationships as they change. Such evidence as exists suggests that patients prefer clinicians as data custodians rather than algorithms driven by accessor properties.

4.4 The NCRS can develop structurally in a number of ways:

(a) a comprehensive patient record held in its entirety in one or more national/central databases;

(b) a distributed virtual record pulled together in whole or in part when required, from disparate patient record databases, and presented for a single instant for a specific user; or

(c) a mixture of both.

4.5 The different structures have different risks and therefore need to be protected in different ways. For example, a higher risk is posed to a celebrity's EPR from a central database presenting "one place to look" to those with malicious intent; whereas a distributed database makes lower demands. There are unresolved questions about data duplication, and data that has been changed and copied to several locations. Ensuring the consistency and timeliness of centrally-held patient data and local records is a concern.

4.6 BCSHIF believe a distributed, (virtual) record approach is the most sensible way forward and most easily secured. It can make use of heterogeneous records from multiple agencies (including those outside NHSCFH), offers a basis for information privacy and confidentiality, and can interact with different informatics solutions proposed in other UK home countries. It would also encourage the convergence of record architectures and semantics over time. This approach seems more in keeping with web-enabled 21st century than a central record.

5. *How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research*

5.1 Valid acceptable secondary uses (those other than for care delivery) include audit, research and development of clinical services, population health management, financial management, performance monitoring and development of healthcare facilities and services. No other uses of the patient record should be permitted.

5.2 Patient consent is still necessary to use patient-identifiable data for secondary purposes, for example for disease registers, clinical trials or research. Where patient data is anonymised/pseudo-anonymised before use, patient consent is not required. However the onus is on those who anonymise/pseudoanonymise data to ensure that patients' identities cannot be inferred from other patient data present. Given that linkage of anonymised/pseudoanonymised fragments of patient data is possible, ongoing use of the Health & Social Care Act 2001 to permit the use of patient-identifiable data for secondary purposes should be greatly reduced. Proposals for secondary uses should be made clear to patients and care providers at the earliest possible time to obtain agreement and allay ongoing concerns.

5.3 In future, analysis of the "cradle to grave" record will improve the way care is delivered and change clinical practice. Currently, little prepares clinicians for the ensuing changes in the way they work. Clinical professions and informaticians should provide clear and comprehensive guidance on good clinical record keeping and sensitive data management in all care sectors during systems implementation. Clinical (and health management) education should include these concepts.

5.4 Patient demographics services, spine directory services and a transaction and messaging service present new challenges. New secondary data sources based on the Secondary Uses Service will require management/administrative staff to have improved management skills and education for handling that data.

5.5 Data quality is critical to realising the benefits of IT investment. Access to comprehensive, accessible and accurate record data, in whatever form, is crucial to appropriate clinical and health management decision making. Work to monitor and improve data quality are key to achieving this.

6. *Current progress on the development of the NHS Care Records Service and the National Data Spine, and why delivery of the new systems is up to two years behind schedule*

6.1 Major reasons for delay are the information governance issues raised in section 5. The Ministerial Taskforce Report on the NHS Summary Care Record, http://www.connectingforhealth.nhs.uk/publications/care—record—taskforce—doc.pdf, is a small step in the right direction, but not enough.

6.2 Work on the technical standards to allow EPR interoperability are now under way, but should have been pursued vigorously from the start of NPfIT to enable greater EPR product convergence sooner.

6.3 The problems outlined in 2.2 are still unresolved. These are particularly apparent in secondary care and mental health providers, where EPRs are a rarity, and coded content in them rarer still. The cultural and information management issues require serious investment to ensure the effective use of the EPR systems being provided. The consequent changes in business processes will take time and resources to introduce. Funding and planning for these activities is not earmarked nationally, and have to compete with other more pressing local priorities.

6.4 Whatever form it takes, the NCRS depends upon comprehensively implementing local EPR systems. Relatively few local systems are operational outside general medical practice, though the number is growing. The readiness of NHS organisations to adopt EPRs varies widely, as does acceptance of the business case for them by local management and would-be users.

6.5 Recent implementations of CBS (Choose & Book) and PACS (Picture Archiving & Communications Systems) demonstrate the need for firm foundations to avoid delay. PACS implementations are relatively trouble free. The systems are tried and tested, have a clear business case and benefits and have clinical support. CBS on the other hand is developing as it is being implemented, and the business case and benefits to those who use it are unclear. Significant delays are being observed.

6.6 Secondary care EPR solutions that are a good fit with local needs are frequently not yet supplied, causing some organisations to take interim non-NHSCFH systems to avoid risks to patient safety. Local Service Provider (LSP) contracts have sometimes meant replacing satisfactory operational systems with NHSCFH-compliant systems that are functionally poorer. Advanced users of existing systems have been understandably reluctant to move to LSP applications that offer little significant benefit to them. This may be answered by increasing the NHSCFH EPR system portfolio from which Trusts and practices can select.

6.7 Better communication/consultation with those with informed domain knowledge and experience will engage health professionals more effectively; and maximize the likelihood of successful deployments that really benefit patient outcomes and NHS efficiency. BCSHIF recommends that NHSCFH is transformed into an open partnership with NHS management, users, the informatics community, suppliers, patients and their carers, grounded in understanding, trust and respect.

6.8 BCSHIF recommends that the Personal Spine Information System (PSIS) element of NCRS be put on hold until its purpose, and overall requirements for, and design of, the NCRS are agreed.

6.9 The NCRS requires realignment with a more realistic business-based informatics strategy and with patient confidentiality requirements to ensure that solutions are fit for purpose and acceptable to users, costs

are contained and delays minimized. A framework is required in which a wider range of heterogeneous systems can share information and workflows, and in which existing systems and existing solution suppliers play a greater part.

Dr M G Rodd
Director, External Relations of the British Computer Society (BCS)

March 2007

Evidence submitted by the British In Vitro Diagnostics Association (EPR 33)

INTRODUCTION

The British In Vitro Diagnostics Association (BIVDA) represents manufacturers and suppliers of *in vitro* diagnostic products operating within the UK. Our membership represents more than 95% of the industry sector which had annual sales in 2005 of £447 million. Our products are the tests which diagnose and rule out disease or physiological conditions, monitor therapy, screen for disease and are also used to ensure the safety of the blood supply. They range from simple self-test kits such as for pregnancy to the most sophisticated molecular technologies and fully automated laboratory systems. We are delighted to respond to this inquiry, and state our thoughts on the subject areas outlined by the Committee.

What patient information will need to be held on the new local and national electronic record systems, and will patients be able to prevent their personal data being placed on systems?

The *in vitro* diagnostic sector provides an essential, yet often underestimated role in the delivery of NHS care. Of all patient data collected for diagnosis, an estimated 70% comes from diagnostic tests.

For example:

The management of diabetes relies heavily on routine measurement of glycated haemoglobin—the results are use to determine how well the patient is maintaining their blood sugar levels day to day which is crucial to prevent, or at least delay, onset of the serious side effects of this condition. The routine test results need to be easily accessible by all healthcare practitioners involved in the patient's care.

Similarly there are tests used to monitor therapy and progress in heart disease such as testing for the levels of the drug Digoxin or using naturietic peptides to monitor patients suffering heart failure.

And there are a battery of essential tests which monitor the treatment of cancers or which can indicate early recurrence such as prostate specific antigen (PSA) or alpha feto protein (AFP). Equally c-reactive peptide is a useful marker of infection which can help determine if an oncology patient needs to be re-admitted to hospital during chemotherapy.

These are just a very few examples of some tests used to monitor some of the more common long tem conditions.

It is clearly crucial that the results of these tests are included on the patient record if the EPR is to perform the functions of assisting early detection, prevention and monitoring. Furthermore, all health professionals involved in patient care have access to this data, to enable decisions and interventions to be made as early as possible.

Who will have access to locally and nationally held information and under what circumstances?

In order to address the capacity constraints on the NHS, there has been a marked increase in the level of point of care testing. This is to be commended—patients are able to be tested much earlier, as health professionals such as community pharmacists are now able to conduct tests that may previously have required a hospital out-patient appointment.

The role of the EPR must therefore take account of these changes in testing location. Community pharmacists and other professionals who have been brought into the diagnosis process through point of care testing must be able to input results into the EPR as well as accessing records.

Failing to take this into account will significantly undermine the advances made under point of care testing.

Will patient confidentiality be adequately protected?

The issue of patient confidentiality is central to the EPR debate. BIVDA fully support the argument that the necessary safeguards must be in place in order for patients to feel reassured about their privacy.

It must be noted, however, that safeguards to ensure patient confidentiality should not be at such a level so as to restrict disease management.

Access to results from IVD tests are crucial to a wide range of management processes, such as detecting infections, ensuring a match for blood or organ transplantation, and screening populations at risk for symptom-less diseases.

A sophisticated process of check points must be developed to ensure that access to test results is permitted at the necessary level to ensure such disease management techniques are uninhibited, without compromising patient confidentiality.

How data held on the new systems will (and should) be used for purposes other than the delivery of care eg clinical research?

The UK has a strong diagnostic sector which can take credit for the development and introduction of a number of cutting edge tests and technologies over recent years. The industry itself is relatively young having grown significantly in the last forty years. Prior to this all tests were discovered and developed in the UK by the professionals working in the pathology laboratories.

Much of this innovation often comes from within the NHS, with essential research based on data obtained from NHS sources. In order to continue the UK's record in the development of new diagnostic services for the benefit of NHS patients, clinical research must be made available to the appropriate engines of healthcare R&D.

The EPR provides a simpler and more effective means to collecting patient data. Such data must continue to be shared with the research sector to ensure the continuation of new product development, whilst adhering to all the sufficient checks to guarantee patient confidentiality.

What are your views on the current progress on the development of the NHS Care Records Service and the National Data Spine?

BIVDA is concerned at the scope of these two initiatives. The connectivity of laboratories to the NHS system is not included in the specifications, despite clear evidence to demonstrate that the lack of a joined up approach between laboratories and primary care practitioners is restricting the effectiveness of services.

Doris-Ann Williams
Director General, British *In Vitro* Diagnostics Association

March 2007

Evidence submitted by the British Medical Association (EPR 40)

EXECUTIVE SUMMARY

- The BMA supports the creation of a summary record. Patients should play a central role in deciding what information, if any, is shared and checking for accuracy. It is the BMA's view that explicit consent should be obtained and patients must have the right to prevent their information being uploaded or shared. It is important that an incremental approach is adopted and that experience of sharing summary care information should be accumulated before detailed care records are shared. Patients must have the right to prevent the sharing of their detailed care records beyond organisational boundaries.
- Information governance presents a significant challenge. There needs to be clarity about how the number of alerts will be managed by Caldicott Guardians, what training and resources will be in place to support Caldicott Guardians, the penalties which will be in place if the system is abused, and about how smart cards can be better managed in busy environments.
- The BMA welcomes the Secondary Uses Service, in principle, and believes that this could bring major benefits to health and healthcare. There are, however, a number of areas which remain unclear as indicated in the response.
- Many of the problems encountered by the programme have been caused by stakeholders, clinicians and patients not being consulted on developments. Following the National Audit Office report, this has started to be addressed but there is still a sense, at times, of proposals being signed off without adequate consultation and an element of secrecy around developments. There needs to be greater transparency and openness with both clinicians and patients about developments and engagement, at every stage, of healthcare professionals who will use the systems.
- Connecting for Health needs to be clearer about its strategy. Many areas remain vague or unanswered including UK integration, who beyond the NHS will have access and how the detailed care record will be implemented. In addition, the workload implications of implementation have not been identified and could be a major rate limiting step for further roll out if not resourced. Connecting for Health needs to work with stakeholders, clinicians and patients to address these unanswered questions.

— The main purpose of an electronic patient care record is to improve patient care. The needs of patients must remain central to these discussions and we hope that the early adopter phase will provide the opportunity to test out some of the theory around the National Care Records Service (NCRS) and find out what patients really require. Further roll out must not go ahead until lessons have been learnt from the evaluation of the early adopters.

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on new systems

1. The BMA supports the creation of a summary care record on the national electronic record system. The current hybrid system of paper and electronic records is far from perfect and we can see the benefits that greater sharing of healthcare information could bring to everyday working practices to improve patient care.

2. It is the BMA's view that it is for patients to decide, in discussion with a healthcare professional where appropriate, the extent to which their clinical information is placed on electronic systems. It is vital that patients are properly informed about any changes and understand the implications of both sharing and withholding information. The BMA's policy is for explicit consent to be obtained before any healthcare information is uploaded onto the system. This will ensure that patients are properly informed and have the opportunity to check their record for potential sensitivities and accuracy prior to any upload. This should not be a one off event; following each consultation, patients should have the opportunity to consider the information which could be shared with others involved in their care. Consideration needs to given to supporting vulnerable groups such as the frail elderly in this process.

3. The systems should support this process by highlighting the clinical information, which could be added to the summary care record. The BMA welcomes the involvement of clinicians in developing standards to support this process. It seems sensible that the summary record should be comprised of basic information such as medications, adverse reactions, allergies, major diagnoses and test results, provided that the patient is in agreement. The early adopters will play a key role in testing this with clinicians and patients. We hope that the independent evaluation will provide essential feedback on patients' decisions to influence future developments and that the deployment timetable allows for appropriate evaluation.

4. If information is to be shared more widely it will become increasingly important that information in patient records is meaningful to the viewer. A prerequisite is that all records, local and shared are accurate. GP practices are being accredited before any information is uploaded and patients will play an important role in checking their summary record before the initial upload. There needs to be an ongoing commitment to ensure that records remain accurate. There must be investment in training clinicians and staff to ensure that data is entered appropriately. Electronic records are dynamic and introduce a new responsibility of data husbandry that needs to be resourced. Potential viewers of the NHS Care Records Service may need to be trained to understand and interpret the context of such records.

5. Patients must have the right to prevent their healthcare information being uploaded onto shared systems. Some patients will want reassurance that their healthcare record will not be shared beyond their GP practice or the organisation in which it was created. We would not want patients' access to health care services unreasonably compromised by making this decision. Failure to provide this option could result in patients withholding healthcare information adversely affecting clinicians' ability to provide proper treatment and increasing patient safety risks. Trust is critical to the success of the NHS Care Records Service.

6. With regard to detailed care records, patients should have the option to prevent their information being shared beyond organisational boundaries. If clinical data is entered onto the GP system, patients must be able to prevent this information being shared beyond the practice team. The BMA also believes that patients must have the option of sharing their summary care information on a national level without sharing their detailed care information at a regional level. Many patients will be happy to share basic information so that it is available in an emergency but may be uncomfortable about sharing their detailed care record outside organisations, which may include embarrassing and/or sensitive information that would not have any impact during an emergency health episode. The BMA also believes that there must be an incremental approach and experience should be accumulated in sharing summary care information before detailed care records are shared with other databases.

7. The BMA accepts that it is necessary for patients' demographic details to be held on a centralised system in order to deliver care, in the same way that NHS patients could not opt out of being recorded on the Exeter system. There may be situations, for example if a patient is in a witness protection programme, or otherwise hiding from violence, when a patient's demographics may be hidden or "flagged sensitive". There needs to be greater clarity about how these patients, who are often vulnerable, will be informed that this option exists, how their health information held on the spine can be accessed and how being flagged sensitive will impact on their use of the health service. For example, will they be able to use GP2GP transfer, Choose and Book and the Electronic Transfer of Prescriptions (ETP) services? It needs to be clear that personal sensitive information will never be held on the Personal Demographic System (PDS). We would also like to see clearer guidance about the consequences of trawling through PDS without reason.

Who will have access to locally and nationally held information and under what circumstances

8. The BMA supports the concepts of legitimate relationships and role based access to control who has access to what information. It is the BMA view that it is important that the system is workable. Access controls must not be so stringent that they delay clinicians providing treatment to patients.

9. Patients should have control over who has access to their records. Patients should have the choice of:

(a) Having no clinical information uploaded onto the national system provided that they understand that limiting the information that will be immediately available via the spine, even in an emergency, may be to their detriment;

(b) Having a hidden summary care record so that it can only be accessed with a patient's explicit consent or in an emergency situation;

(c) Having a summary care record so that it can be accessed by those directly involved in a patient's care but restrict the sharing of their detailed care record to the organisation it was created in;

(d) Sharing their summary and detailed care record nationally and regionally, respectively;

(e) Placing sensitive information in sealed or "sealed and locked" envelopes to restrict sharing. The BMA supports the concept of sealed envelopes but is concerned about delays in their delivery and the practicalities of their implementation.

10. The BMA supports developments such as Healthspace, which enable patients to have greater access to their own records. We support developments which enable patients to be more involved and potentially add to their own records at any time. The BMA hopes that this will allow patients to include advanced directives and views on organ donation on their record. Urgent consideration needs to be given to children and arrangements for accessing Healthspace by "Gillick competent" children.

11. The BMA recognises that in some circumstances it may be beneficial for some groups outside the NHS who provide care, to access the summary care record, including dentists, opticians, community pharmacists and social care workers. In such circumstances access must only be possible if a patient has chosen to have a summary record and has provided explicit consent for each of such groups to have access to the summary record. Patients and clinicians may feel concerned about this and there needs to be consultation with stakeholders about the extent to which records are shared beyond the immediate NHS.

12. As part of NHS system reform, private providers will increasingly provide care to NHS patients. Private providers should be subject to the same access controls and should be responsible for their own local detailed records. There needs to be clarification about what happens to the record when a private provider ceases to deliver NHS services. Arrangements should be in place for the local detailed record to remain part of the of the patient's record.

13. The primary function of the NHS Care Records Service is to provide care for patients and the BMA would strongly oppose any plans to allow other government agencies access to the NHS Care Records Service, for example, social services, the police and the Home Office. There are other more appropriate routes for information sharing, when necessary, with these agencies. The purpose of the NHS Care Records Service is to provide care to patients and allowing other agencies access would undermine trust in the system and the doctor/patient relationship. There must be strict penalties for anyone who attempts to inappropriately access the NHS Care Records Service.

14. The BMA is concerned that there appears to be little progress in supporting patients who live close to the UK home country borders. The need to ensure that systems are integrated across the UK was raised by the BMA at the outset of the programme. Thousands of patients live close to the borders and there needs to be a mechanism in place to ensure that if a patient receives care across the border, clinicians can have access to necessary information and share healthcare information so that they do not receive sub-standard care. There are also an estimated quarter of a million people who migrate between the 4 nations and many patients who receive treatment as temporary residents. Having a nationally available summary care record with local detailed records supports by interoperable clinical messaging with support this need.

Whether patient confidentiality can be adequately protected

15. The protection of patient data falls into two categories: (i) the technical security and (ii) information governance. The BMA believes that the technical security arrangements provide a sound basis requiring only modest changes to provide the technical support required to meet all of the confidentiality issues we have identified. The security framework does not provide mechanisms that allow the particular issues that relate to the protection of the records of NHS staff to be addressed. It is the information governance and "people" side of security, which in many ways, presents the greater challenge.

16. However secure the system, there is always a risk to confidentiality when increasing the number of people who have access to the system. Some actions which put the data at risk may be accidental such as leaving smart cards in the system. Other actions may be to speed up processes; there have already been cases of smart card sharing due to the time it takes to log into systems, for example at an acute hospital in South Warwickshire, or giving receptionists a clinician role in Choose and Book. There will also be occasions when staff access records for inappropriate reasons.

17. These issues are not new but become a greater challenge with a centralised system. Whilst an alert system may detect inappropriate access, it will only become apparent after the event. The BMA is yet to receive clarification about how the number of alerts will be managed by Caldicott Guardians and is concerned that illegitimate access may go undetected or uninvestigated.

18. The BMA has already raised concerns with Connecting for Health over the funding and resourcing of Caldicott Guardians and privacy officers. The BMA welcomes the establishment of the Caldicott Guardian Council, and the recent publication of *The Caldicott Guardian Manual 2006*, but is concerned that despite these efforts, training and resources will not be available to ensure that Caldicott Guardians and privacy officers will be able to fulfil their new extended responsibilities under the NHS Care Records Service. Given that the government is placing emphasis on safeguards that these individuals will police, as a means of reassuring the public and the profession that they can have trust in the system, it is vital that these resources are planned and made available.

19. Preventing access in the first place is crucial. It must be made very clear that inappropriate access will result in penalties. There also need to be very clear information governance guidelines in place to support the culture change, which is necessary to implement Electronic Patient Records.

20. The security of any system can never be guaranteed. It is therefore for patients to weigh up the benefits and the disadvantages of the new system and consider to what extent they wish to be involved. For this reason, a well balanced and unbiased public information campaign is extremely important.

How data held on the new systems can and should be used for purposes other than delivery of care eg clinical research

21. The BMA welcome the Secondary Uses Services (SUS), in principle, as one of the key ways in which the NHS Care Records Service could bring major benefits to health and healthcare. The existence of accurate, well coded and linked non-identifiable data could revolutionise activities such as population needs assessment, public health surveillance, drug monitoring and epidemiological research. This could impact in a positive way on all clinicians and patients in the future. There are, however, a number of unanswered questions surrounding SUS.

22. Data must be kept secure and confidential. It must be clear where, how and at what point the data is anonymised or pseudo-anonymised and if the data is held at any point in an identifiable form what security will exist to protect that data and ensure that only those with a legitimate relationship have access to the data. Secondary uses should use anonymised or pseudo-anonymised data and other privacy enhancing techniques (PETs) wherever possible.

23. It must be made clear to patients that their data will be used for secondary uses. The Department of Health must be open and transparent about the use of the data. There needs to be clarity about who will be allowed access including non-NHS organisations and commercial companies. Will any organisations be charged to access information and if so, what will happen to this payment? Will it include data from private providers and ISTCs? Will patients be able to request that their data not be used for these purposes, or put limits on the types of secondary uses that their data are used for? Other areas which need clarification are the legal status of the SUS and the relationship of the Secondary Uses to the European directive, which excludes research.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule

24. The original timescales were extremely optimistic. Delays were inevitable with a programme of this size. Lessons should have been learnt from previous NHS IT programmes, as detailed in the Audit Commission's report of August 2000. More achievable targets should have been set from the start. Providing clinical data to clinicians in out of hours settings, as has been achieved in Scotland, could have been a sensible first step. This would have engaged and gained the confidence of local clinicians before progressing in a more incremental way.

25. At the outset, there was no clarity about what the summary care record would look like and what it would deliver. There have been changes in specification and it has been difficult to keep track of the latest plans. A clearer strategy and understanding of what was required from the start was required.

26. The delays are partly due to wholesale replacement of systems rather than working with and integrating existing systems. Systems, particularly in primary care, were and are highly developed and have evolved over a number of decades and this enthusiasm and knowledge and expertise should have been drawn upon by the programme, rather than largely starting from scratch. Following pressure from clinicians the GP Systems of Choice agreement with accredited interoperability will hopefully help address this in primary care. Recent announcements regarding a changed emphasis towards an approved catalogue of suppliers committed to interoperability is also welcomed by the BMA.

27. Not all systems have been delayed. Some systems including QMAS, EPS and GP2GP in primary care and PACS systems in secondary care have been delivered successfully. The reasons for these successes should be understood and disseminated.

28. The BMA is concerned about delays in delivering new systems in secondary care. Planning blight and delays in delivery are forcing Trusts to make do with systems which are in urgent need of replacing or implementing interim solutions at extra cost and disruption. Staff need training on interim solutions, which takes time away from caring for patients. We suspect that timescales were put in place to meet political targets, which leave Trusts unsure of whether to wait for the promised systems or go ahead with their original deployment plans.

29. Some of the delays could have been avoided if there had been greater engagement of patients and healthcare professionals at the outset of the programme. Developments have been dictated from the centre and representative and accountable clinicians have felt disengaged. Representatives from all grades of doctors need to be engaged including junior doctors and medical students. A greater involvement of clinicians and stakeholders could have highlighted potential problems, at an earlier stage and helped ensure that systems are fit for purpose. Instead clinicians are concerned that systems will offer less functionality than those they are currently using. If clinicians and patients were engaged they could have put pressure on getting systems implemented and worked with Connecting for Health. For many clinicians their first encounter of change was Choose and Book or coding to deliver payment by results, which only served to disengage them. Changes are now happening as a result of greater engagement for example ensuring that patients can refuse to have a summary care record and bringing forward the implementation of Healthspace so that patients can check their records.

30. Messages from Connecting for Health have not always been aligned with what has been happening at a local level. The National Local Ownership Programme has recently been launched and may begin to address this. Organisational changes are required to ensure that systems are used as they are intended and this has not happened. This was particularly highlighted by the implementation of the Choose and Book system. Lessons must also be learnt from when things have not gone smoothly and this will help move the focus from central policy to clinical integration.

31. The financial difficulties within the NHS will have also contributed to the delays. Spending on Information Technology will not be a priority for Trusts and PCTS. Ring-fenced funding could have ensured that money was spent on implementation.

Dr Vivienne Nathanson
British Medical Association

16 March 2007

Evidence submitted by the British Psychological Society (EPR 45)

The British Psychological Society welcomes the opportunity to contribute to the Committee's inquiry into the development of the Electronic Patient Record and its use.

The Society is the learned and professional body, incorporated by Royal Charter, for psychologists in the United Kingdom, has a total membership of over 45,000 and is a registered charity. The key Charter object of the Society is "to promote the advancement and diffusion of the knowledge of psychology pure and applied and especially to promote the efficiency and usefulness of members by setting up a high standard of professional education and knowledge".

The Society is authorised under its Royal Charter to maintain the Register of Chartered Psychologists. It has a code of conduct and investigatory and disciplinary systems in place to consider complaints of professional misconduct relating to its members. The Society is an examining body granting certificates and diplomas in specialist areas of professional applied psychology. It also has in place quality assurance programmes for accrediting both undergraduate and postgraduate university degree courses.

Members of this Society, as Applied Psychologists work as Clinical, Counselling, Health, Forensic and Educational Psychologists as well Neuropsychologists. They and other members also undertake research. Their NHS patients will be directly affected by the introduction of the Electronic Patient Record. Our comments reflect our concerns in relation to aspects of electronic records, particularly in the context of mental health services. We do not propose to cover the many technical and supply problems that continue to bedevil this project, as we are sure these will be adequately addressed by other colleagues.

In submitting our views, we recognise that there is a strong case for the introduction of electronic health records in terms of potential benefits for patients, clinicians and management.

This response was prepared on behalf of the British Psychological Society by its representatives on the British Computing Society Forum:

— Dr Adrian Skinner, Department of Clinical Psychology, Harrogate—Member of the Division of Clinical Psychology and Associate Fellow, British Psychological Society.

— Prof Michael Berger, Royal Holloway, University of London—Member of the Division of Clinical Psychology and Fellow, British Psychological Society.

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems?

At a Local Level

CfH is intended to store patients' medical record, including all health episodes, centrally. NHS staff with a legitimate clinical interest in a patient will have access to that record. The Code of Conduct of the Society requires that the patient and the psychologist decide who should have access to psychological records other than under specific circumstances such as a Court Order. Centralisation of these records will remove this responsibility.

Particular issues arise in relation to mental health data and data from vulnerable/other groups who may lack "capacity" to consent to and monitor information about themselves—people with dementia, learning difficulties, acquired brain injury dysfunctions. Such issues need to be addressed.

Associated with this is the complex matter of mental health patients' access to records—such as determining which parts of records may be potentially harmful if revealed, dealing with third party information. Currently, such questions arise when an individual requests access. If all records are to be subject to individual scrutiny, particular attention will need to be given to how this process will be implemented.

At a National Level

Contents of the summary record in relation mental health records and those of other vulnerable groups require specification. Patient access and control remain issues at this level, again specifically in relation to data for those with mental health problems and for vulnerable individuals.

Who will have access to locally and nationally held information and under what circumstances?

The means of determining access to records is described as "Role Based Access Control". We are concerned that it will not be possible to produce a satisfactory algorithm, and that this will result in a far wider variety of people having access to records.

Information in healthcare covers every aspect of human functioning and in mental health, it is highly sensitive and confidential information about diverse aspects of functioning and relationships, the veracity of some of which may be questionable, for instance in forensic settings. This information, commonly essential to treatment, is usually given in the context of a developing trusting relationship and in most circumstances, is private to that relationship. The possibility of access by others could block, impair or distort the information made available, undermining the treatment efforts of the clinician. Hence special consideration needs to be given to access and the related issue of protection of confidentiality in relation to mental health information.

The issues are not just about deciding about access rights on a spectrum from no-access for anyone other than the involved clinicians, to unfettered access. They are also about validating that an individual with access to highly sensitive and confidential information is a specific individual with the specific level of access rights. The recent instance of a single smartcard being left in the card reader to counter the slow response of the validating system is an illustration of the sorts of issues involved. This raises the need for the use of biometric smartcards in certain situations.

What kinds of data are stored?

The lay, and medical, view of a medical record is of a straightforward collection of bits and bytes of hard information eg serum potassium levels.

However, for psychology and a number of other disciplines the information is "soft", ie expressed in language, variable, and consisting of opinion and conclusion. We are concerned that the electronic *record* could both give spurious authority to transient junior opinion and preserve erroneous information that could have been corrected in a paper record.

Privacy

CfH is aware that patients will not wish all clinical staff to have access to all records, for instance sexual or mental health episodes, and propose a scheme of "Sealed Envelopes" that may be breached only by senior staff under specific circumstances.

The problem is that other NHS staff will be aware of the existence of these sealed envelopes, with sometimes undesirable consequences. For instance, employers (including the NHS) may request an inspection of medical records as part of the Occupational Health Assessment; if such an inspection found sealed envelopes it is likely that the potential employee might be required to grant access as a condition of employment.

One solution to this problem is to give every record a "Sealed Envelope". This way, no individual will be marked out as having "something they wish to hide". Those who wish to use this facility would then insert material that would only be accessible to those with special privileges.

Consequences

There are two potentially serious consequences of the above; we stress that, because of existing computerisation, these consequences already occur.

First, people may avoid seeking treatment for problems that they classify as embarrassing or threatening to their lifestyle in some way.

Second, clinicians may be reluctant to record certain sorts of information for fear of this information "leaking" to the harm of the patient; an unintended consequence of this could be the failure to pass on information about someone's care to a clinician who needed it.

How Data Held on the New Systems Can and Should Be Used for Purposes Other Than the Delivery of Care eg Clinical Research

Access to personal health data for research should be available provided ways of ensuring that usual ethical principles are followed. However, there should be a formal systematic review, involving patients and other potential user groups from within the NHS, medical and other professional training groups, to assess whether or not electronic records pose special problems so that supplementary ethical and other guidance can be introduced if necessary.

In this regard, there will need to be provision for special informed consent about likely use for research.

Dr Martin Crawshaw
Chair, Professional Practice Board, British Psychological Society

16 March 2007

Evidence submitted by BT (EPR 51)

Executive Summary

The National Programme for IT (NPfIT) embraces a number of initiatives to bring modern computing to the operation of the NHS as a means of improving patient experience. BT has responsibility for two components of the system which delivers the electronic patient record; N3—the Virtual Private Network (VPN) for the electronic patient records, and the National Data Spine (Spine)—the summary data of every patient record in the UK. The Committee's Inquiry and our submission focus on the Spine programme.

The foundations of the NPfIT system provided by BT are now built, operating and are secure. Culturally integrating these systems so they become second nature for NHS staff is well underway. Over the next five years, the goal is to complete this programme. BT believes that generations of NHS staff, patients and taxpayers will benefit as a result.

This submission focuses on areas for which BT has responsibility and where we can bring our experience to bear in giving the Committee a supplier's perspective. The Committee's terms of reference cover five key areas of the programme. We have therefore centred our submission on these priorities.

In summary:

- Putting patient records online is not a choice for the NHS, but a necessity for patients and staff and for successful healthcare, and will form an important part of the Government's overall IT reform agenda. *(Para 2)*
- We are confident about the effectiveness of the system for which we have contracts as being sufficient for what the NHS has specified. This will be a step change for the NHS in terms of the reliability and availability of its medical records. *(Para 5)*
- Even in summary form, we are told by the NHS workforce that Spine data is sufficient to give A & E clinicians an immediate opportunity to make a diagnosis or begin treatment. *(Para 10)*
- Patients with existing conditions are likely to benefit from their records being available on Spine. We understand that those without conditions will have little on their record that is not already in the public domain. Clinicians, however, will benefit equally from both as each is indicative of a patient's health. *(Para 11)*
- Added control over protection for confidential data is available to patients through the "sealed envelope"; an option we have developed which, when deployed, restricts access to individual pieces of information if this is what the patient requests. *(Para 12)*
- There are approximately 1.2 million NHS employees of whom circa 800,000 will ultimately have controlled role-based access to Spine. *(Para 13)*

— We have in place rigorous technical controls to ensure that users being registered receive the correct level of access which will be significantly more secure than the current paper-based system of collating medical records. *(Para 14)*

— It is BT's view that the specification of the system we are delivering achieves an important balance between value for money, operational effectiveness and ease of use, likely threat of infiltration and potential for damage through infiltration. *(Para 19)*

— We believe that the technical levels of security are adequate for the information being stored and the likelihood of infiltration for unlawful purposes is low. *(Para 20)*

— To ensure that the maximum benefit can be drawn from the data available on Spine, we have developed forms of aggregating and presenting the data that ensure the confidentiality of individual patients. *(Para 24)*

— Progress on delivering Spine is good. All 11 of the last Spine software releases have been deployed on or ahead of time. There are sound and sensible reasons why the timetable for delivery has changed from its original specification. Against a very ambitious timetable, considerable progress has been made. *(Para 28)*

— Cultural antipathy towards the Electronic Patient Record (EPR) and Spine is on-going but, in our view, decreasing. Public confidence has been affected by misunderstandings of what the Programme can deliver (and is already delivering) and the risk to patient confidentiality. We believe that a stronger focus on communication and training with users would accelerate the acceptance of the Programme particularly in comparison to the "paper" systems it replaces. *(Para 33)*

A. *The National Programme for IT (NPfIT)*

1. The NPfIT embraces a number of initiatives to bring modern computing to the operation of the NHS as a means of improving patient experience. BT has responsibility for two components of the system which delivers the EPR; N3 and the Spine. The Committee's Inquiry and our submission focus on the Spine programme.

2. We believe that putting patient records online is not a choice for the NHS, but a necessity for patients and staff and successful healthcare and will form an important part of the Government's overall IT reform agenda. The programme is transforming the way the NHS works; ensuring it catches up with the technology NHS staff and patients increasingly use elsewhere in their everyday lives (eg online banking, shopping and e-government).

3. BT considers that the benefits of this programme significantly outweigh the risk that any IT project brings. BT has the responsibility for delivering the back-office technology that allows these benefits to be realised.

4. A key success criterion for this programme will be its acceptance across the NHS. We firmly believe that, in ten years' time (as with the advent of anti-biotics), NHS staff and patients will wonder how they managed without it. The success of the project will be as much about change management within the NHS as it is about technological advancement.

B. *Delivering the Electronic Patient Record (EPR)*

5. We are confident about the effectiveness of the system for which we have contracts as being sufficient for what the NHS has specified. This will be a step change for the NHS in terms of the reliability and availability of its medical records.

6. Since our appointment as National Application Service Provider (NASP) in December 2003, BT has:

— Established N3 across the NHS—creating the largest VPN in Europe with more than 18,000 connections.

— Registered 330,000 of the potential 800,000 NHS staff to the appropriate level of clearance for access to Spine.

7. This is a permanent system which includes elements of future-proofing against IT development in the coming years. Once in place, the infrastructure will not need to be replaced on a wholesale basis. It has been designed so it can be added to as new requirements are defined and as technology evolves.

C. *Patient information and confidentiality*

8. Patient data is owned by the NHS, the processes are owned by Connecting for Health and BT works under direction and is not responsible for the accuracy of individual data entries. BT has been assisting Connecting for Health in cleansing the data and ensuring consistency and accuracy through standardising terms used in records. This is the first "deep clean" of certain NHS records data, possibly ever, and means

that clinicians across the NHS are now able to use records (that have been the subject of this data cleansing exercise) with greater confidence and without the risk of duplicated or contradictory data which has previously led to numerous errors or unnecessary administrative work in the process.

9. Spine contains information that can positively impact on patient care; at present in summary form but, through the Early Adopters programme, this is being extended to full medical records.

10. Even in summary form, we are told by the NHS workforce that Spine data is sufficient to give A & E clinicians an immediate opportunity to make a diagnosis or begin treatment, confident in the essential primary information about a patient (e.g. on allergies, pre-existing conditions etc).

11. Patients with existing conditions are likely to benefit from their records being available on Spine. We understand that those without conditions will have little on their record that is not already in the public domain. Clinicians, however, will benefit equally from both as each is indicative of a patient's health. The certainty of the record saves time and money and can lead to a quicker, more reliable diagnosis.

12. Added control over protection for confidential data is available to patients through the "sealed envelope"; an option we have developed which, when deployed, restricts access to individual pieces of information if this is what the patient requests.

Restricting Access to Patient Information

13. There are approximately 1.2 million NHS employees of whom circa 800,000 will ultimately have controlled role-based access to Spine. The decision on who gets access and to what level is determined by Connecting for Health. Of these 800,000, circa 100,000 will, in time, have controlled access to more than Spine summary details.

14. As of 1 March 2007, BT has registered 330,000 users. We have in place rigorous technical controls to ensure that users being registered receive the correct level of access which will be significantly more secure than the current paper-based system of collating medical records.

15. The management of data on Spine (its uploading, accuracy and updating) is the responsibility of Connecting for Health. No BT employee has automatic or designated access to any data nor could any BT employee alter a record. However, due to BT's technical responsibility for the management of the system, between 30–40 people only who are BT employees working on Spine are able to view data. Doing so, however, is subject to stringent security procedures which would ensure that any illegitimate use would be immediately spotted. No NHS data is allowed to be stored abroad.

Protecting Patient Confidentiality

16. There are two types of security system that protect patient data: Technical Security and Operational Security.

17. As NASP, BT is responsible for building and managing Technical Security and for developing the components necessary for Operational Security. BT is responsible for preventing infiltration of Technical Security. Policing Operational Security is the responsibility of the individual NHS authority in which the system is operating.

18. The levels of security involved in Spine are comparable with those of online banking. In order to infiltrate Spine, one would need to be determined, knowledgeable and able to breach both the Technical and Operational Security systems. Access would be needed into N3 through its privacy and access regimes. Any infiltration would require access to a Spine ID card and its relevant passwords. Achieving this without the assistance (intentional or accidental) of a registered user would be near impossible.

19. We have not become complacent as we recognise that no system is infallible. The system, therefore, is subject to ongoing security tests as standard practice. It is BT's view that the specification of the system we are delivering achieves an important balance between value for money, operational effectiveness and ease of use, likely threat of infiltration and potential for damage through infiltration. Spine has not yet been penetrated.

20. We believe that the technical levels of security are adequate for the information being stored and the likelihood of infiltration for unlawful purposes is low.

21. Whilst breaching the Technical Security system is solely dependent upon the strength of the system, there are elements of Operational Security that require additional vigilance due to the nature of the environment in which the system is being operated:

- Many NHS buildings are uncontrolled. Establishing failsafe procedures (e.g. on access to areas of hospitals linked to N3) would be impossible without compromising the ongoing work of the building.
- The NHS does not have locked down desktop systems.
- Within Trusts, IT security may not be properly enforced. It is, for example, unlikely to be a priority for those working in an A&E department due to the pressures of work.

— To cope with the workload, registered users may be tempted to lend colleagues their Spine ID Card (mutual authentication) or leave their computers logged on to the system when away from their desk.

22. As a result of these operational security risks we have developed a series of additional tools for maximising potential system security. These include timed logouts, strict filters on access levels and predictive algorithms to spot misuse and unusual practices.

23. If it had been specified that Spine needed to be on a stand alone system, Operational Security would have been enhanced. However, this would have been impractical for use by the NHS with significant on-costs and the risk of a reduced take up by staff as end users would be reluctant to switch terminals in order to access Spine.

D. *Potential uses for the data*

24. To ensure that the maximum benefit can be drawn from the data available on Spine, we have developed forms of aggregating and presenting the data that ensure the confidentiality of individual patients. Pseudonymising the data is a further step in protecting identity.

The Secondary User Service (SUS) pseudonymisation service is commonly referred to as P14N , this reflects the fact that SUS will pseudonymise up to 14 inbound data fields, including NHS number, address, name, postcode. The fields are contained within inbound CDS data flows, on arrival in SUS they are encrypted using an industry standard encryption algorithm (currently Blowfish and about to change to AES 128). These values are then presented to an anonymisation engine which transforms the encrypted value using a mathematical algorithm which allocates a unique value to the encrypted attribute. SUS then stores these values in a protected key store which is used as a look up for future inbound values to ensure a value is only encrypted and pseudonymised once.

A further level of encryption is applied to the psedonymised attribute when the data is reported on or extracted, this "group encrypted value" is uniquely applied by organisation. So when SUS data is extracted by non NHS organisations the anonymised values are presented as different keys for each group.

25. Over the next five years, it will be possible to use Spine data as a primary determinant for UK health trends; for identifying clusters (eg to identify emerging epidemics in real time); for conducting clinical and comparative audits across Strategic Health Authorities (SHAs) and Trusts; and to predict future clinical and pharmaceutical needs.

26. Through Spine, monitoring the dispensing of prescriptions will become significantly cheaper[35].

27. Making the aggregated data available to pharmaceutical companies (as occurs in Australia) would not only assist R & D but would provide the NHS with a substantial income source. By using pseudonymised data, each of these developments could be achieved without compromising patient confidentiality.

E. *Current progress on development and delivery*

28. Progress on delivering Spine is good. All 11 of the last Spine software releases have been deployed on or ahead of time. There are sound and sensible reasons why the timetable for delivery has changed from its original specification. Against a very ambitious timetable, considerable progress has been made.

29. Even at this stage, there are immeasurable benefits that have been delivered which are assisting in the cultural transformation of the NHS:

— A greater appreciation within the NHS of the importance of IT in its future and the benefits that will accrue for individual clinicians as well as for the NHS as a whole;

— 90 million records already cleaned and uploaded; and

— The largest VPN in Europe.

30. Changes to the original timescale for the project have been caused by a multitude of reasons including the making of necessary modifications to the specification of what was to be delivered and by when (as, for example, Ministerial commitments are made/change), which is to be expected in a programme of this size and scope. Likewise, the Programme was subject to changes in Connecting for Health's business priorities which impacted upon BT as other programmes were progressed at the expense of Spine to meet Ministerial demands.

31. On an operational level, the inherited data was less consistent and of a lower quality than was estimated by all parties—hence we have conducted the first deep clean of NHS data.

32. Going forward, the biggest obstacle to the completion of Spine is the need for the NHS to agree the clinical terminology to be used. Despite Connecting for Health's best efforts, the adoption of SNOMED (which contains a dictionary of 800,000 terms) is still not complete. This is, in our experience, a problem not limited to the NHS and Connecting for Health's leadership in attempting to finalise a global solution is to

[35] Prescription Pricing Authority Business Plan refers to savings circa £2.4 million pa.

be applauded. Until this is achieved, the full benefits of the system (for example in fully utilising aggregated data) will not be accrued. We continue to work in partnership with Connecting for Health however, to ensure that delivery is effective.

33. Cultural antipathy towards the EPR and Spine is on-going but, in our view, decreasing. Public confidence has been affected by misunderstandings of what the Programme can deliver (and is already delivering) and the risk to patient confidentiality. We believe that a stronger focus on communication and training with users would accelerate the acceptance of the Programme, particularly in comparison to the "paper" systems it replaces. The following are common misconceptions:

- Anyone in the NHS can access private medical records: There are strict parameters of access to Spine data which ensure that only those who need a patient's medical records for clinical use can access them. Patients who wish to restrict access to data about their records further can use the "sealed envelope" facility.
- The system "is not working and is not going to work": 90 million summary records have already been uploaded. Spine and N3 are already working well.
- The system will fail if only X% of the population refuse access: It is up to individual patients whether they want their summary data on Spine but using the system is fast becoming standard practice across the NHS. It is being implemented in such a way as to maximise its ease of use by authorised NHS employees.
- Patient care is being compromised: Patient care is being enhanced through Spine. At present, 20–40% *[estimate]* of care in the NHS is being delivered without notes with all the associated risks of incomplete information for diagnosis and case history. In less than a generation, we believe that NHS staff will look back and wonder how they coped.
- Patients could discover they have cancer by reading their record: Patient access to records will only occur when they are checking their data.

Robin Seaman
British Telecommunications plc

March 2007

Evidence submitted by Computer Sciences Corporation (EPR 46)

1. This submission is made in response to the invitation by the House of Commons Health Select Committee to submit evidence on "The Electronic Patient Record and its use".

2. Computer Sciences Corporation (CSC) is a global information technology (IT) services company. Employing over 70,000 staff throughout Europe, the Americas and Asia, CSC has enormous experience and track record in major IT programme delivery and assurance for leading private sector multinationals and large public sector organisations.

3. In 2003 CSC was appointed by NHS Connecting for Health as the Local Service Provider (LSP) for the North West and West Midlands cluster and has more recently (as from 8 January 2007) assumed LSP responsibilities from Accenture plc across two additional clusters—the North East and Eastern clusters.

4. As the largest Local Service Provider, with experience of successfully delivering healthcare systems globally as well as part of the NHS National Programme, CSC is extremely well placed to provide evidence to the Committee on the role and use of the Electronic Patient Record and the significant benefits that this will provide for patients and clinicians alike.

5. As a Local Service Provider CSC acts as an integrator, providing systems which support healthcare in both hospitals and GP surgeries and which interface to national applications such as Choose and Book and the Spine (the latter through which the National Electronic Patient Record will be accessed). CSC delivers systems across a wide range of care settings including acute trusts, mental health trusts, community hospitals, child health settings and GP practices, working with NHS staff on the frontline to ensure benefits of these new systems are fully realised.

6. In the North West and West Midlands (NWWM) cluster (which includes the North West Strategic Health Authority and the West Midlands Strategic Health Authority) CSC has successfully deployed over 70 Patient Administration Systems (PAS), 10 Picture Archiving and Communication Systems (PACS) and 10 Radiology systems across hospital trusts, with a total of nearly 50,000 registered NHS users to date. More than 950 individual sites have been provided with access to systems provided through the National Programme for IT. The PAS systems have laid the foundations for improved patient care by: Supporting national initiatives such as the reduction of waiting times and greater patient choice; supporting Choose and Book; and providing reliable accessibility 24 hours a day, seven days a week. The PACS systems have enabled diagnostic images such as X-rays and scans to be stored and viewed electronically, so that doctors and other healthcare professionals can access the information and compare it with previous images at the

touch of a button. This delivery of efficient image processing will, by 2008, directly help contribute to meeting the NHS objective of a maximum 18 week wait, as well as providing the obvious benefits of faster and better diagnosis.

7. In the North East and Eastern clusters significant progress has also been made across a number of healthcare settings. 550 GP surgeries now have new systems which will help reduce time spent on administrative processes and will support increased patient choice with Choose and Book. Best practice diagnostic tools, such as "Map of Medicine", are providing clinicians with access to specialised clinical knowledge whilst child health systems are providing a continuous record of the health of a child from birth to age 19, putting to an end paper-based vaccination and examination results.

8. As has been well publicised, however, the delivery of parts of the programme, including the systems being deployed by the Local Service Providers, has not been in keeping with some of the ambitious early plans. What must be made clear, however, is that this is a ten year programme and the size and complexity of what is being delivered is breaking new ground. The technology itself is not cutting edge but it is bespoke to the NHS and the National Programme for IT. What is cutting edge, however, is the deployment of technology across an organisation as complex and far reaching as the NHS. Delays and re-planning have arisen as a result, but it is the firm belief of CSC in this submission to the Committee that not only has much been learned and delivered over the past three years, but the future benefits which will be further derived from this programme will save lives, improve patient care, provide patient choice and provide our National Health Service with massive cost savings over the Programme 10 year horizon as well as into the future.

9. Central to the National Programme and the Health Select Committee investigation is the Electronic Patient Record. The record will exist on two levels: A locally accessible "Detailed Record" and nationally accessible "Summary Record".

10. The bulk of detailed patient information will be held and stored locally at the GP and "local health economy" level. Instead of having fragmented health records in different places, NHS organisations in a local health economy will be able to share a Detailed Care Record for a patient. This includes details of medication, X-rays, operations and a history of medical conditions. This is already being put into place with significant benefits to patient care.

11. Ensuring privacy is, of course, at the forefront of the Electronic Care Record implementation. Organisations that need to access patient information will need to first be authorised by a Registration Authority. Once authorised, individuals (whether care professionals for clerical staff) will be issued with a smartcard which will govern what level of access they are granted. The card itself is similar to chip and pin credit cards and can be printed with the name and photograph of the user. The card contains a unique user identity number. Individuals will only be given access to the patient information that is appropriate to their work and level. As an example, a receptionist will be given limited access that will allow for appointments to be booked for a patient, but would not be provided with a patient's full clinical record.

12. Patients will be able to opt out from sharing data outside the organisation that is providing care. Such opting out will prevent clinical information collected in one healthcare setting being made available to another, other than where it is specifically communicated as part of a correspondence between clinicians involved in the treatment of the patient. Such opting out needs to be made by an individual in the knowledge that to do so may result in less effective treatment or even an increased risk of harm as decisions on future treatment may be based on a less complete clinical picture.

13. It is also important at this juncture to overview the concept of "Sealed Envelopes". A patient will be able to request for specific information to be accessible only when direct consent is given. This will be explained to patients and a campaign is being planned by the NHS that will explain this process in full. In addition, clinicians will be able to restrict what is viewed by patients where sensitivities exist—for example, confidential parts of their record which relate to a third party.

14. The national Summary Record will be pulled from the detailed record. This will show high level medical information such as details of current medication, allergies and other health issues. Its primary purpose is to support treatment of the patient when their (locally held) detailed record is not needed, or not available. This might happen for example, if the patient is taken ill on holiday, or needs to be treated in an emergency. In the future, the Spine, the central mechanism for accessing patient information, may allow for a transactional way of obtaining detailed patient information remotely and in this way act as a "bridge" between local or regional systems i.e. not storing the detailed patient record itself but "knowing where it is stored".

15. There are legitimate concerns over the security and privacy of highly sensitive personal data when it is stored on computers, and when a number of smaller systems are aggregated together into fewer, larger ones. The National Programme for IT is installing IT systems which are shared across a number of care settings, in order to provide a joined-up health service, whereas today the majority of IT systems are dedicated to one individual care setting, for example a GP surgery or an acute hospital. CSC is responsible for the provision of regional systems which contain detailed clinical information about patients and would therefore wish to address these concerns directly.

16. In all respects, we believe that the level of security and confidentiality of patient data held within our systems is considerably higher than in the systems that we are replacing, and of course, over the paper based systems which are almost ubiquitous in secondary care today. Regarding security and confidentiality, we would make the following additional points:

(i) The systems provided by CSC are hosted in secure data centres, rather than locally on NHS premises as are many of the current systems.

(ii) All data transmitted over the networks between the CSC data centres and NHS premises is encrypted using approved encryption techniques.

(iii) Before commencing live operation our systems are subject to specific security testing and penetration testing—which includes "ethical hacking". These tests are approved and witnessed by external parties through NHS Connecting for Health.

(iv) Our applications enforce strict access controls to patient data through several levels of security. This starts with smartcard access to systems as described in paragraph 11 above. Access to data is then restricted based on the role of the user. A ward clerk, for example, would not see any clinical data. Further restrictions on access are then applied so that the user must be involved in the patient care in order the gain access to data. It should be remembered that the professional code of ethics of NHS staff, together with NHS policy enforcement, is at least as important as the technical and physical security measures used.

(v) The new systems we are installing maintain an audit trail which keeps a record of who has accessed patient data. This is possible because the smartcard log-on uniquely identifies the person who performed each action using the LSP systems.

(vi) All CSC staff that support NHS systems containing identifiable patient data are security cleared to at least SC level 2.

17. The benefits to be derived from this system are numerous and are central to the motivation for this programme. The ultimate benefit for patients is better, safer healthcare through clinicians having more complete, more accurate information about them and reduced waiting times. Care professionals and clinical staff will have easier access to up-to-date information which will improve diagnosis and treatment. They will also have a lower incidence of lost records and test results and will be able to access patients' records from more than one place. For the NHS, improved availability of information, reduced duplication of effort and streamlined business processes will increase efficiency allowing better use of scarce and expensive resources. Cutting down on the filing and storage of paper files will result in real cost savings and care will be delivered to a higher and safer quality. Ultimately patients benefit when decisions made about their care are based on accurate, up-to-date information. Too often, with the current plethora of disparate healthcare systems, this is not the case.

18. The National Health Service in England, however, is not alone in acknowledging the benefits that are to be gained by going from a system of paper patient records to one of electronic based records.

19. In the Netherlands, CSC is responsible for the build and maintenance of a system comparable to the Spine. The initiative launched in 2003 is the foundation of a country-wide roll-out of an electronic patient record (EHR) that is being developed under the direction of the Dutch National ICT Institute for Healthcare (NICTIZ). The system, known as the National Switch Point for Healthcare, makes it possible for patient information to be accessed and supplemented from anywhere in the country. The motivation for this Programme can be seen in research provided by the institution of pharmacists in the Netherlands (WINAp) which estimated that there are 90,000 hospitalisations a year which were a direct result of avoidable medical errors. In addition to this, research carried out by TNS-NIPO (a market research company) for NICTIZ shows that approximately 800,000 Dutch people over the age of 18 have been victims of errors due to the inadequate transfer of medical information.[36] Given the total population of the Netherlands in 2006 was estimated at 16.5 million, both of these statistics are significant. Similar to the Spine in England, access is only provided to physicians who have the relevant smartcard that authenticates identity. The system successfully went live in January 2006 and early adopter sites have already been connected to the system allowing for remote access to patient records.

20. Looking elsewhere across Europe, Denmark is perhaps the most advanced country in terms of utilising electronic records. More than 95% of GPs are using electronic medical records in their practices and there is 100% electronic access to hospital discharge letters, referrals to specialists, lab results, billings, prescribing, home care and pharmacies. Through Scandihealth, its wholly owned subsidiary, CSC has been actively involved in developing healthcare applications applications, and is responsible for systems which support the management of approximately 70% of hospital beds and Clinical Records throughout Denmark. A study into the Danish system by the Canadian government agency (Canada Health Infoway) charged with delivering electronic health records showed that doctors saved on average 50 minutes each, per day, that had previously been spent contacting hospitals to seek clarification or track results. Electronic prescriptions meanwhile have been credited with cutting medication problems by more than half and labelling errors in labs to almost zero.

[36] Refer to Dutch National ICT Healthcare overview:
http://www.nictiz.nl/uploaded/FILES/Corporate%20communicatie%20English/corporate%20profile.pdf

21. In Canada, the Health Infoway has been charged with accelerating the implementation of electronic health information systems. Their mandate is to provide for 50% electronic records by 2009 and 100% by 2010. The implementation of this is well underway with provinces such as Alberta and Newfoundland are successfully leading the way and realising the benefits of quicker and more accurate access to patient records.

22. In the US, CSC is at the forefront of an initiative, supported by over 100 public and private organisations to determine the approach to developing a national care record system appropriate for the US health economy. Similarly in France, CSC is actively involved in a new programme, in the early stages of development to create a national patient record system. Both countries are referencing the UK in this regard.

23. The adoption of Electronic Medical Records is now a global trend and one which is motivated by widespread benefits to patients and healthcare professionals alike. While concerns of privacy will continue to be debated with vigour we must ask ourselves if a stack of patient case notes left in a hospital corridor are more protected than the stringent security measures which will be provided by this programme, if doctors time and the money of the NHS must continue to be wasted on paper medical records, or if, and perhaps most importantly, the safety of patients must continue to be placed at avoidable risk in the 21st Century?

Computer Sciences Corporation

16 March 2007

Evidence submitted by Computer Weekly (EPR 64)

Computer Weekly supports the main objectives of the NHS's National Programme for IT NPfIT], particularly the aim of providing an accurate, useful and up to date electronic health record that is always available to clinicians when they need it.

Some of our readers have told us how the treatment of their relatives was not what it should have been because the paper records were not available.

However—and this is one of our biggest concerns about the NPfIT—strong, well supported objectives do not justify a flawed project.

For more than 15 years we have investigated the common factors in IT-based projects and programmes that succeed or fail to meet expectations. We hope the NPfIT succeeds and there have indeed been some specific successes. On the whole, however, the programme has already fallen into traps that have ensnared some other large, high-risk IT-based projects and programmes. There are doubts it will work as originally intended.

For these reasons we believe that there should be a published and genuinely independent review of the NPfIT. If all is well the results of the review may placate those who are concerned about the £12.4 billion programme. It may also provide evidence with which to market the programme's benefits to doctors and nurses.

If all is not well, a review would provide evidence of the need for a rethink; and the sooner the better, before billions are spent without commensurate benefit to the NHS and patients.

In 1998 Computer Weekly urged the Transport subcommittee to ask the government to commission an independent review of a project to build air traffic control systems at Swanwick in Hampshire. That review's recommendations arguably made the difference between success and failure.

The Swanwick project had then been running about four years behind schedule. Our call for an independent review was opposed strongly by National Air Traffic Services. Its directors told the Transport subcommittee that a review would be an unnecessary distraction—the argument put forward by the Department of Health in opposing a published independent review of the NPfIT. In the case of the Swanwick systems, the government decided in 1999 to commission independent reviews in opposition to National Air Traffic Services.

The Department of Health's rejection of a published independent review of the NPfIT is one of our main concerns about the programme. We are advised by senior members of the Association for Project Management that a high-level review of the NPfIT could be carried out in less than a month and by no more than six people if they are given access to the right documents and senior personnel. It would establish the health or otherwise of the programme.

Below we list some of those traps and some of chief concerns expressed to us about the NPfIT:

1. The delay in the delivery of core software, which in the case of the NPfIT includes a Care Records Service, has proved in some past projects to be a symptom not of teething difficulties but deep-rooted defects in design, scope and ambition that could affect the successful outcome of the programme.

2. Delays in the delivery of core software were symptoms preceding the failure of the Libra project, the main aim of which was to install a unified case management system for magistrates' courts across the country. Today, more than 15 years after the initial project attempt failed, no single system has been rolled

out across the country, though there have been several attempts. One problem is complexity: magistrates' courts have different ways of doing things—as have hospitals. And despite Libra's complexity, it is a tiny project compared with the NPfIT. Libra's case management system is a fortieth the size of the NPfIT.

3. Long delays in the successful delivery of core technology were also symptoms in the failure of a system for the Performing Right Society. The Society's overly ambitious PROMS system—Performing Right On-line Membership System—had to be scrapped, largely because the new business processes that accompanied the IT had not been thought through adequately. We can provide other similar examples if requested.

4. Two major suppliers have withdrawn from the NPfIT programme for reasons that have never been fully ascertained. We believe that Accenture and IDX should be asked why they withdrew. Over-optimism among suppliers and government agencies is a common factor in IT-related failures. For example, after a Single Payment System failed to meet its original objectives at the Rural Payments Agency, two ministers told Parliament they were given over-optimistic reports from their civil servants on the state of the IT project. We believe that directors of suppliers who decide to pull out of projects should have their concerns aired and taken into consideration. Instead, it seems to us, the views of executives at Accenture and IDX have been sidelined or not even sought.

5. The complexity of the NPfIT, and whether its objectives are achievable as originally configured, may have been factors in the withdrawal of Accenture and IDX. There are, for example, concerns about whether it is possible for software that has been designed for a small number of individual sites to work at many health sites with diverse needs.

6. We and the National Audit Office have studied common factors in project successes and some things stand out: a clear objective (which congestion charge has for example) and simplicity of design and ambition. The NPfIT, it can be argued, does not have a clear objective and it has labyrinthine complexity. Its ambition, complexity and cost make it the largest civil IT-based programme in Europe and perhaps the world.

7. Truth and openness become the first casualties in projects that are in serious trouble. Defensiveness and a resentment of criticism—and the critics themselves—have characterised the NPfIT.

8. The Department of Health and Connecting for Health have put much information in the public domain, but not the key facts we have requested. Our NPfIT-related requests under the Freedom of Information Act have been rejected. And though Connecting for Health publishes statistics it does not publish any details of the specific high severity incidents that affect the hospitals that install new national systems. These incidents can affect the care and treatment of patients.

The Department of Health has declined to publish the results of its reviews on the NPfIT, including those undertaken by consultants and, separately, by the Office of Government Commerce. If any of these highlight fundamental flaws in the programme, it is in the public interest that they are published.

In summary:

We would expect Connecting for Health to argue that our concerns are misplaced and that the programme is headed for success. To this we would suggest that it publishes evidence of success in the form of the published results of a genuinely independent review. We believe that the review carried out by consultants Arthur D Little report on the Swanwick air traffic control systems was a model exercise. As we said earlier, we believe that this report made the difference between success and failure.

We would like the NPfIT to succeed, and so we would urge the Health Committee to ask the government to commission a published, genuinely independent of the NPfIT.

Tony Collins
Executive Editor
Computer Weekly

19 March 2007

Evidence submitted by Diabetes UK (EPR 54)

Diabetes UK is one of Europe's largest patient organisations. Our mission is to improve the lives of people with diabetes and to work towards a future without diabetes through care, research and campaigning. With a membership of over 170,000, including over 6,000 health care professionals, Diabetes UK is an active and representative voice of people living with diabetes in the UK.

1. Introduction

1.1 Diabetes UK welcomes the opportunity to submit evidence to this inquiry. Diabetes UK supports moves to develop the process of storing patient information and develop the level of information stored.

2. *What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems*

2.1 Diabetes UK believes that population based registers are an essential component of the delivery and monitoring of diabetes services at primary care organisation or managed diabetes network level. They form the basis of inter-agency communication within the NHS, and are currently the best method for maintaining a diabetes electronic health care record between primary, secondary, and community care. Registers have a central role to play in the implementation of clinical governance, and in ensuring a seamless, quality service for all people with diabetes.

3. *Who will have access to locally and nationally held information and under what circumstances and whether patient confidentiality can be adequately protected*

3.1 Diabetes UK takes the position that the use of data on registers requires the informed consent of people with diabetes. Ideally this should be supported with written consent, but this is not a substitute for discussion and ensuring that the consent is informed. The topic should be revisited periodically and people should be informed that they can withdraw their consent at any time. There is no consensus on how frequently consent should be sought. Diabetes UK suggests every three years, as being a reasonable interval.

3.2 People with diabetes should be told how their information will be used, in particular less obvious uses such as clinical audit and financial checks and explanation of any potential implications from this, such as being approached to allow their information to be used for research. People are often concerned about inappropriate and non-consensual disclosure to third parties such as insurers or employers. In general consent should be sought when information is used in an identifiable form. People with diabetes should also be informed about the systems in place to ensure confidentiality, in line with the spirit and requirements of the Data Protection Act 1998.

3.3 The Information Commissioner has issued guidance on the use and disclosure of health data, which can be found at www.dataprotection.gov.uk/dpr/dpdoc.nsf. Health data systems within the NHS should follow the recommendations of the Caldicott report (The Caldicott Committee: Report on the review of patient-identifiable information, December 1997, www.doh.gov.uk/ipu/confiden). This requires that Trusts/PCOs have a monitoring system in place to ensure that confidentiality is respected for all identifiable health data. Most feedback to Diabetes UK indicates that few people with diabetes would choose to opt out from a register when these requirements are adhered to.

3.4 The legal position regarding the use of all health data within the NHS has changed in England and Wales with the passing of the Health and Social Care Act 2001 (www.hmso.gov.uk/acts/acts2001/20010015.htm). The relevant sections of the Act (60 and 61), grant the Secretary of State for Health powers to determine how patient data can be used in the NHS. The Secretary of State must, nevertheless, comply with the requirements of the Data Protection and Human Rights Acts. Section 60 includes a process that permits application for patient data to be used without consent, under particular circumstances. Section 61 of the Act prescribed that an expert Patient Information Advisory Group (PIAG), be set up to advise the Secretary of State and the Department of Health on applications under Section 60. The use of this application process is to be reviewed annually, until such time as the infrastructure necessary, either to seek and record individual consent is established, or for data to be acceptably anonymised for uses other than direct care of the patient. The Patient Information Advisory Group and application process for Section 60 is now in use. Further information on the group and application process can be found on their website at www.doh.gov.uk/ipu/confident.

3.5 The Department of Health is not concerned about identifiable information collected at practice level, for the direct care of patients ie for call and recall, provided that patients are appropriately informed and due attention is paid to confidentiality. Information gathered for the direct care of the patient is deemed to have consent through the normal activities of a patient consultation. Local clinical audit is included in this as it has a direct impact on the quality of care a patient receives, although this is a use which is less obvious to most people with diabetes.

3.6 In Northern Ireland, the Task Force on Diabetes has identified Information Management and Diabetes Registers to be one of the key areas for early action. It has recommended that integrated diabetes care must be supported by a Northern Ireland wide information system supporting diabetes care delivery in primary and secondary care and linking general practice and hospital information. The Task Force has emphasized that good information systems are central to planning and delivering high quality services and that the availability of a Diabetes Register would facilitate regular monitoring and screening systems to be put in place.

3.7 The Northern Ireland Health Service has stated that it does not have the capacity currently to fully comply with the fair and lawful processing requirements of the DPA 1998 and the Common Law requirement of confidentiality. They have and continue to rely on the implied consent of service users for the processing of personal identifiable information. There is a recognition that this is no longer sustainable and that in the future:

— provision of more information to the public and service users about how the health service uses personal information, must be made;

— personal information should be acceptably anonymised wherever possible for uses other than clinical care;

— where anonymisation is not possible the aim is to gain user consent for the use of their personal information; and

— new legislation should be considered to address this situation.

3.8 In Scotland, confidentiality issues have been subject to a major review through the Confidentiality and Security Advisory Group Scotland (CSAGS), an independent committee which produced its final report, Protecting Patient Confidentiality, in April 2002 (report can be found at www.show.scot.nhs.uk/csags/). CSAGS recommends that "patients must be informed about how information about them is used", "wherever possible, data must be anonymised" and if data cannot be anonymised to an acceptable degree, "the patient has a right to object to their use". CSAGS also rejects the introduction of new legislation similar to Section 60 of the Health & Social Care Act in England & Wales. It does so on the basis that "in a patient-centred service, the implications of any legislation which restricts rights of individual patients . . . must be taken seriously". The report's recommendations are currently being considered by the Scottish Executive.

3.9 As a general principle information should be de-identified as much as possible and only the minimum information necessary for the purpose should be disclosed to other authorised bodies.

3.10 Diabetes UK will continue to monitor the situation and review its position in light of any changes.

4. *How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research*

4.1 Other uses such as service planning, audit above the level of individual care provider and research should be acceptably anonymised, or informed consent gained or support under Section 60 sought as appropriate. It is envisaged by PIAG that generally, audit should be done through anonymisation/pseudonymisation (see glossary). Given current technical constraints, and the need to integrate with other linked initiatives, like the Integrated Care Record Service, it is likely that it will take some time to implement pseudonymisation or consent fully. In such situations Section 60 support should be sought as an interim measure until pseudonymisation or consent can be achieved. Rarely Section 60 support may lead to regulations providing more permanent support where neither pseudonymisation nor consent is feasible.

5. Conclusion

5.1 Diabetes UK believes the key issues are to ensure that people are made aware of confidentiality issues, that there is a dialogue and that it is made clear to them what the information is used for and who can access it.

Diabetes UK

March 2007

Glossary

Registers: A disease register is a list of patients with a given condition. Often register information is combined with clinical information from a number of sources to facilitate better quality of care for the individual. This information can be used for call/recall to ensure all patients receive regular check ups and also for non-clinical purposes such as audit, service planning and epidemiological health outcomes research. Anonymisation: Where information, which might be used to identify the person, has been removed eg name, address, postcode, date of birth. Sometimes individual items of data would not identify a person if used on their own, such as date of birth but if used in combination with another item such as postcode would make the person identifiable. Acceptably anonymised therefore refers to records where the risk of identification through combined factors is very small.

Pseudonymised: This is where data has been anonymised but which contains an identifier such as new NHS number, or Community Health Index (in Scotland). On its own this identifier does not identify the individual. It is only if the person looking at the data also has access to the key linking the identifier number with individual names that the data becomes identifiable again. This is called pseudonymisation or linked anonymisation. It is useful as it enables data from different episodes of care for the same individual to be linked, whilst protecting their identity. It also means that researchers can qury data that may have been

wrongly recorded and the Trust holding the patient's record could track the information back to an individual and check the accuracy of the data. This therefore helps ensure data quality and consequently the reliability of research results.

Informed Consent: This is an approval process in which the patient receives a full and understandable explanation of purpose, risks, benefits and rights of withdrawal of the approval. Explicit consent means that a patient is asked verbally or in writing to approve a particular procedure, or in the case of registers the transmission and storage of clinical information. Current practice often involves using posters in a surgery about certain policies or initiatives and it is assumed that the patient agrees with them unless they explicitly withdraw their consent. This has been called implied consent. The view of the Patient Information Advisory Group (PIAG) is that this is not adequate in terms of providing information to patients and therefore consent based on this is unlikely to be valid, legally or in terms of ethical practice.

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Evidence submitted by Dignity in Dying (EPR 49)

1. Executive Summary

1.1 Dignity in Dying welcomes the Health Select Committee's inquiry into the development of the electronic patient record, and is pleased to respond to its consultation. Dignity in Dying works to put patient choice at the heart of all end of life medical treatment decisions, in order to achieve a dignified death for all. We are committed advocates of palliative care and have more than 115,000 members and active supporters. We are the UK's leading provider of Living Wills and regularly advise members of the public, NHS Trusts, GP surgeries, care homes and solicitors in relation to advance and other end of life decisions. We recently produced a "toolkit" to assist healthcare professionals working in the hospital setting when presented with Living Wills scenarios, which was commissioned by the Department of Health.

1.2 Living Wills, which are referred to in the Mental Capacity Act 2005 as "advance decisions to refuse life-sustaining treatment", enable patients to set out their wishes with respect to life-sustaining medical treatment, in case they become seriously ill and lose mental capacity. Our "Pro-Choice Living Will" is distinctive in its non-ideological approach, which enables patients to make known their wish to refuse or request life-sustaining treatment—although, unfortunately, the latter option is not legally binding.

1.3 With 64% of deaths now involving an end-of-life decision,[(i)] a growing number of people are choosing to make a Living Will to ensure their end-of-life wishes are respected. 91% of the British public welcome the inclusion of Living Wills in the Mental Capacity Act 2005 as a move that will "reassure people that their wishes will be respected if they lose capacity".[(ii)]

1.4 Living Wills give peace of mind to patients, and clarity and support to their loved ones and healthcare professionals. They prevent unwanted medical interventions and hospitalisations, and can help patients to achieve their wish of dying at home, amongst other benefits.

1.5 Unfortunately however, some patients' Living Wills are not acted on because the attending healthcare team is unaware of their existence. This is because there is currently no central recording system for Living Wills, to ensure they are drawn to the attention of healthcare professionals at the necessary time. This is a matter of great concern for the public and for organisations and individuals representing medics, older people and people with long-term medical conditions.

1.6 It is very important that electronic patient records are used to record and alert healthcare professionals to the existence of patients' Living Wills, to prevent these distressing situations from occurring in the future and to protect healthcare professionals from prosecution. Dignity in Dying has the support of Baroness Greengross, the College for Emergency Medicine, the MS Society, the National Pensioners' Convention, Action on Elder Abuse, Counsel and Care, and the British Kidney Patients Association, amongst others in its work to secure this outcome.

1.7 Dignity in Dying is pleased that this proposal has received support from the Department of Health, and we hope that every effort will be made to realise this important work, and make sure the British public's end-of-life wishes are respected.

2. Introduction

2.1 A recent survey found that 91% of the British public welcome the inclusion of Living Wills in the Mental Capacity Act 2005 as a move that will "reassure people that their wishes will be respected if they lose capacity"[iii]. And, with 64% of deaths now involving an end-of-life decision,[iv] the uptake of Living Wills is rising fast. (For more information on the uptake of Living Wills—and on their benefits to the public and healthcare professionals—please see Section 3, below).

2.2 Unfortunately, some patients' wishes—as set out in their Living Wills—are not acted on because the attending healthcare team is unaware of the Living Wills' existence. This is because there is currently no central recording system for Living Wills, to ensure they are drawn to the attention of healthcare professionals at the necessary time.

2.3 Failure to act on a patient's valid Living Will can cause great distress to the patient, their loved ones, and the healthcare team. It also puts Primary Care Trusts (PCTs) and individual healthcare professionals at risk of prosecution for negligence, trespass or assault. This is a matter of great concern to many people who have made, or are considering making Living Wills; to organisations working with, or representing, people who have long-term medical conditions, and to a growing number of healthcare professionals.

2.4 Dignity in Dying believes it is vital that the electronic record system is used to identify patients' Living Wills and alert healthcare professionals to their existence, even in emergency situations. We are supported in this view by many organisations, including the College for Emergency Medicine, the MS Society, the National Pensioners' Convention, Action on Elder Abuse, Counsel and Care, and the British Kidney Patients Association, and by leading experts on health and older people's issues, including Baroness Greengross.

2.5 We further believe this cost- and time-effective measure carries great support from the public. Many people have told us that whilst they might wish to restrict other personal information on their record, they would welcome its use for communicating the existence of Living Wills to healthcare professionals.

2.6 Dignity in Dying is pleased that the Minister of State for Quality supports the principle that the electronic patient records should provide the facility for alerting healthcare professionals to the existence of patients' Living Wills. We hope that every effort will be made to ensure that patients' Living Wills are respected, and the Health Select Committee supports this effort.

3. The Benefits of Living Wills

3.1 Many people—particularly older people—are concerned that they should not be subjected to invasive treatment or surgery if, for example, they are terminally ill and have no hope of recovery. A growing number of British people are choosing to make a Living Will because they want peace of mind that they will not receive medical treatment against their wishes, in case they become seriously ill and lack the mental capacity to make their wishes known.

3.2 Research shows that Living Wills can help patients to prevent unwanted and sometimes distressing interventions and hospitalisation, and enable more people to achieve their wish of dying at home, amongst other benefits.[v]

3.3 Additionally, Living Wills provide clarity and support for loved ones and healthcare teams as to how they should proceed in challenging and sometimes highly distressing situations. Such clarity reduces family stress at the time of a decision to withdraw life-sustaining treatment, and research indicates that the use of a Living Will also aids the bereavement process.[vi]

3.4 Research conducted with the British Geriatrics Society found that 56% of the geriatricians surveyed had cared for patients with Living Wills.[vii] (The nature of geriatricians' work means that they are amongst those most likely to be presented with Living Wills). Of those who had cared for the patient at the time the Living Will came into effect, 39% said that they'd changed treatment as a direct result of the Living Will and 78% felt that decisions had been easier to make.

3.5 96% of geriatricians said that even when the Living Will had not yet come into effect, it still improved discussion with the patient (96%). 76% said that Living Wills improved discussions with relatives (76%).

3.6 Additional benefits of Living Wills were identified as follows:

(a) Living Wills clarify how to proceed in grey areas.

(b) Living Wills enable the physician to treat less aggressively.

(c) Living Wills promote an earlier trend towards palliative care.

(d) Living Wills made doctor-patient discussions regarding the end of life more easy.

(e) Living Wills help non-physician staff and relatives reach consensus.

(f) Living Wills were also seen to aid communication, reduce paternalism, and increase patient autonomy.

4. The Uptake of Living Wills

4.1 The most recent independent Living Wills survey (ICM, September 2006) found that 13% of respondents had a Living Will, and 23% of respondents over the age of 65 had a Living Will. A further 51% were considering making a Living Will.[viii]

4.2 This research indicates that the uptake of Living Wills is rising at a fast rate. (In 1995, just 2% of the population were found to have Living Wills[ix]; in 2005, this was 8%)[x].

4.3 It follows that the number of instances where patients' Living Wills are not acted upon (for reasons set out below) will also increase unless the electronic patient records are used to remedy this problem.

5. Problems Caused by the Current Lack of a Central Recording System for Living Wills

5.1 There is currently no system for identifying and recording the existence of patients' Living Wills, to ensure that they are brought to the attention of the attending healthcare team. This means that patients are, in effect, responsible for making their healthcare team aware of their Living Wills at all times. This is both unreliable and risky, as patients may have lost capacity prior to being admitted to hospital.

5.2 Dignity in Dying is frequently contacted by people whose loved one's Living Will was not respected because the healthcare team was unaware that it existed. This is very worrying, not least because it puts PCTs and individual healthcare professionals at risk of claims for negligence, trespass and assault. It can happen for several reasons, eg:

(a) The patient may have logged the Living Will with the GP in his or her medical records, but this information is not passed on to the hospital when the patient is admitted in an emergency (or non-emergency) situation.

(b) The Living Will is not recorded in a suitably prominent place in the patient's medical records.

(c) The new healthcare team is not alerted to the Living Will's existence when the patient is transferred between wards, hospitals or institutions.

(d) The patient has need of emergency treatment whilst visiting another part of England and neither the Living Will nor his/her medical records can be quickly accessed.

(e) The patient has a Living Will at home which can not be quickly accessed, so the healthcare team proceeds with administering life-sustaining treatment.

(f) Regrettably, healthcare professionals still do not check whether the patient has a Living Will.

6. Including Living Wills on the Electronic Patient Records will Protect Patients and Professionals

6.1 All of the risks identified above could be avoided by flagging the existence of Living Wills in the nationally available electronic patient records currently being developed by NHS Connecting for Health, alongside other key information about the patient, eg, allergic reactions to drugs.

6.2 Recording the existence of Living Wills in the Summary Care Records along with other important medical information would enable healthcare professionals to act swiftly and in accordance with their patients' wishes, even in emergency situations.

6.3 The benefits of identifying the existence of Living Wills in the electronic patients' records will include:

(a) Helping to ensure patients' wishes are respected and preventing prosecutions by increasing ease and speed of access to the necessary information:

  (i) Recording Living Wills in patients' Summary Care Records would ensure that healthcare teams are made aware of their patients' Living Wills at the necessary time, and can act accordingly.

  (ii) Recording Living Wills and other "emergency" information in one place would help healthcare professionals to avoid delays whilst they made several checks or calls for different information.

  (iii) PCTs and individual healthcare professionals would not risk prosecution for failing to take reasonable steps to identify and act in accordance with a patient's Living Will.

(b) A cost-free and time-effective project that will avoid bureaucracy and be easy to implement:

(i) Additional funds would not be required as the Care Records Service is an existing project and has already been budgeted for (no additional software would required for the same reason).

(ii) Living Wills data could be transferred to patients' Summary Care Records at the same time as other data is transferred (as this has yet to happen).

(iii) Healthcare professionals would not have to repeatedly record the existence of a Living Will in different medical documents, as it would be logged on the central system.

(c) Improving doctor-patient communication and supporting healthcare teams:

(i) Prior to adding the Living Will onto the patient's Summary Care Record, the doctor would have the opportunity to review it, and make sure that it fulfilled the criteria set out in the Mental Capacity Act's requirements for valid (and legally-enforceable) Living Wills.

(ii) The doctor could also use this opportunity to suggest ways to improve the Living Will and make it more clear or more applicable to medical scenarios which might arise.

(iii) Living Wills work best when they are used as an aide to ongoing doctor-patient discussion regarding the patient's prognosis and values. Bringing the doctor and patient together in order to discuss and record the Living Will on the patient's Summary Care Record would have the additional benefit of helping to improve the patient's understanding of different end-of-life scenarios, and the doctor's understanding of both the patient's values, and how he or she would like to be treated in different end-of-life situations.

6.4 Identification of Living Wills on electronic patient records should be voluntary rather than mandatory, in accordance with the Care Record Guarantee. Due to the obvious benefits of including Living Wills on the electronic patient records, and based on our conversations with people who are concerned to see their Living Will is respected, Dignity in Dying envisages that a significant proportion of people with Living Wills would make use of this option. However, professionals should of course be encouraged to make reasonable efforts to check whether a Living Will exists if it does not appear on the Summary Care Record, in accordance with the Mental Capacity Act.

6.5 Healthcare professionals who have a conscientious objection to undertaking an activity with respect to a patient's Living Will should act in accordance with the Mental Capacity Act Code of Practice and BMA guidelines.

Dignity in Dying

March 2007

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(vi) Tilden V P, Tolle S W, Nelson C A, Fields J, "Family decision making to withdraw life-sustaining treatments from hospitalised patients", *Nursing Research* 2001; **50 (2):** 105–115.

(vii) Schiff R, Sacares P, Snook J *et al, "*Living wills and the Mental Capacity Act: a postal questionnaire survey of UK geriatricians", *Age and Ageing* 2006; **35:** 116–121.

(viii) "Living Wills", ICM Research, 2006.

(ix) Donnison, D and Bryson, C, "Matters of life and Death: attitudes to euthanasia", in Howell, R, Curtice, J, Park, A, Brook, L, and Thomson, K (eds), *British Social Attitudes: the 13th report,* (Aldershot: SCPR Dartmouth, 1996).

(x) "How to have a good death", ICM Research, 2005. NB Dignity in Dying believes this growing interest in Living Wills has been fuelled in large part by debate generated by the Mental Capacity Bill, and subsequently the Mental Capacity Act 2005, which has increased public awareness of end-of-life options.

Evidence submitted by the Faculty of Family Planning and Reproductive Health Care (EPR 18)

EXECUTIVE SUMMARY

The Faculty of Family Planning and Reproductive Health Care (FFPRHC) of the Royal College of Obstetricians and Gynaecologists contributes to the National Advisory Group for Connecting for Health, and has been concerned about the slowness and uncertainty regarding the development of sealed envelopes to keep people's sexual and reproductive health secure. The majority of community contraceptive services are currently not supplied with computerised systems to manage appointments, collect and submit statistical returns, and do not have the capacity to operate electronic records; there is concern that the implementation of the EPR will depend on PCTs finding funds to purchase and support computers linked across localities, and uncertainties about details of what will be required have hampered services looking at interim solutions.

1. *What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems:*

1.1 Members of the FFPRHC work in areas of sensitive public health. This may be in services providing contraception and sexual health operating as one unit within a single unit commissioned by one health organization, or as a combined service across organizations.

1.2 Research has shown that concerns about confidentiality, particularly where young people have chosen to access community/alternative services rather than their GPs, are paramount in whether or not health-seeking behaviour and disclosure of areas which may need protection, will be sought.

1.3 Our understanding is that sexual and reproductive health data will be on a separate "work group" to other community or hospital electronic records, with access only by those working in that service.

1.4 Many people access our services wishing to protect their identity, and register with false names, dates of birth and addresses, which may result in duplicate registrations even across different sites of the same service.

1.5 If NHS number is to become a mandatory field, there are issues about people not registered with GPs, or who do not know this number.

2. *Who will have access to locally and nationally held information and under what circumstances:*

2.1 Our understanding is that at least initially no sexual health information will be uploaded onto the National spine, and that locally the only people to see any information about access to our services are those with a legitimate relationship defined by the work group, and not accessible by other people working within a community or hospital setting.

3. *Whether patient confidentiality can be adequately protected;*

3.1 There are issues about the timing and operation of sealed envelopes which need to be determined before clinicians can have confidence to use any local or national systems.

3.2 Community services are likely to need to have access as a team rather than an individual to protected data due to the way the services run (ie often open access and as non-appointment sessions).

3.3 Until this is agreed, it is difficult to envisage adequate continuity of patient care whilst preserving confidentiality.

4. *How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research;*

4.1 Central statistical returns (KT31 for contraception and KC60 for sexually transmitted infections) should as now be on non-identifiable aggregate data.

4.2 The Common Data Set for Sexual Health is being developed to replace these returns which currently do not capture all the public health input in the 2 settings.

Alyson Elliman
Faculty of Family Planning and Reproductive Health Care of RCOG

14 March 2007

Evidence submitted by the Foundation for Information Policy Resarch (EPR 61)

The Foundation for Information Policy Research is an independent body that studies the interaction between information technology and society. Its goal is to identify technical developments with significant social impact, commission and undertake research into public policy alternatives, and promote public understanding and dialogue between technologists and policy-makers in the UK and Europe.

We welcome the opportunity to comment on the electronic patient record.

The Uses of Clinical Records

A useful starting point is "What information is already held?" Doctors maintain medical records for the primary purpose of treating their patients better. There are many secondary uses, such as scientific research and drug development, not all of which are supported by all patients. Patient surveys have consistently shown that while most support access to records by staff involved directly in their care, most oppose access to individually identifiable records by outsiders.[37,38] As such access has become pervasive over the past fifteen years, a gap has opened up between actual practice on the one hand, and the expectations and views of patients on the other.

The Department of Health used copies of invoices from hospitals to health authorities to amass a database (now the NHS Secondary Uses Service, or SUS) containing summaries of all secondary care episodes. As many of the most sensitive procedures—from terminations of pregnancy to HIV tests—are performed in hospitals or hospital labs, SUS already contains a lot of highly sensitive material, and it is used for many tasks, from scientific research to answering parliamentary questions. There are further central databases for matters such as patient registrations and drug prescriptions. These are also very sensitive; prescriptions for antiretroviral drugs or even antidepressants can be stigmatising, while the Helen Wilkinson case was sparked by an erroneous record that Mrs Wilkinson was a patient of an alcohol abuse service.

By the mid–1990s, secondary uses had got out of hand. The Caldicott Committee found dozens of illegal information flows in the NHS. For example, data on HIV/AIDS sufferers that had been supplied anonymously by hospices and other carers, but with patients' postcodes and dates of birth, were collated and re-identified by the Department. The government's response was the Health and Social Care Act 2000, which empowers the Secretary of State to regulate secondary uses of personal health information, a task now devolved to the Patient Information Advisory Group. This was presented to Parliament as a stopgap mechanism to keep the NHS legal while proper consent and anonymity mechanisms were developed;[39] they have not been, and instead the powers have become a convenient catch-all for ever more information sharing. Many more people have access to medical records than most patients realise, and information-sharing practices remain open to challenge under European law, according to which secondary uses of sensitive personal information require either consent or statutory provision—but not just any kind of statutory provision. Rather, European law requires that any statutory provisions allowing for such data processing must not be over-broad; people confiding in their doctor must be able to foresee what will happen to their data, and to object to (and in all but a few cases, thereby prevent) secondary uses of those data with which they disagree. Patients must be informed of any secondary uses so that these rights can be exercised effectively.[40] Legal challenges are likely as more people become aware of what is happening.

Ever more contentious secondary uses are regularly introduced or proposed, ranging from the use of NHS registrations to track illegal immigrants to police monitoring of opiate prescriptions (which was introduced in 1996 but failed to detect Dr Shipman). The Home Office wants to use health information to identify children at risk of becoming delinquent.[41] There have already been serious abuses; in 2003, the Real IRA infiltrated the Royal Victoria Hospital in Belfast and used its records to target policemen and politicians for murder.[42]

Tussles over access to medical records are not unique to the UK. In the USA, widespread medical privacy abuses led to the passage in 1996 of the Health Insurance Portability and Accountability Act; this was helped through Congress by a case in which a convicted child rapist working as a technician in a Massachussetts hospital phoned up over 900 women and girls, using knowledge of their health records to gain their confidence and ask for sex.[43] In Iceland, a proposal to create a national medical and genetic database

[37] Hassey GA, Wells M "Clinical Systems Security—Implementing the BMA Policy & Guidelines", in *Personal Medical Information—Security, Engineering and Ethics*, Springer 1997 pp 79 – 94.

[38] Singleton P ERDIP Evaluation Project N5—Patient Consent and Confidentiality Study Report. NHS Information Authority. May 2002.

[39] FIPR Response to the Consultation on Proposals to use Section 60 Powers, Jan 30 200, at http://www.fipr.org/040130s60.html

[40] Some of the provisions in the Data Protection Act 1998 (in particular, Schedule 3, para. 8) expressly override these principles, but in a way that contravenes the EC Directive on data protection and the European Convention on Human Rights—and thus the Human Rights Act.

[41] *Children's Databases—Safety and Privacy*, FIPR Report for the Information Commissioner, November 2006; at http://www.fipr.org

[42] "Dissident Operation" Uncovered", BBC News, July 3 2003, at http://news.bbc.co.uk/1/low/northern—ireland/3038852.stm

[43] Brelis M, "Patients' Files Allegedly used for Obscene Calls", Boston Globe, Apr 11 1995; in comp.risks v 17 no 7.

resulted in 11% of the population opting out. Eventually the Icelandic Supreme Court found that it had to be opt-in rather than opt-out, and now the database contains the records of only about half the Icelandic population.

The UK has so far failed to develop a robust political and legal mechanism for balancing patients' privacy interests with the many requests by others for access to their data. There has also been a settled view in the Department of Health that more sharing is better, while public opinion and the popular media have not yet engaged the issues (unlike in the USA and Iceland). There are signs that public engagement is now starting. Thus, if sharing medical data becomes entrenched as CfH wishes, serious disruption will be likely when patients say "enough".

CfH assumes that all medical records will be kept on central machines, and this is not just a matter of hospital and practice archives. Anyone who attends hospital and needs an X-ray will have this stored at the LSP—and there is simply no provision for treating a patient who does not consent to people outside the hospital having access to her data. There are no longer mechanisms, whether physical film X-rays or local data storage, for medical images to be taken and used locally.

While a few dissidents might be accommodated by the Department paying for them to be treated privately, or by ad-hoc mechanisms such as pseudonyms, an opt-out on a large scale—or, equivalently, a European-law case—will present an acute challenge.

Electronic Patient Record Architecture

Against the background of a struggle for access to and control of medical records, the electronic aspects are far from being value-neutral. The movement over the past 15 years to market the "electronic patient record" has generally seen its role as one of centralising records that are at present maintained by different health service providers.

In the USA and continental Europe, initial enthusiasm for the EPR has calmed into a realisation that, in practice, individual records have to be maintained by the organisations that provide the care, and links provided to support appropriate information flows. This is what we already had in the UK: electronic patient records are kept by GPs, and separately by hospitals. The GP holds the lifetime record, which contains references (referral letters and discharge notes) linking to records of hospital care. This architecture naturally follows NHS working practices. It is less convenient for secondary uses; a researcher interested in a particular group of patients, or a civil servant researching the answer to a parliamentary question, may have to chase around numerous hospital and surgery systems. From their viewpoint, centralising everything would be convenient. But the main purpose of medical records is to support care rather than research; optimising access for researchers rather than carers is bad engineering and a waste of money.

Unfortunately, the idea that everyone should have a single EPR, to be opened in the IVF clinic and archived on autopsy, was adopted in the 1990s as the vision for the NHS Information Management and Technology Strategy. NHS computing strategists have clung to this vision even as the rest of the world has moved on. The vision must be abandoned.

1. Clinicians want to use the best system for them—be it the best GP system, the best cardiology system, or the best diabetes management system. In a globalised competitive world, this means assembling systems from different suppliers and connecting them up, rather than a single one-system-fits-all approach.
2. Clinical systems have historically worked best when their functionality is driven directly by the demands of their users. A crude way of putting this is that "systems bought by doctors generally work and systems bought by civil servants generally don't." A GP who wants new functionality on (say) his practice system can call the sales engineer, or go along to the user-group conference and give a talk. Even so, GP system developers are perceived to have become less responsive over the past 10 years, as the Department of Health has interfered more and more in their design; clinical features have been crowded out by mechanisms sought for reporting and targets. There is wide concern about the consequences of having CfH doing all the purchasing in future.
3. Trust and control follow architecture. So long as patient records sit on PCs in doctors" surgeries, GPs retain some autonomy and patients some privacy. The move since 2004 towards "hosted systems"—where the records are removed from the surgery and placed on a server in a hosting centre—undermines this. No matter that the GP remains the data controller for now; once the data are "hosted" it is a simple matter for the Department to make the Chief Medical Officer the data controller. For this reason, back in 1996, the BMA adopted the principle that trust structures in e-health should reflect those in existing professional practice. (We'll discuss privacy in more detail in the next section.)

The alternative to centralisation is interoperability; this is the approach being taken in Europe and North America, as shown in a recent study by FIPR for the National Audit Office.[44] The UK is an outlier, and is likely at some stage to be compelled to follow the rest of the developed world. (CfH is watched with appalled fascination by colleagues overseas.) The NHS has a long, sad history of failed attempts at autarky in IT; an

[44] *Healthcare IT in Europe and North America*, FIPR, National Audit Office, 2006.

example is the attempt in 1994–96 to standardise the NHS-wide network on X400 email protocols rather than using SMTP, which had already achieved dominance on the Internet. The effect was to delay by several years the uptake of email by GPs and (especially) hospitals. Similarly, we believe that one of the main reasons the Care Records Service is years late is that it is simply the wrong system to build. It is not how the rest of the world works, and it does not correspond to the actual requirements of healthcare providers.

Privacy, Confidentiality and Security

These terms are often (deliberately) confused. Privacy refers to the right patients have under data-protection and human-rights law to control information about themselves; confidentiality refers to a duty that people have to others as a result of an employment or other contract; and security refers to mechanisms that enforce particular policies on information flow. In an ideal world, the patient's right to privacy is upheld by the doctor's duty of confidentiality and both are supported by information security mechanisms. The Committee should be very wary if questions about patient privacy are answered by reference to information security mechanisms, such as using smartcards to stop outside "hackers" getting access to information. The threat to privacy comes from insiders. Someone wanting access to health information will typically phone up, pretend to bean insider, and find someone careless enough to disclose it.

In 1996, an experiment was conducted to train staff at the North Yorkshire Health Authority to deal with this problem, by logging calls and calling back to numbers obtained from the phone book rather than the caller. This uncovered 30 false-pretext calls per week.[45] The BMA asked the Department of Health to introduce such operational-security measures throughout the NHS; their response was to order the NYHA to stop. Smartcards are not the answer to this problem.

Various other technical security policies have been proposed from time to time by the Department of Health for a national EPR. Not one of them has been convincing. In 1995 the proposal was for a multi-level system of the type commonly used in the civil service, in which prescriptions would in effect be classified "Restricted", ordinary medical records at "Confidential" and HIV/AIDS data at "Secret". The BMA pointed out at the time that this was unserviceable; what about a prescription for AZT? The BMA's counterproposal was a compartmented security policy, with records kept by healthcare providers rather than centrally, and rules based on existing practice to regulate flows between them[46] This has been implemented in a number of hospital systems, but the Department opposed it as inimical to its centralising vision.

The Department's current computer security proposals are little changed. Multilevel security has been replaced by role-based access control, and there is a promise that access by care-delivery staff will be restricted on the basis of legitimate patient relationships. But it is not clear how this will be implemented. The Department's historic lack of concern with patient privacy (as seen in the NHYA incident) does not give confidence that effective controls will be developed; neither does the Cabinet Office's "e-Government framework for Information Assurance" [47] which seeks to reduce the protection given to personal information in the public sector[48] Yet the fact remains that aggregating large quantities of sensitive information, to which more and more people then need access in order to do their jobs, simultaneously increases the value of the target and the number of people through whose carelessness or disloyalty it can be compromised.

The department has also proposed "Sealed Envelopes" as a mechanism for patients to restrict access to particularly sensitive information. There are several problems. First, although they would bar access to some clinical staff (who could override them if thought necessary) the envelopes will not bar access to the secondary users—the very people whom most patients believe should have no access. Second, sealed-envelope systems have not been built, and it is not clear that they can be. A recent report from the Department's own consultants concluded that sealed envelopes would not work as well as local data storage[49] It is disturbing that CfH proposes to roll out a nationwide medical-records system without proper confidentiality safeguards—merely an assurance that some safeguards will be developed eventually.

Local, or compartmented, systems are widely used for data that governments really do want to keep confidential, such as defence and intelligence information. Exactly the same considerations apply to information whose disclosure would harm private individuals as where disclosure could harm soldiers or ministers. It is a principle of security engineering that we can build systems with functionality, scale or security—or indeed with any two of these attributes, but not all three. Secure and highly functional systems have to be local, or compartmented.

[45] Anderson RJ. Security Engineering—*A Guide to Building Dependable Distributed Systems*. Chapter 8. Wiley 2001; at www.cl.cam.ac.uk/~ja14/book.html

[46] Anderson RJ. *Security in Clinical Information Systems*. BMA, 1996.

[47] Draft 5.1, December 2006, at http://www.cabinetoffice.gov.uk/csia/consultation/

[48] Anderson RJ, Bohm N, Gladman G, Whitehouse P, *Framework for Information Assurance*, March 13 2007, www.fipr.org

[49] Det Norske Veritas, *Sealed Envelopes Risk Assessment Project*, 29 Sep 2006, at www.nhsconfidentiality.org

There are grave problems with records of especially sensitive matters, such as sexually transmitted diseases and psychiatric care[50] In the world of paper records, a psychiatrist simply keeps his files locked up, but if there is to be a single womb-to-tomb record, then his notes must be kept there—and what sort of assurance can be got that the large numbers of secondary users of health information will not leak information and cause harm? No-one knows how to write a security policy for a lifelong EPR—there are just too many complications (these were explored in some detail when the BMA developed its security policy in 1996).

Finally, the Committee asks how medical data should be used for research. The short answer is "within the law'. There are researchers who believe they should have a right to know everything about everyone with the disease in which they are interested (cancer specialists argued this during the passage of the Health and Social Care Act 2000). But that is not consistent with European law or with patients' views. Where records can be effectively anonymized, well and good; but in the many cases where they cannot, consent matters. The committee should consider two important precedents: how the cavalier attitude to laboratory animal welfare in the 1970s spawned the Animal Liberation Front; and how disdain for consent in the context of human tissue led to the damaging Alder Hey scandal. If contempt for medical privacy causes widespread withdrawal of consent, research will suffer even worse damage.

Risks of IT-driven Business Change

A further driver for centralisation is the perception that it is needed to "modernise" the NHS. It may be argued that central GP records make it simpler to discontinue an inefficient general practice and award the business instead to, say, a drop-in centre run by a supermarket chain. But if the Secretary of State wishes to move patient records from an unsatisfactory practice to a new one, she can already regulate for this. More generally, when organisations to try to change the way they operate by imposing IT systems, rather than by finding or constructing proper incentives to drive the change, poor outcomes are common. In the public sector there have been some spectacular failures, such as the London Ambulance Service disaster. There is a real risk of an even bigger CfH disaster.

Conclusions

Electronic medical records already bring many benefits, via faster communications, better record availability, and reduced errors. However, the Committee should not confuse these benefits with the centralisation agenda.

Centralisation is principally about power and control in the management of the health service. It is driven by the conflict between administrative convenience and professional autonomy. The Department seeks to resolve this conflict by controlling all information systems. The inevitable side-effects—mediocre systems and the destruction of patient privacy—would be severe. Patient trust in the medical profession will be undermined, and the Department would be vulnerable to challenges under European law. However, the strategy is not working, and is not likely to. It is time for it to be abandoned, and for CfH to return to providing the standards and infrastructure for interoperable systems, as its equivalents do elsewhere.

Professor Ross Anderson
Dr Ian Brown
Dr Fleur Fisher
Professor Douwe Korff
Foundation for Information Policy Research

15 March 2007

Evidence submitted by the General Medical Council (EPR 69)

Set out below is the General Medical Council's written submission for the Health Select Committee inquiry into the electronic patient record and its use. Please accept our apologies for the delay in providing these comments. I hope that the Select Committee will be able to consider them.

1. The GMC welcomes the opportunity to assist the Health Select Committee in its inquiry into the Electronic Patient Record and its use. This submission provides information on the following:

(a) Our statutory role as the regulator for medical practitioners registered in the United Kingdom.

(b) Our advice to the profession, pursuant to our statutory functions, on issues of confidentiality.

(c) How the NHS Care Record Service (CRS) might affect doctors' duty of confidentiality and our advice about their responsibilities.

[50] NHS Confidentiality Consultation—FIPR response, last updated June 29 2005, at http://www.cl.cam.ac.uk/⩾rja14/fiprmedconf.html

The Role of the General Medical Council (GMC)

2. The GMC's role in the regulation of doctors is defined in our statutory and charitable purposes: to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. The law gives us four main functions under the *Medical Act 1983*:

(a) Keeping up-to-date registers of qualified doctors.

(b) Fostering good medical practice.

(c) Promoting high standards of medical education.

(d) Dealing firmly and fairly with doctors whose fitness to practise is in doubt.

3. We are not in a position to respond to all the issues raised in the Committee's terms of reference, although we have followed what Connecting for Health have advised on what patient information will be held on the new local and national electronic record systems, and who will have access to locally and nationally held information and under what circumstances. We have been assured about the intentions for robust access controls, security arrangements and audit, so that only those with a legitimate relationship should access patients' records. Legitimate relationships and role-based access, if properly implemented and robustly monitored, should go a long way to ensuring information is not accessed inappropriately.

4. We continue to be engaged, through membership of the Information Standards Board and Care Record Development Board working groups on secondary uses of data and on children, with the detailed development plans for rolling out the CRS.

5. We welcome the intended benefits to patient care and safety that the CRS offers in terms of the timely access to up-to-date information when it's needed. And additional benefits of effectively anonymising patient data for use in healthcare management and planning, research and other secondary uses opens up possibilities for better protecting patients' privacy than currently exist.

Published Guidance on Confidentiality

6. Confidentiality is central to the trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care.

7. In our published guidance, *Confidentiality: protecting and providing information*[51], we explain doctors' duty to respect patients' autonomy and confidentiality and the consequent need to seek patients' consent before sharing or using their personal information, wherever that is practicable. This reflects common law and statutory obligations as well as important ethical principles.

8. We also advise that doctors who are responsible for health information about patients should ensure that it is effectively protected against improper disclosures and make reasonable efforts to ensure that they connect to networks which have appropriate systems for the protection of data.

9. This guidance was drafted in an age of simpler local or area networks, within practices or hospitals or with local PCTs. We are not in a position to assess the security arrangements of the CRS and it would not be reasonable to expect doctors individually to do so. Of course, if doctors have concerns about data security, we would still expect them to raise concerns when they believe that patient safety is being compromised by inadequate premises, equipment or other resources.

Consent, Confidentiality and Patient Control

10. In considering our own contribution to the recent "opt-in/opt-out" debate, and in response to queries about pilots, we have concluded that the format and means of recording information are matters for the health service providing care, either within the NHS or private sector. Patients cannot, for example, require doctors to record information about them on paper records rather than on computer systems to which others have access. How the records are used, shared or disclosed—the matters governed by the law and ethics of confidentiality—are matters for individual patients and doctors to determine in accordance with the law and professional guidance.

11. Patients usually have the right to decide with whom identifiable information about them is shared. Most people understand and accept that information must be shared within the healthcare teams that provide their care. In our guidance we explain that it should be made clear to patients when information is to be shared with anyone employed by another organisation or agency which is not contributing to their care, and the wishes of any patients who object to information being shared should usually be respected (see paragraph 10 of our guidance[52].

[51] See www.gmc-uk.org/guidance/current

[52] General Medical Council, 2004, Confidentiality: Protecting and Providing Information.

12. It is essential that patients are provided with sufficient, appropriate information and given time to make informed choices about whether to opt-out of the CRS or its constituent parts or to have parts of their records placed in "sealed envelopes" when that option becomes available. The information provided by Connecting for Health as part of the roll out of the CRS will be crucial in this regard and doctors will play an important role in explaining patients' options and addressing their concerns as they are raised.

13. We have emphasised and sought to ensure that the CRS, when implemented, provides at least an equal standard of confidentiality for patients as current paper and computer systems.

Dr John Jenkins
Chairman, Standards and Ethics Committee

March 2007

Evidence submitted by the Health Protection Agency (EPR 31)

EXECUTIVE SUMMARY

1. The Health Protection Agency (HPA) is submitting evidence to the House of Commons Health Committee with regard to the area of interest "How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research".

2. The HPA believes that Connecting for Health offers a vision for healthcare information which could revolutionise the collection and use of data for public health purposes and enable the HPA to provide a quicker and more responsive service.

INTRODUCTION

3. The HPA is an independent body that protects the health and well-being of the population. The Agency plays a critical role in protecting people from infectious diseases and in preventing harm when hazards involving chemicals, poisons or radiation occur. We also prepare for new and emerging threats, such as a bio-terrorist attack or virulent new strain of disease.

CURRENT SYSTEMS

4. The Health Protection Agency undertakes surveillance of infectious diseases and other environmental threats to health through a range of local, regional and national surveillance systems. The purpose of these surveillance systems includes acute alerting and response to health protection threats, the longer term monitoring of trends and distribution in disease, hazards and exposures, and elucidation of the determinants of disease epidemiology and the natural history of diseases due to infections and other environmental threats to health. A key requirement of health protection surveillance systems, and one that is almost unique amongst disease surveillance systems, is the need for real time or near real time, capture and analysis of data in order to detect and inform the response to outbreaks and other emerging infectious disease problems.

5. The Health Protection Agency draws on data from a wide variety of sources within the NHS, and beyond, as well as using data derived from its own frontline units and laboratories. Among the many data sources and systems used to monitor the wide range of infectious disease and other environmental threats to health there are a number of core systems that underpin much of the Health Protection Agency's surveillance activity, these include:

- Voluntary confidential reports from microbiology laboratories (and some other pathology departments).
- Notifications of infectious disease made under the provisions of the 1984 Public Health Act and 1988 Public Health Regulations.
- Pseudonymised clinical reports of HIV/AIDS.
- Data from Primary Care reporting networks including the Royal College of General Practitioners network and the QRESEARCH and QFLU networks.
- Outpatient return data, in particular from genitourinary medicine clinics (KC60).
- Vaccination uptake information, derived from child health and other relevant information systems.
- Data on hospital patients including case reports of surgical site infections and other healthcare associated infections, and hospital episode statistics.
- Mortality data from the Office for National Statistics.

6. The amount of person identifying data, demographic information, and other information relating to clinical status or risk factors varies between these surveillance systems, but, as noted above, the common feature of many of these surveillance flows is that the data are collated and analysed on as near a real time

basis as is possible. Many of the surveillance systems are based on voluntary reporting by clinicians and pathologists (notifications are unusual in that reporting is mandated in law) and for some data flows, in particular laboratory reports that constitute the mainstay of surveillance for many conditions, data flows are supported by ad hoc electronic reporting systems that could be compromised by the implementation of National Programme for IT Systems unless those systems are explicitly specified to deliver the required data. A project is currently in progress to provide this specification.

VISION

7. There is the potential for Connecting for Health to deliver a nationwide system that moves the necessary data (disease, microbiology etc) from all parts of the NHS to the Expert Surveillance Centres in real time and that can also support longitudinal monitoring of individuals to enable surveillance of the long term effects of infectious disease and other environmental threats to health. It will be important that the process of implementation of this system does not disrupt or compromise existing systems, and that the fully implemented system inter-operates with complementary, cost effective and validated schemes.

8. The benefits that Connecting for Health could realise for organisations such as the HPA cannot be overstated. In an emergency such as an Influenza pandemic, the automation of key information flows would ensure the Agency is kept up to date and is able to respond at a time when key staff would be taken ill and unable to support existing processes. The vision offered by Connecting for Health will enable better protection of health in England in a more cost-effective way.

James Freed and Mike Catchpole
Health Protection Agency

15 March 2007

Evidence submitted by Help the Aged (EPR 63)

EXECUTIVE SUMMARY

1. The electronic patient record should include the single assessment process assessment and care plan and should be compatible with existing electronic SAP systems.

2. Information on the assessment of met and unmet need and whether outcomes have been met for people who use health and social care services should be capable of being collated and anonymised from the electronic record to inform commissioning.

3. Medication histories should be recorded and shared on the electronic record as communication is often poor across primary and secondary care in providing co-ordinated medicines management. This has serious consequences for people who are on four or more medications, most of these people are over 60 years old.

INTRODUCTION

4. Help the Aged welcomes the opportunity to comment on the electronic patient record as this provides an opportunity for sharing information about a person's assessed needs and wishes and the care plan that has been developed with them.

5. The national service framework for older people (NSF) introduced the use of a single assessment process (SAP) so that information about an older person's needs, wishes and aspirations could be shared across health and social care to avoid duplication of assessment and to improve communication in delivering a seamless service.

6. Successful implementation of SAP has been dependent upon health and social care staff having access to electronic records that can be shared across agencies. This challenge has resulted in slow progress with implementation of SAP across health and social care communities. The electronic patient record may support implementation, provided lessons are learnt from the implementation of SAP and existing SAP systems are compatible with the electronic patient record.

7. The sharing of information on medication is another important issue as older people are often prescribed more than four drugs at one time and the medical history on medication is not always shared successfully across primary and secondary care. Failure to manage medicines effectively and carry out regular reviews with patients on more than four medications can lead to serious complications.

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems?

8. Help the Aged are not aware of what information will be held on the new local and national electronic record systems. However, we strongly recommend that this includes the SAP assessment and resulting care plan and information on medicines prescribed.

9. Patients should be asked to agree for personal information to be recorded and shared and if they have any objections to being asked which specific information they would not want to share. Patients should have a copy of the SAP assessment and care plan as they own this information.

Who will have access to locally and nationally held information and under what circumstances?

10. At a local level all professional and care staff providing health and social care services to an individual should have access to their electronic patient record. This includes staff working in the primary care trust (PCT), acute hospital trust, mental health trust and social services.

11. At a PCT level information should be collated and anonymised to inform commissioning and decommissioning of services. The development of commissioning plans based on individual assessments of need through the SAP was outlined in the white paper *"Our health, our care, our say"*. However, this has not been achieved in England to date due to the quality of information collected and the inadequacy of the existing electronic systems. The electronic patient record system should be capable of collecting information on individual met and unmet needs, measuring outcomes for people who use services. Commissioning managers and heads of service would need access to this anonymised information to develop a commissioning strategy and make commissioning decisions for the local population

12. The medication history of individuals should be shared at a local level across primary and secondary care and with social care. At a PCT, regional and national level this information could be used for the purposes of audit, provided that it was first anonymised.

Whether patient confidentiality can be adequately protected?

13. All professional and care staff should be bound by their code of practice and their job description to respect patient confidentiality, regardless of how the information is collected and stored. The sharing of information across professional groups and agencies is less clear and this has caused problems in the past with the implementation of an electronic SAP system as professionals are uncomfortable with sharing information. Clear guidelines are required on what can be shared and for what purpose if electronic records are to result in the effective sharing of information to improve the quality of care.

How data held on the new systems can and should be used for purposes other than delivery of care e.g. clinical research?

14. The data held on the new systems can provide valuable information for:
- — monitoring the quality of contracts
- — carrying out local and national audits of services

15. If information is collated and used in this way it should first be anonymised

Recommendations for Action

16. The electronic patient record should include the single assessment process assessment and care plan

17. The electronic patient record should be compatible with the existing electronic SAP systems

18. The electronic patient record should include medication history

19. Guidelines should be produced for frontline staff on sharing information

20. Data from the electronic patient record should be collated and anonymised to inform commissioning

21. Data from the electronic patient record should be anonymised and collated for local, regional and national audit

Help the Aged

March 2007

Evidence submitted by the Information Commissioner (EPR 24)

Summary

In this evidence the Information Commissioner has made it clear that he is generally pleased with the current level of contact with NHS Connecting for Health (CfH) over the development and introduction of electronic patient records in England. He feels that some valuable progress has been made in ensuring that CfH plans and actions are compliant with the Data Protection Act 1998.

The Commissioner is conscious that these plans inevitably pose significant data protection risks—for example in relation to patient awareness, confidentiality, accuracy and security—but throughout his discussions he has been assured that CfH is aware of the various risks and is taking steps to address them.

He continues to monitor the implementation and operation of the NHS Care Record Service in order to ensure that;

— Patients are provided with adequate information,

— That information is fit for purpose, and

— Effective security safeguards are in place to protect information.

He has also outlined his concerns about the challenges in policing the consistency and security of access arrangements across the NHS as a whole and he has drawn attention to some of the possible abuses of the electronic patient record. In particular the unlawful obtaining, procurement and disclosure of personal data and the widening of the uses of the unique identifier that is the NHS Number for non-medical purposes.

1. The Information Commissioner Office is the UK's independent public body set up to promote access to official information and protect personal information by promoting good practice, ruling on eligible complaints, providing information to individuals and organisations, and taking appropriate action when the law is broken. The Information Commissioner is the regulator for the Data Protection Act 1998 (DPA) and the Freedom of Information Act 2000 (FOIA). The comments in this evidence are primarily from a data protection perspective.

2. The Information Commissioner fully supports the idea that the National Health Service (NHS) should make the best use of new technology to improve patient care by better management of patients' records. The Commissioner has been in discussion for some time with NHS Connecting for Health (CfH) about the plans for the introduction of electronic patient records in England. The Commissioner is conscious that these plans inevitably pose significant data protection risks—for example in relation to patient awareness, confidentiality, accuracy and security—but throughout his discussions he has been assured that CfH is aware of the various risks and is taking steps to address them. The Commissioner has made it clear in particular that information about a patient's health is sensitive data and the processing of such data must comply with the provisions of the DPA. He continues to monitor the implementation and operation of the NHS Care Record Service in order to ensure that this happens and that patients are provided with adequate information, that information is fit for purpose and that effective security safeguards are in place to protect information.

3. This is not only necessary to ensure that the NHS complies with its legal responsibilities under the DPA. It is also vital to gain the public's confidence about the introduction and operation of computer systems that ultimately will process sensitive personal data about everyone who uses the NHS in England.

4. The Information Commissioner is generally satisfied with the steps that CfH have taken so far to publicise the development and introduction of electronic patient records. However, in view of the opportunities to exercise choice that will be available, it is particularly important that each individual adult patient is fully informed of the way that these developments will affect them with sufficient opportunity to exercise the choices on record keeping that will be available to them.

5. The DPA requires, amongst other things, that any processing of personal data must be carried out in compliance with certain defined conditions. The DPA provides a number of possible conditions for the processing of sensitive personal data contained within electronic patient records. One of these conditions is where the processing of sensitive personal data is necessary for medical purposes and is undertaken by a health professional or a person who owes a duty of confidence equivalent to that of a health professional. The Information Commissioner is satisfied that the NHS can rely on this condition in order to process the sensitive personal data in electronic patient records. However, having established a proper basis for processing, the limitations attached to this basis must be complied with along with other aspects of the DPA most notably the eight data protection principles.

6. Amongst other things, the data protection principles require that personal data is adequate and fit for purpose. With this in mind the Information Commissioner expects that the arrangements for the "uploading" of personal data to create the electronic patient records will be robust enough to ensure that the highest possible levels of data quality are maintained at all times particularly as clinical judgments will be made based on this data.

7. The Summary Care Record (SCR) will form the first part of the full electronic patient record. The SCR will be launched in Spring 2007 in a small number of Primary Care Trusts (PCTs). Initially, the SCR will contain a patient's demographic information such as name, address and contact details plus basic details from existing GP records about such things as allergies, current prescriptions and bad reactions to medicines. The NHS has decided to allow patients an opportunity to opt out of a summary care record. This is a welcome option allowing an element of patient choice and patients who choose not to permit this use of their personal data will not have a SCR created for them but this is not a strict requirement of the DPA. Patients will be informed that they do not have a right to prevent demographic information being held by the NHS even if they choose not to have a SCR.

8. The local detailed care record is the main record which will be relied on for care and which will include detailed clinical information. The Information Commissioner is satisfied that the NHS could rely on the medical purposes condition to process the sensitive personal data in the local detailed care record. It is not yet entirely clear whether the NHS will still provide any options for patients to exercises any choices over the content of the detailed care record and whether this could result in confusion for patients over the different levels of control provided to them.

9. CfH is developing "sealed envelope" arrangements which, when fully functional in 2008–09, should allow patients to request that some specific sensitive information within their record is only accessible with their consent other than in exceptional circumstances. The Information Commissioner fully supports these proposed arrangements to give patients control over who may access their details and remains keen to ascertain how these will operate in practice.

10. CfH is developing comprehensive plans and procedures to deal with the controls over access to electronic patient records. CfH has kept the Information Commissioner informed of these plans and so far they appear to comply with requirements of the Data Protection Act 1998 although it remains to be seen how well they work in practice particularly as some abuses of the current access control arrangements have been reported recently

11. The NHS Care Records Registration Authority, which is responsible for registering and verifying the identity of NHS staff who need to use the NHS Care Records Service and related IT systems and services, is a key part of CfH plans. There will also be local Registration Authorities which will be responsible for validating users, registering user profiles and issuing smartcards. Access to electronic records by NHS staff will be via a personal Smart Card and Personal Identification Number (PIN). In addition the type and level of access a member of staff can have will be determined by their role. For example a doctor involved in a patient's care will need to have access to detailed clinical information whereas a receptionist in a surgery may only need access to a patient's contact and appointment information. NHS staff would have to have a recognised "legitimate relationship" with the patient to access patient records. Doctors in an A&E Department will be amongst the few NHS staff able to create an immediate legitimate relationship with patients. This is because care in A&E Departments is generally unplanned so there would probably be no existing legitimate relationship between doctor and patient.

12. The Information Commissioner can foresee some challenges with the control and policing of these access arrangements within the context of a national system for electronic patient records. Despite its name, in reality the NHS is not a unified organisation. It consists of numerous disparate and separately managed regional and local units such as Hospitals, Primary Care Trusts and GP Practices.

13. Initial decisions about what level of access to give to staff may be made locally. For example, it is conceivable that some Hospitals or GP Practices will give their reception staff access to the full patient record including clinical information whereas others may only give them access to patients contact and appointment information. These differences almost certainly exist already across the NHS and there may well be long standing and sensible operational reasons for them. However, within the context of a national system for electronic patient record, such differences could lead to inconsistencies in and increased risks to the security surrounding patient records in different parts of the country.

14. The Information Commissioner also has concerns about how the NHS will police the secure and proper use of access arrangements. Even though he is aware that there will be a detailed audit trail of access to patient records he is aware of one recent publicised incident in which the Board of a Hospital agreed that clinicians working in an A&E Department could share their personal Smart Cards to access patient records.

15. Whilst the Board defended its decision on operational grounds the Information Commissioner is concerned that if incidents of this type are allowed to continue they will increase the risk of serious breaches of security and confidentiality. This particular incident was the subject of discussions between the Information Commissioner and CfH. CfH has assured the Information Commissioner that it will take all action necessary to prevent any further such incidents during the implementation and operation of the NHS Care Record Service.

16. Patients will also have access to their own electronic patient records. As now they will have a statutory right of access under the DPA and those who choose to have a SCR will also be able to register for "HealthSpace" which will provide them with online access to their SCR. The Information Commissioner has already made it clear to CfH that the patient's right of access to their own health records under the Data Protection Act 1998 should not be adversely affected in any way by the implementation of the NHS CRS. With respect to HealthSpace, the Information Commissioner has asked about the present planned arrangements for access controls, registration and authentication of applications for access to HealthSpace and although reassurance has been provided in relation to these it remains to be seen how well they work in practice.

17. The Information Commissioner is concerned about the possibility of third parties requiring individuals to provide them with enforced access to their HealthSpace for example as a pre-condition of employment. Although it is not yet clear to what extent this may be a problem it is a matter that requires careful consideration.

18. The Information Commissioner is also concerned that, in common with most large scale computer systems, the NHS CRS will be vulnerable to the unlawful obtaining, procurement and disclosure of personal data. This type of offence is known as "blagging". The Information Commissioner's Regulatory Action Division has developed expertise in dealing with offences of this type. The nature and extent of the problems were documented in two reports published during 2006—*What Price Privacy?* and *What Price Privacy Now?* The Commissioner is delighted that, with CfH support, the government has recently accepted the central recommendation—to increase substantially the penalties available to deal with the illegal trade in personal information. The Commissioner has offered to work with CfH to research and develop the best methods of preventing and investigating the "blagging" of personal data from electronic patient records.

19. CfH has made the Information Commissioner aware of the increasing number of requests to share data from patient records that it has received and continues to receive from other public bodies. Given the drive for ever wider information sharing the Information Commissioner envisages an increase in the number of situations where the wider lawful sharing of information is appropriate within the public sector. However, a very cautious approach is appropriate where health records are concerned given the sensitive nature of much of the information likely to be on NHS systems. The Information Commissioner has offered to assist where CfH requires support when making decisions with difficult and questionable requests to share information from patients' health records. The Information Commissioner will be publishing a framework code of practice and associated guidance on information sharing in the next few months and will ensure that there is close contact over this with CfH.

20. CfH has informed the Information Commissioner that detailed policy recommendations from a multi-disciplinary group about wider, possibly non-medical, uses of the NHS Number are currently with Ministers for approval. The Information Commissioner is concerned about the use of unique identifiers such as the NHS Number for other than their original purposes and has made CfH aware of this. In order to safeguard patients' information and prevent misuse of the NHS Number the Information Commissioner has recommended to CfH that the NHS Number is prescribed by the Secretary of State as a general identifier under the DPA with additional safeguards restricting its use.

Conclusion

The Information Commissioner is generally pleased with the current level of contact with CfH over the development and introduction of electronic patient records in England. He feels that some valuable progress has been made in ensuring that CfH plans and actions are compliant with the requirements of the DPA.

He continues to monitor the implementation and operation of the NHS Care Record Service in order to ensure that;

- Patients are provided with adequate information;
- That information is fit for purpose; and
- Effective security safeguards are in place to protect information.

Richard Thomas
Information Commissioner

14 March 2007

Evidence submitted by Intellect UK (EPR 67)

Intellect sees the current programme as just one phase in a long-term multi-decade effort to improve the capabilities and performance of information systems in healthcare, not for their own sake but as a vital infrastructure for patient care.

There are two areas in particular where better information systems can deliver direct benefit to patients, a joined up approach shared amongst organization and a dynamic cooperation between different healthcare providers.

Our members experience so far indicates that shared health and social care systems encourage the generation and use of good-quality patient records, as they provide workflow and unite organisations. The key to further adoption is through integration to core systems in each care setting, and guided external funding of this may be expected to realise benefits comparable to those emerging from the spine.

The electronic decision support makes (secondary) use of data held on the system to enable safer prescribing and dispensing at the point of care. The open standards are key to achieving interoperability of information together with flexibility in the management of ICT assets. NHS Connecting for Health has been an exemplar of good practice in the UK public sector in developing open standards and has also demonstrated good practice by engaging in technical consultation.

As a final point, the lesson learned across the National Programme is that the phased approaches, with room for manoeuvre as understanding grows on both sides, deliver better value in the long run. This should be seen as growing maturity, not "failure to deliver".

1. Introduction

This submission has been prepared by Intellect in response to the press notice issued by the Health Select Committee on 5 February 2006.

Intellect is the UK trade association for the IT, telecoms and electronics industries. Its members account for over 80% of these markets and include blue-chip multinationals as well as early stage technology companies. These industries together generate around 10% of UK GDP and 15% of UK trade. Our membership spans blue chip multi-nationals through to early stage technology enterprises. Intellect's website is located at www.intellectuk.org

This response focuses primarily on the Information and Communications Technology (ICT) element of the Electronic Patient Record programme; this is the area where Intellect members have most expertise and are most engaged with the programme.

2. Reflections on NPfIT to Date

We see the current programme as just one phase in a long-term multi-decade effort to improve the capabilities and performance of information systems in healthcare, not for their own sake but as a vital infrastructure for patient care.

3. Areas which can Benefit from NPfIT

Two areas in particular where better information systems can deliver direct benefit to patients are:

- Where several organisations need to work together to deliver "joined-up" care, for example to vulnerable elderly people (as well described in the January 2006 White Paper Our Health, Our Care, Our Say).
- With individuals with long term conditions (such as diabetes), where co-ordination between different healthcare providers, together with full engagement by patients themselves and their carers, is a key practical and policy goal.

In both these areas, a flexible, pragmatic approach to information systems procurement and deployment, meeting needs of regions with different geography and demographics in different ways, is preferable to a "one size fits all" approach. For example, in areas of high population density such as London and the West Midlands, it is important to take a regional approach so that services can be integrated across local administrative boundaries, and to enable efficient sharing of specialist facilities. In more rural areas, the challenge is rather to enable scarce and geographically dispersed resources to work together. Neither just a national shared record, not just local shared records, will deliver what is needed. Systems need to be both flexible and integrated, with the National Care Records System playing its part alongside, and integrated with, local and regional systems. Policy and practice are moving in this direction, and that is to be welcomed.

Our members experience so far indicates that shared health and social care systems encourage the generation and uses of good-quality patient records, as they provide workflow and unite organisations. The key to further adoption is through integration to core systems in each care setting, and guided external funding of this may be expected to realise benefits comparable to those emerging from the spine.

4. Drug Related Clinical Decision Support

Electronic decision support makes (secondary) use of data held on the system to enable safer prescribing and dispensing at the point of care.

- Electronic active clinical decision support (eg alerts for allergy, contraindications & precautions) is wholly dependent on SNOMED CT[53] encoded clinical data being of high quality and consistently present on the system.
- It is not yet evident that NCRS[54] data will be sufficiently robust for clinical decision support.
- Native use of SNOMED CT within clinical applications would significantly improve data quality and progress interoperability.

[53] SNOMED Clinical Terms (SNOMED CT) is a dynamic, scientifically validated clinical health care terminology and infrastructure that makes health care knowledge more usable and accessible.

[54] NHS Care Record Service.

5. Open Standards

Open standards are key to achieving interoperability of information together with flexibility in the management of ICT assets. NHS Connecting for Health has been an exemplar of good practice in the UK public sector in developing open standards (the NPfIT Message Implementation Manual) for systems integration within its scope of influence, and has also demonstrated good practice by engaging in technical consultation with the implementation community during the development of these standards (for example, through HL7 UK, see http://www.hl7.org.uk).

6. Lessons Learned from NPfIT

As a final point, the original cost figures and timescales for NPfIT were set "hard" as a policy measure, before the requirements were fully understood, and this approach is well known to nearly guarantee timescale and/or cost overrun on initial figures in complex ICT projects. Phased approaches, with room for manoeuvre as understanding grows on both sides, deliver better value in the long run. This lesson is slowly being learned across the National Programme, and this should be seen as growing maturity, not "failure to deliver".

Intellect

16 March 2007

Evidence submitted by Londonwide LMCs (EPR 41)

Londonwide LMCs is the umbrella organisation representing the 5,000 plus GPs in London. It is consortium of 24 individual Local Medical Committees (LMCs), each of which is coterminous with the relevant local authority. LMCs are independent professional organisations with statutory functions, elected, inter alia, to represent GPs to Primary Care Trusts. They are not trade unions.

Londonwide LMCs welcomes the opportunity to submit evidence to the Health Select Committee inquiry into the electronic patient record.

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on new systems?

Londonwide LMCs believes the current hybrid system of paper and electronic records is less than perfect and appreciates the potential benefit greater sharing of information could bring to patient care.

We firmly believe that patients should decide, in discussion with their GP, the extent to which their clinical information is placed on a national electronic system. We also believe patients should have the opportunity to check their records before the initial upload. GPs will have a crucial role in enabling their patients to fully understand the implications of sharing and withholding information.

We support the BMA policy that explicit consent must be obtained before any information is uploaded on to the system. The doctor-patient relationship is the cornerstone of general practice and if that relationship is to be maintained,GPs and their staff must be able to reassure patients that their medical records will not be shared beyond the practice without their consent. If patients cannot receive this assurance they may decide to withhold information which could adversely affect practices' ability to provide proper care and put patient safety at risk.

The above comments apply equally to summary and detailed care records.

If it is accepted as necessary that patients' demographic details should be held on a centralised system, Londonwide LMCs would value greater clarity as to when and how, in certain cases, patient demographics may be hidden or flagged as sensitive.

Who will have access to locally and nationally held information and under what circumstances

Patients should have control over who has access to their records and have the freedom to decide whether:

(i) No clinical information is uploaded onto the national system;

(ii) Having a hidden summary care record that can only be accessed with explicit consent or in an emergency situation;

(iii) Having a summary care record that can only be accessed by those directly involved in their care;

(iv) Sharing summary and detailed care records nationally;

(v) Placing sensitive information in 'sealed envelopes' to restrict sharing.

We believe that private providers should be subject to the same access controls as NHS providers.

The doctor-patient relationship could suffer if patients believe that government departments and agencies outside the NHS could access their medical records. GPs will need to be able to reassure patients that this cannot happen without their explicit consent.

Whether patient confidentiality can be adequately protected

At present, it is far from clear that patient confidentiality can be adequately protected on a central system, mainly because the more people have access to information, the greater the risk of breaches of security.

We understand it is proposed that the security of the system will be monitored by Caldicott Guardians and privacy officers. They must be adequately trained and resourced for GPs and their patients to have confidence they will be effective.

How data held on the new systems can and should be used for purposes other than delivery of care, eg clinical research

GPs will need to be able to clarify to their patients who will be will be allowed access, particularly non-NHS and commercial organisations.

Patients may wish to request that their medical data is not used for secondary purposes, or to place limits on the uses their information is put to and GPs must be in a position to respond positively to such requests. Patients will need to be confident their medical data will be kept secure, confidential and properly anonymised.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new system is up to two years behind schedule

It is clear that an initial reluctance to consult clinical stakeholders, including GPs, or work with and integrate existing systems, have contributed significantly to the delays. Primary care IT systems are highly developed and effective but little attempt was made to engage with GPs and build on these existing systems. Recent developments, eg the move towards an approved list of suppliers, are to be welcomed, but there remains a need for greater transparency and openness.

The financial pressures upon PCTs are also a contributory factor as spending on IT is unlikely to be a priority for PCTs.

Londonwide LMCs

16 March 2007

Evidence submitted by the Medical Protection Society (EPR 55)

EXECUTIVE SUMMARY

- In our experience the breakdown in communications is one of the most frequent causes of adverse incidents, claims and complaints. We support, in principle, the development of an integrated centralised health record system.
- Patients should not be required to expressly consent to have their data uploaded onto the NHS Care Records System. However, patients should have the right to opt out of the system or limit access to some of their clinical data.
- Healthcare professionals must have a legitimate justification to access patient information on centralised system based on a therapeutic relationship.
- Information on the centralised system should be tiered to permit access only to the areas of a patient's record which are necessary for a healthcare professional to carry out their work.
- The existing framework of confidentiality and patient access to information should be replicated in the centralised records system.

DETAILED EVIDENCE

1. The Medical Protection Society (MPS) is the world's leading indemnifier of health professionals. As a not-for-profit mutual organisation, MPS offers support to members with legal and ethical problems that arise from their professional practice.

2. MPS membership offers peace of mind to more than 240,000 health professionals and their patients worldwide. Members commonly seek help with clinical negligence claims, complaints, medical council inquiries, legal and ethical dilemmas, disciplinary procedures, inquests and fatal accident inquiries. They

have access to expert advice from a 24-hour emergency helpline and, where appropriate, legal assistance and compensation for patients who have been harmed through negligent treatment. We also run risk-management and education programmes to reduce adverse incidents and promote safer practice.

3. MPS is not an insurance company. All the benefits of membership of MPS are discretionary as set out in our Memorandum and Articles of Association.

4. We welcome the Health Select Committee's enquiry into the Electronic Patient Record and its use. The development of the NHS Care Records service is a hugely ambitious project which has the potential to make a significant difference to the delivery of healthcare in England.

5. We support, in principle, the development of an integrated centralised health record system. In our experience the breakdown in communications is one of the commonest causes of adverse incidents, claims and complaints.

6. We have experience of claims and complaints arising from circumstances where the patient has changed GP practices and consulted a new doctor who hasn't had the benefit of the patient's records. This has compromised the doctor's ability to get the full clinical picture; exposing the patient to sub-optimal care. Access to accurate relevant information for appropriate healthcare professionals through a centralised records system has the potential to significantly enhance patient safety.

7. The introduction of a centralised records system inevitably raises issues about confidentiality, access and security. It is vital that the NHS Care Records Service is developed in a way which complies with the existing legal and ethical frameworks surrounding confidentiality and that the confidence of both the profession and the public in the accuracy and security of the information stored on the system is not undermined.

What patient information will be held on the new local and national electronic record systems

8. If the intention is that the NHS Care Records Service should be the sole repository of patient information, then it must be comprehensive, tiered according to levels of sensitivity and with access limited to those who have a legitimate reason to have that information.

9. On the other hand, if the NHS Care Records Service is intended principally as a summary, then there will need to be clear guidelines about what should or should not be recorded. There would be a risk that absent data on one patient's record would indicate that there was nothing to record which could potentially mislead a clinician.

10. We understand that the Department of Health intends the record to be the primary comprehensive source of information about the patient and that other records would be phased out over time.

Should patients be able to prevent their data being placed on systems

11. We support a system where all patients should be deemed to have given consent to the uploading of their health information unless and until they expressly opt out or choose to limit the information available.

12. We understand that some organisations have proposed that patients should have the right to expressly opt into the system. We think that such proposals are wholly unworkable and would place an unrealistic administrative burden on highly pressed clinicians, particularly in the primary care sector. The level of work involved in gaining each patient's express consent would be completely disproportionate to the potential benefit.

13. Currently, the General Medical Council (GMC) guidance makes it clear that (unless there are exceptional circumstances) a patient's refusal to allow information to be shared with another healthcare professional should be respected. We believe that patients should have the same right with the electronic record.

14. Patients should be able to expressly opt out of the centralised records system. A patient's right to limit access to their clinical information could be addressed by the "sealed envelope" system. Patients could limit access to elements of their record by requesting that certain information is hidden from normal view. Further thought needs to be given to how patients will be able to restrict access to their clinical information.

15. A large number of patients opting out of the system would undermine one of the core benefits of a centralised records system. We hope that opt outs would be a limited to a small proportion of patients. The onus is on the Department of Health to ensure that the security of the system is sufficiently robust and that the system is rolled out in a way that captures the confidence of the public.

Access to locally and nationally held information

16. The mere fact that a person is a healthcare professional working in the NHS should not be sufficient to allow unrestricted access to a patient's records. Currently, patient records are held locally in paper and summary electronic form. It is possible for anyone working in a primary care setting to access patients' records without first being required to demonstrate a legitimate justification. The only restriction is in terms of confidentiality clauses in employment contracts.

17. The new system must be underpinned by the principle that access is only possible by those who have a legitimate justification to access health records in the delivery of healthcare or other legitimate purpose.

18. The legitimacy should be based on a therapeutic relationship, save in only the most exceptional circumstances. Additionally, access to the system must be tiered to permit access only to the areas of a patient's record which are necessary for a healthcare professional to carry out their work. For instance a receptionist in a GP practice will only need access to, for example, the patient's name, address, telephone number, and possibly limited access to some clinical information such as test results.

19. As mentioned above, patients should be able to restrict access to certain information contained in their record.

20. Presently, under the Data Protection Act patients have a right to see their records whether they are paper or electronic. It might be helpful, as a means of increasing public confidence in the new system, if patients could "log in" to the system to view their own data and to enable them to see an "audit trail" detailing who has accessed their data. Patients' rights of access to their own data should be subject to the same therapeutic restrictions that are enshrined in the Data Protection Act.

Patient confidentiality

21. Security of electronic data is a global concern. The new system must employ the most robust national and international security measures to ensure that patient data remains confidential. The scope and number of potential users of the NHS Care Records System must be a potential weakness that will need to be addressed.

22. Technology aside, the major problem is the human factor which is not subject to system controls. Addressing the human element is a matter of education and training, legal requirements to comply, and enforcement.

23. The question of whether information of a highly sensitive nature should be excluded from the system during the pilot phase should be carefully considered.

24. While security requirements must be rigorous, they should not be so onerous and time consuming that they interfere with the ability of healthcare professionals to meet patients' clinical needs, particularly in an emergency situation.

Data used for purposes other than the delivery of healthcare

25. It is sensible that organisations outside the NHS but involved in the delivery of healthcare should have access to the appropriate information in the patient's electronic record. However, the patient should be given the opportunity to refuse to allow information shared outside the NHS. For instance, a GP referring a patient to receive NHS treatment through a private healthcare provider should explain to the patient that the provider will have access to appropriate information contained in their electronic record and give the patient the opportunity to refuse or limit access to the provider.

26. Using data stored on the new records system for clinical and management purposes is acceptable if the data has been anonymised or pseudonymised in accordance with the recommendations of the Information Commissioner.

27. The trend in clinical research has been for increasing transparency and a proper consent process. That should remain the case for any use of patient identifiable data save where there are statutory requirements for disclosure and processing of data for specific purposes.

We would be pleased to provide any further evidence either in writing or orally which might be helpful to the Committee's inquiry.

Medical Protection Society

March 2007

Evidence submitted by the NHS Alliance (EPR 19)

Executive Summary

- Patients should have access to their full primary care record.
- The patient should retain control of the data.
- The personal health record should be designed to enable patients to understand the contents and thus form the basis for:
  (a) empowerment;
  (b) shared decision-making;
  (c) more involvement in their care and management; and
  (d) the ability to integrate often fragmented care.
- Access to records should also be seen as a way of improving the accuracy of the record.
- We support the approach to confidentiality and authentication taken by NHS Connecting for Health, although we recognize inherent risks in the Spine design.
- We support the current developments towards a more cooperative approach with suppliers. This is likely to build on existing energy and innovation, rather than stifle it.

1. Introduction

1.1 The NHS Alliance understands that the Health Select Committee seeks opinion on the current NHS Connecting for Health (CfH) plans for the Electronic Patient Record (EPR). We shall respond to those interests.

1.2 In addition, however, we should like to draw the committee's attention to other approaches to the EPR, particularly with regard to:

- access to the record by patients
- sharing the record between primary and secondary care.

1.3 It has become clear that the original vision of a unitary system designed from scratch has had to give way to a more polyglot version where CfH works alongside existing providers. This has enabled other solutions to common problems and these need to be taken into account when considering the EPR process.

2. *What patient information will be held on the new Local and National Electronic Record Systems, including whether patients may prevent their personal data being placed on systems*

2.1 NHS Alliance understands that CfH plans for a Summary Care Record to be available in 2008. This will contain the patient's problem list, allergies, immunisations and a medication list. Censored from both the problem and medication lists will be any mental health or sexual health information.

2.2 We feel that this is a significant step forward in patient safety. To have this information available wherever the patient presents to the NHS will make life easier and safer for staff and the public.

2.3 However, the Alliance is concerned about the limitations that this arrangement imposes. In particular, eliminating sexual and mental health history means that it will be difficult for clinicians to rely on the data they see: the patient may be taking other drugs not listed. There may be other conditions that need to be taken into account. This partial data set may be more risky in some circumstances than no data at all.

2.4 We would recommend that:

- the patient's full record is made available,
- that the patient retains control of the data (Chapter 1 Section 13 NHS Plan 200 "Each patient will have a record . . . to which the patient will hold the key")

2.5 This is available through at least two systems in the UK at the moment: the full primary care record is under the patient's control and they can show it to clinicians at will. In one system, because the record is available online, it can be shown to a clinician by the patient wherever there is access to a web-browser: in outpatients, in A + E or abroad. In the other system, full record access is via card with a USB. Whatever system is in use, sealed envelopes will be needed: patients can place in these data that they do not want clinicians to see. These are not available at the moment.

2.6 So far as patients preventing their personal data being placed on the CfH Spine, we understand that this has now been agreed in principle. It is also clear to the NHS Alliance that, if a patient does insist on their data being kept off the Spine, their health care is likely to suffer to some extent, and the patient will need to understand that.

2.7 The Alliance also understands that, in order for patients to be able to decide with their GPs whether information should or should not go on the Spine, there will need to be a conversation between the GP and the patient. The Alliance is concerned that this will lead to an unacceptable workload for GPs. If the process could be automated, this would make life easier for all concerned. There are now systems that can make this possible.

3. *Who will have access to locally and nationally held information and under what circumstances?*

3.1 *Who will have access?* Clinicians

3.1.1 The NHS Alliance feels confident that the current arrangements proposed by CfH are safe, on the whole. That is, within the limitations of human error, patient data will be held securely and that access will be offered only to those who need it at the time they need it.

3.1.2 The limitations of human error include the consequences of clinicians leaving their identity cards in situ, enabling others to gain access inappropriately; clinicians leaving computer screens on and unattended with their identity cards in situ. This will have to be tackled by education and sanctions.

3.1.3 One possible source of inappropriate access against which it is difficult to guard is organized crime. The more centralized the storing of patient records, the more of a prize for organized crime—and the more data could be stolen at one time.

3.1.4 Again, the NHS Alliance would recommend that:

— the patient's full record is made available;

— that the patient retains control of the data;

— that patients have access to the audit data trial and can see who has or has not accessed their record;

— patients should also be informed when their sealed evelopes have been opened. This is not planned at present and is a SERIOUS omission; and

— it is also possible that patients could be alerted by e-mail when their record has been accessed. This happens in systems in the USA.

In this way, the patient always knows who has access and who does not.

3.1.5 The main disadvantage of this approach is the difficulties posed by access when the patient is unconscious. Those patients who know that unconsciousness is possible could share their authentication details with someone close to them to use in an emergency: proactive consent. For the unexpected situation, the Spine arrangement would be the best.

3.1.6 Because there are advantages and disadvantages to the various access systems available at the moment, the NHS Alliance recommends that clinicians and patients be able to move between the different systems to maximize benefit to the patient. There should be an arrangement whereby the clinician can see both the summary record through the Spine as well as working with the patient to see their full GP record when needed. The advantage of the latter is that there would be access to all electronic investigation results, all scanned letters, all recent GP consultations.

3.2 *Who will have access?* Patients

Some of the comments below stem from experience with alternative systems currently available that allow patients access to their full GP record.

3.2.1 The NHS Alliance recommends that patients should have access to their full GP record at will. There needs to be safeguards in place in respect of complex issues such as third party information, access to children's records by parents and data that has been generated and entered into the record but has not been processed by the responsible clinician. In addition, research suggests that, although patients understand most of what they read, it would be important that technical data is linked with information for the patient.

3.2.2 Systems available now link raw data in the record with information for the patient. For instance, a problem title such as "asthma" can be linked with accredited patient-centred information and health advice about the topic. It can also be linked with patient-facing NICE guidelines, national patient groups and also with decision aids which have been shown to help patients make real choices in the management of their care.

3.2.3 In addition, it is possible to link the record with reminders for better care. For instance, if a patient is overdue for a blood pressure check or smoking review, they can be reminded when they look at their record.

3.2.4 Research suggests that the benefit of full record access includes:

— It enhances communication between clinician and patient;

— It increases the onus on the clinician to tell the truth;

— It increases patient satisfaction;

— It enables patients to correct data errors, the commonest ones being demographic data, but the errors can also be about clinical process and outcomes;

— Patients feel better informed and almost always reassured, even when they read bad news;

— Patients feel they understand about 70% of what they read;

— It appears to improve compliance and support health education messages, such as smoking quit rates; and

— It is likely to improve self-care.

3.2.5 In this way, access to their own full health record can act, for the patient, as:

— an aide-memoire;

— a teaching tool;

— a stimulus and personal trainer to better health;

— a method of empowering patients to take more part, if they choose, in shared decision-making; and

— to coordinate often fragmented clinical care

It is potentially a transformative technology.

3.3 *Who will have access?* Carers.

3.3.1 So long as the patient has given their informed consent, people close to them can access their records also.

3.3.2 This offers significant benefits. For instance, as has already been shown with current experience, carers:

— can coordinate fragmented care;

— have a much clearer idea about what is happening to the patient;

— can inform the patient about their care;

— can be more effective advocates;

— can monitor progress from abroad; and

— can transform the quality of care for patients in care homes and units for severely disabled.

3.3.2 Again, this benefit is significantly enhanced if carers have access to the full record.

3.4 *Access under what circumstances?*

3.4.1 To maximize benefit, clinicians and patients and their representatives should be able to have access in a range of circumstances

3.4.2 Clinicians should be able to have access both in the presence of the patient, conscious or unconscious. In addition, it should be possible to have access, with the patient's consent, to their record when the patient is not there, in some circumstances. For instance anonymised, for research, information governance and clinical governance and for checking data.

3.4.3 Patients should be able to see their records in any circumstance. The simplest approach is online. However, this does currently exclude a substantial minority of people, particularly perhaps those who would benefit most from access: those with long-term and/or co-morbid conditions, and the elderly.

3.4.4 For this reason, the NHS Alliance suggests that it may be important, for the next few years, to enable access through other means, for instance through kiosks in GP waiting rooms or in libraries or on portable storage devices, with adequate facilities for confidentiality.

4. *Whether patient confidentiality can be adequately protected*

4.1 As described above, and subject to the caveats expressed above, the NHS Alliance feels that patient confidentiality is well served by the current CfH programme. It also feels that over zealous confidentiality can act against the patients' best interests,

4.2 Authentication issues at this stage still need clarification, but they will soon be finalised and will be acceptable to the information commissioner and practical to implement.

4.3 Security of the record itself is also well-protected by CfH systems, as the NHS Alliance understands it.

4.4 The other systems currently available are in the same position.

5. *How data held on the new systems can and should be used for purposes other than the delivery of care*

5.1 The NHS Alliance endorses the idea that clinicians should be able to use the record for research. However, the data must be anonymised and, if not, the patient must give informed consent.

6. *Current progress on the development of the NHS Care Record Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule*

6.1 The NHS Alliance feels that the CfH will deliver what is needed in time but there have been unacceptable delays. The current delays have caused problems in themselves and have had a morale sapping effect on CfH and how it is perceived

6.2 We feel that the reasons for the delay are multiple, including:

- a dogged refusal for some time to include existing providers who were and are offering good service to the NHS;
- persistence in a top-down approach that failed to use existing expertise; and
- inadequate clinician and public and patient engagement.

6.3 Most of these problems are slowly being addressed. In our view, harnessing existing expertise and using systems that we know work well and have the confidence of users will be the most effective way forward, For instance, the system that enables patient record access offers more functionality than HealthSpace at a small fraction of the cost.

Dr Brian Fisher, GP
PPI Lead for the NHS Alliance
Lead for the Record Access Collaborative (funded by EMIS)
Co-director of PAERS, a company enabling patients to see their electronic health record

15 March 2007

Evidence submitted by the NHS Confederation (EPR 57)

The NHS Confederation is a membership body that represents over 90% of all statutory NHS organisations across the UK. Our role is to provide a voice for the management and leadership of the NHS and represent the interests of NHS organisations. We are an independent organisation.

The NHS Confederation welcomes the opportunity to give evidence to the Health Select Committee on the Electronic Patient Record and its use. This evidence sets out our views, based on feedback from a cross section of our member forums.

EXECUTIVE SUMMARY

- There is a lack of clarity and understanding both with patients and within the NHS over the information which will be held nationally and that held locally.
- NHS computer systems already hold and exchange patient demographic data.
- The security built into the National Care Record System (NCRS) is tighter than that currently in place for either existing computer held or paper based systems.
- If patients are given the option to opt out it will be important for them to understand the potential clinical risks of doing so.
- A greater level of public awareness and engagement is required.
- Many in the NHS have concerns over the scope and architecture of the overall programme, though in many cases this may be due to a lack of clarity within the service about the detailed plans.
- Delays in the delivery of key operational systems which feed NCRS, such as Patient Administration Systems is causing real problems and costs within the service.
- Generally, government policies such as the 18 week target and the choice agenda will be severely hit if the new computer systems are not made to work effectively.

FACTUAL INFORMATION

1. *What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems*

The NHS Care Record Service comprises two groups of data/applications/systems:

Locally held detailed electronic records will typically contain:

(a) Name, address, date of birth and NHS number.

(b) Details of health conditions such as allergies, asthma or a heart problem.

(c) Details of any medicines and diagnostic test results.

(d) Notes (including diagnostic images) relating to diagnosis, treatments, therapies, operations.

(e) Notes on contact details with the patients such as out-patient visits, GP attendances, including the details of clinicians providing care.

(f) Correspondence between clinicians providing care.

(g) Planned treatment or visits including reminders.

(h) Occasionally additional information that the patient has shared where this is relevant to the patient's health care e.g. about family or work.

(i) Applications that support the clinician in delivering care such as electronic ordering, prescribing, scheduling, decision support, alerts and reminders.

Nationally held summary records that are subset of the detailed local records and will hold information that is potentially required to be shared between caring organisations and teams. Summary records are held by the Spine. The Spine comprises:

(a) **The Personal Demographics Service (PDS)** that stores basic demographic information about each patient together with their NHS Number.

(b) **The Personal Spine Information Service (PSIS).** This is a summary of patient's clinical information, such as allergies and adverse reactions to medicine.

(c) **The Secondary Uses Service (SUS)**, uses data from patient records to provide anonymised and pseudonymised business reports and statistics for research, planning and public health delivery

(d) The Spine also provides a set of **Security Services**, to ensure access to information stored on the Spine is appropriately controlled (see below).

Clinicians have a duty of care under the professional rules of the GMC and other medical practice to record personal and clinical information about their patients. The Care Record Service will become the primary patient record and source of information for the individual or groups of clinicians providing care for patients. It may neither be possible nor advisable therefore for patients to seek to prevent their personal data being placed on these systems.

Patients need to be reassured that the information held is confidential. There are arrangements within the design of the Care Record Service to limit the sharing of personal data once it has been collected. Patients will be able to request that specific personal data items are place in a "sealed envelope" and not seen without consent. This will allow patients to determine which parts of their records should be accessible to those who provide care. The sealed envelopes are under development but alternative interim arrangements are in place for the early deployments of the spine.

The Chief Executive of the NHS recently held a summit on the issues surrounding the national programme at which the NHS Confederation and many patient groups were represented. Not surprisingly the issue of patient confidentiality was prominent in the discussions. All parties agreed that further explanation and communication over the current and proposed safeguards are required. It is not clear that patients understand that the information available nationally will be only a small subset of their medical history. Many patients assume that all their information will be available across the country.

If patients are able to prevent their personal information to be placed on the system, the question becomes how a national system then operates with some participants excluded and to what extent are they prejudicing their own care? The systems in place will be the basis not only of delivering care for patients but also the business processes and payment systems. Will patients be compelled to allow their demographic details to be held but have a veto on the medical history aspects? Demographic information is already stored on NHS systems and transferred between them, albeit on an historic basis. NCRS makes this information available in real time wherever the patient presents for treatment and, for the first time, includes key data which may be invaluable to those providing the treatment.

2. *Who will have access to locally and nationally held information and under what circumstances?*

Once the new service is fully in place, only those who are directly involved in a patient's care will be able to access an individual's information on the Care Record Service. They will need a smartcard, protected by a chip and pin, which are only issued after thorough security checks. Even then not everyone involved in a patient's care will be able to see all of a patient's records. The amount of information they will see will depend on their role. Other care professionals—such as social workers, with a need to know, may also have access to parts of a patient's records.

Others involved in public health, research, planning and statistics will have access to anonymised and pseudonymised information on the Spine.

3. *Whether patient confidentiality can be adequately protected*

The Care Record Service has a set of security measures, to ensure access to information is appropriately controlled. An automatic record will be kept of anyone who has accessed an individual care record; who they are, what information they accessed and how they processed the data. Patients can ask to see this record.

These are much stronger measures than are in place for current paper records where no record is kept of who has access or how the data is recorded or used. Also, with access being limited to staff involved in the care of individual patients, the normal best practice rules of confidentiality still apply. It remains an act of gross misconduct for staff to divulge confidential information.

4. *How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research*

Only anonymised and pseudonymised data can be used for research, public health, statistics and planning. A number of exceptions exist where patient identity can be shared. These need special permission and include:

- reporting some infectious diseases;
- reporting gunshot wounds to the police;
- following a court order;
- when a serious crime has been committed;
- where there are serious risks to the public or NHS staff; and
- to protect children.

5. *Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule*

It is important to recognise that this is an extremely ambitious project. It is for the Project Sponsor and Responsible Officers to explain any delays. We understand that there has been some diversion to develop systems in support of new NHS priorities—Quality Outcomes Framework in support of the new GMS contract, Choose & Book, PACS, etc plus huge deployment volumes as evidence of real progress.

The NHS Confederation can give some perspective and feedback from our member NHS Trusts and Primary Care Trusts.

NHS organisations continue to be fully committed to the overall vision of the NHS Care Records Service (NCRS). However, member feedback indicates

- A persistent feeling of disconnect with the National Programme. At a local level members are concentrating on the local deployment of systems as they become available under the National programme. They are not at all clear on either the content or the progress of NCRS. They do not see it is a component that they own or have any particular responsibility for. As a result their commitment to NCRS is somewhat limited. This affects their ability to be advocates for the initiative both within their organisations and with the wider public.
- Many IM & T managers in the NHS see that based on their understanding of what is to be held on NCRS the programme as too ambitious in its scope and that the architecture is over-complex. Many are unconvinced that the balance between what is held centrally and what is held locally may not be appropriate. Concern has been voiced that the amount of clinical information really required for a patient who is treated physically away from their usual address is minimal and restricted to allergies and high risk factors. The view is that restricting the national database to only these items would both aid the implementation and reassure patients around the confidentiality issue. The concern is that the range of clinical indicators to be held at national level is likely to grow and that this itself will undermine public confidence in the security of their personal information.

— The National Care Record System (NCRS) consists of the spine information held centrally and the detailed clinical record held locally. Much of the information required to be held locally is already held albeit in an incomplete and piecemeal basis with General Practice. NCRS appears not to have the confidence of the public or clinicians. Arguably this is in part because ownership is not resolved. Better to build on the practice data sets. Make it clear that the practice, Commissioning Group and PCT are responsible for the quality of the data and making it available to providers when required. The NCRS spine should only hold the basic demographic details which can point a provider to the correct PCT, PBC and Practice, together with any key risk factors. Indeed should we get national identity cards in the future, this information could be held there. Practice Records will need to be both complete and available. They must be the property of the PCT, held by the practice.

— Delivery of NCRS is wholly dependent on the availability of the key feeder systems such as hospital patient administration systems (PAS). The deliverability of these key systems has been, to say the least, disappointing. Many Trusts are having to extend contracts on existing and outdated PAS, deploying patches and fixes to maintain required functionality.

Recommendations for Action

— Initiate a communication exercise with the public and the professional associations through existing patient groups and the media around the elements and safeguards of NCRS.

— Provide better staff briefing and communication with key NHS staff around the scope and architecture not only of NCRS but of the National Programme for IT as a whole.

— Restrict to a minimum the amount of clinical information held at the national level.

— Designate PBC Groups as custodians of individual patient clinical data. Build the locally held NCRS from existing GP systems.

— Provide a realistic timescale for the implementation for key feeder systems.

NHS Confederation

March 2007

Evidence submitted by Patient Concern (EPR 11)

Summary

1. Patient Concern is broadly supportive of an electronic records scheme, which has many potential benefits but we have serious reservations about the way current plans are preceding. It seems that the push to get the system up and running, after so many delays, means that the pilot scheme for summary records is being launched before various important issues have been resolved.

Options on Opting Out

2. There is enormous confusion among patients on opting out provisions, as a direct result of the mixed messages put out by the various agencies involved. Patient Concern has been corresponding with those most involved and we have been told in writing:

(a) that patients will be able to opt out under section10 of the Data Protection Act; and

(b) that section10 of the Data Protection Act is not the appropriate way to opt out as this would mean proving that such a record would cause an individual substantial unwarranted damage or distress.

We have also been told that:

(a) that GP practices are responsible for the decision to enter records, so that patients should register any objection with their doctor; and

(b) that requests by patients to the Department of Health to opt out have been refused on the basis of inaccurate information—eg that any professional would be able to see their records. If patients' still wish to opt out, they must write to the Department of Health again. Then their wishes will be respected.

Informed Consent

3. Patient Concern considers that informed consent is necessary before patients' confidential health information is uploaded. The current proposals for pilot sites by no means meet this requirement.

4. If patients are to make informed decisions about records going on the spine, they must know exactly what information is to be uploaded. It seems that in pilot areas, patients will be notified of the scheme by post and if they do not make any objections known within two months, their details will be uploaded automatically.

5. This is putting doctors, with their confidentiality obligations, in an impossible position and flies in the face of medical ethics.

6. Imposing a time lag beyond which consent will be assumed is quite inappropriate. There will doubtless be people who, for one reason or another (eg extended business trip abroad) will be unaware of what is happening or who do not take action because they fail to appreciate the significance.

7. The Department of Health has stated that it is impractical to obtain explicit consent from every patient affected. If this is so, then perhaps it is impractical to begin uploading records. What is possible in France and Greece should be possible here.

8. Patient Concern would suggest that, as the plan is to write to each patient in pilot areas informing them of the scheme, a copy of the proposed upload of their data should be sent, together with a tick box form giving or refusing consent.

9. This should cover the problem, identified by the task force, of vulnerable people being unlikely to take advantage of an "opt in" scheme. With the information clearly before them, they would be able to take advice from whichever individual or agency normally assists them with medical decisions.

Quality Control

10. We are assured that "all data that goes on the Summary Care Record will have to pass quality controls". The time and place for quality controls is before any data is entered, when patients can check accuracy, so every effort should be made to ensure that all patients can do this, preventing mistakes being uploaded.

11. Any patient who has tried to correct mistakes in existing health records knows that this is next to impossible. The regulations are very strict and the best patients can normally hope for is that their views are added to the record if they dispute its contents. We appreciate the reasons behind this but the patients trying to achieve accuracy find it thoroughly unsatisfactory. The only way to prevent problems is to make sure that no errors are uploaded in the first place.

Access

12. Patients have, as yet, no clear idea who will have access to their summary record. We are told that access will be limited to "members of our health community" but this does little to clarify the situation.

13. We understand that it is likely that NHS Direct will have access. We consider it inappropriate that those working on telephone help-lines, where the usual advice is "go to your GP", should be able to view patients' personal details.

14. It is also reported that community pharmacists wish to have access (and to be able to update the record). As pharmacists' prescribing abilities expand, there may be some basis for this. However, if patients in small communities, where the pharmacist is known to them, were aware of such access, they might prefer to opt out.

15. Smart cards for patients do not yet exist. We are told that in time we shall be able to view our records on Health Space—though this will not be available throughout the pilot areas this year—but of course this will only be possible after the fact. The record will already have been uploaded.

Sensitive Data

16. As the summary care record is limited to medications, allergies and adverse reactions, the scope for sensitive data is limited. Nonetheless, the listed medications may reveal more than a patient wishes to disclose (eg HIV status or mental illness).

17. The sealed envelope system that we were promised is still at the planning and development stage. Meanwhile we are told that patients can choose to have such sensitive areas omitted. This begs the question of whether an incomplete record is misleading or in some circumstanced harmful. Perhaps it would be more responsible to advise such patients to opt out altogether at this stage?

Security

18. We leave IT experts to comment on the detail of "the state of the art protection' offer, save to say that patients are not convinced of the efficacy of the "stringent security controls".

19. Some 300,000 smart cards have been issued to staff though none are promised for patients in the near future. In late January, South Warwickshire General Hospitals NHS Trust confirmed that its board had agreed that staff in A and E could share smart cards. They claim that they are not breaking guidelines laid out in the National Care Records Service Acceptable Use policy. This has been followed by much comment revealing the common practice of sharing smart cards—which of course makes any genuine audit trail impossible.

20. In addition, those who work in hospitals remark on how frequently computers are left open, displaying supposedly confidential data.

21. Patients need to be convinced that the smart card system is fit for purpose.

The Full Electronic Record

22. All the publicity about summary records has detracted from the many issues as yet undecided (or, if decided, not revealed to patients). We argue that, without the answers to certain questions, patients cannot properly decide whether to allow records to be uploaded at this stage.

- Will the complete opt out option still be available when full records are uploaded at some unspecified time in the future?
- Which details will be uploaded automatically and which will require consent? We have been told by the Department of Health that "blood tests and Xrays will automatically generate records within the system" and that when "care is dependent on the use of these systems there can be no flexibility for those who receive that care". Does this also apply to referral and discharge letters?
- Will historical data be included?
- How will access to the full record differ from access to the summary record?

Patient Concern's Previous Contribution to Inquiries

23. Patient Concern gave oral evidence to the Shipman Inquiry and to the Joint Select Committee of the Lords and Commons on the Mental Capacity Act 2005.

We should be pleased to answer oral questions from the Health Select Committee on this important subject.

Joyce Robins
Patient Concern

March 2007

Evidence submitted by Press for Change (EPR 06)

Summary

1. Trans people are a small and vulnerable minority whose needs have historically been overlooked in legislation, creating injustices which have taken decades to resolve.

2. Protection for vulnerable minorities must be assessed before the uploading of any data to the Electronic Patient Record.

3. The uploading of data without patient consent would leave General Practitioners open to prosecution.

4. If the benefits of the Electronic Patient Record are as great as the Government claims, then trans people need to be persuaded of those benefits—not just omitted because it would be more expedient.

About Press for Change

5. Press for Change (PFC) is the largest representative organisation for transsexual people in the UK. PFC was formed in 1992 to "achieve equal civil rights and liberties for all transgender people in the United Kingdom, through legislation and social change".

6. The campaign seeks to achieve its objectives through education and engagement rather than confrontation or demand-making. Good relations have been established with Ministers and officials, as Government has addressed the problems faced by trans people.

7. In 1997-99 PFC took part in consultation and negotiation with the DfEE as it set out to introduce the Sex Discrimination (Gender Reassignment) Regulations 1999. PFC made substantial contributions to the work of the 1999-2000 Interdepartmental Working Group on Transsexual People.

8. During 2002-04 PFC was involved as the main stakeholder with the Department for Constitutional Affairs in the shaping of the Gender Recognition Bill 2004, working closely with ministers, officials, and parliamentarians of all parties as the bill progressed. We have since been closely involved with the implementation and promotion of the Act.

About Trans People

9. Transsexual people, or trans people as is preferred, identify themselves as members of the sex opposite to that assigned at birth, and may undergo medical treatment known as gender reassignment.

10. Trans people are a discriminated against minority who guard their privacy jealously.

11. A soon to be published report for the Government's Equalities Review reveals that 20% of trans people consider their General Practitioner to be trans-unfriendly. Such attitudes traverse the NHS, affecting not only trans people's access to gender identity treatments but colouring all interactions with the "caring profession'.

12. PFC calls for detailed study of this phenomenon and the development of the appropriate training and good practice before trans people are requested to consider disclosing their details in a way that could seriously affect the quality of their healthcare.

The Electronic Patient Record

13. Press For Change is concerned that the Department of Health has made proposals for the medical records of patients to be uploaded to a central repository without the express consent of the patient.

14. Whilst we accept that there are good reasons for medical personnel to have immediate access to a patient's records in the case of an emergency, we believe that these records would be available to any person working in the healthcare industry—from receptionist upwards, as well as IT professionals managing the system.

15. Section 22 of The Gender Recognition Act 2004 makes it a criminal offence to disclose protected information that has been acquired in an official capacity to a third party. This would include any medical information that a doctor may possess regarding their patient as well as the fact of a Gender Recognition Certificate.

16. Paragraph 5 of the Gender Recognition (Disclosure of Information) (England, Wales and Northern Ireland) (No. 2) Order 2005 (Statutory Instrument 2005 No. 916) gives exemption where the disclosure is made on medical grounds. It does, however, draw very strict boundaries within which this is permissible.

> *5.— (1) It is not an offence under section 22 of the Act to disclose protected information if—*
>
> *(a) the disclosure is made to a health professional;*
>
> *(b) the disclosure is made for medical purposes; and*
>
> *(c) the person making the disclosure reasonably believes that the subject has given consent to the disclosure or cannot give such consent.*

17. The intention to upload the medical histories of trans people who are in receipt of a Gender Recognition Certificate without their express consent would therefore fall foul of at least paragraph 5(1)(c) of the above S.I.

18. Published good practice suggests that, where the existence or otherwise of a Gender Recognition Certificate is unknown, the assumption should be that the trans person has been legally recognised in their correct gender and they should be treated accordingly.

19. We therefore ask that you protect General Practitioners from the danger of criminalization by recommending that all patients are asked for their consent before their most personal information is uploaded to any central servers.

20. We believe that to compel trans people to have their most intimate details recorded on the Electronic Patient Record (or to do it without seeking their informed consent) would be to condemn those people to the inevitability of discrimination and second class care.

21. Conversely, we recognise the potential health benefits that could accrue to anyone having details accessible in an emergency, so the solution is not to simply exclude trans people from the Electronic Patient Record.

22. It is not a clear cut case of being included (with the risk of discrimination) or being excluded (with the risk of medical professionals not having access to vital details in an emergency). A lose-lose choice is not a choice. If there are genuine benefits to be obtained from the Electronic Patient Record then we want trans people to be able to enjoy those benefits equally to anyone else; the caveat is simply that adequate research

of the problems currently experienced, and effective steps to ameliorate them are both necessary before asking trans people to accept a system that's otherwise guaranteed to disadvantage every member of our community.

Tracy Dean
Press for Change

25 February 2007

Evidence submitted by the Renal Association and the Renal Information Exchange Group (EPR 30)

EXECUTIVE SUMMARY

- Patients and health professionals in the renal community understand the crucial role of IT in delivering efficient, safe health care. This is based on 25 years experience using clinical information systems in some aspects of healthcare for renal patients.
- We are therefore strongly supportive in principle of the development and establishment of electronic patient records, which underlies the Connecting for Health initiative to introduce a National Care Record Service and a National Data Spine.
- Connecting for Health has:
  - Failed to assure the renal community that its strategy respects clinical need as well as technical solutions;
  - Failed to develop an understanding of the specific IT needs of ours and other specialist health communities;
  - Failed to convince the health community that its strategy of nationwide procurement and development through large scale Local Service Providers will succeed;
  - Eschewed opportunities for "early wins" by demonstrating benefit in chronic disease management in local health communities which would have won clinical confidence in its strategic goals and products;
  - Threatened the survival of specialist clinical software suppliers who understand well the needs of the healthcare community with which they work.

SUBMISSION CREDENTIALS

Professor Feehally is Professor of Renal Medicine at the University of Leicester and Consultant Nephrologist at University Hospitals of Leicester NHS Trust. Professor Feehally is President of the Renal Association and chair of the national Renal Information Exchange Group. The Renal Association is the professional society of nephrologists and renal scientists in the UK.

The Renal Information Exchange Group [RIXG] represents the whole renal community and includes representatives from professional and patient groups. Members include the Renal Association, British Renal Society, British Transplantation Society, Scottish Renal Association, National Kidney Federation, and Kidney Research UK. RIXG works to maximise opportunities for the renal community to influence the new information and knowledge environment in the NHS. RIXG adopted the Renal Information Strategy developed as a companion to the National Service Framework for Renal Services for England.

The renal community is among the most IT literate in the NHS. For example:

- Many kidney units have used electronic clinical information systems in routine clinical care for more than twenty five years.
- There are national databases of patients with established kidney failure treated by dialysis or kidney transplant [Renal Association UK Renal Registry and UK Transplant] which are of proven value for secondary uses including audit and health planning, and these continue to be enhanced.
- A renal specialist library has been developed within the National Electronic Library for Health
- The renal community through RIXG has been innovative in developing the opportunities of electronic systems for patient benefit. Uniquely in the NHS it has developed RenalPatientView, which allows patients to have direct web-based access to their personal clinical information held on their kidney unit clinical system. This award winning initiative [supported by Department of Health funding] has been warmly welcomed by professionals and has strong endorsement from patients. It has been developed independently of Connecting for Health.

The principles behind the introduction of electronic patient records currently envisaged as the National Care Record Service and the National Data Spine are strongly endorsed by RIXG.

SUBMISSION

In this submission we respond specifically to the topics raised by the Health Committee.

1. *What patient information will be held on the new local and national electronic record systems?*

1.1 The system for the development of National Datasets which are to be held on the National Spine is sound, and has good clinical engagement. Members of the renal community have dedicated time and energy to work with the Information Centre to produce the National Renal Dataset, which is now awaiting Information Standards Board approval.

1.2 As we understand there is still organisational debate about the extent of data to be held locally or nationally on the spine.

1.3 Information held must be sufficient for the care record to be meaningful in clinical practice throughout care pathways which traverse traditional boundaries between primary, secondary, and tertiary care. Datasets including the results of all relevant laboratory investigations must be supported by clinical information less dependent on numerical data entry, such as imaging, clinical letters, information on past and present medication, and data on previous major health events.

1.4 If the system is to be launched with a minimal dataset, technical and organizational solutions must allow for future extensive expansion of datasets, the content of which cannot necessarily now be predicted.

1.5 Many renal centres have well-developed decision support systems that should not be lost by the introduction of generic less flexible systems. It is unclear whether the proposed Lorenzo solution will be able to offer the same level of sophistication on which we have come to rely.

2. *May patients prevent their personal data being placed on systems?*

2.1 Personal autonomy in withholding data does not make sense for individual healthcare which is likely to be compromised. Health professionals would need to make decisions with incomplete data, and opportunities for error would increase.

2.2 It is our experience that patients with chronic disease such as chronic kidney disease do not wish to withhold data about their health; they recognise from personal experience the risks to their healthcare of incomplete availability of data to health professionals. One local health community has recently integrated its information systems for the care of people with long term conditions [independently of Connecting for Health] ; no patient has chosen to opt out.

2.3 Data will also have important uses other than direct clinical care including healthcare planning, audit and clinical research. Such data are usually pseudonymised. Such work will be compromised by incomplete data. The scope of "personal autonomy" needs to be judged against a national "greater good" which in our opinion can be achieved with appropriate safeguards.

2.4 Patients should have personal access to most aspects of their own health records. The introduction of RenalPatientView demonstrates that this can be secure and appreciated.

3. *Who will have access to locally and nationally held information and under what circumstances?*

3.1 Access should be for anyone involved in the clinical care of a patient. By seeking healthcare, the patient is *de facto* approving that the involved health professional has access to relevant personal health information, just as is now the case with paper records. No health professional should restrict access to other health professionals to clinical data they hold.

3.2 While individuals from time to time raise concerns about inappropriate access to personal information, this must be understood in the context of the plethora of problems which arise when incomplete health information is available, especially during acute illness. Such problems can be life threatening, for example incomplete information about allergies to medications, or inaccessibility of previous X-rays to allow informed comparisons.

3.2 Such problems arise much more commonly for patients with chronic disease [such as kidney disease] who are often involved with a number of specialist clinics in different hospitals as well as their primary care team. Lack of immediate access to records is a common cause of wasted time, substandard care, and risk. These problems are self-evidently the issues which NHS Care Records Service and the National Data Spine are designed to overcome. The plan is significantly weakened if patients can opt out.

3.3 If a system is chosen which allows patient opt out, patients must be made aware of the risks they are taking.

3.4 Access to patient identifiable data for secondary uses is appropriately controlled by the Patient Information Advisory Group.

4. *Can patient confidentiality be adequately protected?*

4.1 We accept it may be impossible to support a system which provides absolute guarantees of confidentiality in every circumstance—we presume a determined hacker can always succeed. Absolute confidentiality would probably paralyse the system as a real time support of healthcare. But it is our view that sufficient confidentiality can be provided in a pragmatic way.

4.2 It is important that the issues related to confidentiality are clear to all NHS staff. There are examples of informatics staff tying the hands of clinical staff by restricting access to vital data on spurious grounds.

4.3 In RenalPatientView we have provided web-based access to personal clinical information held by the NHS with the level of security afforded for example in personal on-line banking. This is workable and has satisfied the Data Protection Act, the concerns of Caldicott Guardians, and patient groups.

5. *How can and should data held on the new systems be used for purposes other than the delivery of care eg clinical research?*

5.1 While the primary goal of the new systems is improvement in the quality of direct clinical care, secondary uses of data are of great strategic importance:

- providing data for needs prediction and healthcare planning;
- enabling national comparative audit, and using that audit as the basis for cycles of quality improvement; and
- enabling clinical research which may have low cost and high product value if data are already captured and appropriately managed.

5.2 The Renal Association's UK Renal Registry is a powerful example of a secondary use of data which is of proven benefit. It collects and analyses data on all patients with established kidney failure in the UK. It produces annual audit and outcome data which are widely used by kidney units and commissioners. Its systems and methods are also internationally respected.

5.3 The introduction of the National Data Spine must not compromise data flows to the Renal Registry, nor hinder opportunities for data analysis and dissemination. The necessary sequences of data collection and validation are yet to be established to the satisfaction of clinical and renal informatics staff.

5.4 Opportunities for patients to "opt out" of data collection crucially weaken the value of such secondary uses of data to the detriment of the whole NHS. The coherent and comprehensive coverage of the NHS means that data collection through the National Data Spine and its proper analysis make the NHS uniquely placed among world health systems to inform its own improvement, but only if datasets are complete.

5.5 In our view "the greater good" outweighs the autonomy of the individual in this setting.

6. *Why is current progress on the development of the NHS Care Records Service and the National Data Spine and delivery of the new systems up to two years behind schedule?*

We have no insight into the internal workings of Connecting for Health but we offer an informed outsider's observations.

6.1 Flawed model

The chosen developmental model with a small number of Local Service Providers developing regional systems in parallel seems to us flawed:

- It has prevented learning from shared experience.
- It has not visibly created energy by competition as was perhaps intended.
- It has meant huge investment without any "proof of concept".
- It has provided no "quick wins' to assure a sceptical healthcare community that the "grand plan' would ever deliver benefit
- It risks the possibility that issues of commercial confidentiality can compromise some of the benefits which might have been envisaged
- The interactions of a number of organisations appear necessary for progress to be made, but their respective roles, responsibilities and lines of command are to us opaque: as well as Connecting for Health and the LSPs, these include the Department of Health, the Information Centre, and the Secondary Users Service.

6.2 Changing leadership

Identified leadership of Connecting for Health within the higher echelons of the NHS and the Department of Health has rotated with disconcerting frequency. To the outsider this suggests recognition of the problems, but uncertainty about the solutions.

6.3 Lack of clinical consultation

From the beginning there has been a lack of clinical engagement.

RIXG, speaking for the whole renal community, itself an unusually IT-literate part of the NHS, has been unable to open any channels of communication with Connecting for Health. Connecting for Health has never come to us to ask about the functionality of our present systems [which must at very least be maintained if not improved in the future] or to enquire about specific insights we might have. This is in spite of the fact that this was highlighted as a necessity in the Renal Information Strategy and in LSP business proposals.

6.4 Underestimate of complexity

Lacking specific interaction, the renal community can only rely on the public stance of Connecting for Health. To our perception this is consistently overoptimistic, assuming that technical advances will overcome very large system-related challenges.

Our scepticism when expressed has regrettably been cast as Luddite, or as a lack of confidence in the technical innovations which we do not understand. The possibility that we might have informed criticism based on 25 years of using electronic care systems in the NHS should be taken seriously.

6.5 Existing systems

6.5.1 The renal community among others has highly effective clinical information systems refined for our purposes and integral to clinical care. From the beginning we were told that the NHS Care Records Service and the National Data Spine would replace our systems, although Connecting for Health has never asked us what functionality it is they are replacing.

6.5.2 Specialist clinical software suppliers have worked with clinicians over many years and understand well the needs of the healthcare community with which they work. The Connecting for Health strategy has appeared to threaten their existence and this could lose much expertise of value to the health community.

6.5.3 Recently we are told there has been recognition that existing systems cannot all be replaced, and that alternative mechanisms are needed for integrating them. From our perspective this is encouraging, but it is symptomatic of the communication issues that the renal community has had to seek out this change of strategy, it has not been communicated to us.

6.6 Focus on making local health communities work—National Service Frameworks and local networks

6.6.1 Clinical computing developed in the UK through the emergence of highly specific systems in specialist areas, for example renal care and diabetes care. The requirement now is for the overlapping information requirements of these disciplines to be fully defined and extended into the community setting. But this needs to be achieved without loss of the specific and clinically valuable functionality which has evolved in these systems over many years.

6.6.2 The specialist nature of clinical provision is acknowledged in the development of the National Service Frameworks [NSF]. In the case of renal services a separate piece of work compiled an available Renal Information Strategy to support and enable the main features of the Renal NSF. The Information Strategy can serve to "ground" the informatics developments in clinical activities, but we see no evidence that the Information Strategy is being used as the basis of any Connecting for Health initiatives.

6.6.3 The goal of nationally available clinical information is attractive—ie ensuring that wherever an individual falls ill or has an accident their health records will be available. But the great majority of health gain from the NHS Care Records Service will be in local health communities. The largest early gains will be in the care of people with chronic disease.

6.6.4 This is exemplified for patients with chronic kidney disease [CKD], a common condition affecting 5% of the adult population, many of whom have coincident cardiovascular disease. In early CKD most care is delivered in the community with a focus on cardiovascular risk management. As kidney disease advances the input of the specialist kidney team gradually increases. By the time there is advanced CKD requiring dialysis treatment or a kidney transplant much of the care is based in the kidney unit. This later stage is characterized by multiple specialist inputs, frequent attendances at multiple healthcare settings, and complex medicines management.

6.6.5 Care pathways are being developed which work across traditional interfaces between primary, secondary and tertiary care for chronic disease management. For CKD these pathways have the potential to delay or prevent progression to established renal failure requiring treatment by dialysis or transplant, which is complex and high, cost [presently consuming $\geqslant 2\%$ of the NHS budget to treat $\geqslant 40{,}000$ people]. It will also be possible to minimize the number of patients previously unknown to kidney units who require urgent dialysis; such patients, colloquially known as "crash landers" have a significantly worse outcome than those with prior care from the specialist team.

6.6.6 Information flows which break down "barriers' and make an electronic care record available across care pathways, will therefore provide major health gains. Seamless IT is integral to modern delivery of chronic disease management as patients move from primary to secondary to tertiary care. The healthcare services which patients access may be in different LSP "clusters".

6.6.7 Clinical staff need to understand the Connecting for Health strategy. Quicker wins, such as could have been delivered in chronic disease management, would have been vital in winning the confidence of the clinical community. They can still be.

6.7 UK perspective

The limitation of Connecting for Health to England is unhelpful. Health care occurs across the UK. Secondary purpose data use as for example in the UK Renal Registry is based on UK wide data allowing nationwide benchmarking. Distinct IT strategies in different parts of the UK add complexity, consume energy, and offer no health gain.

Professor John Feehally,
President, Renal Association and
Chair, Renal Information Exchange Group

March 2007

Evidence submitted by the Royal College of General Practitioners (EPR 17)

1. The College welcomes the opportunity to comment on the inquiry into the electronic patient record and it use.

2. The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the voice of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 26,000 members who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

What Patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on new systems

3. The RCGP supports the creation of a summary care record on the national electronic record system and the greater use of local detailed electronic records within organisations.

4. We recognise that the appropriate content for any summary is context dependent: ie it depends on the purpose of the summary and the identity of the person for whom it is written. Consequently the scope of the summary care record will need to be limited, since it is a largely context-free item.

5. We are aware that General Practice records necessarily contain large amounts of information relating to social, family, and relationship matters. This needs to be recognised in conversations about what elements of the local detailed care record should be shared.

6. Consequently, we are in favour of maintaining organisational boundaries around information in the detailed care record. We are also strongly in favour of giving the patient control over what information of theirs is shared. We see the health record as the property of the individual, not of their medical advisers, nor the Secretary of State.

Who will have access to locally and nationally held information and under what circumstances?

7. Access controls are determined by the principles of Legitimate Relationship and Role Based Access Control. Provided that these are properly implemented and applied in practice they ensure that only a clinician who is, at that time, properly involved in the care of that patient has access to the record. This should apply to both locally and nationally held information.

8. The concept of sealed envelopes offers a mechanism for some items of information to be hidden from specified groups of clinicians, under the patient's control. The technical implementation of sealed envelopes remains uncertain. Clinicians may, if they feel it is justified, "break the glass" and inspect the contents of a sealed envelope.

9. One concern is that the sanctions for inappropriate access to records are retrospective through an audit trail and alerts. This deters, but does not prevent inappropriate access.

10. We feel that it is very important for the patient to retain control of who sees which part of their records. "My Health Space", by letting the patient view what is in their record, is an important point of this process.

11. We are aware that some groups of clinicians feel that this patient centred approach may hinder their ability to care for patients. We feel that utilitarian and pragmatic arguments of this sort should not override the principles of privacy and self determination. From the point of view of patient safety, an assumption of incomplete knowledge (ie awareness that one does not know everything about a patient) is preferable to a false assumption that a particular record is complete and accurate.

Whether patient confidentiality can be adequately protected

12. Security of information is governed by a combination of technical measures and proper use of the system by practitioners. The more open a system, in terms of number of users and ease of movement of information across organisational boundaries, the more security depends on good practice in terms of information governance. There is a large element of education and training required to support this, and it is not clear if this is being addressed by CFH.

13. There is again a conflict here between the rights of the patient to confidentiality and the convenience of clinicians. We feel that increased patient understanding of these issues through unbiased information campaigns, and placing the patient in control of access to specific items in their record, constitutes the best way forward.

How data held on the new systems can and should be used for purposes other than delivery of care eg clinical research

14. The College recognises the potential value of using pooled data for epidemiological research, for assessing the health needs of populations as well as for other purposes.

15. It is essential that no patient-identifiable data is used in this way, that patients are aware of this usage of data, and that such secondary uses of information lie within the law.

16. As with all other usage of shared information, secondary usage will only be of value if the original contributing records are accurate and correctly expressed in a coding language that is reliably interpreted by the recipient system. Use of clinical terms varies among different professional groups. There is another training issue that is to do with consistency of coding and preservation of meaning in electronic records that are transferred from place to place. Again it is not clear that CFH have fully appreciated this need nor planned to address this training need. The wide diversity of potential contributors to this pooled information is a risk to the utility of the data.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule

17. Opinions on this have been expressed by organisations ranging from the British Computer Society to Private Eye.

18. There is a general agreement that the original timescales were unrealistic and that there was a lack of understanding among officials and politicians of the degree of complexity that characterises the health informatics domain.

19. We feel that there does remain a reservoir of goodwill among clinicians towards the aim of joined up electronic health records in the NHS. There was inadequate engagement with clinicians in the early stages of the National Programme for IT. It is to be hoped that this mistake is not perpetuated.

20. I acknowledge the contributions of Dr Paul Robinson and Professor Nigel Sparrow towards the above comments. While contributing to this response, it cannot be assumed that those named all necessarily agree with all of the above comments.

Dr Maureen Baker
Honorary Secretary of Council, Royal College of General Practitioners

14 March 2007

Evidence submitted by the Royal College of Nursing (EPR 43)

1. Executive Summary

1.1 The RCN supports the direction of travel of the national programmes in all four countries of the UK, including the English National Programme for IT. As was pointed out in the recent Royal Society report Digital Healthcare: The impact of information and communication technologies on health and healthcare that, "the single most important factor in realising the potential of healthcare ICTs is the people who use them".[55]

1.2 Nurses are the largest group of healthcare professionals in the NHS, and because of their particular role in co-ordinating as well as delivering care to patients nurses are already major generators of patient information and will be major end-users of the electronic patient record. It is therefore vital that they are fully involved in the development of the e-health programmes, and have the appropriate knowledge and skills to obtain, hold, share, use and store sensitive information, whether paper-based or paperless, about patients.

1.3 Connecting for Health and the Strategic Health Authorities to whom responsibility for implementing the programme has now been devolved should ensure that:

- Nurses are fully involved in decisions at local, regional, and national levels concerning the development and use of the electronic patient record.
- Adequate resources in terms of money and time, including backfill requirements are allocated to the education and training of nurses to enable proper use of the EPR, including the use of structured documentation and standardised terminology.
- The nursing content of the EPR is nationally agreed and is included in the specifications for all EPR systems.

1.4 Connecting for Health should restore immediately the funding to support nurse engagement.

1.5 Investigation is undertaken to identify the most appropriate devices to support point of care recording in settings outside hospitals.

1.6 Local employers must ensure that frontline staff have the time and skills necessary to ensure that patient are able to make fully informed decisions about the safeguards and choices related to information sharing and the implications of measures such as sealed envelopes.

2. Introduction

2.1 The Royal College of Nursing (RCN) represents over 390,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets in the UK. This makes the RCN the largest professional union of nursing staff in the world. The RCN promotes patient and nursing interests on a wide range of issues by working closely with government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations.

2.2 The RCN believes in the effective management and use of information to support excellence in patient care and nursing practice. Information management is central to the RCN definition of nursing as "the use of clinical judgement in the provision of care"[56]. The expansion of nursing practice and the requirement to take on new tasks and roles in response to future healthcare challenges increases the significance of clinical decision making in nursing practice and with it the need for such decisions to be supported by accurate and timely information. This requires nurses to develop their skills in decision making and information management, and also to be fully engaged with the development of Information and Communication Technologies (ICTs) in healthcare, in particular the development and use of the electronic patient record (EPR).

2.3 For these reasons the RCN supports the direction of travel of the national programmes in all four countries of the UK, including the English National Programme for IT. As was pointed out in the recent Royal Society report Digital Healthcare: The impact of information and communication technologies on health and healthcare that, "the single most important factor in realising the potential of healthcare ICTs is the people who use them".[57]

2.4 As the largest group of healthcare professionals in the NHS, and because of their particular role in co-ordinating as well as delivering care to patients, nurses are already major generators of patient information and will be major end-users of the electronic patient record. It is therefore vital that they are fully involved in these developments, and have the appropriate knowledge and skills to obtain, hold, share, use and store sensitive information, whether paper-based or paperless, about patients.

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[55] Royal Society (2006) Digital Healthcare: The impact of information and communication technologies on health and healthcare. London. Royal Society. http://www.royalsoc.ac.uk/displaypagedoc.asp?id=23835

[56] Royal College of Nursing 2004 Defining Nursing London, Royal College of Nursing; http://www.rcn.org.uk/downloads/definingnursing/definingnursing-a5.pdf

[57] Royal Society (2006) Digital Healthcare: The impact of information and communication technologies on health and healthcare. London. Royal Society. http://www.royalsoc.ac.uk/displaypagedoc.asp?id=23835

3. *What patient information will be held on the new Local and National Electronic Record Systems, including whether patients may prevent their personal data being placed on the system*

3.1 If the EPR is to achieve its main purpose of enabling safe, comprehensive, and co-ordinated care, the patient record must contain all the information that is necessary to support clinical decision making. In addition to administrative data such as patient identity, demographic data, and service data, the clinical information required includes information about the problems with which the patient presents, assessment and diagnostic data, allergies, current and past medications, diagnoses, interventions and treatments, and expected and achieved outcomes.

3.2 In order to achieve co-ordinated multi-disciplinary care, the record must not be limited to medical data but must include the parallel clinical data from all disciplines, including nursing. This means that nursing diagnoses, interventions, and outcomes must be recorded alongside medical diagnoses, interventions and outcomes. The system should allow users to record all actions prescribed by the plan of care, including progress notes, flowcharts, critical paths and other forms of nursing documentation. There are recognised and well researched classifications of nursing diagnoses, nursing interventions, and nursing outcomes, and the terminology to be used to describe them in the patient record is already incorporated within SNOMED-Clinical Terms, which the NHS has already decided should be the standard terminology for use in electronic records. Nursing data standards (including Nursing Minimum Data Sets) are in use in many countries; in the UK national agreement on standards for nursing record content and nursing data is urgently needed. The RCN is currently seeking support for work on practice standards for the nursing content of patient records.

3.3 In order for the information to be easily accessed and retrieved, the record must be properly structured, and in order to avoid ambiguity, the information must be expressed in standardised terminology. This will require a move away from current methods of documentation that rely on unstructured narrative and idiosyncratic language. The RCN recognises that these requirements demand considerable investment in education and training, and are concerned that these issues are being neglected in the current debates which appear to focus exclusively on security and confidentiality.

3.4 The RCN believes that patients should own and control their own data. This means that they must have the right to withhold it. However, where their personal data is relevant to the quality of care they will receive is properly explained to people, and if the safeguards for confidentiality and security are adequate, then very few people would withhold this data. A case was reported in the press recently where a woman died because although she was seen by no fewer than eight different doctors during the few days before her death, none of them had access to the information which would have enabled appropriate treatment to prevent her death.

3.5 However, the RCN supports the concept of the sealed envelope where patients can choose to withhold certain aspects of the information stored on the EPR noting that clinical staff who have the skills and time to do so must ensure that this is a fully informed decision by the patient. This is particularly important with young people and other vulnerable groups who may not be used to claiming their rights to dissent or refuse sharing of information.

3.6 It is important to recognise that while people may be able to exercise these rights when they are well and able to articulate their needs, the situation may be very different at the point of care when a patient is unwell, frightened, in pain or even unconscious.

4. *Who will have access to locally and nationally held information and under what circumstances*

4.1 The key principle is that access should be restricted to those who need to know, but that everyone who needs to know has access to the relevant information. This means that all health care professionals who are involved in the care of a patient need to have the information about the patient that is relevant to the care to be provided.

4.2 If the purpose of the information is to ensure that the patient receives safe and appropriate care wherever they receive it, we see no point in a distinction between what is available locally and what is available nationally. The data may be held centrally or in several places; what matters is that wherever it is held it can be made available at the point of care.

5. *Whether patient confidentiality can be adequately protected*

5.1 Issues of security and confidentiality are of paramount importance both to patients and to health professionals. However, they apply equally to paper-based as to computerised records. The security systems now available for computer systems are much more rigorous than any system currently available for paper records. We are aware of the very careful consideration currently being given to this issue within the NHS IT programmes. Electronic systems must also operate within the law, in particular legislation relating to data protection and the professional duty to maintain patient confidentiality.

5.2 The duty of confidentiality is a core element of the Code of Professional Conduct published by the Nursing and Midwifery Council (NMC) to which all registered nurses must adhere. Breach of confidentiality is a serious disciplinary matter. All nurses understand this. Confidentiality in respect of computerised patient records is no different from confidentiality in respect of any other aspect of patient information.

5.3 The RCN believes that with the right training and appropriate access to data patient confidentiality can be adequately protected. Electronic systems must support an audit trail which identifies where, when and by whom the clinical record has been accessed or amended. There must be universal policies and procedures and methods shared by organisations to ensure patient data is entered and extracted according to agreed standards. The RCN has recently published guidance for nurses entitled Competencies: An integrated career and competency framework for information sharing in nursing practice.[58]

6. *How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research*

6.1 The RCN is interested in the secondary uses of aggregated anonymised data which computerisation makes possible. Research in other countries (eg Belgium and USA) using data mining techniques applied to large databases of anonymised patient records is already showing how clinical outcomes can be identified to provide the evidence base for best practice in nursing and in other clinical areas.

6.2 These data sets have other applications for instance nursing clinical data can be linked to administrative and staffing data to show the effects of different levels of staffing and skill mix for use in workforce planning.

6.3 In short, the information contained in aggregated data is as important and useful for management and policy decisions as is individual patient data for clinical decisions. However, its ability to achieve these purposes depends entirely on the inclusion of appropriate nursing content in a structured and standardised format as outlined above. Thus use of data in this way must of course be properly regulated in exactly the same way as are other research projects.

7. *Current progress on the development of the NHS Care Record Service and the National Data Spine and why delivery of the new system is up to two years behind schedule*

7.1 The RCN recognises that although there are problems, an enormous amount has been achieved. However, we have serious concerns about the lack of consultation, communication and engagement with frontline staff, especially but not limited to nurses, which will certainly (as considerable research in other countries has shown) inhibit its proper use.

7.2 Surveys undertaken by the RCN during the past three years concerning nurses' views on the introduction of IT and in particular the EPR in the NHS have shown that while nurses support these initiatives overall, they do not have adequate information about these developments, are not adequately engaged in them, are not adequately involved in the development of the systems, and are not receiving appropriate training in their use.

7.3 In 2006[59] the RCN survey of 4,500 members found 65% had not received adequate information or any information at all about the new system; while 74% said there had been inadequate consultation or no consultation. The results showed there had been very little progress on this issue in the two years since the first IT survey was carried out by the RCN when 77% of members expressed concern about the lack of engagement. This has led to a loss of confidence in the introduction of IT into the NHS. In 2004 the survey showed that 70% of members believed that this technology would improve patient care, and 59 per thought it would improve nursing practice. In 2006, 56% of nurses surveyed believed computer records would improve patient care and 49% nursing practice. However, detailed analysis revealed that those respondents who had direct experience of using the systems were more positive than those who did not.

7.4 We repeat, and cannot stress too strongly, the need for the engagement of the nurses who will be the main users of the electronic patient record and the systems that support it. We were especially distressed to hear at the meeting of the Connecting for Health National Advisory Group held on March 13, that financial support for the Nursing Professions Information Group has been withdrawn, and that the Connecting for Health Nursing Development Programme has been discontinued. We repeat that these measures, affecting as they do the very group in which investment is most needed, will be counterproductive.

7.5 The RCN believes that the Connecting for Health programme is very ambitious and subject to timescales which could not realistically be achieved. Although the aims were laudable, the top-down, contract driven approach to implementation has presented tremendous challenges to those who are trying to introduce and implement new systems and ways of working within the clinical environment. We note the very different modes of implementation being used in Scotland and Wales, and endorse the recommendation

[58] *RCN (2006)* Competencies: an integrated career and competency framework for information sharing in nursing practice *http://www.rcn.org.uk/publications/pdf/information_sharing_in_nursing_practice.pdf*

[59] *RCN (2006)* Nurses and NHS IT developments: Results of an online survey by Nursix.com[nbsp]http://www.rcn.org.uk/publications/pdf/nurses_and_NHS_IT_developments_survey_2006.pdf

No 4 of the Royal Society report Digital Healthcare: The impact of ICT on health and healthcare that particular attention is paid to evaluations of the different speeds and scales and the levels of user engagement in the different countries.

7.6 There are a number of other issues and policy drivers which are likely to bring further challenges to the E-Health programmes and potentially delay their implementation or indeed compromise their aims which the RCN believes the should be brought to the attention of the Committee specifically: the policy shift from acute to community; education and training; and evaluation.

7.7 We are also concerned that the focus on the acute as opposed to the community health care setting runs counter to government policy to move care from the acute to the community. The focus of EPR development appears to be on its use in secondary care. This does not recognise two key facts: that healthcare for most people most of the time tends to be delivered in their own homes and by community based services, not in acute hospitals; and government policy as outlined in White Paper *Your Health, Your Care, Your Say* sets out to shift care closer to home away from the acute to the community setting.

7.8 Furthermore, basic ITC infrastructure is especially inadequate in the community setting, and nurses as a key health group have limited access. Community nurses such as health visitors and district nurses have particular difficulties in accessing computers and in accessing and recording patient information at the point of care; much greater investment is necessary in the development and testing of mobile communications. The emphasis to date appears to have been largely on systems to replace paper, rather than systems integrated into and supporting workflow i.e. the care process.

7.9 While the technical challenges of introducing the electronic patient record are enormous, the culture change that is also required is even greater. This will require major investment in education and training—not only training in how to use the particular systems, but also in understanding the underlying concepts of information management. Adequate funding (including funding for backfill to enable staff to be released from their normal work roles) and time must be provided by employers. Training must be undertaken by trainers who understand the complexities of the clinical process and the way that nurses practice. "One size fit all" training will not be sufficient to address different levels of knowledge and skills amongst the entire workforce. Special attention must be paid to those nurses who, for whatever reason, lack basic IT skills. Supported "booster training" for these nurses must be provided.

7.10 Education is necessary to ensure existing nurses (a) understand the role of technology in the delivery and organisation of care; (b) understand the legal and ethical issues associated with managing and sharing patient information; (c), can extract data to support decisions and monitor the outcomes of practice; and (d), document nursing practice with this new technology. However, changes in pre-registration education are at least as important. We endorse the recommendation of the Royal Society, ". . . that the higher education institutions and professional bodies responsible for the different disciplines adapt their curricula to integrate the use and understanding of healthcare ICTs into the basic training and continuing professional development of healthcare profession."

7.11 The RCN is devising a set of E-Health Principles to provide standards against which developments, proposals and initiatives in e-Health can be evaluated. These principles will test the extent to which these developments will support nursing practice and enable nurses to deliver high quality care for patients. These principles will cover ethics, trust, confidentiality, quality and overall the promotion of patient care and a patient centred approach.

8. Recommendations

8.1 The RCN has a number of recommendations for consideration by the Committee.

8.2 Connecting for Health and the Strategic Health Authorities to whom responsibility for implementing the programme has now been devolved should ensure that:

- Nurses are fully involved in decisions at local, regional, and national levels concerning the development and use of the electronic patient record.
- Adequate resources in terms of money and time, including backfill requirements are allocated to the education and training of nurses to enable proper use of the EPR, including the use of structured documentation and standardised terminology.
- The nursing content of the EPR is nationally agreed and is included in the specifications for all EPR systems.

8.3 Connecting for Health should restore immediately the funding to support nurse engagement.

8.4 Investigation is undertaken to identify the most appropriate devices to support point of care recording in settings outside hospitals.

8.7 Local employers must ensure that frontline staff have the time and skills necessary to ensure that patient are able to make fully informed decisions about the safeguards and choices related to information sharing and the implications of measures such as sealed envelopes.

Royal College of Nursing

March 2007

Evidence submitted by the Royal College of Paediatrics and Child Health (EPR 59)

1. The Royal College of Paediatrics and Child Health would like to make the following submission to the House of Commons Health Select Committee in response to Health Committee Press Notice number 12 announcing the enquiry into the Electronic Patient Record and its use and inviting contributions of written evidence to the Committee regarding this enquiry. The main objects of the College are to advance the art and science of paediatrics, improve standards of medical care to children, and to educate and examine doctors in paediatrics. Additionally, the College has a function in providing information to the public on the health care of children. The following points deal specifically with the needs of children and young people.

2. There must be adequate safeguards for confidentiality. This is primarily a technical design issue although staff training will be required. Where there are genuine safety concerns, for example in the context of a partner fleeing form domestic violence, safeguards about revealing the address and location of the family can be increased without the health data needing to be hidden.

3. Regardless of the complexity of information being held on the system, it cannot be in the interests of children and young people for their data to be withheld from the system. Indeed if parents are able to prevent their children's data from being entered onto the system it is likely that the planned information sharing index supporting the aims of the Government document Every Child Matters cannot be developed. Most parents can see the benefit of health information being shared and it is likely that the most vulnerable children, whose parents desire to disengage from services, would be the ones asking for their children's data to be withheld.

4. Access to named patient data should be based on the individual's role and justifiable on the basis of need to know (for instance in order to deliver health care). There should be a clear audit trail and regular audits of who has accessed what data.

5. Basic demographic data (such as name, date of birth, sex, address, General Practitioner with whom registered and educational establishment attended) will need to be transferred form the national spine to set up the information sharing index (ISA), which will also carry the name of involved professionals (barring some specified exempt services such as sexual health services) and whether a common assessment framework has been carried out. Detailed specifications for the ISA will be available from the DfES.

6. If we assume that the delivery of care includes secondary uses of data such as commissioning and auditing services this should include monitoring of selected outcomes of key processes such as immunisation coverage, waiting times for treatment for disabled children and age at identification of severe hearing loss among many others. The data should be available subject to confidentiality agreements to agreed research projects. In some cases it may not be possible to obtain retrospective subject consent but if no harm is deemed likely (as for testing of anonymised stored blood samples) the research should still go ahead for the benefit of the entire population.

7. A comprehensive record available instantly throughout England is a dream worth working for but is beginning to look like a mirage with an ever receding completion date. It may be more realistic and useful to concentrate on developing an agreed summary electronic health record for children covering the child health promotion programme, the domains of the common assessment framework, the individual's current health problems and medication and then ensuring immediate transmissibility of such a summary. Further details can be requested as necessary, for example, it is useful to know a child has had an operation for squint but not so useful to have a blow by blow account of the operation.

8. In our view the delays in the delivery of the system are due to:

- poor communication between IT specialists and clinicians;? disregard for work that may have already been done in many clinical departments on their information needs;
- a failure to grasp the complexity of the delivery of health care, especially for vulnerable groups such as children, patients with mental health and learning disability and where social care and education are intimately involved;
- an unrealistic pace—clinicians cannot set aside seven whole days in the next two months (the current request for clinical involvement for LORENZO) to develop IT systems in the face of their current workload. Seconding clinicians to Connecting for Health (CFH) is only partly the answer as the clinicians still on the ground are reduced in numbers and still need to become involved;

— an unrealistic aim—whereas transmitting x-rays is relatively simple using informatics transmitting complex clinical information and clinical judgements is more difficult. In our view transmitting summaries in an agreed format, developed nationally for each subspecialty, would ensure the availability of essential data.

9. Therefore work should concentrate on developing the summary templates and their messaging as the fist step for all areas. The only real success story of CFH so far is PACS; sending x-rays pictures relied upon a summary of the information in an agreed format (pixels for pictures plus a report) being messaged instantly across the entire network.

10. The development of the clinical record for children is seen as a major priority particularly after the Lamming report. The potential for timely and accurate information exchange could potentially save lives by alerting professionals to abnormal or atypical patterns of care access by parents and deficiencies in care delivery by professionals. There is high interest amongst paediatricians to develop this quickly and in a standardised way. However, the commercial interests of developers have the potential to slow this development unless appropriate sharing of intellectual property rights with NHS staff is facilitated. The DH and DFES need to have a close liaison in the development of a holistic care record that takes advantage of the developments such as ISA and CAF.

Dr Hilary Cass
Registrar, Royal College of Paediatrics and Child Health

16 March 2007

Evidence submitted by the Royal College of Physicians (EPR 48)

The Royal College of Physicians (RCP) plays a leading role in the delivery of high quality patient care by setting standards of medical practice and promoting clinical excellence. We provide physicians in the United Kingdom and overseas with education, training and support throughout their careers. As an independent body representing over 20,000 Fellows and Members worldwide, we advise and work with government, the public, patients and other professions to improve health and healthcare.

1. Introduction

1.1 The Royal College of Physicians welcomes the opportunity to contribute to this inquiry. For many years the College has championed the need for better, more structured health records, and the need for these to be developed in electronic form, to bring benefits to patients.[1]

1.2 The debate about electronic patient records (EPRs) is bedevilled by a lack of clear definition and therefore common understanding of what the term EPR means. It is clear that concepts have shifted within the National Programme for IT within the last few years, which has added to the confusion.

1.3 The current concept appears to assume that a useful individual summary health record can be accumulated by coalescing a wide variety of communications about a patient. We believe that this will be of limited value in practice.

1.4 The EPR should be the cornerstone of the individual patient's health record. Health care is delivered in widely differing contexts but the underlying processes are always the same—the patient is assessed, actions are planed and executed and the patient is reviewed. This sequence may take place over a matter of minutes in the emergency situation, or many months in the management of chronic disease. However, the capture of essential data on assessment (whether from the patient's history, examination or test results) and the planning and execution of actions (whether talking to the patient, prescribing drugs, arranging tests or performing complex procedures) will contain essential pieces of information that need to be captured to build up the electronic record.

1.5 Against this background it is possible to develop a concept of the electronic patient record that is:

— truly patient-focused;

— built using a common, generic architecture but customised for appropriate use in the wide variety of contexts in which the patient is seen (from nurse-led community care to highly specialised tertiary units);

— summarised at a high level to contain essential data of relevance to other carers;

— also containing very detailed data of relevance only to those who look after patients in specific contexts;

— a mix of structured and unstructured (free-text) data;

— protected and accessible on a need-to-know basis.

1.6 It is not possible to build such a record by extracting data from systems that support the processes of care (such as scheduling, booking, ordering and communicating). There is a need to address how data are recorded in the course of patient/professional interaction, as well as through the ordering and execution of investigations and procedures.

1.7 The concepts outlined above imply

— a need for an agreed, common architecture for the record;

— common standards for data entry, particularly in structured records; and

— a preparedness amongst health professionals to collect data as accurately as possible and to these common standards.

1.8 The need for such common standards is seen as important by physicians. A recent poll of RCP Fellows and Members was overwhelmingly in favour.[2]

Table 1

RESULT OF POLL OF RCP MEMBERS AND FELLOWS

In answer to the question: "*The same, standardised headings should be used in all NHS hospitals in the admission clerking of Acute Medical Admissions".*

Results:

			Strongly agree	*Agree*	*No opinion*	*Disagree*	*Strongly disagree*	*Total*
Grade	Consultant	Count	201	338	33	35	20	627
		% within Grade	32.1	53.9	5.3	5.6	3.2	100.0%
	Specialist Registrar	Count	77	195	11	42	17	342
		% within Grade	22.5	57.0	3.2	12.3	5.0	100.0
	Non consultant career grade	Count	6	15	0	2	0	23
		% within Grade	26.1	65.2	0	8.7	0	100.0
	SHO	Count	15	25	3	3	2	48
		% within Grade	31.3	52.1	6.3	6.3	4.2	100.0
	Other	Count	17	23	3	3	1	47
		% within Grade	36.2	48.9	6.4	6.4	2.1	100.0
Total		Count	316	596	50	85	40	1,087
		% within Grade	29.1	54.8	4.6	7.8	3.7	100.0

2. *What patient information will be held on the new local and national electronic record systems?*

This question needs to be considered in two parts: local data and national data.

2.1 Local data

2.1.1 The data which are held in the record at a local level will depend on the context in which the patient is seen. Thus a general practitioner or district nurse may need relatively little information, seen as a summary of the overall patient story. On the other hand, a gastroenterologist will need a detailed record of the patient's endoscopy findings, and a cardiothoracic surgeon will need a detailed theatre record or cardiac assessment. The definition of this detail and the structure of the record to record it should be agreed nationally, based on work undertaken by appropriate professional bodies such as the Royal Colleges and Specialist Societies. To date the Colleges have not been requested to undertake this work but it is an area where clinical engagement and leadership could be very profitably harnessed.

2.1.2 The Royal College of Physicians has already pioneered the development of standards for record-keeping in the context of the acute medical admission, based on a review of the evidence relating to benefit; two polls of practising hospital doctors to ascertain their views; and a wide assessment of current practice. The Royal College of Physicians has developed both generic medical record-keeping standards and standards for the structure and content of the acute medical admission. Further work will be undertaken to address other contexts.

2.2 National data

2.2.1 The data which are held at a national level must be sufficiently comprehensive to enable primarily the safe and efficient care of the patient when first seen by a practitioner who does not know their story and, secondly, to support a wide variety of secondary purposes. The latter use will be discussed below. In order to inform the primary purpose of the care of the patient, information is needed on:

- the patient's current problems;
- active diagnoses;
- significant past history including both illnesses and operations;
- relevant social circumstances;
- current drugs and other treatments;
- allergies; and
- patient wishes.

3. *How should data held on the new systems be used for purposes other than the delivery of health care?*

3.1 The Royal College of Physicians supports the use of data held in the patient record for other purposes including individual performance monitoring, service development and clinical research. However, work done by the College has shown currently data extracted from paper records and held centrally are not fit for these purposes.[3] The findings of this work strongly support the need for structured records, as described in the introduction to this submission. They also suggest the need for professional engagement, preferably through professional bodies such as the Royal Colleges, who can give strong leadership to the profession.

3.2 We have shown that data can support clinical research if collected rigorously and in structured form but this requires the health record to be clinically rich, the data to be collected to common standards, and professional attention to the accuracy of the data recorded.[4]

4. *Should patients be able to prevent their personal data being placed on systems?*

We believe that patients should have the right to veto the recording of certain data (which might include the whole record) but should be made aware of the risks to their personal health care this brings. Having considered the arguments, we believe this should be handled on an opt-out basis rather than an opt-in basis for hospital-based medicine. Patients should be fully informed of those data items which will be held on their summary record, and given the opportunity to object. Due to the timescales involved we have not had the opportunity to consult our Patient and Carer Network (a group of 75 patients, carers and members of the public recruited to help the College with its work) on this topic in detail, but hope to do so during the course on your enquiry. The topic is scheduled to be discussed at a workshop on 17 April 2007. However, we have encouraged the Network to respond directly to the Inquiry with their own personal comments.

5. *Who will have access to locally- and nationally-held information and under what circumstances?*

Access for patient care should be on a need-to-know basis. All users should be identifiable and the NHS should invest in rigorous security systems that identify the user without relying solely on passwords. If such systems are instituted we believe patient confidentiality can be adequately protected.

Access for secondary purposes depends upon whether the data are anonymised. Those responsible for individual patient care should continue to have access to identifiable data when monitoring performance or developing services. Use of data for research should be protocol-driven and only with consent of patient if identifiable data are used. Wherever possible data should be anonymised, and sophisticated techniques used to ensure this when different datasets are linked.

Royal College of Physicians

March 2007

References

[1] Standards in Medical Record Keeping, Robin Mann and John Williams, ClinMed 2003;3:329–32,

[2] Result of Poll of RCP members and Fellows.

[3] Engaging Physicians in improving data quality in the NHS http://hiu.rcplondon.ac.uk/documents/EngagingCliniciansDataQualityNHS.pdf

[4] Williams J G, Cheung W Y, Cohen D, Hutchings H, Longo M, Russell IT. The value of routine data in health technology assessment: can randomised trials rely on existing electronic data? Health Technology Assessment 2003; vol 7: no 26.

Evidence submitted by the Royal College of Psychiatrists (EPR 25)

Summary

1. The Royal College of Psychiatrists recognises the potential benefits that can accrue through improved information management and communication from the use of information technology as the basis for the patient's health record. It has the potential to provide better patient information, improved cost efficiency and more reliable information for quality control and health services planning. Nevertheless the developments of the Electronic Record transgress the traditional boundaries of the individual patients' direct relationship with a healthcare professional and creates "a new risk scenario which calls for new additional safeguards as counterbalance" (Article 29 Data Protection Working Party, 2007).

2. Where sharing of information outside the healthcare team is anticipated, including any proposed uplift of information to the summary care record, patients' express consent should be sought.

3 Concerning information sharing for direct patient care, it will be important that those who need to know receive appropriate and accurate information and that clinicians, reflecting the wishes of their patients, retain control of the flows of this information. Dissemination of information should be as limited as possible, consistent with, among other things, the maintenance of a safe situation.

4. The use of patient identifiable information for secondary uses, including research, should be based on patient consent unless there is justification under Section 60.

5. The particular concerns and needs of specific groups of patients should be recognised. Mental health issues, where stigma continues to attach, must be recognised as one of several areas where patient information is of a particularly sensitive nature. Patients with mental health needs therefore may have understandable anxieties about the sharing of personal identifiable information for purposes and for distributions they have neither known of nor consented to. Four particular groups require specific consideration:

- Patients who are suspicious or paranoid.
- Patients within the criminal justice system (or with histories of the same).
- Patients with particular privacy needs (for example high public profile, witness protected).
- Patients with impaired decision making capacity.

Background

6. We understand that the NHS Care Record Service (NCRS), being delivered by NHS Connecting for Health, is central to the National Programme for IT for England. It consists of several linked national and local applications to be delivered over the next few years as a network of patient records. The key elements of the NCRS are:

- the Summary Care Record (SCR) consisting of essential elements of a person's care records;
- the Detailed Care Record consisting of the person's care record for that organisation and elements of all care records relating to that person in other organisations.

7. The vehicle for information sharing will be the Summary Care Record. Significantly the report of the Ministerial Taskforce on the NHS SCR states "initially it (SCR) will contain a small but important dataset of current medications and allergies and adverse reactions which will be uplifted from GP systems, initially as text and subsequently in coded form. Over time the content will increase, subject to consent, to include a more complete dataset from GPs and also information from detailed records held by other providers of care for example hospitals and community services".

8. The College welcomes the Task Force's commitment to the highest levels of IT security.

Consenting Arrangements

9. The Taskforce states "before the Summary Care Record is implemented in a geographical area, a public information programme will be carried out to explain to the public how it works . . . and how . . . members of the public . . . can limit the sharing of their information through the Summary Care Record". The Taskforce recognised clear difference of view between both the BMA and the Ethics Committee of RCGP on the one hand and the Department of Health, its advisors and many Royal Colleges on the other over issues of consent. The College has concerns regarding the ethical and possibly the legal justification for the placing of patient information on the Summary Care Record based solely on an information campaign and inferred consent in the absence of dissent (opt-out).

10. The College welcomes the following recommendations from the Task Group with respect to the foregoing:

- An Advisory Group of stakeholders drawn from patient, clinical and management interests is created to oversee the future development of the NHS Summary Care Record and to advise on its use.

— Patients must know what range of information is in the Summary Care Record and who will see it, and this process must continue throughout the development of the Summary Care Record. Once sealed envelopes are available patients will have far more control over who will see their information. The Summary Care Record will become more valuable over time as, with consent, its content becomes more complete. The Care Record Guarantee sets out how the NHS uses patient information and how it is protected.

11. It is our understanding that the initial arrangements for uplifting information from GP records to form the SCR (or spine) some diagnoses will not be uploaded. These include mental health, sexual health and some infections. The College is concerned that prescription information specific to a disease category, such as HIV medication or antipsychotic medication, will be included.

12. As patients present to their General Practitioner they will have the opportunity to check their SCR and to consent (or not) to their sensitive information being added to the Summary Care Record. The College position is that these arrangements must be rigorously upheld in order to ensure public and professional confidence and protect patient's privacy rights.

Patient Information acquired within Specialist/Secondary Care Services including Mental Health Services

13. The College has sought clarification on the proposed development of the SCR in relation to secondary care services with Mr Harry Cayton, Chair, Ministerial Task Force on the Summary Care Record. He has given a clear indication that the default position will be that not only can patients request not to have a Summary Care Record or that their Summary Care Record is not shared outside the organisation which created it, but can also request that some parts of their clinical information is not sent to their Summary Care Record. Later in the programme Sealed Envelopes will be available which will allow patients to "seal away" some of the information in their Summary Care Record so that it is only accessible with their express permission although the rest of the SCR may be available.

14. The College welcomes the establishment by the Care Record Development Board of a working group to explore the ethical issues surrounding the secondary uses of patient information.

The College's Position on Protection, Uses and Disclosure of Patient Identifiable Information

15. The College's guidance on confidentiality and information (Royal College of Psychiatrists 2006) provides guidance to its members relevant for all systems and media, including electronic patient records, Summary Care Records and Detailed Care Records.

Principles

16. Psychiatrists must not disclose any clinical information about a patient to others, without that patient's consent. However, the Duty of Confidentiality also exists within a wider social context in which doctors have other moral and legal obligations, which may need to be balanced with their Duty of Confidentiality.

17. Although patient identifiable information is generally held under ethical and legal obligations of confidentiality, it is widely recognised that there are three categories of exception to the Duty of Confidence, and thus three categories of circumstance where the Duty of Confidentiality can be waived, namely:

— Where the individual to whom the information relates has consented;

— Where there is a legal compulsion or other legal basis to disclose otherwise confidential information, either by virtue of statutory law, or by order of the court;

— Where, in the opinion of the clinician, the duty to the public overrides the Duty of Confidentiality.

Keeping Patients Informed

18. Patients must be informed of both the primary uses (for their healthcare) and secondary uses (healthcare purposes not directly related to their care) of their healthcare information. They must also be informed of the choices surrounding such uses and whether they can opt out. Patients should also be informed about decisions to share information outside the NHS and the reasons why this is necessary. Explicit consent to such disclosure must be sought, and the outcome of the discussion recorded.

Uses of Information for Direct Clinical Care

19. Where patients have been informed of the use and the sharing of their information, and the choice that they may have, then express consent is not usually required for the extent of the information sharing needed to provide healthcare. This guidance refers to the usual sharing within the patient's healthcare team.

Secondary Uses

20. Many current uses of confidential patient information do not directly contribute to or support the healthcare that a particular patient receives, but instead provide more general benefits, such as patient groups as a whole. It cannot be assumed that patients seeking treatment are content for their information to be used in these ways. Patients are owed a Duty of Confidentiality and have the right to object to the use or sharing of confidential information that identifies them. Patients need to be made aware of this right. Efforts to gain consent are required. Alternatively approaches that do not rely on confidential and identifiable information should be adopted, for example anonymisation of information. Where patients object to specific secondary uses their refusal should be respected.

Conclusion

21. Based on the College Guidelines, a key principle informing all uses of the Electronic Patient Record is patient control of their information. In order to safeguard privacy patients must be given control over their records. Where sharing of information outside the healthcare team is anticipated, including any proposed uplift of information to the summary care record, patients' express consent must be sought. This is essential to upholding the dignity and rights of our patients, for maintaining their trust and confidence and is part of our duty of care. Concerning information sharing for direct patient care, it will be important that those who need to know receive appropriate and accurate information and that clinicians, reflecting the wishes of their patients, retain control of the flows of this information. Dissemination of information should be as limited as possible, consistent with, among other things, the maintenance of a safe situation. The use of patient identifiable information for secondary uses, including research, should be based on patient consent unless there is justification under Section 60.

22. While the foregoing applies to all patients, the particular concerns and needs of specific groups of patients should be recognised. Mental health issues, where stigma continues to attach, must be recognised as one of several areas where patient information is of a particularly sensitive nature. Patients with mental health needs therefore may have understandable anxieties about the sharing of personal identifiable information for purposes and for distributions they have neither known of nor consented to. Four particular groups require specific consideration:

- Patients who are suspicious or paranoid.
- Patients within the criminal justice system (or with histories of the same).
- Patients with particular privacy needs (for example high public profile, witness protected).
- Patients with impaired decision making capacity.

23. It will be important that such patients are not further disadvantaged as a consequence of any blanket rules regarding the Electronic Patient Record.

24. The College would welcome an opportunity to discuss these issues with the Committee.

Professor R J McClelland
Chair, Confidentiality Advisory Committee

12 March 2007

Prepared for the Royal College of Psychiatrists by its Advisory Committee on Confidentiality

Acknowledgement and References

The Confidentiality Sub-Committee gratefully acknowledged the advice of the Ethics Committee of the Royal College of General Practitioners.

Article 29 Data Protection Working Party (2007), working document on the processing of personal data relating to health in electronic health records.

Royal College of Psychiatrists (2006) Confidentiality and Information Sharing. Council Report 133.

Evidence submitted by the Royal College of Radiologists (EPR 35)

1. The Royal College of Radiologists (RCR) has approximately 7,000 members and Fellows worldwide representing the disciplines of clinical oncology and clinical radiology. All members and Fellows of the College are registered medical or dental practitioners. The role of the College is to advance the science and practice of radiology and oncology, further public education and promote study and research through setting professional standards of practice.

2. This response outlines the RCR's views on what information should be held in the Electronic Patient Record (EPR) and emphasises that it should build on and enhance the current roll-out and implementation of the national Picture Archiving and Communications System.

What patient information will be held on the new local and national electronic record system

3. The Electronic Patient Record (EPR) should consist of a Summary Care Record containing a very brief summary of the event, time and place, with hyperlinks for those with the appropriate access permissions to more detailed on-line information.

4. The types of events that should be recorded on the summary are:

- Previous major surgery.
- Previous inpatient episodes.
- Previous diagnoses.
- Information on allergies, including alerts relating to contrast media.
- Existing chronic conditions.
- Current medication.

5. We have debated what level of content would be appropriate for logging on the summary care record. It was felt that any significant episode which could impact on the patient's future healthcare management would be useful and every inpatient or daycase episode of hospital care is essential.

The date that the record was last updated should also be noted.

6. The summary should then link to more detailed information including the patient's radiological reports and images and, in the future, cumulative exposure to radiation.

7. It is important to ensure that the Electronic Patient Record builds on and enhances the current roll-out and implementation of the national Picture Archiving and Communications System (PACS). PACS enables the electronic storage and transfer of images. The benefits of this are numerous.

- From a patient perspective, it prevents images being lost or unavailable for consultations, therefore speeding up diagnosis and treatment. It also reduces the need for repeat imaging, meaning that patients need not be subjected to unnecessary radiation.
- From a clinician perspective, it allows for a much more efficient use of time and quicker reporting. As the images will be available across sites immediately, multidisciplinary discussions can take place at once, even if participants are in different places. It also allows the networking of services through hub and spoke type models.

Therefore, it is vital that the EPR incorporates the benefits that PACS is bringing to patients in terms of safety and efficiency of care.

Whether patient confidentiality can be adequately protected

8. It is vital that patient confidentiality is maintained. However, it is equally important that this is not detrimental to patient care. All those who need access to a patient's records to diagnose or treat them, must be able to do so easily and efficiently.

How data held on the new systems can and should be used for purposes other that the delivery of care

9. The data could be useful for research, audit and teaching purposes.

Professor Janet Husband
President, The Royal College of Radiologists

15 March 2007

Evidence submitted by the Royal College of Surgeons of England (EPR 26)

EXECUTIVE SUMMARY

The Patient Liaison Group at the Royal College of Surgeons of England has been monitoring the progress of this initiative, and their representative attended the Care Record Development Board Annual Conference in November 2005, which afforded the opportunity to ask questions. The impression taken away from this Conference was distinctly that of a project not sufficiently thought through from the beginning. Issues which should have been developed long before the project commenced were being dealt with as and when they arose, leaving all stakeholders uncertain about many issues. Such questions as how the use of the patient records would be shared with private medical care, and whether confidentiality clauses would have to be built into individual contracts of employment in the private medical sector remained unanswered, with the proviso that this was work which had yet to be developed. These are fairly basic considerations for a project of this kind. The Patient Liaison Group holds the view that the uncertainties revealed from the Annual

Conference demonstrate a project which was not sufficiently piloted before large sums of money were engaged in the project. A more prudent and measured investigation should have been allowed to reveal the potential difficulties in a project of this magnitude.

Whilst the benefits of an electronic patient record are generally accepted, this was an overly ambitious project untested anywhere else in the world. The haste with which the project was launched did not appear to consider whether the national record justified such expenditure or whether a more modest upgrade of existing local IT systems would not have delivered the same benefits.

The conclusions of the Ministerial Taskforce on the Summary Care Record made recommendations retrospectively, which should have been part of the initial Project Plan. These include point 2 which states that problems, faults and practicalities are resolved before the system becomes widely available. Point 4 which recommends producing standards for good electronic patient summaries in general practice is again work which should have formed part of the early pre-project planning phase. Point 6 shows that a training package is only latterly being considered.

We are very surprised that an independent IT agency or some other form of external expertise was not used to monitor the progress of the private firms undertaking the work, so that it could report back to the Care Record Board with early problems and to keep track of expenditure. The project suffered from the division between those who had some understanding of the IT systems side of the project and the project directors who appear to have no understanding of this, and had to rely on the IT firms without any means of auditing them. The lack of scrutiny in a project of this size appears to break the basic rules of project management. When contracts were agreed with the IT providers, there appears to have been laxity in allowing overspends to occur and no strictly fixed budget or one with slight flexibility was negotiated at the outset.

The failure to engage clinicians in the NHS in the Project was another error and many GPs appear openly hostile to the system, coming at the same time as the disruption of Choose and Book.

There have been so many reported problems that public confidence in the ability to deliver a safe and confidential system has now been shattered. It is therefore very important that patients are reassured with practical examples of how the record will operate to assure the confidentiality of their records.

Our conclusions are inferred from our own experience when engaging with the Care Record Development Board Conference and the inadequacy of their ability to give clear direction when questioned. An idealised vision of the outcome and benefits of the care record appears to have been at the expense of practical delivery. However, we refer to the major criticisms of the Dossier of Concerns dated 2 February 2007 by 23 academics, who refer to poor project management and failure to pilot. Whilst we have been tracking the Project at some distance, our observations concur with this Report.

The lack of easily-accessible public information about the electronic record is concerning. Any individual wanting to find internet information needs to know where to look—a simple Google search does help—and even then it is difficult or impossible to find up-to-date or helpful information. The Connecting for Health or Department of Health websites need a section for the public which gives a clear history of the project, planned delivery dates, issues that have been raised and links to key proposal and review documents.

The Patient Liaison Group, based on a member's personal experiences, has concerns about the accuracy of the information that is being put on the record and, in the clinical setting, the ability of trainee doctors to interpret and use the information. Therefore in addition to checking and confirming a patient's ID, their past history be checked with the patient or their representative as far as possible.

Brief Introduction to Patient Liaison Group (PLG)

Membership is made up of 12 lay people and six surgeons, with two other *ex officio* surgeons. The lay chair is an invited member of College Council. The Group has a full-time administrator funded by the College, access to advice from other College staff and is able to link with the President as required. Lay members are recruited nationally via the press and formal interview. They have direct extensive experience of being surgical patients, family carers of surgical patients and/or membership of patient organisations. Maximum membership of five years ensures regular new members but is long enough for members to develop extensive knowledge of College work and of health policy.

Lay members represent the Group on approximately 35 other committees and working parties, inside and outside the College. The Group is strongly supported by its surgical members who provide extra insight into the NHS and advice. The Group frequently responds to consultation documents, both under its own name and as contributions to College responses. It develops some of its own work to further its aims, for example a review of research into communication skills and a forthcoming guide to help surgeons improve their patients' journeys. It belongs to and works with the Patient Liaison Group of the Academy of Medical Royal Colleges. It produces a bi-annual newsletter as an information link and source of feedback between the Group, patients and the College membership.

Recommendations for the Committee to consider in its Report

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being place on the systems

1. Patients may not wish certain illnesses to be on the spine, but difficult decisions and rules will need to be made where the disclosure of certain conditions will be necessary to protect healthcare workers, in the event that they care for the patient in an emergency situation. This would include perhaps HIV status and mental health status, where the patient might pose a risk to staff. Some of these sensitive diagnoses might also need to be included as they would affect possible medications which could be given in an emergency.

2. The "sealed envelope' had not been fully thought through at the Conference in 2005. Page 6 of the 2005 Care Record Review Document states that "there will be limits to a person's ability to reduce their participation. They will not be able to restrict entries when to do so would put others in danger or put public health at risk. For example, an accurately recorded history of violence towards health workers would be included in both the Detailed Care Record and the Summary Care Record regardless of the person's wishes'. However, patients can opt out of the electronic record system, and, in these circumstances, an alert would record that there was missing data. It would be up to the person to agree to share the information with the healthcare professional treating them. This appears contradictory if the system is to protect healthcare workers. Full, or at least fuller, development of the sealed envelope by now would have enabled more confidence in the confidentiality and effectiveness of the whole system.

3. Information is to be stored anonymously using an NHS number, and there is potential for errors. Where some communities share the same surname, the use of electronic access to records must not substitute the additional check of confirming the identity of the patient who presents for treatment.

Who will have access to locally and nationally held information and under what circumstances

4. It is stated that those accessing a patient's records must have a "legitimate relationship' with them which means they are directly involved in the care of the patient. Another problem which emerged at the Conference was the issue of patients being moved around the hospital to other wards, who then took over the legitimate relationship or of tests arriving at the old department which the patient had just left.

5. The NHS Connecting for Health Shared Care Record Review Document—Revised Version for Discussion released on 29 July 2005 was suitably vague on the use of the Record by other agencies, stating on pagg 3 that: "However, for more complex care, it will sometimes be necessary for several organisations to access all or parts of each other's contributions to the Detailed Care Record and perform other functions that are made easier by shared access to the Detailed Care Record such as ordering tests. This wider access will require explicit consent at first; in time it may be agreed that some such access can be implicit." This is typical of the vagueness of language which tells stakeholders nothing of what might actually be envisaged.

6. It is to be noted that the above document at 4 2.2. states that the summary care record may include components from a dental practice and so on. There is also mention of input from an optician, where early signs of eye disease were detected. This latter input seems inappropriate as they should refer the patient to a GP and onward to an Eye Clinic if they suspect eye disease.

7. There will always be concerns that governments will grant access to electronic data to bodies other than those originally intended to have it, and that databases store data they don't necessarily need. There should be stronger reassurances and liaison with the public and a body which represents the public's interests so that use of information is agreed to. Individual permission must be sought from members of the public if data is to be shared for example with insurance companies, but also use of anonymised group data, or traceable group data, must be agreed by a group representing and accountable to the public, and must follow legal process.

Whether patient confidentiality can be adequately protected

8. Whilst the Care Record Guarantee Document gives broad statements in safeguarding patient privacy and confidentiality, it remains a theoretical document.

9. When attending the Care Record Development Board Annual Conference in 2005, it was noted that confidentiality, privacy and security were issues of importance to patient representatives in attendance. However, there were no practical demonstrations of how this might be assured in the working environment. No demonstrations were given by IT experts. Participants were assured that the firewall and audit trails for misuse were in place. This was not convincing and we had to take this on faith with our questions remaining unanswered. Confidence has now been eroded to such an extent that the onus lies on the Care Record to prove itself a safe and confidential system of holding and exchanging information on patients.

10. The use of a smartcard by healthcare staff with chip and pin and personal identification number appears to have no safeguards which would prevent the sharing of cards and security codes between staff in a busy department. The audit trail (*Caldicott Guardian*) would not be able to identify misuse by this means where a card was shared between individuals. The July 2005 Care Record Review Document Page 5 states that "although there has been considerable work in this area already, there needs to be further work in order

to define more clearly who will be able to see what." Recent press reports of healthcare staff sharing computer logins for access to patient data are disturbing and undermine confidence. There is no point in having levels of access for different staff, sealed envelopes and audit trails if logins are shared.

11. A National Information Governance Board was launched in December 2006 to look at the quality of information governance and give advice on confidentiality and security of patient information. Again, this should have been dealt with much earlier in the project.

How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research; and

12. The Patient Record does allow great opportunity for the accumulation for research purposes of anonymised patient data on medication use etc. Anonymised data should be used without the need to gain permission from patients. However, if research is not anonymised, then patients should give permission for disclosure by the process of informed consent. An audit trail should be in place for data extraction and retention for research purposes.

13. The records also have a role in tracking public health issues and alerting doctors and patients to forthcoming vaccination and test dates.

14. Please see concerns raised in paragraph 7.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule

15. There are many issues which remain underdeveloped as this project progresses. The summary care record or spine will be in text and then transferred over to codes. There may be problems with codes in their ability to be interpreted in the same way by differing healthcare professionals. They may also not reflect the complexities of clinical information. This was discussed but no resolutions proposed at the Conference. It may be that time has been spent in resolving this problem?

The examples used always refer to the positive aspects of the Care Record for particular patients, and not where difficulties might arise.

16. At the Conference in 2005 questions on the impact of system failure were brushed aside with assurances that there was a good backup system. We can only wonder why stakeholders were not given more detailed explanations of the back-up system, and whether the project leads might have taken the assurances of the IT companies on this issue at face value.

17. Training issues for the input and use of the system must have slowed up the project. The record will only be as good as those who input the information accurately. We would pose the question as to whether this aspect of the project was sufficiently addressed and planned earlier on in the project, in the light of the data loss which has occurred.

18. The core question appears to focus on the supervision and monitoring of the ability of the IT companies to deliver so complex a system.

19. The delivery of the system is now dependent upon publication to the public of their right to view their record. If patients take no action in this regard, it will be assumed that implicit consent has been given for their details to be held on the spine and detailed record. This is a worrying precedent for all issues of consent with regard to the holding of data on an individual. We also wonder whether, in fact, assent by inaction is giving valid informed consent as the patient needs to be fully informed. Some patients may be abroad or miss the publicity announcements. We would like our concern to be noted.

Liz Symonds
Chairman, Patient Liaison Group,
Royal College of Surgeons of England

15 March 2007

Evidence submitted by the Royal Pharmaceutical Society of Great Britain (EPR 56)

1. Introduction and Summary

— 27% of medication errors are caused by poor information availability, costing the NHS £500 million per year.

— Pharmacists should have appropriate role based access to any electronic patient records.

— The modernisation agenda of the NHS is threatened without appropriate access.

— The pharmacy profession has received no firm assurances that it will have access to the electronic records.

1.1 The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis. The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy. The Society leads and supports the development of the profession within the context of the public benefit.

1.2 Pharmacists are the healthcare experts in medicines and spend four years in University before undertaking a years pre-registration training. Community pharmacies are located in the communities in which people live and work, and are the most easily accessible part of the NHS.

2. Information that Should be Held on the Record

2.1 A prescription is an almost universal intervention for patients with Long Term Conditions, and is a factor in the management of most acute episodes. In most cases the only accurate description of what has actually been dispensed to a patient comes from pharmacy computer systems. We would expect this information to be part of future electronic record systems.

2.2 When considering patients preventing personal data being placed on systems it is important to consider the potential consequences of this data not being available. For example, clinicians may not be aware of drug allergies, duplications in treatment or previous dose adjustments which could have serious patient safety implications.

3. Pharmacy Access to the Record

3.1 The RPSGB believes that pharmacists should have appropriate role-based access to any electronic patient record. The information they would have access to would be a pre-determined data set and only information that was required to carry out their role with regard to the individual patient. This might include medication, clinical conditions, allergies, laboratory results and previous adverse reactions.

Effective Treatment

3.2 Currently, pharmacists in community pharmacy only have access to the information included on the prescription they dispense and any previous prescription that they have dispensed for the same patient. If the patient obtains some of their prescriptions from other pharmacies or from secondary care, the pharmacist may not have a full picture of all the medicines being prescribed for the patient. They will also have little information about the conditions being treated. This makes it difficult to assess the appropriateness of the medicines prescribed or whether they may interact with other medicines that the patient is taking. In turn, it is difficult to advise fully the patient about their medicines without an understanding of what diagnoses have been made.

Patient Safety

3.3 The NHS Connecting for Health NHS Care Records service website[60] quotes the following figures:

- The root cause of 27% of medication errors is poor information ability.
- 1,200 people die each year in England and Wales as a result of medication errors, costing the NHS £500 million a year.

3.4 Other research[61] shows that 6.5% of admissions to hospital are related to an adverse drug reaction at an estimated cost of £466 million per year. Pharmacists have the skill and knowledge to be able to detect and prevent many of these safety issues, but do not have access to sufficient patient information to be able use systematically their knowledge and skills to reduce the number of errors, adverse drug reactions and admissions to hospital.

3.5 Access to the record would support pharmacists in helping the Government meet its target of reducing by 40% the number of serious errors in the use of prescribed drugs as well as helping reduce the human and financial cost of prescribing errors.

Modernisation of the NHS

3.6 The Government has been pursuing an agenda of modernising the role of Health Professionals. Pharmacy has been at the core of this. New legislation now allows pharmacists to prescribe independently of GPs. The government has launched its "Pharmacists with a Special Interest" framework to allow pharmacists to provide a more specialist service to patients and to improve access and convenience to patients.

[60] http://www.connectingforhealth.nhs.uk/delivery/programmes/nhscrs (accessed 15 March 2007).

[61] Pirmohamed M et al Adverse drug reactions as cuase of admission to hospital: prospective analysis of 18,820 patients. BMJ 2004; 329: 15–19.

3.7 The new primary care contractual frameworks allow pharmacy to play a more central role in patient care, with more scope for making clinical interventions and integration with the primary health care team. As part of these new arrangement, community pharmacists undertake Medicines Use Reviews, conduct public health campaigns and advise patients on self care and the treatment of minor ailments. Many pharmacists are also involved in providing other locally commissioned services to meet the needs of patients in their locality, for example diagnostic testing, substance misuse, sexual heath and services to care homes.

3.8 Appropriate role-based access to electronic records could also support the seamless transfer of care between primary and secondary care, and improved multidisciplinary working for example with GPs.

3.9 All of these new services have been designed to fully utilise the pharmacists expertise in medicines and integrate this into the NHS. These new pharmacy roles are already improving patient access to services, helping to reduce waiting times, reducing admissions and increasing capacity in primary and secondary care and delivering value for money. However, future success is dependant on appropriate access to electronic records. Without it, the benefits of all of these recent changes may never be fully realised.

Pharmacy Access

3.10 To-date there have been no firm assurances that community pharmacy will have access to the care record database or to the other IT developments other than those required to operate the electronic prescription service.

3.11 Access from pharmacy is also supported by the consumer group "Which?" who have stated "consumers want and expect continuity of care and all healthcare professionals (including pharmacists) involved in their care to have access to their medical record. Without this, how can care be patient centred?" Access was also supported by MP panel members at the October 2006 meeting of the All Party Parliamentary Group on Patient Safety.

4. Confidentiality

4.1 Pharmacists are bound by a professional "code of ethics" produced by the RPSGB. Breaches in this code can lead to removal from the register, meaning that person can no longer practice as a pharmacist.

4.2 Pharmacists have operated patient medication records for a number of years and already have robust systems in place for handling patient confidential information, and in addition to the above ethical requirements are subject to a wide range of legal, ethical and professional requirements.

4.3 Pharmacy contractors are required to comply with the legal obligations of the Data Protection Act 1998 and the common law duty of confidence and under the NHS community pharmacy contract, pharmacy contractors and their employees must conform with the NHS code of practice on confidentiality. The clinical governance framework ensure compliance by including policies for ensuring staff are appropriately trained and that all staff contracts include clauses on patient confidentiality.

4.4 The RPSGB welcomes the additional safeguards being introduced, including the use of "smartcards" to control access. It is important that these safeguards, however, do not impinge on patient safety by unduly restricting access at the same time respecting an individuals right to confidentiality.

5. Progress of Connecting for Health

5.1 The RPSGB feels that the CfH programme would benefit from greater clinical engagement, and welcomes the recent changes to its structure that are being made to address this. There are still concerns, however, over the level of engagement with the pharmacy profession and its involvement with this and other aspects of the programme.

5.2 Overall the RPSGB is supportive of the Connecting for Health programme and the progress it is making.

The Royal Pharmaceutical Society of Great Britain

16 March 2007

Evidence submitted by the Socialist Health Association (EPR 62)

The Socialist Health Association was founded in 1930 to campaign for a National Health Service and is affiliated to the Labour Party. We are a membership organisation with members who work in and use the NHS. We include doctors and clinicians, managers, board members and patients. Our interest in public and patient involvement is longstanding. Our members are involved in a wide variety of ways in health and social care. This submission is made on behalf of the Association.

1. There is a lot of hysteria about electronic health records. Those of us who have worked inside health institutions have no illusions about the safeguards applied to paper records which in most healthcare establishments are open to casual inspection and interference by anyone who has sufficient determination to find them. Furthermore the paper records are very often not available when needed, even in the institution where they are created. There is almost no system for making records available to any other institution. We think that any decisions made about electronic records need to be put in that context. Electronic records, however imperfect, are likely to be an immense improvement on what exists now.

2. We would want to see the most comprehensive information kept in electronic record systems. We are alarmed to discover that it is proposed to exclude mental and sexual health from the record. In our view that seriously undermines the clinical usefulness of the system. It also contributes to the continuing stigma attached to these areas. If this foolish idea continues we hope that it will be possible for patients to decide to include this information in their record.

3. It is important that patients have free access to anything in their own record. That should improve trust between patients and clinicians and encourage both to be truthful and to see healthcare as a joint responsibility. For some patients—children and those unable to make their own decisions—it will be important that carers also have full access. We would like to see computers made available in GP surgeries and hospitals which could be used by those who do not have access to their own facilities. Some information in the record may need some sort of interpretation if the patient is to understand it. And the record might include reference to information which is not there—like recent records of blood pressure or alcohol intake. We suggest that it might help confidence in the system if individual patients were able to make their own decisions about who was allowed to access their records and in what circumstances. However we find it hard to see who any clinician could be expected to take responsibility for the care of a patient if they were not allowed access to the record. A system which alerted patients when their electronic record was accessed, if they were not present, might also help instill confidence.

4. We would want to see widespread access to aggregated data which did not identify individual patients. Anyone wanting access for research purposes to data about individual patients should need to demonstrate informed consent.

5. The question of whether patient data can be adequately protected is a technical one on which we are not qualified to comment. However it seems hard to see how electronic records could be less protected than the existing paper systems.

Martin Rathfelder,
Director, Socialist Health Association

16 March 2007

Evidence submitted by South East Health Ltd (EPR 13)

1. Executive Summary

We are a not-for profit limited company, providing out of hours primary care services to a population of over 900,000, covering parts of East Kent, together with the East Sussex coast including Brighton. Our services are commissioned by four Primary Care Trusts (Eastern & Coastal Kent PCT, East Sussex Downs and Weald PCT, Hastings & Rother PCT and Brighton & Hove City PCT.)

We note the focus of this new inquiry and our written evidence relates to three of the five areas given in Press Notice No. 12, namely:

(a) *Who will have access to locally and nationally held information and under what circumstances.*

Our submission below stresses the importance of our out of hours primary care service having access to "in-hours" patient records, and in particular, those held by the patient's GP Practice.

(b) *What patient information will be held on the new local and national electronic record systems*

Our submission below indicates that generic patient details should be accessible for matching and verification. We also advocate that a patient summary should be made accessible to the clinicians of our out of hours service, compiled from information stored in the computerised GP Practice patient record.

(c) *Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to 2 years behind schedule.*

Our submission below stresses the importance of delivering the new systems in the out of hours context. We mention some previous complaints concerning the out of hours service which have highlighted the problems which can arise when continuity of patient care is jeopardized by lack of access to previous medical history.

2. Submission

(a) *Who will have access to locally and nationally held information and under what circumstances.*

South East Health Ltd welcomes the interest of the Committee in this area of focus. Our organisation is commissioned by a group of Primary Care Trusts (PCTs) to provide an out of hours primary care service to their combined populations in East Kent and East Sussex. The total population served is around 900,000.

The demography is diverse in terms of age ratios, population distribution and culture. Large parts of the Romney Marshes and the Rother Levels are rural, thinly populated areas. In contrast Brighton is densely populated, multi-cultural and cosmopolitan.

As a result of the new General Medical Services Contract 2003, GP practices were no longer obliged to provide patient services in the evenings, or at weekends or Bank Holidays. The responsibility for such provision, which had previously been handled by groups of practices working together as GP Co-ops, was now passed to the local PCT. The PCT then commissioned the service from out of hours provider organisations such as South East Health Ltd.

The Department of Health and indeed HMG, have been concerned to stress the importance of a 24/7 Health Service. This cannot work effectively without continuity of care.

South East Health Ltd employs doctors on a sessional basis, to cover its evening/overnight and weekend shifts. The likelihood of a GP seeing one of his/her practice patients when the GP is working for South East Health Ltd as an out of hours duty doctor, is remote.

The out of hours duty doctor will have the following patient information available to him/her when a telephone advice consultation or a face to face patient consultation is about to be made:

(i) generic details of the patient—name, date of birth, address, own GP

(ii) current symptoms/health problem(s) (as described by the patient or their carer, to the South East Health Ltd call operator)

(iii) references to previous calls, if any, made to South East health Ltd.

(iv) special Notes if any—essentially, attention flags for the information of the clinician, provided by and at the discretion of, the GP practice or other healthcare provider, eg if the patient has been removed from a practice list and is subject to a local violent patient scheme.

It follows therefore that medical history details, including operations, illnesses, allergies, allergic reactions to medications, etc, etc, could be of significance in the context of the out of hours consultation, and under existing arrangements, may well not be known to the out of hours clinician.

At best this situation compromises continuity of health care—at worst it is dangerous and might be life threatening.

We would therefore strongly urge the Committee to be mindful of the need for access to GP practice patient information by the out of hours service.

(b) *What patient information will be held on the new local and national electronic record systems*

We hope that we have justified our need for access to patient records out of hours, as in 2a) above.

The out of hours clinician needs to have historic details of the patients and details of recent healthcare events or episodes. The natural source of this information will be the patient's computerised GP notes. For example, a patient who has contacted the out of hours service for advice/treatment might have had a recent hospital episode.

The patient or carer may not be fully aware of the details of this episode. However, a discharge summary will have been sent by the acute hospital to the GP practice, and the details will have been captured and stored within the GP patient record.

We would advocate that an extract summary of the patient's GP record should be routinely posted on the National Data Spine so that it can be made available to the out of hours clinician.

An extract summary could include:

— Generic patient details

— History of illnesses

— History of other significant events eg pregnancies

— History of medical treatments

— List of current medication (Repeat and Acute)

— Immunisation record

— History of operations
— Allergies
— Recorded reactions to medication
— Medications contra-indicated
— Summary of hospital episode(s)
— Existing Special Notes / Management protocols

(c) *Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to 2 years behind schedule*

In common with other out of hours providers, South East Health Ltd (formerly Seadoc Ltd and Brightdoc Ltd) has file records of a number of complaint cases in which the continuity of care had been compromised by the lack of access to previous medical history. In a minority of cases the complaint had escalated to the Healthcare Commission and in two instances, to the Parliamentary & Health Service Ombudsman.

In such cases we have been at pains to point out that we have promoted and implemented upgrades to our out of hours database software to go as far as we can in minimising the risk of repetition. For example the system now alerts clinicians to previous out of hours contacts (last six calls).

However we have also respectfully pointed out that the lack of access to GP practice summary patient extracts is outside our control.

Ron Owttrim
Chief Executive, South East Health Ltd

March 2007

Evidence submitted by Statis Ltd (EPR 05)

STALIS LTD

Our credentials for making this submission to the Select Committee are that Stalis Ltd, based in Oxfordshire, has for the past 25 years provided a range of IT systems and services to the NHS whose long standing clients include Moorfields Eye Hospital NHS Trust, The Oxford Radcliffe Hospitals NHS Trust and Sheffield Children's NHS Trust as well as the independent Capio hospital group.

Following the introduction of the NPfIT Stalis has majored on assisting Trusts and their LSPs with Data migration, cleansing and the provision of interim Patient Administration Systems (PAS). Over the past three years Stalis has undertaken contracts with BT (for 9 London PCTs to migrate and archive data from legacy Child health systems), Accenture (for 4 Essex based PCTs to migrate and archive data from legacy Child health systems) and Fujitsu (directly contracting with 4 NHS Hospital Trusts to migrate, cleanse and archive data from PAS, A&E, Theatres and Maternity modules). We are also in the final stages with Moorfields of replacing their mission critical PAS due to the fact that BT and its main systems partner IDX (and now Cerner) could not provide an adequate solution to meet the Trust's needs.

Based on this past and current experience of working with LSPs, their system suppliers and NHS Trusts we respectfully submit this assessment as evidence of both the failings with the NPfIT and the opportunities for the programme to be salvaged for the benefit of the NHS, tax payers and patients. Specifically the response addresses the item:

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule.

INTRODUCTION

1. The purpose of this submission is to provide a synopsis of the background to and lessons that might be learned from the NPfIT and its management by Connecting for Health (CfH). It further indicates how the current problems with the failure to deliver Care Record Services (CRS) to NHS hospital Trusts can be turned round within the current investment levels.

2. As one of, if not the, most ambitious public sector ICT project ever undertaken it is not surprising that NPfIT has so far fallen far short on its overall delivery goals, and in particular, the Care Record Service (CRS). In 2006 the National Audit Office report, indicated that the programme is at least two years late. This is not to say all aspects are suffering the same delays but the key components of the National Spine, Choose & Book and, most of all, the Care Record Service (CRS) for acute hospitals is significantly adrift from its original goal.

Reflections on NPfIT so far

THE CONTRACTING PROCESS

3. Given the magnitude of the undertaking and the history of failure with previous public sector IT projects (Passport Office, Child Benefits etc) the programme was placed in the hands of an externally recruited senior IT figure—Richard Granger from Deloitte & Touche. With a launch budget of £2.3 billion and a timescale of approximately two years to put in place all the necessary suppliers and contracts, NPfIT was launched. This was exceedingly ambitious by any standards and the "haste" contributed to a serious lack of NPfIT, supplier and solution due diligence. The speed of procurement also precluded user (Trust and specifically Clinician buy in to the solution). This lack of buy in caused much of the delay during the early months of deployment.

4. It is to Mr Granger's (and the CfH team) credit that he achieved the early "political" goals in that contracts were placed more or less within the two years and the total contract value was held within the £2.3 billion). However, all this was accomplished at a price and against some ill founded concepts as set down below:-

5. Mr Granger had never undertaken a programme approaching this magnitude of scale and complexity—in fairness, few if any have—and had no prior knowledge of the healthcare IT requirements within the NHS.

6. From the outset Mr. Granger, and those within government directly involved, appeared to believe that all current systems operating within the NHS were in need of replacement. (At a public meeting with the IT industry at the outset of the programme Mr Granger was heard to describe current systems as "rubbish") and that no UK suppliers had the capability of meeting the needs. Furthermore, Mr Granger told the supplier industry that "UK companies had not served the NHS well and so could not expect much business". This demonstrated the lack of understanding at the time that was instrumental in guiding the programme.

7. The original concept was that all legacy systems would be replaced in a few years—a feat that was never realistic and demonstrated a total lack of understanding within NPfIT / CfH. The "Legacy Systems Team" within CfH quickly came to recognise the value of the existing systems and the magnitude of the task facing the NHS in replacing these. CfH then renamed the team to "The Existing Supplier Team" reflecting that some/many legacy systems are strategic and will need to be retained for many years.

8. CfH made clear that they considered only companies with no previous track record in the NHS were likely to be successful, and in particular, US companies. This view prevailed during the early stages of the procurement process thus encouraging companies to participate who would otherwise have seen their lack of experience as a material weakness (rightly) in any such project.

9. Only large global service companies (Local Service Providers—(LSP)) would be considered as main contractors as they were the only ones likely to have the human resources to scale up for the projects and the balance sheets to take on contracts with severe financial penalties. The issue of whether they had NHS IT experience was not viewed as key at the final selection/contract stage.

10. Because Mr Granger had no previous experience in healthcare he initially failed to appreciate the complexity and diverse nature of the requirements. Similarly, none of the LSPs had in-depth healthcare IT expertise in the UK, or really understood the needs of the NHS. Thus for the first three years of the programme (two years of procurement and the first year of implementation) NPfIT was driven in an environment of ignorance of the true NHS environment.

11. The funding for the projects did not include the provision of funds for the migration and cleansing of data from existing systems to the CRS or even acknowledge the significance of this part of the program. In many cases, it was not even understood that data migration into the new systems would be required as part of the ongoing support of the Trusts' operational systems. NHS patient data is generally of a poor standard with most hospitals having electronic records that contain many duplications, incomplete fields of data and data stored in areas of the systems for which the systems were not designed. Trusts have records spanning between 10 and 20 years so the need to clean these is significant to the success of NPfIT and the CRS.

IMPLEMENTATION EXPERIENCE

12. The LSPs commenced the programme with little or no experience in UK healthcare and little experience anywhere of the systems required by the NHS. Although this has improved with some LSPs it is not consistent across the NHS and remains an issue today.

13. The LSPs appeared to place their reliance on what their sub-contractors committed to deliver and placed their trust in the contract terms to hold them safe. LSPs also fell into the trap of believing the NHS would accept the systems without question and would abide by project timescales imposed by the LSPs. The naivety of this contributed to the early implementation experiences when it became apparent Trusts would not accept (and could not for resource and operational reasons) inferior systems compared to what they already had.

14. There was little experience of the existing "legacy" systems. In conjunction with this, there was little appreciation of the number and variety of systems to support clinical applications that were "held together" by the existing legacy Patient Administration Systems (PAS) due to be replaced.

15. The LSPs built project teams very quickly in the naive belief that the NHS would accept their delivery schedules and that the software would be ready. They, the LSPs did not have the skill or experience to evaluate the software suppliers, hence many of the problems with iSOFT, IDX and Cerner, are systemic and continue to this day—the US company Cerner cannot provide the reporting capabilities necessary to support NHS Trusts (as is evidenced from the early users in the Southern Cluster).

16. Both IDX and Cerner systems have never been successfully implemented in the UK, being systems configured for the US market (which is one focussed on patient billing in discrete establishments rather than the UK model of focus on administrative/clinical systems over multiple site establishments).

17. Large teams of project staff worked to a rigid methodology that was ill fitted to the NHS and the implementation of clinical systems. Many Trusts acknowledged that there was a huge culture gap between the NHS approach and the LSP approach.

18. The NHS was not prepared for the magnitude of change required, and is still not after more than three years. Trusts are unprepared for the tasks required by NPfIT to create a secure patient information system and for the data migration involved.

19. Because of the delays and the unsuitability of the CRS software especially at the hospital level, Trusts have lost three years of progress and are now being forced into implementations where they may lose important functions in their systems.

20. The project approach by the LSPs has been to deliver to an implementation plan which has been ratified by the NHS at the cluster level, but with no recourse or discussion with existing suppliers. The existing system suppliers have also been held at arms length from the LSPs and their partners delivering the replacement systems thus ensuring that communication is at best convoluted or at worst, non- existent. We have had experience of this as a supplier of data migration services, not contracted through the LSP, being prevented from direct communication with the system supplier, and we believe this has also been the case for the Trusts. The situation has improved in some areas but largely due to local initiatives rather than a deliberate policy.

21. Although the UK healthcare IT supplier industry contained a wealth of skill, experience and useful systems these were largely ignored by the LSPs in the first two years of implementation. This has changed somewhat but is still far from ideal in that the LSPs do not make communication with outsiders easy. This may be due to the conflict of interests in areas where suppliers are in direct competition with the LSP for additional services.

Lessons for future success of NPfIT

22. Attempt to introduce any major IT programme against political led time schedules is fraught with danger and should not be the basis for any future implementation timescales. Although projects need targets, and there is nothing wrong in having challenging timescales, project goals must be realistic and those for NPfIT in general and CRS in particular were not.

23. Governments, of whatever political persuasion, will likely wish to change their strategies on public sector health care and so continually alter the data set and reporting requirements—as evidenced by the 18 week wait policy. Specification creep is a nightmare for NPfIT, Trusts and IT suppliers to deal with in a project of this magnitude. Such changes also underpin the need for NHS specific Patient Administration Systems rather than non UK solutions which are designed for very different healthcare environments such as the US.

24. Most healthcare systems vary significantly country to country especially in respect of administrative, billing and HR rules and requirements. It is these issues that cause the most problems for healthcare providers and their suppliers. Systems are typically designed for their home markets and not for a multi country/world model approach.

25. The US healthcare market is very different from the public sector systems found in the UK, Ireland and parts of continental Europe. As such, any systems built in the US face the prospect of the greatest changes.

26. Replacing working PAS and the like is counterproductive. It is better to leave the PAS functions to local suppliers whereas clinical applications are more widely applicable and so can be added and allow faster progress to be made.

27. Centrally driven projects are rarely successful. It would have been far better (as supported by the BCS) for CfH to set the standards, control the national applications like the Spine, and allow the Trusts to choose from an accredited supplier portfolio who meet the national standards (as advocated for GP systems). This would have created local impetus, ownership of the solution, and a vibrant competitive UK industry in which the overseas firms could have competed but not dominated.

28. The success to the implementation of systems is not having large global corporations. It is recognising that the software must be fit for purpose and that this can come from small companies with appropriate healthcare expertise within the local economy. Large resources in service companies for volume roll-out can be trained.

Impact assessment

29. Overall the programme remains in place despite all the setbacks and failures. It is to the Government's credit that they continue to support NPfIT and give encouragement to all stakeholders to stay the course. The message that NPfIT is material to the NHS and its reforms remains an essential underpinning of the investment

30. For the NHS as a whole and its staff, NPfIT has shown few benefits with the exception of improved networking (part of the original plan) and GP payments, email and PACS (all added later). By contrast many NHS Trusts have been significantly disadvantaged by having to wait for the delivery of systems that could have been provided by smaller UK suppliers (iSOFT notwithstanding).

31. Although the "central" message is that the tax payer has been protected this is not true in that ultimately the tax payer picks up the cost of delay and the increased cost of the programme (now estimated at £12 billion). Delays to delivery, the waste of NHS resources due to repetitive work following inadequate software deliveries, and the lack of progress in improving workflows all has a cost to the NHS and thus the tax payer

32. The failure to modernise the NHS to the extent required is in part due to the fact that NPfIT has not met its objectives. However, NPfIT is not wholly at fault. The NHS has not applied itself to the programme due in part to the series of NHS re-organisations during the past four years.

33. NHS staff have and continue to suffer from the burden of having inappropriate systems "not fully fit for purpose" forced on them. The NPfIT made no allowance for the fact that NHS staff and clinicians are under pressure and have little time to devote to the magnitude of the change especially when LSP's are forcing delivery dates on them as they now are due to the financial pressures caused by non payment. It is well known that the LSPs are faced with significant losses which exacerbates the pressure on Trusts to "go-live" with systems that are not fit for purpose nor rigorously tested.

34. Ruling out the UK supplier industry from the programme was a fundamental mistake and all but destroyed the sector. This has meant that much of the ICT skills and software development potential that could have help build our health IT industry into a world class industry was handed to mainly US companies (Cerner, IDX, Accenture, CSC). Now, due to the delivery slippage and underperformance the value of UK suppliers and their systems is being recognised and has the potential to save the programme.

35. The belief that only large companies could handle the programme was flawed. It is true that large volumes of human resources are needed for managing and implementing multiple concurrent projects. However, the production and supply of NHS specific software does NOT require large companies. On the contrary the majority of successful systems in the NHS come from relatively small suppliers. If NPfIT had appreciated that the basic software could be provided by UK suppliers the LSPs could have been trained to implement the software to meet the CRS requirements.

The Way ahead

36. The NPfIT has achieved some considerable and measurable improvements in the provision and application of modern IT systems for the benefit of the NHS and its patients. Most notable among these are PACS (imaging systems), the BT provided N3 broadband network, and some GP/Community systems. Choose & Book and the Spine have made some progress but both remain some way from their original goals. It is noteworthy that the most progress towards Choose & Book has been made by Trusts enhancing their existing PAS, not replacing for one of the new NPfIT solutions.

37. The Care Record Service (CRS) is the one programme within NPfIT that has the worst record of delivery and yet it is, perhaps, the most needed. Although LSP CSC continues to implement the legacy iSOFT system to the benefit of those Trusts with archaic legacy systems it is not the modern futuristic solution (Lorenzo) originally contracted. Likewise, in the London and Southern clusters, both Fujitsu and BT are underperforming due to the Cerner Millennium product needing far more change than expected, and there are doubts that it can ever meet the underlying and changing needs of the NHS for a robust NHS workflow related PAS which underpins CRS.

38. However, much of the time that has been lost could be made up if the strategy was changed. What we respectfully suggest is that consideration be given to the following:-

39. There are many Trusts with perfectly adequate PAS that could be supported for many years to come. Instead of replacing these they should be retained and clinical systems added to them. This offers significant benefits

(a) Although the data cleansing would still need to be undertaken there would be no data migration

(b) The Trust's operational support is unaffected and resources are not wasted on a one year cycle of replacement

(c) Clinical systems can be implemented to the benefit of clinicians and patient care far sooner than with the current programme

40. Those Trusts that need to replace their PAS should use pre existing UK developed systems (of which there are several) that already meet the NHS requirements especially for reporting. This strategy would allow BT and Fujitsu particularly to recover lost ground and would provide a sound IT platform on which to implement the Cerner clinical applications. It would also overcome the lack of reporting capability in the Cerner product.

41. CSC has demonstrated with iSOFT that, despite the latter's inability to deliver its new system Lorenzo, the deployment of a UK built PAS (iPM) can meet NPfIT needs. CSC has implemented more PAS than the rest of the LSPs combined (including Accenture prior to their departure). CSC is showing that a UK PAS with a separate solution for clinical applications is viable (the iSOFT iCM product originated from the US).

42. Such a strategy would also save the programme significant new expenditure. We understand that when CfH/DoH requires changes (usually known as Data Set Change Notices—DSCNs) the charge made by Fujitsu/Cerner for even minor amendments is substantially in £six figures—this would be avoided.

43. Trusts should be free to choose which PAS suits them best from an approved list of suppliers which are committed to meeting the mandatory standards of the NPfIT .

44. With this approach the modernisation of IT within the NHS can gather pace—without this the CRS programme will continue to under-perform to the detriment of the NHS, its patients and tax payers.

R Roger Wallhouse
Chairman, Stalis Ltd

March 2007

Evidence submitted by Symantec (EPR 37)

1. Symantec welcomes the opportunity offered by the Health Select Committee to submit evidence on issues relating to the use of patient data in the development of electronic record systems and the importance of ensuring the security and confidentially of individuals' sensitive medical information.

EXECUTIVE SUMMARY

2. Building an electronic healthcare information system in the UK presents both real opportunities and challenges. We are convinced that the implementation of information communication technology can improve the quality, efficiency and cost effectiveness of NHS operations whilst also providing more citizen centric services. However, the deployment of such an extended IT infrastructure to support the NHS objectives could raise some concerns over the security and confidentially of personal information processed, stored and shared electronically. At the same time different NHS bodies and institutions are moving towards greater interoperability and networked collaboration at varying rates and speeds; resulting in the development of a complex IT infrastructure. Symantec understands and recognizes the immense challenges being faced by the NHS in implementing technology across a vast, varied and largely decentralized organization. We believe an integrated approach to information and systems management is needed across the NHS, at both a local and national level, to ensure the security and confidentially of patient data is assured and that medical information is readily and securely accessible to a broad array of individuals including patients and staff.

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems?

3. It is understood that a summary of information on each NHS patient will be held on a national database of electronic records known as the Spine. However, due to the lack of bandwidth allocated to the database, the Spine will not be able to hold all the medical information relevant to each patient. The lack of bandwidth means the amount of data able to be stored on the database will be limited and the ability to download the data in any meaningful timeframe restricted. As a result the majority of patient data will remain stored and managed at local level by NHS entities on local databases and existing record systems. Within this current NHS landscape the main responsibility for patient information will rest at the local level. As a result there is an implicit requirement on local bodies to have in place effective data management tools and security solutions currently available in the market.

4. However, there is a concern that the local NHS bodies responsible for storing patient data do not have adequate processes, procedures and systems in place to ensure the available, integrity and confidentially of patient information. For example, no standard policies or procedures currently exist for data management across all NHS local healthcare bodies. This has lead to a variety of approaches taken to storing data relating to patients; ranging from the storage of all data, resulting in the creation of complex and unmanageable databases, or only minimum data being stored resulting in vital patient information, for example contained in emails correspondence simply being deleted. NHS organisations need to understand and recognize the importance of a holistic approach to data security, management and storage across the NHS. This will require a change in the businesses practices of local NHS bodies and a recognition that technology alone cannot be relied upon when developing and implementing new electronic record systems. Education and training of NHS staff, at all levels, on the importance of data management will also be required.

5. The right of patients' to remove records from the NHS electronic record schemes presents a major barrier to the NHS realizing the full benefits from technology enabled change. The trust and buy-in of citizens to share personal information with government online databases is vital to the success of the new era of public sector delivery. It is also an aspect of regulatory compliance with the Data Protection Act for NHS. We believe having standard and common processes and procedures in place to ensure the integrity, confidentially and security of patient's information when shared, processed, accessed by the individual right holder and stored by the NHS, whether it be at a local or national level is key to gaining patients trust.

Who will have access to locally and nationally held information and under what circumstances? Can patient confidentiality be adequately protected?

6. Fears over unauthorised access, misuse and possible theft of medical information presents a major challenge to the successful implementation of an electronic healthcare information system in the UK. Ensuring access to patient information, whether at a local or national level, is only allowed to appropriate medical professionals is therefore a key factor in gaining the trust and buy-in of citizens. Data management solutions currently exist that can enable patient information is not only held securely but can be accessed by appropriate medical professionals when required in a way that ensure patient confidentially is maintained.

7. Data management systems enable data across an organization, such as an NHS Trust, to be held centrally and according to standard policies, procedures and requirements. Having a standard system in place enables access levels to be allocated to particular types and levels of data. The introduction of access controls in the NHS electronic records system would ensure only designated NHS personnel have the right to access patients sensitive information; reassuring citizens that their data is not vulnerable to unauthorized access or misuse. The access given to NHS staff could be monitored and audit trails produced, providing additional reassurance to patients that the confidentially of their data is being maintained. Access levels can also be used to dictate the information that can be shared outside an organsiation for example to another NHS body or even to the NHS Spine database itself. The introduction of effective access levels in an electronic records system would require common data management procedures and practices to be developed and implemented by all NHS bodies connected to the system. It is argued that such an approach to data access would have been easier to enforce if a national NHS data store, as originally envisaged under the NHS Spine project, had been achieved. Now that we have a situation where data is spread across many disparate systems and NHS bodies, putting a common system in place that can ensure secure access levels to patient data will be much more difficult.

8. While having access levels in place can ensure electronic patients records stored on databases can be held securely, there is a real concern that the confidentially of patients sensitive information is being put at risk by the increasing use of email and internet based communication tools. The NHS has come to rely on email, and increasingly Instant Messaging (IM), to improve communications within organisations and enable the sharing of patient information with partners quickly and efficiently. While this is enabling the level of patient care to be improved, Symantec is concerned that email and IM systems are increasingly becoming large repositories of patient's sensitive personal information. In particular we are concerned at the use of IM by medical staff due to the security vulnerabilities of this type of communication. IM is generally unprotected and unmonitored leaving it vulnerable to attacks. The infection of one computer with a computer virus using IM can result in messages being sent to all users in an IM contact list on that machine, creating the potential for rapid spread of security threats. We believe consideration needs to be given to the security procedures in place to protect the confidentially of patient information stored in emails and common agreed policies for the use IM by all NHS bodies. The current lack of procedures and processes for the secure management of patient data captured within emails and used in IM is resulting in patient information being open to misuse, attack and theft.

9. Having patient information that is readily accessible, and yet secure, to medical staff as and when required is an essential requirement of creating an effective electronic healthcare system. However, we are concerned at the lack of procedures and systems in place by NHS bodies to ensure critical information, applications and systems are continuously available. The lack of common policies and procedures for data backup by NHS bodies is regarded as a key threat to the availability and confidentially of patient data. For example, within a small doctor's surgery it is common for an office administrator—usually untrained in data management issues—to be relied upon to manage backup tapes. The offsite management of these tapes usually consisting of staff simply taking tapes home overnight. For large bodies such as NHS Trusts, few

have disaster recovery systems in place that can ensure if data is lost or destroyed at one site it would be accessible from a secondary secure site. If the NHS is to have safe and secure access to patients data across a number of disparate sources and bodies, serious consideration needs to be given to the development and implementation of standard data retention policies, disaster recovery procedures and data storage and retrieval systems across all NHS bodies.

10. It is also considered important that patients are assured that the confidentially of data is protected even when it is no longer required. Disposal and destruction of redundant, modified or corrected data, and the legacy systems or devices that patient data may have been saved on is just as important as protecting current patients medical data. Data destruction technology exist that can ensure NHS requirements can be adhered to. However, this is an example where it is not just the technology solution that must be considered but also the processes and training needed for NHS employees to understand and recognize the need to protect patient information that is no longer required or relevant. In an era where identity theft is a key concern, it is vital that the NHS recognize the need to protect patient information from the cradle to the grave and beyond.

How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research?

11. The introduction of new technology provides the NHS with opportunities to provide improved services and develop new innovative ways of to addressing patient's needs. Current demographic trends suggest that the number of elderly people in the UK will increase dramatically in the coming years. As a result the NHS is expected to move towards delivering clinical services to patients away from hospital and doctor's surgeries and out into local communities and patients homes. A move away from hospital centric care means NHS staff will require remote real-time access to up-to-date and accurate patient information from mobile networked enabled devices such as laptops and PDAs. As a result the established perimeters for data usage, storage and security will disappear as information begins to flow outside hospitals. This will lead to mobile NHS workers responsible for the security of sensitive, and potentially valuable personal information, becoming increasingly targeted and vulnerable to online security attacks. If the NHS is to move towards a new of service delivery where doctors and nurses are using such mobile devices, the security of the data held and shared via these devices is an issue that must be addressed sooner rather than later.

12. Symantec is concerned that many NHS organisations are enabling staff to access NHS systems containing electronically stored patient records often on unmanaged laptops and other endpoint devices. There are no guarantees that these devices have the latest security patches, up-to-date antivirus definitions or a personal firewall. In addition there is also a concern that mobile NHS staff may be relying on patient's home wireless connections to access internet based databases. Without the latest security patches, up-to-date antivirus technology or even firewalls, devices being used by NHS staff may already be infected with security threats and as a result could be putting the NHS network at risk from security attacks. For example an insecure wireless connection can lead to personal sensitive medical information being open to possible unauthorized access, misuse and even theft. We believe a key priority for the NHS to ensure the confidentially of patient data is the development of common and standard IT security policies should be in placed across all NHS organisations to ensure that only compliant and secure devices are used to process sensitive patient medical data and also connect to NHS networks. There is a concern that different NHS organisations that currently collaborate and share patient information do not have adequate security policies put in place to protect information that is shared.

13. For example, it is understood that NHS Acute Trusts and Primary Care Trusts (PCTs) have autonomy to develop their own policies and requirements to control remote access to patient data. While it is not suggested that the autonomy granted to these authorities should be removed, it is important to note that a clinician providing services remotely to a patient, whose records are held by two different hospitals, may be required to conform to multiple policies, requirements and procedures in order to access patients data. A situation where clinicians are required to adhere to multiple sets of procedures or processes for accessing data could result in errors being made in the processing and accessing of data that may have a direct impact on the delivery of patient care. It is suggested that consideration should be given to the development of common access control procedures and policies that can enable the development of a single system for access to patient information securely and accurately. In England this system should be shared by the ten Strategic Health Authorities; similar common procedures should also be developed for use in Northern Ireland, Wales and Scotland. The development of a single, common and agreed policy that is shared by all NHS bodies could ensure the processes put in place would not need to be changed as the boundaries of the NHS map continue to evolve.

14. The data gathered and held by NHS bodies may be useful for the provision of other services other than treatment. However, the use of the data must not jeopadise patients right to confidently. If data is going to be used for purposes other than treatment then strong safeguards, such as informed consent and appropriate access levels, must be in place.

What is the current progress of the development of the NHS Care Records Service and the National Data Spine and why is delivery of the new systems up to two years behind schedule?

15. The delays that have occurred in the projects to date can be attributed to many factors including ongoing changes to the design and specification of key systems, radical project re-thinking, tensions over payments for completed development work and the departures of key project partners. It is also suggested that delays have occurred due to a lack of consultation and involvement by the NHS bodies themselves in the design and specifications of proposed systems and services. For example, a lack of consultation with local NHS bodies on the types and amount of patient data they currently hold and would need to be incorporated into a national medical records database. This resulted in the Spine database being developed without the adequate bandwidth required; resulting in the re-thinking to and significant delays experienced in the delivery of the Spine project. There is real concern that a lack of consultation with NHS staff on the development of new systems has the potential to create an aversion by local disenfranchised staff to use the new technological solutions introduced even possibly a desire to see the new mistrusted systems fail. Going forward the trust and buy-in from NHS doctors and nurses, will be just as an important to the success of technology enabled change in the NHS as will patient's willingness to share their medical information with electronic online record systems.

Susan Daley
Symantec Corporation

16 March 2007

Evidence submitted by the UK Clinical Research Collaboration (EPR 52)

1. Executive Summary

1.1. The UK Clinical Research Collaboration (UKCRC) is a partnership of organisations working together to establish the UK as a world leader in clinical research. The UKCRC brings together the key organisations that shape the clinical research environment and includes the main UK funding bodies, academia, the NHS, regulators, patients and industry. Its key drivers are to improve national health and increase national wealth.

1.2. We have a unique opportunity to access data from a National Health Service (NHS) providing healthcare to a population of more than 50 million patients in order to conduct high quality research for patient benefit. This opportunity has been identified by numerous stakeholders as a unique selling point for health research in the UK and one in which the UK should be in a position to take a global lead.

1.3. If this is to be achieved we need to ensure that the NHS Care Records Service (CRS) is developed in a way that facilitates high quality research and we also need to ensure that robust and transparent mechanisms are in place to protect the rights, safety and dignity of the people whose data is held on the NHS CRS.

1.4. The UKCRC R&D Advisory Group to Connecting for Health (CfH) was established under the sponsorship of Professor Sally Davies, Director of Department of Health Research & Development Directorate and Richard Jeavons, Director of Implementation for CfH. Chaired by Professor Ian Diamond (CEO of Economic and Social Research Council) the role of the Advisory Group is to consider the feasibility of using the NHS CRS to conduct high quality research for patient benefit. The Group have recently commissioned a series of simulation exercises to investigate the feasibility of using the NHS CRS as a platform for health research. The resulting report considers the technical, operational and governance issues that need to be addressed in order to facilitate high quality research for patient benefit. It demonstrates the immense potential that linked electronic records have to enable research across a very wide range of applications which will have the potential to impact positively on patient health and safety. The report includes recommendations for change and is currently being considered by the Group's sponsors.

1.5. In parallel with the work of the UKCRC R&D Advisory Group to CfH, complementary work has been conducted by a subgroup of the Care Records Development Board (CRDB) on secondary uses of patient data. This multi-stakeholder group, chaired by Sir Robert Boyd has concentrated on consideration of the appropriate governance arrangements needed to enable secondary uses of the data. Robust information governance will need to be responsive to the needs of research that relies on access to data that may need to be linked (using a unique identifier) at a patient level (identifiable data).

1.6. Facilitating access by the research and public health communities to electronic patient records has substantial benefits for patients and the health service. Since research shares a mission of improving patient care and patient safety it is integral to patient benefit. Access to patient data for this purpose should be considered a primary and not a secondary use.

2. Background

2.1. The UK Clinical Research Collaboration (UKCRC) is a partnership of organisations working together to establish the UK as a world leader in clinical research. The UKCRC brings together the key organisations that shape the clinical research environment and includes the main UK funding bodies, academia, the NHS, regulators, patients and industry. Its key drivers are to improve national health and increase national wealth.

2.2. The UKCRC was established by the Chancellor of the Exchequer in his 2004 Budget and the Partners have been working together for a little over two years focusing activity on five main areas: Building up the infrastructure for research in the NHS; Building up the research workforce; Developing incentives for research in the NHS; Streamlining the regulatory and governance environment; and Coordinating research funding.

2.3. Key achievements over this period include:

- Establishing a UK-wide infrastructure within the NHS to underpin clinical research, the UK Clinical Research Network (UKCRN).
- Launching a £134 million coordinated initiative to build a national framework for experimental medicine research, supported by a range of funders.
- Agreeing major initiatives to streamline the regulatory and governance environment and starting to implement change.
- Developing, funding and implementing a new integrated and flexible training pathway for clinical academics.
- Carrying out the first ever UK-wide analysis of health research funding.
- Developing a joint £20 million initiative to fund Public Health Research Centres for Excellence in the UK.

2.4. An important part of the UKCRC's work is to promote cultural change and develop new ways of working, in particular with the bioscience, healthcare and pharmaceutical industries.

2.5. In 2006 the UKCRC commissioned McKinsey and Company to carry out a study in order to build on the work of Pharmaceutical Industry Competitiveness Task Force and Healthcare Industry Task Force to identify those factors that could make the UK unique internationally for later phase clinical research in the eyes of the bioscience, healthcare, devices and pharmaceutical industries.

2.6. The study concluded that if UK plc, and its National Health Service, aspires to be a leader in commercial clinical research it must develop a distinctive value proposition, namely—'A single system that reliably delivers distinctive quality and rapid access at reasonable cost'. A key part of this aspiration would be Industry's ability to access patients and expertise at the right pace, through a comprehensive and flexible healthcare IT system. Building on the asset of a single national healthcare provider, the UK could create the world's largest integrated patient record IT system.

3. Introduction

3.1. In January 2006 the Department of Health in its research strategy[62] made a commitment to ensure that data collected via the NHS Care Records Service (NHS CRS) and supporting infrastructure could be harnessed to meet the needs of the research and public health communities to confer benefits for the UK. "*. . . The National Programme for IT transforming our ability to recruit patients to clinical trials and gather data to support work on the health of the population and the effectiveness of health interventions . . .*" www.dh.gov.uk/researchstrategy

3.2. At the same time reports from the Council for Science and Technology[63] and the Academy of Medical Sciences[64] highlighted the potential of the NHS CRS to accelerate our understanding of health and disease by enhancing public health research on a national scale.

3.3. The UKCRC R&D Advisory Group to Connecting for Health (CfH) was formed under the sponsorship of Professor Sally Davies, Director of Department of Health Research & Development Directorate and Richard Jeavons, Director of Implementation for CfH. The Advisory Group chaired by Professor Ian Diamond (CEO of Economic and Social Research Council) commissioned a series of simulation exercises to investigate the feasibility of using the NHS CRS as a platform for health research and examine the technical, regulatory and governance issues raised by areas of health research that use patient data.

3.4. The report of these simulations is currently in draft format and will be available later this month. It demonstrates the immense potential that linked electronic records have to enable research across a very wide range of applications which will have the potential to impact positively on patient health and safety and

[62] Best Research for Best health: A new health research strategy (Department of Health—January 2006).
[63] Better use of personal information: Opportunities and risks (Council for Science and Technology, November 2005).
[64] Personal data for public good: Using Health Information in Medical Research (Academy of Medical Sciences, January 2006).

makes a number of recommendations around data quality, data availability and data access as well as recommendations that highlight the need for engagement with the National Programme for IT (NPfIT) advances made in other parts of the UK.

3.5. Our focus in this response is therefore on the *research* aspects of the Committee's Inquiry and our submission concentrates on the three most relevant areas of your terms of reference: Who will have access to locally and nationally held information and under what circumstances; Whether patient confidentiality can be adequately protected; How data held on the new systems can and should be used for purposes other than the delivery of care e.g. clinical research.

4. *Who will have access to locally and nationally held information and under what circumstances?*

4.1. Whilst medical records are obtained to support and improve individual patient care, there is a wider use for these records. These are often described as secondary uses. The secondary uses that we wish to discuss in our response are to support and improve public health and treatment using evidence from research.

4.2. The benefits of research using patient data include enabling more evidence based practice in the NHS (improving quality and safety of care) and evidence based policy (including public health policy).

4.3. The draft report of the UKCRC/ CfH research simulations which is likely to address these issues will be available next month.

5. *Whether patient confidentiality can be adequately protected?*

5.1. In parallel with the work of the UKCRC R&D Advisory Group to CfH, complementary work has been conducted by a subgroup of the Care Records Development Board (CRDB) on secondary uses of patient data. Whilst the remit of this working group is wider than research, many of the issues raised by the secondary uses of patient data (initially provided for the purpose of personal care) are identical. There have been close links between these two groups.

5.2. The secondary uses working group was formed to advise the CRDB and through it the NPfIT, on how the potential for the National Care Record Service to support research, population health and NHS management can be realised in compliance with the Care Record Guarantee[65] and the secure and ethical use of patient records.

5.3. The terms of reference of this working group *include* consideration of anonymisation of patient data (removal of identifiers), direct communication with the public, professionals on behalf of the research and public health users of this data; and consent for the use of this data.

5.4. Whilst it is not appropriate to comment on specific aspects of recommendations in the draft report, it is likely to address issues of patient consent and anonymisation of patient data for secondary uses.

5.5. The report of this working group will be presented to the Patient's Tsar—Mr Harry Cayton, Chair of the Care Records Development Board and then published in April 2007. Harry Cayton was also chair of a Ministerial taskforce on the NHS Summary Care Record[66]. The report of this taskforce also makes some useful recommendations regarding patient consent.

6. *How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research?*

6.1. Both the Council for Science and Technology and the Academy of Medical Sciences (AMS) reports outline in some detail the potential of the NHS IT systems to support research that seeks to understand disease and public health. The AMS report in particular considers the merit of research and the level of constraint on the use of health information.

6.2. Both the UKCRC simulations and the CRDB secondary uses reports discuss the need for robust information governance that is also responsive to the needs of research. This is particularly important as although much research can be conducted using information about patient groups rather than individuals, data may need to be linked and comprehensive at a patient level in order to have the maximal value. This process relies on the use of a unique identifier which in turn will require identifiable data to be accessible at some stage in the process.

6.3. Much discussion around enabling access to patient data for purposes other than direct individual care currently centres on the use of the Secondary Uses Service (SUS). SUS is being delivered as part of the CfH programme and is ". . . *a system designed to provide timely, pseudonymised, patient-based data and information for management and clinical purposes other than direct patient care . . .* ". The simulation report from the UKCRC will discuss opportunities to build on existing expertise to enhance the service to the research community from that currently proposed for the SUS.

[65] Care Records Guarantee www.connectingforhealth.nhs.uk/crdb

[66] Report of the Ministerial Taskforce on the NHS summary Care record www.connectingforhealth.nhs.uk/publications/care_record_taskforce_doc.pdf

6.4. There is a real opportunity to develop an enhanced infrastructure that can link and integrate patient information, in a secure format to provide a comprehensive service producing direct benefits for patients.

UK Clinical Research Collaboration

16 March 2007

Evidence submitted by UK Computing Research Committee (EPR 29)

EXECUTIVE SUMMARY

1. UKCRC has the expertise to respond to two of the Committee's questions: whether patient confidentiality can be adequately protected; and why delivery of the new systems is up to two years behind schedule.

2. We believe that protecting patient confidentiality will present very substantial technical challenges and that the systems associated with the EPR need to be designed, built and analysed using state-of-the-art methods. We are unable to tell whether this will be done and, even if it is, we believe that there will almost certainly be security breaches.

3. We believe that there are many reasons why there can be very little confidence in any current schedule for the delivery of the EPR and its associated systems. In particular, it appears that the specifications are not yet complete and stable. Delivery schedules are almost never over estimated, so it is unsurprising that current forecasts are optimistic.

4. We believe that there are important aspects of the NPfIT EPR systems that should be openly reviewed by specialists.

DETAILED EVIDENCE

5. The UK Computing Research Committee (UKCRC), an Expert Panel of the British Computer Society, the Institution of Engineering and Technology and the Council of Professors and Heads of Computing, was formed in November 2000 as a policy committee for computing research in the UK. Its members are leading computing researchers from UK academia and industry.

6. UKCRC has the expertise to address the second and part of the fifth questions identified by the committee:

- Whether patient confidentiality can be adequately protected; and
- Why delivery of the new systems is up to two years behind schedule.

7. Our expertise is in computer-based systems, not in clinical practice, although some of us have carried out research into computer systems in medical practice and into the ways in which clinical and administrative staff work with these systems and the work-arounds that they employ when the systems are seen to have deficiencies.

8. The Electronic Patient Record (EPR) is part of the National Programme for IT in the NHS (NPfIT). NPfIT is a very large socio-technical system, by which we mean that the computer systems have to interact with and support the work processes carried out by NHS staff. These work processes are very diverse, and many of them are carried out under stressful conditions. Professional, legal and human considerations all mean that the short-term interests of the patient will be given a very high priority by NHS staff, even if this means disregarding the documented operating procedures for computer systems.

9. We have not managed to find a clear business case for the EPR, that analyses whether the total benefits will exceed the total costs, and whether the equally valuable benefits could be obtained more cost-effectively in some other way. We hope that such an analysis exists, as otherwise the project may be a certain failure in cost-benefit terms even if it succeeds technically.

WHETHER PATIENT CONFIDENTIALITY CAN BE ADEQUATELY PROTECTED

10. Whether the confidentiality of data contained in the EPR can be adequately protected depends on several factors:

- whether the design of the EPR and related systems restricts access sufficiently to ensure confidentiality;
- whether the procedural safeguards that restrict access are practical, fit in with the working practices and values of staff, and are perceived as usable by those staff so that they are followed consistently in practice;
- whether the software implementation of the EPR has been designed with adequate technical security measures;
- whether the technical design has been implemented correctly; and

— whether there is adequate control over data archiving, database maintenance, and software and hardware updating to ensure that the confidentiality cannot be compromised, deliberately or by accident.

11. All these factors are difficult to achieve, and the archives of the *Forum on Risks to the Public in Computers and Related Systems*, moderated by Professor Peter Neumann, contain many examples of the loss of confidential data from important systems in recent years.

12. As a general principle, a single system accessible by all NHS employees from all trusts maximises rather than minimises the risk of a security breach. It increases the number of patients affected by the worst case breach and increases the opportunity for access to any one patient's data from some point on the extended system. In short, it provides both a bigger target and a larger number of points of attack than a series of smaller systems. No system can be totally secure, and networked systems are particularly vulnerable; it is important that a formal analysis is carried out to identify risks and show that they have been reduced as low as reasonably practicable.

13. We do not know whether the EHR will be encrypted in the database and when transmitted between systems. This would provide some protection against data loss, if the encryption and key management were state-of-the-art. We recommend that the design of this part of the NPfIT is published in full, so that it can be scrutinised by experts.

14. We understand that access to the EHR will be controlled by the use of smartcards that identify individual staff and their roles, coupled with system policies designed to ensure that only staff with legitimate access to the data can see it. This form of access control suffers from several vulnerabilities; for example, smartcards may be shared or a user may leave a computer logged in or with sensitive data on screen where it can be read by others, smartcard security can be broken, authorised users of the system may access data illegitimately (possibly using colleagues' smartcards), or the data may be accessed by other means.

15. If the EHR is accessible on the internet, perhaps so that patients can check their own records as has been promised by Connecting for Health, it will be very difficult to prevent unauthorised access to these records, through password-cracking, phishing,[67] or other standard attacks. Depending on the design of such web-based systems, it may be possible to break the server software and to gain access to large numbers of EHRs.

16. The Secondary Uses Service (SUS) provides access to patient data for research, billing and other purposes. It is very difficult to provide such data in a form that guarantees that the identity of the patient cannot be recovered, even when the data has been "anonymised", because many characteristic elements are necessarily preserved.

17. It is very difficult to design software systems that are really secure, especially where they include off-the-shelf software. It is impossible to establish that systems are secure by testing them because even several years of testing would leave most of the possible states of the system untested. Rigorous analysis can show that the system does not contain some of the possible security vulnerabilities, such as buffer overflows, but such analysis will only be possible if the systems have been designed with this analysis as a primary objective.

18. It is inevitable that the EPR will introduce some risks—of breaches of confidentiality, of loss of data, of corrupted or otherwise erroneous data, and of the EPR being temporarily inaccessible. These risks should be made public, just as the risks of any medical procedure are public.

19. For all the above reasons and more, we recommend that the NPfIT systems that handle the EHR, and all the procedures for maintaining the systems and the data, should be independently reviewed by experts in secure systems, and that the results of that review should be published. The history of IT system development consistently shows that a system's developers are often overconfident about its security and safety. Early third-party examination of the specifications and design will usually expose vulnerabilities that were not anticipated by the developers, leading to a more robust system.

Why Delivery of the New Systems is up to two years behind Schedule

20. The introduction of new computer systems into an organisation almost always necessitates significant changes to the ways that staff work. Almost all successful projects recognise this explicitly; they are seen as business change projects, enabled by computer systems, rather than as IT projects. Business change takes time, resources, planning and commitment, and until the plans are in place and the affected staff are committed to the success of the project, the technical requirements cannot be finalised. Self-evidently, until the technical requirements are finalised, the dates for delivering the computer systems cannot be forecast with confidence and the overall project timescales are at risk.

21. The alternative approach, of finalising the technical requirements and requiring staff to fit in with the decisions made by the package developers, runs the risk that the necessary adjustments to ways of working will prove impractical, or unacceptable to affected staff.

[67] Phishing is the name given to luring internet users to fraudulent web-sites, usually by sending them fake emails, so that the unsuspecting user enters their account number and password and the fraudsters are then able to misuse the account.

22. The NHS is a very complex organisation, so staff working practices may differ substantially from group to group. Until the full consequences of these differences have been understood and analysed, any implementation schedule is little more than a guess.

23. The scale of the NPfIT systems associated with the EPR is very great, and it is well established that the historic failure rate of large projects has been far higher than the failure rate of small projects. To maximise the chance of success, the EPR should be introduced as several small projects, shown to be successful, and grown incrementally into an interconnected national system.

24. We understand that the detailed content of the electronic patient record has not yet been finalised and that significant concerns have been raised by clinicians and patient groups about the uses to which the data will be put and the privacy implications. Until these issues have been resolved satisfactorily, it will not be possible to know whether the data in the patient record will be available, accurate, and up to date sufficiently often to support new working practices that depend on the EPR, nor to design working practices that can be shown to be practical and acceptable to staff and patients.

25. It appears that many of the technologies are new and have not been tested. In particular, at the heart of the EPR are two standards—HL7 v3 and SNOMED-CT. We understand that neither has ever been implemented anywhere on a large scale on their own, let alone together. Both have been criticised as seriously flawed. It is imprudent to base the EPR, which will be part of the UK's national critical infrastructure, on a technology experiment.

26. It is essential that safety-related systems are as safe as reasonably practicable, and the NPfIT systems related to the EPR are, we assume, safety-related. Showing that these systems are adequately safe requires a safety-case: an analysis of the possible hazards and a logical argument, based on objective evidence, that the risk to patient and staff safety has been eliminated or reduced to a practical and acceptable minimum. For well-understood technical reasons, it is very difficult to produce an adequate safety case unless the software has been designed with this in mind; in particular, evidence from tests carried out on the system is rarely adequate on its own.

27. It is even more difficult to show that systems are adequately secure than that they are adequately safe, because of the need to consider all the ways in which the system can be deliberately subverted, in addition to the ways in which it may fail accidentally.

28. Whilst the techniques of safety analysis are well developed in the aviation and nuclear industries, and security analysis is well developed for military systems, the combined analysis for a very large socio-technical system such as NPfIT is beyond anything that we are aware has been done previously, and should be expected to take considerable time, effort and specialised expertise. We encourage the Health Committee to satisfy itself that adequate plans already exist for this work.

29. In summary, it seems from the information available to us that the EPR requirements focus on the technology rather than on the desired organisational changes, and that the technical specifications of the systems that implement and support the EPR are not yet complete. The implementation schedule for the EPR cannot therefore be well founded.

30. UKCRC would be pleased to provide additional evidence, orally or in writing, on any of the points mentioned above.

Dr Martyn Thomas
UK CRC

March 2007

Evidence submitted by the Wellcome Trust (EPR 42)

1. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending around £500 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and well being.

EXECUTIVE SUMMARY

2. The Wellcome Trust considers that the use of electronic patient records offers huge benefits in improving patient care and safety and that a secure system of access for biomedical researchers should be seen as an integral part of patient record use that contributes to these patient improvements.

3. One of the unique selling points for biomedical research in the UK is access to a National Health Service (NHS) with more than 50 million users. The National Programme for IT (NPfIT) being delivered by Connecting for Health (CfH) should:

— bring patient data into an electronic format, enhance patient safety and take patient care into the 21st century;

— provide an individual electronic care record for all England's 50 + million users, securely accessible to patients and their carers;

— enable researchers to access patient health information that is comprehensive, standardised, accurate, up to date and can rapidly be analysed on a large scale; and

— help to ensure that the UK maintains and builds on its global lead in biomedical research, attracting inward investment from the bio-pharmaceutical research sector.

4. Developing an appropriate infrastructure to enable secure access for biomedical researchers to NHS data is something the Wellcome Trust supports and we are committed to working, in partnership with others, to develop a programme of e-health research activity using electronic patient data, including that available through the NHS Care Records System. The forthcoming Research Simulation Report of the UK Clinical Research Collaboration (UKCRC) R&D Advisory Group to CfH is highly relevant here and we would recommend that report to this Committee when it is published in March. Richard Jeavons, Director of IT Service Implementation, CfH and Sally Davies, Director General for Research and Development, Department of Health were the sponsors of this report.

5. Establishing public confidence and support for the use of electronic patient records in patient care, for patient safety and for research, is a key priority and needs to be given further attention. From work recently commissioned by the Wellcome Trust we found that public awareness of the use of electronic patient records is low and there is a limited amount of research to understand public opinion in this area. Further research needs to be done to inform policy decisions.

Response to Specific Questions

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems

6. The UK Clinical Research Collaboration (UKCRC), of which the Wellcome Trust is a member, has recently commissioned a series of research simulation exercises to scope out what the research requirements for patient data available from the NPfIT are that would enable a wide range of public health research to be undertaken. The Report of Research Simulations, due to be published in March, will set out a number of recommendations pertinent to this inquiry including what research can be done, and the health benefits that can be realised, with anonymised data. It will also give examples of where the use of identifiable data will be beneficial for public health. The recommendations will:

— Inform future development of the NHS Care Records Service (NHS CRS).

— Highlight technical, regulatory and governance issues.

— Inform plans for any further simulations and full pilots to test the capacity of the infrastructure, using real patient data with appropriate safeguards when this becomes feasible.

7. The Wellcome Trust would recommend this report to the Committee and considers that a presentation of its findings from Professor Ian Diamond (Chief Executive of the Economic and Social Research Council (ESRC) and the Chair of the UKCRC R&D Advisory Group to Connecting for Health) would be highly relevant to the scope of this inquiry.

8. The Care Record Development Board (CRDB) Working Group on the Secondary Uses of Patient Information is also preparing a report that will make a number of recommendations on consent and governance issues. The Wellcome Trust would welcome further work to improve the guidance for researchers in this area.

Who will have access to locally and nationally held information and under what circumstances

9. Biomedical researchers should be seen as core, not secondary, users of patient records. Active research use of patient data improves the quality of the patient record and subsequent patient safety and care. An electronic record and the use of unique identifiers enable large-scale studies to be undertaken integrating data from different sources to answer questions important for public health.

10. For example a study in Denmark cross referenced data on the Danish Civil Registration System, which assigns a unique identification number to every live-born infant and new resident in Denmark, with MMR-vaccination status obtained from the Danish National Board of Health and combined that with children's autism status obtained from the Danish Psychiatric Central Register. This study, on more than 500,000 cases, provides strong evidence against the hypothesis that MMR vaccination causes autism.[68]

[68] Madsen KM, Hviid A, Vestergaard M *et al.* A population-based study of measles, mumps, and rubella vaccination and autism. N Engl J Med 2002; 347:1477–1482.

11. In a study in Scotland researchers used linkage of national pregnancy and perinatal death registries to undertake a retrospective cohort study of more than 130,000 women having a second birth in Scotland whose first infant was liveborn. This study, unable to be undertaken by any other method, indicates that complicated first births of liveborn infants are associated with an increased risk of unexplained stillbirth in the next pregnancy.[69]

12. The UKCRC R&D Advisory Group to CfH Research Simulation Report will cover these areas in some detail.

Whether patient confidentiality can be adequately protected

13. The UKCRC report and the CRDB Working group on the Secondary Uses of Patient Information report both make recommendations in this area and in deciding the appropriate governance structure to allow access for researchers to patient information a balance will need to be struck between preserving individual confidentiality and establishing practical mechanisms to enable public benefit research to be undertaken.

14. The Wellcome Trust has recently commissioned a research team from the University of Surrey to undertake a study on "Understanding Public Perspectives on the Governance of Biomedical Research: a qualitative study in a deliberative context". This report is currently undergoing peer review and will be completed and published after this.

15. From this work, and in a recent survey of public attitudes on the use of identifiable medical data from the National Cancer Registry published in the British Medical Journal,[70] it is clear that there is strong public support for medical research, particularly for research into cancer. There appears to be little evidence to support the policy position that the public will prioritise privacy over the use of their patient records for health research.

16. Therefore, it would appear that more engagement with the public is required to understand public attitudes to the use of their records for research; otherwise there is a danger that an overly restrictive governance framework is put in place that prevents the full range of beneficial health research to be undertaken.

How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research

17. Recent reports from the Council for Science and Technology[71] and Academy of Medical Sciences[72] have highlighted the potential of the CfH programmes for accelerating our knowledge and understanding of health and disease and improving the potential for conducting public health research on a national scale.

18. If the development of the CfH programmes engages researchers appropriately then it will provide research opportunities in the following areas:

Public Health

- Improved understanding of patient epidemiology and disease burden/unmet needs (especially when linked with disease registers, hospital episode statistics, Local Service Providers etc).
- Exploring the underlying causes of ill-health and health damaging behaviour from links with non-health data (eg housing, economy, environment).
- improved analysis of the effectiveness of different interventions/treatments (eg new vaccination schedules, screening programmes, devices etc).
- All of the above by specific groups (by age, geography, ethnicity).

Health Services Research

- Improved analysis of effective service delivery systems through linkages with other information such as clinical audit data.

[69] Smith GC, Shah I, White IR, Pell JP, Dobbie R. Previous preeclampsia, preterm delivery, and delivery of a small for gestational age infant and the risk of unexplained stillbirth in the second pregnancy: a retrospective cohort study, Scotland, 1992–2001. Am J Epidemiol. 2007; 165:194–202.

[70] Barret, G, Cassell, JA, Peacock, JL, Coleman, MP (2006) National Survey of British public's views on use of identifiable medical data by the National Cancer Registry. *BMJ,* 332: 1068–1072.

[71] "Better use of personal information: opportunities and risks" (Council for Science and Technology, November 2005).

[72] "Personal data for public good: using health information in medical research" (Academy of Medical Sciences, January 2006).

Clinical Trials and Pharmaceutical Development

— Improved feasibility study and identification of the target size of a disease population.
— Recruitment of suitable patient groups made easier.
— Potential to directly link NHS records into a clinical trail database.
— Improved pharmacovigillance/adverse event reporting (identification of side effects, drug interactions and rare events).
— Post-approval monitoring.

Personalised Medicine

— When combined with information from cohort studies, use of platform technologies and other developments, the patient data available through the Secondary User Service could improve our understanding of the heterogeneity of diseases and population, accelerating the move towards pharmacogenetics/personalised medicine.

19. Following the UKCRC research simulation exercise one of the emerging recommendations is to build on the existing databases and clinical registries that currently provide a valuable resource to biomedical research in the UK using electronic patient records. For example, the General Practice Research Database (GPRD) and Q-Research as well as a number of ongoing population and cohort studies. The information on the Secondary User Service will add to this data but is not able to provide a complete solution. Therefore, there is a need and a real opportunity in the UK to develop a federation of databases that can link and integrate patient information, in a secure format to provide a more comprehensive and effective research service for public health.

20. The Wellcome Trust is committed to working with others in developing a roadmap to set out the physical and governance infrastructure for research using electronic patient records under an "e-health" programme banner. In developing such a roadmap all appropriate stakeholders in both academic and industry research will need to be engaged as well as taking into account the need to ensure patient confidentiality and maintain public support for biomedical research.

21. We would support the development and fund the research that would use such a service and would look to Government to provide a similar commitment within the next Comprehensive Spending Review to provide the resources to put in place the infrastructure to deliver such a research service including data on the Secondary User Service.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule

22. No comments to make.

Mark Walport
Director, The Wellcome Trust

16 March 2007

Evidence submitted by Mr Nicholas Beale (EPR 14)

In summary I submit that: *The problems with the EPR are fundamentally because the NPfIT is not part of a well-conceived change initiative that meets real user requirements led by a senior respected user; long experience shows that such large IT programmes in complex organisations are almost certain to fail.* My detailed comments are as follows:

1. I have been following IT in the NHS as an external observer since the mid 1990s. I am a liveryman of the Worshipful Company of Information Technologists and have been a member of its Medicine and Health Panel since 1996, though I write in a personal capacity. I was professionally active in IT from 1973–89, and I now advise Chairmen and top-management of FTSE 100 companies on strategic and people issues—not specifically IT.
2. Whilst strongly supporting the goal of using IT more effectively to enhance healthcare, I consider that NPfIT was misconceived, and now requires radical re-thinking and re-scoping, with new leadership rooted in the user community.[73] I consider that this is the fundamental reason why delivery of the new systems is up to two years behind schedule and why there are so many other problems—some well-publicised, others less so.

[73] It makes no difference that it is done under the banner "*Connecting for Health*" which is a classic case of hoping a real problem go away if something is re-branded.

3. Long experience has shown that large-scale complex IT systems in large-scale complex organisations can only succeed (ie provide benefits significantly greater than their costs) as parts of well-conceived change initiatives that meet real user requirements, and that pretty well the only way to achieve this is to have a senior and respected *user* in charge.[74]

4. So a National Programme *for Information Technology*, with a CIO *from outside the NHS*—however talented—was almost certain to fail. Perhaps it might have been OK if the CIO had reported to a strong and engaged SRO within the NHS—but this has been a revolving door. The present difficulties are symptoms of this fundamental problem. I do not think that anyone, however wise or consultative, could have succeeded coming in from the outside to this role. The fact that inadequate consideration has been given to issues of exactly what information would be held, how it would be protected and used *from a clinical and patient point of view* is yet another symptom of the underlying cause which is a programme driven by politicians and IT Specialists rather than one driven by Users to meet real User needs in a cost-effective and timely manner.

5. In my view the programme needs a fundamental re-scoping so that it is technically, organisationally and managerially feasible and appropriate, with a leader *appointed from the NHS with a real user perspective and strong credibility amongst clinical and management staff*, who will stake his or her reputation on delivering a re-defined set of benefits within a re-defined timescale and budget over the next 5 years. If the NHS does not employ anyone with the requisite internal background and credibility prepared to do this with the present programme, this is conclusive evidence that it will almost certainly fail in its present form. The NHS must find the best leader it can and scale back the programme to be well within her/his capabilities. The rest can be considered in later Phases, as capability and credibility develop. This course of action may be politically embarrassing and people with a strong financial interest in the programme continuing more or less at present may claim that it is nearly ready. Such claims are always made during large-scale IT disasters and are almost never true.

6. I would commend the article *Mastering the Three Worlds of Information Technology* in the Nov 2006 *Harvard Business Review*. This distinguishes between:

   — *Function IT* that assists with the execution of discrete tasks;

   — *Network IT* that facilitates interactions without specifying their parameters;

   — *Enterprise IT* that specifies business processes.

   The author says that "*all the successful [Enterprise IT] adoptions I've studied have used the same process for avoiding failure, and all the unsuccessful [ones] have not used it: They have decided at the outset how key issues . . . will be raised and settled. The most important participants in this task are not IT specialists or consultants but business leaders from the areas affected by the new technology. The more areas there are . . . the more the adoption effort needs a seasoned leader*." (by which he means a business leader). NPfIT is currently an "Enterprise IT" project; it has not used the process described and in my view will almost certainly fail in its present form. But if it were scaled down to a Network IT project then it could well succeed.

7. Mature discussions with the industry should be able to minimise the loss of public money: frankly, pretty much all of the foregoing was well-known to the IT industry at the time the contracts were let. It is better and cheaper to make necessary adjustments now than to prolong the agony and face a bigger write-off later. There is also a substantial opportunity cost in delaying sound IT systems that will provide real heathcare benefits.

8. The new leader should be supported by independent technical, clinical and managerial experts who would function very much as Non-executive directors. They would ideally operate as part of a Board chaired by the CEO of the NHS, with full access to information, and be accountable to the "shareholders" ie the taxpayers and NHS patients. Any NED who resigned should have the right, and perhaps the duty, to explain why to the PAC and/or to your Committee.

9. I consider that any competent group of independent advisers who were not pressurised by the DH/NHS and believed that they would be listened to would reach similar conclusions. It might well be helpful if your Committee and/or the PAC established such a panel.

Nicholas Beale
Director, Sciteb

13 March 2007

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[74] The congestion charge system was a large and complex IT *project* but was not in a large and complex *organisation.*

Evidence submitted by Mr Tom Banks (EPR 70)

Executive Summary

1. This memorandum of evidence addresses the intent and realisation to date of plans for the creation of "detailed' patient record in electronic format both locally and nationally. In particular it is intended to assist the Committee in its deliberations upon:

- What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems.
- Whether patient confidentiality can be adequately protected.
- Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule.

as listed in the Terms of Reference for the inquiry.

2. This evidence statement asserts in relation to the first bullet point (electronic record systems) that:

- The intention to assemble patient records in electronic format nationally (on what has been termed the dataspine) was flawed from its inception and there is no evidence that it can be attained with currently available technologies.
- The creation of patient records in useful electronic format at the "point of care delivery" has been retarded rather than advanced by the activities of Connecting for Health.
- Patients would be well advised to be wary of permitting any electronic records to be deposited in a national repository, for fear that the impact of erroneous data could outweigh any potential benefits from "shared" data.

3. This evidence statement asserts in relation to the patient confidentiality bullet point that:

- Primary legislation will be required to provide a degree of patient confidentiality sufficient to avoid frequent referrals by patients to the UK and European Courts alleging breaches of European "Data Protection' directives and increasing amounts of patient litigation in relation to patient record accuracy and integrity.

4. This evidence statement asserts in relation to the last bullet point that the gap between delivery of service and the timetable originally published has been caused by:

- Failings in the original contracting process deployed by the National Programme for IT.
- In particular, the allocation of "monopoly" concessions (franchises) to selected commercial companies to deliver "local services" to NHS bodies.
- The lack of appropriate authority being contractually delegated to NHS Bodies with ultimate responsibility for implementation of franchised monopoly concessionaires' services.
- The decision of the then Secretary of State for Health, Mr John Reid, in 2004 to include the NHS Information Authority in his programme "winding up arms length bodies".

5. The opinion is expressed that there is no evidence published to indicate that the "Care Records Service" element of the National Programme could be delivered in the next decade, and there exists technical evidence that the original goals of the National Programme for IT are unattainable. This memorandum therefore supports the representation previously made to the Committee by the "Group of 23 Senior Academics in Computing and Systems" that a detailed open technical review of the Programme be commissioned, in a transparent manner that will enable the resultant recommended actions to be progressed in a climate of widespread acceptance and support.

Author Details

I am a management consultant who specialises in supporting the effective management of healthcare. I have worked with the NHS in England, Wales and Scotland and with health and social care in Hong Kong, Singapore, Norway and the USA. Between 1995 and 1997, I was seconded to the NHS Executive in Leeds where I led the NHS Number project, a successful national IT based project delivered fully in England and Wales. I have first hand experience of the national programme for IT, through supporting trusts in various parts of England to improve their NHS IT services often despite the challenges thrown up by Connecting for Health.

I am a Fellow of the British Computer Society, and a member of the Worshipful Company of Information Technologists Medicines and Health Panel. I am also a member of the all party Parliamentary IT Committee where I serve on the programme committee assisting MPs and Peers with their liaison with healthcare bodies and organisations. However, I offer this evidence in an entirely personal capacity.

EVIDENCE STATEMENT

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems

6. Creating patient records in useful electronic format at the "point of care delivery" is a substantial challenge. In England, such records have been produced in GP practices in a programme of nationally led activity that was well underway as early as 1994. However, in very many GP practices, paper records remain in common use adding detail to that held in electronic format. In the trust sector—acute, mental health primary care, etc—an even greater percentage of those delivering patient care depend upon patient detail recorded on paper.

7. Even in the United States, to which the Department of Health frequently looks for inspirational new ideas, the majority of clinicians utilise paper records to a greater extent than electronic ones. In the last few weeks, the "Bush" administration has again appealed to health maintenance organisations and others to increase their use of electronic recording of patient data. However, at the same time, the "Washington Post" Blogs recorded evidence that details of weaknesses in electronic patient records contributed to the Walter Reed Army Hospital scandal.

8. The attempt by the Department of Health in England to produce both local and national electronic record systems in the same Programme in essentially the same timescale was hugely ambitious and recognised as such. The NHS Confederation Briefing of August 2003 recorded as its opening paragraph:

> "The largest investment programme in information technology (IT) and building infrastructure in the NHS in England is under way. The next three years will see an investment of £2.3 billion in IT. The IT changes being proposed are individually technically feasible but they have not been integrated, so as to provide comprehensive solutions, anywhere else in the world."

9. In the view of many informatics engineers the Programme has been doomed from the start. Connecting for Health has never been able to define and publish any detailed data architecture that covered both the central patient record depository and the local records.

10. There is broad acceptance that patient records in electronic format should be produced and used locally. The challenge of creating patient records in useful electronic format at the "point of care delivery', although substantial, is a challenge that in the various NHS Bodies have been willing to accept.

11. The controversial issue has been central infrastructure item of the national patient data repository.

12. The Output Based Specification for the National Programme for IT (OBS) requested that a national "personal spine information service record" be produced for each patient. This would include a record of all of the patient's healthcare history in electronic format. Every NHS and social care organisation nationwide would be able to share access to the patient's details through this national record.

13. Perhaps the best published description of the national patient record depository is contained in the OBS in the section "Clinical Spine Application Service". Appended to this evidence statement is a simplified diagrammatical illustration of how it was envisaged that use of the Clinical Spine Application Service by a clinician during a patient presentation might work.

14. A calculation of the potential size of such a record structure as indicated in the OBS will have been made during the procurement process by several bidders. At least one such calculation indicated that the proposed scheme was beyond that realistically implementable on current technology. Further, a calculation of the volume of messages that would need to be supported if everyone in the NHS depended upon a central patient data depository to support their patient consultations, also suggests a performance demand well beyond the capability of current day technology.

15. Connecting for Health has not published any calculation details that it has made to demonstrate that the scale of the implementation is technically achievable. The NASP contract for the "spine" signed with BT is understood never to have warranted that it could handle a fully detailed central patient data depository and such volume of transaction activity as a fully detailed central patient record system might have presented to it.

16. The Group of 23 Senior Academics in Computing and Systems have deployed their experience and expertise to examine at a high level the technical basis for expecting the National Programme to succeed. They have expressed considerable concern that "success' may not be achievable and recommended that a detailed open technical review of the Programme be commissioned, in a transparent manner that will enable the recommended outcome to be progressed in a climate of widespread acceptance and support.

17. The OBS contained target milestones for the delivery and deployment of the national "Clinical Spine Application Service". The 2004 and 2006 milestones have both been missed. A revised simplified proposal for creating embryonic shareable patient records on the "spine" has been developed. This proposal is considered to be an ill-defined fudge.

18. The detail of what patient data items would be held on the national spine has changed frequently and only a "first step" "summary" is defined currently. Clinicians are broadly agreed that the current "first step" "summary" detail is of extremely limited value to them. No timeline pathway has been published by Connecting for Health to describe how and when these first steps will build to attain the full, or even a useable, "Clinical Spine Application Service".

19. One challenging question is the degree to which clinicians should rely upon the data in their local records when a patient presents or rely on the nationally held detail? Which is the more likely to be correct and which should take precedent when the details are not identical? The OBS included a few "rules' that would assist in the governance of the data and in answering some data precedence queries. But no data architecture model or comprehensive precedence rule-set has been published that would suggest that the alternatives have been carefully analysed.

20. In particular, the Department of Health has not published any comprehensive guidance on who is accountable, including from a litigation viewpoint, for clinical or other care errors made through reliance upon national patient electronic record data, which may be incorrect or incomplete or outdated.

21. Informed patients may be most reluctant to allow any data allegedly related to them to be included in a national depository for fear that misinformation could contain more damaging risks than no information at all.

22. There is view that Connecting for Health, by concentrating on the central infrastructure items of the "spine" and the national patient data repository, has produced the result of NHS Trusts being retarded rather than advanced in their development of local electronic record systems.

23. In 2002, there were many instances throughout England of NHS bodies engaged in acquiring systems to improve their local electronic record management. Several of these bodies had formed collaborative ventures to procure systems widely approved by the local clinicians and IT professionals. Among these were the Shires initiative in the South West and the Birmingham and Black Country initiative. In May 2003, Government Computing announced that both of these initiatives had been cancelled.

24. "Government Computing" reported Martin Carter, a spokesperson for the Shires consortium, as saying, it was "disappointing" that the Government had pulled the plug at such a late stage. "Our project has been scrapped but what we'll eventually see on the national programme will be very much like the project we were trying to introduce", he said. "It's a very big and complicated project but in the end we will see an electronic patient record that will apply to all sectors, all areas of health and social services. That is the holy grail and we will see how it progresses."

25. The Boards of some Trusts refused to "pull the plug on their procurement and implementation initiatives'. For example in 1999–2000 I assisted trusts in East London to develop a "Local Information Systems Strategy'. This strategy was followed up by Newham University NHS Trust and Homerton University NHS Trust. After careful consideration they decided collaboratively to procure and implementing systems independently of the National Programme. Ironically, the supplier they chose, Cerner Inc, was initially shortlisted but not selected by NPfIT to support any consortium, but has now been belatedly adopted by Connecting for Health as a key system. By acting outside of the National Programme, Newham and Homerton have the most advanced Cerner systems in the UK currently.

26. Another example was University College London Hospital, which successfully implemented the IDX Carecast system under a contract that was independent of Connecting for Health. This was some time before the first (and only) Connecting for Health IDX Carecast implementation in London. Plymouth Hospitals NHS Trust, although geographically in an IDX/Cerner region, installed effective versions of the iSoft products and the "Plymouth" or "Derriford" option was subsequently offered by Local Service Providers to NHS Bodies in the Northern clusters. In summary those NHS Bodies with Trust Boards resolute enough to exercise their own judgement have made the better progress.

Whether patient confidentiality can be adequately protected

27. The Data Protection Act 1998 gives effect in UK law to EC Directive 95/46/EC, and introduces eight data protection principles that set out standards of information handling. The term "health record' is defined by Section 68 of the Act, and means any record which:

— consists of information relating to the physical or mental health or condition of an individual; and

— has been made by or on behalf of a health professional in connection with the care of that individual.

The term "health professional" is also defined by the Act.

28. There has long been tension in the NHS regarding whether the practices for ensuring patient confidentiality are complied with in a sufficiently disciplined manner to conform with the Act and often a lack of clarity about who would be accountable for any breaches. On 18 October 2001, Nigel Crisp wrote in his management letter,

> "There has been widespread concern about the need to comply with legal requirements and professional guidelines, notably the need in certain circumstances to obtain patient consent prior to disclosure and use of patient identifiable data. Whilst it is clear that current NHS practice does not always meet required standards, the NHS is dependent on information collected from and about patients and the Department of Health policy is to encourage and support the necessary improvements without disruption to important NHS and related work. The General Medical Council, the Information Commissioner, and many others, are working with the Department to ensure that reasonable and managed progress is made but it is clearly in no-one's interests for any aspect of health service provision to be impaired. The Department of Health will shortly publish a strategy document that will set out . . . new powers provided under section 60 of the Health and Social Care Act 2001 that can be used to support key uses of patient information where there are particular concerns".

The Health and Social Care Act 2001 requires that resulting regulations under section 60 of the Act to be laid under affirmative process. It is understood that few such regulations have been laid.

29. In May 2002, the then Information Commissioner, Elizabeth France, published "USE AND DISCLOSURE OF HEALTH DATA—Guidance on the Application of the Data Protection Act 1998". This 43 page document was the principal source of guidance to NHS staff for several years. It is a document that addresses practical issues related to the confidentiality of patient data in a detailed clear manner.

30. In 2005 the Department of Health published a "Care Record Guarantee", which it revised in 2006. This "Care Record Guarantee", which is understood to have no statutory basis, is increasingly being viewed by NHS staff as a justification for ignoring the more detailed guidance contained in USE AND DISCLOSURE OF HEALTH DATA—Guidance on the Application of the Data Protection Act 1998".

31. In January 2007, the current Information Commissioner published a brief paper entitled "The Information Commissioner's view of NHS Electronic Care Records". The phrases included in this "leaflet" have been interpreted by some as giving a seal of approval to whatever use Connecting for Health wishes to make of data collected from or recorded about patients. Others are confused as to the legal responsibilities that continue to reside with data controllers, with staff who created a patient record, with "Caldicott guardians", with the Secretary of State and with unincorporated bodies such as the Care Record Development Board or Connecting for Health, when data is extracted without explicit data subject consent from local depositories and then is misused subsequently.

32. NHS staff are aware that data often referred to as "anonymous data" is often only pseudonymised using reversible algorithms. Some staff therefore harbour concerns that personal patient subject data that they may have recorded, is subsequently used in the National Programme Secondary Uses Service or by research bodies, and may expose them to litigation if misused.

33. During the last 12 months, misuse of patient data in electronic format in the USA has become a major cause for concern and even prompted articles in "*Readers Digest*". The larger number of issues in practice have not been caused externally, such as hacking by outsiders, but rather have resulted from improper collaboration and/or malpractice by staff legitimately allowed access to the computer system and sometimes with a potential need to have access to a particular patient's records.

34. It is asserted that the current framework directing practice in the NHS in relation to patient confidentiality is insufficiently clearly defined and that detailed statutory regulations are needed to provide an appropriate base to enable permitted data sharing by staff to occur free from the threat of legal redress.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to 2 years behind schedule

35. In June 2002, Health Minister Lord Philip Hunt announced the publication of "Delivering 21st Century IT support across the NHS", a radical new national programme for Information and Communication Technology in the NHS. He announced improved management and implementation support including "franchise" plans with funding agreed by the national IT programme director. The concept of awarding franchises to external IT suppliers to serve a defined geographic part of the country was new to the NHS and progressed without having any good practice precedent to follow.

36. The inadequacy of the NPfIT franchise procurement process has been a major contributory factor causing the delay. Computer Weekly revealed in May 2004, that "only five months after the deal was signed" it had "run into contractual issues". Quoting from a leaked BT document, CW reported the issues as arising from "detailed definition of requirements and practical deployment not envisaged at the Effective Date of the Agreement".

37. The reason that BT (and other franchised LSPs) faced up to "detailed definition of requirements and practical deployment not envisaged" is that after the contracts were signed, the Contractors had to produce a substantial amount of detail on an "agree to agree" basis. In different contracts, post signature documents were said to be required for "Service Level Specifications", Help Desk Interworking Procedures', Detailed Annual Implementation Plans, Component System Descriptions, Quality Plans, Disaster Recovery Plans, Module testing plans and specifications, etc, etc.

38. The delivery details for the National Data Spine contract had to be "reorganised and replaced" as early as December 2004. The recent NAO report on the National Programme recorded that the core care records element of the Accenture contract was revised "into four releases" the last of which was "13 months later that the original target date" and that CSC customers could fare even worse with a "five release" rescheduling, the last element of which would be nearly two years late.

39. The delays have created the greatest impact at the Trust level. It has been stated recently in a Committee of Public Accounts Report that fourteen Trusts have asked for contributions to costs incurred as a result of delays in the implementation of the National Programme for IT.

40. In awarding its franchise contracts, the Department of Health approved the use of particular software products as being suitable for deployment at the Trust level, but did not contract directly with the provider of the software that was to be used. As a result, the Department has had no direct leverage available to ensure that the software offered to Trusts was suitable for use or would be delivered "on time".

41. In the three northern franchises, the iSoft "Lorenzo" offering was selected from paper descriptions of its intended scope and with minimal demonstrations of prototype software elements. The first Lorenzo version to be available, that may deliver certain key elements of the detail promised during the procurement process, is known as version 3.5 and is understood still not yet available from the development laboratories in India. When "version 3.5 functionality" software is ready, iSoft have indicated that they may evaluate it first in Germany and Singapore. Neither of these two countries requires solutions that closely mirror the NHS in England.

42. The two southern franchises proposed software from an American company, IDX. The NPfIT version of IDX has only been installed in one London hospital. Both southern franchise holders (Fujitsu and the BT consortium) have now terminated their relationship with IDX and propose to supply a product from another American company Cerner.

43. This decision casts shadows over the quality of analysis work undertaken by the NPfIT procurement team. During the procurement the Cerner solution, which was included in a shortlisted consortium, was examined and rejected. Apparently it was considered to be less suitable than the other computer software offerings. The once rejected Cerner is now the "great hope" of Connecting for Health.

44. The implementations in the southern clusters to date have confirmed what USA health organisations' implementations have demonstrated: That it is difficult to "build' and implement Cerner Millennium without very close interaction between Trust IT and clinical staff and Cerner technicians in Kansas. The LSP and Cluster team structure gets in the way of that necessary very close interaction.

45. Another unique aspect of the National Programme arrangements is that Trusts with the "responsibility" for local implementation have no contractual agreement with either Cerner or the franchised LSP. The original contracts between the Secretary of State and the franchised LSP made provision for a further tripartite contract to be agreed between the Secretary of State, the franchised LSP and the Trust, known as an accession contract. It does not appear that any such tripartite contracts have been signed. This raises the question about the degree of adherence to corporate governance and risk management present in the current implementation activity.

46. Finally, members of the Committee may wish to explore the degree to which NHS staff have been developed and trained to ensure the success of this high risk venture. As early as March 2004, Sir Christopher Bland, whose company was said to have won the biggest contracts in its history to implement key parts of the programme, said it will be a "real challenge" to get the initiative to work. He said BT was excited by the challenge but "somewhat frightened by the enormity and complexity of it". At the same conference the Minister John Hutton said it would be an "enormous challenge" to make a success of the programme and it would be "foolish to ignore the risks".

47. In early 2002, Lord Hunt and Prof Sir John Pattison commissioned a report entitled "Making Information Count: A Human Resources Strategy for Health Informatics Professionals". This project identified that the NHS contained some 20,000 health informatics staff and one conclusion of the report was that "high quality, credible, recognised education, training and development are essential components to ensure the NHS has an effective Health Informatics workforce now and for the future".

48. As a result the NHS Information Authority sought tenders to develop and deliver a range of training that would prepare NHS to work effectively with the LSP franchise staff in ensuring local delivery of the Programme and awarded contracts to three companies. The courses commissioned by the NHSIA included such topics as "Gaining clinical commitment", "Managing outsourcing contracts" "Delivering successful projects with LSPs", "Managing NHS business change" and "Developing health community cooperation". Some 500 NHS health informatics staff attended one or more of these courses during 2003 and 2004.

49. In 2004, the then Secretary of State for Health, Mr John Reid, included the NHS Information Authority in his programme "winding up arms length bodies". As a result the NHS Information Authority's programme of NHS staff training was terminated. Details of the NHS staff development activity are known to have been conveyed to NPfIT (as Connecting for Health was then called) senior management but no decision was made by NPfIT to continue the staff development courses. No equivalent training has been made available from any other source.

50. The winding up of the NHS Information Authority resulted in significant numbers of experienced NHS IT staff either resigning, being made redundant or being offered early retirement terms. NHS staff development and training was just one of a number of valuable resource areas that ceased to be available in the reorganised NPfIT.

Recommendations For Action

51. The key recommendations in this memorandum are:

- That the challenges presented by the National Programme are fully recognised and the probability that the original goal is unattainable is acknowledged, hence that a detailed open technical review of the Programme be commissioned, in a transparent manner that will enable the recommended outcome to be progressed in a climate of widespread acceptance and support.
- That the NHS concentrate upon implementing electronic record systems at the point of care to build a foundation of patient records in electronic format in care delivery institutions and that work on the national electronic record system (the dataspine) be suspended pending the completion of the recommended technical review and the concept of a national patient electronic record depository be reconsidered sometime in the next decade.
- That the failure of the franchise approach to implementing Information Systems in the NHS be recognised and hence that Trusts should be both permitted and encouraged to seek from outside the current franchisees, private sector partners to assist in implementing electronic record systems who fit with the Trust's ethos and possess the requisite complementary skills.
- That NHS Trusts should contract directly with the supplier of their IT service, or at least can adopt formal governance responsibility as the senior party to a tripartite agreement.
- That the substantial number of experienced informatics professionals in the NHS have their skills updated through the reintroduction of appropriate IT staff development courses.
- That the statutory and other rules for permitted access to, and the management of, health records be clarified through primary legislation on patient record confidentiality.

Tom Brooks

20 March 2007

APPENDIX

A SIMPLIFIED DIAGRAMMATICAL ILLUSTRATION OF HOW USE OF THE CLINICAL SPINE APPLICATION SERVICE BY A CLINICIAN DURING A PATIENT PRESENTATION MIGHT WORK

In the National Programme for IT OBS, in the section "Clinical Spine Application Service", the potential use of the NPfIT architecture to support a clinician during a patient presentation is described. When the options have been simplified, such as in the example below, the sample IT journey for the professional could embrace 11 (or more) steps that access various local and national data depositories. The clinicians IT actions can be:

1. Sign on to their own home page (which will be user modifiable to show the information that the health care professional personally wishes to see).

2. Conduct a patient search to find the patient.

3. Having located the patient, view the standard patient summary (this initial summary will be a single screen with a snapshot of information derived from the demographic services and the spine information services).

4. The clinician may view the patient problem list.

5. The clinician may view patient allergies.

6. The clinician may view patient procedures and intervention histories.

7. The clinician may view the patients visit and encounter summary.

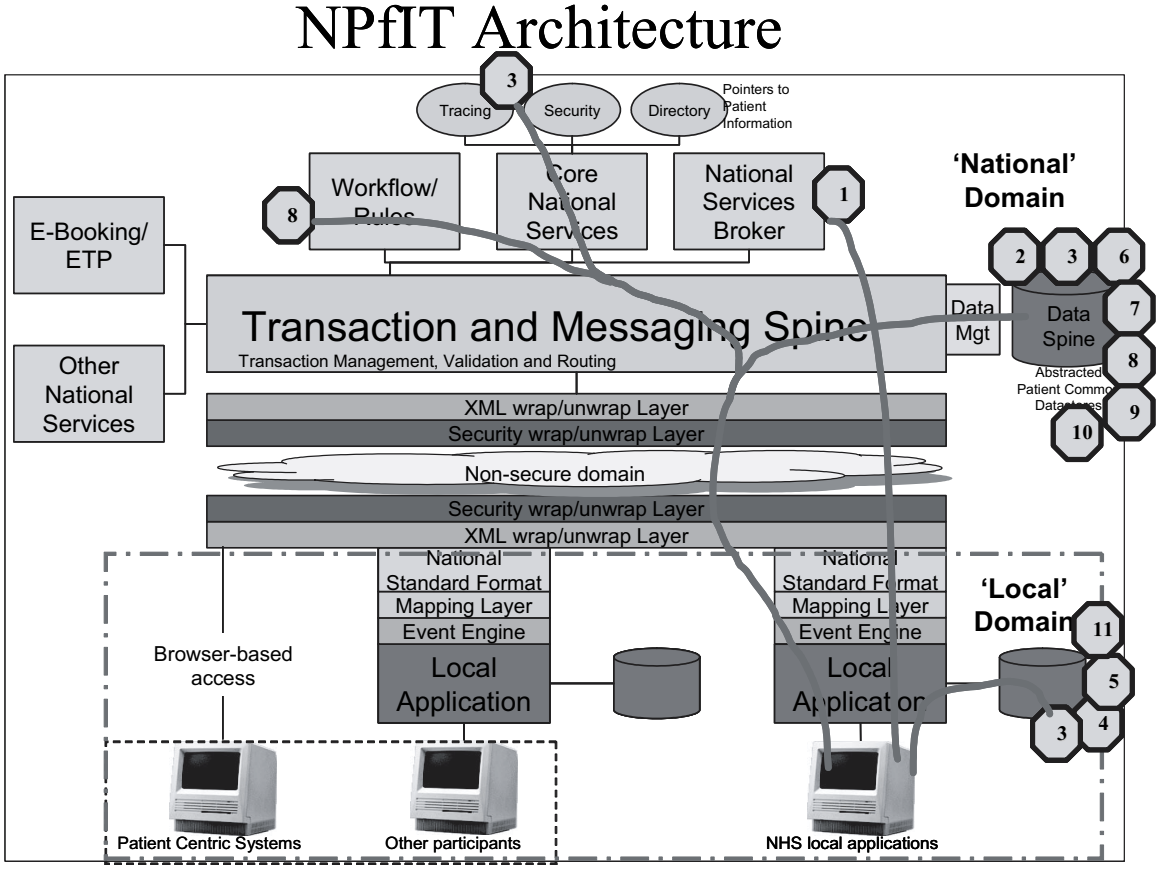
8. The clinician may view patient health care tracking along care pathways considered to be of particular importance where the patient is subject at any one time to a "dual diagnosis situation" such as mental health and diabetes.

9. The clinician may view family and social history, tests ordered and their results.

10. The clinician may view the patients medication profile.

11. The clinician may view the patients medication profile alerts.

This raises many questions, too many to be addressed in this evidence statement, but it does illustrate the complexity of the architecture envisaged and hence the scale of the challenge in delivering it.



Evidence submitted by Dr Gerard Bulger (EPR 28)

I am lead for Practice Based Commissioning in Dacorum[75] and a GP in Bovingdon, Hertfordshire, at Archway Surgery,[76] I am a member of CfH GPSoC Committee[77] and recently joined the Royal College of General Practitioners Doctors Working in Secure Environments Group[78]

I worked in East London, as a GP, and in hospitals, for 20 years. For nine years I was Medical Officer for Redbridge and Waltham Forest's Unit for Physically Disabled People where I organised an interface for the severely disabled[79]. In the 1990s I established the Fundholders' Support Agency[80] which was partly a data warehouse, carrying data for 350,000 patients. I also developed the Consultant Provider Agency[81], an outpatient and minor surgery service. These were heavily dependent on IT systems. I have been involved in the design of a clinical system since 1990. I have installed an IT system within a prison and have been working part-time in prisons for five years.

SUMMARY

1. The UK medical IT industry was effectively nationalised at the inception of Connecting for Health by using the Government's monopoly purchasing powers for the NHS, denying current suppliers of a market.

2. HM Prison Service may have a clinical IT system imposed on it without any tender or user review process.

[75] www.daccombbc.org
[76] ii www.careprovider.com
[77] www.connectingforhealth.nhs.uk/delivery/serviceimplementation/engagement/gps/systems_of_choice/
[78] http://www.rcgp.org.uk/default.aspx?page=2401
[79] http://www.spinal.co.uk/community/default.asp?step=28&id=75&printpage=1
[80] http://www.careprovider.com/itm00018.htm
[81] http://www.careprovider.com/itm00019.htm

3. Access to previous records is designed to prejudice the care in order to reduce investigation and duplication, but that can literally prejudice care. We are changing and dying organic beings, so a previous record or diagnosis can be rendered wrong or irrelevant the very next day.

4. Deleting an incorrect entry seems to be impossible when there is a single record collected from different sources. The only correction possible is for a new correcting entry to be posted, but negation codes do not exist on most GP systems. The validity of a record depends on its provenance, but the very nature of data depends on what it was collected for. To get round this CfH spine date will be in sections, (GP data, hospital data) so not really a single record at all[82].

5. Agreeing how we record drug allergies, becomes a complex process once we accept that it is a core component of a central record. To unite us with absolute definitions would bind us down in such complex data entry coding systems that the system would become unworkable.

6. Keep data local to where it is collected, and where its purpose and meaning is understood. A Google type internal NHS net search engine could find it. There is no need for a single record. Indeed it is probable that Google Health, which exists already, could render the core plank of the NHS IT programme redundant.

7. CfH's need to centralise data extends to GP surgeries. CfH seeks to ban GPs from holding their patients' clinical data on a server in the practice. ALL GP practice data is to be held on central servers. GPs could be cut off from their own patient's records.

8. Few patients know that, under CfH plans, as soon as a key is pressed in a GP surgery, the data is outside the surgery building. Indeed all patient data, not just that held on the spine, is held outside the surgery on a central working server. Nothing remains in the surgery.

9. A safer approach for doctors and patients would be for GPs to retain their servers and governance of the data, and for CfH to run an offsite encrypted backup service. This would also alleviate the problem of narrow broadband connections which cannot support off-site serving of clinical systems on a large scale. Indeed BT has told us that no clinical system should be dependent on N3/internet connections to function. CfH demands just that.

UK Medical IT Industry

10. The UK had a vibrant primary care IT industry, with small innovative competing suppliers developing systems that had to be able to use common communication and coding standards for NHS use. These companies had every GP practice as a potential customer and they needed to sell their product directly to clinicians. When NPfIT, later CfH, was established in October 2002, that market was taken away. The Primary Care IT companies were stripped of their customer base and their potential customers. There was only one customer, the Government. Since then PCTs, in order to save their costs, have encouraged and bullied GPs to move to CfH LSP solutions, as the costs of LSP solutions were "free" to PCTs. Few GPs obliged, but new surgeries have had to use the LSP "solutions". It is difficult for existing companies to invest or innovate in this single purchaser environment.

Prison Service and Clinical IT

11. The Committee may like to look at the prison service and IT. Here it makes sense to have a central record because of the high rate of recidivism; the prison service also moves prisoners around the prison estate. The size of the system required is quite small, compared to NHS standards, looking after 80,000 prisoners at a time, with a turnover of about 150,000 prisoners a year.

12. Quantum EDS,[83] which has the prison service contract, would not allow clinical systems to use their cables, let alone computers. PCTs have installed some GP systems with limited NHS connectivity. Many PCTs held off as it was assumed that the prison service was to have its own Clinical system, which was in the pipeline. The draft specifications did state that the system should be based on standard Primary Care GP systems. It was assumed that CfH would handle it though the LSPs. But that would have meant that a prisoner in London would not be able to have the same record when he moved prisons, say, out of London to Hertfordshire, which is covered by a different LSP.

13. CfH is on the brink of awarding the Prison Service Healthcare contract to one system supplier without any tender process, simply on the grounds that it is at three out of the five LSPs. Once again smaller fish have not had any opportunity to contract for a part of NHS CFH programme.

14. LSPs do not need to house the system at all. Under GP Systems of Choice all the major clinical suppliers are developing their own data centres. Any of the GP clinical suppliers could tender for the Prison Contract but they are not being allowed to do so.

[82] http://www.connectingforhealth.nhs.uk/delivery/serviceimplementation/engagement/gp-engagement-forums-2013-questions-and-issues£3

[83] http://www.publicservice.co.uk/pdf/home_office/autumn2000/p58.pdf

System Design

15. **Why have a single medical record?** The assumption is that a single record is a good thing. All medicines and procedures have their side-effects, some of which can be dangerous. The balance of risk over benefit is never discussed by CfH. A single record is held to be a good thing.

16. At a CfH conference "Your Care Your Record", on 23 November 2006[84] professional actors, at NHS cost, demonstrated the advantages of having a single record. Little did they know that their little play, unchanged, demonstrated the risk of having a single medical record.

17. The scene was of a patient at a bus stop becoming ill. The ambulance arrives and attaches the new technology to the patient, such that the details are sent to the hospital in the town. The habit of crews in writing down essential readings on the back of their gloves was ridiculed at the CfH conference, implying IT systems would automatically be as reliable and as useable in an emergency.

18. At the hospital the main advantage of a single care record was described by the acted scene in which the patient holding his chest and breathless was assured "we have your full record here and see that you have chest problems". All further discussion was stopped. The implication was that the single record would represent a huge saving to the NHS and save lives.

19. The trouble is with this scenario that the patient could still have a new condition and could well be having his first heart attack. The doctors would be biased by instant access to his records, and the data will allow the staff to be lazy.

20. To be safe you need to take a history and examine the patient from scratch. Humans are changing biological beings and a fresh look is needed in an emergency presentation. The information in the record may be neither accurate nor relevant as the patient's condition has changed. Digging out the records or asking the GP a few days later is reasonable. You do not need it at midnight. Instant access to records may deny patients that valuable second opinion.

Example of Access to Records Prejudicing Care

21. My relative was admitted to hospital last year. He could not swallow. Why not? The hospital staff replied that it was because of his dementia. That was a surprise to us.

22. It seems that the GP team or coder had accepted his wife's statement "he is demented" and placed the read code "F110" (Alzheimer's Disease) on the computer. In fact it was the wife who was fragile of mind and intolerant of her husband's Charles Bonnet syndrome (visual hallucinations). The condition was caused by blindness from glaucoma. He was not demented and could name the time, date, and place, the name of the PM—and the entire cabinet.

23. Instant access to the GP's full record got in the way of managing that man's condition. He was not investigated on arrival because the access to the GP's record distorted the management during those vital first few days of his admission. After that it was too late. He died 12 days later with no diagnosis.

Deleting Incorrect Data

24. It will be a complex process to delete data. Say a hospital assumes that a patient has penicillin allergy, but as GPs we know that the patient has not (as we have given it many times before). It seems that the GP would have to add another entry countermanding the first. Our current Read coding system does not allow for negating codes. We would not be able to delete the incorrect entry, just add another. A search would still find the "allergic to penicillin" line and would deny the patient the most potent range of antibiotics, most of which are still based on that molecule. Similarly it is not clear how my relative's incorrect diagnosis of dementia would be corrected, once it was on the spine. Someone's impression that he was demented could be seen forever and continue to prejudice care.

25. On current GP systems incorrect data like that can be deleted; we often do just that. There is an audit trail to say what was done and by whom but it is seldom referred to. Sharing data on a single platform amongst different organisations, whilst making sure it is correct, is too complex to contemplate. CfH seems to have backtracked and the record would be subdivided such that a GP will have to ask a hospital trust to correct the hospital's incorrect entry. The single care record is going to be divided up into sections according to who put it there, in which case I ask why does the data have to be centralised in the first place?

The Nature of Medical Data

26. Definitions of disease vary and can be arbitrary. For example the diagnosis of diabetes is not as absolute as one might think. Each piece of data, if drilled down onto it, opens up like a fractual. The complications increase the closer you get—just as the UK coastline is not 7,760 miles, if you were to count the edge of every rock and inlet at low tide. Medical data is similar.

[84] http://www.connectingforhealth.nhs.uk/crdb/2006-conference

27. The central recording of Allergy has been heralded as a major safety advance of the single record. But allergy recording becomes complex once it is to be shared. The nature of data depends on the provenance of the record and what you originally collected it for. CfH attempts to bring together information collected for different purposes (and their different meanings) into a single place for a new purpose.

28. GP clinical systems allow one to mark a patient as being allergic to a particular drug. The computer gives warnings if you attempt to give that drug, or any drug of the same family, if known to give similar reactions. The GP, for his purposes, will mark a patient record should the patient complain about a drug. The reaction could be a true dangerous allergy and collapse, or it could simply be intolerance to the drug, or a mild rash. It requires a pocketful of coding to describe exactly the patient's reaction, from a code for a profound dislike of anything coloured blue, through to intolerance (cough with ramipril or stomach pains with an antibiotic). The GP wants to remind himself not to give that again, and upset his patient, so codes the allergy. His clinical system reminds him henceforth. That entry collected for one purpose at a GP's surgery, would now be assumed by a hospital to mean that the patient was at great danger and would collapse if given that drug again. To get the NHS to agree on allergy coding we have to agree a new set of coding and subdivisions, complicating data entry.

29. Coding data in this way becomes so complex that frustrated clinicians end up putting in junk codes. One of the most common codes used in many practices is £8CB: "had a chat to patient". If the NHS is too pedantic on coding, it will develop cumbersome systems and meaningless data.

A Google within the NHS?

30. A clinician at a hospital could, under CfH, be able to search for records wherever they were held within the secure NHS Net, and to leave an audit trail and a notice to the patient that he had done so. That way a record and provenance of each piece of information could be built up, so that the hospital clinician could make a new judgment and make up his own record on the day. He would not be relying on ONE record or any one system. It would require standards for searching on different systems. There are already programmes running that can undertake searches on any GP clinical system; Miquest[85] and Apollo.[86]

31. Google, or similar, may well render the whole of CfH redundant by inventing just such a system on an international scale. Google already has a department working on medical data run by Google's Vice President Adam Bosworth.[87]

Central Data Centres and GP Servers

32. CfH insists that GP data is stored in data centres. This is still the case—despite the Buncefield explosion affecting NHS trusts using who were using off-site services.

33. Under CfH's plans GPs are not to have any clinical servers in their surgery and GPs will be clients of external servers.[88] That means all data is external. My patients have worries enough about having just a fraction of their data going onto the spine. They are horrified to hear that one day, under CfH, as soon as their doctor presses a key on the desktop computer, their data will be on a working server outside the surgery (in our case in Derby). No matter that it is encrypted—all their clinical data will no longer sit in their doctor's surgery, nor would a copy of the data, as there is no local server.

34. Those patients who refuse to have their data outside the surgery will force us to use paper records again, or to create a new surgery-only clinical computer system.

35. Patients can cope with the idea of an encrypted dumb back-up file sitting off-site, and indeed even expect such a thing, as they do not want their records lost. But in my discussions patients assumed that only their surgery team had the key to restore the data.

36. Under CfH plans, if anyone accidentally digs up the cable outside the surgery, there will be NO data whatsoever for GPs to treat their patients. No patient records would be available at all—a nightmare scenario in a busy surgery.

37. A BT/CfH N3 (broadband) team, made up of Stuart Hill, Len Chard N3 Project, and Garry Jupp N3 Head of Service attended my surgery in January 207 after they had read my blogs about the N3 bandwidth.[89] The team stated that BT had have pointed out to CFH that no clinical systems should be dependent on N3 connections to function, because no communication system could guarantee being up 100%.

[85] http://www.connectingforhealth.nhs.uk/miquest
[86] http://www.apollo-medical.com/qof/
[87] http://en.wikipedia.org/wiki/Adam_Bosworth
[88] http://www.ehiprimarycare.com/comment_and_analysis/index.cfm?ID=190
[89] http://www.careprovider.com/granger.htm

N3 Connection Bandwidth

38. CfH lacks of bandwidth on N3,[90] the NHS Intranet. To run systems remotely requires fast upload speeds. Many practices have only 256k upload speeds and this pipe is simply not wide enough to transfer the level of data up to a data centre. It can lead to jerky cursors and fix the GP's eye on the screen far more than occurs already. The way around this is to have "store and forward". The data is kept locally and transferred up when the lines are quieter. Indeed BT protests that its N3 lines are quiet and that GPs are not using their current lines at anything like capacity. That underestimates the bursts of activity of any IT system. A Monday surgery with busy clinics, and data being scanned in, will be followed by pauses and a quiet night.

39. There are other pressures on bandwidth. Each machine in a GP's surgery requires windows updates and virus software updates and NHS Net email.

40. Data should be kept locally. An NHS Net secure data engine could search for data with a patient's consent (or in an emergency without it). Both the data holder and patient are informed of the search and by whom it was made. There would be no need for a central record.

Single Interface: Freezing NHS IT in the past

41. The NHS is spending £40 million with Microsoft[91] to develop a common interface for the NHS. Fixing a common interface may simply set the NHS systems in aspic. The interface with programmes is the most complex part of software. We are less likely to have innovative approaches to interfaces if we are to have one interface imposed upon us. Out there on the internet, new non-windows interfaces may be developed but will be denied to NHS users.

Messages

42. Keep Data local . . . under the control and protection of GPs, and search for it if needed, notifying the GP and the patient that the data have been gathered.

43. Provide reliable offsite live backup systems rather than demanding the use of hosted systems.

44. Setting standards of medical IT communication and searching, and applying and developing international standards.

45. Develop and keep a live market in Medical IT and encourage the smaller firms . . . one of them could be the next Google.

Dr Gerard Bulger

March 2007

Evidence submitted by Mr Frank G Burns (EPR 60)

Introduction

It is, frankly, astonishing that a Committee of the House of Commons should, at the beginning of the 21st century feel compelled to undertake an inquiry into the value and mechanics of managing health care records in electronic form.

This is not a criticism of the Committee which is rightly responding to the ongoing controversy attached to the consistently poor performance of the NHS in convincing the "naysayers" about the importance of electronic records and even poorer performance over the last 20 years in delivering electronic records.

The Case for Electronic Records

1. Healthcare is not a once in a lifetime event. From the moment we are born we begin a process of interaction with healthcare professionals that goes on throughout our life and which becomes increasingly frequent as we get older.

2. We see many different healthcare professionals in many different locations and for many different reasons throughout our life.

3. Each time we meet a new healthcare professional with a new health problem (or even an ongoing problem) there is a fundamental need to treat the new problem in the context of an accurate picture of our healthcare history.

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[90] http://www.n3.nhs.uk/faqs/displayfaq.cfml?faq=96

[91] http://www.microsoft.com/uk/nhs/improving-healthcare/cui.mspx

4. A service delivery policy that "divvies up" care between an increasingly wide range of public and private service providers (both local and further afield) makes the task of maintaining a properly integrated health record both more difficult and more important.

5. The volume, range and complexity of data items (about us) that our interactions with healthcare professionals generate over our lifetime cannot be properly stored and most definitely cannot be properly retrieved by paper record systems.

6. The difference in convenience and access between electronic and paper records is like the difference between using the local Library and an Internet Search Engine to research a given subject. Electronic data capture has literally revolutionised every aspect of our daily lives and the progression of this technology is on an unstoppable evolutionary path.

7. Having to make the case for electronic health records is on a par with having to make the case for the telephone, the television, central heating, and the motor car.

The Specific Questions Posed by the Committee

What should be held on electronic records?

8. A record is a record—the electronic record serves the same purpose as the current paper record. It captures important information that may be important to the care of the patient at a future date. An incomplete record can be dangerous. The vast majority of patients will take for granted that their health record (whether paper or electronic) should contain everything that is relevant to their future care. The real issue of public concern (and even this isn't a regular topic of conversation down the pub) is the adequacy of arrangements to ensure that access to records is confined to bona fide health professionals actively engaged in the care of the individual concerned.

National versus local (and related issues of public confidence)

9. If a patient is asked if they object to the creation of an integrated health record at local level for use by the health professionals involved in their care they will generally not object. Not only will they not object to their GP and specialists at the local hospital exchanging relevant information they will be annoyed if failure to do so adversely affects their care (as it often does).

10. This tolerant public attitude to a locally created electronic record can be demonstrated by an exercise on the Wirral where just such a proposition was put to the local population (of 350,000 people) with an option to opt out. Only 25 people have asked to opt out over a period of more than two years.

11. On the other hand if a patient is asked if they object to their health information being "uploaded" to a "national database", ostensibly for the same purpose, they will form a different perception of what is being created. They will wonder why their personal health information needs to be held and managed on a national database and be concerned about the greater potential for malicious use (whether by government departments or otherwise unauthorised access). The downside of the digital revolution that many ordinary people do understand is the indiscriminate creation of personal databases for commercial use and exploitation. People may well be prepared to put up with the fact that their local supermarket analyses and sells information about their purchasing habits but they will not tolerate even the theoretical possibility of use of their personal health information for other than their own care.

12. Public confidence in the development and use of electronic records will be more easily established if it is seen to be an operationally driven process of real-time information sharing and record keeping for the healthcare system in which they reside and in which they get their care.

13. The current NPfiT programme has given a huge amount of priority to rolling out a summary electronic record that can be accessed to support out of area emergency care.

14. This an enormous distortion of priorities for a number of reasons:

- The vast majority of emergency care is provided by the local NHS and as such it follows that clinician access to a fully integrated local record would provide a much more complete context for emergency treatment than will be available through a "thin', incomplete, separately generated summary.
- Creating a national summary record before the local systems are in place to properly populate this with up to the minute information is putting the cart before the horse.
- The actual frequency with which records need to be accessed "out of area" in an emergency are relatively rare and in many cases adequate information can be got from the patient or by a phone call.
- The setting up of a national summary record to support out of hours, out of area care should have waited until the local systems were fully deployed. At that point it might be possible to devise an access protocol that gives remote carefully authorised access to a standardised summary of the

local record, via a secure national gateway, as an alternative to creating and maintaining a separate national database for this purpose where failure to update key information immediately and reliably will pose risks to patients.

15. The clinical community in the NHS does not see the national summary record as a priority compared with the development of locally integrated electronic records that support the work of local healthcare professionals in the day to day care of their patients. This is particular important for older and other patients with chronic illnesses who are simultaneously accessing many services in tertiary , secondary and primary care and who may, in the future, be receiving some of their care from Non NHS providers.

Can patient confidentiality be adequately protected?

16. Where properly devised and implemented, technical access controls to electronic records will be hugely more effective than access controls to paper records.

17. A casual walk round any hospital chosen at random will expose the myth that current paper records are secure.

18. No doubt the committee will get wheelbarrow loads of evidence from the technical experts on both sides of the argument but the conclusion that has to be reached is that no guarantees can be given that any system of record storage is safe from determined attack by sophisticated criminals with unlimited resources.

19. Nonetheless access controls to electronic information does make it more possible to restrict day to day access to patient's records to the people involved in their care and to exclude access by those who are not. A patients name written on a white board at the nurse's station is there for all to see—when the same information is on a computer terminal it requires a password to see and the computer will record the fact when people who don't need to see it are trying access it.

20. The argument about security can only be sensibly conducted in relation to day to day reality. The arcane debates between the experts about the difficulty of achieving the holy grail of the unhackable database should not get in the way of the beneficial use of new technology in health care. As with all things the balance of advantage has to be carefully weighed. Large numbers of NHS patients come to serious harm on a daily basis through poor access to patient's previous history or test results and poor or non existent communication between health and social care professionals. 10% of NHS patients (one million patients!) suffer harm each year through some sort of error and 2000 of these will die. Many of these errors relate to record keeping and communication. The massive improvements in this area that come with properly integrated electronic records render the technical debate on how to achieve ultimate security completely redundant.

Why the delays with NPfIT?

21. The top down approach with centrally procured systems that characterises the current national programme arose from the acknowledged failure of the local implementation approach advocated by the 1998 Strategy *Information for Health*.

22. It is important to note, however, that the clinical emphasis and local approach advocated in *Information for Health* was universally and enthusiastically supported by all the key professional bodies.

23. It was clear at the time of launching *Information For Health* that the senior management (CEO) community and some of the political advisors would have preferred a more prescriptive approach. This was principally attributable to a desire on the part of CEOs to have this traditionally challenging and difficult agenda delivered by the "centre" as a gift wrapped and imposed solution. Many CEOs, DH officials and advisors simply assumed that clinical IT could be rolled out across the NHS in the same way that "check out" technology could be rolled out by a supermarket chain. This was then, and is now, a grotesquely over simplistic view of the transition from paper records to electronic records in the Health Sector. The problems encountered by the national programme provide graphic and painful evidence of the consequences of underestimating the complexity of implementing clinical IT systems and of trying to impose standard solutions on healthcare professionals.

24. In the event the *Information for Health* strategy failed through lack of financial support and through not being given sufficient priority by local managers (who, to be fair to them, were understandably pre occupied with ever more demanding waiting time and other targets.)

25. The government, understandably frustrated with this setback to their modernisation programme accepted the case made by the advocates of a more robust nationally controlled implementation and as a consequence NPfIT was born in 2002.

26. A simple summary of the reasons many senior NHS staff would cite for the subsequent problems with the national programme would include the following:

— A national procurement process that, by its very nature, couldn't possibly allow sufficient engagement by practising clinicians.

— A feeling by many of the clinicians who did get involved in the procurement that in the end their requirements and advice were subordinated to the bottom line cost.

— An impression that the most important part of the contract was the penalty clauses for non delivery. Whilst this has properly ensured that the NHS shouldn't pay for what it hasn't had, the better outcome would be if the NHS was in a position to pay up for timely delivery of what was bought.

— Covering the whole of England with only 5 LSPs (contracts) created implementation projects of unprecedented size and scale each involving up to 150 NHS organisations. Tackling an agenda already known to be the most difficult change management agenda for the NHS in the manner and on the scale being attempted was always a very tall order.

— In many parts of the country, and setting aside the widespread resentment regarding imposed, standardised solutions, there have been mounting delays which have not been helped by the withdrawal of one of the LSPs and 2 of the 5 LSPs changing to a different clinical system supplier some years into the programme.

— One major system supplier is currently the subject of takeover discussions and openly acknowledges that its definitive system (ie that which it is contracted to deliver will not be fully developed until at least 2008).

— With contracts on this scale any major problem affects large swathes of the NHS simultaneously. Worryingly this has also been found to be true for system failures where these have occurred.

— Many in the NHS believe that by the time the systems procured are implemented and taking into account the need to standardise and simplify to allow simultaneous multiple site implementations—what they end up with will not be the sophisticated clinical management systems that they need for modern healthcare.

— There has been a serious lack of local management ownership and accountability for ensuring successful local implementation. Setting up a multi £ billion investment in NHS IT with almost no personal accountability for delivery on the part of local NHS CEOs was and remains a monumental error of project management.

— NPfIT and IFH before it both addressed the IT needs of an NHS in a position of the monopoly supplier of healthcare. More recent policy is encouraging the entry of private sector providers into the NHS in all sectors of care. These new providers further fragment the treatment pathways and as yet there is no clear view of how NHS clinical data created in non NHS environments is to be integrated into the patient record.

— There is a lack of clarity (at least to some) as to how under the national programme the fully integrated local electronic health record is to be created. At one stage it was though this might be done through the national spine but more recently it seems that the programme will only a deliver a summary emergency record through the national spine. As argued previously the more urgent practical requirement for the NHS is not the emergency record but the integrated local record that supports 99.9 % of day to day care.

Where now?

27. There have been signs recently that the DH has recognised the urgency of introducing more local ownership and a degree of local freedom around enhancements to the systems that are eventually delivered through the NPfIT process. The more that this is possible (allowing for the limited room for manoeuvre in contracts that have been entered into) the more positive the NHS will become about this agenda.

28. The NHS is capable of implementing sophisticated electronic patient management systems. GPs throughout the country have been using their own electronic records for many years and a number of hospitals had installed sophisticated systems before the advent of NPfIT. In some areas of the country local progress has been made in sharing electronically the information in Hospital and GP records. It is important to recognise that in all these cases progress has been made by local clinicians working with local managers and IT staff and focussing on their own local priorities.

29. Whatever adjustments are made to current policy these should be made in relation to the most urgent service priorities for better use of IT. These include:

— Rapid deployment of functional clinical systems into secondary care.

— Rapid deployment of functional clinical systems to support community staff.

— Rapid deployment of functional clinical systems to support the work of the many multi site clinical networks (eg cancer networks) that are providing care on a collaborative basis to some of the sickest patients in the service.

— An urgent review of the most effective way of accelerating the capture and availability to all health professionals of clinical information about individuals that is spreading over an increasingly wide range of public and private sector providers.

Frank G Burns
Independent Healthcare Consultant

March 2007

Evidence submitted by Dr Sarah Dilks (EPR 10)

SUMMARY

1. The development of local and national electronic health records opens up considerable challenges around patient confidentiality and ensuring genuine patient participation in care. These comments focus on the issues raised for mental health services.

2. These are personal comments based on my experience of working as a Consultant Clinical Psychologist with people experiencing psychosis within London community mental health services. They are informed by my experience of using an electronic patient record system within my NHS mental health foundation trust (a local system developed specifically for the trust).

3. I have concerns about the erosion of confidentiality with the use of an electronic record. A trust-wide or national electronic system opens up the possibility of wider access to a health record than is possible with a paper record, simply because of the ease of remote access. For instance, a Support Time Recovery worker working in a CMHT (community mental health team) need not necessarily know all the details of an individual's history of childhood sexual abuse disclosed to the team psychologist during therapy in order to support that individual patient in returning to education, although all this information could be contained in the same health record. It would therefore seem important to look at the IT strategies for "partitioning" sections of an electronic record so that these are only available to particular services or clinicians. Such a system would be likely to be complex to administer (eg coping with staff changes and patient movement between services); therefore the NHS would need to allocate resources to support such administration on an ongoing basis.

4. Within our trust patients are unable to opt out of the electronic system. It is unclear whether patients are clear currently about how widely information could potentially be shared within an electronic system, particularly a national one. So, for instance, would a patient want their diabetic nurse to be able to see details of their contact with mental health services? As it stands in my Trust an individual's electronic record can be accessed by A&E psychiatric liaison staff, acute psychiatric wards, CMHTs, Home Treatment Teams, Drug and Alcohol services: in short any part of the Trust's services. Of course, only those staff who are directly involved in an individual's care should access the electronic record but this is not necessarily a comfort to the individual patient who finds that their record has been accessed more widely than they expected. Informal feedback from patients indicates this is a concern; one patient remarked that she would not have discussed much of what she had (usefully) addressed in psychological therapy if she had been aware that ward staff could later look at this in her electronic record.

5. It can be an advantage in terms of continuity of care to have access to the same record across an individual trust (for instance if someone with serious mental health problems presents at A&E in a crisis but is already known to another part of the trust). However, as with a paper record, this still depends on the quality of information entered into the record.

6. Specifically in relation to the stigma associated with mental health problems it would seem important that patients can be assured that details of their contacts with mental health services are kept separate from their physical health record and also from the department of work and pensions.

7. In addition, I have specific concerns about the configuration of an electronic system within mental health services as regards supporting recovery focused and socially inclusive care as opposed to medically driven care. So an electronic record would need to be structured in such a way as to allow holistic assessment and treatment of an individual, taking into account their needs across the range of life domains and not reducing these to symptoms and diagnosis. There should be a range of outcome measures (covering measures of subjective psychological distress, social and occupational functioning and including those outcomes most valued by patients/carers) to monitor and evaluate the care provided. And the electronic record should allow activity monitoring of individual professional input within multidisciplinary services to track specific elements of a care package (eg an episode of NICE guidelines recommended CBT for psychosis provided by a psychologist within the overall care package delivered by a CMHT to someone with a diagnosis of schizophrenia). There also need to be adequate resources for the ongoing development of an electronic system and staff training as the health context evolves.

8. In addition, I have concerns about the impact of an electronic record on patient/carer participation in the care planning process. The practicalities of showing the electronic care plan or assessment

documentation to patients/carers and inputting their contributions impede collaborative participation. While there may be technical solutions to this, eg portable laptops or PDAs, these bring their own difficulties (principally data security, resourcing and staff training).

9. Use of data for research is attractive for services but raises issues about confidentiality. Can patients really be expected to agree to any possible future research use of their records?

Dr Sarah Dilks
South London and Maudsley NHS Trust

March 2007

Memorandum by Peter Fairbrother (EPR 43)

1. Introduction

My name is Peter Fairbrother. I am a cryptologist with a special interest in the design of secure systems.

1.1 *The Patient and GP today*

As a patient I may tell my GP or Consultant information which I wish them to keep private—by which I mean I do not want them to tell anyone else, unless necessary. I rely on them to decide when it is necessary for them to tell anyone else, mainly if the information is of clinical significance to my treatment.

My GP also knows less sensitive information like my address—again, I would not want him to give it out unless he thinks it is necessary or appropriate.

GP's surgeries have now for the most part been computerised and interconnected, and it is easy for a GP to decide on a set of rules under which he gives out or does not give out different types of information, or to place a particular piece of information in a different category—for instance my address is not very secret, but that of a film star or protected witness might be much more secret.

1.2 *Data security and privacy in the existing patient-GP relationship*

There are two important security/privacy aspects to this—trust, and need-to-know. I decide whether to trust my GP to decide when it is important that information be available, and to keep it secret when it is not. If I decide I cannot trust him I can choose another GP.

Need-to-know is a very powerful security technique designed to minimise the number of people who know a data item (as a rule of thumb we consider that the security of a secret is inversely proportional to the square of the number of people who know it), and in large systems need-to-know is essential for any kind of security.

Need to know means that only people who need to know a data item can access it—but it also implies that the person who decides whether a person has a need-to-know himself needs to know the data item in order to make that decision.

In general, it is both necessary and convenient that the person deciding is a person who already knows the data item, ie he needs to know it for his own reasons, and the function of deciding whether another has need-to-know is given to him for that reason. In the medical context, it makes even more sense, as the GP (unlike the system operator) will be trained in medicine, and can decide when it is clinically important to give out data.

1.3 *The spine*

The spine is a collection of proposals, many innouous or even sensible, but including the attempted centralisation of data and centralisation of control of access to that data. I say "attempted" because in large part it is unlikely to be feasible. This will be done by taking copies of data in GP and Hospital records, and making the copies available according to some access strategy.

There is some remaining question of whether the GP and Hospital records might be stored centrally instead of in the GPs surgeries, but this would be very hard to do, very expensive, and would result in a record system which would be eg fragile in the case of a national emergency, so I do not think it should happen.

1.4 *Patient data security and privacy after the spine*

The proposed spine, especially the PSIS and LSPs, make the decision-to-trust impossible—there is no point in choosing another doctor if I don't trust the one I have to keep secrets, as the doctor does not keep the secrets any more.

More important, they destroy any effective need-to-know policy—if implemented, no matter what the access policy rules are, any person of criminal intent will be able to access medical records at will. This has clinical significance as well—the patient may decide not to tell the GP something relevant to his treatment.

The next part is about the design of the spine, including some suggestions for changes. These are mostly about how the existing databases in GP's surgeries and Hospitals could be used without duplication to perform all the functions needed or proposed. These suggestion are meant to show what is possible rather then to be a prescriptive guide—if nothing else, space prevents me from attempting that.

2. Designing the Spine

The Spine is the name given to the proposed national database of key information about a patient's health and care, which will form the core of the NHS Care Records Service (NHS CRS) part of NPfIT.

The spine consists of the *Transaction Messaging Service*, the *Spine Directory Service*, the *Personal Demographics Service*, the *Personal Spine Information Service*, *Local Service Providers*, the *Secondary Uses Service*, the *Clinical Spine Application*, and an *Access Control Framework*.

There is another function needed, some form of staff identity authentication—this varies from the NH-ID card to local authentication schemes, none of which seem to work well.

2.1 The *Transaction Messaging Service* is non-contentious (as long it is solely a messaging service between Healthcare providers), and should be straightforward to implement. The N3 virtual private network could provide the required connectivity and confidentiality and the NHS card could provide convenient and reliable authentication. Whether they will in fact do so is another matter, but to do so is well within the bounds of present art.

2.2 The *Spine Directory Service* is also non-contentious. It could be implemented on a single server, probably duplicated for reliability, and the information on it would not change much.

2.3 The *Personal Demographics Service* (PDS) is "the central and single source forpatient demographic information, such as NHS number, name, address and date of birth". It should also contain previous address data in order to make it easy to identify patients when they move address or change GP, and the patient's registered GP.

However, except in very unusual circumstances, which could be dealt with manually, the only information it ever needs to give out is the patient's NHS number and registered GP.

If an enquirer wishes to know the patient's address they would request it from the patient's GP. If the patient had not requested that their address be withheld then the GP's computer would supply the address in about the time it takes an internet page to load. This would allow famous people,witnesses, and so on to hide their addresses by simply asking their GP to withhold it.

Note that the decision whether or not to give out the address lies with the GP, in accordance with the patient's wishes. Note also that the GP's computer system does the actual work, the GP only has to enter that the address should be withheld once.

If he address request is refused, the enquirer could send the mail to the GP's address for forwarding, or could contact the GP or his surgery to explain why the address was needed.

2.4 The *Personal Spine Information Service* (PSIS) is the most obviously contentious part of the spine, partly because it is the part that is most likely not to be implementable and partly because it is the most privacy-invasive part, and the part that could be most misused.

Initially it was intended to contain all patient records, but by about mid-2003 it was realised that that intention would be impossible to implement, and the present proposal is that the records contained in the PSIS are a summary only, with the main records held in GP's surgeries and Hospitals.

There are two insurmountable technical problems with the present proposal—it would be impossible to ensure that the records held centrally and those held in GP's surgeries and Hospitals match, and the legacy idea that the summary should be the definitive record cannot stand. There is a third problem which is probably insurmountable, or at least very expensive, too—the methods we know about do not scale well to a database of that size.

Leaving the insurmountable aside, there are two more problem areas—cost, and privacy issues. The cost of such a system would be huge, and the benefits are almost zero—it does basically the same job as the Personal Demographics Service.

The only data contained in the PSIS in the latest proposal which is not in the PDS is "patient allergies" and "Courses of treatment undergone". However I see no reason why patient allergies and "Courses of treatment undergone" could not be held, like the rest of the clinical record, at the GP's surgery. Again, external access to this information is by request to the surgery.

Thus there is no need for the PSIS at all, nor for anything to replace it—although it might be desirable to upgrade the computers in GP's surgeries for better guaranteed availability, which might cost £5,000 for each of the 8,000 surgeries involved, a total of £40 million. However as this would remove any last possible justification for the PSIS, the overall saving would be very large.

2.5 *Local Service Providers (LSPs)* are also copying datasets, deciding access control strategies, and taking control of patient data away from the GP and health professional. The methods and policies vary according to region, which is another matter for concern, but as the issues are the same whether the action is performed by the PSIS or the LSP I will not comment further—except to ask why there are five of them? If they were providing off-the-shelf solutions and they had good local knowledge it might make some sense, but to have five sets of people doing simultaneous development of the same thing seems absurdly wasteful.

2.6 The privacy issues surrounding the PSIS and LSPs are wideranging, and the main driving force here is that as planned it is technically impossible to limit the persons who have access to a patient's medical records to eg those who have the patient in their care. These issues are not just the result of the PSIS and LSP datagrabs however, they more generally concern who decides when information is revealed, and the freedom a GP and a patient has to conceal information.

For instance if some information is embarrassing or endangering to the patient for social reasons but is of no clinical import, then there is no reason why it should be available to clinicians even when they are treating the patient. However, it might be useful to have it available for research or administrative purposes. For research it might be available in anonymised form, and for administrative purposes it might be available as part of a statistic of how many times that event had occurred.

If the GP is free to conceal information in these circumstances, then all the privacy issues go away—ar rather they go on the shoulders of the GP, where they have always lain. Note that the GP will be required to do very little to enforce his privacy decisions and policies, the computer does almost all the work, but he will have to make decisons and policies.

2.7 *Access control framework*

2.7a A prerequisite here is some form of personal authentication, which does not seem to have been properly settled. The NHS-ID card is having speed and scaling problems, and locally issued authentications are being misallocated and misused. It is important that the authentication states not simply that the person is employed by the NHS, but in what category and where, else a cleaner or administrator could pretend to be a Doctor and access information at an inappropriate level.

2.7b However even with proper identification, whatever access control framework is used cannot work as well in a centralised system as in a distributed net with local control, because in a centralised system need-to-know is both almost impossible to establish and too many people need to know in order to run the system. In the present case I do not think any set of access control rules can be made to work sufficiently well to give any privacy at all—either the the rules will be too strict so the is of little use, or the rules will be less strict in order that the system can be used and then access will be runaway. In my opinion there is no possible happy medium.

I find little benefit in talking about specific access control proposals now, as there are too many of them, often contradictory, and I can find no guidance on what the definitive proposals are.

2.7c There is one other point which I would like to raise, the question of the use of medical records in criminal investigations. For good reasons ("would you like your daughter to catch TB from an illegal immigrant who was too scared to see a doctor?") the Police and Criminal Evidence Act considers medical record to be "special procedure material" and limits the way it can be demanded—but it is alleged that the Police have been using medical records to find illegal immigrants.

I do not know if this is true, or under what laws it is collected, but I would like some assurance that the same special procedure applies to all medical records, whether held on a GP's computer, in the spine, the or elsewhere. Also I would like to see a requirement that data not be given out without going through the special procedure process—at the moment the Police can ask for private information, and there is nothing to stop eg BT from giving it to them.

2.8 *Secondary uses service*

2.8a The present secondary uses service is contracted to McKesson, a US corporation. We do not know much about what they will do, or how much McKesson paid the NHS for the privilege of getting their hands on the dataset. However, I would specifically ask the committee to investigate one question—is there any guarantee that the data will be kept in the UK and not copied to the US or elsewhere, where it might be subject to a Court order, like the SWIFT data?

2.8b Leaving that aside, all the desired functions except secrecy of search can be easily implemented in a distributed dataset. For example, a *pro-bono* research request might first go to an ethics committee (perhaps run by the BMA) who would recommend that GPs run the search on their computers at night when they were idle. Most GPs would probably do this.

For commercial searches, first the searchstring should be published, along with documents explaining whatdata is requested and why. A committee should consider the searchstring (that is the actual terms of the reque, as fed into the GPs computer) and if they approveit then GPs can run it and get paid for doing so. It should probably be an offence to run a search for payment unless approval has been granted. Note that the GP is never forced to run these searches. LHAs, PCTs and the like might be allowed to demand some searches are run for purposes of administration only.

3. Conclusions

CfH propose taking a dataset which is continuously generated in-house by GPs and Hospitals, copying it (there will be errors, this is a well-known property of this type of database) by force majeur and thereby taking control of the data and patient trust away from the GPs where it belongs, trying to call the copy the "definitive record" when it clearly isn't and cannot be, giving access to the copy to thousands of people without being able to effectively check need-to-know (and thus destroying any chance of even a modicum of security) and performing searches on the dataset in secret. At a cost of around £10 billion.

This is £10 billion utterly wasted. There is no need to copy the dataset, and all the proposed functions (except the secret searches—non-secret searches are fine) could be implemented using the existing dataset in GP's and Hospital's computers, although a better N3 network might be needed—but my last broadband 2Mb/s to 8Mb/s upgrade was free. The cost of doing it this way, mostly in staff training, would be in the low hundreds of millions rather than the billions.

So why have they done it this way? I do not know. It seems that around 2002 someone made a policy decision that all records were to be kept centrally, and a year or so later they discovered that this would not be practicable—but it's hard to find out who made the decision. CfH etc. then came up with this mixmash of proposals which not only has the privacy, security and operational disadvantages of a centralised dataset, but which also has problems of its own, like synchronising databases.

I was originally going to title this "Redesigning the Spine", but I cannot see much evidence that it was ever designed in the first place.

Peter Fairbrother

March 2007

Evidence submitted by Dr Peter Gooderham (EPR 08)

1. I am writing to submit evidence to this inquiry in a personal capacity.

2. My locus for submission is as follows. I qualified in Medicine from Cambridge University in 1988. I completed GP training in 1994. Thereafter I worked part-time in General Practice. I subsequently studied Law, graduating LLB (Open) in 2003, and LLM (Wales) in Legal Aspects of Medical Practice in 2004. Currently I am studying for a PhD at Cardiff Law School, about Clinical Negligence, in combination with teaching law. I have taught Criminal Law, Tort, and Medicine, Ethics & Law on the Cardiff LLB course. I have also taught various subjects of the LLM course, including the topic of Confidentiality and Access to Medical Records. I am concerned about confidentiality and have requested that my data should not be placed upon an electronic database. While I do not claim any special expertise, I am sufficiently concerned to contribute to this exercise.

Executive Summary

3. Medical records are sensitive personal information, and as such, benefit from legal protection, and also protection from medical professional ethics. Proposals for use of electronic databases, particularly a national database, do not appear to recognise this protection adequately. That is especially so, given the likely extreme difficulty in protecting confidentiality with a national database. That itself carries a risk of identity theft. If opt-outs were only to be confined to certain classes of citizens, eg prominent individual, that would be potentially discriminatory and would need careful definition. The Department of Health has, it seems, belatedly recognised that patients will be able to refuse consent for inclusion of their data on a national electronic database. Private companies taking over NHS activities stand to benefit from a ready-made, easily accessible database, although this is not a reason to proceed. Patient-held smart cards should be considered.

What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems

4. As I understand it, it is proposed initially to hold on a national database a "summary record," including diagnoses, medication, allergies and adverse reactions. However it seems likely that it would soon include most clinical information, including referrals, consultation notes, day-to-day records, requests for investigations, results of investigations and clinical images. These are already held on local databases. Transfer onto a national database gives rise to concern that because there will be many more users, security will be reduced, and that there will be a great threat to confidentiality of medical information.

5. It has been argued by the Department of Health that patients may prevent their personal data being held if this would cause distress. In fact, s 10 of the Data Protection Act 1998 provides:

> "(1) Subject to subsection (2), an individual is entitled at any time by notice in writing to a data controller to require the data controller at the end of such period as is reasonable in the circumstances to cease, or not to begin, processing, or processing for a specified purpose or in a specified manner, any personal data in respect of which he is the data subject, on the ground that, for specified reasons—
>
> (a) the processing of those data or their processing for that purpose or in that manner is causing or is likely to cause substantial damage or substantial distress to him or to another, and
>
> (b) that damage or distress is or would be unwarranted."

6. A breach of confidentiality might be regarded as "substantial damage" whether or not this is associated with distress.

7. Subsection (2) of the Act provides:

> (2) Subsection (1) does not apply
>
> (a) in a case where any of the conditions in paragraphs 1 to 4 of Schedule 2 is met, or
>
> (b) in such other cases as may be prescribed by the [Secretary of State] by order.

8. The relevant provisions from Schedule 2 are:

> "1. The data subject has given his consent to the processing.
>
> . . .
>
> 4. The processing is necessary in order to protect the vital interests of the data subject."

9. So there may be an argument that the Secretary of State could prevent refusal of data processing by the subject, or that it is in subjects' "vital interests."

10. One point of interest is whether prominent individuals, such as Members of Parliament, will be able to prevent their data being processed on grounds of confidentiality. If such an exception is to exist, it will seemingly represent an implied acknowledgment that there is a significant risk of breach of confidentiality. There is then the issue of who may object and who may not. A distinction may be discriminatory. Would anyone be able to object on the basis that they may at some point achieve a position of public prominence?

11. My understanding of the current Department of Health position, as stated by Harry Cayton, National Director for Patients & the Public, Department of Health,[92] is that patients will be allowed to prevent processing of their data. He stated that this was conceded by the Department of Health because of the extent of opposition which had built up to the Electronic Patient Record. He also cited section 10 of the Data Protection Act in support of this position.

Who will have access to locally and nationally held information and under what circumstances;

12. Clearly if an electronic record exists, then those health professionals treating a patient should have access. The access must be secure and confidential, with sanctions for breach of confidentiality. However, with many users, there must be great scope for breach of confidentiality (see below).

13. Access by the government, police and the security services is a source of concern. It is already not unknown anecdotally for access to be sought in individual cases without the patient's consent. If access to an electronic database can be established by a government employee without having to satisfy a data controller (such as a General Practitioner) that consent has been given, the protection would be inadequate.

14. The growing privatization/corporatisation of the NHS is relevant to the establishment of a national database. If access to medical records is readily available to an incoming private provider, then that has positive implications both for patients and the private provider. However, this may be desirable but is not necessary, and does not in itself constitute a compelling reason to establish a national database in the face of concerns about the law and ethics of confidentiality. Access to a greater number of people makes breaches of confidentiality more likely.

[92] Conference, "Connecting for Health," BT Tower, 28 February 2007.

Whether patient confidentiality can be adequately protected

15. In answer to this, I would suggest that it would be extremely difficult to protect confidentiality in a national scheme which has tens of thousands of users, and which is anticipated to send data around the world, eg for radiology reporting in Australia. Illegitimate use of a database by someone with legitimate access is an important potential threat to confidentiality. It has been acknowledged by Richard Granger, Director General of NHS IT, that sharing of usernames and passwords has happened and will happen,[93] which is a cause for concern. Illegitimate access is also a potential threat to confidentiality. Even with the existence of appropriate sanctions, some people will from time to time misuse their access to data[en rule] even police officers.[94] It should also be viewed with extreme concern that health records may be rich material for identity theft; this has been reported in other countries.[95]

16. With those points in mind, I think it is appropriate to consider the nature of confidentiality of medical information.

17. Medical confidentiality is a time-honoured principle. The Hippocratic Oath includes the following commitment:

> "All that may come to my knowledge in the exercise of my profession or outside of my profession or in daily commerce with men, which ought not to be spread abroad, I will keep secret and will never reveal."

18. The current professional guidance is to be found in the General Medical Council (GMC) publication, Confidentiality: Protecting and Providing Information.[96] Paragraph 1 states:

> "Patients have a right to expect that information about them will be held in confidence by their doctors. Confidentiality is central to trust between doctors and patients. Without assurances about confidentiality, patients may be reluctant to give doctors the information they need in order to provide good care. If you are asked to provide information about patients you must:
>
> — inform patients about the disclosure, or check that they have already received information about it;
>
> — anonymise data where unidentifiable data will serve the purpose;
>
> — be satisfied that patients know about disclosures necessary to provide their care, or for local clinical audit of that care, that they can object to these disclosures but have not done so;
>
> — seek patients' express consent to disclosure of information, where identifiable data is needed for any purpose other than the provision of care or for clinical audit—save in the exceptional circumstances described in this booklet;
>
> — keep disclosures to the minimum necessary; and
>
> — keep up to date with and observe the requirements of statute and common law, including data protection legislation."

19. Paragraphs 4 and 5 provide:[97]

> "Protecting information
>
> 4. When you are responsible for personal information about patients you must make sure that it is effectively protected against improper disclosure at all times.
>
> 5. Many improper disclosures are unintentional. You should not discuss patients where you can be overheard or leave patients' records, either on paper or on screen, where they can be seen by other patients, unauthorised health care staff or the public. You should take all reasonable steps to ensure that your consultations with patients are private."

20. Paragraph 9 states:

> "Disclosing information about patients
>
> 9. You must respect patients' confidentiality. Seeking patients' consent to disclosure of information is part of good communication between doctors and patients. When asked to provide information you must follow the guidance in paragraph 1 of this booklet."

21. It seems to me that uploading patient information onto a national electronic record is inconsistent with these requirements, particularly the professional obligation to keep disclosure to the minimum necessary.

22. There is a common law duty to protect confidential information. Leading cases include *Coco v Clark* [1969] RPC 41 which recognised three elements to establish a breach of confidence:

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[93] Conference, "Connecting for Health," BT Tower, 28 February 2007.

[94] See, for example, *Attorney General's Reference No 1 of 2007 sub nom R v James Andrew Hardy* LTL 7/03/07 Document no. AC9700372. (As yet, unreported elsewhere).

[95] See, for example, "Diagnosis: Identity Theft." Business Week, 8 January 2007 At http://www.businessweek.com/magazine/content/07_02/b4016041.htm Accessed 8 March 2007.

[96] Confidentiality: Protecting and Providing Information, GMC, 2004. Available at http://www.gmc-uk.org/guidance/current/library/confidentiality.asp#1 Accessed 2 March 2007.

[97] ibid.

— The information must necessary quality of confidence.

— Circumstances import obligation of confidence.

— Unauthorised use of information must have occurred.

23. *A-G v The Observer and Others* [1990] 1 AC 109 added two more:

— Information must not already be in the public domain.

— It must be in the public interest to protect the information.

24. In *Hunter v Mann* [1974] All ER 414, the court held that:

> ". . . the doctor is under a duty not to [voluntarily] disclose, without the consent of the patient, information which he, the doctor, has gained in his professional capacity."

25. In *Campbell v Mirror Group Newspapers* [2004] 2 AC 457 the House of Lords recognised that medical information is "obviously private."[98]

26. The Human Rights Act 1998 incorporates into UK Law the European Convention on Human Rights, to which the UK was in any case previously a signatory. Article 8 of the Convention provides:

> *"Article 8 Right to respect for private and family life*
>
> 1. Everyone has the right to respect for his private and family life, his home and his correspondence.
>
> 2. There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others."

27. In *Z v Finland 25 EHRR 371*, the European Court of Human Rights held:

> "Respecting the confidentiality of health data is a vital principle in the legal systems of all the Contracting Parties to the Convention."[99]

28. *X v Y* [1988] 2 All ER 648 was a case in which a newspaper obtained unauthorised disclosure of information about two doctors who had HIV. A health authority obtained an injunction to prevent their names being published by a newspaper. Rose J did not force the newspaper to reveal its source but indicated that a prison sentence would be appropriate if the informer repeated the breach of confidence. This sort of breach would become more likely the greater the number of users of a records system. The seriousness is indicated by the judge's comment on the possible sanction.

29. It is of course, accepted that there are situations in which confidence may be breached. These include disclosure in the public interest,[100] disclosure required by statute,[101] and disclosure in the patient's best interests.[102]

30. The sharing of information for therapeutic purposes is of course recognised as legitimate disclosure, but it is limited to that which is of therapeutic value. The GMC states:

> **"Sharing information in the health care team or with others providing care**
>
> Most people understand and accept that information must be shared within the health care team in order to provide their care. You should make sure that patients are aware that personal information about them will be shared within the health care team, unless they object, and of the reasons for this. It is particularly important to check that patients understand what will be disclosed if you need to share identifiable information with anyone employed by another organisation or agency who is contributing to their care. **You must respect the wishes of any patient who objects to particular information being shared with others providing care, except where this would put others at risk of death or serious harm."**[103] [my emphasis]

31. In *Cornelius v de Taranto* 68 BMLR 62, the Court of Appeal criticised disclosure of material which had no therapeutic relevance.

32. It will be seen that confidentiality is the subject of significant case law and professional ethical guidance. A striking feature of the controversy about a national electronic database is that the law and ethics seem to have received inadequate attention from proponents of the database. One point worthy of further consideration is storage of data on patient-held electronic records, using smart cards. This would overcome some of the concerns and would be consistent with the growing respect for patient autonomy.

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[98] Lord Hope of Craighead at 95.

[99] 405–406, para 95.

[100] See, for example, *W v Egdell* [1990] 1 All ER 835.

[101] For example, Terrorism Act 2000, section 19; Road Traffic Act 1988 section 172.

[102] Op cit. 2, para 29.

[103] Op cit. 2, para 10.

How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research.

33. Subject to the concerns about confidentiality, it seems to be accepted that a medical record is an appropriate research tool. Data can be used for research if it is approved by a recognised ethics committee and permanently anonymised.[104] There is of course statutory authority covering some research. Section 60 of the Health and Social Care Act 2001 provides for processing of data for certain purposes. The Health Service (Control of Patient Information) Regulations SI 2002/1438, provides that processing patient information in accordance with the regulations shall be taken to be lawfully done despite any duty of confidence owed by that person in respect of it. The scope of SI 2002/1438 includes public health/ communicable diseases, trends in diseases and risks, preventing/controlling disease, monitoring and managing communicable disease, immunisation programmes, adverse reactions, food and environmental risks, and giving of information about diagnosis and risks.

34. The main issue with respect to a national electronic record is security, as discussed above. It is essential to protect against reversal of anonymisation. Records which, although anonymised, allow identification of the patient, should not be disclosed.

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to 2 years behind schedule.

35. I am not able to comment in detail on this point as I do not possess the necessary knowledge of the progress of the NHS Data Spine. I wonder, however, if there is technical difficulty, which may have an impact on the security points made above.

36. For example, I understand that patient access controls, otherwise known as "sealed envelopes" have been advanced as an important method of protecting patient confidentiality.[105] However, the technology was not in existence at the time the Department of Health described them, and may not be able to protect the confidentiality of some forms of patient data, eg images, and information from other systems which do not offer "sealing." This appears highly unsatisfactory.

37. Suggested further reading

Mason, JK, & Laurie, GT "*Mason & McCall Smith's Law and Medical Ethics*" 7th edition, pub OUP, 2006. See Chapter 8, "Medical Confidentiality."

Thornton, Dr Paul. "*Why might National NHS Database proposals be unlawful?*" January 2006. At http://www.ardenhoe.demon.co.uk/privacy/NHS%20database%20proposals%20unlawful.pdf

38. I hope these thoughts are helpful to the Committee.

Dr Peter Gooderham

8 March 2007

Evidence submitted by Robin Guenier (EPR 23)

Guenier is an independent consultant and chairman of the medical online research company, Medix UK plc. In 1996, he was Chief Executive of the Central Computing and Telecommunications Agency reporting to the Cabinet Office. He is a Liveryman of the Information Technologists Company (a City livery company) and is chair of its medicine and health panel. He has written this note in his private capacity, in no way is it intended to represent the views of Medix or of the ITC.

EXECUTIVE SUMMARY

This evidence is based on findings of surveys of doctors' views of the NHS National Programme for IT (NPfIT) conducted by Medix UK plc. It indicates, in particular, that most doctors are worried about the confidentiality of electronic patient clinical records on the national database. A majority, however, recognises the benefits of such a record with many saying that some additional risk to confidentiality is therefore acceptable. But about 50% say that they will not or are unlikely to upload clinical details to the database unless a patient has given specific consent. Doctors' main concerns are that hackers and public officials from outside health or social care might access the records.

Unless these concerns are overcome, the successful implementation of the electronic patient record seems likely to be in doubt. Keys to progress, both for NPfIT as a whole and for the electronic record, are (a) considerably better engagement with all users and especially with clinicians and (b) substantial improvement in doctors' confidence regarding the project's implementation. Neither will be easy.

[104] *R v Department of Health, ex p Source Informatics [2000] 1 All ER 786.*

[105] "Sealed Envelopes" briefing paper, Department of Health, 2005. Document record ID Key NPFIT-FNT-TO-PRJMGT-0035.10.

1. Introduction

1.1 This evidence is concerned mainly with doctors' views, in particular, about the data privacy and confidentiality issues associated with the electronic record systems to be introduced under NPfIT and referred to in the inquiry's terms of reference. (Throughout this document this is referred to as "CRS" (the NHS Care Records Service)). It will also consider doctors' views on the CRS concept as a whole, so as to contribute to the Committee's review of its benefits and progress and why its introduction is late. It will examine what conclusions can be drawn regarding actions necessary to ensure that NPfIT, and hence CRS, is successfully implemented.

1.2 This evidence is based mainly on surveys of doctors' views conducted by Medix UK plc (Medix). There are also references to surveys conducted by Nursix and by Ipsos MORI.

2. Background

2.1 Medix UK plc has conducted seven major surveys of doctors' views of NPfIT, starting from February 2003. The most recent was carried out in November 2006 and is principally referred to in this evidence. The full results are submitted to the Committee as supplementary material.

2.2 The survey was commissioned by the *British Journal of Healthcare Computing and Information Management*, *Computer Weekly*, *E-Health Insider*, the *Guardian* and *GP* and ran from 7 to 13 November 2006. The objective was to investigate doctors' views about NPfIT and to consider how those views had changed over three years. Respondents were over 1% of the 90,000 or so doctors who practice in England and are therefore affected by NPfIT. They covered a wide and well-balanced range of specialties and, in terms of grade, commitment and decade of qualification, were a good representation of practising doctors on the GMC register (see the demographic details set out in Appendix B to the survey results).[26] That and the large sample achieved are strong indicators that respondents represent the views of the wider population of doctors affected by NPfIT.

2.3 Respondents were asked six questions relevant to the main focus of the inquiry:

Q11a Are you aware of when you will be expected to start uploading your patients' clinical details to the national database as part of the Care Records Service (CRS)?

Q11b Do you agree that the advent of the Care Records Service (CRS) is likely to mean that the confidentiality of patients' records will be more secure than it is today?

Q11c Do you agree with the following statement: "*CRS will benefit patients by enabling clinicians to make better decisions by having easy access to a complete, up-to-date record of clinical information*"*?*

Q11d If you agreed with the above statement (Q11c), do you agree that some additional risk to patient confidentiality would be acceptable?

Q11e What are your key concerns about the possible impact of the Care Records Service on patient record confidentiality?

Q11f To safeguard confidentiality, the DH has published a "Care Record Guarantee". In view of this, are you prepared to upload a patient's clinical details to the national database if that patient has not given their specific consent?

3. The Confidentiality of Patient Records

3.1 Respondents were concerned about the security of clinical records uploaded to the national database. 79% of GPs and 55% of non-GPs (largely hospital doctors) said that the advent of CRS is likely to mean that confidentiality will be less secure than it is today. Only 6% of GPs and 16% of non-GPs thought it likely to be more secure.

3.2 This was the third time that Medix has asked the question. Results from all surveys (January 2005, January 2006 and November 2006) indicate that doctors are becoming less sure about confidentiality. GPs appear to be more concerned than non-GPs. See Table 1.

[26] The NHS Plan: A Plan for Investment A Plan for Reform; Department of Health; 2000.

Table 1

SUMMARY OF FINDINGS RE EFFECT OF CRS ON RECORD CONFIDENTIALITY

Effect of CRS on the confidentiality of patient records?		*Q647 Jan 2005*	*Q849 Jan 2006*	*Q1066 Nov 2006*
GPs	Better	6%	8%	6%
	Worse	70%	71%	79%
Non-GPs	Better	18%	15%	16%
	Worse	42%	46%	55%

3.3 That a majority of doctors is increasingly concerned about confidentiality could well prejudice the introduction of CRS. That would have serious consequences for NPfIT as a whole and may be relevant with regard to the third bullet point of the inquiry's terms of reference.

3.4 However Medix's most recent survey went further than earlier surveys. When asked if some additional risk to confidentiality was acceptable in view of CRS's potential for patient benefit, 55% of the 65% of those respondents who thought there was such benefit (i.e. 36% of all respondents) said either that there was no such risk or that any such risk was acceptable. This indicates that, in practice, some doctors might be willing to accept a lessening of patient record confidentiality. See Tables 2 and 3.

Table 2

Q11c Do you agree with the following statement: "*CRS will benefit patients by enabling clinicians to make better decisions by having easy access to a complete, up-to-date record of clinical information*"?

	GP	*nonGP*
Strongly agree	7	18
Agree	44%	47
Disagree	21%	14
Strongly disagree	8%	5%
Unsure	15%	10%
Insufficient information to comment	5%	7%

Table 3

Q11d If you agreed with the above statement (Q11c), do you agree that some additional risk to patient confidentiality would be acceptable?

	GP	*nonGP*
I don't think there will be any additional risk	3%	8%
Strongly agree	3%	4%
Agree	42%	46%
Disagree	29%	24%
Strongly disagree	12%	8%
Unsure	9%	8%
Insufficient information to comment	2%	3%

4. Key Concerns

4.1 Respondents were asked what concerned them in particular. See Table 4. The greatest concerns were outsiders hacking into the system and access to the system by public officials from outside health or social care. This latter finding may be of interest to the Committee with regard to the second bullet point of the inquiry's terms of reference.

Table 4

Q11e What are your key concerns about the possible impact of the Care Records Service on patient record confidentiality? (*Select any three—unless first option selected*)

	GP	*nonGP*
I don't think CRS is likely to make patient records less secure	10%	14%
Clinicians not adhering to the rules	24%	22%
IT technicians not adhering to the rules	21%	17%
Social services staff not adhering to the rules	26%	19%
Researchers not adhering to the rules	16%	9%
Bribery or blackmail of people with access to the records	34%	22%

	GP	*nonGP*
Outsiders hacking into the system	62%	56%
Inadequate access controls	48%	42%
Access by public officials outside health or social care	62%	51%
Unsure	2%	7%
Insufficient information to comment	5%	8%
Other	4%	2%

5. Patient Consent

5.1 Another important new finding was that 51% of GPs and 47% of non-GPs said that they will not or are unlikely to upload a patient's clinical details to the national database unless that patient has given specific consent. Only 13% (GPs) and 18% (non-GPs) said that they would or probably would upload such details in these circumstances. See Table 5.

5.2 This finding may be of interest to the Committee with regard to the first bullet point of the inquiry's terms of reference. It is a significant finding and, together with the finding about doctors' concerns about confidentiality (3 above), underlines what could be a serious problem for delivery of CRS and thereby of NPfIT.

Table 5

Q11f To safeguard confidentiality, the DH has published a "Care Record Guarantee". In view of this, are you prepared to upload a patient's clinical details to the national database if that patient has not given their specific consent?

	GP	*nonGP*
Yes	5%	5%
Probably	8%	13%
Unsure	22%	14%
Unlikely	13%	13%
No	38%	34%
Insufficient information to comment	13%	15%

6. A Wider View

6.1 The survey found that, overall, doctors were positive about NPfIT's potential for patient benefit. For example, 58% of GPs and 69% of non-GPs believe it will improve clinical care in the longer term (see also the Medix/Ipsos MORI comparison submitted as supplementary evidence), although these figures are almost halved when they were asked about the next year or two. This finding reflects some comments by respondents to the survey (see Appendix D to the survey results) that, despite any deficiencies or concerns, the NPfIT concept is vital to the NHS.

6.2 CRS in particular is supported by a majority of doctors. In its last six surveys, Medix has asked doctors whether they regarded CRS as important and the majority said it was. However, over the years that support has been declining: see Table 6.

Table 6

SUMMARY OF FINDINGS RE SUPPORT FOR CRS

The Care Records Service is important or very important	*Q354 June 2003*	*Q476 Feb 2004*	*Q558 July 2004*	*Q647 Jan 2005*	*Q849 Jan 2006*	*Q1066 Nov 2006*
GPs	77%	81%	79%	59%	59%	56%
Non-GPs	83%	82%	88%	73%	69%	69%

6.3 This reflects a much harsher deterioration in support for NPfIT as a whole. Since its first survey, Medix has asked doctors if they thought NPfIT was an important priority for the NHS and if they thought it a good use of resources (not asked in July 2004 and January 2005). Since its third survey, Medix has asked doctors if they were enthusiastic about NPfIT. The findings (see Table 7) indicate a serious decline in support.

Table 7

SUMMARY OF FINDINGS RE SUPPORT FOR NPfIT

	Q265 Feb 2003	*Q354 June 2003*	*Q476 Feb 2004*	*Q558 July 2004*	*Q647 Jan 2005*	*Q849 Jan 2006*	*Q1066 Nov 2006*
NPfIT is an important priority for the NHS							
GPs	67%	66%	70%	58%	41%	38%	35%
Non-GPs	80%	73%	80%	73%	68%	56%	51%
I am fairly/very enthusiastic about NPfIT							
GPs	56%	45%	21%	26%	25%		
Non-GPs	-	-	75%	65%	51%	45%	41%
*NPfIT is a good use of NHS resources**							
All doctors	47%	43%	31%	-	-	17%	11%

* Results confirmed in surveys conducted by Ipsos MORI for CfH—see the Medix/Ipsos MORI comparison submitted as supplementary information.

6.4 The surveys do not determine why this deterioration is happening. However one question, asked in January and November 2006, may be a pointer: when asked how they rated NPfIT's progress so far, on both occasions only 1% of all respondents considered it excellent or good and 8% satisfactory. In January 75% of GPs and 63% of non-GPs rated it poor or unacceptable and, by November, these figures had increased to 82% and 72%. These findings illustrate sharply the immense challenge facing Connecting for Health in persuading doctors that it is doing an competent job.

6.5 Another concern is poor consultation:

6.5.1 From the outset doctors have complained about their not being engaged with NPfIT: see Table 8.

Table 8

SUMMARY OF FINDINGS RE CONSULTATION (ALL DOCTORS)

		Q265 Feb 2003	*Q354 June 2003*	*Q476 Feb 2004*	*Q558 July 2004*	*Q647 Jan 2005*	*Q849 Jan 2006*	*Q1066 Nov 2006*
How much consultation with you about NPfIT?	Adequate	2%	2%	4%	5%	5%	5%	5%
Is consultation with you important?	Yes	-	85%	88%	84%	86%	89%	92%

6.5.2 An associated finding (Q1) is that, as recently as November 2006, 50% of doctors had little or no information about NPfIT (from any source), with 3% saying that the survey was the first they had heard of it. These findings echo a Nursix survey of 4,451 nurses conducted by Medix in June 2006 that found that 65% of respondents had either inadequate or no information about CRS.

6.5.3 Also relevant is a survey of doctors conducted by Ipsos MORI for NHS Connecting for Health in February 2006 and published in June which found that 68% of respondents had little or no information about NPfIT, 11% saying they had "no information at all". (A table showing the similarity of key Medix and CfH's Ipsos MORI findings is submitted as supplementary information.)

7. Development and Delivery

7.1 The Medix survey casts light on the matters referred to in the fifth bullet point: when asked (Q11a) if they were aware when they would be uploading patients' clinical details to a national database, a big majority was unsure or didn't know. See Table 9.

Table 9

Q11a *Are you aware of when you will be expected to start uploading your patients' clinical details to the national database as part of the Care Records Service (CRS)?*

	GP	*non GP*
I am already doing so	4%	1%
Fully aware	4%	3%
Slightly aware	8%	9%
Unaware	64%	63%
Unsure	12%	12%
Insufficient information to comment	8%	7%
Not appropriate to me	1%	7%

This finding confirms that the development of CRS has a long way to go and contrasts with the then minister in the Department of Health David Lammy's reply to a parliamentary question on 28 February 2003. He said that a target was that, by December 2005, "All primary care trusts, and all NHS trusts (will be) actively implementing elements of electronic patient records". The suggestion in the Committee's terms of reference that the new systems are "up to two years behind schedule" may prove optimistic.

7.2 The fifth bullet point asks why CRS is late. An Office of Government Commerce / National Audit Office "agreed list of common causes of project failure" (see the Annex to the recent NAO report "Delivering Successful IT-enabled Business Change") had as its third cause (out of eight) "Lack of effective engagement with stakeholders". At least so far as clinicians are concerned, that would appear to be a major obstacle to NPfIT and hence CRS success—see 6.5 above. Unfortunately, most of the remaining seven causes on the OGC/NAO list also raise serious doubts about the overall management of NPfIT.

8. Conclusion

These findings indicate, in particular, that a lot needs to be done to regain clinicians' support for NPfIT and hence for CRS. An immediate action must be detailed, genuine and widespread consultation: if an electronic patient record, with its attendant advantages, is to be introduced successfully, the above findings make it clear that clinicians have to be consulted and involved. The findings suggest also that doctors have to be persuaded that NPfIT's implementation is sound. It seems likely that the commissioning and publication of an independent review of NPfIT, as recently recommended to the Committee by leading academics, could make an important contribution to achieving that.

Consultation will be a huge (about 700,000 people would be involved) and expensive task, made particularly difficult by being started so long after the project was announced. Yet it should not be a hopeless task: doctors and nurses have consistently said that the objectives of NPfIT and particularly of CRS are worthwhile. Until it is done, however, it's hard to see how doctors in particular can be persuaded that serious and effective action is being taken to protect the confidentiality of patient records under CRS (see 3, 4 and 5 above). And, until that is done, the overall development and delivery of the service (fifth bullet point) seems likely to be in jeopardy. Giving evidence at a Department of Works and Pensions Select Committee hearing on 2 February 2004, Sir Peter Gershon (then chief executive of the Office of Government Commerce) said, "If the staff are not brought in to new ways of working, new ways of delivering benefits to the population, however successful the technology is the systems will not be successful." If the NPfIT systems are not successful, questions of concern to the Committee about the protection of patient data confidentiality and the benefits of an electronic patient record could be irrelevant.

Robin Guenier

15 March 2007

Annex

COMPARISON OF MEDIX AND IPSOS MORI SURVEYS

(re doctors' views of the National Programme for IT (NPfIT))

In the Executive Summary of its November 2006 survey, Medix said: *The findings confirm earlier Medix findings that a majority of doctors believes that NPfIT has the potential to benefit clinical care. However, they also confirm that doctors are increasingly critical of the project—especially of its costs and of how it is being implemented. But knowledge of NPfIT is unchanged: few doctors have a lot of information about it and a large majority continues to say that they have had inadequate consultation about it.*

It is not easy to compare the Medix surveys with those conducted by Ipsos MORI for NHS Connecting for Health as few questions used are precisely the same. Also the methodologies are different and the Medix sample sizes are much larger. Nonetheless, the following indicates that the Ipsos MORI results fit an overall pattern established by Medix—reflected by the above extract from the Medix Executive Summary.

		Medix Feb 2003	Medix June 2003	Medix Feb 2004	Medix July 2004	Medix Jan 2005	MORI July 2005	Medix Jan 2006	MORI Feb 2006	Medix Nov 2006	Comment
Likely effect on clinical care? term)	Improvement	60%	60%	63%	53%	54%	65%	63%	68%	69%	These are encouraging findings, especially as the trend is clearly upwards.
Is NPfIT a good use of NHS resources?	Yes		47%	43%	31%	–	25%	17%	20%	11%	In contrast, this indicates a marked reversal of view since NPfIT's inception.
	No		27%	28%	30%	–	46%	57%	50%	68%	
How much information have you had?	Little/none**	94%	94%	77%	71%	64%	66%	56%	68%	50%	It is remarkable that so many doctors still know little about such an important project. (And see Note 2)

Notes:

1. – Question not asked in this survey.

2. ** An Ipsos MORI finding in February was that 11% of doctors said they had "no information at all" about NPfIT—illogically, elsewhere in the survey, 25% said they had "never heard of it". If accurate, that is extraordinary over four years from the programme's inception.

Evidence submitted by Andrew Hawker (EPR 15)

Summary

The Care Record Guarantee (May 2006) lists worthy aspirations, but too many of them are qualified by terms such as normally and if possible. It assumes that NPfIT is being implemented perfectly and seamlessly, which is not the case. The Guarantee is not underpinned by credible procedures for control or redress.

The plans for the electronic patient record reveal some contradictions in government policy. On the one hand, there is a strong emphasis on patient choice. Yet the demeanour of the DoH towards patients who would prefer not to be included in the CRS is one of suppressed hostility.

The DoH is also expanding the use of outside contractors in many aspects of health care. But its policies on information governance do not reflect this.

The DoH has recently adopted a very centralised, top-down approach to system implementation. This makes good sense for the procurement of core systems, in terms of economies and standards. But it does not follow that there has to be anything more than a unique patient identifier at the heart of the system. Nor does the centre need to operate (as opposed to monitor) more than a few minimal but strict controls once the system is in operation.

At the very least, any implementation of the CRS should be deferred until the IT framework of which it is a part has been installed completely, and has been thoroughly tested for privacy protection (eg by tiger teams).

In the numerous guidance documents issued by the DoH, more attention should be given to questions of the copying and retention of data within linked electronic systems. The documents themselves should comprise fewer generalisations, and more concrete examples.

Submission

1. This submission is made as an NHS patient. I have no connection with any medical or commercial body involved in the NHS.

2. I feel like a passenger boarding a plane. On board are technicians arguing about how the plane's controls should be wired together, and who should do it. The plane has not had many test flights, and some of those have crashed. Meanwhile, flight attendants are handing out brochures saying how safe it all is.

3. I have read through the Care Record Guarantee, and I have compared it with some other guarantees which cover appliances in our house. If these were written in the style of the CRG, they would assure me that the appliances were made with great care and that everyone had the best possible intentions. Actually, real guarantees are mainly concerned with spelling out exactly what remedies are available to me. They specify *how* I should make a claim, and any particular circumstances which might invalidate my claim.

4. From the CRG I learn that some key decisions may be made on my behalf without consulting me (p 5) and that there will be a complaints procedure via the PALS (p 6). My impression is that the PALS typically lacks the kind of IT expertise needed to investigate situations covered by the CRG. Caldicott Guardians were and are an excellent idea, but these people too need time, technical skills, and support from computer forensic services when and wherever they need them. They are only mentioned once in the entire document (p 5).

5. So, the reader is left with no clear idea about how compliance with the principles in the CRG is to be enforced. This becomes even more worrying when one considers the contracting out of medical treatment. How, exactly, will the compliance of outside contractors be checked? Will they be permitted to transfer patient records onto their own systems? If so, how long will they be permitted to retain them?

6. If, in the light of my concerns about the CRS, I wish to withdraw consent for the inclusion of my record, the DoH assumes that it must be because I am concerned and distressed (DoH standard letter). This is a strange choice of language. It seems intended to imply that I am a bit over-emotional. The DoH is apparently unable to accept that patients may simply lack faith in the assurances it is giving.

7. Other parts of the CRG imply considerable complication and bureaucracy. I can request a list of everyone who has accessed my records (p 7) and eventually check my own records on-line (p 9). I currently use on-line banking, and access my accounts once or twice a week. The banks I deal with have elaborate access controls, based on reference number, a check number, and key names and dates which can be requested at random. Such ID checks are expensive to set up and maintain, but make sense for a bank since it is much cheaper than having me take up the time of staff in the local branch. In the case of the NHS, most patients will only to want to pursue self-checking very infrequently, if at all. The proposed Home Office ID card will, as with many other on-line situations, be of no practical use. This whole area needs to be re-thought.

8. A much simpler approach is of course to make sure that each patient has a unique ID, but otherwise to keep patient data in as local and circumscribed a way as possible. The supposed benefits of the CRS owe more to clichés in the minds of politicians than to medical priorities. During my own encounters with the NHS I have often been asked to repeat details of my history, and occasionally to have tests re-done. Doctors are sometimes sceptical about what is already on the record, and this seems to me a good thing. The scenario of the unconscious patient in casualty with a severe allergy can be targeted by other technologies, at a much lower cost than a universal CRS.

9. If the DoH remains persuaded that the CRS is needed, then it should be phasing it in only when it can prove (rather than merely claim) that it is operating "in line with internationally approved information security standards" (CRG p 1). This proof should be provided by inviting sceptical parties (ie not the normal run of government consultants) to test the system. For example, experts in this field can be found at Cambridge University. Similar independent validation should be carried out of the resources and facilities available to the internal audit teams charged with overseeing privacy protection.

10. At the same time, the DoH should declare a moratorium on issuing prescriptive guides about good information governance. It is unrealistic to expect medical staff to wade through these, let alone digest them: (the good practice guidelines for GPs, for example, run to more than 70 pages). Instead, the DoH should be constantly inviting clinicians and others to submit examples of individual situations they believe to be problematic. These should be analysed and fed back into the design and monitoring of systems. And in the longer term, any advice could be much more interesting and effective if more of it were example-based.

11 In the process of getting the new IT infrastructure up and running, the DoH is overlooking the quite stupendous scale of the data now being collected together, and the many different ways in which it is being stored. For example, it is unavoidably duplicated each time a back-up copy is taken or an email is sent and received. Hitherto, NHS policies on document retention have focussed on minimum times for retention. This has been because, in most instances, only one copy of the record has existed. In the new electronic era, these policies need to be revised to identify one root (authoritative) version of each element of a record, which would be subject to a minimum retention time. All other versions or copies would be subject to maximum retention times. In some cases, eg for outside contractors carrying out single operations or procedures, these retention times should be extremely short.

Andrew Hawker

12 March 2007

Evidence submitted by Ms A Jones (EPR 07)

SUMMARY

Thank you for the opportunity to comment on the above. My background is IT and this system has fantastic potential, but only if the confidentiality issue is taken very seriously. We need to be sure that Doctor/Patient confidentiality is maintained to the highest degree, and that GPs/other medical professionals will not be required to pass on our personal information under any circumstances without our (written?) consent. This system is unique in that it should, and must, stand alone from all the other proposed/existing database systems. The key to its success is privacy and anonymity. Already a growing number of people visit a GP's surgery at random claiming to be on holiday and possibly using a false name and address rather than having their condition logged on their own record on their GP's system. The greatest danger is that people with various sensitive conditions will not present for treatment or help if the issue of confidentiality is not robustly enforced.

1. *What info should be held?*

The absolute minimum level of personal data should be held to preserve privacy without compromising health, eg:

- Initials and surname (*not* full name).
- Age band (*not* age/date of birth).
- Sex (*not* title).
- House number and post code (*not* full address) (Apparently a surname, house number and post code are sufficient to have a letter delivered).
- Optional—phone/mobile phone number and email address.

With the consent of patients, certain medical conditions, immunisations, operations, allergies and current medication should be noted. This includes Parental Consent for children under 16 years. A time limit should be considered eg: only data for past 10 years. GP/other narrative comments should be omitted.

We all know our NI Number so it should be possible to allocate a permanent NHS number if necessary to ensure the correct record is accessed.

Patients should be able to opt-out of the system if they wish. If a good, robust and secure system is seen to work efficiently and effectively then perhaps people may choose to opt-in at a later date.

2. *Access (local and national)*

- Only the patient's GP should have full access—not auxiliary medical or admin staff at surgeries.
- Hospitals should only have access via GP giving permission to a hospital consultant so a log of authorised access is created. A system to control this "out of hours" and in an emergency should be developed.
- Nursing and other staff in hospitals/surgeries should not have full access to complete patient records—their need for information should be confined to current treatment and information directly relevant as directed by the patient's consultant or GP. This is absolutely essential in the case of sensitive circumstances or conditions (alchohol/drug use; STDs; domestic violence; depressive illnesses etc). Perhaps thought should be given now to the manner which information relating to these sensitive issues is stored and used. Failure to address this will lead to people not seeking appropriate treatment or help. No other body should have access to medical records under any circumstances.
- A patient should be able to view their full record at any time and there should be a clear and simple procedure to correct any wrong or misleading data.

3. *Protection of patient confidentiality*

This is the greatest weakness in the system. Briefly—I experienced a leak of three distinct pieces of my medical info. I could do nothing as I had no absolute proof. I sold my house and moved 250 miles away. This was due to a community medical staff known to me socially (not a GP) having what seems to be unlimited access to records. This is why every possible step must be taken to limit the personal or identifying data held in the patient record and there must be very clear and stringent penalties for any abuse of the system—no matter how trivial. In my case if my full name, address etc had not formed part of my record it would not have been possible for the gossip to be connected to me. Thought needs to be given as to why this specific and full identifying data needs to be included rather than my suggestion at Para 1. The confidentiality issue is not really about what the GP knows—it has more to do with the casual users of the system who may not be involved in your care or who may see your data in passing.

- When attending a medical appointment there is no need for your complete record to appear on screen in front of the Administrator. A time-out should be build in to guard against a patient record being accidently left on-screen.
- A chip and pin-type card held by the patient should be used to access the full patient record. The argument that we may forget or loose a card does not hold water. We all manage to carry our various credit, debit and store cards and remember our various pins. Alternative arrangements could be made for those who genuinely could not reliably use this card system. For the minority who find themselves in an emergency without their card the same procedures apply as now—medical professionals do their best in the circumstances.
- The proposed system will not remove the need to describe your condition several times to various medical professionals. The comprehensive patient held notes used during pregnancy do not avoid this happening as it is easier/quicker for medical staff to talk to you than to read pages of notes.
- There is no reason to link this database with any other database. A Medical Record should be a completely separate entity to other public or private Personal Information databases.

4. *Data for other purposes*

— Patients could be asked to sign up to their statistical data (not personal data) being collected for other purposes eg: research. In a database system it is very easy to implement this.

— The GP or hospital consultant should be the gatekeeper of this data, providing total numbers or percentages or depersonalised case histories for research purposes. Most people would be comfortable with this.

5. *Progress and delay*

If this system is implemented without thorough open discussion and debate it will become an expensive failure. Time taken now to think through all the implications and to listen to people's genuine fears and concerns will ensure the final design is acceptable and fit for purpose. The system needs to be thoroughly piloted and tested before implementation. All major IT systems take years. In this instance it is essential to invest the time to make sure it is absolutely watertight and foolproof—unfortunately this will take longer than you think.

Thanks for your time.

A Jones (Ms)

7 March 2007

Evidence submitted by Dr Jon Orrell (EPR 53)

I would like to address the question:

Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule.

The reason is that NPFIT was designed by international "experts" with no knowledge of the complexities of medical informatics in the NHS. They started from the top down, dismissing existing systems as being legacy and intended to rip and replace with new monopoly suppliers.

To the casual and uninformed IT management consultant it seemed obvious that the big multinationals had the answers and the little people doing the job on the ground were superfluous and irrelevant. One would have imagined from the outside that Hospital systems were the key and a national system would start with a spine, then Hospitals, then primary care and GPs later.

In fact the truth is the reverse. The best integrated electronics are already held in primary care by GPs. We have already had the lifelong record, integrating summaries, medication, allergies, letters and tests for over a decade. The sensible thing would have been to build from the bottom up with this solid foundation as the basis.

We tried the one size fits all approach in 2000 as part of an NHS pilot site. It failed twice and two years later we adopted integration with existing systems. It worked. CfH have exactly matched our timescales and conclusions. I warmly commend the excellent pragmatic work of Gillian Braunold, who has determindly bought the programme back from the brink of disaster (original centralised plan) and come up with good work around solutions. Keeping existing working GP systems being a brilliant example.

There are examples of success in action with some ideas on consent. The key being to leave the GP as the custodian, editor and monitor for the NHS patient record.

The key to success is to build on existing systems by integration. This is quick and incredibly cheap compared with the 12 billion rip and replace plan.

There are examples of success in action. http://www.e-health-insider.com/news/item.cfm?ID=2506

This Graphnet integration is the one we used in our pilot, It was also used in Hampshire (see below). It costs a fraction of the CfH rip off price and works in weeks.

http://www.bmj.com/cgi/content/full/333/7559/146-a?maxtoshow=

http://www.bmj.com/cgi/content/full/333/7557/39 << Weymouth IT pilot site lessons for the NHS v2.rtf >>

Dr Jon Orrell GP
Weymouth

16 March 2007

Evidence submitted by Ivor Perry (EPR 58)

My area of research is in the deployment of systems that enact business processes, and the effect they have on organisational culture. A list of my publications can be found at http://www.cse.dmu.ac.uk/⩾iperry/Publications.htm

1. Scope of evidence: this document discusses the delay in implementing Electronic Patient Records systems in the NHS, and the inefficiencies and inadequacies of planning that have led to it.

2. Prior to the inception of the NPfIT, some useful work on modernising the administrative and "customer-facing" systems in the NHS had already begun. For example, work done between 1995 and 1999 at The Robert Jones & Agnes Hunt hospital in Oswestry, producing electronic patient records, was described by an independent report as "exemplary". During this period, Trusts were largely allowed to make their own decisions on IT expenditure. At the same time, the Government was establishing standards for the use of interactive systems; for this type of system, the use of XML standards and associated techniques was (quite properly) recommended.

3. Inevitably, with such an approach, there will be issues of control (if systems are to interact across some kind of national communications infrastructure, there have to be agreed standards of data structures, for example). Also, there would be problems of speed of deployment (there would be little pressure on Trusts to conform to some national timetable). On the other hand, Trusts would be able to set their own priorities, to engage suppliers that served regional (geographic) areas and/or were truly specialist in their field.

4. At this point, it is worth noting the history of large systems development in the NHS. These have mostly been failures, or at least partial successes, and have been comprehensively written up in the literature.(1) Further, the NHS had been subjected to around 20 major IT initiatives in the previous 21 years.(2) The result of those experiences was, according to writers on both the NHS and on organisational culture, to increase resistance to IT-mediated change and to reduce the likelihood of IT success, where it was imposed on user populations. The impact of such numerous and major IT changes cannot be underestimated; no private company, so far as I am aware, has been through so many, so public, and so unsuccessful IT changes in a similar period.

5. There have been a number of fundamental, structural problems with the way NPfIT, and Connecting for Health have been implemented.

(a) The decision (if that is what it was) to impose a national system on an unwilling and "bruised" user population was unwise in itself.

(b) The process of enforcing the acceptance of systems providers who had not been clearly chosen by the local IT and user communities only added to the burden.

(c) The major suppliers were chosen for their ability to deliver large systems, which appears sensible; however, none of them had any real expertise in the area of EPR, and mostly they selected as subcontractors companies who either had "big company" pedigrees, or who had experience of EPR in the USA. Neither of these bases for selection was going to be successful, unless by chance. The USA practice in regard to medicine delivery, let alone EPR, is very different from the UK, and an assumption that "what works in Little Rock Arkansas, will work in the UK" is dangerously wrong.

(d) The promised control over major suppliers has not materialised. Despite the public statements by Mr Granger about disciplining suppliers who did not perform, the suppliers have not been held to account significantly, further reducing user acceptance.

(e) Arguably, the sums of money—for example, the proposed £30 million for just six pilot sites—have been vastly in excess of what was actually needed. In what I have seen so far in both the UK and the USA, that figure should be nearer £3,000. The prospect of very large revenues will always attract large, expensive undertakings to justify, or at least accommodate, the budgets.

6. The future? Curiously, in view of what I have said, it is worth looking at what is happening in the USA. I am not advocating their healthcare model, but the sheer fragmentation of their healthcare system has resulted in some interesting approaches which we could learn from. Having attended a series of workshops at Claremont University, California, recently, I was impressed by a number of the EPR systems that are being developed in America. In default of a Federal initiative, let alone a Federal budget, for EPR systems nationally, individual counties, hospitals, companies and charities are all developing their own systems.

7. A side effect of this lack of national planning is that most systems are quite small developments, designed with the needs of their user community in mind, yet built according to well documented IT standards that mean that data can be exchanged easily between say, that charitable hospital that administers healthcare, the patient's company that pays the bills, and the insurance company that underwrites those payments. In this context, the differences between the UK and US models of healthcare serves to demonstrate that systems are being developed with the right kind of flexibility and communications ability.

8. The US companies that are developing these systems are not always the large US companies that we have seen in this country. Mostly they are small organisations, able to focus on certain areas (eg social care units, geriatric care centres, local hospitals etc) so that the EPR is customised to suit the needs of the user community.

9. Does similar expertise exist in this country? Undoubtedly. There are a number of small, specialist companies operating in the EPR area, at minimal cost, but with quite impressive track records of customer satisfaction.

10. The challenge in using this kind of development model will be control. However, a strategy- and standards-based body at the centre of the NHS should be capable of ensuring that, where required, such systems can communicate with others.

(a) The opportunities of such an approach are obvious.

(b) Enormous cost savings.

(c) Speed of deployment of individual systems, delivering results where needed, rather than according to a national prescriptive plan.

(d) Conformance to local and/or specialist need.

(e) Ease of replacement: if these systems are design and built using generally accepted standards, then they will not pose major problems of replacement should user needs change or should the systems become obsolete.

11. I am aware that this is a brief note, and I apologise that I have been unable to frame a more detailed, and closely argued, response. I have just returned from teaching overseas, and was unaware of the call for evidence.

Ivor Perry

March 2007

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Evidence submitted by Professor Brian Randell (EPR 20)

The submission is on behalf of the group of 23 senior academics in computing and systems, listed at the end of this document

Executive Summary

This submission addresses the issue: "Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to 2 years behind schedule". It draws on the Dossier of Concerns regarding NPfIT that we have assembled from a variety of sources, and recently made available to Members of the Select Committee. Despite the difficulty of assessing NPfIT's plans and progress, caused by the Programme's size and complexity, the secrecy regarding detailed system specifications, and the atmosphere of fear that prevents many NHS staff from expressing criticisms, our Dossier contains extensive evidence, some but by no means all anecdotal, that supports our assessment that the Programme is in serious danger. The huge range of problems, covering technical matters, methods of procurement, the lack of buy-in from stakeholders, privacy and security questions, delivery delays and spiralling costs, greatly complicate the task of correctly identifying the fundamental causes and most effective remedies. Hence **our recommendation that a detailed technical review of the Programme be commissioned**, a review that must be open and manifestly independent if public confidence in NPfIT is to be regained.

Brian Randell was with IBM Research in the States 1964-69, before being appointed to a Chair at Newcastle University. He has published nearly two hundred technical papers and reports, and is co-author or editor of seven books. He is now Emeritus Professor of Computing Science, and Senior Research Investigator, at Newcastle University. He received the 2002 IEEE Emanuel R. Piore Award for his research on system dependability.

Introduction

1. We, a group of concerned senior academics in computing and systems, first wrote to the Select Committee last April, saying that we believed that NPfIT was showing many of the symptoms we have seen in major IT systems that had eventually been cancelled, overrun massively in terms of time and anticipated budget, failed to deliver an acceptable service to users or to reach business benefit targets for their organisations. We are pleased that the Committee has now agreed to hold an inquiry into the critical aspect of NPfIT, its support for and use of Electronic Patient Records (EPRs).

2. Since we first wrote we have compiled, and made available in printed form to all Members of the Committee, an extensive Dossier of Concerns. This has been assembled from nearly 600 published and unpublished sources, ranging from scholarly research papers to what might (unwisely) be dismissed as mere media rhetoric. Our submission makes numerous references to this Dossier— for convenience simply by indicating the relevant section number, eg "3.8.8", in the printed version of the Dossier, dated 18 January 2007. (This version can be found online, along with the current further-extended version, via our website at http://nhs-it.info.)

3. As one of the MPs we sent our Dossier to remarked to us, it is very difficult to obtain an adequate picture of NPfIT free of the "entanglements of political axe-grinding, professional jealousies and commercial interests". An even greater difficulty is the climate of fear in the NHS that has prevented many from expressing publicly the views that they have been willing to share with us in private. Nevertheless, even though much— though by no means all— of the evidence in our Dossier is anecdotal, and from secondary sources, we believe that it provides strong support for our assessment that NPfIT is in serious danger. What is significant about our Dossier is not just its size, but the range of problems noted, covering technical matters, methods of procurement, the lack of buy-in from a range of stakeholders, questions of privacy and security, delays in delivery and spiralling costs.

4. We have also attempted, as outsiders, to assess the technical merits of NPfIT, particularly those of direct relevance to the safety and reliability of the overall system. However many details of NPfIT (even the contractual integrity and availability requirements and specifications) are regarded as commercially highly confidential, making this task virtually impossible. (Such difficult-to-justify secrecy has, we are certain, also contributed to the lack of confidence that many working in the NHS have in the Programme [3.8.8].)

5. Our hope is that the outcome of the Committee's Inquiry will be the setting up of **an open independent constructive technical review, ideally of NPfIT as a whole, but at least of the centrally-provided NHS Care Records Service (NHS CRS), and of the various systems being provided by the Local Service Providers (such as Patient Administrative Systems, Clinical Systems and Departmental Systems), that together support the creation, maintenance and utilisation of EPRs**. Dr Granger and his senior colleagues publicly expressed support for such a review following our meeting with them last April. It is we believe the best way of arriving at a disinterested expert assessment of NPfIT and of significantly improving the chances of a successful, timely and well-accepted outcome of this major investment by the NHS. (The current refusal by NHS to contemplate such a review is worryingly reminiscent of management attitudes during London Stock Exchange's disastrous Taurus project [Drummond 1996].)

The Electronic Patient Record

6. Virtually all the claimed clinical advantages for patients of centralised EPRs (at cluster or national level) could be achieved by replacing paper records with electronic ones at the local (ie trust) level [2.6, 3.5.21]. The claimed importance of being able to access a central EPR directly when a patient requires treatment far from home is not supported by evidence [2.7]. Making what could have been local record keeping part of a cluster-level, leave alone an immense national-level, "system-of-systems" introduces system interdependencies that, because of their effect on system complexity, pose risks to system reliability and availability that in our judgement are likely to prove out of all proportion to any potential benefits [3.8.8]. Also the integration of EHR files at cluster, and certainly national, level greatly exacerbates the problem of maintaining patient confidentiality [Javitt 2005, 2.8, 3.5.3, 3.8.25].

7. Electronic records need to be generated as a by-product of relevant medical activity, and at the time of that activity, if they are to be of direct support to health care (for example in preventing possible clinical errors, such as related to drug dosage) [2.1]. If in contrast their generation has (perhaps because of usability or system performance limitations) to be undertaken as a supplementary time-consuming after-the-fact task, especially if it is one of little evident direct benefit to patients or clinicians, there will be much less incentive on the part of staff to undertake detailed record generation or to maintain quality control [Brennan 2005, 7.1.1].

8. Moreover, such are the differing circumstances from hospital to hospital that centrally-imposed standard EPR systems will often prove ineffective, and will not be used as intended, as Professor Eason, for example, has convincingly demonstrated in his study of mental health trusts [Eason 2007]. The clear implication is that it would be better to let local experts decide how best to satisfy local needs and circumstances, to identify minimum standards needed for interlinking local systems, and to defer such interlinking until after local systems have been successfully implemented and gained general support.

The Causes of Delayed Delivery of the New Systems

9. Many studies have reported significant time delays, cost overruns and, all too frequently, complete failures of projects that involve extensive software development or customisation. For example, a 1995 study [Jones 1995] of 164 software projects concluded that over 24% of projects were cancelled and that two-thirds experienced significant cost and time overruns. A 2001 survey [Taylor 2001] reported that of more than 500 development projects, only three met the survey's criteria for success. A 2002 survey of 13,552 IT projects

[Standish Group 2002] reported that only 34% were completed on time and to budget and that 51% though completed and operational were over-budget, over the time estimate, and offering fewer features and functions than originally specified.

10. The ever-growing levels of ambition on the part of system builders and system commissioners are such that the situation is not improving: in 2007 a US National Institute of Standards and Technology report stated that: "By most estimates, over half of all large application development projects . . . end in failure—after all the time and money is spent, the product still cannot be used operationally".

11. Hence it is clear that the utmost care has to be taken to (i) avoid undue ambition, (ii) make sure that the most circumspect software acquisition processes are employed, (iii) minimise undue dependence on the continuous correct functioning of the complete system, (iv) evolve towards the intended overall system via a sequence of practical and cost-effective intermediate systems, and (v) avoid at each stage the trap of specifications that are vague, changing or in conflict [Curtis 1988, 3.8.25].

12. Many healthcare systems are necessarily large and complex, but the NHS is huge and organisationally highly intricate [Beynon-Davies 1994; Wyatt 1995]. A fully-integrated NHS-wide healthcare system is vastly larger and more complex than any previous healthcare system [Javitt 2004]. Indeed it is admitted to be the world's largest civil IT project ever. Thus NPfIT is by definition an undertaking that is inherently "at risk". Moreover, given the crucial and pervasive role played by EPRs, we believe much of this risk arises from the complex systems supporting cluster-level and national-level EPRs.

13. Adverse outcomes from large IT projects rarely can be linked to a single cause (Lyytinen and Hirschheim 1987). Indeed analyses have identified many different causes. Some we list here, with representative references to relevant sections of our Dossier, as a contribution to identifying problematic aspects of NPfIT.

- cryptic or concealed agendas [3.3.2, 3.8.31]
- not involving users or not incorporating organisational needs [2.1, 2.3-4, 3.4.1-3, 3.4.9-10, 3.4.12, 3.4.16-17]
- treating a project as an IT project rather than as a business change project [3.8.5, 3.8.8-9, 4.2]
- ill-defined, unrealistic or conflicting objectives [2.1, 3.1.18, 3.7.33, 3.8.29]
- suppression or mismanagement of risks and uncertainties [2.8, 3.1.21, 5.3.7]
- ineffective project or resource planning [2.2, 3.1.10-12, 3.1.14, 3.4.6, 3.7.8]
- planning for "big-bang" instead of evolutionary delivery and failure to plan for longer-term evolution [2.2, 3.8.13-14, 3.8.28]
- fixing objectives, timeframes or costs when excessive uncertainty still exists [1.2.5, 3.1.11, 3.7.28]
- ignoring costs of business change [2.2, 3.8.1, 3.8.8]
- insufficient political support [2.3, 3.4.18-19]
- over-dependency on, and/or failure to control, suppliers [3.1.14, 3.1.26, 3.3.10-13, 3.3.20, 3.7.27]
- excessive project size and complexity [3.1.12, 3.2.11, 3.3.17, 3.7.32, 3.8.15]
- unproven technology or approach, especially exceeding the limits of proven performance [3.1.25, 3.1.30]
- inadequate provision for data transfer and quality [2.6, 3.3.14, 3.8.9]
- lack of provision for information governance [3.8.26, 3.8.47-48]
- failure to identify or achieve relevant standards [2.6, 3.7.25, 3.8.26]
- failure to plan for necessary levels of safety, security or recovery [2.8, 3.3.19, 3.5.1-47, 3.6.1-23]
- lack of project or technical skills [1.6.4, 2.2, 3.1.14, 3.7.32, 3.8.21]
- undefined exit conditions [1.2.5]
- inflexibility, inappropriate aggression and machismo [3.3.13, 3.5.34-35, 3.8.34]
- loss of political support [1.6.5, 3.4.11, 3.8.33]
- resources not properly allocated [3.3.6-7, 3.8.44]
- failure to create effective partnership with contractors [3.2.2, 3.2.9, 3.8.22, 3.8.46]
- unreliable progress reporting [3.1.14, 3.3.9, 3.8.16]
- unrealistic timeframes or budgets [1.2.5, 3.1.11, 3.7.30, 3.8.21, 3.8.40]
- inattention to quality [3.1.14, 3.3.14]
- barriers to communication [3.8.17, 3.8.31]
- fear of failure [3.6.8, 3.8.14]

14. We find it quite remarkable, and extremely worrying, that our Dossier shows that *all* of the above lengthy list of generic system problems would appear to exist in NPfIT.

15. Our Dossier also provides extensive evidence of a number of further problems that are specific to, or particularly challenging in, NPfIT including:

- inadequate clinical engagement during system requirements analysis and specification [2.3-4, 3.4.3, 3.4.9, 3.4.16-17, 3.8.22, 5.3.9]
- replacement of existing successful well-trusted systems by standard systems that are perceived to be inferior [3.6.8, 3.8.9, 3.8.39]
- employing Patient Administration Systems that were designed for the very different US healthcare market [3.8.10]
- inadequate response to the medical profession's concerns regarding issues of patient confidentiality [3.4.5, 3.5.1, 3.5.11, 3.5.30, 3.5.34]
- excessive reliance on IT consultants and suppliers with little knowledge of UK healthcare and the NHS [2.4, 3.8.7]
- implementing a complex centralised system in a situation in which the NHS is constantly faced by changes in organisation, medical practice and even the law [2.6, 3.8.23, 9.3]
- identifying and managing the changes in NHS working practices needed to complement, shape, and exploit proposed new IT facilities [3.8.5, 3.8.8, 3.8.9]

16. The above exercise of identifying relevant references in a large collection of evidence, gathered mainly from the public (albeit mainly specialised) media, is a far from satisfactory way of assessing the real extent and seriousness of the issues which should be addressed if NPfIT is ever to succeed. We argue however that our analysis illustrates very dramatically the number, variety and complexity of the concerns surrounding NPfIT, and thus provides a compelling argument for commissioning a detailed review of the project, carried out by evidently-independent experts with full access to all relevant information and personnel.

17. It will, we believe, take such a review to pinpoint the most important causes of the present delayed delivery of the Programme, in particular those aspects related to EHRs. More importantly, such a review is needed to determine whether there are, as we suspect, strong reasons to assume that the Programme will actually fail, not just continue to over-run its schedule and budget, unless appropriate remedial action is identified and undertaken urgently.

Concluding Remarks

18. A well-known aphorism in the IT industry is: "A complex system that works has evolved from a simple system that worked" [Gall, 1975]. Another hard-won insight is that the most successful highly-critical large IT systems, such as the worldwide VISA payments system [Stearns 2006], achieved their success through ruthless control of their complexity, and minimisation of the level of dependence that needed to be placed on them, as well as through high levels of hardware/software reliability. A further crucial insight concerns the criticality of employing evolutionary procurement methods, and socio-technical expertise, in order to determine precise specifications that meet the various stakeholders' requirements [2.2]. **A detailed constructive review of NPfIT in the light of these insights could, we argue, greatly increase the likelihood of the project's eventual success.**

19. The NHS has many good working systems, and NPfIT is planning and delivering others, but our and others' research and experience suggests that NPfIT's problems, especially those centred on EHRs, are daunting; our expert opinion therefore is that there is a high (but probably avoidable) risk that the Programme will fail. Hence our recommendation that an open independent technical review is an essential first step toward managing that risk in a professional manner. (In making this recommendation we are not seeking to review NPfIT ourselves—being entirely independent of NPfIT, we are simply acting out of strong professional concern and in the public interest.)

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Evidence submitted by Dr Maurice Rosen (EPR 12)

EXECUTIVE SUMMARY

The evidence submitted is purely concerned with whether patients may prevent their personal data being placed on systems. It is suggested that an individual should have the right of refusal based on the strong moral arguments that can be put forward based on personal autonomy, non maleficence, beneficence and fairness. To do otherwise will be treating the individual as a means to someone else's end, when everyone is entitled to be treated as an end in their own right.

MEMORANDUM

1. My concern is purely whether patients (in other words any of us, for at some time or another all of us have registered with a general practitioner, whatever medical care we have subsequently received), may prevent their personal medical data being placed on the new local and national electronic record system.

2. It is my intention to argue over the next few pages the case for any individual to be able to have the right not to allow his/her medical details to be recorded on this new system without their permission.

3. If we are to value and respect every individual as an individual in their own right we have to treat them as ends and not as a means towards someone else's satisfaction. Every individual will have different criteria and means of deciding what it is that is important for them. As a consequence of these individual values each person will decide on what actions they wish to take in relation to any decision they have to make which will have an influence on their life. This is what is simply known as personal autonomy. As long as the action/decision involved in personal autonomy does not as a consequence harm anyone then to interfere in that individual's decision would be a breach of their autonomy and hence immoral. We do not yet as a society force people with medical conditions which require treatment, to receive such treatment against their wishes if they are considered to be in complete control of their mental faculties. We accept their right to make decisions for themselves. To do otherwise would involve us being on a slippery slope leading back towards any number of inequalities, hence discrimination and stigmatisation of certain groups. I thought, as hard as it might be, we were as a society, trying to move away from that situation and attempting to build a society that was more tolerant of people's differences and hence respected them as individuals, as their own ends. If not, why then, all the fuss about the removal of organs from dead children's bodies at Alder Hey hospital without consent of the parents.

4. If you do not feel the argument of personal autonomy goes far enough lets explore the argument of non-maleficence. Namely, one should not cause harm to another person than, as can be argued, to protect oneself from harm being caused to oneself by another, the well known argument for self defence.

5. However, I hardly feel that an individual not allowing their personal medical details to be on a national computer could be construed as an assailant, and thus likely to cause harm to others by not being involved in some research project. After all, any medical research project has to go before an ethical committee before it can be allowed and subsequently, every individual patient or member of the public to be involved in the project has to give his or her permission. With what is being suggested under this new electronic patient record, it would no longer take into account an individual's feeling about being involved in a research project no matter how invasive or not it might be. Quite apart from this completely undermining personal autonomy, it needs to be remembered that harm is not always physical but can be psychological as well. It will no doubt be argued that the majority if not all of the research using a person's personal/medical details will be of an epidemiological nature, and no personal details will emerge. Further, if research of an invasive nature is to be carried out, an individual's permission would still be needed. This however, would lead to inconsistency and what matters in ethics is consistency and clarity. Even allowing for the fact that none of the different moral theories have been able to demonstrate consistency and clarity at all times, does not mean we should adopt a system which perpetuates inconsistency.

6. No doubt there will be those who wish to argue the case against a right to opt out as being counter to beneficience—do good unto others. For to opt out, especially if too many people opted out, would undermine the benefits the increased numbers involved in any research project would bring. However, we already know statistically the lower limit of the number of persons needing to be involved in a piece of research if it is to have any reliability or validity. What matters is that the research can be repeated independently and be tested as to its accuracy. It is hardly likely that everyone in the population is likely to say "no" to being registered. Even if every member of the population did say "no" to being registered it is hardly likely to undermine medical research as the vast majority of people when asked if they are prepared to participate are more than willing to say "yes", thus demonstrating personal beneficience, which is the level it should be at—not assumed for one by the state. It is often forgotten that morality is a personal decision, not a state decision. A further problem on relying on a persons' details which have been entered onto the computer without checking with them first raises the question as to the accuracy of the information entered onto the computer. If you cannot be certain as to the accuracy of the information entered onto the computer it rather undermines the reliability and validity of the research project, quite apart from misrepresenting the individual and possibly causing them harm as a consequence.

7. Finally, under the heading of justice as understood morally (do) as opposed to legally (do not), I accept there are many headings here which could be considered. However, I will concern myself with that of fairness. Fairness can only come about if an individual's views are not only taken into account but are further respected, which brings us full circle to personal autonomy. We need to be on guard against any government that takes upon itself any decision that ignores the rights of the individual when the individual causes no harm to others. This is what Tallyrand referred to as "the danger of the majority which needs to be guarded against".

Dr Maurice Rosen

March 2007

Evidence submitted by Mr Norman Sanders (EPR 71)

PREAMBLE

One of the items in the Terms of Reference is as follows:

— Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to two years behind schedule.

The progress of the systems can be determined only by a detailed examination of the initiation documents; the specification of requirements, the system design, the implementation plan and much else. The answer to the question is that the two years was probably a political number based on thin documentation. This document is an attempt at providing a solid basis towards eliciting a more reliable picture of the system(s), in particular trying to predict initial delivery times and costs as well as long-term follow-up costs.

1. THE UNDERLYING QUESTIONS

At every step of the way the underlying questions are:

— Who was the project owner?
— Who were the members of the steering group that created the specifications?
— May we see those specifications?
— May we see the resulting system design?
— Who was the designer?
— May we see the project plan?
— Who was the project manager?
— May we see the resulting cost estimate?
— Who approved the estimate?

2. FEBRUARY 2002

At the Downing Street meeting, and attended by David Bennett, McKinsey, Andrew Pinder, the Delivery Unit, Lord Hunt, Health Minister, and John Pattison, NHS Director of Information, all apparently agreed that the NHS could and should be radically transformed by IT.

— What does "radically transformed" mean?
— To what problem was the radical transformation the alleged solution?
— Were they not aware that throughout the NHS, from the GP's surgery via the hospital booking systems to the individual technical equipment in the wards and operating theatres the computer had already become ubiquitous?
— Were there any medical professionals present? Doctors, nurses?

In particular, during the meeting the question was asked, how long will this take? Apparently John Pattison said three years. This answer was unacceptable and he reduced it to two years and nine months.

— What was meant by *this*?
— What made John Pattison think it should take three years?
— What enabled the meeting to change the estimate to 2.75 years?
— What was the meeting's estimated cost?
— If the question wasn't asked, why wasn't it?
— Whose job would it have been to answer the question?
— Why did that person not volunteer the question unasked, or require that an answer be produced before making a decision to go ahead?
— Was this far-reaching decision concerning computers made without a single computer-competent person present?

3. A FEW WEEKS LATER

John Pattison produced some sort of blueprint for the project in the spring of 2002.

— What did the blueprint consist of?
— A specification?
— A design?
— An implementation plan?
— A cost estimate?

— What was this based on?
— Who was intended to be the project manager?
— Was he or she involved in any way in creating the blueprint?

4. Cost Estimates

It was reported that at about that time, early 2002, the cost estimate was some £2 billion but was increased in the first draft of the Pattison blueprint to some £5 billion based on what seems to have been a fairly realistic estimate of the true nature of the project. But when the report was published this estimate had been deleted.

— What was the published version of the blueprint cost estimate? Was this the £2.3 billion figure reported in the press?
— Who removed the £5 billion from the draft?
— Why?
— To whom did John Pattison protest at this removal?

5. A First Milestone

It has been reported in the press that a "full national health record service" would be delivered by Christmas, 2005.

— What did this service comprise?
— Who was the project owner?
— Who was the project manager?
— What was the cost estimate?
— Who approved it?
— What, if any, penalty clause was included in the contract?

6. September 2002

It seems that the project was handed over to Richard Granger, a Deloittes consultant, in September 2002. Later he became head of the agency running the programme, Connecting for Health.

— Was Richard Granger the project manager?
— If not who was, and what was Richard Granger's role?
— To whom did Richard Granger report? And the project manager?
— What control over the project did the NHS authorities have?
— In what was this control vested?
— How closely to the plan did the project keep? What time and cost overruns were there?
— How many designers/programmers were involved?
— What documentation was produced; implementation, training?
— Over the next two years how many senior responsible managers were there for the project?

7. May 2003

Bidders for what seems to be a changed contract splitting the project over five regional monopolies were issued a 500-page draft specification with a five-week deadline for bids to do the work.

— Who wrote the specification?
— Is it the intention to produce five different systems?
— If so, to what extent can this be called a single national system?
— If not, what steps are being taken to ensure conformity between them?
— To what extent were medical professionals involved in the decisions?
— What other consultants were involved in the process?
— Was five weeks, at 100 pages per week, considered sufficient time in which to provide a thorough and reliable basis for a contract?
— How does this figure compare with other major computer contracts?
— To what extent did confidentiality clauses prevent public audit of the contracts?
— How many of the 176 acute hospital trusts were due to become users of the system by the end of 2006?

— How many actually did become users?
— Who carried out the acceptance tests?
— Against what specification?
— How many people needed training?
— Who wrote the documentation?
— How much did each installation cost the user?
— Where did the budget come from?
— What arrangements are there now in place to report problems? Hardware/software?
— Who has the responsibility for fixing them?
— What arrangements are there in place for processing requirements for improving the functionality of the system?
— How much has been budgeted for continued support and development of the system?
— Are the users satisfied with the system?

8. Cost Estimates

It has been reported in the press that the £2.3 billion figure quoted in section 4 increased to £6.2 billion, and that the two years nine months had been increased to 10 years.

— Is this true?
— What is the reason for this increase?
— On what is the current time estimate based?
— What is the current cost estimate?
— How many major systems that have just come on stream today were specified in 1997?

9. Clinical Leadership

At some point there was a professional leader of the project, by name Professor Peter Hutton. However, he left the project—which should mean that he is free to answer questions and express his opinion.

— Who appointed him?
— To whom did he report?
— What was his remit?
— Its duration?
— Who was in his team?
— What happened to the project during his tenure?
— Why did he leave it?
— Who replaced him?

10. Political Leadership

Someone who might be able to shed some light is Richard Bacon MP. He is quoted in the press as saying that a set of contracts had been signed "before either the government had understood properly what it wanted to buy or what the suppliers had understood what it was they were expected to supply".

— Was he allowed to see the contracts?
— Who has he talked to about the project?
— Would he be willing to talk about it?
— In particular what is his current opinion of its health?

11. Companies Involved

It would be interesting to review the roles played by some of the participating companies and their associated consultants. Underlying the discussion is the impression that they stand to make a lot of money and are not being tightly controlled.

iSoft

iSoft is a software company who had promised to deliver a package called Lorenzo by March 2004. This was supposed to be the computer tool for the major companies to use for their contracts for the 100 acute hospitals. By early 2006 the package had not been delivered. Instead a new date of 2008 was set.

Questions for iSoft are:

— Why was Lorenzo delayed?

— What effect did the delay have on the work of its intended users?

— What is the probability of its being further delayed?

— What penalty clauses are there in the contracts for its delivery?

— How are the intended users going to honour their contracts without it?

BT

BT have the contract for the London area under contracts totalling some £1 billion. So far only about £3 million have been earned for delivery. Some 47 total systems were due for installation by March, 2007. So far only one has been delivered.

Questions for BT are:

— Why has so little been done?

— Why did BT replace their collaborating company, IDX, with Cernet, (both American), and could this shed any general light on the problem?

— What is the revised plan for spending and delivery?

— May we see the original baseline and the current version of the plan?

— To what extent has BT been paid by the NHS for systems yet to be delivered?

Accenture

Accenture have the contract for the east and northeast. It seems that when Lorenzo failed to materialise Accenture repeatedly offered to fulfil its contract using other companies' software but the proposals were rejected by the NHS as this might have bankrupted iSoft. As a result Accenture decided to withdraw from the project, handing their contract over to Computer Sciences Corporation (CSC), an American company apparently under investigation for boardroom corruption. As things stand an American company now has the contract for some 60% of the contract.

Questions for Accenture are:

— What reasons did Accenture give for their withdrawal?

— What light has Accenture shed on the technical and financial problems of the system?

— How much money had Accenture lost on the project before withdrawing?

— More generally, with the experience gained by Accenture to what extent could they advise the NHS on the future of the project?

12. User Training

At some point during the project implementation phase training needs to be carried out for all the expected users. The timing is a bit of a balancing act. It cannot start until enough of the eventual functionality is in place to ensure that the trainers understand their job and have been able to create the necessary documentation; the trainers themselves need to be trained. On the other hand it must be in time for the users to be ready for delivery. The training phase of computer projects is notoriously shambolic. It is as though each computer project is a brave new adventure without anyone remembering what happened last time, and how we made the users so frustrated. It should also be mentioned that the cost of training sometimes dwarfs that of the implementation. Ironically, this is usually when the training is properly scheduled, budgeted and carried out and therefore computable. On the other hand, the cost of not training must exceed that of training but is never made known.

— May we see the training features of the contracts?

— How much time and cost has been allocated to the training?

— Have all the potential users been identified and informed?

13. Post Delivery Costs

A newly delivered system is always a Trojan Horse, except that it contains two armies rather than the one; the inevitable bugs, however carefully the quality control procedures were carried out, and the inevitable

discoveries of the missing and inadequate features, however carefully the system was designed. Each requires considerable expenditure of money over an indefinite period. To what extent has this expenditure been discussed and provided for?

13.1 *Quality control*

Standard practice in the computing industry at the initiation of any project is to include in the contract a detailed specification of the testing regimen and the consequent post-delivery maintenance procedures; a project is incomplete without a guarantee of smooth functioning. Normally the procedure comprises an internal evolutionary sequence of testing starting with that of each (small) feature as it emerges from the programmers, systematically integrated with neighbouring features until it appears (to the implementation team) to function well enough to begin to involve the potential users. We call this the alpha test phase.

This is followed by the beta test in which friendly customers subject the system to real life situations using field data. This phase also tests the effectiveness of the training given by to the nurses, lab technicians, doctors etc.

Quality control includes the retention of the project teams to solve all problems encountered. The best people to solve problems are those who created them. Bringing in new people at this stage involves unacceptable delays in their familiarising themselves with the detail.

— How much time and cost has been estimated and scheduled for the quality control procedures?
— Have these been adequately provided for in the contracts?
— What do they amount to in terms of both time and cost?

13.2 *Acceptance testing*

The time when the computer salesman dropped a cardboard box on the customer doorstep and rode swiftly over the horizon is long past. Not a penny must be invoiced or paid before a system has survived a thorough acceptance test involving all concerned; users, trainers, programmers, designers, lawyers—and perhaps even an occasional patient. Acceptance testing must involve real life use of the system; Monday morning queues of patients.

— How much time and cost has been estimated and scheduled for the acceptance testing procedures?
— Have these been adequately provided for in the contracts?
— What do they amount to in terms of both time and cost?
— To what extent do the contracts provide for the retention of the project teams until the systems have been accepted?
— What penalty clauses are included in the contracts?

13.3 *Continued maintenance (evolution)*

By maintenance we don't mean that systems get rusty, we mean that bugs are always present, even after acceptance, and the users inevitably discover weaknesses that need redressing as well as good ideas for further improvement. The procedures for reporting problems during quality control and acceptance testing must remain in place indefinitely. Computer systems, once installed, remain in place for years until replacing them with significantly better versions is a better option than continuing to evolve them.

— What thought has been given to the continued evolution of the system?
— At what budgetary level?
— Has this all been prescribed in the contracts?

14. System Deliveries

NUMBERS OF SYSTEMS PLANNED AND DELIVERED AS AT FEBRUARY/MARCH 2007

	Admin Systems		*Clinical Systems*	
Region/Provider	*Planned*	*Installed*	*Planned*	*Installed*
NW & W Midlands/CSC	45	10	40	0
East/Accenture	27	0	27	0
North East/Accenture	22	2	22	0
London/BT	24	1	23	0
South/Fujitsu	37	3	37	0
Total	155	16	149	0

15. Contractual Values

A TABLE OF CONTRACT VALUES AS AT 31 OCTOBER 2006, GIVEN IN A PARLIAMENTARY ANSWER OF 12 DECEMBER

Contract	*Contractor*	*Contract value in £million*	*Amount earned for delivery by 31/10/06*
National data "spine"	BT	620	297
N3 broadband network	BT	530	213
Choose & book	Atos Origin	64	31
Local service providers			
London	BT	996	3
North East	Accenture	1,099	83
West Mids & North West	CSC	973	170
East	Accenture	934	95
Southern	Fujitsu	986	27
Total		6,202	918

(Accenture was replaced by CSC from January 2007)

16. Vulnerability

All computer systems fail; it is impossible to guarantee the 100% continuous operation of any agglomeration of software and hardware. Computer programs always contain bugs because there is no foolproof method of finding them in the first place or theorem to prove that they have all been fixed at any time. And computer hardware, both central and peripheral, as with all physical things, breaks down from time to time, despite the most stringent maintenance regimen. Today's computer is a very complicated system of literally millions of interacting components, most of them invisible to the naked eye. And the bigger the system the greater its vulnerability to the hazards of interactivity; the probability of failure increases with some high power of the number of components. Moreover, large computer systems imply a high level of importance; you would not try to create a large single system if there were no good reason for doing so. They must be attempts at solving very serious problems; problems involving large amounts of money, goods or people. Such importance must in turn imply a need for extremely high levels of reliability. Most such systems can undoubtedly tolerate periods of malfunction; we can usually wait a while for a bank transaction to take place. But systems involving human welfare and life support must work continuously and reliably once they are turned on; there can be no toleration of interruption in computer support any more than interruption of blood supply or anaesthetic.

— Has a risk assessment been made of any component of the contracted systems?
— How much effort, in terms of man hours and cost, is being assigned to solving the problem of reliability in the contracts?
— What is the maximum delay acceptable in the contracts due to system failure?
— What are the envisaged consequences of system failure?
— What plans have been made to revert to backup systems in the event of system failure?

17. Support

Intrinsic to the question of vulnerability is that of support. Most medical computer systems seem to be delivered by specialist companies who also have the contract to support the using organisations. (This is much the same for schools.) Whenever anything goes wrong the user requests the support company to fix the problem—and they need it done now! But it is never done now. It cannot be. There is always a delay, sometimes as much as a week, during which time the user staff has to keep things going as best it can. The problem facing the support organisation is that it is difficult to provide a satisfactory level of support and make a profit. Or it is difficult to get the user to pay the price of a level of support that they really need.

And in addition to the question of cost is that of proximity, or lack thereof. You are far less vulnerable if the support person is only a few minutes away; even in this day of electronic conversation, in times of crisis face-to-face talk is still the best, amplified by printouts, screen pictures, sketches etc. A profound problem with a centralised, monolithic system is that it is ipso facto remote from almost all its customers' premises. If things go wrong at the centre they can be fixed at the centre. No need for site visits. But if things go wrong at a remote site what arrangements might there be for local support?

— To what extent has the support problem been analysed within the NHS?
— Since most NHS computer systems are still locally generated has any attempt been made to aggregate support costs to the national level?
— Is there a single system for logging faults, waiting times, patching programs etc?

— Are there standard contractual agreements for levels of support?
— What are the current prices for levels of support?
— What is the total annual NHS computer support budget today?
— What would it be within a monolithic system?
— Are support costs part of the current financial figures?

18. A Question of Cost

A final thought concerning cost is that of the human cost vs that of the hardware. Hardware is getting cheaper by the day, and always has done. For £20 you can buy as much computer memory today as there was on the entire planet not so many years ago; a billion bytes contained in a 7.5 cm long "USB stick". At the same time people costs have steadily risen and will continue to do so. Out of a £1 billion contract well over half must be the "peopleware", the cost of system designers, programmers, managers, writers, trainers etc. Suppose it were only a half. At, say, £50,000 per person per annum, £500,000,000 would pay for 10,000 people. You can run an army of that size, but it is very difficult to manage a deeply integrated technical project of that size in which so much information has to flow, even if you can find enough technically competent people. It is simply too big, and that is the reason why they have tried to split what is supposed to be a single entity into five, the irony being that you then have five entities created by five disparate teams who cannot help but produce incompatible versions. But even 2,000 people is a mighty software horde. Where would they all sit?

— How many people are employed on the NHS system by the contracted companies?
— How large are the individual groups of programmers etc?
— What is the turnover picture? Rates of hiring and training new people?
— Are there problems of finding people of adequate calibre?
— Of the total to date, what is the ratio of people costs to equipment costs?

19. Conclusion

This is a very short version of a survey of the NHS system. Before any reliable recommendation could be made a much more thorough investigation would be needed. But who would do it? How cooperative would the current participants be? How long would it take? Meanwhile the contracted work would carry on and more money spent. The obvious fear is that good money would be spent trying to rescue bad. And as time went by it would be ever more difficult for anyone to call a halt. With the growing investment of time and money, and the inevitable changes of project owners and managers, computer systems take on a life of their own.

One very important feature of this system that has not been mentioned here is its monolithic nature. Although the contract has been split geographically and by provider, it is nevertheless a single endeavour; it is a national program. Moreover it does not appear to have wide support from the PCTs or the hospitals. In addition to the vulnerability of large monolithic computer systems, the massive and possibly life-threatening consequences of computer breakdown, its national nature means that local initiative would no longer be tolerated. Removing local enterprise would have a demoralising effect on the NHS, adding to its current malaise.

However, I hardly think it necessary to carry out an investigation. To an experienced computer person this system bears all the hallmarks of massive failure. It is simply too big to design, plan, estimate, manage, implement, verify, install and keep alive. It can only drain the NHS of incalculable amounts of money and frustrate the day-to-day work. The long-term consequences of the project cannot even be guessed at. It would take a brave man to put an end to it today, but it would need a veritable hero to do so five years hence. But if it is allowed to continue the cost of the initial installations could easily reach £20 billion and more, and the annual continuation cost of supporting the installations could be several billion. And somebody might die.

Instead, write off the one billion spent so far and let initiative flow locally from the bottom where it is most likely to be competent; let the mistakes be limited and recoverable. At the same time create a small monitoring group at national level with the remit to keep us informed of what's going on. Somebody, somewhere might have a good idea they'd be happy to share.

Norman Sanders

26 March 2007

Evidence submitted by Alan Shackman (EPR 38)

Executive Summary

E1. This submission focuses solely on progress on the development of the core Local NHS Care Record Service, CRS, the area from which the vast majority of the benefits of NPfIT will be delivered.

E2. Not only is delivery of core CRS at least 2 years behind schedule but, as of early 2007, there remains no definitive timescale for introducing the clinically focused software that would take functionality in any significant way beyond the basic patient administration functionality that was available to the NHS when NPfIT began in 2002.

E3. Deployment of CRS cannot be said truly to have begun at any NHS organisation in the North West & West Midlands, North East, and East clusters because patient administration system (PAS) solutions that have been implemented under NPfIT are interim and will have to be replaced. Deployment of CRS proper is not expected to take off until 2009–10. Even this date cannot be assured given the as yet unresolved financial problems of iSoft, the supplier of core software, and the risk that development of the Lorenzo system will not be completed. these clusters

E4. The situation in London and South clusters is more positive now that there is a real indication that Cerner, the core software supplier in those clusters, has successfully anglicised the PAS element of its Millenium product for acute trusts. This at least gives hope that deployment of the clinical elements of CRS will not be long further delayed.

E5. The key objective of CRS to provide a seamless service across all care settings—GPs, community, mental health and acute hospitals—is in danger of being lost now that the original intention to have a single integrated system in each cluster has been abandoned. It has been agreed that GPs can have their system of choice; and, at any rate in London, an additional core software supplier has been brought in to provide for the specific needs of mental health trusts and PCTs. Whilst there is little doubt that a solution can be found, there are as yet no plans for how a cross-organisational, joined up CRS is to be obtained.

E6. There is no evidence that NHS organisations are committed to changing working practices in order to reap the benefits of CRS as it begins to be deployed.

E7. The first major theme in suggested ways forward is to bring additional suppliers of core CRS software into LSP consortia. This would have a dual purpose: to move core CRS forward more quickly particularly in the North West & West Midlands, North East and East clusters where progress to date has been negligible; to provide choices locally with a view to creating greater local ownership and thereby helping to obtain commitment to change working practices.

E8. It is suggested that current LSP contracts be reassigned from the Secretary of State to SHAs or PCTs in order to give those now being given responsibility for implementing NPfIT systems the full authority and power to enable them to succeed.

E9. The final suggestion is to make use of work undertaken under "Information for Health', the national programme that preceded NPfIT, to provide guidance on achieving cross-organisational information sharing.

The Submitter

Alan Shackman has over 20 years experience as an independent consultant to the public sector, principally to the NHS, specialising in the business/user focused elements of preparing for and implementing IT systems. He is an expert in the usage of IT at grass roots level in the NHS, the majority of his assignments having been directly with NHS trusts covering all sectors—acute, mental health, community and primary. Over the past 15 years his work has focused on patient administration (PAS) electronic patient record systems. In that time he has prepared business cases and detailed definition of requirements, led procurements of PAS and electronic patient record systems at major acute trusts and across local health communities, developed benefits strategies and realisation plans, and facilitated the management of change.

Alan is familiar with the products being offered by the two suppliers of core CRS software to NPfIT having worked on PAS replacement projects in both the South and North West and West Midland clusters. During 2004 and 2005 he acted as NPfIT programme facilitator for the north east sector of Greater Manchester comprising an acute trust, a mental health trust and five PCTs. Prior to that he helped two local health communities in Greater Manchester and Lancashire develop and implement their strategies under the "Information for Health" initiative.

At national level, Alan led the development of a national output based specification for electronic patient record for acute trusts as part of the NHS IM&T Procurement Review of 1999. Earlier in the 1990s he was a member of the NHS Information Management Group's panel of consultants advising trust boards on electronic patient records. He was also a member of the team that reviewed the national resource management programme.

He has recently been acting as an advisor on NHS IT matters to Richard Bacon MP of the Public Accounts Committee.

Alan is a Chartered Engineer and Member of the Institution of Engineering & Technology. In an earlier phase of his career he was a member of the UK Industrial Space Committee and represented the UK on international telecommunications standards and regulatory forums.

Comments on Progress on the Development of the NHS Care Record Service, CRS

Scope and context

1. This submission focuses on progress on the development of the core Local NHS Care Record Service, CRS. This where the overwhelming majority of NPfIT funding is allocated and it is from the core Local CRS that the vast majority of the benefits set out in the NPfIT Business Case will be delivered. The submission excludes consideration of Picture Archive and Communication Systems (PACS) because these were not originally included as core deliverables; for the same reason it also excludes the plethora of relatively minor acute and primary/community departmental systems that LSPs have implemented.

2. The submission shows that:

(a) not only is delivery of core CRS up to two years behind schedule but that, as of early 2007, there remains no definitive timescale for introducing the clinically focused software that would take functionality in any significant way beyond the basic patient administration functionality that was available to the NHS when NPfIT began in 2002;

(b) the way in which CRS is now being introduced has been significantly altered with the result that the original intention that CRS should "provide a . . . service accessible . . . by health professionals whether they work in hospital, primary care or community services"[106] is in danger of being lost;

(c) even when systems are introduced the danger has increased since the inception of the Programme that changes in working processes necessary to obtain the benefits from the investment in CRS will not be driven through.

Review of CRS deployment to date

3. By now, all 155 acute hospital trusts in England should have implemented new NPfIT patient administration systems (PAS) as the essential first step in the introduction of Local CRS. As of April 2006, according to the NAO Report, the actual number was nine hospitals. Since then, so far as I am aware, the number has increased by only six.[107] This gives the flavour of CRS deployment to date. The position is different in those clusters in which iSoft is the software supplier for core systems (North West & West Midlands, North East, and East) and those clusters (South and London) in which Cerner is core software supplier now that IDX the original supplier has been replaced. iSoft dependent and Cerner dependent clusters are therefore considered separately.

. . . in clusters where iSoft is core software supplier

4. iSoft was contracted as the Local CRS software provider on the basis of its proposal to develop a new product, Lorenzo. Phase 1 of Lorenzo was stated in iSoft's 2005 Annual Report to have been available in 2004. It was not. iSoft now states, as reported by e-Health Insider on 11 December 2006, that Lorenzo will be delivered to CSC, the Local Service Provider, LSP, for the three clusters, in the first quarter of 2008, but that it will then be some months before it becomes available to trusts and that thereafter its introduction will be gradual, supposedly to occur in the 2009/10 timeframe at the earliest. However, confidence that this will be achieved must be tempered in the light of iSoft's current difficulties as widely reported in the media: that the company's accounting practices are being investigated by the FSA, that its share price has collapsed and that it has yet to obtain the long term funding it requires to meet its commitments.[108]

5. In lieu of Lorenzo, the CSC has been offering to trusts existing pre-NPfIT, non-CRS iSoft products known as iPM and iCM. iPM is a PAS with no clinical functionality. iCM is an additional module which includes some clinical functionality relevant primarily to acute trusts eg ordering pathology tests and X-rays. Some 10 acute and mental health trusts with a pressing need to replace their existing PAS have successfully deployed iPM. Those without a pressing need—the vast majority—have decided against because, even with the cash releasing benefit to them of CfH picking up the recurring revenue costs, iPM is considered inferior to their current PAS and certainly not a good enough reason for taking the risk and disruption of replacing a current working system—all the more so since it has become clear that moving to a Lorenzo solution from around 2009 would effectively be another major replacement exercise, not just an upgrade.

[106] Connecting for Health Business Plan 2005–06.

[107] The way in which information on the progress of implementation is presented in the Connecting for Health website is poor. Users are directed to the individual Clusters' sites for detailed data. Such data, however, either does not appear or is in too summary a format. It is not possible, for example, to obtain detail of which precise elements of the Local Care Record Service has been implemented, and where and when.

[108] "We have secured bank funding until late 2007, but it is clear that if the business is to prosper we must soon put in place long-term funding arrangements", quote from Chairman's report, iSoft interim results 11 December 2006.

6. Few PCTs had any corporate system for helping them managing the community services they provide and a considerable number, perhaps 50, in the North West and West Midlands cluster according to its website have deployed iPM. Some, to my personal knowledge, have rolled the system out widely to the various community disciplines. At others, I am told, the deployment has been more limited, the apocryphal "a couple of podiatrists use it every other Thursday morning". iCM has some facility for recording clinical notes but otherwise offers little to community clinicians. PCTs will therefore have little opportunity to progress unless and until Lorenzo becomes available, and even then, as for acute trusts, they will presumably have to face another major replacement project, not just an upgrade.

. . . in clusters where Cerner is core software supplier

7. Release 0, essentially the PAS element, of the Cerner Millenium product, has now gone live at some five acute trusts in South cluster. This was after a false start, causing considerable operational difficulties at the trust involved (Nuffield Orthopaedic), resulting from the LSP's eagerness to begin deployment before, as it transpired, this product from the US had been properly anglicised. At the time of writing post implementation reviews are awaited from the two latest trusts to go-live (Milton Keynes and Mid Hampshire) but early reports are encouraging. Release 0 has not been implemented at any mental health trusts or PCTs in South cluster.

8. London, having completed just one PAS replacement using the IDX system, has not yet undertaken any PAS replacements at acute trusts with the Cerner Millenium system. However, the LSP (BT) has moved away from the concept of having a single supplier of core software and, in lieu of a suitable product from Cerner, has adopted CSE Servelec's RiO system as its strategic solution for mental health trusts and PCTs. RiO offers considerable core clinical functionality as well as PAS functions; it has now started to be deployed at a number of trusts.

9. GPs continue to use their existing systems and have been little affected by NPfIT.

10. It is noted that responsibility for managing further implementation of NPfIT is now being passed down through SHA level to PCT Chief Executives.

Absence of firm plans for introducing clinical aspects of CRS

The position regarding the all-important clinical functionality of core CRS as at March 2007 is summarized as follows.

11. For acute and mental health trusts in the three "iSoft" clusters (North West and West Midlands, North East, and East). The 10 trusts who have taken iSoft's interim solution, iPM, have the opportunity to deploy its clinical counterpart, iCM, to obtain at least some core CRS clinical functionality in the medium term. Those waiting for Lorenzo—the vast majority—must wait probably until 2010–11, always assuming, of course, that Lorenzo development is completed.

12. For acute trusts in the two "Cerner" clusters (London and South). Little core clinical functionality is available until Release 1 of the anglicised Cerner Millenium product is available, timeframe as yet unclear. Fundamentally, however, Millenium is a clinically rich, proven product working successfully in the USA and at other overseas locations

13. For mental health trusts and PCTs in London Cluster. Considerable core clinical functionality is potentially available from the RiO product (see paragraph 8)

14. For mental health trusts and PCTs in Southern Cluster. Fujitsu, the LSP, is only offering Cerner solutions: therefore little core clinical functionality until Cerner development available, timeframe unknown.

15. GPs will continue in the medium term to enjoy the strong clinical functionality in their current standalone GP system. NPfIT's initial intent for the longer term was that the core systems being provided by the LSPs to the other care settings would also be deployed for GPs but this strategy has now been superseded by the GP System of Choice concept. My understanding is that there will shortly be a formal EU procurement which will result in CfH contracting with a number of GP system suppliers from whom GPs will then be free to choose.

The original CRS vision is being lost

16. The delay and continuing uncertainty of the timescale for introducing core clinical elements situation described in paragraphs 11 to 14 means that even if things go well from now on—by no means assured—it will only have been possible to deliver a fraction of the intended clinical functionality by the time NPfIT contracts expire.

17. But that is not the only concern. The central purpose of NPfIT to provide a Local Care Record with detailed clinical information and functions such as ordering tests and information easily and immediately available across all local care settings—GP, out-of-hours service, community, mental health, acute hospitals—is being lost. With GPs having, in effect, opted out no LSP will be able to deliver the original

intent of NPfIT of a single, truly integrated system. Nor in reality does there appear much prospect of single systems serving the subset of acute, mental health and community applications. Fujitsu in the South cluster and CSC in the North West and West Midlands, North East, and East continue to cling to this ideal but in fact their respective software suppliers are nowhere near being able to deliver it. BT in London which is currently achieving relatively the most success in terms of introducing functionality of use to clinicians (referring to the RiO implementations) has done so by ignoring the original contracted plan to provide a single suite of integrated software and introducing a standalone system for PCTs and mental health trusts entirely separate from the Cerner system for acute trusts.

18. Local CRS will remain a collection of independent systems, not in any sense joined up, unless steps are taken to introduce what is usually termed in IT-jargon as an "integration engine", the function of which is to sit over standalone systems and expedite information sharing between them. No plans such plans have been announced. (The National Spine, it should be noted, is designed neither to contain detailed clinical information nor to provide the facility, for example, for GPs to order hospital services such as pathology tests, and is therefore not suitable for this integration engine function.)

Benefits delivery

19. Connecting for Health is focused on delivering the systems. As and when software that supports clinical functions is introduced it becomes essential if expected benefits are to be obtained that all NHS organisations get to grips with the management of change. To begin with it requires commitment at trust Board level, commitment which it has to be said is increasingly lacking as confidence in Connecting for Health's ability to deliver ebbs. Assuming this can be turned round, there is then the need for resource not only in the form of funding but also in freeing local staff time. First and foremost it requires local "clinical champions" to be made available at grass roots level. These people have to be allowed significant time away from their normal day-to-day duties to take charge of winning local support and actually making things happen. It requires a number of senior administrators and clinicians to think carefully through changes to processes and procedures. It requires all staff to be released for training. It requires organisations to be given the "space' in their perform targets over the period of change. It requires some measure of external, expert facilitation. Particularly in the current financial climate it remains unclear where this resource is to come from.

20. In 2002 the Department stated[109] that "we will work closely with the Modernisation Agency to change working practices so that IT is used effectively". The Modernisation Agency ceased to exist in March 2005.

CONCLUSIONS

21. The Local Care Record Service in the North West & West Midlands, North East, and East clusters is dependent upon iSoft successfully completing the development of Lorenzo. According to present plans, mass deployment of the patient administration (PAS) element of Lorenzo will begin in the 2009–10 timeframe, presumably with the all important clinical elements to follow, say, from 2010–11. Given iSoft's track record in developing Lorenzo and the company's unresolved financial problems, the Department cannot be confident that this timescale will be met.

22. Implementation of the Local CRS cannot be said truly to have begun at any NHS organization in the North West and West Midlands, North East, and East clusters. The majority of acute and mental health trusts have implemented nothing. Some 10 acute and mental health trusts and a considerable number, around 50, PCTs have deployed as an interim measure an old, pre-NPfIT iSoft PAS known as iPM. iPM has successfully filled an immediate administrative need and with the addition of iCM may provide some clinical functionality albeit primarily for acute trusts only. Organisations which have implemented iPM have not, however, taken any meaningful step towards CRS because moving from iPM to Lorenzo (assuming Lorenzo development is completed) would not be a simple upgrade but would in fact take on many of the characteristics of a full PAS replacement.

23. There is now a real indication that Cerner is coming good for acute trusts in the South and London clusters and that deployment of clinical functionality in the Millenium product will quickly follow that of the PAS deployments achieved so far. But it must be emphasised that as yet the delivery of clinical elements of CRS for acute trusts has not begun, nor has any timetable for doing so been published.

24. It is not known when Cerner plans to develop functionality within Millenium for mental health and community (PCT) applications. Until such time mental health trusts and PCTs in the South cluster will not be able to begin implementing CRS. They have, however, been able genuinely to set out on the CRS path in London because BT, the LSP, has adopted the CSE Servelec product, RiO, as its strategic solution rather than wait for Cerner development. Incidentally, the approach adopted in London reveals what an opportunity is being lost, particularly to PCTs, in the North West & West Midlands, North East, and East clusters with the decision to use iSoft's iPM/iCM systems as interim solutions when much more clinically rich alternatives are available.

[109] "Delivering 21st Century IT Support for the NHS", Department of Health, 2002.

25. The key objective of CRS to provide a seamless service across all care settings—GPs, community, mental health and acute hospitals—is in danger of being lost now that the original intention to have a single integrated system in each cluster has been abandoned. It has been agreed that GPs can have their system of choice; and, at any rate in London, an additional core software supplier has been brought in to provide for the specific needs of mental health trusts and PCTs. Whilst there is little doubt that a solution can be found, there are as yet no plans for how a cross-organisational, joined up CRS is to be obtained.

26. There is no evidence that NHS organisations are committed to changing working practices in order to reap the benefits of CRS as it begins to be deployed.

Suggestions on the Way Forward

27. Before formulating any suggestions for the way forward it is worth observing that the following principles have been established by Connecting for Health:

(a) that a non-performing software supplier will not be tolerated: witness the dismissal of IDX from the Fujitsu-led LSP consortium in South cluster;

(b) that an LSP can have more than one core software supplier: witness BT now using CSE Servelec in addition to Cerner;

(c) that trusts may be offered choice: witness plans for establishing a catalogue of additional systems suppliers.[110] (My understanding is that CfH may be intending that this catalogue be used only for non-core systems but there is no reason in principle why choice should not also be available for core CRS.)

Bearing in mind the principles set out in paragraph 27 and the conclusions of paragraphs 21 to 26 the following questions need to be asked and the results of more detailed investigation acted upon.

28. What is the benefit to the NHS in keeping iSoft as core CRS software supplier to CSC in the North West & West Midlands, North East and East clusters given the company's inability to date to deliver any CRS systems and that the future availability of Lorenzo is by no means assured? Even if iSoft is retained, why are NHS organisations not being offered the option of an alternative supplier with a more proven product?

29. Should both other LSPs (Fujitsu and CSC) be encouraged to follow BT's example in bringing a specialist supplier of mental health and community (PCT) applications into its consortium?

30. Can funding from NPfIT can be justified for any further implementations of iSoft's interim iPM solution given that iPM cannot truly be said to be a step towards CRS? In the event that Lorenzo development is not successfully completed, what would be the consequence to those trusts and PCTs which having already implemented iPM are now tied in to iSoft?

31. Should the putative catalogue of additional systems be extended to core systems thereby enabling local communities to choose the core CRS supplier or combination of suppliers of their choice? Would so doing create a greater feeling of local ownership and thereby help obtain commitment to changing working practices in order to reap the full benefits of CRS?

32. Can the current LSP contracts be reassigned from the Secretary of State to SHAs or PCTs in order to give those now being given responsibility for implementing NPfIT systems the full authority and power to enable them to succeed?

33. Might the Local Information Strategy (LIS) plans developed under "Information for Health', the national programme that preceded NPfIT, provide guidance on achieving cross-organisational information sharing? (It should be noted that LIS work was very much focused on sharing information across entire local health communities and that a number of local communities were well on the way to getting systems in place when projects were put on hold in 2002.)

34. Some of the questions in paragraphs 28 to 33 overlap; all are difficult to answer. A working party should be set up as a matter of urgency. It should be chaired by a senior member of the Department. It should be drawn from expert witnesses who have made submissions to the Health Select Committee and to the Committee of Public Account's pending report on NPfIT, representatives of the NHS at SHA and trust level, representatives of Connecting for Health.

Alan Shackman

March 2007

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[110] As reported in E-Health Insider on 1 March 2007.

Evidence submitted by Dr Peter Smith (EPR 03)

Summary

1. The introduction of the electronic method of recording medical information has been one of the great successes for primary care in the United Kingdom in the last decade. The new technology has made it possible to hold information in a manner that was previously unimaginable, permitting detailed analysis of patterns of health and the effectiveness of treatment.

2. In the hands of trained medical practitioners, working with clinical systems and file servers based securely in their own premises, the advantages for improvements in health care have been immense, yet the fundamental trusting relationship between patient and doctor has been maintained.

3. Who may view the data, is presently clearly understood by patients. They believe that information given in confidence will remain under the stewardship of their physician and only imparted to other persons as and when necessary. The lines of accountability are also short and well defined.

4. The extensive use of clinical codes to record items of data, which would have formerly been written to paper, presently allows academic enquiries and searches of anonymised information, which is perfectly adequate for most lines of research. Search engines for these purposes are already being used regularly in primary care under the supervision of the medical practitioners who are responsible for the security of the patient data.

5. For some patients, there may be advantages if some of their clinical information is held at a remote site and accessible to other clinicians. For the majority there are no specific reasons why this should be assumed to be necessary. Alternative methods, by which data may be made available with explicit consent, already exist and have been disregarded, in the pursuit of a centralised and all-encompassing database.

6. If the National Data Spine becomes available to patients, the emphasis should to encourage those with the greatest need to share clinical data to opt-in, rather than enter into a vexing period of debate as to whether patients should be permitted to opt-out.

Introduction

7. I am a general medical practitioner and clinical data user. I have been in the forefront of the transition from paper records to electronic format over a period of 15 years. The practice in which I work has been one of the first to recognise the potential for electronic record to revolutionise and streamline health care. Initially the technology was not suited to mass storage of vast amounts of information and was therefore mainly used to perform repetitive functions such as repeat prescription issuing. As advances in electronic hardware has permitted greater volumes of information and scanned images to be held for rapid retrieval, we have moved to the point where many practices in the UK have become either paper-light or even paper free. Throughout this period of transition we have become increasingly aware of the issues of ownership of patient data. Many patients view their data as being their own, despite the protestations of successive Secretaries of State, either in print at the foot of our old Lloyd-George record cards, or through a tacit assumption that provision of electronic hardware confers intellectual property rights to the data held therein. This paradox is at the heart of the present anxiety about the right to withhold personal data from the State, which is not viewed in all quarters as entirely benign in its intentions, at all times. I have worked for 30 years in primary care and for more than 10 years as a director of out-of-hours services in my locality. I have led on clinical governance issues and data protection on behalf of my Primary Care Trust.

Relevant Information

8. The reasons for a high level of computerisation of records in general practice have not just been due to technical advances. Leadership from within the profession at the highest level and political support for primary care, have combined to build an appropriate regulatory framework and financial incentives, particularly the present Quality & Outcomes Framework, have encouraged GPs to use computers extensively.

9. It is the responsibilities of those engaged in the conduct of research and particularly those involved in undertaking ethical review, to decide that the public interest in conducting the research substantially outweighs the public interest in privacy. This sits most comfortably with those most closely associated with the data subjects.

10. Only a small percentage of patients actually need large amounts of complex information to be made available to other health professionals at all times. Even in emergency situations, it is rarely impossible to make a diagnosis or institute treatment without reference to primary care medical records.

11. Medical records in summary or detail can presently be provided by GPs within 48 hours or shorter periods of time, upon appropriate and verifiable requests from other clinicians. These are generally transmitted by facsimile, which is virtually "un-hackable". Increasingly electronic data will be able to pass directly between clinical systems upon request.

12. A distributed database, with file servers in each practice, is less vulnerable to massive data loss through equipment failure or power outages and malicious interceptions than area-wide or National databases.

13. Alternative web-based solutions, permitting patients to lodge clinical biometric data or clinical summaries, already exist. The patient may access this data much in the same manner as a personal bank account.

14. Electronic memory has become very affordable in recent years, permitting an entire medical record to be fully transportable in other devices such as mobile telephones, personal data assistants, memory sticks and credit-style cards. Such arrangements encourage personal responsibility for health and should not be underestimated.

15. The National Data Spine is overly complex and unwieldy for the intended purpose. Considerable savings will accrue from limiting the scope and remit of the service, even at this late stage of development.

Recommendations for Action

16. The Select Committee should recommend the Government cease its pursuit of hegemony over the entire medical record of each of its citizens, since this is in direct contravention of *Article 12.* Universal Declaration of Human Rights that no one shall be subjected to arbitrary interference with his privacy, family, home or correspondence, or to attacks upon his honour and reputation. Everyone has the right to the protection of the law against such interference or attacks.

17. The National Data Spine has merit in that specific medical data may be placed there with explicit consent, in order that is may be shared with other clinicians. This should be a service that is offered to patients and not a compulsion.

18. Access to services such as Choose and Book, for arranging hospital appointments should not be dependent on uploading of entire medical records to the National Data Spine.

19. Alternative arrangements for the self-management of personal medical and biometric data by patients should be encouraged, through the use of secure, independent web-based solutions and portable data storage devices.

Dr Peter Smith

19 February 2007

Evidence submitted by James Stuart (EPR 02)

1. Executive Summary

1.1 This is written evidence to the Parliamentary Health Committee regarding the Electronic Patient Record (EPR) and its use. This evidence is original and has been compiled from in-depth working knowledge of changing patient requirements, NHS needs and government drivers.

1.2 Why is EPR important? EPR is important because of:

- changing population demographics
- changing needs and requirements
- new procedures and medications
- finite resources
- the need to increase the delivery of care to patients
- the need to achieve consistently high levels of quality care

1.3 This points to an ever increasingly complex healthcare system. The traditional paper based system, which has served its purpose well until now, will no longer be fit for purpose. On the grounds of patient safety and increases in patient care, as well as cost effectiveness, the paper based system will not be able to keep pace with the changes outlined. Therefore a new system that will allow increases in patient care and cost effectiveness should be investigated and introduced if found to be beneficial. This solution is likely to be EPR: a new method of information management using technology as a core business enabler.

1.4 A full investigation will be required to assess the present information needs and future requirements. This investigation will be independent. It will produce a detailed plan of progression in order to advance the concept and reality of EPR for the benefit of patients and the future of healthcare in the UK.

1.5 EPR will also give rise to a new generation of local, regional and national information analytics essential for prevention, care provision and disease control. Reference 3.4.

2. Introduction

2.1 Introduction of the EPR will be a major step forward in the enhancement of patient care and safety. If implemented and tracked properly, EPR can also generate significant and sustainable cost savings and productivity increases. It is this implementation, and overcoming the NHS cultural barrier of resistance to change, which will provide the greatest challenge. In order to avoid costly project overruns of the like that has been recently experienced, such barriers and other mistakes should be understood and appreciated. Safeguards will be put in place to avoid a re-occurrence of the mistakes of the past.

2.2 This will require a high degree of planning and communication as well as the early identification, tracking and realisation of business benefits in order to provide the required enhancements in patient care and safety, and the cost savings / productivity increases.

2.3 The early focus on patient care along with the early engagement with managers and stakeholders will be necessary to ensure the success of EPR as a properly designed and implemented programme of improvement.

2.4 EPR will also allow the public and private sector combination of information to provide a full nationwide view of health and health trends. This can be utilised to drive health improvements for the benefit of the potential patients and at much lower cost to the NHS.

3. Addressing the Issues

3.1 *What patient information will be held on the new local and national electronic record systems, including whether patients may prevent their personal data being placed on systems?*

3.1.1 Patient information will have to be locally inputted. Decisions will have to be made on the viability of locally held Vs nationally held data. For ease of use and cost effectiveness the "hub and spoke" nationally centred model would be the most efficient. However, there may be a strong GP / PCT desire to retain control of patient data locally. This latter will decrease efficiency for out of locality treatment and for any necessary trend analysis.

3.1.2 EPR should exist to ensure ease of use and the relative free flow of essential information. It should not exist to create further barriers and to increase cost.

3.1.3 For security and access reasons, patient information will have to be tiered:

Tier 1: contact details and unique identifier

Tier 2: Outlying medical history

Tier 3: Detailed medical history

3.1.4 It may be that patients can be given the right to prevent their personal data being placed on systems. If this is undertaken, there must be relevant and easy to understand information regarding the advantages of EPR and the disadvantages of not being on the system, as well as allaying any security fears.

3.1.5 Emphasis should be on full population inclusion. For the patient this should not be a matter of information management, rather a matter of enhanced care delivery and patient safety.

3.1.6 EPR will also give the private sector the distinct opportunity to add to the available health records. This can only benefit overall patient care and the tracking of statistical trends to assess future need. In a world of changing demographics and finite resources, the assessment of the future need is likely to prove critical. Therefore, it is essential to gain a holistic view and not just a partial view.

3.2 *Who will have access to locally and nationally held information and under what circumstances?*

3.2.1 Access will be strictly controlled. Access will also be strictly audited. Information changes will be tracked. How information will be inputted and the quality of this information will have to be standardised to negate error and misunderstanding.

3.2.2 Access to patient information will be based on need. For example, the need of a medical secretary will be different from the need of a GP and the need of a PCT. This is where access will be controlled.

3.2.3 Doctors directly treating the patient will have full access to data. Those national agencies providing information and analysis, for example the NHS Information Centre and the Secondary Uses Service, will have access to anonymised data only. This data may or may not be encrypted.

3.3 *Whether patient confidentiality can be adequately protected?*

3.3.1 All data—whether paper based or electronic—is at risk. These risks include unauthorised infringement. Risks also include loss, fire and spoiling of paper based records. They also include disposal of old records.

3.3.2 No records of any format can ever be assumed to be 100% secure.

3.3.3 However, with present mechanisms, there can be a high degree of surety regarding confidentiality, risk and disposal. These protective mechanisms are increasing in sophistication.

3.3.4 Although there are objections over security, the underlying main objection to using e-information mechanisms is not necessarily security. It is more a matter of perception.

3.3.5 Overall protective mechanisms can only be finalised following the decision on having either locally held data or nationally centred data. Some similarities exist between the two choices—for example, encryption and secure access—yet with some differences that have to be examined—for example, which type of data store to protect and the multiple access points into the data store.

3.3.6 Data warehousing in general is a secure repository for data. This can also provide significant safeguards over traditional paper based records in terms of other security and backup, as well as physical space and the real time updating of records.

3.4 *How data held on the new systems can and should be used for purposes other than the delivery of care eg clinical research?*

3.4.1 The use of paper based records for purposes other than direct care can be both costly and unwieldy. As a result there is no clear national view of the nations health and future trends from the holistic public sector and the private sector. For example, a third of all hip replacement operations are conducted in the private sector. This is not included in the overall countrywide health statistics.

3.4.2 E-data, updated in real time or on a daily basis, will provide access to a wealth of analysed information. This information can provide snapshots or general trends. These will prove essential in the planning of patient centric healthcare. In todays world this is important for health prevention and the out of hospital care agenda to increase relevant care delivery and reduce costs.

3.4.3 Real time updating of e-data will also prove to be an essential component in combating any outbreak of disease. For example, in an extreme case, a H5N1 pandemic if the virus genetically jumps species to become highly pathogenic to humans. During the Sydney Olympic Games (2000) health information from the immediate population was updated every 4 hours in order to gain early warning of any infectious conditions.

3.5 *Current progress on the development of the NHS Care Records Service and the National Data Spine and why delivery of the new systems is up to 2 years behind schedule?*

3.5.1 No comment can be made on the specific lateness of this particular project.

3.5 2 However, from a significant level of public sector consultancy experience, there is a general observation that may be relevant. The observation is that the majority of public sector projects/programmes exceed budget and time. In general, the main reasons for this are:

- initial requirements are vague;
- requirements are prone to change from public sector managers or politicians following the design or implementation stage;
- there is little or no change control;
- there is little or no change management;
- there is little or no identification, tracking or realisation of benefits—the project is carried out because someone told them to do it. This is poor communication and management; and
- there is significant public sector cultural resistance to change.

3.5.3 This latter point is wholly concerned with the amount of unfocused change there has been, typified by a lack of relevant communication to all levels of staff and a lack of realised benefits due to project overruns in both time and money.

3.5.4 Only if these points are understood and successfully tackled will any future programme be successful in terms of the benefits delivered and costs incurred. The Health Committee have an opportunity to turn the tide of NHS implementations and ensure a successful outcome for EPR.

4. Recommendations

4.1 To engage in a proper and full scoping study in order to identify the advantages/disadvantages of EPR versus the advantages/disadvantages of non-EPR. This study should be conducted independently. It should have a specific timeline for completion and be formally presented to the committee. Only by this means can every member of the committee gain the high level view of the same information. Feedback should be incorporated into the study.

4.2 Publish the scoping study and grant access to interested parties. This will begin the necessary dialogue and uncover barriers.

4.3 If the decision is to progress with the process, the study should be used to begin the full and in-depth consultation with interested parties. This consultation will be for the purposes of engaging with the barriers at an early stage—and finding a way around the barriers—as well as to raise awareness/educate with respect to the benefits achievable—and then gain wider support.

4.4 There should then be a final decision on data and information standardisation.

4.4 This will be followed by a decision on the local or national data model.

4.5 Followed by the decision on confidentiality measures and access.

4.6 There should be a pilot project to assess on the ground impact as well as take account of any unforeseen difficulties.

4.7 Lessons learned from 4.6 should be cascaded into an overall implementation plan for national EPR.

4.8 The core benefits will have to be identified.

4.9 A communication plan should be in place to keep all interested parties properly informed and to deal with barriers should they arise.

4.10 To minimise the already extensive delays, progress should be agreed as a matter of urgency.

James Stuart
Health and Information Consultant

February 2007

Evidence submitted by Dr Paul Thornton (EPR 50)

I have been a General Practitioner since 1989 and have been lead IT partner in taking two practices through to "paperless practice". I have a particular interest in patient confidentiality and privacy arising from a two year post in 1995-6 based in the Public Health Department of Coventry Health Authority with the remit to develop HIV care and prevention within General Practice and Primary Care. I was recruited to the Public Health working party of the Caldicott Committee, a DoH review of patient information use in the UK.

A paper I prepared for the RCGP and BMA, when supported in part by the office of the Data Protection Registrar, was influential in amending joint guidance between the British Medical Association and the Association of British Insurers with regard to the content of reports provided by General Practitioners to insurance companies.

I was subsequently nominated by the RCGP to participate in the Eurosocap[111] project, an EU sponsored multination, multidisciplinary working group charged to produce European Standards on Confidentiality and Privacy in Healthcare. The objective was to confront and address the challenges and tensions created within the healthcare sector between theinformation or knowledge-based society and the fundamental legal and ethical requirements of privacy and confidentiality of healthcare information.

1. I wish to provide the committee with:
   - an explanation for the established cultural vulnerability of existing UK medical records.
   - further information arising from a previous paper[112].
   - comments in respect of a recent "view" from the Office of the Information Commissioner.[113] This provides a pre[acute]cis of a new detailed paper that I have made available on the internet reviewing the extensive privacy and confidentiality issues that persist despite the opt out from the summary care record announced by Lord Warner.

2. In making these criticisms I wish to stress that I am not at all Luddite in these matters having taken two surgeries through the process of becoming "paperless". It is impossible to argue with the acknowledged need for better information handling in the National Health Service and clearly this must require the use of modern technologies. The secondary care sector needs at least bringing up to the standard of computerisation which General Practitioners had already achieved prior to the turmoil imposed by Connecting for Health.

3. There is a direct conflict between the sharing of information, even among health care professionals, and the protection of patient privacy. Patients divulge information to individuals, perhaps to teams, rarely to institutions and certainly not to the entirety of the National Health Service. The risk to privacy increases in proportion to the number of users of a database.

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[111] http://www.eurosocap.org/

[112] Why might National NHS Database proposals be unlawful?
http://www.ardenhoe.demon.co.uk/privacy/NHS%20database%20proposals%unlawful.pdf

[113] The Information Commissioner's view of NHS Electronic Care Records
http://www.ico.gov.uk/upload/documents/library/data_protection/introductory/information_commissioners_view_of_nhs_electronic_care_reco%E2%80%A6.pdf

4. In a recent review of the CfH proposals, the British Computer Society[114] recommendation is to put the Personal Spine Information Service "on the back burner". In essence they recommend the development of secure local databases with good quality secure communication between them. They suggest systems which provide better privacy and confidentiality as well as providing better implementation, usability and care. The BCS recommendations are likely to provide better quality data for research and managerial purposes and merit wider critical discussion and debate.

The Established Cultural Vulnerability of UK Medical Records

5. Since 1917, the UK health service has had the nearest paper equivalent to a single record and this has already increased the vulnerability of patient information. We have a unique system whereby almost everyone at any one time is registered with a single identified General Practitioner who provides near monopoly access to all health care—NHS & private. The records created by the GP combine with copies of correspondence with specialists and other health workers to create an accruing record which passes to involved GP's throughout the life of the patient. In other countries, patients self refer to primary care and specialist doctors who may not necessarily communicate.

6. UK records provide a tremendously powerful foundation for efficient patient care and provide a resource for research. But the ease with which such complete records can be located makes them vulnerable to enquiry.

7. It has become routine in our society for secondary users, such as insurers, prospective employers, the courts and government departments e.g. the DWP and the DVLA to obtain information from those records. While such access is generally based upon consent, custom and practice is so established that the patient commonly does not have a valid choice over whether or not to give consent. Individuals who dissent are denied the advantages that might otherwise accrue from their relationship with the third party. Patients are treated detrimentally if they have communicated freely with their General Practitioner. Under UK systems, the consent of patients who have no detrimental information in their records effectively trumps the dissent of the stigmatized minority.

8. By definition, it is difficult for doctors to know what we are not being told, and particularly to research this. Indeed, given that so many patients do trust us and divulge so much sensitive information, it is easy even for doctors to perceive that there is no problem here.

9. There is good evidence that embarrassment and concern about confidentiality is already a negative contributory factor in the up take of services for young people and in delayed presentation in mental health and in cancer, with a direct effect on clinical outcomes and morbidity. Epileptic drivers commonly do not inform their GP's about the fits which they experience.

10. The problem became clearly manifest with the HIV pandemic. Patients with stigmatising risk behaviours, or confirmed infection, were able to self refer to departments of Genito-urinary medicine who respected the patients wishes that their information should not be shared, even with other involved clinicians such as the General Practitioner. The DoH accepted that the practice of insurance companies seeking reports from GP's inhibited HIV prevention, testing and treatment.

11. In other European countries, third parties have no option but to rely on information provided directly by the patient on their own behalf. They are dependent on the patient identifying the doctors that have been consulted and the conditions treated. As a consequence, there is no tradition of such information release by doctors to third parties and such enquiries that do occur are culturally recognized as intrusive. Protection is maintained less by *confidentiality* laws: the patient can still consent to, or request, the provision of information. Rather protection is achieved through *privacy* laws: society recognizes the need for medical information to be fully protected and the third party is not allowed to ask.

12. It is this historical emphasis on privacy rather than confidentiality that has given rise to a different perception, implementation and enforcement of the EU data protection directive, even though the legal texts are largely shared.

13. In the context of all the major public health dangers—alcohol, drug use, sexually transmitted infection & HIV, teenage pregnancy, psychiatric illness etc, the protection of a patient's privacy is essential. It is against that background that one should judge the proposals for a national database of the entirety of medical records. Computerisation should have provided a substantial opportunity to improve the privacy of medical records. We need bringing up to the European standard.

"Are the NHS Database Proposals Lawful?": Further Information

14. I enclose a copy of my earlier report[2] and some associated correspondence with Mr James Johnson, Chairman of Council at the BMA.

[114] The Way Forward for NHS Health Informatics; Where should NHS Connecting for Health (NHS CFH) go from here? http://www.bcs.org/server.php?show=ConWebDoc.8951

15. In short this confirms that Lord Warner sought a further counsel's opinion in respect of the arguments I had provided. So far as I am aware, that opinion has not been published.

16. The select committee may wish to obtain the Counsel's opinion in full, and provide an opportunity for that advice to be subject to informed scrutiny, from the perspective of patients who would choose to restrict the recording and dissemination of their information to the fullest extent.

17. Lord Warner has provided the BMA with two brief extracts from the Counsels advice.

Summary care record

18. "Officials have received reassurance from counsel that the planned process for uploading data to the summary care record is lawful". However, by that time it had been conceded that patients would be given an opt out from the Summary Care record which had not previously been intended. It remains my belief that the legal obligations that required that "op out" provision apply to the remaining components of the Connecting for Health proposals.

Patient Demographics Service

19. The department has provided a justification for a register of patient demographic details which has existed for many years. This may be lawful and such a database has been in existence for many years. The change is that this information has now been made much more widely accessible. Is such widespread accessibility lawful?

20. (In addition, The PDS is not just demographic information. For security purposes the PDS contains an audit trail identifying every one who accesses each patient's demographic detail. The unintended corollary of this is that the audit trail provides a list of all the clinicians consulted by the patient. This is of itself highly sensitive information. There is no clarity about who will be able to access that audit trail.)

The Information Commissioners View of NHS Electronic Care Records

21. The Information Commissioner has recently published a response to enquiries from the public in respect of NHS care records. While it is guarded in tone, he is reported as being "content with their general approach."

22. However, the description of the approach adopted by Connecting for Health, as described by the IC's office, is contradicted by a review of the detailed technical papers that have been published by Connecting for Health.

Summary Care Records

23. The information commissioner is at least clear that patients should not be obliged to have a summary care record.

24. "Patients will be informed of the intention to create such a summary care record and advised of their options to limit the future scope of the information on the Summary care record or the option not to have one at all." And further if information is uploaded on to the NHS Summary record, a patient will subsequently be able "to remove some or all of the information initially uploaded."

25. The limited information in a summary care record will be sufficient to cause a substantial risk of sensitive diagnoses being widely deduced.

26. However, the pilot summary care records commence today in Bolton. Connecting for Health will take information outwith the control of the GP, who is the registered data controller, and place it on a Department of Health controlled internet site. Ostensibly to allow patients to control their own records, this transfer of the data is taking place before patients have been advised of the proposal and before they have been given the opportunity to decline.

27. Vulnerable patients will find it difficult to resist pressures from "friends", abusive spouses, and parents to access and divulge the contents of their summary record.

28. While patients will be given a period to consider their options, unless the patient responds records that have already been placed on the internet site will be revealed on the national NHS Summary Care Records database.

29. In the recently published "view", the Information Commissioner gives the impression that he accepts that "the initial upload will take place without explicit consent", and acknowledges that "explicit consent is only one of the conditions required for processing sensitive personnel data in schedule three of the data protection act". However, he then observes somewhat obliquely that "Connecting for Health are confident they are able to meet the requirements of one of the other conditions." Does this imply that while CfH are confident, the Information Commissioner is uncertain? Have Connecting for Health stipulated the DPA condition(s) which they believe renders their processing lawful in the absence of consent?

30. It is difficult to reconcile the Commissioner's contentment with Connecting for Health's "general approach" with very recent confirmation from his office that guidance issued by his predecessor, Mrs Elizabeth France, remains in force and has not been rescinded.

31. In 2001, Mrs France insisted *"It is clear, however, that for consent of any sort to be given, there must be some active communication between the parties. It would not be sufficient, for instance, to write to patients to advise them of a new use of their data and to assume that all who had not objected had consented to that new use."*[115]

32. Having acknowledged that legal and ethical obligations require that patients are allowed to opt out of having a summary care record, it behoves the Information Commissioner's Office to confirm that a patient should similarly not be obliged to have their sensitive medical information transferred on to other components of the Connecting for Health systems. In the conclusion of the report, the Commissioner places great emphasis on patients being provided with choice. There must remain the choice for records to remain solely in the care of the registered data holder that has provided care. If needed the option for paper records must be allowed to persist, but stand alone computerised records would be preferable.

Secondary Uses Database

33. Particularly, the IC understands from Connecting for Health that "no records are currently being up loaded to the new England wide database". This fundamental observation is incorrect.

34. Substantial sensitive patient data is already being collected and stored in *identifiable* and *accessible* form by Connecting for Health on to the "Secondary Users Service". The secondary uses services is intended to provide information for NHS management, research, clinical audit and management.

35. This national database is not anonimised. It is designed so that the data can be processed and then the patient re-identified. These patient records are being collected by a diversion of established, hidden, managerial data flows and by lifting data from the new messaging systems, "Electronic Transfer of Prescriptions" (ETP) , and "Choose and Book" (C&B). The Secondary Users Service database will harvest data from Summary and Detailed Care Records as they are developed, without patient consent and without the involvement of the professional who records the information. Even if the promised safeguard of metaphorical sealed envelope software can be made to work, patient wishes asserted using sealed envelopes will be ignored by the Secondary Uses Service data collection.

36. It is here that the most fundamental misrepresentation of CfH's intentions has crept in to the report from the Information Commissioner's office. His office acknowledges there are circumstances by which information that has been uploaded to the NHS care records service can be released beyond the NHS without explicit consent. The release may be "allowed" or "required"—the distinction is important. It is however claimed that such requests for information will be dealt with in the same way as requests are handled today. This is not correct. There is no provision in the CfH proposals to prevent such information being released by anyone who has access to the system.

37. Currently, requests for information are made to a professional who has direct knowledge of the patient, has existing lawful access to the information and who is qualified to determine if the information requested meets the DPA requirements, particularly for fair processing, necessity, relevance and non excess. They also have the authority to with hold information pending court order while defending the patient's right to privacy.

38. Against that background, it is reasonable for any patient to dissent for their information to be recorded on the Connecting for Health databases.

Detailed Care Records

39. The proposed access to "Detailed care records" (DCRs) seems to have been misconstrued by the Information Commissioners office. DCR's *will* be accessible more widely than simply "*your GP surgery along with the other care providers you may be referred to, such as your local hospital.*" The national database is devided into geographical areas called clusters and then further subdivided into groups of service providers which share IT infrastructure known as "instances". Information recorded in any one "instance" will be accessible to staff working in any other organisation using that "instance". If the proposed safeguard of "sealed envelopes" is ever established it is intended that staff in the same instance will be able to over ride the patient sealed envelope provisions. Each "instance" will include a large number of service providers over a large geographical area.

40. Paradoxically, however, General Practice Detailed Care Records and the Detailed Care Records created in nearby hospitals are likely to be quite separate for many patients. GP services and hospital services are likely to be set up as part of separate "Instances". Certainly DCR's will not be shared where patient care

[115] "USE AND DISCLOSURE OF HEALTH DATA:Guidance on the Application of the Data Protection Act 1998" Information Commissioner May 2002
http://www.ico.gov.uk/upload/documents/library/data_protection/practical_application/health_data_-_use_and_disclosure.pdf

crosses the boundary between "clusters". In such circumstances the system can never provide the level of detailed data sharing which would be necessary for shared care. Additional systems that provide for the proactive messaging of detailed information between *involved* clinicians, and *only* involved clinicians, will be needed—the IT model which should have been adopted from the outset.

41. All the above observations are clarified in more detail with supporting references in the enclosed report. *The NHS Database: Lord Warner's opt out decoy. A review of persisting privacy and confidentiality issues*[116].

Suggested Questions for the Information Commissioner

Given that the records of a consultation can be made on paper or on a GP controlled computer system then,

A. If patients instruct a GP, or any other independent registered data holder in the NHS, not to transfer information on to a DoH/CfH controlled database, is there any obligation on the data controller to over ride the patients mandate in every case?

B. What circumstances would require a registered data holder within the NHS to override the wishes of a patient by placing their information onto any Connecting for Health/Department of Health controlled database?

I hope this is of assistance to the committee. Please do not hesitate to contact me if clarification of any points is required. I would be please to meet with members of the committee or the supporting secretariat if that would be of assistance.

Dr Paul Thornton

16 March 2007

Evidence submitted by Helen Wilkinson (EPR 65)

My story begins in August 2004 when I first became aware of the national database for medical records—the NHS Care Records Service. As an NHS Manager I knew immediately that I did not wish to be on any such Department of Health/NHS database.

I naively assumed that one just wrote to the local Primary Care Trust to opt out of this database. But when I contacted my local Primary Care Trust they did not know how I could opt out. My MP Mr Paul Goodman then intervened and obtained an Adjournment Debate in June 2005 about the issues I had raised. The Department of Health (DoH) eventually agreed to remove all my personal and clinical details from all NHS databases, but it has taken them two years to remove all my details and has left me without access to any medical care whatsoever.

John Hutton, former Health Minister, was invited with me onto the Radio 4 Today programme on the 31 March 2005 where he stated, "Mrs Wilkinson does not have to have an NHS Care Record if she does not want one". Indeed Caroline Flint, Minister for Health, in my Adjournment Debate stated that no-one would be denied NHS care if they chose to have some or all of their medical records removed from these NHS databases. However, as my case highlights, the reality is somewhat different.

The Department of Health have stated that Section 10 of the Data Protection Act applies to me, whereby "the holding, storing and processing of my personal and clinical details is likely to cause [me] substantial and unwarranted distress" under the Act. They have said that none of my demographic, personal or clinical details should be on any NHS/DH database. But nothing whatsoever has been put in place to allow me to access medical care. And in an email from Linda Percival, Director of Customer Services at the Department of Health, I was told that if I were to attend any NHS hospital there is very little I can do to stop the hospital putting my personal and clinical details on their own database—which will give me an NHS Care Record and result in my identifiable, demographic, personal and clinical details being used for Secondary User Services purposes!

I also have direct proof that NHS databases can be accessed by researchers without patient consent. My name, address and GP details were given to a research study by the National Strategic Tracing Service (NSTS) database withoutmy consent and I was later contacted by researchers, the week before I was due to undergo major surgery. Given my ongoing concerns, this could have had very serious consequences—had I decided not to go ahead with the surgery.

To ensure that I am not placed on the Personal Demographics Service (PDS), which would give me an NHS Care Record, my GP has very kindly de-registered me from the NHS—but still sees me as a patient free of charge. This is not, however, the solution for all patients and it is doubtful that many GPs would

[116] http://www.ardenhoe.demon.co.uk/privacy/decoy.pdf

agree to offer this. A further downside is. that as soon as I need hospital treatment, I would again have an NHS Care Record without my consent and my demographic, clinical and personal details would be used for Secondary User Services.

At the present time I am left completely without access to medical care, other than being able to see my GP as a non-registered patient. Even though the Department of Health have said that Section 10 of the Data Protection Act applies to me—where me being on NHS database is likely to cause me substantial and unwarranted distress—absolutely nothing has been put in place to ensure that I can access medical care. This is contrary to the Health Minister's assurances in both my MP's Adjournment Debate and on Radio 4's Today programme.

My story can be found here in *The Guardian:*

http://politics.guardian.co.uk/publicservices/story/0, 1937018A0.html

The 93C3 Code just is not enough to ensure patient confidentiality all this achieves is to prevent the patients Summary Care Record from being shared. However the actual detailed medical consultation notes and in depth patient identifiable clinical details will still be stored on the Detailed Care Record and used by the Secondary Uses Services (SUS) without patient consent. Information used by the Secondary Uses Service is patient identifiable as the document I obtained under the freedom of Information Act states the Department of Health deem it impractical to anonymise these patient records.

http://wwvv.Iightbluetouchpaper..org/2006/08/09/anonymous-datathat-isnt/

Indeed in the Department of Health Patient Information Advisory Group minutes of September 2005 (which are attached, paragraph 6.1)[117] it clearly states that it would be a waste of parliamentary time to debate the issue. Also is the attachment document which looks at Long Term Medical Condition programme it again clearly states that the Department of Health are fully aware that the use of patients identifiable medical data in this manner is potentially unlawfully A large number of both NHS and private companies have access to this highly confidential identifiable patient information including the Department of Health, Primary Care Trusts, Strategic Health Authorities, Researchers and even Dr Foster.

In my own personal circumstances the Department of Health have deemed that Section 10 of the Data Protection Act applies to me and to on any DH or NHS database would cause me substantial and unwarranted distress under the Act. Even though the Department of Health have categorically agreed this is the case I personally have been left without access to any medical care. I seriously injured my eye last September 2006 and I enclose a copy of the email I received from Mrs Linda Percival Director of Customer Services at the Department of Health which clearly states that even though legaly under Section 10 of the DPA the DH and NHS cannot hold, store or process any of my demographic, personal or clinical details to receive medical care I have no choice but go back on all the DH and NHS databases.The DH are trying to cause me immense and immeasurable distress by asking me prove Section 10 of the DPA applies to me each time I am ill. This is contrary to the Data Protection Act one should only have to prove that Section 10 of the DPA applies once only not each time one needs medical care.

The Department of Health have repeatedly failed to put anything in place to ensure I can access medical care. This is contrary to my Adjournment Debate where Caroline Flint Health Minister clearly states that no patient will be denied medical care if they choose not to be on any of these NHS/DH databases. Ifeel so incredibly strongly about these confidentiality issues that even in a medical emergency I would refuse all medical treatment if any of demographic, personal or clinical details where placed on any of these DH/NHS databases.Its worth noting that the DH deem I would be caused substartial and unwarranted distress under Section 10 of Data Protection if any of **my demographic, personal or clinical details** where placed on any DH or NHS database. let in view of this nothing has been put in place for me to be able to access medical care and I am completely reliant on the goodwill and kindness of both my GP and Hospital Consultant who see me free of charge. I am completely and totally unable to have access to NHS services such as blood tests, x-rays, out of hours care, community services for eg District Nurses, attend any Community Clinics for eg podiatry, attend any hospital as either an inpatient or outpatient, access any maternity services or have any NHS prescription-the list is long way.

This is purely due to these DH and NHS databases as well as Section 10 of the DPA applying to me.

My personal view is that I do not want nor would I ever consent to any of my demographic, personal or clinical details leaving either my GP or Hospital Consultants consulting room without my explicit consent. I firmly believe that the NHS Care Records Service and Connecting for Health should be disbanded and there should be secure local databases, by this I mean hospital and GP Surgery's should have their own databases that communicate with one another only with explicit patient consent.

I also believe that medical data used for Secondary Services Uses (SUS) or for research purposes should either be truly anonymous or only to used with explicit patient consent.

By profession I am an NHS Manager with over 20 years experience I have worked as a Manager in General Practice, for a Health Authority and for two London Teaching Hospital Trusts what has amazed me about this situation is that until I investigated and researched the whole area of patient confidentiality and the DH/ NHS databases I ones truly amazed and horrified that all this highly confidential identifiable

[117] Not printed here.

patient information was being used potentially unlawfully withoutpatient consent. In view of this I set up The Big Opt Out Campaign to inform patients about both the NHS Care Records and patient confidentiality.

The Big Opt Out Campaign has been a huge success. The demand from patients is enormous. The Campaign was formally started on 29 November2006. Over 75,000 people have downloaded our OptOut Letter. I taking approximately 100 phone calls a day from patients and dealing with 50 emails a day. I have anecdotal evidencethat numerous patients are so concerned that they are de-registering from the NHS so their medical records are destroyed and so that they do not get put on NHS CRS. I have also had other patients tell me that they are prepared to lie about their symptoms, medication they are taking and medical history as they cannot opt out of the Detailed Care Record or prevent their records being used by the

Secondary Uses Services. It begs the question what use is this medical data going to be to the DH and Researchers if it is inaccurate? Patients are also expressing huge concerns that unless they opt out of the Summary Care Records local high street pharmacists will be able to access this clinical information and their demographic details, including ex-directory phone numbers. I am seriously worried that there will be an under class of people left without any access to medical care whatsoever.

With regards my own case I am left in the clinically highly dangerous position of being unable to access any medical care due to Section 10 of the DPA applying to me and the DH are totally refusing to do anything to enable me to access medical care. Hence the current highly unsatisfactory situation continues to cause me immense and immeasurable distress.

Helen Wilkinson
The Big Opt Out Campaign

March 2007

Annex

Email from Linda Percival, Department of Health, to Helen Wilkinson

To receive care from your GP as a patient of the NHS you have to be registered as being a patient of the practice. This is a requirement in law and the PCT is legally required to enter your contact details on the register which is held within the NHS Health Authority Information System. I am aware that you are not happy about this but it is a legal requirement and as such the provisions of section 10 of the Data Protection Act 1998 do not apply. Once registered the GP can of course refer you to a specialist in the normal manner.

Alternatively you may directly access services through A&E and seek referral to the appropriate specialist through this route. As you have no NHS GP there should be no issue with this happening. The hospital will create records of the care and treatment it provides but as a block has been placed on the NHS Wide Clearing Service any automated transfer of information from the hospital will be prevented so the information created will remain at the local level. You may be able to agree with the hospital that minimal records be kept or that records be kept under an alias or largely on paper, though I accept that most hospitals will be very reluctant to do this. If the creation of these records locally causes you distress you are of course entitled to request their deletion by the hospital by providing a written section 10 request that meets the requirements set out in the Act, including the reasons for your distress so that the hospital can male a judgement as to whether or not to comply.

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