

Text of letter sent from the Department of Health to patients expressing concern over electronic care records

I am replying to your letter addressed to the Secretary of State regarding your participation in the NHS Care Record Service (NHS CRS). Your letter raised some specific concerns about your personal health information being held electronically in a new NHS database as a summary care record, indicating that having your information held by the NHS in this way may cause you substantial unwarranted distress. You therefore asked the Secretary of State for Health to stop the process of adding your information to the new NHS database.

I have responded to the reasons you have indicated for your distress in detail in an annex to this letter. However, much of what has been published on this matter is inaccurate and I am therefore providing the context for my response by setting out the reasons for the introduction of the NHS Care Records Service.

The introduction of modern information technology is at the heart of the Government's Modernisation Plan for the NHS. The current record-keeping systems within the NHS desperately require modernisation. Many patients are harmed every year due to the unavailability of records, no readily accessible record of allergies and drug reactions, poor handwriting and transcription errors. Others have to repeat their painful stories over and over. Appointments are missed and tests are repeated because records go missing. It is not a situation we can or should sustain, especially where we have the means to improve it significantly.

The new systems will improve healthcare for millions of people as well as preventing thousands of unnecessary deaths. These improvements will be delivered by ensuring that crucial patient information is available at the point of need. The changes we are making to the way the NHS holds and allows access to health information will lead to more accurate diagnosis and prescribing and reduce adverse reactions to treatment; providing safer and better quality health care. Of particular importance in the context of the concerns you have expressed is that the NHS will move from a position where patients have little or no knowledge of what is in their records and little or no control over who accesses them to one of greater knowledge and control.

I understand that people will always have concerns about the potential implications of new technology and I can assure you that these concerns were considered very carefully during the design stages of the new systems, on which there was wide consultation. To address these concerns, we have published the NHS Care Record Guarantee which sets out how we will record, use and share care records and how we will keep them safe and confidential. I enclose a copy for your information.

The new NHS CRS systems have been designed specifically to support patient confidentiality and to restrict access only to those who need to see parts of your records in order to provide you with care. They will be more secure than existing systems, which were not designed specifically with confidentiality in mind.

Returning now to the request in your letter that the Secretary of State for Health should stop the process of adding your information to the new NHS database on the grounds that it is likely to cause you substantial unwarranted distress, I am afraid that I am unable to agree your request.

The reasons that you gave as the basis for claiming substantial and unwarranted distress are not, as I hope I have made clear in the Annex, based on an accurate understanding of the summary care record. The Department of Health believes that the summary care record will benefit both you and the clinicians that care for you in that it supports them to provide better care. There needs to be, therefore, a genuine reason linked to substantial and unwarranted distress, for the NHS not to process your information.

Should you feel that there are further unique and personal reasons for claiming substantial and unwarranted distress that are not addressed by the safeguards and choices I have described, you should write, explaining those reasons, to:

The Customer Service Centre
Department of Health
Richmond House
79 Whitehall
London SW1A 2NS

I hope you find this helpful.

Detailed response to the reasons for claiming distress

In your letter, you make the following assertions:

- (1) No 'sealed envelopes' yet exist to limit access.
- (2) No online patient system yet exists to correct errors.
- (3) Data uploaded may include genetic, psychological or sexual information.
- (4) It is intended to make your data available to social workers, researchers and commercial firms.
- (5) Your consent will not be asked before beginning processing.
- (6) Adequate criminal penalties against abuse do not yet exist.
- (7) Police and other agencies can gain access to a potentially unlimited range of information about you. There is abundant evidence that computer databases - including police, vehicle licensing and banking computers - are routinely penetrated by private investigators on behalf of clients, including media organisations.
- (8) 250,000 smart cards have been issued granting access to the Spine.
- (9) The department threatens to withhold appropriate medical care to objectors.
- (10) Doctors say there is no necessity to design the Spine in this way.

My response to each of these assertions is set out below. I should first clarify that the database has been created to support the delivery of care to patients by the NHS in England. Different arrangements apply in other parts of the United Kingdom and you will need to make separate enquiries to the relevant health organisations in respect of treatment outside of England.

(1) The “sealed envelope” procedure

“Sealed envelopes” will enable patients to identify specific entries within their records and to place them under additional controls so that they are not seen without consent. This will allow patients to determine, providing it does not put another person at significant risk, which parts of their records should be accessible to those who provide care. It is correct that they do not yet exist because they are still at the planning and development stage.

However, equally secure, though less flexible, measures are in place for the initial phase of the summary care record service. The initial extract of information from the GP record will contain only basic information, that is, details of patient medication and allergies. This will help to support treatment when unscheduled care is needed, for example in an Accident and Emergency Department.

However, you will be able to have your personal record flagged so that the summary care record cannot be accessed without your permission and, to ensure your wishes are known, you can do this even before the summary is created. If you are concerned, for example, that your medicines may indicate your condition and you do not want this information to be accessible, your record can be flagged and rendered invisible to NHS staff. The point is that you are in control. When you see your GP you will be able to discuss whether more detailed information should be added and whether any of the information that has been added should be removed. You have the choice of a full summary, a partial summary, or a summary that can be seen only with your permission.

The same level of security that will be available through the “sealed envelope” procedure will therefore be available, through different means, in these early stages, to limit access to your records.

The “sealed envelope” functionality, which will give you even more choice, will be available in due course. We are currently working with the major suppliers of information technology systems to the NHS to incorporate the “sealed envelope” approach into their products as soon as this can be achieved.

This approach has been agreed following consultation with the major clinical bodies, patient groups and the Care Record Development Board. It has their support, but we will be proceeding cautiously and evaluating carefully as this represents a significant change to NHS record-keeping.

(2) On-line provision for patients to correct errors

For safety and ethical reasons, there are very strict rules on altering clinical records, though health professionals are required to make a note within a record if a patient disagrees with what has been written. Complete records are essential to protect the interests of patients and staff, including ensuring that claims of negligence or malpractice can be investigated. In addition, information contained in records may be needed to explain why subsequent decisions were taken.

However, the Department of Health recognises the need for a process for looking at the merits of each request for a record to be corrected and is consulting on new guidance for the NHS to clarify the circumstances where information may be amended or removed from clinical records. This guidance will be published before the first summary care records are introduced.

In addition to supporting more effective and efficient healthcare through effective IT systems, a new facility known as Healthspace is being developed to enable patients to view the content of their summary care record and to identify any inaccuracies. Healthspace will be made available as soon as this is feasible.

(3) Genetic, psychological or sexual information

The summary care record will be created from data uploaded from the GP record. At first, this will be limited to details of medication and allergies. If patients are concerned that these may reveal more about them than they are comfortable with, they may register their dissent to information sharing, which will prevent anyone from seeing the summary without permission.

Subsequently, when patients visit the surgery, their GP will discuss adding more detail to the summary and patients can request that nothing be added if they have any concerns. They can also ask for information that has been added to be removed. In due course, the introduction of “sealed envelopes” will provide patients with even more control, allowing the information to remain in the summary in case of need, but locked away unless express consent is given to its disclosure.

(4) Availability of patient data to social workers, researchers and commercial firms

It is not true that personal patient data will be accessible by social workers, researchers and commercial firms. The current arrangements for dealing with any requests for information will continue to apply.

The clinical information in your summary record will be controlled tightly and used only for providing care, supporting the provision of care and quality-assurance of the care provided. The Care Record Guarantee, endorsed by the Care Record Development Board (CRDB) and Health Ministers, makes clear that permission will be obtained before any information is shared outside of the team providing you with care.

Clinical data may also be released through the “Secondary Uses Service” but only in an anonymised form and only under strict controls that have been endorsed by the Patient Information Advisory Group (the independent statutory body that advises on patient information issues), and, where appropriate ethical approvals and information governance arrangements are in place. The Secondary Uses Service is used by researchers and public health analysts to monitor trends and to plan for the treatment of illnesses and epidemics. This service is a more efficient and modern approach to supporting non-clinical uses of information that are both lawful and longstanding across the NHS.

Whilst it is possible that the law or the Courts may require information to be disclosed, this is an extremely rare occurrence and is no different from what happens with patient records now. In very limited circumstances, the law also allows identifiable data to be used without patient consent for purposes such as important research. Again, this is not new, but, if you have registered within the new system that you dissent to information sharing, your records will not be used in this way. This is an improvement on older systems where your preference could not be recorded.

(5) Opportunity to act before the process begins

There has been extensive public consultation on both the practical difficulties of creating summary care records and the enormous safety benefits that will be provided by these records. An incremental approach to implementation has been agreed that starts with information being extracted from GP records and placed on the NHS database. At first this will contain only details of patient medication and allergies, but even this simple information will save many lives and improve health outcomes. A Taskforce including representatives of patients, doctors, nurses and other health service professionals is advising on implementation.

The first summary care records will start to be extracted from a limited number of GP records during 2007 for patients already registered with GPs. Primary Care Trusts will

notify registered patients in advance and it will be possible to discuss the matter with your GP before any information is extracted. Most importantly, in advance of a summary care record being created for you, you can ask for your records to be flagged so that they are not visible after they have been added to the database, so that even though you will not be asked for specific consent, you can register your dissent. The choice remains yours.

Subsequently, when you see your GP for care purposes you will be able to agree what other information should be added to your national summary care record. Be assured that there will be extensive communication within each community prior to the summary care record being introduced locally so that everyone has the opportunity to make this choice. The Information Commissioner is concerned to ensure people are well informed and we continue to keep him informed about our plans as they develop to ensure that they are as effective as possible.

(6) Adequacy of criminal penalties for abuse

The Secretary of State for Health has strongly supported the Information Commissioner's call for greater penalties for misuse of people's personal information.

NHS staff have access to sensitive information now, with few safeguards, and there is no suggestion that there is widespread abuse. In future, access will be controlled far more closely, fewer staff will be able to access full clinical records, and the system will record who has done what. NHS staff risk disciplinary action if they behave inappropriately. Staff who misuse NHS IT systems or who breach patient confidentiality are breaking the law and may face legal action as well as dismissal. Offending doctors and nurses will be reported to their professional regulatory bodies and may face additional disciplinary action, including losing their licence to practice. However, if you are concerned that having a national summary care record places your information at risk you may ask for information to be withheld from it.

(7) Access by police and other agencies

Police and other agencies do not and will not have direct access to any NHS data or to the new NHS database. They have to request information specifically. Public interest rules for disclosure to the police will not change when the new system is introduced and as now, disclosures will only be considered in cases of serious crime or where there are significant risks to other people. Similarly, the NHS will remain liable to comply with statutory obligations to disclose, but these are always for specific purposes agreed by Parliament, for example to protect public health. Whilst criminal access to data, such as hacking, may be impossible to prevent entirely, the safeguards we are putting in place around the new systems will make them far more secure than existing NHS systems. If you remain concerned about the risks, you can choose to keep information out of the summary care record.

(8) Number of smart cards issued

Smartcards are secure tokens that, together with a password, confirm the identity of staff and determine access rights to information in line with the highest level of government standards. They are more secure than the normal controls over public access to internet bank accounts. They are issued only when satisfactory evidence of identity and residence is provided in person by staff eg by production of a passport and utility bill.

In respect of the clinical record, possession of a smart card does not provide staff with uncontrolled access to records. Patient information is safeguarded by four levels of control. The smartcard is itself the first control. The second control is that access is limited to specific roles that are assigned (role-based access), which limit the information that can be seen by NHS workers depending on what they need to know to deal with you. Staff will be able to access only information that is relevant to their role within the healthcare team, so a receptionist will see information about your appointment, but would not be able to look at your detailed clinical records. The third control is that the system will not permit anyone to access your summary record unless they are registered within the system as working in a team that is providing you with care or are checking the quality of care provided – a new and very powerful safeguard that is referred to as a legitimate relationship. The fourth control is provided by staff who oversee compliance with security processes. A record is kept within the system of who has done what. If required, it is possible to check if an irregularity is suspected.

I believe these safeguards are extremely strong but if you remain concerned your summary record can be flagged so that no staff can see it without your permission or you can talk to your GP about what information it should contain.

(9) Withholding of appropriate medical care to objectors

It is not true that the Department threatens to withhold appropriate medical care to objectors. Entitlement to NHS care will be unaffected. But the NHS does need to operate on an efficient basis and deliver the maximum benefits to the maximum number of patients. Using scarce NHS resources to provide care that relies upon antiquated systems and processes and which is consequently less safe as well as more costly, is neither economically sustainable nor something that doctors and nurses should be asked to do.

Whilst the current modernisation programme is unprecedented in scale, it builds upon previous changes that demonstrate clearly the advantages of modern and efficient equipment. The vast majority of pathology tests have been reported upon electronically for a number of years, dramatically improving the delivery of test results. Electronic prescriptions are eliminating the real dangers caused by handwriting that is hard to decipher. Many older imaging and scanning machines have already been replaced and with good reason. A recent study showed many hospitals reporting that 20% of X-ray films were missing when required. Some patients have to be x-rayed twice – an avoidable risk to patients that the new systems eliminate. We are replacing older machines with new digital imaging equipment as swiftly as we can.

You are of course entitled to refuse treatment where you are concerned about the consequences, whether these relate to a type of surgery, a particular medicine or the record keeping that is required. But the care will always be there for you when you need it, subject to your choosing to take advantage. If you object to having your scans and x-

rays held digitally in the new systems, it will be increasingly difficult to perform these tests as outdated machines are decommissioned and replaced. The controls we have introduced, which allow you to withhold personal information from the summary record or to prevent access to the record without your permission, give you control over the information held within the system without having to forego the benefits of modern healthcare.

(10) Design of the Spine

While a few doctors have said that the Spine could have been designed in a different way, the majority – including some of the most senior and respected doctors in the country - are supportive and believe that it will improve the delivery of healthcare to patients. On 16 November 2006 Mr James Johnson, Chairman of the British Medical Association wrote to all doctors urging them to become fully aware of the new systems so that they can inform their patients about the changes, the benefits they bring and the choices that will be available. Joined up and accessible records are necessary to provide joined up and accessible care and the Government believes that it is unacceptable to prevent citizens from taking advantage of the available technology to improve diagnosis, care and treatment of illness.