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Care Records Development Board
Ethics Advisory Group

Ethical issues of consent to recording and disclosure
of health records

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Purpose

This paper sets out the views of the CRDB Ethics Advisory Group regarding ethical dimensions of citizens' rights to control the recording or disclosure of their healthcare records through the National Care Record Service.

In particular, EAG was requested by CRDB to provide a report that:

1. Describes the rationale that others have laid out for favouring an 'opt-out' rather than an 'opt-in' approach to recording and sharing of citizens' information about their health and health care;
2. Tests the arguments against the Ethical Principles which have been established for the development and use of the NHS Care Record; and
3. Provides an 'ethical audit trail' which will be a transparent way of identifying what decisions have been taken and why.

In addressing these issues, it became evident to the EAG that it would be helpful to lay out what will remain the same, and what will differ once NCRS components are fully operational.

The distinction is drawn between the control over recording of information in an electronic healthcare record and control over subsequent disclosure to others (sharing).

Throughout its considerations the EAG related its observations to the Ethical Principles¹ and, where relevant, the pertinent Principles are referred to in this paper.

What does not change

It is important to recognise that the design of NCRS and associated information systems is intended to meet the aspirations set out in the NHS Plan and to support current and foreseeable models of health care delivery. Much of healthcare will continue substantially unchanged and many of the rights and duties of citizens and health care professionals will be unaffected. With particular relevance to this paper are the following:

- the multi-disciplinary, multi-professional, cross-organisational nature of modern health care delivery;
- the importance of health records as a document of care, in coordinating service delivery, communicating intentions, informing management of the NHS, contributing to service improvement and other purposes;
- the duty of a health care professional to make complete and accurate records of their activities and to ensure effective communication of their intentions and expectations;

¹ The principles are described in the paper entitled 'CRDB Ethics Advisory Group Ethical Principles version 1.0' as approved by the CRDB in November 2004.

- the duty of the Secretary of State to ensure that a national health service is provided to the whole population of England;
- the right of the individual to gain access to records about them (or their children) under the provisions of the Data Protection Act; but
- the absence of any legal right of an individual to stipulate what will and will not be recorded by health care professionals in their healthcare records, nor where those records will be held.

Current practice on how health records are created and used varies across England. There are communities in which electronic records are integrated across primary, community and secondary care organisations and shared on a need to know basis. In contrast there are other parts of the country where each organisation maintains its own sets of health records, still based on paper and not always available when required.

The NHS is committed to a direction of travel in which healthcare records are made available to whoever needs them to deliver care in the right place at the right time. There are issues of trust and confidence in the safeguards and accountability surrounding NCRS. However, such services are already working in practice in some parts of the country with apparent success. Some work does remain to be undertaken to find the best solutions and efforts should be made to draw lessons from these pioneering communities.

What will change

NCRS will introduce new facilities intended to improve patient autonomy and the effectiveness of service delivery centred on patient needs. The aim is that these should result in:

- data being reliably available at the point of care;
- data also being available in more than one place at the same time;
- a more complete view of the record being available to those to whom a patient is referred than at present, which should reduce the need to repeat the same questions at each stage of a patient journey;
- controls being provided to restrict which parts of a record may be seen according to the NCRS user's role;
- controls being provided to restrict whose records may be seen according to the relationship between the NCRS user and patients;
- the ability for citizens to directly access and contribute to their own records;
- citizens will be able to conceal specific items of the record from general view (using the so called 'sealed envelope');
- a record being made of every occasion that the record has been accessed and of every change made to the record – this 'audit trail' will be made available to patients upon request; and

- system functions that will automatically alert key personnel of suspicious activity that might involve misuse of confidential data.

The means of achieving these potential benefits introduce risks that have raised concerns, particularly with regard to the more widespread availability of the records and the robustness of controls limiting what any user can see in a healthcare record. There is a risk of loss of public trust and that bad clinical practices (such as keeping certain aspects of a person's care on paper records) might be encouraged if confidence is not built concerning these issues.

The widespread availability of the electronic record will be accepted by public and health professionals only if the controls over who has access are sufficiently precise and robust to prevent unnecessary disclosure, but sufficiently specified so that all the necessary information is available to enable the health professional to exercise their duty of care. Some potential consequences of failing to provide adequate controls include:

- patients and clinicians choosing to resort to keeping paper records of particularly sensitive information;
- clinicians preferring not to record certain sensitive data in the electronic record for fear of causing distress to the patient; or
- the erosion of public trust in the confidentiality of the patient-clinician relationship thereby undermining the basis of the health service.

Citizens' rights of control over their health record

Data Protection Act

Everyone with a health record has rights under the Data Protection Act 1998. These include:

- to expect their records to be held and used securely and fairly.
- to see what is recorded about them in their records (subject to specific exclusions);
- to request that *factual* inaccuracies are corrected (medical opinion is not fact) or that their views on the accuracy of content are recorded; and
- to request the cessation of processing should they have experienced, or might in the future experience substantial damage or distress.

There is currently no clear definition of what constitutes 'substantial damage or distress' nor is there an agreed measure of the likelihood of harm arising from continued processing.

The EAG recommends that the NPfIT works with the Information Commissioner to:

- **determine what is meant by substantial damage or distress;**

- **identify appropriate measures of the likelihood of harm arising; and**
- **investigate further safeguards for addressing their source of distress without the need to cease use of electronic records.**

Recording and disclosure

When considering the ethical dimensions of citizens' control over their records, it is helpful to distinguish the *recording* of healthcare data and its subsequent *disclosure* to others (*sharing*).

Control over recording

There are three main aspects of control over recording:

- a) whether a record should be made at all;
- b) whether selective parts of their care should not be recorded; and
- c) the circumstances in which existing data should be amended or deleted.

Not having a record on NCRS

Reliance is increasingly being placed upon electronic systems to deliver healthcare, such as electronic booking of appointments, digital imaging technologies and processing of samples within a clinical laboratory. The seamless integration of all NHS clinical and administrative activities through application of NCRS functionality is a major perceived benefit of NPfIT and a goal of the NHS Plan.

The consequences for a patient who refuses to allow any records to be held on NCRS could include: impeding the coordination of their care; compromising their safety by lack of decision support provided through NCRS; and being asked to repeat the same information as they move through their care journey. Furthermore, the duty of a health care professional to maintain adequate records and to ensure effective communication of intentions for the patient will be seriously compromised.

There is a further mechanism to protect patients who might be at risk of substantial damage or distress: it is possible for a 'stop note' to be placed upon their entry in the Patient Demographic Service (PDS) that will prevent any identifiable records made against that identity from being retrieved, unless complete demographic information about the patient is already known by the User. The patient can also be provided with a new registration on PDS, including a new NHS number, in effect providing a new identity. This mechanism is intended for those requiring an alias, for example as protection against a violent partner, and others who have a special confidentiality requirement. This mechanism might offer a further safeguard for addressing people's source of distress without the need to cease use of electronic records.

The EAG recommends that people should not be offered the choice to opt out of recording their healthcare data on NCRS.

Omission of specific items from the record

The consequences of refusing to allow the recording of specific items in the NCRS healthcare record might be less than when none of the data are recorded. The practice

of keeping very confidential information separate from the case notes 'in a bottom drawer' has been common practice in the past but the professional organisations do not condone such practices and partial omission is discouraged because it can lead to flawed decisions based on incomplete information.

The consequence of omitting specific items of data from the healthcare record will depend upon the type of data, its context and the potential impact on the patient, the healthcare professional and the wider health service.

It is acknowledged that there is a potential risk that patients may not disclose information pertinent to their care but that they do not wish recorded and that this might undermine the confidential patient-clinician relationship. However, this must be balanced against the duty of a health care professional to make clear, accurate and contemporaneous records.

The EAG recommends that any decision not to record new specific items of data in the healthcare record rests with the health care professional, who has an ethical duty to record but who should, in discussion with the patient, take due account of the potential impact on patient, healthcare professional, the health service and society. Furthermore, it is recommended that the incidence of this is researched and the implications of the findings considered by the professional regulatory bodies.

Circumstances in which existing data should be amended or deleted

There is a right under the DPA that, if a claim of substantial damage or distress be upheld, records must be deleted and/or processing terminated. A further right to have factual inaccuracies corrected is also relevant as there is currently no way in which a patient can have a recorded medical opinion amended or removed, with claims of damage or distress being rejected on the grounds that a complete record of medical opinion is a professional obligation.

The EAG recommends that a process be developed, including professional regulatory representation, to determine whether or not current or likely damage or distress warrants the cessation of processing or the amendment or deletion of parts of a record.

Ethical dimensions of recording

Health care professionals have a duty to record their actions. The General Medical Council, in its publication 'Good Medical Practice', states:

"In providing care, you must... keep clear, accurate and contemporaneous patient records which report the relevant clinical findings, decisions made, the information given to patients, and any drugs or other treatment prescribed."

The citizen has no legal right to stipulate what will and will not be recorded by health care professionals in their healthcare records, nor where those records will be held.

Whilst the right to refuse recording might put the interest of patients first, and supports patient choice, the patient will be faced with a tension between the desire for confidentiality and the expectation of receiving high quality care.

It can be argued that the person who refuses the recording of data may be limiting their own personal autonomy should they subsequently decide to participate in the electronic recording. There would be a gap in their record that would otherwise have been available. Conversely, dissenting to disclosure whilst allowing data recording (the current proposal for NCRS opt-out) arguably maintains a person's autonomy since there will be a complete record in existence, should the person change their view about disclosure in the future.

Other consequences of failing to record data owing to a person's refusal include:

- that a health care professional who is prevented from recording and communicating their actions is placed in an ethical dilemma and might find it difficult or impossible to provide the appropriate care to that patient;
- it would be difficult to ensure that the right information was available to the right people at the right time; and
- that public safety may be compromised if notifiable diseases or other key information is not recorded or processed electronically.

Members of the public have a responsibility towards, and an interest in maintaining, the social fabric in which they live. People using the NHS should understand that their records make an important contribution to the information underpinning the health service. Should consent to recording be withheld by a significant number of citizens, say 1% of the population, the credibility and accuracy of information derived from anonymous aggregation of records would be compromised. This might jeopardise the management and efficiency of health services.

EAG recognises the legitimacy of people's concerns but it believes that many of the reservations that lead to objections can be met by using the sealed envelope. The broader benefits of NCRS are thought sufficient to require those with reservations but who cannot show substantial distress or damage to use that mechanism rather than refuse to have information recorded. Experience would suggest that the majority of patients would withdraw their demand not to have any data recorded about them once the consequences on delivery of healthcare are explained.

That the provision of 'sealed envelopes' is not planned to be made available from the outset of NCRS implementation is a cause for concern within EAG since many of the recommendations and controls are contingent on their use.

Security of distributed record keeping

Suggestions have been made that some data should be recorded only at a local level, for example within the originating organisation. However, if it can be demonstrated that the same degree of security and confidentiality can be assured wherever health records are recorded, there are few arguments for insisting on recording only at a local level as a means of maintaining the security of the data. [There may be issues of performance and resilience of wide area networks but these are not considered here.] The EAG believes that concerns over local storage of data are more appropriately considered under the section on disclosure, since the perceived risks are more to do with the strength of protection of records afforded in remote services than to their

physical location. Indeed, it is already practice in some communities for GP records to be stored in a computer facility remote from the premises.

Control over disclosure

The potential benefits of maintaining a record that pools the data entered by the various healthcare professionals engaged in care for a patient include:

- a shared understanding of the care provided and planned for a patient;
- reduction in the need to repeatedly ask the patient for the same information;
- improved decision making based upon available clinical records, including the use of decision support software;
- improved patient safety, for example by avoiding inappropriate prescribing;
- improved efficiency, for example by avoiding duplication of investigations; and
- the facility to better coordinate the planning and delivery of care, particularly across organisational boundaries.

A prerequisite (but not the only one) for these benefits to be realised is ensuring that all the healthcare professionals (and other stakeholders) engaged in care for the patient are granted access to the parts of the pooled record that they need to fulfil their duty of care.

People's concerns include:

- whether health care professionals might see more than they need (for example a hospital doctor being able to see a record of marital or sexual difficulties disclosed in confidence to their GP);
- whether non- NHS personnel who are involved in their care might have access to their records (for example social workers);
- whether their records might be used for purposes other than provision of health care; or
- suspicion of government motives in creating a national database.

Mechanisms are being provided (principally legitimate relationships, role-based access control, 'sealed envelopes' and robust physical security measures²) that are intended to offer a high degree of control over disclosure of healthcare records. Once all the controls are in place people will be able to specify parts of their record that they wish concealed (by use of the 'sealed envelope'). However, there are two issues here. The first is how responsive the 'sealed envelope' provision will be for specific

² A glossary of terms is available on the NPfIT website: <http://www.npfit.nhs.uk>

instances of sharing. And, until that facility is fully provided (in Phase 2 release 2 of implementation of NPfIT) the only control people may exercise over disclosure of their records will be to dissent from sharing, through NCRS, of their records for the purposes of direct patient care.

The latter control, namely dissenting from sharing, is a very blunt instrument that will prevent health care professionals in one organisation from seeing any of the healthcare records contributed by other organisations, unless those records are conveyed in a separate clinical communication (such as a referral). This in effect continues the current fragmented situation across most of the country, where no pooled records are in operation and access is therefore generally limited to those within the same organisation.

Sharing of records will in general be controlled by creation of a 'legitimate relationship' between the patient and the 'workgroup' (i.e. a team of health care staff providing care) and by ensuring that staff who need access to the patient's record are assigned to that workgroup. The management of this process will be critical to the maintenance of confidentiality.

The EAG recommends that the accountability, standards and processes associated with creation of legitimate relationships and workgroups are clearly defined. Only then can individuals be held accountable for maintaining the confidentiality of the shared records.

The creation of a new legitimate relationship (for example during the process of referral) would appear to be the most appropriate occasion on which to discuss with the patient the need for data sharing and whether any items in the record should be withheld through being put into a 'sealed envelope' (once available).

The EAG recommends that, when a new legitimate relationship is due to be created, every practical effort is taken by health care staff to ensure that the patient exercises their right to choose how much of their record is shared.

However, the details of how the 'sealed envelope' will operate and how fine a level of control that a patient may have has yet to be fully defined.

Ethical dimensions of disclosure

Providing citizens with control over disclosure puts their interests first and supports informed consent and patient autonomy. It also reflects common law on health records, which provides for control over disclosure and that confidence be protected.

Concealing information might interfere with the principle of the right information being made available. For example, if a person conceals an item of clinical information, disclosure of which might have permitted a more appropriate decision to be taken by the healthcare professional, care may be compromised. On the other hand, information such as a history of recurrent mental illness might unduly (and possibly unreasonably) bias a healthcare professional and the care they offer. There is a potential tension between what a patient or service user might consider reasonable to share with a healthcare professional and what the healthcare professional might consider necessary to fulfil their duty of care to the patient.

If the mechanisms that are intended to prevent unnecessary disclosure of parts of the record (legitimate relationships, role based access and 'sealed envelopes') do not allow control to be exerted to the level of detail that patients might expect, people accessing the record through 'role-based access' might see information against the patient's wishes. There is a balance to be struck in the precision of control afforded to patients: being able to specify from which individual users a particular item of the record should be concealed might be open to inappropriate use, such as denying access to staff from a particular ethnic background. Conversely, making control too broad-brush would result in far more being concealed than the person really intended.

If people choose to opt-out from sharing, or to conceal substantial amounts of their records, appropriate care may not be possible. It might also increase the risk of harm to the individual because the benefits of shared data for decision support would be compromised.

Because a strategy of recording but controlling disclosure of identifiable data would still permit access to anonymous data for administrative and statistical purposes, the principles of availability of a sound research base, and well managed and effective services, are both fulfilled.

Should a person opt-in or opt-out from disclosure (sharing)?

Given an 'opt-out' policy to data sharing, whereby an individual must actively seek to prevent disclosure through NCRS, it is likely that the majority of the population will have records that are available across the NHS (subject to access controls), and that the principle of appropriate care being available should be supported. This principle would be less sustainable were people to expressly opt-in to sharing, since a higher proportion would likely not choose to exercise their right to opt-in.

The EAG recommends that, on balance, a policy whereby data are shared over NCRS unless the individual elects to opt-out better satisfies the Ethical Principles than a policy of requiring people to elect to opt in to sharing their data;

Scope of disclosure

Within the NHS

An important aim of NCRS is to facilitate seamless end-to-end care tailored to the needs of patients, as envisioned in the NHS Plan. All NHS staff are bound by the NHS Code of Confidentiality and record systems must be operated securely.

Role-based access control is the principal mechanism used within NCRS to constrain access to only that information in a patient's record that a user needs to know to fulfil their duty of care to that patient. It is difficult to determine in advance and with sufficient precision which items of a record a user will be able to see when assigned to a particular role. Discussions are already identifying the need for more specific tailoring of the extent of access according to individual circumstance at the time of consultation. It is not yet clear how many roles will be necessary to ensure a good match of available data to a user's needs, nor whether maintaining the mapping of role profiles will be a manageable task across the NHS. The EAG is concerned that

this may result in role-based access controls that are compromised and fail to meet patient and staff expectations for confidentiality.

The EAG recommends that it is ethically sound to share healthcare records amongst NHS employees who have a need to know to discharge their duties of care to patients, on the basis of implied consent, in compliance with strict policies and code of confidentiality, and given effective mechanisms of role-based access control and ‘opt-out’ from such sharing.

With organisations contracted to deliver care on the NHS behalf

It is assumed that organisations contracted to deliver care on behalf of the NHS will thereby acquire a right to claim legitimate relationships with the patients for whom they provide care, in order to contribute to their record. Such organisations should be bound by the same accountabilities, standards and processes for use of NCRS records as apply to staff employed by the NHS.

The EAG recommends that it is ethically sound to share healthcare records with non-NHS organisations that are legally contracted to deliver care for the NHS and who require access to healthcare records, as long as they are bound by the same duties of confidence, standards and processes as are used to govern NHS employees. However, the practicalities of sharing the NHS record with outside bodies – including ensuring system security and confidentiality, remain to be worked out.

With social services

As social and health care services become more closely integrated the distinction between health and social care records is becoming blurred. This is particularly the case with the data shared for the purposes of the Single Assessment Process, where social care data may be stored in the health record, or some health data stored in a social care record. In the case of the Single Assessment Process, it is clear that specific consent is needed from older people before their information is collected, recorded and shared. This principle of consent should feed through into provisions for explicit consent when there is a question of a person’s personal health information being shared with people working for non-NHS agencies.

With non-NHS agencies engaged in direct patient care

The need to share health records without patient consent with other agencies who are engaged in direct patient care but are doing so without formal contracts with the NHS will need to be justified. Otherwise health data should only be disclosed to them with the specific consent of the patient.

With other non-NHS agencies

It is assumed that non-NHS agencies will not have direct access to NCRS healthcare records and therefore will not be able to create a legitimate relationship in NCRS.

The EAG recommends that:

consent must be obtained from the patient prior to the disclosure or transfer of any part of their health records to non-NHS agencies (unless

there is a legal requirement or public interest justification to disclosure without consent);

only those social care staff who do not transfer confidential healthcare data to non-NHS systems may be considered a part of the NHS direct care team for the purposes of information sharing, and, as such, may have access to those parts of a health record they need to know without specific consent of the patient;

at least until issues of accountability and codes of practice are clarified, social services staff under the employment of local authorities should be considered non-NHS agents. Similarly, social care staff under the employment of the NHS but who intend to transfer data from health records to databases under local authority control should only do so with the specific consent of the patient;

accountability, standards of practice and processes for the acceptable use of health records by social care staff are defined as soon as possible.

Summary of recommendations

Data Protection Act

- R1. That NPfIT works with the Information Commissioner to:
- determine what is meant by substantial damage or distress;
 - to identify appropriate measures of the likelihood of harm arising; and
 - to investigate further safeguards for addressing their source of distress without the need to cease use of electronic records.

Recording

- R2 people should not be offered the choice to opt out of recording their healthcare data on NCRS
- R3 any decision not to record new specific items of data in the healthcare record rests with the health care professional, who has an ethical duty to record but who should, in discussion with the patient, take due account of the potential impact on patient, healthcare professional, the health service and society. Furthermore, it is recommended that the incidence of this is researched and the implications of the findings considered by the professional regulatory bodies.
- R4 a process be developed, including g professional regulatory representation, to determine whether or not current or likely damage or distress warrants the cessation of processing or the amendment or deletion of parts of a record

Disclosure

- R5 the accountability, standards and processes associated with creation of legitimate relationships and workgroups are clearly defined. Only then can individuals be held accountable for maintaining the confidentiality of the shared records.
- R6 when a new legitimate relationship is due to be created, every practical effort is taken by health care staff to ensure that the patient exercises their right to choose how much of their record is shared.
- R7 on balance, a policy whereby data are shared over NCRS unless the individual elects to opt-out better satisfies the Ethical Principles than a policy of requiring people to elect to opt in to sharing data;
- R8 it is ethically sound to share healthcare records amongst NHS employees who have a need to know to discharge their duties of care to patients, on the basis of implied consent, in compliance with strict policies and code of confidentiality, and given *effective* mechanisms of role-based access control and 'opt-out' from such sharing.
- R9 it is ethically sound to share healthcare records with non-NHS organisations that are legally contracted to deliver care for the NHS and who require access to healthcare records, as long as they are bound by the same duties of

confidence, standards and processes as are used to govern NHS employees. However, the practicalities of sharing the NHS record with outside bodies – including ensuring system security and confidentiality, remain to be worked out.

- R10 consent must be obtained from the citizen prior to the disclosure or transfer of any part of their health records to non-NHS agencies (unless there is a legal requirement or public interest justification to disclosure without consent).
- R11 only those social care staff who do not transfer confidential healthcare data to non-NHS systems may be considered a part of the NHS direct care team for the purposes of information sharing, and, as such, may have access to those parts of a health record they need to know without specific consent of the patient.
- R12 that, at least until issues of accountability and codes of practice are clarified, social services staff under the employment of local authorities should be considered non-NHS agents. Similarly, social care staff under the employment of the NHS but who intend to transfer data from health records to databases under local authority control should only do so with the specific consent of the patient.
- R13 accountability, standards of practice and processes for the acceptable use of health records by social care staff are defined by the NHS as soon as possible.