



Royal College of
General Practitioners

NHS
Connecting for Health

Informing shared clinical care

Final report of the Shared Record Professional Guidance project

June 2009

The RCGP Health Informatics Group

The Royal College of General Practitioners (RCGP) is pleased to present this "Shared Record Professional Guidance" (SRPG) report, commissioned by NHS Connecting for Health (NHS CFH). We have been fortunate to benefit from the enthusiastic involvement of professional and patient stakeholder groups in order to achieve a wide agreement on principles. The significant interest, contribution and involvement across the spectrum has been quite exceptional, and demonstrates the clear priority given to having a unified, multi-professional approach to record keeping and quality care.

There has been considerable development of multi-disciplinary care in the GP and community settings over the last ten years, and it is now crucial to maintaining and improving health, particularly for those with chronic illness, rehabilitation and palliative care needs. Developing models of information sharing and record systems to support these requirements have been patchy, and not uniformly led by common principles of clinical communication and governance. The publication of these SRPG principles, underpinned by sound research, is likely to guide and accelerate the processes of information sharing that are crucial for improving care.

We hope this report will prove immediately useful to a wide range of professional groups, and that the principles established are worthy of wider consideration throughout the NHS.. Each clinical professional group, however, holds the key to turning the principles into professional standards and practice guidance for their own discipline. Such a step will ensure that patients and clinicians can have increased confidence that future shared records will be fit for all the intended purposes, and focus on quality and safety within a clearly understood governance framework.

We look forward to the application of these principles in partnership with other clinical professions and the public, and to the continued evolution of shared electronic patient records that support better, safer care.

A handwritten signature in black ink that reads "Steve Field". The signature is written in a cursive style and is underlined with a single horizontal line.

Professor Steve Field FRCGP
Chairman of Council

Acknowledgements

The project steering group was enormously influential and supportive throughout the project lifetime and I am especially thankful for the excellent chairmanship and support provided by Dr Peter Short and Dr Manpreet Pujara, the GP National Clinical Leads for NHS Connecting For Health (NHS CFH). The makeup of the steering group provided both a challenge and an opportunity for the development of a multi-professional approach to the governance of shared patient records. I am extremely grateful to all the members of the steering group for their input, guidance and support.

Within the Royal College of General Practitioners (RCGP), I would like to express my thanks to Dr Colin Hunter (Hon. Treasurer RCGP), Mr Mike Whelan (Head of Policy and Governance RCGP) who managed the project on behalf of College, Collette Marshall (head of RCGP Clinical Innovation Research Centre) who produced the project Quick Reference Guide and those members of College Council who guided the project through its final stage. I would also like to acknowledge the contribution of Rachel Merrett at the British Medical Association, who played a key role in highlighting issues for the team to consider and in coordinating medical stakeholder engagement in the project.

The RCGP Informatics Group chaired by Dr Paul Robinson and Dr Libby Morris undertook most of the project work with important contributions by members of the Primary Health Care Specialist Group (PHCSG) of the British Computer Society. The RCGP Informatics Group and the PHCSG include health informaticians of the highest calibre and I was lucky that many of them saw this as an important project to which they could make a contribution. I would particularly like to acknowledge the contributions of Paul Robinson, Leo Fogarty, Ewan Davis and Bob Milne.

Professor Jeremy Wyatt's team at the University of Dundee deserve special thanks for tackling the enormous task that was the literature review. To have completed such a comprehensive review within the constraints of the project was a considerable achievement and an important contribution to knowledge in this field. Dr Bob Milne's team at the University of Aberdeen performed the analysis of the stakeholder survey providing important insights to inform the report.

I am also very grateful to all the stakeholder organisations for the time and effort they have spent engaging with the project and hope this report does justice to their contributions.

Dr Alan Hassey
Shared Record Professional Guidance project leader
RCGP Informatics Group

1. Introduction

The purpose of the Shared Record Professional Guidance (SRPG) project was to develop a set of professionally led guidelines that would consider the governance, medico-legal and patient safety consequences of Shared Electronic Patient Record (SEPR) systems in the primary care domain. This project was commissioned by NHS CFH.

Computerisation of health records offers the prospect of rapid sharing of data and information in ways that are not possible with paper records. The potential benefits of this, in terms of patient safety, and efficiency and flexibility of healthcare provision have been widely promoted. There is, however, disagreement about just what should be shared, and by what mechanism.

In England the National Programme for IT (NPfIT) set out to establish a single, centralised, detailed record that can be used in hospitals, primary care and other settings. This policy has been modified as a consequence of experience of early use of the Summary Care Record and deployment of Local Service Provider (LSP) solutions. Concerns about privacy and consent have been heightened by security lapses in other national IT projects. This has increased interest in other models of sharing clinical information.

In Scotland the Emergency Care Summary (ECR) shares clinical information differently. In Europe and the Americas, Kaiser Permanente, for example, shares detailed records in a decentralised way. Existing suppliers in England offer different models of sharing records: these models range from “one patient one record” (which mirrors the NHS Connecting For Health ambition) to models that rely on interoperability of dispersed systems.

Against this background the SRPG project aimed to examine record sharing in a generic way that was not related to particular systems or architectures.

We recognised from the beginning that ‘information sharing’ and ‘shared electronic patient records’ are not synonymous. The distinction between the two also comes out of our findings: the focus of this work is the shared electronic patient record.

This report is expected to provide evidence and principles that inform generic guidance for consideration and implementation by primary care and community professional groups who use existing and future shared, multi-contributory electronic record systems. Guidance should support optimal quality record keeping that is ‘fit for purpose’ meeting all the individual professional regulatory requirements. It should reflect requirements for confidentiality and data protection, promote safe effective health care, improve communication and support the ‘Next Stage Review’ quality agenda.

The SRPG project report consists of this short main report, a longer reference report and a quick reference guide for clinicians. The reference material comprises a background report in seven chapters as described below:

1. Introduction (background, context, scope)
2. Project plan
3. The national context (description of current and proposed SEPR systems)
4. Information governance (legal framework and professional guidance)
5. Shared records - the literature review
6. The clinical scenarios
7. The stakeholder survey

The reports are available online at the RCGP website:

http://www.rcgp.org.uk/get_involved/informatics_group/shared_record_professional_guidance.aspx

2. Project approach and methods

The project was undertaken by the RCGP Informatics Group on behalf of the RCGP, co-opted domain specialists and teams from the University of Dundee, led by Prof Jeremy Wyatt and the University of Aberdeen, led by Dr Bob Milne.

One of the difficult areas we faced at the start of this project was lack of clarity and agreement about semantics and definitions. The descriptions and definitions below are limited to the context of the NHS Care Record Service (NHS CRS). However, the scope of NHS CRS does not cover everything that the NHS might regard as detailed record functionality. We anticipate that these guidelines will have important implications for all models of shared electronic patient records.

For the purposes of this project, we decided that we were concerned with records of *prime entry* that were *shared* by two or more (probably many more) legal entities. It is important to differentiate this from shared records (usually summary records) created by an act of publication from the records of prime entry of one or more individual organisations.

Throughout our report we have used the term *Shared Electronic Patient Record* (SEPR) as a generic term to encompass all forms of shared electronic patient records. An organisational (or local) *Detailed Care Record* (DCR) is a record of everything that is relevant to the care of that patient known to the organisation maintaining the patient health record. A *shared DCR* (sDCR) is a subset of information derived from contributing DCRs that can be usefully shared between two or more organisations (legal entities). This may seem rather vague, but has the advantage of defining the purpose of a shared detailed care record without imposing any technical or architectural constraints on such records.

The key questions for this project to address were:

- *What are the purposes of shared detailed care records?*
- *How can these requirements be delivered safely?*
- *What are the principles and practice that ensure clarity, safety and continuity?*
- *At what level does responsibility for shared detailed care record governance lie?*

This project brief was to focus on shared electronic patient record systems in the form of current Existing System Provider (ESP) and LSP primary care IT systems and provide guidance that covered:

- The implementation of patient decisions on consent to share electronic detailed care records
- Governance of clinical records relating to clinical staff that currently have the ability, or potential, to add records (including GPs, practice, community and clerical staff)
- The work was expected to cover ownership, responsibility and governance of record elements, together with medico-legal record integrity and liability.

The first stage of the stakeholder engagement process was a formal invitation to participate in the project. During this phase, the other main strands of the project began:

- A review of current and planned shared electronic record systems in the UK (Ch. 3). This chapter includes a review of the NHS CRS, the purposes of health records and a review of shared record implementations in the UK.
- A review of professional guidance produced by the health professional regulatory bodies and representative groups that was relevant to record keeping – part of our larger information governance review (Ch. 4). This chapter includes a detailed description of the legal and professional framework within which health professionals operate and a review of consent issues in a shared record environment.
- A literature review focused on identifying and reviewing material from a wide variety of published and unpublished sources relevant to the key topics that arise in the context of changing from records held within a single primary care organisation to records held and shared across professional and organisational boundaries (Ch. 5). Nine topics were initially identified after a preliminary screen of the literature on shared records and later revised:
 - The benefits of data and record sharing
 - The rationale for and methods for preserving privacy
 - Getting and managing permission to access data in the shared electronic patient record
 - The organisation and labelling of data items in the record

- The meaning, interpretation and semantics of data across professions and organisations: data entry, coding, import and translation
- Responding to significant data in the shared electronic patient record
- Data or record quality and validity
- Record preservation and deletion
- The knowledge and training needs of professionals with respect to shared records
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We adopted the meta-narrative review approach of Greenhalgh et al, modified¹ for the limited time and resources available and the volume and heterogenous nature of the literature reviewed.

- There is uncertainty about what is meant by record sharing and thus in defining different types of shared record. We decided that looking at a small number of scenarios in detail would help to clarify matters (Ch. 6). The idea of analysing scenarios was not in the original project plan, but arose out of a feeling that another part of the project (the enquiry into models of record sharing that are currently in use in clinical systems) was being conducted in something of a vacuum.

The project steering group identified and agreed with NHS CFH a list of key stakeholders and interested parties to be consulted as part of the guidelines development process, including:

- Professional regulatory bodies
- Medical professional representative groups
- Nursing and Midwifery professional representative groups
- Allied Health Professional representative bodies
- Medical Defence Organisations
- Clinical system suppliers and users
- The Office of the Information Commissioner
- Institute of Healthcare Management
- The Primary Health Care Specialist Group of the British Computer Society
- Patient representative groups

This project is different from other projects undertaken by the RCGP Informatics Group, in that its key aim was to develop guidance that can be endorsed by all key stakeholder groups in the primary care setting. This would require multi-professional stakeholder engagement and consultation throughout the project (Ch. 2). We used the results from the systems and professional guidance review to develop a briefing pack for the stakeholder groups, to help them understand the issues and address the four key questions that the SRPG project had set out to address.

¹ Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O, Peacock R. Storylines of research in diffusion of innovation: a meta-narrative approach to systematic review. *Soc Sci Med.* 2005 Jul;61(2):417-30.

Given our resource limitations and time constraints, some important areas were deemed 'out-of-scope' for the SRPG project; notably community pharmacy, child health and protection services, care of vulnerable people, mental and sexual health services.

Key stakeholders in the primary care domain were identified with the help of the RCGP, NHS CFH and the project steering group. Stakeholder organisations contacted by the project are categorised and listed in chapter 3.4. We decided to approach a range of organisations representative of the main groups of primary health care professional groups and individual primary care health professionals from the various groups who had knowledge and experience of working with shared electronic patient record systems.

The main aim of the second phase of the stakeholder consultation process was to develop a set of professionally endorsed principles from the earlier strands of work that would help define the clinical and information governance requirements for shared DCRs. Our aim was to see if it would be possible to build a stakeholder consensus around the principles where there are high levels of agreement between the different stakeholder organisations (Ch 7).

The principles were developed from relevant guidance material produced by stakeholder professional regulatory bodies and representative organisations (Ch. 4) and presented back to the various stakeholder groups and individuals in survey format. The stakeholder survey included a description of the project aims and the stakeholder engagement process together with a set of 28 questions formulated as principles about shared electronic patient records. Respondents were asked to mark their agreement, or disagreement, with each principle statement on a five-point Likert scale from strongly disagree to strongly agree, followed by a space for comments. The survey concluded with a general question on shared electronic patient records and a further space for comments (Ch 7 and appendix A1).

Surveys were sent by email or post to key contacts identified in the first part of the stakeholder engagement process, who were asked to respond within 30 days. Non-respondents were contacted several times (email and telephone) by the project leader and a member of the project steering group representing the non-responding professional group (e.g. nurse, AHP or GP) to ensure a high response rate.

The stakeholder organisations are a heterogenous group who employed a variety of methods of responding to the survey. Some stakeholders nominated a key individual or small group to respond on their behalf while others conducted more formal surveys of their members. In view of these factors we decided to use simple statistical methods to analyse and present the survey responses to the quantitative arm of the survey and perform a thematic analysis on the comments after each question and at the end of the survey that represent the qualitative arm of the survey.

The overall response rate to the survey was very high from the full range of stakeholder groups identified by the project team (40/43 = 93%). There was a

high level of stakeholder agreement on 24 of the principle statements (see figure 8.3.c), with lower levels of agreement on principles five and nine and disagreement with principle statements 10 and 14.

The draft report was based on our analysis of the information governance review, literature review, clinical scenarios and stakeholder survey. The main purposes of the draft report were:

- To establish a shared multi-professional understanding of the issues arising from working in a shared record environment
- To develop draft guidelines to present to the stakeholders
- To invite stakeholder feedback to inform this, our final report.

3. The national context

The NHS Care Records Service (Ch. 3.1)

Over the next few years, as the NHS CRS develops, instead of having separate records in all the different places where a patient receives care, NHS organisations which normally work together in a local area, such as hospitals, clinics and GPs, will develop and begin to link and access detailed electronic records for each patient. These groupings will be determined locally, by need and technical capability. A patient who has attended NHS organisations in different areas may have more than one set of linked detailed (care) records.

The overall objective is a single detailed record for an individual patient that is accessible by the GP and by community and local hospital care settings.

Shared electronic patient record systems can be classified as follows:

- A read-only shared record following an act of publication (e.g. the SCR in England and the ECS in Scotland)
- A read-only system giving access to an external electronic health record system (e.g. EMIS Web and Graphnet)
- Read and write access to a single logical record - or separate records (e.g. TPP SystemOne)
- A shared record dependent on messaging (e.g. pathology request and report)

Shared record implementations in the UK (Ch. 3.3)

This section reviews shared record systems currently deployed or planned in the UK, which involve the sharing of records beyond the boundary of a single legal entity.

- England
 - The Summary Care Records (SCR) – partially implemented
 - Graphnet's Shared Care Record – implemented. This technology draws together data from existing systems to provide a shared view and can also include additional components to fill the gaps between existing systems

- EMIS/Vision/Adastr consortium – implemented. This consists of a set of views to the source records mediated through EMIS Web
- The North, Midlands and East (NME) Programme for IT plan to provide a single shared record based on iSoft's Lorenzo product. In addition the NME Programme for IT have implemented TPP's SystemOne product on a significant scale
- Scotland
 - The Emergency Care Summary – implemented
 - Tayside Shared Record
- Wales
 - CSW
 - Graphnet
- London
 - Acute care – Cerner Millennium
 - General practice – INPS Vision and possibly EMIS
 - Community care – CSE Servalec Rio
 - Mental health – CSE Servalec Rio
 - The London Shared Patient Record. This provides a store of documents created by care settings applications, which can be retrieved by those with an appropriate role and a legitimate relationship with the patient

4. Discussion and recommendations

Some of these principles are more easily met by some forms of shared electronic patient record systems than by others. Those relating to patient sharing decisions, record governance, system design and responsibility are all potentially problematic for any system which offers read and write access to a single shared electronic patient record. Consideration needs to be given to how such systems can meet these principles.

Shared electronic patient record systems that give read-only access to external electronic health record systems avoid some of these difficulties. Questions of semantics, attribution of an item and differences of opinion are less problematic because the information is viewed in the context of the original record. Governance issues are also much clearer when authorship of record items is explicit in this way.

Patients and health professionals are generally less happy about the use of implied consent on SEPR/sDCR systems than in shared organisational records. These views were very clearly expressed in the survey particularly by patient groups and it is essential that patients can trust their health professionals and the information systems they rely on to support clinical care.

4.1. What are the purposes of shared detailed care records?

The purposes of clinical records are examined in detail in the reference report (Ch. 3.2.1) and can be summarised as:

- Clinical purposes (to facilitate the care of individual patients)
- Assist in the clinical care of populations (e.g. health needs assessment, screening programmes)
- Non-clinical purposes (e.g. audit, commissioning, medico-legal and research)

The objective for the NHS CRS is a single record for an individual patient that is accessible by the GP and by community and local hospital care settings. So the vision for the NHS CRS is of a patient-centred secure electronic patient record, linked and accessible across (health) organisational boundaries, with patients able to make choices about sharing some or all of the content of their detailed (care) records with health professionals involved in their care.

The literature review (Ch. 5.4.1) found that the main health benefits of **shared records** are probably improvements in the quality and safety of care, in access to care or in cost effectiveness. However, these anticipated improvements in efficiency, safety, equity and cost-effectiveness of care have not been realised in the few rigorous studies on a large scale anywhere in the world.

The evidence base for the development and deployment of SEPR/sDCR systems is weak. Therefore we feel that systems deployment should be accompanied by rigorous evaluation.

Principle 1.

The success of SEPR/sDCR programmes should be measured alongside the operational characteristics of these programmes allowing evaluation of such systems in a wider context.

In the case of shared records, any evaluation should focus on the extent to which shared records improve the process and outcomes of care. The literature review (Ch. 5.4.1) recommended that measures of success probably need to include:

- The amount of data sharing between professionals / organisations for treatment of patients
- Patient opinion about the benefits of data sharing
- The benefits of sharing data with patients or patient consent about sharing

The clinical scenarios (Ch. 6) demonstrated that clinical communication between health professionals is likely to be central to the purpose of SEPRs/sEHRs, to inform and shape the practice of colleagues which requires an understanding of each other's roles and ways of working, and a means of communication that accommodates the different semantic frameworks of

different professional groups. The clinical scenarios also highlighted that patients and health professionals all wanted different things from a SEPR/sDCR including, a confidential record of treatment, a health and social record and a patient resource to be shared with an informal support network.

The key messages to emerge from this phase of the project were:

- While the sharing of records may facilitate communication, it is not an alternative to a purposeful dialogue between health care professionals and patients
- Shared records should facilitate communication and coordination between different professionals in different organisations
- In the shared care and shared record environment each practitioner has a responsibility to inform the practice of others involved in the care of the patient

The stakeholder survey showed high levels of agreement across all respondents that appropriate information sharing is essential to the safe, effective provision of care (Ch. 7).

The English SCR and Scottish ECS already contain much of the information that respondents in the stakeholder survey (Ch. 7.4.29) listed as their priorities for the clinical content of a shared record (e.g. medication items, allergies, adverse reactions and patient identifiers). Over time, the content of the SCR and ECS is likely to become richer to include many of the specific data items requested by survey respondents. Therefore, it may well be the case that in many situations, shared access to a national summary record will provide sufficient shared health information to meet the clinical needs of primary and community care health professionals.

4.2. How can these requirements be delivered safely?

Good clinical and information governance practice is essential for the safe use of SEPR/sDCR systems. Health organisations and health professionals need to be familiar with relevant legislation, common law, acceptable ethical practice and relevant Department of Health (DH) policy and standards. Professional regulatory bodies and representative organisations produce useful guidance for their members but there are areas where guidance is unclear or incomplete and will require interpretation (Ch 4).

Principle 2.

Joint guidance on record sharing should be produced and maintained collaboratively by professional regulatory bodies and representative organisations to ensure a multi-professional approach to record quality, consistency and clarity.

The guidance from professional regulatory and representative bodies clearly supports the sharing of appropriate health information between health professionals for the process of clinical care and audit. However, there is also a consistent emphasis on obtaining appropriate consent and informing

patients how their health data may be used. This was strongly supported in the stakeholder survey (Ch. 7)

SEPR/sDCR systems need to be designed so that the clinical responsibility for each aspect of current care is clear. This might be done by identifying responsibility against items in a problem list or care plan. Mechanisms need to be provided which enable the transfer of such responsibility and these may differ between transfers within a health organisation and transfers between health organisations.

Principle 3.

A community using a SEPR/sDCR system should establish governance rules and processes that ensure the clear allocation of responsibility and define the rules and mechanisms for its transfer. The rules need to be clear on who has responsibility for content and for action based on the record content within and between organisations.

These issues may be addressed by:

- Transfers of responsibility should not be effective until accepted by the individual or organisation to which responsibility is being transferred
- Another appropriate individual or organisation may be able to assume responsibility without consulting the current responsible entity although the system should notify the latter of such transfers
- Systems should support shared responsibility to support shared care
- The individual or organisation initiating a test or investigation should be responsible for ensuring that results are acted on appropriately.

Principle 4.

SEPR/sDCR systems should be designed to support the governance principles outlined in Principle 3 (above).

Medication creates special issues and we suggest the following:

- Anyone responsible for any aspect of a patient's medication should consider the entirety of the patient's medication in relation to any changes they make to the medication for which they are responsible. Where they are not satisfied of their competence to do so (e.g. when others are prescribing medications with which they are not familiar and for conditions with which they are unfamiliar or for which they have no responsibility), they should seek appropriate advice
- The responsible prescriber for each item of medication should be clear in the record and mechanisms should exist to allow another competent prescriber to assume responsibility for any or all, current medications in defined circumstances (i.e. a hospital doctor might take over responsibility for a patient's medication during an inpatient spell). When one prescriber takes over responsibility this should conform to locally agreed governance rules and the system should inform the original prescriber of the change in responsibility

- The system should enable a current prescriber to request that another takes over responsibility for ongoing prescribing of that item, but the transfer should only be effective when it is accepted by the new prescriber (e.g. a hospital doctor might ask a GP or other prescriber to take ongoing responsibility for medication on discharge from hospital inpatient or outpatient care. A GP may take over completely – agreeing with the treatment – prescribe with a shared care protocol where roles and responsibilities are governed by the protocol – or refuse completely)
- Changes to medication should be made by the currently responsible prescriber or their current deputy or locum. Where this is not possible, a new prescriber should take responsibility and then make changes as the new responsible prescriber. Systems should support bulk transfer of responsibility to a prescriber's successor in role in relevant circumstances
- The requirements on Non-Medical Prescribers (NMP) are slightly different and it is important to understand that NMPs are only accountable for prescribing within their own areas of competence. It is essential that all prescribers work together to ensure safe and effective clinical practice and medicines management.

These issues are also examined in detail in the literature review (Ch. 5). There are several striking similarities between the findings of the literature review and the clinical scenarios; for example, one key issue to be addressed is how to develop and support professional responsibility for responding to abnormal data and take appropriate action when new clinically important data is added to the record (Ch. 5 and 6). The importance of addressing this issue is reinforced by the stakeholder survey responses (Ch. 7).

Maintaining good quality records that are complete, accurate and up-to-date requires significant effort both in their creation and ongoing maintenance. Those using records need education and training to understand the value in making this effort and to equip them with the skills to do so. The key issues identified from the literature review (Ch. 5.10) were:

- Deciding on access rights for data entry by different health professionals without compromising the quality of data
- Defining an acceptable standard of data quality within and across professions and organisations
- The role of audit trails to help ensure the quality of data in shared records
- The shared responsibility of the different organisations concerned to ensure the quality of data in a shared record
- Minimising system level errors in electronic shared record e.g. prevention of data loss during transmission from one organisation to another, ensuring that different systems are able to match and maintain the patient's identity

Principle 5.

Health professionals have an individual responsibility for maintaining and assuring data quality in SEPR/sDCR systems.

One absolutely central dimension to clinical safety is the education and training needs of health service staff. To maintain the quality of data in a shared electronic patient record it is important to ensure that all users of that record have sufficient knowledge and training in the use of the system. Patient data can then be interpreted and used by other healthcare professionals. In a shared DCR, the issues of terminology, coding and data organisation are more complicated than with a single-organisation record, and training needs are more complex (Ch 5.12).

Principle 6.

Health professionals should be properly educated and trained to meet their legal, ethical and professional responsibilities for using and managing SEPR/sDCR systems. This should form part of their ongoing professional development.

Various factors influence the ability of a healthcare professional to input, edit and interpret the data in a shared electronic record and these are discussed in the literature review (Ch. 5).

4.3. What are the principles and practice that ensure clarity, safety and continuity?

We have already highlighted the importance of dealing with issues of data in terms of responsibility for content, action and data quality. Other areas that must be addressed for SEPR/sDCR systems include:

- Semantics – clinical safe communication demands that meaning is preserved. This requires the transfer of more than just coded data and must be sensitive to issues of language, interpretation and context. These issues are discussed in the clinical scenarios (Ch. 6.3.6). The three key issues identified from the literature review (Ch. 5.8.1) under this heading are:
 - Differences in the meaning of data items across clinical settings and professions and how they can be overcome
 - The choice and use of clinical coding systems and terminologies, and problems that can arise from them
 - The development and use of an *ontology* (a model of the concepts in a domain and their relationships – in this case the domain is patient data items) to support safe mapping of data items from one coding system and record to another

Principle 7.

Semantic issues should be considered in the design and implementation of SEPR/sDCR systems so that meaning is preserved and must be sensitive to issues of language, interpretation and context.

- Errors - it is essential that there are governance arrangements in place to deal with errors and differences of opinion in records. Shared DCR systems must provide the tools to support these governance arrangements. There are three possible scenarios:
 1. An error is identified which is acknowledged by the originator or their successor
 2. An error is identified which the originator will not acknowledge, but in relation to which a factual determination is possible
 3. A difference of opinion exists on which agreement cannot be reached and in relation to which it would not be reasonable to impose third party resolution.

In the first two scenarios correction is relatively simple, the record needs to be amended so that future use is based on the corrected state. In the third scenario, it is probable that both parties will wish future actions within their locus of control to reflect the state of the record as they see it. Systems need to be able to handle this dissonance.

Principle 8.

Governance arrangements should be in place to deal with errors and differences of opinion in SEPR/sDCR systems.

Generally speaking, we believe it is desirable for errors in the SEPR to be corrected by the originator but where they are unable to do so (e.g. lapsed legitimate relationship) then it should be possible for others to make amendments. Systems need to be able to clearly mark errors as such, point to corrected information and ensure future processing is based solely on the corrected data. The original entry is retained in the audit trail but "processing" involves only the updated/corrected record. The audit trail should be easily accessible so that users can understand how others may have acted on erroneous data they believed to be correct at that time. It is essential that errors in electronic patient records are removed to ensure correct processing of the data in the record (e.g. for decision support and QoF purposes).

Principle 9.

Organisations should have the facility to update/correct erroneous information added to their DCRs from other sources, (with the original information retained in the audit trail).

- Provenance – provenance data needs to unambiguously identify the originator or editor of an entry in the sDCR. In a shared electronic health record where the users are unlikely to know each other, it is important that provenance data includes the name, role and status of the author and the context in which it was recorded.

Principle 10.

Content and provenance data should identify unambiguously the originator or editor of each entry in the SEPR/sDCR.

- Relevance - the range of users of a shared electronic health record will be greater than that in a single organisation and systems will need to store and present information in styles that meet the users' needs.
- Workflow - sharing access to records does not replace the need for structured communications between users of that record or the organisation's duty to act on information it has originated (Ch. 6).

Principle 11.

SEPR/sDCR systems should be able to store and present information in styles that meet the particular user's needs.

The literature review identified the following key issues in terms of the organisation and labelling of data items in shared records (Ch. 5.7):

- Risk of a health professional missing data items in the record if the organisation of the record is unfamiliar, or is designed for a different professional group
- Risk of a health professional misinterpreting a data item in a shared record because it is labelled differently from how it would be labelled in a profession-specific record
- Significant issues about the transfer of "meaning" between different clinical settings. The context (narrative) is vitally important in clinical communications and the transfer of coded data alone is neither sufficient nor safe.

Issues around what should be recorded in the sDCR are highlighted in the clinical scenarios (Ch. 6) and arise from uncertainty about who might read the record in future, how it might be interpreted and what the patient might wish. The conclusions from this section of the report are central to our overall findings.

1. Consideration of scenarios based on individual cases with multiple carers has led us to focus on inter-professional communication.
2. Information transfer on its own is not the same as communication, which is much richer. Acts of communication carry expectations and take account of context and the semantic frameworks of others.
3. Accurate recording of data is not sufficient to support shared care of a patient. There is a responsibility on every clinician to inform the practice of other professionals who may be involved, and to inform the patient too.
4. Ways of working and information systems need to be organised in parallel to facilitate effective shared care.
5. In the complex shared care described in these scenarios contemporary communication between the professionals involved is more pertinent to patient care than historical archives of information.
6. The primary care record, like the psychological record, contains items that are social rather than medical. Their inclusion in a shared health record requires consideration.

Principle 12.

SEPR/sDCR systems should improve the quality and safety of care by facilitating communication and coordination between health professionals and informing best clinical practice.

Principle 13.

SEPR/sDCR systems should support structured communications between users (e.g. referrals).

“Human communication is fundamental to the process of informing and cannot be substituted by a combination of computer algorithm and data bucket” (SRPG project meeting, Edinburgh, Jan 2009)

4.4. At what level does responsibility for shared electronic patient record/detailed care record governance lie?

Patients and health professionals may struggle to comprehend the “what” and “who” of data sharing, depending on the specific SEPR/sDCR implementation in their locality. To date there is no consistent approach to consent issues in current implementations (Ch. 3). However, professional guidance consistently emphasises the need to obtain appropriate consent and inform patients how their health data may be used (Ch. 4). This is all the more important because there is no single point of access where patients may view their SEPR/sDCR, unlike *HealthSpace* for the SCR for example. There is as yet little patient or professional experience of SEPR/sDCR systems so professional custom and practice has not yet emerged (Ch. 4) and there remain uncertainties about the legal and ethical framework for these transactions.

Therefore, we believe it is essential to engage patients as full partners in these sharing decisions, to inform professional practice and maintain patient confidence in both health professionals and the information systems used to support the care process.

The very nature of a “shared” record complicates the issues of responsibility. However it is clear from the contents of the report so far, that responsibility for safe and effective governance of sDCR systems exists at many levels and includes:

- Government
 - To understand the business requirements of the service and commission systems that are fit for purpose. This means that systems must be able to support patient sharing decisions as highlighted in the stakeholder survey (Ch. 7)
 - To provide an appropriate legal framework within which good clinical practice can be established
- Clinical professions

- To ensure that professional guidance is developed and delivered to health professionals working with shared record systems and that this is reflected in professional requirements for registration, training and Continued Professional Development
- Health organisations
 - To ensure that high quality clinical and information governance practices are followed. The survey responses indicate (Ch. 7, fig 7.3c) that there would be stakeholder support for an organisational (or team) guardian responsible for that organisation's shared DCRs and organisational DCR and that healthcare organisations should have the facility to update/correct erroneous information added to their DCRs from other sources
 - To provide an appropriate education and training framework for staff
- Health professionals
 - To ensure they understand and follow best practice in relation to clinical record keeping and are aware of the particular issues and challenges presented by shared health records. The stakeholder survey demonstrated support (Ch. 7, fig 7.3c) for health professionals taking on the responsibility for informing patients how their health data might be used in a shared DCR environment and using and sharing only that information which is relevant for their care
- Patients
 - Patients are key stakeholders and should participate as full partners in these matters. They have made it clear in the stakeholder survey that they wish to participate in decisions about shared records both in terms of consent and record content (Ch. 7, fig 7.3c)

The evidence from the literature review about patient views regarding sharing of their health data suggests that the public are more willing to share their information with health professionals directly caring for them than with others who require access for secondary uses (Ch. 5.6). Many people believe that their health records are shared more widely than is the case. Most studies revealed that patients were more willing to share information with doctors over other health professionals.

Deciding what information might and might not be disclosed in a shared DCR depends fundamentally on the human relationships between patients and their health professionals. Such decisions depend on context, content and consent given (or refused - Ch. 4). The Data Protection Act and Common Law duty of confidence (Ch. 4) are particularly important in this context. Guidance from professional regulatory bodies is also clear that confidentiality is central to trust between health professionals and patients. Without assurances about confidentiality, patients may be reluctant to seek attention or give health professionals the information they need in order to provide good care. But appropriate information sharing is essential to the efficient provision of safe care, both for the individual patient and for the wider community of patients.

When people use the NHS, they expect a confidential relationship with the members of the care team they see. But it may be misleading to discuss this relationship in isolation. Patients expect that a practice or NHS Trust will take corporate responsibility for their care and to collaborate with other organisations around a care pathway that provides a package of complementary elements managed to suit the patient's individual circumstances. This might also reasonably include regulators and others responsible for detecting unsafe or ineffective practice. This creates a tension between the need to share health data for legitimate corporate reasons and preserving patient confidentiality (Ch. 3.2).

Patients do not in practice expect everything to come to a stop (until they consent) at each step when a new individual has to take part in organising a care package. Patients want seamless high quality care. There is no contradiction in recognising that they also want an effective mechanism when some particular information is especially sensitive and they have a right to object to uses that could be harmful to them.

The Data Protection Act (DPA) does make the bridge between the clinician's duty of confidentiality and the corporate duty to protect personal information, which falls on the organisation. The reconciliation of clinical confidentiality with the corporate duty comes when:

- The uses are within the reasonable expectation of the patient, given what he/she has been told about the purposes necessary for the provision of appropriate care (the "legitimate interests of the data controller" in this case), and when
- The uses do not prejudice the rights and freedoms or legitimate interests of the patient; and when
- The care record can be viewed so that particular people use the parts of it they need for their role, and the staff or others who use the information for these purposes are bound to keep it confidential.

The care team is not an entity recognised by legislation. Anyone who uses sensitive information for medical purposes has to be under a suitable duty of confidence. That is one of the conditions that apply to the corporate responsibility of a data controller using personal information relating to a person's "physical or mental health or condition".

The DPA requires that patients are informed about how and why information about them is used and who will have access to their information. It does not prevent information being used for healthcare purposes providing the principles are satisfied but may prevent health information being used for non-healthcare purposes without a patient's explicit consent. The key points are that the processing (use) of sensitive personal information has to be:

- For a legitimate purpose
- No more than is necessary for the purpose, and
- In the case of use for a medical purpose, processed by health professionals or other people under the same duty of confidence.

The proper use (and sharing) of sensitive personal information for medical purposes depends:

- First on using it to the extent necessary for the purpose, and
- Second on limiting the use to people who will keep it confidential

Interpreting the DPA in terms of SEPR systems provides useful scenarios to guide and help inform sharing discussions with the patient (below):

1. Scenario A: Use of the confidential patient record by health professionals, allied professions and support staff when the patient is clearly aware that they are members of the team providing an episode of care (and are therefore within the same boundary of confidentiality)
2. Scenario B: Use of the necessary parts of the patient record by health professionals, allied professions and support staff within the same organisation who need to know in order to deliver other elements of that episode of care (confidential use for purposes within the patient's reasonable expectations of that episode of care, but when the staff are not known to the patient, so there needs to be an explanation available to shape the patient's expectation of the uses of information required to deliver that episode of care)
3. Scenario C: Access to/sharing of specified parts of the patient record (confidential use for purposes within the patient's reasonable expectations of the care pathway, but when the staff are not known to the patient, so that there needs to be an explanation available of the uses of information necessary for that care pathway, and the arrangements to protect privacy)
4. Scenario D: Disclosure to anyone for purposes beyond the patient's reasonable expectations (normally with explicit consent) other uses of personal information when that information is normally public knowledge but some of it may be sensitive for some people, so practices and NHS bodies need to be ready to comply with the DPA as controllers of data when the subject expresses preferences or raises objections which identify that information as sensitive.

How might this be translated into guidance for good clinical practice in a shared care/shared record environment? We suggest that the Care Record Guarantee² provides a form of words that health professionals might use to inform and advise patients about sharing decisions. The extract from the Care Record Guarantee (below) is a useful starting point for these discussions.

² http://www.nigb.nhs.uk/guarantee/crs_guarantee.pdf

Everyone looking at your record, whether on paper or computer, must keep the information confidential. We will aim to share only as much information as people need to know to play their part in your healthcare. When we provide healthcare, we will share your record with the people providing care or checking its quality (unless you have asked that we limit how we share your record).

We will not share health information that identifies you for any reason other than providing your care, unless:

- ***You ask us to do so;***
- ***We ask and you give us specific permission;***
- ***We have to do this by law;***
- ***We have special permission for health or research purposes;***
or
- ***We have special permission because the public good is thought to be of greater importance than your confidentiality.***

This is entirely consistent with professional guidance which states that (Ch. 4); *“You should make sure that information is readily available to patients explaining that their personal information may be disclosed for the sake of their own care and for local clinical audit, unless they object. Patients usually understand that information about them has to be shared within the healthcare team to provide their care. But it is not always clear to patients that others who support the provision of care might also need to have access to their personal information. And patients may not be aware of disclosures to others for purposes other than their care, such as service planning or medical research. You must inform patients about disclosures for purposes they would not reasonably expect, or check that they have already received information about such disclosures.”*

Principle 14.

Health organisations should be able to explain to patients who will have access to their SEPR/sDCR and must make information available to patients about such disclosures.

Principle 15.

Health professionals should respect the wishes of those patients who object to particular information being shared with others providing care through a SEPR/sDCR system, except where disclosure is in the public interest or a legal requirement.

We recommend that health organisations review their information and clinical governance strategies to ensure best practice is followed in the deployment of SEPR/sDCR systems.

Principle 16.

There should be an organisational (or team) guardian with clinical and information governance responsibilities for that organisation's shared and organisational DCRs, in order to assure best practice is followed.

The NHS CRS that is being implemented by NHS CFH will change the pattern of data controllers across the service. The concept of locally held data will probably gradually disappear and there will be a number of data controllers sharing responsibility in common for each data subject.

Unfortunately it is not clear who the data controller is for shared electronic health records. It would seem that the data controller of each participating organisation has a role and the idea of a "data controller in common" has been proposed, where the data controllers of each participating organisation have a shared responsibility for the total contents of the shared electronic health record. It is not clear how current legislation supports this concept or how it could be organised in practice.

Requirement 1.

The Information Commissioner should be asked to clarify how the requirements for a Data Controller and other obligations under data protection legislation should be met in the context of SEPR/sDCR systems and provide policy advice on implementation in practice.

Responsibility for data preservation and deletion is another key dimension to be considered under this heading. The issues are examined in the literature review (Ch. 5.11), which concluded that there is as yet, no good evidence available to guide policy decisions on the optimal strategy for shared record preservation. This will need to be addressed alongside the data controller issue identified above.

Requirement 2.

Government should be asked to clarify issues of data and record preservation and deletion in shared patient record systems.

5. Conclusion

In producing this report, we have reviewed the background, context, current and planned implementations for SEPR/sDCRs, developed working definitions for such systems and identified and engaged with key stakeholder groups. We have outlined a governance framework within which SEPR/sDCRs should operate and drafted governance principles for such systems. We have produced the most comprehensive literature review yet on shared records to inform this report. Through the clinical scenarios, we have developed a new method for testing our understanding of the issues and challenges presented by shared electronic health records systems. We have also carried out the first multi-professional and patient stakeholder survey of attitudes to shared electronic patient records. Finally, we have described and developed governance guidelines and principles to inform and support the clinical practice of health professionals working with shared records.

This report represents the first steps in developing professional guidance about the use of SEPR/sDCR systems to support shared clinical care. The scope of this project was constrained and several important areas were excluded from our remit. It is important that these principles and guidance are tested in other shared care clinical scenarios, particularly relating to child health and protection, care of vulnerable people, mental and sexual health services and by a wider spectrum of professional users. The report acknowledges the limitation of the project remit to primary and community environments, but we 'offer' the principles outlined here as equally deserving of consideration in other, wider 'multi-contributory' electronic record environments.

We believe that appropriate information sharing is essential to the safe, effective provision of care in a modern health service and implementing the principles and guidance in this report will increase public and professional confidence in SEPR/sDCR systems.

RCGP Informatics Group (June 2009)

Appendix - SRPG project organisation

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