

Care Record Development Board

Report of the Care Record Development Board
Working Group on the Secondary Uses of
Patient Information

Amendment history

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1 Introduction

- 1.1. The Care Record Development Board [ref 1] agreed in March 2006 that a sub-group should be established to consider the issues around uses of patient-identifiable data for purposes other than direct patient care. This report presents the outcome from this Working Group.
- 1.2. As the Care Record Development Board is a body dealing with England only, the recommendations in this report are aimed at England only.
- 1.3. The issues considered concerned the implementation of recommendations from the Better Regulation Executive report "[Making a Difference: Safe and Secure Data Sharing Between Health and Adult Social Care Staff](#)" that 'a single set of guidance on the secondary uses of personal information for medical research, population health and management' should be developed [ref 2].
- 1.4. The aim and terms of reference for the Working Group were as follows:

Aim:

To advise the Care Record Development Board and through it the National Programme for IT, on how the potential for the NHS Care Records Service [ref 3] to support research, population health and management can be realised in compliance with the NHS Care Record Guarantee for England [ref 4] and the secure and ethical use of patient records.

Terms of Reference:

To consider:

- Anonymisation and pseudonymisation of data;
 - Direct communication with the public, as NHS users, on behalf of research or public health organisations;
 - Clarification of the Care Record Guarantee in relation to the use of information for management, population health and research purposes;
 - The use of patient data without consent; and
 - Obtaining for management, public health and research purposes, sensitive personal and demographic information.
- 1.5. The membership of the Working Group is in Annex A. The Group met six times between May 2006 and January 2007.

2 Background

2.1. A considerable amount of information is collected during the provision of care and treatment, some of it specific to the patient being treated some of it not. The primary purpose of this information is to support and improve individual patient care and much of it is held under professional and legal obligations of confidentiality. However, this information, often in conjunction with other administrative health records, such as existing Cancer Registries, is of value for many other purposes to support healthcare and providing appropriate steps are taken to meet confidentiality obligations, whether through consent, anonymisation or legal authorisation, this information can legitimately be used to support these other purposes (called “secondary uses”). In practice, secondary uses covers a very wide spectrum including:

- Improving the quality of local clinical care, for example through the audit of clinical practice;
- Protecting the health of the public through surveillance and immediate response to infectious disease and other environmental threats to health, monitoring adverse effects of therapeutic interventions, and informing and evaluating screening;
- Improving the management of the health system, for example by supporting the more efficient commissioning of services and payment by results;
- Identifying patients who interact with multiple parts of the health system in order to monitor equity of access and provision;
- Ensuring that health policy is evidence-based through carrying out empirical research;
- Providing better information to the general public about healthy lifestyles; and
- Improving the quality and safety of care or reducing the impact of new risks to population health through for instance :
 - Research by the patient’s clinical team;
 - Research by others using data collected by the care team but involving no contact with the team’s patients; or
 - Research which requires further contact with patients or former patients.

Figure 1 (page 6) gives examples of “secondary” activity.

2.2. There are many benefits from the use of information to support secondary uses. The health and well-being of the population are improved by activities such as disease surveillance, screening, needs assessment and preventative activities.

2.3. Research has led to major benefits in health practice such as the cure of duodenal ulcers, prevention of spina bifida, effective treatment of breast cancer, and the carrying out of hip replacements. Research has also reduced risks through a greater understanding of HIV prevention, the relationship between smoking and lung cancer and the ill effects of the use of aspirin for children. In the UK as in other countries, regulation of new medicines and other treatments relies on evidence of safety and efficacy from clinical trials. Trials and other research also provide fundamental evidence to inform guidance from the National Institute for Health and Clinical Excellence.

Figure 1: Examples of Existing Secondary Uses of Data

Checking quality of care

- Testing the safety and effectiveness of new treatments and comparing the cost-effectiveness and quality of treatments in use;
- Clinical audit activity on site;
- Supporting Healthcare Commission audit studies for Cancer, Heart Disease, Diabetes, etc;
- Comparative performance analysis across clinical networks; and
- Ensuring the needs of patients within special groups are being met e.g. Children at risk, chronically sick, frail and elderly.

Protecting the health of the general public

- Drug surveillance (pharmacovigilance) and other research-based evidence to support the regulatory functions of the Medicines and Healthcare products Regulatory Agency;
- Surveillance of disease and exposures to environmental hazards or infections and immediate response to detected threats or events;
- Vaccine safety reviews;
- Safety monitoring of devices used in healthcare;
- Linking with existing National Registries for diseases / conditions;
- Analysis of outcomes following certain health interventions [i.e. public health interventions as well as treatments];
- Monitoring the incidence of ill health and identifying associated risk factors; and
- Identifying groups of patients most at risk of a condition that could benefit from targeted treatment or other intervention.

Managing NHS spending

- Data for Payment by Results;
- Data for practice-based commissioning; and
- Data for payment of GPs through QMAS (Quality Management Analysis Service) – based around the aggregated Quality and Outcome Framework (QOF) indicators.

Managing the health service

- Capacity and demand planning;
- Commissioning;
- Data for Standards and Performance Monitoring;
- National Service Frameworks;
- Clinical indicators;
- Information to support the work of the Healthcare Commission;
- Evidence to support the work of the National Institute for Health and Clinical Excellence;
- Measuring and monitoring waiting times, in support of the 18 week target;
- Data to support Productivity Initiatives (e.g. the GMS contract and the new Consultant contract);
- Agenda for Change; and
- Benchmarking.

Investigating concerns or complaints about healthcare

Teaching healthcare workers

Supporting research

- Assessing the feasibility of specific clinical trials designed to test the safety and/or effectiveness and/or cost-effectiveness of healthcare interventions;
- Identification of potential participants in specific clinical trials, to seek their consent;
- Providing data from routine care for analysis according to epidemiological principles, to identify trends and unusual patterns indicative of more detailed research; and
- Providing specific datasets for defined approved research projects.

- 2.4. The implementation of the NHS Care Records Service provides an opportunity to build an information base across the whole population with significant potential benefits both for public health and research.
- 2.5. In December 2005, the report of the Academy of Medical Sciences on the use of data for research purposes [ref 5] identified a number of the benefits of research. It also expressed concern that overly conservative access controls might hinder research activity and hence reduce such benefits.
- 2.6. This reinforces the need to ensure that “secondary use” activities can be properly carried out in the context of the Care Record Guarantee for England and within the legal and professional obligations for ensuring confidentiality of personal information.
- 2.7. The Care Record Guarantee for England gives the commitments to people that the new system will:
- *Allow you to control whether information in electronic records made about you by the organisation providing your care can be seen elsewhere in the NHS;*
 - *Allow only those involved in your care to have access to records about you from which you can be identified, unless you give your permission or the law allows; and*
 - *Allow us to use information about your health care, to improve the services we offer or to support research, in a way that doesn't reveal your identity.*
- 2.8. It also states that information identifying an individual will not be shared (particularly with other government agencies) 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 interests of the public are thought to be of greater importance than your confidentiality.
- 2.9. In circumstances where information is shared without permission, all users are required to follow the NHS Confidentiality Code of Practice [ref 6] and other national guidelines on best practice.
- 2.10. The Patient Information Advisory Group (PIAG) [ref 7] assesses applications for the sharing of identifiable patient information in accordance with the provisions of section 60¹ of the Health and Social Care Act 2001 [ref 8]. This provides a formal framework for seeking specific or class support from the Secretary of State for Health for the use of personal data without prior consent.

¹The Health Service (Control of Patient Information) Regulations 2002, which were made under section 60 of the 2001 Health and Social Care Act, but continue to have effect under section 251 of the 2006 National Health Services Act, provide for confidential patient information to be processed without breach of the common law duty of confidence in certain circumstances where carefully constructed safeguards are in place. The regulations are referred to as s60 throughout this document as this is how they are known within the NHS and research communities.

- 2.11. Anecdotal evidence suggests that many patients are unaware of the existing possible uses of their data within the NHS other than for their direct care, e.g. for management purposes, for audit, for public health or for research.
- 2.12. There is clearly a tension between the need to use data for secondary purposes and the need to safeguard patient confidentiality in a way that builds trust and understanding.
- 2.13. The Working Group also considered the legal position in the UK and in other countries. The Academy of Medical Sciences hosted a meeting in June 2006 on the legal requirements of using patient identifiable information [ref 9]. This meeting highlighted the legal complexities around confidentiality. It was recognised that a correct and proper interpretation of one aspect of the law, might actually conflict with an equally proper interpretation of another piece of applicable legislation. This led to confusion in practice and made it difficult to address the tension between an individual's right to privacy and the use of information for the public good. Moreover, since both EU legislation and UK common law are applicable, changes to UK legislation intended to clarify matters would not in themselves lead to any significant simplification or improvement.
- 2.14. It is evident from the above that differing interpretations of the law and a lack of clear guidelines and protocols have led to inconsistency of application. One of the Working Group's remits was to address the problem of a lack of clarity and to improve communications. The Working Group acknowledges the importance of the NHS Care Record Guarantee for England and the NHS Confidentiality Code of Practice in this context and as indicated previously these need to be the standard that is applied. The Code of Practice was developed with, and endorsed by, the Information Commissioner, the General Medical Council and the British Medical Association.
- 2.15. The Code of Practice makes it clear that information provided in confidence should not be used or disclosed in a form that might identify a patient without his or her consent. There are a number of important exceptions to this rule that are particularly relevant to secondary uses of data, but it is the starting point for ethical and lawful use of confidential data and should apply in most circumstances.
- 2.16. The exceptions to the requirement for consent are limited to:
- Where statute law requires or permits the disclosure and/or use of confidential information;
 - Where the Courts order disclosure; and
 - Where the holder of confidential information believes, judged on a case by case basis, that the public good that would be achieved by disclosure outweighs both the obligation of confidentiality to the patient concerned and the broader public interest in the provision of a confidential service.

3 The Evolving Future Position

- 3.1. The previous section identified public health and research as two major areas where secondary uses of data already provide substantial benefits.
- 3.2. A recent consultation exercise co-ordinated by the Department of Health has refined the Public Health Information Strategy, 'Better information, better choices, better health: Putting information at the centre of health' [ref 10] which identifies ways in which data may be used to improve information about health and well-being, with benefits for patients and the public.
- 3.3. In January 2006, the government's health research strategy [ref 11] committed the Department of Health to ensure that the data collected via the NHS Care Records Service and supporting infrastructure meet the needs of researchers and public health practitioners because of the potential for NHS electronic patient records to confer unique benefits to the UK as a site for clinical research. Sir David Cooksey's report to the Chancellor of the Exchequer on UK Health Research Funding in December 2006, [ref 12], emphasised the potential benefits to UK economy from strategic coordination of health research, including stronger partnerships with health industries and charities, and access with safeguards to the care record for important research such as clinical trials and subsequent pharmacovigilance of newly released drugs.
- 3.4. A number of organisations currently use information which is a by-product of the health administrative systems. Nationally, the Information Centre for Health and Social Care has a responsibility for analysing information, setting standards, ensuring comparability and data quality, and producing reports and outputs. Other public bodies also publish information, including the Health Care Commission whose information focuses primarily on the purposes of benchmarking organisations' performance. The private sector also has needs for detailed health activity data: it is vital to the research of pharmaceutical companies and other suppliers of health interventions; and for the services and products produced by data intermediaries.
- 3.5. The Cooksey Report and other activities have highlighted the increased opportunities resulting from informed and responsible use of data. In the meantime, NHS Connecting for Health has been implementing mechanisms to assure patient confidentiality.
- 3.6. The specification for the NHS Care Records Service, which is being implemented as part of the National Programme for IT in the NHS, includes comprehensive coverage of security and confidentiality measures to be put in place. These address the control of users and the data to which they have access.
- 3.7. Under the Role-Based Access Control scheme [ref 13], each user is registered with a set of access rights specific to their role within an organisation. For instance, a doctor, a nurse and a receptionist will each have access to different functions. Access is implemented through a smart card and an associated Personal Identification Number (PIN). Each transaction (including read access to a record) is then logged against the individual user.
- 3.8. Such control is based on "legitimate relationships" between patients and those caring for them. A legitimate relationship is created, for instance, by a registration with a General Practice, or by a referral to a clinical team for a particular condition in a hospital.

- 3.9. Patients have the right to ask for their information not to be shared and the record of a patient's dissent prevents patient-identifiable information from being available across organisational boundaries unless it is part of a direct clinical communication such as a referral.
- 3.10. The future use of sealed envelopes will allow patients to "mask" part of their records which can then only be seen with their express permission.
- 3.11. The NHS Care Records Service is being implemented at local level through the Local Service Providers, with a national NHS Summary Care Record being created initially through an extract derived from the primary care record.
- 3.12. The Secondary Uses Service [ref 14] is designed to provide access to a range of information for purposes other than the direct care of patients.
- 3.13. For the purposes of this report, the following definitions apply:
- **Patient-identifiable information** relates to information from which patient identities may be derived because it contains identifiers such as names, NHS Numbers or post codes. In some instances, it may be necessary to provide name and address (e.g. if individual patients needed to be contacted). There are, however, circumstances when the data itself are anonymous but the dataset requested could contain information which might, exceptionally, identify an individual because of small sample size or a unique characteristic such as very rare conditions, experiences or isolated locations. It should be noted that this potential for identification can be avoided if the governance arrangements on the use of data include minimum research cell sizes. But the use of minimum research cell sizes may not always be possible, depending on the nature of the research – for example to relate the occurrence of disease to possible environmental hazards.
 - **Linked pseudonymised information**, in which specific patient identifiers are replaced by alternative (and otherwise meaningless) alphanumeric fields, and in which potential identifiers such as post code and date of birth are provided only in partial form. Linked pseudonymised records use a consistent set of keys to generate the alternative identifiers so that records relating to the same patient can be linked. These might be used, for example, to carry out a long-term study into outcomes.
This type of pseudonymous data enables quality checks and validation of data which is often a pre-requisite for high quality research.
 - **Anonymised data**, in which identifiers are removed and there is no means of re-establishing a link with the identity of the patient concerned. The data are still provided at a detailed (individual patient) level, however, with one record per transaction. These might be used, for example, for a one-off piece of research.
 - **Aggregated data**, in which no personal information is provided, but results are presented as summary tables.

4 Principles

4.1. The previous sections have introduced the background and the evolving position for the secondary uses of data. It is important to ensure that recommendations for future action are framed in the context of agreed principles.

4.2. The following principles should underpin future plans and activities:

- i. The expectation should be that data for secondary uses are provided in unidentifiable (aggregated or anonymised) form except where specific justification can be made and approvals provided. Thus the default is the use of data which cannot be linked back to individuals. Where there is a need to link data from different data sets or over time, linked pseudonymised data should be used with the key to re-establishing identity not available to the researchers/users.
- ii. Where the case is made for access to data relating to identifiable individuals the informed consent of these individuals should be obtained wherever reasonably practicable.

An individual patient has the right to determine that no identifiable information about them should be used for secondary purposes, except where statutes apply or an unequivocal argument of public interest over-rides this request. NHS IT systems need to be able to capture and act upon the stated preferences of patients.

Where an Ethics Committee or equivalent has approved that there is a need to approach patients directly, for example to participate in a particular study, this should be achieved by an approach from the GP or, by a clinician responsible for the patient's care relevant to the topic under study.

- iii. Where access to identifiable data is required, and where patient consent cannot be obtained, then there must be formal justification for access via a statutory provision. The usual route is to seek access to use this data under Section 60 of the Health and Social Care Act 2001 from the Patient Information Advisory Group (PIAG) although there may be some situations where other statutory provisions apply (see footnote on page 7). Approval from PIAG would depend upon the extent to which it had been demonstrated that the use of identifiable data would;
 - Benefit current, former or future patients in either the short or long term
 - **And** where it is not reasonably feasible to achieve these benefits through consent or the use of anonymised data.
- iv. All users of data for secondary purposes should be subject to enforceable standards regarding confidentiality and security of data.

- v. The system for secondary uses of data must be open and transparent and have the active involvement of patients and the public.
- vi. The process of determining and granting access to data should be transparent and follow principles of good communication with all parties in order to achieve the appropriate balance between individual privacy and public benefit. The involvement of patients and the public must be regarded as essential.

4.3. In the next section, these principles are developed into a set of recommendations covering:

- The management of pseudonymised, anonymised and aggregate information (principle i);
- The management of patient consent (principle ii);
- Governance arrangements for access to identifiable data (principle iii and principle vi)
- Supporting cultural and good practice issues for users (principle iv); and
- Transparency and openness (principle v).

5 Recommendations of the Working Group

5.1. Uses

- 5.1.1. Principle 4.2.i is that the expectation is that data for secondary uses should be provided in unidentifiable (aggregated or anonymised) form except where specific justification can be made and approvals provided. To implement this, it will be necessary to ensure that the data is appropriately managed and made available to users. This requires the existence of an “honest broker” and one, or a small number, of “safe havens”, which have the capabilities and are assessed suitable to manage the disclosure of information to users.
- 5.1.2. An honest broker is a trusted custodian of the data who has responsibility to implement systems of access according to the Care Record Guarantee, the web of complex legislation and in accordance with the decisions and guidance of relevant Information Governance Boards. The honest broker would have responsibility for ensuring that the pseudonymisation and anonymisation processes are correctly specified and implemented, including ensuring that information did not flow back into the patient’s medical record. This is especially important in relation to personally sensitive data including the management of anonymised information from sealed envelopes. An honest broker would also be responsible for:
- Carrying out any permitted statistical linkage of different sources of identifiable health and social care data; and
 - Carrying out data quality checks which are not possible for researchers and other data users to do themselves for reasons of confidentiality.

The role of the honest broker is dual – they must ensure the confidentiality and security of the data and ensure the scientific integrity of the data during linkages. They therefore require the absolute trust of the patient/governance community and of the potential secondary users of this data, including the research community. In turn they must exercise the same level of confidentiality, accountability and responsibility as the clinical holder of the information.

- 5.1.3. A safe haven is a designated physical or electronic area that provides the most appropriate level of security for the use of the most sensitive and confidential information. The model employed in many countries is that of the Research Data Centre [ref 15]. These offer one means of providing researchers and others with access to confidential micro data from surveys and other administrative records. Increasingly, government agencies are relying on research data centres because of growing concerns about data security and confidentiality of respondents.

[Recommendation 1] It is recommended that requirements for honest brokers and safe havens be agreed and published, together with a supporting regulatory framework.

[Recommendation 2] It is recommended that an honest broker and initial safe haven or havens be established to establish and demonstrate good practice.

The responsibility of implementing recommendations 1 and 2 could lie with the Information Centre for Health and Social Care which from September 2007 will, like all NHS bodies, have its information governance arrangements overseen by the National Information Governance Board. [ref 16]

5.1.4. Many current secondary users of health information are not accustomed to being restricted to anonymised or even pseudonymised information, particularly in the case of secondary uses by people who are also primary users with routine access to unanonymised data. It is important to ensure that valid business functions are able to continue and that users for secondary purposes are supported in understanding and observing the appropriate safeguards. Two activities are underway to address this:

- The National Programme for IT Secondary Uses Service Programme is conducting pseudonymisation pilots to assess the usability of pseudonymised information for applications such as commissioning and public health; and
- The UKCRC Research & Development Advisory Group to Connecting for Health [ref 17] which is a joint group between NHS Connecting for Health and the UK Clinical Research Collaboration has completed a set of simulator projects looking at the availability of data and implications for supporting different types of research activity.

[Recommendation 3] It is recommended that the outputs from the simulation exercises be published by the body who undertakes them, together with resulting recommendations and actions.

5.1.5. One of the reasons previously given by users for access to identifiable data is to enable linkage between different datasets and to overcome some of the difficulties of poor quality and incomplete data. The Secondary Uses Service should enable both issues to be addressed through the use of the NHS Number as a consistent identifier for data collection, and through stringent validation checks on the data being loaded. If such data in anonymised form were provided more quickly to users, applications for access to identifiable data would be reduced. Where a case is made for more specialised or detailed data quality checks, these could be conducted by the honest broker on request.

5.1.6. When a specific query results in the identification of only a small number of qualifying records, or when the combination of a large number of variables leads to small numbers in a category, it may be possible to deduce patients' identities. This issue of small numbers has been extensively researched by official statisticians across the world and good practice guidelines have been produced as to how to reduce the probability of identification in such circumstances. The UK Office of National Statistics [ref 18] has undertaken studies of relevance to this problem.

[Recommendation 4] It is recommended that the availability and nature of data in aggregate and anonymised form should be widely publicised and that its use in this form is encouraged and promoted through efficient, effective, and rapidly responsive data services, in order to develop a culture of informed and responsible data use.

[Recommendation 5] It is recommended that the Office of National Statistics proposals to reduce the risk of identification through appropriate handling of 'small numbers' (referred to in 5.1.6) be adopted for use by the NHS and kept under review.

5.2. Consent

- 5.2.1. The second principle highlights the need for patient consent. The NHS Care Record Guarantee for England has provided a clear undertaking to patients that, if they wish, they can ask that their information not to be shared with others in an identifiable form. It also includes mention of the exceptional circumstances where a patient's wishes cannot be respected, as identified at paragraph 2.16.
- 5.2.2. The group agreed the following in regard to consent. That:
- Whilst consent can be assumed for healthcare purposes where a patient has been effectively informed about what may occur, it would be wrong to assume consent for secondary purposes. Additional efforts to gain consent are required for these purposes. These can range from a targeted communications exercise to a signed consent form. The evidence from the large existing research databases such as GPRD (5% of all UK data from GPs) and that in Tayside (9% of Scottish data using record linkage of data from various computer systems) is that a system of targeted communications can be acceptable to the general public. Both these systems operate with researchers using pseudonymised data and both operate using an "opt-out" system with posters and leaflets. In both cases the rate of opt-out is extremely low, at less than 1 per 1000 patients; and
 - Where the data used is in identifiable format and generally felt to be personally more sensitive, recorded informed consent with positive 'opt-in' is more likely to be appropriate than a communications exercise and a negative 'opt-out' consent model.
- 5.2.3. Where a patient has asked that their information is not disclosed in an identifiable form then there must be mechanisms in place to ensure these wishes are implemented. Equally, if someone has expressed a wish to be considered for research it should be possible to respect that wish. For example, when others make decisions on behalf of a person who has lost the capacity to consent, the Mental Capacity Act 2005 [ref 19] requires them to take account of the wishes the person expressed before losing that capacity. If there is a statutory or other defensible reason for a secondary user to have access to the data in identifiable form, then this must be justified and wherever practicable full records of the access maintained which must be available to the patient, or to a legal representative of the patient.

[Recommendation 6] It is recommended that consideration be given to the design of electronic mechanisms to record consent, and to ensure that the consent choices of an individual are automatically adhered to when providing data from their record. On a wider perspective this facility should also allow patients to actively register their willingness to be involved in research, perhaps into a specific condition that they have, facilitating subsequent invitations to join relevant studies.

[Recommendation 7] It is recommended that the mechanisms for handling and auditing/inspecting of the recording of consent be published. The National Information Governance Board is suggested as the owner.

- 5.2.4. It is necessary to consider how consent will be applied according to the different levels of sensitivity of records particularly in relation to the handling of 'sealed envelopes'. At this stage, the detail around the application of sealed envelopes is still under discussion, but the principle of consent for anything other than fully anonymous use for data held within sealed envelopes still holds.

[Recommendation 8] It is recommended that the design work for sealed envelopes takes into account the need to ensure appropriate anonymisation of this information for secondary use purposes. NHS CFH suggested as the owner.

- 5.2.5. Clear communication is important to ensure that patients are aware of their choices whilst also understanding that their consent is not needed for the use of anonymised data.

It is important that patients and the public are aware of when and how their information might be used and of the role of the Secondary Uses Service.

An important aspect of the management of consent is the transparency around the governance arrangements, including clear penalties for breaches of confidentiality. Part of the UKCRC's remit is to raise public awareness about the value of involvement in research and the use of personal data for research.

[Recommendation 9] It is recommended that a comprehensive communications strategy be drawn up to raise awareness and understanding of the existing and likely future secondary uses of data and the principles by which this is governed. This strategy should also encompass mechanisms for ongoing public and patient involvement and include the involvement of appropriate organisations such as the UKCRC and INVOLVE. The SUS programme board and NHS CFH public information team are suggested as the owners.

- 5.2.6. The Group were clear that consent or refusal to consent should always be recorded as part of an auditable process. As the systems being delivered by NHS Connecting for Health matured they saw significant benefit in recording consent (including approval by PIAG) or refusal in the electronic record. As public confidence in the ability of the new system to maintain confidentiality grows over time, they also felt that it should be possible to record, or allow patients to record, a willingness to be invited to participate in research in general.
- 5.2.7. Members of the group recognised that aspects of their current thoughts on consent may need to be modified as policy around aspects of safeguarding the confidentiality of the NHS Care Records Service are developed and also in the light of particular cases. The challenge will be in managing the transition from the current to the future position.

[Recommendation 10] It is recommended that the Secondary Uses Programme Board takes an active role in implementing the transition to the future position.

5.3. Governance

- 5.3.1. The previous sections describe some important secondary uses of information which require access to identifiable data. This will continue to be the case even in an environment where the use of anonymised or pseudonymised data is encouraged. In all cases where access is provided to any identifiable data, even those for which patient consent has been given, the data must be appropriately governed, with clear arrangements in place both to approve proposals and to ensure that applicants implement acceptable and auditable measures to protect patient confidentiality.

[Recommendation 11] The group recommends that all uses of any healthcare data be undertaken within appropriate and clearly defined, transparent governance processes for approving such uses. Approvals must be dealt with in a timely and efficient way. Governance processes must be put in place to address the handling of the data and to clarify the obligations of data users.

This should be managed as far as possible through the existing governance structures rather than requiring the introduction of new arrangements. For research it is believed that research ethics committees, professional bodies, and scientific bodies operating within guidelines already promulgated for epidemiology and pharmaco-epidemiology etc form such an existing structure.

- 5.3.2. From comments received and previously reported in the Better Regulation Executive report "Making a Difference: Safe and Secure Data Sharing between Health and Adult Social Care Staff", the Working Group was concerned that, guidance from various professional bodies had resulted in further confusion within the research community. Whilst the Working Group agreed that the NHS Care Record Guarantee and the NHS Confidentiality Code of Practice provide the basic framework for secondary uses utilising identifiable data, and should be promoted as such, there is a need for clear guidance based on the recommendations in this report.

[Recommendation 12] We recommend that clear guidance on the secondary uses of identifiable data is issued in line with the recommendations in this report.

- 5.3.3. The Common Law and the Data Protection Act [ref 20] protect individual rights to confidentiality and to fair processing of personal information supplied for particular purposes. Currently, the exception is that identifiable information may be used for research without patient consent if, following an application, the Patient Information Advisory Group (PIAG) recommends to the Secretary of State an exemption from Common Law confidentiality under Section 60 of the Health and Social Care Act 2001 (see footnote on page 7). The measures outlined in this report are designed to reduce the proportion of uses requiring special approval by better enabling the use of anonymised and pseudonymised data and by advocating better patient information to facilitate the obtaining of consent, but central oversight and approval will still be required. The Department of Health has recently announced the formation of a new National Information Governance Board, which will take responsibility for such oversight.
- 5.3.4. Some applications for data use will relate to repeated or on-going activities and will require repeated access to the data. Many public health applications and some routine activities related to research will fall into this category. Other applications, such as many research projects, will have to be assessed on their own merits.

[Recommendation 13] The research community should ensure that it maximises the efficiency of its applications to PIAG and should involve PIAG in its discussions on how this can best be achieved.

[Recommendation 14] Protocols governing the use of identifiable information for secondary purposes should be published and a system of monitoring introduced through the NHS Information Governance Toolkit [ref 21] to ensure that organisations and individuals can be assessed for conformance, both in terms of how data has been obtained and how due measures to protect patient confidentiality have been implemented.

- 5.3.5. Any breaches of confidentiality by secondary users should attract equivalent disciplinary sanctions to breaches by members of direct care teams using the information for primary purposes. These sanctions may need strengthening to cover the arrangements for both local and international collaborative research. There should be an appeals system for individual complaints by those who feel that their confidentiality has been breached. The Working Group noted that some users will belong to professional bodies which do not have regulatory powers and are also not regulated via other means and therefore sanctions for transgressions will need to take this into account.
- 5.3.6. As is the case with primary use of data, all technical and governance aspects of data handling for secondary use should be carefully scrutinised to minimise use of systems or practices which might allow accidental or deliberate public identification of individuals.

[Recommendation 15] It is recommended that standards for the secure handling of information are established and promoted and that, through the regulators, appropriate sanctions should be put in place for addressing poor performance in the handling of data for secondary use purposes.

5.4. Education and Good Practice

5.4.1. It is imperative that the system for secondary uses of data be open and transparent to patients and the public but also to those using the system as well as NHS staff generally.

5.4.2. This report has already made a number of references to the importance of effective and ongoing communications in embedding and ensuring confidence in the system devised. This communication will need to happen at a number of different levels within the NHS. It is also likely that a variety of methods will need to be employed to reach different audiences effectively. Emphasis should be placed on raising awareness and understanding among the public generally at a national and local level. But also on communications that builds on the existing trust which exists between healthcare professionals and patients. Mechanisms also need to be found beyond PIAG for the active involvement of patients and the public in the ongoing design and evaluation of the system as it develops.

All systems and procedures for secondary use should be deployed in a cultural environment which encourages continued learning from best practice and improvement. It is vital that all staff are fully aware of their obligations for the safeguarding of patient information and are trained in the application of published protocols. This includes those responsible for recording patient consent as well as those who have access to data.

5.4.3. It is important that these procedures are put in place for all users of data for secondary purposes. This includes, therefore, not just those in the NHS, but also academic units and private companies.

5.4.4. Delays in meeting the legitimate requirements of secondary users could seriously reduce the public benefit which may flow from secondary use of information. A focus on minimising time delays should be an element in all governance processes.

5.4.5. The Information Governance Toolkit which currently provides a lot of relevant information should be expanded to cover the issues addressed in this report. Appropriate sections of it could be treated as guidelines for research governance.

[Recommendation 16] It is recommended that the Information Governance toolkit be extended to address issues such as the recording of consent, and the timely handling of data for secondary purposes.

6 Next Steps

- 6.1. This report has been commissioned by the Care Record Development Board. The Board acts as an adviser to the National Programme Board which oversees the National Programme for IT. This report is submitted to the Care Record Development Board.
- 6.2. A number of recommendations have been made: some for action by the Department of Health, some by NHS Connecting for Health and some by the Information Centre for Health and Social Care. Some also call for action with the Office of the Information Commissioner and with bodies that issue good practice guidelines for health professionals, academic researchers and others, to promote consistent interpretation of the principles and approaches we recommend.
- 6.3. The Care Record Development Board is committed to reviewing the Care Record Guarantee on at least an annual basis, and will pass on these responsibilities to the National Information Governance Board when it is established. The National Information Governance Board should continue to monitor the implementations of the recommendations in this review at least annually.

Annex A - Members of the Working Group

Name		Representing
Prof. Sir Robert Boyd	(Chair)	
Prof. Denise Lievesley	(Deputy Chair) Chief Executive of the Information Centre, Chair Secondary Uses Service Programme Board	The Information Centre for Health & Social Care
Sarah Buckland	Director	INVOLVE
Prof. Mike Catchpole	Consultant in Public Health Medicine & Head of Knowledge and Information Management, Health Protection Agency	PIAG
Simon Denegri	Chief Executive	AMRC
Lorraine Foley	Head of Informatics (or Acting Head of Accessible Information)	Health Care Commission
Prof. Peter Goldblatt	Chief Medical Statistician	National Statistics
Wally Gowing	SUS Programme Team	CFH
Ian Hayes	Trustee of Terrence Higgins Trust	Patients/Service Users
Dame Deidre Hine	Immediate Past President	BMA
Rhidian Hughes	Information & Reporting Manager	CSCI
Dr John Hyslop	Consultant Radiologist, Royal Cornwall Hospitals NHS Trust	CRDB
Dr John Jenkins	Chair, Standards & Ethics Committee	GMC
Jane Moore	Director - Healthcare Quality, representing Deputy Chief Medical Officer, DH	DH
Mary Nettle	Mental Health User/Consultant	Patients/Service Users
Jane O'Brien	Head of Standards and Ethics	General Medical Council
Dr Liam O'Toole	Chief Executive	UKCRC
Julietta Patnick	Director, NHS Cancer Screening Programmes	CRDB
Dr Anne Slowther	GP and Senior Lecturer in Medical Ethics	The Ethox Centre
Marc Taylor	Head of R&D Systems and Governance	DH R&D
Jeremy Thorp	Director of Business Requirements	CFH
Dr Mark Walport	Director	The Wellcome Trust
Prof. Graham Watt	Professor of General Practice, the University of Glasgow	Academy of Medical Sciences
Jan Wilkinson	Independent Business Consultant	CRDB
Richard Willmer	Head of Statistics, Standards and Quality Analytical Team	DH
Sally Parkinson	Secretariat	CRDB Manager

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