



Department
of Health

Information: To Share or not to Share

Government Response to the Caldicott Review

September 2013

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Ministerial Foreword



Better information sharing will mean more effective health and care services and an improved experience for people using those services. So I am extremely grateful to Dame Fiona Caldicott

and her team for their comprehensive review. In this document we set out the Government's response.

Dame Fiona's review has given us a tremendous opportunity to get information sharing right - to improve safety, to prevent the need for patients to have to repeat themselves to different health professionals, to make care more efficient, and to find new cures and therapies for killer diseases. At the same time, it is vital that we respect people's privacy and put them more in control of how their information is used. This is a fine balance to strike, but an achievable one.

In the past, information governance rules have prioritised systems over people. Too often they have been seen as an insurmountable obstacle and an excuse to avoid sharing information. We outline a new approach here.

This new approach will mean that frontline staff will be confident about when to share information with other members of a person's care team and how to do so safely. Frontline staff will also have much greater

confidence that anyone else who shares information will do so responsibly and properly. And people will know how their care information is used and shared and how to object if they want to.

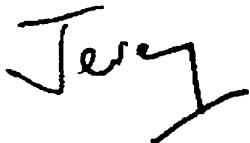
Our response sets out how individuals and organisations should improve the way that information is used for research, commissioning and above all good care. Giving people a say in how their information is used is an essential component of a good system. Where someone is concerned about their information being shared, they have the right to make their objection heard.

Information must be held securely. Several safeguards will be put in place. They include: making sure that health and care staff are appropriately trained in information governance, responding to a data breach honestly and immediately, and having a designated leader on information governance.

The Health and Social Care Information Centre's Code of Practice on Confidentiality will provide much needed clarity to organisations on how the rules work and how they can be applied consistently.

I have been encouraged by the willingness of organisations across health and care to work with the Department of Health to effect the cultural change we are seeking. Dame Fiona will monitor the progress made following her review, and will publish a report a year from now.

Information is compiled, stored and shared because doing so improves people's health, but at the same time their data must be treated with propriety and respect. The prize for achieving this is very great indeed.

A handwritten signature in black ink, appearing to read 'Jeremy'.

Rt. Hon. Jeremy Hunt MP
Secretary of State for Health

The revised Caldicott principles

1. Justify the purpose(s)

Every proposed use or transfer of personal confidential data within or from an organisation should be clearly defined, scrutinised and documented, with continuing uses regularly reviewed, by an appropriate guardian.

2. Don't use personal confidential data unless it is absolutely necessary

Personal confidential data should not be included unless it is essential for the specified purpose(s) of that flow. The need for patients to be identified should be considered at each stage of satisfying the purpose(s).

3. Use the minimum necessary personal confidential data

Where use of personal confidential data is considered to be essential, the inclusion of each individual item of data should be considered and justified so that the minimum amount of personal confidential data transferred or accessible as is necessary for a given function to be carried out.

4. Access to personal confidential data should be on a strict need-to-know basis

Only those individuals who need access to personal confidential data should have access to it, and they should only have

access to the data items that they need to see. This may mean introducing access controls or splitting data flows where one data flow is used for several purposes.

5. Everyone with access to personal confidential data should be aware of their responsibilities

Action should be taken to ensure that those handling personal confidential data – both clinical and non-clinical staff – are made fully aware of their responsibilities and obligations to respect patient confidentiality.

6. Comply with the law

Every use of personal confidential data must be lawful. Someone in each organisation handling personal confidential data should be responsible for ensuring that the organisation complies with legal requirements.

7. The duty to share information can be as important as the duty to protect patient confidentiality

Health and social care professionals should have the confidence to share information in the best interests of their patients within the framework set out by these principles. They should be supported by the policies of their employers, regulators and professional bodies.

Chapter 1. Introduction

- 1.1 The Government is committed to a health and care system which puts those who use it at the heart of the system. The Department of Health (the Department) wants equality of opportunity for everyone so that everybody who uses both health and social care services receives integrated care from services that work together to address health inequalities and give the best care based on a person's personal circumstances.
- 1.2 To do this, service users need access to information, and service providers need to be able to share information with other providers and commissioners. The 2012 Care and Support White Paper¹ recognised the importance of information sharing to support the integration of services and clause 3 of the subsequent Care Bill sets out a duty on local authorities to promote integration of care and support with health services.
- 1.3 The NHS Constitution² commits to rights to privacy and confidentiality and to the NHS keeping patients' confidential information safe and secure. In the 2013 update of the NHS Constitution, the Government included
- a new right for patients to request that their confidential information is not used beyond their own care and treatment and to have their objections considered, and where their wishes cannot be followed, to be told the reasons, including the legal basis.
- 1.4 The way that information is used, kept secure and overseen is known as 'information governance'. Information governance is the term used to describe the principles, processes and legal and ethical responsibilities for managing and handling information. It sets the requirements and standards that organisations need to achieve to ensure that information is handled legally, securely, efficiently and effectively.
- 1.5 The NHS Future Forum called for a review of the current rules on information governance, and how they are applied. The Government's Information Strategy, *The Power of Information: Putting all of us in control of the health and care information we need*,³ accepted the need to be clearer about when to share data between professionals. Most people would expect and want this to happen routinely, but would also want assurance that only those involved in

1 www.gov.uk/government/publications/caring-for-our-future-reforming-care-and-support

2 www.gov.uk/government/publications/the-nhs-constitution-for-england

3 www.gov.uk/government/publications/giving-people-control-of-the-health-and-care-information-they-need

their care should have access to confidential information, unless they have given specific consent for other purposes, such as research aimed at improving the way in which services are delivered to protect and improve health and care. This applies across the age range. The Children and Young People's Health Outcomes Forum⁴ also identified the need for improved information sharing to ensure better integrated services.

- 1.6 The Department asked for the review of information governance to ensure that there is an appropriate balance between the protection of confidential data and the use and sharing of information to improve people's health and social care and for the benefit of wider society.
- 1.7 Dame Fiona Caldicott was asked to undertake the review and on 26 April 2013 published the Report⁵ which includes revisions to the original Caldicott principles to emphasise the need to give greater focus to sharing information. The Government is pleased to accept in principle all of its recommendations. The review contains much helpful content beyond the 26 recommendations, and the Department will be looking to deliver the spirit of the review, rather than confine itself to the recommendations.

What this will mean for us all

- 1.8 In her foreword to the Report, Dame Fiona said that every citizen should feel confident that information about their health is securely safeguarded and shared appropriately when that is in their interest. The Government agrees with this view and the intention of all the actions laid out in this response is to give citizens that confidence.
- 1.9 Our overarching ambition for people within the health and care system is for them to no longer feel that information governance is complex and daunting. Everyone should understand how to protect and, where appropriate, share information about the people they care for, either directly or indirectly.

4 www.gov.uk/government/publications/independent-experts-set-out-recommendations-to-improve-children-and-young-people-s-health-results

5 www.gov.uk/government/publications/the-information-governance-review

What this means for patients, care service users and their families and carers

- People will feel more in control of their personal confidential information.
- Everyone will feel confident that information about their health and care is secure, protected and shared appropriately when that is in their interest.
- People will be better informed about how their information is used and shared while they are receiving care, including how it could be used in anonymised form for research, for public health and to create better services.
- People will know how to object if they don't want their information to be shared in this way.
- People will be increasingly able to access their own health and care records.
- Dame Fiona Caldicott will be reporting on progress towards achieving these ambitions.

What this means for everyone working in the health and care system

- Health and care professionals will make decisions about how information is shared and used in the best interests of people and patients using the five rules of confidentiality set out in new HSCIC guidance.
- Front-line staff will no longer feel that information governance is complex and daunting.
- Everyone working in health and care will understand how to protect and, where appropriate, share information about the people they care for.
- GPs and all care providers will respect a person's right to object to their information being shared.
- Health and care staff will adhere to the principles of the Caldicott Report and the NHS Constitution on data sharing in their efforts to improve care and support for patients and people who use services.
- Staff will follow consistent guidance on implied consent where they need to share information for care and they cannot get direct consent.
- There will be appropriate training and education for different groups of staff including social care workers.

What this means for organisations within health or social care

- Boards or their equivalents will make sure that their organisation has due regard for information governance.
- Employing organisations will adhere to the principles of the Caldicott Report and the NHS Constitution on data sharing in their efforts to improve care and support for the benefit of patients and people who use services.
- Employing organisations will help professionals to share information appropriately in order to help to integrate care and improve services.
- Organisations will be open and honest – explaining and apologising if a data breach happens, and taking action to prevent it happening again.
- Organisations will have a Caldicott Guardian or a Caldicott lead and will offer suitable training and education for all staff on information governance.
- Over time social care providers and commissioners will adopt more of the best practice that is already in place across much of the NHS so that the way personal information is treated is the same whether the care is provided by a GP, hospital or care home.

1.10 When Dame Fiona's Independent Information Governance Oversight Panel reports on progress against these recommendations, the Department would like to hear that it has found both that there is more secure sharing of information to support direct care of patients and service users and that there has been a reduction in improper use of personal confidential information – fewer breaches and data losses and fewer organisations using identifiable information where anonymous information would suffice.

1.11 The Department also hopes that the panel finds that all citizens are better informed about how their information is used and shared and are increasingly able to access their own health and care records and have their own interests upheld.

The challenge and the opportunity

1.12 The Report recognises the need to use people's health and care information to drive improvement to services and treatments, but stresses that the health and care system needs to share the information safely and securely for many purposes, including for the care of the individual, clinical audit, research, commissioning, performance management and public health. People have very strong views about how information that the health and care system collects about them is used. Some feel comfortable that it is used for a range of purposes; others do not. The Department must get the balance right between using information effectively and making sure that, where people don't want it shared, it won't

- be. The Government believes that the recommendations in the Report will help to achieve this.
- 1.13 The health and care system now, more than ever, depends on organisations communicating electronically with each other. Many of Dame Fiona's recommendations cannot be delivered by the Department alone. To achieve the step change there must be a concerted effort, at national and local level.
- 1.14 The Department has a key role to play in setting the strategic vision and direction, acting as steward of the system to oversee delivery of the review's recommendations; for example, through establishing principles, ensuring that regulations are fit for purpose and working with national partners to set the framework for delivery through local organisations.
- 1.15 The key mechanism for the Department will be the collaborative Informatics Services Commissioning Group (ISCG) which will provide a forum for the system to make decisions on the prioritisation and commissioning of all informatics services, including data collection, in health and care. The ISCG has set up an information governance sub-group to provide leadership in this area. Membership has been drawn from bodies and organisations representing the NHS and NHS commissioners, social care, research, public health and regulators.
- 1.16 But the Department will also be looking to key partners – NHS England, the Care Quality Commission (CQC) and the Health and Social Care Information Centre (HSCIC) – to undertake much of the work that is required nationally. For example, the Health Research Authority Confidentiality Advisory Group⁶ will promote and protect the interests of the patient while at the same time facilitating appropriate use of confidential patient information for purposes beyond direct patient care, through advising whether applications for access without consent to such information should be supported. Also, NHS England has included implementation of Caldicott recommendations in its Information Governance Work Programme. And this goes beyond the health and care system. Discussions are taking place on the recommendations across Government, for example with the Department for Education and working closely with the Information Commissioner's Office (ICO).
- 1.17 The new emphasis on integration gives us opportunities to improve the sharing of information between health organisations and local authorities and providers of social care. The Department will work with Public Health England, the Association of Directors of Adult Social Services (ADASS) and the Local Government Association (LGA) to ensure that local authority commissioners of care are supported and encouraged to lead the local action that is required to respond to the recommendations.
- 1.18 Many organisations have already committed to include information governance as part of their 'business as usual' work and this government response reflects some but not all of those commitments. The Department

⁶ www.hra.nhs.uk/hra-confidentiality-advisory-group/

acknowledges all those who have made commitments to new ways of working to enable better sharing of information while still working within the law.

Cultural change required to realise the review's recommendations

- 1.19 As set out in the NHS Constitution, the Winterbourne View Report,⁷ the Francis Report⁸ and the Berwick Report⁹ among others, the interests of patients and service users must come first in everything and this necessarily includes the way that information is used. This requires cultural change.
- 1.20 This is not just about putting something in guidance or in a contract or an agreement – it is about local people championing the principles and making sure that they translate into new ways of working among front-line staff for the benefit of patients, service users and carers.
- 1.21 The Report confirms that this cultural change is needed to ensure that decisions about how information is shared and used are made in the best interests of people and patients. Smaller care providers, for example, may not be generally aware of the Caldicott Review. It is vital that people trust professionals to share their data safely, so that they get the best care and treatment. Health and care professionals must not use information governance as a reason not to share data when sharing it is in the best interests of people they are caring for. Indeed, the duty to safeguard children or vulnerable adults may mean that confidential information should be shared, even without consent, because it is in the public interest to do so. Where there is a risk of significant harm to a child, either directly through abuse or neglect, or indirectly where they live in a household where other people are suffering harm (for example, domestic violence), there may be a strong basis for sharing information to protect the child.
- 1.22 The Department expects that everyone, including educators, clinicians and social workers, administrators and board members, should look at information governance best practice and how it affects their work.
- 1.23 Perhaps the most important recommendations of the Report relate to the emphasis that should be placed upon sharing information to support direct care. The common law 'duty to care' includes a requirement to share information, but often professionals and staff are prevented from doing this by their own organisation's procedures. The Department does not expect professionals to act against their employer's information governance arrangements, but does expect these employing organisations to make it easier to share information and to follow the best practice of the organisation. The Department is calling on all organisations to examine their existing arrangements, and to lead by example. There are several supporting programmes under way.

7 www.gov.uk/government/publications/winterbourne-view-hospital-department-of-health-review-and-response

8 www.midstaffspublicinquiry.com/report; www.gov.uk/government/publications/government-initial-response-to-the-mid-staffs-report

9 www.gov.uk/government/publications/berwick-review-into-patient-safety

- 1.24 The Information Strategy published by the Department in 2012 described how information can be used to drive integrated care across the health and social care sector, both within and between organisations. The recent publication *Integrated Care and Support; Our Shared Commitment*¹⁰ included a commitment from national bodies to provide timely advice and support on information governance and an expectation that localities will adhere to the principles of the Caldicott Report and the NHS Constitution on data sharing in their efforts to integrate care and support for the benefit of patients and people who use services. The Minister for Care Services Norman Lamb has invited local areas to apply to become integration ‘pioneers’.
- 1.25 Working closely with the Integration Pioneer Programme, the Public Service Transformation Network¹¹ is a new virtual organisation, a collaborative venture between central government and localities with the aim of supporting local areas to design and deliver fundamental service redesign and transformation, building on the learning already derived from the Whole Place Community Budget pilots. Initially the network will be working with nine new localities across a range of public services, including integration of health and social care.
- 1.26 Government is now taking further steps to support local areas to design and implement plans for integrating care. On 26 June 2013 the Chancellor of the Exchequer George Osborne, as part of
- the Spending Review,¹² announced a £3.8bn pooled fund to promote joint working between the health service and care and support in 2015/16. The Integration Transformation Fund¹³ includes a number of national conditions, one of which is that local plans for use of the fund must include proposals for better data sharing between health and social care. Further information on this will be provided as part of the planning round guidance to be issued by NHS England later in the year.
- 1.27 Also in the Spending Review the Chancellor announced that a centre of excellence is to be developed, building on the foundations laid by the Improving Information Sharing and Management (IISaM) project,¹⁴ which has demonstrated over the last two years that it is possible to help local areas and central government to work together to resolve issues around information sharing. The aspiration is to make the centre of excellence the place to go for practical and impartial advice on information sharing issues across public services more broadly. Localities are also investing independently, including London where the newly launched London Connect¹⁵ programme has a workstream on information governance.
- 1.28 The Department will also be considering what guidance is needed to help people who are organising their own care to make decisions that do not put their personal confidential data at risk.

10 www.gov.uk/government/publications/integrated-care

11 www.gov.uk/government/news/nine-new-places-join-next-phase-of-local-public-service-transformation

12 www.gov.uk/government/uploads/system/uploads/attachment_data/file/209036/spending-round-2013-complete.pdf

13 www.england.nhs.uk/2013/08/09/hlth-soc-care/

14 <http://informationsharing.co.uk/>

15 www.londonconnect.org/

Chapter 2. People's right to access information about themselves

- 2.1 The Department agrees with the review recommendation that people who use health and social care should have a right of access to personal information which covers GP records, hospital records, care plans, community records and other personal confidential information held by all organisations within the health and care system. The vision set out in the Information Strategy is “for all of us to have secure electronic access to services and to our own health and social care records”.
- 2.2 The Report made the following recommendation:
- People must have the fullest possible access to all the electronic care records about them, across the whole health and social care system, without charge.*

An audit trail that details anyone and everyone who has accessed a patient's record should be made available in a suitable form to patients via their personal health and social care records. The Department of Health and NHS Commissioning Board should drive a clear plan for implementation to ensure this happens as soon as possible.

Recommendation 1 (section 2.4)
- 2.3 NHS England is leading work on electronic access to health records to deliver the Information Strategy commitment to providing online access to all GP records by 2015 as a first step towards providing electronic access to all health and care records. The Department will work with partner organisations to consider how this might be extended to care records outside the NHS.
- 2.4 The Report stated that “the objective of increasing patients' access to their own records requires that there is a secure but straightforward means to identify and authenticate anyone who has had access... and a way of seeing that this access has been used appropriately”. The Department strongly agrees that it is essential that patients and service users have confidence that their information has been kept safe and secure.
- 2.5 There are a number of ways in which this may be achieved, and the Department has noted that NHS Scotland has opted to invest in privacy breach detection tools instead of creating a viewable audit trail of access. The Department will work with partner organisations to commission an options analysis in order to determine the best approach by the end of this financial year.

Chapter 3. Direct care of individuals

3.1 Sharing information to support better care is one of the fundamental requirements to support many of the Secretary of State's priorities, including vulnerable older people and compassionate care. The Report's view is that good professional practice goes hand in hand with good information governance practice and the Department expects the two to become fully integrated.

3.2 Direct care is the term used by the Review to include clinical care, social care and public health activity relating to individuals. It also includes activity such as audit and management of untoward incidents where these are carried out by people who have a legitimate relationship for that person's care.

3.3 The Department agrees that there is a need for improved trust between providers, particularly at the boundary between health and care – the best interests of patients and service users must not be undermined by cultural differences between different parts of the health and care system.

3.4 The Report made a number of recommendations relating to the direct care of individuals:

For the purposes of direct care, relevant personal confidential data should be shared among the registered and regulated health and social care professionals who have a legitimate relationship with the individual.

Health and social care providers should audit their services against NICE Clinical Guideline 138, specifically against those quality statements concerned with sharing information for direct care.

Recommendation 2 (sections 3.3 and 3.4)

3.5 Sharing information to support care is essential. It is not acceptable that the care a patient or service user receives might be undermined because the different organisations providing health and care to an individual do not share information effectively.

3.6 Sharing personal information effectively is a key requirement of good information governance, and cultural change in the health and social care system is key to achieving this. Many projects, pilots and demonstrators have highlighted how sharing information securely can work for the benefit of patients and service users.

- 3.7 Important work in this area will be led by the CQC – which will focus its role in monitoring information governance on how well health and care providers share information effectively to support care. The CQC is in the process of reviewing and transforming its regulatory model for different health and care sectors; as part of this, it will work to ensure that it can assess the effectiveness of information sharing in different settings and pathways of care. The Department is currently reviewing the CQC regulations and will take the revised Caldicott principles into consideration when looking at the regulation relating to records.
- 3.8 The Department welcomes the specific recommendation on the National Institute for Health and Care Excellence (NICE) clinical guideline for patient experience in adult NHS services and recommends that providers audit their information sharing practices against this guideline and that commissioners use the associated Quality Standard 15¹⁶ in commissioning and monitoring adult NHS services (in relation to information sharing). However, since the Information Governance Review report was published, a number of other independent reviews of the NHS have reported, including the Berwick Report, which more fully addresses safety and quality of patient care. Any further work in this area will be done in close co-operation with those responsible for taking the Berwick and Francis recommendations forward to ensure that there is consistency of messages for the NHS. For social care, the Department will include the spirit of this recommendation in the ongoing work with the bodies that provide guidance and best practice advice to local authorities and to care providers, and with regulators and professional bodies.
- 3.9 A culture change is needed to encourage sharing of relevant personal confidential data among the registered and regulated health and social care professionals who have a legitimate relationship with the patient or service user. The work referenced in this document will help to bring about this change – including adoption of the new duty to share by leading health and care organisations and its integration into programmes of work, training and education, guidance and standards with the aim of seeing employing organisations supporting professionals to share appropriately.
- 3.10 At the same time, some patients and service users are concerned about potential lack of confidentiality and are reluctant to reveal information about their health and circumstances in case it is shared more widely than they expect. Professionals' duty of confidentiality is not undermined by any of the actions in this response. It still remains the case that, for direct care, where it is in the best interest of the individual for information not to be shared, it won't be shared.
- 3.11 NHS Employers have been asked to work together with Trade Union Partners through the National and Regional Social Partnership Forums to identify areas of good practice which can inform future development work in this area. As an initial step a joint workshop with NHS England and Social Partnership Forum partners is scheduled for September 2013.

16 <http://publications.nice.org.uk/quality-standard-for-patient-experience-in-adult-nhs-services-qs15>

The health and social care professional regulators must agree upon and publish the conditions under which regulated and registered professionals can rely on implied consent to share personal confidential data for direct care. Where appropriate, this should be done in consultation with the relevant Royal College. This process should be commissioned from the Professional Standards Authority.

Recommendation 3 (section 3.5)

3.12 The Department is commissioning the Professional Standards Authority to ensure that all health and social care professional regulators publish consistent guidance that reflects the messages in the HSCIC's forthcoming Confidentiality Code of Practice. Together with other work mentioned under recommendation 4, this will mean that there is no conflict between the guidance on implied consent that professionals receive from their regulator and their employing organisation.

3.13 The General Medical Council and the Academy of Medical Royal Colleges have offered to help in this work, building on work already under way in the Royal Colleges.

3.14 The commission will make it clear that consideration must be given to those whose understanding is limited, for example through learning disabilities or because they speak little or no English.

Direct care is provided by health and social care staff working in multi-disciplinary 'care teams'. The Review recommends that registered and regulated social workers be considered a part of the care team. Relevant information should be shared with members of the care team, when they have a legitimate relationship with the patient or service user. Providers must ensure that sharing is effective and safe. Commissioners must assure themselves on providers' performance.

Care teams may also contain staff that are not registered with a regulatory authority and yet undertake direct care. Health and social care provider organisations must ensure that robust combinations of safeguards are put in place for these staff with regard to the processing of personal confidential data.

Recommendation 4 (sections 3.6 and 3.7)

3.15 Possibly the most important message to come out of the Report was the need for better sharing of relevant information to support direct care. Successful delivery of this recommendation is crucial to achieving this ambition.

3.16 The national bodies will take action to establish the right conditions for improved sharing. The HSCIC's Confidentiality Code of Practice will include a discussion of what constitutes a care team – and health and care organisations are now legally

required to have regard to this once it is published.

3.17 The CQC's information governance monitoring work will focus on how well information is used and shared to support delivery of good quality care. The CQC's approach will evolve as it develops its new regulatory model across different sectors. This will encompass:

- *the quality of care records;*
- *how health and care providers ensure effective and consistent information governance practice;*
- *the use of information across teams and within organisations; and*
- *the sharing of information along care pathways and across organisational boundaries.*

3.18 The Information Governance Toolkit, a tool used by health and some care organisations to assess their performance, provides a way in which organisations can assess themselves against the Department's information governance standards and policies, and allows the public to view a summary of these assessments. The toolkit covers health, social care and the independent sector and has been recently extended to cover the voluntary sector. It provides a shared language, enabling people to discuss information sharing using common terms and reference points and a consistent framework which can be applied across different health, social care, voluntary and independent sector organisations.

3.19 A small number of local authorities are already using the toolkit and a pilot project in Leeds is exploring the potential for its wider use, with the support of the Local Authority Chief Information Officer Council. The ISCG information governance sub-group will consider how best to support the extension of the toolkit across local authorities.

3.20 NHS England has undertaken to give a clear steer to commissioners of care with regards to the need to monitor provider information governance performance using a variety of mechanisms, and to take account of the findings of inspection reports published by the CQC where poor information sharing practice has been identified. NHS England will also be looking to include this in the Clinical Commissioning Group (CCG) Assurance Framework and the Standard Contract which are under development during 2013.

3.21 One of the difficulties in sharing is in establishing trust, so that registered and regulated professionals can share information with unregistered and unregulated members of the care team working in other organisations – for example, when discharging patients from hospital to a care home. While the main thrust of this response is about tipping the balance away from over-cautiousness about sharing, this is one area that is slightly different. Sharing will only be improved when professionals are confident that there are appropriate safeguards for unregistered and unregulated professionals.

- 3.22 Implementation of data sharing agreements between organisations will help by improving the trust between organisations and the professionals (whether registered and regulated or not) who work in them – this is covered in more detail in the section on recommendation 20.
- 3.23 At the same time that this response is being published, Skills for Care is launching the voluntary Social Care
- 3.24 Commitment.¹⁷ Users of care services will be able to check whether providers and their employees have made a public commitment to providing the highest standard of care. It includes commitments about understanding confidentiality issues and handling confidential information.
- 3.25 Recommendation 5 is considered in the next chapter.

¹⁷ www.skillsforcare.org.uk/developing_skills/thesocialcarecommitment/the_social_care_commitment.aspx

Chapter 4. Personal data breaches

- 4.1 The Review Panel concluded that there should be a single definition of a “personal data breach” used by the whole health and care system and included a suggested definition. The Department will include consideration of this suggested definition in the work undertaken in response to recommendation 22.
- 4.2 The report made 2 recommendations in this area.
- In cases when there is a breach of personal confidential data, the data controller, the individual or organisation legally responsible for the data, must give a full explanation of the cause of the breach with the remedial action being undertaken and an apology to the person whose confidentiality has been breached.*

Recommendation 5 (section 3.10)
- 4.3 The new standard NHS contract includes a duty of candour for providers which may eventually become a statutory duty. This contractual duty places an obligation on NHS providers – not just individual clinicians who already have a professional duty of candour – to be open with patients when things go wrong and harm has been caused.
- 4.4 Recommendation 5 suggests that, for every breach, whether the harm is potential or actual, there must be an explanation, remedial action and an apology – very closely aligned with the new duty of candour in the NHS. The Review Panel heard that, as a result of recent high profile financial penalties imposed by the ICO, organisations have reduced information sharing for direct care and are reluctant to admit that breaches have happened. The ICO confirmed to the Review Panel that it has not imposed any such penalties for problems arising from formal data sharing to support direct care – recent cases of penalties have been in relation to poor processes and poor security.
- 4.5 The Department agrees with the review finding that there is no contradiction between increasing data sharing for care and improving the safeguards for personal confidential data.
- 4.6 The ICO works with organisations to improve their processing of personal data in a number of ways – providing practical advice to organisations about how they can make improvements to comply with the Data Protection Act. Following the publication of the Francis Report, there is an increased emphasis on being open and honest about mistakes generally. The Department expects every organisation within the

health and care system to explain and apologise for every data breach, with appropriate action agreed.

- 4.7 If organisations remain concerned about breaches and cautious about improving their sharing for direct care as a result, the Department recommends that they refer to the Confidentiality Code of Practice and if still in doubt, seek advice from the ICO.
- 4.8 The Department will work with the social care, public health and research sectors to support them in any specific local actions.

The processing of data without a legal basis, where one is required, must be reported to the board, or equivalent body of the health or social care organisation involved and dealt with as a data breach.

There should be a standard severity scale for breaches agreed across the whole of the health and social care system. The board or equivalent body of each organisation in the health and social care system must publish all such data breaches. This should be in the quality report of NHS organisations, or as part of the annual report or performance report for non-NHS organisations.

Recommendation 6 (section 4.6)

- 4.9 The Department agrees with the review recommendation that there should be a standard severity scale for breaches agreed across the whole of the health and social care system, and that the board or equivalent body of every organisation in the health and social

care system should publish all such data breaches.

- 4.10 The Department is pleased to report that a new incident reporting mechanism was introduced in June 2013 by the HSCIC, with a standard scale for severity of breaches agreed with the Department and the Information Commissioner. This new online reporting tool will go some way to addressing the issues covered by this recommendation. NHS trusts are already required to publish details of incidents and the Department will, with local authorities, pursue the requirement, for example through the Annual Governance Statement that local authorities are required to produce. The guidance available from the Chartered Institute of Public Finance and Accountancy (CIPFA) and the Society of Local Authority Chief Executives and Senior Managers (SOLACE) includes a section on corporate risks and issues. The Department will ask these organisations to consider this recommendation when next updating their guidance.
- 4.11 The Department has also asked Monitor to consider this recommendation when they next update their requirements for foundation trusts' annual reports (which serve the requirement of the Quality Account regulations for foundation trusts), the NHS Trust Development Authority to do the same for non-foundation trusts, and NHS England to do likewise for other healthcare providers that are required to produce annual Quality Accounts.

- 4.12 Local care providers may be too small to have shareholders and annual reports. The Department expects that commissioners will deal with data breaches by providers, including these smaller providers, as they do with all mistakes and errors and demand transparency. In addition, the Department will ask the Leeds project mentioned under recommendation 4 to include incident reporting in its work.
- 4.13 For services purchased directly by the users of the services, there is no commissioner to enforce standards but the Data Protection Act still applies. In addition, service users can refer to published guidance on selecting a service while providers can give assurance on their services by signing up to voluntary agreements such as the Social Care Commitment.

Chapter 5. Information governance and the law

5.1 The Department agrees with the review conclusion that health and care organisations should do more to increase people’s understanding of how their personal confidential data is used and the choices they can make about who can access their records. The Department acknowledges that this means that practitioners will need to record patients’ and service users’ preferences about how their personal information is used, and that organisations will need to ensure that IT systems support them in doing this.

5.2 The Review report uses the term “de-identified data” in relation to personal data that has been through an anonymisation process conforming to the ICO Anonymisation Code of Practice.¹⁸

5.3 The Report made two recommendations in this area:

All organisations in the health and social care system should clearly explain to patients and the public how the personal information they collect could be used in de-identified form for research, audit, public health and other purposes. All organisations must also make clear what rights the individual has open to them, including any ability to actively dissent (i.e. withhold their consent).

Recommendation 7 (section 5.5)

5.4 The NHS Constitution makes it clear that everyone has the right to be informed about how their information is used and the right to request that their confidential information is not used beyond their own care and treatment. Where their wishes cannot be followed, they should be told the reasons including the legal basis.¹⁹ The NHS Constitution also lays out clearly that the NHS will anonymise information contained in medical records for use by researchers to support healthcare improvement.

¹⁸ www.ico.org.uk/for_organisations/data_protection/topic_guides/anonymisation

¹⁹ www.gov.uk/government/publications/the-nhs-constitution-for-england

- 5.5 NHS England is working with CCGs and Health Education England (HEE) to co-develop and implement a joint strategy for promoting and embedding the Constitution in everything that the NHS does, including an appropriate means of monitoring progress and impact.
- 5.6 The NHS Constitution is also discussed under recommendation 9.
- 5.7 Giving citizens confidence that they know how their information is used and that they are content is essential to support the Government's ambition to put people more in control of their health and care information.
- 5.8 Successful implementation of this recommendation will improve transparency and enable people to exercise their legal right to be informed about how their data is used. It builds upon an existing legal requirement in the Data Protection Act for processing to be fair and the HSCIC will make this requirement explicit in its Confidentiality Code of Practice.
- 5.9 In addition, the Code of Practice will make it clear that individuals are entitled to object to their data being shared with the HSCIC, for example through exercises to collect GP data run by the HSCIC under powers created by the Health and Social Care Act 2012. Any patient who does not want the personal data held in their GP record to be shared with the HSCIC will have their objection respected.
- 5.10 NHS England has been working alongside the HSCIC, the British Medical Association (BMA) and the Royal College of General Practitioners (RCGP) in the development of materials for patients about the collection and use of their data for a wide variety of purposes to support the new *care.data* programme, providing patients with information more generally about how their information is used and what rights they can exercise to control this.²⁰
- 5.11 The ICO will support this work, in particular to ensure that a clear and easily understandable message on how their information is used is delivered to patients, people who use care and support and the wider public.

Consent is one way in which personal confidential data can be legally shared. In such situations people are entitled to have their consent decisions reliably recorded and available to be shared whenever appropriate, so their wishes can be respected. In this context, the Informatics Services Commissioning Group must develop or commission:

- *guidance for the reliable recording in the care record of any consent decision an individual makes in relation to sharing their personal confidential data; and*
- *a strategy to ensure these consent decisions can be shared and provide assurance that the individual's wishes are respected.*

Recommendation 8 (section 5.5)

²⁰ www.england.nhs.uk/ourwork/tsd/data-info/

5.12 Some IT systems that hold care records already provide tools for managing consent decisions; the common law relating to confidentiality requires this. The Department will work with NHS England to develop a consent management standard that is applicable to all such systems and across the whole health and care system including the research sector, and will consider how best to enable the implementation of mechanisms for sharing the decisions of individuals between different systems. It will take time to upgrade/replace older systems, but the Department will recommend to the ISCG that these standards are considered to be a priority. NHS England will also draw attention to this within the Technology Strategy, due to be published in December 2013.

The rights, pledges and duties relating to patient information set out in the NHS Constitution should be extended to cover the whole health and social care system.

Recommendation 9 (section 5.9)

5.13 The NHS Constitution reflects the current legal position in relation to patient rights, and the duties of organisations and staff within the NHS. While staff working in social care are not part of the NHS and so do not need to have regard to the NHS Constitution, all of the legal rights in relation to respect, consent and confidentiality extend to the social care sector including privately funded social care.

5.14 Following the recent public consultation on the NHS Constitution, revised documents, including a supplement about public health, were published in April 2013. This supplement explains how the NHS Constitution applies to anyone undertaking their public health functions even if they are not working in NHS organisations. The Department will work with the adult social care sector to consider how, where they do not already exist, the rights, pledges and duties of the NHS Constitution might be extended to the adult social care system.

5.15 The ICO welcomes the plans to extend the rights, pledges and duties and will support work to increase awareness among patients and the public about the existence of the NHS Constitution and what it contains.

5.16 Until a revised NHS Constitution and associated documents are published, the rights and duties will be gathered together in the Confidentiality Code of Practice, which is applicable across health and social care.

Chapter 6. Research

- 6.1 This Government is determined that the life sciences sector (including industry, NHS, academia and charities) thrives in the UK; researchers and clinicians have a vibrant, exciting and world-class environment in which to work; and patients have access to leading-edge treatments early. The Review rightly highlighted the enormous value of health data to research and the huge potential for research and development to lead to improvements in health and social care.
- 6.2 The *Strategy for UK Life Sciences*,²¹ published in December 2011, outlined a number of actions including a new secure data service. The Clinical Practice Research Datalink (CPRD) was established in 2012 and offers data services, with the support of the HSCIC, to include: providing access to data for researchers (NHS, social care and others); data matching and linkage services; and data validation to support the clinical trial and observational study work of the life sciences research community. There will be occasions when it is not possible to use services like CPRD and it can be demonstrated that obtaining consent is not practicable. For these circumstances the Health Research Authority has the
- power to approve research applications for access to patient information without consent taking into consideration advice provided by the Confidentiality Advisory Group.
- 6.3 The Caldicott Report concluded that the research community has established many good practices and developed robust solutions to enable access to detailed patient information while ensuring that confidentiality is protected. Models of access such as CPRD and the South London and Maudsley NHS Foundation Trust safe haven (see page 72 of the Report) provide researchers with straightforward access to anonymous information to support their work without compromising patient confidentiality or consent. These services are being promoted to industry, academia and the voluntary sector, both nationally and internationally, the latter via UK Trade and Investment.²²
- 6.4 The review identified that the pool of research candidates could be larger. The Report concluded that more should be done to increase people's understanding of the benefits of research and why researchers may need access to information about 'well'

21 www.gov.uk/government/uploads/system/uploads/attachment_data/file/32457/11-1429-strategy-for-uk-life-sciences.pdf

22 www.ukti.gov.uk

individuals, and also to inform them about how to get involved.

6.5 The NHS Constitution, published after the Report was completed, included a new commitment to inform people about research and to use anonymised information to support research. The UK Clinical Trials Gateway has been developed in response to the Life Sciences Strategy, to inform citizens about clinical trials in which they might be eligible to participate. Additionally, NHS England, working with the HSCIC and CPRD, is issuing patient information leaflets and posters to GP Practices explaining how patient information is used to support a range of needs, including research.

6.6 The NHS Mandate requires NHS England to ensure that the new commissioning system promotes and supports participation by NHS organisations and NHS patients in research funded by both commercial and non-commercial organisations, most importantly to improve patient outcomes, but also to contribute to economic growth. NHS England is working to ensure that all commissioners and providers take research seriously. For example, to achieve authorisation, NHS England has included a requirement for CCGs to have a research strategy, and the criteria for Academic Health Science Networks include a requirement for plans to ensure that the network, including NHS providers, shares data (usually anonymised data but also identifiable data where there is a legal basis) to support research and promote participation in both commercial and non-commercial trials.

6.7 Safe havens for research were recommended in the Data Sharing Review.²³ They have been in use for many years for statistical research and feature three characteristics: a secure environment for processing data; only those with approval can gain access to the data; and penalties for anyone who abuses the data.

6.8 The Report made the following recommendation:

The linkage of personal confidential data, which requires a legal basis, or data that has been de-identified, but still carries a high risk that it could be re-identified with reasonable effort, from more than one organisation for any purpose other than direct care should only be done in specialist, well-governed, independently scrutinised and accredited environments called 'accredited safe havens'.

The Health and Social Care Information Centre must detail the attributes of an accredited safe haven in their code for processing confidential information, to which all public bodies must have regard.

The Informatics Services Commissioning Group should advise the Secretary of State on granting accredited status, based on the data stewardship requirements in the Information Centre code, and subject to the publication of an independent external audit.

Recommendation 10 (section 6.5)

²³ www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Personal-information/Data-Sharing-Review/index.htm

- 6.9 Commissioners in the NHS and public health as well as researchers want access to complex data from multiple sources. There is a need for more information to be linked safely without disclosing personal confidential data where there is no legal basis. The Department is leading work to confirm the challenges to be overcome and the options for consideration including accredited safe havens. Representatives of the research and public health communities and regulators will be involved in this work along with NHS commissioners.
- 6.10 If the decision is taken that accredited safe havens are a solution to the challenges, then the actions in recommendation 10 will be taken forward by the Department and national partner organisations.

Chapter 7. Commissioning

- 7.1 The Department agrees with the review's findings that health and care commissioners should be able to meet their objectives without compromising patient confidentiality or public trust in the health and care system.
- 7.2 A clear legal basis is required to process personal confidential data. In order to understand why there were calls for access to confidential data by NHS commissioners, a team from the review worked with representatives from across a local health economy and the then NHS Commissioning Board. They identified seven types of commissioning activity for which access to personal confidential data might be required. These activities included analyses of populations and outcomes, monitoring integrated care services, and for specialised commissioning. After thorough analysis, the Review Panel gained assurance from the NHS Commissioning Board and from primary care trust representatives that most of the challenges could be overcome in other ways without using confidential data. The Department welcomes the work that the Review Panel and NHS staff did in this area.
- 7.3 When the Health and Social Care Act 2012 was implemented, a range of new commissioning organisations were established, whose staff have had to develop new organisational structures, processes and relationships. Maintaining business continuity in this context has therefore been a challenge, even without the added requirement of moving from primarily using personal confidential data to using pseudonymised or de-identified data as the norm. It is not surprising, therefore, that many commissioners are not yet convinced of the feasibility of using de-identified data for commissioning purposes particularly given the increasingly personalised nature of commissioning and its role in supporting integrated care.
- 7.4 NHS England obtained interim support under the Section 251 regulations to cover an initial period following implementation of the Act. This support was designed to ensure business continuity. More recently approval under Section 251 has been granted to allow time for certain commissioning organisations to become 'accredited safe havens', a status that will allow them in future to process "de-identified data for limited access" under strict conditions.
- 7.5 NHS England is now working with the HSCIC to review systematically the data needs of commissioners and to identify options for how these needs might be delivered without recourse to using identifiable data. This review will

also identify areas in which the HSCIC will need to develop additional capacity and capability to process personal confidential data under its powers, as well as any outstanding issues that may require long-term statutory support.

- 7.6 In the meantime, NHS England is working on short-term solutions for those activities where there is an urgent need for identifiable data, and the Department is consulting with members of the ISCG information governance sub-group so that this work is considered in the wider context of the whole health and care system.
- 7.7 One of the options that will be considered by the ISCG information governance sub-group is the establishment of accredited safe havens as suggested by the review. These accredited safe havens could hold de-identified data subject to strong controls enabling them to link information together and release linked but anonymised data sets to commissioners and others. If new statutory support for commissioning is required, it may be provided through regulations made under Section 251 of the NHS Act.
- 7.8 The Department also welcomes the Confidentiality Advisory Group's intention to provide further guidance to applicants who are intending to seek Section 251 approval to use personal confidential data. The guidance will provide advice on other options with the aim of minimising the use of Section 251.

The right to object

- 7.9 The Report recommended:

The Information Centre's code of practice should establish that an individual's existing right to object to their personal confidential data being shared, and to have that objection considered, applies to both current and future disclosures irrespective of whether they are mandated or permitted by statute.

Both the criteria used to assess reasonable objections and the consistent application of those criteria should be reviewed on an ongoing basis.

Recommendation 11 (section 7.4)

- 7.10 While the Department agrees with this recommendation in principle, and encourages all organisations to implement this recommendation, it may not be technically feasible to implement it across all care settings and all computer systems. Even so, progress is already being made.
- 7.11 The Department has made it clear in relation to the provision in the Health and Social Care Act 2012 for the HSCIC to obtain confidential information that patients and service users are able to block their own information from being disclosed.
- 7.12 There are two places where patients can object to their information being shared. Firstly, the Secretary of State has announced that any patient who does not want personal data held in their GP record to be shared with the HSCIC will have their objection

respected, unless there is legislation to support mandatory disclosure. Secondly, NHS England has made a commitment that personal confidential data that has been shared with the HSCIC will not be shared further without explicit patient consent unless there is a legal basis or an overriding public interest in disclosure.

- 7.13 This right to object is being implemented in the NHS.
- 7.14 As already mentioned in the discussion on recommendation 7, NHS England, the HSCIC, the BMA and the RCGP have worked collaboratively to produce guidance and frequently asked questions on *care.data*. These materials are intended to support GP practices in raising patient awareness and to ensure that GP practices know what to do if a patient objects to the use of personal confidential data beyond their direct care.
- 7.15 The HSCIC will include this in its Code of Practice, and it is a core principle that the Department will retain in respect of future policy making in this area. The HSCIC is monitoring the rate of objections. Where there appears to be an abnormal number of objections, the BMA and NHS England will explore with practices why this might be occurring. Further, as stated before, the Department agrees that the existing rights of individuals to object to their confidential data being shared should be respected. The Department also agrees that, where there is no overriding public interest to justify the sharing of such information, legislation should not be used to remove an individual's right to object.

- 7.16 Leading national organisations from across the health and care system have agreed to promote the Code of Practice and the opportunity to object to employers and organisations.

Organisational compliance

The boards or equivalent bodies in the NHS Commissioning Board, clinical commissioning groups, Public Health England and local authorities must ensure that their organisation has due regard for information governance and adherence to its legal and statutory framework.

An executive director at board level should be formally responsible for the organisation's standards of practice in information governance, and its performance should be described in the annual report or equivalent document.

Boards should ensure that the organisation is competent in information governance practice, and assured of that through its risk management. This mirrors the arrangements required of provider trusts for some years.

Recommendation 12 (section 7.6)

- 7.17 The Department has a clear expectation in relation to the Report recommendation that all organisations responsible for processing confidential patient information for commissioning purposes should implement appropriate arrangements in relation to information governance, including the demonstration of strong leadership on information governance. The

- Department also agrees that healthcare commissioners should adopt information governance procedures that are equivalent to those already established by healthcare providers.
- 7.18 NHS England will ensure that where this requirement is not already included in requirements for both commissioners and providers it will be included as soon as possible, for example in the Standard Contract and the CCG Assurance Framework. Where appropriate, NHS England will require NHS commissioning organisations to provide reassurance on this. One of the ways of achieving this may be through the Information Governance Toolkit, although other mechanisms for publication to ensure effective transparency will also be needed. The HSCIC has been requested to build new requirements into the next release of the toolkit to cover these issues.
- 7.19 The CQC will use the Confidentiality Code of Practice to inform its monitoring plans for information governance in order to reassure itself that organisations are reviewing their practices and adhering to the required standards, and they will be directed towards the best practice contained in the Code of Practice.
- 7.20 For social care, local partners will be expected to use the Information Governance Toolkit and regulated social care providers will be covered by the CQC's use of the Confidentiality Code of Practice. The Department will ask its delivery partners such as Skills for Care and the National Skills Academy to ensure that their products support the appropriate application of information governance.
- 7.21 The NHS Leadership Academy publishes guidance to help NHS boards to develop their board effectiveness and governance. The latest version, published earlier in 2013, includes a section on information governance and the academy has committed to amending the next version to include a reference to the need for the board to include the new duty to share in its information governance responsibilities. The academy is also planning to embed information governance in its work, including its Top Leaders Programme.

Chapter 8. Public health

- 8.1 The Department agrees with the review conclusion that it is important to be clear about the circumstances in which public health practitioners use personal confidential information, and that these should be underpinned by statutory provision and clear information governance arrangements.
- 8.2 The Report made the following recommendation:
- The Secretary of State for Health should commission a task and finish group including but not limited to the Department of Health, Public Health England, Healthwatch England, providers and the Information Centre to determine whether the information governance issues in registries and public health functions outside health protection and cancer should be covered by specific health service regulations.*

Recommendation 13 (section 8.6)
- 8.3 The Department believes that, wherever possible, public health practitioners should work with anonymised data or through the solutions that are to be developed following the work outlined in reference to recommendation 10. The Department agrees with the Report conclusion that essential public health activity should have statutory support to process confidential personal information where alternative arrangements are insufficient. The Department will lead a review into what is required during the latter part of 2013.
- 8.4 The Department will also work with Public Health England, Healthwatch England, NHS England, the HSCIC, the LGA, the Health Research Authority including the Confidentiality Advisory Group, and other stakeholders identified by the review.

Chapter 9. Education and training

9.1 The Department agrees that there needs to be a significant shift in the approach to learning about information governance, away from a reliance on the mandatory online training tool in the Information Governance Toolkit, which is the only training most people receive. Health and care professionals should have formal information governance education at undergraduate and postgraduate level, and through continuing professional development.

9.2 For those who are not experts, information governance can seem complex and daunting. The HSCIC has published confidentiality guidance²⁴ that includes five simple rules for staff on how to deal with personal confidential data. The rules are backed up with explanations and more information and will be a good basis for those developing education and training material for non-specialist staff.

9.3 The Department also agrees that networks of information governance leads should be strengthened and extended to foster greater mutual learning from experience across the health and social care system.

9.4 The Report made two recommendations:

Regulatory, professional and educational bodies should ensure that:

- *information governance, and especially best practice on appropriate sharing, is a core competency of undergraduate training; and*
- *information governance, appropriate sharing, sound record keeping and the importance of data quality are part of continuous professional development and are assessed as part of any professional revalidation process.*

Recommendation 14 (section 9.2)

9.5 The Department agrees with this recommendation.

9.6 Information governance is included within the Professional Capabilities Framework for social workers. The Department will work with The College of Social Work and Higher Education Institutes to ensure that social work qualifying courses contain the most up-to-date legal requirements and best practice. Similarly, the Department will work with Skills for Care to ensure that

24 www.hscic.gov.uk

appropriate training is available for social care workers and with the National Institute of Health Research for the research community.

- 9.7 Health Education England is committed to working with professional regulators and education institutions to incorporate the revised Caldicott principles and good practice into new curricula as they are developed, adjusting existing curricula as part of the regular refresh cycle and also including good information governance and good information sharing practice in the current work on training and development of healthcare assistants and other junior staff.
- 9.8 The Academy of Medical Royal Colleges will include information governance in reviews of curricula for postgraduate training.

The Department of Health should recommend that all organisations within the health and social care system which process personal confidential data, including but not limited to local authorities and social care providers as well as telephony and other virtual service providers, appoint a Caldicott Guardian and any information governance leaders required, and assure themselves of their continuous professional development.

**Recommendation 15
(section 9.4.2)**

- 9.9 The Department is supportive of the role carried out by Caldicott Guardians. The arrangements have worked well in health and adult social care and the Department recommends that all organisations in the health and social care system appoint a Caldicott Guardian. Smaller organisations should appoint a Caldicott lead and ensure that they have access to a Caldicott Guardian.
- 9.10 Local authorities should consider extending Caldicott Guardian arrangements to children's services where they have not already done so. All Caldicott Guardians and Caldicott leads should be offered effective training and support. NHS England will include this requirement within the Standard Contract for providers and CCG Assurance Framework (December 2013). The Department is exploring how to best support the appointment, training and development of Caldicott Guardians in social care and local government and in the research community.
- 9.11 As discussed under recommendation 12, the Department is expecting organisations across health and social care to strengthen their leadership on information governance through ensuring that Caldicott Guardians or leads, Senior Information Risk Owners and appropriate information governance staff are in place, trained and have time to focus on information governance.

Chapter 10. Children and families

- 10.1 The Report highlighted issues around management of, and access to, ‘family records’, which are an important part of children’s social care. The Department agrees that there are important legal and ethical issues that need to be resolved around how information about each family member is obtained, how organisations check the accuracy of information provided by third parties, and with whom this information might be shared.
- 10.2 The Report made the following recommendation:
- Given the number of social welfare initiatives involving the creation or use of family records, the Review Panel recommends that such initiatives should be examined in detail from the perspective of Article 8 of the Human Rights Act. The Law Commission should consider including this in its forthcoming review of the data sharing between public bodies.*

**Recommendation 16
(section 10.3)**
- 10.3 The Law Commission will be consulting on issues relating to data sharing²⁵ between public bodies during the autumn and this issue will be included. The final report from the Law Commission is expected in the spring of 2014. The Department is working with the Department for Education to input to the Law Commission’s review.
- 10.4 The Department also recognises the valuable contribution that Jean Gross, the former Government’s Communication Champion for children, has made to this debate.
- 10.5 The Report concluded that there would be clear benefits if a single, common approach to sharing information for children and young people could be adopted. The Department does not believe that there is a need for additional guidance in this area – *Working Together to Safeguard Children*²⁶ and *Information Sharing: Guidance for practitioners and managers*²⁷ provide a clear blueprint for organisations and professionals who work with children. However, the Department does not believe that it is

25 <http://lawcommission.justice.gov.uk/areas/data-sharing.htm>

26 www.education.gov.uk/aboutdfe/statutory/g00213160/working-together-to-safeguard-children

27 www.education.gov.uk/childrenandyoungpeople/strategy/integratedworking/a0072915/information-sharing

acceptable to tolerate bad practice in relation to safeguarding children. The Department will work with the Department for Education – involving external regulators such as the CQC and Ofsted, as well as professional regulators – to see whether there is a need to develop an approach to identifying and tackling bad practice. This new approach will need to be clear that the public interest may justify sharing information about children and other family members where there are safeguarding concerns. Evidence from a number of sources, including domestic homicide case reviews, suggests that some health professionals are not applying the public interest disclosure test appropriately, and tackling this will form a key part of our work with the Department for Education.

10.6 The Department also agrees with the review's conclusion that changing the NHS number for children, including adopted children, should be avoided wherever possible. While there will be cases where the location and/or identity of a child will need to be protected, and placing 'shielding requirements' on the child's health and social care records would be a better option than changing their NHS number, this could have repercussions for the health and care received by the child. The Department will therefore work with the Department for Education and those involved in caring for children to ensure that appropriate arrangements for assessing the risk to a child are established so that shielding requirements are used only when absolutely necessary.

10.7 The Report also made the following recommendation which the Department is considering here rather than under the heading of data management:

The Department of Health and the Department for Education should jointly commission a task and finish group to develop and implement a single approach to recording information about 'the unborn' to enable integrated, safe and effective care through the optimum appropriate data sharing between health and social care professionals.

**Recommendation 18
(section 12.8)**

10.8 The Report explained some of the complex issues relating to health and care for pregnant women and used the term 'the unborn' to describe the foetus. The Department accepts the recommendation that there should be an agreed approach to recording information about the unborn to address the complex ethical and legal issues. The Department is discussing options with the Department for Education on how to take this forward.

Chapter 11. New and emerging technologies

- 11.1 The Department shares the Report's concern that there is a perceived lack of clarity about a patient's right to access the record of 'virtual' consultations and uncertainty about for how long records would be kept. The Department agrees that patients should have access to information about themselves even if it was obtained through new or non-traditional approaches (for example, virtual consultations) to delivering health and care services.
- 11.2 The Report made the following recommendation:
- 11.3 This is already required practice, but the Department accepts the Report's evidence that it is not widely understood. NHS England will ensure that there is clear guidance available for those offering virtual consultations on health matters and for medical devices used for biometric monitoring. The Department will explore what might be offered to support commissioners of social care utilising new technologies to support care.

The NHS Commissioning Board, clinical commissioning groups and local authorities must ensure that health and social care services that offer virtual consultations and/or are dependent on medical devices for biometric monitoring are conforming to best practice with regard to information governance and will do so in the future.

**Recommendation 17
(section 11.2)**

Chapter 12. Data management

12.1 The Department shares the Report's view that there should be consistency in the information governance requirements for providers.

12.2 The Report made two recommendations:

All health and social care organisations must publish in a prominent and accessible form:

- *a description of the personal confidential data they disclose;*
- *a description of the de-identified data they disclose on a limited basis;*
- *who the disclosure is to; and*
- *the purpose of the disclosure.*

Recommendation 19
(section 12.9)

12.3 The Department believes that this recommendation is closely linked to recommendations 7 and 9 which also relate to providing individuals with information. The Confidentiality Code of Practice will make it clear that all parts of the care system should act transparently and meet the requirements of the Data Protection Act for fair processing. The work to address recommendations 7 and 9 will

also help to deliver this recommendation.

12.4 The Department expects all health and care organisations to ensure that the information provided does not exclude disadvantaged groups.

The Department of Health should lead the development and implementation of a standard template that all health and social care organisations can use when creating data controller to data controller data sharing agreements. The template should ensure that agreements meet legal requirements and require minimum resources to implement.

Recommendation 20
(section 12.10)

12.5 Data sharing agreements set out a common set of rules to be adopted by the various organisations involved in a data sharing operation. The ICO has published a Data Sharing Code of Practice,²⁸ which includes guidance on the content of such data sharing agreements. The Department agrees that a standard template for data sharing agreements would be helpful, particularly to support issues around

²⁸ www.ico.org.uk/for_organisations/data_protection/topic_guides/data_sharing

sharing with non-registered, non-regulated staff. The Department will ask the ISCG information governance sub-group to commission the required work for completion by the end of

2013 building on the local initiatives to develop and implement standard data sharing agreements that are already under way.

Chapter 13. System regulation and leadership

13.1 The Department agrees that there needs to be a way of holding the health and social care system to account on information governance.

13.2 The Report made the following recommendations:

The Health and Social Care Information Centre's Code of Practice for processing personal confidential data should adopt the standards and good practice guidance contained within this report.

**Recommendation 21
(section 13.2)**

13.3 The HSCIC's Confidentiality Code of Practice is statutory guidance to which all health and social care organisations, including the research community, are legally required to have regard. It will incorporate the standards and good practice contained in the Report.

The information governance advisory board to the Informatics Services Commissioning Group should ensure that the health and social care system adopts a single set of terms and definitions relating to information governance that both staff and the public can understand. These terms and definitions should begin with those set out in this document. All education, guidance and documents should use this terminology.

**Recommendation 22
(section 13.3)**

13.4 The Department agrees that a single set of terms and definitions relating to information governance would be helpful, and the ISCG information governance sub-group will lead on taking this forward, to be completed by 31 March 2014. The Department will ask the ISCG to consider whether or not the resulting glossary should be adopted as an Information Standard. Once a single set of terms and definitions has been developed, Health Education England will incorporate it into its education programmes for staff, including staff at bands 1–4, as referred to in the Francis Report. The Department will ask Skills for Care to

do the same for care staff. The Department will also ask the HSCIC to adopt the glossary for the Confidentiality Code of Practice, will discuss with the new Information Sharing Centre of Excellence opportunities for extending the glossary across all the relevant bodies, and will explore with the National Institute for Health Research how to extend the glossary across the research community.

The health and social care system requires effective regulation to ensure the safe, effective, appropriate and legal sharing of personal confidential data. This process should be balanced and proportionate and utilise the existing and proposed duties within the health and social care system in England. The three minimum components of such a system would include:

- *a Memorandum of Understanding between the CQC and the ICO;*
- *an annual data sharing report by the CQC and the ICO; and*
- *an action plan agreed through the Informatics Services Commissioning Group on any remedial actions necessary to improve the situation shown to be deteriorating in the CQC-led annual 'data sharing' report.*

**Recommendation 23
(section 13.3)**

13.5 The Department welcomes this recommendation and is pleased that the ICO and CQC have confirmed that work has already started to formalise these partnership arrangements; a Memorandum of Understanding will be agreed by October 2013.

13.6 The focus of this joint work is to articulate where information about concerns in relation to the protection of people's information rights or in relation to the quality of care should be shared between the respective regulators. The partnership will make clear that the CQC's remit is concentrated on the quality of care that people receive. They will also work together with others in the system to understand how best to collect and publish information about data breaches to ensure that the system is efficient and avoids duplication of reporting requirements (see also recommendation 6).

13.7 The Department also agrees that professional regulators have a role to play in ensuring good information sharing practices that do not disadvantage patients. In addition, defence unions should be encouraged to support professionals who share information in the best interests of their patients or in the wider public interest.

13.8 The Department will work with the professional regulators to investigate professionals who have undermined patient care by failing to share information effectively, and with defence unions to support professionals who share information in keeping with the standards and good practice contained in the review.

Chapter 14. Conclusion and recommendations

14.1 The Department agrees that the standards, good practice and principles contained in the Report should underpin information governance across health and social care services. While it will not always be possible to implement recommendations to the letter, the aim is to do so within the spirit intended by the review's findings.

14.2 The Report made three final recommendations:

The Review Panel recommends that the Secretary of State publicly supports the redress activities proposed by this review and promulgates actions to ensure that they are delivered.

**Recommendation 24
(section 14.1)**

14.3 The Department supports this recommendation. The ISCG is best placed to take forward the work required to drive the implementation of the recommendation. The Secretary of State for Health has asked Dame Fiona Caldicott to establish an advisory group, the Independent Information Governance Oversight Panel, to oversee this activity and to report to

the Secretary of State on progress annually, with the first report to be one year after the publication of this government response.

The Review Panel recommends that the revised Caldicott principles should be adopted and promulgated throughout the health and social care system.

**Recommendation 25
(section 14.2)**

14.4 The original Caldicott principles were well received by the clinical and practice communities, and many Caldicott Guardians have relied upon them in their daily work for some 15 years since Dame Fiona's first Report. Dame Fiona's revised principles represent a welcome update and offer a new opportunity to promote information governance throughout the health and social care system and challenge a culture that undermines the quality of patient care by failing to share information effectively.

14.5 The HSCIC guidance, published alongside this response provides simple rules that complement the revised Caldicott principles. The guidance will help everyone working in

health and care to follow good information governance practice in their daily work.

14.6 The Department accepts the revised Caldicott principles and will ensure that the principles and the actions in this response, particularly those relating to information sharing, are aligned. The principles will be included in the Confidentiality Code of Practice published by the HSCIC.

14.7 The Department has adopted the revised principles along with many other organisations across the health and care system. In addition, the ICO welcomes these revised principles as an effective way to help those working with sensitive personal data in the health and care system to meet the requirements of the Data Protection Act. The Department and a growing number of organisations are working the principles into their guidance, training and other work programmes. For example:

- the Department will review its internal policies in autumn 2013 to ensure alignment with the revised Caldicott principles;
- the NHS Leadership Academy will build these principles into its leadership programmes for the NHS; and
- the Professional Standards Authority is reviewing its document *Standards for Members of NHS Boards and Clinical Commissioning Group Governing Bodies in England*²⁹ over the coming months and will consider

whether the wording should be amended to include reference to the new Caldicott duty to share. The revised standard will be used to measure performance in 2014/15.

The Secretary of State for Health should maintain oversight of the recommendations from the Information Governance Review and should publish an assessment of the implementation of those recommendations within 12 months of the publication of the review's final report.

Recommendation 26
(section 14.3)

14.8 HSCIC will provide a team to support and co-ordinate the implementation of many of the actions in this response. The ISCG information governance sub-group will be responsible for monitoring progress on all of the actions described in this response. In addition, as noted above, Dame Fiona Caldicott has established an advisory group, the Independent Information Governance Oversight Panel, to oversee this activity and will report to the Secretary of State on progress annually, with the first report to be one year after publication of this government response.

14.9 Some of the actions outlined in this response require significant further work. Work undertaken by the Department will include appropriate impact assessments and consideration of public duties including the health inequalities duty and the public sector equality duty.

29 www.professionalstandards.org.uk/library/document-detail?id=89114436-21e2-47df-b5a0-7d5308b66b8e

Table of commitments – who’s doing what

This table summarises the expectations and commitments that are within the body of this government response with a reference to the section or recommendation where the commitments or expectations can be found.

Who	What
Department of Health commitments	<ul style="list-style-type: none"> • set the strategic vision and direction and act as steward of the system to deliver the review’s recommendations (introduction) • work with national partners to set the framework for delivery through local organisations (introduction) • routinely include information sharing and information governance in all its work to improve care (introduction) • consider what standards and guidance are needed to help people who are organising their own care (introduction) • work with ADASS and the LGA to ensure that local authority commissioners of adult social care are supported and encouraged to lead the local action required (introduction) • work with partner organisations to consider how electronic access might be extended to care records outside the NHS (1) • commission an options analysis to determine whether audit trails are the best approach (1) • take the revised Caldicott principles into consideration when reviewing the CQC regulations (2) • include the recommendation on the use of NICE Clinical Guideline 138 in the ongoing work with the bodies who provide guidance and best practice advice to local authorities and to care providers and with regulators and professional bodies (2) • commission the Professional Standards Authority to work with other organisations to ensure that all health and social care professional regulators publish consistent guidance that reflects the messages in the HSCIC’s Confidentiality Code of Practice (3) • work with the social care, public health and research sectors to support them in any specific local actions relating to reporting of data breaches (5) • ask CIPFA and SOLACE to include a reference to publishing data breaches when next updating their guidance on Annual Governance Statements (6) • work with local authorities to encourage them to publish details of incidents (6)

Who	What
Department of Health commitments	<ul style="list-style-type: none"> • ask the Leeds project to include incident reporting in its work (6) • work with NHS England to develop a consent management standard, consider how best to enable implementation of mechanisms for sharing the decisions of individuals between different systems and recommend to the ISCG that these standards are considered a priority (8) • work with the adult social care sector to consider how, where they do not already exist, the rights, pledges and duties of the NHS Constitution might be extended to the adult social care system (9) • lead work to confirm the challenges to be overcome and the options for consideration in relation to commissioners' access to personal confidential data – across the NHS, public health and research (10) • ask delivery partners such as Skills for Care and the National Skills Academy to ensure that their products support the appropriate application of information governance (12) • lead a review into whether public health activity should have further statutory support to process confidential personal information where alternative arrangements are insufficient (13) • work with The College of Social Work and Higher Education Institutes to ensure that social work qualifying courses contain the most up-to-date legal requirements and best practice (14) • work with Skills for Care to ensure that appropriate training is available for social care workers (14) • undertake further work to support the appointment, training and development of Caldicott Guardians in social care and local government and research (15) • work with the Department for Education and others to see whether there is a need to develop an approach to identifying and tackling bad practice (16) • work with the Department for Education and others to ensure that appropriate arrangements for assessing the risk to a child are established (16) • develop and implement an agreed approach to recording information about the unborn (18) • explore what might be offered to support commissioners of social care for those offering virtual consultations and for medical devices used for biometric monitoring (17) • ask leading organisations to extend the use of the glossary (once agreed) across the health and care system (22) • work with the professional regulators and defence unions to promote the standards and good practice contained in the review (23) • promote the revised Caldicott principles (25)
Independent Information Governance Oversight Panel commitment	<ul style="list-style-type: none"> • report to the Secretary of State on progress annually, with the first report to be one year after publication of this government response (26)

Who	What
All staff and workers within the health and care system expectation	<ul style="list-style-type: none"> • be aware that the duty to safeguard children or vulnerable adults may mean that information should be shared, if it is in the public interest to do so, even without consent (introduction) • look at information governance best practice and how it affects their work (introduction)
All health and care organisations expectations	<ul style="list-style-type: none"> • examine their existing arrangements, and lead by example with their local partners to make it easier to share information (introduction) • expect that relevant personal confidential data is shared among the registered and regulated health and social care professionals who have a legitimate relationship with the individual (2) • seek advice from the ICO and refer to the HSCIC's Confidentiality Code of Practice for further advice on managing and reporting data breaches (5) • explain and apologise for every personal data breach, with appropriate action agreed to prevent recurrence (5) • clearly explain to patients and the public how the personal information they collect could be used in de-identified form for research, audit, public health and other purposes (7) • make clear what rights the individual has open to them, including any ability to actively dissent (7) • use the best practice contained in the HSCIC's Confidentiality Code of Practice when reviewing their information governance practices to ensure that they adhere to the required standards (12) • that social care providers use the Information Governance Toolkit (12) • appoint a Caldicott Guardian or Caldicott lead with access to appropriate training and support (15) • local authorities consider extending Caldicott Guardian arrangements to children's services (15) • strengthen their leadership on information governance (15) • ensure that the information provided to inform citizens about how their information is used does not exclude disadvantaged groups (19) • use the revised Caldicott principles in all relevant information governance material and communications (25)
Local NHS providers expectation	<ul style="list-style-type: none"> • audit their information sharing practices in adult NHS services against NICE Clinical Guideline 138 (2)
Local commissioners expectations	<ul style="list-style-type: none"> • use the NICE Quality Standard 15 in commissioning and monitoring adult NHS services (in relation to information sharing) (2) • investigate, manage, report and publish personal data breaches and ensure that commissioned bodies are investigated, managed, reported and published appropriately (6) • implement appropriate arrangements in relation to information governance including the demonstration of strong leadership on information governance and adopt information governance procedures that are equivalent to those already established by healthcare providers (12)

Who	What
Leading national organisations expectations	<ul style="list-style-type: none"> • take action to establish the right conditions for improved sharing (4) • have regard to the HSCIC's Confidentiality Code of Practice and promote the Code of Practice and the objection details to employers and organisations (11) • welcome the revised Caldicott principles and work the principles into their guidance, training and other work programmes (25)
Academy of Medical Royal Colleges commitment	<ul style="list-style-type: none"> • include information governance in reviews of curricula for postgraduate training (14)
BMA commitment	<ul style="list-style-type: none"> • with NHS England, explore reasons for abnormal number of objections to sharing of information with <i>care.data</i> (11)
Confidentiality Advisory Group of the Health Research Authority commitment	<ul style="list-style-type: none"> • provide additional guidance on the website to applicants who are intending to seek approval under Section 251 to use personal confidential data (10)
CQC commitments	<ul style="list-style-type: none"> • the evolving approach to information governance monitoring work will focus on how well information is used and shared to support delivery of good quality care and ensure that it can assess the effectiveness of information sharing in different settings and pathways of care (2 & 4) • use the HSCIC's Confidentiality Code of Practice to inform its monitoring plans for information governance (12) • agree a Memorandum of Understanding and produce an annual data sharing report with the ICO (23)
Health Education England commitment	<ul style="list-style-type: none"> • work with professional regulators and education institutions to incorporate the revised Caldicott principles, a single set of terms and definitions and good practice into curricula and work relating to bands 1–4 and other staff (14 & 22)
HSCIC commitments	<ul style="list-style-type: none"> • monitor the rate of objections to the sharing of information with the new <i>care.data</i> service (11) • build new requirements into the next release of the toolkit to cover the relevant aspects of the issues in recommendation 12 (12) • provide a team to support and co-ordinate the implementation of many of the actions in this response (26)
ICO commitments	<ul style="list-style-type: none"> • support ongoing work by others to ensure that a clear and easily understandable message on how their information is used is delivered to patients, people who use care and support and the wider public (7) • support work to increase awareness among patients and the public about the existence of the NHS Constitution and what it contains (9) • agree a Memorandum of Understanding and produce an annual data sharing report with the CQC (23)

Who	What
ISCG information governance sub-group commitments (if directed by the ISCG)	<ul style="list-style-type: none"> • consider how best to support the extension of the Information Governance Toolkit across local authorities (4) • consider the establishment of accredited safe havens (10) • commission work to produce a data sharing agreement template (20) • agree a single set of terms for information governance and consider whether it should be adopted as a standard (22) • drive implementation activity and monitor progress on all of the actions described in this response (24 & 26)
Monitor commitment	<ul style="list-style-type: none"> • when they next update their requirements for foundation trusts' annual reports, consider including a requirement to publish all data breaches (6)
NHS Employers commitment	<ul style="list-style-type: none"> • work together with Trade Union Partners through the National and Regional Social Partnership Forums to identify areas of good practice which can inform future development work starting with a joint workshop with NHS England and Social Partnership Forum partners in September 2013
NHS England commitments	<ul style="list-style-type: none"> • lead work on electronic access to health records (1) • give a clear steer to commissioners of care on the need to monitor provider information governance performance through using a variety of mechanisms, and to take account of the findings of inspection reports published by the CQC where poor information sharing practice has been identified (4) • include actions to take the Caldicott recommendations forward, for example in work on the CCG Assurance Framework and the Standard Contract (4, 12 & 15) • include data breaches in scope for the duty of candour including in any monitoring and reporting (5) • when they next update their requirements for Quality Accounts, consider including a requirement to publish all data breaches (6) • include the proposed new standard on consent management within the Technology Strategy, due to be published in December 2013 (8) • review the intelligence requirements for NHS commissioners' access to personal confidential data, identify options to meet these data needs and, where alternatives to using personal confidential data cannot be found, work with the Department to identify options that could satisfy these requirements (10) • with BMA, explore reasons for abnormal number of objections to sharing of information with <i>care.data</i> (11) • require NHS commissioning organisations to provide reassurance on recommendation 12 and to publish findings (12) • develop guidance for those offering virtual consultations and utilising devices and holding personal confidential data, for example for remote telemonitoring on health matters (17)
NHS Leadership Academy commitment	<ul style="list-style-type: none"> • include the new duty to share in guidance for NHS boards and Top Leaders Programme (12)
NHS Trust Development Authority commitment	<ul style="list-style-type: none"> • when they next update their requirements for trusts' annual reports, consider including a requirement to publish all data breaches (6)

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