



INFORMATION
to **share** or
not to share

The First Year

**The Independent Information Governance
Oversight Panel's report to the Secretary of
State for Health**

December 2014



Foreword by Dame Fiona Caldicott

This Report to the Secretary of State for Health in England is based on the work of the Independent Information Governance Oversight Panel, since its establishment a little over a year ago.

He asked us to examine the implementation of the recommendations that we had put to him in 2013 in our Report on the Review of Information Governance, and which the government had accepted.

The key principles underpinning our recent work are those that I described in my foreword to that Report. I said: “Every citizen should feel confident that information about their health is securely safeguarded and shared appropriately when that is in their interest.” Citizens should feel similarly confident about their social care information. My 2013 foreword added: “Everyone working in the health and social care system should see information governance as part of their responsibility.”

Unfortunately the cultural change that we called for in relation to information governance has only emerged in parts of the system. However, the recent establishment of the National Information Board and the development by the Department of Health of structures to address the challenges around it, not least the greater awareness by the public of these issues, can give some optimism that the next year will see much improvement.

As this report is being finalised the new role of a National Data Guardian for health and social care has been announced. I am delighted to accept Secretary of State’s invitation to be its first holder.

I should like to thank all the members of the Panel and our Support Team for their unstinting work since we were established. Their commitment has been outstanding.



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Executive summary

Chapter 1: Introduction

People's lives may be lost if information is not shared appropriately across the care team looking after them. People's trust may be damaged if information they have provided in confidence is improperly disclosed. When handling people's confidential data for their care, health and care organisations must not compromise either their safety or individuals' trust. All health and care organisations must share information wisely and protect it with vigilance, in the interests of all service users, all of the time.

These apparently simple principles are reflected in laws, rules and procedures that are known as information governance. In 2012-13 an Information Governance Review was carried out for the Department of Health by Dame Fiona Caldicott. Her report, published in April 2013, became known as the Caldicott2 Report to distinguish it from an earlier report that she delivered to the Department in 1997.

The Government accepted all the 26 recommendations in the Caldicott2 Report and the Secretary of State for Health asked Dame Fiona to set up a new independent panel to provide annual updates on what progress was being made in implementing them. The Independent Information Governance Oversight Panel was also tasked with reporting on the state of information governance across the health and care system as a whole. This is IIGOP's first annual report.

The introduction explains IIGOP's role and ways of working. It notes that IIGOP began its work in a rapidly changing environment which brought advantages and disadvantages. The advantages included widespread support for the principles and recommendations in the Caldicott2 report, which could be considered to have established a new consensus about how health and social care information should be safeguarded and shared.

However, an unintended consequence of the changes introduced by the Health and Social Care Act 2012 was the loss of centres of expertise in information governance that had existed in Strategic Health Authorities and Primary Care Trusts. The emergence of new organisational structures at a time of financial stringency appears to have made it difficult to employ sufficiently expert information governance staff. In spite of helpful interventions by Ministers, senior people in some of these new organisations were slow to appreciate the complexity and importance of information governance in the health and social care system.

The Introduction explains the structure of this report and makes an important observation about transparency.

Chapter 2: Progress on Caldicott2 recommendations

Bringing about appropriate sharing of information at every stage of the care pathway required a fundamental change in professional and organisational culture. It was not realistic to expect that this would be achieved within a single year.

There is evidence of inspirational progress being made in local initiatives across England, where direct care staff, on their own initiative, are sharing appropriately without compromising security and trust. Chapter 2 gives examples. It also commends national actions to encourage the sharing of information across boundaries between registered and regulated professionals for direct care, such as the Guide to Confidentiality, published by the Health and Social Care Information Centre in September 2013.

However, in too many organisations across England, the necessary change in culture has not been apparent. It is the view of IIGOP that progress in achieving appropriate sharing of information for direct care will not be satisfactory until core building blocks are in place at national level. These include a clear definition of who is included in the direct care team and clear guidelines about when people must give explicit consent to information about them being shared and when consent can be implied. Consistency is also required in the arrangements for people to be able to object or opt out of information about them being used for research or other purposes.

IIGOP's agenda during its first year has included frequent discussion of how much identifiable information about people is needed by commissioners to deliver their statutory functions. Progress in resolving this issue has been slow. It is regrettable that problems identified by the Caldicott2 Review team in the autumn of 2012 remain unresolved in the autumn of 2014.

Chapter 2 looks at the progress made in implementing the 26 recommendations in the Caldicott2 report, but to retain readability, most of the detail is given in the Annex to this report.

It notes that leadership in parts of the health and care system has been disappointing. There was evidence of Ministerial leadership and intervention, but the Department of Health was not able to provide sufficient resource to drive the necessary actions relating to information governance, or to emphasise the priority that other organisations should give to this work. More recently there has been welcome evidence that the Department is adopting a more proactive approach.

Chapter 3: Current state of information governance

Over the past year, the subject of information governance has moved from the backwaters of organisational management into the mainstream of public discussion. The main driver of this heightened interest was the first attempt to launch of *care.data*, a programme to extract data from GP records and combine it with other data to create a richer understanding of people's health and care experience. Chapter 3 explains the Panel's reservations about how the programme was communicated to the public and describes its subsequent role of providing advice before the programme was ready to be trialled.

Although *care.data* may have distracted IIGOP from other useful work, it has produced a significant benefit in leading to much greater public awareness of the importance of information governance. Public debate has become better informed, as well as more intense.

In spite of the public becoming more suspicious of data harvesting initiatives, trust in medical¹ professionals remains extremely high. Public opinion research has shown that most patients want any healthcare professional who treats them to have secure electronic access to key data from their GP health record. Most were surprised that emergency care doctors do not have automatic access to records, and concerned that lack of access may lead to delays in treatment and fatal errors. The public's main concerns about the use of information about them were suspicions around usage creep, lack of personal benefits and loss of data.

The disestablishment of the National Information Governance Board (NIGB) on 31st March 2013 left the system in England without a statutory arbiter, to which organisations could turn for the authoritative resolution of difficult questions. Although IIGOP has tried to assist organisations over the past year by offering its opinion, when asked, it has not had the NIGB's level of statutory authority or resource.

Some of the NIGB's functions were successfully transferred to the Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA). The Care Quality Commission has made significant progress in fulfilling its new statutory duty to monitor the information governance practices of registered health and social care providers. It has made questions about information governance a "Key Line of Enquiry", to be asked in inspections of all health providers and it has strengthened the information governance component in adult social care inspections. The next stage is for the CQC to be able to show that enhanced monitoring leads to improvements in practice.

The need for information sharing gained added impetus as politicians of all parties called for greater integration between health and social care. Integration was championed by ministers and introduced in practice through the integration pioneer projects.² On the 11th November 2013 the Government announced that 14 areas of the country had been selected with the aim "to make health and social care services work together to provide better support at home and earlier treatment in the community to prevent people needing emergency care in hospital or care homes." However, many of the pioneers identified challenges to effective information sharing. In addition the Care Act 2014 required local authorities to improve continuity of care by transferring a wide range of information to another council when a service user intends to move. Other initiatives such as pooled budgets are also dependent upon information sharing.

Chapter 4: The future of oversight

Soon after IIGOP was established, discussions began in the Department of Health about how the panel's role might be enhanced. Officials set out a vision of a "three-pillar model" for identifying and resolving system-wide information governance issues.

The first pillar was to be made up of system leaders from the DH, the NHS and social care, who would set the strategy for the health and care system on technology and information, and commission the work needed to deliver it. The second pillar would be constituted by experts from the DH, NHS England, the Health and Social Care Information Centre, Public

¹ The term 'medical' is used here, rather than clinical, as this is the term used in research. It is not intended to be medically biased.

² <https://www.gov.uk/government/news/integration-pioneers-leading-the-way-for-health-and-care-reform--2>

Health England and other bodies, who would suggest solutions to problems. The third pillar would provide independent assurance on whether these suggested solutions were appropriate and had been subjected to adequate public consultation. It was suggested that IIGOP's role and resources could be enhanced to permit it to become this third pillar. Chapter 4 explains this thinking and provides a graphic on page 24 with the names of the organisations that were formed to perform these functions.

During a debate in the House of Lords in May 2014, in the face of criticism of the *care. data* programme, the Government said it was sympathetic to calls for IIGOP to be placed on a statutory footing. The system of oversight, scrutiny and advice had to be "robust and coherent". Ministers would explore with Dame Fiona Caldicott and all interested parties how best to achieve this.

Chapter 4 describes how this developed in November 2014 into the appointment of Dame Fiona as the first National Data Guardian for health and social care, "*to be the patient's champion when it comes to the security of personal medical information*".³

Chapter 5: Conclusions and Recommendations

In addition to the findings of individual chapters that have been set out above, the Panel has reached some overarching conclusions about implementing and promulgating the recommendations and about building public trust. The recommendations that flow from them are that transparency and openness is required to enable public understanding and participation, that individuals must be able to opt out of data sharing arrangements and be confident that their wishes are being respected consistently across the system and that all organisations need strong leadership to drive the delivery of the recommendations above.

The report also contains Appendices, which are described in the Index. A separate Annex to this report provides further detailed comment.

³ https://www.gov.uk/government/speeches/innovation-and-efficiency?utm_source=twitter&utm_medium=social



1 Introduction

This is the first annual report of the Independent Information Governance Oversight Panel (IIGOP), a body established at the request of the Secretary of State for Health and announced by the Department of Health on 5th November 2013. The role of IIGOP is to advise, challenge and report on the state of information governance across the health and care system in England. The panel is non-statutory and independent.

Good information governance⁴ in a health or social care organisation is essential for maintaining the safety and effectiveness of care, efficiency and trust. In a good organisation, information about patients and those seeking care will be shared appropriately among members of the team responsible at every stage of the care pathway. There will be no improper use of confidential personal data; patients and service users will be able to confide in the professionals without fear of unauthorised disclosure. And in a good health and social care *system*, there will be strict rules to allow data to be used for other purposes such as research and planning better services without breaching confidentiality.

A critical issue in relation to information governance in health and social care is maintaining public trust. This requires careful attention to the protection of the confidentiality of people's data while ensuring that it is shared effectively when that is indicated. Lack of appropriate information security – or inappropriate sharing of personal information provided in confidence – could betray people's sensitive medical or social details and damage their trust. Equally, lack of adequate information sharing within the direct care team could prevent access to the best care and endanger their lives. All health and social care organisations must balance these twin responsibilities of protecting and sharing information.

This report looks at developments over the past year in sharing for direct care. It also considers initiatives for using data about individuals for purposes other than direct care, including helping commissioners to fulfil their role and for making new uses of patients' GP records through the proposed *care.data* programme.

Before giving an account of progress during the past year, it is useful to provide some background.

Origins of IIGOP

In 2012 the then Secretary of State for Health asked Dame Fiona Caldicott to lead an independent review of information governance across the health and care system in England. Dame Fiona agreed and in order to distinguish this review from her previous report to the Department of Health in 1997, it became known as the Caldicott2 Review. The final report from the Review panel was sent to Secretary of State in March 2013 and published in April 2013.⁵

⁴ Information governance (IG) is defined as “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.” Information: To share or not to share? The Information Governance Review. <https://www.gov.uk/government/publications/the-information-governance-review>

⁵ Information: To share or not to share? The Information Governance Review. <https://www.gov.uk/government/publications/the->

The Secretary of State immediately welcomed the report and published a full, considered response in September 2013,⁶ accepting all of its 26 recommendations. One recommendation was that the Secretary of State “*should maintain oversight of the recommendations*” and, within 12 months, “*publish an assessment of the implementation of those recommendations.*”

The Secretary of State had anticipated the need for continued oversight when he wrote to Dame Fiona in March 2013 asking her to design and chair a new independent panel. He said: “*As you know, improving the use of data and information is one of my key priorities for the health and care system. Proper information governance is an essential part of this and I would look to the Independent Panel to provide independent advice and challenge to the whole health and care system.*” He added: “*I would welcome annual updates from the Panel on progress made in implementing the recommendations and proposals in your forthcoming Information Governance Review and on the state of information governance across the health and care system. I would also welcome the Panel’s scrutiny of the work of the newly established Informatics Services Commissioning Group and, more broadly, its advice and challenge to the health and care system on Information Governance issues.*”

Dame Fiona accepted this invitation and began assembling the panel, which is now known as the Independent Information Governance Oversight Panel. Its terms of reference are given in Appendix 1.

Membership of the panel was by personal invitation from Dame Fiona. Its 11 members have a broad range of experience: in health and social care; the NHS and local government; doctoring and nursing; community, primary and secondary care; foundation trusts and commissioning. However, it remains a panel of individuals, not representatives of organisations. Dame Fiona reports directly to the Secretary of State. Members of the panel are listed in Appendix 2.

Role and working method

The prime functions of IIGOP are:

1. To provide annual updates to the Health Secretary on what progress has been made in implementing proposals in the Caldicott2 report and on the state of information governance across the health and care system as a whole.
2. To provide advice to the health and care system on information governance issues. Such advice is most likely to come in response to a request from a health or care organisation faced with a difficult problem.
3. To provide challenge to the health and care system on information governance issues.

IIGOP meets quarterly. Between meetings, the work is supervised by a steering group made up of Dame Fiona, five other panel members and a very small support staff. The steering group meets once a month, often in two locations (London and Leeds) joined by a video-conference link. At other times business is conducted through email exchanges to agree a

⁶ <https://www.gov.uk/government/publications/caldicott-information-governance-review-department-of-health-response>

response, or to help Dame Fiona to respond to an issue. This way of working has relied on a high level of personal commitment and a low level of public funding.

IIGOP began its work in a rapidly changing environment which brought advantages and disadvantages. The advantages included support for the principles and recommendations in the Caldicott2 report from the Secretary of State and leading organisations in health and social care. Indeed the report could be considered to have established a new consensus about how health and social care information should be safeguarded and shared.

However, an unintended consequence of the changes introduced by the Health and Social Care Act 2012 was the loss of centres of expertise in information governance that had existed in Strategic Health Authorities and Primary Care Trusts.

Large organisational changes included the appearance of new structures: NHS England, Clinical Commissioning Groups (CCGs), Commissioning Support Units (CSUs), Public Health England and other important bodies. NHS England took over responsibility for specialist commissioning, while local authorities became responsible for the local commissioning of social care, public health and sexual health services. However the emergence of these new structures at a time of financial austerity appears to have made it difficult to employ sufficiently expert information governance staff. Although Ministers have taken active steps to support clarity and improvements in information governance issues, at a senior level there has been a delay in appreciating the complexity and importance of information governance in the health and social care system.

In spite of these barriers, IIGOP observed considerable progress – often at local level – in implementing the recommendations of the Caldicott2 Review.

Structure of this report

Chapter 2 of this report seeks to provide an update on the implementation of the recommendations of the Caldicott2 Review and of the commitments required from health and social care organisations in the Government's response. There were 26 recommendations and 86 commitments. To retain readability, most of the detail is in the Annex to this report. The panel noted that there are a range of initiatives across Government departments and the Cabinet Office that impact on information sharing in health and social care, such as policies for troubled families, criminal justice and child protection. These have not been discussed at length, but are briefly addressed in relation to the delivery of recommendations and commitments.

Chapter 3 looks more generally at the state of information governance in the health and social care system. It describes how the *care.data* programme created great public interest in whether patients' GP data could be anonymised and used for other purposes to benefit research and NHS service improvement. This was the development that moved information governance out of the backwaters of clinical management into the mainstream of political, media and public interest. Other initiatives have also increased the importance of information governance, including greater integration of health and care services, supported across the political spectrum. Integration cannot be effective without improved information sharing among all the professionals involved in people's care. The chapter

includes evidence about changing practice in organisations, drawing on public opinion research and evidence from Information Governance Toolkit returns.

Chapter 4 considers proposals to strengthen the role of IIGOP.

Chapter 5 draws conclusions after IIGOP's first year and makes three new recommendations.

Transparency

When the Department of Health announced the establishment of IIGOP in November 2013, it said: *“All the independent advice and challenge which the panel provides will be published so that maximum transparency is achieved. Dame Fiona Caldicott, chair of the new independent panel, is committed to making the work of her panel as public as possible ...”*⁷

The Panel committed to achieving maximum transparency, while reserving the right to deliberate in private about the advice and challenge that it might in future provide. However, Government rules prevented IIGOP from publishing its advice and challenge on a website under its own control and there was no outlet for the Panel to comment officially on matters of interest or concern. One consequence is that this annual report is longer than it would have been if regular public updates had been possible through the year. Fortunately, in November 2014, the Department of Health found a way of resolving this matter and the Panel looks forward to being able to operate in a more transparent, accountable manner in future.

⁷ <http://digitalchallenge.dh.gov.uk/2013/11/05/caldicott-panel/>



This graphic and others on pages 27, 39 and 43 were kindly provided by London Connect, part of the Academic Health Science Network for South London. It works to improve the way in which patients and health and social care professionals in London use and share information.



2 Progress on Caldicott2 recommendations

The Caldicott2 report made 26 recommendations and drew many other conclusions. In a response in September 2013, the Government welcomed the report and broadly accepted all the recommendations. Its response included 65 “commitments” to actions that it wanted from national organisations and 19 “expectations” of actions by other organisations and by employees in the health and social care system. This was an exceptionally positive endorsement of Caldicott2.

It would have been pleasing to report just over a year later that these recommendations, commitments and actions have all been implemented. However, there are three reasons why such swift progress was never realistic. Firstly, IIGOP is aware that the major change envisaged by Caldicott2 required a shift in a deep-seated professional and organisational culture which could not be achieved within a year. Secondly, some of the commitments and expectations were overtaken by changes in the health and social care environment that could not have been anticipated at the time of writing the Caldicott2 report. Laws and regulations have been amended in such a way that the specific detail of some recommendations no longer applies, although the principles remain intact. And thirdly, it was never the case that the commitments and actions identified were sufficient to meet all the recommendations. Although it was possible to link the recommendation to one or more committed or expected actions, the actions listed were not sufficient in themselves to deliver the recommendations in full.

To avoid excessive complexity, this chapter concentrates on the big picture and looks at how well organisations in health and social care have implemented the spirit of the Caldicott2 recommendations. It focuses particularly on the key information governance environments of:

- Sharing for direct care
- Sharing for commissioning functions
- Sharing for other health and care purposes
- Sharing for purposes beyond health and care

It then seeks to identify several key themes: leadership; transparency; terminology; consent management; and objection and opt out.

More detailed information about commitments and expectations is given in the Annex to this report. This information is extensive, but not comprehensive. Although IIGOP was quickly established with a remit to include reporting to the Secretary of State for Health on implementing the recommendations of the review, it took time to agree suitable arrangements for monitoring support and there were further delays before staff could be recruited to the Caldicott Implementation Monitoring Group (CIMG). The CIMG was dependent on responsible organisations answering requests for progress reports, which were not always provided in a timely manner. This has had an impact on the information available for IIGOP to assess progress. Information in the Annex to this report shows the position reached by the end of September 2014.

Any judgement about whether progress in implementing the recommendations has been good enough is inevitably subjective. The Panel was reluctant to score health and care organisations on the basis of incomplete evidence. However, it could not avoid being disappointed by the pace of change. On only six of the 26 recommendations could progress be said to be good; on 16 it was partial; and on four it was either not apparent or imperceptibly slow. The report card at the end of the first year after the Government's acceptance of the Information Governance review reads: "Must try harder."

A summary gap analysis, suggesting areas where the commitments and expectations fell short of implementing the full Caldicott2 recommendations and conclusions, is given in the Annex to this report.

Sharing for Direct Care

Direct care⁸ is the primary reason for sharing health and social care information. The Caldicott2 report established as a fundamental principle that the duty to share information can be as important as the duty to protect patient confidentiality. It said: *"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."*

That principle was supported by **Recommendation 2**, which said: *"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."*

In addition, **Recommendation 4** said: *"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."*

There is evidence from a range of initiatives across England that the principle and the recommendations are being actively promoted through (for example) the work of the Pioneer Programme,⁹ the London Connect programme and progress reports from individual trusts and local authorities. One example is the sharing between multi-disciplinary care teams at South London and Maudsley NHS Foundation Trust, King's College Hospital NHS Foundation Trust and Guy's and St Thomas' NHS Foundation Trust. This initiative is described in Case Study one.

⁸ The Information Governance Review defined direct care as follows: "A clinical, social or public health activity concerned with the prevention, investigation and treatment of illness and the alleviation of suffering of individuals. It includes supporting individuals' ability to function and improve their participation in life and society. It includes the assurance of safe and high quality care and treatment through local audit, the management of untoward or adverse incidents, person satisfaction including measurement of outcomes undertaken by one or more registered and regulated health or social care professionals and their team with whom the individual has a legitimate relationship for their care."

⁹ <https://www.gov.uk/government/news/integration-pioneers-leading-the-way-for-health-and-care-reform--2>

Case study one: Sharing across organisational boundaries in London

Clinicians and technical staff at King's Health Partners (KHP) in London thought long and hard about the recommendations made in 2013 by Dame Fiona Caldicott's Information Governance Review. They were particularly interested in the new seventh Caldicott principle: that the duty to share information can be as important as the duty to protect patient confidentiality.

This seventh principle brought special challenges and opportunities for KHP, one of the academic health science centres accredited by the DH in 2009. It is a collaboration between South London and Maudsley NHS Foundation Trust, King's College Hospital NHS Foundation Trust and Guy's and St Thomas' NHS Foundation Trust. Patients previously treated in one organisation may now have their care relocated to another. People with physical and mental health needs may be under the care of several departments in more than one trust, and may go to any of the partners for emergency attention.

Across the NHS, it had always been possible for a clinician in one organisation to request medical notes from a clinician in another, but the process might be slow and not always reliable, given a fear of sharing across organisational boundaries. KHP decided that essential clinical information about a patient must be available within seconds. That required giving clinicians electronic access to key information about their patients that was known to colleagues in other departments and other partner organisations.

KHP's solution was to develop "KHP Online". Clinical staff with a legitimate need to access personal confidential data about an individual in their care may use the KHP portal to view a continually updated summary record. It includes risks, medications and diagnoses that may be relevant to the current episode of care. Accessing information on KHP Online must be in line with the Caldicott principles on a 'need-to-know' basis, in adherence to professional codes of conduct and employment contracts. Effort is made to inform patients about the scheme and they are given an opportunity to dissent before a clinician makes use of the sharing facility.

KHP Online is used only for patients' direct care and no access is given to researchers or administrative staff. For the time being KHP Online contains only electronic hospital records. However, KHP is currently in discussion with GPs in the London boroughs of Southwark and Lewisham about including primary, community and social care records in this programme in 2015. The aim is to support integrated care for local residents.

There were other useful steps taken to implement Recommendations 2 and 4:

- The sharing of information across boundaries between registered and regulated professionals for direct care was emphasised in the HSCIC's Guide to Confidentiality, published in September 2013.

- The Rt Hon Norman Lamb, the Care and Support Minister at the Department of Health, has been influential in seeking clarity for direct care professionals so that they can share information confidently across boundaries in support of the integration agenda.
- IIGOP has provided advice for those trying to enable multi-agency sharing for detainees and the military. It has supported the development of simple guidance such as a 'share for care' leaflet, which was requested by Mr Lamb.¹⁰
- There have been local collaborative efforts such as a data sharing Memorandum of Understanding by Central London, West London, Hammersmith and Fulham, Hounslow and Ealing (CWHHE) Clinical Commissioning Groups, which IIGOP reviewed and thought demonstrated good practice that could be shared more widely for the benefit of others.

Positive examples of information sharing were often the product of local enthusiasm for implementing Caldicott2. In too many organisations across England this enthusiasm has been absent and professional teams are still not sharing for direct care as much as they should.

Case study two: HealthWatch England special inquiry – sharing for direct care

During 2014 Healthwatch England undertook a special inquiry into people's experiences of discharge from hospital and other institutional settings. It found disturbing evidence of the harm caused by failure to share information appropriately. The inquiry focused on the experiences of older people, people with mental health conditions and people who are homeless. Emerging findings, which have been shared with IIGOP, show how a poor flow of information within and between the various organisations responsible for people's direct care is impacting on safety and continuity of care.

Examples included older people being discharged from hospital back to care homes or their own home without a flag being raised about changes in their condition or needs. There were cases of care support workers not realising someone had been moved on to a palliative care pathway and care staff accidentally continuing to administer an individual's existing medication as well as the new medication that was supposed to replace it.

"The home didn't know my mother was in need of palliative care and I didn't know either. They didn't have the equipment she needed because the hospital hadn't sent over a nebuliser. The discharge plan was communicated over the phone to a member of the nursing care staff who didn't record anything. It was appalling. My mother could've had a much more peaceful and dignified death."

The inquiry found a number of people who were discharged unsafely because the information collected during their admission was not used to inform the decisions about the support people would need back in the community. This included a homeless man who was discharged into temporary accommodation with late stages of

¹⁰ <https://www.gov.uk/government/consultations/data-sharing-for-health-care-professionals-guidance-leaflet>

mouth cancer; a nurse subsequently found him there unable to eat or drink, shivering and without any support from the local authority which placed him there.

“He was a homeless man receiving chemotherapy. He was discharged to a flat with no heating, unable to feed himself and with three large bags of meds. He had no idea how or when to administer them. The homeless outreach nurse was notified, but had to wait three hours in the housing department to find out the address. She had to break into the flat and found him shivering in a thin fleece, soaking wet. He couldn't swallow properly or feed himself.”

Healthwatch England said: “We also spoke to people experiencing mental health problems who were known to have engaged in self-harming and suicidal behaviour previously (and had usually been admitted for this reason.) This information had been recorded on their notes, but on discharge were only offered a crisis support phone number, which proved to be an inadequate safeguard when they returned to their home. In a number of cases this led to a substantial escalation of crisis and in a couple of cases resulted in death.

The inquiry spoke to people who did not get support when a professional was unable to gain access to the relevant information – because it had gone missing or had not been passed on by another organisation. This included a number of cases where people were turned away from a crisis support service post discharge because the team could not access the relevant files. One man undergoing a mental health crisis was asked to read a book for a couple of hours while he waited. In other cases information vital to a person's recovery or rehabilitation had been lost in the hand over between services. This included older people's scans, test results and consultant notes being misplaced.

HWE is planning to publish full results of the special inquiry in 2015.

IIGOP was disappointed by lack of progress in implementing **Recommendation 3**, which called for agreement on *“the conditions under which regulated and registered professionals can rely on implied consent to share personal confidential data for direct care.”* Those conditions have not yet been agreed.

It is the view of IIGOP that progress at a nationwide level in achieving appropriate sharing of information for direct care will not be satisfactory until core building blocks are in place, including agreement on terminology, clarity on consent and consistency of arrangements for objection and “opt out.” These themes will be discussed later in this chapter.

Sharing for commissioning functions

IIGOP's agenda during its first year has included frequent discussion of how much identifiable information about people is needed legitimately by commissioners to deliver their statutory functions. This has mainly focussed on NHS commissioners, Clinical Commissioning Groups and NHS England, in relation to their clinical commissioning

responsibilities; but IIGOP has also considered wider commissioning arrangements in the health and social care system for personal care – including support for the integration of health and social care commissioning and the resultant services to the individual needs of people.

Clearly, clinical commissioners cannot plan to improve or target services without knowing a certain amount about the people using them. They also need to validate invoices to ensure that care funded from the public purse was indeed provided and to meet their legal obligations.

The Caldicott2 review identified these issues as a potential problem during the autumn of 2012 and drew it to the attention of senior officials in the Department of Health and NHS England. Members of the review team worked with officials in a local group of primary care trusts and in NHS England to establish how far these commissioning activities could be performed without access to confidential personal data. The results of this work were encouraging. The Caldicott2 Review, published in April 2013, explained how commissioners could gain individuals' consent for some of these tasks and use anonymised information for others.¹¹

At the time of publication of the Review, NHS and DH officials were considering how a network of local “accredited safe havens” could be set up to perform this anonymising function under clear information governance rules. Without knowing the detail, the Caldicott2 Review could not validate this approach. It said: “*This important issue constitutes important unfinished business.*” However, those involved in this work were not despondent and it seemed likely that solutions would be found quickly.

That view turned out to be over-optimistic. After the primary care trusts were abolished at the end of March 2013, local NHS commissioning became the responsibility of Clinical Commissioning Groups (CCGs). Commissioning Support Units were also created to support CCGs, to varying degrees, in some of the activities associated with commissioning services through a formal contractual arrangement. There was considerable anxiety in these new organisations that managerial and support staff could not deliver their responsibilities without using confidential personal information; but their ability to do so was restricted by law. This resulted in understandable concern and no small amount of frustration. The Caldicott2 Review has been blamed by some for creating the problems that it had warned about. However solutions that were suggested by the Review were not implemented.

To avoid a crisis in commissioning, NHS England applied for legal exceptions to be made. Section 251 of the NHS Act 2006 allows the Secretary of State for Health to make regulations to set aside the common law duty of confidentiality for defined medical purposes. Since April 2013 the body that has advised the Secretary of State about these regulations has been the Confidentiality Advisory Group (CAG), a committee of the Health Research Authority. NHS England made a series of applications to the Secretary of State to allow NHS commissioners short-term access to a certain amount of confidential patient data for invoice validation and other purposes in order that they could deliver their statutory duties. In response to these requests CAG recommended that the Secretary

¹¹ Recognising that there will be a few occasions, including some instances of invoice validation, where it may not be appropriate to seek consent and there may be no current practicable alternative to the use of identifiable data.

of State grant time-limited approval, with strict conditions attached, while urging NHS England to hasten a more permanent solution consistent with the recommendations of the Caldicott2 Review.

It is not the role of IIGOP to stand in the way of effective commissioning and it appreciates the diligence of CAG in reaching carefully balanced recommendations to the Secretary of State. It is regrettable, however, that problems identified by the Caldicott2 Review team in the autumn of 2012¹² remain unresolved in the autumn of 2014.

One of the long-term solutions discussed in the Caldicott2 report was for commissioners to use anonymised information. As mentioned above, this was to be achieved by setting up a network of local “accredited safe havens” (ASHs) to perform the anonymising function under clear information governance rules. The Department of Health published a consultation paper in June 2014, with proposals for accredited safe havens that could be used for commissioning purposes including invoice validation and risk stratification. The consultation closed in August and the government is considering the responses received as part of deciding how to respond to the consultation. Issues concerning the development and approval of ASHs, the level of access to identifiable or potentially identifiable information, and security controls are a concern. IIGOP would support progressing as fast as possible towards a position where commissioners can utilise the statutory powers of the HSCIC to collect relevant data and disseminate it to public bodies, if necessary or expedient to their statutory functions, plus an agreement by commissioners to only use highly de-identified data or indeed data that is anonymous in the context it is being used.

A further area of consultation included sharing for “case management” as a commissioning activity. IIGOP was consulted prior to public consultation and advised that the term “case management” could be confused with “direct care case management” undertaken by a registered and regulated professional acting as care-coordinator. (See section on Terminology below.)

In addition to discussion of the information needs of NHS commissioners in relation to clinical commissioning, IIGOP has also looked at wider commissioning arrangements in the health and social care system for personal care – such as support for the integration of health and social care responses to the needs of individual people. IIGOP recognises that the drive to integrate the delivery and planning of health and care services for citizens means that local solutions may emerge increasingly quickly; the need for an agreed and deployable solution is urgent.

At the instigation of the Care and Support Minister, the Department of Health commissioned a team of experts, including some IIGOP members, to review work at the Southend Pioneer Project to help resolve information governance issues related to integrated commissioning. This has resulted in action to clarify Data Controller and Data Processor relationships and an application to CAG to provide a lawful basis for disclosure of confidential patient information in cases where explicit patient consent is not practicable.

¹² Information Governance Review, Chapter 7, pp 73-84: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

Sharing for other health and care purposes

IIGOP was pleased to note the care taken by the research community in health and social care over questions of ethics and information governance. There was greater clarity among the research community than among commissioners about the rules that should be applied and explained to patients and service users.

However, **Recommendation 7** of the Caldicott2 Report stated that *“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).”* This is the area in which IIGOP has issued the greatest volume of advice and challenge. It has contributed to the development of the law and regulations, having been consulted on the EU’s proposed data protection regulation for health and research and the Department of Health’s data sharing regulations.

It is fair to say that a lot of effort and good will has been put into actions to try and deliver this recommendation. But the challenge posed is significant and it must continue to be addressed to ensure the development of arrangements capable of delivering: a step change in awareness; national consistency whilst addressing local requirements; and common understanding of the opportunities for individual patient dissent. In addressing this challenge it is important that the public are informed in an understandable manner about how their information is used and their ability to dissent. Part of the solution concerns “Fair Processing Notices” (also known as “Privacy Notices”).¹³ Such notices should be published by all parties using the data in a consistent manner.

Recommendation 6 (processing data without a legal basis to be dealt with as a data breach), **Recommendation 8** (sharing consent decisions), **Recommendation 10** (accredited safe havens), **Recommendation 11** (objections) and **Recommendation 20** (template for data controller to data controller agreements) are all relevant to this area of activity. Some of the challenges are significant, but progress has been made. Outputs such as regulations have been issued for consultation and the results are awaited.

Finally **Recommendation 13** stated: *“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.”*

The Government’s response included the commitment: *“To lead a review into whether public health activity should have further statutory support to process confidential personal information where alternative arrangements are insufficient”*. It was stated that *“PHE are considering this in parallel with the consultation on data sharing regulations during June and July 2014”*.

Final decisions on new regulations are awaited.

¹³ http://ico.org.uk/for_organisations/data_protection/the_guide/principle_1

Sharing for purposes beyond health and care

The Caldicott2 Report and the Government's response raised information sharing issues that went beyond the remit of the Department of Health and its Arm's Length Bodies.

Child Protection/Safeguarding

Recommendation 16 stated: *“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.”*

The Government's response included: a commitment to *“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”*; and a commitment to *“work with the Department for Education and others to ensure that appropriate arrangements for assessing the risk to a child are established”*.

Recommendation 18 stated: *“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”*. The Government's response includes the commitment to: *“Develop and implement an agreed approach to recording information about the unborn”*.

The Panel has been told that work is progressing, albeit slowly. It welcomes the pragmatic approach being taken by NHS England, the Department for Education, the Association of Directors of Children's Services, and the providers of children's social care record systems to enable appropriate sharing of information about the “unborn” that are subject to child protection plans. This involves using the mother's NHS number as the common identifier. However, that does not resolve all the issues in this area.¹⁴

Troubled Families

The Caldicott2 Report noted the work being undertaken in relation to troubled families. Whilst IIGOP has not focussed on this area of sharing, the Panel considers that the issue of linking information about different family members may present ethical and information governance challenges to the health and social care system that have yet to be resolved.

Crime prevention and detection

IIGOP did not concentrate on crime prevention and detection, or border control issues, but has noted that such issues have been a feature of enquiries to the UK Council of Caldicott Guardians.

¹⁴ <http://systems.hscic.gov.uk/cpis>

Other initiatives

IIGOP has noted that there are proposals for changes to European law and it welcomes the engagement from the health and social care community in those debates. The Panel also noted government initiatives that are being brought forward for wider information sharing and would welcome the opportunity to be engaged in their developments as they impact on the health and social care system.

Leadership

Recommendation 25 of the Caldicott2 Report said: *“The Review Panel recommends that the revised Caldicott principles should be adopted and promulgated throughout the health and social care system.”* To a certain extent the Government implemented this in its response by endorsing the principles and setting out the commitments and expectations explained at the start of this chapter. However, effective promulgation required leadership at every level of the health and care system. At some levels leadership has been disappointing.

There was evidence of Ministerial leadership and intervention, but the Department of Health was not able to provide sufficient resource to drive the necessary actions, or to emphasise the priority that other organisations should give to this work. The lack of a Caldicott2 implementation plan at official level in the DH was a significant omission.

However, recently the DH has taken a more proactive approach. New governance structures have emerged, led by the National Information Board, chaired by Tim Kelsey, National Information Director, and the Information Governance Oversight Group (IGOG), chaired by Will Cavendish, the DH’s Director General of Innovation, Growth and Technology.¹⁵ The Information Governance Alliance was set up to be an authoritative source of information governance advice, hosted by HSCIC.¹⁶ The information governance sub-group of the Informatics Services Commissioning Group (ISCG), which was given tasks in the DH’s response to the Caldicott2 Report, evolved into a new body called the Information Governance Forum.¹⁷ The Care Act 2014 extended the role of the Confidentiality Advisory Group, which will now advise the HSCIC before that body discloses any information in

¹⁵ The Terms of Reference for the IGOG have not yet been published but the draft version dated state that “The Information Governance Oversight Group (IGOG) is being established as part of the Informatics Governance Accountability Review to drive resolution of major problems relating to the use of information across the health and social care system.

¹⁶ The IGA (<http://systems.hscic.gov.uk/infogov/iga>) has been developed with the 3 following objectives:

- Creating a single authoritative source of information and guidance for the health and care sector
- Providing support to front line health and care staff, managers and their organisations to help them handle personal information confidently in the best interests of patients and service users
- Developing the capacity and capability of the IG profession through knowledge sharing networks and provision of support through expert knowledge, advice and other resource

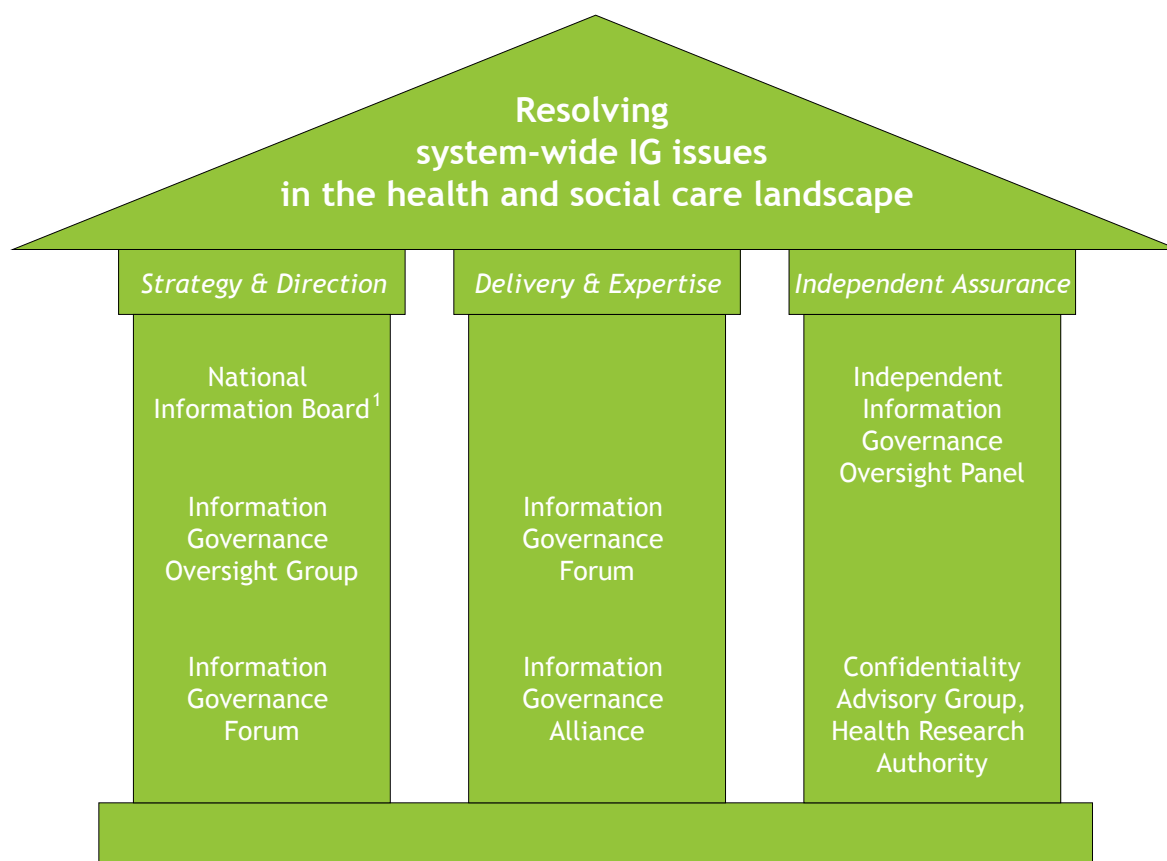
¹⁷ The IG Forum was formerly known as the Informatics Services Commissioning Group (ISCG) IG Sub-group and has the same membership. The IG Forum has not yet published its Terms of Reference. The Terms of Reference of the ISCG IG Sub-group (061213) said its objectives were:

- Facilitating the development and implementation of a robust system-wide and coherent information governance framework that provides
- Supporting and coordinating improvement activities across the health and care system to enable the continuous improvement of records management and information quality systems and processes, contributing to improved patient care.
- Ensuring effective leadership and coordination across the system, fostering a culture that values and utilises information effectively, securely and safely, with appropriate confidentiality.
- Addressing the complex and different attitudes and cultures across the health and social care system in respect of sharing and managing access to information.
- Ensuring ISCG is fully informed about ongoing progress on implementation of Caldicott2 recommendations.

a form that could enable an individual to be identified.¹⁸ These new structures are a welcome development and IIGOP is optimistic that they will be able to deliver consistent leadership that is more visible. Table 1, below, shows the relationship between the groups.

Responses to the CIMG indicate that local and regional leadership is also developing. This is further explored in Chapter 3.

Table 1: Governance in the IG Landscape¹⁹



Transparency

Recommendation 25 on the need for promulgation of the Caldicott principles requires transparency, which is also necessary at a practical level to allow the public to exercise their rights to information about themselves. **Recommendation 1** of the Caldicott2 Review said: *“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.”* It called for an audit trail that details anyone and everyone who has accessed a patient’s record to be made available in a suitable form to patients via their personal health and social care records.

¹⁸ Schedule 7, Care Act 2014. The Care Act also amended the Health and Social Care Act 2012 to require the HSCIC to have regard to the advice given (see S262A HSC Act 2012 added by Care Act 2014 c. 23 Pt 4 s.122(4)).

¹⁹ Further explanation of the “Three Pillar Model” is set out in Chapter 4, p40

²⁰ The National Information Board sets out the strategy and direction for the health and care system on technology and information. The strategic direction agreed by the National Information Board will steer the priorities and commissioning for technology and information services delivered by the HSCIC and other agencies, and partner organisations.

<https://www.gov.uk/government/groups/national-information-board>

There have been useful local initiatives such as the “Myhealthlocker” initiative outlined in Case Study five on page 34. However this recommendation has not been advanced nationally to a significant extent, and has been notably constrained by the lack of audit capability. The ICO Code of Practice for responding to Subject Access Requests²¹ was released in February 2014 and brought these issues into sharp focus.

Transparency requires consistent use of language. In particular specialist terminology needs to be explained and used consistently. There must also be transparency about the consent model. These issues are considered below.

Terminology

Recommendation 22 said: *“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.”*

IIGOP challenged the ISCG IG sub-group to develop a system-wide glossary and work has started on this, but there has been no public output. IIGOP has noted that clarity on terminology continues to present challenges:

- The term “confidentiality” is defined in s. 263 of the Health and Social Care Act 2012 in a way which is unfamiliar to any information governance specialist or member of the public, yet this forms the basis of the Code of Practice on handling Confidential Information which organisations must have regard to by law.
- The terms “direct care” and “direct care team” are not used consistently, with the concept of direct care sometimes being interpreted as including commissioning functions. This is exacerbated by using terms such as “facilitating direct care” to extend the use of personal identifiable information and “implied consent”.
- The use by commissioners of the term “case management” creates problems. It is often confused with “care management” and “care co-ordination”, which are terms used in relation to the functions of registered and regulated professionals with legitimate relationships with the person (case).
- The term “objection” has a specific legal meaning and the term “opt-out” provides a mechanism for dealing with “objections”. However, these meanings are not well understood by the patients and service users who might want to object or opt out. This may contribute to a communications breakdown when officials want to use correct legal language and are misunderstood. The problem has been explored in some depth by Ipsos MORI in work commissioned by NHS England.

There are many more examples which emphasise the need for consistent terminology to underpin the delivery of other recommendations. IIGOP is keen that this is addressed as soon as possible.

²¹ http://ico.org.uk/for_organisations/data_protection/-/media/documents/library/Data_Protection/Detailed_specialist_guides/subject-access-code-of-practice.PDF

Consent management

Recommendation 8 said: *“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.”*

IIGOP notes that “consent management” is about much more than dealing with consent. It should include the processes to address the issues of those temporarily or permanently lacking capacity to consent. There is broad support for the principle that consent is the preferred legal gateway in most circumstances, but the current processes are patchy, inconsistent, confusing and in some cases absent.

If consent would normally apply, but cannot be sought directly from the person, how do the professionals providing care proceed? There is some evidence that there is a lack of understanding about the correct course of action and lack of appropriate guidance.

Consent management requires proper application of legal obligations including those outlined in the Mental Capacity Act, the adult safeguarding provision of the Care Act 2014; the consent processes relating to court appointed Welfare Deputies or those with Enduring Powers of Attorney as well as the management of “best interest” decisions involving carers, relatives and advocates. IIGOP issued advice to this effect to the ISCG Information Governance sub-group in January 2014, advising that direction/policy is developed. In August 2014 IIGOP issued a challenge specifically in relation to *care.data* consent management to which IGOG has responded positively.

Objections and opt outs

Recommendation 11 called for greater clarity about the individual’s right to object to their personal confidential data being shared, and to have that objection considered. The Government’s response anticipated that the HSCIC’s Code of Practice would address this. At the time of writing this report, the Code has not yet been published.

Part of the challenge in explaining objections and opt outs to a lay audience has been the lack of a consistent approach. In September 2013 the Secretary of State made a specific commitment giving people a “right to object” to having their data used for the *care.data* programme. He said:

“... If someone has an objection to their information being shared beyond their own care, it will be respected. All they have to do in that case is to speak to their GP and their information won’t leave the GP surgery.”²²

²² Department of Health, 12th September 2013: <http://digitalchallenge.dh.gov.uk/2013/09/12/caldicott-response/>

This commitment went further than the principles in the NHS Constitution, which said: *“You have the right to request that your confidential information is not used beyond your own care and treatment and to have your objections considered, and where your wishes cannot be followed, to be told the reasons including the legal basis.”*²³

IIGOP welcomes the Secretary of State’s enhancement of the “right to object” in the *care.data* programme, but calls for a more consistent approach. It is not reasonable to expect the public to understand objections and “opt outs” if there are different rules for different programmes. This remains unfinished business. A fuller account of the information governance aspects of *care.data* will be given in Chapter 3.

IIGOP issued advice on objections on several occasions over the past year, including in relation to the Public Health England strategy, the HSCIC Strategy and to the Health Select Committee.

Everyone working in health and social care should see Information Governance as part of their responsibility

hin Health Innovation Network South London

Imperial College Healthcare NHS NHS Trust

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²³ The NHS Constitution for England, 26th March 2013: page 8. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/170656/NHS_Constitution.pdf



3 Current state of information governance

Over the past year, the subject of information governance has moved from the backwaters of organisational management into the mainstream of public discussion. Debate about when it is right to share people's care data is no longer restricted to policymakers, technical experts and medical ethicists. The topic is now frequently discussed in the media and raised in Parliament.

The main driver of this heightened interest was the first attempt to launch the *care.data* programme. Many people were suspicious of the proposal to extract data from GP records and combine it with other data from hospital records to create a more comprehensive source for researchers to gain a better understanding of people's health and care experience. This was at a time of greater public concern about the use of "big data" by governments and security services and its impact on privacy. Although the *care.data* programme planned to establish strong safeguards to prevent the disclosure of confidential personal information about individuals, this was not well explained.

NHS England communicated the proposal in a leaflet that was supposed to be delivered to all homes across England in January 2014. A copy of the intended leaflet was sent to IIGOP shortly before the quarterly meeting of the panel on 9th December 2013.²⁴ On the following day IIGOP advised NHS England that its leaflet was not fit for purpose, but was informed that it had already been sent to the printers and would not be recalled.

When the leaflet was distributed, it raised more questions than it answered, triggering debate in the media and in Parliament. There were concerns that patients were not adequately informed about their right to refuse to allow their data to be uploaded from their GP surgery, or to restrict its subsequent use, without any impact on their direct care. Many people could not recall receiving the leaflet and there were doubts about how widely it had been distributed. There was also concern that there were insufficient safeguards to stop data being disclosed outside the NHS, including the absence of a prohibition on disclosure to insurance companies.

NHS England announced in February that there would be a pause in the roll out of the *care.data* programme, and embarked on a new, broader consultation exercise. The Government placed additional restrictions on the dissemination of data by the HSCIC through section 122 of the Care Act 2014. The HSCIC may now disseminate information, including data gathered through the *care.data* programme, only for the purposes of the provision of health and social care or the promotion of health.²⁵ This is intended to prevent any disclosure for purely commercial purposes, including use by insurance companies or for other purposes, without a health or care benefit.

²⁴ The published minutes recorded: "The Panel discussed the proposed 'care.data' information leaflet for the public and recommended that the following amendments were necessary to ensure that the leaflet was fit for purpose:

- Earlier emphasis that the individual had an option to opt out;
- Earlier emphasis that the individual's decision would not impact their direct care;
- Correction of commitments regarding individuals' contacting their GP to stop PCD (personal confidential data) flowing from other settings to the HSCIC, taking into account feasibility."

²⁵ S261 Health and Social Care Act 2012 provides a number of other specific circumstances in which data may be disseminated by the HSCIC e.g. in response to court order or where necessary for the purposes of exercising a statutory function.

NHS England responded with plans for a phased roll out of the *care.data* programme, starting with between 100 and 500 GP practices early in 2015. IIGOP agreed to provide advice on the implementation of this Pathfinder stage of the programme and to evaluate the results. In November 2014 the Secretary of State asked Dame Fiona Caldicott to “*be the patient’s champion when it comes to the security of personal medical information*”.²⁶

Although *care.data* may have distracted IIGOP from other useful work, it has produced a significant benefit in leading to much greater public awareness of the importance of information governance. Public debate has become better informed, as well as more intense.

Transparency

Concern about the *care.data* programme sparked wider interest in the way health and care data is collected and shared. Leaders of the HSCIC were called to account for their stewardship at the House of Commons Health Select Committee. In response to criticism, they asked Sir Nick Partridge, one of the HSCIC’s non-executive directors, to lead a review of data released between April 2005 and March 2013 by the NHS Information Centre, one of the HSCIC’s predecessor organisations. In a report in June 2014 Sir Nick said: “*It disappoints me to report that the review has discovered lapses in the strict arrangements that were supposed to be in place to ensure that people’s personal data would never be used improperly.*”²⁷

The unintended consequence of *care.data* was a positive cycle of change, with greater public interest causing organisations to respond with greater transparency and stronger information governance. An example of how this positive cycle worked at the HSCIC is given in Case Study three.

Case study three: Helping the NHS to improve its data handling

The HSCIC, tasked by the Health Secretary to support the NHS in improving its data security and information handling generally, began dealing with a Hospital Episodes Statistics (HES) breach in June 2014. New inspection procedures introduced by the HSCIC had uncovered a number of organisations which were sending HES data and failing to follow data dictionary standards. This meant they were inadvertently enabling personal confidential data to enter the data base. Following an alert to the Information Commissioners’ Office this was understood as a large scale problem, although having a low level potential impact, as the affected data fields were unknown to either senders or receivers of HES data. The relevant organisations were contacted to gain their cooperation in closing the breach, without alerting any unfriendly observer to the location of the confidential details. This was important to preserve the general ignorance of the detail of the breach and continue to protect individuals’ privacy. Trusts and others were encouraged to provide named contacts who would then start cleaning up their data flows to the HSCIC. In order to manage any untoward reporting in the media, trade titles were informed and briefed about the importance of restricting their reporting to avoid any risk of leading people towards this confidential data. The organisations concerned are now following data dictionary standards and the specialist press reported the breach responsibly.

²⁶ https://www.gov.uk/government/speeches/innovation-and-efficiency?utm_source=twitter&utm_medium=social

²⁷ <http://www.hscic.gov.uk/datareview>

Public opinion

Although people became more suspicious of data harvesting initiatives, trust in medical professionals remains extremely high.

The pollsters have shown that most patients want any healthcare professional who treats them to have secure electronic access to key data from their GP health record.²⁸ Many have been surprised that emergency care doctors do not have automatic access to records, and are concerned that lack of access may lead to delays in treatment and fatal errors.²⁹

Ipsos MORI found that “public sector healthcare providers” came top out of 11 sectors in terms of level of trust that they would use information about the public in the right way, whilst private companies were less trusted. A clear hierarchy was found, with most support for sharing data with researchers, then charities, and lastly companies. If the organisation is also working with/for the government, support increases further. People accept data-sharing within government for security, combating fraud, or for patients’ health.

The public’s main concerns about the use of information about them were suspicions around usage creep, lack of personal benefits and loss of data.³⁰ Safeguards have been found to be reassuring for the public, but with no mention of safeguards, the balance of opinion is against data-sharing. Around half would be in favour of data sharing within government, so long as safeguards are in place – compared with one third against. The safeguard providing people with most reassurance is a promise that data will be anonymised, but providing people with an opportunity to opt out, harsh penalties for breaches and controls on access to data also provide reassurance.

Such surveys informed the debate and reinforced the position held by Caldicott2.

Leadership

The disestablishment of the National Information Governance Board (NIGB) on 31st March 2013 left the system in England without a statutory arbiter, to which organisations could turn for authoritative resolution of difficult questions.³¹ Although IIGOP has tried to assist organisations over the past year by offering its opinion, when asked, it has not had the NIGB’s level of statutory authority or resource.

Some of the NIGB’s functions were successfully transferred to the Confidentiality Advisory Group (CAG) of the Health Research Authority (HRA), which provides recommendations to the Secretary of State and the Health Research Authority about when to grant access to confidential patient information by researchers, commissioners and others for medical purposes.³² The role of CAG has been extended and it is now also to provide independent advice to the HSCIC on the disclosure of data that might enable an individual’s

²⁸ Onmedica reported this to be 85%. See <http://www.onmedica.com/newsarticle.aspx?id=6e8f91d9-2945-45c7-aba1-1ccbbae70c>

²⁹ <http://www.onmedica.com/newsarticle.aspx?id=6e8f91d9-2945-45c7-aba1-1ccbbae70c>

³⁰ Ipsos MORI citation to be confirmed Royal Statistical Society, Public attitudes to the use and sharing of their data Research for the Royal Statistical Society by Ipsos MORI July 2014

³¹ The NIGB was chaired during the last two years before its disestablishment by Dame Fiona Caldicott.

³² Access is under the Health Service (Control of Patient Information) Regulations 2002. The power to lay these regulations was re-enacted as S251 NHS Act 2006. Support under the Regulations is commonly referred to as S251 support.

identification. The Health and Social Care Act 2012 was amended to require the HSCIC to have regard to such advice.³³ The Health and Social Care Act 2012 also gave the Care Quality Commission a new responsibility for monitoring and seeking to improve information governance practices of registered health and social care providers. However, other NIGB functions were not sustained.

No single body had the NIGB's breadth of responsibility and, as a result, information governance had less national leadership than before. In addition to the Department of Health, there are 23 national organisations that form the upper tier of the health and social care system, excluding Royal Colleges, professional organisations and trade organisations. All have some aspects of information governance that are relevant to their activities, and all should be showing leadership and commitment to best practice in this area of activity. However, they have had many other pressing priorities.

The Care Quality Commission has made significant progress towards fulfilling its new statutory duty to monitor and seek to improve information governance practices of registered health and social care providers. As required by the Health and Social Care Act 2012, the CQC set up a National Information Governance Committee to advise it in this work. The NIGC urged the CQC to take advantage of the new system of inspection that was being trialled during 2013-14 to include questions about information security and information sharing in routine inspections of hospitals, GPs, community healthcare and social care. In the first waves of inspection under the new inspection regime, questions were included among the "prompts" suggesting points that inspectors might ask. Analysis of a sample of inspection reports found problems including:

- A mental health unit where confidential information about individual service users was on display on staff office walls;
- Although records on a stroke unit were excellent, records in other wards in the same establishment were not fit for purpose;
- 30 boxes of patients' archived records were found stored in a public corridor where they were an information disclosure risk as well as a fire hazard.

Some providers in the sample were issued with compliance actions for poor record-keeping, unsecured storage, poor information sharing, or ineffective mechanisms to report quality information to the board to support effective oversight of quality and risks across services.

However, inspectors were not at this stage required to ask all the "prompts" or report on all the answers – good or bad. In an interim report to the CQC Board on 17th September 2014,³⁴ the NIGC said this approach could not be a reliably effective method of monitoring. It urged the CQC to make questions about information governance a "Key Line of Enquiry", to be asked by inspectors on every inspection and assessed without fail. The CQC Board adopted this suggestion in the handbooks for inspection of all health providers and strengthened the information governance component in adult social care inspections.³⁵

³³ S262A Health and Social Care Act 2012

³⁴ <http://www.cqc.org.uk/sites/default/files/CM091407%20Item%207%20NIGC%20Interim%20report.pdf>

³⁵ <http://www.cqc.org.uk/sites/default/files/CM091407%20Item%207%20NIGC%20Interim%20report.pdf>

IIGOP welcomes this radical move to strengthen the monitoring of information governance among registered health and social care providers. The next stage is for the CQC to be able to show that enhanced monitoring leads to improvements in practice.

Local and regional leadership

The Caldicott Implementation Monitoring Group has identified that there are currently 35,855 registered organisations delivering health and social care in England. In addition to the 24 national agencies there are:

- 160 Acute Trusts
- 56 Mental Health Trusts
- 34 Community Providers
- 24 Ambulance Trusts
- 211 CCGs
- 34 NHS England Area Teams
- 152 Councils with Adult Social Care Responsibilities (CASSRs)/providers of Local Public Health Teams
- 8,230 GP practices
- 20,100 registered Care Homes
- 6,830 registered Care Agencies

At this level there are some good examples of strong regional leadership and collaboration in tackling information governance issues, as the following case studies show. Leadership requires listening and engaging with the public and staff at all levels, and then taking decisions which are promulgated clearly, through a range of media, given the current public interest in this area.

Case study four: Health and social care sharing information in Nottingham City

In 2012 the organisations responsible for health and social care in Nottingham City introduced a new model of care delivery to make their services more user friendly. Commissioners and providers from the NHS and the local authority embarked on a transformational programme to coordinate their activities. They divided the city into eight “care delivery groups.” Each locality was made up of groups of GP practices and neighbourhood teams of adult health and social care staff. The aim was to tailor services to meet local needs and tackle health inequalities.

This initiative, pioneered by NHS Nottingham City Clinical Commissioning Group (CCG), working in partnership with Nottingham CityCare Partnership and Nottingham City Local Authority, hit some early barriers regarding information sharing. At first there was lack of confidence among frontline staff about sharing information, particularly across the traditional boundaries between health and social care.

The authorities in Nottingham were delighted when the Caldicott2 Review was published in 2013, providing absolute clarity about the need for staff to share information for the purpose of direct health care where this was deemed relevant and in the patients’/citizens’ best interests.

The CCG developed a flyer for frontline staff entitled ‘Sharing Information for Direct Care – Myth Busting and the Facts’. It was well received by key staff involved in the care delivery programme and is used by them as an authoritative source facilitating better information sharing, which will ultimately provide for better patient/citizen care.

A social care link worker based at one of the eight care delivery groups, said: “In this new role we have the ability to shape things; you can have direct conversations with the right people in health, whether GPs or district nurses, about someone’s care. When you’re working right across the city there can be a level of complexity, but working within the care delivery groups you’re in a concentrated area and that creates more opportunities for appropriate information sharing and good partnership working”.

A carer of a patient with a long term condition said: “Everyone who comes to see us – be it a nurse, their GP or social services – all know exactly what the other is doing. They are all singing off the same hymn sheet and they all know what the next step is and what the previous care has been. I think this is a great thing to happen to the NHS in Nottingham and I think it will better the lives of thousands of adults who have lots of medical problems.”

Case study five: Mental health patients get access to their own records

Many patients at the South London and Maudsley NHS Foundation Trust (SLaM) are now able to sign up to gain online access to their electronic mental health records. If they choose to open a “myhealthlocker” account, they are able to see records made about them by the mental health teams in the hospital and by their GP. Information is shared directly to the patient’s personal health record, which they are empowered to manage, curate and share with those they trust. They can also feedback to their clinicians in SLaM adding structured survey data of their own – not changing the clinicians’ notes, but supplementing them.

By using mobile internet devices patients can feed into myhealthlocker remote measurement of health outcomes such as blood pressure, activity and weight. By using a mood rating survey facility they can monitor medication side effects, negative thoughts, anxiety, sleep, exercise and anything else relevant to their health.

The programme aims to empower patients by giving them a better understanding of the interaction between physical and mental health conditions and becoming actively involved in their healthcare. The clinicians benefit too – from feedback sent by patients to their care team and from the extra information provided by the remote measurement and surveys.

The clinicians make the programme available to those patients who they expect to benefit from it, but it is the patient’s decision whether to open an account. Patients may also choose to incorporate other medical records concerning aspects of physical health, such as diabetes, to permit a more holistic assessment of their needs.

Myhealthlocker offers other online advantages including up to date information on medication and its side effects as well as information on welfare benefits.

Since the programme went live in October 2012 user feedback has been positive and the platform has been highly commended by industry (HSJ 2012, EHI 2014) and presented as an exemplar of information sharing by the Department of Health (The Power of Information, 2012) and listed as a “High Impact Innovation” for the future (Department of Health High Impact Innovations, 2013/2014).

The integration agenda

The integration agenda has brought the importance of information sharing into sharp focus from a political perspective. The need for greater integration between health and social care is not a new idea, but the subject has risen up the agenda of all political parties. Their proposals about integration are all dependent on information sharing, cutting across party lines. It has been championed by ministers and introduced in practice through the integration pioneers. Current initiatives such as pooled budgets are dependent upon information sharing.

In November 2013 the Department of Health announced that 14 areas had been chosen as integrated care pioneers in England. The pioneers were selected by the National Collaboration on Integrated Care and Support, a group of 12 national organisations who are all, in part, responsible for enabling integrated care.

Each pioneer site has a different focus but have a common aim “to make health and social care services work together to provide better support at home and earlier treatment in the community to prevent people needing emergency care in hospital or care homes”.

Case study six: Integration Pioneers

Integrated Care Pioneers are a ministerial priority. They aim to enable and drive change throughout the whole health and social care system. An issue had arisen which suggested that information governance was hampering rapid advancement by the Pioneer sites. In addition to the support offered by NHS Improving Quality, Norman Lamb, the Care and Support Minister, asked for a team of experts to work with one Pioneer site to resolve issues and produce ministerial advice on how a solution could be achieved.

The Pioneer site visited was Southend-on-Sea and involved representatives from Southend-on-Sea Borough Council, Southend CCG, NHS Central Eastern CSU and PI Benchmark. The challenges for this site concerned local secondary uses of information requiring integration of person level data from several health organisations and social care. The issues identified included establishing the legal basis for each data flow and clarifying Data Controller and Data Processor roles.

This was followed by a workshop including all 14 pioneer sites to share and disseminate findings and practice, as well as ascertain whether any significant issues remained outstanding and hence would require a second site visit. The minister was fully involved and keen for this work to be completed early in 2014

The outcomes of the visit to Southend-on-Sea were shared at a workshop for all Pioneers in February.

One outcome was the need to undertake a site visit, this time to South Tyneside, where direct care was the primary focus of the pioneer. No information governance barriers were identified. The issues and challenges concerned clarity about business requirements and processes.

The real challenge in relation to direct care is about enabling and supporting good professional practice. Clinicians and social workers must be empowered to make appropriate decisions to share data for direct care rather than creating false information governance issues.

Evidence of Changing Information Governance Practice

The Panel did not focus its attention on the IG Toolkit but was aware that the Toolkit changes each year and that the changes between Version 10 (“V.10” for year ending March 2013) and Version 11 (“V.11” year ending March 2014) had not changed requirements significantly, but had adjustments to reflect the changing organisational structures. The Panel had envisaged that trend analysis would have been readily available to indicate if improvements in information governance had taken place between March 2013 and March 2014. However such an analysis was not available by the 30th September 2014. The CIMG has attempted to plug this gap undertaking some analysis of the available data.

The analysis has focussed on the six groups of requirements in the IGTK for the following organisation type views: (of the 25 current and 4 archived views)

- General Practices
- Care Commissioning Groups & Contract Support Units
- Commercial Third Parties
- Community Health Providers
- All “Acute Trusts”

The groups of requirements are:

- Information Governance Management
- Confidentiality and Data Protection Assurance
- Information Security Assurance
- Clinical Information Assurance
- Secondary Use Assurance
- Corporate Information Assurance

The analysis is presented in Annex 3. Care needs to be taken in interpreting the results for several reasons including:

- Minor changes to the toolkit itself.
- The IG Toolkit is a self-assessment tool, not an independent audit.
- The numbers of organisations completing the toolkit (for example 8,507 GP practices made returns for V10, whilst only 5,894 made returns for V11).
- The number of requirements for which the returns were blank are, in some circumstances, significant (for example for GPs V10, there were an average of 2,691 blanks for Information Governance Management requirements. However the V11 report has no blanks).
- Different settings do not have requirements for all six groups of requirements (for example GPs only report on 13 requirements covering only three of the groups, whereas CHPs have 39 requirements covering all six groups).

In theory, the different number of requirements and groups of requirements is intended to reflect the functions of the different settings. However it is not clear why GPs do not have any requirements relating to Clinical Information Assurance or secondary Use Assurance. It is more understandable that, at least for small GP practices, the Corporate Information Assurance is not a feature.

With those caveats, it appears that the following judgements may be made for the changes in information governance practice between V10 and V11 of the toolkit.

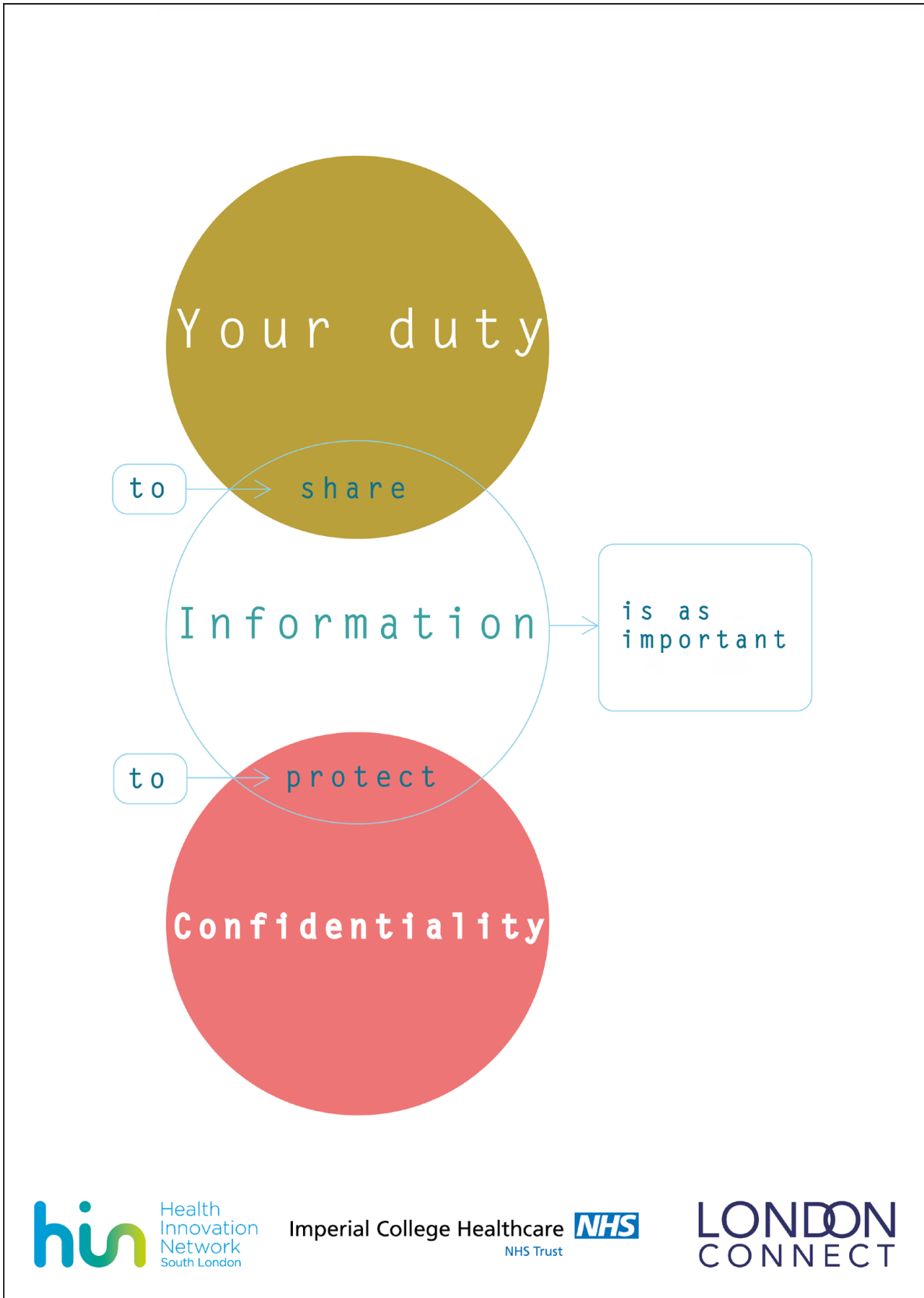
- For General Practices:
 - Information Governance Management: the % on the lowest two bands fell from 0.5% to 0.2% of the returns
 - Confidentiality and Data Protection Assurance: the % on the highest two bands had increased from 67.8% to 69.1%
 - Information Security Assurance: the % on the highest two bands had increased from 67.1 to 68.1%
 - These changes suggest a slight improvement, but the significant reduction in total number of practices and the lack of blank returns in V11 raises questions about the reliability of the data.

- Care Commissioning Groups & Contract Support Units (267 returns for V10 and 227 for V11)
 - Information Governance Management: the % on the highest two levels has increased from 21.3% to 49.7%
 - Confidentiality and Data Protection Assurance: the % on the highest two levels has increased from 18.5% to 44.3%
 - Information Security Assurance: the % on the highest two levels has increased from 19.9% to 42.5%
 - Clinical Information Assurance: the % on the highest two levels has increased from 11.6% to 20.2%
 - Secondary Use Assurance: the % on the highest two levels has increased from 1.4% to 15.5%
 - Corporate Information Assurance: the % on the highest two levels has increased from 2.7% to 7.2%
 - These changes appear to show a significant improvement, as would be expected from new organisations. However the very high % of blanks (60.0% to 98.1% for V10 and 50% to 92.1% for V11) are a significant cause for concern.

- Commercial Third Parties (returns from 1,254 organisations in V10 and 355 for V11, but with high “blanks” in V10 and no “blanks” in V11.)
 - Information Governance Management: the % on the highest two levels has increased from 30.8% to 98.6%
 - Confidentiality and Data Protection Assurance: the % on the highest two levels has increased from 25.4% to 83.1%
 - Information Security Assurance: the % on the highest two levels has increased from 30.2% to 98.1%
 - Clinical Information Assurance: No Requirements
 - Secondary Use Assurance: No Requirements
 - Corporate Information Assurance: No Requirements
 - For the organisations making a return, this appears to be a significant improvement, but blanks in V10 and much lower number of organisations in V11 suggests much smaller improvement and concern about fall in returns.

- Community Health Providers (34 organisations V10 and 41 for V11)
 - Information Governance Management: the % on the highest two levels has increased from 88.9% to 90.7%
 - Confidentiality and Data Protection Assurance: the % on the highest two levels has fallen from 85.6% to 84.8%
 - Information Security Assurance: the % on the highest two levels has fallen from 89.4% to 85.1%
 - Clinical Information Assurance: the % on the highest two levels has fallen from 90.6% to 87.8%
 - Secondary Use Assurance: the % on the highest two levels has fallen from 89.7% to 87.8%
 - Corporate Information Assurance: the % on the highest two levels has fallen from 77.4% to 75.6%
 - At first glance this appears to be a slight decrease in performance, but new entries to the system could not achieve level three in their first year; so the change is not significant.
- Acute Trusts
 - Information Governance Management: the % on the highest two levels has increased from 93% to 97%
 - Confidentiality and Data Protection Assurance: the % on the highest two levels has increased from 63% to 95%
 - Information Security Assurance: the % on the highest two levels has increased from 85% to 92%
 - Secondary Use Assurance: the % on the highest two levels has fallen from 77% to 75%
 - Corporate Information Assurance: the % on the highest two levels has increased from 56% to 98%
 - This appears to be a real increase in performance, however changes in number of requirements and the number of blank entries means that caution in interpreting the results is necessary.

Overall, it is difficult to come to a clear conclusion about any improvement in performance in relation to the IG Toolkit between V10 and V11. There are concerns about the significant, and unexplained, fall in number of organisations completing the toolkit for GP practices and Commercial Third Parties. In theory the reduction in “blanks” represents an improvement, provided it does not reflect a failure to return. Acute Trusts do appear to have improved overall.





4 The future of oversight

Previous chapters have shown how IIGOP has already provided useful oversight of information governance in health and social care across England. This included tracking the progress made in implementing the recommendations of the Information Governance Review, and offering advice and challenge. However, almost at the same time as the panel was established, discussions began in the Department of Health about how the panel's role might be enhanced.

Department of Health officials sketched out a vision of a “three-pillar model” for identifying and resolving system-wide information governance issues, which developed into the organisational structure shown in the graphic on page 24. According to their vision, the first pillar was to be made up of system leaders from the DH, the NHS and social care, who would set the strategy for the health and care system on technology and information, and commission the work needed deliver this strategy. This first pillar began to take shape during the summer of 2014, with key players including the National Information Board (NIB) and the Independent Information Governance Oversight Group (IGOG), which would identify system-wide information governance issues and be responsible for approving solutions or policies to resolve them.

The second pillar would be made up of experts who would suggest solutions to issues raised by IGOG and would include the Information Governance Alliance, a bringing together of information governance experts created at the request of IIGOP to derive a credible and consistent point of advice. These include the DH, NHS England, the HSCIC and Public Health England.

The third pillar would provide an independent check on whether these suggested solutions were appropriate and had gone through adequate public consultation. It was suggested that IIGOP's role and resources could be enhanced to permit it to become this third pillar. The panel welcomed this suggestion, not least because of the difficulties it was experiencing in fulfilling its existing terms of reference and having meaningful impact on the system.

Putting the Panel on a statutory footing?

Discussion of IIGOP's future role had been taking place behind the scenes at the DH. However, the issues began to be taken up by a variety of external stakeholders, including academics and privacy lobby groups, and surfaced during a debate in the House of Lords on 7th May 2014. The debate centred on amendments to the Care Bill that had been tabled by the Government to give additional reassurance in response to criticism of the *care.data* programme. In response, Lord Owen proposed a new clause “*that would place on a statutory footing the current non-statutory Independent Information Governance Oversight Panel.*”³⁶

³⁶ House of Lords, consideration of Commons amendments to Care Bill, 7th May 2014 (col 1520.)

Speaking for the Government, the Rt Hon Earl Howe, Parliamentary Under Secretary of State for Quality at the Department of Health, said:

“We are sympathetic to the desire to see the oversight panel placed on a statutory footing...There may well be merit in establishing the panel in law and giving legal force to its advice on data sharing.” He added: “I strongly feel, however, that ... it is vital that we ensure the system of oversight, scrutiny and advice is robust and coherent. I undertake that we will explore with Dame Fiona Caldicott and all interested parties how best to achieve this, which may include using existing legal powers.”³⁷

The way ahead

These discussions continued during the summer of 2014. IIGOP made it clear to ministers that it would welcome being placed on a statutory footing at the earliest legislative opportunity. Meanwhile there was much that could be done to ensure that the role of the panel would be strengthened and enhanced, including refined terms of reference and suitable resourcing. Consideration was given to signalling these changes by renaming IIGOP and the Secretary of State proposed that Dame Fiona Caldicott should take on a broader role as National Data Guardian for health and social care.

In a letter to Dame Fiona in October 2014, the Secretary of State said:

“I agree that your panel is well-placed to deliver the robust scrutiny and oversight required to assure patients, people who use services and the public about the use of their health and care information in the health and care system.

“The new role of the Panel, alongside its existing responsibilities, is to provide scrutiny, challenge and advice to me and the Department, and to the Department’s arm’s length bodies, always acting from the viewpoint of the patient and wider public, and as a champion of their interests. I am happy to confirm my agreement to your proposals for the steps that we can take now, and on the importance of seeking to legislate at the earliest opportunity to place your panel on a statutory footing.

“I strongly welcome your commitment to the principles of independence and transparency, and I agree that an important aspect of your independence is your ability to scrutinise and challenge both me and my Department’s arm’s length bodies without invitation or constraint.”

The Secretary of State also asked Dame Fiona to act as an independent arbiter to challenge and support the *care.data* programme, with particular attention to the arrangements for communications, objections and opt-outs during the pathfinder stage. *“Confirmation that your expectations have been addressed, and all reasonable steps have been taken to minimise potential concerns, will be necessary before any data extraction can commence as part of the pathfinder stage,”* he added.

In November 2014 the Secretary of State for Health announced a new role for Dame Fiona Caldicott as the first National Data Guardian for health and social care *“to be the patient’s*

³⁷ House of Lords, consideration of Commons amendments to Care Bill, 7th May 2014 (col 1528)

*champion when it comes to the security of personal medical information”.*³⁸ The Secretary of State said:

“She has agreed that it will be her responsibility to raise concerns publicly about improper data use. And organisations that fail to act on her recommendations will face sanctions, either through the ICO [Information Commissioner’s Office] or the CQC [Care Quality Commission], including potentially both fines and the removal of the right to use shared personal data.

“I have already asked Dame Fiona to provide independent advice to me on care data. No data will be extracted from GP practice systems – including during the ‘pathfinder’ pilot phase of the programme – until she has advised me that she is satisfied with the programme’s proposals and safeguards.

*“I intend to put the National Data Guardian on a legal footing at the earliest opportunity, but even before that the CQC and the ICO have committed to pay special attention to her recommendations, including sanctioning organisations where they find breaches ... so patients will benefit immediately from a much tougher and more transparent regime.”*³⁹

IIGOP’s remit will be enhanced. Alongside advice and challenge, key activities will include continuing scrutiny of the *care.data* work, advising on the state of information security, contributing to a revised care record guarantee, contributing to proposals to be published in the Cabinet Office’s data sharing white paper and annually reviewing whether regulations made under section 251 of the NHS Act 2006 continue to be necessary.

The Panel will act as a catalyst for change by seeking resolution of information governance issues through appropriate National Information Board commissioning channels.

On the day of the announcement of the role of National Data Guardian, the National Information Board and Department of Health published a framework for action to make better use of data and technology to improve the quality of health and care services while reducing the cost.⁴⁰ The framework included proposals for building and sustaining public trust. It said:

“Under the auspices of the NIB and the National Data Guardian, a working group will carry out a wide-ranging public consultation on how the care system should handle the dissemination and use of sensitive data. This will develop proposals that enable citizens to access a transparent audit that records the uses made of their patient data for secondary purposes and details the benefits for health and care that have resulted.” The Panel welcomes the NIB’s intention to carry out this consultation and develop these proposals. It looks forward to assisting the National Data Guardian in providing assurance that the work is done well.

³⁸ https://www.gov.uk/government/speeches/innovation-and-efficiency?utm_source=twitter&utm_medium=social

³⁹ Ibid

⁴⁰ *Personalised Health and care 2020*: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/384650/NIB_Report.pdf



You are

**responsible for keeping
patient and personal
information confidential
and secure**

Any questions, ask your IG Manager



5 Conclusions & recommendations

Conclusions

In addition to the findings of individual chapters that have been set out above, the Panel has reached some overarching conclusions.

Implementing the Caldicott2 recommendations

In spite of considerable effort by many people in many organisations, progress in implementing the recommendations of the Caldicott2 report has not been quick or comprehensive. As noted in Chapter 2, the report card at the end of the first year after the Government's acceptance of the recommendations reads: "Must try harder." It is now time for the health and care system to increase the pace of efforts to get information governance right.

In the view of the Panel, the action needed to improve the public's trust in how data is used in health and social care should include:

- Action at the centre to create a clear implementation plan, establishing the responsibilities of each organisation to achieve the recommendations in the Caldicott2 report and setting a timescale for delivery. This implementation plan should be agreed by the Department of Health and its partners in the National Information Board and the Information Governance Oversight Group. The Panel suggests that the task of overseeing the relevant health and social care organisations to ensure that the plan is delivered could usefully be included among the responsibilities of the Information Governance Alliance;
- Action in every health and social care organisation should be monitored using a new version of the Information Governance Toolkit, which should measure how well the organisation is implementing the Caldicott2 recommendations and, in particular, how well it performs in sharing information for direct care. While the toolkit is being updated, tested and formally approved as an Information Standard, there should be an interim monitoring survey, also formally approved as an Information Standard;
- Action should be taken at professional level to develop awareness and understanding among staff about the Caldicott principles and their relevance to practice in health and care. This should be supported by meaningful training in information governance within each organisation and broader education initiatives to develop understanding of information governance during professional education and in continuing professional development.

Promulgating the Caldicott2 principles

During the work of the past year, the Panel has not found any reason to amend the principles set out in the Caldicott2 report. One of the report's recommendations was that

these principles should be adopted and promulgated throughout the health and social care system. It is fitting that they should be repeated here. The seven principles are as follows:

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 items 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 is 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.

Building public trust

The entity called IIGOP will shortly go out of existence. It is expected to be replaced by a new Panel supporting the work of the National Data Guardian for health and social care,

as described in Chapter 4. Appointments to the new Panel had not been made at the time of writing this report. It is fitting for the IIGOP Panel to express wholehearted approval for the new arrangements. The Secretary of State has stated his intention of placing the office of National Data Guardian on a statutory footing at the earliest opportunity. A conclusion from the work done over the past year is that such statutory underpinning is necessary to maximise effectiveness – and by so doing to maximise public trust.

Recommendations

The Panel recommends that the following priorities are consistently addressed in all plans to implement the Caldicott2 recommendations and the further conclusions of this annual report.

1. *Transparency and openness is required to enable public understanding and participation:*
 - All organisations and individuals who are data controllers have to ensure that their handling of data complies with the principles of “fair processing”. This means that people need to be fully informed about the purposes of the data use, distinguishing when it is being used for the direct care of individuals and when for indirect purposes such as medical research or business planning
 - Successful fair processing involves preparing communications materials in collaboration with the public and organising a national information campaign outlining the purposes of data use.
 - Public understanding depends on consistent terminology, which needs to be both accessible and published.
 - Fair processing information, readily understood, should be available at all points in the patient journey.
2. *Individuals must be able to opt out of data sharing arrangements and be confident that their wishes are being respected consistently across the system. This requires:*
 - A national policy and guidance on consent and objections to data sharing.
 - Common standards for coding language and technology.
 - Objection policy needs to take into account the virtual world so that, for example, new services such as NHS 111 are included when implementing this policy.
 - There need to be clear and distinct routes for individuals to object to their data being shared for their direct care AND indirectly for other purposes.
3. *All organisations need strong leadership to drive the delivery of the recommendations above, including:*
 - A named sponsor for each of the national organisations, who will be a senior figure and responsible for making sure these recommendations are followed.
 - Meaningful training in information governance and broader education initiatives to develop awareness and understanding amongst staff and training embedded within each organisation so that:
 - This leadership should be both guided by and evidenced through an IG Toolkit which is made relevant to information sharing across the diverse health and social care landscape. Continued implementation of the recommendations from the 2013

IG Review and the recommendations above should be evidenced through a new IG Toolkit requirement. Analysis of the new IG Toolkit should be automated and published so that the public can see year on year improvements or deterioration in effort.

- In summary, the goal should be a state of information governance in which the following proposition prevails: “Organisations have no hiding places, the public have no surprises.”



Appendix 1: Terms of reference

Purpose/role:

The Independent Information Governance Oversight Panel has been established at the request of the Secretary of State to advise, challenge and report on the state of information governance across the health and care system in England. It is non- statutory, independent and will work in an advisory capacity.

Background:

The report from the NHS Future Forum work stream on information recommended that:

“The Government should commission a review of the current information governance rules and of their application, to report during 2012. The aim of the review should be to ensure that there is an appropriate balance between the protection of patient information and the use and sharing of information to improve patient care.”

In January 2012, the Government accepted this recommendation, and the then Secretary of State for Health asked Dame Fiona Caldicott to lead an independent review of information governance across the health and care system in England. Dame Fiona agreed and in order to distinguish this review from Dame Fiona’s report in 1997, it became known as the Caldicott2 Review.

The final report of the review was sent to Secretary of State in March 2013 and published in April 2013.

Following the abolition of the National Information Governance Board (NIGB) in March 2013, there is no independent scrutiny of information governance across health and social care. This was identified as a major risk by a number of key stakeholders to the independent Review panel and also by NIGB in letters to Ministers. This Government wishes to pursue its agenda of open data and transparency but recognises that independent scrutiny continues to be required.

It also acknowledges that governments have in the past launched policy initiatives that failed to deliver the desired outcomes and potential benefits. This Government wishes to ensure that the recommendations that it accepts following the review of information governance by the panel led by Dame Fiona Caldicott are delivered and do achieve the intended outcome.

In March 2013 the Secretary of State for Health in England wrote to Dame Fiona to ask her to design and chair a new independent panel to *“provide independent advice and challenge to the whole health and care system”* and to provide *“annual updates... on progress made in implementing the recommendations and proposals in your forthcoming Information Governance Review and on the state of information governance across the health and care system.”* He added: *“I would also welcome the Panel’s scrutiny of the work of the newly established Informatics Services Commissioning Group and, more broadly, its advice and challenge to the health and care system on Information Governance issues.”*

Aims/Responsibilities:

Based on the mandate above, the functions of the Independent Information Governance Oversight Panel (the panel) are:

- To provide annual updates to the Secretary of State on progress in implementing the recommendations and proposals in the Information Governance Review report and on the state of information governance across the health and care system
- To provide advice to the health and care system including the Information Services Commissioning Group (ISCG) on information governance issues
- To provide challenge to the health and care system including the ISCG on information governance issues.

Aspects the panel will consider:

1. Whether Personal Confidential Data is being processed lawfully and according to good practice.
2. Information Governance in the health and care system in the light of the implementation of the Health and Social Care Act 2012.
3. Specific Information Governance issues that affect individuals.
4. Specific Information Governance issues that affect organisations.

The recent Information Governance Review panel chaired by Dame Fiona sought the views of patients, service users and carers and kept them in mind throughout its work and the panel will do the same.

Scope:

The health and care system formally includes the Department of Health, its executive agencies and the 'arm's length bodies' as well as commissioners and the commissioned health and care service providers in England. However, the scope for the panel is similar to that of the Information Governance Review and therefore includes all generators and users of patient and care service information.

The panel will have formal relationships with:

- The sponsor – the Department of Health, External Relations Directorate
- Informatics Services Commissioning Group and its IG sub group

An initial list of key stakeholders based on that within the IG Review scope is at annex 1 but this will be updated as the work of the panel develops. The master list will be maintained in the panel's stakeholder management plan.

Membership:

Membership of the group is by invitation from Dame Fiona and will be limited in size. Members will be independent and will not represent their employing organisations. The panel will initially contain members with interests and experience drawn from community, primary and secondary care within the NHS, nursing, local government, social care, the Foundation Trust Network and commissioning.

The duration of appointment of Panel members will be up to three years normally but may be extended by a further two years. Once fully established, the overall change in members should be approx. one third of members in any given year. This helps to give consistency and provide continuity – but also enables a rotation of members as issues develop and as the panel comes to greater understanding of IG issues in the new health and care landscape. Open appointment to the panel will be considered.

The Panel will be considered quorate when at least 60% of members can attend.

Accountability:

Dame Fiona is accountable to the Secretary of State for Health.

Review:

The group will review the relevance and value of its work and the terms of reference annually.

Working methods/ways of working:

This will include receipt of papers of ISCG⁴¹ and attendance by Dame Fiona (or Professor Martin Severs as a deputy) at its meetings where appropriate and practical.

The work programme of IIGOP should be:

- Both reactive and proactive.
- Within the scope of the Terms of Reference or be part of a recommendation to widen those Terms of Reference.
- Always be presented at IIGOP with a 1-2 page briefing note including clarity of the IIGOP decisions needed and accompanied by any additional detailed papers.
- Associated by preparatory work through the IIGOP Steering Group and support team when acting in reactive mode.
- Output in general as summary points from each meeting as the Annual Report.
- Output in specific instances as a letter from the IIGOP Chair.
- Available to members as papers at least one week before the meeting takes place to allow enough time for reading and reflection.
- Managed within at least 4 quarterly meetings, chaired by Dame Fiona Caldicott, each lasting approximately 4 hours.
- Managed as much as possible through email and 'Quickr' (or an equivalent online portal) for documents.

Meetings

At least four meetings will be held each year in London, chaired by Dame Fiona. In addition, virtual meetings may be required, to develop and agree responses to issues raised by ISCG and others. Additional meetings can be requested by the Chair.

The panel may also occasionally meet with the reference groups mentioned in Annex 1.

⁴¹ ISCG has been replaced by NIB since these ToR were agreed.

Topics for the agenda can be suggested by the panel, by the sponsor, the secretariat and by ISCG. Agenda items may be generated by issues arising through contact with the panel, the courts or the media. There will be some agreed standing agenda items.

Non-members will be invited to the meetings from time to time, by invitation from the chair.

Funding:

The secretariat will be hosted by the Department of Health with funding/resources for the panel and its secretariat provided by members of ISCG.

Sharing of information and resources (including confidential materials)

The panel will share material using Quickr⁴² (or an equivalent online portal) – the site will be managed by the secretariat. Confidential material will be handled according to the Department of Health rules.

Annex 1: Key Stakeholders (taken from IG Review scope with amendments)

People, organisations and staff in scope for this review include:

1. Patients and service users plus patient and service user groups
2. Local Authorities and the Local Government Association
3. Registered health care providers
4. Registered social care providers
5. Commissioners
6. Department of Health and its Arm's Length Bodies, Non- Departmental Public Bodies and Executive Agencies
7. Professional regulatory bodies including Professional Standards Authority/health and care regulators and the Health and Care Professions Council
8. Academic researchers in universities
9. Medical Royal Colleges in relation to professional training
10. The Information Commissioner's Office
11. Data management and analysis companies contracted as data processors
12. "Information intermediaries" with access to patient and service user data
13. Industry, for example pharmaceutical, medical devices, data management and analysis companies, seeking to access "person-level" patient and service user data for their own purposes
14. The police and other government agencies and public bodies.
15. The National Information Governance Committee (within the Care Quality Commission)
16. The Confidentiality Advisory Group (within the Health Research Authority)
17. Organisations with formal responsibility to provide data to the HSCIC, as well as the General Practice Extraction Service and its Independent Advisory Group

⁴² In August 2014 IIGOP moved from QUICKR to DH Exchange following technology changes at DH.

18. The Department of Health's Health and Social Care Transparency Panel (chaired by Dr Dan Poulter, MP)

2 December 2013



Appendix 2: IIGOP panel members

- Dame Fiona Caldicott, Chair, (Oxford University Hospitals NHS Trust)
- Ian Atkinson (Sheffield Clinical Commissioning Group)
- John Carvel (Healthwatch England)
- Janet Davies (Royal College of Nursing)
- Dr Alan Hassey (Information Governance Clinician)
- Eileen Phillips (Health and Social Care Information Centre)
- Professor Martin Severs (University of Portsmouth)
- Anne Stebbing (Hampshire Hospitals NHS Foundation Trust)
- Mark Taylor (University of Sheffield)
- Caroline Tapster (former CEO Hertfordshire Council)
- Richard Wild, (National Data Guardian Panel, Director)



Appendix 3: Glossary of terms

Term or Abbreviation	Definition/Full Name
CAG	Confidentiality Advisory Group
Care Team	The care team consists of the people providing direct care to a person. It may be a multi-professional team and a multi-agency team. It will consist of registered and regulated health and social care professionals and staff working to their instructions.
<i>care.data</i> programme	The programme building on existing data services and expanding them to provide linked data that will eventually cover all care settings, both in and outside of hospital. NHS England is commissioning this from the Health and Social Care Information Centre (HSCIC) on behalf of the entire health and social care system.
CCGs/Clinical Commissioning Groups	Local commissioning organisations for NHS in England
CSUs/ Commissioning Support Units	Specialist data processing organisations supporting one or more CCGs.
DH	Department of Health
Direct Care	Direct Care is the provision of health and/or social care services to a person in need of those services that requires some interaction between the person and health and/or social care. Examples include assessments, performing medical procedures, providing other health and social care interventions, and developing care plans.
HRA	Health Research Authority
IG	<p>Information Governance</p> <p>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 (Information Governance Review definition).</p> <p>Information Governance provides a framework to bring together all the legal rules, guidance and best practice that apply to the handling of information, allowing:</p> <ul style="list-style-type: none"> • implementation of central advice and guidance; • compliance with the law; • year on year improvement plans.

Term or Abbreviation	Definition/Full Name
	<p>At its heart, Information Governance is about setting a high standard for the handling of information and giving organisations the tools to achieve that standard. The ultimate aim is to demonstrate that an organisation can be trusted to maintain the confidentiality and security of personal information, by helping individuals to practice good information governance and to be consistent in the way they handle personal and corporate information. (IGA Definition).</p>
IGA	<p>Information Governance Alliance</p> <p>The Information Governance Alliance (IGA) is a group of national health and care organisations that are working together to provide a joined up and consistent approach to information governance.</p> <p>The core members of the IGA are the Department of Health, NHS England, Public Health England and the Health and Social Care Information Centre.</p> <p>The IGA aims to improve information governance in health and care by:</p> <ul style="list-style-type: none"> Providing a single authoritative source of information and guidance Providing support to front line staff, managers and their organisations to help them handle personal information confidently and in the best interests of people who use their services Developing the capacity and capability of the information governance profession by providing expert advice and a knowledge sharing network
IGAR	Informatics Governance Assurance Review
IGTK	<p>Information Governance Toolkit. The Information Governance Toolkit is a Department of Health (DH) Policy delivery vehicle that the Health and Social Care Information Centre (HSCIC) is commissioned to develop and maintain. It draws together the legal rules and central guidance set out by DH policy and presents them in in a single standard as a set of information governance requirements. The organisations in scope of this are required to carry out self-assessments of their compliance against the IG requirements.</p>
IIGOP	Independent Information Governance Oversight Panel
ISCG	Informatics Services Commissioning Group. Subsequently reformed as NIB.
LA/Local Authorities/ CASSRs	<p>In this report, used to describe Councils with Adult Social Care Responsibilities. Local Authorities in England also have responsibility for statutory adult social services, children’s services & public health.</p>

Term or Abbreviation	Definition/Full Name
Lower tier local authorities/ District Councils	The local authorities that are not CASSRs, but may be involved in provision of social care services, including social housing.
NHS England	The national commissioning organisation for the NHS in England.
NIB	National Information Board
NIGB/National Information Governance Board	NIGB was disestablished on 31 March 2013. Some of its functions were transferred to CAG (see above.)
PHE	Public Health England

