NATIONAL INFORMATION BOARD
Personalised Health and Care 2020

WORK STREAM 4 ROADMAP
Build and sustain public trust

Deliver roadmap to consent based information sharing and assurance of safeguards

June 2015

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1 CONTEXT

1.1 Background

Data collected by the health and care system is a rich resource for the benefit of UK citizens. There is enormous potential for data to drive improvements in health and care. There are many thousands of interactions between patients and health and care professionals every day and each one involves the collection or use of data for the benefit of the patient. Fully utilising health data will improve results for patients. Data is also needed to run health and care services efficiently, to evaluate the effectiveness of those services and to regulate their safely.

A further use of data is to ensure that UK citizens can access the newest and most effective treatments. The UK is already a world leader in health research and is known for innovative projects which provide tangible and substantial benefits to patients. The UK Biobank aims to improve the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses by following the health of 500,000 adults across the country. The 100,000 Genomes Project will lead to better treatments and earlier diagnosis for patients for generations to come. Based on the consent of NHS patients with cancer or a rare disease, their genome and clinical data will be used for ethical research purposes. The project is already returning results; two families have now been diagnosed with rare diseases as part of a project at Newcastle Hospitals and University and will therefore be able to receive effective and personalised treatment.

1.2 Use of data

There are two types of data: (a) data which identifies an individual or could be used to do so (effectively, any person-level data); and (b) grouped and anonymised data.

There are four principal reasons for using health and care data:

- To support an individual's direct care;
- To run the NHS and health and care system more effectively and efficiently. Commissioning, providing and regulating services based on the best available data and evidence;
- To promote research, including to develop innovative new medicines, treatments and services; and
- To protect and improve health and reduce health inequalities.

The need for better use of data and technology was highlighted in the NHS Five Year Forward View as a tool to help address the health and wellbeing gap, the care and quality gap, and the funding and efficiency gap.

However, there are ethical, legal, professional, technical and behavioural barriers to fully utilising the UK's health and care data for the purposes described above. This underpinning work stream is directed to ensuring that public and professional confidence can be restored, sustained and strengthened in order to be able to use data safely and effectively. This trust is a prerequisite for the success of the NIB therefore close engagement with all work streams is maintained.

2 RESEARCH AND EVIDENCE

A number of studies provide valuable insight into the questions around the use of data:

- The Nuffield Council on Bioethics published *The collection, linking and use of data in biomedical research and health care: ethical issues* in February 2015, considering the relationship between public and private interest;
- Weale and Clarke published *Information Governance in Health* in 2011, considering the debate of how best to reconcile the benefits of improved health services and research with social values including consent, privacy, and fairness and reciprocity; and
- A 2013 study by the OECD argued that 'it makes economic and ethical sense to use this data as much as possible: to improve population health and to improve the effectiveness, safety and patient-centeredness of health care systems'.

The Wellcome Trust found that the public have "no/very few objections to medical data being used for the 'general good' (perceived as helping find cures and causes), provided commercial gain is not the priority".[1] Work conducted by Ipsos MORI also suggested that GP surgeries, the NHS, and academic researchers and universities are trusted institutions and that the public are happy for health and care services to use their data but often feel uneasy about its use by external parties such as insurers, entrepreneurs and other Government departments. The HSCIC may only disseminate information where there is a clear purpose for the provision of health care or adult social care or the promotion of health, and not for solely commercial purposes, such as insurance.

Work is needed to rebuild the public's trust in the health and care system's ability to manage personal confidential data safely and securely. A balance must be found between the desire to use data for the public good and the need to keep that data safe and secure. A clear consensus is needed between patients and health and care professionals and others about how data relating to them will be used. This can only be based on a transparent understanding of the uses to which information will be put, and a clear explanation of the benefits for patients and service users. The health and care system needs to provide a clear vision to the public that transforms the relationship between the state and the citizen about their health and care data. This is not merely a technical exercise to counter negative media attention; substantial change and long-term work is needed to deliver the benefits of data use.

The first step will be a wide-ranging engagement process to establish a full picture of citizens' attitudes to use of data by the health and care system. It is important to establish a baseline for the public mood in order to measure future progress, including key concerns where work is needed and demographic information e.g. which sections of the population are or more or less concerned about their data. In addition, the views of health and care professionals must be captured as their support is vital to building public trust.

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[1] http://www.wellcome.ac.uk/stellent/groups/corporatesite/@msh_grants/documents/web_document/wtp053205.pdf

3 BUILDING THE PICTURE FOR DELIVERY

3.1 Public dialogue – the key

The priority for this Work Stream, and a prerequisite for the success of other work streams, is to get the public dialogue right.

The Nuffield Council on Bioethics' 19 June 2015 is a roundtable event on securing the use of health and care data in a way that sustains public and professional trust. The event provides an opportunity for leaders in the NHS and health and care system to meet informed and influential stakeholders to engage in debate and generate options for building public trust in the use of health and care data. The outcomes of this event will be used, along with an options paper produced by the DH Policy Support Team, to initiate a discussion with Ministers. Thereafter a decision will be needed on how the public dialogue should be carried out, over what timescales and under whose leadership.

Another activity currently being undertaken by the NIB, is the creation of a communications framework for all of the work streams to ensure that all public and professional engagement is consistent. An upcoming opportunity to present this consistent communication are the NIB regional roadshows planned for summer 2015. These roadshows, aimed at stakeholders, commissioners and providers, will cover the whole of the NIB framework but, as a form of public engagement, will be useful in informing the ongoing engagement planned by Work Stream 4.

The choice of language is central to the communication of this Work Stream and the wider NIB. The Ipsos MORI work suggests that choice of language is extremely important (e.g. using the term "opt out" rather than "objection" because the former is widely understood even though the latter is the correct legal term – indeed, "preferences" may be an even more straightforward way to describe this). Use of legalistic terms, rather than more intuitive terms, may inadvertently be confusing the public and undermining public trust and confidence.

3.2 National Data Guardian

If patients and service users are to be confident in allowing the health and care system to use their data, there needs to be robust safeguards to ensure that this is done in a lawful and appropriate way. An independent and trusted 'challenge' function is essential. The National Data Guardian (NDG) role was established by the Secretary of State in November 2014, with a remit to speak without fear or favour about the safe use of personal health and care information.

Dame Fiona Caldicott and the Independent Information Governance Oversight Panel (IIGOP) have already, without recourse to legislation, built a strong reputation as an effective and authoritative voice.

A public consultation is likely to be required in the summer of 2015 to clarify the National Data Guardian's role, including how it relates to the Information Commissioner's Office. Primary legislation will most likely be used to place the independent NDG role on a statutory basis, with further opportunity to comment on the regulations concerning the detail of the role. This legislation will provide public reassurance that health and care data is being held safely.

3.3 Preference models

Patients and the public should have the confidence that their preferences for the use of their data are being upheld wherever possible, and health and care professionals should be confident in the legality of using a patient's data for their own care. The use of personal data to support direct care is already lawful, albeit on the basis of the common law principles of consent. Reliance on the common law, combined with a lack of training in information governance, can lead to a 'risk-averse' approach preventing health and care staff from cooperating as they should for the benefit of patients.

The Health and Social Care (Safety and Quality) Act 2015 places a duty on health and adult social care providers to share information about a person's care along their care pathway with other health and care professionals. Clinicians providing a person's care and treatment will have the information they need at their fingertips so they can treat that person more effectively.

Further work is being undertaken within the HSCIC in the following areas:

  a) A review of the current consent and objection options in national and local systems.
  b) The development of a new preferences model.

Work has also been undertaken to look at some of the dependencies that the implementation of a system wide preferences model will place on other NIB work streams.

The HSCIC is undertaking work to develop a model for recording patients' preferences for the use of their data. This model is being developed to be fully extensible (i.e. to manage preferences at a number of different levels, across a number of different dimensions) and generalisable (i.e. that it can initially be implemented in a simple manner, but extended as requirements develop over time).

The preferences model will be used to inform the public dialogue in terms of the different levels at which preferences can be set and managed. The final definition of the model will be aligned with outcomes of the public dialogue, both in the definition of types of data and the purposes for which information can be shared.

The Information Governance Alliance has also been commissioned to develop clear guidance on the legal basis for the overriding of objections and disclosures in the public interest, and to produce a glossary of terms, which will be essential to underpin any meaningful dialogue.

3.4 Information and cyber security

The Department of Health and the HSCIC are working with NHS England, Monitor and the Trust Development Authority (plus other ALBs and relevant professional bodies) to make sure that organisations, systems and patient data are safe and secure from the risk of malware and other potential forms of cyber-attack. The Information Security and Risk Board (ISRB) was recently established, and comprises senior officials from across the health and care system and Cabinet Office. The principal focus will be on information and system security.

A key tool to deal proactively and effectively with cyber-security risks will be the CareCERT facility (the health and care central computer with emergency alerting, response and support capability which is to be established by the HSCIC). The aim of CareCERT is to provide a proactive service which enables rapid, controlled dissemination of information about, and fixes to, cyber threats identified within public sector systems.

Within our current care system, the information security culture is diverse and more work is needed to ensure consistency of risk assessment, and mitigating treatment. It is essential that the issue of behavioural change at board-level is addressed.

3.5 Information Governance

Unlike other countries such as Sweden, where Information Governance is relatively straightforward, the system in England is complex, with a web of the common law, multiple Acts of Parliament, and decades' worth of Government policy and commitments. The resulting uncertainty means data is not always used effectively to improve care. This Work Stream is an opportunity to simplify this system and strengthen its role in assuring public confidence.

The Information Governance Alliance (IGA) was set up in July 2014 in response to a request from the IIGOP and the National Data Guardian. The IGA brings together resources from member organisations to consolidate specialist knowledge, provide a single source of authoritative and credible guidance and to establish a national information governance network.

The Information Governance (IG) Toolkit provides a roadmap for achieving excellent information governance. It is also a performance assessment, incident reporting and management tool satisfying the Cabinet Office requirement for DH to provide assurance that all parts of the NHS are meeting mandated data handling standards.

The IG Toolkit needs to be updated to meet the developing demands of the health and care system. The HSCIC is working to re-launch the content of the IG Toolkit by October 2015, including launching a Beta release of a module aimed towards the needs of independent contractors and smaller organisations. In stages running to 2018, the HSCIC will extend assurance options to allow an outcome based focus that goes beyond reporting on processes. HSCIC will work closely with the IGA to create a single, authoritative source of Information Governance support and guidance for the health and care system.

Further possible options could include exploring issues of identity and branding, in order to make the IGA and the Toolkit easily understandable to the public; and publishing a register of all health and social care organisations showing their current IG toolkit level and trajectory.

4 BENEFITS

Work Stream 4 is not expected to have explicit cash-releasing quantifiable benefits. Instead, this Work Stream will help 'unlock' the potential benefits of other work streams. Public trust is a prerequisite for the success of all other work streams and therefore all of the benefits are linked.

In particular, Work Stream 4 will enable the benefits of the following work streams:

- Providing patients and the public with digital access to the health and care information and transactions
- Providing citizens with access to an accredited set of NHS and social care "apps"
- Setting the commissioning and regulatory roadmap for implementing digital standards by 2018/2020 (including agreement on the standards)
- Developing a roadmap for comprehensive data on the quality, efficiency, and equity of health and care services for secondary uses (i.e. all uses that are not direct care)
- Bring forward life-saving treatments and support innovation and growth.

Patients, citizens, carers and clinicians will all benefit:

Patients/Carers
- Patients will have confidence that their personal records are only being accessed by the relevant staff in order to deliver their care.
- Patients will be confident that their data is being used in de-identified formats to improve health and care services.
- Providing data, in accordance with people's preferences, to researchers and organisations who undertake academic or health service improvement research to develop new medicines, treatments and services that will improve patient care.

Citizens
- Improved data will result in smarter commissioning which will mean improved health outcomes for citizens and users, and more efficient and equitable use of taxpayer money.
- Citizens will be provided with transparent information about how health and care services are using their data and therefore have increased trust and confidence in these institutions.
- Public health benefits will include better health literacy, improved lifestyle and wellbeing, disease prevention, and keeping citizens safe from communicable and environmental hazards.

Clinicians/ Professionals
- Care Professionals will have the ability to access high quality data on patient safety, patient experience, and the outcomes that matter to patients, including patient reported outcome measures (PROMS).
- Professionals will be able to collaborate as a care giver team, without any uncertainty about the legality or consequences of sharing data with the relevant professionals in a patient's care pathway.
- Clinicians will have the ability to access data on the clinical activities

each care professional has been involved in so that they are able to benchmark themselves and generate evidence for revalidation and for continuous improvement.

- The use of data will be a key source of insight in identifying efficiency opportunities from improved coordination, reduced duplication and more proactive care management.

APPENDIX A: TIMELINE FOR WORK STREAM 4 ROADMAP

June 2015
19th – Nuffield Council on Bioethics roundtable

Initial discussion with Ministers on the shape of public dialogue

July 2015
Contract Award for HSCIC supplier partner for CareCERT

Ongoing public dialogue

Provisional start of public consultation on the role of the National Data Guardian

October 2015

Autumn (timing TBC) – CareCERT Phase 1 go-live

Information Governance Toolkit re-launch

2016

Development of suite of cyber security tools by HSCIC, to support health and care system, including SIRO support proposals

Timings TBC – National Data Guardian role to become statutory

April 2016
Provisional date for publication of a roadmap for moving to a whole-system, consent-based approach to sensitive data

2020
Preferences model to be developed and implemented