

DATA SHARING

Sponsoring division:

Contact: ext

Who will present:

Please confirm that in developing the policy/proposal/guidance you have considered Welsh Language, Equality, Sustainable Development, United Nations Convention on the Rights of the Child and socio economic impacts

Confirmed – please include a short description of how in the body of the paper, including confirmation that the necessary impact assessments have been completed.

Not applicable

If not applicable, why not (e.g. internal corporate matter)

Internal corporate matter

Has the Policy Assurance Board considered this paper?

Yes

Not applicable

If not applicable, why not (e.g. internal corporate matter)

As above.

Please state if the paper is for:

Discussion

Decision

Information

EXECUTIVE DIRECTORS TEAM IS ASKED TO:

List clearly what EDT is asked to do.

To *agree* a course of action

To *endorse* a decision

To *advise* on an approach

To *identify* action required

To *note* for information

Situation

There is a need for a clear and well understood framework for sharing of data on individuals across Health and Social Services to improve care and for the safe delivery of A Healthier Wales and the Informatics Statement of Intent.

The HSSG Digital Health and Care team has undertaken an appraisal of the options, and engaged with stakeholders, including gaining support from the information Commissioner's Office in Wales and discussion at the Wales Information Governance Board, and has arrived at the approach recommended in this paper.

Background

The NHS and social services across Wales gather a wide range of data that is essential for providing safe and effective health and care services. A robust set of systems and legislation needs to be in place to manage this data securely and maintain public confidence in how data is shared. In October 2017, the Welsh Government published its Statement of Intent committing to make better use of health and care data, setting out four key priority areas:

1. Develop a more transparent framework for how we manage, use and share health and care data.
2. Put in place the digital solutions to ensure that health and care information is available as a resource for use at national and local levels, by consolidating and building on existing data flows and management.
3. Develop the skills and resources required to realise the full value of the data we hold.
4. Improve information collection and quality

This paper addresses the point one, which is to:

“develop a more transparent framework for how we manage, use and share health and care data and to ensure everyone involved, most importantly the public and patients, understands the way we use and share data”.

The remit of the information governance discipline covers distinct areas of data privacy that in turn promote public confidence in its use. This includes how health and care data can, and should, be shared to benefit the citizen and affects those organisations charged with responsibility for its processing.

Currently there is a range of information governance arrangements which are fit for purpose in their specific context, however there is no overarching scheme or framework, meaning approaches to data sharing are often inconsistent or not followed for fear of doing the wrong thing. This uncertainty often acts as a barrier to appropriate data sharing and undermines the ability to harness the full benefits of the effective use of data.

Legal position

It is clear that everyone involved, most importantly the public and patients, needs to understand the way data is used and shared across health and care in Wales. This includes managing consent and protecting privacy.

Personally identifiable data can already be shared across health and care when there is clear need to do so for direct care purposes and where it is required by law (e.g. safeguarding regulations). Data can also be shared after it has been anonymised. It is only for sharing personally identifiable data for other purposes (see below) that the consent of the individual is normally required. However, this is not universally understood or acted upon and which can prevent the effective sharing of information.

Where it is not possible to use anonymised information and where seeking consent is not practical, having regard to the cost and technology available, Section 251 (S251) of the NHS Act 2006, enables the common law duty of confidentiality to be lifted to enable disclosure of confidential patient information for medical purposes.

As a safeguard to these regulations, the UK Confidentiality Advisory Group (CAG) was established as an independent panel providing expert advice and scrutiny on Section 251 applications. The CAG provides advice to the Secretary of State for Health and Social Care in England for applications which require access to patient identifiable information where patient consent or the use of anonymised information is not practicable. The use of S251 also extends to applications in relation to national collections of data used by the NHS Wales Informatics Service (NWIS) and Public Health Wales Trust.

Typical reasons for applications to CAG for approval to access personally identifiable information include:

- To identify a cohort of patients and subsequently seek their consent;
- To allow access to a deceased person's data;
- For time-limited access to undertake record linkage/validation and to anonymise the data;
- To confirm validity of consent (i.e. where the data controller states that the wording of the original consent is insufficient to provide a legal basis to allow access)
- Data cleansing of historical studies
- To be able to administer surveys on behalf of the Care Quality Commission

We are seeking to remove the reliance on CAG and the Secretary of State to grant approval and provision this in Welsh law, so that decisions on the appropriate use and sharing of data within a Welsh context are made within Wales.

To support this, Welsh Ministers (Transfer of Functions) Order 2018, laid last year, transfers powers of the Secretary of State in S251 of the NHS Act 2006 to the Welsh Ministers in so far as they relate to Wales. Legal Services have been asked to provide advice on the regulatory changes required in order for Welsh Ministers to be able to take decisions on processing of patient identifiable information. There will also be a need to develop a governance framework to support Welsh Ministers.

Until then, the Health Service (Control of Patient Information) Regulations 2002 continue to apply and the responsibility for taking decisions, following receipt of CAG advice, remains with the Health Research Authority and the Secretary of State. .

Other Home Nations

In England, Caldicott 3: The National Data Guardian's 3rd Review of Data Security, Consent and Opt-Outs made a number of recommendations to the Secretary of State for Health. These were aimed at strengthening the safeguards for keeping health and care information secure and ensuring the public can make informed choices about how their data is used.

The review proposed the introduction of a national data opt-out, which would apply to use of confidential patient information. On the 25th May 2018, NHS Digital in England launched a national data opt-out to apply to use of confidential patient information for purposes beyond individual care across the health and adult social care system. This opt-out in England only applies to identifiable data that is shared for planning and research purposes.

The English programme offers patients the opportunity to opt out of their personally identifiable data being shared for research to find cures and better treatment for illnesses; and planning to improve or provide more health services. There are scenarios where consent is not required, and opt-out not possible, such as for safeguarding issues.

Scotland are currently reviewing their national IG landscape and work is being undertaken to allow linkage of data within the wider public sector for research and statistics purposes. As part of that, they are exploring new ways of public engagement.

They do offer an opt-out in instances when they feel there is a reasonable expectation that the data under consideration is likely to be considered particularly sensitive.

Decisions over the local processing of personal data, for research or non-research, are currently made at health board or GP level as applicable. They are also currently finalising a joint controllership national agreement between health boards and GPs that includes some arrangements for joint decision making. Decisions that involve personal data at a national scale or more than one health board go to their Public Benefit and Privacy Panel (PBPP) for scrutiny and advice.

In Northern Ireland, there is an opt-out of information sharing across the Northern Ireland Electronic Care Record (NIECR). The NIECR allows primary care information to be viewed in secondary care, mainly the emergency care information although being expanding over time. Information will still be held and recorded on patients by the clinician treating them, but it won't be shared on the common platform.

In Northern Ireland in April 2019 there were 97 patients opted out, of whom seven were under 18 years of age. The number of opted out patients has remained quite constant as new opt-outs have been offset by opt-ins. Northern Ireland have had 34 patients opt back in. While negligible in percentage terms, the process still has to be managed.

Options development

In developing this paper, the Digital Health and Care team engaged with key stakeholders, including:

- Internal Health and Social Services policy leads;
- Wales Information Governance Board;
- Information Commissioner's Office in Wales;
- Information Governance Managers Advisory Group;
- Informatics Planning and Delivery Group;
- Public Health Intelligence Network;
- All Wales Heads of Information Services;
- Bio-banking Task and Finish Group;
- Members of the Confidentiality Advisory Group¹;
- HSS Deputy Directors Policy Group.

That led to four options being a fuller options paper is available if required):

Option 1 – Strengthen existing arrangements

Option 2 – Subscribe to England's opt-out scheme

Option 3 – Develop separate opt-out scheme for Wales

Option 4 – Develop a 'Data Promise'

The policy approach was narrowed to two options:

Option 2: Subscribe to England's opt-out scheme and

Option 4: Develop a 'Data Promise'.

Develop a 'Data Promise' was the preferred option supported by stakeholders.

It is considered that the 'Data Promise' has the best potential to deliver a sustainable and comprehensive settlement for health and care data governance in Wales. The "Data Promise" as currently drafted is that:

“Health and care services will routinely, appropriately and securely share your data within health and care, to deliver high quality, safe and integrated care.

No identifiable data about you will leave health and care without either your explicit consent or a legal requirement (such as for safeguarding).”

The essence of the “promise” is that data will continue to be shared within the NHS and Social Services when appropriate and legitimate. Consent will be sought when there is a requirement identified for the information to be shared more widely.

It would put Wales in a position to make decisions on how we use data in the future, such as defining what we see as 'direct care' in a digital era and providing an opportunity

for people to have granular and multiple opportunities to consent to their personally identifiable data to be shared on specific occasions.

There is clear support to establish and implement the Data Promise. A range of activities is required to enhance effective data sharing within Health and Care for the benefit of patients and services within Wales, including:

- Legal advice and implementation of regulation to confirm and enable the proposed approach to data sharing by Welsh NHS and Social Services organisations. Legal Service have been asked to advise on detail;
- Refinement and implementation of a robust Wales-specific policy on data sharing, to foster and maintain public confidence in the sharing and use of data within the health and care system in Wales;
- Remodelling and expanding/strengthening the remit of information governance structures to support clearer accountability and safeguards in line with the policy.

Risks and issues

Work has been ongoing to better understand the impact, resource, technical and legal ramifications of the 'Data Promise'. This was discussed at a Health and Social Services Group Policy Support Workshop. Members supported the 'Data Promise' as being the preferred policy position, but identified a number of risks and issues around this:

- There was concern that without an effective Information Governance framework in place there is a significant risk to delivery of the intentions of an Healthier Wales;
- The buy-in of stakeholders is a critical part of delivering the policy intention and further engagement and support from relevant policy officials is vital;
- Appropriate resources need to be in place to drive and co-ordinate this agenda;
- There is a risk to the continuity of current sharing agreements in relation to Section 251 and the Confidentiality Advisory Group if there is delay in making a policy decision;
- Phrasing of the "Data Promise" may need reworking at some point depending on feedback and further advice.
- If we promise to share information we will raise expectation in the public that we will share that information and that will require a shift in current practice.

Concern was subsequently raised by GPC Wales colleagues about data they manage as data controllers being shared. Primary Care commissioned an external legal review to consider these issues and GPC Wales agreed with the intent to introduce Regulations to clarify this matter, whilst recognising the detail of that legislation is imperative to satisfying their concerns.

There is a further risk that implementation of the Data Promise might reveal current bad practice in Health organisations.

Recommendations

- EDT agree that Welsh Government adopt the Data Promise as our policy direction and support a recommendation to the Minister on that basis;
- Support development of a task and finish group with colleagues to consider the impact and agree next steps to implement the Data Promise within their policy areas.

Note that Legal Services have been asked for advice on regulatory changes.

- Recognise that resource will be required to implement the Data Promise effectively. (England worked extensively with GPs and other key stakeholders to be champions for their opt-out scheme, which would require engagement resource and activity if replicated here. They also spent approximately £650,000 on radio and print advertising)