Northern Ireland Assembly

Research and Information Service Bill Paper

10 September 2015

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Health and Social Care (Control of Data Processing) Bill

NIAR 97-2015

This paper examines the key provisions of the *Health and Social Care (Control of Data Processing) Bill* proposed by the Department of Health, Social Services and Public Safety (DHSSPS) in Northern Ireland, and considers some differences between the proposed Bill and the legislation in England and Wales.

Paper 88/15 **10 September 2015**

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Key points

Uses of information

Information collected in confidence as part of the direct care of a patient is called “primary use information”. This information can be of significant value beyond the direct care of the patient. This is called “secondary use information”. Using data in this way can support improvements in healthcare - for example, for service commissioning and research.

Legal obligations - secondary use of data

Departmental guidance states that secondary use patient information can only be disclosed for specified, justified and lawful purposes. Complex legal and ethical obligations also exist in terms of patient privacy, confidentiality and the re-use of data for secondary purposes. These fall under the Data Protection Act (DPA), the Human Rights Act (HRA) and the common law duty of confidentiality. Currently, disclosure of secondary patient data may be justified if the patient has given their consent. If this is not possible, the data may be disclosed without their consent if it is anonymised or psuedonymised (changed using codes), to ensure the patient cannot be identified.

Problems with the current situation – public interest

Issues arise for health and social care (HSC) organisations wishing to use secondary patient data where consent and anonymisation is not possible – examples include large scale studies, confidential inquiries, or disease registries. In these instances, HSC organisations that satisfy the DPA and HRA rely on the *public interest defence* under the common law duty of confidentiality to use the data.

However, *public interest* is problematic. It is not defined in common law and is open to interpretation. What is "in the public interest" can also mean trying to reconcile conflicting perspectives - namely patient privacy against the wider benefits to Health and Social Care (HSC) services and its users. It can also leave HSC organisations using data *without* consent open to legal challenge, although no such legal challenges have occurred in Northern Ireland to date.

DHSSPS policy proposals

DHSSPS policy proposals seek to address the current ambiguity regarding public interest by providing a statutory basis for processing secondary information for *medical and social care purposes* in limited situations and where there is a clear benefit. The proposals enable a new Committee to be established to assess applications from those seeking to use confidential secondary data - only where patient consent has not been obtained and where anonymised or psuedonymised information is insufficient.

A DHSSPS consultation on the policy proposals was conducted in 2014. 59 responses were received. Whilst respondents showed broad support, several issues were identified such as:

- questions about the scope of the proposed legislation;

- lack of detail about the remit of the proposed Committee;
- safeguards – given the recent misuse of patient data in England;
- mechanisms to opt-out;
- the processing of sensitive information about children and vulnerable groups;
- the lack of public awareness about the proposals;
- concerns about patient privacy and human rights obligations.

In addition, the consultation responses showed that views of patients were not widely represented; rather, the majority of respondents were users of secondary patient data.

The Bill itself

Whilst the Bill is intended to be enabling legislation - a framework to support regulations, there has been criticism about the broad terminology used in the Bill, the potential for data misuse and no indication of a cost-benefit analysis. The Bill provides some high level details about how decisions of the proposed Committee will be reached; yet it does not indicate what test will be used when determining when an individual's right to privacy of their information will give way to wider health benefits. In addition, the threat of legal challenge on the decisions taken by the Committee may be reduced, but will still exist.

The DHSSPS plans to provide further detail about how the Bill will operate in subordinate regulations which will also be subject to public consultation. Given the sensitivities about processing confidential patient data, and in the absence of any great detail, such regulations should be subject to robust scrutiny.

Legislative provisions elsewhere

The final section of the paper considers practices in the rest of the United Kingdom (UK) and the Republic of Ireland (ROI). Like Northern Ireland, Scotland and the ROI have no specific legislation for processing secondary patient information. England and Wales do, and this is contained within Sections 251 and 252 of the NHS Act (2006)[1] and its supporting regulations. Although the Bill's proposals are similar to existing provisions in England and Wales and the system appears to work well, comparisons must be made with caution. Notable differences include for example:

- the scope of the Bill in Northern Ireland - which will extend to the processing of "medical ***and*** social care" patient information;
- the proposed Committee for Northern Ireland - which will have powers to make decisions about applications to process secondary patient data. The equivalent oversight body in England and Wales only provide *advice* and do not take final decisions.

Finally, if a similar system is adopted in Northern Ireland, there will be challenges in terms of raising public awareness and cost implications.

[1] Previously known as Sections 60 and 61 of the Health and Social Care Act (2001).

1. Introduction: Patient Information

People using health and social care (HSC) services are entitled to expect that the information they disclose to care providers will be treated in confidence, knowing that this information will not be improperly disclosed.[2] HSC staff have strong legal and ethical obligations to protect this information.[3] Yet confidential information about service users collected by HSC organisations can also have value beyond the direct care of the patient, for example for commissioning or research purposes. Governing the disclosure of information beyond direct care purposes is the focus of this Bill.

1.1 Current position: Uses of patient information

The use of patient information can be divided into two main categories; primary use and secondary use.[4] The Bill is only concerned with the latter - secondary use information. Both types of information are briefly explained below.

Primary use information is when a patient attends, for example, their GP. In seeking help, they disclose information, sometimes of a sensitive nature, about themselves and in confidence. Patients have a legal right to confidentiality and staff are bound by a duty of confidence.[5] The information collected may, where necessary and if in their best interests, be shared with other health professionals.[6] This is called primary use information because it is used in association with the patient's direct personal care.

Typically, patient information is given where it is expected that a duty of confidence applies, meaning it cannot normally be disclosed without the person's **consent**.[7] Consent to use the information can be either explicit (written or verbal) or implied if it forms part of their treatment or care arrangements. Disclosing information beyond their direct care could lead to a breach of confidentiality.[8] The exceptions to this are when required to do so by the law or by the Courts, or when the public interest that might result from disclosure outweighs the duty of confidentiality.[9]

Secondary use information is when identifiable information (such as the patient's name, address, postcode, date of birth, or their Health and Care Number)[10] and information

[2] Health and Social Care Information Centre (2013) A guide to confidentiality in health and social care. Available online at http://www.hscic.gov.uk/media/12822/Guide-to-confidentiality-in-health-and-social-care/pdf/HSCIC-guide-to-confidentiality.pdf
[3] DHSSPS (2012) Code of Practice on protecting the confidentiality of service user information, p12. The right to confidentiality is guaranteed partly by the Data Protection Act 1998, partly by the Human Rights Act 1998, and partly by principles established by judges on a case by case basis (the common law).
[4] DHSSPS (2014) Consultation on a proposal to introduce primary legislation for the use of health and social care service user identifiable information for secondary purposes in controlled circumstances, p6.
[5] DHSSPS (2012) Code of Practice on protecting the confidentiality of service user information, p12.
[6] This could also be in the form of electronic records, paper records, blood samples, x-rays and so forth.
[7] DHSSPS website. The Common Law Duty of Confidentiality. Available online at http://www.dhsspsni.gov.uk/gmgr-annexe-c8 Website accessed 22.7.15
[8] DHSSPS Health and Social Care (Control of Data Processing) Bill Explanatory and Financial Memorandum NIA Bill 52/11-16 EFM p2. There can be several exceptions to this, such as for safeguarding purposes, or in medical emergencies.
[9] Guidance notes Section 60 of the Health and Social Care Act 2001, p9.
[10] Service users' right to privacy and the staff's duty of confidentiality apply regardless of the form in which information is held.

obtained through their direct personal care are used beyond primary means - for other health and social care purposes.[11]

2. Uses of secondary patient identifiable information

2.1 Purposes of secondary use patient information

Developments in technology have changed how healthcare data can be collected and used, and the information generated can be an important resource to improve care.

The HSC sector currently uses patient identifiable information for secondary purposes in certain circumstances. This information can be used for a number of purposes such as:

- Health service commissioning;
- Financial and clinical audit;
- Healthcare management;
- Risk stratification;
- Service planning;
- Investigation of complaints;
- Teaching and research[12];
- Public health monitoring and disease surveillance.[13]

2.2 When can secondary patient identifiable data be disclosed?

Many people are currently unaware about how their healthcare data may be used and shared. The DHSSPS acknowledges that current practice for sharing secondary use personal identifiable information in the HSC sector varies considerably[14] but it insists that robust procedures and guidance for sharing are in place (see Appendices 1, 2, and 3).

DHSSPS guidance states that secondary use patient identifiable information can only be disclosed for specified, justified and lawful purposes.[15]

[11] What is considered "identifiable" is often determined on a case-by-case assessment.
[12] Approval by the Research Ethics Committee NI is required prior to the release of information.
[13] British Medical Association (2014) Requests for disclosure of data for secondary purposes, p2. Available online at: http://bma.org.uk/-/media/files/pdfs/practical%20advice%20at%20work/ethics/releasingdataforsecondaryuses.pdf
[14] DHSSPS and HSC (2011) Protocol for sharing service user information for secondary purposes, p5.
[15] DHSSPS and HSC (2011) Protocol for sharing service user information for secondary purposes, p11.

Disclosure of personal information for secondary uses in the HSC may be permitted in certain circumstances. In addition to departmental guidance, HSC organisations use a series of steps, as shown in Figure 1, to help assess whether secondary data may be processed and shared.

Patient consent:

In the first instance, staff or organisations should always seek informed consent from patients/service users to use their information for secondary purposes. A person can refuse to consent (or opt out), and, under Data Protection legislation[16] this should be respected and their information not disclosed by the data controller.[17]

Without patient consent- anonymisation:

If it is not possible or practical to obtain consent because for example: the age or traceability of patients is difficult, or substantial costs are involved in gaining consent, information can be disclosed without the patient consent if it is anonymised[18] or psuedonymised.[19] This can be done by:

- Reducing identifiers – such as patient name, address etc.
- Reducing the precision of information – such as putting ages into age groups
- For psuedonymised information, replacing personal identifiers with a code.[20]

When patient information is anonymised, the provisions of the Data Protection Act no longer apply (as the information ceases to be 'personal').

However:

Without patient consent or anonymisation:

Where patient consent cannot be obtained, and where anonymised and pseudonymised information are not possible or practical, secondary use patient identifiable information *may* be disclosed if it satisfies:

- The Data Protection Act (DPA) and;
- The Human Rights Act (HRA) and;
- The common law duty of confidentiality

Under the common law duty of confidentiality, sharing of identifiable patient information without consent can only be justified if:

a) A statute, court or tribunal imposes a requirement to disclose the information, or

b) It can be demonstrated that an 'overriding public interest' outweighs the public interest of maintaining patient confidentiality.[21]

Figure 1. Secondary patient information: what to consider before disclosure

[16] The Data Protection Act only applies to living individuals.
[17] DHSSPS (2012) Code of Practice on protecting the confidentiality of service user information, p7.
[18] Anonymised data –for example personal identifiers such as name, age, address removed so that risk of disclosure is minimized. With anonymised data the level of detail is reduced rendering a reverse compilation impossible.
[19] This is where the most identifying fields are replaced with artificial identifiers, or pseudonyms. For example, a name is replaced with a unique number. The replaced data that should allow tracking back of the data to its original state.
[20] Within the BSO there is also an Honest Broker Service recently established to provide non identifiable (anonymised and pseudonymised) information to the DHSSPS, to HSC organisations and for ethically approved health related research. This is at present a largely untapped data warehouse with only a few applications for data requests being submitted.
[21] DHSSPS (2012) Code of Practice on protecting the confidentiality of service user information, p24 and DHSSPS and HSC Protocol for sharing service user information for secondary purposes, p7.

In summary, where:

- consent not possible or practical
- anonymisation cannot achieve desired outcome

Then there is a reliance on common law duty of confidentiality to share and process patient information. But within the common law, if no statutory basis exists to release information, HSC organisations rely on satisfying the "public interest" test for the information to be processed lawfully.

3. Legal instruments and patient privacy

Use of secondary patient identifiable information gives rise to concerns about privacy. However, a number of overlapping legal measures exist to protect patient privacy. Both primary and secondary use information is governed by the Data Protection Act (DPA 1998), the Human Rights Act (HRA, 1998) and the common law duty of confidentiality.

3.1 Data protection, human rights and the common law duty of confidentiality

The interaction between these legal instruments is complex and goes far beyond the scope of this paper, nevertheless they can be summarised as follows:

The **Data Protection Act** (1998) aims to protect the right of (living) individuals to privacy in relation to the processing of personal information. It came into force in March 2000 and gives effect in UK law to Directive 95/46/EC.[22] The DPA contains eight principles (Appendix 5), the first of which is that personal information must be processed *lawfully and fairly*. It also states that personal data shall not be processed unless at least one of the conditions in *Schedule 2* is met, and in the case of sensitive personal data (i.e. health data), at least one condition in *Schedule 3* is also met.[23]

The DHSSPS consultation document states that the DPA does not always require patient consent.[24] Conditions for processing sensitive data include Schedule 3 (7), processing "for the exercise of any functions of the Crown, a Minister of the Crown or a government department" – and Schedule 3 (8) those necessary for "medical purposes."[25] The DHSSPS consultation document further states that identifiable patient information may already be legitimately processed in the HSC for healthcare management and commissioning,[26] via existing conditions relied upon in Schedule 2 and 3 of the DPA.[27]

[22] EU Directive 95/46/EC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML As the Act is based on European Union law, the Data protection Act cannot be modified unless the Directive is modified (and this is currently under consideration).
[23] DPA Schedule 2 http://www.legislation.gov.uk/ukpga/1998/29/schedule/2 and Schedule 3 http://www.legislation.gov.uk/ukpga/1998/29/schedule/3
[24] DHSSPS (2014) Consultation on a proposal to introduce primary legislation for the use of health and social care service user identifiable information for secondary purposes in controlled circumstances, p35.
[25] Preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.
[26] Also of note, processing information for secondary purposes, even if compatible with the DPA could still be in breach of the common law.
[27] Information Commissioner's Office, response to DHSSPS consultation.

Article 8 of the **European Convention on Human Rights** (incorporated into UK law because of the Human Rights Act, 1998) sets out the right "respect for private and family life".[28] This right is not absolute and may be set aside in a range of instances including for public safety, economic well-being and for the protection of health. The Act highlights that privacy is important and must be respected, but confidentiality may be breached *where other significant interests prevail*.[29]

The **common law duty of confidentiality** protects against unauthorised or unreasonable breaches of confidence. Unlike the Human Rights Act and Data Protection Act, is not codified in statute. Instead, it has evolved from previous court judgments - known as case law. Whilst the duty to maintain confidentiality is not absolute, and is subject to certain ethical and legal limitations,[30] it is widely accepted that information held in confidence can only be disclosed if:

1) a person gives their consent, or,

2) if a statutory basis requires disclosure, or,

3) if the balance of public and private interest favours public disclosure.[31]

Appendix 4 provides further information on the complex permutations that can arise under the common law duty of confidentiality in terms of disclosing secondary use patient information.

3.2 Why an issue arises

Under the common law duty of confidentially, patient consent, or the statutory basis for disclosure, are generally straightforward to evidence. However, if this is not possible and the *public interest* is relied upon, the DHSSPS argues that, in the absence of a statutory framework, any sharing of information without consent could be open to legal challenge.[32] Nevertheless there have been no such legal challenges to date relating to secondary use patient information and the public interest test in Northern Ireland.[33]

Organisations using secondary patient identifiable data whereby the public interest test is relied upon include disease registries like the NI Cancer Registry and the NI Cerebral Palsy Register.[34] The current situation has also meant that the HSC has had to refuse opportunities to participate in UK-wide epidemiology studies and confidential inquiries because it has been unable to share patient-identifiable information.[35] It also creates

[28] European Convention on Human Rights. See http://echr-online.info/article-8-echr/
[29] DHSSPS (2013) Privacy impact assessment in relation to the secondary use of HSC service user information in NI.
[30] DHSSPS (2012) Code of Practice on protecting the confidentiality of service user information, p18.
[31] Health and Social Care (Control of Data Processing) Bill Explanatory and Financial Memorandum, p2.
[32] DHSSPS (2014) Consultation on a proposal to introduce primary legislation for the use of health and social care service user identifiable information for secondary purposes in controlled circumstances, p7.
[33] Ibid p7.
[34] An "opt-out" system is also in place for patients if they do not want their information to be processed.
[35] DHSSPS (2014) Consultation on a proposal to introduce primary legislation for the use of health and social care service user identifiable information for secondary purposes in controlled circumstances, p7.

difficulties, for example, for patient satisfaction surveys where personal information is needed to contact people for their opinions regarding services or treatments but views cannot be gathered in the first place without the patient's consent.

3.3 Problems with the public interest

Part of the current difficulty is that "public interest" can cover a wide range of values and principles relating to the public good or what is perceived to be in the best interests of society.[36] The public interest already exists in common law, but it is not defined. Therefore, what constitutes the "public interest" (in this context for medical and social care) relies on judgments by HSC staff and is open to interpretation.

Another difficulty with the public interest is about balancing competing interests (see Figure 2). While individuals have privacy interests in the use of data, they also share group interests in the wider use of data for health research. This broader public interest may come into conflict with individual privacy.[37]

Any organisation relying on the defence of public interest therefore has to demonstrate that sharing the information outweighs the risks of negative effects or harm to the individual. The DHSSPS Code of Practice on Protecting the Confidentiality of Service User Information states that "*Any proposed use of personal identifiable information must be for some clear general good or for the clear benefit of service users. That is, there must be a clear public interest involved*".[38] The DHSSPS also states that *"in such situations, there must be substantial public interest favouring disclosure which outweighs both the private interests of the individual and the public interest in safeguarding information".*

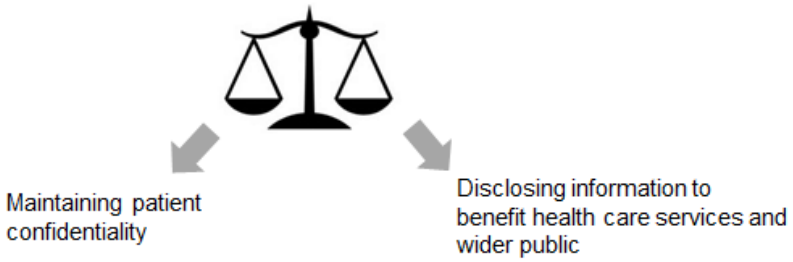

Figure 2. Balancing patient confidentially against the benefits to health and social care

By sharing information without consent, HSC organisations need to be confident in the public interest arguments they make for disclosing identifiable patient information.[39] In trying to strike a balance, several factors need to be considered. This includes for example, the nature and sensitivity of information; any harm or distress that could

[36] Information Commissioners Office: The public interest test. Available online at: https://ico.org.uk/media/for-organisations/documents/1183/the_public_interest_test.pdf
[37] Nuffield Council on Bioethics (2014) The collection, linking and use of data in biomedical research and healthcare, p46.
[38] DHSSPS (2012) Code of Practice on protecting the confidentiality of service user information, p8.
[39] DHSSPS and HSC Protocol for sharing service user information for secondary purposes, p8.

come to the individual; who will have access to the information; and the safeguards in place to protect it.

4. What the proposed Bill seeks to do

The proposed Bill will enable the controlled and limited use of patient identifiable information within the HSC sector *specifically* for "medical or social care purposes". The Bill's policy objectives, as stated in the Explanatory and Financial Memorandum are[40]:

- To provide a statutory framework, with safeguards, to enable patient identifiable secondary use information to be used without their consent, for purposes beyond what it was primarily obtained for, for the benefit of HSC services and the wider community.
- To clarify when such information can be used. Only where it is impossible or impracticable to obtain patient consent, or, when anonymised or pseudonymised information cannot be used, will provisions of the Bill be utilised. A Committee to authorise usage of such information will be established.
- To minimise the risk of legal challenge the DHSSPS and the Health and Social Care sector could face if patient identifiable information is used for purposes beyond the direct care of the individual.

Put simply, the Bill will allow the setting aside of the common law duty of confidentiality in cases where patient consent is not possible or practical, or if anonymised or pseudonymised information will not achieve the desired outcome. It will not set aside the Data Protection Act or the Human Rights Act. Only when it has been shown to be impractical otherwise (i.e. in very limited circumstances) would a committee established under the Bill independently assess whether such information may be released. This means that organisations relying on the public interest defence will no longer have to do so.

The Department insists that the legislation is not going to allow for the "*wholesale, unlimited access to service user personal information*".[41] Those seeking to use such data will only have access to the minimum required to achieve the outcome; not to entire medical records.[42] The DHSSPS envisages that, in some cases, the newly proposed Committee could approve an application for secondary use data whereby patient contact details are the only information released - so that patients can be contacted and their consent requested for the particular secondary purpose.[43] The DHSSPS propose that a statutory framework will remove ambiguity as applications will come through a single gateway; which it states will provide additional safeguards to patients, provide a greater level of assurance to HSC organisations and data users,

[40] DHSSPS Health and Social Care (Control of Data Processing) Bill EFM NIA Bill 52/11-16 EFM p1.
[41] DHSSPS (2014) Consultation on a proposal to introduce primary legislation for the use of health and social care service user identifiable information for secondary purposes in controlled circumstances, p18.
[42] Personal correspondence with author and DHSSPS on 27/8/15.
[43] Personal correspondence with author and DHSSPS on 27/8/15.

and lessen the risk of a successful challenge from patients/service users.[44] This will be a more centralised system compared to what exists at present (Figure 3).[45]

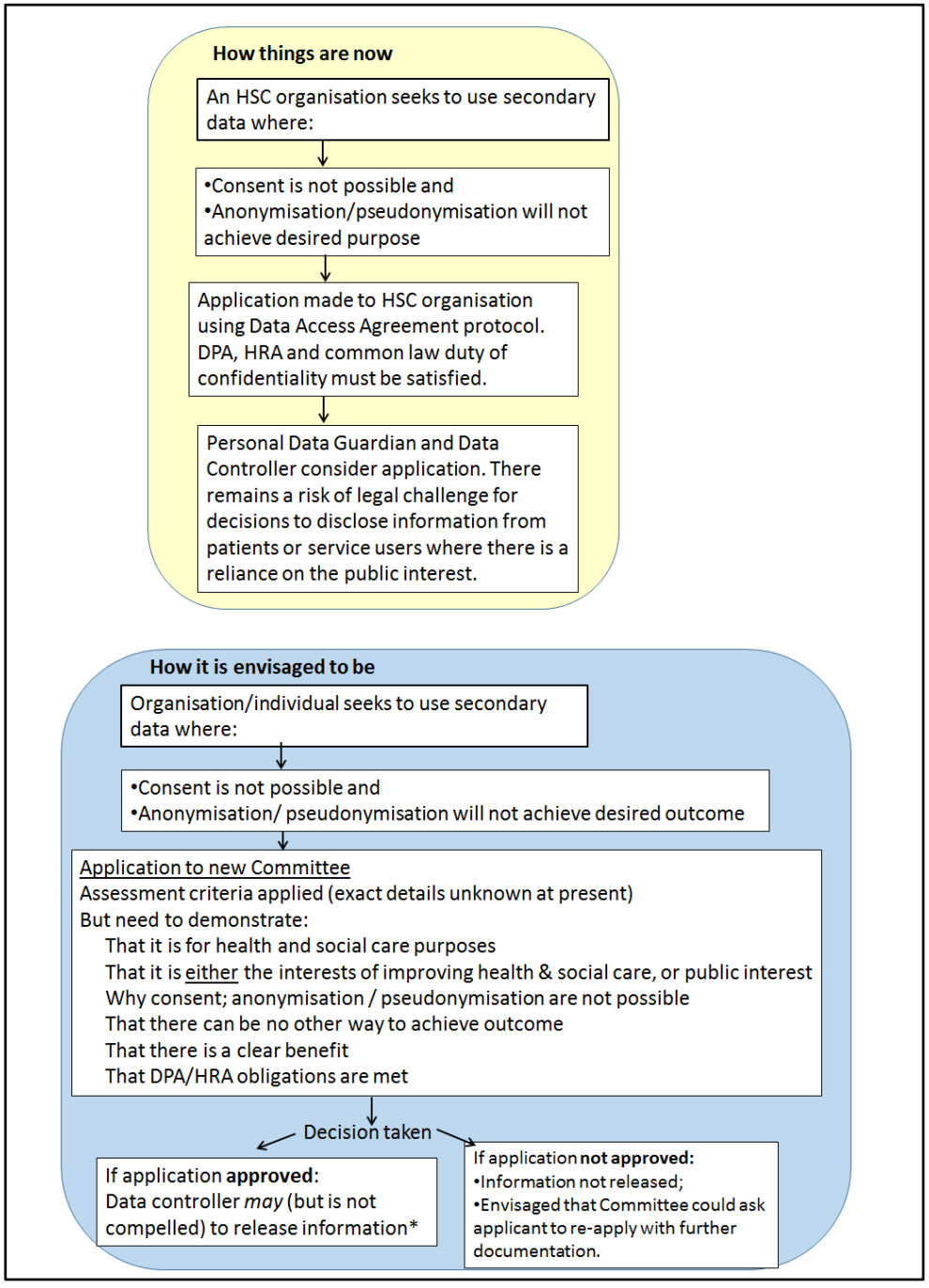

Figure 3. Current and proposed system for secondary use data processing

* The DHSSPS has stated in oral evidence that that the proposed legislation will not place a requirement on organisations that hold such information (i.e. data controllers) to share it. Rather the legislation will be an enabler for such information to be shared -

[44] DHSSPS (2014) Consultation on a proposal to introduce primary legislation for the use of health and social care service user identifiable information for secondary purposes in controlled circumstances, p7.
[45] Personal correspondence with author and DHSSPS on 27/8/15.

if the Committee deems it so and the HSC organisation holding the data wishes to disclose it.[46] However, it should be noted that the Bill - as introduced, also provides the power for regulations to be created that can require prescribed patient information to be disclosed and processed.[47]

It should also be noted that the establishment of a new authorising Committee is an attempt to minimise (but not completely mitigate) the risk of legal challenge.

4.1 Consultation on the policy proposals

A consultation on the policy proposals was conducted by the DHSSPS between 7 July 2014 and 10 October 2014. The consultation document considered five options and decided to consult on their preferred way forward; Option 5 - which aims to:

> *"introduce NI legislation similar to sections 60 and 61 of the G.B. Health and Social Care Act 2001 (which were replaced by sections 251 and 252 of the National Health Service Act 2006) but include the sharing of social care information".*[48]

In total 59 responses were received (the majority from health and social care, medical and charitable / voluntary organisations, and 12 from individuals comprising of doctors and consultants, 1 from a patient representative and 1 member of the public). The DHSSPS reported broad support for the policy proposals.[49] The findings are summarised in table 1 as follows:

[46] NI Assembly Hansard 17 June 2015. Committee for Health, Social Services and Public Safety. Health and Social Care (Control of Data Processing) Bill: DHSSPS Briefing, p4.
[47] DHSSPS HSC (Control of Data Processing Bill), Clause 1.
[48] Ibid, p16.
[49] DHSSPS (2014) Caring for you and your information. A proposal for legislation. Consultation response document.

Consultation question	Summary of responses
Question 1 – Introduce legislation to regulate the secondary use of service user information.	50 responded directly to this question. 47 of the 50 respondents agreed with the proposal for such legislation. 3 did not give a specific answer.
Question 2 – Provision for the establishment of an advisory group to consider applications for the use of service user information for secondary purposes.	54 out of 55 respondents agreed with this proposal. 1 disagreed due to concerns with how proposals fit with anonymised and pseudonymised information, and the use of the term "advisory group" relating to the oversight committee.
Question 3 – Any other comments on the proposals?	Common themes were: ▪ Any processing of information should be compliant with existing laws; ▪ Unrestricted access to HSC service user information should not be allowed; ▪ The proposals should apply to all health care settings, not just the statutory sector.
Question 4 – Are there any other models the DHSSPS should consider?	40 responses received, of which 29 stated that there is no other model which the Department should consider. 7 respondents did not know or had no views. 4 respondents suggested some changes to the proposed model: ▪ A model which is broader in its remit – to include health related information held by non-HSC bodies; ▪ That the decision making should be the responsibility of the HSSPS Minister; and ▪ That certain diseases should be prescribed as "notifiable diseases"[50].
Question 5 – Equality and human rights screening.	42 responded to this question. 34 agreed with the conclusions reached by the Department. 4 disagreed and 4 had no views. Concerns expressed included: ▪ That the Department had not identified service users as key stakeholders; ▪ That the proposals will impact more on certain demographics than others.
Question 6 – Privacy impact.	With one exception, there was general consensus that the conclusions reached in the Department's Privacy Impact Assessment[51] were correct.
Question 7 – Other impacts: economic; social; rural; environmental; victims; community safety.	The Department did not receive any responses to indicate that any further Impact Assessments would be required in these areas.

Table 1. Summary of consultation responses[52]

4.2 Further analysis of responses

The responses were analysed in further detail by the author. Along with the broad sense of support for the proposals and the benefits controlled secondary information

[50] A notifiable disease is any disease that is required by law to be reported to government authorities.
[51] DHSSPS (2013) Privacy impact assessment in relation to the secondary use of HSC service user information in Northern Ireland. This assessment was carried out to highlight any new privacy concerns as a result of the proposed legislation.
[52] Data extracted from DHSSPS (2014) Caring for you and your information. A proposal for legislation. Consultation response.

processing would bring, a number of additional issues were identified under the following themes:

Scope:

- Clarity is needed on the scope of the legislation; will it extend to non-HSC service user information in Hospices, care and nursing homes etc.
- Concerns about processing identifiable information relating to children; that more stringent criteria needs to be in place for secondary uses of child information.
- Concerns about how the legislation would interact with the right to privacy under Article 8 of the ECHR, and the Human Rights Act.

The new Committee:

- Several respondents stressed that the role of the new Committee was key and its terms of reference should be clearly defined.
- The application process should not be arduous, that timely decisions should be made, and the process kept under periodic review.
- Safeguards should be robust and committee membership should comprise a range of individuals with relevant expertise - including service users.

Processing social care information:

- Further explanation is required about what types of social care information can be shared without consent.
- Some organisations questioned the processing of secondary information for "social care purposes" with regard to the Data Protection Act, where consent is usually required.[53]
- Some uncertainty amongst professionals regarding when - and if - sensitive information can be shared, for example, relating to sex offenders.
- Concerns about small numbers of people with specific medical or social circumstances; safeguards are needed to ensure their identities are protected.
- Stigma attached to mental ill health may make people more reluctant to disclose information in future, thus having a detrimental impact on their care.

Data sharing concerns:

- Security concerns about data handling as it moves away from the original source and transfers to third parties.
- Examples of breaches of confidential information in England were cited as having eroded public trust and that selling data to third parties had infringed on patients human right to privacy and with dubious societal benefit.

[53] The Information Commissioner's Office, the Law Centre NI, and the Privacy Advisory Committee.

- Some patients will not want their data to be shared regardless of the benefit; the proposals could be seen as being paternalistic i.e. making decisions for swathes of people without their individual consent.
- A right to "opt out" would be an important safeguard.
- One patient group felt that the main aim of the proposals was to reduce the likelihood of legal challenge for the Department, rather than for the clear benefit of patients.
- Proactive engagement with service users was essential to 1) allay fears with the "care.data"[54] system in England and 2) to raise awareness about the proposed legislation for Northern Ireland.

Impact:

- The impact of the experiences in England should have been identified in the Preliminary Equality Screening.
- Possible impact on the issue of trust, privacy, and the doctor-patient relationship.
- Possible negative impacts on people more likely to suffer harm - such as people with disabilities (including people with a mental illness), children, and people from a different sexual orientation.

It should also be highlighted that the majority of responses were from the users of data (such as HSC bodies, universities, disease registries) and not service users or patients. The Patient and Client Council (PCC) received no public views on the issue and thus were not in a position to respond.[55] The author contacted the PCC to ask if they specifically sought the views of service users, they responded they had not conducted a bespoke engagement on this subject.[56]

5. The Bill

Following the policy proposals consultation, the Health and Social Care (Control of Data Processing) Bill was introduced to the Northern Ireland Assembly by the HSSPS Minister on 16 June 2015. The Bill contains six clauses:

5.1 Clause by clause overview

Clause 1: **Control of information.** This clause contains a range of enabling provisions which set out the circumstances whereby the DHSSPS may make regulations to make provision for and in connection with requiring or regulating the processing of HSC

[54] Care.data is a different system used in England. It concerns the extraction patient GP data to a central database in the Health & Social Care Information Centre in England to combine this with existing hospital records in order to support e.g. earlier diagnosis and disease monitoring. Data can be made available both in and outside of the NHS (the latter pay a fee). The legal basis for the project is provided by the Health & Social Care Act 2012. Data are protected by a different set of safeguards and patients can opt out of this system.
[55] Patient and Client Council. Response to 'Caring for your information' DHSSPS consultation. Response dated 9.10.2014
[56] Personal correspondence with Patient and Client Council. August 2015.

information "for medical or social care purposes"[57] in the interests of 1) improving health and social care, or, 2) in the public interest. This clause also creates penalties for offences of data breaches. Any processing of patient information must comply with the Data Protection Act.

Clause 2: Establishment of an authorising Committee. Clause 2 stipulates that the DHSSPS may make regulations to establish a Committee to authorise processing of confidential information in prescribed circumstances. These regulations may enable provisions for the membership of the Committee, the appointment of a Chair, the Committee procedures, payments and expenses, and the publication of authorisations granted by the Committee.

Clause 3: Code of Practice. Clause 3 places an obligation on the DHSSPS to publish a Code of Practice about the processing of information which is to be reviewed every 2 years. The Code of Practice can be revised when appropriate. HSC organisations and HSC individuals who provide health and social care must have regard for the Code.

Clause 4: Regulations. This relates to control of regulations made under the Bill. Draft regulations must be approved by the Northern Ireland Assembly.

Clause 5: Interpretation. Sets out the definitions of specific terms used within the Bill.

Clause 6: Short title and commencement dates. Set out the Act title and that the Act will come into effect the day after Royal Assent.

5.2 Impact assessments

Before the introduction of the Bill, the DHSSPS has also considered possible impacts the policy proposals may have. These are summarised as follows:

- In 2013 the DHSSPS conducted a **privacy impact assessment** which was designed to highlight privacy concerns stemming from the policy proposals. It concluded "*the Department believes that the current safeguards and those set out within the proposal are robust.*"[58]
- In the initial consultation, the DHSSPS deemed that an **Equality Impact Assessment** (EQIA) was not necessary. However, the DHSSPS reviewed this decision following the consultation responses, but remains content there will be no adverse impact.[59] The EFM states that *none of the consultation responses indicated that any of the proposed measures would have an adverse impact on any of the nine section 75 groups*.[60] This appears somewhat inconsistent with the consultation responses which highlighted concerns for those likely to suffer

[57] DHSSPS (2014) Consultation on a proposal to introduce primary legislation for the use of health and social care service user identifiable information for secondary purposes in controlled circumstances, p21.
[58] DHSSPS (2013) Privacy impact assessment in relation to the secondary use of HSC service user information in Northern Ireland, p4. This assessment is developed by the Information Commissioner's Office.
[59] DHSSPS Health and Social Care (Control of Data Processing) Bill EFM NIA Bill 52/11-16 point 20.
[60] DHSSPS Health and Social Care (Control of Data Processing) Bill EFM NIA Bill 52/11-16 point 21.

harm - such as people with disabilities (including mental illness), children, and people of a different sexual orientation.

- A full **Regulatory Impact Assessment** was deemed unnecessary.[61]
- In terms of human rights, the Explanatory and Financial Memorandum (EFM) accompanying the Bill states that the Bill is compatible with the European Convention on Human Rights.[62] Article 8 of the ECHR states that the right to privacy can only be interfered with if it meets specified legitimate needs. The DHSSPS has stated that whilst the proposed legislation will broaden the use of personal information, it will only be considered in prescribed conditions with legitimate need and social benefit.[63]
- The EFM also stipulates that the Bill will not impose any significant additional costs on the DHSSPS and the HSC sector.[64] The DHSSPS stated at a recent HSSPS meeting that a robust costing exercise had not been conducted, but that it envisages that the cost of introducing the Bill will be nominal.[65] Some cost implications are considered further on page 24.

5.3 Further considerations

Several aspects of the Bill have been considered by the HSSPS Committee and by MLAs at the Second Stage debate.[66] Areas of contention can be summarised as:

- the sharing of information without patient consent;
- the broad scope, terminology and definitions used within the Bill that have led to issues with its interpretation (for example, "*public interest*" (Clause 1:1b); "*social well-being*" and "*other similar circumstances*" (both Clause 1: 11b); and usage of the word "*may by regulations*" (for example, Clause 1:1a), which it was felt should be strengthened.
- the lack of detail about: safeguards, penalties for data breaches or a cost benefit analysis.

In addition to these, and those raised through the consultation document, further clarification is needed about the following:

Clause 1:1(a) of the Bill: processing of prescribed information *"(a) in the interests of improving health **and** social care, **or** (b) "in the public interest*". Does this wording mean that the processing of the prescribed information must be in the interests of improving both health and social care, rather than one or the other?

[61] DHSSPS Health and Social Care (Control of Data Processing) Bill EFM NIA Bill 52/11-16. This is because the DHSSPS posits that the proposals do not bear any impact for local businesses, charities, social economy enterprises etc.
[62] DHSSPS Health and Social Care (Control of Data Processing) Bill EFM NIA Bill 52/11-16 point 19.
[63] DHSSPS (2014) Consultation on a proposal to introduce primary legislation for the use of health and social care service user identifiable information for secondary purposes in controlled circumstances, p21.
[64] DHSSPS Health and Social Care (Control of Data Processing) Bill EFM NIA Bill 52/11-16, point 18.
[65] NI Assembly Hansard HSSPS Committee (17 June 2015) http://data.niassembly.gov.uk/HansardXml/committee-14239.pdf
[66] See NI Assembly Hansard HSSPS Committee (17 June 2015) http://data.niassembly.gov.uk/HansardXml/committee-14239.pdf and NI Assembly Hansard Plenary (29 June 2015) Volume 106. http://aims.niassembly.gov.uk/officialreport/report.aspx?&eveDate=2015/06/29&docID=240045

- Clauses 1:1 of the Bill namely – "*The Department may by regulations make such provision for and in connection with requiring or regulating the processing of prescribed information*…" and Clause 1:2(a) "*for requiring or authorising the disclosure or other processing of prescribed information…*". Like the legislation in England and Wales[67] there will be a power within the Bill to mandate that patient information be released. This does not seem in line with the policy intent that the Committee will make decisions that can permit, but not compel, the data controller to release information. Should this provision be more permissive and should it clarify further when such a requirement to process information is needed, if at all?

- What type of new assessment by the Committee will be adopted? What level of *proportionality* will be considered when deciding if an individual's right to privacy of their information will give way to the health benefits of society as a whole and how will this balance be struck in order to assure public confidence in the decisions being taken? Will the outcome of decisions be published? Are Committee decisions final or open to appeal? Will organisations currently relying on the public interest defence - such as the NI Cancer Registry have to apply to the new Committee retrospectively?

- Will specific restrictions be included within the Bill for example, so that secondary use information cannot be sold or used for certain commercial purposes? The DHSSPS has re-iterated that such activities would not meet, for example, the "for medical and social care purposes" condition - but the Bill would be more robust if such a restriction is explicitly stated.

- The processing of social care information highlighted in the consultation responses - especially under the "processing conditions" of the DPA (see page 9) is an area which may require further consideration. The DHSSPS has since taken legal advice and is content the Bill is compliant with the DPA. [68]

- More widely, what impact could there be on the Bill if the European Data Protection Regulation[69] comes into force?

The Bill is written as enabling legislation whereby the details will be contained in subsequent regulations. As the exact details of the regulations are as yet unclear, they will require robust scrutiny by the Assembly.

[67] Please see Guidance Notes Section 60 of the Health and Social Care Act 2001, p5. https://www.igt.hscic.gov.uk/KnowledgeBase/KB%5CDH%20guidance%5CDH_Guidance%20notes%20section%2060.pdf

[68] Personal correspondence with author and DHSSPS on 27.8.15

[69] The aim of the new European Data Protection Regulation is to harmonise the current data protection laws in place across the EU member states. The fact that it is a "regulation" instead of a "directive" means it will be directly applicable to all EU member states without a need for national implementing legislation. It will replace EU Directive 95/46/EC http://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX:31995L0046 Any changes at EU level will impact on the Data Protection Act.

6. Other jurisdictions

The final section of the paper examines the current situation in relation to secondary use personal identifiable information in the rest of the UK and Republic of Ireland (ROI) (Figure 4) all of which have data protection, human rights and common law duty of confidentiality obligations.

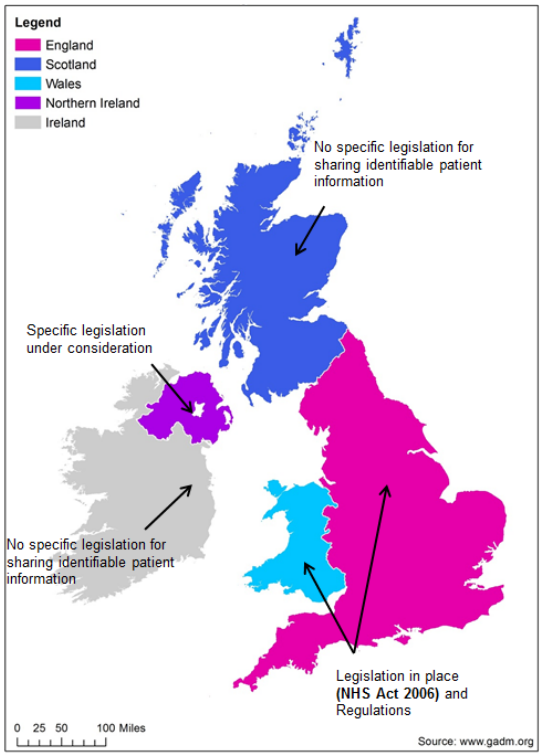

Figure 4. Secondary use legislation – UK and ROI

6.1 Comparison: England and Wales and Northern Ireland (NI)

In 2007, a report was presented to the Privacy Advisory Committee in Northern Ireland assessing whether NI would benefit from having legislation similar to that in England and Wales.[70] Several years on, and the Bill essentially mirrors what is now the Sections 251 and 252 of the *National Health Service Act* (2006) which applies to the processing of secondary use patient identifiable information in England and Wales.[71] This legislation was first introduced in the *Health and Social Care Act* (2001)[72] and the relevant sections (Sections 60 and 61) were repealed and re-enacted in the 2006 Act. The Act is supported by the *Health Service (Control of Patient Information) Regulations (2002).*

[70] Harper, C. (2007) Does Northern Ireland need and equivalent to Section 60 of the Health and Social Care Act 2001? A report to the Privacy Advisory Committee of the NI DHSSPS.
[71] National Health Service Act (2006) Sections 251 http://www.legislation.gov.uk/ukpga/2006/41/section/251 and 252 http://www.legislation.gov.uk/ukpga/2006/41/section/252
[72] Health and Social Care Act (2001) Sections 60 and 61. http://www.legislation.gov.uk/ukpga/2001/15/section/60 and http://www.legislation.gov.uk/ukpga/2001/15/section/61

The 2006 Act established a Patient Advisory Group (PAC) which would later become known as the Confidentiality Advisory Group (CAG).

The role of CAG in England and Wales is to scrutinise applications for secondary use patient information; it advises applicants whether or not the processing request is in the public interest, if it fulfils a medical purpose, and that there is no other reasonable way in which to carry out the activity. The CAG have adopted the view that the 2002 Regulations should be applied permissively, rather than in mandating disclosure of patient information.[73]

Table 2 overleaf provides an overview of how the 2006 Act may compare with Northern Ireland's proposed legislation. Any comparison should be treated with some caution due to differences in these HSC structures.

[73] Health Research Authority Principles of Advice: Exploring the concepts of 'public interest' and 'reasonably practicable', p6..

Purpose of the legislation:	To enable the common law duty of confidentiality to be temporarily lifted so that confidential patient information can be transferred to an applicant without the discloser being in breach of the common law duty of confidentiality.	
	England and Wales	**Northern Ireland**
Legal framework	Enacted: • Section 251/252 of the National Health Service Act 2006. • The Health Service (Control of Patient Information) Regulations 2002.[74]	Proposed: • Health and Social (Control of Data Processing) Bill • Subordinate regulations (yet to be consulted upon and drafted)
Scope	Medical purposes	Medical **and** social care purposes
Who assesses applications?	**Confidentiality Advisory Group** (**CAG**) – established in 2013.[75]	A **Committee** to be established and defined in subordinate regulations.
Remit of the assessment body	CAG assess if processing of patient information without consent (where anonymised information will not suffice) should be **recommended**. CAG consider whether the activity is in the public interest, or in the interests of improving patient care.	Intent will be the Committee will assess if the processing of service user information without consent (and where anonymised information will not suffice) may be approved - which they will have the power to do. Will consider if the activity is in the public interest or improving health and social care.
Application	Submitted online	Yet to be determined.
Decisions	The CAG **provide advice only** – final decisions are taken by either: the **Health Research Authority** (for research applications) or, the **Secretary of State for Health** (for non-research applications). CAG must take account the restrictions and exclusions contained in the regulations. A number of outcomes are possible – e.g. fully or conditionally supported, more info needed etc.	**Committee** is envisaged to have powers to take final decisions on both research and non-research applications. Questions remain about its membership and remit, and how it will interact with the Privacy Advisory Committee, the Research Ethics Committee, and the Regional Data Warehouse and the Honest Broker Service housed within the HSC's Business Services Organisation.
Membership	16 publicly appointed members who meet on a monthly basis (Appendix 5).	Not defined in Bill. Membership to be further defined in subordinate regulations.
Opt out system	Included; patient objection must be respected. This is not carried out or controlled by the CAG, but rather with patients at a local level with their care provider, e.g. patient notifies their hospital or GP that they do not wish to be included in any processing, this is then flagged up on the providers system.	Opt out system not defined in the Bill - to be considered in subordinate regulations.
Exclusions	Applications from cancer and communicable diseases are outside the CAG's remit. These fall under the remit of Public Health England.	To be determined. These may come under the remit of the Public Health Agency.
Support and Review	Approved applications are subject to annual review / on-going support	Not defined at present.
Other considerations	Data Protection Act has to be adhered to.	Data Protection Act has to be adhered to.
Code of Practice	No. There are Standard Operating Procedures – which outline the framework under which CAG operates	Code of Practice to be published by DHSSPS.

Table 2. Legal framework in England and Wales and NI's proposed Bill[76]

[74] The Health Service (Control of Patient Information) Regulations 2002
[75] The CAG advisory function was previously carried out by the National Information Governance Board's Ethics and Confidentiality Committee (ECC, 2009-2013) and prior to that, the Patient Information Advisory Group (2001-2008)

As table 2 shows, there are notable differences in how the legislation will operate in Northern Ireland; for example,

Who takes decisions: the CAG remit is to provide approval *advice,* compared to the proposed Committee which has *powers* to approve applications. CAG members are publicly appointed.

Differences in structures: approvals in England and Wales are divided into "research" and "non-research" proposals which are given final approval by different entities (either the Health Research Authority – HRA, or the Secretary of State for Health).

Differences in the scope: namely for "medical purposes" under the English/Welsh Act, compared to the broader scope of "medical and social care purposes" to reflect the integrated HSC system in Northern Ireland.

6.1.1 Criteria for making assessments

To give readers a sense of the criteria used to assess applications for secondary use patient identifiable information in England and Wales, factors considered by the CAG panel are set out below (Figure 5 - this list is not exhaustive)[77]. It should also be noted that these are not defined in the Act or the Regulations:

- Is there a practicable alternative?
- Can consent be obtained? Give reasons why consent may not be an option.
- Can another organisation that legitimately holds the information, process and provide the applicant with an anonymised dataset?
- Are there any technological developments that mean access to identifiers could be restricted?
- Would the public interest in the disclosure and potential benefits, on balance, outweigh the breach of confidentiality?
- Have patient groups or service users been consulted to test the acceptability of the proposal to help identify the reasonable expectations of a patient on the proposed data use, and subsequently the public interest?
- How will the applicant manage the activity so that processing information without consent in future would no longer be necessary?
- Is the activity compliant with the provisions of the Data Protection Act?
- Are appropriate standards of governance and security in place?

Figure 5. Factors the CAG considers when deciding whether to support an application

[76] Table compiled with assistance from personal correspondence with Deputy Confidentiality Advice Manager - HRA on 26.8.15
[77] Health Research Authority, Recommendations and Approval Decisions, p 1.

When a recommendation is approved by the CAG, there are also a number of processing restrictions in place – these are embedded in the 2002 Regulations[78]:

- so far as is practical, reduce the identifiability of the information;
- restrict access to those who need to access it for the purposes of processing and know the purposes of processing;
- adopt appropriate technical/ organisational measures to prevent unauthorised access;
- review at least every 12 months the continued necessity/extent of the processing;
- make available on request by any person or body, information about the steps taken to comply with the regulations.[79]

6.1.2 Application support

The Health Research Authority has also published online guidance about the CAG's application process, including an online tool for organisations that want to apply before submitting an application. Applicants can also apply for pre-submission advice via a draft application.[80] In addition, Standard Operating Procedures outline the application process and governance framework.

After consideration by the CAG, applications which are successful receive on-going support and annual reviews. Minutes of CAG meetings are published online, as is a database of approved applications. Whilst these details have yet to be determined for Northern Ireland, if a similar system is adopted, it is likely to have resource and cost implications.

6.1.3 Types of advice approved by CAG

Minutes of CAG meetings detailing the applications under consideration are documented in detail online. In terms of the number of applications, figures have been obtained from the HRA. It states:

> "*between April 2013 and March 2015 the CAG reviewed approximately 229 applications. Around 44 were not approved on first review, however approximately 50% of these were deferred which means that they may have come back with further submissions and subsequently been approved.* ***Around 20% are not approved on first submission but 50% of these are due to the fact the committee needs more information****".*

These more recent CAG figures would indicate a higher approval rate of applications than those indicated by the DHSSPS. The DHSSPS suggested around 30% - one in

[78] Health Service (Control of Patient Information) Regulations (2002) p4.
[79] Health Research Authority Principles of Advice: Exploring the concepts of 'public interest' and 'reasonably practicable', p2.
[80] Standard Operating Procedures available online at http://www.hra.nhs.uk/documents/2015/08/cag-sops-v1-2-2.pdf p5.

three applications were refused since the legislation came into effect.[81] These more recent figures (from the last 2 years) demonstrate that around 80% of applications are now approved (on first review).

The CAG for England and Wales have considered around 100 applications per year, and, given the small population size of Northern Ireland, it is likely that Northern Ireland would receive fewer applications.

The Health Research Authority in England publishes a database of applications online that have received approval. Some examples are shown in Table 4.

Examples of Health Research Authority approved research applications[82] - most of these research applications were from Universities
• Melanoma lifestyle study • Cancer risks in the British rubber manufacturing industry • Secondary prevention of burns and scalds in children • Bariatric surgery and colorectal cancer • Impact of overweight on prognosis of diabetes mellitus • Investigating the accuracy of current estimates of self-harm • Preventable incidents, survival and mortality study • Parenting support via family nurse partnership to reduce maltreatment in children • Survival of children born with congenital heart disease • Recall and reoffending outcomes of mentally disordered offenders after discharge from a UK Medium Secure Unit

Examples of approved Secretary of State for Health non-research applications[83] - these come from a variety of sources such as NHS England, Royal Colleges etc.
• National COPD audit • Maternity information system data linkage pilot • Ambulance survey of callers to clinical support desks • Inflammatory bowel disease registry • National prostate cancer audit: analysis of existing datasets • Community mental health survey • Inpatient survey 2015 • Congenital anomaly and rare disease registration service • Why do people with autism fare so differently in adult life?

Table 4. HRA and Secretary of state approved applications for secondary use.

6.2 Scotland

Scotland has no specific legislation for processing secondary use patient identifiable information. Instead, use of patient identifiable data for secondary purposes is covered

[81] NI Assembly Hansard HSSPS Committee.17 June 2015 DHSSPS: "*In fact, of the 900 applications that England has processed since 2001, a third have been rejected. Many of the 600 that were approved have had very stringent requirements placed on them about how the data is handled and processed*."
[82] Health Research Authority http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/cag-advice-and-approval-decisions/
[83] Ibid

by the Data Protection Act, the Human Rights Act, European Convention on Human Rights, the common law of confidentiality, the seven Caldicott principles[84], and other legislation. When a request for secondary use of patient identifiable data is received, the following is considered;

- Is there a power to share?
- Does it interfere with Article 8 of the HRA in a way which would be disproportionate to a legitimate aim?
- Will the sharing breach any common law obligations or any data protection principles?

Decisions are made on a case-by-case basis and to aid this, applications are considered by Caldicott Guardians[85] along with Information Governance staff from two or more NHS Scotland Health Boards and Scottish Government. In the event that an application proves to be contentious, it is presented to the Caldicott Guardian forum for a wider group of Caldicott Guardians to consider.[86] Scotland also has a Privacy Advisory Committee to provide advice on applications for access to health data, HSC administration research and other specific purposes.

6.3 Republic of Ireland

Like Northern Ireland and Scotland, the Republic of Ireland does not have legislation to permit the secondary use of patient identifiable information. Consideration of secondary use data relies upon for example, their two data protection Acts, the Irish Constitution, the European Convention on Human Rights and the common law duty of confidentiality.[87]

The Department of Health and Children is preparing new legislation on the usage and transfer of personal health information as well as ensuring that the privacy of such information is appropriately respected. This will become known as the Health Information Bill. At the time of writing the Bill has not come into effect.

6.4 Elsewhere

There are problems in trying to make comparisons about models of secondary use patient information with other jurisdictions. For example, much of the difficulty is that other European Union (EU) states are civil rather than common law jurisdictions and do not have a common law duty of confidentiality with which to draw comparisons.[88] Outside of the EU it is also difficult to make comparisons because of the different human rights and data protection laws.

[84] In 1997 the Review of the Uses of Patient-Identifiable Information, chaired by Dame Fiona Caldicott, devised six general principles of information governance that could be used by all NHS organisations with access to patient information.
[85] A Caldicott Guardian is a senior person responsible for protecting the confidentiality of patient and service-user information and enabling appropriate information-sharing. Each NHS organisation is required to have a Caldicott Guardian; as mandated for the NHS by Health Service Circular: HSC 1999/012.
[86] Correspondence from Scottish Government to SPICe on behalf of NI Assembly query. Response dated 26.2.15.
[87] Personal correspondence with P. Lennon, Assistant Principal, Legislation Unit, Department of Health (Ireland) 13.8.15.
[88] Harper, C. (2007) Does Northern Ireland need and equivalent to Section 60 of the Health and Social Care Act 2001? A report to the Privacy Advisory Committee of the NI DHSSPS, p7.

In 2012 the Irish Health Information and Quality Authority published an international review of secondary use personal information looking at the current model in England and further afield: including Canada, New Zealand and Australia.[89] It concluded that legislative provisions concerning the secondary use of information are typically contained within general privacy or data protection legislation, and that guidance is now beginning to focus on what secondary uses are appropriate. The guidance that was reviewed stresses the need for organisations to be open and transparent with service users about the various uses to which their information is put.[90]

[89] See: Health Information and Quality Authority (2012) International Review of Secondary Use of Personal Health Information. Available online at: http://www.higa.ie/system/files/Review-Secondary-Use-Health-Info.pdf
[90] Health Information and Quality Authority (2012) International Review of Secondary Use of Personal Health Information, p9.

Appendix 1. Secondary use patient information: Key departmental publications

- Code of Practice on protecting confidentiality of service user information (DHSSPS, 2012)

This revised Code of Practice (since the 2009 edition) was developed by the Privacy Advisory Committee and it sets out the laws relating to confidentiality and disclosure. Currently, patient identifiable information used beyond direct care (i.e. secondary use) has to satisfy the requirements outlined in the 1998 Human Rights Act, the 1998 Data Protection Act and the common law duty of confidentiality.

- A Protocol for sharing service user information for secondary purposes (DHSSPS, 2011)

This Protocol outlines current good practice within the HSC for sharing secondary use patient identifiable information. A Data Access Agreement (DAA) is drawn up by the HSC partner organisations for the purposes of sharing identifiable patient information. The organisation wishing to access identifiable patient information provides evidence to the partner organisation (i.e. the data controller) of what aspects of data are needed and why it is necessary; issues around consent, anonymised data, data protection requirements, and how the information will meet security standards also need to be evidenced. If the organisation has the power to release the data, and is willing to do so, a Personal Data Guardian in that organisation will approve the DAA if appropriate and necessary. The protocol also addresses complaints and breaches of confidentiality.

Appendix 2: DHSSPS Safeguards - protecting information[91]

A range of measures currently exist to safeguard information, including senior individuals within each HSC organisation to oversee the safe and secure use of service user information. They are responsible for ensuring that their organisation has in place a robust, systematic and planned approach to the management and security of the information it holds. Measures include, for example, legal and ethical obligations on staff to protect service user information, disciplinary procedures for breaches of data protection, and regular training programmes on information governance.

All HSC organisations must have an information risk policy and risk assessment process and test it regularly. They must also understand what information they hold, how it is moved and who has access to it. The Department seeks annual assurance that these duties are fulfilled.

A Regional Data Warehouse, within the Business Services Organisation (BSO), hosts service user information on behalf of the local HSC Trusts. Another strand of collaborative data sharing, the Honest Broker Service (HBS), was recently established by the Department within BSO. This service can provide anonymised and pseudonymised information to the HSC family and anonymised data for ethically approved health related research. The HBS is a safe and secure environment where service user data can be processed (and in some cases linked to other data), before being provided in an anonymised or pseudonymised format. To date the HBS has had around 15 requests of which around half have been refused as the data requested was identifiable.

The Northern Ireland Privacy Advisory Committee was established in 2006. Its principal role is to advise HSC bodies about the use of information relating to patients and clients. Their Terms of Reference[92] is as follows:

- To oversee the implementation of the recommendations agreed by Minister on protecting personal information;
- To manage a Project Team to complete a Programme of Work to give effect to the recommendations agreed by Minister;
- To report regularly to the Department on progress on implementing the recommendations;
- To keep consent and confidentiality matters in HPSS under continuous review and to provide timely and relevant best practice advice to HPSS bodies; and
- To consider current and new uses to which personal information is put in HPSS bodies and to authorise such uses of personal information taking particular account of the legal and ethical issues surrounding privacy and confidentiality

[91] Data extracted directly from DHSSPS (2013) Privacy impact assessment in relation to the secondary use of HSC service user information in Northern Ireland, p9.
[92] Privacy Advisory Committee website: PAC Terms of Reference. Available online at: http://www.privacyadvisorycommittee.hscni.net/PAC%20Terms%20of%20Reference_July%202006.pdf

Appendix 3: DHSSPS Good practice principles

For use and disclosure of personal identifiable information for secondary purposes[93]

- All organisations seeking personal identifiable information for other than direct care should be seeking anonymised or pseudonymised data.
- To assist the process of pseudonymisation the Health and Care Number of service users should be used wherever possible. It should be noted that the HCN is a potential identifier and not a pseudonymiser.
- All organisations seeking to use personal identifiable information should provide information to service users describing the information they want to use, why they need it and the choices they have.
- Any proposed use of personal identifiable information must be for some clear general good or for the clear benefit of service users. That is, there must be a clear public interest involved.
- Service users and/or service user organisations should be involved in the development of any project involving the use of confidential information and the associated policies.
- Where an organisation has a direct relationship with a service user it should be aiming to implement procedures for obtaining the express consent of the service user. For all proposed research uses of personal identifiable information the express consent of the service user should normally be sought.
- Where consent is being sought this should be by health and social care staff who have a direct relationship with the individual service user.
- Organisations should not use personal identifiable information for secondary uses where a service user has opted out by specifically refusing consent.
- Where data is to be disclosed only in aggregate form the potential identification of individuals from small numbers should be considered and appropriate protections applied.

[93] DHSSPS (2012) Code of Practice on protecting the confidentiality of service user information, p24.

Appendix 4: Common law duty of confidentiality and disclosure of patient identifiable data[94]

Common law duty of confidentiality ↓			
1) Has the patient given valid consent?	**Yes**	**No**	**Additional information**
	If yes, and consent is given, the data controller may consider disclosing data, but is not obliged to do so. The final decision to release the data rests with the controller who will assess the benefits and the risks of sharing the information and base a decision on that analysis.	If no and consent is refused, data should not be disclosed solely relying on this condition. However, the use of anonymised or pseudonymised information could be considered.	If valid consent is not possible or practical to achieve (e.g. large numbers of patients) and there is no statutory basis to release the information, then assess if the public interest test can be met.
2) Is there a statutory basis to release information? E.g. public health emergency, Order of court or tribunal	If yes, there is a statutory requirement for the data controller to release data - whether consent is given or not, and regardless of the public interest test.[95]	If no, data cannot be disclosed solely relying on this condition. However, the use of anonymised or pseudonymised information could be considered.	If there is no statutory basis, then assess patient consent or the public interest test.
3) Is there a public interest that can be demonstrated?	If yes, the data controller may consider disclosing the data. However, the decision to release the information rests with the controller and is open to legal challenge.	If no, or unclear, the information should not be disclosed, but the decision rests with the data controller and is open to legal challenge.	Satisfying the public interest test is a subjective test about assessing the benefits and the risks of sharing the information, and basing a decision on that analysis.

[94] Compiled with assistance from J. McDowell, DHSSPS (July 2015).
[95] If a data controller knows it is likely to be legally required to disclose certain kinds of personal data, it is good practice to tell individuals about this when the information is collected from them. Telling individuals about the legal requirement is compatible with the disclosure of personal data to comply with the requirement.

Appendix 5: Data Protection Act (1998)

The Data Protection Act (1998) (DPA) is the key legislation governing the protection and use of identifiable patient information.[96] There are eight Data Protection Principles in the Act that set out standards of information handling. Data must be:

Principle 1: processed fairly and lawfully;
Principle 2: obtained only for the purpose stated;
Principle 3: adequate, relevant and not excessive;
Principle 4: accurate and, where necessary, kept up-to-date;
Principle 5: not be kept for longer than is necessary for that purpose;
Principle 6: processed in accordance with the rights of data subjects under the Act;
Principle 7: appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing personal data and against accidental loss or destruction of, or damage to, personal data;
Principle 8: not transferred to countries without adequate protection.

In order to process sensitive personal data lawfully at least one of the conditions set out in Schedule 2 and Schedule 3 of the DPA must be satisfied.

[96] Data Protection – government website. Available online at: https://www.gov.uk/data-protection/the-data-protection-act

Appendix 6: CAG membership (England and Wales)[97]

There are currently 15 CAG members listed on the CAG website at present;

1. Senior Lecturer in the School of Law
2. G.P. & Senior Clinical Lecturer
3. Retired G.P.
4. Consultant Haematologist
5. Independent Lay Member
6. Retired Medical Director
7. Professor with expertise in communicable diseases
8. Professor of Epidemiology and General Practice
9. Retired chief superintendent within the Police
10. Professor and Director of the National Perinatal Epidemiology Unit
11. Independent consultant
12. Former dental surgeon; Head of Information Governance
13. Independent advisor on governance & regulation of research in health and social care
14. Independent Lay Member
15. Director of an Evidence Based Practice Unit

[97] CAG members. Information obtained from CAG website. Available online at: http://www.hra.nhs.uk/about-the-hra/our-committees/section-251/cag-members/ website accessed 17.8.15.