Department of
Health, Social Services
and Public Safety
www.dhsspsni.gov.uk

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

HEALTH AND SOCIAL CARE IN NORTHERN IRELAND – CARING FOR YOU AND YOUR INFORMATION

Contents

Alternative Format

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INTRODUCTION

[by Andrew McCormick]

Government policy places a strong emphasis on the need to share relevant personal information across organisational and professional boundaries in order to ensure effective co-ordination and integration of public services. Equal emphasis is placed on the security and confidentiality of personal information in this process.

The Health and Social Care Sector (HSC) may currently share personal information as long as the identity of the individual remains protected. The sharing of information has proven essential in the development and delivery of services and the undertaking of research.

However the current arrangements have limitations and in other jurisdictions (including England and Wales) legislation is already in place to allow for the sharing of user identifiable information for secondary use[1] in limited or specific circumstances that can be controlled. This provision has been shown to improve patient care through such things as the ability to plan, commission and manage services whilst still complying with the safeguards in place to protect how personal information is used.

In this consultation document the Department of Health, Social Services and Public Safety is seeking your views on a proposal to introduce primary legislation which would extend the use of service user identifiable information, to include sharing for secondary use in controlled circumstances. This proposal applies to the processing of both health and social care information.

Under the proposals anyone applying to make use of HSC data will be required to demonstrate to an advisory group that the use of service user identifiable information is absolutely essential to the successful outcome of their work; that similar results could not be obtained by using anonymised or pseudonymised service user information; and that it is either impossible or impracticable to gain consent from

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[1] Secondary Use is the use of information for any reason other than the purpose for which the information was originally collected

every individual whose data may be used. Where research is involved, ethical approval will also be required.

Based on the experience in other areas, adopting this approach would allow delivery of significant benefits in the HSC. Areas that could benefit include the management of health and social care services; improved public health monitoring; accurate and detailed disease registries; and the effective monitoring of infectious diseases.

The primary legislation would allow information to be shared within the HSC family to better inform a range of health and social care services and would enhance the collaborative, professional approach to the management and commissioning of these services.

Sharing information about the care service users receive helps the understanding of the health needs of everyone and the quality of the treatment and care provided. It would assist research by supporting studies that identify patterns in diseases, responses to different treatments, and the effectiveness of different services. This could lead to economic benefits through improving the overall health of the population of Northern Ireland. The opportunities created within research could also bring further economic benefits through increased opportunities for job creation within this sector.

In delivering the benefits outlined we will ensure there are robust safeguards in place which prevent inappropriate sharing of personal information.

This consultation is aimed at all stakeholders with an interest in the processing of HSC service user information including: members of the public; community and voluntary groups; health and social care service providers; commissioners; and academia.

THE CURRENT POSITION IN NORTHERN IRELAND

Every individual in Northern Ireland will use the services of the HSC at some point in their life. In presenting for health or social care from their GP, hospital consultant or other health or social care professional these service users will provide information about themselves. They provide this information in confidence to be used for their direct, personal care (this is known as “primary use”). Consent for this use can be implied as part of the consent given for treatment or personal care arrangements. Any additional use of this information, beyond the direct care of the individual, is known as “secondary use”.

Obtaining the consent of the individual for the use of personal information has always been, and must always remain, the primary consideration for those seeking to process service user information for secondary uses.

Under current arrangements, express informed consent should be sought from every individual for the use of their personal information for secondary purposes where it is possible to do so. In the majority of cases in which it is not possible or practical to gain consent, the use of information which no longer identifies any individual may be used. This is called anonymised[2] or pseudonymised[3] information. This is in line with the common law duty of confidentiality and the statutory obligations of both the Data Protection Act and the Human Rights Act. The current legal framework governing the use of service user information is attached at **Annex 1.**

Increasingly we are seeing a need for a collaborative approach to the use of patient data throughout the HSC. This approach can help doctors and other health and social care professionals to spend more quality time with the individual and make more informed decisions; essentially, fuller use of the information available means better care, leading to better outcomes for the individual.

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[2] Anonymised data has the personal identifiers removed to minimise the risk of disclosure

[3] Pseudonymised data is anonymous to the recipient but contains information or a code which allows the data originator to identify an individual from it.

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, 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 Honest Broker Service 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.

There are however circumstances where it is not possible to obtain consent and/ or the use of anonymised and pseudonymised information would not provide a sufficient level of detail to deliver the outcomes required. It is in these circumstances that the proposals contained in this document would be utilised.

Under current secondary purposes arrangements, where the Data Protection and Human Rights requirements have been addressed (**Annex 1**), the common law duty of confidentiality must also be satisfied. The common law duty states that personal information may only be disclosed if one of the following three conditions is met:

- The service user has given a valid consent;
- Disclosure is in the public interest; or
- A statutory basis exists which permits or requires disclosure.

Evidencing service user consent or a statutory basis under the common law is straightforward. Consent has either been obtained or there is a statutory basis under which the sharing can happen. Satisfying the public interest under the common law is more complex. It is about assessing the benefits and the risks of sharing the information and basing a decision on that analysis. Using service user identifiable information for secondary purposes where there is a reliance on the public interest therefore carries the potential risk of a legal challenge to the decision that has been made.

To date there have been no such legal challenges in Northern Ireland. However, given the potential risk it would be prudent to establish a more robust arrangement for decision-making which would be supported by legislation. The legal provision would enable a greater level of assurance to the organisation and the individual and mitigate against the risk of successful challenge.

THE CHALLENGES OF THE CURRENT POSITION AND THE CASE FOR CHANGE

The previous section set out the current legal framework and the associated challenge of relying on the public interest within the common law duty when seeking to share service user identifiable information for secondary purposes. This section sets out the challenges of the current position.

One of the primary users of patient identifiable health information for secondary purposes is the Northern Ireland Cancer Registry. The information it obtains from many sources is anonymised prior to statistical analysis or publication. The identifiable information is used to remove duplicate patient information, facilitate genetic requests and link patient data with death certificates.

The Cancer Registry currently provides information to service users about its functions and use of service user information. A patient leaflet explains this and provides information about “opting out” of the process to have personal information processed by the Registry. Having satisfied itself that it meets the Human Rights and Data Protection requirements, the Registry relies on the public interest within the common law duty of confidentiality for the collection and processing of the patient identifiable information it uses. As previously set out this is open to legal challenge putting the registry and its extremely valuable work at some risk.

The registry relies on the public interest as there is no current statutory basis which permits or requires disclosure. Obtaining individual patient consent would require considerable effort given the large numbers of notifications of cancer or pre-malignant disease made annually in NI. The distressing circumstances in which consent would have to be sought must also be taken into account along with the very real risk that consent might be refused in a significant numbers of cases resulting in incomplete and/or biased data.

The Northern Ireland Cerebral Palsy Register is also a secondary user of patient identifiable health information. It too relies on the public interest within the common law duty of confidentiality. It provides information on the Register and the opportunity to opt out of the process via a leaflet provided to parents of children with cerebral palsy. The maintenance of a cerebral palsy register in Northern Ireland contributes significantly to developments in the understanding of the causes of cerebral palsy. It also helps to address the needs of children with the condition and the optimal environments necessary for them to achieve maximum participation and quality of life. The Register estimates that creating a system to obtain individual consent to the use of information would double the Register's running costs.

Northern Ireland has had major difficulties in participating in national initiatives such as confidential inquiries as consent from each individual concerned is usually required. This is because there is no statutory basis which permits or requires disclosure and it is not felt that the public interest case is sufficiently robust. The use of anonymised/pseudonymised information is in some circumstances insufficient to meet the needs of the inquiry being undertaken.

Recently Northern Ireland has been unable to participate in UK-wide epidemiology studies (the study of patterns, causes, and effects of health and disease conditions). This is due to being unable to share patient identifiable information with those undertaking the studies on behalf of the wider NHS.

Local initiatives such as clinical audits, health monitoring, HSC research studies, counter-fraud cases and health related audits would also benefit from access to personal information. A recent proposal for a patient satisfaction survey for those having received cancer treatments met difficulties when it came to collecting patient data for this secondary use. While individual HSC Trusts agreed with the benefits of the survey, they were unable to share the names and addresses of the individuals.

Complete data is also needed to underpin decisions about planning to meet future health needs and service delivery. This ensures that forecasting is as accurate as possible and thus any risk is reduced as far as possible. Decisions based on complete data could assist the HSC to achieve better value for its limited resources leading to better outcomes for service users.

In 2011 a scheme was jointly launched by this Department, the Department for Social Development and the Office of the First Minister and Deputy First Minister to make winter fuel payments to those undergoing cancer treatment. This required identifiable information to be shared between the HSC and central government departments. The administration of this scheme was considerably more difficult as the sharing of patient identifiable information without consent was not permissible. This meant that the process of making a payment to those who were eligible was more resource intensive than may have been necessary had the legislation to enable the sharing of service user identifiable information in controlled circumstances been in place.

This clearly demonstrates the benefits to be gained by the secondary use of service user information.

CURRENT SAFEGUARDS

There is a very strong focus on protecting service user identifiable information within the Department and HSC organisations. In protecting this information, as well as the legal obligations set out within the Human Rights Act and Data Protection Act, the ethical and moral obligations are a key consideration. In addition over the last few years, the Department and HSC organisations have sought to strengthen the safeguards which maintain the integrity of service user information. A range of measures exist to ensure there is a strong, consistent focus on compliance with the Data Protection Act 1998 and, indeed, on the protection of all information entrusted by service users to the HSC in Northern Ireland.

Senior staff members have been appointed within each HSC organisation to oversee the safe and secure use of service user information. These individuals 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.

The Northern Ireland Privacy Advisory Committee was established by the Department in 2006 to provide advice on steps to be taken to ensure the privacy rights of service users are properly protected. The Committee’s terms of reference are set out at **Annex 2**.

The Committee, at the Department’s request, developed a Code of Practice on Protecting the Confidentiality of Service Users. This was issued in 2009 and revised in 2012. The Code is aimed at supporting HSC staff in making good decisions about the protection, use and disclosure of service user information.

These measures provide assurance that information held across the HSC is maintained in a manner that effectively meets each organisation’s needs and those of its service users in line with relevant legislation.

Despite all of the steps taken to ensure that service user data is processed in a safe and effective way, the fact remains that there are situations where service user identifiable information is being processed for beneficial secondary purposes, as set out earlier, but with a reliance on the public interest which is open to legal challenge. In some such situations, it was decided that, despite the benefits, the public interest under the common law was not strong enough for Northern Ireland to participate in the proposed project.

However, for the HSC in Northern Ireland to maintain, and build upon, the benefits which may be achieved from the sharing of information, consideration is now being given to introducing legislation. This will enable the Department to control how and when the information of HSC service users locally may be accessed. This would permit the limited use of user identifiable information for secondary purposes, in controlled circumstances, where clear and significant improvements to patient care or more general benefits to the wider public can be expected.

Such an approach is already accepted as best practice internationally - similar provision is already in place in countries such as the United States of America, Australia, Finland and Norway.

In England and Wales legislation provides the statutory basis that enables the sharing of service user identifiable information to support a limited range of medical purposes. A Confidentiality Advisory Group assesses applications for access to service user identifiable information, providing advice that assists in the final decision as to whether access to the information should be granted.

In Scotland there is currently not any legislation to permit the sharing of service user identifiable information under the common law. A Privacy Advisory Committee provides advice to NHS National Services Scotland regarding the release of data that is or has the potential to be person-identifiable.

In the Republic of Ireland the position is similar to that in Northern Ireland. There is currently no statutory basis to permit the sharing of service user identifiable information for secondary purposes. Ireland is, however, considering statutory powers to achieve this.

The positions in England and Wales, Scotland and the Republic of Ireland are set out in more detail in **Annex 3**.

It will remain the Department's policy that, primarily, an individual's consent would be obtained for the use of their information. In circumstances in which this is not possible, or practical, then anonymised or pseudonymised information should be used. Only once these options have been shown to be impractical, would consideration be given under the proposed legislation to a request to access and process service user identifiable information, subject to the approval of an advisory group, and any limitations and controls they may specify in that approval.

OPTIONS CONSIDERED

As outlined in the previous section Northern Ireland is not alone in seeking to introduce legislation which would enable, in limited circumstances, use of information available within the HSC for the benefit of service users outside of the provision of direct personal care. Having looked at the models used elsewhere, the Department considered a number of options. Set out below are the key options considered. **Annex 4** provides a more detailed analysis of each of these options.

1. **Continue on the current basis – the "do nothing option".**

   This option was discounted as it would not address the risk of legal challenge to the secondary use of service user information. The lack of a definitive statutory basis would mean that a successful legal challenge would significantly impair the valuable work of the local registries, such as the cancer registry.

2. **Make specific diseases and conditions notifiable by including provision in the Public Health (Northern Ireland) Act 1967.**

   This option was discounted on the basis that, although this would address the secondary use needs of those diseases and conditions which are notifiable (allowing the current registries to continue) it would leave a range of other secondary uses, such as planning to meet future needs and service delivery, taking place without a secure legal basis.

3. **Introduce legislation for each envisaged secondary use making legal each individual use or disclosure.**

   This option was discounted as, given the developing and changing nature of secondary uses, the overarching challenge would be the need to continually develop legislation to meet the needs of each new secondary use.

4. **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).**

   This option would provide a solution similar to that which currently exists in England and Wales but would not cover the secondary use of social care information**.** Given the integrated nature of health and social care in Northern Ireland, it would seem imprudent to consider the options for future sharing of medical information for secondary uses and give no consideration to the sharing of social care information for similar purposes. To do so would continue to leave both the Department and the HSC, as secondary users of social care information, exposed to the risk of legal challenge.

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

   This option would address all the health and social care needs of the Department and the HSC where patient identifiable information is required for secondary purposes. This option was identified as the preferred option.

PREFERRED OPTION AND HOW IT WOULD BE IMPLEMENTED

The HSC sector in Northern Ireland already has robust procedures and protections in place for processing service user information. The proposed enhanced access to user identifiable information, in limited and controlled circumstances, will, as has been previously set out, provide the opportunity to deliver further benefits for service users and the wider public. The integrated nature of HSC services in Northern Ireland means that we are in the position to make use of all pertinent information to ensure our services meet the ever changing needs of the population.

The introduction of legislation would provide a clear statutory framework for the sharing of service user identifiable information, without consent, for secondary purposes. In line with internationally accepted good practice, and in keeping with the approaches successfully adopted in other jurisdictions, the Department now proposes to introduce legislation to the Assembly. This proposed legislation would confer upon the Department the power to make regulations which would allow the use of prescribed service user identifiable information. These Regulations would be the subject of further consultation.

The legislation which is proposed would also establish an advisory group. This group would receive and consider applications for the secondary use of service user identifiable information and advise whether those applications should be given support under the provisions of the legislation, subject to any controls and limitations the group may consider necessary.

Under the proposals, applicants would have to demonstrate to the advisory group that the use of service user identifiable information is absolutely essential to the successful outcome of their work; that similar results could not be obtained by using anonymised or pseudonymised service user information; and that it is either impossible or impracticable to gain consent from every individual whose data may be used.

The advisory group would be at the heart of the process to ensure that recommendations to allow access to service user identifiable information are consistent, impartial and transparent and to reassure service users that decisions taken are in their best interests and the best interests of the HSC organisations that hold the information.

It is important to note that all uses of service user identifiable information under any new legislation would still need to comply fully with the Data Protection Act 1998 and the Human Rights Act 1998.

The proposals for legislation must be balanced against the public's right to confidentiality. What the Department is proposing is a structure which would oversee and regulate the use of information; it is not a proposal for wholesale, unlimited access to service user personal information.

IMPLEMENTATION/NEXT STEPS

Following the consultation, it is the Department’s intention to revisit the proposals in light of the responses received. The Department may then seek to introduce a Bill to the Assembly within this current mandate.

The subsequent regulations which would allow the use of prescribed service user identifiable information in limited and controlled circumstances and the establishment of an advisory group will be the subject of further consultation.

SCREENING/IMPACT ASSESSMENTS

Human Rights and Equality Implications

Section 75 of the Northern Ireland Act 1998 requires Departments in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity:

- between persons of different religious belief, political opinion, racial group, age, marital status or sexual orientation;
- between men and women generally;
- between person with a disability and persons without; and
- between persons with dependants and persons without.

In addition, without prejudice to the above obligation, Departments should also, in carrying out their functions relating to Northern Ireland, have due regard to the desirability of promoting good relations between persons of different religious belief, political opinion or racial group. Departments also have a statutory duty to ensure that their decisions and actions are compatible with the European Convention on Human Rights and to act in accordance with these rights.

DHSSPS has carried out a preliminary screening of the proposals and as part of this screening process has concluded at this **stage that an Equality Impact Assessment is not necessary.**

Human Rights

Article 8 of the European Convention on Human Rights guarantees a right to privacy which can only be interfered with when it is necessary to meet specified legitimate needs. The Department recognizes that the proposals for legislation broaden the use of personal information provided to the HSC, but would stress that this will only be considered in prescribed conditions, and in circumstances which clearly have a legitimate need and a social benefit.

Privacy

The Department has conducted a Privacy Impact Assessment to consider the impact of the proposals on the right to privacy of the individual. The Department acknowledges that the proposal raises concerns in respect of the further use of personal information, but believes that the societal benefits, the safeguards in place and the further controls proposed mitigate the concerns and risks involved. The Department is satisfied that the proposals and associated implications are justified and proportionate.

Rural Proofing

It is considered that there are no negative impacts on rural productivity or the provision of services to the rural community as a result of these proposals. The proposals apply equally to all sections of the local population and do not have a different impact on those in rural areas.

Health Impact

It is considered that these proposals will have a positive impact on health by enabling improved management of HSC services, and facilitating research and disease registries.

Sustainable development

It is considered that there are no negative impacts on sustainable development opportunities. By facilitating better health outcomes the proposals may, in the longer term, provide social and economic benefits.

Regulatory Impact Assessment

The Department does not consider that a Regulatory Impact Assessment is required as the proposals do not bear any impact for businesses locally.

HOW TO RESPOND TO THIS CONSULTATION

The consultation will run from 07/07/2014 to 10/10/2014.

In order to facilitate analysis it is important that respondents use the Questionnaire provided. To ensure that your response is fully understood, please write or type your response on the consultation response questionnaire; you do not have to respond to all the questions.

You should send your completed consultation response questionnaire to:

Email: caringforyourinfo@dhsspsni.gov.uk

Post: Department of Health, Social Services and Public Safety
Information Management Branch
Castle Buildings
Belfast
BT4 3SQ

Completed Consultation Response Questionnaires must be received by the Department by 5.00pm on Friday, 10/10/2014.

Before you submit your response please read the information below about the **Freedom of Information Act 2000 and the confidentiality of responses** to public consultation exercises.

A summary of consultation responses will be made available on the DHSSPS website at http://dhsspsni.gov.uk/index/consultations/currentconsultations.htm as soon as possible after completion of the consultation and in any event no later than three months after the consultation closes.

FREEDOM OF INFORMATION

DHSSPS will publish a summary of responses following completion of the consultation process. Your response, and all other responses to the consultation, may be disclosed on request. The Department can only refuse to disclose information in exceptional circumstances. **Before** you submit your response, please read the paragraphs below on the confidentiality of consultations, they will give you guidance on the legal position about any information given by you in response to this consultation.

The Freedom of Information Act 2000 gives the public a right of access to any information held by a public authority, namely, DHSSPS in this case. This right of access to information includes information provided in response to a consultation. DHSSPS cannot automatically consider as confidential, information supplied to it in response to a consultation.

However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity should be made public or be treated as confidential.

This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances. ***If you do not wish information about your identity to be made public, please include an explanation in your response, this will be considered should an access for information request be received by the Department.***

The Secretary of State for Constitutional Affairs’ Code of Practice on the Freedom of Information Act provides that:

- The Department should only accept information from third parties in confidence, if it is necessary to obtain that information in connection with the exercise of any of the Department’s functions, and it would not otherwise be provided;

- The Department should not agree to hold information received from third parties “in confidence” which is not confidential in nature; and

- Acceptance by the Department of confidentiality provisions must be for good reasons, capable of being justified to the Information Commissioner.

For further information about confidentiality of responses please contact the Information Commissioner’s Office (or see the web site at:

http://www.informationcommissioner.gov.uk/).

QUESTIONNAIRE

(Please tick a box)

I am responding: as an individual ☐ on behalf of an organisation ☐

Name: ______________________________

Job Title: ______________________________

Organisation: ______________________________

Address: ______________________________

CONSULTATION ON PROPOSALS TO USE HEALTH AND SOCIAL CARE SERVICE USER IDENTIFIABLE INFORMATION IN CONTROLLED CIRCUMSTANCES

Views are invited on the following questions;

Introduction

Q1. Do you agree with the proposal to bring forward legislation to enable the Department to regulate the use of service user information for secondary purposes in controlled circumstances?

Yes ☐ **No** ☐ **Don’t know/no views** ☐

Additional Comments

Q2. Do you agree that the Department should make provision in the legislation for the establishment of an advisory group to consider applications for the use of service user identifiable information?

Yes ☐ **No** ☐ **Don’t know/no views** ☐

<u>Additional Comments</u>

Q3. Do you have any other comments on these proposals?

Yes ☐ **No** ☐

(If yes please provide your comments below.)

Additional Comments

Q4. Is there another model which we should consider?

Yes ☐ **No** ☐ **Don’t know/no views** ☐

(If yes please provide your comments below.)

<u>Additional Comments</u>

IMPACT ASSESSMENTS

Equality and Human Rights implications

Q5. Do you agree with the conclusions reached by the Department in the preliminary Equality and Human Rights screening? (The screening document is on the consultation web page)

Yes ☐ **No** ☐ **Don’t know/no views** ☐

If no, please give further details, along with any supporting evidence.

Privacy Impact

Q6 Do you agree with the Department's Privacy Impact Assessment that any adverse impact on privacy is mitigated by the benefits to society, the safeguards already in place and the further controls proposed? (The Assessment document is on the consultation web page)

Yes ☐ **No** ☐ **Don't know/no views** ☐

If no, please give further details.

Q7. Do you have any views on the conclusions reached by the Department to screen out from further assessment the implications of the proposals in respect of:-

(a) economic impacts; (b) social impacts; (c) rural impacts; (d) environmental impacts; (e) victims; (f) community safety; and (g) others?

Yes ☐ **No** ☐

Is there any other evidence which you consider should have been taken into account?

<u>Additional Comments</u>

Further Comments

Please use the box below to insert any further comments, recommendations or suggestions you would like to make in relation to this proposed legislation.

ANNEX 1

CURRENT LEGAL FRAMEWORK GOVERNING THE USE OF SERVICE USER INFORMATION

The Data Protection Act 1998

The purpose of the Data Protection Act 1998 (DPA) is to protect the right of the individual to privacy with respect to the processing of personal information. The Act only applies to information which relates to a living individual and which identifies that individual, it does not apply to anonymised information. The Act requires, amongst other things, that this personal information shall be processed fairly and lawfully.

The DPA does not, however, mean that the consent of an individual is always required for the use of their data. The first data protection principle requires organisations to process personal data fairly and lawfully and, in particular, not to process unless certain conditions are met. These conditions include processing data “for the exercise of any functions of... a government department.” and processing which is “necessary for medical purposes and is undertaken by:

(i) a health professional, or
(ii) a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional.”

“Medical purposes” includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services. So HSC service user information may already legitimately be processed by the HSC in relation to wider healthcare management and commissioning. Paragraph 7 of Schedule 3 to the DPA further allows for the processing of information which would enable the Department and the HSC bodies to make use of similar information for the management and commissioning of Social Care services.

Common law duty of confidentiality

The common law is based on previous judgments in court. Whilst various interpretations of the common law may be possible there is widespread acceptance that, where service users' personal information is held in confidence, disclosure may only be justified under the common law in one of three ways:

- The service user has given a valid consent (which can be express or implied);
- Disclosure is in the public interest; or
- A statutory basis exists which permits or requires disclosure.

Consent for the use of service users' information for direct care can be implied as part of the consent given for treatment. However, it is not acceptable to assume that service users, in giving consent for their information to be used for the purpose of their direct care, are also giving consent for that information to be used for a range of other uses which are not directly related to their direct care and of which they may be unaware.

Therefore, while it is recognised that there are circumstances in which the use of anonymised or pseudonymised information is not appropriate and in which it is necessary to use information which could potentially identify individual service users, the Department and HSC bodies are bound by the common law duty of confidentiality.

Human Rights Act 1998 (the HRA)

A right to "respect for private and family life" is enshrined in Article 8 of the European Convention on Human Rights, which is part of UK law because of the HRA. This right is not absolute, and may be set aside in circumstances where the law permits where this is necessary "in the interests of national security, public safety or the economic well- being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others". The effect is similar to that of the common law: privacy is an important principle which must be respected, but confidentiality may be breached where other significant interests prevail.

ANNEX 2

Privacy Advisory Committee – Terms of Reference

The NI Privacy Advisory Committee (PAC) has the following ongoing responsibilities:

- 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 HSC under continuous review and to provide timely and relevant best practice advice to HSC bodies; and
- To consider current and new uses to which personal information is put in HSC bodies and to authorise such uses of personal information taking particular account of the legal and ethical issues surrounding privacy and confidentiality.

The PAC shall have a Chairperson appointed by the Department and shall have such members as agreed with the Department as necessary to carry out its responsibilities listed above. The members of the PAC shall be drawn from a wide range of individuals including health and care professionals and service users. A secretariat shall provide administrative support to the PAC.

A Project Team shall be established to devise and complete a Programme of Work, which will be agreed and managed by the PAC and will give effect to the recommendations agreed by Minister.

ANNEX 3

POSITION IN ENGLAND AND WALES

The NHS in England and Wales has long recognised that there are essential activities, and important medical research, that require the use of service user identifiable information. Legislation was introduced in 2001 to control the use of the information of patients presenting to the NHS, and allow application to be made for secondary uses. This is contained in Sections 60 and 61 of the Health and Social Care Act 2001 ("the 2001 Act").

Sections 60 and 61 of the Health and Social Care Act 2001 were introduced in England and Wales to -

(i) provide the Secretary of State for Health with the power to authorise or require that patient identifiable information is used for activities that fall within defined medical purposes where there is currently no secure basis in law other than the consent of the patient concerned and it is thought that there are real barriers to seeking or obtaining consent, and
(ii) to establish an independent body, the Patient Information Advisory Group, to oversee the use of section 251 powers (this has since been replaced by the Ethics and Confidentiality Committee of the National Information Governance Board and subsequently the Confidentiality Advisory Group within the Health Research Authority).

Sections 60 and 61of the Health and Social Care Act 2001 were repealed by the National Health Service (Consequential Provisions) Act 2006[4] and re-enacted by sections 251 and 252 of the National Health Service Act 2006. The purpose of sections 251 and 252 is identical in purpose to sections 60 and 61.

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[4] 2006 c.43

The power in section 251 can only be used to support a limited range of medical purposes[5] that are in the interests of patients or the wider public where consent is not a practicable alternative and anonymised information will not suffice. It is largely intended as a transitional measure while consent or anonymisation procedures are developed. This transitional aspect is reinforced by the requirement to review annually each separate use of the power.

The Health Service (Control of Patient Information) Regulations 2002[6] were made in GB under section 60 of the Health and Social Care Act 2001 and continue to have effect under section 251 of the National Health Service Act 2006. These Regulations provide either specific or class support for the use of confidential patient information. Specific support applies to particular activities that have been approved by Parliament. To date the Regulations have provided specific support to the Health Protection Agency and other public health staff to collect data relating to communicable disease surveillance and for surveillance of other risks to public health. They have also provided specific support for Cancer Registries to collect data relating to cancer.

The class support mechanism allows section 251 powers to be used by the Secretary of State without needing to lay regulations before Parliament for each use of the powers. This support is available for the following purposes:

- the process of anonymising patient records
- analysis of geographical location
- work to identify and contact patients with a view to inviting them to participate in medical research or to allow their data or tissue to be used for medical research or to allow their tissue to be used for other medical purposes

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[5] In section 251 “medical purposes” means the purposes of any of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of health and social care services, and informing individuals about their physical or mental health or condition, the diagnosis of their condition or their care and treatment.

[6] SI 2002/1438

- record linkage and validation
- auditing, monitoring and analysing the provision made by the health service for patient care and treatment
- allowing access to confidential patient information for one or more of the above purposes

Any use or disclosure of identifiable information under a “section 251” type arrangement must be consistent with the Data Protection Act 1998[7]. The Data Protection Act 1998 gives effect in UK law to Directive 95/46/EC of the European Parliament. The aim of the Directive, and thus of the Data Protection Act 1998, is to protect the rights of people in respect of the processing of personal data; not only their privacy rights, but all their fundamental rights insofar as they may be affected by such data processing. As its source is in EU law, the Data Protection Act 1998 implements the requirements of the Directive and cannot be modified unless the Directive was to be modified.

The first data protection principle contained in the Data Protection Act 1998 requires organisations to process personal data fairly and lawfully and, in particular, not to process unless (a) at least one of conditions in Schedule 2 is met, and (b) in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met.

Condition 8 in Schedule 3 states “The processing is necessary for medical purposes and is undertaken by:

(iii) a health professional, or
(iv) a person who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional.

For the purpose of condition 8 “medical purposes” includes the purposes of preventative medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.

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[7] Section 251(7) of the National Health Service Act 2006 refers.

This therefore is the most likely Schedule 3 condition for processing medical information for some secondary uses which fall within the definition of “medical purposes”.

Safeguarding Information - The Confidentiality Advisory Group (CAG)

The Confidentiality Advisory Group (CAG) assesses applications for access to service user identifiable information within England and Wales. The CAG advise whether there is sufficient justification to access the requested confidential patient information. Using that advice as a basis for their consideration, the Health Research Agency (which considers applications for research purposes), or the Secretary of State (all other secondary purposes) will take the final decision on whether to approve the access.

When offering advice, the CAG must take into account the restrictions and exclusions that are contained within the Regulations. In particular, where an individual is processing confidential patient information under the Regulations he or she must not process that information any more than is necessary to achieve the permitted purposes and also they shall not process confidential patient information unless they agree to maintain a duty of confidentiality which is equivalent to that which would arise if they were a health professional. The advisory group referred to within this consultation document would be expected to fulfil this role in Northern Ireland.

Details of all applications that have been approved in England and Wales are held in the Register of approved applications. This Register contains a summary of the activity, details of the identifiers approved and contact details for the applicant and can be viewed at http://www.hra.nhs.uk/hra-confidentiality-advisory-group/cag-advice-and-approval-decisions/.

POSITION IN SCOTLAND

Scotland does not currently have legislation in place to permit the secondary use of service user identifiable information. Scotland does, however, have a Privacy Advisory Committee (PAC) which is an independent advisory committee to NHS National Services Scotland (NSS). The Committee provides advice on the protection of patient information to help NSS decide on applications for access to health data for health and social care administration, research and other well-defined purposes. PAC's views are particularly sought in relation to any request for access to information that would involve the release of data that is, or has the potential to be, person-identifiable, and in respect of any new record linkages.

PAC advises on the correct balance between protecting personal data and making data available for research, audit and other important uses and ensures that any information releases are carefully controlled.

Further information on PAC may be found via the link below:
http://www.nhsnss.org/pages/corporate/privacy_advisory_committee.php

POSITION IN THE REPUBLIC OF IRELAND

The Republic of Ireland (RoI) is in a similar position to Northern Ireland in that there is currently no provision for the sharing of service user identifiable information without consent for secondary purposes. The Government in the RoI has however acknowledged the positive benefits experienced in other jurisdictions and is moving to allowing access to identifiable information in limited and controlled circumstances.

Their current Legislation Programme therefore contains a Health Information Bill. Some of the stated goals of this Bill seek to address the same issues we face locally. These include:

- ensuring that there is a sound legislative base for the use of information throughout the health system so as to provide best patient care and safety;

- ensuring that health information can flow between the public and private health sectors in line with patient care requirements;

- facilitating the establishment of national population registries (similar to the National Cancer Registry);

- protecting the privacy, confidentiality, security and integrity of personal health information and ensure that these principles apply explicitly to all persons who have a legitimate reason, in certain situations, to be involved with or access such information; and

- establishing a framework that provides clarity to all involved on the obtaining, use, retention and disclosure of identifiable personal health information for management and research purposes in situations other than where the informed consent of the individual is given.[8]

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[8] DoHC Discussion Paper on Proposed Health Information Bill – June 2008

ANNEX 4

ANALYSIS OF THE KEY SECONDARY USES OPTIONS

1. Allow the use of service user identifying information for secondary uses to continue on the current basis.

FOR

To date, there have been no legal challenges in Northern Ireland to the use and disclosure of service user identifying information for secondary purposes. There is a case for not giving any further consideration to the issues and adopting a “wait and see” approach. Maintaining the status quo would present no resource implications in terms of finance or manpower.

AGAINST

Recent high profile losses of personal and sensitive information have raised awareness and concerns on how information which public bodies hold is used and managed. The Department, along with HSC organisations and other Arm’s Length Bodies (ALBs), are aware of the increased concerns and have taken steps to mitigate the risks, but these do not remove the potential for legal challenge.

The fact remains that the use and disclosure of service user identifying information for secondary purposes is taking place within the HSC sector without a statutory basis and to allow this to continue, when we are aware of the issue and the potential risk of legal challenge, would be imprudent.

Dr Colin Harper in his paper “Does Northern Ireland need an equivalent to section 60 of the Health and Social Care Act 2001?” a Report to the Privacy Advisory Committee of the Northern Ireland Department of Health Social Services and Public Safety provided in July 2007 states that “There does not appear to have been a case at the European Court of Human Rights on the secondary use of health and social care information, but other relevant cases suggest that current practice may well fall short of what the Court would expect in terms of respect for private life.”

Bodies such as the Northern Ireland Cancer Registry are also strongly in favour of providing statutory support for the type of information processing which they require.

2. Make specific diseases and conditions notifiable by including in the Public Health Act(Northern Ireland) 1967[9]

It could be argued that where government determines that a secondary use clearly serves a public interest which overrides the public interest in confidentiality this should be recognised in statute.

Over the years mortality and morbidity patterns have changed significantly so that some diseases, which are still notifiable by law by virtue of the Public Health (Northern Ireland) Act 1967, are no longer a major threat to public health in the way that cancer and other diseases and conditions are today. Given that the rationale for making diseases notifiable was monitoring and control of the disease, the case could be made that these diseases and conditions ought to become a statutorily notifiable diseases.

FOR

Many countries already have a law that makes cancer a statutorily notifiable disease. These include: Australia, Canada, the Czech Republic, Denmark, Finland, Israel, Kuwait, Latvia, Malta, New Zealand, Norway, Poland, Slovakia, Slovenia, Sweden, and the USA. There is no evidence that the citizens of these countries have suffered in any way as a result of forfeiting some of their right to privacy under strictly defined circumstances, nor are we aware of any campaigns to repeal such legislation. Indeed politicians in the USA demanded legislation when they realised that cancer registration was operating in some states but not their own.

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[9] 1967 (c.36)

Contrary to assertions that it is not possible to legislate for all diseases in this way, legislation in some of the Nordic countries goes beyond cancer registration to cover almost all health-related data. This ensures that full population data needed for many health research and related activities is collected. However this does not give researchers the freedom to do whatever they wish. For example, in Denmark, a data inspection agency, scientific ethical committees and a patient right law regulate the use of data where it is not realistic to get the consent of the individual.

The Northern Ireland Human Rights Commission in its response to the Department's Consultation Exercise in October 2002[10] said that "further consideration should be given to making cancer a notifiable disease".

AGAINST

While this would enable the secondary use of information on those diseases and conditions which are notifiable it would leave a range of other secondary uses, such as planning to meet future needs and service delivery, taking place without a secure legal basis. Any additional diseases or conditions which are identified would require new legislation with the resource issues which that would raise.

These diseases and conditions are not contagious or communicable therefore including them as notifiable diseases may be difficult within the framework of the existing legislation and, although they are more widely acknowledged and discussed these days, cancer, for example, is still a dreaded condition and to have it bracketed with cholera and plague, with connotations of poverty and poor hygiene, might be unhelpful to public perceptions of the condition.

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[10] See Northern Ireland Human Rights Commission, Response to the Department of Health, Social Services and Public Safety Consultation Exercise, Protecting Personal Information, October 2002, page 9, paragraph 15

3. Introduce legislation for each envisaged secondary use making legal each individual use or disclosure.

This could be used for activities that are so critical they should not be subject to obligations to gain consent with the associated risk of service users opting out.

FOR

This would clarify the legal situation for both service users and staff.

AGAINST

Regulations to allow for information to be used without consent in specific circumstances would undoubtedly miss some information flows that are worthy of protection. A new disease may appear in the future (as vCJD did in the 1990s) and the data required to investigate the disease may only be partial because no-one could predict in advance that this would happen and that regulations were necessary.

Therefore, given the developing and changing nature of secondary uses, this would be an on-going process with significant on-going resource issues to develop new regulations when necessary.

4. Introduce NI legislation similar to sections 60 and 61 of the Health and Social Care Act 2001[11] (which were replaced by sections 251 and 252 of the National Health Service Act 2006[12]) (Model for England and Wales)

This would provide a solution similar to England and Wales but would not deal with the secondary use of social care information**.** The Department and the HSC, as secondary users of social care information would continue to be exposed to the risk of legal challenge as secondary users of social care information.

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[11] 2001 c.15

[12] 2006 c.41

FOR

Creating legislation of this nature for Northern Ireland would reduce the likelihood of legal challenge by addressing the lack of cover under the common law and the lawful processing requirements set out in Principles 1 and 2 of the Data Protection Act 1998. It would provide a clear basis for sharing information lawfully and establish an advisory group which would perform a role similar to that of the Confidentiality Advisory Group for England and Wales.

Perhaps the most important argument for legislation is that full population data is needed for many health related activities. For example the Northern Ireland Cancer Registry (and other disease registries) need complete, unbiased coverage to ensure that the true disease burden is known, that comparisons and projections of future burden are reliable and health inequalities can therefore be reliably measured. Complete data is also needed to underpin decisions about planning to meet future needs and service delivery (eg Transforming Your Care project) to ensure that forecasting is as accurate as possible and thus any risk is reduced as far as possible. Decisions based on complete data will ensure that the HSC can maximise its return on investment for limited resources. The same argument applies to research projects. If a proportion of the population does not consent to their data being used then all those who have an interest would be working with partial data that would be subject to bias. The level of this bias would be hard to predict because little would be known about those who had refused consent.

AGAINST

This option would require considerable time and resources firstly to achieve the legislative solution and then to appoint and support the advisory group which would oversee the use of the legislative powers and advise the Minister.

Legislation of this type could be seen to restrict an individual’s right to privacy. This might have the effect of causing service users to lose faith in the HSC and to withhold information because of concerns that confidentiality might be breached.

5. Introduce NI legislation similar to sections 60 and 61 of the Health and Social Care Act 2001 (which were replaced by sections 251and 252 of the National Health Service Act 2006) (English model) but include the sharing of social care information

Health and social care is an integrated service in Northern Ireland and it would seem imprudent to consider the options for future sharing of medical information for secondary uses and give no consideration to the sharing of social care information for similar purposes.

As detailed in Annex 3 (Position in England and Wales), any use or disclosure of service user identifiable information under a “section 251” type arrangement must be compatible with the Data Protection Act 1998. Paragraph 8 of Schedule 3 to the Data Protection Act 1998 permits processing of sensitive personal information for medical purposes without the explicit consent of the individual and is the most likely basis for processing medical information for certain secondary purposes. Paragraph 7 of that schedule also permits such processing for “the exercise of any functions of ... a government department”. The provision of Health and Social Care services is a function of this Department.

FOR (In addition to option 4)

Service user identifiable social care information is used for a variety of secondary uses, for example planning, management of risk, trend forecasting, internal audit, commissioning, case management reviews, enquiries, advisory groups, adoption orders, supervision treatment orders and regional committees.

It may on occasion be unavoidable that the Department itself may need to refer directly to service user identifiable social care information in the exercise of its performance management, governance and accountability functions with arms length social care bodies (for example in relation to performance of delegated statutory functions and corporate parenting responsibilities). The Department therefore is a secondary user of service user identifiable social care information and ultimately the data controller for information which it holds and processes.

The sharing of service user identifiable social care information is necessary to ensure a collective, professional approach to safeguarding and planning services for children, vulnerable adults and the wider community. It also enables a more holistic approach to some secondary uses where, for example, integration is required or research straddles health and social care.

The Department also needs service user identifiable information to make considered, measured decisions in individual cases; it is important to learn lessons from these individual cases which will then be used to inform policy development.

The sharing of social care information is very emotive and both the Information Commissioner and the Courts have, in the past, queried the sharing and non-sharing of social care information.

The view of the Office of Social Services, DHSSPS is that social care information should be included in any considerations around the creation of legislation similar to sections 60 and 61 of the Health and Social Care Act 2001 (which was replaced by sections 251 and 252 of the National Health Service Act 2006).

This legal support would give clarity and confidence to professionals to enable them to share service user identifiable social care information for secondary purposes.

The NI Longitudinal Study has expressed the same opinion.

AGAINST

In addition to the arguments advanced against option 4, the nature of the information we are considering must be borne in mind. The extreme sensitivity of social care information means that any proposals to share this type of information for any purpose without the explicit consent of the service user, even with a legal basis, may attract criticism.