

The Health and Social Care (Control of Data Processing) Bill – submission by the Privacy Advisory Committee (N Ireland)

Introduction

On behalf of the Privacy Advisory Committee (N Ireland) I thank you for the invitation to meet with the Committee for Health and Social Care and Public Safety on the Health and Social Care (Control of Data Processing) Bill. As preparation for our meeting we have prepared the following paper which provides some relevant background to the proposed legislation together with comments on the Bill.

The Privacy Advisory Committee (PAC) was established by the Department of Health and Social Services in 2006 as one of 14 recommendations agreed by Minister. Our central task was to oversee the implementation of the 13 remaining recommendations on protecting personal information.

As part of our terms of reference PAC has kept consent and confidentiality matters throughout the Health and Social Care (HSC) family under continuous review. We have provided regular advice on current and proposed uses of personal information in HSC bodies. We have introduced and overseen training for Personal Data Guardians and with whom we meet on a yearly basis. We liaise with our sister organisations in the other home countries on a need to basis. These activities have kept PAC closely engaged with the ethical and legal issues and challenges across the spectrum of health and social care.

Two of the 14 recommendations of Minister are central to the present legislative proposals:

- the development of a comprehensive Code of Practice on confidentiality;
- consideration of the need for legislation in Northern Ireland similar to section 60 of the Health and Social Care Act 2001.

Code of Practice on Protecting the Confidentiality of Service User Information

A Code of Practice on confidentiality was introduced by the Department 2009 to provide support and guidance for all those involved in health and social care, concerning decisions about the protection, use and disclosure of service user information. This Code was revised and updated by PAC in 2011 and issued by the Department in January 2012.

The aim of the Code of Practice is to support staff in making good decisions about the protection, use and disclosure of service user information. It provides practical guidance to assist decision-making with respect to service user information.

The following extract from the Code of Practice is of relevance for the Committee's present consideration of the Bill. Chapter three, "The purpose of any anticipated use or disclosure of person identifiable service user information", states:

" 3.2 The particular purpose of any contemplated use or disclosure of service user information will be one of the following:

- (A) use and disclosure of personal identifiable information for the direct care of that service user;*
- (B) use and disclosure of personal identifiable information for purposes of health and social care not directly related to the care of that service user (secondary uses);*

(C) *uses and disclosures of personal identifiable information for purposes other than A or B.*”

It is important to note that a use or disclosure for any of these purposes may have several possible justifications. In particular, instances of use or disclosure might be justified on the basis of the consent of the service user, a statutory obligation or an overriding public interest. Given the Committee’s concerns around public interest justifications the following statement from the Code of Practice is likely to be of interest:

“3.25 In all cases of discretionary disclosure in the public interest there is no legal obligation to disclose, rather whether or not disclosure can be justified depends on balancing the interests that are in conflict in each case; for example protecting a third party from serious harm. It needs to be borne in mind that every disclosure is an interference with the service user’s right to privacy, while the benefits of disclosure will often be less certain. While a balancing of the service user’s right to privacy against other rights and interests is always difficult, it is usually more easily performed where the conflict is with rights of identifiable third parties, such as in child protection, than where there is a conflict with a more diffuse public interest such as national security or public health. It is not sufficient that such disclosure might serve the protection of such an overriding public interest; rather the test is one of strict necessity in the specific circumstances of each case.

3.26 In situations involving disclosure to protect overriding rights of third parties, each case must be considered on its merits. The test is whether the release of information to protect the interests of a third party exceptionally prevails over the duty of confidence owed to the service user and the public interest in a confidential health and social care service.”

It will be seen from the foregoing that the Department’s Code of Practice sets a high threshold for considering disclosure of a service user’s personal health or social care information for any overriding public interest.

Secondary uses. Use and disclosure of personal identifiable information for purposes of health and social care not directly related to the care of that service user (secondary uses) is increasingly required for evidence-based practice and for a rational approach to providing and managing our health and social care services. On this the Code of Practice is quite clear: “when the proposed use or disclosure relates to health and social care, but is not directly for the care of that service user, the express consent of that service user is usually required, unless the information is in an unidentifiable form. The possible exceptions to this requirement for consent are where a statute, court or tribunal imposes a requirement to disclose or there is an overriding public interest in the use or disclosure.”
(3.16)

PAC has not, over its nine years of work, found any proposed use or disclosure of personable identifiable information for a secondary purpose that would meet the criteria “where the release of information to protect the interests of a third party exceptionally prevails over the duty of confidence owed to the service user and the public interest in a confidential health and social care service”.

Over the six years since the Department’s Code of Practice has been in place PAC has observed a real shift in the standards of informational privacy across health and social care. Custom and practice

concerning the assumptions around data sharing for Secondary uses has gradually shifted to a recognition and observance of the standards set out in the Code.

While having achieved this important objective, situations arise where the consent of service users cannot practicably be obtained for use or disclosure, yet there are important health and social care interests at stake. Examples include disease registries for secondary uses, financial inspections - including probity checking to provide assurance on the level of service provision, regional and national audits, confidential enquires.

Ways Forward

From the experience of PAC over the last 8 years there is no single solution. That said there are a number of ways forward.

A first objective has been optimising the use of de-identified information. Again the Code of practice states: *“All organisations seeking personal identifiable information for other than direct care should be seeking anonymised or pseudonymised data.”*

Within trusts, anonymisation by staff with a direct care relationship is an important option.

Second is Safe Haven with Honest Broker provision. An exemplar of local provision is the Northern Ireland Longitudinal Study database, including its information governance arrangements.

In our 2013 submission to Minister (Appendix) PAC recommended a Departmental policy steer to establish safe haven and honest broker functionality. It is most encouraging to see the progress that has been achieved on these provisions. The Honest Broker provisions will apply to data that is already being held centrally for direct care purposes.

Many of the requirements for secondary uses, presently unmet could be addressed through Northern Ireland-wide ‘safe haven’ and ‘honest broker’ provision.

Legislation

Even with optimal provisions for effective anonymisation, situations arise where it is not possible or practicable to obtain consent or to anonymise personal identifiable health and social care information. Such situations include clinically important national and regional audits and inquiries, such as inquiries into asthma-related deaths, suicides, perinatal deaths. They also include work that can be achieved with specific disease registries, such as the Cancer Registry and the Cerebral Palsy Registry. In these situations specific consent requirements may not have been foreseen or may not be obtainable.

In order that such health and social care purposes can be considered a statutory basis for setting aside the common law duty of confidentiality is required. The Privacy Advisory Committee, in its submission to the Minister in 2013 recommended, as it had earlier to the Department in 2008, the provision of legislation for Northern Ireland authorising the making of appropriate regulations to deal with these situations, that is to introduce NI legislation similar to sections 251 and 252 of the National Health Service Act 2006 and to include social care information.

We also recommended the creation of a body with responsibility of scrutinising requests and the authority to grant organisations and individuals permission for the secondary uses of service user information, in a way which complies with the common law and also with the Human Rights Act 1998 and the Data Protection Act 1998.

The Data Protection and human rights law

Any proposed secondary use or disclosure of health and social care information must still conform to the requirements of the Data Protection Act 1998. Secondary uses of information gathered from service users also engage the human right to ‘a private life’, which is protected by both the European Convention on Human Rights (in Article 8) and the Human Rights Act 1998. Any proposed use of the information would be required to have the minimum possible impact on a person’s private life. There would also need to be close and effective scrutiny of the way the information is in fact used.

Specifics Comments on the Bill Proposals

The Privacy Advisory Committee welcomes the introduction of the Health and Social Care (Control of Data Processing) Bill. We believe that these proposals address what the Committee sees as a gap in the law’s current provision for protecting the privacy rights of users of health and social care services in Northern Ireland.

We have a number of comments on the details of the proposals.

1.-(1) We consider (a) is redundant and that the interests are much broader than improvement. The health and social care purposes that require to be addressed by this Bill cover a range of activities directed at enabling all health and social care organisations to carry out their tasks effectively and efficiently. This will include improvements where necessary and possible. We suggest that 1(b) is incorporated into the preceding paragraph:

“The Department may by regulations make such provision for and in connection with requiring or regulating the processing of prescribed information of a relevant person for medical or social care purposes and which are in the public interest.”

Any refusal for such processing should be respected.

2.-(1) We consider the establishment of a committee to authorise processing of confidential information an imperative. We suggest that the wording in 2(1) should reflect this namely that the Department “must” by regulation establish a committee.

3.-(4) Health and social care bodies must consciously consider the equality duty in section 75 of the Northern Ireland Act 1998 and have “due regard” to the Code of Practice.

Roy McClelland OBE
Chairman Privacy Advisory Committee (N. Ireland)

Appendix

Proposals for Legislation Governing Secondary Uses of Service User Information

A briefing paper prepared by Privacy Advisory Committee (Northern Ireland)

Introduction

One of the functions of the Privacy Advisory Committee is to provide the Minister and the Department with advice on what steps may need to be taken to ensure that the privacy rights of users of health and social care services in Northern Ireland are properly protected. The purpose of this briefing paper is to identify what the Committee sees as a gap in the law's current provision for protecting those rights in Northern Ireland and to suggest measures to address that gap.

The gap we have identified relates to the uses of personal identifiable service user information for health and social care purposes which are not directly related to the care of the individual service user, commonly referred to as 'secondary uses'.

The use and sharing of personal identifiable service user information form an essential part of the provision of health and social care. The use and sharing of such information can benefit individual service users and is often necessary for the effective functioning of health and social care services and in the public interest. The essential nature of such use and sharing, however, needs to be set alongside the expectations which service users have that all their personal information will be kept confidential.

The principle of consent

The principle of consent is central to respecting patients' rights, including their right to privacy, and occupies a pivotal role in legitimising the uses and disclosures of a service user's information.

From a consent perspective, a clear distinction must be drawn between disclosures which are necessary for the direct care of a service user and disclosures which are for necessary for maintaining or improving the general functioning of health and social care services. While the co-operation of service users can provide a basis for inferring their consent to the use and disclosure of information for their direct care, there is no behaviour which clearly implies consent to secondary uses. Also, situations arise where the consent of the service user cannot practically be obtained and yet the use or disclosure of their information is important for public health and social care purposes.

Any proposed use or disclosure of personal identifiable information, not related to direct care, therefore ethically and lawfully requires the express consent of the service user, unless a specific statutory justification permits the setting aside of the common law duty of confidentiality.

Safe haven and honest broker provision

We consider that many of the requirements for secondary uses, presently unmet, could be addressed through the development of Northern Ireland-wide 'safe haven' and 'honest broker' provision.

On the one hand, we note that data warehouse development has occurred on ad hoc basis, without much policy development on information governance and confidentiality. On the other hand, there is a growing need within the health and social care family and the wider health and social care research and development community for access to service user information for important public interest purposes. These include essential health and social care management and monitoring, public health surveillance, and health and social care research. The ability to access service user information through appropriate anonymisation arrangements, including linkage arrangements, is essential for this work to occur efficiently and effectively.

We recommend that a specific Departmental policy steer should be given to prioritise a strand of activity within the ICT Programme that is aimed at ensuring appropriate safe haven and honest broker functionality.

Regulations for the role, functioning and oversight of a safe haven for Northern Ireland's health and social care information are likely to be required. An exemplar of local provision is the Northern Ireland Longitudinal Study database, including its information governance arrangements.

Anonymisation at Trust and primary care level

Safe haven proposals apply principally to data that is already being held centrally for direct care purposes. Data required for secondary uses is also held at the direct care level within hospitals or primary care. To ensure that its confidentiality is protected secure and effective anonymisation or extraction arrangements are required.

There may be circumstances where these processes may not be readily achievable by those providing direct care, including administrative staff. In such circumstance regulations will be necessary to permit this activity to proceed.

Common law set-aside

Even with optimal provisions for effective anonymisation, situations arise where it is not possible or practicable to obtain consent or to anonymise personal identifiable health and social care information. Such situations include clinically important national and regional audits or inquiries, such as those into asthma-related deaths, suicides, perinatal deaths, or outcomes of specific health interventions. They also include work done by important registries, such as the Northern Ireland Cancer Registry. In these situations specific consent requirements may not have been foreseen or may not be obtainable. Exceptionally, it may be necessary and justified to make contact with former service users to obtain their consent

to participate in a study or to anonymise their information, in circumstance where the person wishing to carry out such work is not a member of that service user's care team.

In order that such activities can be permitted or considered, a statutory basis for setting aside the common law duty of confidentiality is required. It will also be necessary to establish a body to consider and authorise requests to undertake activities which require this set-aside.

The need for legislation

In 2007 the Privacy Advisory Committee commissioned Dr Colin Harper to review the current situation and to suggest options for legislative provision. Dr Harper noted that it was clearly recognised in the DHSSPS Consultation Document on 'Protecting Personal Information' (2002) that there were problems with current practice in using service user information for secondary purposes. These problems related to the legal and ethical bases for such uses. The key question was whether something like section 60 of the Health and Social Care Act 2001, which applied in England and Wales only, was the best way to deal with this current anomaly. That section allowed a special committee to consider and approve requests to set aside the legal requirements concerning confidentiality and data protection.

There was no consensus in the responses in the Consultation Document as to how the problems associated with secondary uses should be addressed. Dr Harper concluded that there was a need for a new legal basis for the use of health and social information and that adjustments to current practice were required in order to achieve greater compliance with the Data Protection Act 1998, the Human Rights Act 1998 and the common law on confidentiality.

Today the relevant legislation operating in England and Wales is section 251 of the National Health Service Act 2006. The purpose of section 251 is to allow organisations to obtain patient identifiable information, for medical purposes, in circumstances where it is impracticable to obtain informed consent from the patients concerned. The section not only addresses the problem of lack of patient consent to secondary uses; it also ensures that there is no breach of the two 1998 Acts or of the common law.

The relevant regulations prescribed by the legislation are the Health Service (Control of Patient Information) Regulations 2002. Applications for set-aside are now considered by the Ethics and Confidentiality Committee, which is accountable to the National Information Governance Board for Health and Social Care. The Ethics and Confidentiality Committee advises the Secretary of State for Health about issues relating to the use of patient information and provides legal support for certain uses and disclosures of confidential health care information by approving applications for permission to make such uses and disclosures. Applications are granted subject to certain conditions being met to ensure that the Data Protection Act 1998 is not breached.

Secondary uses of health and social care information and data protection law

It is important to realise that any use or disclosure of health and social care information under section 251 must still conform to the requirements of the Data Protection Act 1998.

In England and Wales, if the conditions set down by the Ethics and Confidentiality Committee for secondary uses are met, personal data may be used for research even if not originally collected for that purpose. Personal data may also be retained indefinitely for the purposes of research, and an individual's access to the data may be withheld.

Social care purposes are not 'medical purposes' as defined in the Data Protection Act, so condition 8 in Schedule 3 to the Act does not apply to them. In other words, no exemption from the Act's requirements is possible, whether in England and Wales or in Northern Ireland, in relation to secondary uses which are for social care purposes. In such situations the express consent of the service user, or anonymisation of the information, would be required.

Secondary uses of health and social care information and human rights law

Secondary uses of information gathered from service users also engage the human right to 'a private life', which is protected by both the European Convention on Human Rights (in Article 8) and the Human Rights Act 1998. The concept of 'private life' covers, for example, the physical and psychological integrity of a person, aspects of an individual's physical and social identity, his or her name, gender and sexual orientation, personal development, and the development of relationships with other human beings. It is possible that the European Court of Human Rights may consider Article 8 of the European Convention on Human Rights to be engaged even where service user information has been anonymised. (On the other hand, the European Court may look for guidance to the European Convention on Biomedicine, which is less restrictive in this regard.)

As protecting the privacy of health and social care information lies at the heart of the right to a private life, any approval for secondary uses granted under section 251 of the National Health Service Act 2006 needs to pass a strong test of proportionality. Thus, any proposed use of the information would be required to have the minimum possible impact on a person's private life. There would also need to be close and effective scrutiny of the way the information is in fact used. The Ethics and Confidentiality Committee in England and Wales bears these points firmly in mind when deciding whether to approve an application for use or disclosure and when stipulating conditions to that approval.

Implications for a way forward for Northern Ireland

The Privacy Advisory Committee recommends, as it has in the past, that there is a need for legislation to be passed for Northern Ireland authorising the making of appropriate regulations to deal with the above situations. In the drafting of that legislation and regulations, particular attention should be paid to the consequences flowing from the fact that in Northern Ireland health services and social care services are provided in an integrated way.

All of the foregoing and related information governance activities must be closely monitored and managed.

We recommend the establishment of a Northern Ireland Information Governance Board. Alternatively these monitoring functions could be shouldered by an existing body, such as the Regulation and Quality Improvement Authority.

We recommend that specific consideration is given to the creation of a body with the authority to grant organisations and individuals permission to make secondary uses of service user information in a way which complies with the Data Protection Act 1998, the Human Rights Act 1998 and the common law.

Any such body should be independent, in the sense that the majority of its members should have no personal interest in the secondary use of service user information, and all of its members should be appointed in accordance with the procedures required for public appointments in Northern Ireland. Procedures should be put in place for how the body should make its decisions concerning the legitimacy of secondary uses, and any guidance or decisions issued by such a body should be binding on those to whom they are directed.

**Privacy Advisory Committee
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1. Section 251(1) reads: 'The Secretary of State may by regulations make such provision for and in connection with requiring or regulating the processing of prescribed patient information for medical purposes as he considers necessary or expedient (a) in the interests of improving patient care, or (b) in the public interest.'
2. letter to Ms Susan Foster, DHSSPS, Personnel and Corporate Services Directorate, 11 July 2008