

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 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 2006.¹ 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

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.'

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,² 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
May 2013**

² letter to Ms Susan Foster, DHSSPS, Personnel and Corporate Services Directorate, 11 July 2008