



Humanitas Research

**Does Northern Ireland need an
equivalent to Section 60 of the
Health and Social Act 2001?**

**A Report to the Privacy Advisory
Committee of the Northern
Ireland Department of Health
Social Services and Public Safety**

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Summary

Introduction

It is clearly recognised in the DHSSPS Consultation on 'Protecting Personal Information' (2002) that there are problems with current practice in using service user information for secondary purposes. These problems are in terms of its legality and ethical basis. The key question then is whether something like Section 60 of the Health and Social Care Act 2001 is the best way to deal with this current anomaly.

There was no consensus in the responses in the Consultation as to how secondary uses should be addressed.

There will need to be both a new legal basis for the use of health and social information and there will need to be adjustments made to current practice to achieve greater compliance with human rights standards and law.

The common law on confidentiality

Whilst they interact in complex ways, it is important to recognize that the DAP98, HRA98 and the common law contain distinct obligations and meeting the obligations of one does not guarantee that one has met the obligations of another.

A breach of confidentiality in the legal sense would traditionally only arise where the following three conditions are fulfilled:

- 1) where the information has the necessary quality of confidence, i.e. it is private and is not in the public domain
- 2) where the information was imparted in circumstances that create an obligation of confidence (for example, in the context of the relationship between a member of health and social care staff and service user relationship)
- 3) where unauthorised use of the information would have a detrimental effect on the patient.

There is not a clear basis in these terms covering many current secondary uses of service user information.

The problem which section 60 was created to address was that information use and disclosure was taking place within the NHS for secondary purposes without a statutory basis, without the consent of patients and without a clearly recognized public interest which would override the public interest in maintaining confidences. Section 60 effectively constitutes a fourth item on the above list.

Section 60 of the Health and Social Care Act 2001

The purpose of Section 60 of the Health and Social Care Act 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.

Section 60 is often described as being set up to address the problem of lack of patient *consent* to secondary uses, but the problem it tackles is lack of *any* of the three possible justifications for a breach of confidence.

The Patient Information Advisory Group (PIAG) was established under Section 61 of the Health and Social Care Act 2001 to advise the Secretary of State for Health about issues relating to the use of patient information. PIAG's role is to provide legal support for certain uses and disclosures of confidential healthcare information to continue whilst also acting as a catalyst to improve practice. This legal support is provided under Section 60 of the Health and Social Care Act 2001 and is granted through an application process. Applications are granted subject to certain conditions being met.

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

Any use or disclosure of health and social care information under Section 60 or any equivalent measure must conform to the requirements of the Data Protection Act 1998.

Social care purposes are clearly not 'medical purposes' as defined in the DPA98 and thus condition 8 in Schedule 3 of DPA98 does not apply to them. It is possible that any Section 60 style arrangements which do not require explicit consent for secondary uses which are for social care purposes would fail to meet the requirements of the DPA98.

Information provided to service users should be sufficient to allow them to exercise their rights in relation to their data under the Data Protection Act 1998. It is clear that the above requirement is not being met with respect to secondary uses of service user information. It will need to do so for any Section 60 style measure.

If the safeguard conditions for the research exemption are met, then: personal data may be used for research even if not originally collected for that purpose; personal data may be retained indefinitely for the purposes of research; and subject access to the data may be withheld.

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

Secondary uses of information gathered from service users engages the human right to 'private life' which is protected by both the European Convention on Human Rights (ECHR) and the Human Rights Act 1998. The concept of "private life" covers: the physical and psychological integrity of a person; aspects of an individual's physical and social identity; gender identification, name and sexual orientation; personal

development, and the right to establish and develop relationships with other human beings and the outside world. The European Court of Human Rights also considers that the notion of personal autonomy is an important principle underlying the interpretation of the guarantees of Article 8 of the ECHR. Elements of 'private life', namely moral and mental integrity, clearly suggest that article 8 of the ECHR can be engaged even where service user information has been anonymised.

The European Court of Human Rights might take an interpretative approach which effectively sees the narrower range of limitations of the Biomedicine Convention as being those which are most appropriately limiting on the right to private life in the use of health and social care information.

As the protection of the privacy of health and social care information lies at the heart of the right to private life, any Section 60 style measure would have to pass a strong test of its proportionality. Any use would be required to have the minimum possible impact on privacy. There would have to be close and effective scrutiny of the measure. There would have to be a means for individuals to be heard.

There does not appear to have been a case at the ECtHR on the secondary use of health and social care information, but other relevant cases suggest that current practice may fall well short of what the Court would expect in terms of respect for private life.

Implications for a way forward for Northern Ireland?

Two key means for the protection of the interests of service users and ensuring that their moral and legal rights are respected are (1) anonymisation of information and (2) only using information with consent. Such measures are important to both meet legal requirements and to build the trust of service users in the health and social care system.

Whilst being important means of ensuring respect for the right to private life, gaining the consent of service users or offering an opt-out are not necessarily sufficient to ensure that this right is being respected.

Anonymisation should be pursued as an important means of protecting the right to private life and of ensuring the proportionality of any measure, but it does not remove completely the use of information from the protections of human rights law.

Any PIAG-style committee should be independent in the sense of not being made up of a majority of those who have an interest in using service user information. An independent appointments process and lay representation are both necessary. Any PIAG-style procedure for making decisions about the legitimacy of secondary uses should be compulsory and any guidance issued by such a body should be binding.

A general principle governing secondary uses of confidential service user information should be that the overriding of the common law obligation of confidentiality is a matter for legislators, not for regulators. Consideration should thus be given to a consolidating law to clarify the legal situation relating to health and social care information.

1. Introduction

As part of its work, the Privacy Advisory Committee of the Department of Health, Social Services and Public Safety (DHSSPS) is examining the possible need for and implications of Northern Ireland enacting an equivalent to S60 of the Health and Social Care Act 2001. This Report was commissioned to assist the Committee in its deliberations.

It examines the legal basis for the use and disclosure of information for purposes of health and social care which are not directly related to care of the service user from whom the information is obtained (secondary uses). Some potential and actual uses and disclosures of service user information are for purposes of health and social care but do not aim at the care of an individual service user. Many uses of service user information are increasingly required for evidence based practice and for a rational approach to health and social care service provision. The following are examples of such secondary uses: planning; financial management; commissioning; risk management; investigating complaints; auditing accounts; teaching; health and social care research; public health monitoring; registries; infectious disease reporting. It is not concerned about the use or disclosure of information for the care of that service user.

Concerns about lack of clarity around the legal basis for the secondary use of patient information in England and Wales were addressed through sections 60 and 61 of the Health and Social Care Act 2001. This report looks critically at the approach adopted in England and Wales and attempts to articulate an appropriately balanced approach to the issues as a way forward for Northern Ireland.

The legal basis for secondary uses of the personal information of service users remain a much debated subject with widely diverging views on the justifications and bases for such use.¹ The debate often seems to separate into two camps with little common ground being found between the main positions adopted. On the one side are those who cannot understand that anyone could reasonably object to secondary or even research uses of information about their health and social care and that therefore such uses should be generally permitted. On the other side are those who would claim an absolute right to privacy and think that they are justified in using such a right to refuse any and all secondary and research uses of information obtained from them. An approach is necessary which recognises and protects the rights of individual service users yet facilitates important secondary uses in a proportionate way given those rights.

In the search for such a balance, it is sometimes argued that the current situation is 'unbalanced' largely due to two pieces of law in particular: the Human Rights Act 1998 (HRA98) and the Data Protection Act 1998 (DPA98). Both of these Acts have their ultimate origin in European law and are sometimes seen as 'foreign' to the UK and obstructive to the best practice developed here over the lifetime of the NHS. One

¹ See Academy of Medical Sciences, *Personal data for public good: using health information in medical research—Report of proceedings at the legal symposium* (June 2006). Although focused on research, this Report is a useful overview of many of contrasting views the legal issues which arise in connection with secondary uses.

side of the argument tends to see these requirements as needing amendment or replacement by a more 'balanced' approach. However, the 'European' origin of these laws makes it unrealistic to expect any amendment or change to their provisions as to do so would require agreed changes at a European level which are both unlikely to be secured and would take a long time to be implemented. Rather than being one side of the argument, the data protection law and relevant human rights law must be seen as the framework within which the debate must take place. Human rights constraints in particular set limits to the kinds of approaches which are open to addressing issues of the secondary uses. With its emphasis on privacy as a fundamental yet limited right, the human rights framework already provides the kind of balanced approach that is needed for secondary uses of health and social care information .

Debates on the secondary and research use of service user information often focus on data protection law and look to other EU countries for alternative models of how such uses can take place on a clear legal basis. However, whilst the requirements of data protection law are undoubtedly important, they are relatively 'fixed' and the legal situation in other EU states is in general much simpler because they are civil rather than common law jurisdictions.² Whilst different approaches are adopted in different European states, none of them need a Section 60 equivalent as none of them have a common law obligation of confidentiality. (Other legal instruments such as statutes and constitutional provisions tend to cover similar issues to those addressed by the common law in the UK.) There is thus a risk in drawing comparisons with practice in other European states when their solutions cannot realistically be seen to address the challenges of the legal environment which were felt to make Section 60 necessary in the first place. The inescapable European context to the regulation of secondary uses can also be seen in that Section 60 was introduced to address issues created by the common law. It does not alter obligations under the Data Protection and Human Rights Acts which still apply. A more useful comparison for issues around Section 60 would be with other common law jurisdictions. They are not subject to the same data protection and human rights law requirements, so caution is required in such comparisons being drawn upon in attempting to formulate a model for Northern Ireland or indeed for the UK as a whole.

Northern Ireland is a society with a strong human rights culture and a relatively high level of awareness of human rights and a willingness to claim them. Through the work of the NI Human Rights Commission, all legal and policy measures are subject to greater scrutiny from a human rights perspective than in the other UK jurisdictions. In a world in which privacy seems continually undermined from various forces, it is important that any new arrangements work to build service user confidence in the handling of their private information by health and social care services. Any new provisions should form part of a comprehensive package of measures designed to increase protection for the privacy rights of service users whilst at the same time providing a legitimate basis for uses and disclosures essential for the provision of health and social care.

² See the website of the PRIVIREAL project (www.privireal.org) for much comparative material and also two of the publications emanating from that project: D. Beyleveld, D. Townend, S. Rouille-Mirza & J. Wright, *Implementation of the Data Protection Directive in Relation to Medical Research in Europe*, (Ashgate, 2004) & D. Beyleveld, D. Townend, S. Rouille-Mirza & J. Wright, *The Data Protection Directive and Medical Research Across Europe*, (Ashgate, 2005).

After some background in this introduction, the Report will consider the following issues. What is the common law on confidentiality? What is Section 60 of the Health and Social Care Act 2001? Secondary uses of health and social care information and data protection law. Secondary uses of health and social care information and human rights law. A possible way forward for Northern Ireland.

Previous HPSS Guidance and the Results of the Consultation

In *The Protection and Use of Patient and Client Information: Guidance for the HPSS*³ the reality of secondary uses was clearly recognised:

1.2 It is in everyone's interests that the HPSS functions efficiently and effectively and makes best use of the resources available to it. To that end personal information about patients and clients is not only essential for the prime task of delivering personal care and treatment. It is necessary for a number of other purposes:

- i. assuring and improving the quality of care and treatment (eg through clinical audit);
- ii. monitoring and protecting public health;
- iii. coordinating HPSS care with that of other agencies (eg voluntary and independent services);
- iv. effective health and social care administration, in particular:
 - managing and planning services;
 - contracting for HPSS services, including the payment of staff, independent contractors and health and social service units for services and the authorization of extra-contractual referrals;
 - auditing HPSS accounts (including fraud investigation/detection and the work of external auditors appointed by HPSS Health Service Audit) and accounting for HPSS performance;
 - risk management (e.g. health and safety);
 - investigating complaints and notified or potential legal claims;
- v. teaching;
- vi. statistical analysis and medical or health and social services research to support (i)-(v) above.

However, the overall tone of this Guidance was one of protecting essentially the data protection rights of patients and clients through HPSS procedures. That service users have a human right to privacy which might set limits on those procedures does not feature significantly. Similarly, the nature and significance of common law obligations of confidentiality were underplayed. There are two aspects to the approach in the Guidance that are cause for concern:

³ *The Protection and Use of Patient and Client Information: Guidance for the HPSS* (1999?). A new *Code of Practice on Protecting the Confidentiality of Service User Information* is currently being consulted upon.

- the obligations of the DPA98 are discussed as if they are almost the only ones that staff need be concerned about when in fact the obligations of the common law and human rights law are much more onerous;
- the use of 'implied consent' as a basis for the use and disclosure of information is stretched beyond its legal limits—often it seems to be deployed as a mantra to evade obligations, rather than in any convincing way as a clear means through which obligations are met.

A consultation paper was circulated in June 2002⁴ which identified the 'current problems':

3.1 It is clear that the HPSS (together with the NHS in England and Wales and NHS Scotland) does not fully comply with the fair and lawful processing requirement of the DPA98 and the Common Law. Instead it relies, by default, on the implied consent of service users for the processing of much, if not all, personal information. HPSS bodies, therefore, risk legal challenge due to breach of the DPA98. Implied consent is based on the assumption that service users are aware of, and understand, all the uses HPSS bodies make of their personal information. However, because of the lack of transparency, service users are largely unaware of how their personal information is used, beyond the provision of direct care and treatment. Implied consent is, therefore, unlikely to be valid for all the uses of personal information at present.

3.2 It is, however, important to ensure that actions by HPSS bodies to comply with current legislation do not restrict or inhibit the benefits which flow from the sharing of information. HPSS bodies need to move to a position where they can comply with current legislation, professional guidance and best practice without unnecessary restriction to essential information flows. This will involve HPSS bodies changing the way they currently deal with service users and use their personal information. In order to do this the following is considered essential:

- i. service users must be informed about how information about them is used, by whom and for what purposes;
- ii. personal data should be anonymised wherever possible;
- iii. if data cannot be anonymised to an acceptable degree service users must give informed consent; and
- iv. the need for new legislation should be considered.

These concerns and 'solutions' clearly mirror those which arose in England and Wales and lay behind the adoption of Section 60, in particular in the requirement for informed consent. In both the Consultation paper and the responses to it⁵ there was a lot of confusion, particularly around the notion of 'implied consent'. It is worth quoting the consultation response on the case for legislation:

2.10 There was no consensus on the question of whether legislation, similar to section 60 of the Health and Social Care Act 2001 to override the duty of confidence, should be introduced, and if so, whether it should be permanent or temporary.

⁴ *Health and Personal Social Services. Protecting Personal Information: A Consultation Paper* (DHSSPS: June, 2002).

⁵ *Health and Personal Social Services. Protecting Personal Information: Responses to a Consultation Paper* (DHSSPS: March, 2003).

It was suggested that information relating to :-

- public health information;
- cerebral palsy;
- communicable disease;
- the Cancer Registry;
- diabetes;
- congenital anomalies;
- accidents;
- heart disease and stroke;
- diagnosis and conditions which are major causes of death
- and morbidity;
- National Joint Registry for Orthopaedics;

should be included in any legislation which is introduced.

However some respondents said that legislation would not be necessary for cancer registries if cancer were to become a notifiable disease.

A number of responses stated that information which is not relevant to the direct care of the patient, but which is of importance for the overall management of health and social care should be included in legislation. Other more specifically cited information relating to probity, planning, targeting of resources and audit. Some concern was expressed that retrospective legislation would be practically difficult, and expensive to implement. Others thought that there should be retrospective legislation to deal with existing records.

Although it states that 'no consensus on the question of whether legislation, similar to section 60 of the Health and Social Care Act 2001 to override the duty of confidence, should be introduced', the arguments against such legislation are not presented as clearly as the arguments in its favour.

A specific question was asked in the Consultation on the case for legislation:

The Consultation Paper said: "The main arguments in favour of legislation are in relation to the greater good, probity and data quality (Paragraph 3.27) and the main argument against legislation is the infringement of the right to privacy" (Paragraph 3.28)

The Consultation Paper asked, "Is there a need for legislation here similar to section 60 to override the duty of confidence? If so, should it be temporary or permanent?"

The responses said

yes

no

permanent

temporary

temporary, then reviewed, then made permanent

Legislation would not be necessary for cancer registries for example if cancer was to become a notifiable disease

No information is provided as to how common each of these responses was, so it is difficult to judge much about the views of staff and the public from this. It does suffice to demonstrate that there is not agreement and that any legislative proposal is likely to be contentious. A further question about 'which information flows should be included' produced the following list of responses:

- Information flows relating to public health
- Communicable diseases
- Information flows to Cancer Registry, National Joint Registry for Orthopaedics and for financial audits
- Diabetes
- Cerebral palsy
- All cancers and pre-cancerous conditions
- Congenital anomalies
- Accidents, heart disease, stroke
- Diagnosis and conditions which are major causes of death and morbidity
- Information flows which are not relevant to the direct care of the patient but which are of importance for the overall management of health and social care
- Probity, planning, targeting

There was no consensus in the responses in the Consultation as to how secondary uses should be addressed.

Two approaches suggest themselves:

1. Adjust the law to make current practice legal
2. Adjust current practice to make it conform to the legal framework as it stands.

In reality, the best approach will probably require an element of both of these. There will need to be both a new legal basis for the use of health and social information and there will need to be adjustments made to current practice to achieve greater compliance with human rights standards and law.

Summary

It is clearly recognised in the Consultation that there is a problem with current practice in terms of its legality. The question then is whether something like Section 60 of the Health and Social Care Act 2001 is the best way to deal with this anomaly.

There was no consensus in the responses in the Consultation as to how secondary uses should be addressed.

There will need to be both a new legal basis for the use of health and social information and there will need to be adjustments made to current practice to achieve greater compliance with human rights standards and law.

2. The common law on confidentiality

The common law is the law that develops over time through the decisions of judges in particular cases. As such it is perhaps less clear at times than law which is created by statute, but many common law concepts are quite clear and have developed over a long period. The common law changes with new judgments, but it can also be stable over long periods.

One of the problems with discussions about the use and disclosure of health information is the possible meanings of 'confidential'. Something can be confidential in different ways. It is not always the legal sense that is meant when it is used in discussions about health and social care information. For example, the *Draft Code of Practice on Protecting the Confidentiality of Service User Information* uses the word in a more general sense in its title and then discusses the particular common law meaning within an appendix. As well as having a legal meaning, 'confidentiality' is also an ethical concept. Ethical obligations in this respect may differ from the legal obligations and may also differ depending on their source. For example: a natural right to privacy; an aspect of 'good conduct' as defined by statutory regulators such as the Northern Ireland Social Care Council; or as defined by international professional organisations such as the World Medical Association.

The legal sense of 'confidential' is narrower than the everyday use of the term as a synonym for 'private' or 'secret'. Something is not confidential in the legal sense simply because it is marked as such. A breach of confidentiality in the legal sense would traditionally only arise where the following three conditions are fulfilled:

- 1) where the information has the necessary quality of confidence, i.e. it is private and is not in the public domain
- 2) where the information was imparted in circumstances that create an obligation of confidence (for example, in the context of the relationship between a member of health and social care staff and service user relationship)
- 3) where unauthorised use of the information would have a detrimental effect on the patient.

It is questionable whether the third criterion above is essential as it is possible for a breach of confidence to occur where information is disclosed which portrays a person in a positive light. It is probably unsafe to assume that where there is no harm to a service user, there cannot be a breach of confidence.

It is important to distinguish between having a general duty to maintain confidentiality and having a particular obligation with respect to particular information. It is sometimes suggested that it makes a difference when a disclosure is made to another health and social care professional who is also under a duty of confidentiality.⁶ Even provided that high standards of confidentiality are maintained, a legal breach can still have occurred. Whilst that someone owes 'a duty of confidentiality which is equivalent' may be significant in terms of the DPA98, it does

⁶ See for example, Confidentiality and Security Advisory Group Scotland, *Protecting Patient Confidentiality: Final Report*, (2002).

