

## **The Information Governance Review and the new legal framework for informatics**

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## **The Information Governance Review and the new legal framework for health informatics**

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### **Introduction**

In March 2011, in an article for a supplement to this journal, I highlighted that there should be statutory reform of the lawful basis on which patient information is shared across the NHS using a system such as the Summary Care Record. At the time, I postulated that the powers the Secretary of State for Health enjoyed to direct matters of health informatics, which the Ministry of Justice had determined subsisted in S.2 of the NHS Act 2006 (as it was then worded), were too broad or vaguely worded, and could not, potentially, withstand scrutiny under principles of human rights law – which in the UK does not tolerate over-broadness or linguistic vagaries very well at all.

The 2013 *Information Governance Review* has updated the key ‘Caldicott principles’ in the light of a shifting legal landscape. They now read, in summary, and in relation to the use and sharing of patient information:

1. Justify the purpose(s)
2. Don’t use personal confidential data unless it is absolutely necessary
3. Use the minimum necessary personal confidential data
4. Access to personal confidential data should be on a strict need-to-know basis
5. Everyone with access to personal confidential data should be aware of their responsibilities
6. Comply with the law
7. The duty to share information can be as important as the duty to protect patient confidentiality

Balancing the sixth and seventh principles, above, is the true difficulty in terms of protecting patient privacy and autonomy, whilst pursuing the aims of public health and public protection.

The statutory basis of health informatics has undergone a real shake-up, but some lingering concerns about patient autonomy in relation to their data has seen the recent *Information Governance Review* also make some suggestions that the new health informatics clearing-house, the Health and Social Care Information Centre, should take pains in its first Code of Practice to ensure the practicable recognition of reasonable patient objections to data sharing out of respect for values of autonomy, privacy and human rights.

### **“Caldicott 2”: The Recent Information Governance Review**

The recent report of the Information Governance Review (known as “Caldicott 2”), included the following pertinent recommendation in relation to the work of the new National Health and Social Care Information Centre:

[Recommendation 11, Information Governance Review, 2013]

“The Information Centre’s code of practice should establish that an individual’s existing right to object to their personal confidential data being

shared, and to have that objection considered, applies to both current and future disclosures irrespective of whether they are mandated or permitted by statute... Both the criteria used to assess reasonable objections and the consistent application of those criteria should be reviewed on an ongoing basis.”

In a press release on 26 April 2013, the Department of Health noted that at a conference used to launch the Information Governance Review report, “[Health Secretary] Jeremy Hunt said that while effective sharing of patient information has enormous potential to improve patient care, services and treatments, this can only be done effectively if patients are given a say over how their personal information is used.”

Hunt apparently announced that:

- “any patient that does not want personal data held in their GP record to be shared with the Health and Social Care Information Centre will have their objection respected” and
- “where personal data has already been shared from a GP practice to the Information Centre, a patient will still be able to have the identifiable information removed...”

The *Information Governance Review* report noted (p.73) that across the NHS “researchers have devised robust solutions to aspects of information governance so they can extract the information that they need without breaching individuals’ confidentiality.”

But, as the report also described, “Those arrangements took many years to evolve and are still in the process of development. By contrast, the arrangements for NHS and local authority commissioners to extract information on the health and social care service in England were in a state of rapid, comprehensive change during the period of this review.”

### **Statutory Frameworks in Relation to Health Informatics**

Under recent reforms to the National Health Service Act 2006, the NHS Commissioning Board (‘the Board’) and the Health and Social Care Information Centre (‘the Information Centre’) have a statutory relationship which allows for the sharing of patient information across the National Health Service in response to the need to use that information for purposes other than for primary care.

The Information Centre has the statutory power and obligation to assist organisations across the NHS and in social care settings to fulfil their particular legal duties and obligations in turn. The Information Centre can do this by gathering and re-packaging data about individuals (and namely patients) using its powers under S.254 of the Health and Social Care Act 2012.

The Secretary of State for Health ('the Health Secretary') has a broad duty to protect public health, under S.2A of the NHS Act 2006 as amended:

(1) The Secretary of State must take such steps as the Secretary of State considers appropriate for the purpose of protecting the public in England from disease or other dangers to health.

The Health Secretary can do this through the means of providing 'information and advice' under S.2A (1)(f) of the 2006 Act, and in essence, the Board can do this on behalf of the Health Secretary, through its 'mandate' under S13A of the Act.

The Health Secretary also has a statutory duty to pursue a research agenda for the NHS, in order to improve the delivery of services and, ultimately, public health.

Since 27 March 2013 the Board has had broad powers to disclose information in pursuit of the notion of public protection and public health, since S.13Z3 of the NHS Act 2006 as amended states that:

- (1) The Board may disclose information obtained by it in the exercise of its functions if—
- (a) the information has previously been lawfully disclosed to the public,
  - (b) the disclosure is made under or pursuant to regulations under [section 113 or 114](#) of the [Health and Social Care \(Community Health and Standards\) Act 2003](#) (complaints about health care or social services),
  - (c) the disclosure is made in accordance with any enactment or court order,
  - (d) the disclosure is necessary or expedient for the purposes of protecting the welfare of any individual,
  - (e) the disclosure is made to any person in circumstances where it is necessary or expedient for the person to have the information for the purpose of exercising functions of that person under any enactment,
  - (f) the disclosure is made for the purpose of facilitating the exercise of any of the Board's functions,
  - (g) the disclosure is made in connection with the investigation of a criminal offence (whether or not in the United Kingdom), or
  - (h) the disclosure is made for the purpose of criminal proceedings (whether or not in the United Kingdom).

It is the information Centre which will obtain the information from disparate NHS bodies to allow the Board to share information using the above provisions – many of which are broadly connected to fulfilling the duty of the Health Secretary to protect public health.

Elsewhere, I have written with Dr. Mark Taylor of the University of Sheffield of the need for the NHS to continue to ensure appropriate respect for patient autonomy in the course of formulating principles for information governance – and this has recently been echoed by the important Information Governance Review published by the Department of Health. The reasons for this necessary emphasis on respecting patient wishes in relation to the use of their data – most vital where that data identifies them and so is certainly confidential medical information – is a set of overlapping legal values and

principles that derive from different sources: both UK and European law respectively, and a sort of blend of the two that has developed since the enactment of the Data Protection Act and the Human Rights Act in 1998.

### **Confidentiality and the Common Law**

Information sharing by public bodies undertaken for public protection purposes (and implicitly for the purpose of protecting public health) must take place only on some lawful basis, i.e. through the use of (implied or explicit) statutory powers, or through the use of some common law powers.

This qualification in the common law of confidentiality suggest that, as the court found in *W v Egdell* [1990] Ch 359, that there is enough substance in the common law to support the sharing of confidential patient information from the medical or healthcare context to another context, i.e. the remit or work of a public protection agency or in the social care setting, for example.

Research purposes will not necessarily be able to qualify from the public protection (or 'public interest') exception to the general principle of medical confidentiality – which is why S.251 of the NHS Act 2006 was enacted to allow the Health Secretary (now to be advised by the Confidentiality Advisory Group of the Health Research Authority) to order that confidential patient information can be shared for research purposes in the face of patient objections and the common law.

### **Data Protection and the European Dimension**

As the recent *Information Governance Review* has noted (p.78) “both Article 8 of the European Convention on Human Rights and the European Data Protection Directive require reasonable objections to the disclosure of personal confidential data to be respected... where there are ‘compelling legitimate grounds’ [to do so].”

Furthermore “the Review Panel noted that the Health and Social Care Act 2012 would not be adequately protected from legal challenge if it failed to be compatible with Article 8 [which protects to the right to respect for private life]”. Recent decisions of the UK courts have drawn on Article 8 in such a way as to place strong emphasis on the need to take into account objections from individuals in the process of making decisions about how their personal information is deployed in sensitive contexts.

### **Issues of Patient Consent and Research Ethics**

Laurie and Postan have argued “that treating consent as a one-off event that can be effectively captured in a written document—as the law tends to do—is an inappropriate and counter-productive approach. The aims of ethical research governance will be better served by seeing consent as continuing relational process, requiring on-going mutual respect, opportunity for communication, and accommodation of changing circumstances”.

This notion of respect for autonomy of patients in relation to the ongoing use of their confidential and identifiable medical or health data, particularly in the research context, in something that has been highlighted, again, in the recent *Information Governance Review*. Laurie and Postan in their recommendations are chiming with the recognition paid by the courts of late to the need for procedural rights to objection and consultation that in turn help to safeguard the rights to privacy and autonomy enjoyed by patients – even in a health culture where ever more emphasis will be placed on research- and evidence-led policy in an era of ‘data mining’. Patients will also have greater rights to objections and consultation over the use of their confidential personal information embodied in the Code of Practice to be published by the Information Centre than NHS ‘service users’ do in relation to consultation and/or the provision of information about decisions and plans that affect the delivery of primary care, under S.242 of the NHS Act 2006

## Conclusions

- The recent Information Governance Review has suggested that there is a meaningful set of processes to safely and efficiently resolve the tension between compliance with the law and the duty to share information can be as important as the duty to protect patient confidentiality.
- The Code of Practice to be published by the Health and Social Care Information Centre (on the nature of the Centre’s duties and powers under S.254 of the NHS Act 200 to gather and distribute patient information) will be crucial in achieving this in practice.
- Thankfully, patients as potential research data subjects will have stronger rights to information, consultation and/or meaningful objection that they have as ‘service users’ under S.242 of the NHS Act 2006.

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