The Information Governance Review and the new legal framework for informatics

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ABSTRACT

To an outside legal commentator, the NHS has recently undergone a distinct shift in the specific legalities that control and empower the sharing of patient information. A great many healthcare managers will be adapting their practices and reacting to these statutory adaptations. Public protection concerns, marketisation economics, health policy, and a push towards greater (appropriate) transparency are the driving forces in this particular context. But the journey is not over. The Code of Practice to be published by the National Health and Social Care Information Centre—the fulcrum of the newly-balanced framework for data sharing—will address the extent to which patients have autonomy and choice with regard to their own information, in a response to the views of researchers, ethicists and politicians alike.

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In 2011, 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 (Grace, 2011). 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 Section 2 of the NHS Act 2006 (as it was then enacted)—were too broad or vaguely worded. They 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.

Recently 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:

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

Balancing the sixth and seventh principles (outlined above) is the true difficulty in terms of protecting patient privacy and autonomy while pursuing the aims of public health and public protection. It is also a challenge for healthcare practitioners working in an environment of professional regulation. Each of these seven principles has important ramifications for healthcare professionals seeking to include these concerns in their decision-making, but this article focuses on the last two of the principles as they are perhaps the most abstract of the seven, and aims to make a little sense of them in the space available here.

The statutory basis of health informatics has undergone a real shake-up, but some lingering concerns about patient autonomy in relation

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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 ('the Information Centre'), should take pains in its first Code of Practice to ensure the recognition of reasonable patient objections to data sharing out of respect for values of autonomy, privacy and dignity, and where practicable.

Caldicott 2: The 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:

'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.' (Recommendation 11: Department of Health, 2013)

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'

'… 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 (Depatment of Health, 2013: 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

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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.'

As a result of the legal landscape of patient information-sharing being radically reshaped in statute, under the Health and Social Care Act 2012, the Code of Practice, soon to be published by the NHS Information Centre, becomes particularly crucial.

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 Information Centre have a statutory relationship which allows for the sharing of patient information across the NHS 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 concerning individuals (and namely patients) using its powers under Section 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 Section 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 Section 2A (2)(f) of the 2006 Act, and in essence, the Board can do this on behalf of the Health Secretary, through its 'mandate' under Section 13A of the 2006 Act.

The Health Secretary also has a statutory duty to pursue a research agenda for the NHS, 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 Section 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. These information sharing powers proscribed for the board must be broad if it is to act as an articulate, responsible and rational 'head' to the corpus of the re-structured NHS, but the legal rationale for their inclusion in the reworked 2006 Act is to ensure that any legal challenges to information sharing by the board on the basis of data protection, human rights and the common law would have markedly less bite—since the courts look for specificity in the lawful construction of powers enjoyed by public bodies.

Elsewhere, I have written with Dr Mark Taylor of the University of Sheffield on the need for the NHS to continue to ensure appropriate respect for patient autonomy in the course of formulating principles for information governance. 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 those data identify them and so are certainly confidential medical information—is a set of overlapping legal values and principles that derive from different sources. They derive from both UK and European law respectively, and a sort of blend of the two that has developed since the enactment of both 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 suggests 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.

However, sharing identifiable patient 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 Section 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

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purposes in the face of patient objections and the common law duty of confidentiality.

This common law duty of confidentiality can also be overridden by the Information Centre when it is requested to collect and share confidential, identifiable patient data from across the NHS by particular bodies (from a list of entitled key organisations, with a flexible membership, dictated at the behest of the Health Secretary in the international context or by further regulations in the UK context) under Section 255 and Section 256 of the Health and Social Care Act 2012.

Allied with the prioritisation of sharing those data for research purposes in the face of confidentiality restrictions under the common law, we have, as a result, now arrived at a situation where patients could be forgiven for feeling that any confidential relationship with healthcare practitioners is patchy or undermined.

Data Protection and the European Dimension

As the recent *Information Governance Review* has noted (DH, 2013: 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 (2012) 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 *Information Governance Review*.

KEY POINTS

- Healthcare managers should continue to develop an active interest in the new statutory powers of the Information Centre and the role of the Confidentiality Advisory Group of the Health Research Authority
- The Code of Practice to be published by the Information Centre is in a way a key underpinning of the 'mandate' possessed by the NHS Commissioning Board
- Ultimately, public health will be improved in ways that stem from the increased sharing of patient information for research and other strategic purposes
- The Health Secretary has a duty to promote this vital work, and the Information Centre will play an important role in the process of developing the best (and most accountable) uses of patient data
- For one view of an appropriately transparent approach to information sharing, see O'Hara (2011)

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 Section 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 (in all its forms and manifestations connected to privacy protection)
- The duty to share information which, as noted by the Review, can be as important as the duty to protect patient confidentiality

Readers of *BJHCM* should be aware that 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 Section 254 of the Health and Social Care Act 2012 to gather and distribute patient information) will be crucial in achieving this in practice

Thankfully, patients as data subjects in the context of health research should have stronger rights to information, consultation and/or meaningful objection under this forthcoming Code of Practice that they have as mere 'service users' under Section 242 of the NHS Act 2006. BJHCM

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