



DATA SHARING REVIEW

Caldicott Guardian NHS National Services Scotland

Summary

Health services rely heavily on secondary uses of health data in providing safe, effective health care and public health services. They recognise the need to do this to high ethical and legal standards and the NHS in Scotland has made great progress in this over the past five years. There remain legal and ethical issues that need to be addressed if this important aspect of health care is not to be undermined.

Response

Thank you for the opportunity to comment on this important issue.

I am one of six public health doctors working for Information Services (ISD), part of the NHS in Scotland. ISD carries out a role similar to the Information Centre in England - although ISD has been in existence for over thirty years. A major part of our work involves secondary uses of health information. We work with clinical and public health colleagues across the NHS in Scotland using health information to improve health and health services.

The NHS in Scotland is a large and complex enterprise made up of a network of legal entities that work collaboratively to provide health care and public health services. NHSScotland (NHSS) collects and uses large amounts of information. This information is used in two distinct ways (although some data are used for both). The 'primary' use of health information is to provide co-ordinated care for individual patients. 'Secondary' uses include activities such as: measuring the safety and quality of care; planning, public health and service evaluation; and ensuring efficient and equitable resource use. Importantly, the former requires access to individual, named data whilst the latter can be carried out largely using data that have been anonymised or pseudonymised¹. (The individual patient benefits from both.)

NHSScotland has developed a wide range of secondary uses that have led to the development of high quality health data systems that compare favourably with the best anywhere. The progress with electronic health information - 'eHealth'² - has increased the potential for gathering and analysing health information and for improving its quality. This has brought benefits, such as better information for planning and monitoring health services, but it has also raised awareness of new risks to patient privacy.

Partly in recognition of this, an independent review of the way in which NHSScotland uses health information was carried out by the Confidentiality and Security Advisory Group for Scotland (CSAGS) and the committee's report was published in April 2002³. CSAGS

¹ Reversibly anonymised using a key available to only specified parties

² eHealth (also written e-health) is a relatively recent term for healthcare practice which is supported by electronic processes and communication, some people would argue the term is interchangeable with Health Informatics (<http://en.wikipedia.org/wiki/Ehealth>)

³ <http://www.confidentiality.scot.nhs.uk/externalresources/csags.htm>

recommended changes in practice and this has resulted in a substantial programme of work over the five years from 2002 to 2007 led by the Scottish Executive Health Department (SEHD). Significantly, CSAGS recommended against any change in the law in Scotland governing how health data could be processed. This is in contrast to the situation in England where Section 60 of the Health and Social Care Act was introduced in 2001 to permit certain types of health information processing. In implementing CSAGS recommendations NHSScotland has, therefore, developed an approach to secondary uses distinct from that taken in England.

Substantial progress has now been made in implementing CSAGS recommendations. A new Code of Practice has been introduced; national standards and systems of reporting and inspection have been established; improved training and information for staff is available; a national framework of Information Governance has been established with the authority of NHS QIS behind it; the networks of key staff required to design and implement the framework have developed and matured considerably.

Secondary Uses of health information

Secondary uses of health information are an essential part of providing high quality care to patients. They allow us to:-

- Undertake Audit and Quality Improvement (are outcomes of care meeting acceptable standards?)
- Improve Patient safety (e.g. monitoring drug side effects or surgical mortality rates)
- Deliver Public Health programmes (immunisation; screening; monitoring cancer rates)
- Evaluate Services (are they effective and cost effective?)
- Plan services (e.g. ICU bed availability; pandemic flu plans; manage changing patterns of demand)
- Manage Performance (e.g. health targets; health outcomes indicators; waiting times)
- Do research (e.g. new drugs and outcomes of treatment)

Examples of this include:

Clinical outcome indicators⁴

Since 1994, Scotland has published a wide range of clinical indicators at hospital and Health Board level – making NHSScotland a world leader in this field – and allowing care providers and patients to see evidence of the outcome of services and areas where variation may be unacceptable.

Information on Prescribing⁵

⁴ <http://www.indicators.scot.nhs.uk/>

The PRISMS system provides information to general practitioners to help them monitor and improve their prescribing and reduce costs.

Waiting times⁶

This is summary information on the waiting times experienced by patients waiting for assessment or treatment on an outpatient or inpatient/day case basis. It is essential information for patients and planners.

The Scottish Audit Of Surgical Mortality⁷

SASM identifies all deaths that occur in hospital under the care of a surgeon in Scotland and subjects them to routine objective peer review – unique in the United Kingdom and highly reassuring for patients. This helps to identify areas of surgical care that could be improved.

Scottish Renal Registry⁸

This national registry of patients with renal failure and other renal disorders in Scotland provides data for quality improvement, audit & peer review, research, service planning and teaching.

The Scottish Hip Fracture Audit⁹

This clinically driven work provides orthopaedic departments with data on care at different centres across NHSScotland, facilitating improvements in the care and rehabilitation of what is a frail and vulnerable group of patients.

The Scottish Cancer Registry¹⁰

The data are used for monitoring trends in cancer; assessing the impact of treatment and screening programmes; and for planning services.

The Scottish Public Health Observatory (ScotPHO)¹¹

This includes the Scotland and European Health for All (HfA) Database which provides Scottish data on the WHO's European Health for All indicators and allows comparison of health in Scotland with that in other European countries.

eSCRIPS¹²

This is a system that allows eligible NHSScotland Consultants to review their own inpatient and daycase data, including diagnoses and procedures, length of hospital stay, elective / emergency admissions and deaths. This allows consultants to review their own practice and supports local audit and service improvement.

⁵ http://www.prismweb.scot.nhs.uk/np_about.htm

⁶ <http://www.isdscotland.org/isd/3454.html>

⁷ <http://www.sasm.org.uk/>

⁸ <http://www.srr.scot.nhs.uk/>

⁹ <http://www.shfa.scot.nhs.uk/Index.htm>

¹⁰ <http://www.isdscotland.org/isd/3535.html>

¹¹ <http://www.scotpho.org.uk/>

¹² <http://www.isdscotland.org/isd/2340.html>

More information on the national data and data use in NHS Scotland for secondary purposes can be found at ISD's main website.¹³

How is this information provided?

A network of information systems has been developed to provide the underlying data for these secondary uses. The data originate in systems such as hospital patient administration systems; primary care systems; national datasets managed on behalf of the NHS Boards and Scottish Executive Health department by ISD, Health Protection Scotland¹⁴ and others; the Community Health Index (CHI)¹⁵; National Health Services Central Register (NHSCR)¹⁶; and information held on the Scottish Care Information (SCI) System¹⁷.

A number of organisations in NHSScotland are involved in providing this service such as: NHSBoards' information departments; Information Services (ISD)¹⁸ and other divisions of National Services Scotland (NSS¹⁹); NHSTayside Health Informatics Centre²⁰; Glasgow Centre for Population Health²¹ and the General Register Office (Scotland)²².

Health services research is carried out by a parallel network that includes the Scottish Universities and other organisations, largely funded and managed by the Chief Scientist Office (CSO)²³. Information is shared but according to restrictions imposed by ethical and legal considerations (see after).

Health information is managed by these organisations on behalf of the clinical and managerial staff in the NHS Boards and the Scottish Executive Health department. The growth of this activity over the past decade reflects the rising demand for high standards of care, for more accountability and to measure progress toward targets for improvement.

This work involves NHSScotland clinical and information staff from primary care; acute care; community services and public health. It includes a wide range of activity ranging from data coding; data collection and quality assurance; through secure holding of data; record linkage and analysis; to data interpretation, database research and policy formulation. It provides the scientific underpinning and evidence base for planning, public health and clinical governance in NHSScotland - the basis on which health services are held accountable for the safety, quality

¹³ <http://www.isdscotland.org/isd/782.html>

¹⁴ <http://www.hps.scot.nhs.uk/>

¹⁵ <http://www.psd.scot.nhs.uk/Medical/CHI.htm>

¹⁶ <http://www.gro-scotland.gov.uk/national-health-service-central-register/index.html>

¹⁷ <http://www.sci.scot.nhs.uk/index.htm>

¹⁸ <http://www.isdscotland.org/isd/>

¹⁹ <http://www.nhsnss.org/home/index.php>

²⁰ <http://www.dundee.ac.uk/hic/>

²¹ <http://www.gcph.co.uk/>

²² <http://www.gro-scotland.gov.uk/index.html>

²³ <http://www.sehd.scot.nhs.uk/cso/index.htm>

and effectiveness of clinical care delivered to patients and a statutory requirement of NHS Boards²⁴

The CSAGS report

An independent review of the way in which NHSScotland uses health information was undertaken in 2000 by the Confidentiality and Security Advisory Group for Scotland (CSAGS)²⁵. The review was commissioned for Scottish Ministers by the Scottish Executive Health Department (SEHD) in order to provide advice on the confidentiality and security of health related information to the Scottish Executive, the public and health care professionals.

The final report 'Protecting Patient Confidentiality'²⁶ was published in April 2002. CSAGS concluded that 'There is no doubt that changes in practice and culture are required so that NHSScotland can fully meet legal and ethical obligations to patients when using their health data.' CSAGS also acknowledged the importance of continued access to health information, emphasizing that....'the future health of the population requires continuing access to these data by healthcare professionals.'

CSAGS recommended changes in practice and a year following the publication of its recommendations SEHD issued NHS HDL(2003)37²⁷ 'The Use of Personal Health Information in NHSScotland to Support Patient Care' which set out details of work to implement CSAGS to promote best practice and continued improvement in the use of personal health information as an integral part of patient care. This has resulted in a substantial programme of work over the past five years that has considerably improved practice. This work is on going. ISD was asked to lead this work by the Chief Medical Officer in Scotland and we would be happy to provide more information if required.

Governance of health information for research

Ethical approval²⁸ from an appropriate NHS Research Ethics Committee is required for any research proposal involving: patients and users of the NHS; individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS; access to data, organs or other bodily material of past and present NHS patients; foetal material and IVF involving NHS patients; the recently deceased in NHS premises; NHS premises or facilities; NHS staff recruited as research participants. In addition applicants have to obtain approval in certain circumstances for access to data from a number of privacy oversight committees e.g. the NSS Privacy Advisory Committee²⁹ (PAC); The Tayside Health

²⁴ <http://www.clinicalgovernance.scot.nhs.uk/section1/introduction.asp> - an introduction to clinical governance.

²⁵ http://www.sehd.scot.nhs.uk/mels/HDL2001_01.htm

²⁶ www.confidentiality.scot.nhs.uk/externalresources/csags.htm

²⁷ http://www.show.scot.nhs.uk/sehd/mels/HDL2003_37.pdf

²⁸ <http://www.sehd.scot.nhs.uk/cso/index.htm>

²⁹ <http://www.isdscotland.org/isd/2466.html>

Informatics Centre PAC; The CHI Advisory Group³⁰; and the NHSCR Governance Board. The NSS PAC has published guidance on the principles it applies in granting access to NHSScotland data for research and other secondary purposes³¹. The permission of local Caldicott Guardians also needs to be obtained for access to NHS Board data for research in many cases.

There is therefore a series of safeguards researchers need to negotiate before getting access to data for research. These are regarded as excessive by some researchers but are what NHSScotland has established as current good practice³².

Some issues currently causing difficulty with health information management in NHSScotland

Consent

This continues to be an intractable issue for those responsible for secondary processing of health information despite various attempts to provide more guidance. In the area of observational research or clinical audit the insistence on burdensome conditions of informed consent makes little sense and can disable information use that is clearly in the public interest and in the interest of patients. Much of it is box ticking that may be legally useful but is not ethically justified. We need what Manson and O'Neill have called an 'interpretation of the DPA and its relation to research – that supports justifiable rather than illusory conceptions of privacy.'³³

One of many examples: NHSScotland needs to track the outcomes of joint replacement operations. There is evidence that some of the newer procedures are associated with serious side effects. In order to know what is happening we need to link data on joint operations with other data e.g. on readmissions and deaths and feed this back to our clinical and managerial colleagues who need this information to ensure services are safe. (There are also serious legal liability issues involved here). The public would be amazed if we said we were unable to tell who had had what implant and what the outcomes were and I am quite sure that those who support the principles of the DPA98 would agree that the act should not be used to obstruct this kind of activity – which has a clear public interest. There are many other examples e.g. linking data on hepatitis C and blood transfusion, the need for cancer registry data to check on possible cancer clusters etc etc. The idea that we can allow people to 'opt out' of allowing the NHS to use these data to improve patient safety doesn't stand up in my opinion and I do not believe there is a valid ethical support for it.

³⁰ <http://www.chiadvisorygroup.scot.nhs.uk/>

³¹ <http://www.isdscotland.org/isd/servlet/FileBuffer?namedFile=PAC-Guidance-on-decision-making.pdf&pContentDispositionType=inline>

³² <http://www.isdscotland.org/isd/4489.html>

³³ Manson and O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge University Press 2007) p.199

It would be helpful to have discussion with OIC on this issues and to have an authoritative view from the Commissioner on the place of informed consent in secondary health data processing.

Personal data and anonymisation

Data protection legislation relies on the notion that data controllers are able to distinguish between personal and non-personal data. In practice this can be extremely difficult if not impossible. Focussing on the nature of data and attempting to categorise it as personal or non personal is highly problematic. What is more important is what we do with the data. If secondary data processing requires the incidental use of identifying data fields that involves no contact with the data subjects and can cause them no harm, then it makes no sense to obstruct it for reasons that have no real ethical justification. We need to have a debate about this and resolve the current difficulties.

Research, audit and service evaluation

It is often impossible to distinguish between these in activities that involve data collection and analysis. In fact data collections often are used for a mixture of related purposes e.g. data collected as part of an evaluation of a screening programme might be used to compare outcomes against standards (audit) and the data once anonymised could be used to derive new knowledge about screening resulting in a peer reviewed publication (research). In reality data collected for one purpose may be used for others – the blanket term ‘medical purposes in DPA98 is very sensible. The terms of reference of medical ethics committees should be revised to reflect this.

My colleagues and I feel this is an extremely important issue in terms of public interest and we would be happy to provide any additional information you would find useful in your review.