Institution: The University of Edinburgh

Unit of Assessment: 20 Law

Title of case study: Case Study 6: Delivering the Good Governance Framework of the Scottish Health Informatics Programme (SHIP)

1. Summary of the impact

Research on health information governance conducted by Laurie (2009-2013) resulted in a transformed and streamlined regulatory environment across Scotland through design and implementation of a state-of-the-art good governance framework for the Scottish Health Informatics Programme (SHIP). This interdisciplinary consortium promotes the facilitation of health-related research through data linkage to deliver new health benefits to current and future generations. Laurie's work overcame regulatory hurdles to effective data linkage and put in place a framework that has been widely adopted and endorsed by NHS stakeholders, researchers, data custodians and publics, as well as the Scottish Government in its cross-sectoral data linkage agenda.

2. Underpinning research

The ability to link health and health-related data is widely acknowledged to be essential to understanding disease processes, drug development and monitoring, and health improvement. This includes data from human tissues held in collections (biobanks). The legal basis for such practices has, however, been a matter of considerable dispute particularly in the absence of explicit consent from patients. While England & Wales have pursued a legislative route to allow linkages, the same is not true in Scotland. The concern among the research community has been a lack of clarity about the role of consent and the increasing regulatory burden in linkage and access procedures. Laurie's work tackles the myths and rhetoric of consent as well as the challenge of reducing regulatory burden. It confronts the pre-existing paradigm of 'consent or anonymise' applied to research on patient data and tissues, demonstrating that this approach is neither necessary nor sufficient in a robust governance framework that promotes responsible data linkage under a well-defined public interest mandate.

These research findings stem from two overlapping projects on which Laurie served as legal lead and Co-Investigator responsible for information governance dimensions (2009-2013, section 3). The Scottish Health Informatics Programme (SHIP) built a world-leading and state-of-the-art infrastructure to facilitate the use of health-related records in medical research through an interdisciplinary collaboration involving the Universities of Dundee, Edinburgh, Glasgow and St Andrews, NHS Scotland and National Records Scotland. It was successfully launched in 2012. Laurie (appointed to Edinburgh in 1995) was responsible for the ethics, law and governance stream and worked with Sethi (Edinburgh Law Research Fellow) and Cunningham-Burley and Pagliari (Edinburgh, examining public engagement dimensions of SHIP). Initial scoping studies on existing legal landscapes and their inherent hurdles (3.1) were used to engage the consortium, the public, regulators, and medical researchers wishing to link data – the key research users of the programme. Parallel work on Reconsent to Research (3.3) was also fed into the design of SHIP's Good Governance Framework (GGF).

The research outputs argued that:

1. It is important to understand and communicate the role and limits of consent as a regulatory mechanism and to exploit fully other legal mechanisms, such as public interest, to legitimate data linkage (3.1 and 3.3);

2. It is necessary to consider the value of principles and best practices in informing decision-making within legal architectures when careful judgement and discretion are required (articulated

in the GGF) (3.4);

3. There is a need to elucidate mechanisms of proportionate and reflexive governance to reduce regulatory burden and enhance regulatory response (3.2 and 3.5);

4. There is value in the design of a risk-assessment matrix to streamline approval mechanisms with respect to applications to conduct research by linkage of patient data (3.4 and 3.5);

5. It is crucial to involve robust public engagement exercises to deliver good governance design in ways that can engender and maintain public trust (3.1 and 3.3).

3. References to the research

Grants

'Scottish Health Informatics Programme' (Wellcome Trust Grant Ref No. 8211, PI: Andrew Morris, University of Dundee; 2009-2013). £3,577,430 in total with £630,126 to the University of Edinburgh for information governance and public engagement (Laurie as lead).

'Reconsent to Research: View of Participants' (Wellcome Trust Grant WT097093MA, PI: M Dixon-Woods, University of Leicester; 2012-13, extended to 2014. Laurie (Edinburgh) Co-I with P Burton, M Murtagh, C Tarrant and S Wallace (Leicester). £39,771 in total with £7,500 to Edinburgh for legal research.

Publications

(3.1) G Laurie and N Sethi, 'Information Governance of Use of Health-Related Data in Medical Research in Scotland: Current Practices and Future Scenarios' (Working Paper No 1, 2011) available on SSRN [http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1946258]

(3.2) G Laurie, 'Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law' (2011) 130 Human Genetics 347-56 [doi: 10.1007/s00439-011-1066-x]

(3.3) G Laurie and E Postan, 'Rhetoric or Reality: What is the Legal Status of the Consent Form in Health-related Research?' (2013) 21 (Summer) Medical Law Review 371-414 [doi: 10.1093/medlaw/fws031]

(3.4) G Laurie and N Sethi, 'Towards Principle-based Approaches to Governance of Health-related Research using Personal Data' (2013) 4 European Journal of Risk Regulation 43-57 [to be supplied by HEI on request]

(3.5) N Sethi and G Laurie, 'Delivering Proportionate Governance in the Era of eHealth' (2013) 13 Medical Law International [doi:10.1177/0968533213508974]

4. Details of the impact

The research findings were used by Laurie to design, test and implement the Good Governance Framework (GGF) for SHIP. This is based on a series of principles and instances of best practice. The GGF was successfully launched in 2012.

The principal users of the GGF are: (i) custodians of health data, such as NHS Scotland, National Records Scotland (NRS), and Caldicott Guardians with special remit for patient confidential data, and (ii) medical and statistical researchers seeking to link data. All were involved in the design of the GGF. Accordingly, the impact can be considered (1) at the level of the governance community, and (2) at the level of the researcher community (5.1, 5.2 and 5.3). A central feature of the claim to impact has been success in overcoming a prevailing 'culture of caution' concerning data linkages.

There are three elements to impact.

(1) Impact on the governance community

Laurie was uniquely placed to act as a conduit between the academy and the governance environment because of his position as Chair of the Privacy Advisory Committee (2005-2013) (5.7). Scottish Chief Scientist (Health), Professor Andrew Morris, has said: 'In concrete terms, Laurie's research since 2009 led to the adoption of entirely novel proportionate governance mechanisms by key data linkage decision-making bodies within Scotland, such as the Privacy Advisory Committee which acts as sole advisor to NHS National Services Scotland and National Records of Scotland - two of the largest and most influential data custodians in the country. This has resulted not only in faster turn-around times for linkage approvals, but also to greater transparency and accountability of the governance systems, leading - we believe - to more trust in health-related research as a crucial dimension of public benefit and economic growth in Scotland. These changes have been directly instrumental in securing Scotland's position as a Go-To country for safe, secure and effective health-research' (5.1).

(2) Impact on the health researcher community

The implementation of the SHIP GGF delivers faster, more transparent and consistent access to researchers, within and beyond the NHS. Furthermore, the research identified an unmet need for training on the legal, ethical and governance issues related to data sharing in medical research. This resulted in the design and delivery of an online training module to accredited researchers to use SHIP. This was piloted by Laurie and Sethi with twenty members of the active research community in March 2012 and launched in the same year. It has since accredited 56 researchers (5.8 and 5.9).

Dr Hester Ward, Medical Director in NHS Scotland National Services said: 'The online SHIP Information Governance Training Course, which was developed by Professor Laurie and colleagues, has become integral to the process of becoming a "SHIP approved researcher". Completion of this course helps NSS to ensure that only "safe people" who have been trained appropriately and understand their legal obligations, gain access to sensitive information. Professor Laurie's work has helped NSS to both develop our information governance processes and ensure that researchers are aware of their legal obligations. These contributions have had a significant impact on making sure that research, which is in the public interest takes place, whilst also ensuring the ongoing maintenance of the privacy of citizens' information' (5.2). Since deployment of the GGF and to 31 July 2013, NHS Scotland National Services had received 344 applications for data linkage to be subject to the GGF proportionate approach.

(3) Impact beyond the health sector

The GGF has been recognised for its transferable value as a model to promote data linkage and key features have been taken up outside the health sector. The Scottish Government public consultation on a proposal for a National Data Linkage Centre focused on the founding principles for the Centre. These were directly taken and adapted from the Principles and Best Practices developed by Laurie (5.4, 5.5, and 5.6).

According to Dr Sara Grainger, Head of Statistics Policy, Scottish Government: 'The arguments set out by Professor Laurie and colleagues in the SHIP Working Papers on Good Governance formed a crucial part of the evidence-base used in developing Scottish Government policy on data access and analysis, published in November 2012 as "Joined Up Data for Better Decisions". The specific influence can be seen in what is now Scottish Government policy to encourage all public bodies to a) adopt a more proportionate approach to managing the risks associated with data sharing and linkage and b) place more emphasis on safe people and safe environments, rather than over-reliance on consent and anonymisation (safe data)' (5.3).

5. Sources to corroborate the impact

(5.1) Testimonial from Chief Scientist (Health), Scottish Government; also PI on SHIP initiative [to be supplied by HEI on request]. Can corroborate the central importance of the research in driving iterative design of the good governance framework and its eventually adopted within NHS Scotland and by Scottish Government.

(5.2) Testimonial from Medical Director in NHS Scotland National Services [to be supplied by HEI on request]. Can corroborate the direct influence of the research in delivering proportionate governance of data linkage for research within NHS Scotland, as well as the introduction of training and accreditation of third parties those wishing to access and link NHS-held data.

(5.3) Testimonial from Head of Statistics Policy, Office of the Chief Statistician and Performance, Scottish Government [to be supplied by HEI on request]. Can corroborate the extended reach of the research through its uptake and influence on government policy in implementing a nation-wide cross-sectoral data linkage initiative.

(5.4) Scottish Government Consultation based heavily on Laurie's Principles: http://www.scotland.gov.uk/Publications/2012/03/3260/4 or http://tinyurl.com/nepbmfq. Provides direct public acknowledgement of the influence of the research on the government consultation process.

(5.5) Scottish Government Strategy and Guiding Principles for Data Linkage acknowledging impact of Laurie's research (ISBN: 9781782562047): http://www.scotland.gov.uk/Publications/2012/11/9015/1 or http://tinyurl.com/nw52myj. Provides direct public acknowledgement of the influence of the research on the principles that underpin the government nation-wide cross-sectoral data linkage initiative.

(5.6) SHIP website with reports on progress (http://www.scot-ship.ac.uk/progress-reports or http://tinyurl.com/pawlhfc) provides evidence of the central role of the research in the iterative design of the SHIP good governance framework that was eventually adopted within and beyond NHS Scotland.

(5.7) Privacy Advisory Committee website and details of changes in working practices: http://www.nhsnss.org/pages/corporate/privacy_advisory_committee.php or http://tinyurl.com/llvkson. Provides evidence of the direct adoption of the notion of proportionate governance by a central body within the regulatory landscape, directly as a result of the underpinning research.

(5.8) Access to the SHIP online training module, which clearly incorporates the GGF: http://www.scot-ship-toolkit.org.uk/ or http://tinyurl.com/lov77rj. Provides evidence of the nature and scope of the training and accreditation scheme that operates to improve standards for health data linkage for any third parties, national or international, seeking access to health data.

(5.9) Link to SHIP public-facing video: http://www.scot-ship.ac.uk/public-interest or http://tinyurl.com/onr2c4c. Provides an illustration of the changes that have been brought about as a result of the research in delivering effective and streamlined governance mechanisms, and explains these to health researchers and the public in an accessible manner.