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On moving targets and magic bullets: Can the UK lead the way with responsible data linkage for health research?

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ABSTRACT

Purpose: To provide an overview of essential elements of good governance of data linkage for health-related research, to consider lessons learned so far and to examine key factors currently impeding the delivery of good governance in this area. Given the considerable hurdles which must be overcome and the changing landscape of health research and data linkage, a principled, proportionate, risk-based approach to governance is advocated.

Discussion: In light of the considerable value of data linkage to health and well-being, the United Kingdom aspires to design and deliver good governance in health-related research. A string of projects have been asking: what does good governance look like in data linkage for health research? It is argued here that considerable progress can and must be made in order to develop the UK's contribution to future health and wealth economies, particularly in light of mis-start initiatives such as care.data in NHS England. Discussion centres around lessons learned from previous successful health research initiatives, identifying those governance mechanisms which are essential to achieving good governance.

Conclusion: This article suggests that a crucial element in any step-increase of research capability will be the adoption of adaptive governance models. These must recognise a range of approaches to delivering safe and effective data linkage, while remaining responsive to public and research user expectations and needs as these shift and change with time and experience. The targets are multiple and constantly moving. There is not – nor should we seek – a single magic bullet in delivering good governance in health research.

1. Introduction: the problem and the vision

The recent debacle over care.data reveals yet another aspect of the multifaceted entity that is data sharing in healthcare [1]. The government and NHS England proposal to extract data from patient records for retention and use in a centralised database – with possible access from commercial entities – has not only generated considerable criticism, but led to suspension of the scheme, in order to allow better consultation with and involvement of patients and public [2]. The initiative has only very recently (partially) re-launched, and it remains to be seen how the four pathfinder projects progress and how they are received by the public [3]. Some of us have argued elsewhere that the initiative was premature and ill-conceived for want of 'social licence': that it, the false assumption that public confidence in GPs could simply be borrowed across to such an initiative [4]. This must also be set against the 2013 Caldicott 2 Review [5] into responsible sharing of patient data which, significantly, added a seventh principle to the Caldicott Guardians' guiding principles: '[t]he duty to share information can be as important as the duty to protect patient confidentiality' [6]. More recently, the Cabinet Office has published a discussion document on data-sharing policy. It points out that the common assumption that government departments can easily share data to improve services is false [7]. Against this, in turn, we have the on-going uncertainty over the legal position on data processing, driven by European Commission plans to introduce a Data Protection Regulation to tighten up the legal regimes across the continent [8], while in England the recent passing of the Care

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Act 2014 now gives power to the Health Research Authority (HRA) to authorise the processing of confidential medical information for medical research, subject to approval by an ethics committee (section 117), and requires the HRA to put '. . .in place and operate a system for reviewing decisions' [9]. All of this typifies, and can be seen as a reaction to, a pre-existing problem identified by the Academy of Medical Sciences in a number of its outputs [10], namely, that a culture of caution prevails in data sharing for (health) research [11].

This is not to suggest that responsible research using health data cannot or does not happen. Indeed, the advent of the Farr Institute of Health Informatics Research builds on projects already delivered around the UK in each of the four nodes that make up the current consortium. Thus for example, SAIL [12]/CIPHER in Wales operates in a privacy-protecting safe haven [13]. There is a secure file transfer system in place for data being brought into the SAIL databank. Secure, remote data access is controlled and possible only when such access has been authorised. All output has to be approved. North of the border, the Scottish Health Informatics Programme (SHIP) has delivered a good governance framework to maximise the value of research using Scotland's rich health datasets. The framework is founded upon a mechanism of risk-based proportionate governance that reduces unnecessary regulatory burden without diluting appropriate scrutiny. At the University of Manchester and in collaboration with NHS partners, a technical solution to the 'consent for consent' problem was developed, enabling researchers to quickly and easily determine the likelihood of recruiting the required number of patients for a clinical trial protocol and to enact the recruitment process [14].

University College London (UCL) has developed an Identifiable Data Handling Service (IDHS) to allow authorised researchers to analyse clinical research data-sets within a data safe haven [15], where identifiable or pseudonymised data do not leave the secure boundary of the system. The service has also provided training workshops for researchers around information governance, and provides assistance for research projects when seeking both Information Toolkit Governance Level 2 compliance and exemption from the Common Law Duty of Confidentiality under Section 251 of the NHS Act.

The vision of the Farr initiative is:

'To harness health data for patient and public benefit by setting the international standard for the safe and secure use of electronic patient records and other population-based datasets for research purposes' [16].

The consortium comprises 24 academic Institutions and two Medical Research Council (MRC) units, bolstered by an additional £20 million in capital funds from the MRC. It aims to deliver high-quality, cutting-edge research linking electronic health data with both other forms of routinely collected data and other areas of research. It is also committed towards capacity building in health informatics research. The Farr Institute aims to provide the electronic infrastructure to facilitate collaboration across the four nodes, support their safe use of patient and research data for health and social care research. It will further enable partnerships through the provision of a physical structure which co-locates NHS organisations, industry, and other UK academic centres.

The common foundational principle that underpins all of the work of the Farr Institute is a commitment to responsible data sharing for the promotion of health and well-being. This commitment, in turn, is founded on a belief that scientifically sound, ethically robust data sharing for health research is in the public interest. This does not ignore the considerable importance of appropriate privacy and security measures, because – equally – robust protection of privacy is also in the public interest. However, nowhere is protection of privacy an absolute. This is true as much in law as in ethics. Indeed, the notion of absolute security of data is probably an unattainable goal, and certainly a foolish policy promise. No custodian of data should lead data subjects to believe otherwise. Responsible data management is about professional and responsible management of risk, and risk comes in many forms. It includes, but is not restricted to:

- invasion of privacy,
- potential discrimination or stigmatisation and resultant distress,
- economic threats and
- loss of trust.

In addition, any data custodian must consider risks to their reputational integrity if unjustifiable or irresponsible data linkages or disclosures are made. This is true even if such linkages or disclosures are entirely lawful. Good governance is not merely a matter of compliance with the law.

And yet the law poses considerable challenges for the data linkage aspirations of entities like the Farr Institute. Until now, the node activities have occurred in three distinct countries of the United Kingdom, subject to two different legal systems and overshadowed by a European regime. The vision to lead international standards complicates matters further, especially any prospect of international data travel. Any attempt to harmonise national – let alone international – arrangements would be futile. There can be no one-size-fits-all approach to such rich and complex regulatory settings. Rather, the governance approach of the Farr Institute is considerably more realistic – to bring about mutual recognition of standards and best practices, drawing on lessons to date from regional successes, and considering where common ground and approaches might be extrapolated to other environments. Approximation is key.

As a crucial first step in this process of approximation of standards, the Farr governance team has identified critical areas of attention which serve as the foundational elements of good governance frameworks, and thus the starting points for further deliberation and construction of initiatives on a larger and more publicly-valuable scale. It is important to stress that the ethos is one of *co-production* of good governance between data custodians, potential data users, and data subjects themselves through robust and iterative engagement. It also requires transparent development and equitable access policies. The immediate lessons from care.data include the serious inadequacy of assuming that it is sufficient to attempt to inform data subjects unidirectionally through leafleting alone. Effective communication with stakeholders, especially with those for whom privacy is in play, must go beyond the mere provision of information. Equally, it is not enough simply to pass law. Care.data had a legal basis under the Health and Social Care Act 2012 [17], but this still did not prevent the adverse reaction to what was proposed. Although the government has attempted to provide yet further legal clarity in the Care Act 2014 for the processing of confidential medical information under the auspices of the Health Research Authority [18], the law can do no more than lay out broad legal parameters for operation. The real challenges will be in the Act's implementation through transparent responsible practices. This is where the approach of the Farr Institute can offer important insights.

2. The approach

The Farr initiative has drawn on its cumulative research expertise thus far to reveal the following features that, we suggest, must necessarily form part of any good governance framework.