

## Trust in the time of markets: protecting patient information

Trust in the protection of confidential patient data in England seems to be at an all-time low given recent breaches in releases of patient data and the finding that hospital data have been sold to companies with insufficient oversight.<sup>1</sup> This follows a Memorandum of Understanding signed in January, 2014, by the Secretary of State for Health for England and his US counterpart in which they agree to “priming their respective markets for innovative new Health IT products and services”.<sup>2</sup>

Concerns have centred on the decision in December, 2013, by NHS England to direct the Health and Social Care Information Centre to establish a system for uploading and linking primary care patient coded data with identifiers.<sup>3</sup> In February, 2014, after a campaign by the British Medical Association, the Royal College of General Practitioners, and the privacy campaign group medConfidential, among others, a 6-month delay in the implementation of this aspect of NHS England’s programme for sharing patient data across the health and social care system, known as Care.data, was announced.<sup>4</sup> In March, 2014, the UK Government proposed amendments to the Care Bill in a bid to allay these concerns.<sup>5</sup> The Care Bill is due to come before the House of Lords on May 7.

Until 2012, two main exceptional uses of confidential patient data were allowed: production of aggregated official statistics under the auspices of the UK Statistics Board and, since 2002, use for defined medical purposes, commonly known as “section 251 approvals”.<sup>6</sup> Between 2009 and 2013, the latter use was overseen by the now defunct National Information Governance Board and currently falls under the remit of the Health Research Authority’s non-statutory Confidential Advisory Group. Section 251 approvals allow use of patient data in relation to neoplasia, communicable diseases, and other public health risks, and in other specified circumstances by health professionals or equivalents. Use of the information to determine individual treatment is not permitted.

Between these two exceptions is the Health and Social Care Information Centre, which was first set up as a Special Health Authority in 2005.<sup>7</sup> The functions of the Centre originally included the collection, analysis, use, and dissemination of information and issuing administrative identification numbers, as directed by the Secretary of State for Health. The Centre obtained information

through section 251 approvals and, from 2008, produced official statistics. The sharing of information, such as Hospital Episode Statistics, held by the Centre with private companies is currently under review.<sup>8</sup>

The 2012 Health and Social Care Act led to far-reaching changes to the health information system of the National Health Service (NHS), not least because commercial contracts are now at the heart of NHS commissioning.<sup>9</sup> Under Part 9 of the 2012 Act, the original Centre was abolished, re-established as a corporate body,<sup>10</sup> and is now generally referred to as “the HSCIC”. It is subject to the Government’s and NHS England’s directions, and is supposed to be a safe haven where confidential data are collected and de-identified before onward disclosure. However, Dame Fiona Caldicott’s review of information governance in March, 2013, considered that “it is unlikely that the Information Centre will have the capacity to de-identify information that local commissioners want to extract from local providers”.<sup>11</sup>

This lack of capacity to de-identify patient data would be a cause for concern because Part 9 of the 2012 Act is already in force and entitles private companies to request the HSCIC to establish a system for the collection and analysis of patient information for their activities.<sup>10</sup> The HSCIC must publish information obtained by using these powers, subject to exceptions. Requests by a company can be made without reference to “medical



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purposes” or public health benefit. Moreover, there is no independent statutory oversight of the HSCIC’s responses to such requests.

The new statutory entitlement that allows sharing of patient data with private companies is backed by the idea of private sector accredited information service providers. Section 267 of the 2012 Act empowers the Secretary of State for Health to make regulations to establish an accreditation scheme.<sup>12</sup> Regulations have not yet emerged, but the idea of “accredited safe havens” is being used by the HSCIC to cover Clinical Commissioning Groups and non-statutory Commissioning Support Units.<sup>13</sup> Some of these Commissioning Support Units, whose future legal operation is uncertain, have already received section 251 approvals to access confidential patient information.<sup>14</sup>

Public trust in general practitioners (GPs) is essential, as is the availability of genuinely anonymised information for public health research, planning, and audit. However, making patient information available to the private sector is likely to erode public trust and might lead many patients to opt out of providing information to GPs so that datasets would become unrepresentative and unreliable.

When the Care Bill returns to the House of Lords on May 7, we are calling for three amendments: to keep confidential patient data in the public sector unless commercial organisations have express consent; to put the Caldicott Independent Oversight Panel on a statutory footing with a duty for its advice to be taken into account; and to ensure independent or parliamentary oversight of directions to the HSCIC and the accreditation scheme.<sup>15</sup> These amendments, however, will not ensure full transparency over data flows, particularly to and among private companies. Further discussion and legislation are needed to put an information system in place that deserves public confidence. The UK Government will have to give careful consideration to the type of safeguards for uses of confidential patient data in light of the new EU General Data Protection Regulation,<sup>16</sup> which will be directly applicable once adopted and will provide an opportunity for that discussion.

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We declare that we have no competing interests.

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