

medConfidential briefing for Care Bill ping-pong, May 7th 2014

## **Building trust in secondary use of NHS patient data: 'consensual, safe, transparent'**

medConfidential respectfully urges members of the House to support amendments 45A and 45B, tabled by Lord Owen, to put the Independent Information Governance Oversight Panel onto a statutory footing, and amendment 45C, tabled by Lord Turnbull, on the definition of research use, which would replace the Government's "promotion of health" clause. This briefing is to lay out medConfidential's concerns and some specific issues in more detail. A copy of this, related briefings and latest updates are available online at: <http://medconfidential.org/2014/lords-care-bill/>

### **Who are medConfidential?**

medConfidential campaigns for confidentiality and consent in health and social care, seeking to ensure that every flow of data into, across and out of the NHS and care system is consensual, safe and transparent<sup>1</sup>.

Founded in January 2013 and incorporated as a company limited by guarantee with charitable objects, medConfidential is an independent, non-partisan organisation working with patients and medics, service users and care professionals, and drawing advice from a network of experts in the fields of health informatics, computer security, law/ethics and privacy. We believe that there need be no conflict between good research, good ethics and good medical care.

### **Why can NHS patients not know who has their data and for what purposes?**

*Barbara Keeley MP: "...can we know who all the end users of our data are?"*

*Kingsley Manning: "No..."*<sup>2</sup>

The admission by the Chair of the Health and Social Care Information Centre (HSCIC) to Parliament in April that the Information Centre did not - and could not - know where NHS patients' data has gone merely confirmed what had been clear for some months now; there is a devastating failure of information handling and information governance at the heart of the NHS.

This is not just limited to HSCIC. Since the abolition of the National Information Governance Board in April 2013, a number of NHS England's initiatives - most notably, care.data - have been shown to be fundamentally flawed; from the uploading of 10 years' hospital records to Google servers<sup>3</sup> to the intended extraction and dissemination of NHS patient information from GP records under care.data.

Though some steps have been taken to remedy some of HSCIC's failings, such as the publication of a partial register of data releases, these have so far done little to inspire public confidence. The register published on 3rd April, for example, was incomplete - omitting to mention releases of

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<sup>1</sup> Additional briefing, *What does medConfidential mean by "consensual, safe and transparent"?*:

<https://medconfidential.org/wp-content/uploads/2014/05/medConfidential-consensual-safe-and-transparent.pdf>

<sup>2</sup> Q272, Health Committee, Oral evidence: Handling of NHS Patient Data, HC 1105, Tuesday 8 April 2014:

<http://data.parliament.uk/writtenevidence/WrittenEvidence.svc/EvidenceHtml/8416>

<sup>3</sup> "NHS England patient data 'uploaded to Google servers', Tory MP says", Guardian, 3/3/14:

<http://www.theguardian.com/society/2014/mar/03/nhs-england-patient-data-google-servers>

information to the police or patient data still being processed under active licence<sup>4</sup>.

We therefore ask that the following issues be taken into consideration:

### **1) Statutory independent information governance oversight body for health and social care**

Given the systemic failures of information governance and an evident lack of appropriate consultation between arms-length bodies, the Department, practitioners, professional bodies and the public, an independent statutory body with information governance oversight of the entire health and social care system is a necessity to regain and inspire public confidence. medConfidential believes the best candidate for such a body would be the Independent Information Governance Oversight Panel, chaired by Dame Fiona Caldicott, established on the request of the Secretary of State to “advise, challenge and report on the state of information governance across the health and care system”.

### **2) Patient opt-out on a statutory basis**

These are not merely ‘data protection’ issues. The right to a private family life is fundamental<sup>5</sup>, and the need for informed consent for the collection and use of identifiable patient data is a requirement of ethical research on human beings<sup>6</sup>. While the NHS operates on a principle of ‘implied consent’ for treatment, expanding this to the secondary use of data is deeply problematic and therefore at the very least requires that patients’ right to opt out of such uses be put on a statutory footing.

### **3) Preventing commercial exploitation of NHS patient data**

More than anything, it has been the exploitation of patient’s medical information by commercial companies that has undermined public trust. The Government amendments as brought forward to address this are defective. Purposes should be limited to the provision of health and adult social care services and legitimate, ethically-approved research use.

### **4) ‘One-strike’ sanction for misuse of patient data**

Sanctions after the fact can only achieve so much. Restricting future access to data would provide a meaningful incentive for institutions and corporate entities to properly train and monitor their employees’ use of NHS patients’ information, and to report any breach or misuse of patient data.

We would be very happy to answer questions or to arrange a briefing on data and privacy aspects of the Care Bill. Please contact medConfidential by e-mail on [coordinator@medconfidential.org](mailto:coordinator@medconfidential.org) or by phone on 0203 675 0505.

Phil Booth and Sam Smith  
medConfidential, 6 May 2014

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<sup>4</sup> <https://medconfidential.org/2014/addendum-to-press-release-hscic-register-inadequate-and-patronising/>

<sup>5</sup> Article 8, Human Rights Act: <http://www.legislation.gov.uk/ukpga/1998/42/schedule/1>

<sup>6</sup> Section 32, WMA Declaration of Helsinki: <http://www.wma.net/en/30publications/10policies/b3/>

## medConfidential concerns with the Government's amendments

medConfidential has a number of concerns with the amendments brought forward from the Commons, which we outline in more detail below. We commend to members of the House amendments that we believe would be more constructive in rebuilding public trust.

### **1) An independent statutory body with information governance oversight for the entire health and social care system**

The Government has brought forward amendments that would expand the advisory role of the Confidentiality Advisory Group (CAG), based at the Health Research Authority, over a wider range of data releases by the Health and Social Care Information Centre (HSCIC) than those for which it is currently responsible.

While we would welcome much-needed statutory oversight of HSCIC, medConfidential believes that the Government's proposed solution fails to address several key issues and is far too limited in scope.

- Part 4 of Government amendment 45 states that when HSCIC publishes or disseminates information it *"must have regard to any advice"* given by the CAG;
- Amendment 49 expands CAG's remit to cover *"any publication or other dissemination by the Centre of information which is in a form which identifies an individual to whom the information relates or enables the identity of such an individual to be ascertained"*;
- Amendment 50 provides for regulations so that CAG can *"be required, in giving advice, to have regard to specified factors or matters."*

The Government amendments acknowledge that information governance at HSCIC and its precursor body the NHS Information Centre is and has been utterly inadequate, but multiple instances of the misuse<sup>7 8</sup> and commercial 're-use'<sup>9 10</sup> of NHS patient information and lack of adequate consultation<sup>11</sup> on aspects of NHS England's deeply-flawed care.data programme - now on 'pause'<sup>12</sup> - clearly show that the problem is not limited to HSCIC alone.

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<sup>7</sup> The uploading of Hospital Episode Statistics to Google servers outside the UK was an NHS England initiative: <http://www.paconsulting.com/introducing-pas-media-site/releases/pa-consulting-group-and-nhs-england-win-cloud-innovation-award/>

<sup>8</sup> "Online tool could be used to identify public figures' medical care, say critics", Guardian, 17/3/14: <http://www.theguardian.com/technology/2014/mar/17/online-tool-identify-public-figures-medical-care>

<sup>9</sup> "Hospital records of all NHS patients sold to insurers", Telegraph, 23/2/14: <http://www.telegraph.co.uk/health/healthnews/10656893/Hospital-records-of-all-NHS-patients-sold-to-insurers.html>

<sup>10</sup> "NHS sells a billion patient records", Sunday Times, 16/3/14: [http://www.thesundaytimes.co.uk/sto/news/uk\\_news/Health/article1388324.ece](http://www.thesundaytimes.co.uk/sto/news/uk_news/Health/article1388324.ece)

<sup>11</sup> "Key Government adviser on NHS Data tells PM the care.data scheme was mishandled", BBC Radio 4 PM programme, 18/4/14: <https://audioboo.fm/boos/2088283-key-government-adviser-on-nhs-data-tells-pm-the-care-data-scheme-was-mishandled>

<sup>12</sup> Official announcement of 6 month 'pause' in care.data rollout, 19/2/14: <http://www.england.nhs.uk/2014/02/19/response-info-share/>

While the Government amendments may go some way towards addressing the lack of independent oversight and appropriate governance *within* HSCIC, they would still provide no oversight or assurance on the many data flows into, across or out of the NHS that take place beyond HSCIC's remit or control.

Expanding the role and remit of the Confidentiality Advisory Group would turn what is currently a body of volunteers which advises the Secretary of State on applications for medical research (and more recently non-research) uses of identifiable patient data without consent into a body responsible for assessing and approving a significantly greater number of releases of data from HSCIC, for a far wider range of purposes than it was ever designed to consider.

Though it currently performs an absolutely vital function in an exemplary fashion, CAG would still only be a committee of the Health Research Authority and if its functions are to be defined in secondary legislation and limited to the functioning of HSCIC it is difficult to see how it could, for example, provide sufficient scrutiny of NHS England data initiatives and programmes - NHS England being the body from which the current issues with care.data have ultimately arisen.

We draw their Lordships' attention to the fact that the National Information Governance Committee (NIGC) of the Care Quality Commission, formed on the abolition of the National Information Governance Board (NIGB) in April 2013, has also failed to provide such scrutiny.

medConfidential believes that an independent statutory body with information governance oversight of the entire health and social care system is a necessity. The best existing candidate from which to create such a body would be the Independent Information Governance Oversight Panel (IIGOP) that the Secretary of State asked Dame Fiona Caldicott to establish to implement the recommendations from her review, 'Information: to share or not to share'<sup>13</sup> and to "advise, challenge and report on the state of information governance across the health and care system in England".

***We therefore recommend Lord Owen's amendments 45A and 45B to put the Independent Information Governance Oversight Panel onto a statutory footing.***

N.B. The wording "enables the identity..." in Government amendment 49 above would still arguably permit the publication or dissemination of de-identified or pseudonymised patient information. Restrictions must be clear and unambiguous, not a matter for interpretation.

To be clear in a way the distinction between 'personal data' and 'non personal data' often is not, the only meaningful division in types of health data is between individual *patient-level data*, however treated, for example by de-identification (removing some identifiers) or pseudonymisation (replacing or obscuring some identifiers) and *properly-treated aggregate statistics*, which is the only sort of data that can be considered 'anonymous'. Rich in sensitive medical detail, linked patient-level data is inherently identifying.

HSCIC itself seems to be moving towards this as a means of categorising patient data. If it wishes to regain the trust of the public, we believe the Government should recognise this as well – though we

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<sup>13</sup> Caldicott review on information governance in the health and care system, published 26/4/14: <https://www.gov.uk/government/publications/the-information-governance-review>

appreciate this may be beyond what is possible in the Care Bill.

## **2) Patient opt-out on a statutory basis**

While the Secretary of State and the arms-length bodies have stated that patient objections will operate as a 'no-quibble' opt out from the extraction of *any* data from patients' GP-held records – not just any identifiable data – and from the dissemination of their identifiable data uploaded to HSCIC from other sources, this 'right' exists only as the gift of the Secretary of State.

If, as the Government has indicated, the sole statutory basis for patients to opt out is to be a Direction under the Health and Social Care Act 2012, then any future Secretary of State - or NHS England itself - could issue a new Direction that removed patients' right to opt out without oversight, consultation or notice. Patients who do opt out could find their decision rendered meaningless by the stroke of a pen that would never be reviewed by Parliament.

Such a Direction would indeed be the very same type of instrument as the one issued to establish care.data in the first place which, in its current wording, requires clinical data to be extracted from the GP records of patients who have opted out<sup>14</sup>.

A Direction that could be ignored or overwritten by subsequent Directions provides no lasting guarantee for patients and therefore fails to address the core issue of public trust. We note that a Direction laid just last month, specifying 'Data Services for Commissioners', similarly mis-specifies the management of patient objections<sup>15</sup>.

Both of NHS England's current Directions will have to be re-issued in order to rectify the incorrect specification of the patient objection process that was determined by the Secretary of State. To ensure the Secretary of State's assurance that patient opt-out will be on a statutory footing will be met in a way that provides maximum public confidence, we recommend that a separate Direction specifying 'Patient Objections Management' for these and all subsequent Directions should first be issued.

***In respect of these issues, we recommend sub-section 8 of Lord Owen's amendment 45B***

## **3) Preventing the commercial exploitation of NHS patient data**

At Report and Third Reading the Government introduced amendment 45<sup>16</sup>, a new clause, of which

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<sup>14</sup> Section 8, p5, Directions for the 'Establishment of Information Systems for NHS Services: Collection and Analysis of Primary Care Data': <http://www.england.nhs.uk/wp-content/uploads/2014/01/cd-directions.pdf> states NHS England's requirement for HSCIC to extract the clinical data of patients who have objected to that extraction, i.e. effectively ignoring that objection. This must clearly be replaced, but is currently still in effect.

<sup>15</sup> Section 10, p8, Directions for the 'Establishment of Information Systems for NHS Services: Data Services for Commissioners': <http://www.england.nhs.uk/wp-content/uploads/2014/04/ig-directions.pdf> - disseminating *pseudonymised* data, as opposed to data from which all identifiers have been *removed*, would mean the data of patients who had opted out would in effect be treated no differently to the data of patients who had not, except arguably in the limited case of 'Section 251' exemptions.

<sup>16</sup> HC Debate, 10 March 2014, c133: <http://www.theyworkforyou.com/debates/?id=2014-03-10a.132.0>

part 3 states<sup>17</sup>:

(3) *In section 261 (other dissemination of information), after subsection (1) insert—*

*“(1A) But the Information Centre may do so only if it considers that disseminating the information would be for the purposes of—*

*(a) the provision of health care or adult social care, or*

*(b) the promotion of health.”*

The Government’s amendment as originally laid in the Commons was worded too narrowly as it limited the purposes only to “the provision of health care or adult social care” – i.e. just part (a) of the above – which effectively prohibited research use. A late second attempt added part (b), without consultation, making the purposes overly and dangerously broad.

This breadth contradicts the stated intention for this part of the clause – to reassure the public by legally barring the sale of medical records for insurance and commercial purposes – and, by including the word “promotion”, actually provides legal grounds for the very commercial exploitation it is supposed to prevent.

Restrictions must be in law, not purely a matter of policy. “Promotion of health” would quite clearly include the promotion of health products via advertising. The obesity measures in care.data would mean, for example, that McDonalds could justifiably make a case for access to NHS patient-level data extracted from GP-held medical records.

While some might argue there is nothing inherently wrong in McDonalds gaining access to patient data if it were to have some sort of positive health benefit, any speculative benefits must be weighed against the catastrophic loss of public trust that such exploitation would cause. The same would apply to tobacco companies or ‘e-cigarette’ manufacturers and patient-level smoking data (including numbers of cigarettes) given to GPs, were plausible health benefits to be claimed.

Public concern is by and large not engaged by academic or public health research, nor even by research into pharmaceutical development – after all, who would want to take a drug that has not been properly tested? – but is rather engaged by the commercial exploitation of patient data, for market research and other purposes<sup>18</sup>.

Investigating data use, medConfidential has found “commercial re-use licenses” awarded to a number of “information intermediaries” who sell data in various forms to marketers, market researchers, business intelligence professionals, product planners and market access teams at pharmaceutical companies<sup>19</sup>. It is uses such as these that have caused significant public outcry and professional and institutional concern at the decisions of the Health and Social Care Information Centre (HSCIC) and its precursor body, the NHS Information Centre.

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<sup>17</sup> <http://www.publications.parliament.uk/pa/bills/lbill/2013-2014/0093/14093.pdf>

<sup>18</sup> HC Deb, 25 February 2014, c147: <http://www.theyworkforyou.com/debates/?id=2014-02-25c.146.9#g147.3>

<sup>19</sup> Statement on homepage of Beacon Consulting website: <http://www.beaconconsulting.co.uk/>



Data sold under commercial re-use licence is used by pharmaceutical marketers, not legitimate researchers. That pharmaceutical companies are prohibited from using the data they already hold and have permission to use for research in this way raises serious questions as to why their marketing divisions are permitted to access it via other routes.

The current wording of part 3 (1A) (b) not only fails to address the issue of commercial exploitation, it would make it worse. This is a change that would benefit McDonalds and other commercial interests, achieving very little or nothing for patients, the public trust or research in the public interest.

***We therefore recommend Lord Turnberg's amendment 45C, defining research use of patient data, to replace the Government's overly broad "promotion of health" clause.***

#### **4) 'One-strike' sanction for misuse of patient data**

We have one final point, on an issue the Government has said it will deal with in Regulations, which is that sanctions after the fact can only achieve so much. A "one-strike" rule – whereby failure to follow the rules or loss or mishandling of data results in a temporary or permanent restriction on receiving further data from HSCIC – would provide a more meaningful incentive for institutions and corporate entities to properly train and monitor their employees' use of patient data, and to report any breach or misuse of patient data.

One-strike penalties should not however apply when the user of the data reports a failure themselves voluntarily. The sanction must not drive data loss and misuse underground.

Also, a failure by one team shouldn't threaten the good work of other teams in the same large institution. It should be noted that Universities, charities and the NHS itself are often one legal entity, whereas commercial enterprises can comprise several legally-insulated entities. An error by one PhD student shouldn't (necessarily) suspend all of a University's medical research using patient data, but the report by the Staple Inn Actuarial Society<sup>20</sup>, for example, was co-authored by 8 different insurance companies using data purchased with funds from Institute and Faculty of Actuaries - each of which should have to face consequences were misuse to be proven.

medConfidential has two further background briefings, which provide more detail on specific issues:

- [\*\*\*What does medConfidential mean by 'consensual, safe and transparent'?\*\*\*](#)
- [\*\*\*Where did all the governance go? Or, why expanding CAG's remit is insufficient\*\*\*](#)

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medConfidential, 6 May 2014

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<sup>20</sup> "Hospital records of all NHS patients sold to insurers", Telegraph, 23/2/14:  
<http://www.telegraph.co.uk/health/healthnews/10656893/Hospital-records-of-all-NHS-patients-sold-to-insurers.html>