Further comments from medConfidential regarding Section 2 of the Access to Medical Treatments (Innovation) Bill, following meeting with Chris Heaton-Harris MP on 30 September 2015

(This note focuses exclusively on Section 2 of the Bill.)

Given previous statements in Parliament[1] and on the face of the Bill, Section 2 does not deliver the clearly-articulated policy intent. This Section confers on the Secretary of State / Department of Health a new power that duplicates the effect of existing powers. Section 2 is therefore unnecessary. This should, however, be seen as a function of the Bill's current framing and not as any indication that the policy intent itself is unnecessary.

Background

Until March 2014, the NHS barely kept track of where it sent billions of patient health events.[2] Following a period of institutional reform, HSCIC now not only keeps track but is becoming capable both of honoring patient opt-outs, and of telling every patient where their data has gone and for what purpose. But even now, in October 2015, the rules from SecState/DH on opt-outs are not final, let alone rules to determine that patients should know what happened to their data (see attached note).

While some data using projects are now underway – the Accelerated Access Review, for example – given the number of projects and their coordination, monitoring of their levels of real world impact is conspicuous by its absence. The Cancer Drugs Fund, at £500m per year, for example, included no mechanism to examine whether the extra funds had any effect. Apparently neither NHS England nor DH thought it sufficiently important to keep track of outcomes. Whether interventions have real world effect must be measured, and learnt from.

What is known is that NHS England has done little to no work to examine how data currently collected around innovative treatments could be used more effectively and/or integrated into existing programmes. Indeed NHS England's data flagship, care.data, has no mechanism for the integration of "innovative treatments" at all – nor does its roadmap include any such plans.[3]

Section 2 of the Bill merely provides DH with duplicates of powers that it already has. It is not the scope of these existing powers that is lacking[4], it is willingness (or lack of it) on the part of DH to

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[1] "Protect the patient: nurture the innovator" - Lord Saatchi, speaking at Second Reading of the Medical Innovation Bill, HL Deb, 27 June 2014, c1449: http://www.publications.parliament.uk/pa/ld201415/ldhansrd/text/140627-0001.htm#st_2

[2] Paragraphs 28 & 29, Sir Nick Partridge's Summary of his 'Review of data releases made by the NHS Information Centre': https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/367788/Sir_Nick_Partridge_s_summary_of_the_review.pdf

[3] This may be indicative of ongoing problems with the current care.data roadmap, but "innovative treatments" have yet to been raised for discussion with the care.data Advisory Group (CDAG).

[4] The Health and Social Care Act 2012 allows either DH or NHS England to Direct the HSCIC to construct an information system to do anything within the scope of the Direction. DH is no more compelled to begin the consultation on the Regulations in this Bill than they are on a Direction they could do now. Directions are also somewhat more flexible than Regulations which may be of benefit, given past experience, e.g. care.data.

use them. If DH has not so far used its extremely broad Direction-making powers under HSCA 2012 to provide the information required for this policy, the issue is not powers, but action.

The Care Act 2014 requires DH to lay regulations around the Confidentiality Advisory Group (CAG) at the Health Research Authority, which are to include safeguards fundamental to public confidence in the handling of NHS patient data. Despite being a priority in the summer of 2014, draft language appeared the week before Christmas 2014, and nothing has happened since – the regulations have apparently gone back to the drawing board. There is not even a public schedule to implement what the Government has already committed to doing.

It is not a requirement on DH to ensure that a Private Member's Bill has material effect. So the potential in this Bill for DH to 'consult' at some point in the future provides no new mechanism to deliver anything. (DH consulted on "safe havens" for NHS patient data in the summer of 2014, and has so far made no response to that consultation – let alone starting the change of direction suggested by various responses to the consultation, which we understand DH to desire.)

We understand and appreciate the desire and intent for "innovative treatments" to be accelerated. But there is no obvious reason why duplicate statutory powers as defined in Section 2 of this Bill, to create a database that could already have happened, would make any meaningful difference to achieving the intent.

An alternative approach for delivering the policy intent of the Bill

Following our discussion, given that the intent of the Bill is to actually increase innovation – rather than to talk about increasing innovation – and rather than duplicating existing powers, and without leaving the consultation remit up to DH at some indefinite point in the future, a sensible alternative approach to Section 2 would be to specify what should be reported to Parliament and provide a deadline. Require that progress is shown, but don't prescribe how.

An alternate Section 2 could require the Secretary of State to report to Parliament on progress and barriers towards implementing: *Access to Innovative Treatments*[5]; the *Accelerated Access Review*; *Information: To Share Or Not To Share?*[6] (Caldicott 2); a review of care.data and the future data infrastructure of the NHS, and others as appropriate; and may include progress towards a properly-integrated data infrastructure to support the NHS in the above points. Some of these may require databases, but this approach does not prescribe them.

An Expert Panel[7] should advise the Secretary of State on the implementation of progress, and possible approaches to further work benefiting patients. The output of this Panel should be included in the Secretary of State's report to Parliament, clearly answering the question: How have these measures helped patients? What more can be done?

[5] http://medicalinnovationbill.co.uk
[6] https://www.gov.uk/government/publications/the-information-governance-review
[7] The honorary Chair of which might be Lord Saatchi, vice-Chaired by an ennobled Clinician.