medConfidential note for LMC Conference, 22/23rd May 2014

medConfidential is an independent, non-partisan organisation campaigning for confidentiality and consent in health and social care; we seek to ensure that every flow of data into, across and out of the NHS and care system is consensual, safe and transparent.

Several motions for LMC conference propose an opt-in process[1]. To help inform debate, this note lays out medConfidential's consideration of some of the principles around consent processes. We would of course comment in detail on any specific opt-in proposals that are made.

No-one disputes that the execution of care.data has been mismanaged thus far, nor that critical systems and processes are in a mess. Efforts are being made to fix these, but this still leaves the fundamental problem of conflation of purposes.

Evidence shows consistently that most patients, if properly informed and asked for their permission, are happy for their medical information to be used in research. It is the breadth of other potential secondary uses that has generated significant public concern. The Caldicott2 report[2] identified significant dangers in presuming on the "consent deal" between patients and the NHS for other secondary uses, which events earlier this year confirmed.

medConfidential understands the superficial expectation that an opt-in would be 'safer' than an opt-out. But it is not necessarily the case that an opt-in will always be better, or in the patient's best interests. For example, a onetime lifelong opt-in based on incomplete or inaccurate information, with no ongoing feedback as to what is being done with one's data and no way to opt out or expunge data at a later date – as one's circumstances or the system or purposes change – would quite clearly be unacceptable.

Parliament has been told new Directions will be issued to HSCIC[3], finally fixing the broken opt-out procedure[4] which medConfidential has consistently worked to ensure is done properly since March 2013, and putting patient opt-out onto a statutory footing. No clinical data will flow from the GP records of patients who have had a dissent code applied, so patients with concerns will be able to definitively exclude themselves and their dependents.

HSCIC has published an initial register of data releases. The current register is incomplete and unfit for purpose, but there must also be a move towards end-to-end audit – which a recent public letter[5] suggests HSCIC will be doing – so that individual patients can know who has got their data and for what purpose. Failure to provide this risks repetition of the egregious breaches of public trust we have already seen, and – in practical terms – would require that patients be written to all over again each time the system or purposes were to change.

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[1] LMC Conference 2014 agenda, p44/45:http://bma.org.uk/-/media/files/pdfs/working%20for%20change/negotiating%20for%20the%20profession/agenda%20lmc%20conference%20-%20ac4%20final%20with%20cover.pdf

[2] 'Information: To Share Or Not To Share? The Information Governance Review': https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/192572/2900774_InfoGovernance_accv2.pdf

[3] HL Deb, 7 May 2014, c1527: http://www.theyworkforyou.com/lords/?gid=2014-05-07a.1527.1

[4] https://medconfidential.org/2014/opt-out-fixed-for-now/

[5] Letter from Max Jones re. Update on HSCIC Data Sharing Arrangements, 9/5/14: http://www.hscic.gov.uk/media/13952/Letter-from-Max-Jones-re-Update-on-HSCIC-Data-Sharing-Arrangements-09-05-2014---Letter-A-v3/pdf/Letter_from_Max_Jones_re_Update_on_HSCIC_Data_Sharing_Arrangements_09_05_2014_-_Letter_A_v3.pdf

Whatever approach is adopted must therefore meet three basic requirements to achieve a balance of consensual, safe and transparent:

1. Writing to patients directly is an absolute necessity, to properly inform them about what is proposed and to provide a clear explanation and consent form for them to exercise their choice.

2. In the case of any extraction from GP records, robust independent oversight - from the GPES Independent Advisory Group, and possibly the enhanced statutory CAG - must be maintained.

3. Patient feedback based on the audit reporting required by HSCIC, with the support of MRC et al., to provide transparency, to 'refresh' consent on a regular basis and - in case of any future breach or abuse - to limit the impact on public trust.

If the status quo is unacceptable, the most obvious options for LMCs would be:

OPTION A: National opt-in – this must be a *good* opt-in, i.e. it must provide a comprehensive explanation of what patients' data will be used for. It would be a 'one-shot' deal; were the system or purposes ever to change, patients would have to be written to all over again. This requirement could arguably be addressed by regular feedback, so that patients would have the opportunity to opt out if for any reason they are not happy in future.

The likely outcome of this approach would be a useful amount of properly-consented data from a minority of patients.

OPTION B: Local choice – devolve the opt-in/opt-out decision to GPs, in line with the original GPES principles. Practices, backed by the BMA and NHS England, can then decide to either opt all of their patients out by default and run a practice-level opt-in, as per option A, or leave things as per the status quo, i.e. opt-out.

This is likely to deliver a greater amount of properly-consented data than current practice-level approaches, e.g. CPRD.

Both of the above approaches would have an obvious impact on research use. Therefore, to build on the trust people clearly already have for legitimate research requires offering a choice that has not yet been presented.

Given that NHS England decided a binary choice was desirable, the choice for patients should reflect a distinction the public already makes. **Given the mechanisms available, under local choice, the ideal decision at practice level would therefore be: opt-out (respecting patients' human rights) for ethically-approved research, opt-in for all other secondary uses.**

Sticking with the status quo, i.e. national opt-out, raises the spectre of mass opt-out if sufficient conditions – including all legal, practical and ethical requirements – are not met.

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