

## medConfidential note for BMA ARM, 25 June 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.*

### **9Nu6: How to achieve both local choice<sup>1</sup> and consensual research use without compromising either principle**

In the recent care.data opt-in/opt-out debate, discussion has been constrained by NHS England's data re-use pipedreams, rather than the needs of patients and their desired choices.

Patients understand the need for research and broadly support *bona fide* medical and public health research<sup>2</sup>, i.e. research in the public interest. It is the wide range of additional purposes, hidden behind research in NHS England's care.data advocacy, that cause significant public concern and which contributed to the collapse of confidence in the HSCIC. All secondary uses are currently conflated behind the single 9Nu0 opt-out code, implementing NHS England's vision as a 'scorched-earth' blunt choice to patients: all secondary uses, or none.

GPs can decide to support the broad expectations of most patients by separating out *bona fide* research<sup>3</sup> from NHS England's long, unclear list of other purposes. This could be achieved by assigning ethically approved, openly published research in the public interest its own opt-out code (creating a new 9Nu6), leaving the existing 9Nu0 code for all other purposes<sup>4</sup>.

**Decisions at practice level to minimise patient concern, recognising the wishes of the majority while respecting the choices of the minority, would give patients the choice to opt-out of ethically-approved research, and the choice to opt-in for all other secondary uses.**

For patients, each should be contacted with a simple letter - the language of which would reflect whether they have already opted out, and contain updated details of the care.data programme and the choices available to that patient.

Patients who have previously opted out must have the research opt-out set by default, since they opted out of all uses - but the letter they receive would give them the option to opt back into research use. This choice is also a clear justification for re-contacting patients about a decision they have already made. Writing to everyone means that patients know what their choice is, and wider publicity can say that they will receive a letter.

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<sup>1</sup> This paper follows on from medConfidential's note to LMC conference, regarding 'Local Choice': <https://medconfidential.org/wp-content/uploads/2014/05/2014-05-15-Note-for-LMC-conference.pdf>

<sup>2</sup> MRC's (ongoing) public consultation on the use of personal health information in research: <http://www.mrc.ac.uk/public-engagement/open-meetings-and-consultations/public-consultation-on-the-use-of-personal-health-information-in-research-ongoing/> and the Wellcome Trust's Monitor, waves 1 and 2: <http://www.wellcome.ac.uk/About-us/Publications/Reports/Public-engagement/WTX058859.htm>

<sup>3</sup> The precise definition of "*bona fide* research" will need a broad range of consultation, but should at least mean a peer-reviewed project with all outputs open-access (so the patients in the study can read them), with an ethical and public interest approval process, irrespective of whether medical or public health.

<sup>4</sup> On creation, 9Nu6 should inherit the current setting of 9Nu0 for each patient.

For GPs, whether a practice is an opt-in or opt-out practice is a decision best left to each GP, in line with the original GPES principles. Practices, backed by the BMA, may decide to opt all of their patients out by default and run a practice-level opt-in. Whichever choice GPs make as the defaults for their practice, the letter to each patient allows these to be explained.

### **Proposed operation of codes**

With the creation of a new 9Nu6 code and its 9Nu7 paired code, the opt-out codes would be as follows:

#### **Existing opt-outs<sup>5</sup>:**

9Nu0 -- prevent all data flows from GP practice

9Nu1 -- allow all data flows from GP practice

9Nu4 -- prevent anything other than de-identified data from leaving HSCIC<sup>6</sup>

9Nu5 -- allow identifiable data to leave HSCIC

#### **Proposed additions:**

9Nu6 -- prevent “*bona fide* research use” data flows

9Nu7 -- allow “*bona fide* research use” data flows

All Read codes include the date that they were set, so the chronological order of codes signifies intent, which can be routinely calculated by the GPES system; 9Nu6 overrides 9Nu1/9Nu4 if set later, and 9Nu7 overrides 9Nu0/9Nu5 if set later. GPs can use this fact to set the defaults for their practice for patients who have not yet made a choice, i.e. whose Read codes are currently entirely unset, before posting the letters to their patients.

According to this proposal, **in the instance where patients are to be given the choice to opt-out of ethically-approved research, and the choice to opt-in for all other secondary uses**, this could be implemented (by GP system providers) by this sequence of steps:

1. Set 9Nu6 for all patients with 9Nu0 - honours existing objections
2. Set 9Nu7 for all patients without 9Nu0 - sets research use by default
3. Set 9Nu0 for all patients without 9Nu1 - sets opt-in for other uses
4. (Optionally, suggested by HSCIC, set 9Nu4 for those with 9Nu0)

While nationally there are four possible variants of setting, each practice will only deal with two; the default local choice made by the GP and a different letter for those who have previously expressed dissent, using 9Nu0. Whether the actual codes are given or not, the form would read something like:

- A. [9Nu0 already set] **Currently, your data will not be used for any purposes other than your direct care. If you have changed your mind, tick here to**

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<sup>5</sup> The 9Nu2/9Nu3 codes which exist seem to be unrelated to care.data.

<sup>6</sup> This is still a suboptimal choice, as it confounds the most reasonable expectation of what ‘opt out’ should mean.

**allow *bona fide* research [set 9Nu7] or tick here to allow all other uses. [set 9Nu1]**

- B. [9Nu0 not set or 9Nu1 set] **Currently your data will be used for any purposes. If you have changed your mind, tick here to allow only *bona fide* research [set 9Nu0 and 9Nu7] or tick here to allow all uses. [set 9Nu1]**

To build on the trust people clearly already have for *bona fide* research requires offering a choice that has not yet been presented. The approach we suggest is likely to deliver a far greater amount of properly-consented data than current practice-level approaches, such as CPRD, and help restore trust.

Sticking with NHS England's current 'scorched earth' approach, i.e. a single national opt-out, could provoke mass opt-out if sufficient conditions - including all legal, practical and ethical requirements - are not met.

That the government not only rejected amendments to define research use, but preferred instead to introduce a loophole that would permit commercial exploitation ("promotion of health") is not encouraging. And that NHS England has yet to commit to funding a direct letter to every patient suggests it has failed to grasp the extent and nature of the problems its decisions about care.data have caused.

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