

medConfidential note to the Review of Opt-outs announced by Lord Bethell

The National Data Opt-out process was *broken by design* when it was created.¹ And, to directly quote the “Head of Stakeholder Engagement” at NHS England, now NHSx, who said to medConfidential the day before its launch: “You are not a stakeholder”.

That culture continues,² and you can easily see the mess it has made.

A “mythbusters” page³ about the National Data Opt-out was published and cross-linked to other pages on the NHS Digital website – we raised concerns at the time, but they were ignored – and when GDPR was announced, it remained prominent, was robustly defended, and was then taken down, and then (later still) the confusing text links that remained on various pages were removed.

At each step there was an insistence that the next step ‘wasn’t necessary’ and ‘wouldn’t happen’... until it did. It would be helpful if the Review of Opt-outs covered what did happen and why, and which organisations did what – and what good medical ethics, good information governance, and good public administration *should* have done.⁴

The Government Digital Service (GDS) has a highly applicable and excellent test for digital services:⁵ you should sit the Minister down at Google (or the gov.uk or nhs.uk front page) and ask them to do the thing that the service is supposed to do. If they are unable to do it, or find it a struggle, then the Minister should not sign off on launch.

This test is a good idea, and should be followed for the National Data Opt-out service, including all relevant DHSC Ministers, and all of the relevant management hierarchies at NHS Digital – at least one of whom should (act as if they) have young children. The Review may wish to consider how this service launched and remained this bad *from 2018 to 2021*.

Headline fixes and issues

1. Law

- a. Following the precedent of the Care Act amendments in 2014,⁶ commit to placing the National Data Opt-out on a statutory footing in the forthcoming NHS / HSC Bill. (Only to be commenced after details are confirmed via an SI, after the processes of implementation are complete.)

¹ <https://medConfidential.org/2018/children/>

² <https://medConfidential.org/2021/children>

³ <https://web.archive.org/web/20210602185252/https://digital.nhs.uk/services/national-data-opt-out/mythbusting-social-media-posts>

⁴ We have suggested this replicate the Partridge Review in 2014, by two NHSD NEDs.

⁵ <https://www.gov.uk/service-manual/service-assessments/pre-july-2019-digital-service-standard#test-with-the-minister-1>

⁶ Earl Howe column 1511, amendment 262A

[https://hansard.parliament.uk/Lords/2014-05-07/debates/14050785000688/CareBill\(HL\)](https://hansard.parliament.uk/Lords/2014-05-07/debates/14050785000688/CareBill(HL))

2. Patient process

- a. The identity verification process for the online National Data Opt-out process is based on the Patient Demographics Service (PDS). Those parents or carers whose PDS entry shows they have children under the age of 16 living at home, who are registered at the same GP – after the identity verification process is complete, and after the parent or carer has made their own choice – should be *automatically* offered the option by the opt-out service to make a choice for those children that live with them. Will this be done?⁷
- b. What is the opt-out process for those patients who do not have a printer, but who have children that are not covered by part (a)?
- c. What is the opt-out process for those who do not have a printer, but who are responsible for a dependant adult?⁸
- d. What should the opt-out process be for pregnant women who give birth after the GDPR programme commences?
- e. Where else are digital pathways being used to discourage other choices?⁹

3. Researchers

- a. As part of ‘data minimisation’ in NHS Digital’s Data Access Request Service (DARS), researchers should be able to *request* data which definitively *excludes* those patients who have expressed their dissent to their data being used for purposes beyond their direct care – *even if* NHS Digital’s processes would not otherwise *require* it to do so. It should be a *researcher’s ethical choice* to be able to receive less data that is more ethically sourced than the data NHS Digital may (even lawfully) be able to give them.
- b. NHS Digital states that all decisions about GP data will be made by IGARD / PAG, and that there will be increased immediate transparency. What about CPRD’s ISAC and its 3 month ‘commercial delay’? Will CPRD data align with what patients and GPs are told, or will it continue to contradict that?¹⁰

⁷ We recognise that families may be complex in ways not visible in PDS, so there will need to be a ‘catch-all process’ for those complexities, but forcing *all* families through the current process was an act of bureaucratic malice unworthy of any claim to be in public service.

⁸ https://assets.nhs.uk/nhsuk-cms/documents/Make_and_manage_a_choice_for_someone_else_PDF_154kb.pdf

⁹ See the last section of our briefing for the Spending Review
<https://medconfidential.org/wp-content/uploads/2021/06/2021-Spending-Review-briefing.pdf>

¹⁰ With apologies for the slew of acronyms; the proliferation of these is just as confusing to patients...

4. Public confidence in the change process

- a. The Review should commit to the immediate publication of all of the agendas and minutes of the original National Data Opt-out Programme Board from its commencement to its closure.¹¹
- b. It should also commit to doing the same for the group which oversees the changes after the Review. (As we were with the independent care.data Advisory Group in 2014, medConfidential would be happy to join that group – and we believe useMYdata should be included too.)

GP dissent

5. A National Data Opt-out should imply a Type 1 opt-out

- a. NHS Digital should therefore delete the data it holds or receives on those patients who have expressed a National Data Opt-out, on ingest.
 - i. There will then, of course, need to be clear justification as to why this will be done for GP data but not hospital data, cancer registry data, etc. (Unless all are to be treated the same.)
 - b. The conflation of “direct care” and “secondary uses” will need to be *deconflated* at NHS Digital.
 - c. Many of the ‘loopholes’ (exemptions, exceptions...) in the National Data Opt-out will need to be closed.
 - d. Remove the burden from GPs
 - i. If a patient expresses a National Data Opt-out, they should also have a Type 1 opt-out added to their GP record¹² – which would also cover all *other* data flows from GPs, prior to those flows coming to an end.
6. Pseudonymisation and anonymisation is data processing, and that processing is dissentable in law. That dissent should be NDOP, which provides a legal basis for enhancing, but not removing, Type 1s.

Confusing Interactions with Direct Care changes planned in the forthcoming Health Bill

7. Shared Care Records

- a. The forthcoming Health / NHS Bill is expected to mandate Shared Care Records, which will have dissent options following existing NHSx / ICO guidance.
- b. The confusion between these new Shared Care Records (ShCRs) with the existing Summary Care Records (SuCR) *and* a new secondary care programme is likely to be significant...

¹¹ We would prefer a proactive commitment from the Government, but will FOI it all if this is not forthcoming.

¹² NHSD may argue this is impossible, but it is the data controller for the NHS App which routinely sends actionable messages to a user's GP. A Type 1 opt-out is simply an instruction from a patient to their GP.

8. Trial post-COVID SCR notifications

- a. Given DHSC's urgency to move forward, it seems sensible to trial post-COVID SCR notifications to patients from July, and to examine the effects in August.

Timescales

9. A sensible timescale; "no artificial deadlines"

- a. If the GP data programme had been good in 2013, research and planning would have had this data for nearly a decade by now. The GDPR programme *could* still be good – but, given the place from where it is now starting, that is clearly going to take some time.

Shall we make it good, this time?

Regards,
medConfidential