

medConfidential outline submission to the Goldacre Review

To be read, and to be implemented, the Review Report will have to be short.¹ In this outline we therefore submit what medConfidential believes the report should say the NHS should do, details of which can be outlined in a longer piece

Every use of data within and around² the NHS should be consensual, safe, and transparent

1) Ban dissemination, replacing it with routine analysis infrastructure and Trusted Research Environments (TREs)

Any repeat analysis that is needed should be able to be produced, automatically, without ongoing interactive access to patient-level data. Most analysis is done periodically for reports and to look for changes; services like openPrescribing should cover all routine and occasional questions for NHS bodies, and the outputs they use to make decisions be automatically created out of repeat standardised analyses, including routine pharmacovigilance. On politically contentious topics, it may be that the principle of indirect-comparability which served for PHE / Fingertips can be replicated into the medium term.

For custom analyses or investigations, and for the development of new statistics, patient-level datasets should be available only within TREs run by public bodies that are data controllers, with only those data fields that are needed for the specified analyses.

One explicit recommendation of the Review should be that, upon the Government publishing its response, NHS Digital should formally ask the Confidentiality Advisory Group at HRA for a formal view on dissemination and confidentiality – and a list of the specific scenarios in which dissemination may continue, as the NHS implements accepted Review steps.

2) Patients must be able to see which analyses are done on data about them, and the outputs and knowledge gained from these uses

Patients should be able to see which studies included data about them, and a lay person's description of the outcomes of those studies. This will help not only individuals to see the benefit of their data being included, but promote wider awareness of and engagement with the research endeavour.

Supporting issues where existing policy should be recommitted to:

3) National Data Opt-out (NDOP)

Patients who dissent from their data being used for purposes beyond their direct care must have that dissent respected; the only exception to this being where there is a legitimate,

¹ <https://www.gov.uk/government/publications/directgov-2010-and-beyond-revolution-not-evolution-a-report-by-martha-lane-fox>

² i.e. every supplier, every provider, every 'customer' - including across government and research users.

lawful reason otherwise – and all such exceptions should be exceptional, not routine.³ After the future mistake⁴, a number of candidates for which are emerging, it will unfortunately be the Goldacre Review that is blamed by those whose dissent was ignored. The Review should therefore recommend that the National Data Opt-out is placed on a statutory footing in the forthcoming NHS Bill.

The direct use of patient-level data for commissioning or decommissioning decisions should be prohibited. All such decisions should make use *only* of published statistics about patients, to maintain public confidence in the whole system.

4) Disease registers

As with the cancer registry at NHS Digital, centrally organised and managed disease registries should cover all major conditions. At the end of the pandemic, NHS England's COVID-19 Data Store should be migrated to NHS Digital as the COVID-19 Disease Registry, including all of the operational / logistics data, to allow process research. Data access should be managed via a single system⁵ across all data facilitated by the NHS.

Existing disease registry operators, including CPRD, should become 'centres of expertise' in the data they cover – with the infrastructure provided by NHSD and the National TREs.

The Health and Social Care white paper contains *no* protections against a repeat of care.data, and several suggestions that would make it easier to do so; the Review should take care that the loopholes and carve-outs do not repeat past mistakes.

To inform future debate and future Reviews

Recommendation: A 'DHSC family' data flow diagram – one of the earliest tasks that the newly formed Ministry of Justice Digital team did was to map the entire data landscape⁶ of the flows of people through the criminal justice system, and how they interacted with many different services. Preferably without analogising researchers to criminals, DHSC should commission an equivalent map / infographic showing all of the different places (to the widest extent of the DHSC family) which may make data available for research (and other secondary uses) and showing the flows of requests, and of data, between them.

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³ I.e. no more 'perpetual Section 251 support' for business-as-usual processes.

⁴ <https://medconfidential.org/wp-content/uploads/2019/10/medconfidential-nesta-radical-visions.pdf>

⁵ That single system being the one NHS Digital has by-and-large successfully run for years and throughout the pandemic, while NHS England and HDR UK singularly failed to do anything useful - much less to the standards of IG and transparency required for public trust.

⁶ <https://mojdigital.blog.gov.uk/wp-content/uploads/sites/58/2015/11/criminal-justice-services-landscape-map.jpg> via <https://mojdigital.blog.gov.uk/2015/12/01/opening-up-data-in-the-criminal-justice-system/>