



The Goldacre Review: Better, Broader, Safer: Using Health Data for Research and Analysis, April 2022

Summary response from **use MY data**

1. We share the view expressed by Professor Goldacre in his report, that our health data needs to be used more effectively to drive research and save lives.
2. The report echoes the views and frustrations of our Members, that there are unreasonable barriers to data for research, slow, confusing, inconsistent and overcomplex approvals routes, and overly risk-averse behaviours, which must be overcome. The report highlights the critical role that Trusted Research Environments (TREs) will play in this.
3. We applaud the report for its honesty. Our Transparency Principles are clear - transparency includes telling bad news as well as good, and some of the practices which Professor Goldacre has identified fall into that former category.
4. We note the supportive comments made in the report about the role of PPIE. However, as Professor Goldacre admits, “exploration of PPIE as a topic in itself was not a specific request in the terms of reference for this review, nor does the team claim to be experts in this domain”.
5. We think that urgent work is needed to clarify what “good PPIE is” at a national level and at a TRE level. This was the most serious omission from the report. Its needs to sit alongside “what a good TRE looks like”, with metrics on data usage, not just data collection. Without that, the Review seems to be about Trusts not trust. A massively missed opportunity.
6. For many years, data has meant power; whoever held the data had the power. We think TREs give the opportunity to split the ownership from the usage (i.e. to break the data=power model).
7. But we have concerns that people may use TREs to simply reinforce the existing silo mentality. Building walls of bullet-proof glass rather than armour-plate will make little difference unless the culture changes from guardianship to usage.
8. We welcome the opening up of the question as to whether Data Controllorship should be highly decentralised as now or whether there should be a move towards a single (or highly restricted small number) - a ‘National Health Data Controller’ - in order to facilitate accelerated yet better controlled research access to data

How do the recommendations in the Review map onto the views of our Members on Trusted Research Environments (TREs)?

The following are the key priority points related to TREs that our Members have previously highlighted, [shown in blue text](#). For each of these we have considered whether the review addresses them.

1. [TREs could be the single biggest prize in moving forward UK data-driven health research](#)

The Review recognises this and agrees with us.

The Goldacre Report clearly agrees with us, recommending that TREs should “become the norm”.

The Review makes calls for modernisation of NHS health data analysis processes, platforms and professions. Any implementation also needs to consider the standardisation as well as modernisation of NHS processes and platforms; many Trusts have different platforms which cannot talk to other Trusts, and there will be cost implications if changing systems is required.

“The system as a whole has huge potential. NHS data is unparalleled in its breath, depth and power.”

“We need secure, efficient platforms - and teams with skills - to unleash this potential. This will be difficult, technical work. It is inspiring to see momentum grow for better, broader, safer use of health data across so many sectors.”

“NHS data is a phenomenal resource that can revolutionise healthcare, research, and the life sciences. But data alone is not enough.”

We agree that “data alone is not enough”. The active involvement of patients and the public needs to take a much higher profile if we are to avoid the mistakes of previous failed data/technology initiatives, which paid scant regard to true involvement. We have long disproved the argument that discussions may go above the heads of patients, not least in the way that our Members play active roles across the UK. Now is the time to build on this.

2. [Patients are frustrated with unwarranted delays in access to patient data for research. TREs have a role to play to reduce these delays](#)

The Review recognises this and agrees with our concerns.

The Review reflects our concerns about the avoidable unpredictability and delays with health data access, and notes “the public support for health data research”.

In particular we liked that a set of actions were identified by Professor Goldacre, to “create one map of all approval processes; require all relevant organisations to amend it until all agree it is accurate; de-duplicate work by creating a single common application form (or standard components) for all ethics, information governance, and other access permissions; coordinate shared meetings when approval requires multiple organisations; have researchers available to address misunderstandings of their project; build institutions to help users who are blocked; recognise and address the risk of data controllers asserting access monopolies to obstruct competitors; publish data on delays annually; ensure high quality PPIE is done”.

However, we would add to this the need to publish the facts of data usage in a consistent register, and the benefits of data usage (both anticipated and realised). Where inconclusive or negative results are found these should also be recorded to help other researchers to benefit from that insight and to avoid repeating the same unhelpful research.

3. TREs offer the opportunity for much more secure and transparent uses of patient data

There is still significant work to do in this area if TREs are to operate in an open and trustworthy manner, including clear and inclusive governance.

The Review interestingly highlights another angle of transparency; that of the lack of transparency and reproducibility of most health data research. The Review identifies the need for reproducible analyses, making the analytical methods as transparent as the data uses.

But secure and transparent uses need to be supported by a strong governance framework, both national and local, which involves and empowers patients.

Further detail needs to be developed which demonstrate that the Transparency Principles developed by our Members are to be followed.

4. Different TREs must be interoperable to avoid geographical or condition-based data-silos

There is still work to do in this area, with only vague commitments and no clear timeline to achieve this. We also think a UK perspective is needed.

The Review makes a clear and justifiable call for TREs but there is less clarity about the numbers of TREs and the apparent proliferation. We might ask why is there not one TRE for all NHS data; is it not one NHS?

The Review is not clear where more than one TRE is needed, or how to deal with those that already exists. From a UK perspective, it is unclear how the Review is going to apply to other parts of the UK or be adopted outside England. We anticipate that setting the number (and standardisation) of TREs will be difficult, and that without a clear standard there will be trust issues.

On a related point, our Position Statement about being able to access our own health records, makes the point about the benefits of patients being able to request corrections to their data. In a similar vein, it is not clear from the Review how the TRE infrastructure will support any corrections to the raw data, when errors are spotted in the analytical data (or indeed how errors can be spotted, and by who).

The Review recognises the crucial question of TRE data quality and the need to invest in data curation (to improve the data quality), but it is not clear how this process would be implemented across multiple TREs each containing similar data, with the same data errors.

Consideration should be given to having researchers record their observations on the quality¹, completeness and representativeness of the data to which they have been granted access in order to help future researchers.

5. TRE "owners" should use this opportunity to develop less risk-averse processes

More work needs to be done in this area, in particular involving patients at the earliest stages to be active participants in the development of new governance, practices and solutions.

The report highlights a key problem of multiple data controlling bodies, highlighting the need to “address the problem of 160 Trusts and 6,500 GPs all acting as separate data controllers” and suggests that this could be “either through one national organisation acting as Data Controller for a copy of all NHS patients’ records in a TRE; or an ‘approvals pool’ where Trusts and GPs can nominate a single entity to review and approve requests on their behalf”.

However, the Review is not clear how patients and the public will become active participants in what could be a step-change in how we see the role of patients in data checking and data quality, in addition to data access and governance.

We also know from the published evidence that the public are least trusting of commercial users of patient data. The report notes that for commercial uses of

¹ By “quality” we would refer to [the HDR-UK Innovation Gateway definition](#).

data, “the barriers to sharing are also driven by misunderstandings about the important role of commercial innovators. This can only be addressed by a frank, systematic and open discussion with the public, explaining the work that is done with commercial partners, and building a consensus in good faith”.

The report recommends to “have a frank public conversation about commercial use of NHS data for innovation, **but only after privacy issues have been addressed** through adoption of TREs; ensure the NHS gets appropriate financial return where marketable innovations are driven by NHS data, which has been collected at great cost over many decades; avoid exclusive commercial arrangements”.

We disagree. Discussions and involvement need to be from the outset. Patients do not need to be shielded from “difficult” conversations, and should be involved in privacy conversations from the outset - we can support them through this.

6. Patients and the public must be involved in all aspects of the TRE accreditation, operations and decisions about data access

There is significant work to do in this area.

Patient involvement as outlined in the report does not clearly describe any role for patients in the overall governance processes. This must be urgently addressed with public/patient involvement in building the governance processes.

Patient engagement does not seem to mean a patient role in governance. The review recommends engaging patients on commercial access to TREs after the TREs are developed, which is too late.

7. TREs do not remove the need for transparency of usage and access

Clarity is needed about this area, not least around the patient role in governance

We have already carried out extensive work to ensure the publication of a data access and release register for the NHS Covid-19 Data Store, and we have a clear position on the need for data access and release registers.

The widespread adoption of TREs will reduce the need for routine data dissemination, but the need for transparency around access to the TREs remains. We would like to see this highlighted.

Equally, there needs to be transparency on the TRE governance, which must include all “decision making” points, such as access review panels, fair value

assessments and prioritisation. All Access Review Panels must include public representation.

8. Patient involvement must be meaningful (not tokenistic) and there needs to be public awareness of such involvement.

The Review recognises its limitations in being able to define what good involvement looks like. Significant work needs to be done in this area.

Patient engagement as described in the Review doesn't emphasise enough the need for a meaningful patient role in governance.

The review recommends engaging patients on commercial access to TREs after the TREs are developed, which is too late.

The authors do say that they aren't experts in PPIE, again reflecting the open approach that the authors have taken.

The report highlights that there could be better nationally focused PPIE ("systematic and robust"), but it doesn't give any insight as to how this might look. This is an area which use MY data would like to discuss with the review team.

Overall, the document reads like PPIE is seen an add-on towards the end of some tasks, rather than having PPIE as an embedded working practice or culture. The culture of embedding PPIE must be led from the top. The recommendations cannot be seen as purely technical. We see the technology as the easy part. We must have much more involvement and empowerment in developing solutions, or we risk perpetuating the same problems of low levels of trust.

9. Synthetic data offers a real opportunity alongside TREs and complex data

The Review doesn't address this.

10. TREs need to be affordable to run, and to be used. If they are a central resource, they should be resourced centrally

This isn't covered in the Review, and so needs to be followed up with implementation tasks, timescales, costs and responsibilities.

Whilst the Review is a well-researched summary of the issues with NHS health data access and analysis, it does not go into feasibility or indeed the cost of its long list of recommendations.

The Review does describe duplicated costs but doesn't give any indication as to how these duplicated costs could be released and "corralled" to be spent more

effectively. We hope that this is picked up by the imminent Data Strategy for Health & Social Care.

We recognise, as does the Review, that TRE operators should be able to recover the costs of servicing data access requests. We would argue that the public should get a share of any Intellectual Property (IP) generated as a result of analysis of TRE data, but we also recognise that this needs to be fully thought through (as the Department for Business, Energy & Industrial Strategy did about three or four years ago).

A further requirement for the Strategy is to be clear about what a successful TRE looks like. For instance, should there be targets on the TREs around the granting of access as well as penalties for breaches of the Five Safes?

Our final point is about central resource to plan and deliver an active communications campaign. Again, this must be addressed in the Data Strategy for Health & Social Care.