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Peer Review

Review of: "Trust and Trade: Patient Perspectives on the Ethics of Real-World Data Monetisation"

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The questions raised in this commentary reflect the questions asked by many patients about why their data should be used for secondary purposes and what mechanisms are in place to ensure that their data are used for public benefit and handled in a trustworthy manner with their confidentiality respected. I would suggest revising the title, however, as there is minimal reference to patient perspectives on the ethics of real-world monetisation, and the few patient surveys referenced may have touched on the topic of 'value' but not explored this in detail. Thus, currently, this article is framed mostly as an opinion piece with some references to support the author's arguments.

This commentary could be strengthened with deeper scholarship and analysis. There is also some misunderstanding of the appropriate regulation and regulatory bodies covering the secondary use of data. Data governance is not the remit of HTA agencies and medical product regulators. References to methodological reporting standards for RWE are also not directly relevant in this context, and all academic journals will expect a statement on the relevant ethical approval for the study (in the case of secondary use of data, this would mean stating the approvals for use of the data). In the EU and UK, the secondary use of data needs an appropriate legal basis. This does not have to be consent, and in the case of non-interventional research using real-world data, there are alternative legal support mechanisms, for e.g., in England, section 251 support that is provided by the NHS Health Research Authority's (HRA) Confidentiality Advisory Group (CAG), which includes lay representatives providing a public perspective. CAG reviews applications for the use of confidential data where seeking individual consent may not be practical, and if there is a strong justification (that balances public benefit against the challenges of seeking individual consent), section 251 support is given on the condition that there are transparency notices informing patients of the proposed use of their data, a clear opt-out mechanism, and an ongoing

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commitment to annual patient and public involvement and engagement (PPIE) exercises, with annual reporting to CAG, including a register of studies undertaken under this support. There are also obligations around patient confidentiality and reporting in case of any data incidents. See (Confidentiality Advisory Group - Health Research Authority

I outline this to illustrate that there is actually a very robust data governance framework and process in place, at least in the UK. This is only a small part of the assurance measures in place. The current version of the commentary, otherwise, can give readers who are unfamiliar with this topic the impression that there are no checks and a regulatory black hole in this area, which is not accurate.

On the matter of 'monetisation', I feel there is a nuance that is lost here, as data curation (including data pipelines and other infrastructure), data quality checks, metadata preparation, compliance with data governance, archiving, etc., all have costs that do need to be recovered. Not all data providers ‘profit’ from data and are merely covering costs. Yet, the fact of there being a data access licence fee is often interpreted as ‘monetisation’ or ‘selling’ of data. Value to the public and patients is not just derived from monetary gains but by the public health benefits yielded by research using these data. It would be good if these other forms of value were explored as well.

There is also another aspect to this topic - that of altruism. For those of us in the UK, the NHS Constitution outlines the NHS pledge to patients, but in turn, there is also an obligation on us as patients to contribute to the ongoing improvement of care by supporting evidence-based healthcare. In fact, the NHS Constitution clearly states that the NHS pledges to ‘to anonymise the information collected during the course of your treatment and use it to support research and improve care for others’. In this respect, as patients using the NHS, we are making this pledge as well. The NHS Constitution for England - GOV.UK

Regarding pharmaceutical company use of data - medical product manufacturers have a regulatory obligation to monitor the post-authorisation safety of their medical products. If they don't have access to an unbiased source of real-world data, the aim of the safety monitoring will be met only partially. Again, I know the commentary acknowledges this, but it could be made more explicit.

I hope this is received as constructive feedback to strengthen the commentary. This is because the message of this commentary has to be clear; otherwise, we risk many more people opting out of sharing their data for research and harming the integrity of the data that is used to inform public health. Already, the national opt-out statistics from November 2025 show that 5.6% of individuals in England have opted out of sharing their data for secondary research. Many don't realise that this includes the use of effectively anonymised data for public health research. Moreover, even if these individuals change their

minds later and opt back in, the technical challenge of adding them back is so resource-intensive that it is near impossible to reverse. See National Data Opt-Out open data dashboard - NHS England Digital

Declarations

Potential competing interests: I head a public sector real world data research service that provides access to anonymised healthcare data for public health research and to support statutory public health functions on a cost-recovery basis.