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Steps in using healthcare systems data as outcome data in clinical trials

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Sharon Love
Please provide a brief biography for the Presenting author(s)
I worked for many years as a trial statistician and leading a team of trial statisticians in an academic clinical trials unit and have experience of input to more than 100 trials. I moved to a trial conduct methodology role and my aim is to evidence base and disseminate information about trial conduct. One strand of work is to expose and provide solutions for the barriers to using healthcare systems data as outcome data in clinical trials.

Macey Murray
Please provide a brief biography for the Presenting author(s)
Macey is a senior researcher within the Conduct Methodology Programme at MRC Clinical Trials Unit at UCL. She is funded by Health Data Research UK (HDRUK) to develop ways to enhance the conduct of clinical trials with routinely collected healthcare systems data, and was seconded with NHS DigiTrials (NHS Digital & NHSX) to improve data access for trialists (2020-2022).

Initially trained as a medical biochemist, Macey has worked in different roles within clinical trials (phase 1-4) in industry and academia, beginning in data management, then to trial management coordinating international breast cancer trials at Imperial College London.

Between 2003 and 2015, Macey conducted research in pharmacoepidemiology and drug safety at the Centre for Paediatric Pharmacy Research, the School of Pharmacy, University of London (now UCL School of Pharmacy). She received her PhD in September 2009 for investigating the use and safety of antidepressants in young people using routinely collected primary care data. Macey participated in four European Consortia to investigate paediatric medicines use and safety, and represented the School in the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), participating in the Working Group on Guidance for Data Integration; the guidance was later incorporated into the ENCePP’s guide on methodological standards.

In 2015, Macey joined the Comprehensive Clinical Trials Unit working on two large UK multicentre trial in sexual health (HIPvac) and in acute ischaemic stroke (OPTIMAS).

Moving to a methodology research role at MRC Clinical Trials Unit in 2019 enabled Macey to bring together her extensive experience to develop ways to improve access, quality and use of healthcare systems data to enhance the conduct of trials. Funded by the HDRUK Infrastructure programme "Transforming Data for Clinical Trials", Macey collaborates closely with colleagues at Oxford, Cardiff, Dundee, and the UK HDR Alliance. Macey is also involved in national groups such as the TMRP Health Informatics Working Group's Routine Data topic group, and the Outcomes Working Group, and gives training on data access.

As of Oct 2023, Macey is the primary supervisor of a MRC-NIHR-TMRP DTP-funded PhD student, looking at the language used in participant-facing materials of trials that use or plan to use routinely collected healthcare systems data.

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Introduction

There are two main drivers for considering the use of healthcare systems data as outcome data in clinical trials. Firstly, clinical trials are financially costly and there are many benefits in bringing this cost down. Secondly, the same data is collected by trials and by government/others. This duplication is unnecessary, impacts on the quality of both sources and shows a lack of efficiency

Methods

To use healthcare systems data in clinical trials, the first action is to find and access the data. The clinical trial sponsor must demonstrate that the data used in a trial is reliable, complete and relevant. This needs to be shown before the collection of trial specific data is stopped or reduced. Here we show methods to show the provenance, integrity and utility of healthcare systems data.

Results

The provenance of healthcare systems data is shown by detailing the origins of the data, the processes and the methods by which it is produced.[1]

The integrity of the data is shown by demonstrating the extent to which the data are complete consistent, accurate and reliable throughout the data lifecycle.

The utility of the data is shown by looking for completeness and agreement between trial and healthcare systems data, followed by showing that the trial specific data and healthcare systems data give the same trial result.[2,3]

Conclusion

Healthcare systems data can be used as outcome data in clinical trials providing a series of steps to prove its validity have been completed.

1https://doi.org/10.5281/zenodo.6047155

2https://doi.org/10.1186/s13063-021-05613-x

3https://doi.org/10.1016/j.cct.2024.107514