BMJ Oncology

Embracing rapid learning in radiotherapy: feasible and acceptable with stakeholder corroboration

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To cite: Poole C. Embracing rapid learning in radiotherapy: feasible and acceptable with stakeholder corroboration. *BMJ Oncology* 2024;**3**:e000327. doi:10.1136/bmjonc-2024-000327

Linked

► http://dx.doi.org/10.1136/bmjonc-2023-000226

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In the realm of radiotherapy, evidence-based medicine is paramount in determining clinical decisions and expected patient outcomes. Randomised control trials (RCTs) are the gold standard for evaluating the safety and efficacy of cancer therapies and radiotherapy treatment strategies through robust methodological approaches. This ensures internal validity however not necessarily external validity due to strict inclusion and exclusion criteria that are applied to RCTs.[1] It is not always clear as to whether the observed treatment effect is transferable to other patient groups of different races, socioeconomic statuses and ages as often the cohorts are highly selected subsets of patients. While RCTs are invaluable for establishing, treatment efficacy, they can be limiting in their generalisability to diverse patient populations encountered in real-world scenarios.[2]

In modern healthcare, real-world data (RWD) is emerging as a new paradigm, where stored healthcare information can be used to give clinicians and researchers greater insight into diverse populations across radiation oncology that can't be accessed by RCTs.[2] RWD is defined by the US Food and Drug Admininstration (FDA) as data routinely collected from a variety of sources such as electronic health records, insurance claims, cancer registries and digital health technologies.[3] RWD seeks to analyse data on patients during their routine clinical treatment, and the optimum methodology to conduct this research is still being debated and progressed. One proposed methodology is the concept of rapid learning that incorporates the use of routine clinical data to lead to a prediction of treatment or toxicity outcomes that are evaluated and tested through an iterative process of learning cycles.[4]

Radiotherapy is one of the most technologically advanced disciplines within medicine and therefore is ideally situated to gather information from diverse sources such as electronic health records and record and verify systems that are mandatory for documenting radiation therapy treatment delivery (radiation exposure).[5] In many radiotherapy departments, change in practice is already implemented by using this gathered clinical data. An example is image-guided radiotherapy (IGRT), where there was evidence of dosimetric and geometric outcomes of radiotherapy innovation before any clinical outcomes/benefits were reported.[1] It was not ethically possible to randomise patients using an RCT for the purpose of IGRT implementation, instead the clinical change in practice was evaluated and tested through an iterative process of learning.[1] Rapid-learning methodology is explored within the literature; however, there is little known about the practicalities of its implementation within radiotherapy.

This article by Kapadi *et al*[6] explores the feasibility and ethical acceptability of implementing a rapid-learning methodology in modern radiotherapy with key stakeholders. This research is a qualitative study situated within the RAPID-RT study, designed to test the use of rapid learning of RWD to improve patient outcomes in lung cancer survival.[7] Generally, participants perceived the rapid-learning approach as having the capability to foster development in radiotherapy practice by potentially offering evidence to address existing knowledge gaps. There was a consensus among interviewees that rapid learning would complement RCTs rather than replace them, as RWD is heterogeneous (unlike well-defined control trials), with the potential for bias or uncontrolled confounding factors. Drawing from their experience, numerous stakeholders raised doubts regarding the accuracy and robustness of both clinician-reported and patient-reported data and the impact this may have

on the robustness of rapid learning in practice.[6] Kapadi *et al*[6] acknowledge that utilisation of RWD is not a novel concern and highlight that it might not be the primary limiting factor in its implementation.

A primary challenge identified across all centres was the matter of data collection, especially in smaller non-academic centres that might lack access to large volumes of diverse data. There may be a lack of expertise, clinician interest to develop and build a local evidence base across centres.[6] Many participants suggested that regulatory bodies and larger academic departments should take the lead in implementation to facilitate widespread adoption across all cancer centres, not just those with sufficient resources.[6] While examining the use of RWD, it was recognised by the authors that there is a need to contemplate the ethical implications associated with repurposing clinical data. Questions regarding the acceptability of this methodology arise due to concerns about data security, legal considerations and ownership of the data.[6] This article could have been strengthened with further exploration of ethical implications, as consent for research is a crucial point that cannot be overlooked, in addition to assessing the quality of the data.

Nevertheless, the feasibility and acceptability of RWD in radiotherapy were consistent across centres with an agreement on its potential to address research questions in radiotherapy in a timely manner and as a complement to RCTs.[6] The research community needs to advocate for the use of high-quality data in this methodology as electronic bases can provide an opportunity to improve patient outcomes.[8] Currently, funding bodies are endorsing non-randomised trials to produce high-quality real-world evidence.[7 9] In alignment with this shift, there is a requirement to enhance digital infrastructure, facilitate data sharing across organisations and provide training and education for effective implementation.[4 6]

Contributors CP is the main author of this manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval Not applicable.

Provenance and peer review Commissioned; internally peer reviewed.

Data availability statement Data sharing not applicable as no datasets generated and/or analysed for this study.

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