Identifying the training needs to inform the development of a Radiographer-led tumour measurement service for clinical trials in the UK.

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Background:

An important feature of the clinical evaluation of novel systemic cancer therapies is the assessment of disease burden, with changes in the number and size of tumours forming useful end points in a clinical trial. In addition to the clinical report provided for every examination performed in radiology, many trials require imaging to be additionally evaluated according to specific evaluation criteria to reduce variability across readers. The Response Evaluation Criteria in Solid Tumours (RECIST v1.1, Eisenhauer et al., 2009) is widely used and with adaptations in specific tumour or treatment groups such mesothelioma (Armato & Nowak, 2018) or trials involving an immunotherapy (Seymour et al., 2017).

Measurement variability decreases with experience (McErlean et al., 2013) (Tovoli et al., 2018), suggesting that the RECIST measurements would be best performed by a Radiologist, however the NHS radiologist workforce is now short-staffed by 33% (The Royal College of Radiologists, 2021) with increasing scanning workloads and additional work required to provide the measurements for clinical trials making it difficult to keep up with demand. In some centres this work is being undertaken by a mixture of staff with variations in practice across institutions.

Radiographers, allied health professionals traditionally responsible for image acquisition rather than interpretation, have established role extension to increase capacity in various roles traditionally undertaken by a radiologist. Eight in ten trusts in the UK are using Radiographers to clinically report imaging (RCR, 2021), demonstrating comparable accuracy to radiologists (Brealey et al 2005, Lockwood 2020, Woznitza et al 2018) after additional training despite fundamentally different job roles and training programmes at qualification. Several Higher Education institutions in the UK offer accredited training programmes in the more mainstream roles.

Pre-pandemic, over 65,000 cancer patients participated in clinical trials annually in the UK (The Institute of Cancer research, 2021) and developing a radiographer-led service in the clinical trial setting could relieve burden on radiologists, whilst providing a high-quality service with an efficient patient pathway. Recruitment and retention are an ongoing issue among radiographers, and the provision of role extension can increase job satisfaction and recruitment and retention in the workforce (Thom, 2018).

A Radiographer is more cost-effective than a radiologist to both train and employ. There is a national tariff associated with the RECIST evaluation (National Institute of Health Research, 2022) claimed from the trial sponsor that can be diverted to the service offering a self-sustaining financial model.

The researcher's NHS Trust, The Royal Marsden NHS foundation trust is currently supporting an existing pilot service in which 3 Radiographers (including the researcher) have received additional locally developed training to undertake these measurements at follow-up timepoints only.

Currently the result is reviewed and agreed by a Radiologist prior to release to the trial team. The Radiologist is responsible for the baseline lesion selection. It is hoped that this programme of work will inform a decision to extend the radiographer scope of practice to work more independently, as well as provide a robust evidence base for a curriculum of accredited training for such a role extension in the future.

Aim:

Traditionally the radiologist has been responsible for undertaking tumour measurements for clinical trials and the role of the radiographer in this activity has not been widely reported. Whilst intra and inter-observer variability of such measurements has been explored and established amongst radiologists (Yoon et al, 2016) (Muenzel et al, 2012) (Bellomi et al 2017), comparison of inter-observer variability between radiographers with additional training to the radiologist (accepted standard) has not.

One aim of this project is to establish the radiographer's technical accuracy when undertaking these measurements at follow-up timepoints, in comparison with radiologists to establish if there is a significant difference between the two groups. This project will also assess the radiographer's ability to select baseline target lesions that adhere to the RECIST 1.1 criteria.

A second work package will focus on establishing the training needs of the radiographers to undertake this task successfully which will be used to inform the development of a teaching curriculum moving forwards.

Methods:

Work package 1:

- Undertake a quantitative retrospective study to perform a direct comparison of measurements taken by Radiographers and Radiologists to assess inter-observer variability when performing RECIST assessments.
- Assess radiographer baseline lesion selection suitability as determined by an experienced radiologist using retrospective clinical cases.

Work package 2:

- Using online interviews, explore the experiences of the small group of radiographers nationally who are undertaking or have previously undertaken this role to gain understanding of their training as well as the barriers and opportunities afforded to them in this role.
- Recruit a group of experts, including radiologists and radiographers currently undertaking tumour measurements for clinical trials and conduct an e-Delphi consensus to establish a comprehensive list of essential and desirable training required as well as an accepted competency level.

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