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A new era for clinical trial quality assurance: A credentialing programme for RTT led adaptive radiotherapy

Introduction

In the United Kingdom (UK), radiotherapy centres have been encouraged to implement adaptive radiotherapy (ART) through clinical trials with associated quality assurance (QA) [1]. Robust image-guided radiotherapy (IGRT) protocols are key to successful radiation therapist (RTT) led ART. The accuracy of image registration and decision making by RTTs should be evaluated, prior to and following clinical implementation [2].

A unique approach to IGRT QA within clinical trials

The National Institute of Health Institute funded Radiotherapy Trials Quality Assurance (RTTQA) group to co-ordinate national clinical trials QA work in the UK [3]. Often, individual centres use clinical trial participation as a driver to implement new techniques supported by a trial protocol with comprehensive QA programmes [3–5].

The HYBRID (CRUK/12/055) trial was the first ART clinical trial in the UK and required participating centres to implement a plan of the day ART approach utilising a library of plans in bladder cancer [6]. This presented challenges of developing a multi-centre QA programme incorporating adaptive plan selection as part of the radiotherapy QA credentialing process. Previous experience from other international trial QA groups described the utilisation of phantoms with the primary focus on equipment and software procedures rather than the operator decision making processes of performing an accurate image registration and making correct adaptive plan selections [7,8]. In order to reproduce the clinical ART treatment process, the RTTQA group adopted an approach of using real patient data for a RTT-specific credentialing programme [2].

The pre-accrual QA programme incorporated the standard trial QA elements of contouring and planning benchmark cases, site visits and ongoing support with the addition of an IGRT training package and associated competency assessment tool. The latter required an environment where RTTs would perform the image analysis and subsequent plan selection using the on-line IGRT software tools they were trained on and familiar with in their own clinical setting. During accrual, QA of RTT plan selection for the first recruited patient from each centre was also implemented through review of centre submitted data. The RTT imaging competency assessment solution was the first of its kind internationally, to the author's knowledge, and centres were asked to provide feedback on this approach.

This novel QA approach has been validated by 71 RTTs from ten UK centres. In general, the entire credentialing package was well received by all centres and the users felt that it prepared them for the adaptive plan selection aspect of the trial.

Future possibilities

The level of complexity within radiotherapy trials is anticipated to increase, with the expectation of more ART incorporating multi-modality imaging. A collaborative approach, between centres, national professional bodies, international trial QA groups and equipment manufacturers, is needed to support the implementation of ART.

Through the HYBRID trial QA programme the first steps have been made to address the challenge of implementing ART within a multi-centre clinical trial. It's suggested that a multidisciplinary approach, particularly with a significant involvement of RTTs, is essential in the development of an effective credentialing programme for RTT led ART.

Author declaration

We wish to confirm that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

We confirm that the manuscript has been read and approved by all named authors and that there are no other persons who satisfied the criteria for authorship but are not listed. We further confirm that the order of authors listed in the manuscript has been approved by all of us.

We confirm that we have given due consideration to the protection of intellectual property associated with this work and that there are no impediments to publication, including the timing of publication, with respect to intellectual property. In so doing we confirm that we have followed the regulations of our institutions concerning intellectual property.

We understand that the Corresponding Author is the sole contact for the Editorial process (including Editorial Manager and direct communications with the office). He is responsible for communicating with the other authors about progress, submissions of revisions and final approval of proofs. We confirm that we have provided a current, correct email address which is accessible by the Corresponding Author and which has been configured to accept email from yatmantsang@nhs.net.

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