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Original Article

The Development of Therapeutic Radiographers in Imaging and Adaptive Radiotherapy Through Clinical Trial Quality Assurance

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Abstract

Aims: Adaptive radiotherapy (ART) is an emerging advanced treatment option for bladder cancer patients. Therapeutic radiographers (RTTs) are central to the successful delivery of this treatment. The purpose of this work was to evaluate the image-guided radiotherapy (IGRT) and ART experience of RTTs before participating in the RAIDER trial. A plan of the day (PoD) quality assurance programme was then implemented. Finally, the post-trial experience of RTTs was evaluated, together with the impact of trial quality assurance participation on their routine practice.

Materials and methods: A pre-trial questionnaire to assess the experience of the RTT staff group in IGRT and ART in bladder cancer was sent to each centre. Responses were grouped according to experience. The PoD quality assurance programme was implemented, and the RAIDER trial commenced. During stage 1 of the trial, RTTs reported difficulties in delivering PoD and the quality assurance programme was updated accordingly. A follow-up questionnaire was sent assessing experience in IGRT and ART post-trial. Any changes in routine practice were also recorded.

Results: The experience of RTTs in IGRT and ART pre-trial varied. For centres deemed to have RTTs with more experience, the initial PoD quality assurance programme was streamlined. For RTTs without ART experience, the full quality assurance programme was implemented, of which 508 RTTs completed. The quality assurance programme was updated (as the trial recruited) and it was mandated that at least one representative RTT (regardless of pre-trial experience) participated in the update in real-time. The purpose of the updated quality assurance programme was to provide further support to RTTs in delivering a complex treatment. Engagement with the updated quality assurance programme was high, with RTTs in 24/33 centres participating in the real-time online workshop. All 33 UK centres reported all RTTs reviewed the updated training offline. Post-trial, the RTTs' experience in IGRT and ART was increased.

Conclusion: Overall, 508 RTTs undertook the PoD quality assurance programme. There was a high engagement of RTTs in the PoD quality assurance programme and trial. RTTs increased their experience in IGRT and ART and subsequently updated their practice for bladder cancer and other treatment sites.

Keywords: Adaptive radiotherapy; bladder cancer; image-guided radiotherapy; radiotherapy; therapeutic radiographer

Introduction

The role of the therapeutic radiographer (RTT) in advanced radiotherapy techniques continues to evolve, as increasingly novel approaches emerge [1,2]. For bladder cancer, the 11th most common cancer in the UK [3], radiotherapy is a viable treatment option [4]. To date, conventional bladder radiotherapy has used large planning target volume margins, of 1.5–3.0 cm [1,2], with weekly volumetric imaging [5]. However, modern radiotherapy options, including plan of the day (PoD), are being clinically implemented, with RTTs central to treatment delivery. The PoD approach generates a library of plans based on population-based or individual margins [6]. Volumetric images, i.e. cone-beam computed

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tomography (CBCT) are acquired by RTTs, before each fraction and the most appropriate plan for that fraction is selected [7]. Thus, the role of the RTT extends beyond reviewing the CBCT to confirm accurate patient set-up and includes decision-making regarding plan selection.

Training programmes are essential when introducing complex radiotherapy techniques such as image-guided radiotherapy (IGRT) and PoD [8]. Previous experience suggests that the successful implementation of PoD across multiple centres requires co-ordinated training [9,10]. To introduce PoD in a clinical trial, a radiotherapy quality assurance programme facilitates training [9–11]. To date, radiotherapy quality assurance groups and trial teams have introduced quality assurance for bladder PoD trials in the UK (HYBRID NCT01810757) and in Australia/New Zealand (BOLARTNCT01142102) [9–12]. Both trials were multicentre and used a choice of three plans to treat the whole bladder [13,14]. PoD guidance and a standardised assessment module were developed for HYBRID by the National Radiotherapy Trials Quality Assurance (RTTQA) Group and HYBRID co-investigators, including representatives from The Royal Marsden Hospital [10]. Seventy-one RTTs, from 10 UK centres, completed the HYBRID quality assurance programme and all centres reported that the pre-trial PoD assessment module prepared them for PoD selections on trial [10]. For the BOLART trial, 185 RTTs completed the quality assurance programme and the Trans-Tasman Radiation Oncology Group further highlighted that the PoD selection process was improved with feedback [11,14–17].

Following the successful implementation of the HYBRID trial, the RAIDER trial (NCT02447549) was developed for patients requiring radical daily radiotherapy. This trial had the added complexity of a concomitant boost [18], which was novel for RTTs, with only one UK centre having experience of this approach before RAIDER [19]. To implement this new technique safely and accurately, a need for additional education and training for RTTs was identified. For this purpose, the PoD quality assurance programme was developed as part of the comprehensive RAIDER quality assurance programme, by the RTTQA Group and RAIDER trial development team. This built upon initial experience from the HYBRID trial [8] and BOLART trial. As RTTs participating in the RAIDER trial may already have had experience in PoD through HYBRID and BOLART, tailoring of the quality assurance programme had to be considered. This work describes the process to train RTTs in IGRT and adaptive radiotherapy (ART), within the context of a multicentre trial timeline. First, the pre-trial experience of RTTs in IGRT and ART was evaluated. Second, the PoD quality assurance programme was implemented and subsequently updated. Finally, the post-trial experience of RTTs in bladder cancer radiotherapy and other tumour sites was evaluated.

Materials and Methods

Quality Assurance and Trial Timeline

The timeline and iterative revisions of the PoD quality assurance programme were as follows:

1. Pre-trial experience of RTTs in bladder IGRT and ART assessed.
2. Pre-trial PoD quality assurance undertaken by RAIDER RTTs.
3. RAIDER recruitment commenced.
4. RTTs feedback on challenges of delivering PoD.
5. PoD quality assurance programme updated.
6. Post-trial experience of RTTs in IGRT and ART assessed.

Therapeutic Radiographers' Pre-trial Experience

A facility questionnaire was circulated to a representative RTT at centres where an interest in trial participation had been expressed. The facility questionnaire addressed ART experience, utilisation of volumetric imaging, frequency of volumetric imaging, image match process and set-up correction process. Further details can be found in Appendix A. Responses were grouped into HYBRID RTTs, BOLART RTTs and RTTs with volumetric bladder imaging experience, reflecting previous IGRT experience. The intensity of the quality assurance programme was adapted with reference to experience.

Plan of the Day Quality Assurance – Stage 1 (September 2015 to July 2017)

The PoD quality assurance programme was introduced, via a remote training session hosted by the RAIDER development team [20]. For ongoing support, the training session was recorded. Following this, the RAIDER pre-trial PoD quality assurance package, comprising PoD guidance, training cases, test cases, a standardised assessment module and access to the pre-recorded training session was circulated. The standardised assessment module was designed to test participants' plan selection against predefined gold standard PoD selections defined by a team of expert RTTs and clinicians. A pass rate of $\geq$10/12 (83%) was required. Two independent attempts of the assessment were permitted. On the third attempt, remote one-to-one training was utilised.

HYBRID RTTs and BOLART RTTs met a predefined level of training and therefore were required to review the guidance and attend and/or listen to the remote training session, as a minimum. All remaining RTTs had to complete the entire training package.

During stage 1 of the trial recruitment, RTTs reported difficulties and queries to the RTTQA Group, highlighting

the complexity of delivering tumour-focused PoD radiotherapy. As a result, the PoD quality assurance programme was revised, tailoring the programme to the needs of the RTTs.

Plan of the Day Quality Assurance – Stage 2 (August 2017 to April 2020)

In response to RTT feedback on the challenges of delivering PoD, the RAIDER PoD quality assurance programme was updated. The revised pre-trial quality assurance programme and guidance included additional case scenarios, flow diagrams to aid decision making and enhanced step by step instructions detailing the image match process and the priorities to be balanced when selecting PoD. Further support was provided through a PoD virtual workshop hosted with RAIDER RTTs regardless of their experience. On-trial PoD complex cases were presented, to illustrate the difficulty of delivering tumour-focused ART, with a dose-escalated component. This was followed by a question and answer session. An additional training video was then produced. This video was generated from the PoD workshop, presentation and question and answer session. It was mandated that all RTTs reviewed the additional training video. Subsequently, one to one training sessions (remote and in-person) were facilitated. Remote sessions were utilised for RTTs requiring support for only one patient/query. In-person sessions were utilised when support was required for multiple patients/queries.

An on-trial quality assurance programme for PoD selections was also implemented. This is a separate piece of work linked to the exploratory end points of the RAIDER trial and is therefore not further discussed here.

Therapeutic Radiographers' Post-trial Experience

A follow-up questionnaire was sent to representative RTTs at 33 recruiting centres to evaluate IGRT and ART experience post-trial. The questionnaire aimed to evaluate if participation in the pre-trial PoD quality assurance programme influenced routine practice. The questionnaire examined bladder imaging practice, routine practice for other anatomical sites including training, imaging and interventions utilised and ART and planning. Further details can be found in Appendix B.

Data Collection and Analysis

All data were retrospectively collated upon completion of recruitment to the trial.

Assessment of Therapeutic Radiographers' Experience Pre- and Post-Trial

The responses from the pre- and post-trial questionnaires from representative RTTs were reviewed, categorised and analysed with descriptive statistics. Qualitative results from the post-trial questionnaire were analysed to offer further insight and enrich findings.

Plan of the Day Quality Assurance Programme Implementation and Impact

The individual RTT assessment scores from the standardised PoD assessment module were reviewed and analysed with descriptive statistics. Median assessment scores were calculated for the first and second attempt of the PoD assessment. Remote one-to-one training was undertaken with RTTs who failed their second attempt.

Results

Therapeutic Radiographers' Pre-trial Experience

Facility questionnaires were returned from representative RTTs in 37 UK centres. This analysis focuses on the 33 responses from RTTs in centres that proceeded to participate in the trial. All returned questionnaires indicated that RTTs were delivering IGRT for bladder cancer patients; however, the experience of RTTs varied between centres. (Figure 1 and Table 1 in Appendix C).

Eleven responses had RTTs with PoD experience, with 10 gaining this experience through participation in the HYBRID trial. One response also had RTTs experienced in using tumour-focused ART. No RTTs reported utilising any alternative ART approach, e.g. real-time adaptation.

In 21 of the 33 responses, all radical bladder patients had CBCTs throughout the course of their treatment, although not all daily. Eleven responses indicated that RTTs were using CBCT for a selection of bladder patients, throughout their treatment. In the remaining response, although CBCTs were not being acquired for patients with bladder cancer pre-trial, CBCT verification was implemented by RTTs before partaking in the PoD quality assurance programme. Considering the frequency of imaging, eight of the 33 responses used daily CBCT, with five acquiring daily CBCTs for all bladder cancer patients and three responses acquired CBCTs for a selection of bladder patients.

For the image match process, 27/33 responses reported an initial review of bony anatomy on the fractions that images were taken, with an additional soft-tissue shift being undertaken when needed. For the set-up correction process, all responses reported an online correction process, on the fractions that images were taken; however, the known extent of the actions taken by RTTs is limited.

Plan of the Day Quality Assurance Programme

In total, 508 RTTs were trained and approved to undertake plan selections for RAIDER through the RAIDER PoD quality assurance programme. This represents 16% of the whole-time equivalent total National Health Service radiotherapeutic radiographic workforce [21]. In total, 461 RTTs passed the assessment on their first attempt; 39 RTTs passed the assessment on their second attempt, after personalised feedback; eight RTTs were approved on their third attempt after individualised one-to-one training.

Twenty-seven centres participated in the first remote training session with at least one representative RTT present.

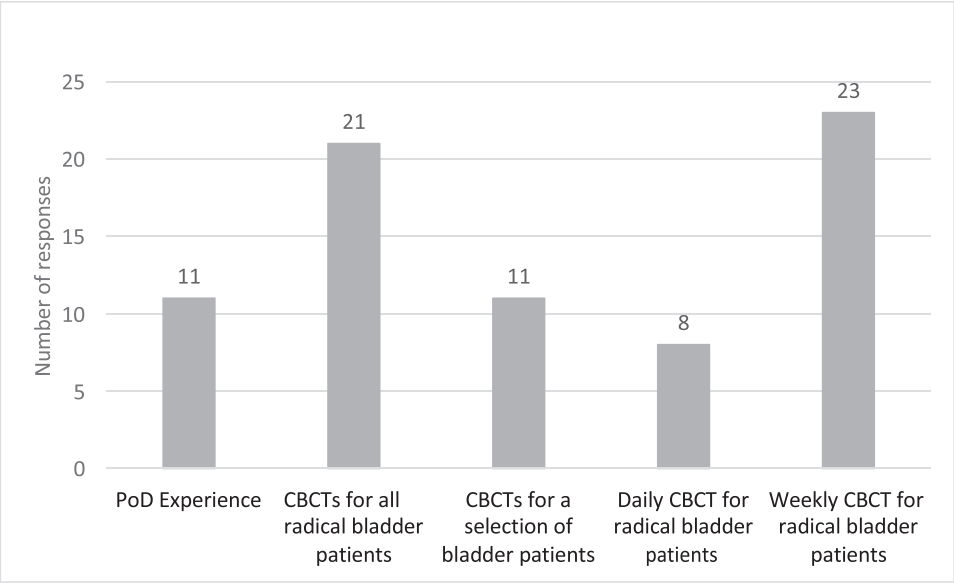

Fig 1. Pre-trial RTT experience in bladder IGRT and ART. Experience of RTT's in IGRT and ART in bladder cancer patients prior to Quality Assurance programme. Two responses not included: One response did not use CBCT, one response only for intensity modulated radiotherapy (IMRT) treatments.

RTTs in 24 UK centres participated in the PoD virtual workshop in real-time and all 33 UK RAIDER centres reported all RAIDER RTTs reviewed the additional training video at a convenient time for them. All 10 international centres (who previously participated in BOLART) also reported that RTTs reviewed the additional training video. Eight centres had one-to-one training sessions (three in-person and five virtually), with a minimum of one RTT in attendance.

Therapeutic Radiographers' Post-trial Experience

Twenty-five of 33 (75%) follow-up questionnaires were returned. There was still a mixed level of experience in bladder IGRT and ART among RTTs; however, RTTs updated their bladder practice (Figure 2 and Table 2 in Appendix D) post-trial. In 17/25 responses, RTTs answered 'yes' to questions 9 and 10 of the follow-up questionnaire. These questions queried if participating in the PoD quality assurance programme and trial changed their routine bladder IGRT. The most common change in bladder practice was a transition from weekly to daily imaging, in 12/25 responses (Figure 2).

In 21/25 responses, RTTs answered 'yes' to questions 11 and 12 of the follow-up questionnaire. These questions queried if participating in the PoD quality assurance programme and trial changed their routine radiotherapy practice for other anatomical sites (Figure 3 and Table 3 in Appendix E).

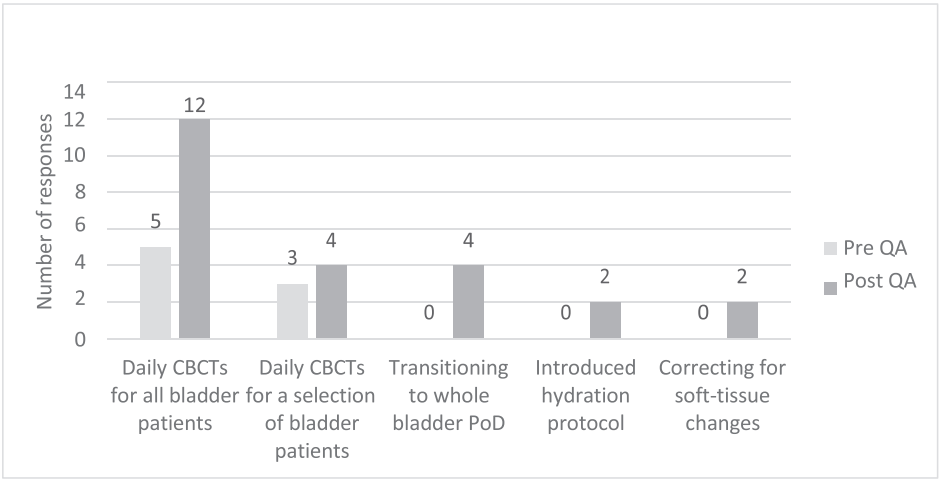

Fig 2. Post-trial RTT experience in bladder IGRT and ART. Experience of RTT's in IGRT and ART in bladder cancer patients after Quality Assurance programme.

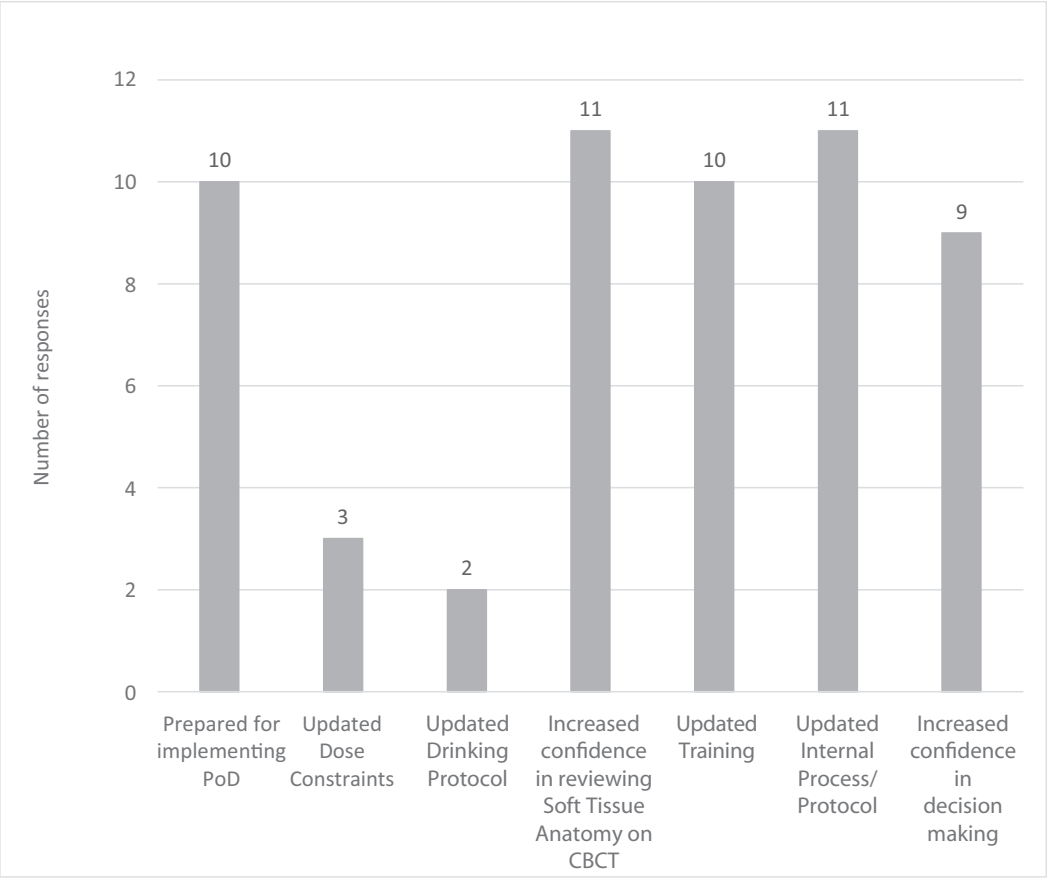

Fig 3. RTTs updates in practice in other anatomical sites post QA. Updates in practice made by RTTs in other anatomical sites after Quality Assurance programme. *Comparison with pre-trial level cannot be made as RTTQA FQ did not capture this information.

Finally, in the open-ended question 13, RTTs were given the opportunity to elaborate further on the updates they had made post-trial (only those responses that ticked 'yes' for questions 9–12). Eleven RTTs completed this open-ended question and, from a selection, it was indicated that:

"Taking part in the quality assurance programme has given radiographers more confidence reviewing soft tissue anatomy."

"The quality assurance presentations provided were very informative and useful for the therapy radiographers. Working through the practice patients with the steps provided gave a very comprehensible routine for reviewing CBCTs and explained and guided the decision making in adaptive plan of the day radiotherapy well."

"The RAIDER guidelines have influenced decisions made for drinking protocols and hydration monitoring … The adaptive protocol and work undertaken for the trial are helping shape current projects … e.g. adaptive cervix and MRI Linac."

"External review and advice on plan of the day selection have been very beneficial. It has given us reassurance and confidence in radiographer's decision making."

Discussion

This study describes the development of RTTs' skills in IGRT and ART, through participation in PoD quality assurance as part of the radiotherapy quality assurance programme for the RAIDER trial. Considering the novel radiotherapy technique utilised in RAIDER, RTTs needed guidance and support when implementing this trial. This is similar to the experience from the introduction of other new techniques in radiotherapy, e.g. intensity-modulated radiotherapy, which required time, resources and a training programme to implement [22]. Radiotherapy trials in the UK have proven to be an important mechanism to facilitate, support and accelerate the introduction of such techniques [23,24]. In introducing a novel adaptive approach, numerous challenges required time and resources to enable the safe implementation of PoD. Additionally, the programme had to be appropriate for an international multicentre trial, thus the flexibility to acknowledge previous experience through streamlining had to be considered [25]. Finally, the PoD quality assurance programme had to address the mixed experience levels of RTTs, pre-trial.

The pre-trial questionnaire showed that the baseline experience of RTTs in IGRT and ART for bladder cancer

was variable. Although HYBRID and BOLART RTTs had experience in PoD quality assurance, only one centre had RTTs experienced in delivering tumour-focused ART. Oppositely, one response had no experience in using CBCT for bladder patients, and before they could start the quality assurance programme and join the trial, they had to introduce this approach locally. Most responses had experience in taking CBCTs for bladder patients, but the frequency (e.g. daily/weekly) and utilisation (all/selection of patients) varied.

As a result, a tailored quality assurance programme was developed, reducing the quality assurance required for RTTs with PoD quality assurance experience compared with those centres with no experience. To ensure the correct level of quality assurance support was provided, the quality assurance team continued to engage with RTTs throughout the trial. This ongoing engagement with RTTs is recommended when implementing new techniques, as it appeared in RAIDER that pre-trial quality assurance training alone did not suffice. It became evident during trial recruitment that RTTs, regardless of previous experience, reported challenges in delivering tumour-focused ART. Additionally, for some RTTs, there was a time delay between undertaking the pre-trial PoD quality assurance and recruiting their first adaptive patient. In response to this, an updated quality assurance programme was produced that RTTs had to participate in.

The updated PoD quality assurance programme utilised various media forms, including text (guidance documents), visual aids (charts and flow diagrams) and videos. A major component of the updated quality assurance programme was hosting a practical training workshop with RTTs together virtually. Recent guidance recommends this approach for multicentre trial quality assurance [25]. It is in contrast to the approach taken in the HYBRID PoD quality assurance programme, where all centres were attended by the RTTQA Group in person [10]. This approach was not feasible or practical for a larger international trial. It is acknowledged that the approach in HYBRID may have allowed for more tailored training; however, the group workshop facilitated conversations among RTTs and with the quality assurance and trial team.

Overall, 508 RTTs were trained in PoD, and this was assessed by collating the results of the PoD assessment module. The RTTs completed this assessment, engaged in the workshops, fed back, discussed difficult cases and ultimately advanced their expertise in PoD. However, the questionnaires were targeted towards representative RTTs only, and were limited in their scope as they did not gauge the development of each individual RTT. Thus, the findings are generalised to the RTT staff group in each centre. It was found that, following participation in the RAIDER trial, RTTs were more confident in adaptive techniques and they reported that their decision making had improved. There was positive feedback on the quality assurance programme, describing it as useful and informative. Moreover, after completing the PoD quality assurance programme, the RTTs utilised their experience to update the treatment of not only their bladder patients but also other anatomical sites. They updated their protocols and procedures, with one centre reporting using the RAIDER training approach as a template [26]. Finally, the changes to routine practice implemented by RTTs appeared to be safe, with no RTT reporting that they had implemented the RAIDER trial approach (i.e. dose-escalated tumour focused) as the standard of care before the trial reported. It has been shown that 508 RTTs completed training in PoD ART as part of the quality assurance programme for the multicentre RAIDER trial. Twenty-one representative RTTs reported that post-trial they updated their routine bladder IGRT and routine radiotherapy practice for other anatomical sites.

Conclusion

The implementation of a programme to develop RTTs to deliver a PoD trial in bladder cancer was successful. Through this process, RTTs were not only trained in IGRT and ART for bladder cancer, but they updated their routine practice post-trial. With the introduction of more advanced radiotherapy techniques, RTTs are vital team members to be included in these developments. It is acknowledged that training is required for this purpose and methods utilised in the trial quality assurance programme, for example workshops, test cases, training documents and ongoing engagement, are suitable approaches to develop RTTs skills and knowledge.

Acknowledgements

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clon.2021.02.009.

Conflicts of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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