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This study is being completed as part of a DProf at Sheffield Hallam University.

Title of project

Clinical Reasoning in Image Guided Radiotherapy: An Observational Study

Lay summary of the project

Radiotherapy treatment plans are often complex and can incorporate hundreds of small beams of radiation. In order for the treatment to be successful the treatment must be delivered with mm accuracy.

Image Guided Radiotherapy (IGRT) has been used since the 1980's to aid the delivery of accurate radiotherapy treatment. In the last ten years traditional 2D methods of imaging have been replaced with 3D-Cone Beam Computer Tomography (CBCT) (1). This technology has been implemented quickly across the UK and there is some concern to suggest that training has not maintained pace with this implementation(2).

This technology has the been shown to improve patient outcome (3,4,5), but the full benefits of this technology can only be realised if the clinical staff using it have the skills to interpret the images and make effective clinical decisions. The evidence base lacks an understanding of how Therapeutic Radiographers (TR) makes these clinical decisions and the factors that impact on the decision making process. To address these questions an observational study will be undertaken. A sample of 15 TRs will be asked to review three image data sets while being observed . While reviewing the images participants will be asked to verbalise their thoughts using a method called Think-Aloud (TA) (6). These observations will be recorded using video equipment, and analysed using thematic analysis. Following the video analysis, interviews will be conducted to confirm the researcher's interpretations of the observations and to explore factors that may impact the decision-making process (7).

Principal Aim of the study

To investigate the clinical decision-making processes used by Therapeutic Radiographers when interpreting Image Guided Radiotherapy.

Research questions

In relation to clinical decision-making based on 3D Cone Beam CT imaging during radiotherapy:

1. What cognitive processes do Therapeutic Radiographers utilise while making clinical decisions?

2. How do Therapeutic Radiographers prioritise the clinical factors observed during Image Guided Radiotherapy?
3. How does clinical experience as a Therapeutic Radiographer influence the decision-making process?
4. How does previous experience with Image Guided Radiotherapy (2D and 3D) influence the decision-making process?
5. How do different methods of Image Guided Radiotherapy training and assessment of competence influence Therapeutic Radiographer's decision-making approach?

Outcomes

The study will fill an important gap in understanding the on the types and range of decision-making processes adopted by TRs when making clinical decisions using CBCT. This will enable the development of an evidence based educational programme for teaching decision-making for IGRT to undergraduate (UG) and postgraduate (PG) students as well providing clinical departments with the information they need to improve their IGRT workflow and protocols. These outcomes have the potential to improve patient care and reduce IGRT error rates.

Review of the literature and identification of current gap in knowledge

To achieve the desired patient outcome of optimum tumour control while minimising toxicity, it is vital that radiotherapy treatment is delivered accurately (9). This can be challenging, particularly when the tumour is in close proximity to radiation sensitive structures.

The benefits of improved accuracy during IGRT include the possibility for reducing normal tissue toxicity. This has been demonstrated in a number of tumour sites including prostate cancer where (3) demonstrated that IGRT reduced moderate toxicity by 9.6% at 3 years ($p=0.02$). Similar reductions in toxicity due to IGRT have been seen in lung (4) and head and neck cancers (5)

The implementation of this technology has not been without challenges. Evidence suggests that staff training and development have not kept pace with the fast implementation. Reporting on their IGRT Clinical Support Programme in 2013, the Society and College of Radiographers (2) highlighted that only 16 (32%) of the 50 departments they visited had satisfactory IGRT training programmes in place; 15 had no training package at all. In addition, The Health Protection Agency report in 2012 (10) on errors and near misses identified issues relating to IGRT processes of the 1353 errors submitted, 194 (14%) related to on-set imaging (i.e. IGRT), making it the second largest category by number of reports.

Clinical reasoning has been studied widely in nursing (11), physiotherapy (12) and medicine (13). There is also a growing evidence base around the decision making processes used by diagnostic radiologists and radiographers in the process of reporting on diagnostic images (14–16).

A systematic literature search on clinical reasoning in radiotherapy highlighted numerous publications discussing the implementation of IGRT (17), the use of clinical protocols in IGRT (1,18,19), the use of in-house training to support IGRT (20–22). However, there is a lack of information about how TRs make clinical decisions when interpreting on-treatment 3D images.

Methodology and method

The methodology of the study needs to reflect the focus of the research questions on how TRs give meaning and understanding to the data displayed in a 3D-CBCT image. For this reason, the methods have been developed under the paradigm of interpretivism (23).

Participants will be invited to review three anonymised patient image and data sets on an electronic software platform that they are familiar with, as they would in clinical practice. The case studies will vary in complexity and anatomical site and will be developed by the researcher and the departmental imaging lead for each of three invited Institutions prior to the observations.

The observations will be carried out using the department's training terminal, ensuring ease of familiarity. Participants will be asked to make a series of clinical judgements on the information presented to them and how they would proceed with the patient's treatment.

While reviewing the images participants will be asked to verbalise their thought processes using the Think-Aloud (TA) method. This method was developed by Ericsson and Simmon (6,24) and has been further optimised by Yang (25) and Lundgrén-Laine and Salanterä (26) for use in the clinical setting.

These observations will be video recorded, and analysed using thematic analysis. On completion of the analysis, face-to-face interviews will be conducted. The interview schedule has been developed with two aims. The researcher will review sections of the recordings with the participants and ask them questions that will to confirm the researchers interpretations of the observations. Any interpretations that are incorrect will be discussed in more detail.

A series of questions will then be asked that are aimed at gaining a greater understanding of the factors that impact on the decision-making process. These will include questions around experience and training. The interviews will be analysed using the Thematic Analysis framework proposed by Braun and Clarke (7). All coding and analysis will be carried out using NVivo 10.10 (QSR International).

The Think-Aloud method

The TA framework is used primarily in psychology (25) and requires individuals to verbalise their thought processes while carrying out a problem-based task (27). The process can be recorded using audio or video based methods,

producing a hard copy of the data that can be transcribed, coded and analysed. Throughout the observation, the researcher makes concurrent observations on body language and other subtleties that may not be picked up in the recording (6).

The TA method has its roots in cognitive psychology (28), but has been used successfully by a number of authors (29–32) in healthcare settings to understand how healthcare professionals make clinical decisions.

Prior to the case study observation, the method will be discussed with the participants and they will be invited to practice verbalising their thought processes using a simple paper-based exercise. This has been shown to improve the quality of the observation that follows, making participants more comfortable about the process (6).

Post-observation interviews

Post-observation interviews have been commonly used in TA studies based on clinical decision-making (33). A number of authors (26,31,34) have stated that the interviews strengthened the credibility, dependability and confirmability of the video interpretations. As the data in the proposed study will also be clinical, certain local processes may not be obvious to the researcher, and the interviews will be essential to fully understand the decision-making processes of the participants.

The interviews will be transcribed and analysed using the Thematic Analysis framework (7). Thematic Analysis is a widely used technique and relevant to decision-making studies (35–38). Thematic Analysis is more flexible than other methods, which are closely tied to a theoretical perspective. This renders it a useful research tool, potentially providing a detailed, yet complex account of the data (7).

Study population and sampling

Research evidence from decision-making studies from other fields suggests that an individual's experience may be significant in the decision-making processes they utilise (39), as well as the training the individual has received (40). There are two elements of experience that must be considered in the TR workforce; overall clinical experience and experience of IGRT.

A case-study approach will be undertaken using purposive sampling to recruit 10-15 participants of varying experience from three UK centres. The centres selected for the study will range in size, IGRT training methods and experience of CBCT. The participants must be voluntary, willing, capable, and competent in thinking aloud (26).

Due to the large amount of data that is generated using this method, studies typically have small participant numbers (28). 10 -15 participants is a standard

sample used in other similar studies and should be sufficient to allow the researcher to study a range of different decision-making processes (26,34,41)

Inclusion Criteria

To address the research questions, three departments will be included in the study, with variations in:

- Number of treatment units
- Experience in using CBCT
- Method of training and assessing competency in IGRT

Within each department, 3 to 5 TRs will be recruited. The study seeks to understand how experience impacts on the decision-making processes used by TRs, so participants will be recruited with varying overall experience as a TR and varying levels of IGRT experience.

An initial pilot study was conducted in October 2014 with an experienced TR and a further pilot study was conducted in April 2015 using two members of academic staff from an Higher Education Institution (HEI). These were both useful exercises and enabled the researcher to gain an understanding of the practical skills required to carry out an effective observation, interview and analysis. The participants were also asked to comment on the methods proposed in the study. They all stated that verbalisation did not impact on their ability to make decisions. The TR also commented that he often reviews images with other colleagues and so it is common practice to verbalise thought processes in clinical practice. No one found the camera and recording equipment obstructive and two of the participants said that they quickly forgot that they were being recorded.

Ethical considerations

Human participants will be involved in the study, none of whom will be categorised as vulnerable adults (42). It is envisaged that the proposed method will not cause any risk of physical or emotional harm to any of the participants and all participants will be sent a participant's information sheet explaining the aims of the study and the expectations should they choose to participate. Participants will undergo a process of informed consent prior to participating in the study (a consent form will be signed by all individuals agreeing to participate). It will be made clear that they can discuss the method or any concerns they have prior to taking part in the study. There will be no obligation to remain part of the study and consent can be withdrawn at any time without the need to give a reason.

The participant information sheet states that the aim of the study is not to assess the clinical competencies of the participants, but to gain an understanding of the processes they are using. This will be emphasised further in the pre-observation brief.

Ethical Approval for the study has been given from the Sheffield Hallam University Research Ethics Committee (Appendix 1.0), and governance approval

from the Research Departments of the three NHS Trusts involved in the study will be sought prior to the study commencing. In order to comply with the guidelines of the Sheffield Hallam University Research Ethics Committee, an Investigator Site File will be maintained for each research site.

Data security and participant anonymity will be maintained at all times. Details of all participants will be kept on a password protected secure server at the Host Institution, with the researcher being the only person with access. Data will also be backed up on two password-protected USB sticks that will be locked in different locations in the researcher's office. Participants will be numbered and only their participant number will be referred to in any documentation outside of this secure setting.

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