

## **Mark Collins**

CoRIPS Research Award £4,723.90

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.

## References

1. McNair H a., Elsworth M, Dean J, Beardmore C. Image guided radiotherapy: Current status of soft tissue imaging. *Radiography* [Internet]. Elsevier Ltd; 2014 May [cited 2014 May 8];20(2):158–61. Available from: <http://linkinghub.elsevier.com/retrieve/pii/S1078817414000054>
2. Society and College of Radiographers, Published CB. Image Guided Radiotherapy ( IGRT ) Clinical Support Programme in England 2012 -2013. 2013;1–34.
3. Zelefsky MJ, Kollmeier M, Cox B, Fidaleo A, Sperling D, Pei X, et al. Improved clinical outcomes with high-dose image guided radiotherapy compared with non-IGRT for the treatment of clinically localized prostate cancer. *Int J Radiat Oncol Biol Phys* [Internet]. Elsevier Inc; 2012 Sep 1 [cited 2014 Oct 30];84(1):125–9. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22330997>
4. Shumway D, Corbin K, Salgia R, Hoffman P, Villaflor V, Malik RM, et al. Pathologic response rates following definitive dose image-guided chemoradiotherapy and resection for locally advanced non-small cell lung cancer. *Lung Cancer* [Internet]. Elsevier Ireland Ltd; 2011 Dec [cited 2014 Oct 31];74(3):446–50. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21676484>
5. Nguyen NP, Abraham D, Desai A, Betz M, Davis R, Sroka T, et al. Impact of image-guided radiotherapy to reduce laryngeal edema following treatment for non-laryngeal and non-hypopharyngeal head and neck cancers. *Oral Oncol* [Internet]. Elsevier Ltd; 2011 Oct [cited 2014 Oct 31];47(9):900–4. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21724448>
6. Ericsson KA, Simon HA, About D, Data V. *Psychological Review*. 1980;(3).
7. Braun V, Clarke V. Using thematic analysis in psychology Using thematic analysis in psychology. 2008;(February 2013):37–41.
8. Health Protection Ag. Data Report on Radiotherapy Errors and Near Misses Report No 2. 2012.

9. The Royal College of Radiologists, Institute of Physics and Engineering in Medicine, Society and. On target : ensuring geometric accuracy in radiotherapy. London; 2008.
10. Agency HP. RTE Data Analysis : August 2011 – July 2012. 2013;(7):7–10.
11. Garrett B. Student nurses' perceptions of clinical decision-making in the final year of adult nursing studies. *Nurse Educ Pract* [Internet]. 2005 Jan [cited 2014 Aug 12];5(1):30–9. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19038176>
12. Cruz EB, Moore AP, Cross V. A qualitative study of physiotherapy final year undergraduate students' perceptions of clinical reasoning. *Man Ther* [Internet]. Elsevier Ltd; 2012 Dec [cited 2014 Aug 15];17(6):549–53. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22748202>
13. Peile E. Teaching balanced clinical decision-making in primary care: evidence-based and values-based approaches used in conjunction. *Educ Prim Care* [Internet]. 2014 Mar;25(2):67–70. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24593967>
14. Brealey S. Measuring the effects of image interpretation: an evaluative framework. *Clin Radiol* [Internet]. 2001 May [cited 2015 Apr 21];56(5):341–7. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/11384129>
15. Majid AS, Paredes ES De, Richard D, Sharma NR, Salvador X. Missed Breast Carcino- ma : Pitfalls and Pearls 1. *Radiographics*. 2003;23(4):881–95.
16. Wood BP, Deitte L. Building clinical decision-making skills. *Acad Radiol* [Internet]. AUR; 2013 Nov [cited 2014 Aug 12];20(11):1468–71. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24119361>
17. National Radiotherapy Implementation Group. National Radiotherapy Implementation Group Report Image Guided Radiotherapy ( IGRT ) Guidance for implementation and use . August 2012. 2012.
18. Korreman S, Rasch C, McNair H, Verellen D, Oelfke U, Maingon P, et al. The European Society of Therapeutic Radiology and Oncology-European Institute of Radiotherapy (ESTRO-EIR) report on 3D CT-based in-room image guidance systems: a practical and technical review and guide. *Radiother Oncol* [Internet]. Elsevier Ireland Ltd; 2010 Feb [cited 2014 May 12];94(2):129–44. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/20153908>
19. Franks KN, McNair H a. Implementation of image-guided radiotherapy. *Clin Oncol (R Coll Radiol)* [Internet]. The Royal College of Radiologists; 2012 Nov [cited 2014 May 12];24(9):625–6. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22801517>
20. Foroudi F, Pham D, Bressel M, Tongs D, Rolfo A, Styles C, et al. The utility of e-Learning to support training for a multicentre bladder online adaptive radiotherapy trial (TROG 10.01-BOLART). *Radiother Oncol* [Internet]. Elsevier Ireland Ltd; 2013 Oct [cited 2014 May 12];109(1):165–9. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23182055>

21. Li W, Harnett N, Moseley DJ, Higgins J, Chan K, Jaffray D a. Investigating User Perspective on Training and Clinical Implementation of Volumetric Imaging. *J Med Imaging Radiat Sci* [Internet]. 2010 Jun [cited 2014 Aug 10];41(2):57–65. Available from: <http://linkinghub.elsevier.com/retrieve/pii/S1939865410000068>
22. Jaffray D a, Lindsay PE, Brock KK, Deasy JO, Tomé W a. Accurate accumulation of dose for improved understanding of radiation effects in normal tissue. *Int J Radiat Oncol Biol Phys* [Internet]. 2010 Mar 1 [cited 2014 Dec 20];76(3 Suppl):S135–9. Available from: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=4041516&tool=pmcentrez&rendertype=abstract>
23. Crotty MJ: *The Foundations of Social Research: Meaning and Perspective in the Research Process* [Internet]. London: Sage; 1998 [cited 2014 Oct 15]. Available from: <http://www.amazon.co.uk/The-Foundations-Social-Research-Perspective/dp/0761961062>
24. Ericsson A, Simon H. *Protocol analysis: verbal reports as data*. Revised Edition. London: The MIT Press; 1993.
25. Yang SC. Reconceptualizing think-aloud methodology: refining the encoding and categorizing techniques via contextualized perspectives. 2003;19:95–115.
26. Lundgrén-Laine H, Salanterä S. Think-aloud technique and protocol analysis in clinical decision-making research. *Qual Health Res* [Internet]. 2010;20(4):565–75. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/19959822>
27. Someren MW, Barnard YF, Sandberg JAC. *THE THINK ALOUD METHOD A practical guide to modelling cognitive processes*. 1994.
28. Charters E. The Use of Think-aloud Methods in Qualitative Research An Introduction to Think-aloud Methods. 2003;12(2):68–82.
29. Schatschneider CW. THINKING ALOUD DURING PROBLEM SOLVING: FACILITATION EFFECTS. 1991;3(2):109–22.
30. Backlund L, Skånér Y, Montgomery H, Bring J, Strender L-E. Doctors' decision processes in a drug-prescription task: The validity of rating scales and think-aloud reports. *Organ Behav Hum Decis Process* [Internet]. 2003 May [cited 2014 Sep 16];91(1):108–17. Available from: <http://linkinghub.elsevier.com/retrieve/pii/S0749597802005290>
31. Funkesson KH, Anbäcken E-M, Ek A-C. Nurses' reasoning process during care planning taking pressure ulcer prevention as an example. A think-aloud study. *Int J Nurs Stud* [Internet]. 2007 Sep [cited 2014 Sep 16];44(7):1109–19. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/16806220>
32. Crebbin W, Beasley SW, Watters D a K. Clinical decision making: how surgeons do it. *ANZ J Surg* [Internet]. 2013 Jun [cited 2014 Jul



- 28];83(6):422–8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23638720>
33. Forsberg E, Ziegert K, Hult H, Fors U. Clinical reasoning in nursing, a think-aloud study using virtual patients - a base for an innovative assessment. *Nurse Educ Today* [Internet]. Elsevier Ltd; 2014 Apr [cited 2014 Sep 8];34(4):538–42. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23938093>
  34. Aitken LM, Marshall A, Elliott R, McKinley S. Comparison of “think aloud” and observation as data collection methods in the study of decision making regarding sedation in intensive care patients. *Int J Nurs Stud* [Internet]. Elsevier Ltd; 2011 Mar [cited 2014 Sep 8];48(3):318–25. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/21056417>
  35. Sansam K, O’Connor RJ, Neumann V, Bhakta B. Clinicians’ perspectives on decision making in lower limb amputee rehabilitation. *J Rehabil Med* [Internet]. 2014 May [cited 2015 Jan 8];46(5):447–53. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/24590358>
  36. Thorne S, Oliffe JL, Stajduhar KI. Communicating shared decision-making: cancer patient perspectives. *Patient Educ Couns* [Internet]. Elsevier Ireland Ltd; 2013 Mar [cited 2015 Jan 8];90(3):291–6. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/22464665>
  37. Chow S-J, Sciberras E, Gillam LH, Green J, Efron D. Paediatricians’ decision making about prescribing stimulant medications for children with attention-deficit/hyperactivity disorder. *Child Care Health Dev* [Internet]. 2014 May [cited 2015 Jan 8];40(3):301–8. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/23445484>
  38. Goldberg HB, Shorten A. Patient and Provider Perceptions of Decision Making About Use of Epidural Analgesia During Childbirth : A Thematic Analysis. 2014;23(3):142–51.
  39. Simmons B, Lanuza D, Fonteyn M, Hicks F, Holm K. Clinical Reasoning in Experienced Nurses. *West J Nurs Res* [Internet]. 2003 Oct 1 [cited 2014 Sep 8];25(6):701–19. Available from: <http://wjn.sagepub.com/cgi/doi/10.1177/0193945903253092>
  40. Hall KH. Reviewing intuitive decision-making and uncertainty: the implications for medical education. *Med Educ* [Internet]. 2002 Mar;36(3):216–24. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/11879511>
  41. Han K-J, Kim HS, Kim M-J, Hong K-J, Park S, Yun S-N, et al. Thinking in clinical nursing practice: a study of critical care nurses’ thinking applying the think-aloud, protocol analysis method. *Asian Nurs Res (Korean Soc Nurs Sci)* [Internet]. Korean Society of Nursing Science; 2007 Jun [cited 2014 Sep 16];1(1):68–82. Available from: <http://www.ncbi.nlm.nih.gov/pubmed/25030545>
  42. World Health Organisation. Ethical issues in Patient Safety Research. 2013.