*Journal of Radiotherapy in Practice*

**cambridge.org/jrp**

# Evaluating the effectiveness of the clinical research radiographer undertaking the on-treatment review of clinical trial patients receiving radiotherapy for prostate cancer

Stacey Murray, Terri M Gilleece and Paul H Shepherd

School of Health Sciences, Ulster University, Newtownabbey, Antrim, UK

**Original Article**

**Cite this article:** Murray S, Gilleece TM, Shepherd PH. (2019) Evaluating the effectiveness of the clinical research radiographer undertaking the on-treatment review of clinical trial patients receiving radiotherapy for prostate cancer. *Journal of Radiotherapy in Practice* **18**: 123–126. doi: 10.1017/S1460396918000626

Received: 18 July 2018
Revised: 11 October 2018
Accepted: 12 October 2018
First published online: 11 December 2018

**Key words:**
Clinical Research Radiographer (CRR); clinical trials; prostate cancer; radiotherapy; radiographer review

**Author for correspondence:**
Terri M Gilleece, School of Health Sciences, Ulster University, Shore Road, Newtownabbey, BT37 0QB, Antrim, UK. E-mail: tm.gilleece@ulster.ac.uk

## Abstract

*Background:* Radiotherapy clinical trials are at the forefront of modern-day prostate cancer patient management. Patients are reviewed during treatment by clinical oncologists or competent on-treatment review radiographers to minimise treatment toxicities. Clinical Research Radiographers (CRRs) routinely monitor and gather research data from patients participating in clinical trials. *Purpose*: The aim of this article is to evaluate the effectiveness of the CRR undertaking the on-treatment review of clinical trial patients. *Method:* An experienced CRR within the Northern Ireland Cancer Trials Network was supervised by a clinical oncologist to undertake the role of the on-treatment review of patients receiving radiotherapy for prostate cancer. The CRR explored published literature and compiled this written evaluation as part of their advanced practice learning. *Results:* The supervising clinical oncologist verified, following the planned period of supervised practice and academic study, that the CRR was competent to fulfil the role. Evidence of the beneficial synergistic impact of co-joining the roles was experienced at first hand during the undertaking of supervised practice. *Conclusion:* Co-joining the roles and responsibilities of the CRR and the on-treatment review radiographer enhanced the quality of care offered to the patients participating in clinical trials.

## Background

Radiotherapy is the treatment of choice for many early stage prostate cancer patients in the UK. Guidelines from The National Institute for Health and Care Excellence (NICE) have suggested that 35% of all prostate cancer patients will have external beam radiotherapy and hormone therapy.[1] It has been suggested that approximately one third of eligible men opt for external beam radiotherapy due to worries about their general fitness to undergo surgery, preferring to consent for a less invasive procedure.[2] The aim of prostate radiotherapy is to obtain tumour control while minimising short- or long-term side effects.[3]

Clinical research and clinical trials are central to the development of evidenced-based practice in radiotherapy and in the management of cancer patients. Prostate cancer patients remain the focus for many local, national and international radiotherapy clinical trials in the United Kingdom where around 47,000 men are diagnosed with prostate cancer annually.[4] The mortality rate for patients with prostate cancer has declined in the past decade and success can be partly attributed to the treatment and management advances made possible through effective clinical trials and research. That said, the mortality rate is significant and remains the second most common cause of cancer death in men.[5]

In Northern Ireland, the Cancer Trials Network is the main hub for cancer clinical trials and translational research activity. Within the Northern Ireland Cancer Trials Network (NICTN), therapeutic radiographers work as clinical research radiographers (CRRs) and play a vital role in the management and care of clinical trial patients. They are responsible for critical data collection and engage with clinical trial patients at every stage of their radiotherapy journey; during pre-treatment, treatment delivery and post treatment follow-up. It makes perfect sense therefore, with suitable experience and professional role development, that CRRs might also adopt the responsibility for providing the on-treatment review and management of patients throughout their radiotherapy experience. This could remove the duplication of effort as the clinical trial patients would no longer need to also be reviewed by the already well established on-treatment review radiographers or by clinical oncologists. The CRRs could in effect provide the necessary support to patients throughout their cancer journey from initial consent for a radiotherapy clinical trial, during radiotherapy treatment and on to survivorship.

Throughout the UK, there are approximately 70 known radiographers working within research at one level or another, representing only 2·5% of the total radiography workforce.[6]



CAMBRIDGE UNIVERSITY PRESS

With the limited number of radiographers working in research/clinical trials, it is not surprising that there is no published literature on the role of CRR led review. There is however published literature on the role of the radiographer led review of patients with prostate cancer—a role extension that is now well established and common place in most Radiotherapy departments. The aim of this article is to evaluate the effectiveness of the CRR undertaking the role of the on-treatment review of clinical trial patients receiving radiotherapy for prostate cancer.

## The Radiographer Led Review of Patients Receiving Radiotherapy for Prostate Cancer

In the distant past, the role of the therapeutic radiographer might have majored on the technical delivery of radiotherapy. In more recent times, the role has evolved with an ongoing drive to develop the remit of the therapeutic radiographer, promoting role extension and advancing practice. The publication of government initiatives such as the NHS plan (2000) and NHS Cancer plan (2004) were important in recognising the need for improved service and modernisation of the NHS.[7,8] The publications acted as a catalyst in advancing the role of therapeutic radiographers within their field and advancing practice that has helped improve the quality of patient care and management.

A multi-disciplinary team approach to managing and optimising patient care and treatment is firmly embedded in prostate cancer patient management.[9] Throughout the UK, therapeutic radiographers carry out the on-treatment review of prostate cancer patients during radiotherapy treatment.[10] One published paper by Colyer concluded that therapeutic radiographers, because of their inherent knowledge of the radiotherapy treatment process, are best placed to address the needs of patients during on-treatment reviews.[11] Further literature by Ellis et al. described the implementation of multi-disciplinary review clinics and concluded that radiographer led review was beneficial to the radiotherapy department in terms of streamlining services and encouraging other radiographers to undertake review training and further development.[12] There is clearly an increased focus on improving patient experience through the introduction of advanced practitioner roles within the radiography profession.

Radiotherapy treatments for prostate cancer have become significantly more sophisticated in the last decade, with the increasing role of intensity modulated radiotherapy (IMRT), image guided radiotherapy (IGRT), stereotactic ablative radiotherapy (SABR), 4D adaptive radiotherapy and brachytherapy.[9] These advances in radiotherapy technique along with developments in technology enable higher radiation absorbed doses to be delivered safely to the prostate tumour target volume without increasing the risk of side effects.[13] Research has suggested that dose escalation in external beam radiotherapy leads to improved loco-regional control, improved biochemical disease free survival, reduced bladder and bowel toxicity and overall increased survival in intermediate and high risk prostate cancer patients.[14,15] However, some patients may still experience side effects to such an extent that their quality of life is negatively impacted.[16]

The role of the review radiographer is to assess radiotherapy side effects and manage symptoms appropriately. Common urinary side effects associated with pelvic radiotherapy include increased urinary frequency, nocturia, reduced urinary flow and dysuria.[17] Treatment review requires a holistic approach as urinary symptoms can have a major impact on a patient's quality of life. Urinary symptoms not only affect a patient's physical functioning but emotional functioning, as nocturia can cause tiredness and fatigue.[17] Sometimes patients are prescribed Tamsulosin for increased urinary frequency and nocturia by the Consultant Oncologist. With the appropriate education and training, therapeutic radiographers can become qualified and undertake supplementary prescribing responsibilities. Radiographer prescribing improves the patient experience by enabling the effective and efficient prescription of medications and additionally reduces workload pinch points for the clinical oncologists.

Bowel toxicity must also be assessed throughout radiotherapy treatment. Patients may experience symptoms such as discomfort when passing a motion, urgency, diarrhoea, bleeding and mucus discharge.[17] Patients must be counselled about expected radiotherapy bowel toxicities since rectal pain and diarrhoea can have a major impact on patient quality of life. Patients who are well informed about their condition, treatment and potential side effects have a better chance of achieving a better quality of life within the constrictions of their disease.[17] Review radiographers currently have the skills to assess bowel symptoms and offer dietary advice as appropriate.

Hormone therapy is widely used in the management of prostate cancer. A study by Widmark et al. demonstrated that the addition of hormone therapy to radiotherapy for men with locally advanced/high risk prostate cancer significantly decreased overall mortality.[18] Side effects associated with hormone therapy can have a detrimental impact on patient quality of life and must be managed effectively. Common side effects associated with Luteinizing Hormone-Releasing Hormone (LHRH) agonists include hot flushes, erectile dysfunction, weight gain and loss of libido.[19] The psychological effect of taking hormones can be distressing for men and can affect patient mood and overall wellbeing. Review radiographers must be able to distinguish between hormone related side effects and radiotherapy induced toxicities and refine their knowledge and skills in order to effectively counsel patients and recommend appropriate support.

The information needs of prostate cancer patients and their families must be satisfied to ensure optimal patient care. Research by Boberg et al. highlighted that prostate cancer patients are not given sufficient information about their prostate cancer diagnosis and management plan.[20] A study by Ormerod and Jessop recommends that review radiographers should source additional specialist training and ensure closer collaboration with other staff groups in order to improve the information needs of the patient.[21] Cancer patients need time and privacy during treatment as they are often anxious about their diagnosis and treatment side effects. The role development of the radiographer led review of patients receiving radiotherapy for prostate cancer is considered to have many advantages for the patient. It helps streamline services within the radiotherapy department; allows more time and opportunity for patients to seek relevant information from trained professionals in a non-pressurised environment, lessens time pressure on clinical oncologists and overall, is considered beneficial for patients.

## CRR Role Development

The level of radiotherapy clinical trial activity throughout the UK has changed significantly since 2009, with more clinical trials being conducted than ever before.[22] The relatively current

https://doi.org/10.1017/S1460396918000626 Published online by Cambridge University Press

publication, Vision for Radiotherapy 2014–24, identifies key national objectives and highlights the expectation to embed research into radiotherapy practice and in doing so further develop and enhance clinical trial opportunities.[9] Clinical trials are important in identifying new and improved ways of delivering radiotherapy treatment and improving outcomes for prostate cancer patients. Radiotherapy clinical trials play a vital role in assessing new treatment fractionations, dose escalation regimes, chemo-radiation techniques, quality of life, toxicity and long-term survival.[22] Recent landmark prostate trials by Dearnaley et al. led to a national change in radiotherapy delivery for low/intermediate prostate cancer patients.[23] The trial randomised more than 3,200 patients between 74 Gray in 37 fractions (control arm), 60 Gray in 20 fractions and 57 Gray in 19 fractions in combination with hormone therapy. The trial concluded that 60 Gray in 20 fractions was effective in terms of progression free survival and acute or late urinary/bowel toxicities and could therefore be recommended as the new radiotherapy standard of care in the UK.[23] Prostate clinical trials are fundamental in improving patient outcomes; the aforementioned trial reduced the number of fractions/outpatient visits and simultaneously increased the radiotherapy machine availability for other patients to be treated.

Within a clinical trial, prostate cancer patients are reviewed at specific time points during radiotherapy to assess treatment toxicity, report any serious adverse events to the trial management team, offer support and enable the patient to ask questions. Patient safety is paramount within a radiotherapy clinical trial. All treatment-related toxicities must be accurately assessed and reported to the trial management team. Reporting measures are documented within each clinical trial protocol. Radiotherapy toxicity is collected using trial specific guidelines, clinical research forms, patient reported outcome measures (PROMs) and common toxicity criteria (CTC) guidelines. Traditionally, patient review within a prostate clinical trial has been undertaken by the clinical oncologist. However, there is potential scope for role development so that CRRs could be empowered to undertake the patient review within the confines of the trial specific guidelines and protocols. CRR led review has the potential to evolve with appropriate training, clinical education and supervision within a competency-based framework. The development of this role could potentially streamline patient care, improve patient information time, reduce pressures on consultants and promote further professional development of CRRs—similar advantages to those experienced by radiographers undertaking the on-treatment review of patients.

All clinical trials are governed by Good Clinical Practice guidelines (GCP).[24] GCP guidelines are based on the protection of human subjects, integrity of data, reproducibility of data and transparency of conduct.[24] These guidelines ensure that clinical trials are conducted to a high standard. Radiographers must be aware of their own personal limits, work within the confines of protocols and know when to refer on to members of the multidisciplinary team when appropriate.[25] Support from the entire medical team is required to ensure CRRs are adequately trained and competent to carry out prostate cancer patient review.

Within clinical trials PROMs and questionnaires are used to collect data. The measures are important as they give an insight into the overall patient well-being and quality of life rather than depending on the traditional administered based scoring systems such as RTOG and CTC.[26] The International Prostate Scoring System (IPSS) is an example of PROMs commonly used within prostate clinical trials. This tool consists of seven symptoms (frequency, nocturia, weak urinary stream, hesitancy, intermittency, incomplete emptying and urgency) and one urinary quality of life question. Each symptom is scored from 0 to 5, with the total IPSS being the total of all seven symptom scores.[27] The IPSS tool is particularly advantageous during radiotherapy as it is patient reported and can give a more accurate indicator of change in urinary function as treatment progresses. CRRs have expert knowledge working with quality of life tools that are used in prostate cancer trials. This has proven to be advantageous during patient review.[28] Patient side effects, not immediately apparent during face to face review were identified within PROMS and the CRR was able to recall the patient and arrange for a consultation with the Clinical Oncologist which led to the timely management of urinary function issues to the wellbeing and relief of the patient.

It is unlikely that PROMs alone could ever replace the professional review of patient quality of life assessment and management. A holistic and systematic approach is required to assess and manage radiotherapy related toxicities for prostate cancer patients. Some patients will not report symptoms during radiotherapy as they are too embarrassed or feel that nothing can be done. The review must be structured, positive and beneficial for patients. Good listening skills and excellent communication skills are essential for patient review in order to ensure that patients feel comfortable disclosing their concerns.[10] CRRs have an established relationship with clinical trial patients suggesting that this role development would promote the continuity of care and improved patient experience.

## Conclusion

CRR role development and the acquisition of advanced skills in patient review and prescribing will certainly be beneficial for patient care and management. The Society of Radiographers has outlined the necessary knowledge, skills and attributes that are required to support radiographer role development throughout the prostate cancer patient pathway.[29] Radiographers are encouraged to develop roles in areas of on-treatment review, assessment of side effects, prescribing, information giving as well as holistic support.[29] Research has already suggested that radiographer led review and the ability to provide care to patients have been associated with increased job satisfaction among radiographers and improved wellbeing for patients.[30] The development of CRR led reviews exploits the natural synergy that exists between the existing role of the CRR and that of the on-treatment review radiographer. Evidence of the beneficial synergistic impact of co-joining the roles has been realised during the undertaking of this evaluation. Reviewing PROMs collected by the CRR as part of a trial in combination with on-treatment review of toxicity metrics led to the early identification and subsequent timely management of urinary function problems. Had the roles remained disparate the review of the PROMs might not have been undertaken in real time and the reluctance of the patient to disclose problems during face to face on-treatment review would undoubtedly have led to a delay, to the detriment of the patient. Co-joining the roles, empowering the CRR to manage the on-treatment review clearly paid dividend on this occasion.

The safety and well-being of patients within a radiotherapy clinical trial are paramount and it is clear that CRRs are ideally placed to undertake the review of prostate cancer patients within clinical trials. It is essential that CRRs work within their scope of

https://doi.org/10.1017/S1460396918000626 Published online by Cambridge University Press

practice and make appropriate referrals when required. With departmental management support, education and training, this extended role can readily be established. CRR led review has the potential to improve service quality, reduce clinic waiting times, reduce pressures on consultants, streamline services as well as raise self-esteem and the profile of the CRRs within the multidisciplinary team. CRRs charged with the fulfilment of the on-treatment review of their clinical trial patients can offer an improved quality of care for the patient. All patients are deserving of the very best service possible and none more so that those individuals who have themselves given so selflessly for the advancement of radiotherapy by consenting to participate in clinical trials.

**Acknowledgements.** The authors thank the staff of the Radiotherapy Department, Northern Ireland Cancer Centre for their support.

## References

1. National Institute for Health and Care Excellence. Prostate cancer: Diagnosis and Management. NICE clinical guideline CG175 developed by the National Collaborating Centre for Cancer. 2014. https://www.nice.org.uk/guidance/cg175. Accessed 7th October 2018.
2. Anandadas C N, Clark N W, Davidson S E et al. Early prostate cancer—which treatment do men prefer and why? BJU Int 2011; 107 (11): 1762–1768.
3. Bauman G, Rumble R B, Chen J, Loblaw A, Warde P. Intensity-modulated radiotherapy in the treatment of prostate cancer. Clin Oncol 2012; 24 (7): 461–473.
4. Cancer Research UK. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/prostate-cancer. Accessed 7th October 2018.
5. Ferlay J, Soerjomataram I, Dikshit R et al. Cancer incidence and mortality worldwide: sources, methods and major patterns in GLOBOCAN 2012. Int J Cancer 2015; 136 (5): E359–E386.
6. ACORRN Research Radiographer Working Party, Russell W, McNair HA et al. Gap analysis of role definition and training needs for Therapeutic Research Radiographers in the UK. Br J Radiol 2007; 80: 693–701.
7. The Department of Health. The National Health Service Plan, a plan for investment, a plan for reform. 2000. https://navigator.health.org.uk/content/nhs-plan-plan-investment-plan-reform-2000. Accessed 7th October 2018.
8. The Department of Health, The NHS Cancer Plan and the new NHS: providing a patient centred service. 2004. http://www.wales.nhs.uk/technologymls/cymraeg/resources/pdf/cancer_nsf.pdf. Accessed 7th October 2018.
9. Cancer Research UK and NHS England. Vision for Radiotherapy 2014–2024. March 2014. https://www.cancerresearchuk.org/sites/default/files/policy_feb2014_radiotherapy_vision2014-2024_final.pdf. Accessed 7th October 2018.
10. Lee L. The role of the "on treatment" review radiographer: what are the requirements? J Radiother Pract 2008; 7: 113–131.
11. Colyer H. The role of the radiotherapy treatment review radiographer. Radiography 2000; 6: 253–260.
12. Ellis T, Ashmore L, Bray D. Multidisciplinary radiographer-led review clinics—an example of implementation. J Radiother Pract 2006; 5: 87–95.
13. Morote J, Maldonado X, Morales-Bárrera R. Prostate cancer. Clinical Medicine 2016; 146 (3): 121–127.
14. Kalbasi A, Li J, Berman A T et al. Dose-escalated irradiation and overall survival in men with nonmetastatic prostate cancer. JAMA Oncol. 2015; 1: 897–906.
15. Kim MM, Hoffman KE, Levy LB et al. Improvement in prostate cancer survival over time: a 20-year analysis. Cancer J 2012; 18 (1): 1–8.
16. Coyne K, Zhou Z, Thompson C, Versi E. The impact on health-related quality of life of stress, urge and mixed urinary incontinence. BJU Int 2003; 92 (7): 731–735.
17. Schaake W, Wiegman M E, de Groot M et al. The impact of gastrointestinal and genitourinary toxicity on health related quality of life among irradiated prostate cancer patients. Radiother Oncol 2014; 110: 284–290.
18. Widmark A, Klepp O, Solberg A et al. Endocrine treatment, with or without radiotherapy, in locally advanced prostate cancer (SPCG-7/SFUO-3): an open randomised phase III trial. Lancet 2009; 373: 301–308.
19. Kumar R J, Barqawi A, Crawford E D. Adverse events associated with hormonal therapy for prostate cancer. Rev Urol 2005; 7 (Suppl 5): S47–S443.
20. Boberg EW, Gustafson D H, Hawkins R P et al. Assessing the unmet information, support and care delivery needs of men with prostate cancer. Patient Educ Couns 2003; 49 (3): 233–242.
21. Ormerod AM, Jessop AJ. An evaluation of support of patients with prostate cancer during and beyond radiotherapy treatment. A local perspective on future provision. J Radiother Pract 2015; 14 (4): 370–377.
22. Evans C M, Burnet N G, Hall E, Huddart R A, Nutting C M, Coles C E. The Radiotherapy clinical trial research landscape in the UK between 2004 and 2013: A cross-sectional analysis. Clin Oncol 2015; 27 (9): 491–494.
23. Dearnaley D, Syndikus I, Mossop H et al. 8LBA 5 year outcomes of a phase III randomised trial of conventional or hypofractionated high dose intensity modulated radiotherapy for prostate cancer (CRUK/06/016): report from the CHHiP trial investigators group. Eur J Cancer 2015; 51 (3): S712.
24. Van Dongen AJ. Good clinical practice, a transparent way of life. A review. Comput Med Imaging Graph 2001; 25 (2): 213–216.
25. White P, McKay JC. Guidelines and legal requirements, which inform role expansion in radiography. Radiography 2002; 8 (2): 71–78.
26. Høyer M, Muren PL, Glimelius B. The evolution of radiotherapy techniques in the management of prostate cancer. Acta Oncologica 2015; 54 (6): 821–824.
27. Chin S, Hayden AJ, Gebski V, Cross S, Turner S L. Long term patient reported urinary function following external beam radiotherapy for prostate cancer. Clin Oncol 2017; 29 (7): 421–428.
28. Crowther K, Shepherd PH, Shiels P, Jain S, Mitchell D. A pilot study of patient reported outcomes evaluating treatment related symptoms and quality of life for men receiving high dose rate brAchytherapy combined with hypo-fractionated radiotherapy or hypo-fractioNated radiotherapy alone for the treatment of localised prostate cancer. tipsRO. 2018; In Press.
29. The Society and College of Radiographers. The prostate/urology specialist cancer workforce: provision of specialist therapeutic radiographers in the treatment and care of men with prostate cancer. 2015. https://www.sor.org/learning/document-library/prostateurology-specialist-cancer-workforce-provision-specialist-therapeutic-radiographers-treatment. Accessed 7th October 2018.
30. Probst H, Griffiths S. Job satisfaction of therapy radiographers in the UK: results of a phase I qualitative study. Radiography 2009; 15 (2): 146–157.

https://doi.org/10.1017/S1460396918000626 Published online by Cambridge University Press