Clinical Oncology 39 (2025) 103732

Contents lists available at ScienceDirect

Clinical Oncology

journal homepage: www.clinicaloncologyonline.net

Overview

Best Practice for Patient-centred Radiotherapy in Clinical Trials and Beyond—A National Multidisciplinary Consensus

H. Green [*][†][‡][1], R. Rieu [*][†][‡][1], F. Slevin [§][1], L. Ashmore [¶], H. Bulbeck [||], P. Gkogkou [**], S. Ingram [††], C. Kelly [‡‡‡], H. Probst [‡‡], R. Shakir [§§], T. Underwood [¶¶], J. Wolfarth [||||], M.J. Merchant [***], N.G. Burnet [†††][2] on behalf of CTRad Working Group 4

[*] *Radiotherapy Department, Royal Marsden Hospital NHS Foundation Trust, UK*
[†] *Institute of Cancer Research, UK*
[‡] *Proton Centre, University College London Hospitals, UK*
[§] *Radiotherapy Department, University of Leeds, UK*
[¶] *Lancaster Medical School, Lancaster University, Lancaster, UK*
[||] *Brainstrust Charity, Isle of Wight, UK*
[**] *Radiotherapy Department, Norfolk and Norwich University Hospital, UK*
[††] *Physics Department, The Christie Foundation NHS Trust, Manchester, UK*
[‡‡] *College of Health and Wellbeing, Sheffield Hallam University, Sheffield, UK*
[§§] *Department of Oncology, Churchill Hospital, Oxford University Hospitals NHS Foundation Trust, Oxford, UK*
[¶¶] *Radiotherapy Department, University College London, UK*
[||||] *Cancer Research Advocates Forum (CRAF-UK), UK*
[***] *Division of Cancer Sciences, Faculty of Biology, Medicine, and Health, University of Manchester, Manchester, UK*
[†††] *Proton Centre, The Christie NHS Foundation Trust, Manchester, UK*
[‡‡‡] *University of Hull, UK*

Abstract

Aims: Patient-centred radiotherapy refers to an approach where patients' needs and preferences are prioritised. Guidelines for this personalised approach are lacking. We present a multidisciplinary national consensus with the aim to provide recommendations for best practice in patient-centred radiotherapy for both clinical trials and routine practice.

Materials and methods: A multidisciplinary working group was formed, comprising of healthcare professionals and patient advocates with lived experience of radiotherapy. Three interlinking themes were identified around patient-centred radiotherapy: information, decision-making, and outcomes. Scoping reviews were carried out for each theme, considering current challenges and recommendations for best practice. Recommendations were shaped through consultation with 12 patient advocates.

Results: There is a pressing need to better support patients prior to, during, and following radiotherapy. Radiotherapy-related patient information is often complex and challenging to understand. Information resources should be cocreated with patient advocates and individualised wherever possible, including for patients from under-served groups.

Shared decision-making (SDM) processes may enhance treatment satisfaction and reduce decision-regret, but these are not widely implemented. SDM requires prepared patients, trained teams, alongside adequate resources and should be offered as per patients' preferences.

Healthcare system data offer complementary information to clinical trials, with the potential to provide additional insight into long-term benefits and risks of radiotherapy within 'real-world' conditions. Patient-reported outcome measures may provide greater insight regarding toxicity and impact on quality of life and should be used in synergy with clinician-reported outcomes. Outcome measures should be collected in the long term, and results should be widely disseminated to both the public and professional communities. Equity of access to radiotherapy, clinical trials, and survivorship services is a priority.

Author for correspondence: H. Green, Radiotherapy Department, Royal Marsden Hospital NHS Foundation Trust, UK.
E-mail address: harshani.green@nhs.net (H. Green).

[1] Joint first authors.

[2] Chair.

https://doi.org/10.1016/j.clon.2024.103732

Conclusion: Patients rightly expect more from healthcare professionals, and it is important that the radiotherapy community recognises this and embraces changes which will enhance patient-centred care. Our recommendations aim to guide best practice for patient-centred radiotherapy.

Key words*:* Clinical trials; healthcare system data; patient-centred; radiotherapy; shared decision-making

Introduction

Patients are the central focus of cancer care. Management of cancer has evolved dramatically in the last 20–30 years, with considerable technical advances in radiotherapy, surgery, and systemic anticancer therapies, and accompanied by substantial development in multimodality treatments and integration of multidisciplinary decision-making [1]. Over a similar timeframe, there has been a seismic shift in focus towards empowering patients to take an active role in decision-making. Contemporary discussions about cancer treatment often involve balancing treatment efficacy against potential for toxicities and negative impacts on health-related quality of life (HRQoL), and there remains much to learn to ensure patient-centred approaches to care are prioritised.

Patient-centred care (PCC) promotes a holistic approach that prioritises the needs, preferences, and values of individual patients [2,3]. Effective communication and fostering of collaborative and trusting relationships that support shared decision-making (SDM) are critical components for the successful delivery of PCC [4].

Radiotherapy is complex, and there is limited public understanding of its practicalities and potential benefits and risks [5]. This presents a challenge to effective delivery of radiotherapy PCC. In addition, inequalities in access to radiotherapy exist across the UK, especially for patients from under-served groups [6]. Radiotherapy centres typically provide a regional service, which may limit availability and access especially for highly specialised services such as for rare cancers or advanced radiotherapy techniques. Travel times to radiotherapy departments in England and Wales vary widely (see Supplement A). There is growing evidence that living further away from healthcare services, including radiotherapy, is associated with poorer outcomes, including reduced survival [7,8]. Additional disparities may result from differences in access to transportation, willingness to travel, ethical or cultural factors, employment factors and caring responsibilities, and the financial toxicity of treatment for individual patients [9,10].

Patient and public involvement and engagement (PPIE) describes a process of working with patients/members of the public to help to shape research and healthcare services [11]. Additional terms such as patient empowerment, participation, and activation have also emerged [12]. Furthermore, the concept of 'knowledge mobilisation' is now increasingly being adopted and refers to the merging of boundaries between knowledge producers and users, incorporating insights from various stakeholders [13]. Examples of participatory design, or codesign, of trials and services, which emphasise cocreation 'with, not for' patients, have been increasingly adopted in health care [14].

A UK national multidisciplinary working group was convened, including patient advocates from Cancer Research Advocates Forum United Kingdom (CRAF-UK), previously National Cancer Research Institute (NCRI) Advocates Forum, with lived experience of cancer and radiotherapy to develop best-practice recommendations for patient-centred radiotherapy.

Methods

The working group was convened through an open application process, coordinated by the previously NCRI, National Clinical and Translational Radiotherapy Research Group (CTRad). Our working group contained 2 patient advocates, 3 medical physicists, 2 therapeutic radiographers, 6 clinical oncologists and 1 multidisciplinary researcher with health economics expertise across multiple centres in Manchester, London, Leeds, Lancaster, Hull, Sheffield, Oxford, and Norfolk. Two initial group discussions were held virtually (28/02/2023 and 23/05/2023) to characterise the key themes considered fundamental for patient-centred radiotherapy. The following themes were developed:

Theme 1. Patient-centred information
Theme 2. Patient-centred decision-making
Theme 3. Patient-centred outcome measures

For each theme, a scoping review was performed, and further refined through sub-group consultation. The current situation, challenges and potential best-practice recommendations were considered for each theme.

Draft recommendations were subsequently presented to 12 patients and patient advocates from the National Cancer Advocates Forum through a 'Dragon's Den-style' virtual consultation on 26/01/2024. Demographics of individual patient advocates were not recorded but included a range of ages, genders, and cancer diagnoses. Engagement work to reach additional less well-represented groups was not carried out due to lack of resource. Ethical approval was obtained from Sheffield Hallam University on 29/11/2023 (Ethics Review ID: ER61126355). The meeting was funded by Science and Technology Facilities Council (Grant number: ST/S005382/1). Feedback from the consultation was used to inform the final set of recommendations.

We present a summary of the challenges and opportunities, alongside a multidisciplinary-panel national consensus and set of recommendations, for best practice in patient-centred radiotherapy to guide both clinical trials and routine practice.

Theme 1: Patient-centred Information

What Challenges Exist to Effective Information Sharing in Radiotherapy?

Patients' baseline understanding about radiotherapy is often limited, and some patients may harbour misconceptions [15–17]. The volume of information provided regarding diagnosis and treatment may be overwhelming and challenging for patients to understand and retain [18]. Information resources may contain excessive medical or technical terminology [19]. This is likely to be magnified for patients from under-served groups, including, but not limited to, patients with educational disadvantage, auditory or visual disabilities, learning difficulties, limited English-speaking proficiency, or for patients with high symptom burden [18].

Workload pressures and resource constraints may act to limit the time healthcare professionals can spend with patients. There may also be variation between radiotherapy centres concerning what information is provided, who provides it, the format of information, and when in the treatment pathway it is given. In addition, patients and clinicians may place different emphases on the relative importance of particular aspects concerning treatment [20]. Certain topics, including sexual practices and sexual orientation, may not be discussed by clinicians and patients [21,22].

Written patient information, either in paper or in online form, is commonly used as a patient education tool and to supplement clinical consultations. However, typical health literacy rates among patients mean that radiotherapy-related written patient education materials are often too complex, which could limit patient understanding [23–25]. Multiple different sources of information are available, including dedicated information produced by individual radiotherapy centres as well as more generic information from charitable and research organisations [17]. It may be confusing to understand which is the most relevant and appropriate information to access. Patients also report information overload, often citing excessive information leaflets as unhelpful [26]. Videos enable subtitles for those with hearing difficulties and can be translated. Group radiotherapy seminars can also be helpful.

Challenges also exist around survivorship once patients have completed radiotherapy and are discharged from routine treatment follow-up. Increasing numbers of patients are experiencing long-term survival following radiotherapy, with unmet needs for information and signposting to support patients regarding disease recurrence, late toxicity, and HRQoL [27–29].

What are the Potential Benefits From Effective Information Sharing?

Patients frequently experience anxiety following a cancer diagnosis [30]. Effective communication and support strategies, including provision of information about radiotherapy toxicities, can reduce patient anxiety [31]. Greater understanding of expected treatment outcomes, including anticipated toxicities, may help to frame patients' expectations [32]. Timely provision of information, education, and support may benefit both patients and radiotherapy services [33]. Well-informed patients are better prepared to effectively navigate their treatment pathway and may experience less distress, better HRQoL, and greater treatment satisfaction [34].

In addition, good-quality information can enhance self-care strategies. A previous qualitative study of patients undergoing radiotherapy reported that information provision appeared to give patients a sense of control and had a positive impact on ability to cope during treatment [35]. A feeling of preparedness for radiotherapy was highlighted as important. Crucial to this was timely delivery of information regarding treatment, a factor identified in other qualitative research into patient experience during radiotherapy [33,35]. Actively seeking treatment information may be a coping mechanism, as seen in younger patients with breast cancer [35]. This emphasises the important role that healthcare professionals can play in supporting patients to meet their own information needs. Fostering an environment where patients feel supported to ask questions ensures they benefit from focussed responses to their concerns. Recommendations for best practice are summarised in Table 1.

Treatment Summary Documents — an Example of Effective Information Sharing

Treatment summary documents contain a record of diagnosis and treatment. Ideally, these are populated iteratively along the treatment pathway and provide individualised information for patients prior to, during, and following radiotherapy. Treatment summaries can provide essential information and signposting for patients and clinicians, especially regarding disease recurrence, late toxicities, and HRQoL. In addition to addressing survivorship issues, treatment summaries can promote better communication and coordination of care between healthcare providers. Treatment summaries produced by the two UK national proton beam therapy (PBT) centres for patients discharged to local healthcare services post treatment were successfully developed following work done between key stakeholders [36]. Manually populating iterative, detailed treatment summary documents is time-consuming and challenging to implement widely in routine care. Digital technologies could be used to efficiently generate and

Table 1
Summary of multidisciplinary panel recommendations for best practice in patient-centred radiotherapy

Patient-centred information
Communication
• Individualise information wherever possible, according to prior knowledge, understanding, and information needs.
• Use lay language and avoid excessively complex terminology. Be concise and limit use of multiple leaflets and resources.
• Provide accurate information about treatment aims, outcomes, and side-effects.
• Allow sufficient time to discuss diagnosis and treatment options and their implications.
• Use a holistic approach to patient information and consider the wider psychosocial and lifestyle impacts of treatment.
• Ensure translation services are available for patients with limited English-speaking proficiency.
• Provide additional support for patients from under-served groups, including those with learning difficulties or auditory or visual disabilities.
• Individualise radiotherapy side-effects information, for example, how skin reactions may differ depending on ethnic background and skin tone.
Supporting information
• Ensure each patient is aware of their named key worker and make it clear to patients how to contact them.
• Provide supporting information using formats which are understandable and cocreated with patient advocates.
• Consider what additional information patients might need, including the practicalities of attending for treatment.
• Signpost other sources of support, such as Macmillan Cancer Support Centres, and other services, such as for financial and psychological support.
• Consider providing an iterative treatment summary document, which provides key individualised information before, during, and after treatment for patients and General Practitioners (GPs), which can also be used to signpost during survivorship.
Patient-centred decision-making
• View SDM as an ongoing process before, during, and after treatment that can empower patients to be active participants in their care, improve treatment satisfaction, and reduce patient distress.
• Discuss potential benefits and risks of different treatment approaches, check understanding, revisit complex topics, encourage questions, and allow appropriate time for reflection to inform decision-making.
• Actively address patient ideas, concerns, and expectations, to inform the SDM processes—use power questions such as 'what is most important to you?'
• Offer SDM as per patients' preferences. Implement validated SDM tools and provide access to SDM training for clinicians.
Patient-centred outcome measures
• Work collaboratively with patient and public involvement representatives when considering the design of radiotherapy services and clinical trials.
• Address inequalities of access to clinical trials and encourage wider dissemination of the potential benefits of participating in research to healthcare professionals and the public.
• Consider implementation of patient-reported toxicity and quality-of-life assessments, including as part of long-term follow-up following radiotherapy.
• Develop national guidance for the standardisation and implementation of validated patient-reported outcome measure instruments.
• Routinely collect longer-term clinically relevant efficacy and toxicity outcome data.
• Address barriers to the standardised collection, integration, and analysis of multicentre real-world data.
• Use healthcare system data to understand and tackle barriers where inequalities exist for under-served patient groups.

SDM, shared decision-making.

populate up-to-date individualised patient records [37]. Recommendations for content are available, but there remains variation in the routine adoption and information provided within treatment summaries across different centres [38]. Guidance for radiotherapy-related treatment summaries is shown in Figure 1.

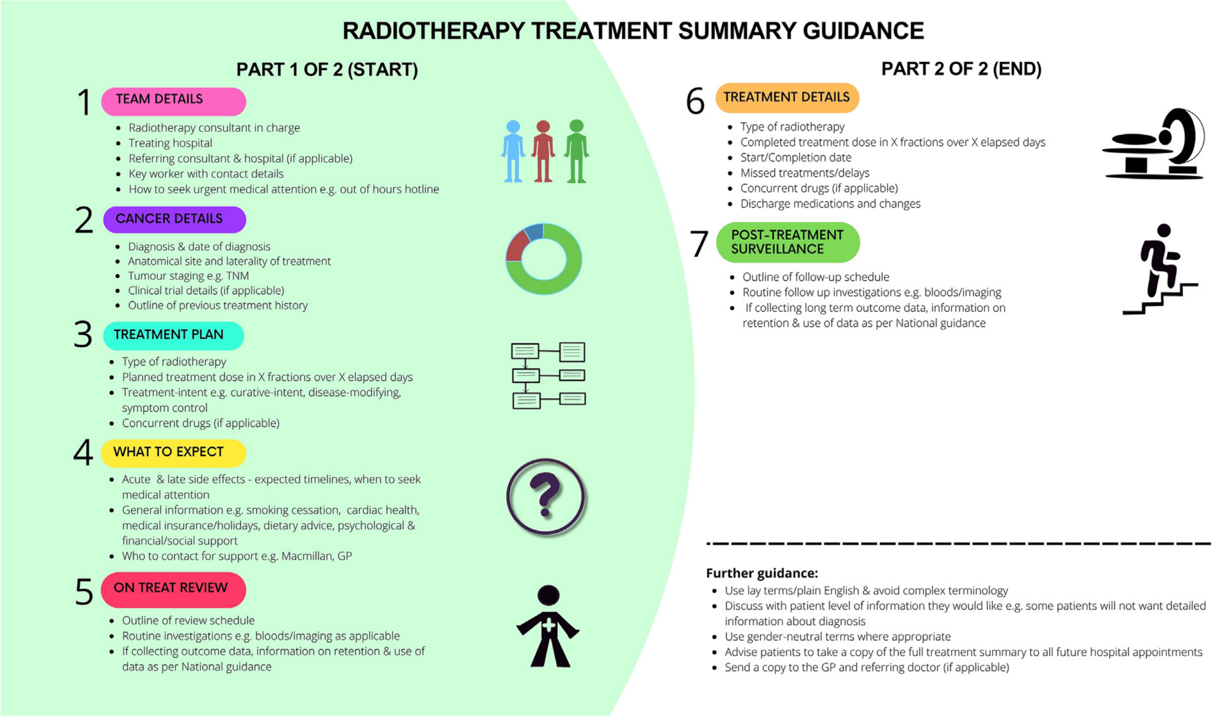
Theme 2: Patient-centred Decision-Making

How are Decisions Made in Current Clinical Practice?

There is relatively little published literature about how decisions are made, or patients' preferences for engaging in decision-making, about radiotherapy in current clinical practice. Decisions about radiotherapy occur within a variety of contexts, and even within the same context, each patient brings their own values, preferences, and life experience. Individuals may have different priorities depending on whether, for example, intent of treatment is cure, disease modification, or symptom palliation. Willingness of patients to be involved in treatment decisions can also be influenced by the urgency of cancer treatment. There is no single approach that suits all decision-making about radiotherapy. SDM, a collaborative process that involves patients and clinicians working together to reach joint decisions about care, may support patients to make a decision that is right for them [39,40].

Opportunities and Challenges to Shared Decision-Making for Radiotherapy

Evidence suggests that patients in the UK do wish to be more involved in treatment decisions [39,41,42]. A collaborative approach, with prepared patients, would encourage both clinicians and patients to share insights, concerns, and



RADIOTHERAPY TREATMENT SUMMARY GUIDANCE

PART 1 OF 2 (START)

1 TEAM DETAILS
- Radiotherapy consultant in charge
- Treating hospital
- Referring consultant & hospital (if applicable)
- Key worker with contact details
- How to seek urgent medical attention e.g. out of hours hotline

2 CANCER DETAILS
- Diagnosis & date of diagnosis
- Anatomical site and laterality of treatment
- Tumour staging e.g. TNM
- Clinical trial details (if applicable)
- Outline of previous treatment history

3 TREATMENT PLAN
- Type of radiotherapy
- Planned treatment dose in X fractions over X elapsed days
- Treatment-intent e.g. curative-intent, disease-modifying, symptom control
- Concurrent drugs (if applicable)

4 WHAT TO EXPECT
- Acute & late side effects - expected timelines, when to seek medical attention
- General information e.g. smoking cessation, cardiac health, medical insurance/holidays, dietary advice, psychological & financial/social support
- Who to contact for support e.g. Macmillan, GP

5 ON TREAT REVIEW
- Outline of review schedule
- Routine investigations e.g. bloods/imaging as applicable
- If collecting outcome data, information on retention & use of data as per National guidance

PART 2 OF 2 (END)

6 TREATMENT DETAILS
- Type of radiotherapy
- Completed treatment dose in X fractions over X elapsed days
- Start/Completion date
- Missed treatments/delays
- Concurrent drugs (if applicable)
- Discharge medications and changes

7 POST-TREATMENT SURVEILLANCE
- Outline of follow-up schedule
- Routine follow up investigations e.g. bloods/imaging
- If collecting long term outcome data, information on retention & use of data as per National guidance

Further guidance:
- Use lay terms/plain English & avoid complex terminology
- Discuss with patient level of information they would like e.g. some patients will not want detailed information about diagnosis
- Use gender-neutral terms where appropriate
- Advise patients to take a copy of the full treatment summary to all future hospital appointments
- Send a copy to the GP and referring doctor (if applicable)

Fig 1. Example of a treatment summary document which ideally should be populated iteratively: Part 1 is for start of treatment, and Part 2 is for end of treatment (EOT). Digital technologies could be used to create a record specific to each individual patient, which could be used by the patient as well as by healthcare professionals (HCPs). The example is based on EOT summaries created by the UK National proton beam therapy service—the Christie Hospital and University College Hospital London. Image created using Canva Pro software Version 1.88.0. TNM: Tumour, Node, Metastasis, GP: General Practitioner.

decision-making responsibilities. To facilitate this, clinicians must understand individuals' needs, and tailor presentation of information accordingly. Presenting information in methodically segmented tiers, starting from basic concepts then building up detail alongside careful timing of information giving, could further empower patients to be involved in decision-making [14]. Information provided before consultation could facilitate more active engagement and decision-making.

Decision-making processes require patients to imagine their future state, including potential impacts from disease and/or treatments on HRQoL. A holistic approach is key to understand what matters to patients, their values, context, and appetite for risk. Patients are the expert on themselves; engaging them in SDM generates insights, shifts dynamics, and facilitates PCC.

SDM requires supportive systems, trained teams, and prepared patients. Opportunities should be provided for patients to be informed about treatment options and their practicalities, benefits, and risks. Adequate time is required to process well-presented information and engage in open conversations. Clinical equipoise is key, and various options should be described where available, inclusive of trials. Tools such as option grids, tailored talks, and peer support from others who have had a similar experience can help patients to be better informed and therefore more able to be an active participant in treatment decisions. Importantly, simply focussing on SDM tools without an accompanying holistic approach could reduce patient-centredness, undermining its contribution to care [43].

SDM is not the same as giving patients the burden of responsibility for radiotherapy decisions. SDM should be interactional, an opportunity for healthcare professionals to share evidence for potential benefits and risks of radiotherapy and for individuals to weigh these up in the context of their own preferences. The 'right' treatment decision will depend on the individual. It is important for healthcare professionals to ask the powerful questions, such as "What is important to you?" and "What are you most struggling with?" Tools, including holistic needs' assessments, can help provide a voice for patients' needs, values, and preferences [40]. Without understanding these, it is difficult to ascertain their impact on that person's decision-making or, in fact, their preferences regarding involvement in decision-making and discussions about treatment [40].

There are barriers to integrating SDM into routine practice. These include patients' knowledge about radiotherapy, power-imbalance in doctor–patient relationships, and time pressures, perceived or real, in which decisions are made [44]. For healthcare professionals, time and resource constraints are a challenge, particularly as there is a 15% shortfall of Clinical Oncology consultants and an 8.9%

shortfall of therapeutic radiographers in England [45,46]. Difficulty identifying which validated tools to use may be another limiting factor [47].

Minimising Risk of Decision Regret

Decisions about radiotherapy, and other cancer treatments, often carry profound implications. Open channels of communication, whereby patients can voice uncertainties, seek clarifications, or simply talk through thought processes, play an instrumental role. Such engagement not only fosters a sense of trust but also solidifies the support framework that patients can lean on during radiotherapy [48,49]. Avoiding decision regret goes beyond just providing information; patients need to understand their options and potential consequences thoroughly. Time for reflection is essential, especially in contexts where the decision is whether to opt for radiotherapy or not [48,49]. Continuous dialogue, reassurance, and opportunities to revisit and discuss doubts are vital [48–50]. This can ensure decisions are not made hastily or under undue pressure but rather from a position of informed contemplation. Time taken to contemplate decisions does, however, need to be considered in the context that delays to radiotherapy can allow cancers to progress, potentially worsening outcomes post treatment [51–54]. SDM could also be supported through patient navigation, a promising strategy where trained volunteers or healthcare and social care professionals support people with cancer when moving through the healthcare system [55]. ‘Navigators’ aim to offer support, bridging hospital and community services, whilst providing companionship and continuity of care. This approach is being evaluated through various international programmes including EU Navigate, the Canadian initiative Navigation: Connecting, Advocating, Resourcing, Engaging (Nav-CARE) and within US Cancer Moonshot [55–57].

Theme 3: Patient-centred Outcome Measures

There is an ever-expanding range of outcome measures and data sources available to healthcare professionals and investigators, including clinical trial databases and healthcare system data (HSD). Randomised controlled trials (RCTs) remain the gold standard to evaluate new clinical management strategies, but there remain variations in access and engagement in trials across the UK. Evidence indicates that research-active organisations have better patient care outcomes, including reduced deaths and improved cancer survival outcomes [58–61]. Wider dissemination of information around clinical trials and education regarding potential benefits for participants and/or future patients is crucial. HSD are data collected outside of tightly controlled clinical trial environments and may be useful when RCTs are not feasible [61–64]. In addition, HSD can provide complementary data, with potential to provide insights into longer-term risks and benefits of radiotherapy and for patient groups less well represented within trial populations. HSD have the potential to offer novel insights to personalise treatment discussions and decisions regarding radiotherapy, stratified by patient demographics, clinicopathological features, treatment, and outcome data [65]. These outcome data must include long-term tumour and toxicity outcomes to better understand the impacts of treatment on patients. However, challenges remain regarding standardised recording, curation, access, privacy, storage, interpretation, and utilisation of HSD. Recognising such limitations, adapting study design, and using RCT data synergistically where possible, will maximise clinically meaningful research outputs [66]. Potential advantages and disadvantages of RCT versus HSD, and the use of clinician-reported outcomes versus patient-reported outcomes, are summarised in Table 2.

Patient-Reported Outcome Measures

A narrow focus on clinician-reported data will fail to provide a nuanced perspective regarding the impact of a disease and its treatment on an individual patient. It is important to set about reframing the problem of measuring quality of life so that we are measuring the presence, rather than the absence, of health [67]. Data suggest that clinician-reported radiotherapy toxicities can under-report side-effects [68–70]. Patient-reported outcome measures (PROMs) may provide greater insight into the true burden of treatment-related toxicities including impact of these on HRQoL and are integral to understanding how radiotherapy impacts patients [67,71,72]. Aggregation of PROM-based data within/between institutions has potential to provide long-term insights into radiotherapy outcomes. PROMs are increasingly integrated into clinical trials but are not yet widely implemented in routine clinical practice [73,74]. Challenges to routine use of PROMs include uncertainties regarding the most appropriate instruments and their format, how to manage and promptly act on clinically important responses, and how to support engagement by patients from under-served groups. National guidance regarding use of PROMs for radiotherapy would support their implementation and facilitate long-term routine collection [75].

The Promise of HSD

HSD are any information collected outside a tightly controlled clinical trial environment and can be used synonymously with real-world evidence (RWE). HSD provide a unique perspective on cancer care, shifting from ideal conditions using fixed regimens and treatment schedules to real-world conditions. This arguably adds considerable value when sharing information with individual patients to inform decisions. Such studies are typically less resource- and cost-intensive than trials and may produce results which better reflect the wider population [76]. Furthermore, patient-wearable devices may contribute precise, real-time personal health tracking data over prolonged time periods [77,78] yet challenges remain as to how to best manage and utilise such data. Through prolonged follow-up programmes, HSD could facilitate deeper understanding of

Table 2

Potential advantages and disadvantages of randomised controlled trials (RCTs) versus healthcare systems data (HSD),and the use of clinician-reported outcomes versus patient-reported outcomes

	Data source		Types of data	
	Healthcare systems data	Trial data	Patient-reported outcomes	Clinician-reported outcomes
Examples	e.g., National Registry Datasets (e.g., Radiotherapy Data Set, RTDS)	e.g., RCTs	e.g., disease-specific, or overall quality-of-life questionnaires.	e.g., Common Terminology Criteria for Adverse Events (CTCAE) toxicity scores
Potential advantages	• Large sample size • Maximises representativeness (covers population) • Potential for longitudinal data • Can identify disparities in care, e.g., across different patient demographics/geographic locations • Efficient: less time and resource intense • Less of a financial burden • Permits analysis of rare cancers or subtypes • Databases are iterative and can adapt in good time and a low cost	• Gold standard, allows causal determination • Minimisation of bias by randomisation ± blinding (limits confounding factors, enhances internal validity) • Highly monitored protocol-based care, often with integrated quality assurance • Standardised data collection • Continuous, contemporary safety monitoring enables early detection of adverse/unexpected events	• Patient-centred care—prioritise the patient's perspective, promotes shared decision-making • May identify patient unmet needs • Allows comprehensive assessment capturing symptoms, quality of life, functional status, and side-effects, useful for cost-effectiveness • Early symptom detection • Improves patient and medical team communication, supports personalisation of care	• Standardised assessment guidelines, most objective • Commonly used, comparison (e.g., between trials/treatments) possible • Objective assessment of clinical parameters • Real-time monitoring
Potential disadvantages	• Knowledge of data, access, and costs is limited • Data access may lead to delay • Incomplete/missing data • Integrity and provenance: data quality may be affected by errors in coding or data entry. • Reporting variability—data collection practices/standards may vary across institutions. • Inconsistent definitions may limit ability to combine across registries. • Limited clinical details—e.g., lack of specific treatment protocols. • Temporal changes—changes in control over time or may not reflect current guidelines • Lack of randomisation—confounding variables affect validity of associations in research. • Limited ability to assess care quality, e.g., adherence to best practice. • Onward data sharing and confidentiality factors to be considered • Need for sustainable infrastructure. • Different registry databases across UK/devolved nations.	• Limited generalisability due to strict inclusion and exclusion criteria • Limited sample size • Significant financial investment • Time- and resource-intensive; sensitive to evolution of standard of care treatment • Limited follow-up (e.g., due to costs) • May not be possible/feasible for some patient cohorts (e.g., rare tumours, where there are ethical concerns in randomisation, late effects). • Blinding challenges: often not possible/ethical to blind participants in RT trials—may introduce bias. • Interference from cross over from one treatment arm to another • Challenge to design with increasingly complex cancer pathways and personalisation of treatments.	• There is no universal approach. There are many different PROM tools, and not all are validated. • Subjective nature—influenced by individual perceptions, bias, and emotional states. • Response bias: may be influenced by concerns about judgement or fear of impact on treatment. • Variability of reporting, especially over time. • Cultural and language barriers may exclude some patient groups • May lack clinical context: e.g., disease recurrence, comorbidities, other confounding factors. • Time- and resource-intensive (may extend clinic times) • Patient burden—can be burdensome on patients who already have physical and emotional challenges. May reduce compliance and data quality.	• Limited patient perspective makes clinical interpretation more difficult (result may not have the same relevance for a patient). • Interobserver variability and bias (influence of experience, personal judgement, subjective impressions/influence of provider characteristics) • Limited information—may overlook important aspects of patient experience. • Resource-intensive • May not capture subtle changes in patient experience.

PROM, patient-reported outcome measure.

life-time treatment risks. Combined with routine use of person-centred processes and outcome measurements, better use of HSD could provide comprehensive, patient-centred, and up-to-date information [36]. Furthermore, it offers scope to adapt with rapidly evolving treatment landscapes in cancer care. Robust long-term outcome data could help to improve information and SDM through a feedback loop, as illustrated in Figure 2.

HSD may shed light on inferior outcomes experienced by patients from under-served groups, which could be related to factors including age and comorbidity, engagement with screening and preventative health programmes, timely presentation with potential cancer symptoms, socioeconomic and educational disadvantage, and distance from specialist treatment services including radiotherapy [79,80].

Holistic data around wider impacts of radiotherapy are required and may inform the adoption of more convenient, tolerable treatment and follow-up processes (for example, virtual appointments). It is important to be mindful to minimise burden to patients in both clinical trial design and routine treatment pathways. PPIE is key, and it should aim to reach and encourage participation from those who are seldom heard to tackle wider disparities.

Practical and Technological Challenges of Radiotherapy-Related HSD Data

Specific radiotherapy HSD challenges include heterogeneity in treatment techniques, delivery platforms, dose-fractionation schedules, use of systemic therapies, and imaging and motion management strategies. HSD could enable evaluation of the impact of such variation; however, data aggregation and integration within and between centres remain a challenge. Radiotherapy-related data are heterogenous and may be stored within multiple different systems, including electronic patient records and dedicated imaging, radiotherapy management, and treatment-planning systems.

There is an aspiration that data access should be improved, as set out by the findable, accessible, interoperable, and reusable (FAIR) principles and UK government strategy [81]. The technical, logistical, and regulatory governance around data access and data-sharing between institutions remains a barrier to effective data sharing. We must consider standardisation of data collection and its curation and storage, so that it is accurate, timely, consistent, up-to-date, and accessible. Mapping standardised data stores is currently a significant challenge for individual institutions, given the expertise required to manage and maintain data quality. This needs to be balanced alongside robust data security processes. Several approaches to data management could address these barriers, including trusted research environments [82], synthetic data generation [83], and federated learning approaches [84]. Whichever approach is used, there is a pressing need to ensure that data collection and use is relevant to patients, placing a higher emphasis on quality-of-life and late toxicity outcomes. There are also increasing efforts to overcome these challenges to integrate HSD into clinical trials [85]. Exemplars of utilisation of HSD are shown in Supplement B.

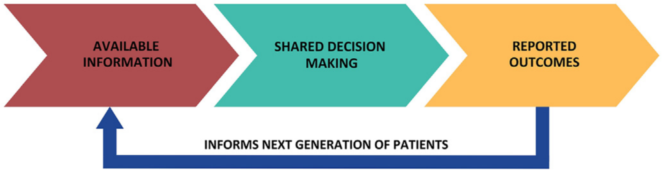


Fig 2. Feedback loop of patient-centred radiotherapy. Available information will drive 'informed' decision-making. Ensuring outcomes are reported in a meaningful manner to both patients and the scientific community allows continuous improvement of available information and better 'informed' decision-making for the next generation of patients. Image created using Canva Pro software Version 1.88.0.

An additional challenge for rare cancers HSD is that the need to maintain anonymity can restrict the data which can be published regarding useful patient-, disease-, and treatment-related metrics, including geographic variation. The Get Data Out project addressed this challenge by publishing data for cohorts of approximately 100 patients, which enabled valuable data to be published whilst respecting patient confidentiality [86].

Conclusion

Patients rightly expect more from healthcare professionals, and it is important that the radiotherapy community recognises this and embraces changes which will enhance PCC. Patient information should be cocreated with patient advocates and simplified and individualised wherever possible, including for people from under-served groups. There is a need to better support patients prior to, during, and following radiotherapy. SDM should be offered as per patients' preferences and requires trained teams alongside prepared patients. HSD offer complementary information to clinical trials, with potential to provide insights into longer-term risks/benefits of radiotherapy and outcomes including for patient groups less well represented within trial populations.

PROMs may provide greater insight regarding radiotherapy toxicity and impact on HRQoL and should be used in synergy with clinician-reported outcomes. Outcome measures should be collected in the long term, and results should be widely disseminated to both the public and professional communities. This will enable a feedback loop to improve the information provided and better support decision-making. Equality of access to radiotherapy facilities, clinical trials, and survivorship services is a priority.

These recommendations are aimed to guide best practice of patient-centred radiotherapy, with the purpose of improving the care we provide to our patients. Some recommendations may be more challenging to implement than others, especially within busy clinical services. However, we must be aspirational in order to achieve more for our patients. The next steps are to work collaboratively with patients, clinical teams, relevant stakeholders, and policymakers to support realistic implementation of our recommendations.

Ethics

Ethical approval was obtained from Sheffield Hallam University on 29/11/2023 for the patient advocate workshop (Ethics Review ID: ER61126355.

Funding

We thank the Science and Technology Facilities Council for contributing funding support for this work (Grant number ST/S005382/1). We thank the Institute of Cancer Research for supporting this work to be published open access.

Author contribution

1. Guarantor of integrity of the entire study: NB.
2. Study concept and design: NB (Chair), MM (Deputy Chair), HG (Early Career Researcher Lead), JW, HB, HP, RR, and FS (patient advocate workshop), HG, RR, and FS (Joint first authors).
3. Literature research; Manuscript editing: HG, RR, FS, SI, HP, HB, PG, RS, CK, TU, LA, JW, MM, and NB.
4. Clinical studies; Experimental studies/data analysis; Statistical analysis: N/A.
5. Manuscript preparation: HG, RR, FS, SI, CK, MM, and NB.
6. Manuscript editing: HG, RR, FS, SI, HP, HB, PG, RS, CK, TU, LA, JW, MM, and NB.

Conflict of interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Neil Burnet reports financial support was provided by Science and Technology Facilities Council. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Not applicable.

Acknowledgement

For working group formation we acknowledge the following:

-Clinical and Translational Radiotherapy Research Group (CTRad), formerly National Cancer Research Institute (NCRI) CTRad.

-Cancer Research Advocates Forum United Kingdom (CRAF-UK), formerly NCRI Consumer Forum. CRAF-UK also supported the patient advocate workshop to refine recommendations.

-United Kingdom Early Career Researchers in Cancer (UK ECRC), formerly NCRI ECR Forum.

We acknowledge Sheffield Hallam Ethics for patient advocate workshop ethical approval. We acknowledge Christie Proton Centre, Great Ormond Street Hospital, and National Health Service (NHS) Improvements for their extensive work developing patient treatment summaries. Alongside work from University College London Hospital Proton Beam Therapy Centre, they have guided our radiotherapy treatment summary recommendation.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.clon.2024.103732.

References

[1] Mee T, Kirkby NF, Defourny NN, Kirkby KJ, Burnet NG. The use of radiotherapy, surgery and chemotherapy in the curative treatment of cancer: results from the FORTY (Favourable Outcomes from RadioTherapY) project. *Br J Radiol* 2023 Dec; 96(1152).

[2] Coulter A, Oldham J. Person-centred care: what is it and how do we get there? *Future Hosp J* 2016 Jun;3(2):114–116.

[3] The Health Foundation. *Person-centred care made simple: what everyone should know about person-centred care* 2016, https://www.health.org.uk/sites/default/files/PersonCentredCareMadeSimple.pdf. [Accessed 25 November 2024].

[4] Angela Coulter, Collins A, King's Fund Centre. *Making shared decision-making a reality: no decision about me*. King's Fund; 2011. p. 45. without me, https://www.kingsfund.org.uk/insight-and-analysis/reports/making-shared-decision-making-reality. [Accessed 25 November 2024].

[5] Liénard A, Delevallez F, Razavi D, Gibon AS, Libert Y, Delvaux N, *et al*. Is it possible to improve communication around radiotherapy delivery: A randomized study to assess the efficacy of team training? *Radiother Oncol* 2016 May; 119(2):361–367.

[6] Gaito S, Aznar MC, Burnet NG, Crellin A, France A, Indelicato D, *et al*. Assessing Equity of Access to Proton Beam Therapy: A Literature Review. *Clin Oncol* 2023 Sep 1;35(9): e528–e536.

[7] Chand CP, Greenley S, Macleod U, Lind M, Barton R, Kelly C. *Geographical distance and reduced access to palliative radiotherapy: systematic review and meta-analysis. BMJ Supportive and Palliative Care*. BMJ Publishing Group; 2022.

[8] Kelly C, Hulme C, Farragher T, Clarke G. Are differences in travel time or distance to healthcare for adults in global north countries associated with an impact on health outcomes? A systematic review. *BMJ Open* 2016 Nov 24;6(11):e013059.

[9] Yip JLY, Poduval S, de Souza-Thomas L, Carter S, Fenton K. Anti-racist interventions to reduce ethnic disparities in healthcare in the UK: an umbrella review and findings from healthcare, education and criminal justice. *BMJ Open* 2024 Feb 28;14(2):e075711.

[10] Vrdoljak E, Gligorov J, Wierinck L, Conte P, De Grève J, Meunier F, *et al*. Addressing disparities and challenges in underserved patient populations with metastatic breast cancer in Europe. *Breast* 2021 Feb;55:79–90.

[11] National Institute for Health and Care Research. Involve Patients, https://www.nihr.ac.uk/career-development/health-and-care-research-introduction/involve-patients. [Accessed 25 November 2024].

[12] Fumagalli LP, Radaelli G, Lettieri E, Bertele' P, Masella C. Patient Empowerment and its neighbours: clarifying the boundaries and their mutual relationships. *Health Policy* 2015 Mar;119(3):384–394.

[13] Langley J, Wolstenholme D, Cooke J. . In: *"Collective making" as knowledge mobilisation: The contribution of participatory design in the co-creation of knowledge in healthcare*, vol. 18. BMC Health Services Research. BioMed Central Ltd.; 2018.

[14] Probst H, Rosbottom K, Crank H, Stanton A, Reed H. The patient experience of radiotherapy for breast cancer: A qualitative investigation as part of the SuPPORT 4 All study. *Radiography* 2021 May 1;27(2):352–359.

[15] Gillan C, Abrams D, Harnett N, Wiljer D, Catton P. Fears and misperceptions of radiation therapy: Sources and impact on decision-making and anxiety. *J Cancer Educ* 2014;29(2):289–295.

[16] Kumar KA, Balazy KE, Gutkin PM, Jacobson CE, Chen JJ, Karl JJ, *et al*. Association Between Patient Education Videos and Knowledge of Radiation Treatment. In: *International Journal of Radiation Oncology Biology Physics*. Elsevier Inc.; 2021. p. 1165–1175.

[17] Smith SK, Yan B, Milross C, Dhillon HM. Radiation therapy for people with cancer: what do written information materials tell them? *Eur J Cancer Care (Engl)* 2016 Jul 1;25(4):675–685.

[18] Giuliani M, Papadakos T, Papadakos J. Propelling a New Era of Patient Education into Practice—Cancer Care Post—COVID-19. *Int J Radiat Oncol Biol Phys* 2020;108:404–406. Elsevier Inc.

[19] Schnitzler L, Smith SK, Shepherd HL, Shaw J, Dong S, Carpenter DM, *et al*. Communication during radiation therapy education sessions: The role of medical jargon and emotional support in clarifying patient confusion. *Patient Educ Couns* 2017 Jan;100(1):112–120.

[20] Halkett GKB, Short M, Kristjanson LJ. How do radiation oncology health professionals inform breast cancer patients about the medical and technical aspects of their treatment? *Radiother Oncol* 2009 Jan;90(1):153–159.

[21] Ralph S. Developing UK Guidance on How Long Men Should Abstain from Receiving Anal Sex before, During and after Interventions for Prostate Cancer. *Clin Oncol* 2021;33:807–810. Elsevier Ltd.

[22] Berner AM, Webster R, Hughes DJ, Tharmalingam H, Saunders DJ. Education to Improve Cancer Care for LGBTQ+ Patients in the UK. *Clin Oncol* 2021;33:270–273. Elsevier Ltd.

[23] Rosenberg SA, Francis DM, Hullet CR, Morris ZS, Brower JV, Anderson BM, *et al*. Online patient information from radiation oncology departments is too complex for the general population. *Pract Radiat Oncol* 2017 Jan 1;7(1):57–62.

[24] Prabhu AV, Hansberry DR, Agarwal N, Clump DA, Heron DE. Radiation Oncology and Online Patient Education Materials: Deviating From NIH and AMA Recommendations. *Int J Radiat Oncol Biol Phys* 2016 Nov 1;96(3):521–528.

[25] Flinton D, Singh MK, Haria K. Readability of internet-based patient information for radiotherapy patients. *J Radiother Pract* 2018 Jun 21;17(2):142–150.

[26] Goldsworthy S, Latour JM, Palmer S, McNair HA, Cramp M. Patient and therapeutic radiographer experiences of comfort during the radiotherapy pathway: A qualitative study. *Radiography* 2023 May 1;29:S24–S31.

[27] De Ruysscher D, Niedermann G, Burnet NG, Siva S, Lee AWM, Hegi-Johnson F. Radiotherapy toxicity. *Nat Rev Dis Primers* 2019 Feb 21;5(1):13.

[28] Miller KD, Nogueira L, Devasia T, Mariotto AB, Yabroff KR, Jemal A, *et al*. Cancer treatment and survivorship statistics, 2022. *CA Cancer J Clin* 2022 Sep;72(5):409–436.

[29] Chan RJ, Crawford-Williams F, Crichton M, Joseph R, Hart NH, Milley K, *et al*. Effectiveness and implementation of models of cancer survivorship care: an overview of systematic reviews. *J Cancer Survivorship* 2023;17:197–221. Springer.

[30] Frick E, Tyroller M, Panzer M. Anxiety, depression and quality of life of cancer patients undergoing radiation therapy: A cross-sectional study in a community hospital outpatient centre. *Eur J Cancer Care (Engl)* 2007 Mar;16(2):130–136.

[31] Lewis F, Merckaert I, Liénard A, Libert Y, Etienne AM, Reynaert C, *et al*. Anxiety at the first radiotherapy session for non-metastatic breast cancer: Key communication and communication-related predictors. *Radiother Oncol* 2015 Jan 1;114(1):35–41.

[32] Schnur JB, Ouellette SC, Bovbjerg DH, Montgomery GH. Breast cancer patients' experience of external-beam radiotherapy. *Qual Health Res* 2009;19(5):668–676.

[33] Mollica MA, Lines LM, Halpern MT, Ramirez E, Schussler N, Urato M, *et al*. Patient experiences of cancer care: scoping review, future directions, and introduction of a new data resource: Surveillance Epidemiology and End Results-Consumer Assessment of Healthcare Providers and Systems (SEER-CAHPS). *Patient Exp J* 2017 Apr 24;4(1):103–121.

[34] Schoenfeld JD, Sher DJ, Norris CM, Haddad RI, Posner MR, Balboni TA, *et al*. Salivary gland tumors treated with adjuvant intensity-modulated radiotherapy with or without concurrent chemotherapy. *Int J Radiat Oncol Biol Phys* 2012 Jan 1;82(1):308–314.

[35] Long LE. Being informed: undergoing radiation therapy. *Cancer Nurs* 2001 Dec;24(6):463–468.

[36] Hwang E, Burnet NG, Crellin AM, Ahern V, Thwaites DI, Gaito S, *et al*. A Novel Model and Infrastructure for Clinical Outcomes Data Collection and Their Systematic Evaluation for UK Patients Receiving Proton Beam Therapy. *Clin Oncol* 2022 Jan 1;34(1):11–18.

[37] Fairhurst K, Gilmore K, Swan R, Laurence N. Creating bespoke end-of-treatment summaries. *Bull Royal Coll Surgeons Engl* 2023 Mar;105(2):76–81.

[38] Hayman JA. Treatment summaries in radiation oncology and their role in improving patients' quality of care: Past, present, and future. In: *J Oncol Pract* 2009. p. 108–109.

[39] Coulter A. Do patients want a choice and does it work? *BMJ* 2010 Oct 14;341:c4989.

[40] NICE National Institute of Health and Care Excellence. *Shared decision making* 2021, https://www.nice.org.uk/guidance/ng197/resources. [Accessed 25 November 2024].

[41] Herrmann A, Hall A, Sanson-Fisher R, Zdenkowski N, Watson R, Turon H. Not asking cancer patients about their preferences does make a difference. A cross-sectional study examining cancer patients' preferred and perceived role in decision-making regarding their last important cancer treatment. *Eur J Cancer Care (Engl)* 2018 Sep;27(5):e12871.

[42] Tariman JD, Berry DL, Cochrane B, Doorenbos A, Schepp K. Preferred and actual participation roles during health care decision making in persons with cancer: a systematic review. *Ann Oncol* 2010 Jun;21(6):1145–1151.

[43] Kunneman M, Gionfriddo MR, Toloza FJK, Gärtner FR, Spencer-Bonilla G, Hargraves IG, *et al*. Humanistic communication in the evaluation of shared decision making: A

systematic review. *Patient Educ Couns* 2019 Mar;102(3):452–466.

[44] Joseph-Williams N, Elwyn G, Edwards A. Knowledge is not power for patients: a systematic review and thematic synthesis of patient-reported barriers and facilitators to shared decision making. *Patient Educ Couns* 2014 Mar;94(3):291–309.

[45] The Royal College of Radiologists. *Clinical Oncology Workforce Census 2003* 2023, https://www.rcr.ac.uk/news-policy/policy-reports-initiatives/clinical-oncology-census-reports/. [Accessed 25 November 2024].

[46] The Society of Radiographers. *Radiotherapy radiographic Workforce UK Census 2023* 2023, https://www.sor.org/learning-advice/professional-body-guidance-and-publications/documents-and-publications/reports-and-surveys/radiotherapy-radiographic-workforce-uk-census-2023. [Accessed 25 November 2024].

[47] Jefford M, Tattersall MHN. Informing and involving cancer patients in their own care. *Lancet Oncol* 2002 Oct;3(10):629–637.

[48] Köksal M, Saur L, Scafa D, R Sarria G, Leitzen C, Schmeel C, *et al*. Late toxicity-related symptoms and fraction dose affect decision regret among patients receiving adjuvant radiotherapy for head and neck cancer. *Head Neck* 2022 Aug 1;44(8):1885–1895.

[49] Leech M, Katz MS, Kazmierska J, McCrossin J, Turner S. Empowering patients in decision-making in radiation oncology – can we do better? *Mol Oncol* 2020;14:1442–1460. John Wiley and Sons Ltd.

[50] Gutiontov SI, Golden DW, McCloskey S, Shumway D, Sullivan DR, Wall TJ, *et al*. Informed Consent in Radiation Oncology. *Int J Radiat Oncol Biol Phys* 2021;109:29–35. Elsevier Inc.

[51] Burnet NG, Mackay RI, Chadwick AL, Whitfield GA, Thomson DJ, Lowe M, *et al*. Proton beam therapy: perspectives on the National Health Service England clinical service and research programme. *Br J Radiol* 2020 Mar 1;93(1107).

[52] Chen Z, King W, Pearcey R, Kerba M, Mackillop WJ. The relationship between waiting time for radiotherapy and clinical outcomes: A systematic review of the literature. *Radiother Oncol* 2008;87:3–16.

[53] Mackillop WJ. Killing time: The consequences of delays in radiotherapy. *Radiother Oncol* 2007;84:1–4.

[54] Hanna TP, King WD, Thibodeau S, Jalink M, Paulin GA, Harvey-Jones E, *et al*. Mortality due to cancer treatment delay: systematic review and meta-analysis. *BMJ* 2020 Nov 4;371:m4087.

[55] EU NAVIGATE. *Supporting older people with cancer* 2024, https://eunavigate.com. [Accessed 25 November 2024].

[56] Nav-CARE. Making Connections. Making a Difference, https://www.nav-care.ca/. [Accessed 25 November 2024].

[57] National Cancer Institute. https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative. Cancer Moonshot https://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative. Accessed 25 Nov 2024.

[58] Jonker L, Fisher SJ. The correlation between National Health Service trusts' clinical trial activity and both mortality rates and care quality commission ratings: a retrospective cross-sectional study. *Public Health* 2018 Apr;157:1–6.

[59] Ozdemir BA, Karthikesalingam A, Sinha S, Poloniecki JD, Hinchliffe RJ, Thompson MM, *et al*. Research Activity and the Association with Mortality. *PLoS One* 2015 Feb 26;10(2):e0118253.

[60] Downing A, Morris EJ, Corrigan N, Sebag-Montefiore D, Finan PJ, Thomas JD, *et al*. High hospital research participation and improved colorectal cancer survival outcomes: a population-based study. *Gut* 2017 Jan;66(1):89–96.

[61] NIHR National Institute for Health and Care Research. Embedding a research culture, https://www.nihr.ac.uk/health-and-care-professionals/engagement-and-participation-in-research/embedding-a-research-culture.htm. [Accessed 25 November 2024].

[62] Price G, Devaney S, French DP, Holley R, Holm S, Kontopantelis E, *et al*. Can Real-world Data and Rapid Learning Drive Improvements in Lung Cancer Survival? The RAPID-RT Study. *Clin Oncol (R Coll Radiol* 2022 Jun;34(6):407–410.

[63] Hanna CR, Lynskey DM, Wadsley J, Appleyard SE, Anwar S, Miles E, *et al*. Radiotherapy Trial Set-up in the UK: Identifying Inefficiencies and Potential Solutions. *Clin Oncol (R Coll Radiol* 2020 Apr;32(4):266–275.

[64] Khozin S, Blumenthal GM, Pazdur R. Real-world Data for Clinical Evidence Generation in Oncology. *J Natl Cancer Inst* 2017 Nov 1;109(11).

[65] Saesen R, Van Hemelrijck M, Bogaerts J, Booth CM, Cornelissen JJ, Dekker A, *et al*. Defining the role of real-world data in cancer clinical research: The position of the European Organisation for Research and Treatment of Cancer. *Eur J Cancer* 2023 Jun;186:52–61.

[66] Kim HS, Lee S, Kim JH. Real-world Evidence versus Randomized Controlled Trial: Clinical Research Based on Electronic Medical Records. *J Korean Med Sci* 2018 Aug 20;33(34):e213.

[67] Bulbeck H. Measuring what matters to the brain tumour community. In: Grisold W, Soffietti R, Obernadorfer S, Cavaletti G, editors. *Effects of cancer treatment on the nervous system*, vols. 1 and 2. Cambridge Scholars Publishing; 2021. vols. 1 and 2.

[68] Bhattacharya IS, Haviland JS, Hopwood P, Coles CE, Yarnold JR, Bliss JM, *et al*. Can patient-reported outcomes be used instead of clinician-reported outcomes and photographs as primary endpoints of late normal tissue effects in breast radiotherapy trials? Results from the IMPORT LOW trial. *Radiother Oncol* 2019 May;134:220–230.

[69] Lapen K, King C, Braunstein LZ, Khan AJ, Kamrava MR, Gillespie EF, *et al*. A Comparison of Patient- and Clinician-Reported Acute Toxic Effects During Radiation Therapy for Primary Breast Cancer. *Int J Radiat Oncology*Biology*Physics* 2022 Oct;114(2):301–309.

[70] Jagsi R, Griffith KA, Vicini F, Boike T, Dominello M, Gustafson G, *et al*. Identifying Patients Whose Symptoms Are Underrecognized During Treatment With Breast Radiotherapy. *JAMA Oncol* 2022 Jun 1;8(6):887.

[71] Kotronoulas G, Kearney N, Maguire R, Harrow A, Di Domenico D, Croy S, *et al*. What is the value of the routine use of patient-reported outcome measures toward improvement of patient outcomes, processes of care, and health service outcomes in cancer care? A systematic review of controlled trials. *J Clin Oncol* 2014;32:1480–1501. American Society of Clinical Oncology.

[72] Faithfull S, Lemanska A, Chen T. Patient-reported Outcome Measures in Radiotherapy: Clinical Advances and Research Opportunities in Measurement for Survivorship. *Clin Oncol* 2015 Nov 1;27(11):679–685.

[73] Hudson EM, Slevin F, Biscombe K, Brown SR, Haviland JS, Murray L, *et al*. Hitting the Target: Developing High-quality Evidence for Proton Beam Therapy Through Randomised Controlled Trials. *Clin Oncol (R Coll Radiol* 2024 Feb;36(2):70–79.

[74] Rieu R, Crellin A, Thomson D, Nutting C. Developing a National Infrastructure for Proton Beam Therapy Trials. *Clin Oncol (R Coll Radiol* 2023 May;35(5):279–282.

[75] Aggarwal A, Simcock R, Price P, Rachet B, Lyratzopoulos G, Walker K, *et al*. NHS cancer services and systems—ten pressure points a UK cancer control plan needs to address. *Lancet Oncol* 2024 Aug;25(8):e363–e373.

[76] Tang M, Pearson SA, Simes RJ, Chua BH. Harnessing Real-World Evidence to Advance Cancer Research. *Curr Oncol* 2023 Feb 2;30(2):1844–1859.

[77] Smuck M, Odonkor CA, Wilt JK, Schmidt N, Swiernik MA. The emerging clinical role of wearables: factors for successful implementation in healthcare. *NPJ Digit Med* 2021 Mar 10; 4(1):45.

[78] Liao Y, Thompson C, Peterson S, Mandrola J, Beg MS. The Future of Wearable Technologies and Remote Monitoring in Health Care. *Am Soc Clin Oncol Educ Book* 2019 Jan;39: 115–121.

[79] Møller H, Coupland VH, Tataru D, Peake MD, Mellemgaard A, Round T, *et al*. Geographical variations in the use of cancer treatments are associated with survival of lung cancer patients. *Thorax* 2018 Jun 1;73(6):530–537.

[80] The Lancet Regional Health - Europe. Reduce cancer inequity and inequality to reduce cancer mortality. *The Lancet Regional Health - Europe* 2023 Feb;25:100591.

[81] Wilkinson MD, Dumontier M, Aalbersberg IjJ, Appleton G, Axton M, Baak A, *et al*. Comment: The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data* 2016 Mar 15;3.

[82] UK Health Data Research Alliance, NHSX, Varma S, Hubbard T, Seymour D, Brassington N, *et al*. *Building trusted research environments - principles and best practices; towards TRE ecosystems (1.0)* 2021, https://zenodo.org/records/5767586. [Accessed 25 November 2024].

[83] Gonzales A, Guruswamy G, Smith SR. Synthetic data in health care: A narrative review. *PLOS Digital Health* 2023 Jan 6;2(1): e0000082.

[84] Rieke N, Hancox J, Li W, Milletarì F, Roth HR, Albarqouni S, *et al*. The future of digital health with federated learning. *NPJ Digit Med* 2020 Dec 1;3(1).

[85] Toader AM, Campbell MK, Quint JK, Robling M, Sydes MR, Thorn J, *et al*. Using healthcare systems data for outcomes in clinical trials: issues to consider at the design stage. *Trials* 2024 Jan 29;25(1):94.

[86] NHS Digital. *The Get data out project* 2023, https://digital.nhs.uk/ndrs/our-work/ncras-work-programme/get-data-out. [Accessed 25 November 2024].