

## **Best practice for patient-centred radiotherapy in clinical trials and beyond – a multidisciplinary national consensus**

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## Highlights

1. A multidisciplinary-panel national set of consensus recommendations on best practice for patient-centred radiotherapy are presented
2. Three interlinked themes are identified as critical to optimise patient-centred radiotherapy: information, decision-making and outcomes.
3. Recommendations are finalised following consultation through a national patient advocate workshop

## Abstract

### Background

Patient-centred radiotherapy refers to an approach where the patient's needs, preferences and wishes are prioritised. Guidelines for this personalised approach are lacking. We present a multidisciplinary-panel national consensus and a set of recommendations for best-practice in patient-centred radiotherapy for both clinical trials and routine practice.

### Methods

A multidisciplinary working group was formed, comprising of health care professionals, academics and patient advocates with lived experience of radiotherapy. Through regular consultation, three interlinking themes were identified around patient-centred radiotherapy: information, decision-making and outcomes. Scoping reviews were carried out for each theme, considering the current situation, problems and potential recommendations. These were then further shaped and finalised following a "Dragon's Den"-style' consultation workshop with twelve patient advocates.

### Results

Patient information is often complex and challenging to understand. We recommend that resources should be co-created with patient advocates and individualised wherever possible, particularly for clinically vulnerable patients. Shared decision-making is not widely implemented in routine practice but offers the potential to reduce decision-regret. It requires prepared patients, trained teams and adequate resource, and should be offered as per patients' preferences. Health services data offer complementary information to clinical trials, enabling wider and longer-term understanding of treatment effects in the real-world. Patient-reported outcome measures may provide greater insight regarding radiotherapy toxicity and impact on quality of life and should be used in synergy with clinician-reported outcomes. Results should be widely disseminated, enabling a feedback loop to better inform patients and health care professionals in decision-making.

## Conclusions

Patients expect more from healthcare professionals with regards to being involved in decisions about their care. It is critical that the radiotherapy community recognise this and embrace change to improve patient-centred approaches in a collaborative and standardised fashion. Future work aims to develop practical solutions to achieve best practice in patient-centred radiotherapy for clinical trials and beyond.

## *Keywords*

Patient-centred

Radiotherapy

Shared-decision making

## *Non-standard abbreviations (foot note of first page)*

HCP – healthcare professionals

HSD – health services data

PCC – patient centred care

RWD -real world data

RWE – real world evidence

SDM – shared decision making

*Word count - 3491*

## **1. Introduction (413 words)**

Patients are at the centre of all cancer care. Management of cancer has evolved dramatically in the last 20-30 years, with considerable technical advances in radiotherapy, surgery, and new systemic anti-cancer therapies. There has also been substantial development of multi-modality treatments(Mee et al., 2023), with increased integration of multidisciplinary decision-making. Over a similar timeframe, there has also been a seismic shift in approaches

to healthcare, particularly the recognition of the importance of empowering patients to take an active role in decisions about their care. Contemporary discussions about cancer treatment often involve balancing the efficacy of treatments against their potential for toxicities and impacts on quality of life, and there is still much to learn about how to ensure a patient-centred approach to these complex decisions.

Patient-centred care (PCC) can be considered as an approach to healthcare that aims to ensure that the patient's voice is heard and valued throughout their journey, promoting a holistic approach that prioritises the needs, preferences and values of individual patients (Coulter & Oldham, 2016; The Health Foundation, 2016). Effective communication and fostering of collaborative and trusting relationships that support shared decision-making (SDM) are critical components for the successful delivery of PCC (Coulter et al., 2011).

Radiotherapy is complex and there is limited public understanding of its practicalities and potential benefits and risks. This presents a challenge to the effective delivery of PCC for radiotherapy. In addition, inequalities in access to radiotherapy exist across the UK especially for patients from under-represented groups (Mee et al., 2023). Radiotherapy centres are predominantly located in large urban centres impacting availability and accessibility of services, especially for highly specialised cancer care such as for rare cancers or advanced radiotherapy techniques. There is growing evidence that living further away from healthcare providers, including radiotherapy, is associated with poorer outcomes including reduced survival (Chand et al., 2022; Kelly et al., n.d.). Additional disparities may result from differences in access to transportation, willingness to travel, ethical or cultural factors, impact on employment and caring responsibilities, and the financial toxicity of treatment for individual patients (Vrdoljak et al., 2021; Yip et al., 2024).

A UK national multidisciplinary working group was convened, including patient representatives from the National Cancer Research Advocates Forum with lived experience of cancer and radiotherapy, to develop best-practice recommendations for patient-centred radiotherapy. We reviewed how to: 1) improve information sharing with patients, 2) support patients in radiotherapy decision-making and discussions throughout their cancer journey and beyond and 3) measure outcomes which are meaningful to patients.

## **2. Methods (207 words)**

The working group was convened through an open application process, coordinated by the former National Cancer Research Institute (NCRI)'s Clinical and Translational Radiotherapy Research Group (CTRad). The working group included representation from clinical oncology, medical physics, therapeutic radiography and patient representatives. 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, problems and potential best-practice recommendations were considered for each theme. The draft recommendations were subsequently presented to 12 patient and carer representatives of the National Cancer Advocates Forum through a “Dragon’s Den” style virtual consultation on 26/01/2024. 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 for patient-centred radiotherapy to guide both clinical trials and routine practice.

### **3. Theme 1. Patient-centred information (838 words)**

#### **3.1 What challenges exist to effective information sharing in radiotherapy?**

Patients’ baseline understanding about radiotherapy is often limited and some patients may harbour misconceptions (Gillan et al., 2014; Kumar et al., 2021; Smith et al., 2016). The volume of information provided regarding diagnosis and treatment may be overwhelming and challenging for patients to understand and retain (Giuliani et al., 2020). They may contain excessive medical or technical terminology (Schnitzler et al., 2017). 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 (Giuliani et al., 2020).

Workload pressures and resource constraints may act to limit the time healthcare professionals (HCPs) 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 (Halkett et al., 2009). Certain topics, including sexual practices and sexual

orientation, may not be discussed by clinicians and/or patients (Berner et al., 2021; Ralph, 2021).

Written patient information, either in paper or 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 (Flinton et al., 2018; Prabhu et al., 2016; Rosenberg et al., 2017). 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 (Smith et al., 2016). 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 (Goldsworthy et al., 2023).

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. Questions remain as to the most appropriate information and signposting to provide concerning disease recurrence, late toxicity and treatment-related quality of life (Chan et al., 2023; De Ruyscher et al., 2019; Miller et al., 2022).

### **3.2 What are the potential benefits from effective information sharing?**

Patients frequently experience anxiety following a cancer diagnosis (Frick et al., 2007). Effective communication and support strategies, including the provision of information about radiotherapy toxicities, can reduce patient anxiety (Lewis et al., 2015). Greater understanding of the outcomes from treatment, including anticipated toxicities, may help to frame patients' expectations (Schnur et al., 2009). The timely provision of information, education and support may have considerable benefits for both patients and radiotherapy services (Mollica et al., 2017). Well-informed patients are better prepared to effectively navigate their treatment pathway and may experience less distress, better quality of life and greater satisfaction with treatment (Schoenfeld et al., 2012).

In addition, good quality information can also enhance self-care strategies. A previous qualitative study of patients undergoing radiotherapy demonstrated the importance of information provision in giving patients a sense of control and the positive impact that this had on patients' ability to cope during treatment (Long, 2001). A feeling of preparedness for radiotherapy was highlighted as important. Crucial to this was the timely delivery of information regarding treatment, a factor which has been identified in other

<b>PATIENT-CENTRED INFORMATION</b>
<b>COMMUNICATION</b>
<ul style="list-style-type: none"> <li>• Individualise information wherever possible, according to prior knowledge, understanding and information needs</li> <li>• Use lay language and avoid excessively complex or technical terminology. Be concise</li> <li>• Provide accurate information about treatment aims, outcomes and side effects</li> <li>• Allow sufficient time to discuss diagnosis and treatment options, and their implications</li> <li>• Use a holistic approach to patient information and consider the wider psychosocial and lifestyle impacts of treatment</li> <li>• Ensure translation services are available for patients with limited English-speaking proficiency</li> <li>• Provide additional support for patients from under-served groups, including those with learning difficulties, auditory or visual disabilities</li> <li>• Individualise radiotherapy side effects information, for example how skin reactions may differ depending on ethnic background and skin tone</li> </ul>
<b>SUPPORTING INFORMATION</b>
<ul style="list-style-type: none"> <li>• Allocate a named keyworker for each patient</li> <li>• Provide supporting information formats which are understandable and co-developed with patient advocates</li> <li>• Consider what additional information patients might need, including the practicalities of attending for treatment</li> <li>• Signpost other sources of support, such as Macmillan Cancer Support Centres, and other services, such as for financial support</li> <li>• Consider providing a treatment summary document, which provides key individualised information before, during and after treatment</li> </ul>
<b>PATIENT-CENTRED DECISION-MAKING</b>
<ul style="list-style-type: none"> <li>• View shared decision-making (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</li> <li>• 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</li> <li>• Actively address patient ideas, concerns, and expectations, to inform the SDM processes</li> <li>• Implement validated SDM tools and provide access to SDM training for clinicians</li> </ul>
<b>PATIENT-CENTRED OUTCOME MEASURES</b>
<ul style="list-style-type: none"> <li>• Consult patient and public involvement representatives when considering the design of radiotherapy services and clinical trials</li> <li>• Consider implementation of patient reported toxicity and quality of life assessments, including as part of long-term follow up following radiotherapy</li> <li>• Develop national guidance for the standardisation and implementation of validated patient reported outcome measure instruments</li> <li>• Address barriers to the standardised collection and analysis of multicentre real-world data</li> <li>• Use health services data to understand where inequalities exist in access to radiotherapy for patients from under-served groups</li> </ul>

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

qualitative research into patient experience during radiotherapy (Long, 2001; Mollica et al., 2017). Actively seeking information about treatment has been shown to be a coping mechanism, particularly for younger patients with breast cancer (Long, 2001). This emphasises the important role that HCPs 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 focused responses to their concerns. Recommendations for best-practice in information sharing are summarised in **Table 1**.

### **3.3 Treatment summary documents – an example of effective information sharing**

Treatment summary documents contain a record of a patient’s diagnosis and treatment. Ideally, it is populated iteratively along the treatment pathway and thereby provides individualised information for patients prior to, during and following radiotherapy. It could provide essential information and signposting for patients, especially regarding disease recurrence, late toxicities and treatment-related quality of life. In addition to addressing survivorship issues, they can promote better communication and coordination of care between healthcare providers. Treatment summaries are in routine use at two UK national proton beam therapy (PBT) centres, when they are discharged to local care services post-treatment (Hwang et al., 2022). Manually populating detailed treatment summary documents would be time-consuming and challenging to widely implement in routine care. Digital technologies could be used to efficiently generate and iteratively populate accurate individualised patient records (Fairhurst et al., 2023). Recommendations for content to be included within treatment summaries are available (Hayman, 2009). An example treatment summary applicable to radiotherapy is shown in **Supplementary Figure 1**.

## **4. Theme 2: Patient-centred decision-making (926 words)**

### **4.1 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. We know that decisions about radiotherapy occur in a variety of contexts within oncology, and even within the same context each patient brings their own values, preferences and life experience. Individuals may have different priorities dependent on the context, for example whether the intent of treatment is cure 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 one single approach that suits all decision-making about radiotherapy. SDM, defined as “a collaborative process that involves a person and their HCP working together to



reach a joint decision about care”, could be key to support patients to make a decision that is right for them (Coulter, 2010a; NICE, 2021).

#### 4.2 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 (Coulter, 2010b; Herrmann et al., 2018; Tariman et al., 2010). A collaborative approach, with prepared patients, would encourage both clinicians and patients to share insights, concerns, and 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 the detail (Probst et al., 2021) alongside careful timing of information giving could further empower patients to be involved in decision-making. For example, providing preliminary information before a consultation could facilitate patients to be more proactive and engaged in their care.

The decision-making processes that patients undergo require individuals to imagine their future state, including the potential impacts that the disease and its treatment may have on their quality of life. It is key to elicit from the patient what matters to them, their values, their context and what their appetite for risk looks like, with the aim to facilitate decisions in the context of their own life circumstances. Patients are the expert on themselves; engaging them in SDM generates insights, shifts dynamics, and allows patient-centred care.

SDM needs supportive systems, trained teams, and prepared patients. We must provide the opportunity for patients to be informed about treatment options, the practicalities, benefits and risks, and must provide time to process well-presented information and engage in open conversations. Tools such as option grids, tailored talks and resources produced by support charities, as well as 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.

SDM is not the same as giving patients the burden of taking responsibility for radiotherapy decisions. SDM should be interactional; an opportunity for HCPs to share the evidence for the 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 HCPs to elicit not just information we are routinely taught to gather, such as their medical history, but the powerful questions, including “what is important to you?”, “what are you struggling with?”. Tools, including holistic needs assessments, can help provide a voice for patients’ needs, values and preferences. 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 (NICE, 2021).

There are barriers to integrating SDM into routine practice. These include patients' knowledge about radiotherapy, the power-imbalance in the doctor-patient relationship, and the time pressure, perceived or real, in which decisions are made (Joseph-Williams et al., 2014). For HCPs, time and resource constraints, and identifying which validated tools to use, may be other limiting factors (Jefford & Tattersall, 2002).

### **4.3 Minimising risk of decision regret**

Decisions about radiotherapy, and other cancer treatments, often carry profound implications. Open channels of communication, whereby patients can voice their uncertainties, seek clarifications, or simply talk through their thought processes, play an instrumental role. Such engagements not only foster a sense of trust but also solidify the support framework that patients can lean on during radiotherapy (Köksal et al., 2022; Leech et al., 2020). 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 (Köksal et al., 2022; Leech et al., 2020). Continuous dialogue, reassurance and opportunities to revisit and discuss doubts are vital (Gutiontov et al., 2021; Köksal et al., 2022; Leech et al., 2020). This can help to support choices that 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 (Burnet et al., 2020; Chen et al., 2008; Hanna et al., 2020; Mackillop, 2007). SDM could also be supported through patient navigation, a promising evolving strategy where trained volunteers or health and social care professionals support people with cancer when moving through the healthcare system (*EU Navigate – Supporting Older People with Cancer*, n.d.). 'Navigators' offer support, bridging hospital and community services, whilst providing companionship and continuity of care. This approach is being evaluated through various international programmes include EU Navigate, Canadian Nav-CARE, and within US Cancer Moonshot.

## **5. Theme 3: Patient-centred outcome measures (957 words)**

There is an ever-expanding range of outcome measures and data sources available to HCPs and investigators, including clinical trial databases and healthcare systems data (HSD). Randomised controlled trials (RCTs) remain the gold standard to evaluate new clinical management strategies, but they are not always feasible (Khozin et al., 2017). Alternatively,

real-world data (RWD) sources can offer novel insights to tailor treatment discussions and decisions regarding radiotherapy, stratified by patient demographics, clinicopathological features, treatment and outcome data. Patient wearable devices can contribute precise, real-time personal health tracking data over prolonged time-periods (Liao et al., 2019; Smuck et al., 2021). However, for all types of data, challenges remain regarding standardised recording, curation, access, privacy, storage, interpretation and utilisation of these data. Potential advantages and disadvantages of RCT versus HSD, and the use of clinician-reported outcomes versus patient-reported outcomes, are summarised in **Supplementary Table 1**.

### **5.1 Patient reported outcome measures (PROMs)**

Clinician-reported data may reduce focus on individual patients and their preferences. A tumour genotype, for example, offers no information on how the disease impacts the person's quality of life or what other stressors are confounding their ability to maintain health and well-being. We often report measures of treatment-quality, but very few of these come from the perspective of the person living with the disease. We should set about reframing the problem of measuring quality of life so that we are measuring the presence, rather than the absence, of health (Bulbeck, 2021).

PROMS may provide greater insight into the true burden of treatment-related toxicities including impact of these on quality of life and are integral to understanding the impacts of advanced radiation techniques (Kotronoulas et al., 2014) (Faithfull et al., 2015). PROMs are increasingly being integrated into clinical trial design, and evaluative commissioning studies particularly through integrating patient advocate involvement (Hudson et al., 2024; Rieu et al., 2022), but have not yet been widely implemented into routine clinical practice. There remain unanswered questions regarding use of PROMS, such as the optimal tools and format, appropriate recording, analysis and management of responses, and how to support engagement from under-served groups. National guidance and validation of PROMs could facilitate more widespread adoption and allow for analysis of aggregated outcome measures.

### **5.2 The promise of Healthcare Systems Data**

HSD is any information collected outside a tightly controlled trial environment and can be used synonymously with RWD or Real-World Evidence (RWE). HSD could strengthen and complement clinical trials (Murray et al., 2022) and may offer alternative study methodology where RCTs are not feasible, for example in rare tumours. HSD provides 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. Studies are typically less resource and cost-intensive

than trials, with more representative results for the wider population (Tang et al., 2023). Through prolonged follow-up programmes, we can facilitate deeper understanding of longer-term 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. Furthermore, it offers scope to adapt with rapidly evolving treatment landscapes in cancer care.

HSD may shed light on inequalities of access to radiotherapy and inferior outcomes experienced by patients from under-served groups, including disparities resulting from geographic distance to radiotherapy centre, or cultural, religious, or socioeconomic factors.

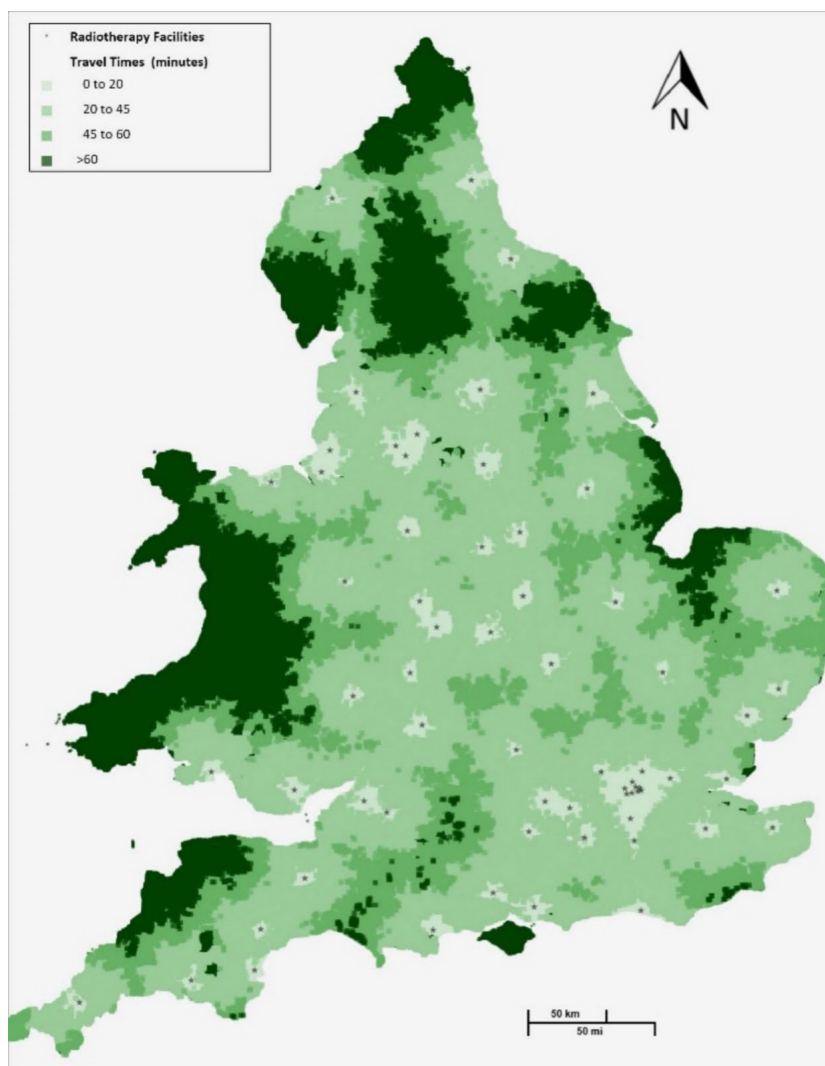


Figure 2 - Travel times to radiotherapy facilities in Wales and  England

**Figure 2** shows travel times to radiotherapy facilities in England and Wales. Holistic data around the wider impacts of radiotherapy are required, and may inform the adoption of more convenient and tolerable treatment and follow-up processes (for example, virtual appointments). We must be mindful to minimise burden to patients in both clinical trial design and routine treatment-pathways.

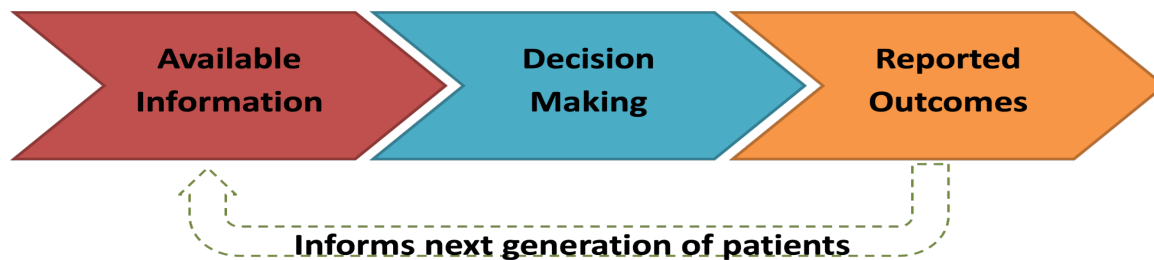
### 5.3 Practical and technological challenges of radiotherapy-related HSD data

Specific radiotherapy HSD challenges include heterogeneity in treatment techniques, delivery platforms, dose-fractionation schedules, use of systemic anti-cancer therapies, imaging and motion management strategies. HSD could enable evaluation of the impact of such variation, however aggregation of data between centres remains a challenge. Radiotherapy data is heterogeneous, and is stored using differing electronic and paper health records, alongside variable imaging and radiotherapy software.

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 (Wilkinson et al., 2016). 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 (UK Health Data Research Alliance et al., 2021), synthetic data generation (Gonzales et al., 2023), and federated learning approaches (Rieke et al., 2020). 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.

Exemplars of utilisation of HSD are shown in **Supplementary Table 2**

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 while respecting patient confidentiality (NHS Digital, 2023). Robust long-term outcome data, can help to improve information and shared-decision making through a feedback loop shown in **Figure 3**.



**Figure 3 – 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.

## 6. Conclusion (158 words)

Rightly, patients expect more from HCPs with regards to being involved in decisions about their care. It is critical that the radiotherapy community recognise this and embrace change to improve patient-centred systems and approaches in a collaborative and standardised fashion. Patient information should be co-created with patient advocates, simplified and individualised wherever possible, particularly for clinically vulnerable patients. SDM should be offered as per patients’ preferences and requires trained teams alongside prepared patients. HSD offers complementary information to clinical trials, enabling wider and longer-term real-world understanding of treatment effects. Outcome measures should include those that are meaningful to patients and results should be widely disseminated to both the public and professional community. This will enable a feedback loop to better inform patients and empower shared decision-making. Future work aims to develop realistic and implementable solutions based on these recommendations in order to bring our goals to fruition for best-practice in patient-centred radiotherapy in clinical trials and beyond.

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### **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, FS (Patient advocate workshop)
3. Literature Research: HG, RR, FS, SI, HP, HB, PG, RS, CK, TU, LA, JW, MM, NB
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7. Manuscript preparation: HG, RR, FS, SI, CK, MM, NB
8. Manuscript editing: HG, RR, FS, SI, HP, HB, PG, RS, CK, TU, LA, JW, MM, NB

### **Data Availability Statement**

Not applicable

### **Ethics Statement**

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

### **Conflict of Interest**

The authors declare no conflicts of interest

	Data Source		Types of Data	
	Healthcare Systems Data	Trial Data	Patient Reported Outcomes	Clinician Reported Outcomes
<b>Examples</b>	e.g. National Registry Datasets (e.g. RTDS)	e.g. Randomised controlled trials (RCTS)	e.g. disease specific, or overall Quality of Life questionnaires.	e.g. CTCAE toxicity scores
<b>Advantages</b>	<ul style="list-style-type: none"> <li>● Large Sample Size</li> <li>● Maximises representativeness (covers great population)</li> <li>● Longitudinal data</li> <li>● Can identify disparities in care, e.g. across different patient demographics / geographic locations</li> <li>● Efficient: Less time and resource intense</li> <li>● Less of a financial burden</li> <li>● Permits analysis of rare cancers or subtypes</li> <li>● Databases are iterative, and can adapt in good time and a low cost</li> </ul>	<ul style="list-style-type: none"> <li>● Gold standard, allows causal determination</li> <li>● Minimisation of bias by randomisation +/- blinding (limits confounding factors, enhances internal validity)</li> <li>● Highly monitored protocol-based care, often with integrated quality assurance</li> <li>● Standardised data collection</li> <li>● Continuous, contemporary safety monitoring enables early detection of adverse/unexpected events</li> </ul>	<ul style="list-style-type: none"> <li>● Patient-centred care – prioritise the patient’s perspective, promotes shared decision making</li> <li>● May identify patient unmet needs</li> <li>● Allows comprehensive assessment capturing symptoms, quality of life, functional status and side effects, useful for cost effectiveness</li> <li>● Early symptom detection</li> <li>● Improves patient and medical team communication, supports personalisation of care</li> </ul>	<ul style="list-style-type: none"> <li>● Standardised assessment guidelines, most objective</li> <li>● Commonly used, comparison (e.g. between trials/treatments) possible</li> <li>● Objective assessment of clinical parameters</li> <li>● Real-time monitoring</li> </ul>
<b>Disadvantages</b>	<ul style="list-style-type: none"> <li>● Knowledge of data, access and costs is limited</li> <li>● Data access may lead to delay</li> <li>● Incomplete / missing data</li> <li>● Integrity and provenance: data quality may be affected by errors in coding or data entry.</li> <li>● Reporting variability - data collection practices/standards may vary across institutions.</li> <li>● Inconsistent definitions may limit ability to combine across registries.</li> <li>● Limited clinical details – e.g. lack of specific treatment protocols.</li> <li>● Temporal changes – changes in control over time; or may not reflect current guidelines</li> </ul>	<ul style="list-style-type: none"> <li>● Limited generalisability due to strict inclusion and exclusion criteria</li> <li>● Limited sample size</li> <li>● Significant financial investment</li> <li>● Time and resource intensive; sensitive to evolution of standard of care treatment</li> <li>● Limited follow up (e.g. due to costs)</li> <li>● May not be possible/feasible for some patient cohorts (e.g. rare tumours, where there are ethical concerns in randomisation, late effects).</li> </ul>	<ul style="list-style-type: none"> <li>● There is no universal approach. There are many different PROMs tools, and not all are validated.</li> <li>● Subjective nature – influenced by individual perceptions, bias and emotional states.</li> <li>● Response Bias: may be influenced by concerns about judgement, or fear of impact on treatment.</li> <li>● Variability of reporting, especially over time.</li> <li>● Cultural and language barriers may exclude some patient groups</li> </ul>	<ul style="list-style-type: none"> <li>● Limited patient perspective makes clinical interpretation more difficult (result may not have the same relevance for a patient).</li> <li>● Interobserver variability and bias (influence of experience, personal judgement, subjective impressions / influence of provider characteristics)</li> <li>● Limited information – may overlook important aspects of patient experience.</li> </ul>



	<ul style="list-style-type: none"> <li>● Lack of randomisation – confounding variables affect validity of associations in research.</li> <li>● Limited ability to assess care quality e.g. adherence to best practice.</li> <li>● Onward data sharing and confidentiality factors to be considered</li> <li>● Need for sustainable infrastructure.</li> <li>● Different registry databases across UK / devolved nations.</li> </ul>	<ul style="list-style-type: none"> <li>● Blinding challenges: often not possible/ ethical to blind participants in RT trials – may introduce bias.</li> <li>● Interference from cross over from one treatment arm to another</li> <li>● Challenge to design with increasingly complex cancer pathways, and personalisation of treatments.</li> </ul>	<ul style="list-style-type: none"> <li>● May lack clinical context: e.g. disease recurrence, comorbidities, other confounding factors.</li> <li>● Time and resource intensive (may extend clinic times)</li> <li>● Patient burden – can be burdensome on patients who already have physical and emotional challenges. May reduce compliance and data quality.</li> </ul>	<ul style="list-style-type: none"> <li>● Resource intensive</li> <li>● May not capture subtle changes in patient experience.</li> </ul>
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**Supplementary Table 1 - A range of healthcare data management solutions which appease the technical, logistical and regulatory hurdles for the data they store and present.**

<b>Solution</b>	<b>Audience</b>	<b>Data</b>	<b>Approach</b>	<b>Origin Country</b>
OpenSAFELY	Researchers	Electronic health records from general practitioner	Fully Synthetic Data, Trusted Research Environments, Open Analytics	U.K
Personal Health Train	Public, Innovators & Researchers	All healthcare data	Federated learning	Netherlands
Predict - breast cancer (Wishart et al., 2010)(Wishart et al., 2010)(Wishart et al., 2010)(Wishart et al., 2010)(Wishart et al., 2010)	Patients, Clinicians, Public	Cancer registry information (1999-2003)	Population output model	U.K
Trusted Research Environment service for England	Researchers	Range healthcare datasets. Viewable using the Data Access Request Service	Trusted Research Environment	U.K
Genomics England Research Environment	Researchers	Wide range of genome data	Trusted Research Environment	U.K
Scotland Data Safe Haven programme	Researchers	Electronic Health Records	Trusted Research Environment and Federated Learning	U.K

**Supplementary Table 2 – Successful example data sources opened to researchers and the public.**

# PART 1 OF 2 TREATMENT SUMMARY GUIDANCE (START)

PART 2 IS PROVIDED AT THE END OF TREATMENT

## 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 details



## 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 TREATMENT SUMMARY GUIDANCE (END)


### 6 TREATMENT DETAILS

- Type of radiotherapy
- Completed treatment dose in X fractions over X elapsed days
- Start date
- 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)

**Supplementary Figure 1.** Example of a treatment summary document which might be populated iteratively: Part 1 is for start of treatment and Part 2 is for the end. 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 HCPs. The example is based on EOT summaries created by the UK national proto beam therapy service - The Christie and University College Hospital London. *Template created using Canva software Version 1.88.*

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