Policies, Processes, and Principles of Informed Consent in Radiotherapy for Gynaecological Cancers: A UK National Survey

Abstract

Introduction: Informed consent is a legal requirement under The Health and Social Care Act 2008 and a vital part of patient-centred care. Despite national frameworks and guidance, there is significant variability in informed consent implementation across settings. This national service evaluation aimed to assess policies, processes, and principles guiding informed consent for gynaecological radiotherapy across United Kingdom (UK) NHS departments.

Methods: A survey exploring processes and training, principles, and values was sent to 58 NHS radiotherapy departments. Data were obtained from 38 departments (66% response rate), representing all UK nations. Ethical approval was obtained.

Results: Variation was observed in staff training, use of best-practice guidelines, and content of consent documentation. While 71% of departments used Royal College of Radiologists (RCR) consent forms, fewer identified professional guidance indicating a potential gap in guideline familiarity. Documentation varied in the number and detail of side-effects described but alignment was observed in core ethical principles. Respondents highlighted structural challenges, notably time and staffing constraints, which limited processes and patient support.

Conclusion: This is the first study to provide a national overview of informed consent policies and practices in NHS radiotherapy departments for gynaecological cancers. It identifies inconsistencies in training, documentation, and guideline awareness, but highlights shared professional values. Findings support the need for national guidance, standardised consent materials, and targeted staff education to ensure equitable and fully informed patient decision-making.

Implications for Practice: Informed consent should be treated as an ongoing, patient-centred process that extends beyond the clinician–patient interaction. All staff should be familiar with policies and procedures to support patients' understanding of treatment and long-term impacts. Standardised materials must be tailored to individual needs to facilitate meaningful, patient-centred discussions.

Keywords: Informed Consent, Radiotherapy / standards, Quality of Health Care, Patient-Centred Care, Communication

Introduction

In the United Kingdom, informed consent is a legal requirement under The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014, Regulation 11 (1) and a cornerstone of ethical, patient-centred care, particularly in oncology where treatment decisions can have profound physical, psychological, and reproductive consequences (2,3). In radiotherapy for gynaecological cancers, clinicians must communicate not only the risks and benefits of treatment but also potential long-term effects, including infertility, sexual dysfunction, bowel or bladder complications, lymphoedema, fatigue, and psychosocial impacts. Inconsistent monitoring and reporting of late effects have historically made it difficult to establish consensus on anticipated radiotherapy outcomes, leading to some effects being under-discussed or minimised (4,5).

Gynaecological radiotherapy often involves a combination of external beam radiotherapy and brachytherapy, which together present complex treatment regimens with a range of potential long-term effects, including sexual, reproductive, and pelvic toxicities (6–8). These intersecting burdens make obtaining truly informed, patient-centred consent especially challenging, though exploring the

principles of consent is relevant to other cancer populations facing complex radiotherapy regimens.

The General Medical Council's (GMC) professional standards outline seven principles that define best practice in obtaining informed consent (Figure 1) (2). These principles emphasise the patient's right to be involved in decisions about their care, to receive clear and relevant information tailored to their needs, and to participate in ongoing dialogue with clinicians. They also highlight clinicians' responsibilities to support patient understanding, respect individual values, and create conditions for truly informed, voluntary choice. Despite this national framework, significant variability persists in how these principles are operationalised across NHS settings, particularly in radiotherapy where multidisciplinary teams share responsibility for patient communication (9).

One

All patients have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able.

Two

Decision making is an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual patient.

Three

All patients have the right to be listened to, and to be given the information they need to make a decision and the time and support they need to understand it.

Four

Medical professionals must try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action.

Five

Medical professionals must start from the presumption that all adult patients have capacity to make decisions about their treatment and care. A patient can only be judged to lack capacity to make a specific decision at a specific time, and only after assessment in line with legal requirements.

Six

The choice of treatment or care for patients who lack capacity must be of overall benefit to them, and decisions should be made in consultation with those who are close to them or advocating for them.

Seven

Patients whose right to consent is affected by law should be supported to be involved in the decision-making process, and to exercise choice if possible.

Figure 1: The GMC Seven Principles of Decision Making and Consent (2)

While no formal national benchmark exists, professional standards expect clinicians conducting consent conversations to be competent in explaining treatment, risks, alternatives, and answering patient questions (2). Furthermore, guidance from the Society of Radiographers (SoR) states that "healthcare practitioners should not assume that patients and service users attending a department for a diagnostic procedure or radiotherapy treatment have fully understood the information given to them and have thereby given true informed consent, because they are often unaware of the exact nature of the procedure which they will undergo" (10). Staff training in consent discussions ranges from formal postgraduate scientific courses (e.g., Master of Science) to one-off inductions or annual

updates (9). Variability in training and practice is concerning because it may result in staff conducting consent conversations beyond their professional remit or without sufficient knowledge to respond to nuanced patient concerns, potentially undermining patient understanding and autonomy.

Evidence from patients in the United Kingdom (UK) reinforces these concerns. People with lived experience of gynaecological radiotherapy have previously reported feeling unprepared for treatment, overwhelmed by information at consent appointments, unsure what to ask, and often saying yes to everything without understanding potential long-term consequences (11,12). Patients described lifelong debilitating effects being minimised or not explained, leaving them disempowered. Personalised patient materials, including written booklets, leaflets, take-home guides, and videos, help patients prepare and clarify questions, though most still value in-person discussions for immediate clarification and reassurance (13,14). The provision of accessible information at multiple points in the pathway is essential to support informed, autonomous decision-making and reduce decisional conflict (15–17).

Shared decision-making (SDM) is central to effective informed consent, ensuring that patient values, preferences, and informational needs are addressed throughout the care pathway (18–20). However, evidence suggests that SDM is often implemented in a mechanistic, "tick-box" manner, neglecting emotional, relational, and contextual factors that influence patient decision-making (21,22). Evidence from radiotherapy, including previous work by members of the research team, indicates that patients desire SDM but that it is rarely implemented, with decisions being presented as non-choices and patients expressing dissatisfaction (11,23,24). Reviews of clinical practice guidelines indicate SDM is not frequently encouraged and advice on its implementation is rarely provided (19). Gender biases in guideline recommendations mean SDM is more consistently promoted in male-only cancers (e.g., prostate) than in female-only cancers (e.g., endometrial), highlighting potential inequities (19).

Guidance from National Institute for Health and Care Excellence (NICE) outlines general principles for patient-centred care and emphasises that meeting patients' informational needs is a core part of shared decision making (25). While these principles support SDM in general, NICE does not provide detailed recommendations for conducting consent discussions in radiotherapy, particularly regarding long-term and non-therapeutic effects. To reduce variability and improve the standards of information provided prior to treatment, national standardised radiotherapy consent forms have been introduced by the Royal College of Radiologists (RCR) (26). The forms aim to encourage adoption of similar consent approaches in the "dialogue" with patients, and support peer review to identify and support any doctors who are using sub-optimal methods to obtain consent (27). However there remains no consensus on which late effects should be discussed, how they are communicated, or the sequencing of discussions (28,29) and they do little to put the patient at the centre of the discussion.

The problem of consent-form variability is compounded by difficulties in readability. A recent analysis of radiotherapy consent documents in multiple institutions in the United States found that only a small fraction met recommended readability standards for patient materials, with many containing complex, technical terminology that patients struggle to understand (30). This suggests that even where forms are used, they may not meaningfully support patient comprehension. This variability may affect patients' understanding of risks, their ability to weigh trade-offs between survival and quality of life, and their overall satisfaction with care.

The GRACE study (Creating patient-centred infrastructures to enhance informed consent and improve patient experience of radiotherapy for gynaecological cancers, NIHR160995) is a multi-phase research programme aiming to create patient-centred infrastructures to enhance informed consent and improve the patient experience of radiotherapy for gynaecological cancers. The service evaluation presented here forms one component of the GRACE study, designed to map current departmental policies, practices, and principles guiding consent across the UK. By understanding

existing consent processes, staff training, patient-facing materials, and the values underpinning practice, this sub-study provides essential evidence to inform the development of patient-centred interventions within the broader GRACE programme.

Methods

The aim of this mixed-method service evaluation was to map current consent practices across all 58 UK NHS Trusts providing gynaecological radiotherapy, identify gaps, and provide evidence to guide interventions supporting patient-centred consent. The service evaluation assessed:

- Policies and documentation used for consent
- Staff training and competence in consent discussions
- Patient-facing informational materials
- The principles and values underpinning departmental consent practices, including alignment with the GMC's Seven Principles of Decision-Making and Consent.

In April 2025, the survey was distributed to all radiotherapy service managers with a gynaecology radiotherapy service in the UK (n= 58: England: 48, Wales: 3, Scotland: 6, Northern Ireland: 1). Managers were asked to forward the survey to anyone in their department involved in consent for patients requiring gynaecological radiotherapy. Follow-up emails were sent with the aim of receiving at least one response from each department. The survey was open for two months.

Ethical Approval

This service evaluation was approved by the Lancaster University Faculty of Health and Medicine Research Ethics Committee (FHM-2025-5213-RECR-3). It was reviewed using the Health Research Authority (HRA) decision tool and determined to be a service evaluation, not research. As such, it did not require approval through the NHS Research Ethics Committee.

Survey Design and Consent

The service evaluation was conducted as an online survey using Qualtrics survey software (31) under license at Lancaster University. The survey was developed by the immediate GRACE survey research team (DA, LA, DH, VK) informed by existing literature on consent practices, including those from other comparable specialities such as the PROMICE framework from genomics (32) and by methodological approaches used in plastic surgery (33). A draft survey was reviewed by the wider GRACE team, including clinicians, qualitative researchers, and patient researcher (HP) who contributed substantially to refining question content, structure, and accessibility.

Questions relating to values and principles were derived directly from the wording of the General Medical Council's guidance to ensure fidelity to nationally recognised standards (2).

The final survey comprised three sections: Processes and Training, Values, and Principles. Section One focused on departmental practice and patient- and staff-facing documentation. Sections Two and Three of the survey explored the principles and values underpinning departmental consent practices, focusing on autonomy, trust, and patient well-being. Well-being was further subdivided into support during consent and following treatment, reflecting the practical and emotional aspects of patient experience.

The survey included a mix of closed- and open-ended questions, document upload boxes, Likert scales, and free-text options for long-form answers. Participants provided consent by reading the information on the survey landing page and continuing with the survey. A copy of the survey distributed to departments is included as Appendix A.

Piloting

The survey was piloted at two NHS radiotherapy centres to assess face validity, usability, and completeness. Revisions were made based on pilot feedback. These pilot centres were included in the main survey distribution, and both submitted official responses, although the individuals

responding were not necessarily those involved in the pilot stage.

Recruitment and Data Collection

An email containing information about the survey, a link to the survey, and contact details for the research team was sent to Radiotherapy Service Managers at 58 UK radiotherapy departments. Recipients were asked to complete the survey themselves or forward it to the staff member responsible for patient consent in their department. Satellite centres and privately funded providers were excluded.

Participation was voluntary. All survey data were stored in a password-protected Qualtrics account on Lancaster University servers and were accessible only to the research team. Once the survey closed, all identifying information was removed to ensure anonymity. Participants provided the name of their department; for departments with multiple responses, scores were averaged to provide an overall view. In duplicate qualitative responses from the same department, all information in terms of long-form feedback and submitted staff and patient-facing documentation, were included in data analysis to ensure completeness of data captured.

Data Analysis

Survey responses and supplementary documentation were analysed descriptively with reference to GMC principles (2), to provide a national overview. Statistical analysis of survey responses was conducted using Microsoft Excel. DA collated and cleaned the dataset and conducted the initial descriptive analysis.

Free-text responses were limited in number. These were reviewed manually by DA and LA, who independently examined all responses to identify recurring words, phrases, and descriptive points relevant to departmental consent practices including examples of good practice, and areas of variability. Analysis remained close to the surface meaning of the text, consistent with a manifest content approach (34). Summary responses presented in the manuscript were selected to illustrate these themes. Selection was descriptive and illustrative rather than systematic, with examples chosen to reflect the range of topics raised across trusts. Interpretations were compared and discussed to ensure shared understanding and consistency in how qualitative findings were summarised. No formal coding framework or computer-assisted qualitative data analysis software was used; discrepancies were resolved collaboratively.

Qualitative descriptors such as “most sites,” “several trusts,” or “in some trusts” reflect the observed patterns in the free-text responses and the variability across trusts. These terms do not represent precise numerical counts, as not all respondents provided free-text comments and responses from multiple staff within a trust were merged. This approach allowed for a national overview of trends without over-interpreting the limited qualitative data.

Results

Response Rate

This service evaluation provides a national picture of how informed consent for radiotherapy in gynaecological cancers is currently managed across NHS departments in the UK. 40 responses were received from 38 of the 58 departments that were contacted, giving a 66% overall response rate, and representing services in all four UK nations (England: 34/48, Wales: 1/3, Scotland: 2/6, Northern Ireland: 1/1).

Two trusts each returned two responses. These were combined to make a single response per trust by averaging numerical scores and combining all free text comments, resulting in 38 unique trust level datasets. Of the 38 trusts, 30 were full responses (78.9%) completing all three survey sections, and 8 were partial responses, completing only section one of the survey.

Out of the 40 total responses, 33 therapeutic radiographers (82.5%), 3 clinical oncologists (7.5%), 2

cancer nurse specialists (5.0%), 1 gynaecological advanced practice radiographer (2.5%), and 1 trainee consultant therapeutic radiographer (2.5%) completed the evaluation. This is shown in Figure 2.

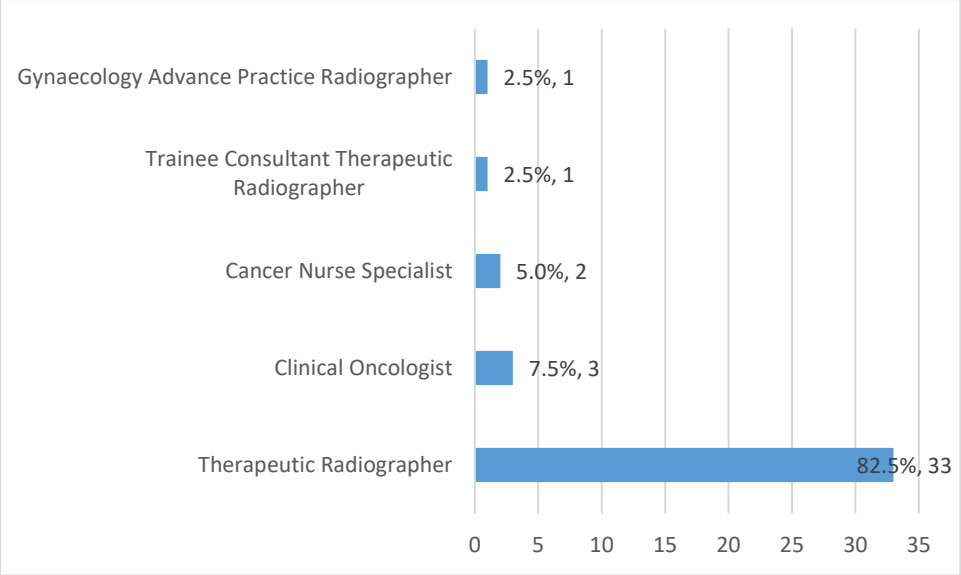

Figure 2. Frequency of profession of survey responses.

The findings summarise national patterns in departmental processes, staff training, consent documentation, and the ethical values that underpin informed consent in radiotherapy. Variation observed across responses reflects local implementation and interpretation of national guidance rather than a unified national standard.

Results are presented in three sections corresponding to the survey structure: (1) Processes and Training, (2) Principles, and (3) Values, to provide a coherent national overview of current practice.

Section One: Processes and Training

Section One explored departmental processes and staff training related to informed consent for gynaecological radiotherapy. Questions used multiple-choice, Likert-scale, and free-text formats, with options to upload supporting documents (see Appendix A).

Most departments (n = 23/38; 60.5%) reported that patients were perceived to be *slightly unaware* of radiotherapy when first attending treatment. A smaller number (n = 5/38; 13.2%) described patients as *highly aware*, while n = 4/38 (10.5%) considered them *highly unaware*. These findings reflect staff perceptions of patient awareness at the point of consent rather than patient self-reports.

All responding trusts (100%) stated that clinical oncologists were responsible for discussing radiotherapy with patients. Other staff frequently involved included therapeutic radiographers (n = 26/38; 68.4%) and cancer nurse specialists (n = 25/38; 66.8%), with smaller proportions naming medical oncologists (n = 10/38; 26.3%), surgeons (n = 8/38; 21.1%), or third-sector staff (n = 2/38; 5.3%). A few departments also mentioned advanced practitioners, registrars, or diagnostic clinicians (Figure 3).

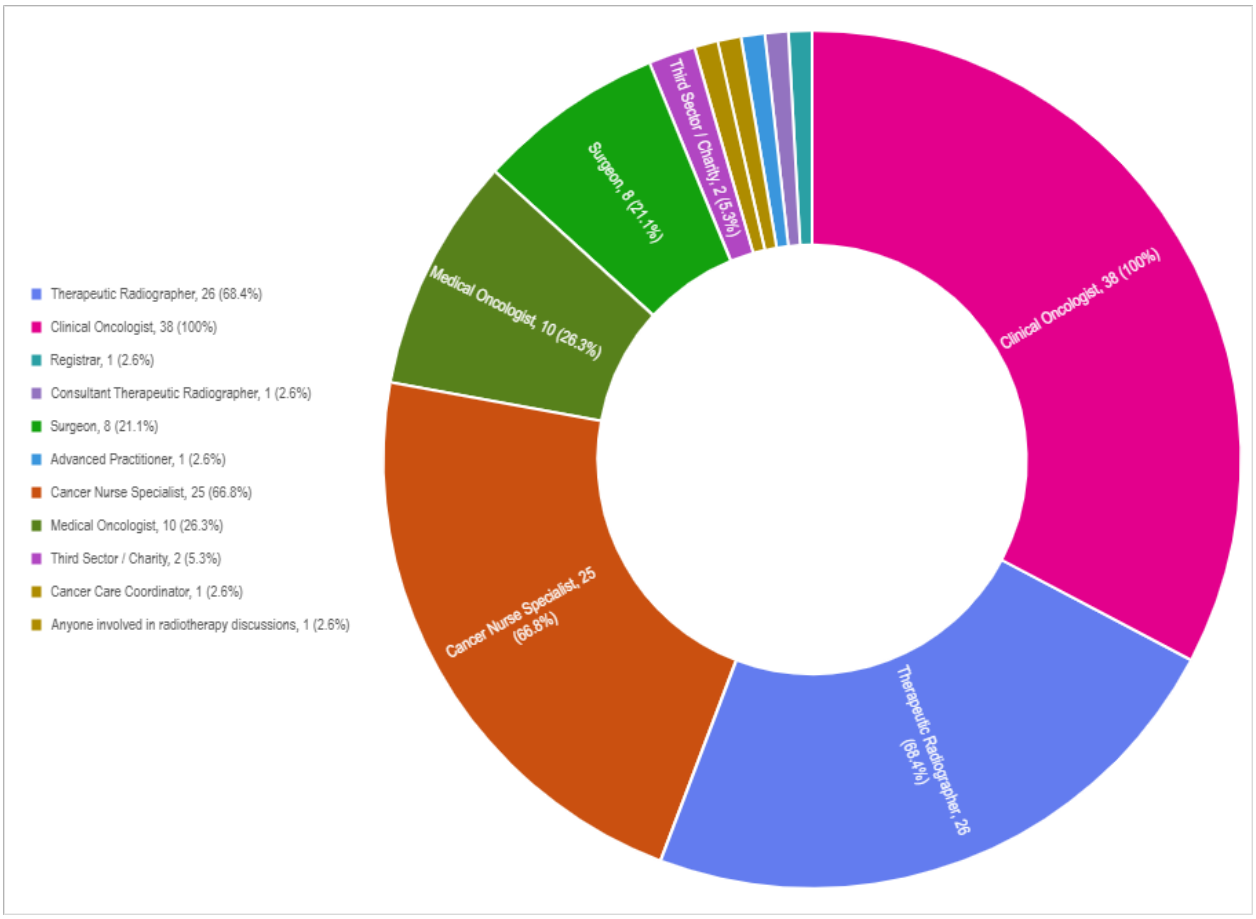

Figure 3. A sunburst chart indicating all who are responsible for discussing radiotherapy with patients along the patient pathway.

Sixteen trusts (n = 16/38; 42.1%) submitted patient-facing documents used during the consent process. These included both locally developed materials and RCR or Macmillan templates. Most trusts (n = 27/38; 71.1%) used RCR consent forms, while n = 9/38 (23.6%) used locally produced versions. Non-RCR forms (n=9) varied in detail of side-effects (range: 8-20), to a maximum of 20 acute effects and 12 late effects being described. The RCR form lists 14 short-term and 25 long-term side effects. One trust included an additional information sheet outlining the consent process, expected side effects, and sample patient questions.

A third of trusts (n = 13/38; 34.2%) reported plans to revise their consent process, most often by adopting RCR forms or introducing e-consent systems. Several intended to update patient information materials by adding QR codes, videos, or links to support organisations such as Macmillan.

Regarding the use of a cooling-off period between initial and final consent consultations, n = 17/38 (44.7%) used a single session, n = 4/38 (10.5%) used two, and n = 9/38 (23.7%) described flexible arrangements based on treatment type or patient preference. Some provided a second opportunity for discussion even if consent was signed at the first consultation.

Training for consent varied by staff group (Table 1). Clinical oncologists and specialty trainees followed formal oncology training programmes. Advanced practice and consultant radiographers combined postgraduate level consent modules with local competency assessments, while radiographers and clinical nurse specialists often received trust-led medico-legal or in-house training. In several trusts, radiographers or nurses explained procedures but did not formally obtain consent.

Table 1: Showing training pathways for staff groups

Staff Group	Training Pathways for Staff	Notes
Clinical Oncologists	Must undertake relevant specialty/registrar oncology training	Most sites reported formal oncology training. A few trusts did not specify training details.
Specialist Trainees	Observed by senior staff (consultants/oncologists) until competent. Undertake registrar/consultant training programmes	In most trusts, trainees are supervised until competency. In a minority of trusts, training procedures were unclear or not reported.
Advanced Practice / Consultant Therapeutic Radiographers	MSc consent modules Trust-led consent training In-house supervision and mentoring Competency packages and clinical logging	Most sites combine postgraduate studies and in-house training. In some trusts, radiographers explain but do not obtain consent.
Clinical Nurse Specialists (CNS)	Some follow same pathway as radiographers (MSc + trust training) Sometimes explain procedures only but not take consent	In most trusts, CNSs do not take consent. In a few trusts, CNSs may explain procedures without obtaining consent.
Others (e.g. Radiographers, Support Staff)	All radiographers receive medico-legal training on consent taking.	Most trusts provide this training; details vary by department.

Eight trusts (n = 8/38; 21%) reported using local or international guidance to support informed consent, most commonly RCR or NICE guidelines, while others cited SoR publications or internal trust policies. Many respondents (n = 24/38; 63%) were unsure whether such frameworks were in

use (Figure 4).

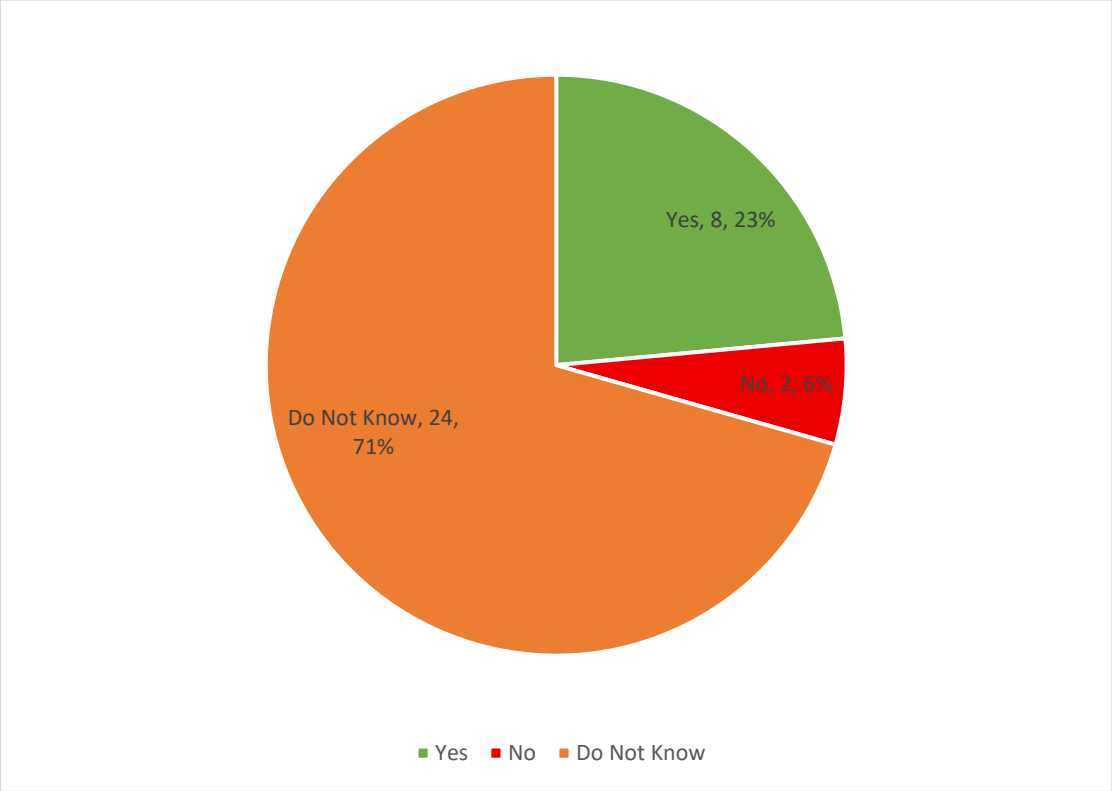

Figure 4. Responses to question, Do trusts use any local or international best practice guidelines or guidance to support informed consent for gynae cancers?

Eight trusts (n = 8/38; 21.1%) submitted staff-facing documentation, ranging from detailed policy guidance to concise checklists outlining consent responsibilities and required discussions.

Section Two: Principles

Section Two examined how departmental processes aligned with the seven GMC principles of decision-making and consent (2). Trusts rated their alignment on a 1–10 Likert scale (1= "Never" to 10= "All the time"), with those scoring below 9 asked to provide explanations in free-text responses. A total of 30 unique trust responses were analysed for this section.

Nine trusts (n = 9/30; 30.0%) reported areas of partial alignment, particularly in maintaining ongoing dialogue, ensuring patient understanding, and supporting patients lacking capacity. Common themes included time constraints limiting repeated discussions, challenges supporting patients with memory or capacity issues, and variable approaches to shared decision-making. Table 2 summarises representative responses.

Table 2: Summaries of responses for each GMC principle

Question	Summary of Responses
Q10.A. Please describe when patients **do not** have the right to be involved in decisions about their treatment and care and be supported to make informed decisions if they are able.	If a Deprivation of Liberty is in place or if patients lack capacity, including to such an extent that consent forms are signed by someone with power of attorney. However, patients will be included in all conversations and should be supported by staff
Q10.B. Please describe when decision making is **not** an ongoing process focused on meaningful dialogue: the exchange of relevant information specific to the individual	Once a patient has begun treatment then consent is assumed for future treatments. This is influenced by time constraints which inhibit future consent discussions.

patient.	Patients may not be involved due to their inability to remember, for example patients with dementia.
Q10.C. Please describe when patients **do not** have the right to be listened to, and to be given the information they need to make a decision and the time and support they need to understand it.	This should never occur and patients should always be supported, however time can be a factor in inhibiting this.
Q10.D, Please describe when those taking consent **should not** try to find out what matters to patients so they can share relevant information about the benefits and harms of proposed options and reasonable alternatives, including the option to take no action.	This would be a rare occurrence and would involve more than one member of staff. If new information comes to light regarding patient's treatment or wishes this should be reported back to other staff.
Q10.E. Please describe when patients whose right to consent is affected by law are **not** supported to be involved in the decision-making process, and to exercise choice if possible.	If there is a lack of capacity, then family members may be included.

Section Three: Values

Section Three explored the values underpinning informed consent. Thirty trusts (n=30/38; 78.9% of the sample) provided responses. This is 52% of UK sites responsible for delivery of gynae radiotherapy (30/58).

Supporting autonomy:

Most trusts described providing comprehensive, accessible information on treatment options, risks, and benefits. Many emphasised allowing patients time for reflection and encouraging questions or second opinions. Inclusion of interpreters, support staff, and family members was also highlighted as key to equitable, patient-centred discussions.

Supporting well-being during consent:

Half of the trusts (n = 15/30; 50.0%) offered emotional and informational support during consent appointments, including access to counselling staff. Departments aimed to allow sufficient time for questions and continuity of staffing to build rapport and trust. Several noted the valuable role of charities such as Macmillan.

Supporting well-being after treatment:

Twelve trusts (n = 12/30; 40.0%) described structured aftercare pathways, including patient-initiated follow-up and staff-led consultations focusing on late effects. Follow-up methods included written or verbal information, phone calls, and in-person clinics, with six trusts (n = 6/30; 20.0%) offering dedicated late-effects clinics.

Fostering trust:

Departments emphasised open, honest communication and consistent staffing. Many adhered to RCR or local consent guidelines and encouraged patients to seek second opinions or alternative clinicians if desired.

Future developments:

Several trusts reported ongoing or planned improvements to consent processes, including implementation of e-consent systems and adoption of RCR-based forms to improve both patient experience and staff efficiency. One trust noted ongoing challenges related to time and staffing constraints affecting the delivery of consent discussions.

Discussion

This service evaluation provided insight into how informed consent for gynaecological radiotherapy

is implemented across NHS trusts in the UK. A 66% response rate, including representation from all four UK nations, allowed a broad overview of current practices.

Variation and Inconsistencies

Nationally, there was notable variability in how radiotherapy departments approach the informed consent process. Departments differed in patient preparation, consent documentation, staff training, and awareness/adherence to best-practice guidance. Although the majority of trusts stated that patients often arrive "slightly unaware" of radiotherapy, the extent to which information is provided before treatment, and the time given to absorb it, varied considerably. This mirrors findings from previous qualitative research in radiotherapy: many patients report that they experienced consent not as a meaningful choice but as acceptance of clinician recommendation, often with minimal explanation of harms and limited opportunity for dialogue (13). Variability in a "cooling-off" period and the quantity or format of informational materials suggests that some patients may lack sufficient time or support to engage in fully informed decision-making, potentially challenging interpretation of GMC Principle 3, which emphasises giving patients "the time and support they need to make decisions" (2).

An uneven adoption of RCR consent forms was also observed: 71.7% of trusts reported using the RCR form, while others relied on trust-specific versions. These varied markedly in the detail of late effects, with some listing as few as eight acute side-effects and six late effects, and others including over twenty acute and twelve late effects. As previous work in the United States found, departmental specific consent forms vary in readability, with many containing complex terminology (30). Where consent forms are developed in house, they must meaningfully support patient comprehension. Any variability has clear implications for how prepared patients are regarding treatment and its consequences. Patients need to know which effects may occur, in order to make informed decisions and access information on how to mitigate or self-manage late effects post-treatment. For example, maintaining pelvic health or managing fatigue, thus supporting autonomy and self-efficacy in the years following treatment. However, few consent forms provided such targeted guidance, reflecting a gap in meeting GMC Principle 1, which centres on meaningful patient involvement and understanding of what matters to them (2).

Moreover, some departments that used RCR consent forms did not identify the accompanying RCR, SoR, NICE, or GMC guidance as "best practice" (2,10,25). This disconnect suggests an educational gap or lack of familiarity with professional standards. The majority of survey respondents, 82.5%, were Therapeutic Radiographers, who in most departments do not routinely obtain formal written consent, unless in an Advanced Practice or Consultant Therapeutic Radiographer role. Nevertheless, professional guidance from the SoR emphasises that Therapeutic Radiographers play an integral role in ensuring patients have fully understood the information provided to them, supporting true informed consent throughout the care pathway (10).

Inconsistencies in guideline awareness risk fragmenting the informed consent process, leaving patients exposed to uneven standards of explanation and support. This finding underlines the need for greater training, audit, and reinforcement of national consent principles to ensure that practitioners across disciplines apply the same professional benchmarks and that patients attending radiotherapy centres are fully informed about the procedures they are undergoing.

Training requirements for staff seeking consent also varied widely, ranging from MSc-level training to internal competency assessments, with several trusts reporting unclear procedures. Where training is inconsistent or informal, there is a risk that consent conversations fail to meet Principle 2: that information must be "shared in a way the patient can understand," and Principle 4, which calls on clinicians to explore what matters to each patient individually (2).

Together, these variations in training, guidance adherence, and information provision highlight a potential gap between the legal and ethical standards of informed consent and their implementation in practice. Robust training with structured cooling-off periods, and multi-format educational

materials, would better align to the GMC's principles of dialogue, understanding, and patient involvement (2).

Gaps Between Aspiration and Reality

While there was variation in practice, strong alignment emerged in the values and principles underpinning departmental approaches. Trusts emphasised accessibility of information, inclusion of family or support persons, and the emotional aspects of consent, reflecting clear commitment to Principle 5, which encourages clinicians to recognise patients' wider support networks and circumstances (2).

However, respondents also highlighted barriers to delivering the standard of care they aspire to, particularly time and staffing constraints. Our findings echo a multidisciplinary review of consent practices in radiotherapy that found having a well informed decision-support person, and ensuring clear, patient centred communication, significantly improves patients' ability to make deliberate informed decisions (24). Limited resources restrict opportunities for extended discussions, follow-up consultations, and continuity of care, conditions essential for maintaining Principle 6 and the SoR guidelines, which stresses that consent is an ongoing process, not a single event (2,10). Structural limitations therefore risk undermining the principles practitioners value, creating a disjunction between aspiration and practice.

Opportunities for Improvement

Thirty-three percent of trusts reported plans to revise their consent processes, including introducing e-consent systems and adopting RCR forms to improve standardisation. These changes may help streamline workflows and ensure consistency but must not compromise relational communication. A purely digital or standardised format could risk depersonalising the consent process, reducing opportunities for dialogue and empathy that are central to Principle 7, the ongoing duty to review decisions as circumstances evolve (2).

Based on the variability identified in this service evaluation, embedding more formalised yet flexible consent procedures may represent an opportunity for improvement in practice. Departments could benefit from formalised cooling-off periods, defined roles for consent-takers, and targeted staff education on national standards, ensuring that the consent principles remain embedded in daily practice. Similarly, greater consensus on the evidence base informing consent forms, particularly around late effects, may help reduce variation and support more consistent, evidence-informed guidance across the UK.

The findings presented here capture staff perspectives on consent processes, including their perceptions of patients' awareness, understanding, and preparedness for treatment. This focus aligns with the aim of this stage of the GRACE project: to map the professional infrastructures, practices, and values that shape informed consent in radiotherapy (NIHR160995). While later phases of the GRACE project will incorporate lived experiences, staff perspectives remain essential to understanding how consent is operationalised in practice and the assumptions that underpin current approaches to communication, timing, and decision-making.

Limitations

This study had several limitations. Responses were dominated by Therapeutic Radiographers (82.5%), meaning some insights, especially regarding Oncologist-led consent, may be underrepresented. Additionally, single responses per trust mean that values and principles may reflect individual perspectives rather than departmental consensus. Nonetheless, the strong participation rate, above that typically achieved in NHS staff surveys, and national reach provide a valuable snapshot of current consent practices across UK radiotherapy.

Conclusion

This is the first study of its kind to provide a comparative analysis of informed consent policies and practices specifically within NHS radiotherapy departments for patients undergoing treatment for

gynaecological cancers. By examining how departmental processes, staff training, and documentation interact with national frameworks, it contributes original insights into the consistency, quality, and ethical foundations of consent within UK radiotherapy.

Findings highlight considerable variation in consent materials, processes, and staff training, alongside strong alignment in the principles guiding practice. While most trusts share a commitment to patient-centred care, disparities in awareness and application of national best-practice guidance, such as GMC, NICE, RCR, and SoR frameworks (2,10,25,26), suggest an educational or familiarity gap. Addressing this through clearer national guidance and targeted training could strengthen consistency and confidence in consent-taking.

Differences in the level of detail provided about acute and late side effects also raise questions about how prepared patients are for post-treatment experiences and whether consent documents draw on consistent, evidence-based information. Ensuring that patients not only understand potential effects but also receive specific advice on mitigating or managing them would support long-term autonomy and wellbeing.

While tools such as RCR consent forms and e-consent platforms may enhance standardisation and efficiency, they must balance completeness with clarity and preserve meaningful patient–clinician interaction. A one-size-fits-all approach risks undermining patient engagement if not supported by flexible, patient-centred implementation.

Although this study focused on gynaecological radiotherapy, the findings have broader implications for consent practices across other oncology and complex treatment settings. Many cancer populations, including patients receiving radiotherapy for pelvic cancers (e.g., colorectal, bladder) and head and neck cancers, face similarly complex regimens with significant long-term effects, such as bone necrosis, dysphagia, or organ dysfunction. The challenges in achieving truly patient-centred consent, variability in staff training, inconsistent use and over reliance on standardised forms, and gaps in patient-facing information, are therefore likely relevant across these groups. Highlighting areas for improvement, including consistency of information, integration of national guidance, and support for meaningful patient-clinician dialogue, can inform broader efforts to enhance informed consent in radiotherapy.

Ultimately, improving informed consent in radiotherapy will require both structural and educational change: protected consultation time, adequate staffing, ongoing staff training, and national efforts to align documentation and guidance. Through these measures, NHS trusts can ensure consent remains a dynamic, collaborative process that empowers patients to make fully informed decisions about their care.

References

1. Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.

2. General Medical Council. Guidance on Professional Standards and Ethics for Doctors: Decision Making and Consent. [Internet]. General Medical Council; 2020. Available from: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/decision-making-and-consent

3. Reyna VF, Nelson WL, Han PK, Pignone MP. Decision making and cancer. American Psychologist. 2015;70(2):105.

4. Nicolaije KAH, Husson O, Ezendam NPM, Vos MC, Kruitwagen RFPM, Lybeert MLM, et al. Endometrial cancer survivors are unsatisfied with received information about diagnosis, treatment and follow-up: a study from the population-based PROFILES registry. Patient Education and Counseling. 2012;88(3):427–35.

5. Szproch AK, Maguire R. A systematic review of the factors associated with regret post-cancer treatment. Journal of Psychosocial Oncology. 2022;40(1):1–25.

6. Sekse RJT, Hufthammer KO, Vika ME. Fatigue and quality of life in women treated for various types of gynaecological cancers: a cross-sectional study. Journal of clinical nursing. 2015;24(3–4):546–55.

7. Pfaendler KS, Wenzel L, Mechanic MB, Penner KR. Cervical cancer survivorship: long-term quality of life and social support. Clinical therapeutics. 2015;37(1):39–48.

8. Hofsjö A, Bergmark K, Blomgren B, Jahren H, Bohm-Starke N. Radiotherapy for cervical cancer - impact on the vaginal epithelium and sexual function. Acta Oncol. 2018 Mar;57(3):338–45.

9. Orr M, Rosbottom K. Departmental practice on informed consent in radiotherapy departments: a UK evaluation. Journal of Radiotherapy in Practice. 2025;24:e1.

10. Society of Radiographers. Obtaining consent: a clinical guideline for the diagnostic imaging and radiotherapy workforce [Internet]. London, UK; 2020 Jan [cited 2025 Oct 6] p. 49. Available from: https://www.sor.org/learning-advice/professional-body-guidance-and-publications/documents-and-publications/policy-guidance-document-library/obtaining-consent-a-clinical-guideline-for-the-dia

11. Ashmore L, Singleton V, Kragh-Furbo M, Stewart H, Hutton D, Singleton C, et al. We need to talk about... radiotherapy for gynaecological cancer. Lancaster, UK: Lancaster University; 2022.

12. Ashmore L. Impacts of Radiotherapy for Gynaecological Cancer on Social, Personal and Sexual Lives: A Qualitative Analysis of Patient Narratives. Women's Health.

13. Smith SK, Nathan D, Taylor J, Van Gelder E, Dixon A, Halkett GK, et al. Patients' experience of decision-making and receiving information during radiation therapy: a qualitative study. European Journal of Oncology Nursing. 2017;30:97–106.

14. Powlesland C, MacGregor F, Swainston K. Women's experiences of information, education and support when undergoing pelvic radiotherapy for gynaecological cancer: An exploratory qualitative study. Radiography. 2023;29(1):70–5.

15. Latest national results [Internet]. National Cancer Patient Experience Survey. [cited 2025 Oct 6]. Available from: https://www.ncpes.co.uk/latest-national-results/

16. Connolly T, Reb J. Regret in cancer-related decisions. Health Psychology. 2005;24(4S):S29.

17. Stacey J. Teratologies. A Cultural Study of Cancer. London: Routledge; 1997.

18. Coulter A, Collins A, Edwards A, Entwistle V, Finnikin S, Joseph-Williams N, et al. Implementing shared decision-making in UK: Progress 2017–2022. Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen. 2022;171:139–43.

19. Rivera-Izquierdo M, Maes-Carballo M, Jiménez-Moleón JJ, Martínez-Ruiz V, Blaakær J, Olmedo-Requena R, et al. Gender bias in shared decision-making among cancer care guidelines: A systematic review. Health Expectations. 2023 June;26(3):1019–38.

20. Green H, Rieu R, Slevin F, Ashmore L, Bulbeck H, Gkogkou P, et al. Best Practice for Patient-centred Radiotherapy in Clinical Trials and Beyond—A National Multidisciplinary Consensus. Clinical Oncology. 2025;39:103732.

21. Kunneman M, Gionfriddo MR, Toloza FJ, Gärtner FR, Spencer-Bonilla G, Hargraves IG, et al. Humanistic communication in the evaluation of shared decision making: a systematic review. Patient education and counselling. 2019;102(3):452–66.

22. Aggarwal A, Davies J, Sullivan R. “Nudge” in the clinical consultation–an acceptable form of medical paternalism? BMC medical ethics. 2014;15(1):1–6.

23. van Hienen AR, Offermann CJW, Boersma LJ, Jacobs MJG, Fijten RRR. Bridging the care gap: patients’ needs and experiences regarding shared decision-making in radiotherapy. Clinical and Translational Radiation Oncology. 2025 Jan 1;50:100897.

24. Leech M, Katz MS, Kazmierska J, McCrossin J, Turner S. Empowering patients in decision-making in radiation oncology – can we do better? Molecular Oncology. 2020;14(7):1442–60.

25. NICE. Shared decision making [Internet]. NICE; [cited 2023 July 7]. Available from: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/shared-decision-making

26. Royal College of Radiologists. National standard site-specific radiotherapy consent forms. London, UK; 2021 p. 13.

27. Kenney-Herbert E, Mylonas M, Murphy T, Roques T. Consent consensus: time for national standard consent forms as an aid to robust consent. BMJ. 2023 July 25;382:p1531.

28. Kenney-Herbert E, Mylonas M, Todd J, Tipples K. Consent Consensus: Time for a National Site-Specific Consent Form for Radiotherapy? Clinical Oncology. 2020;33(1):1–4.

29. Kok DE, Winkels RM, van Herpen CM, Kampman E. Toxicity-induced modification of treatment: what is in a name? European Journal of Cancer. 2018;104:145–50.

30. Perni S, Rooney MK, Horowitz DP, Golden DW, McCall AR, Einstein AJ, et al. Assessment of Use, Specificity, and Readability of Written Clinical Informed Consent Forms for Patients With Cancer Undergoing Radiotherapy. JAMA Oncol. 2019 Aug;5(8):e190260.

31. Qualtrix XM. Qualtrics XM Survey Software [Internet]. 2025. Available from: (2025) [accessed 5/8/25] Qualtrics XM: The Leading Experience Management Platform

32. Koplin JJ, Gyngell C, Savulescu J, Vears DF. Moving from 'fully' to 'appropriately' informed consent in genomics: The PROMICE framework. Bioethics. 2022;36(6):655–65.

33. Cooter RD, Brightman LA, Deva A, Murphy RXJ, Larsen M, Khashaba A. Developing an International Framework for Informed Consent in Plastic Surgery: A Focus on Cosmetic Breast Augmentation. Plastic and Reconstructive Surgery – Global Open. 2023 Nov;11(11):e5371.

34. Dooley KJ. Using manifest content analysis in purchasing and supply management research. Journal of Purchasing and Supply Management. 2016;22(4):244–6.