

Departmental practice on informed consent in radiotherapy departments: a UK evaluation

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Abstract

Introduction: Valid and informed consent in healthcare is an ethical and legal requirement. This evaluation reports the practices within UK radiotherapy departments surrounding consent processes and therapeutic radiographer (TR) education. This article focuses on those patients who are considered to lack the capacity to consent.

Method: This service evaluation adopted a qualitative research design. Seventy-six radiotherapy department managers were sent the online survey: containing a combination of open, closed and free text questions relating to consent practices. Descriptive analysis using Microsoft Excel was performed; additional correlation analysis was attempted with Fisher's exact test using Statistical Package for the Social Sciences.

Results: TRs from 39 radiotherapy departments (51%) completed the survey. Analysis of results demonstrated obtaining written consent before radiotherapy treatment was completed in all departments. Assessment methods used to determine capacity to consent varied across the departments. Responses identified 37 departments employ a different consent form for those considered to lack capacity. Thirty-eight departments have a policy surrounding consent; 16 departments reported no formal TR education in consent. Of the remaining 22 departments, 13 departments included lack of capacity within their education package.

Conclusion: To ensure best practice throughout the UK, it is recommended that radiotherapy departments review their consent processes to ensure they are in the best interests of the patient. It is recommended that TRs are familiar with their regulatory body standards and the ethical and legal issues surrounding consent; all departments should consider capacity and those considered to lack capacity within their education and training framework.

Introduction

Informed consent is a fundamental ethical and legal requirement in healthcare; informed consent elicits dialogue between patients and clinician before any type of medical test, examination or treatment is undertaken.¹ In 2015, following the outcome of the *Montgomery v Lanarkshire Health Board* case in the United Kingdom Supreme Court, the standard of informed consent was redefined, embracing patient autonomy through meaningful and clear conversations.² Written consent for radiotherapy is advised due to the complexities of the treatment, significant risks it poses and can be withdrawn at any time.^{1–3} Traditionally obtaining written consent has been completed by a medical professional such as a clinical oncologist; however, delegation to suitably qualified allied health professionals (AHPs) including consultant radiographers working within a defined scope of practice is increasing.⁴ Good consent practices include offering a copy of the consent form to the patient; providing additional information such as leaflets and utilising a two-part consent process 'confirmation of consent' to ensure that patients wish to go ahead with their radiotherapy.^{1,5} National site-specific radiotherapy consent forms were launched in May 2021 to support clinicians when consenting for radiotherapy and include these good practices.⁶

Mental capacity

Mental capacity is concerned with a person's ability to exercise their autonomy to make decisions; as such they have the right to decline or refuse treatment if they wish to do so.⁷ It is suggested that in England and Wales there are approximately two million people who lack the mental capacity to make decisions for themselves due to illness, injury or disability.⁷ In 2021, there were over 940,000 people in the UK living with dementia,⁸ a proportion of which may lose the capacity to make decisions for themselves or have fluctuating capacity. Projections suggest the number living with dementia will rise to one million by 2030.⁸ Over 950,000 adults in England are living with a learning disability,⁹ and it is inferred that 100,000 of working-aged adults have moderate to severe learning disabilities and are receiving long-term social care support and so may lack the capacity to make decisions for themselves.¹⁰

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Respect for autonomy is an ethical principle within healthcare; for patients to make self-determined treatment choices, they need to be given appropriate information and to have the capacity to understand the information given to them. Mental capacity assessments are based around a person's capability to comprehend information and to use that information to make an informed decision.¹¹ For radiotherapy, a person's capacity is to be established before the signing of a consent form; any decision for someone who is considered to lack capacity must be made in that person's best interest, with a different consent form known as consent form 4 or NHS best interests form recommended for use.^{1,3}

Guidance for assessing capacity to consent has been provided by professional bodies,^{3,12,13} but there is little agreement on a choice of capacity assessment tool or if professional judgement solely is sufficient. A systematic review conducted by Pennington et al reported 9 UK-legal capacity assessments, including MacArthur competence assessment tool treatment (MacCAT-T), the competency to consent to treatment instrument and structured interview for competency or incompetency assessment testing and ranking inventory.¹⁴ While considered reliable and validated tools there are limitations in using these including a significant training and administrative burden, it is suggested that the most rigorous approach is an assessment tool and professional judgement¹⁴ how this would work in a radiotherapy environment has not been researched.

Education

Within radiotherapy, Mowbray and Mowbray considered the impact of dementia on the consent process and concluded that knowledge of guidelines and staff education were essential for good practice.¹⁵ More recent professional body guidance similarly highlights importance of education in consent including when capacity to consent is questioned.¹² Recent standards of proficiency for radiographers refer to understanding the importance of consent and capacity.¹⁶ Lifetime risk of cancer increases with age; therefore as the UK population ages, cancer incidence and subsequently the number of people unable to make decisions for their own medical care and treatment will also increase. Radiotherapy is required in 50% of cancer patients' care;¹⁷ so it is feasible to suggest that more people will require radiotherapy who also lack mental capacity in the coming years. For those unable to make decisions but who may benefit from radiotherapy, the decision is made in the person's 'best interests'.¹⁸ (p3) It is crucial that departmental practice allows for TRs treating these patients to have the relevant knowledge and understanding of the consent process, including those who lack capacity underpinned in their department.

The study aimed to evaluate UK departmental practices surrounding radiotherapy consent processes including patients who may lack the capacity to consent in order, and if recommendations from recent clinical guidelines have been implemented within departments.

Methods

This evaluation adopted a quantitative research design. Via the Chair of the radiotherapy managers group, all UK radiotherapy service managers (n = 76) were invited to forward the email to a TR within their department for completion of the survey.

Ethical approval

All required institutional permissions were obtained from both the University Human Research Ethics Committee and Clinical Governance Manager prior to distribution.

Research tool

The survey was self-designed. The final survey was divided into 3 sections, following participant information and consent. Section 1 included departmental practices on consent procedures; section 2 incorporated those patients who are considered to lack the capacity and section 3 related to TR education of consent. The survey comprised of both open and close ended questions and some free-text responses (Appendix 1).

Pilot Study

The survey was piloted for clarity of wording and fitness for purpose. The survey was distributed to 5 TRs employed at consultant radiographer or advanced practice with a known interest in consent. Minor changes were made following feedback given.

Recruitment and completion of survey

Information of the survey and the link was emailed to all 76 radiotherapy service managers in the UK including both NHS and private facilities but not satellite departments. Managers were asked to identify and forward the email on to a TR with specific expertise and/or responsibilities for consent within their Trust.

Data collection

The survey link and participant information was distributed by email to all radiotherapy departments in the UK. Once the link was accessed participant information and consent was obtained through agreement to 6 short statements. All data was anonymous and participation was voluntary. Participants were asked to specify their department to ensure no duplication of the survey if the manager had passed to multiple TRs, while identifying if these were NHS or private departments. This information was coded for pseudo-anonymity purposes.

Data analysis

Statistical analysis using Microsoft Excel was performed, and additional correlation analysis between the type of consent policy and date of update was attempted with Fisher's exact test using Statistical Package for the Social Sciences (SPSS) version 24 (SPSS Inc., USA). For this, significance was determined at the level of $p = 0.05$.

Results

TRs completed the survey from 39 departments (51%); providing a good representation of UK radiotherapy departments. Of these, 36 were NHS and 3 were private departments.

Departmental processes on consent procedures

All respondents reported that written consent is routinely obtained. 10% (n = 4) of all departments do not have a system in place to provide patients with a copy of the consent form. The number of patients receiving copies of their consent forms

Table 1. Frequency and assessment methods used to assess a patient's capacity to consent

	Methods used to assess capacity				
	Capacity assessment tool	Clinical judgement	Cognitive assessment tool	Family/Next of Kin/Carer wishes	Health professional judgement
Single method of assessing capacity (n = 5)		3			2
Two methods used to assess capacity (n = 14)	4	13		2	9
Three methods used to assess capacity (n = 11)	5	11	1	5	11
Four methods used to assess capacity (n = 7)	6	7	2	6	7

Table 2. Options on how consent is obtained for each department for those who are considered to lack the capacity to consent

	1 option closely matching to departmental practice (n = 29)	2 options closely matching to departmental practice (n = 8)
The standard written consent form is used with no signature from the patient		
The standard written consent form is used with the patient's representative signing the form on their behalf	2	2
The standard written consent form is used with the patient who lacks capacity signing the form		1
A separate consent form designed especially for those who lack capacity to consent is completed by the clinician with involvement from the patient's representative	24	7
A separate consent form designed especially for those who lack capacity to consent is completed by the clinician with no involvement from the patient's representative	3	6

varied; 44% (n = 17) give a copy of the consent form to all patients; 46% (n = 18) give patients a copy most of the time. Reasons why patients may not receive a copy of their consent form included:

- declined by the patient (n = 14),
- forgetting to give the patient the copy (n = 4)

Prior to treatment, confirmation of consent for radiotherapy was documented in 95% (n = 37) of departments.

Patients who are considered to lack the capacity to consent

All departments (n = 39) reported delivering radiotherapy to patients who lack the mental capacity to consent; however, assessment of a person's capacity to consent varied across the UK.

One TR reported that they were unsure of how capacity was assessed in their department and one did not answer this question. Of the remaining 37 departments, the majority (n = 32, 86%) assess if the patient has capacity to consent or not by using multiple methods. Table 1 demonstrates the frequently each assessment method is used and, the number of methods used to assess capacity within the department. For example, 14 respondents identified that in their departments two methods are used to assess capacity, and clinical judgement was used in 13 of those departments as one of the two methods. Family/next of kin wishes were reportedly used within 13 departments alongside other assessment methods but never as the sole assessment of capacity. Clinician judgement and health professional judgement were used in 34 and 29 departments, respectively, to assess capacity. Clinical and health

professional judgement were reportedly the sole assessment of capacity in 5 departments.

Considering those patients who lacked capacity and due to receive radiotherapy, the question was asked which of the options for obtaining consent closely matched their departmental practice (Table 2); 95% (n = 37) of departments referred to having a separate consent form for those who lack capacity.

Policy and education in consent and capacity

One NHS department identified that there was no policy in place for consent; of the remaining 38 departments, 52% (n = 20) of the policies were written as Trust-wide policies, 32% (n = 12) had specific policies in the radiotherapy area and 16% (n = 6) had a consent policy that spanned the oncology area. Twenty departments (52%) reported their policy for consent had been updated since 2018 and with 25% (n = 5) of these departments refer to the 2018 SCoR guidance on consent.¹¹ A Fisher Exact Probability Test failed to identify any relationship between type of consent policy and when it was updated (p = 0.122).

TRs completed some formal education that included consent within 22 departments across the UK, of these, capacity to consent/lack of capacity was included in 59% (n = 13) of these.

The format of this education was not asked; however, 4 departments reported they had radiographer-led consent training; it is inferred that this is completed by a TR who has completed M-level study in consent. The frequency of education varied across the UK (Table 3). Annual education in consent was reported by TRs in only 4 departments. Similarly, it was reported that 4 other

Table 3. The frequency of consent education for departments in the UK

Frequency of consent education	Number of departments
Annual	4
Two-yearly	1
Three-yearly	1
Optional education	4
On appointment	3
Single point	2
Consent education included within other training	2
Unsure of frequency of education	1
No education of consent	16
Not answered	1

departments have consent education, but is not mandated for TRs. Five departments in the UK complete consent education as a one-off either as part of their induction training following appointment ($n = 3$) or at another time point (not specified) ($n = 2$) there is no further education following this single time point.

Discussion

This evaluation of UK departmental practice has provided a clearer picture of consent practices, policies, and education within the UK. Response rate was just over 50% of departments but relied on managers passing the information on to the most appropriate TR. In contrast to earlier work by Colyer,¹⁹ all departments who completed the survey obtain written consent for radiotherapy. At the time of the evaluation, the national radiotherapy consent forms were not published; it is welcomed that reference to both confirmation of consent and copy of consent are included in these⁶ and following the outcome of the Montgomery 2015 ruling,² material risks and alternative options are included within these. It is possible to infer that if departments use these consent forms, forgetting to give a copy of the consent form to patients or having no system in place will be reduced. Not documenting confirmation of consent will reduce as both these elements are included within the national radiotherapy consent forms; supportive of the model consent processes¹ while also embracing a patient's autonomy.

Capacity to consent

Several methods were identified to assess capacity to consent in departments, with no single assessment method preferred for use in UK radiotherapy departments. The results suggest that a combination of assessment tools are used but judgement of clinical and health care professionals are the preferred methods for establishing if a patient has the capacity to consent for radiotherapy, reflecting the findings from previous published work.^{14,20} It was beyond the scope of this evaluation to identify which capacity/cognitive assessment tools are routinely used in current practice, yet the need for these to be administered by specialist professionals and an estimated time demand of 20–45 minutes suggest that these would be challenging to implement routinely in radiotherapy departments.^{21,22} Assessing capacity is considered a core skill and does not necessarily require a specialist professional² providing the following:

A 2-stage test of capacity and that a patient is unable to make a decision if they are unable to do one or more of 4 things

- “understand the information relevant to the decision;
- retain that information for long enough to make the decision;
- use or weigh up that information as part of the process of making the decision;
- communicate their decision in any way.”^{2,18}

Everything practicable should be completed to support a patient to make their own decisions before a lack of capacity to make a decision is concluded.²³ (p5) these are not one-off assessments and capacity should be regularly assessed for each decision needing to be made.^{7,24} (p) The medical professional responsible for requesting the radiotherapy treatment is ultimately responsible for ensuring if a patient does or does not have the capacity to make decisions but may involve other professionals and/or tools to aid that conclusion.^{14,23} (p8) Carers cannot influence a capacity assessment; however, it is recognised that consideration should be given to those who know the patient well.²³ (p8) Carers also play an integral role in best interests decisions alongside medical professions as they can consider both the medical implications of radiotherapy but the social effects of the treatment.²⁴ (p11),²⁵ such as radiotherapy induced side effects. The evaluation results confirm those departments are working in line with medical guidance^{23,24} and the increasing need to involve carers²⁵ in supporting a true multi-method approach is completed within several radiotherapy departments, ensuring rigour and that actions taken by all are in the best interest of the patient.

Education

Education of TRs for consent processes and mental capacity awareness is paramount, initially raised in 2007²⁶. The recent 2023 HCPC standards of proficiency identifies:

‘[A radiographer should] understand the importance and be able to obtain valid consent... has due regard to capacity... understand[s] the importance of capacity.’¹⁶

It is concerning that 16 departments reported having no formal training in consent, with 13 of the remaining 22 departments identified their training included capacity to consent despite the specific radiotherapy recommendations published many years ago,^{15,26} and more recent cancer publications^{25,27} identifying education as a need.

With the variation of frequency for TR education and overall capacity education lacking in many departments further work is required. Arguably, it remains the TR's responsibility to ensure that as autonomous professionals they are meeting the 2023 HCPC standards of proficiency.¹⁶

Two departments reported that the patient's representative signs the standard consent form; these two departments also reported having no consent training. The clinical, legal and professional responsibility of obtaining informed and valid consent lies with the person taking the consent.^{1,2} but arguably TRs have some professional accountability for ensuring good practices are followed when obtaining consent including those who lack capacity. At the least, basic awareness for a TR should include familiarity of the 10 recommendations for obtaining consent written by the SCoR³ and their departmental codes of practices. It would be advisable that departments review their consent processes to ensure good practice is maintained, effective, in the best interests of the patient and in accordance with the law.

Limitations

There are some limitations to this study, namely the lack of responses from all UK departments and the corresponding lack of statistical power. The data collection was also dependent on a single practitioner's response and may not represent the views and practices of their colleagues with their department. Despite this, the response rate does provide a useful indication of the UK picture on departmental practice surrounding consent processes.

These findings lay a good foundation for developing relevant education resources that can be used by departments and individuals to enhance knowledge and understanding of the importance of consent including those who lack capacity. By increasing awareness of the role that valid and informed consent has in daily working practice and a TRs legal and ethical responsibilities, a training package will not only enhance increased patient and family care within radiotherapy departments but also the increased awareness will support care quality commission inspection frameworks and professional body recommendations.³

It may be useful to further understand how capacity is assessed by way of the actual capacity and cognitive assessment tools used and what methods clinicians/health professions assess capacity within departments in the UK. Future research in this field may identify if there is a preferred tool or medical judgement is sufficient, this work would need to be focused on those professionals who obtain consent.

Conclusion

The demand for radiotherapy is increasing, as too is the number of people with brain or mind impairments. This UK evaluation survey provides a reassuring snapshot of the UK departmental practice of informed consent. It highlights that many UK departments assess capacity in a variety of ways and that correct best interest processes are in place for those who lack the capacity to consent for radiotherapy utilising patients' representatives and separate consent forms. With the introduction of national consent forms, it would be recommended to repeat some aspects of this evaluation to see if the confirmation of consent is completed within every department.

This evaluation is the first to report on UK departmental practice surrounding consent processes in radiotherapy with focus on mental capacity and education. Based on the results of this evaluation, education for TRs is paramount with few departments having robust policies and training. It is important that departments review their consent policy for those patients who are considered to lack capacity to ensure they are working to current legislation and guidance. In addition, departments should consider implementing local training for consent including mental capacity to optimise professional TR practice and ultimately enhance patient care in radiotherapy departments.

Supplementary material. The supplementary material for this article can be found at <https://doi.org/10.1017/S1460396924000335>

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