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# Designing and evaluating a patient decision aid for patients with locally advanced or locally recurrent rectal cancer: a national multicentre mixed methods study protocol

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## ABSTRACT

**Introduction** Approximately 5%–10% of new rectal cancers are locally advanced (locally advanced rectal cancer (LARC)) at presentation with 4%–8% recurring (locally recurrent rectal cancer (LRRC)) after initial treatment. Patients with potentially curable disease have to consider many trade-offs when considering major exenterative surgery. There are no decision tools for these patients and current resources have found to not meet minimum international standards. The overall aim of this study is to produce a validated patient decision aid (PtDA) to assist patients considering radical pelvic exenteration for LARC and LRRC created in line with international minimum standards.

**Methods and analysis** This study is a national, multicentre mixed methods project and has been designed in keeping with guidance from the International Patient Decision Aids Standard.

This study is in four stages. In stage 1, we will develop the PtDA and its content using agile developmental methodology. In stage 2, we will assess the content and face validity of the PtDA using mixed-methods with key stakeholders. In stage 3, we will assess the feasibility and efficacy of the PtDA. In stage 4, we will establish the barriers and facilitators to the use of a PtDA in the outpatient setting. Questionnaires including the QQ-10, EORTC PATSAT-C33, Preparation for Decision-Making Scale and the NoMAD survey will be analysed during the study. Interviews will be analysed using thematic analysis.

**Ethics and dissemination** Research ethics approval from North of Scotland Research Ethics Service 19/NS/0056 (IRAS 257890) has been granted. Results will be published in open access peer-reviewed journals, presented in conferences and distributed through bowel research UK charity. External endorsement will be sought from the International Patient Decision Standards Collaboration inventory of PtDAs.

**PROSPERO registration number** CRD42019122933.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Develop a patient decision aid (PtDA) that meets international standards for patients considering pelvic exenteration for locally advanced rectal cancer or locally recurrent rectal cancer.
⇒ Multicentre evaluation of the produced PtDA.
⇒ Provide evidence for the acceptability of the PtDA in routine clinical practice for patients and clinicians.
⇒ Provide evidence of any implementation issues regarding the use of the PtDA in the clinical setting.
⇒ This study will not provide evidence of the value of the PtDA within the international forum due to development and validation limited to UK practice; however, further studies could validate its use on an international platform.

## INTRODUCTION

In the UK, 14 000 new cases of rectal cancer are diagnosed every year and 704 000 new cases worldwide were estimated in 2018,[1] of which 5%–10% are locally advanced (locally advanced rectal cancer; LARC) at presentation.[2 3] The incidence of locally recurrent rectal cancer (LRRC) after treatment is 4%–8%.[4 5] Without treatment, the prognosis for both LARC and LRRC is poor, with median survival estimated at less than 1 year and only 5% of patients surviving 5 years.[6 7] Patients are faced with a choice of chemoradiotherapy, best supportive care or surgery. Pelvic exenteration (PE) is the only potentially curative treatment option available. It is, however, associated with a significant risk of morbidity (31.6%–86%) and mortality (0%–8.7%, median 0%).[8]

Patients with potentially curable LARC or LRRC have to consider many trade-offs when considering major exenterative surgery. These include consideration of the impact of surgery and postoperative morbidity on Quality of Life (QoL) and functional status and balancing this against the potential of curative treatment and survival. Greater involvement of patients in decision-making

should allow decisions that are congruent with patient preferences.[9] Shared decision-making (SDM) is a model that seeks to include both the patients and their healthcare providers in the decision-making process.[10] The principles of SDM include sharing the current best evidence-based medicine with the patient, considering the patients' intentions, values and preferences and working together to reach a decision. A good clinical decision is one that is well informed, consistent with personal values, acted on and where patients express satisfaction with the decision-making.[11] SDM encourages patients to play an active role in decisions concerning their health, which is a goal of patient centred care.[12]

To complement and facilitate SDM, patient decision aids (PtDAs) have been introduced into clinical practice. PtDA's are designed to help patients make specific and deliberate choices about healthcare options through the presentation of accurate and unbiased, evidence-based information on all treatment options available and their associated outcomes.[13] PtDAs outline the health problem and the associated clinical decision being addressed and provide information on options/benefits/harms, thus helping patients clarify which benefits and harms matter most to them as individuals.[14] Some PtDAs also provide additional information, including the probabilities of treatment, narratives describing patients' experiences with decision-making, guidance with regards to the process of decision-making and engagement with healthcare.

The effectiveness of PtDA has been demonstrated in several systematic reviews.[9 15] They have been shown to improve knowledge acquisition, improve decisional conflict related to feeling uninformed and unclear about personal values, improve treatment indecision, improve realistic expectations of treatment outcomes, reduce the proportion of people who were passive in decision-making postintervention and improve agreement between patient values and healthcare option chosen.[9 16]

Despite the proven value of decision aids, there are no decision tools for patients being offered PE for LARC or LRRC within the Decision Aids Library Inventory (DALI).[17] There is also little available online health information relating to PE for LARC or LRRC. The currently available online information is of poor quality.[18] At present, there is no available decision aid to provide patients with informative, accurate material to aid decision-making in PE for rectal cancer. This is a key priority not only to address in order to meet the Royal College of Surgeons (RCS) and the National Institute of Clinical Excellence (NICE) guidelines but also to avoid medicolegal redress following the Montgomery 2015 ruling.[19]

Relatively few PtDAs are regularly used in clinical practice,[20–22] despite their proven role in SDM. A systematic review of PtDA implementation identified a host of logistical barriers, including clinicians' perception of time necessary to use PtDAs, lack of reimbursement and perceived bias inherent in the PtDAs themselves.[23] In the UK, the department of health (DoH) has been at the centre of policy developments for the promotion of SDM, with significant financial investments made available to support this.[24] The drive to improve healthcare using SDM by NICE, DoH and RCS may change clinical behaviour when implementing new changes and strategies.

The overall aims of this study are to develop and validate a PtDA for patients considering PE for LARC or LRRC for use in clinical practice as an adjunct to patient counselling.

The key study objectives are to:

1. Develop a decision aid to support patients in their decision regarding the available treatment options, with the key clinical question centred on the decision to pursue PE.
2. Validate the decision aid.
3. Pilot an evaluation study for the implementation of a PtDA for PE and assess health professionals' barriers of the decision aid in clinical practice.

## METHODS

This study has been designed as a mixed-methods project underpinned by guidance from the International Patient Decision Aid Standards (IPDAS) Collaboration and the Ottawa Decision Support Framework (ODSF).

Consensus standards for PtDAs were established by IPDAS in 2003 using the Delphi method to develop the criteria for the assessment and evaluation of the quality of a PtDA.[14 25–27] The ODSF is a decision-making framework informed by cognitive, social and organisational psychology theory that guides the assessment and development of the PtDAs,[28] which also contributed to the development of the IPDAS.[29] ODSF guides practitioners and researchers to assess participants' decisional needs, provides decision support and evaluates their effects on decisional outcomes.[17]

The process of designing a PtDA follows a number of key steps, including scoping and design, development of a prototype, 'alpha' testing with patients and clinicians in an iterative process (testing by people directly involved in the development process), 'beta' testing in 'real life' conditions (field tests with patients and clinicians not involved in the development process) and production of a final version for use and/or further evaluation[11] (online supplemental figure 1).

### Patient and Public Involvement

Patients' priorities, experience and preferences were established in the first part of the study through qualitative semistructured interviews. Three patients are included on the steering group of the study. Due to study design, patients were not involved in study recruitment.

### Stage 1: scoping and design

The development of the decision aid was undertaken as part of a larger study and was underpinned by four stages of scoping/design work. This included:

1. Systematic reviews of PubMed, Cochrane databases and DALI to identify literature relating to decision aids for PE.[18]

2. A review of the grey literature registered on PROSPERO to identify key perspectives and priorities important to patients when making decisions.[18]
3. Identifying available patient literature at exenterative centres involved in the PelvEx collaborative or ACPGBI IMPACT initiative.
4. Qualitative interviews with patients and clinicians (approximately 20–30 until data saturation) to explore their views regarding what is important for them when making decisions regarding PE surgery.

The aim of this stage was to identify and prioritise the key information needs for patients undergoing PE into key themes and to use this to underpin the design of a PtDA.

### Stage 2: development of a prototype

The aim of this stage is to develop a PtDA using themes identified from stage 1, which will inform the content and design of the PtDA using agile methodology. Agile developmental methodology (ADM) is a dynamic and flexible approach usually employed in software programming, whereby new programmes are developed over a series of short cycles (sprints) by harnessing user feedback (7). Each theme identified in stage 1 will inform a component of the PtDA and will be developed during fortnightly sprints with an expert steering group to the point of final consensus. Each meeting will be facilitated by a single dedicated researcher (AW). A topic guide will be established to conduct the meetings. The expert steering group will be composed of clinicians and patients and will be established to aid the content and to assess its relevance, acceptability, comprehensibility and usability. The prototype will be developed according to IPDAS and the ODSF, which has a strong theoretical foundation that has been extensively validated.[30] Health communication will be addressed in the development of the PtDA. There is good evidence that patients have a better understanding of risk if outcomes are presented as numbers. Yet there is an emerging awareness that how risk information is provided can improve people's understanding or bias their risk perceptions. We will use principles outlined by Trevena *et al*[31] for including numeric estimates in the PtDA. Pictures will be used to link written text as they markedly increase attention to and recall of health education information as well as improving comprehension.[32] All patients benefit, however, those with low literacy skills are especially likely to benefit.[32] There may be situations where personal stories and narratives could enhance the effectiveness of PtDAs, however, given the heterogeneity of both disease process and surgical intervention it could produce bias and persuasion.[33] There is also insufficient evidence that adding personal stories to decision aids increases their effectiveness to support people's informed decision-making.[34]

#### Sample

A purposive sample of healthcare professionals and patients will be invited to take part in the core-steering group. The steering group will be established to reflect those participating in the multidisciplinary team meeting (MDT) together with patient representatives. Purposive sampling of the steering group across all participating sites will ensure recruitment of a representative sample of both healthcare professionals and patients involved.

#### Recruitment

A steering group consisting of three patients, five exenterative surgeons, one oncologist and two CNS will be recruited over the five nominated study sites. Patients will be identified through pre-existing prospectively kept databases at each centre.

Inclusion criteria includes patients who have undergone PE for LARC or LRRC within the last 12 months or patients who have undergone chemoradiotherapy for LARC or LRRC within the last 12 months, aged ≥18 years, able to provide informed written consent to participate and able to read and write in English. Exclusion criteria includes patients who have undergone palliative treatment of their LARC or LRRC, have cognitive impairment, participated in an earlier phase of the study, are unable to speak/read and/or write English or are unable to provide informed consent. Patients will be provided with a patient information sheet together with a consent form to participate in this stage of the study.

Healthcare professionals will be identified by the nominated research assistant at each site. The eligibility criteria include: surgeon, oncologist or CNS participate in the PE MDT and work within one of five nominated UK centres as part of PelvEx collaborative and have not already participated in the earlier part of the study. The rules of engagement for the ADM will include upfront commitment to fortnightly meetings until the end of the process (expected 3–6 cycles).

#### Data collection and analysis

Each component of the PtDA will be assessed iteratively by a core-steering group to assess its design, relevance, acceptability, comprehensibility and usability on fortnightly basis with changes being implemented before the following meeting. Each meeting will be recorded and transcribed verbatim. Themes will be generated from the data and coded using NVIVO V.12 (QSR International, Melbourne, Australia). Analysis of the transcript data will be qualitatively analysed following each steering group meeting. The development of the PtDA is an iterative process and fortnightly meetings will be repeated until the comments are minimised. This process will produce a provisional PtDA to inform the next phase.

### Stage 3: 'alpha' testing with patients and clinicians in an iterative process (testing by people directly involved in the development process)

The aim of this phase is to assess whether the developed provisional PtDA possesses content validity. This measures the extent to which the set of items comprehensively covers the different components of health to be measured[35] and face validity, which assesses whether the items of each domain are sensible, appropriate and relevant to the people who use the measure on a day-to-day basis.[36] This will be with both patients and clinicians. We

will use a mixed methods approach using both qualitative and quantitative data across the same five sites, using qualitative cognitive 'think aloud' interviews and quantitative measures using the QQ-10.[37]

### Sample

A purposive sampling of healthcare professionals and patients not involved in any other part of the study will be invited to take part. We expect to recruit a sample size of 20–30 patients and 10 clinicians. Both patients and clinicians will undertake qualitative cognitive interviews to assess content from both perspectives. Patients will also be asked to complete the QQ-10 questionnaire. The QQ-10 is a 10-item self-completed and a three-item free-text questionnaire that measure of face validity which was specifically designed to assess the face validity of a patient-reported outcome measure.[37] It has been used in previous studies and includes Likert scales relating to the acceptability and utility of questionnaire use from the patient's perspective, producing valid scales relating to value and burden.[37]

### Recruitment

Both patients and clinicians will be identified from all five study sites as described in stage 2. Inclusion and exclusion criteria together with consent will be as described in stage 2. Prior to the interview, the researcher will post a copy of the PtDA and a QQ-10 questionnaire to the patient and arrange a telephone interview within 7 days to fully evaluate the PtDA. Clinicians will have the option to receive the document either on paper format or electronically.

### Data collection

Data collected from the interview will relate to participant feedback regarding the PtDA, including understanding, wording, sufficient information, readability and overall acceptance. Semistructured, qualitative interviews will be conducted using a topic guide and transcribed verbatim for analysis. Data from the transcripts and QQ-10 data will be stored securely.

### Data analysis

#### *Qualitative*

Patient interview transcriptions will be coded using NVivo V.12 computer-assisted qualitative data analysis software (QSR International, Australia). Analysis will use an inductive thematic approach, outlined by Braun and Clarke using a systematic five-step approach: familiarisation, generating initial codes, searching for themes, reviewing themes and defining and naming themes.[38] The themes actively generated by the researchers from the data will be discussed by the steering group. The steering group will subsequently refine the aid based on the results of this stage. If there are significant changes required, further qualitative work will be undertaken prior to progression to stage 4. Qualitative thematic analysis will be performed on comments received in response to the three free-text questions at the end of the QQ-10.

#### *Quantitative*

Quantitative analysis of the QQ-10 scores will be undertaken. Likert ratings from strongly disagree to strongly agree (coded as 0–4) will be analysed separately for questions 1–6 comprising the value score and from questions 7–10 comprising the burden score.

The study team will ensure that this document will be proof read by three lay members of society with no previous knowledge of rectal cancer following changes ensued by alpha testing. This will ensure that the PtDA provides comprehensible, transparent, unbiased and complete information to the average reading level.[39]

## Stage 4: 'beta' testing in 'real-life' conditions (field tests with patients and clinicians not involved in the development process)

The aim of this phase is to assess the feasibility and efficacy of the PtDA prototype in real-life with individuals who have not been involved in the design of the PtDA. We will conduct a before and after study to assess the impact of the introduction of the PtDA in clinical practice. Patients will be asked to complete two questionnaires to assess patient decision-making and satisfaction with decision-making: the EORTC PATSAT-C33 questionnaire[40] and the Preparation for Decision-Making Scale.[17] PtDA evaluation using before and after studies has demonstrated PtDA effect on choice, patient comfort with decision-making, outcomes of decisions and patient acceptability.[30] This will follow a mixed-methods approach across the five sites.

### Recruitment

Patients will be prospectively recruited from the five participating sites over a 6-month period as described in stages 1 and 2. Patients who have been offered a PE as part of their treatment will be invited to participate. Eligible participants are: (1) aged ≥18 years, (2) able to provide informed written consent to participate and (3) able to read and write in English. Participants will be excluded if they: (1) participated in an earlier part of the study, (2) have cognitive impairment, (3) are unable to speak/read and/or write English or (4) are unable to provide informed consent

The cohort recruited in the first 3 months will make up the 'before' group. Following on from this, we will introduce our PtDA into routine clinical practice for use in consultations with patients being counselled for exenterative surgery. All sites will use the PtDA to facilitate decision-making. The latter 3-month cohort will make up the 'after' group. We aim to recruit a maximum sample size of 40.

### Data collection and analysis

Patient satisfaction questionnaires EORTC PATSAT-C33 and the Preparation for Decision-Making Scale will be analysed according to the developers guidance.[40] Summary scores for the EORTC PATSAT-C33 and Preparation for Decision-Making Scale will be calculated and analysed using parametric (two-way ANOVA) and

non-parametric ($\chi^2$) tests, as appropriate. Regression analysis will compare scores between the pre and active implementation phase.

### Stage 5: production of a final version for use and/or further evaluation

Assessing implementation of a PtDA in this setting is essential in ensuring its future utility by all stakeholders. Our implementation strategy will address the ease of implementation of the PtDA into clinical practice and will identify barriers and facilitators to the incorporation of the PtDA into clinical practice. The modified Normalisation Measurement Instrument (NoMAD)[41] will assess the implementation processes from the perspective of professionals directly involved in the work of implementing the PtDA in the healthcare setting, which will inform the topic guide for the semistructured interviews. We aim to circulate approximately 30 online questionnaires together with electronic copies of the PtDA. We will undertake 10 interviews with healthcare professionals.

#### Recruitment

Clinicians at all sites performing PE in the UK will be invited to complete a modified NoMAD following introducing the PtDA to clinical practice. A piloted, anonymous, online survey will be circulated.

#### Data collection

The survey will enable data collection on the views about how the PtDA impacts on their work and their expectations about whether it could become a routine part of their work. It will also enable data collection on coherence (responses may indicate that the intervention 'makes sense' to participants) and cognitive participation. NoMAD survey findings will inform the topic guide for semistructured interviews to establish the barriers and facilitators to the use of a PtDA in the outpatient setting. Interviews will be piloted and conducted by telephone using a topic guide. Anonymised participant characteristics will be used to allow exploration of different perspectives on implementation issues.

#### Data analysis

##### *Quantitative*

NoMAD survey findings will be analysed according to the developers' guidance.[41] Anonymised participant characteristics will be used to allow exploration of different perspectives on implementation issues. The survey will identify clinicians' insights into the challenges of implementing PtDA to normalisation process theory (NPT) to provide a structure for implementation strategy. Descriptive statistics will summarise responses and cross-tabulations will examine perceptions of intervention fit and NPT domains.

##### *Qualitative*

NoMAD survey findings will inform the topic guide for semistructured interviews. The interviews will be recorded and transcribed verbatim and subjected to thematic analysis using the approach described above. The themes actively generated by the researchers from the data will be discussed by the steering group. The steering group will subsequently refine the aid based on the results of this stage.

## ETHICS AND DISSEMINATION

Research approval for the study has been obtained from North of Scotland Research Ethics Service 19/NS/0056 (IRAS 257890). The validated PtDA will be assessed by PelvEx collaborative involving over 100 units across five continents for approval. Provided this meets their approval it will be disseminated as PelvEx document, which will engage all centres to consider its use in the clinical setting and subsequent dissemination. Its role will be an educational tool to aid the decision-making process for patients.

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**Competing interests** None declared.

**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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