Brief decision aid protocol for PrefCoRe "quantifying and implementing patient preferences for the treatment of high-risk rectal cancer, including the new strategy of organ preservation"

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Background: There are over 16,000 new cases of rectal cancer diagnosed per year in the UK[1]. The standard course of treatment for patients with high-risk rectal cancer includes chemoradiotherapy (CRT) followed by major resection surgery which involves the risk of postoperative mortality, surgical complications, colostomy and a long-term impact on quality-of-life. Recently, it has been established that it is possible for the tumour to completely disappear after CRT (known as a clinical complete response (cCR)) in up to 25% of the patients who will have the opportunity to completely avoid surgery +/- stoma and instead opt for a watch-and-wait management programme[2]. Patients who opt for watch-and-wait undergo routine examinations and follow-up visits to ensure tumour regrowth has not occurred. Approximately 30% of the patients on this management programme will experience local regrowth and will require salvage surgery but patients without a local regrowth will successfully avoid a colostomy by opting out of surgery. Regardless, there are fears that residual cancer cells may remain untreated and remanifest later as inoperable local recurrence or as metastatic disease and compromise survival. Therefore, there is a need to support patients through making the difficult decision to choose between these different types of cancer management programmes and balance the benefits and risks associated with each alternative. There is currently no research that addresses patient preferences and the tradeoffs they are willing to make between watch-and-wait and major surgery.

Project aims:

1. To quantify patient preferences through a DCE for watch-and-wait vs surgery following a cCR to chemoradiotherapy for high-risk rectal cancer
2. To develop a rectal cancer web-based patient decision aid (PtDA) informed by the DCE
3. To conduct preliminary tests of the PtDA and understand its position in treatment pathways

This protocol outlines the PtDA development and preliminary testing to achieve aims 2 and 3.

Methods:
A web based PtDA will be developed iteratively with input from a steering group (comprising clinicians and patients), following best practices in decision aid development[3,4]. First, an initial draft of the PtDA will be designed using PowerPoint. Its content will be informed by a literature review, national guidelines, patient information leaflets, expert elicitation (where required) of figures not available in the literature and discussions with the steering group. The PtDA will use plain language that could be

[1] Cancer Research UK. Distribution of cases diagnosed by anatomical sites. https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/bowel-cancer/incidence#heading-Four

[2] Renehan AG, Malcomson L, Emsley R, et al. Watch-and-wait approach versus surgical resection after chemoradiotherapy for patients with rectal cancer (the OnCoRe project): a propensity-score matched cohort analysis. *Lancet Oncology* 2016; **17:** 174–83.

[3] International Patient Decision Aid Standards (IPDAS) at http://ipdas.ohri.ca/

[4] Coulter A, Stilwell D, Kryworuchko J et al. A systematic development process for patient decision aids. *BMC Medical Informatics and Decision Making* 2013; 13(Suppl 2): S2

understood by a person aged 12 years. The position of the PtDA in the care pathway for rectal cancer patients with a cCR will be determined through discussions with stakeholders in the initial stages of the development process. These discussions will take the form of a patient focus group and 1:1 interviews with clinicians. These discussions will also be used to determine:

- The appropriate length of the PtDA
- Its contents
- Whether it should be used with the clinician or the nurse or either (depending on the hospital)

The PtDA will be intended for use in the clinic with the patient's doctor but the patient will be asked to watch the animation video at home prior to the appointment. They will also be asked to read text information about the treatment decision as well as completing knowledge questions. The answers to the knowledge questions will help the clinician understand the extent of the patient's knowledge and whether more information is needed or whether the patient has correctly understood everything. It will be made clear to the patients that PtDA is *not* designed to help them decide, rather prepare them for a discussion with their consultant. The main purpose of the PtDA will be to inform the patient-clinician discussion rather than help patients decide.

Design of the PtDA

An animation video will be used to explain concepts and set the scene for the treatment decision.

The part of the PtDA that patients will be asked to complete at home (when PtDA is implemented in clinical practice) will comprise short information on:

- Treatment decision
- Surgery
- Watch-and-wait
- Different aspects of the PtDA

This part will also comprise:

- Knowledge questions to assess patient's understanding of the treatment options. There will be 6-8 questions concerning risks and benefits associated with each treatment option. For e.g. which option is most likely to provide the highest chance of avoiding a stoma?
- SURE test to understand how sure the patient feels about their decision. This will comprise four yes/no questions:
    1. Do you feel SURE about the best choice for you?
    2. Do you know the benefits and risks of each option?
    3. Are you clear about which benefits and risks matter most to you?
    4. Do you have enough support and advice to make a choice?

The part of the PtDA that patients will complete in the clinic with the doctor home (when PtDA is implemented in clinical practice) will comprise:

- An options grid to summarise how both treatment options vary in terms of different aspects such as avoiding stoma, minimise effect on health etc. (see attached PowerPoint for more info).
- A value clarification exercise (VCE) comprising rating scales to reflect the trade-offs that patients are willing to make between different aspects of the treatment decision. These aspects will be informed by a survey that was completed as part of this project (ethics reference 2020-10479-16953). Rating scales as a VCE has been chosen due to its simplicity to enhance participant understanding and increase PtDA completion rates.

Specific values for the attribute levels will not be included in the PtDA, rather a range of these values based on the literature and expert opinion will be included with the intention being that the consultant will be able to provide a more accurate risk figure tailored to each patient.

To design the PtDA, the IPDAS[5] minimal criteria will be used to ensure that it qualifies as a decision aid.

Evaluation

Once a prototype of the PtDA has been created, it will be evaluated using interviews with people with experience of cancer and clinicians. People with experience of cancer will take part in an in-person interview which will comprise eye-tracking, System Usability Scale (SUS)[6] questionnaire followed by debriefing questions. Clinicians will take part in a 1:1 zoom think-aloud interview, followed by the completion of the SUS questionnaire.

Study sample:

Design

A steering group, which will consist of (n=3) clinicians and (n=4) patients, will be set up to guide the development of the PtDA. The patients will be those that have previously participated in the survey part of this project and expressed a willingness to participate in future studies. Expert clinicians will be recruited from the project team's research network.

Evaluation

The preliminary testing of the PtDA to understand its acceptability (involving eye-tracking, interviews and SUS questionnaire) will comprise n=20 individuals (including some members of the steering group) with experience of cancer (living with cancer or caring for someone with cancer). These participants will be recruited from Bowel Research UK and those from the PrefCoRe focus groups who previously expressed a willingness to participate in future studies as part of the PrefCoRe project. The clinicians will be recruited from existing research networks and collaboration.

Data collection:

Design

Feedback on the PtDA will be gathered iteratively from the steering group in the form of focus group, interviews and email communication. Specifically, feedback will be sought on the clarity, understandability and relevance of the PtDA along with any potential improvements that could be made (e.g., colours, infographics and navigation features).

Evaluation

People with experience of cancer

Eye tracking

- Participants (who have experience of cancer) for preliminary testing will be invited to the university campus and shown the PtDA while their eye movements are tracked using an eye-tracking device that will collect data on eye fixations, saccades (eye movements between fixations) and pupil dilation while using the PtDA. This component of the evaluation will be used to understand which elements of the PtDA are the most important to participants with experience of cancer (i.e. which elements attract the most attention and where do participants spend the most time looking) and which elements do participants skip over. These data will be used to potentially reduce the length of the PtDA (if deemed too long by participants with experience of cancer and clinicians) by removing elements that do not

[5] International Patient Decision Aid Standards (IPDAS) at http://ipdas.ohri.ca/

[6] Brooke J. SUS-A quick and dirty usability scale. Usability Eval Ind. 1996;189:194.

attract attention and are not deemed to be critically important by clinicians. Conversely, if data suggests that participants with experience of cancer do not spend sufficient time looking at elements that are deemed critical by clinicians for the patient to make an informed choice, the PtDA will be adapted to ensure that these elements are being considered by patients.

The eye-tracking device will record data for pages that would be completed in the clinic if the PtDA was implemented into clinical practice (in order to overcome data storage capacity issues).

Saccadic patterns will be used to understand how quickly a participant can locate a target (i.e. visual responsiveness) and how they seek information (the observed pattern of eye movements). Pupil size will be measured to gauge the cognitive burden experienced by participants (pupils dilate when an individual thinks about a difficult task or when information that requires a significant memory load is being processed). Eye-tracking data will be summarised in terms of the key outcome measures: fixation, saccades and pupillometry.

The setup for the eye-tracking will involve attaching an eye-tracking camera to the display laptop via a laptop mount that will show the PtDA. Participants will then be asked to look at the display laptop while having their eye tracked. They will not be required to use a chin rest and will be free to move but will be encouraged to sit in a still position to ensure accuracy. The distance from the front of the camera to the participant's eyes will be about 52 cm. The display laptop screen will be tilted to ensure that the participant's eyes are perpendicular to the screen. This experiment will use the EyeLink Portable Duo eye-tracking device.

- After completing the eye tracking exercise, participants will be asked to complete the SUS questionnaire to understand the user-friendliness and acceptability of the PtDA in clinical practice.

- Following this, participants will be asked debriefing questions to gather qualitative information on their views regarding the PtDA such as its length and contents, and offer them an opportunity to expand on their responses to the SUS questionnaire.

- All three parts of the interview will be conducted in a well-ventilated room and the researcher will wear a mask at all times. The participant will also be encouraged to wear a mask but it will not be a requirement.

Clinicians

- Clinician think-aloud zoom interviews will involve clinicians being asked to complete the PtDA while verbalising their thought process.

- Following this, they will be asked to complete the SUS to understand the usability of the PtDA.

Data analysis:

The eye-tracking data generated from the PtDA testing will be summarised using descriptive analysis to determine the attention to information that is being considered by the participant (fixation), whether they are having to search for information to make their decision (saccades) and the level of cognitive processing which relates to the complexity of the task at hand (pupillometry).

First, the PtDA screen will be segmented into areas of interest (AOI) that will be chosen based on the sections that the respondents might find mentally stimulating (e.g., risk figures and descriptions for each attribute in the options grid). Fixation data will be analysed in terms of the number of fixations, their duration (measured in milliseconds) and the total time spent fixating (called dwell time) on a particular AOI. Fixations will be defined as less than 1 degree of movement for 75 milliseconds. These

measures will be used to assess respondents' information processing where longer and a greater number of fixations indicate that the respondent was processing more information. Saccade (movement between fixations that occurs while searching for information) data will be used to calculate the number and direction of saccades. Pupillometry data will be used to calculate the average pupil size and the average change in pupil size (pupil dilation) per participant when they are fixating on an AOI. Pupillometry data will be used to evaluate the cognitive burden associated with using the PtDA.

Each outcome measure (fixations, pupillometry, saccades) will be summarised using count data for each individual and each predetermined element of the PtDA. Aggregated total dwell time will be summarised for each element of the PtDA.

Data generated from the SUS will be used to generate a total score which will be compared against the suggested threshold of over 68 considered to be above average and scores under 68 considered to be below average[7]. Answers to the debriefing interview questions will be analysed using thematic analysis and compared against their SUS scores to assess whether the SUS scores reflect the participants' views.

Dissemination: Results will be disseminated at conferences and in peer-reviewed manuscripts. The online PtDA will be promoted via relevant major charities such as Bowel Cancer UK.

[7] Brooke J. SUS-A quick and dirty usability scale. Usability Eval Ind. 1996;189:194.