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Use of a computerised decision aid (DA) to inform the decision process on adjuvant chemotherapy in patients with stage II colorectal cancer: development and preliminary evaluation

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ABSTRACT

Objectives: To develop a computerised decision aid (DA) to inform the decision process on adjuvant chemotherapy in patients with stage II colorectal cancer, and examine perceived usefulness, acceptability and areas for improvement of the DA.

Design: Mixed methods.

Setting: Single outpatient oncology department in central London.

Participants: Consecutive recruitment of 13 patients with stage II colorectal cancer, 12 of whom completed the study. Inclusion criteria were: age >18 years; complete resection for stage II adenocarcinoma of the colon or rectum; patients within 14–56 days after surgery; no contraindication to adjuvant chemotherapy; able to give written informed consent. Exclusion criterion: previous chemotherapy.

Primary outcomes: Patient perceived usefulness (assessed by the PrepDM questionnaire) and acceptability of the DA.

Results: PrepDM scores, measuring the perceived usefulness of the DA in preparing the patient to communicate with their doctor and make a health decision, were above those reported in other patient groups. Patient acceptability scores were also high; however, interviews showed that there was evidence of a lack of understanding of key information among some patients, in particular their baseline risk of recurrence, the net benefit of combination chemotherapy and the rationale for having chemotherapy when cancer had apparently gone.

Conclusions: Patients found the DA acceptable and useful in supporting their decision about whether or not to have adjuvant chemotherapy. Suggested improvements for the DA include: sequential presentation of treatment options (eg, no treatment vs 1 drug, 1 drug vs 2 drugs) to enhance patient understanding of the difference between combination and single therapy, diagrams to help patients understand the rationale for chemotherapy to prevent a recurrence and inbuilt checks on patient understanding of baseline risk of recurrence and net benefit of chemotherapy.

Strengths and limitations of this study

- This study evaluated patient acceptability, perceived usefulness and understanding of a decision aid (DA) using mixed-methods at the point patients made their decision about whether or not to have adjuvant chemotherapy.
- We recruited men and women with a range of different ages and levels of education, including people with no educational qualifications, enabling us to capture a range of different responses to the DA.
- People educated to degree level or above were over-represented in the study, and this may have led to an overestimate of perceived usefulness and acceptability of the DA.

INTRODUCTION

Ethical considerations and recent policy changes have put patients at the centre of health decisions, aiming to make shared-decision-making 'the norm'.[1 2] One key issue for people who have undergone surgical resection of colorectal cancer is the decision about whether or not to have adjuvant chemotherapy, which is typically either 5-FU or capecitabine, given alone or in combination with oxaliplatin.[3 4] While surgery is highly effective for localised disease, up to 85% of patients with lymph node involvement (stage III) relapse within 5 years. Since chemotherapy can prevent recurrence in up to 25% of patients with stage III disease,[5] it is offered routinely. For patients without lymph node involvement (stage II), the risk of relapse is lower (20–40%) and a smaller number of patients (3–7%) are expected to benefit.[6 7] Since there is a risk of side effects following chemotherapy, some of which can be life-threatening or permanent and the balance of harms and benefits is marginal in

patients with stage II, the use of adjuvant chemotherapy in this patient group has remained controversial.[8]

Patients with colorectal cancer have expressed a desire for more information, notably about their cancer, prognosis and treatment options,[9] [10] and effective communication of diagnostic and prognostic information has been shown to enhance patient well-being and patients' perceptions of the quality of doctor–patient interactions.[11] However, patients can hold more positive views on adjuvant therapy than physicians[12] and may want chemotherapy even when there is little evidence that it will help prevent a recurrence;[13] [14] for example, women with breast cancer with a low risk of recurrence are more likely to decline chemotherapy if they are aware of the (small) impact,[15] underlining the need for effective communication. People have problems understanding risk information,[16] and while there is an emphasis on patients making decisions that are consistent with their values, evidence points to the instability of preferences, with some researchers arguing that true preferences may not always exist, but are constructed 'on the spot' using the information available at the time of decision-making.[17]

Decision aids

To facilitate informed decision-making, a wide range of decision aids (DAs) have been developed. DAs are used alongside patient–physician interactions and contain detailed information about clinical options and outcomes, are explicit about the choices facing the patient and encourage patients to express their preference. DAs typically result in greater knowledge, a higher proportion of people with accurate risk perceptions, lower decisional conflict (eg, feeling better informed and clearer about personal values) and more active roles in decision-making compared with usual care.[18] Although DAs have been developed to aid treatment decisions for a number of different cancers,[19–22] little research has been done in the context of colorectal cancer. One exception is a booklet to help patients make decisions about adjuvant chemotherapy or radiotherapy, although this was only evaluated among patients who had opted to have adjuvant therapy, and was developed to be used by the patient at home rather than as part of a clinical consultation.[10] [23]

The aim of the present study was to develop a DA for chemotherapy for stage II that included the information identified as important to patients in previous research[9] [10] and examine its usefulness and acceptability to patients making a decision about whether or not to have adjuvant chemotherapy, as well as to identify any areas where patient understanding of key information could be improved.

METHODS
Development of the DA

PROforma decision support technology (a formal language for automating clinical processes and protocols)

and the Tallis tool set (used to design the decision support, check the syntactic integrity of the programme and run the application in a test environment) were used to develop the DA;[24] [25] http://openclinical.net/index.php?id=390. A variety of decision support applications based on PROforma technology have demonstrated a significant positive impact on a number of outcome measures such as reducing prescription errors and adherence to evidence-based guidelines.[26–28]

The DA captured patient demographic and clinical information (eg, histology type, evidence of extramural vascular invasion), as well as patient fitness to undergo chemotherapy (assessed via the presence of comorbidity and ECOG performance status[29] ranging from fit and well (0) to bed bound (4)).

Risk of recurrence with and without chemotherapy was mathematically derived based on: (1) the baseline risk of recurrence without chemotherapy, which was calculated for each patient using information from the published SEER database (http://seer.cancer.gov/data/) using the adjuvant!online risk calculator (http://www.adjuvantonline.com);[30] and (2) the effectiveness of single and combination chemotherapy, taken from published randomised controlled trials and meta-analysis.[6] [7] This calculator matches baseline risk of recurrence data to the individual patient's clinicopathological characteristics (T stage, number of lymph nodes examined, histology type and histopathological grading). The age-specific natural mortality was derived from published national mortality data.

In line with the presentation of information in Adjuvant!online, and consistent with recommendations, we used a simple percent format, and absolute risk when conveying information about the net benefit of chemotherapy along with a bar chart showing the likelihood of different outcomes, thereby using visual and numeric information to convey risk of recurrence information, keeping the denominator consistent and stating the reference class and time frame.[31] [32]

Patients were first shown one graph detailing their baseline risk of recurrence in the absence of chemotherapy (see figure 1) and graphs showing the net benefit of single and combination chemotherapy on the final page of the DA (see figure 2). Since the risk prediction of Adjuvant!online does not include clinical presentation (obstruction or perforation), or the risk factors vascular, lymphovascular and perineural invasion, these were included under headings for 'indicators for good prognosis' (eg, tumour stage T3) and 'indicators for bad prognosis' (eg, extramural vascular invasion), presented on the final page of the DA (see figure 2).

Information about the method of administration for the different drugs, the need for the insertion of a central line, the number of times the patient would need to come to hospital and the duration of treatment was given. The list of side effects were put into three different sections: common (>30% of patients affected), less common but serious (potentially life-threatening)
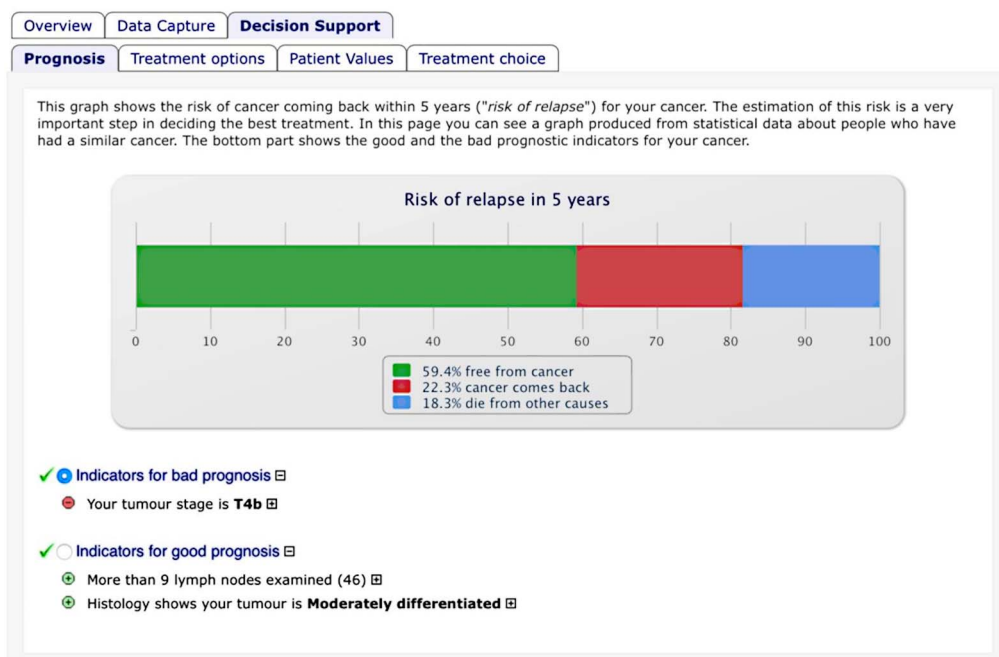
Figure 1 Graph showing baseline risk of recurrence.

and potentially permanent side effects. It was made clear that the first two sections related to all chemotherapy options, but that the long-term side effects only related to the two-drug chemotherapy option (oxaliplatin carries a high risk of long-term numbness of the hands and feet).[4]

The values clarification exercise was adapted from one developed for use in colorectal cancer screening among elderly people[33] to capture the main issues involved in the decision, including features identified as important to patients with colorectal cancer[9] (see online supplementary table S1). Patients were asked to complete the questionnaire on the computer, selecting 1 of the 2 options presented for all 10 questions. Patients were able to review and change their responses to the questions at any time during or after the consultation.

The final page of the DA combined graphical presentation of risk of recurrence information for the three treatment options alongside arguments laying out the pros and cons for each option, and the results of the values clarification exercise (see figure 2).

Design

A mixed methods design was employed.

Participants

Potential patients were identified at the colorectal multidisciplinary team meeting at the Royal Free NHS Trust. Inclusion criteria were: male or female patients aged >18 years; patients who had undergone complete resection for stage II adenocarcinoma of the colon or rectum; patients within 14–56 days after surgery; no contraindication to adjuvant chemotherapy; able to give

written informed consent. The exclusion criterion was previous chemotherapy. Target N was 12 in line with similar research on DAs.[34] Patients were recruited consecutively.

Procedures

After informed consent, patients were randomised to receive the DA at either the first or second consultation. All patients were given written information about the side effects of chemotherapy, as per current practice. When seen back in clinic, after 1–2 weeks, patients were given the opportunity to ask questions, at which point the patient's treatment decision was recorded. Patients were invited to complete the values clarification exercise on the computer, but received help from relatives or the clinician if requested.

All consultations took place in the Outpatients Oncology Department at the Royal Free London NHS Trust. Patients were given a questionnaire assessing responses to the DA after the consultation at which the DA had been used.

Questionnaire

Information about age, gender, educational level, ethnicity and employment status was collected. Perceived usefulness of the DA in preparing the patient to communicate with their doctor and make a health decision was assessed with the PrepDM questionnaire, a 10-item scale designed to measure the usefulness of DAs, developed across a number of different patient groups, including patients with cancer, with good internal reliability and validity.[35] Cronbach's α in this study was 0.935. Example items include: 'Did the decision aid…Help you
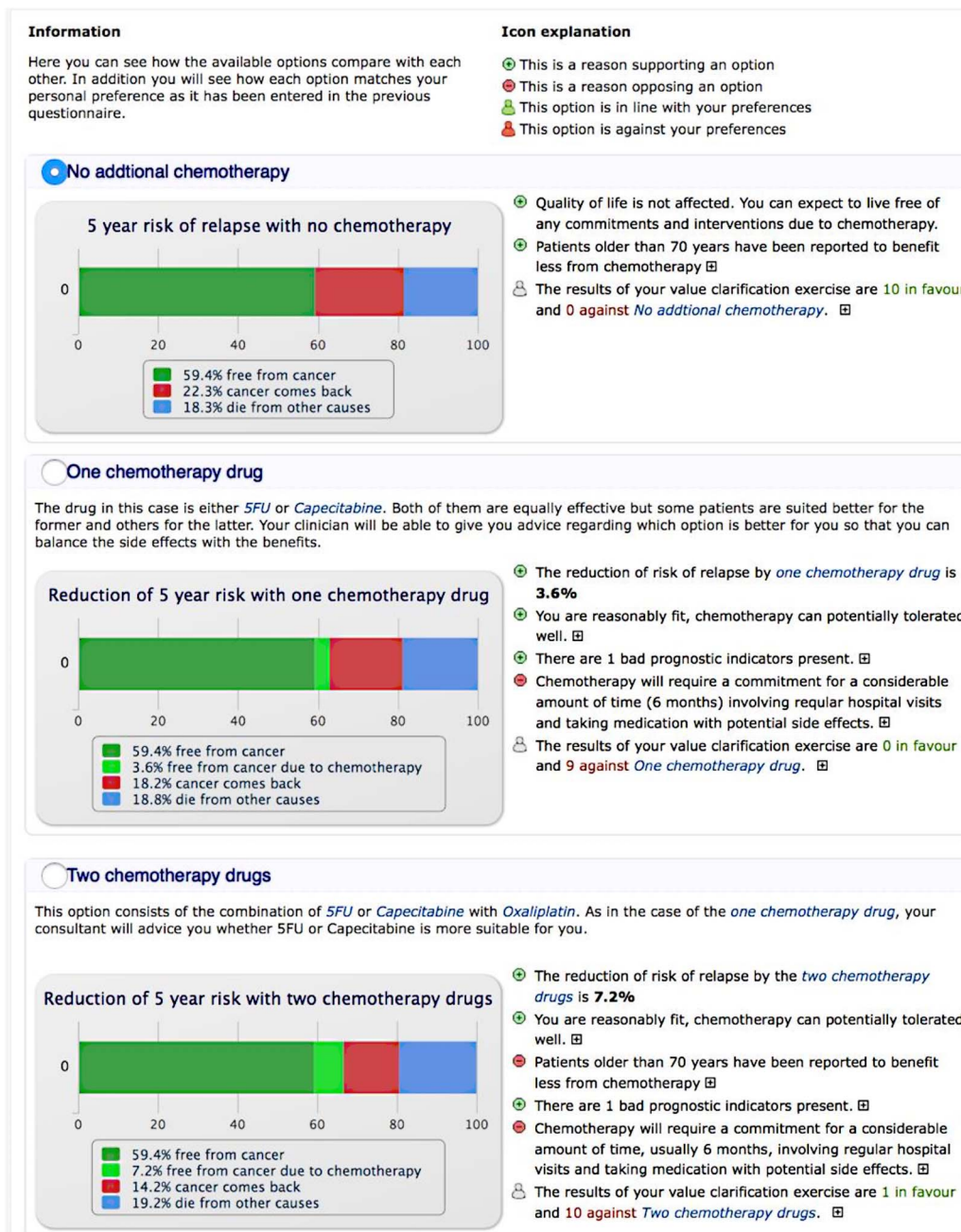
Figure 2 Final page of decision aid showing risk of recurrence and net benefit of treatment options alongside pros and cons of different treatment options.

think about the pros and cons of each option? … Help you identify questions you want to ask your doctor?' Response options are on a five-point Likert scale with higher scores indicating higher agreement. Acceptability of the DA was assessed using seven items; three were from Bennett et al,[35] while the remaining items were developed for this study (see table 1 for questions and response options). Data were analysed using SPSS V.22.

Interview

Face-to-face interviews were used to gain an in-depth understanding of patients' responses to the DA, and their understanding of key information. These were conducted face to face at the hospital following the second consultation, between March 2012 and July 2014, by AMi, who has experience of conducting interviews with patients with colorectal cancer,[36] and was not involved in the patients' care. The interviews lasted an average of 33 min (range: 18–54) and were recorded and transcribed verbatim by a transcription company, and reviewed for accuracy by AMi using the original recordings. The initial Topic Guide is provided as online supplementary data, but during the interviews, it became clear that patients were confused about what

Table 1 Perceived usefulness and acceptability of the decision aid

	Number
Usefulness of information in preparing patient for decision (PrepDM) (1–5) mean (SD)	4.28 (0.90)
Acceptability of DA[35]	
Helpful	
Very	10
Somewhat	1
A little	1
Not helpful	0
Recommend to others	
Definitely yes	6
Probably yes	5
Probably not	1
Definitely not	0
Information clear	
Everything clear	8
Mostly clear	4
Some clear	0
Mostly unclear	0
Did the DA add anything to the consultation	
An extreme amount	1
Very much	7
A moderate amount	4
A little bit	0
Nothing	0
Graphical representation in the DA helpful	
Extremely	4
Very	6
Moderately	2
A little bit	0
Not at all	0
Understood risk of recurrence info. in DA	
Yes	10
No	0
Not sure	1
Helpfulness of risk of recurrence info. in DA	
Extremely	3
Very	6
Moderately	1
A little bit	1
Not at all	0

risk of recurrence meant and how chemotherapy could act on the body to prevent this. Subsequent patients were therefore asked about these issues in more detail. Data were analysed using thematic analysis,[37] facilitated by the software package NVIVO V.10. AMi developed the codes by examining all instances in the data set that related to the DA, risk of recurrence information and the rationale for having chemotherapy. Themes were derived and developed via an iterative process, with constant comparisons of the data that identified similarities and differences within and across individual interviews. The codes and supporting quotes were reviewed for appropriateness and accuracy by AMa. Patients were not asked to verify the thematic analysis as we did not wish to increase participation burden.

RESULTS

Fifteen patients were approached by clinic staff, 13 were recruited, with 12 completing the study. The age of participants ranged from 33 to 82, with a median age of 67. The ratio of men to women was 1:2. Over half (n=7) were educated to degree level or equivalent and the majority were of white ethnicity (British or Irish) (n=9). Approximately half were employed (n=6), one was unemployed and the remainder were retired. One patient reported having had chemotherapy prior to surgery (s6). This person was included since it was not felt to impact on the reported outcomes. Eleven of the 12 patients declined chemotherapy (all except s8).

Patients' perceptions of the usefulness of the DA in helping them communicate with their doctor and make a decision were good, with scores (mean 4.28, SD 0.9) comparing favourably with those reported in other clinical populations, where scores ranged from 3.3 to 3.9.[35] Patients also reported finding the risk of recurrence information in the DA and graphical representation of information in the DA helpful, with all except one reporting that they were happy they understood the meaning of the information in the DA about risk of recurrence (see table 1).

Graphical representation of information on risk

A number of patients felt the graphs increased the clarity of the risk of recurrence information, "I liked the graphs, I suppose they're accurate really… I worked with statistics enough to know that you can kind of hide the numbers…. it made me consider chemotherapy more than I possibly would if I was just given words" (s10). Another participant described how the graphical presentation looked more scientific and hence more credible than being told the same information verbally: "Really it's no different to what the surgeon had already told us yesterday… it's a very much more scientific, you know, sort of presentation to it…" (s4).

For some patients, the graphs provided information they would otherwise have overlooked: for one patient, it was the additional benefit conferred by two, compared with one, chemotherapy drug "I didn't realise that the one was quite like a significant difference there, between the two (chemotherapy drugs)" (s3); for another patient, it was the risk of death from other causes: "When we're there we only talk about coming back and not coming back. But we do know that death is something that can come anytime… So I just put them in the two categories but on the graph I saw the three there" (s9).

Some patients found it helpful to see the portion of the graph that illustrated the net benefit of chemotherapy, whether they wanted chemotherapy or not, and used it to help them cope with their decision: "that made me feel quite positive… even though there was only 5%… I'm going into the chemotherapy, now, thinking about that line" (s8), "the graph…the bit that she

was talking about (net benefit of chemotherapy) is just tiny is quite good" (s3).

Some patients liked the positive information about their general prognosis—"I was quite pleased to see that. That was nice. There was lots of green (baseline risk of recurrence)" (s8). One person liked it because they described themselves as 'a visual person' (s3).

However, not everyone was able to articulate whether or why they had found the graphical information helpful, particularly if they had taken a younger relative into the consultation with them and felt confident their relative understood what was being said. "I didn't really understand it very much...I'm a bit of a dinosaur... I know my niece would have understood it all" (s11), "I just can't say...My son was with me now and he was very informative afterwards, he was, talked about it a lot...I think he found it very helpful" (s12).

Values clarification

The belief that they could not predict whether they would benefit from chemotherapy, the small risk of cancer coming back and the long-term side effects of chemotherapy were the main barriers to chemotherapy (see online supplementary table S2). Of least concern were the short-term side effects, insertion of a central line and repeat attendance at hospital, although around half were still concerned about these things.

Reactions to the values clarification exercise were more mixed than to the graphical display. Some patients found it helpful, while others reported conflicting feelings about the information. Positive reactions included the feeling that it was an accurate reflection of their (often mixed) views about chemotherapy, was clearer, more explicit, more rational and less emotional, and empowering for the patient: "it's good in terms of sometimes you struggle to articulate why you make one decision versus another" (s10) "getting me to kind of click on things, and say yes... puts the onus on me to make a decision and own my decision and feel empowered to make a decision independent of what the doctor thinks..." (s8). "Rather than having an emotional response, there's an actual figure there to say, 'This is what you decided.' ...it's good to be logical" (s3).

Others commented on the fact that not all the items were equally important and that numbers for and against chemotherapy were a bit simplistic, or having to select a choice yes/no without saying why did not tell the whole story.

One patient reported feelings of guilt when answering the values clarification exercise, because although they viewed their health as important they were opting to do something that did not necessarily maximise their chances of maintaining their health: "my health comes first above everything. And so a lot of questions there made me feel when I opted for a different answer to that, to really putting that first, I felt very guilty about, which was quite interesting. And I did pause and stress about that a little bit... But just because I answered the

other way doesn't mean I still don't have my health, you know, at the forefront of my thoughts... However, there are other issues at stake here" (s4).

Another felt it highlighted the importance of life over everything else: "I'm worrying about hair loss and this and that.... And what about that? Is that more important than life itself? Well, no, it isn't... But that tool...did think, you know, all of that is trivial in comparison with life itself. It's very precious" (s7).

However, one woman felt she only needed the risk of recurrence statistics to make a decision, and did not need the values clarification exercise: "It didn't seem to be difficult to answer really.... the biggest thing that sticks out in my mind is the statistics and the fact that taking the chemo again made really very little difference, that my mind was pretty well made up straight away" (s6). Others forgot whether or not they had performed the exercise: "In all honesty, I'd forgotten that, you know. I don't remember I did or not do" (s11).

Patient understanding of risk of recurrence statistics

The majority of patients understood that the aim of chemotherapy was to reduce the chances of cancer coming back, although people were more likely to mention the figure for net benefit of one chemotherapy drug (2–3%) rather than two (5%): "if I had chemotherapy, my chances of living more than five years would be about one or two percent increased, compared with not doing anything" (s1). "The chance of the cancer coming back was low—without the chemo, was low, anyway... Yes, the chemo might improve it by a couple of percent" (s4).

Two patients (both in their 30s) reported higher net benefit of chemotherapy figures (of 5%) and a clearer understanding of the difference between one and two chemotherapy drugs. "I think off the top of my head there was 86% chance of it not recurring within five years if I stopped it now... then for every additional drug chemo that I had was approximately a 2.5% additional chance of survival" (s10). One patient confused net benefit (additional 2–5% avoid recurrence) with overall recurrence rates (20–40%). "(Oncologist's name) said to me, 'There's just 2% chance.' When I'd said, 'No, I do not want chemo,'.... I took for granted that sort of the chances of it coming back is extremely low" (s11).

Patient understanding of how and why cancer recurs and how chemotherapy may act to reduce risk of recurrence

There was confusion over whether the figures about recurrence referred to another primary cancer or progression of the current episode, or both. "Was it a recurrence of the same cancer or was it from somewhere else?" (s6). While some patients understood that any recurrence would potentially be more aggressive and harder to treat than their colorectal cancer had been, others assumed the recurrence would be in the gut: "When you say it's a recurrence, you presume it will be

expected to be from the same site where the primary is… somewhere in the gut…" (s6). "Actually, in the beginning I was thinking that they were talking about that, the cancer will affect my bowel again. But from what she's (the oncologist) saying…it's not only the bowel, but you can get other type of cancer" (s9). "Obviously if it comes back it's not going to be as straightforward… It wouldn't be as simple as just having an operation and removing it, cos it might go to another part of the body" (s7).

An additional area of confusion was whether they were currently cancer free or not, and the rationale for giving chemotherapy when no cancer was apparently present or if you were a person 'prone' to cancer. "People say that you're 'cured' now because the cancer's been removed surgically. But then you've got this risk of recurrence. I found that quite difficult to wrestle in my head because it doesn't feel like I'm cured. It feels like I've got cancer and I've got to see what happens over the next five years…" (s8). "But that has been my problem. Even taking the chemotherapy, if you're talking about, well if cancer, prone to cancer. If cancer will come and chemotherapy wouldn't…. if it were there, I agree it would affect it, but if you will come back I don't think chemotherapy can stop it. That's my understanding; maybe I'm wrong" (s9). But some patients did not think their cancer would come back, and this belief seemed to be the basis of their decision to refuse chemotherapy: "I'm sure that if I thought there was a possibility of it coming back, for me, I would…. I would go for treatment. But I'm just hoping that it doesn't happen" (s12).

DISCUSSION

We developed a DA for patients with stage II colorectal cancer to facilitate an informed decision process for adjuvant chemotherapy. Patient perceptions of the usefulness of the DA were above scores reported in other patient groups,[35] but there was evidence of a lack of understanding of key information among some patients, in particular: their baseline risk of recurrence, the net benefit of combination chemotherapy and the rationale for having chemotherapy when cancer had apparently gone.

The method of communicating risk of recurrence information based on Adjuvant!online improves patient understanding of the likelihood of disease-free survival.[15] Numeric information about risks enhances patient understanding.[38] While visual displays can be very helpful, not everyone can extract the relevant information from them.[31] Consistent with previous research,[15] we found that despite presenting numeric and visual risk information, there was evidence of a lack of understanding of risk information among some patients.

Research on members of the general population has shown that understanding of the graphical risk

information given in Adjuvant! online is improved if people are presented with fewer options at any one time,[39] and that sequential presentation of treatment options leads to improved understanding of key information about risk of recurrence and net benefit of treatment.[40] In this study, patients were presented with all three options at once, and patient understanding of combination chemotherapy might have been enhanced by presenting just two options at a time (eg, no treatment vs one drug, no treatment vs two drugs). In addition, any benefit of single agent chemotherapy has only been observed among patients with bad prognostic factors,[4] which may be limited to T4.[41 42] Significant efforts are being made to develop better prognostic indicators including the search for gene signature sets that predict response to chemotherapy in this patient group.[43 44] This suggests that, in future, even more complex information may need to be presented to patients.

The values clarification exercise required patients to select arguments for and against chemotherapy. Although the pros and cons method is the most commonly used method for values clarification purposes, a variety of different methods are available, such as ranking, and social matching (how another person values the characteristics of different options and how similar that person is to you), but owing to a lack of research, there are no explicit recommendations about best practice, and no firm evidence about how and whether values clarification exercises actually inform and help the decision-making process.[45] Patient feedback showed that some patients found the exercise useful, and for one clarified the bottom line of the decision: prolonging life versus experiencing side effects. However, for others, the process was less helpful, either because understanding of the information contained in the DA had effectively been delegated to a younger member of the family (niece/son) or because the risk of recurrence information was all they felt they needed to make a decision. There is a lack of research about which patients may benefit from values clarification exercises, and the best methods to engage people with different cognitive ability or lower literacy levels and these issues remain to be explored.[45] The values clarification exercise used in this study had a higher than recommended readability level, and a simpler method of eliciting patient preferences will be needed for patients with lower levels of literacy.

A further suggested modification of the DA is the addition of information that helps people understand the rationale for being given chemotherapy when cancer has apparently gone. The information booklet developed by Jefford et al[10] included diagrams showing how colorectal cancer can spread around the body, and similar information should be included in a revised DA.

A key limitation of this study is that patients educated to degree-level or above were over-represented, which may have led to an overestimate of perceived usefulness

and acceptability of the DA as measured by the PrepDM and other questionnaire items.

The American Cancer Society estimated that a third of people diagnosed with colon cancer in 2013 will be diagnosed at stage II,[8] resulting in a substantial number of patients potentially faced with making a decision about adjuvant chemotherapy. It is clear that challenges remain in communicating risk of relapse information to patients and the need to check patient understanding of key information should be integrated in future DAs, for example, with the insertion of quizzes and representation of key information that patients appear to have misunderstood. In addition, much more research is needed into the best way to facilitate patients in making judgements about what is most important to them through a greater understanding of values clarification methods in assisting complex decisions.

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