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Signature  Date 01.05.14
Acknowledgments

First and foremost, I would like to thank the women who participated in my research and for whom this thesis is dedicated to. This thesis exists through their experiences and their contribution to the development of the CA-125 decision aid will help so many women with ovarian cancer who have to go through this difficult decision-making process. Thanks also to the health professionals who kindly gave their time to participate and whose expertise will help to shape what comes next.

I would like to sincerely thank my academic and clinical supervisors, Dr Paul Graham Morris and Dr Belinda Hacking for their extremely helpful feedback, support and encouragement throughout the project, which has been invaluable. I have felt very lucky to have such expertise guide me through this process. A big thank you to Dr Ethel Quayle for her guidance throughout the analysis process. Thanks to the Consultant Oncologists in the Edinburgh Cancer Centre, Dr Melanie MacKean, Professor Charlie Gourley and Dr Fiona Nussey for helping to get the project off the ground and for their support throughout the project development and recruitment stages. Their enthusiasm for the project and for the development of the decision aid has been both appreciated and infectious!

I would also like to thank my wonderful family and friends for their enduring love and unconditional support throughout the last three years, and indeed throughout all of my years in education. Last thesis, I promise!!

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To my darling Bailey, for always keeping me in the present and for reminding me every day that the simple things in life are the most important-sleep, food, exercise and cuddles!
To my amazing husband Jamie: for your love, support, patience and encouragement over the last three years of training; for being my rock, my greatest supporter and for bringing so much love, laughter and happiness into my life. I couldn’t have done it without you!

And finally….. to my beautiful baby boy, Daniel. Thank you for being so kind to your Mummy and for giving her the most stress-free pregnancy possible in order to write this thesis! I love you more with every passing day and hope to make you very proud of Mummy and her work.
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Research Portfolio Abstract

**Aims:** This thesis had three aims: to review evidence evaluating the effectiveness of decision aids at increasing cancer patients' treatment-related knowledge and reducing decisional conflict; to explore the decision-making processes of ovarian cancer patients who had opted for or against CA-125 testing during post-treatment surveillance; and to elicit patients’ and health professionals’ views on the proposed development of a decision aid aimed at helping women decide for or against CA-125 testing during post-treatment surveillance for ovarian cancer.

**Methods:** A systematic review was conducted of evidence relating to the effectiveness of cancer treatment-related decision aids at increasing treatment-related knowledge and reducing decisional conflict. In the qualitative study, semi-structured interviews were conducted with ovarian cancer patients (n = 18) and health professionals (n = 6) in an outpatient gynecological oncology clinic. Framework analysis was used to identify themes in the qualitative data.

**Results:** Overall, results from the systematic review supported previous research where decision aids were found to improve patient knowledge and reduce decisional conflict across a range of cancer treatment-related decisions. However, the lack of psychometric support for the treatment-related knowledge measures used in the majority of the studies compromised their ability to address the review question. In the qualitative study, accurate knowledge about CA-125 testing in post-treatment surveillance was found to greatly influence participants’ decision-making processes. Most women with less knowledge about the test chose to have testing based on the false belief that earlier detection of recurrence would lead to earlier treatment and prolonged survival. There was strong enthusiasm from patients and health professionals for the development of the proposed decision aid to assist women facing this treatment decision.

**Conclusions:** The systematic review findings add to previous research supporting the use of decision aids in cancer-related treatment decisions and advocate for their
continued development, evaluation and implementation into the healthcare system. The need for a decision aid to ensure accurate knowledge about CA-125 and to aid decision-making for women with ovarian cancer was supported. As well as assisting women with this decision, the proposed decision aid may ultimately support health professionals in practicing shared decision-making regarding CA-125 testing with ovarian cancer patients.
Systematic Review

Are decision aids for cancer treatment-related decisions effective at increasing treatment-related knowledge and reducing decisional conflict? A systematic review.

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Paul Graham Morris ²
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Abstract

**Background:** A small number of systematic reviews have found support for the effectiveness of patient decision aids in increasing knowledge and reducing decisional conflict in cancer treatment-related decisions. However, reviews have tended to only include randomized controlled trials and explored a limited number of cancer diagnoses. This review aimed to evaluate the effectiveness of treatment-related decision aids at increasing patient knowledge and reducing decisional conflict, regardless of cancer type or study design.

**Methods:** Multiple electronic databases were systematically searched and reference lists of identified articles were scanned. Twelve studies were methodologically appraised using quality criteria developed to address the review question.

**Results:** Results supported previous research where decision aids were found to improve patient knowledge and reduce decisional conflict across a range of cancer treatment-related decisions. In the controlled studies, patients receiving decision aids had higher knowledge and lower decisional conflict scores compared with controls. However, the lack of psychometric support for the treatment-related knowledge measures used in six out of the seven studies compromised their ability to address the review question.

**Conclusion:** The findings add to previous research supporting the use of decision aids in cancer-related treatment decisions and advocate for their continued development, evaluation and implementation into the healthcare system.
Keywords: Cancer, treatment, knowledge, decisional conflict, decision aids, decision-making

Article word count (excluding tables, figures & references) = 5496
Introduction

In recent decades, greater emphasis has been placed on the importance of shared decision-making (SDM) in healthcare systems worldwide (Joseph-William et al 2014). In the United Kingdom, SDM is embedded within the National Health Service where the motto of “No decision about me without me” encapsulates the vision of the service to develop a more patient-centred healthcare system (Department of Health, 2012). SDM is “the process of interacting with patients who wish to be involved in arriving at an informed, values-based choice among two or more medically reasonable alternatives” (O’Connor et al, 2004, pp. 64). In cancer care, existing health literature suggests that most patients prefer an active role in treatment-related decision-making (Stewart et al 2000; Gattellari et al, 2001; Keating et al, 2002; Stacey et al, 2010). However, barriers exist for patients to engage properly in the decision-making process. Apart from the emotional burden of adjusting to the cancer diagnosis itself, patients are often faced with ‘preference-sensitive’ decisions, where two or more medically equivalent treatment options exist with varying degrees of potential benefits and side effects. In these situations, patients must make an informed decision that is consistent with their values (Stacey et al, 2008).

There has been a significant investment in the development of decision support tools, particularly decision aids (DAs), to assist patients and health professionals with preference-sensitive decision-making and to encourage SDM. DAs are evidence-based tools that assist patients with preference-sensitive decision making by outlining the decision that needs to be made, informing patients about the options and outcomes and by clarifying patients’ personal values for the benefits versus harms of the
different options available (O’Connor et al, 2007). DAs come in a variety of formats including booklets, decision boards, computer programmes, videos and interactive websites, but differ from usual health education materials because of their individualised focus on options and outcomes (O’Connor et al, 2009).

DA development is closely linked with The Conflict Theory of Decision Making (Janis & Mann, 1977), which is based on the key assumption that a life-altering situation that produces a decision dilemma leads a person to experience decisional conflict, which generates a certain degree of stress. According to the theory, this stress arises from concern about personal and material losses that may occur from the chosen alternative, as well as from concern about the subjective losses that may lower self esteem (Janis & Mann, 1979). The theory assumes that in coping with this stress, an individual chooses one of five coping patterns during the process of trying to resolve the decisional conflict: (1) unconflicted adherence; (2) unconflicted change; (3) defensive avoidance; (4) hypervigilance; and (5) vigilance. According to the model, the first four coping patterns (where there is an absence or excess of stress) are maladaptive and associated with unproductive information search, assessment and decision making patterns. Only the last of these, vigilance, is adaptive, where an individual will seek out information and weigh the options carefully. Deliberation tools such as decision aids are designed to help individuals accomplish these goals as information is organized in such a way as to provide clarity about the nature of the decision, and to accentuate the differences between alternatives.
Systematic reviews of clinical trials assessing the effectiveness of DAs for cancer-related decisions have reported improvements across a number of decision-related outcomes (Waljee et al, 2007; Stacey et al, 2008; O’Brien et al, 2009; Spiegle et al, 2013). As highlighted by Neuman and colleagues (2007), whilst it may seem intuitively obvious that DAs would help patients to make health-related decisions, it is important to objectively evaluate this. Health professionals must also be confident of the efficacy of DAs in order to invest their time in using them and facilitating their implementation within everyday clinical practice. Additionally, health service managers and policymakers also need strong evidence of DA efficacy in order to provide support and funding for their development, evaluation and implementation.

Knowledge and decisional conflict (DC) are important outcome variables by which to judge the effectiveness of DAs. Health care professionals are bound by both legal and ethical obligations to ensure that patients provide informed consent for treatment-related decisions (Feldman-Stewart et al, 2013). Knowledge is a prerequisite for informed decision-making, ensuring that patients make choices in line with their personal values (Smith et al, 2012). A wide variety of both prescriptive and descriptive theories of decision-making all suggest that a solid knowledge base of the decision-related problem needs to be developed by patients in order to establish personal, knowledge-based preferences (Feldman-Stewart et al, 2013). The primary goal of DAs is to increase patients’ knowledge about their condition and present unbiased and balanced information about their treatment options (O’Connor et al, 2003). A recent Cochrane review comparing DAs to usual care in terms of the effects of knowledge scores found that patients using DAs had significantly higher scores (Stacey et al, 2014).
According to the Ottawa Decision Support Framework, DC is a key determinant in decision-making (ODSF 2014). DC is commonly experienced by patients where preference-sensitive decisions are involved, where there is a ‘choice dilemma’ or ‘conflicted decision’ that leads to a feeling of uncertainty (O’Connor & Jacobsen, 2007). According to DC theory, several modifiable deficits can increase or decrease the level of uncertainty perceived by patients facing health-related decisions including: (1) feeling uniformed; 2) unclear values regarding the relative desirability or importance of the benefit versus harm of the available options; 3) perceived inadequate support; and 4) the overall perception that a poor quality or ineffective decision has been made (O’Connor & Jacobsen, 2007). A recent study found that cancer patients who had greater involvement in decision-making had significantly less DC as compared to patients with less involvement (Brown et al, 2012). Similar to knowledge, evaluation research has supported the use of DAs for reducing DC in cancer-related treatment decisions (Stacey et al, 2014).

Rationale for the current review

To date, systematic reviews specifically assessing the effectiveness of cancer treatment-related DAs have been limited by a focus on published studies using a RCT design only (O’Brien et al, 2009; Spiegle et al, 2013), thus excluding the opportunity for a wider review of non-randomised or non-controlled studies that may provide additional insight into DA effectiveness. The results of one of these studies largely reflected DAs in the cancer screening context, with only 5 out of the 34 studies included in the review relating to treatment, thus limiting the ability for the results to
be definitive about the impact of cancer-related DAs in the treatment context (O’Brien et al, 2009). Additionally, the focus in the second related study was limited to only four specific cancer diagnoses from the outset: breast; colorectal; lung; and prostate (Spiegle et al, 2013). This highlights the paucity of research evidence assessing the effectiveness of DAs in other cancer diagnoses in the treatment context.

Main Aim of the Systematic Review

The current review aims to systematically evaluate the effectiveness of cancer treatment-related DAs at increasing patient treatment-related knowledge and reducing decisional conflict, regardless of cancer type or study design.

Method

Review protocol

As a first step, the Cochrane Database of Abstracts of Reviews and Effects (DARE) was searched in order to ensure that a similar review had not been recently conducted. The DARE search identified four articles that were related to the current review: first, a systematic review on the feasibility and effects of DAs (Molenaar et al, 2000); second, a systematic review on the impact of cancer-related DAs (O’Brien et al, 2002); third, a systematic review and meta-analysis of the effectiveness of cancer-related DAs in screening, prevention and treatment (O’Brien et al, 2009); and fourth, a systematic review on DAs for health treatment or screening decisions (Stacey et al,
2014). Subsequently, as recommended in guidance for undertaking reviews in healthcare produced by York University’s Centre for Reviews and Dissemination (CRD, 2009), a study selection protocol was developed prior to undertaking the literature search in order to minimize bias and facilitate transparency. The protocol comprised an outline of the review question, the rationale for the review, a definition of a DA, eligibility criteria, outcomes of interest, planned search strategy, planned data extraction methods, quality assessment methods and the intended method of synthesising and disseminating the findings (see Appendix 2).

Eligibility

_Inclusion & exclusion criteria_

Studies were retained for review if they: (a) quantitatively evaluated a decision aid for adult patients with a histologically-proven cancer diagnosis facing a choice related to treatment; and (b) included outcome measures of treatment-related knowledge and/or decisional conflict pre and post the decision aid intervention; and (c) had a minimum sample size of 10 participants. Studies were excluded where full text articles could not be sourced either as a complete published article or by contacting the authors directly for complete unpublished drafts.

_Literature search strategies_

The literature search was conducted in February 2014. Systematic searches of relevant databases were undertaken and all databases selected were searched from
their inception. MEDLINE (1946 to February 2014), PsychInfo (1974 to February 2014), CINAHL Plus (Cumulative Index of Nursing and Allied Health Literature; 1982 to February 2014), EMBASE (1947 to February 2014), Sociological Abstracts (1952 to February 2014) and the Cochrane Library (1994 to February 2014) were all searched for relevant titles. The following search string was used within each database: (‘decision aid’ OR ‘decision support technique*’ OR ‘decision tool’ OR ‘decision support system*’ OR ‘education* aid’ OR ‘education* tool’) AND (‘cancer’ OR ‘neoplasm*’) AND ‘treatment’. Additionally, relevant journals within the years 2009 to 2014 were hand searched: Medical Decision Making, Patient Education & Counseling, Journal of Clinical Oncology, BMC Medical Informatics & Decision Making.

Study selection

Figure 1 provides an overview of the search selection process and details each stage. Of 2846 potentially eligible articles, 223 abstracts were screened for eligibility and 40 full-text articles were retrieved. The search process was completed by a manual hand search of the reference lists of these 40 studies in order to detect any studies that may have been missed. A further four reviews were identified during this process. In addition, the reference lists of the four reviews identified during the DARE search (Molenaar et al, 2000; O’Brien et al, 2002; O’Brien et al, 2009; Stacey et al, 2014) were screened but no further studies were identified. Thirty-two of the 44 studies were excluded for reasons provided in Table 1. The remaining 12 studies were selected for methodological review and appraisal.
Table 1. Overview of excluded studies following full text review

<table>
<thead>
<tr>
<th>No. of Studies Excluded</th>
<th>Reason for Exclusion (n = 32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Did not assess treatment-related knowledge and / or DC</td>
</tr>
<tr>
<td>8</td>
<td>Did not assess treatment-related knowledge and/or DC pre and post the DA intervention</td>
</tr>
<tr>
<td>4</td>
<td>DA pilot studies</td>
</tr>
<tr>
<td>4</td>
<td>Qualitative DA evaluation studies</td>
</tr>
<tr>
<td>3</td>
<td>Participants without a histologically-proven cancer diagnosis</td>
</tr>
<tr>
<td>1</td>
<td>Less than 10 participants</td>
</tr>
<tr>
<td>1</td>
<td>Full-text article could not be sourced</td>
</tr>
</tbody>
</table>
Figure 1. Flow chart of the search selection process
Data extraction

Information was collated using a data extraction form for each of the 12 studies included in the final selection for systematic review. This included study characteristics, participant characteristics, intervention, setting and main study findings (Table 3).

Assessment of methodological quality

As there was no existing quality criteria checklist appropriate for this review, quality criteria pertinent to the current review question were developed by the authors (Appendix 3). As recommended by the CRD, the quality criteria encompassed the assessment of: the risk of bias; the choice of outcome measure; statistical issues; and external validity (www.york.ac.uk/inst/crd/). F.E.W rated each of the 12 studies in relation to 10 quality criteria developed using the following six outcome ratings: ‘well covered’; ‘adequately addressed’; ‘poorly addressed’; ‘not addressed’; ‘not reported’; or ‘not applicable’. The following overall quality ratings, originally created by author P.G.M and adapted to fit the current review, were assigned to the studies: excellent; good; adequate; or poor (Table 2). Eight out of the twelve papers (66.6%) were independently rated by two researchers, where P.G.M independently reviewed three papers and a further five papers were rated by a trainee clinical psychologist (C.G). Rating discrepancies were discussed and all authors reached a joint decision on the overall quality rating of each paper.
<table>
<thead>
<tr>
<th><strong>Excellent</strong></th>
<th>All or a considerable majority of the criteria have been well covered. Limitations of the study are thought to be very unlikely to have affected the findings or conclusions.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Good</strong></td>
<td>Considerable majority of the criteria have been well covered or adequately addressed. Limitations of the study are thought to be unlikely to have affected the findings or conclusions.</td>
</tr>
<tr>
<td><strong>Adequate</strong></td>
<td>Majority of the criteria have been well covered or adequately addressed. Limitations of the study may have modestly affected the findings or conclusions.</td>
</tr>
<tr>
<td><strong>Poor</strong></td>
<td>Many or most criteria were not well covered or adequately addressed. Limitations of the study are thought likely or very likely to have affected findings or conclusions.</td>
</tr>
<tr>
<td>Author &amp; Year</td>
<td>Cancer Type</td>
</tr>
<tr>
<td>---------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Berry et al 2013 USA</td>
<td>Prostate</td>
</tr>
<tr>
<td>Collins et al 2009 USA</td>
<td>Breast</td>
</tr>
<tr>
<td>Davidson et al 2007 Canada</td>
<td>Prostate</td>
</tr>
<tr>
<td>Feldman-Stewart et al 2012 Canada</td>
<td>Prostate</td>
</tr>
<tr>
<td>Fiset et al 2000 Canada</td>
<td>Lung</td>
</tr>
<tr>
<td>Jibaba-Weiss et al 2011 USA</td>
<td>Breast</td>
</tr>
<tr>
<td>Peate et al 2012 Australia</td>
<td>Breast</td>
</tr>
</tbody>
</table>

Table 1. Overview of selected studies
<table>
<thead>
<tr>
<th>Author &amp; Year</th>
<th>Cancer Type</th>
<th>Treatment Options outlined in the DA</th>
<th>Study Design</th>
<th>DA Group Sample size</th>
<th>Control Group? (Y/N plus sample size)</th>
<th>Outcome Measures</th>
<th>Main Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sivell et al 2012</td>
<td>Breast</td>
<td>(freezing OR ovarian suppression OR egg and embryo donation)</td>
<td>Pre/post study</td>
<td>54</td>
<td>N</td>
<td>10 true/false questions</td>
<td>Knowledge with significant difference reported in DA versus control group</td>
</tr>
<tr>
<td>UK</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Street et al 1995</td>
<td>Breast</td>
<td>Mastectomy OR breast conserving surgery with radiotherapy</td>
<td>Pre/post study</td>
<td>30</td>
<td>Y-30</td>
<td>11 multiple choice questions</td>
<td>Knowledge scores significantly improved for both groups post-DA. No significant difference between groups according to DA format</td>
</tr>
<tr>
<td>USA</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Van Tol-Geerdink et al 2008</td>
<td>Prostate</td>
<td>Choice between two radiation treatment doses</td>
<td>Pre/post study</td>
<td>150</td>
<td>Y-144</td>
<td>10 point knowledge scale</td>
<td>Significant improvement in subjective &amp; objective knowledge in the DA group versus control group</td>
</tr>
<tr>
<td>Netherlands</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vodermaier et al 2009</td>
<td>Breast</td>
<td>(1) Mastectomy OR lumpectomy and radiation (tumour size T1 group) (2) Preoperative chemotherapy followed by surgery OR standard therapy (tumour size T2/ T3 group)</td>
<td>RCT</td>
<td>55</td>
<td>Y-56</td>
<td>DCS</td>
<td>No intervention effect emerged on the Total DC scale. A significant group effect emerged on the informed subscale</td>
</tr>
<tr>
<td>Germany</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Whelan et al 1995</td>
<td>Breast</td>
<td>Breast irradiation post-lumpectomy OR no treatment post-lumpectomy</td>
<td>Pre/post study</td>
<td>30</td>
<td>Y-52</td>
<td>10 true/false statements</td>
<td>Patient knowledge was similar between groups but patients who used the decision board had increased understanding regarding the fact that breast irradiation could not be repeated</td>
</tr>
<tr>
<td>Canada</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

DA: Decision Aid; DCS: Decisional Conflict Scale (O’Connor et al, 1995)
Results

Characteristics of included studies

As summarized in Table 3, 12 quantitative studies undertaken in six countries between 1995 and 2013 were selected for appraisal and review of their methodological quality. Of the 12 studies included, four were RCTs and eight were non-RCTs (using a pre/post intervention study design). Four of the eight non-RCT studies were prospective cohort studies and the remaining four studies compared one form of DA to another. Decision aids used in breast, lung and prostate cancers were studied. Four of the reviewed studies focused on knowledge, five focused on decisional conflict, and three considered both knowledge and decisional conflict. A total of 2056 patients were included with sample sizes ranging from 20 to 494 participants. Decision aids were offered by means of interactive computer programmes, booklets, videos with/without linear booklets and decision boards. Details of participants’ treatment options are presented in Table 3.

Quality of included studies

Table 4 provides ratings for each of the studies on the 10 quality criteria. In relation to addressing the review question, included studies were of good methodological quality overall, with 8 of the 12 papers achieving a well-covered score on five or more quality criteria. Berry et al (2013) stood out as the most rigorous in terms of design and methodology, achieving the highest rating (well-covered) in all nine applicable categories. In terms of reviewing the quality of the included studies, the
aspects of study design that are particularly pertinent to answering this review question relate to the representativeness of the clinical sample and the outcome measures selected for treatment-related knowledge and decisional conflict.

Regarding representativeness, a true clinical sample of patients was represented in the majority of studies (well-covered/adequately addressed), where a consecutive series of potential patients had been approached in a clinical setting(s), of which over 60% completed the study. In terms of number of recruitment sites, two studies in particular stood out as being especially strong in this category. Peate et al (2012) recruited across 19 sites and Berry et al (2013) recruited across 6 sites, thus contributing to the external validity, reliability and generalisability of their results. This was in contrast to the majority of included studies whose recruitment was limited to one clinical location (Street et al, 1995; Whelan et al, 1995; Fiset et al, 2000; Davidson et al, 2007; Collins et al, 2009; Vodermaier et al, 2009; Feldman-Stewart et al, 2012).

Regarding the measurement of patient treatment-related knowledge, six out of seven studies were allocated a poorly addressed rating as they used non-standardised instruments developed by the authors, generally consisting of true or false statements. The Jibaba-Weiss et al (2012) study stands out compared to the other six studies evaluating the effectiveness of the DA on this outcome, as it was the only study to report internal consistency for their developed scale (Cronbach’s alpha = 0.63). However, the knowledge measure used was not included within the journal article. Indeed, the knowledge scales developed were only included in three of the seven articles (Street et al, 1995; Whelan et al, 1995; Sivell et al, 2012). Thus, measures used to assess knowledge in six of the seven studies were not established to be valid.
and reliable for the relevant populations, which significantly limits the ability of these studies to address the review question.

In contrast, all eight studies assessing DC used a version of the validated and reliable Decisional Conflict Scale (DCS; O’Connor, 1995). The full DCS version comprises 16 items, within five sub-scales. The first four sub-scales elicit the extent to which a person feels: certain, informed, clear regarding their values, and supported in decision-making. The last sub-scale elicits the person’s overall perception of the effectiveness of the decision-making process. Each item is scored on a 5-point Likert scale (1, strongly agree to; 5, strongly disagree). The DCS total score is obtained by summing up the 16 item scores and dividing by 16, resulting in a score that ranges from 1 to 5. A higher score indicates a higher level of DC (i.e. more discomfort with the decision made). This is a widely used scale that is sensitive to change and shows excellent validity and reliability. Five of the eight studies used the complete 16-item instrument (O’Connor, 1995), with one using the German-translated version (Vodermaier et al, 2009). The remaining three studies used the low-literacy version of the DCS, a 10-item shorter version (made up of four subscales), which is recommended for those with limited reading or response skills (O’Connor, 2010). The use of a psychometrically sound measure across these studies increases confidence in the findings related to patients’ DC post-DA exposure.

Regarding the remaining quality criteria, most studies with control groups had applied randomization, which reduced the risk of bias. Follow-up of outcome measures post-DA intervention was reported in half of the studies, where four of the six studies carried out follow-up for a minimum of three months. As evident in Table 4, analyses
in the majority of studies were appropriately reported and justified, with some providing more extensive detail and depth of exploration than others.
### Table 1. Overview of methodological quality ratings

<table>
<thead>
<tr>
<th>Study</th>
<th>1</th>
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<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>Overall Quality Rating</th>
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<tbody>
<tr>
<td>Collins et al (2009)</td>
<td>P/A</td>
<td>N/ADD</td>
<td>N/ADD</td>
<td>W/C</td>
<td>N/ADD</td>
<td>N/APP</td>
<td>W/C</td>
<td>W/C</td>
<td>A/A</td>
<td>P/A</td>
<td>Poor</td>
</tr>
<tr>
<td>Fiset et al (2000)</td>
<td>A/A</td>
<td>N/ADD</td>
<td>N/ADD</td>
<td>P/A</td>
<td>N/ADD</td>
<td>P/A</td>
<td>W/C</td>
<td>W/C</td>
<td>N/R</td>
<td>N/ADD</td>
<td>Good</td>
</tr>
<tr>
<td>Sivell et al (2012)</td>
<td>P/A</td>
<td>N/ADD</td>
<td>N/ADD</td>
<td>A/A</td>
<td>N/ADD</td>
<td>P/A</td>
<td>N/APP</td>
<td>W/C</td>
<td>A/A</td>
<td>N/ADD</td>
<td>Poor</td>
</tr>
<tr>
<td>Whelan et al (1995)</td>
<td>W/C</td>
<td>W/C</td>
<td>P/A</td>
<td>P/A</td>
<td>N/R</td>
<td>P/A</td>
<td>N/APP</td>
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<td>P/A</td>
<td>N/ADD</td>
<td>Poor</td>
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<table>
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<tr>
<th>Well Covered</th>
<th>Not Addressed</th>
<th>Adequately Addressed</th>
<th>Not Reported</th>
<th>Poorly Addressed</th>
<th>Not Applicable</th>
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<tr>
<td>W/C</td>
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</table>

1. A true clinical sample of patients was represented in the study
2. A suitably controlled design was used
3. Assignment to groups was randomised
4. Sample size was sufficient for analyses relating to knowledge and/or decisional conflict outcomes
5. Similar levels of knowledge and/or DC between intervention and control groups, or differences were controlled for in analyses
6. Knowledge outcome was measured in a valid and reliable way
7. Decisional conflict outcome was measured in a valid and reliable way
8. Appropriate analyses used
9. Levels of attrition were equivalent for treatment versus control
10. The intervention was evaluated for an appropriate duration
Narrative Synthesis

Two outcomes, treatment-related knowledge and DC, were considered for quantitative meta-analysis. As aforementioned, in the studies assessing patient treatment-related knowledge, several different methods were used, and the majority of these studies did not provide evidence of the validity or reliability of their knowledge scale. The heterogeneity of methods and measures and lack of standardized questionnaire use made a meta-analysis impractical for the knowledge outcome. Similarly, in the studies assessing DC, meta-analysis was not possible due to the heterogeneity of the studies in terms of their methodology and DCS versions used. As a result, a narrative description of the results is provided.

Patient Treatment-Related Knowledge

Among the seven studies measuring treatment-related knowledge, the DAs appeared to increase patients’ knowledge concerning the cancer and its related treatment options, with all seven studies reporting an increase in patient knowledge scores following DA-exposure (Street et al, 1995; Whelan et al, 1995; Fiset et al, 2000; van Tol-Geerdink et al, 2008; Jhiba-Weiss et al, 2011; Peate et al, 2012; Sivell et al, 2012). This difference was statistically significant for participants in five of the seven studies (Fiset et al, 2000; Jhiba-Weiss et al, 2011; Peate et al, 2012; Street et al, 1995; Whelan et al, 1995). However, it is important to note that the lack of psychometric support for the measures used in six out of the seven studies assessing
treatment-related knowledge compromises their ability to confidently address the review question.

It is important to consider methodological issues within the included studies in relation to the results. In the first of the two cohort studies, Fiset et al. (2000) found a significant improvement in knowledge scores (p < 0.001) from a mean of 72% correct answers at baseline to 90% after DA-exposure. However, this study only achieved an adequate quality rating overall, with a small sample size (n = 20), which highlights the need for caution when interpreting the results. The second cohort study was also methodologically weak in comparison to the majority of included studies. Sivell et al. (2012) found that although knowledge scores on their 10-item questionnaire increased after DA exposure, the increase was not significant (baseline mean = 8.28, post-intervention mean = 8.51). The authors acknowledged that this lack of improvement might reflect the lack of validity and reliability of the measure. It is also worth noting that only women who requested further information on surgery following the standard pre-surgical consultation were invited to use the DA. Thus, it is unsurprising that their pre-DA scores were also high relating to treatment-related knowledge. The results were in contrast to those of the other two studies assessing treatment-related knowledge surrounding the decision to opt for mastectomy or breast conserving surgery and radiation for breast cancer (Street et al., 1995; Jibaba-Weiss et al., 2011), where a significant difference in knowledge scores post-DA was reported in both.

Four studies compared DA with usual care (Whelan et al., 1995; van Tol-Geerdink et al., 2008; Jibaba-Weiss et al., 2011; Peate et al., 2012). Inclusion of a control group is likely to have helped eliminate possible alternative explanations of the results related
to treatment-related knowledge following DA exposure. In three of these four studies, the DA group had significantly higher than average knowledge scores (van Tol-Geerdink et al, 2008; Jibaba-Weiss et al, 2011; Peate et al, 2012). For example, van Tol-Geerdink et al (2008) found that subjective knowledge (means 6.8 versus 6.3, p < 0.001) and objective knowledge (means 6.9 versus 4.4, p < 0.001) improved in the DA over the control group. The fourth study reported similarities between the DA and control groups on all but one knowledge question, where patients who used the DA had increased understanding of the fact that breast irradiation could not be repeated to the same breast (p < 0.001) (Whelan et al, 1995). However, this study was notably weaker in methodological quality compared to the three other studies, particularly regarding sample size and attrition levels. Out of the two studies with follow-up assessments (Jibaba-Weiss et al, 2011; Peate et al, 2012), one maintained long-term follow-up scores (Peate et al, 2012). However, the control group in the second study’s knowledge had increased almost to the level of the DA intervention group at 1-year follow-up (Jibaba-Weiss et al, 2011). Of note, however, the time from T2 to T3 in the latter study varied from a few days to almost one year. Therefore, patients may have become more knowledgeable about treatment over time, which could have affected outcomes.

The final study randomly allocated participants to a brochure format DA versus a computer programme DA (Street et al, 1995). Knowledge scores on an 11-item multiple-choice questionnaire were assessed at baseline, post-DA and post-consultation. Repeated measures ANOVAs assessed knowledge means by experimental condition and time. A strong effect for time was found at Time 1 versus Time 2 (F = 36.35, p < 0.001) but knowledge scores after the consultation were
essentially the same as post-DA exposure scores. The effect for method of education (brochure versus computerized programme) approached significance ($F = 3.30, p = 0.07$), as patients in the computer group tended to learn more than the brochure group. However, limitations of the study included the lack of a ‘no education’ group and a relatively small sample size (30 participants per group).

**Decisional Conflict**

All eight studies assessing DC reported a significant decrease in DC in treatment decision-making on subscales of the DCS post-DA exposure. The two prospective cohort studies reported statistically significant reductions in DC over time (Fiset *et al.*, 2000; Collins *et al.*, 2009). Collins and colleagues (2009) assessed DC over three time points (baseline, post-DA and post-surgical consultation) and reported that reductions in overall DC were primarily driven by two subscales: feeling informed and unclear about personal values (paired $t$ test $P < .01$). However, this study was conducted at a single medical centre where decisional support is incorporated into the clinical care process. It is therefore likely that patients in this system would have lower than usual baseline DC scores compared to patients who do not receive decisional support as routine practice. Fiset and colleagues (2000) also reported a statistically significant decline in DC ($P < 0.001$), with the mean score declining by 0.6 out of 5 (95% CI: 0.4, 0.8), where the smallest change was noted in the support subscale. However, caution should be taken when interpreting results from this limited sample of participants.
Three of the four RCTs assessing differences between DA versus control groups reported statistically significant reductions in DC (Jibaba-Weiss et al, 2011; Peate et al, 2012; Berry et al 2013). For example, Peate and colleagues (2012) found that compared with usual care, women who received the DA had reduced DC ($\beta = -1.51; 95\% \text{ CI; -2.54 to 0.48; } P = 0.031$), after adjusting for education, desire for children and baseline uncertainty. The sub-scale scores of the DCS were examined in two of these three studies and results varied as to where the greatest and most consistent benefits from DAs were observed. After adjusting for confounding or influential variables, Berry and colleagues (2013) reported significantly reduced DC over time for the subscales of uncertainty, -3.61 units (95% CI, -7.01 to -0.22) ($p = 0.04$) and values clarity, -3.57 units (95% CI, -5.85 to -1.30) ($p = 0.002$), but not among the informed, support or effective decision subscales. Jibaba-Weiss and colleagues (2011) also reported that DA participants had scores indicating that they were significantly clearer about their personal values related to the decision regarding breast cancer surgery than controls. The authors reported the greatest difference on the ‘informed’ subscale, where the DA group reported being more informed about surgical options and related risks ($p = 0.007$). Indeed, none of the women in the DA group were unsure about their surgery choice, while 10.5% of the controls were. All three studies were methodologically strong, thus increasing confidence in the results relating to reductions in DC post-DA exposure.

The fourth controlled study assessing DC reported no intervention effect on the DCS total scale, but did find a significant group effect on the ‘informed’ subscale, indicating that the DA group felt better informed after exposure to the DA (Vodermaier et al, 2009). However, the study noted that a strong culture of shared
decision-making between clinicians and patients existed in the study centre, such that all patients experience a high degree of participation in treatment decision-making. This could explain why the DA had little impact on DA-exposed versus non-DA exposed patients’ DC scores. Two of the four trials measured the longer-term effect (12 months follow-up) of DAs on total DC. Statistically significant group differences were maintained for participants in one study (Peate et al, 2012) but group differences were not apparent after the same time period in the other study (Jibaba-Weiss et al, 2011).

Of the remaining two studies assessing DC, Davidson and colleagues (2007) compared a generic versus individualized DA and Feldman-Stewart and colleagues (2012) compared a DA to an identical one that included an additional explicit values-clarification exercise. Neither study reported significant differences between groups at either baseline or post-DA exposure. However, significant decreases in DC were reported for all participants following use of their respective DAs in both studies over time. Both studies were considered in the current review to be of good methodological quality. However, results in the Davidson et al (2007) study are only generalizable to newly diagnosed prostate cancer patients who want access to additional information and decision support after their treatment consultation. In the Feldman et al (2012) study, only 37% of potentially eligible patients in two of the participating clinics took part in the study, with the majority approached declining on the basis of not experiencing any decisional conflict related to their treatment decision. Participating clinics were noted to have active patient education programmes.
Discussion

This study systematically reviewed the literature in order to investigate the effectiveness of cancer treatment-related decision aids at improving patient knowledge and reducing DC. Despite the variability in cancer diagnoses, decisions and measurement, the studies found that DAs were successful in improving patient knowledge about treatment options and outcomes and reducing their DC. Consequently, the findings of the current study are consistent with other reviews of DAs in a broader health treatment context and in cancer-related care (Neuman et al, 2007; Waljee et al, 2007; O'Connor et al, 2009). However, as only one DA was made available by the authors of the included studies for review (Peate et al, 2012), variation and comparisons relating to the quality of the DAs used could not be commented upon.

Overall, the studies included in this review found a positive effect for DAs in improving patients’ treatment-related knowledge, suggesting that patients who use DAs generally feel more informed about their treatment options. The finding of higher treatment-related knowledge scores among DA-exposed participants in the controlled studies suggests that the usual consultation method for health professionals used to inform patients about various treatment options and possible outcomes for these complex decisions may not be good enough, where evidence suggests that little of the imparted clinical information is retained (Lavelle-Jones et al, 1993; Lloyd et al, 1999). Patients need to fully understand the information in order to make an informed decision. Thus, the results of the reviewed studies appear to support previous research suggesting that reinforcement of verbal information with written or visual material
may enhance patient knowledge and understanding about cancer treatment options (Neuman et al, 2007; Spiegle et al, 2013). However, use of non-validated scales for assessing the knowledge effect both highlights the need for more robust measures to be developed or for researchers to test the validity and reliability of self-developed tools. This issue was also highlighted by Spiegle and colleagues (2013) in their recent systematic review of cancer treatment decision support interventions, where all but one study used non-validated knowledge scales. Whilst knowledge is among the most common outcome variables used to assess DA effectiveness, few studies have explicitly described how knowledge items on measures used were generated, reviewed or tested (Smith et al, 2012). Thus, the overall results relating to treatment-related knowledge in the current review must be interpreted with caution.

The post-DA reduced scores for total DC and for most DC subscales across studies indicate and provide support for the argument that DAs help patients to feel more comfortable with their treatment choices (O’Connor et al, 2009; Stacey et al, 2014). Participants receiving the DA in the controlled studies had less DC than participants who did not use such a tool (Brown et al, 2012), providing further support for the implementation of DAs into usual care. However, some limitations of these studies should be considered. A lack of significant differences between DA-exposed versus control groups in the controlled trials on some of the DCS subscales was noted. This may be due to the fact that all four controlled studies assessing DC highlighted the fact that participating clinics had active patient education programmes/decision support as part of standard care (Collins et al, 2009; Jibaba-Weiss et al, 2009; Vodermaier et al, 2009; Feldman-Stewart et al, 2012). Therefore, it not surprising that DC scores fell for all participants in these studies if a high level of decisional support...
was already in place. This may not be representative of usual care control groups in other controlled trials assessing the effectiveness of DAs in reducing treatment-related decisional conflict. Additionally, Davidson and colleagues (2007) only recruited men who had requested additional information about their treatment above the usual amount, thus limiting the generalizability of their findings to the wider prostate cancer treatment population. The response rate of less than 40% in two of the participating centres that kept eligibility statistics also affects generalizability of the study findings (Davidson et al, 2007).

**Strengths of the review**

Unlike many other systematic reviews, a strength of this review was the decision to broaden the inclusion criteria to include all studies (and not RCTs alone) in order to increase the likelihood of a more comprehensive review of available DAs for cancer treatment. The potential for subjective bias in methodological analysis was also reduced as two-thirds of the included articles were independently rated with regard to methodological quality. The study did not exclude any articles based on language from the initial search and the search was not limited to DAs developed in Western countries.

**Limitations of the review**

Only one researcher carried out searches and selection of final papers, whereas the project would have benefitted from two or more researchers taking part in every stage of the review process but unfortunately, due to limited resources, this was not
possible. Despite the widespread use of knowledge and DC as outcomes in effectiveness of DA trials, few studies have determined baseline measures prior to DA exposure. In order to ensure that the effectiveness of the DA in reducing DC and and/or increasing treatment-related knowledge was directly resulting from exposure to the DA itself, the decision was made for the current study to exclude nine studies without such baseline measures. This rigid inclusion criterion could be considered as a potential limitation as it limits the ability to place the statistically significant reductions in DC found in the current review in the context of previous studies.

Implications for research

One of the main questions to arise from this review is, ‘What measure of knowledge should be employed to evaluate decision aid effectiveness?’ There is definite scope for more validated tools to be developed by researchers. There also appears to be a paucity of tools available to measure DC in health-related decision-making. Whilst the DCS has been shown to be a valid and reliable research instrument for measuring DC (O’Connor et al, 2010), a potential limitation of the scale is the lack of comparative measures. Thus, further validation work is required to enhance the psychometric properties of the scale, particularly in terms of its construct and content validity. Additionally, the limited number of cancer types included in the review highlights the need for treatment-related DAs for other cancer diagnoses to be developed for appropriate preference-sensitive decisions. A more general next step for decision aid research would be the comparison of different types of decision aids to determine which features actually impact upon decision-making for patients. Such research would help developers to achieve the most effective DA design possible.
Overall, further research is necessary to solidify the evidence base concerning the impact of DAs on cancer treatment-related knowledge and DC, and the link between these and other relevant outcomes.

*Implications for clinical practice*

On a practical level, the main implication is that DAs should be used to help patients make difficult cancer-related treatment choices. Treatment-related DAs are already being incorporated into clinical practice in the NHS and this review provides support for their continued implementation in cancer-related care. Improvements in patient knowledge and reductions in DC regarding treatment-related decisions accord with the aim of the NHS (Department of Health, 2012): to implement a SDM model and to enable patients to make informed choices. Thus, from the perspective of policymakers, there may be value in investing in the development of DAs.

*Conclusions*

Treatment decisions are likely to increase in complexity with the arrival of new technologies and treatment options. Consequently, the need to inform and educate patients properly becomes predominant. This review has systematically examined the existing literature evaluating the effectiveness of patient DAs for improving knowledge and reducing DC in treatment-related cancer decisions. The available evidence indicates that DAs are better than usual care in improving patients’ knowledge and reducing DC regarding these treatment preference-sensitive decisions.
Declaration of interests

The first author conducted the systematic review as part of a portfolio thesis for a Doctorate in Clinical Psychology undertaken at the University of Edinburgh. This training place was jointly funded by NHS Education Scotland and NHS Lothian health board. No other sponsorship, funding or support was received.
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/Liberating-the-NHS-No-decision-about-me-without-me-Government-response.pdf
(Accessed 14 February 2014).


Journal Article 1

Ovarian cancer patients’ decision-making surrounding CA-125 testing during post-treatment surveillance: A qualitative study.

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Belinda Hacking³
Melanie McKean⁴

Produced according to submission guidelines of the British Journal of Cancer (Appendix 1). Tables are included within text as per instructions in the University of Edinburgh / NHS (Scotland) Clinical Psychology Training Programme Research Handbook 2013/2014, but will be formatted for submission as per the British Journal of Cancer guidelines.

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**Abstract**

**Background:** This study explored the decision-making processes of ovarian cancer patients who had decided for or against CA-125 testing during post-treatment surveillance, in order to assess the need for a decision aid.

**Methods:** Semi-structured interviews were conducted with 18 women in an outpatient gynecological oncology clinic in Scotland. Transcripts were analysed thematically using the ‘Framework’ approach.

**Results:** Accurate knowledge about CA-125 testing in post-treatment surveillance was found to greatly influence participants’ decision-making processes. Most women with less knowledge about the test chose to have testing based on the false belief that earlier detection of recurrence would lead to earlier treatment and prolonged survival. Women who placed importance on the CA-125 test during the diagnostic and treatment stages appeared more likely to opt for testing post-treatment. CA-125-related anxiety was present for women opting to have testing. However, among the participants still in remission, this anxiety was outweighed by the perceived reassurance provided by testing.

**Conclusion:** Clinicians must ensure that patients are fully informed about the pros and cons of CA-125 testing in post-treatment surveillance and be aware of individual values and preferences among women surrounding this decision. The need for a decision aid to ensure accurate knowledge about CA-125 and to aid decision-making for women was confirmed.
Keywords: CA-125 testing, ovarian cancer, oncology, decision-making, decision aid, qualitative, post-treatment surveillance, follow-up

Article word count (excluding tables & references) = 5580
Introduction

Ovarian cancer is the leading cause of death amongst gynecological malignances (Marcus et al, 2014). Despite an encouraging response from primary treatment, 70-80% of patients with advanced disease (stages III or IV) will relapse within the first two years (Martin & Schilder, 2009). Unfortunately, as full remission is rarely possible, treatment following relapse of ovarian cancer is palliative (Ledermann & Raja, 2011). Post-treatment surveillance for ovarian cancer is standard practice in Europe and the United States (Verheijen et al, 2012), and follow-up care typically includes cancer antigen 125 (CA-125) serum testing (Bast et al, 1981). CA-125 is a protein found in the blood, commonly referred to as a “tumour-marker” due to its ability to provide information about the biological state of ovarian cancer (Tiller et al, 2003). It is elevated in over 80% of women with advanced epithelial ovarian cancer (Goonewardene et al, 2007). However, high CA-125 levels are not specific for ovarian cancer and can be elevated under various conditions, and false-positive elevations can occur (Cannistra, 2004).

Elevated CA-125 levels are known to accurately predict recurrent disease on average five months before symptom development (Rustin et al, 2010). While it is widely accepted that patients with a rising CA-125 level and physical symptoms should commence treatment, a debate is ongoing regarding whether asymptomatic women with rising CA-125 levels alone should be treated, and indeed, whether or not CA-125 monitoring should be a routine part of post-treatment surveillance (Markman, 2003; Rustin, 2013). Results of the recent multinational European trial (MRC OVO5/EORTC 55955) studying the role of CA-125 in post-treatment surveillance has
challenged accepted practice of routine CA-125 testing (Rustin et al, 2010). The trial concluded that there was no survival benefit from early treatment performed on the basis of an elevated CA-125 level alone in asymptomatic women. This finding lends support to the results from recent systematic reviews where none of the identified studies supported a survival benefit from hospital-based follow-up treatment after completion of primary treatment for ovarian cancer (Lajer et al, 2010; Geurts et al, 2011). Additionally, trial participants randomly allocated to the early-treatment trial arm suffered from higher levels of anxiety and a lower quality of life than women whose treatment was delayed until physical symptoms of recurrence presented. As a result of this trial, international guidelines (Verheijen et al, 2012; Society of Gynecologic Oncologists, 2013) recommend that the role of CA-125 and the advantages and limitations of routine monitoring should be discussed with patients in order to aid the decision-making process.

Studies have highlighted the unrealistic expectations that many women have about the role and impact of the CA-125 test in terms of survival (Doyle et al, 2001; Palmer et al, 2006; Harrison et al, 2009; Oskay-Oezcelik et al, 2009) and the small amount of research in this area suggests that patient knowledge about the test and its significance in post-treatment surveillance is limited (Parker et al, 2006; Reid et al, 2011). Notably, it has been highlighted that women with lower levels of knowledge about CA-125 can be more preoccupied with it, which in turn is associated with lower mood (Parker et al, 2006) and higher levels of anxiety. Anxiety surrounding CA-125 testing has been reported in several studies researching follow-up care for ovarian cancer (Hipkins et al, 2004; Parker et al, 2006; Matulonis et al, 2008; Mirabeau-Beale et al, 2009; Oskay-Oezcelik et al, 2009; Reid et al, 2011). Patients may initially opt for
regular testing due to their feelings of fear and uncertainty in the post-treatment period and loss of their safety net of intensive professional monitoring (Hipkins et al., 2004; Lydon et al., 2009). However, research evidence suggests that this decision can lead to patient preoccupation with the CA-125 level (Harries & Gore, 2002; Palmer et al., 2006; Coupe et al., 2010; Jordens et al., 2010) and rising CA-125 levels have been reported to trigger panic, profound fear and devastation that the cancer has recurred (Guidozzi, 1993; Howell et al., 2003). Alternatively, fear of recurrence has been noted as ovarian cancer patients’ greatest concern (Wenzel et al., 2002; Matulonis et al., 2008; Lewis et al., 2009; Dahl et al., 2013) and studies have found that the reassurance provided by regular CA-125 testing can alleviate anxiety surrounding a possible recurrence for some women (Bradley et al., 1999; Jordens et al., 2010). Many women also find reassurance in being as fully informed as possible about their disease status and information is viewed positively (Bradley et al., 1999). Thus, individual factors and the potential impact of CA-125 monitoring on quality of life should be a serious consideration for women in their decision-making process.

The Present Study

The decision about regular CA-125 testing in post-treatment surveillance for ovarian cancer is a preference-sensitive decision for patients. The goal of making a preference-sensitive decision is to make a “quality” decision rather than the “right” decision, based on being fully informed and consistent with the individual’s values (Ropka et al., 2006). Despite the central role CA-125 currently plays in the monitoring for recurrence of ovarian cancer, few studies have set out to explore women’s decision-making processes surrounding the option to have CA-125 testing in post-
treatment surveillance. Thus, the aim of the current study was to explore the decision-making processes of ovarian cancer patients who had opted for or against CA-125 testing during post-treatment surveillance.

**Methods**

*Participants*

Following ethical approval, participants were recruited from a National Health Service (NHS) outpatient gynecological oncology clinic within a city-based Scottish healthcare trust. Potential participants were identified by their Consultant Oncologist, informed about the study during a routine consultation, and given a study information pack containing an information leaflet, consent form and stamped-addressed envelope for use if they wished to participate. Following receipt of the returned consent forms, author FEW contacted potential participants by telephone. Eligible participants had a diagnosis of epithelial ovarian cancer of any stage, had completed first-line treatment and were a minimum of six months post-decision making about CA-125 testing at the time of recruitment. Women deemed to be significantly cognitively impaired by their consultant were not approached, as informed consent was a necessary prerequisite for participation. Ten women who had chosen to have regular testing (mean age = 62.6 years; range = 45-74 years) and eight women who had decided against it (mean age = 61.12 years, range = 49-76 years) were recruited between September 2012 and October 2013. As most women choose to have regular CA-125 testing, it had been anticipated that those deciding against it would be more difficult to recruit.
Procedure

Consenting participants were interviewed at a time and date of their convenience in a private room at the outpatient clinic or in their home. Author F.E.W conducted all 18 in-depth, semi-structured interviews (mean = 40 min; range = 25 – 60 mins). The authors developed a semi-structured interview schedule for the purposes of the study. In order to assess participants’ knowledge about CA-125 testing, the women were presented with a patient vignette regarding a slight rise in a woman’s CA-125 level and asked to choose what they perceived to be the most likely scenario occurring. As shown in Figure 2, option 4 is the correct answer out of the five options provided. Interviews were digitally recorded and transcribed verbatim for analysis.

Jane had surgery for her ovarian cancer nine months ago. Since then, she has been having CA 125 monitoring as part of her post-treatment follow-up care. She is currently feeling well. However, her most recent CA 125 count is 45. Her previous two CA 125 counts were 15 and 17.

What does this rise in CA 125 mean for Jane? Please choose one of the possible reasons below:

1. The doctors have spotted her relapse early and they will be able to cut it out
2. Jane will be able to start chemotherapy sooner and that will mean that she will live longer
3. Jane has a better chance of being cured because the cancer recurrence has been spotted early
4. Jane’s cancer is probably coming back but she is currently feeling okay so perhaps she will need more tests to confirm cancer recurrence but doesn’t need any treatment now. These tests will allow Jane and her doctors to plan for treatment in the future.
5. It is likely to be something else other than the cancer coming back

Figure 2. Patient scenario vignette
Data Analysis

The framework approach was adopted in order to provide a structured and transparent method to approach data analysis (Ritchie & Lewis, 2003; Smith & Firth, 2011). The utility of framework analysis within healthcare research has become increasingly recognised in recent years (Smith & Firth, 2011), and it is deemed particularly useful when considering practice-related questions. Framework analysis is differentiated from other qualitative data analysis techniques in that as well as encouraging themes to emerge inductively, it often starts deductively from the pre-determined aims and objectives of the research (Pope et al, 2000). As the study sought to explore some broad pre-determined topics (including CA-125 related knowledge, the CA-125 decision-making process and CA-125-related anxiety) in order to inform future development of a decision aid it was deemed a desirable approach to adopt. Analysis involved moving through a number of stages (see Table 5) and was aided by using QSR NVivo 10 qualitative data analysis (QSR International, 2012) to help organise and track the analysis process.
Table 5. Framework analysis procedure

<table>
<thead>
<tr>
<th>Stage</th>
<th>Steps Taken</th>
</tr>
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| Stage 1           | Familiarisation with the interviews  
The lead researcher read and re-read each transcript to become familiar with the whole data set. |
| Stage 2           | Initial Coding  
Independent initial coding of six randomly selected transcripts by two researchers. |
| Stage 3           | Developing a working analytical framework  
Researchers met following independent coding to agree on a set of codes to apply to all subsequent transcripts, forming the initial analytical framework. |
| Stage 4           | Applying the analytical framework  
Following completion of coding of the remaining transcripts using the initial analytical framework, the framework was revised to incorporate new and refined codes. |
| Stage 5           | Charting data into the framework matrix  
Following completion of coding using the final analytical framework, the data was summarized in a matrix using Microsoft Excel. |
| Stage 6           | Interpreting the data  
Themes were generated from the data set by reviewing the matrix and making connections within and between participant and categories. |

Results

For the purposes of this article, Testing Group will refer to the participants having regular CA-125 testing and Non-Testing Group will refer to those who decided against it. Five overarching themes emerged from analysis of the data and are outlined below: knowledge about CA-125 testing; the CA-125 decision-making process; CA-125-related anxiety; reassurance; and false beliefs about earlier detection of cancer recurrence (see Table 6).
Table 6. Final coding index or analytical framework

<table>
<thead>
<tr>
<th>Themes</th>
<th>Sub-Themes</th>
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| Knowledge about CA125 testing | • General knowledge about CA-125 testing  
• Impact of diagnosis and treatment on information retention during consultations |
| CA125 Decision-Making Process | • Personal significance of CA-125 testing at diagnosis and during treatment  
• Time taken to decide  
• Additional decisional support sought  
• Personality factors |
| CA125-Related Anxiety | • Anxiety in the 10-day test period  
• Strategies to cope with CA-125 testing-related anxiety  
• Worry in general about CA-125 count  
• Informing loved ones about the decision |
| Reassurance | • General feeling of reassurance with testing  
• Reassurance versus anxiety  
• Fear of cancer recurrence  
• Reassurance provided by health professionals |
| False beliefs about earlier detection of cancer recurrence | • Unrealistic expectations despite knowledge about delaying treatment until physical symptoms show |

Knowledge about CA125 testing

General Knowledge About CA-125 Testing

Participants were asked about their knowledge of the CA-125 test and its function during post-treatment surveillance. Apart from the knowledge that the CA-125 test was a blood test, the majority of participants in the Testing Group appeared to have little understanding about the test and its function during post-treatment surveillance, and only half of the group chose the correct scenario from the patient vignette (see Figure 2). Those who had answered incorrectly selected option 3, surmising that the
patient’s cancer had returned and that she had a better chance of being cured because
the recurrence had been spotted early. Participants in this group reported receiving
varying degrees of information about CA-125 testing from their oncologists, with
only two participants recalling any information given about the pros and cons of
testing or surrounding the fragility of the test in terms of accurately diagnosing
disease recurrence. As one participant stated:

‘A lot of information on CA-125 testing is not something I specifically remember but it might
have just been one thing in amongst a whole load of things to take in. I may well have been
told about it in more detail? If you don’t have any medical experience the information that all
the medics are giving to you is a lot!’ (P2)

In contrast, participants in the Non-Testing Group had greater knowledge about CA-
125 testing in follow-up care and had discussed both the fragility of the test and the
OV05 trial results with their oncologist. Indeed, seven of the eight participants in this
group cited the trial evidence as the main influencing factor over their decision to
decide against regular testing:

‘Based on the OV05 trial that it wasn’t going to make a huge amount of difference with an
early diagnosis and start of treatment if there was a recurrence or not’ (P8)

‘I think the fact that it wasn’t totally necessary and that it didn’t always give a proper reading
for people as well and you would know with other ways. And I think as Dr [name] had said
that it [the test] maybe helps to find it [cancer recurrence] sooner but it didn’t make that much
difference in the treatment whether they discovered it sooner or later. So I thought that it
wasn’t that necessary then.’ (P16)
Of note, these seven participants also correctly identified the most likely scenario within the patient vignette.

*Impact of Diagnosis & Treatment on Information Retention During Consultations*

Analysis within cases across both testing groups revealed that participants who had admitted to having little knowledge about CA-125 testing had commented upon the emotional impact of the diagnosis and/or treatment on their ability to retain information during clinical consultations. As these two participants described:

‘When I got diagnosed, I was kind of shocked at how big the cyst was that they found and that I hadn’t realized that I had it! And you often go in [to a consultation] and you have so many questions and sometimes someone will respond to that question. And that answer will be the thing that you remember from the whole [conversation], everything else goes. You don’t remember all of the other stuff’ (P6, Testing Group)

‘My daughter-in-law would remember all of this better than me because I got all agitated the first time you know? She [Consultant] said that there was a small bit of the cancer that they couldn’t remove and that I couldn’t have radiation because they couldn’t get to it. And of course I got upset and I was concentrating so much on that that I really can’t remember much else or much about the blood test?’ (P1, Non-Testing Group)

*The CA-125 Decision Making Process*

*Personal Significance of CA-125 Testing At Diagnosis & During Treatment*
Most participants in the Testing Group commented upon the significance of the CA-125 test both in the initial detection of their cancer and during their treatment phase when discussing their rationale for their decision. As the following women noted:

‘Well as far as I understand it, before I had treatment it was all about diagnosis. And it was the CA-125 count that made everybody move very quickly! Then came chemotherapy, then surgery, then more chemotherapy. Before each lot of chemotherapy, the week before there was a CA-125 blood test. And that showed dramatic drops once the chemotherapy had started.’ (P3)

‘I think it’s interesting if you ask women how much they know about CA-125 before the diagnosis with ovarian cancer. But it’s one of the things that you’re told in the very beginning. It’s sits there, this CA-125. That it’s a tumour marker and it’s up. But we’re aiming to get it with chemotherapy. So, it is a feature, a big feature, of the treatment you know?’ (P7)

This sub-theme did not emerge within the interviews with participants in the Non-Testing group.

*Time Taken to Decide*

Results revealed that only one woman in the Testing Group took time to deliberate on the decision, with the remaining nine making the decision on the spot or by the end of the consultation:
‘I made it on the spot. I just thought well why not? It’s just a blood test! It wasn’t a big deal. I just told Dr [name] to go ahead with it’. (P10)

‘Well I said yes straight away. I’d rather meet something head on. I think the decision for me, a blood test, it’s not as if they were digging into you to find something. I thought it was an easy thing to know, a reassuring thing.’ (P5)

In contrast, only a few participants in the Non-Testing Group made the decision during the consultation session, with the majority choosing to take the three months offered before their next consultation to decide:

‘I certainly remember going away thinking that I must think about this, it was a big decision’ (P7)

‘I did take my time. And I decided for the following check-up which was in another three months that I wouldn’t have it’ (P9)

**Additional Decisional Support Sought**

Results were varied regarding participants’ need to consult loved ones to aid decision-making, with some participants involving family members and others choosing to decide alone. Participants who made their decision on the spot were less likely to consult others than those who took more time to deliberate. The majority of participants in both groups did not seek additional information about CA-125 testing outside of the consultation:
‘I’m not a kind of person for reading books on anything like that. I believe in just taking whatever comes and dealing with it at the time. Otherwise you look up the internet, you look up books, you’ll end up killing yourself with worry rather than the cancer getting you! So, I’m not a believer in that’ (P5)

The participants who did seek out information on CA-125 testing on the internet or in educational pamphlets on ovarian cancer did not feel that doing so had had a major influence on their decision-making.

**Personality Factors**

An interesting finding regarding the decision-making process related to the participants’ perceptions of the influence of personality factors on their decision-making regarding testing. As one participant described:

‘It all depends on your personality and the type of person you are. An awful lot’s to do with your, and it can be a burden to you, but to do with your personality. It does help with decision-making for me.’ (P4)

A comparison of the two groups regarding personality factors found that participants in the Testing Group stated the need to be fully informed about all aspects of their care, despite the fact that women in this group were found to have lower levels of knowledge about CA-125 testing:

‘I’m definitely a facts sort of person. I need to be fully informed. That’s how I cope best’ (P6)
‘All along I’ve been told exactly what was happening which was what I wanted. I wanted to know everything that was happening to me.’ (P14)

In contrast, members of the Non-Testing Group admitted to basing their decision either on the fact that they would actually be more anxious if they were having testing, or the fact that they wanted to maintain a positive outlook for the future:

‘I guess in a way part of it was getting yourself stressed out for no reason. I think I’m sure if I got the test and it [the result] was slightly up on the last one I probably would worry. And also because I’m aware that it’s not always 100% accurate and I didn’t want to go getting myself all hyped up and worried for nothing.’ (P17)

‘I think for me, I don’t think testing that would be helpful. Because the way I look at it, I’m feeling great, I’m carrying on with my life as normal. And if I can do that, then that’s what I want to do.’ (P18)

**CA125-Related Anxiety**

*Anxiety in the 10-Day Test Period*

Participants who had chosen to have CA-125 testing described their experiences of anxiety surrounding the test. Most participants in the Testing Group reported experiencing anxiety in the 10-day waiting period between having the blood test and getting the result from their oncologist:
‘How could it not? If you said to anybody, you’ve got to go to court tomorrow, they would start fretting! Even if they were a witness! And it is that sort of position you’re in with the test, it’s not great.’ (P4)

Strategies to Cope with CA-125 Testing-Related Anxiety

These participants discussed various coping strategies used to deal with this anxiety, with many contacting their GP a few days prior to their oncology consultation to obtain the result. As one participant outlined:

‘I worked out a system of getting the blood test done the Thursday before clinic and called for the result Friday to have time to digest the result before seeing the consultant the following week. To me that works well and allows me time and a little bit of space before my appointment’ (P12)

Worry in General About the CA-125 Count

The only participants who described worrying about their CA-125 level outside of this 10-day waiting period were the only two women that had experienced relapsed disease. Both individuals commented upon the psychological impact of detecting recurrence via CA-125 testing and the impact of testing on their quality of life:

‘I suppose if someone could prepare you for the psychological difficulty that you get when the count is starting to go up. Because up until then you think you’re the one that got away and you feel, well, you’re going to be cured and that awful thing’s gone and then it’s apparent
that it hasn’t and that it’s spread around through your blood to other bits. And it’s the CA-125 test that shows this up.’ (P3)

‘It has impacted upon my quality of life because now every three months you’re having your possible life examined and foreshortened and brought into question. And you can build yourself up and build yourself up and get so anxious about the result that you sometimes can’t see a way out. When it first started to come back [CA-125 level rising] I was a wreck. I was really was all over the place mentally. I couldn’t stop crying, you know?’ (P12)

Informing Loved Ones About the Decision

A further sub-theme emerging from the data relating to CA-125 anxiety surrounded the decision by many of the participants within the Testing Group to not inform their loved ones that they were having regular testing. These participants stated that they had made this decision in order to protect their loved ones from experiencing anxiety about the test result. Family members of the participants who had been informed about the testing were also reported to experience anxiety within the 10-day testing period.

Reassurance

The theme of reassurance emerged within both groups.

General Feeling of Reassurance with Testing
Within the Testing Group, this predominantly related to the perceived reassurance provided by regular CA-125 testing and the feeling of safety resulting from post-treatment surveillance:

‘Well basically, it’s a very strange thing but when you have chemotherapy, for all it’s nastiness and the side-effects are horrible, you kind of feel safe. Because, you know that they’re [doctors] watching it and something is trying to kill this horrible thing. When that stops, you feel vulnerable and once anybody’s been told that they’ve got cancer, it’s on your shoulder all the time. It’s like being stalked, it never goes away. So when you stop the chemo and you’re feeling vulnerable, you’re looking for something else you see because you’re frightened that as soon as you stop the chemo, it’s going to come back. So you’re looking for something to spot it.’ (P3)

Reassurance Versus Anxiety

The participants in the Testing Group who had not experienced relapsed disease and who had reported experiencing CA-125-related anxiety all commented upon the reassurance of testing out-weighing their anxiety. As one woman described:

‘And the blood test, for all it destroys your peace of mind, sometimes it gives you peace of mind as well. Because you know that they’re going to pick it up and do something for you if they can’ (P4)

Some of these women had even requested or were planning to request more frequent or extended testing to continue to experience this feeling of reassurance:
‘I’ve six month check-ups now. But then I spoke to my own GP and she asked me if I was okay with this and I said, “Well, I would have preferred every three months but I suppose you’ve got to move on.” And she very kindly does it every three months for me." (P5)

‘I think that I’d be happier if I had one [a CA-125 test] every wee while. Even when the five year surveillance programme’s over. Even if it’s just once a year.’ (P4)

_Fear of Cancer Recurrence_

Fear of cancer recurrence was a recurring sub-theme for this group and many women commented on the usefulness of the test in reassuring them that cancer had not recurred:

‘I just thought, “Well, if there’s a test that we can do that helps monitor something other than just, “I feel a bit this way or I feel a bit that way”, then for me it felt like it was at a more cellular level. Because you do think about the cancer all the time. That doesn’t go away’ (P6)

‘The fact that I feel great means nothing. There’s nights that I don’t sleep that well. I feel tired and I think, “Am I tired because the cancer’s back or am I just tired?” So you’re constantly reviewing things and the CA-125 helps in that respect’ (P15)

_Reassurance Provided by Health Professionals_

Of note, the sub-theme of fear of recurrence did not emerge within the Non-Testing group. However, many women spoke about the reassurance they received from their
oncology team and the trust placed on their Consultant Oncologist to provide them with accurate information to aid their decision-making about CA-125 testing:

‘I did tend to go by what he [Oncologist] said because he's an expert and obviously dealing with this day in day out! He always puts me at ease!’ (P17)

‘I was aware that she [Oncologist] wasn’t pushing it [CA-125 testing] and I thought, “Well if she doesn’t think that it’s that important then it can’t be that important. I mean I’m trusting! I’m assuming that they are doing the best for me. I’ve no reason to doubt that because they’ve been fabulous. But, no I thought well if she’s not putting a huge importance on it then it’s not important. And if it’s not important then, heck, I’ve got life to get on with!’ (P18)

False Beliefs About Earlier Detection of Cancer Recurrence

Within the Testing Group, an additional theme of note emerged from the data, where most women referred to a belief that earlier detection of recurrence with CA-125 testing would lead to earlier treatment and prolonged survival.

‘I feel that it’s another, sort of, indicator that things are looking good. And if there was an increase then it could be a wee early warning that things were not so good. And then you would, you know, get treatment for that earlier than if you waited for other signs’ (P2)

‘I just felt that I wanted this thing controlled and so if there’s anything that’s going to pinpoint it starting back again, the sooner it’s caught the better. The sooner they find it, the sooner they can start treating it. I mean that’s all you want is for somebody to treat it. Keep it under control. Keep you feeling well as long as possible’ (P3)
‘What I felt was at least if someone was tracking it, the treatment would be appropriate at the appropriate time. And that if I left it and waited for how many years I don’t know, maybe I’ll miss the boat.’ (P12)

This was despite an acknowledgement by some of being informed by their oncologist of the reasons why immediate treatment would not commence upon detection of a rise in CA-125 level alone:

‘I was told that if it started to go up and it meant that the cancer had come back, that it wouldn’t be curable but that it would be treatable. But I thought that if I did, if it started to creep up then the doctors would know and surely do something about it and stem the disease if they could. So, I thought, okay, you know, best monitor it and any treatment if it’s treatable would get it as soon as you can to prolong your life hopefully.’ (P5)

‘I believe that with this blood test being done, if they spot anything early, I know they don’t always jump in and do chemotherapy straight away because they don’t know really when to start it, but I think it gives them a better idea of what’s going on. And if it rises any higher up they can maybe look further into it. I just thought, well the quicker you [health professionals] know, the better for me’ (P10)

Importantly, these women identified this belief as the main influencing factor for their decision to have regular CA-125 testing.
Discussion

This qualitative study sought to gain a greater understanding of the decision-making process surrounding CA-125 testing in post-treatment surveillance among ovarian cancer patients, in order to assess the need for a decision aid for women making this decision in real-time. To our knowledge, this was the first study to carry out such work among ovarian cancer patients.

The results indicate that accurate knowledge about the CA-125 test in follow-up care appears to greatly influence participants’ decision-making processes. Women in the Non-Testing Group had a much greater understanding about the fragility of the test and the fact that a detected rise in CA-125 would not initiate immediate second-line treatment, than those in the Testing Group. This knowledge base was the main deciding factor for the majority of women in this group, suggesting that such an understanding provided them with the confidence to make an informed decision based upon their preferences and values. In contrast, the majority of participants in the Testing Group had limited knowledge about CA-125 testing and based their decision on the expectation that a raised level would lead to immediate treatment and prolonged survival. These results appear to support the Conflict Theory of Decision-Making (Janis & Mann, 1977), which suggests that a ‘vigilant’ coping style leads to careful information seeking and deliberation, whereas ‘unconflicted adherence’ or alternatively, ‘hypervigilance’ are maladaptive and associated with unproductive information-seeking and decision-making patterns. The latter finding also adds to the body of research highlighting the discord between patient expectations and realistic treatment scenarios (Doyle et al, 2001; Palmer et al, 2006; Harrison et al, 2009;
Oskay-Oezcelik et al, 2009). Overall, the results from this group highlight the need for health professionals to be aware of the potential emotional impact of a diagnosis and/or treatment on patients’ abilities to retain information during consultations, a finding commonly described elsewhere (Fallowfield & Jenkins, 1999). Thus, it is recommended that health professionals ensure that patients fully comprehend the pros and cons of CA-125 testing and the OV05 trial results. The results of the current study surrounding the influence of accurate knowledge on decision-making provide support for the development of a decision aid to assist health professionals in ensuring that this is achieved.

Regarding the decision-making process itself, it was interesting to note that individuals who had mentioned the significance of CA-125 testing at the point of diagnosis and/or during treatment all chose to continue testing in follow-up care. This may indicate that patients who choose testing generalize the information about CA-125 testing at these earlier stages to post-treatment surveillance, where it is perceived that continuing testing may have treatment benefits for recurrence in the absence of other symptoms. This may have been a factor in why these individuals made a decision quite quickly, needing less deliberation time than participants in the Non-Testing Group. It may also be linked to the continued need for these individuals to feel in control. This was in contrast to the Non-Testing Group participants who felt that having testing would be more likely to cause them anxiety. The influence of personality factors and personal values in patient’s decision-making should not be underestimated. As decision aids are designed to take these important factors into account, these findings provide additional support for a decision aid where clear information would be introduced post-treatment to ensure that women are fully
informed about the unlikely commencement of treatment for possible recurrence based on a rising CA-125 count alone. As there was a notable contrast between women making the decision either in the consultation or waiting three months, a decision aid would also encourage women who decide on the spot to give the decision further consideration to reduce the chance of experiencing decisional regret at a later date.

Similar to other studies, CA-125-related anxiety was experienced by many of the participants who had chosen to have regular testing (Hipkins et al, 2004; Parker et al, 2006; Oskay-Oezcelik et al, 2009; Anderson et al, 2011). It cannot be discounted that women with an anxious predisposition may be more likely to opt for CA-125 testing. As reported elsewhere it would appear that this anxiety was accepted and endured as a result of the perceived feeling of reassurance and safety provided by the test (Bradley et al, 1999). However, it is likely that once this feeling of reassurance has been taken away with the knowledge of rising CA-125 levels, patients experience panic and fear about the recurrence (Harrison et al, 2009) and the fact that second-line treatment is unlikely to commence without physical symptoms present (Jordens et al, 2010). This probability was supported by the current study findings, whereby the two participants who had experienced anxiety more generally, and reported a negative impact of testing on their quality of life, were the only participants who had experienced relapsed disease. Given the high statistical chance of recurrence with ovarian cancer, it is not surprising that fear of recurrence is the greatest concern for patients (Wenzel et al, 2002; Matulonis et al, 2008; Lewis et al, 2009; Dahl et al, 2013), yet it is essential that those choosing to have regular testing are fully informed about the pros and cons of that particular decision. Patients would also greatly benefit from more
research focused on investigating the psychological impact of CA125 testing, particularly among women with relapsed disease whose recurrence was detected via a rising CA125 count. Such research would help facilitate the provision of targeted psychological support for this group coping with relapsed disease.

There were some limitations to this study that should be acknowledged, including its small sample, which may not provide results that can be generalised to a larger population. Data saturation was sought where recruitment stopped at the point at which no new themes emerged. However, it is impossible to preclude the possibility that had further interviews been conducted, new themes might have arisen. Thus, whilst the interviews with participants provided a range and richness of data on the topic of interest, there are likely to be other perspectives that exist, which would extend the range of views that have been gathered in this study. Additionally, the fact that only women in the Testing Group were asked about CA125-related anxiety is another limitation, as this may be the reason why a fear of recurrence was not raised by women in the Non-Testing Group.

Conclusions

In conclusion, more emphasis has now been placed on shared decision-making and patient choice surrounding the use of CA-125 testing for post-treatment surveillance. The importance placed on shared decision-making for this medical scenario has highlighted a gap in the literature for a decision aid to assist women during this process, which the current study results would support.
References


Society of Gynecologic Oncologists (2013) *Statement on Use of CA125 for Monitoring Ovarian Cancer*,


Journal Article 2

A decision aid for CA-125 testing during post-treatment surveillance of ovarian cancer patients: A UK qualitative study exploring patients’ and health professionals’ views.

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Produced according to submission guidelines of the British Journal of Cancer (Appendix 1). Tables are included within text as per instructions in the University of Edinburgh / NHS (Scotland) Clinical Psychology Training Programme Research Handbook 2013/2014, but will be formatted for submission as per the British Journal of Cancer guidelines.

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Abstract

**Background:** The aim of the current study was to elicit patient and health professionals’ views on the proposed development of a patient decision aid aimed at helping women to decide for or against CA-125 testing during post-treatment surveillance for ovarian cancer.

**Methods:** Semi-structured, in-depth interviews were conducted with ovarian cancer patients (n = 18) and health professionals (n = 6) in an outpatient gynecological oncology clinic in Scotland. Transcribed data were analysed using the Framework approach.

**Results:** There was strong enthusiasm for the development of the proposed decision aid to assist women facing this treatment decision in real time. The preferred setting for use of the decision aid was the home environment but views were mixed about the timing of decision aid delivery to patients. Regarding decision aid content, patients regarded personal stories surrounding the decision as a helpful addition.

**Conclusion:** Women would benefit from the use of a decision aid when considering CA-125 testing during post-treatment surveillance for ovarian cancer. As well as assisting women with this decision, the proposed decision aid may ultimately support health professionals in practicing shared decision-making regarding CA-125 testing with ovarian cancer patients.
Keywords: Decision-making, decision aid, ovarian cancer, post-treatment surveillance, follow-up, CA-125 testing, qualitative

Article word count (excluding tables & references) = 5498
Introduction

Cancer-antigen 125 (CA-125) testing has played an important role in both the diagnosis and treatment of ovarian cancer (Pignata et al, 2011). However, controversy surrounds the use of CA-125 testing in post-treatment surveillance for the disease (Chitale, 2009; Pignata et al, 2011; Morris & Monk, 2010). CA-125 is a blood protein, commonly referred to as a ‘tumour-marker’ due to its ability to provide information about the biological state of ovarian cancer (Tiller et al, 2003). It is elevated in over 80% of women with advanced epithelial ovarian cancer (Goonewardene et al, 2007) and elevated CA-125 levels are known to accurately predict recurrent disease on average five months before symptom development (Rustin et al, 2010). While it is widely accepted that patients with a rising CA-125 level and physical symptoms of recurrence should commence treatment, a debate is ongoing about whether asymptomatic women with rising CA-125 levels alone should be treated, and indeed, whether or not CA-125 monitoring should be a routine part of post-treatment surveillance at all (Markman, 2003; Pignata et al, 2011; Rustin, 2013).

Post-treatment surveillance is based on the assumption that patients will benefit if recurrent disease is treated early (Jordens et al, 2010). The recent multinational European trial (MRC OVO5/EORTC 55955) studying the role of CA-125 in post-treatment surveillance has challenged this assumption, as the trial concluded that there was no survival benefit from early treatment performed on the basis of an elevated CA-125 level alone in asymptomatic women. As a result of this trial, it is now advocated that the decision surrounding CA-125 testing in post-treatment surveillance should rest with the patient and that the advantages and limitations of routine
monitoring should be discussed with patients (Verheijen et al, 2012; Society of Gynecologic Oncologists, 2013). Patient education and involvement in medical decision-making is widely considered to be very important (O’Connor et al, 2009). This is particularly relevant in the case of preference-sensitive decision-making. A preference-sensitive decision in one where the decision requires weighing patients’ values for benefits and risks across options, including the option of doing nothing, in order to achieve a higher quality decision (Stacey et al, 2008). Such decisions are common considerations for cancer patients (Sepucha et al, 2007).

Over the past few decades, significant advancements have been made to improve patients’ ability to make cancer-related treatment decisions (Whelan et al, 2004; Waljee et al, 2007; O’Brien et al, 2009, O’Connor et al, 2009; Spiegle et al, 2013). The development of decision aids (DAs) is one such advancement. DAs differ from traditional health educational materials by providing a detailed and balanced description about available options, and the risks and benefits of each option using explicit probabilities to outline them (Sawka et al, 1998; O’Connor et al, 2007). A systematic review of DAs has shown that, compared with controls, patients receiving DAs had higher knowledge, lower decisional conflict, more active participation in decision-making and lower decisional regret post-intervention (O’Connor et al, 2009). DAs exist for women at risk of ovarian cancer (Tiller et al, 2003), and as an aid for asymptomatic women with rising CA-125 levels regarding decisions for second-line treatment (Anderson et al, 2011). However, the Cochrane Registry of DAs contains no DAs developed to assist women faced with the decision of having regular CA-125 monitoring after first-line treatment (Ottawa Hospital Research Institute, 2014).
It is strongly recommended that both clinicians and patients be involved in the DA development process (Informed Medical Decisions Foundation; IMDF, 2014; International Patient Decision Aids Standards Collaboration; IPDAS, 2014; Ottawa Decision Support Framework; ODSF, 2014). Stage one of this process should involve information gathering on preferences, knowledge, and attitudes surrounding the decision to be made (ODSF, 2014). DA content is crucial when examining the informational preferences and needs of cancer patients, including a balanced view of a range of possible options open to patients (O’Connor et al, 2009). For example, whether DAs should include personal stories about individuals in similar situations who have already gone through the decision-making process is currently being explored and debated (Khangura et al, 2008; Winterbottom et al, 2008; Bekker et al, 2013). Following the results of the aforementioned European trial, Rustin (2011) argued that women should be provided with three options surrounding CA-125 testing during post-treatment surveillance for ovarian cancer (see Tables 1 & 2). Whether or not the addition of the third option would be useful to patients, or health professionals (HPs) in charge of their care, has not yet been explored.

Thus, the decision surrounding regular CA-125 testing during post-treatment surveillance is a preference-sensitive one for the majority of ovarian cancer patients. As a result of the OV05 trial, more emphasis has now been placed on individual patient choice, and the importance placed on shared decision-making (SDM) for this medical scenario has highlighted a gap in the literature for a DA to assist women during this process.
**The Present Study**

The goal of this study was to elicit patient and HPs’ views on the proposed development of a patient DA designed for ovarian cancer patients surrounding the decision to have CA-125 testing during post-treatment surveillance in order to identify important factors to consider in the development of such a tool. A qualitative approach was adopted in order to capture participants’ views on pre-determined questions, whilst also allowing for the emergence of issues or concerns that had not been anticipated by the research team.

**Methods**

**Study Design**

The Ottawa Decision Support Framework (ODSF) guided the study design for the development of the proposed DA, which emphasizes a three-step process of development (ODSF, 2014). According to the ODSF (2014), the first step involves the need to assess patient and clinician determinants of decisions to identify decision support needs. The current study reports results from the second part of the needs assessment interviews conducted with ovarian cancer patients who had already gone through the decision-making process surrounding CA-125 testing. Detailed results from the first part of these interviews have been described elsewhere (Wilson *et al*, thesis submission). HPs were also recruited to consult on the development of the proposed DA. In addition to design-related questions, HPs were asked their opinion regarding the advantages and disadvantages of CA-125 testing for women entering
post-treatment surveillance. It was deemed important to gain from their professional knowledge and clinical experience in order to ensure accurate content of the pros and cons of testing in the proposed tool.

**Participants**

*Patient Sample*

Potential participants were identified by their Consultant Oncologist, informed about the study during a routine consultation, and given a study information pack containing an information leaflet, consent form and stamped-addressed envelope for use if they wished to participate. Following receipt of the returned consent forms, author FEW contacted potential participants by telephone. Eligible participants had a diagnosis of epithelial ovarian cancer of any stage, had completed first-line treatment and were a minimum of six months post-decision making about CA-125 testing at the time of recruitment. Women deemed to be significantly cognitively impaired by their consultant were not approached, as informed consent was a necessary prerequisite for participation. The study aimed to gain a balanced perspective from patients who had decided for and against regular CA-125 testing. Consequently, ten women who had chosen to have regular testing (mean age = 62.6 years; range = 45-74 years) and eight women who had decided against it (mean age = 61.12 years, range = 49-76 years) were recruited between September 2012 and October 2013. All 18 participants also consented to being contacted following the development of the proposed decision aid (Step 2) in order to evaluate it (Step 3) (ODSF, 2014).
Health Professional Sample

Health Professional (HP) participants were recruited from the gynecological oncology team at the same outpatient clinic as patient participants. The sample consisted of three Consultant Oncologists and three clinical nurse specialists (CNSs). All six individuals had extensive experience in providing professional decisional support to ovarian cancer patients surrounding the decision to have CA-125 testing or not in follow-up care.

Measures

As part of the interview and in order to ensure that both patients and HPs had an understanding of what a DA was, participants were shown an example of an existing DA which was the closest example available on the subject of CA-125 testing (Anderson et al, 2011). Participants were also shown an information sheet outlining the pros and cons of each of the three options proposed by Rustin (see Tables 7 & 8), in order to ensure that they fully understood the implications of these options. The information sheet was developed using simple, everyday language.

Table 7. CA-125 testing options proposed by Rustin (2011)

<table>
<thead>
<tr>
<th>Option Proposed</th>
<th>Option Outline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1</td>
<td>To have routine CA-125 measurements prior to each clinic visit where both the patient and oncologist are aware of the results</td>
</tr>
<tr>
<td>Option 2</td>
<td>Not to have routine CA-125 measurements provided that the patient is well and has no symptoms suggesting relapse</td>
</tr>
<tr>
<td>Option 3</td>
<td>To have routine CA-125 measurements prior to each clinic visit but only the oncologist will be made aware of the results</td>
</tr>
</tbody>
</table>
Table 8. Overview of possible CA-125 testing options

**Option A**

*To have CA-125 test prior to each clinic visit and both you and your doctor know the result*

<table>
<thead>
<tr>
<th>POSSIBLE BENEFITS</th>
<th>POSSIBLE DOWNSIDES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reassuring when good (i.e. not rising)</td>
<td>Anxiety around waiting for the result and anxiety if rising</td>
</tr>
<tr>
<td>If blood test is rising, it allows you and doctor to plan treatment ahead of time</td>
<td>Anxiety of knowing cancer is coming back, if this happens, around 5 months earlier (on average) than before you would have done with other options</td>
</tr>
<tr>
<td>Allows you more warning to plan your life around knowing when you might be back on treatment if the cancer recurs</td>
<td>Does not tell you or your doctor when to start treatment</td>
</tr>
<tr>
<td>Allows entry into research trials based on rising blood test with no symptoms</td>
<td>Does not improve the cure rate or the length or quality of overall survival</td>
</tr>
<tr>
<td>Allows possible treatment with hormone tablets if your tumour is ER (estrogen receptor) positive. These take time to work</td>
<td>Involves an extra visit to the GP for a blood test prior to clinic and an extra needle</td>
</tr>
<tr>
<td>Lets you and your doctor know to watch for symptoms of relapse if CA-125 starts to rise</td>
<td>False reassurance if cancer is relapsing without blood test rising (not common)</td>
</tr>
</tbody>
</table>

**Option B**

*Not to have CA-125 test unless new symptoms develop*

<table>
<thead>
<tr>
<th>POSSIBLE BENEFITS</th>
<th>POSSIBLE DOWNSIDES</th>
</tr>
</thead>
<tbody>
<tr>
<td>No anxiety around waiting for the result and anxiety if rising</td>
<td>Lack of reassurance</td>
</tr>
<tr>
<td>No extra visit to the GP for a blood test prior to clinic and an extra needle</td>
<td>May miss out on the opportunity to use hormone therapy if ER positive tumour</td>
</tr>
<tr>
<td>No chance of false reassurance if cancer is relapsing without blood test rising (not common)</td>
<td>Does not allow entry into research trials based on rising blood test with no symptoms</td>
</tr>
<tr>
<td>Around 5 months extra (on average) of living well without knowledge of cancer coming back if this happens</td>
<td>Less time to plan treatment if cancer comes back</td>
</tr>
<tr>
<td>You and your doctor focussing on quality of life only</td>
<td></td>
</tr>
</tbody>
</table>

**Option C**

*To have CA-125 test prior to each clinic visit but only your doctor knows the result*

<table>
<thead>
<tr>
<th>POSSIBLE BENEFITS</th>
<th>POSSIBLE DOWNSIDES</th>
</tr>
</thead>
<tbody>
<tr>
<td>No anxiety around waiting for the result and anxiety if rising</td>
<td>Lack of reassurance</td>
</tr>
<tr>
<td>You and your doctor focussing on quality of life only</td>
<td>No chance of false reassurance if cancer is relapsing without blood test rising (not common)</td>
</tr>
<tr>
<td>Around 5 months extra (on average) of living well without knowledge of cancer coming back if this happens</td>
<td>Extra visit to the GP for a blood test prior to clinic and an extra needle</td>
</tr>
<tr>
<td>Doctor can advise you on the opportunity of entry into research trials based on rising blood test with no symptoms if this happens</td>
<td>Anxiety that doctor knows something you do not and that may create issues for you both</td>
</tr>
<tr>
<td>Doctor can advise you on the opportunity to use hormone therapy if ER positive tumour if suitable</td>
<td>Less time to plan treatment together if cancer comes back</td>
</tr>
<tr>
<td></td>
<td>Potential loss of trust in the patient-doctor relationship</td>
</tr>
</tbody>
</table>
Data Collection

Following ethical approval from the local Research Ethics Committee, participants were recruited from a Scottish National Health Service (NHS) outpatient gynecological oncology clinic within a city-based health board trust. Consenting patient participants were interviewed at a time and date of their convenience in a private room at the outpatient clinic or in their home. Author FEW conducted all 24 in-depth, semi-structured interviews (mean = 45 min; range = 25 – 65 mins). Interviews were digitally recorded with the participants’ consent, anonymised and transcribed verbatim for analysis.

Data Analysis

The framework approach was adopted for data analysis (Ritchie & Lewis, 2003). The utility of this method within healthcare research has become increasingly recognized in recent years (Smith & Firth, 2011) and it is deemed particularly useful when considering practice-related questions. Framework analysis is differentiated from other qualitative data analysis techniques in that as well as encouraging themes to emerge inductively, it often starts deductively from the pre-determined aims and objectives of the research (Pope et al, 2000). As the current study sought to explore some pre-determined topics in order to inform future development of a decision aid it was deemed a desirable approach to adopt. Analysis involved moving through a number of stages (Ritchie & Lewis, 2003) (see Table 9) and was aided by using QSR NVivo 10 qualitative data analysis (QSR International, 2012) to help organise and track the analysis process.
Table 9. Framework analysis procedure

<table>
<thead>
<tr>
<th>Stage</th>
<th>Steps Taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage 1</td>
<td>Familiarisation with the interviews</td>
</tr>
<tr>
<td>Stage 2</td>
<td>Initial Coding</td>
</tr>
<tr>
<td>Stage 3</td>
<td>Developing a working analytical framework</td>
</tr>
<tr>
<td>Stage 4</td>
<td>Applying the analytical framework</td>
</tr>
<tr>
<td>Stage 5</td>
<td>Charting data into the framework matrix</td>
</tr>
<tr>
<td>Stage 6</td>
<td>Interpreting the data</td>
</tr>
</tbody>
</table>

Results

For the purposes of this article, Testing Group will refer to the participants having regular CA-125 testing and Non-Testing Group will refer to those who decided against it. Five overarching themes emerged from analysis of the data and are outlined below: usefulness of the DA in the decision-making process; including patient stories; DA setting; DA timing; and the preferred choice of options.

Usefulness of the DA in the Decision-Making Process

Patient Perspectives

All patient participants felt that a DA would be very useful for women who were making the decision in real-time and proposed a number of reasons why. Many
participants felt that a DA would reduce the chance of experiencing decisional conflict and regret:

‘Because it wasn’t so much of an informed decision in the beginning for me, it was a gut reaction. If you had something like that [DA], you’d be much more confident that you’ve made the right decision for you.’ (P3, Testing Group)

‘I have to say that I’ve always wondered if I hadn’t made that decision what it would have been like. So if I’d gone through that process [with a DA], maybe I wouldn’t have that question? Or maybe I’d still have that question but go back to my decision aid and say, ‘Why did I write that?’ So, having that tool might have erase that question.’ (P12, Testing Group)

‘I would have found that quite useful because I’m feeling now that I made a rash decision. I just made the decision within a minute of being asked really which probably in hindsight wasn’t ideal. I think if they’d [HPs] said, “Take this [DA] away and read it and let us know what you think”, it would have been a lot better.’ (P18, Non-Testing Group)

Patients also highlighted the importance for women of feeling a sense of empowerment and control over their decision-making, and stated that having such a tool would provide women with the ability to do this. As one patient commented:

‘It’s important that you’re in control of the decision. So having something like that [DA] would help to reinforce that feeling’ (P4, Testing Group)

Patients also reflected upon the difficulty that they had experienced making the decision regarding CA-125 testing during the post-treatment period due to fatigue and chemotherapy side-effects and stated that such a tool would assist with this process:
'I think at the time you’ve got to make the decision, your head’s not in it. You're just saying to them [the doctors]. “Whatever you think, whatever you think” and you don’t really know what you’re entering into? You’re just so tired by that point. So having that tool would be so useful.’ (P4, Testing Group)

‘It would be so helpful because that’s the most vulnerable time at the end of treatment. If you don’t have any medical experience the information that all the medics are giving to you is a lot! I wish I had had that [DA] when I had to decide!’ (P12, Testing Group)

Finally, one patient commented upon the fact that a DA would ensure that all ovarian cancer patients are getting the same information from their oncology team:

‘It means that everyone is getting the same information. You know what I mean? Because some doctors will say this and some doctors will say that but if you give them that booklet then everybody gets the same thing.’ (P17, Non-Testing Group)

*HP Perspectives*

All six HPs stated that the proposed DA would be an extremely helpful tool for encouraging SDM:

‘I think that it would be so helpful. I think that with patients with ovarian cancer, their future is so uncertain that they almost feel that they don’t have control over their own life. But to actually be able to take control and make that decision for themselves would be quite good.’ (HP1)
‘Actually, just even going through it with the patients like that in a written down format might make it easier. Because we do explain to them their options when we have this discussion but it’s probably at the end of quite a long consultation and they may not take it in.’ (HP5)

‘I think it’s all about instead of having patient leaflets, having things that help people to make the right choices for them. So I just think this is really the way to go! I’ve done many, many patient leaflets in my time and they are, by their very nature, paternalistic. They’re very hard to involve people in. They’re not a discussion.’ (HP6)

HP participants discussed their perceptions surrounding the advantages and disadvantages of CA-125 testing for women. Advantages highlighted included: the ability for women to make future plans following detection of suspected relapsed disease; the possible option of entering into clinical trials; and a perceived sense of reassurance from testing. However, all six HPs regarded the main disadvantage of testing to be the anxiety that it created for women and commented on how fixated patients could get about the CA-125 count itself:

‘I think that a lot of patients get really focused on the number and what the number means. And they get so focused on the number that they forget about living their life. So psychologically it’s quite damaging’ (HP2)

‘There’s certainly a sizeable cohort of individuals who get totally fixated on their CA-125. And when they come in to see you they’re not really interested in telling you how they’re doing. They just want to know the number!’ (HP5)
This anxiety was hypothesised to result from a lack of understanding about the purpose of CA-125 testing in follow-up care, and HPs highlighted the usefulness of a DA to improve patient knowledge. As one participant described:

‘I think it’s because they [patients] don’t understand enough about it. When patients start to become obsessed with their CA-125 count I usually try to sit them down and explain what a CA-125 means and why we do it. Sometimes that does help but I almost think it’s too late because they’ve already got it in their head that the actual number is the most important thing. So I don’t know whether they actually take in what you’ve said to them? So having a DA would be really helpful in those scenarios to ensure that they do understand the facts, and I suspect would actually reduce the levels of anxiety that we see in clinic’ (HP1)

Including Patient Stories

Patient participants were asked whether having had access to knowledge of other women’s stories about the decision-making process surrounding CA-125 testing would have been helpful during their own decision-making, and if the inclusion of such stories in the proposed DA would be a useful addition. Views were mixed as to the personal impact of having access to these stories on their own decision-making, with the majority reporting that access to these accounts would have been helpful but some individuals pointing out how personal the experience of having cancer is:

‘Well I would have read about it and seen what other women said but I think at the end of it there’s only one person who can really make up your mind and that’s yourself. I mean it’s like listening to other people about childbirth. It’s not the same for everybody. So, I think
you’ve got to decide what’s best for yourself, what you feel about things.’ (P5, Testing Group)

Despite varied opinions given, all patient participants advocated for stories to be included in the proposed DA for a number of reasons. Many participants felt that it would provide the option for women to engage in the material or not and that it would be helpful in providing a more balanced view of the decision options. Moreover, it was considered a helpful addition for someone who was experiencing decisional conflict:

‘When it’s difficult to make decisions sometimes we feel confused and it’s difficult to work out what’s right for you. So, sometimes it’s good just having that, well, “This is the process that I went through and now I’m here and I feel that I made the right decision”, or “I made the wrong decision and this is why I think it was the wrong decision”. So yeah, I think it would be helpful’ (P6, Testing Group)

For those women who did not report experiencing decisional conflict, it was still deemed useful to include stories in order to understand the reasoning behind individuals who chose the opposite option to their own one. As one woman who opted to have CA-125 testing explained:

‘I think it might have been helpful to hear from the other side because the women who walk away [opt against regular testing], we never hear about how they’ve got on? And why they opted out of it? So yes, I think it would have helped to have a few stories about various decisions and how they felt about it.’ (P12, Testing Group)
Other participants felt that including stories could provide a feeling of reassurance for some women:

‘Just knowing that you’re not the only one to go through the decision-making process. You tend to think that it’s just you but you know perfectly well that it’s not.’ (P14, Testing Group)

Some participants hypothesised that having other women’s stories available in the DA would provide a similar feeling of reassurance as the one gained from reading patient stories on internet blogs:

‘I think that people need a lot of reassurance. When people look up the internet and hear from other people, “Well this is normal and that’s normal,” it’s comforting.’ (P4, Testing Group)

‘Yeah I think everyone’s different and has different responses, but I follow some of the websites and with some of the women I say, “Yeah, I totally agree with that. That’s really helpful’, but with others I think, ‘Nah, I disagree with you.” But it’s helpful to read both sides of the story. So I think it’s helpful to have other women’s views.’ (P7, Non-Testing Group)

**DA Setting**

**Patient Perspectives**

The overwhelming majority of patients felt that the DA should be given to patients to take home to use and to return to their next consultation with any further questions that they may have. The main reason stated for this preference was the need to take time going through the DA in order to fully comprehend it:
‘It would be good to take it home and you could really absorb it, you can read it again and look at it quietly. So, I think a bit of information beforehand, then get this [DA] and if you’ve got any immediate questions you could ask them and then take it away and really absorb the information.’ (P2, Testing Group)

‘In some ways I’m leaning towards taking it away and being able to sit at home and read it through however many times you need. Then possibly coming back to see your consultant and discussing what you’ve decided.’ (P13, Non-Testing Group)

Some patients felt that completing the DA during their oncology consultation might feel a bit overwhelming and impact upon decision-making:

‘I think it might be a wee bit more upsetting sitting talking to an oncologist about it because it’s kind of like a final decision thing isn’t it? I think that you need time to digest it all.’ (P5, Testing Group)

‘I think if you had it at home you would have time to think about it. Rather than a doctor breathing down your neck as you’re going through it because then it would be totally your own opinion.’ (P16, Non-Testing Group)

‘I think that you should have time to read it by yourself or with someone else at home and really think about it because sometimes yes-or-no decisions can be difficult. And it doesn’t always reflect how you’ll feel all the time. So you need to let it seep in a wee bit. The need to fill this out in clinic will be getting in the way of the ability to fill it out.’ (P11, Non-Testing Group)
Similar to patient participants, the consensus among HPs was that it would be preferable for women to take the DA home in order to go through it at their own pace:

‘Perhaps a brief outline in the clinic and then to give it to them to take home so they could digest it. It might be a bit much to go through it all in one consultation.’ (HP1)

**DA Timing**

**Patient Perspectives**

The optimal time for introduction of the DA for patients emerged from the analysis and views were mixed. Some patients stated that the DA would be most valuable at the end of treatment:

‘I think that the best time to do it is after you’ve had your last chemo, your last scan and you come for the results of what the whole treatment plan has done for you. That’s the time to do it.’ (P3, Testing Group)

However, the majority indicated that the most appropriate time would be at the first follow-up appointment with the oncologist, and where patients would have a three-month window to decide before their next appointment.
Two HPs stated that post-treatment might be an overwhelming time to receive the DA and that prior to treatment would be of most value. As one HP commented:

‘It might be too late when they’ve finished treatment because what I’m thinking is that to get someone to sit and read that in-depth, you’ve got to get them at a time when they’re taking on what’s happening with them. You know when someone is first diagnosed, they’re right onto everything. When they’re finished treatment, a lot of them really don’t want to know about what’s happening next.’ (HP3)

However, the remaining four HPs considered the first follow-up consultation as being the most appropriate time, when the discussion surrounding CA-125 testing usually took place.

The Preferred Choice of Options

Patient Perspectives

While some women felt that a choice of the three proposed options should be included (see Tables 7 & 8), the majority of patients thought that the DA should only include the two more straightforward options of either choosing to have or to not have CA-125 testing in follow-up care. Inclusion of the third option was considered unhelpful by patients because of the potential for it to create unnecessary anxiety and paranoia for women:
‘I can’t really think what advantage there is in option C? I think that you would just constantly worry. You’d be analysing the doctor and if she were off with you, you’d be thinking, “Is she a little bit worried?” It would make me personally fret more with that one I have to say!’ (P3, Testing Group)

‘I can’t understand why a patient would come after having the blood’s done and sit there and not be curious? It’s only human nature! You would sit and look at that doctor and think, “Do you know something that I don’t?” I think you could put yourself into a worrying state. Personally, I would think that if Dr [name] was sitting with some information and I didn’t know about it I would have myself worked up for the next 3 months until I get the bloods done again and then she’s sitting with information again! That wouldn’t work for me! (P5, Testing Group)

HP Perspectives

In the HP group, the three CNSs felt that the third option should be included in order to provide patients with the reassurance that they were being monitored, and to capture the preference of the minority of patients who preferred a more paternalistic-style of relationship with their oncologist. As one CNS described:

‘I think option C might be useful because I suppose it gives the person the option of not knowing until they need to know so that they can carry on with their life. But it would give them the reassurance that someone’s monitoring them. I also think that there’s probably a group of patients that falls under the category of, “The doctor knows best so, I’ll just let him get on with it.” And I think that that [option] would probably suit those patients.’ (HP1)
However, the three oncologists were very opposed to the idea both for practical reasons and due to a feeling of discomfort about the ‘paternalistic nature’ of the option:

‘No, because I think that you could get into a difficult situation with that option. Because you know but the patient doesn’t know and you probably need to tell the GP but they’d need to be clear that they can’t tell the patient. But, I suppose if the patient asks them [the GP] they’ll tell them. So I think with option C you’d have to be careful because that might become more of an issue than it is already.’ (HP4)

‘No, because it creates a scenario where you’re potentially not telling the patient everything which makes me feel uncomfortable. It makes me feel that the patient-doctor relationship is altered and it goes back to the old days where patients didn’t expect the doctor to tell them anything. We certainly like to help patients think that we’re telling them everything and so I would find that really difficult as an oncologist.’ (HP5)

**Discussion**

The aim of this qualitative study was to elicit patient and HP opinions on the proposed development of a DA for women contemplating CA-125 post-treatment monitoring for ovarian cancer. The proposed DA would, to our knowledge, be the first DA to assist women in deciding for or against CA-125 testing. Overall, our findings indicate a high general interest and positive appraisal by ovarian cancer patients and HPs for the proposed DA. Indeed, all 24 participants were extremely positive about the potential role of this tool in a woman’s decision-making process regarding CA-125 testing, particularly in reducing the risk of experiencing decisional conflict and regret.
and promoting more active participation. Therefore, these findings provide further support for the benefit of DAs among individuals facing cancer-related treatment decisions (e.g. Whelan et al, 2004; Spiegle et al, 2013). Highlighting CA-125-related anxiety, HPs also considered it to be a useful tool to have during consultations, in order to increase patient knowledge about the pros and cons of the decision, as advocated by relevant international bodies (Verheijen et al, 2012; Society of Gynecologic Oncologists, 2013).

There was a general perception that the proposed DA would encourage SDM during consultations between patients and HPs. Participants reflected upon the difficulties that women have with decision-making in the post-treatment phase, and hypothesized that a DA would be help patients to feel a sense of empowerment and control over their decision-making and assist HPs with effective communication. The positive impact of clinical decision support systems to improve clinical practice has been evidenced previously (Kawamoto et al, 2005). Thus, it is likely that the proposed DA would provide a framework that enables SDM, leading to increased confidence in decision-making for both parties.

Despite the ongoing debate about the inclusion of patient’s personal stories in DAs within the literature (e.g. Khangura et al, 2008; Winterbottom et al, 2008), all patient participants in the current study were enthusiastic about their inclusion in the proposed DA. Whilst it was acknowledged as not being personally useful to some, importance was placed on offering the choice to women to engage in the material or not in order to help reduce any decisional conflict and to provide reassurance. With respect to location of use, the majority of participants suggested that the DA should be
given to use at home, in order to give patients the opportunity to work through the material in their own time. However, there was some debate about the ideal timing for patients to receive and use the DA. While the majority viewed the first follow-up appointment as the most appropriate time, others were of the opinion that this may be too late for some women. Consideration of the most appropriate time to introduce a DA is important, being mindful of introducing it too soon and possibly overwhelming a patient or waiting too long and missing the opportunity to assist with decision-making. These results suggest that DA timing in the care pathway may affect the usefulness of the tool to patients. Therefore, it is suggested that HPs gauge the correct time based on their knowledge of the patient and her informational needs. Overall, the results have highlighted the fact that timing is an issue requiring further investigation during the piloting phase of the proposed tool.

An important consideration for the content of the proposed DA was the inclusion or exclusion of the third option for patients proposed by Rustin (2011), which involved having CA-125 testing but not being informed about the results. The value of adopting a qualitative approach in the current study to investigate this question was evident by the reasons elaborated upon by the majority of participants for their recommendation to exclude the third option. It was particularly interesting to note the split in opinion between the CNSs and the oncologists in the HP sample, with the former advocating for inclusion of the third option and the latter strongly opposed. Whilst it is impossible to make any proper conclusions or assumptions from such a small number of participants, it raises the question as to whether the direct professional role of a HP in the CA-125 decision-making scenario impacts upon their view regarding this debate. In the current study setting, the discussion surrounding
CA-125 testing is usually introduced to patients by their oncologist during a consultation, with the CNSs providing additional decisional support if necessary out-with these discussions. Therefore, one questions whether the experience of being directly, versus indirectly, involved in the SDM scenario influences professional opinion on the inclusion of the more paternalistic third option? Further research with a larger sample of HPs is suggested to explore their perspectives on this issue.

Limitations of the study included the limited generalisability of the findings due to a small sample size and the fact that the study was conducted at a single location, which makes it unlikely to be representative of follow-up services offered on a national or international basis for women with ovarian cancer. Additionally, the opinions provided by participants surrounded a hypothetical DA that they did not have in person to evaluate. Therefore, it will be important to confirm these views with participants using an evaluation study once the actual DA is devised and ready for piloting.

Conclusions

Our findings emphasise the usefulness of decision support tools to aid decision-making in cancer care, and the importance of clinician and patient involvement in the DA development process (IMDF, 2014; IPDAS Collaboration, 2014; ODSF, 2014). The results illustrate that a proposed patient DA for women deciding about regular CA-125 testing during routine post-treatment surveillance for ovarian cancer would be considered to be an appropriate and important tool to assist patients with this preference-sensitive decision. The proposed DA may ultimately support HPs in
practicing SDM regarding this decision with ovarian cancer patients. Participant opinions on the exclusion of the third option regarding CA-125 testing is likely to be particularly influential in the proposed development of this tool.
References


Cancergazing? CA125 and post-treatment surveillance in advanced ovarian cancer.


NVivo qualitative data analysis software; QSR International Pty Ltd. Version 10, 2012.


Society of Gynecologic Oncologists (2013) *Statement on Use of CA125 for Monitoring Ovarian Cancer*,


Appendices

Appendix 1. British Journal of Cancer Submission Guidelines

Manuscripts should be submitted via our Online Submission site
Submissions are the responsibility of:
BJC Main Editorial Office, First floor Angel Building, 407 St John
Street, London, EC1V 4AD UK bjc@bjcancer.net Tel: +44 (0)20 3469 6179
Fax: +44 (0)20 3070 0638
You are welcome to ask for their advice and support.

Manuscript format
Manuscripts, which must be written in English, should be typed using double spacing with a wide margin all round the text. Manuscripts must be concise, overly long manuscripts may be rejected on that basis.

- **Full papers** should not normally exceed approximately 5000 - 5500 words and up to eight figures or tables supported by key references. They should be divided into sections: a structured abstract; introduction; materials and methods; results; discussion; acknowledgements; and references.

- **Short communications** of approximately 1500 words and up to three figures or tables supported by a shortened list of references. They should have the section headings; introduction; materials and methods; results; discussion; acknowledgements and a shorter structured abstract of approximately 100 words.

- **Mini reviews** should have 3000-3500 words, with appropriate reductions for one or two figures or tables, and should include a brief abstract, an introduction, a conclusion, and no more than 30 references.

Title page
Your title page, numbered as 1, should give the title in bold letters (not normally exceeding 100 letters), a running title (not to exceed 50 letters) and all the authors' names (as they are to appear), affiliations and complete addresses, including postal
(zip) codes. Indicate the corresponding author clearly. Both an e-mail address and a full postal address are required for the corresponding author. Authors are asked to recheck the order in which names are to appear and to recheck and update addresses of all authors when preparing the final version of their submission, ensuring that addresses are complete and properly identify the institutions where authors are working.

**Structured abstracts and keywords**

You should prepare an abstract of your manuscript, of a maximum of 200 words summarising its content (reduced to about 100 words for a short communication). BJC requires structured abstracts for research papers and short communications. Please use these headings for your abstract: Background, Methods, Results, and Conclusion or Interpretation, following the structure of your paper as closely as is possible.

BJC uses unstructured abstracts for minireviews, reviews and similar papers. Letters and editorials do not need abstracts.

Type your abstract on a separate sheet following the title page. At least three and no more than twelve keywords, should be listed after the abstract.

**Units & abbreviations**

Please avoid abbreviations in the title and abstract. All unusual abbreviations should be fully explained at their first occurrence in the text.

All measurements should be expressed in SI units. For more detailed recommendations, authors may consult Baron DN & H McKenzie-Clark (eds) (2008) *Units, Symbols and Abbreviations: A Guide for Authors and Editors in Medicine and Related Sciences* (Sixth Edition).

**Drug names**

Generic drug names should be used.

**Reference Style**

BJC papers are referenced using a modified Harvard referencing style. Please see below for examples:
Only papers closely related to the author's work should be quoted, and these should wherever possible be original papers rather than reviews. Exhaustive lists should be avoided. Citation of conference proceedings or meeting abstracts should also be avoided unless there is no other reference.

References in the text should be made by giving, in brackets, the author's surname, with the year of publication.

When the reference is to a specific part of a book, the page number should also be cited. When reference is made to a work by three or more authors, the first name followed by et al, should be used for all citations in the text (Weiss et al, 2001). If several papers by the same first author and from the same year are cited, a, b, c, etc, should be added after the year of publication. Authors are asked to check the accuracy of all references before submitting a manuscript. References should be brought together at the end of the paper in alphabetical order, where titles of papers and all authors' names should be given in full.

Names of journals should be abbreviated as in Index Medicus, followed by the volume number and the initial and final page numbers, e.g.:


Wherever possible, include the digital object identifier (DOI), from the article's title page. Please note the following example:


References to books and monographs should appear as in the following examples:


**Figures**

Figures and images should be labelled sequentially, numbered and cited in the text. Figure legends should be printed, double spaced, on a separate sheet titled 'Titles and legends to figures'. Figures should be referred to specifically in the text of the paper but should not be embedded within the text. The use of three-dimensional and shadowed histograms is strongly discouraged when the addition of the third dimension gives no extra information. If a table or figure has been published before,
the authors must obtain written permission to reproduce the material in both print and electronic formats from the copyright owner and submit it with the manuscript. This follows for quotes, illustrations and other materials taken from previously published works not in the public domain. The original source should be cited in the figure caption or table footnote. (see Permissions)

Artwork Guidelines
A detailed guide to preparing artwork for submission can be downloaded at http://www.nature.com/aj/artworkguidelines.pdf. Please submit production quality artwork with your initial online submission. If your paper is accepted for publication and you have followed the Guide to Preparing Artwork, it will not be necessary to resubmit the artwork following the peer-review process, unless changes are required by the reviewers or our Editor.

Colour in print
Full colour illustrations may be included in the printed text, at the discretion of the editor. However, a charge may be made to the author to cover the extra costs incurred in originating and printing colour illustrations. It is helpful if authors who submit colour figures indicate in their covering letter whether they are willing, in principle, to meet these costs. Prior to publication, authors will be advised of the costs, which depend on the size and quantity of colour illustrations.

Colour online
We are usually able to substitute colour versions of illustrations in the HTML version of the online journal at no additional cost. The online PDF of the paper exactly matches the printed journal and will therefore carry the black and white version of the figure, as printed. Authors wishing to take advantage of this facility are asked to submit a 300 dpi black and white and a colour file for the electronically published version. Please refer to the Guide to Preparing Artwork.

Tables
Tables should only be used to present essential data. Each must be on a separate sheet with a title or caption and be clearly labelled, sequentially. Please make sure each table is cited within the text and in the correct order, e.g. (Table 3).
Tables should ideally be presented in Excel, one table per workbook. It is imperative that the tables are editable. Please save the files with extensions .xls / .xlsx / .ods / or .doc or .docx. Please ensure that you provide a 'flat' file, with single values in each cell with no macros or links to other workbooks or worksheets and no calculations or functions.

BJC has recently changed its style for tables. Please consult some of the papers published in Volume 108 (2013) for examples of the current layouts and follow one of those as closely as possible.

**Supplementary online material**

Authors wishing to provide additional material supporting their paper, may wish to have this published online as supplementary material linked to the paper on the BJC website.

All supplementary materials must be submitted with the original manuscript and will be shown to referees. This allows papers to have greater depth, online enhancements, such as video clips and additional data sets, making them more useful to fellow specialists in the field who require detail, without distracting more general readers.

Authors should ensure that supplementary information is supplied in its FINAL format because it is not subedited and will appear online exactly as submitted. It cannot be altered, nor can new supplementary information be added, after the paper has been accepted for publication. All supplementary material must be cited in the text of the manuscript, sequentially.
Appendix 2. Systematic Review Protocol

Outline of the review question

Title: Are decision aids for cancer treatment-related decisions effective at increasing treatment-related knowledge and reducing decisional conflict? A systematic review.

Aim: To evaluate the effectiveness of treatment-related decision aids at increasing knowledge and reducing decisional conflict in cancer patients.

Rationale for the systematic review

A search of the Cochrane Database of Abstracts of Reviews and Effects (DARE) identified four articles that were related to the proposed systematic review:

1. Molenaar et al (2000) - a systematic review on the feasibility and effects of DAs
2. Stacey et al (2014) - a systematic review on DAs for health treatment or screening decisions.
4. O’Brien et al (2009) - a systematic review and meta-analysis of the effectiveness of cancer-related DAs in screening, prevention and treatment (most closely linked to the proposed study)*


- Only RCTs where randomization was used for allocation to experimental and control groups were included. Thus, no attempts to identify unpublished data.
- Search terms were not reported and publication bias was not considered in the report.
➢ Validity was assessed using established criteria, but results of the assessment were not reported, which made it difficult to assess reliability of the evidence presented.

➢ Only 5 out of the 34 trials included in the study were related to treatment and the authors identified the need for further research to determine the effectiveness of decision aids in the treatment context.

A recently published article focusing on treatment-related decision support interventions for cancer was identified during a Google Scholar search (Spiegle et al, 2013). The objective of the study was to identify alternative types of decision support interventions (DSIs) for cancer treatment and a meta-analysis to compare the effectiveness of these DSIs to decision aids. Overall, no significant differences in knowledge, anxiety, satisfaction or decisional conflict scores between DAs and other DSIs were found.

However, the study had a number of limitations:

➢ Only published studies using a RCT design were included
➢ Only studies based on treatment decision-making for breast, lung, prostate and colorectal cancer were included.
➢ Only included decision aids that were evaluated relevant to standard/usual care and not alternative interventions.

**Decision aid definition**

Decision Aid definition for this review:

DAs are tools that help patients become involved in decision making by making explicit the decision that needs to be made, providing information about the options and outcomes, and by clarifying personal values using values clarification exercises (O’Connor et al, 2007).
Eligibility Criteria

Inclusion criteria

- Quantitative studies evaluating a decision aid for adult patients with a histologically proven cancer diagnosis facing a choice related to treatment
- Studies which include measures of treatment-related knowledge and/or decisional conflict pre and post a decision aid intervention
- Studies with a minimum sample size of 10 participants in the DA group

Exclusion criteria

- Studies where full text articles can not be sourced either as a complete published article or by contacting the authors directly for complete unpublished drafts

Outcomes of Interest

- Patient knowledge of treatment options
- Decisional conflict

Planned search strategy

(a) The following electronic databases from their inception to February 2014:

- Medline
- Embase
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Sociological Abstracts
- Cochrane Library
- PsychInfo

(b) Reference lists of published systematic reviews of decision aids
(c) Reference lists of full text articles considered for inclusion
(d) Hand search of the following journals from 2009-2014: Medical Decision Making, Patient Education & Counseling, Journal of Clinical Oncology, BMC Medical Informatics & Decision Making.

Planned search terms (following a consultation with a University of Edinburgh Librarian)

- Decision aid
- Decision support technique*
- Decision support system*
- Decision tool
- Education* aid
- Education* tool
- Cancer
- Neoplasm*
- Treatment

Planned data extraction methods

Data will be extracted using a pre-designed form. A single reviewer will extract all the data, and a second reviewer will independently check the completed data extraction forms for accuracy and completeness.

Data will be collected on:
- first author, year of publication, country,
- cancer diagnosis,
- types of treatment options available to participants,
- study design,
- outcome measures
- number of participants in each group
- main study findings
Quality assessment methods

The methodological quality of the studies included will be assessed by means of a quality criteria checklist devised by two or more reviewers.

Intended method of synthesising & disseminating findings

Data synthesis

- Summary of overall review findings
- Quality ratings for each of the dimensions identified
- Limitations of available research
- Areas identified for future research
- Clinical practice implications

Dissemination

- Chapter in portfolio doctoral thesis
- Submitted for publication
## Appendix 3. Quality Criteria for Systematic Review

### Quality Criteria

<table>
<thead>
<tr>
<th></th>
<th>Quality Criteria</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>A true clinical sample of patients is represented in the study</td>
</tr>
<tr>
<td>2</td>
<td>A suitably controlled design was used</td>
</tr>
<tr>
<td>3</td>
<td>Assignment to groups is randomised</td>
</tr>
<tr>
<td>4</td>
<td>Sample size was sufficient for analyses relating to knowledge and/or decisional conflict outcomes</td>
</tr>
<tr>
<td>5</td>
<td>Similar levels of knowledge and/or decisional conflict between intervention and control groups, or differences were controlled for in analyses</td>
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<tr>
<td>6</td>
<td>Knowledge outcome is measured in a valid and reliable way</td>
</tr>
<tr>
<td>7</td>
<td>Decisional conflict outcome is measured in a valid and reliable way</td>
</tr>
<tr>
<td>8</td>
<td>Appropriate analyses used</td>
</tr>
<tr>
<td>9</td>
<td>Levels of attrition are reported and equivalent for treatment versus control</td>
</tr>
<tr>
<td>10</td>
<td>The intervention is evaluated for an appropriate duration</td>
</tr>
</tbody>
</table>

### Operationalisation of Quality Criteria

1– A true clinical sample of patients is represented in the study

<table>
<thead>
<tr>
<th>Well covered</th>
<th>Patients have been recruited in a clinical setting and a consecutive series of potential participants were approached, of which over 70% completed the study</th>
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</thead>
<tbody>
<tr>
<td>Adequately addressed</td>
<td>Patients have been recruited in a clinical setting but potential bias in those approached (e.g. the sample was not made up of a consecutive series or completion rates from consecutive sample were below 60%)</td>
</tr>
<tr>
<td>Poorly addressed</td>
<td>Not recruited in a clinical setting or a highly selected clinical sample</td>
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<td>Not addressed</td>
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<td>Not applicable</td>
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<td>Notes</td>
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2– A suitably controlled design used

<table>
<thead>
<tr>
<th>Well covered</th>
<th>A suitable control group (i.e. ‘treatment as usual’) was recruited alongside the intervention group.</th>
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</thead>
<tbody>
<tr>
<td>Adequately addressed</td>
<td>An alternative intervention group (e.g. simpler educational pamphlet) was recruited but no control group (i.e. ‘treatment as usual’)</td>
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<tr>
<td>Poorly addressed</td>
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<tr>
<td>Not addressed</td>
<td>No control group was recruited</td>
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3 – Assignment of subjects to the groups is randomised

<table>
<thead>
<tr>
<th>Well covered</th>
<th>Clear information is given regarding the method of randomisation</th>
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</thead>
<tbody>
<tr>
<td>Adequately addressed</td>
<td>Randomisation occurred although insufficient information given regarding methods used</td>
</tr>
<tr>
<td>Poorly addressed</td>
<td>Assignment to groups is not adequately described and may be non-randomised</td>
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<tr>
<td>Not addressed</td>
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<td>Not reported</td>
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<td>Not applicable</td>
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<td>Notes</td>
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4 – Sample size was sufficient for analyses relating to knowledge and/or decisional conflict outcomes

<table>
<thead>
<tr>
<th>Well covered</th>
<th>Number of participants who completed both pre and post intervention measure(s) was sufficient to enable Power of at least 0.8 for simple main effects (uncontrolled trials) and interaction effects (where 2 groups). Effect size was anticipated to be medium and alpha was 0.05</th>
</tr>
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<tbody>
<tr>
<td>Adequately addressed</td>
<td>Number of participants who completed both pre and post measure(s) was sufficient to enable Power of at least 0.7 for simple main effects (uncontrolled trials) and interaction effects (where 2 groups). Effect size was anticipated to be medium and alpha was 0.05</td>
</tr>
<tr>
<td>Poorly addressed</td>
<td>Number of participants who completed both pre and post measure(s) was only sufficient to enable Power less than 0.7 for simple main effects (uncontrolled trials) and interaction effects (where 2 groups). Effect size was anticipated to be medium and alpha was 0.05</td>
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<td>Not reported</td>
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5 – Similar levels of knowledge and/or decisional conflict between intervention and control groups, or differences were controlled for in analyses

<table>
<thead>
<tr>
<th>Well covered</th>
<th>Baseline measures of knowledge and/or decisional conflict were sufficiently alike between conditions (difference within 0.5 standard deviations on measures), or any differences were suitably controlled for in analyses (e.g. via ANCOVA).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequately addressed</td>
<td>Baseline measures of knowledge and/or decisional conflict were somewhat alike between conditions (difference within 1.0 standard deviations on measures), but not suitably controlled for in analyses (e.g. via ANCOVA).</td>
</tr>
<tr>
<td>Poorly addressed</td>
<td>Baseline measures of knowledge and/or decisional conflict were not alike between conditions (difference more than 1.0 standard deviations on either/both measures), but not suitably controlled for in analyses (e.g. via ANCOVA).</td>
</tr>
<tr>
<td>Notes</td>
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</tbody>
</table>
6– Knowledge outcome was measured in a valid and reliable way

<table>
<thead>
<tr>
<th>Standardised outcome measure(s) used with well-reported psychometric properties (i.e. valid and reliable) in the cancer population that the decision aid was designed for</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardised outcome measure(s) used with adequate psychometric properties</td>
</tr>
<tr>
<td>Non-standardised outcome measures used.</td>
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<tr>
<td>Not addressed</td>
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<tr>
<td>Not reported</td>
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<tr>
<td>Not applicable</td>
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<tr>
<td>Notes</td>
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</tbody>
</table>

7 – Decisional conflict outcome was measured in a valid and reliable way

<table>
<thead>
<tr>
<th>Standardised outcome measure(s) used with well-reported psychometric properties (i.e. valid and reliable) in the cancer population that the decision aid was designed for (e.g. the Decisional Conflict Scale).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardised outcome measure(s) used with adequate psychometric properties</td>
</tr>
<tr>
<td>Non-standardised outcome measures used.</td>
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<tr>
<td>Not addressed</td>
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<tr>
<td>Not reported</td>
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<tr>
<td>Not applicable</td>
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<td>Notes</td>
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</table>

8 – Appropriate analysis

<table>
<thead>
<tr>
<th>Analysis described sufficiently to determine that analyses conducted appropriately post-intervention-appropriate statistics used.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reasonably clear that appropriate analysis carried out post-intervention with appropriate statistics used but may be lacking in clarity/detail.</td>
</tr>
<tr>
<td>Inappropriate analyses post-intervention</td>
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<tr>
<td>Not addressed</td>
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<tr>
<td>Not reported</td>
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<td>Not applicable</td>
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<td>Notes</td>
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</table>
### 9- Levels of attrition were equivalent for treatment versus control

<table>
<thead>
<tr>
<th>Well covered</th>
<th>Levels of attrition (from allocation to completion of post-intervention measures) for both treatment and control group (where present) are sufficiently alike (within 10% of each other)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequately addressed</td>
<td>Levels of attrition (from allocation to completion of post-intervention measures) for both treatment and control group (where present), are somewhat alike (within 20% of each other)</td>
</tr>
<tr>
<td>Poorly addressed</td>
<td>Levels of attrition are significantly different between conditions</td>
</tr>
<tr>
<td>Not addressed</td>
<td>Levels of attrition not described</td>
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<tr>
<td>Not reported</td>
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<td>Not applicable</td>
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### 10 – The intervention is evaluated for an appropriate duration

<table>
<thead>
<tr>
<th>Well covered</th>
<th>Follow-up carried out for a minimum of 3 months (where measures of knowledge and/or decisional conflict were completed as at post-intervention)</th>
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</thead>
<tbody>
<tr>
<td>Adequately addressed</td>
<td>Follow-up carried out for a minimum of 1 month (where measures of knowledge and/or decisional conflict were completed as at post-intervention)</td>
</tr>
<tr>
<td>Poorly addressed</td>
<td>Follow-up less than one month carried out</td>
</tr>
<tr>
<td>Not addressed</td>
<td>No longer term follow-up carried out</td>
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<td>Not reported</td>
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<td>Not applicable</td>
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</table>
Appendix 4. NHS Lothian Ethics Approval Letter

University Hospitals Division

Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

CPP/SS/approval

28 August 2012

Dr Fiona Kelly
Department of Clinical Psychology
Western General Hospital
Crewe Road South
Edinburgh
EH4 2XU

Dear Dr Kelly

Lothian R&D Project No: 2012/W/01/27
Title of Research: Assessing Decisional Support Needs and Developing a Decision Aid for Women Considering Post-Treatment CA-125 Monitoring for Ovarian Cancer

REC No: 12/SS/0137
CTA No: N/A
EudraCT: N/A

Patient Information Sheet: Version 2 dated 12 August 2012
Health Professionals Information Sheet: Version 1 dated 10 July 2012

I am pleased to inform you that this study has been approved for NHS Lothian and you may proceed with your research, subject to the conditions below. This letter provides Site Specific approval for NHS Lothian.

Please note that the NHS Lothian R&D Office must be informed if there are any changes to the study such as amendments to the protocol, recruitment, funding, personnel or resource input required of NHS Lothian. This includes any changes made subsequent to management approval and prior to favourable opinion from the REC.

Substantial amendments to the protocol will require approval from the ethics committee which approved your study and the MHRA where applicable.

Please inform this office when recruitment has closed and when the study has been completed.

I wish you every success with your study.

Yours sincerely

[Signature]

Dr Christine P Phillips
Deputy R&D Director

Cc Paul Dearie, QA Manager

Please note: the author’s maiden name at the time of data collection was Kelly and is now Wilson.
Appendix 5. Site Specific Approval Email

From: Gorman, Clare
Sent: 20 August 2012 15:51
To: Kelly, Fiona E

Subject: FW: R&D site specific form authorisation request

Fiona,

Many thanks for your email. 
I am happy to authorise this study on behalf of Service Management.

Clare Gorman

Service Manager
Cancer and Palliative Care Services
Tel: 07850 929644
Appendix 6. Patient Study Information Sheet

Patient Participant Information Sheet

Study: The CA-125 Decision Aid Development Study for Ovarian Cancer.

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The aim of the study is to identify women’s decisional support needs related to the CA-125 blood test used for the post-treatment monitoring of epithelial ovarian cancer. The results of this study will then be used to develop a decision aid tool for women who have completed their primary treatment (i.e. surgery and chemotherapy) for epithelial ovarian cancer and are considering whether or not to have regular CA-125 tests. The decision aid will be a booklet which helps women to make this decision by providing evidence-based information about the options and possible outcomes, as well as leading the individual through a process of understanding their values and preferences before decision-making.

Why have I been asked to take part?
You have been asked to take part as you have previously been diagnosed with epithelial ovarian cancer, have already completed your primary treatment and have made the decision to have or not to have CA-125 monitoring at least six months ago. We are inviting women who have already gone through this decision-making process in order to gain an understanding of what it is like to make this decision so that we can use this information to help women who are making this decision in real-time.
**Do I have to take part?**

No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare you receive in any way.

**What will happen if I take part?**

If you decide to take part, please keep this information sheet and sign the attached consent form and return it to the researcher. The researcher will then contact you by telephone to arrange to meet with you at a time and place that is convenient for you to conduct the interview.

During the interview, the researcher will ask you some questions about your knowledge of the CA-125 test, your decision to have or not to have regular CA-125 tests and your thoughts and feelings now about the decision you made. The interview will take no longer than one hour, and will be recorded with a small audio recording device so that the researcher can listen back to it and examine the information you give in conjunction with interviews from other participants. At the end of this interview, you will be invited to participate in the evaluation stage of the project where you will be asked for your opinion on the decision aid produced. It is completely your choice whether or not you wish to take part in this later phase of the project and you are under no obligation to do so.

**Will my taking part in this study be kept confidential?**

Yes. Your participation in this study will be kept anonymous and those who read the final report will not have any way of identifying that you took part. Only the lead researcher will have access to the recording of your interview. This will be transferred onto a secure password protected NHS Lothian computer as soon as possible and deleted from the recording device. All the information we collect during the course of the research will be kept confidential and there are strict laws that safeguard your privacy at every stage. Your name will be removed from the data so that you cannot be recognised from it. Typed interview transcripts will also be fully anonymised, and will be stored securely on NHS premises. Transcripts and recordings will be archived as per NHS Lothian Research & Development Department (Crown Records Management) protocol, and NHS Lothian R&D has a nominated individual who has overall responsibility for archiving within the department. Direct quotes
from your interview may be published in the final report, however, these will be fully anonymized and you will not be identifiable. With your consent, we will inform your GP that you are taking part.

Under those exceptional circumstances under which there appears sufficient evidence to raise serious concern about your safety or the safety of others, confidentiality may not be maintained. If this happens, the researcher will need to discuss her concerns regarding your safety or the safety of others with colleagues and follow up any concerns they may have with management and other relevant people. If this happens, your data will no longer be required for the study. This will be discussed with you in more detail before the interview, and you will have the opportunity to ask the researcher any questions at this time.

**What are the possible benefits of taking part?**
By taking part in this study, you will have the opportunity to directly contribute to the development of a decision aid tool that will help other women with ovarian cancer who are facing the difficult decision of having CA-125 monitoring or not.

**What are the possible disadvantages and risks of taking part?**
Whilst the focus of the interview is on your decision to have CA-125 monitoring or not, we understand that you may feel upset by talking about something closely related to your cancer diagnosis and your experience of living with cancer. You will be reminded at the start of the interview that if you feel any distress or get upset to either ask for a break or request to stop the interview altogether. You may also choose to not answer any questions you feel uncomfortable answering. Additional support from staff at the Edinburgh Cancer Centre will also be available if you need it, including a referral to the clinical psychology service if necessary. If you are concerned about experiencing distress during or following the interview, then we advise that you do not participate.

**What will happen to the results of the study?**
The study will be written up as a Clinical Psychology Doctoral Thesis, and will be available electronically and manually through the University of Edinburgh library. The final results may also be shared through conferences and peer reviewed scientific journals. Your identification will not be included in any publication. We will also send each participant a copy of the final decision aid booklet in gratitude of their participation.
**Who is organising the research and why?**
This study is being organised and funded by the University of Edinburgh in collaboration with NHS Lothian.

**Who has reviewed the study?**
The study proposal has been reviewed by the lead researcher’s academic supervisor at University of Edinburgh and clinical supervisor at the Edinburgh Cancer Centre. The study has also been reviewed by two Consultant Oncologists at the Edinburgh Cancer Centre. A favourable ethical opinion has also been obtained from South East Scotland REC 01. NHS management approval has also been obtained.

**If you have any further questions about the study please contact Fiona Kelly by phone 0131 537 3094 or email fiona.e.kelly@nhslothian.scot.nhs.uk.**

If you would like to discuss this research with someone independent of the study please contact: Claire Gittoes, Trainee Clinical Psychologist, Pennywell Resource Centre (Tel: **0131 537 4217**). Claire works as a Trainee Clinical Psychologist for NHS Lothian, and is also enrolled on the University of Edinburgh Clinical Psychology Doctoral Programme.

If you wish to make a complaint about the study please contact NHS Lothian:
NHS Lothian Complaints Team
2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5708

*Thank you for taking the time reading this information sheet.*
Appendix 7. Patient Consent Form

Patient Participant Consent Form

Project Title: The CA-125 Decision Aid Development Study for Ovarian Cancer.

Name of Chief Investigator: Dr Fiona Kelly
Ph: 0131 537 3094

Thank you for reading the information about our research project. If you would like to take part, please read and sign this form.

Participant’s name:____________________  Telephone No.____________________

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<tr>
<td>1.</td>
<td>I confirm that I have read and understand the participant information sheet dated 10.07.12 (Version 1) for the above study and have had the opportunity to ask questions.</td>
<td>Please initial box</td>
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<td>2.</td>
<td>I understand that participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.</td>
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<td>3.</td>
<td>I agree that the audio information I provide in the interview can be audiotaped and transcribed. I understand that the audio recording will be deleted at the end of the project.</td>
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<td>4.</td>
<td>I understand that research data obtained during the study will be fully anonymised so that others could not identify me. This unidentifiable research data may then be stored and used for purposes in the public interest.</td>
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<td>5.</td>
<td>I understand that under those exceptional circumstances under which there appears sufficient evidence to raise serious concern about my safety or the safety of others, confidentiality may not be maintained.</td>
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<td>6.</td>
<td>I agree to my General Practitioner being informed of my participation in this study.</td>
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<td>7.</td>
<td>I agree to take part in the above study and that if the study is published, I understand that all data will be fully anonymised and I will not be identifiable.</td>
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<td>8.</td>
<td>I allow NHS Lothian, as a sponsor of this study to access my medical records to ensure the study is being run correctly.</td>
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____________________  __________________________  ____________
Name of Participant  Signature  Date

____________________  ____________
Chief Investigator  Signature  Date

Thank you for agreeing to participate in this research.
Appendix 8. Health Professional Study Information Sheet

Health Professional Participant Information Sheet

Study: The CA-125 Decision Aid Development Study for Ovarian Cancer.

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The aim of the study is to identify women's decisional support needs related to the CA-125 test used for the post-treatment monitoring of epithelial ovarian cancer. The results of this study will then be used to develop a decision aid tool for women who have completed their primary treatment (i.e. surgery and chemotherapy) for epithelial ovarian cancer and are considering whether or not to have regular CA-125 tests. The decision aid will be a booklet which helps women to make this decision by providing evidence-based information about the options and possible outcomes, as well as leading the individual through a process of understanding their values and preferences before decision-making.

Why have I been asked to take part?
You have been asked to take part because you are currently a staff member involved in the direct medical care of women with epithelial ovarian cancer at the Edinburgh Cancer Centre.

Do I have to take part?
No. It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason.
What will happen if I take part?
If you decide to take part, please keep this information sheet and sign the attached consent form and return it to the researcher. The researcher will then contact you by telephone to arrange to meet with you at the Edinburgh Cancer Centre at a date and time that is convenient for you to conduct the interview.

During the interview, the researcher will ask you some questions about your current practice regarding use of the test, your opinion on the recent results from the MRC OVO5 trial and your opinion on the advantages and disadvantages of CA125 testing for women entering post-treatment surveillance. The interview will last about an hour, and will be recorded with a small audio recording device so that the researcher can listen back to it and examine the information you give in conjunction with interviews from other participants. At the end of this interview, you will be invited to participate in the evaluation stage of the project where you will be asked for your opinion on the decision aid produced. It is completely your choice whether or not you wish to take part in this later phase of the project and you are under no obligation to do so.

Will my taking part in this study be kept confidential?
Yes. Your participation in this study will be kept anonymous and those who read the final report will not have any way of identifying that you took part. Only the lead researcher will have access to the recording of your interview. This will be transferred onto a secure password protected NHS Lothian computer as soon as possible and deleted from the recording device. All the information we collect during the course of the research will be kept confidential and there are strict laws that safeguard your privacy at every stage. Your name will be removed from the data so that you cannot be recognised from it. Typed interview transcripts will also be fully anonymised, and will be stored securely on NHS premises. Transcripts and recordings will be archived as per NHS Lothian Research & Development Department (Crown Records Management) protocol, and NHS Lothian R&D has a nominated individual who has overall responsibility for archiving within the department. Direct quotes from your interview may be published in the final report, however, these will be fully anonymized and you will not be identifiable.

What are the possible benefits of taking part?
By taking part in this study, you will have the opportunity to directly contribute your knowledge and skills to inform the development of a decision aid tool which is anticipated to
greatly improve the decision-making process for women at this stage of decision-making and which will also be of considerable value during patient-doctor consultations.

What are the possible disadvantages and risks of taking part?
As this interview is focused on your knowledge of the CA-125 test and your opinion on its use in current practice we do not anticipate any possible disadvantages or risks if you take part.

What will happen to the results of the study?
The study will be written up as a Clinical Psychology Doctoral Thesis, and will be available electronically and manually through the University of Edinburgh library. The final results may also be shared through conferences and peer reviewed scientific journals. Your identification will not be included in any publication. We will also send each participant a copy of the final decision aid booklet in gratitude of their participation.

Who is organising the research and why?
This study is being organised and funded by the University of Edinburgh in collaboration with NHS Lothian.

Who has reviewed the study?
The study proposal has been reviewed by the lead researcher’s academic supervisor at University of Edinburgh and clinical supervisor at the Edinburgh Cancer Centre. The study has also been reviewed by two Consultant Oncologists at the Edinburgh Cancer Centre. A favourable ethical opinion has also been obtained from South East Scotland REC 01. NHS management approval has also been obtained.

If you have any further questions about the study please contact Fiona Kelly by phone 0131 537 3094 or email fiona.e.kelly@nhslothian.scot.nhs.uk.

Thank you for taking the time reading this information sheet.
Appendix 9. Health Professional Consent Form

Health Professional Participant Consent Form

Project Title: The CA-125 Decision Aid Development Study for Ovarian Cancer.

Name of Chief Investigator: Dr Fiona Kelly
Ph: 0131 537 3094

Thank you for reading the information about our research project. If you would like to take part, please read and sign this form.

Participant’s name:__________________________    Contact Ph: ____________________

1. I confirm that I have read and understand the participant information sheet dated 10.07.12 (Version 1) for the above study and have had the opportunity to ask questions.

2. I understand that participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my employment and other rights being affected.

3. I agree that the audio information I provide in the interview can be audiotaped, transcribed, stored with my name removed from all records and my words used in the presentation of the research. I understand that my words will not be used to identify me.

4. I understand that the any data obtained during the study will be fully anonymized, and only the researcher will have access to the identifiable audio recording.

5. I agree to take part in the above study and that if the study is published, I understand that all data will be fully anonymized and I will not be identifiable.

______________________    Name of Participant    ______________________    Signature    ____________________________    Date

______________________    Name of Investigator    ______________________    Signature    ____________________________    Date

Thank you for agreeing to participate in this research.
Appendix 10. Patient Interview Schedule

Semi-Structured Interview for Patient Participants

Part one:

Knowledge surrounding the CA-125 test and its purpose post-treatment

1. Introduce patient vignette
2. Can you tell me what you know about the CA-125 test? Prompt if necessary: What does it measure?
3. What is your understanding about the function of CA-125 testing during post-treatment surveillance/follow-up care for ovarian cancer?

Questions about the decision-making process

4. What information did you receive about the CA-125 test post-treatment?
5. Did your oncologist outline the pros and cons of having regular CA-125 testing?
6. What was helpful about the information you received in aiding your decision-making?
7. What was unhelpful?
8. Did you feel that you were given adequate time to make this decision?
9. Were you advised to go away and think about it or consult family/friends about it?
10. Did you make the decision on the spot or did you take some time?
11. Did you discuss the decision with family/friends?
12. Did you look for any additional information about CA-125 testing to help with your decision-making? Prompt if necessary: For example, on the internet?
13. Overall, what factors influenced your final decision?

Anxiety-related questions for women who chose to have CA-125 monitoring

14. Has the decision to have regular CA-125 testing prior to your clinic visits caused you to experience any anxiety?
15. Do you worry about your CA-125 count/level in general?
16. Do you feel that having the CA-125 test has impacted upon your quality of life in any way?

Part two: Opinion on the use and development of a decision aid tool regarding this decision

Participant is shown an example of a decision aid tool produced by Anderson et al (2011) to explain the function of such a tool in aiding decision-making.

17. Do you think that such a tool would be useful for patients making the decision regarding post-treatment CA 125 surveillance? If so, why?
18. When you made your decision about CA-125 testing, would other women’s stories about how they made their decision have been helpful to know? Why/why not?
19. Do you think that it would be helpful to include patient stories in a decision aid about CA-125 testing during post-treatment surveillance? Why/why not?
20. Where do you think would be the best place for patients to use the decision aid? Why?
21. When do you think would be the best time for patients to be given the decision aid for helping with their decision-making? Why?

Part three: Possible decision options

Participants are shown the three CA-125 post-therapy options proposed by Rustin (2011) and asked for their opinion on the inclusion of all three options in the decision aid or the possibility of only including options 1 and 2 (i.e. to have the test or to not have the test).
Appendix 11. Health Professional Interview Schedule

Semi-Structured Interview for Health Professionals

Part one:

Questions regarding current practice & advantages/disadvantages of CA-125 testing

1. What is your current practice regarding CA-125 testing?
2. How would you typically discuss the test with women post-treatment?
3. What in your opinion, are the advantages and disadvantages of CA-125 testing for women?
4. What are the advantages and disadvantages for you as the health professional in charge of their care?
5. If you were a patient and had to make a decision to have CA-125 post-treatment surveillance or not, what would you choose and why?

Questions about the OVO5 European Trial

6. What is your opinion on the results of the recent MRC OVO5 trial?
7. Have the results influenced your practice regarding the CA-125 test?
8. Did the results surprise you?

Part two: Opinion on the use and development of a decision aid tool regarding this decision

The health professional is shown an example of a decision aid tool produced by Anderson et al (2011) to explain the function of such a tool in aiding decision-making.

9. Do you think that such a tool would be useful for patients making the decision regarding post-treatment CA-125 surveillance? If so, why?
10. Would you find such a tool helpful during your consultation?
11. Where do you think would be the best place for patients to use the decision aid? Why?
12. When do you think would be the best time for patients to be given the decision aid for helping with their decision-making? Why?

Part three: Possible decision options

Participants are shown the three CA-125 post-therapy options proposed by Rustin (2011) and asked for their opinion on the inclusion of all three options in the decision aid or the possibility of only including options 1 and 2 (i.e. to have the test or to not have the test).