

Women's views of two interventions designed to assist in the prophylactic oophorectomy decision: a qualitative pilot evaluation

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Abstract

Introduction A qualitative pilot evaluation of two different decision interventions for the prophylactic oophorectomy (PO) decision: a Decision Chart and a computerized clinical guidance programme (CGP) was undertaken. The Decision Chart, representing current practice in decision interventions, presents population-based information. The CGP elicits individual values to allow for quality-adjusted life years to be calculated and an explicit guidance statement is given. Prophylactic oophorectomy involves removal of the ovaries as an adjunct to hysterectomy to prevent ovarian cancer. The decision is complex because the operation can affect a number of long-term outcomes including breast cancer, coronary heart disease and osteoporosis.

Methods Both interventions were based on the evidence and were administered by a facilitator. The Decision Chart is a file, which progressively reveals information in the form of bar charts. The CGP is a decision-analysis based program integrating the results from a cluster of Markov cycle trees. The research evidence is incorporated with woman's individual risk factors, values and preferences. A purposive sample of 19 women awaiting hysterectomy used the decision interventions (10 CGP, nine Decision Chart). In-depth semi-structured interviews were undertaken. Interviews were transcribed and analysed to derive themes.

Results Reactions to the different decision interventions were mixed. Both were seen as clarifying the decision. Some women found some of the tasks difficult (e.g. rating health status). Some were surprised by the 'individualized' guidance, which the CGP offered. The Decision Chart provided some with a sense of empowerment, although some found that it provided too much information.

Conclusions Women were able to use both decision interventions. Both provided decision clarification. Problems were evident with both interventions, which give useful pointers for future

development. These included the possibility for women to see how their individual risks of different outcomes are affected in the Decision Chart and enhanced explanation of the CGP tasks. Future design and evaluation of decision aids, will need to accommodate differences between patients in the desire for amount and type of information and level of involvement in the decision-making process.

Introduction

A 'good' decision has been defined as having a number of characteristics; including reduced uncertainty, improved knowledge, more realistic expectations, improved clarity of values, improved congruence between values and decision taken and increased satisfaction with the decision-making process.¹

A large number of aids have now been developed to help with 'improving' decision-making. These vary considerably both in the medium of delivery of information and the format and framing of risk information, from 'low-tech' leaflets² and decision boards³ to 'high-tech' computer programs⁴ and videodisks.⁵ Research has demonstrated that people vary in their preferred formats for health information delivery and that 'framing' effects are important.⁶ Some prefer more descriptive explanations of risk with scenario building whilst others prefer numerical or graphical representations.^{7,8} Evidence from a systematic review also suggests that individualizing risk information is important in communication with patients.⁹

Most decision aids involve information provision although few include explicit values clarification. Those interventions which do include values clarification, use a number of different methods.^{10,11}

Recent systematic reviews of the range of decision aids and their evaluations^{12,13} have been undertaken. Amongst other findings they showed that considerable variation exists, both in evaluating decision aids, in measures used to determine the effectiveness of decision aids and in types of participants involved (actual patients or volunteers). In general it is clear that few qualitative evaluations of decision interventions

have been undertaken and that studies have not evaluated whether risk communication has achieved improvements in understanding.⁹ The authors of the systematic reviews conclude that further evaluation of decision aids is required to determine their acceptability, feasibility and effectiveness across a range of clinical decisions and diverse patient groups, and in order to assess what elements of a decision aid prove to be most helpful.^{12,13}

We designed two different evidence-based decision interventions: a computerized clinical guidance programme (CGP) which incorporates a patient's individual risk factors and individual preferences for generic health states, with the evidence, to produce individualized guidance,¹⁴ and a paper-based Decision Chart, similar to the decision board.¹⁵⁻¹⁷ The Decision Chart provides numerical population-based information on outcomes, with concomitant discussion of risk. Both aids were designed to be used by patients with a facilitator and both were designed to help women in the prophylactic oophorectomy (PO) decision.

The aim of this paper is to report findings from a pilot qualitative evaluation to explore the use of and acceptability of these two different decision aids for a small purposive sample of women considering the PO decision.

Background

Prophylactic oophorectomy involves removal of healthy ovaries at the same time as hysterectomy in order to remove the risk of ovarian cancer. It is a relatively common procedure, which is surgically technically as easy as hysterectomy on its own (It has been estimated that 7% of women have a PO before the age of 60 in the UK with

a comparable figure of 5% in Finland).^{18–20} Women who undergo a PO suffer a 'surgical menopause' and are strongly encouraged to use hormone replacement therapy (HRT) because the operation causes an abrupt loss of their own circulating endogenous hormones which can result in severe menopausal symptoms.²¹ There are important and commonly occurring long-term outcomes of oophorectomy besides the reduction in the risk of ovarian cancer. These include increases in the risks of coronary heart disease and osteoporosis and a potential reduction in the risk of breast cancer, all of which should be weighed up as part of the decision to undertake the operation.^{22–25} There is variation in practice and in decisions as to the age of women on whom gynaecologists usually undertake the operation.

Methods

Design and use of the decision interventions

A literature review was undertaken in order to provide the evidence base for the decision interventions. Evidence was gathered using routinely collected data and from systematic searches of the literature on oophorectomy, HRT and effects on four main outcomes: ovarian cancer, coronary heart disease, breast cancer and osteoporosis.

Focus groups and interviews were held with women from voluntary organizations (local hysterectomy support groups, the National Osteoporosis Society and the National Hysterectomy Society) to ensure the relevance of the range of topics to be covered in the decision aids. The aids also underwent pre-piloting with these groups and with gynaecologists.

In designing the Decision Chart, we aimed to mimic the Decision Board philosophy,^{15,16} which includes:

- a graphical representation of the options facing the patient;
- some textual information about each option and the outcomes that results from it;
- quantitative information about the probability of key uncertain events;

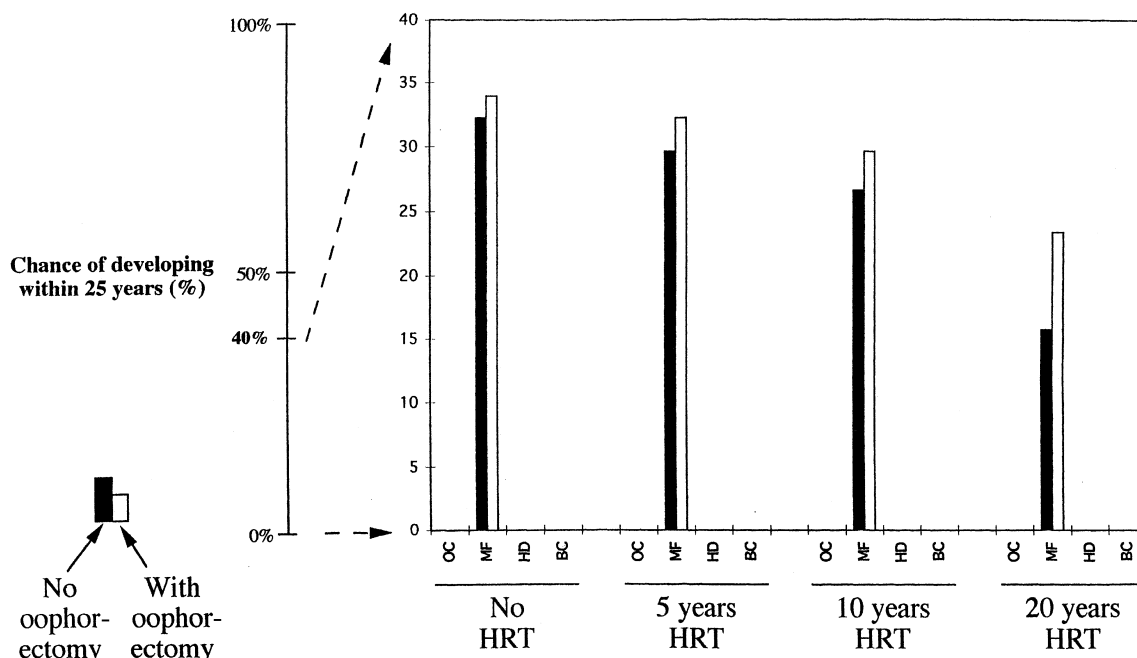
- progressive revelation of information with opportunity for patient interaction.

We also aimed that working through the Decision Chart should take about 15 min.

Using the literature review data, the Decision Chart was constructed as a file in which the four outcome conditions (ovarian cancer, breast cancer, coronary heart disease and osteoporosis) are covered sequentially, with the effects of the two basic treatment options (oophorectomy and no oophorectomy) discussed for each one. The effects on the outcomes of four different durations of HRT-taking were also included (0, 2, 5 and 10 years).

We used vertical bars to represent the probabilities so as to permit easy comparison of the different interventions effects on each outcome condition, given different HRT durations. We also provided text-based information about each outcome, together with details about risk factors affecting probabilities. The patient was asked about individual risk factors (e.g. smoking) during the text phase for each condition and told the direction of any adjustment which she would need to make to 'individualise' the average figures she was looking at. The Decision Chart was presented to each woman so that she could talk through each outcome condition in turn with the researcher, covering the effects of the different treatment options (oophorectomy or no oophorectomy), and the effects of different HRT durations on each outcome condition. A hard copy of the full chart was also produced so that it could be taken away by the women at the end of the session. It included the text-based information on the outcomes and risk factors together with the vertical bar chart representations of all the different outcomes discussed, making a summary presentation. (Fig. 1 shows a representative page of the chart – the bar charts for major fractures, and Fig. 2 shows the final text presentation, after all the outcome measures have been discussed in turn.).

The clinical guidance programme (CGP) is a computerised program which was designed to integrate the research evidence with a woman's own individual risk factors and preferences for health states. A decision analytical framework



Note: all rates are average estimates and are subject to uncertainty

Figure 1 Bar charts from decision chart showing risks of major fracture (MF) with and without oophorectomy.

was used in order to arrive at an explicit recommendation. The program was designed to produce guidance using both quality adjusted life expectancy (QALE) and life expectancy. The final output of the CGP is presented as a comparison of quality-adjusted life expectancy and life expectancy for each treatment option (oophorectomy or no oophorectomy). A simple guidance statement screen is then presented which states the option the CGP would 'recommend' on the basis of the evidence. (The following statement appears on the screen: 'Given the information you have provided, the CGP recommends the "no-oophorectomy" option.'). The woman is then invited to explore the reasons for the guidance with a series of further information screens.

Women work through the program as a series of tasks on separate screens. The contents of each task are described in Table 1.

The process of performing the calculations rests on a series of equations using a cluster of Markov cycle tree models.²⁶

The more complex elements of the CGP from the point of view of the woman are the standard gamble task and the valuations of different

health states. Following on from the work of Cher, Miyamoto and Lenert,²⁷ the standard gamble item in the CGP establishes the patient's risk preference. The result is used to risk-adjust subsequent time trade-off valuations. As a result of pre-piloting, alternative methods of eliciting patients health state valuations were included and patients were given a choice of elicitation techniques [standard gamble, time trade off or visual analogue scale (VAS)]. The standard gamble task and the health state valuation task are shown in Figs 3 and 4, respectively. For both these tasks it is possible for a woman to opt for population-based values if she wishes. When all the tasks are completed, the calculations are undertaken and the results are presented as guidance. The guidance is printed out and the printout can be taken away. When the tasks involved in the CGP have been completed, it is possible to view the information and evidence on which the guidance statement is based. A more detailed description of the development of the decision interventions is provided elsewhere.^{26,28} Table 2 provides a summary of the characteristics of the two interventions.

Your oophorectomy – hormone replacement therapy decision

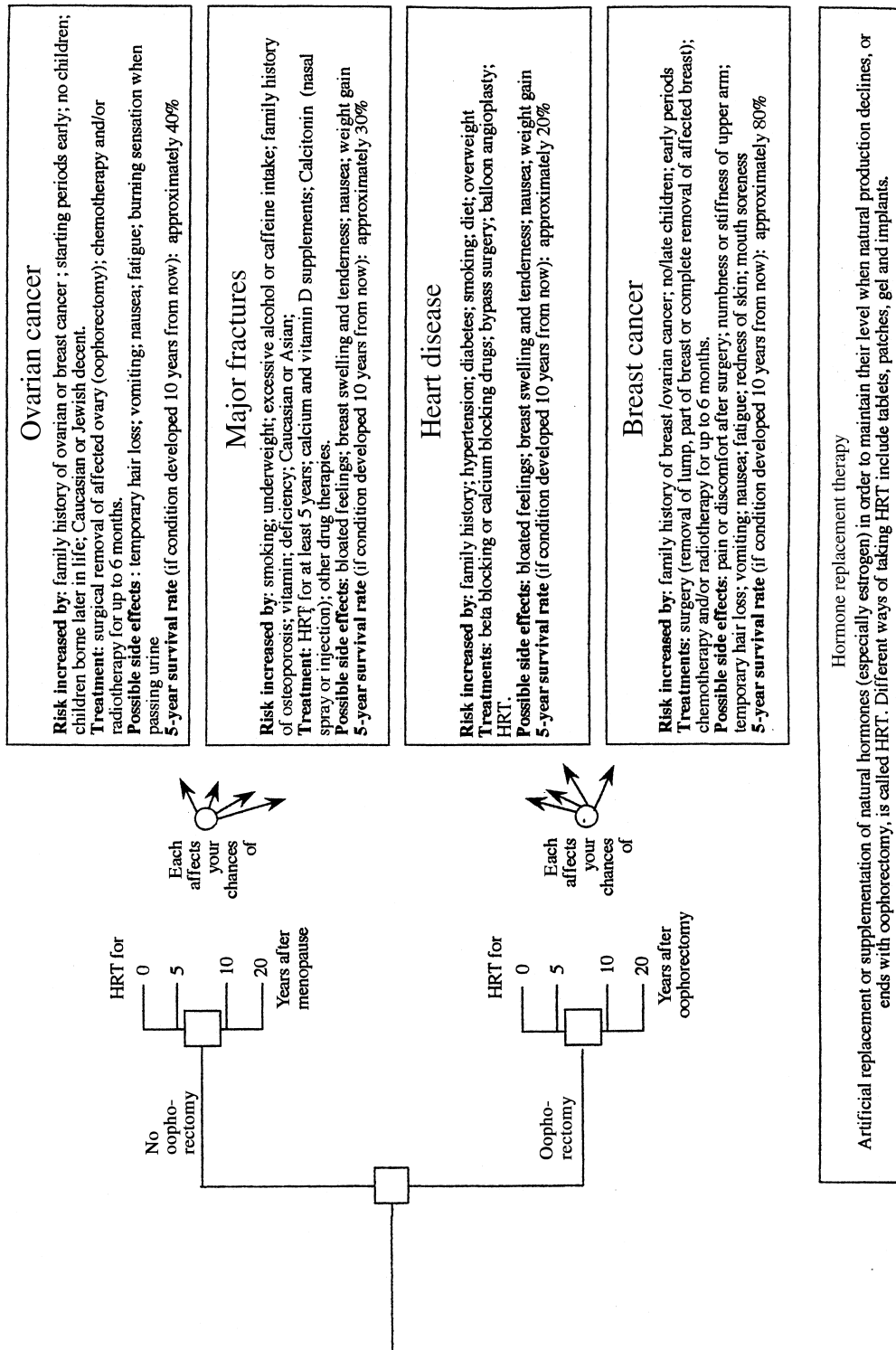


Figure 2 Final text summary for all four outcome conditions presented in decision chart.

Table 1 Details of tasks undertaken in CGP and information gathered

Task	Details of tasks and information gathered
Gather patient information	Patient age Patient risk factors: questions asked about relevant risk factors, e.g. smoking, family history, exercise, other illnesses
Explain context	'Decision tree' screen showing the various elements of the decision: treatment options, HRT use and four outcomes
Define and value current state of health	Women's current health state health defined using the EuroQoL-5D (visual analogue scale 'thermometer' and five dimension, three level report form)
Define personal risk coefficient	Women's attitude to risk is calculated using a single standard gamble question (see Fig. 3)
Value a number of health states	A number of different health states are described; women value them using the time trade-off technique. (see Fig. 4) Provision is also made for valuations to take place using the standard gamble or visual analogue technique here if women prefer.
Define anticipated HRT usage	Women are asked whether they think they will be likely to take HRT and if so for how long (i) if they do have an oophorectomy and (ii) after natural menopause if they do not have an oophorectomy
Perform calculations	Women's risk factors, current health state, attitudes to risk, valuations of health states and estimates of anticipated HRT use are integrated with epidemiological and research evidence from the literature to produce a comparison evaluation of the two treatment options – oophorectomy or no oophorectomy using life expectancy and quality-adjusted life expectancy.
Perform calculations and produce printout	The programme presents individualized guidance to the woman based on her answers to all the tasks and risk factors and she is given an A4 printout to be taken away.

Validation of the decision interventions

The decision interventions were subjected to review by clinical experts, the study steering group, a patient group and a healthy volunteers group, and modifications were made to their format and content in response to this review. At the preliminary testing stage of the CGP, a sensitivity analysis was undertaken, varying the assumptions about the evidence. Anticipated guidance from the CGP was compared with actual practice in the proportion of women undergoing PO at different ages using a prospective data set of 16 000 women undergoing hysterectomy in the UK in 1994/95,¹⁴ and it was also compared with previous analyses.^{29–31}

Data collection and analysis

Multi-site ethics committee approval was obtained. A purposive sample of women on the waiting list, who were about to undergo hysterectomy and who had to take the PO decision was

invited to participate during 1999/2000. Consultants from six hospitals in London and the south-east of England and research staff invited women to participate. Women were allocated in blocks of 10 to use the two different interventions with a facilitator member of the research team (VB). The aim was to recruit approximately 15–20 women to use each decision intervention.

Women used the decision interventions either at home or in hospital at a pre-admission clinic within 2 weeks of the date of admission. All women were sent a general information leaflet with some background information about oophorectomy, the menopause and consequences of taking HRT in relations to the four outcomes. Women were also given preparatory material related to the decision aid they were to receive. For example the leaflet for the CGP explained what a standard gamble task was and gave a national lottery example. It was made explicit both before and after using the Decision Chart and the CGP, the interventions were being piloted and that women should make the final

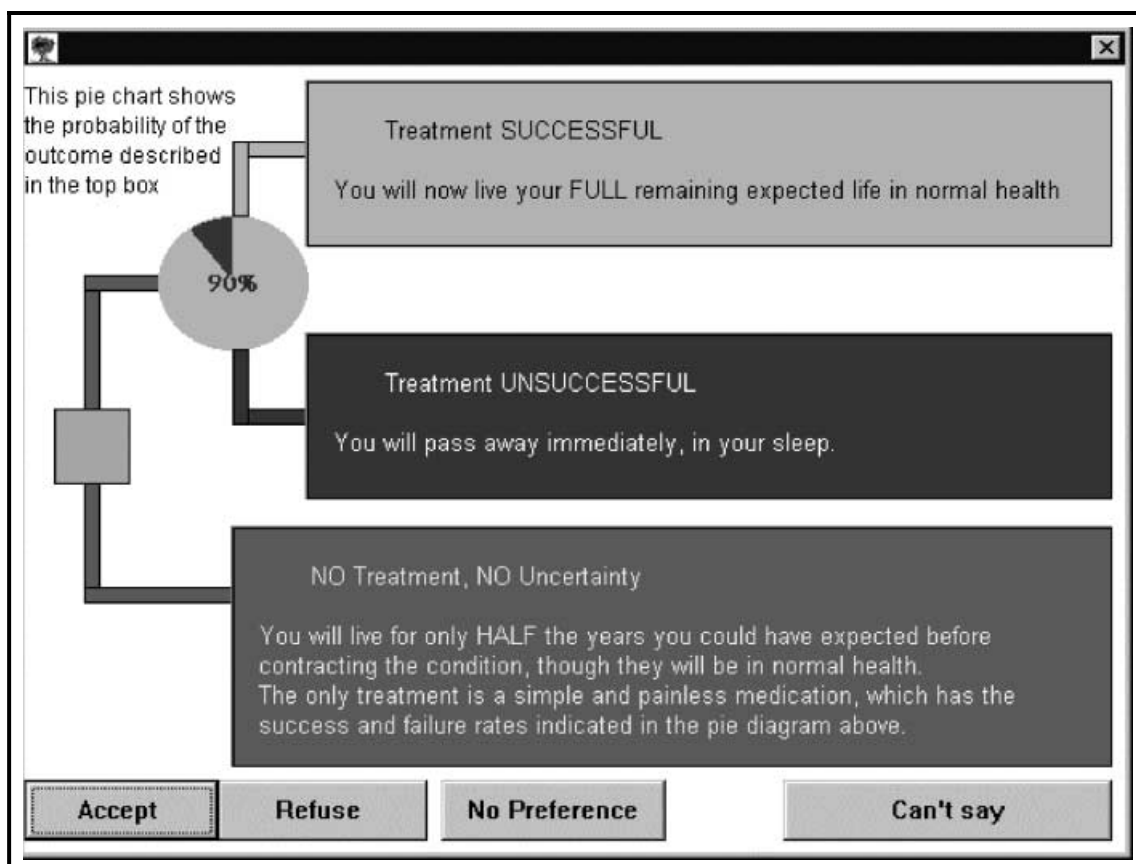


Figure 3 Standard gamble task.

decision that they felt was best for them in conjunction with their doctors.

Women were interviewed just before and immediately after the use of their decision intervention. A formal semi-structured interview guide was used. The interviews and the consultation were tape-recorded using a Sony tape recorder and transcribed in full.

Two researchers (VB, AC) read transcripts and categories and themes were identified independently and then agreed jointly. Data were organized into broad categories using Nud*ist (a qualitative analysis software package) and then coded. Throughout the process of coding, categories and themes were compared with each other and the existing literature to allow for links to be made or coding categories to be transformed or collapsed. A grounded theory approach was used.³²

Results

Forty-two women overall, agreed to take part. A further five women responded too late to use the decision interventions before their surgery. Three of the 42 were subsequently unable to participate for other reasons (including one who was not eligible). Of the remaining study sample of 39 women, 19 were allocated to the CGP and 10 were allocated to the decision chart. (Ten were allocated to receive a booklet and are not further considered here.) Of those using the CGP and the decision chart, 18 (12 CGP, six Decision Chart), agreed to have their consultations with the decision interventions tape-recorded and to undergo in-depth interviews. The results of these interviews are further reported here. The study sample had a mean age of 46 years [standard deviation, 5.0; mean age of

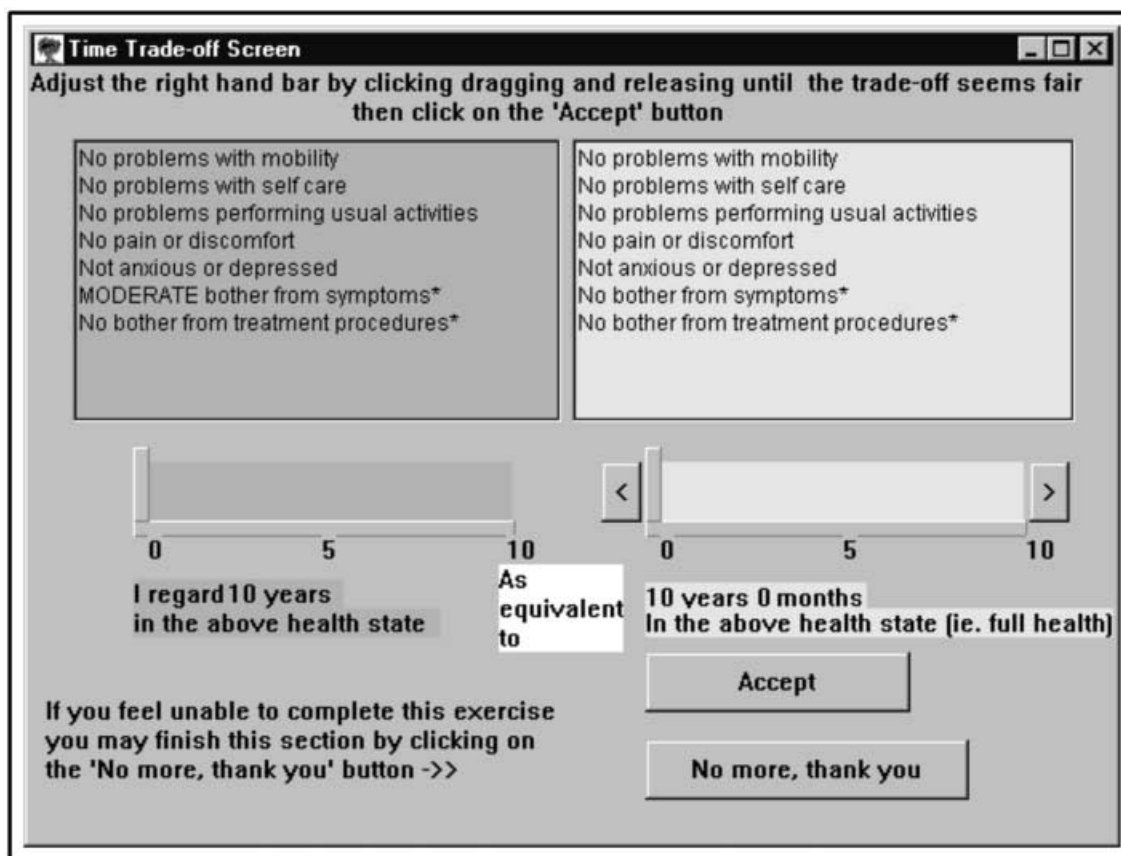


Figure 4 Time-trade-off (TTO) screen.

Table 2 Summary of characteristics of two decision interventions

	Decision Chart	Clinical guidance programme
Time for administration	15 min	15–20 min
Format	Paper based	Computer Program
Facilitator required to administer?	Yes	Yes
Complexity of tasks	Moderate (synthesis and assimilation of a lot of information)	Moderate (especially standard gamble and time trade o tasks)
Information provided on risks of relevant outcomes	Yes – but general information only	Yes – at varying levels of complexity but only on request
Individual risks, attitudes to risk and preferences taken into account	Explicitly discussed	Yes, explicitly incorporated
Quality adjusted life expectancy calculated	No	Yes
Explicit guidance statement given	No	Yes
Paper copy of results to take away	Yes	Yes

all women in study, 45 years (SD 6.2)]. The sample had a higher age of leaving full-time education than that reported in the general population. (Age of leaving full-time education in the general population of women is, 16 years

or under 61%; 17–18 years 21%; 19 or over 18%; the figures for the study sample were 54, 26 and 20%, respectively.) The consultation lasted 15–20 min and interviews lasted between 25 min and 1 h.

Women's views of the decision interventions were classified under the following headings: expectations; the process of using the interventions; reactions to the output from the interventions; impact on decisions and attitudes towards overall presentation. Results for the Decision Chart and the CGP are presented under these headings, and Table 3 provides a summary of the findings.

The Decision Chart

Expectations

Women saw the session as providing help to understand things more clearly, information, which they felt they lacked and an opportunity to talk about their views and concerns.

'Make me see things a little bit clearer, understand things, I know you can read things but I have never sat down and talk to no one about it.' (319)

Process of using the Decision Chart

Women actively engaged with the Decision Chart by using it in a number of ways indicated some understanding of the information presented and some attempt to apply that information

to their individual circumstances. Some women used the information to think aloud about their own individual risk profiles.

'So that is, if I still keep to my same diet and what have you, and I don't take calcium supplements, and I don't exercise, do aerobic exercise and things like that, whereas if I did then, presumably that would come down (pointing to major fractures bar chart).' (414)

Women were evidently able to use the charts in various ways to gain an overall understanding of the information. However, in most cases, although women recognized their own individual risk factors, very few were able to explicitly relate this information to the size of the bar charts, or to their own anticipated risks of the main outcome conditions.

'So there's a link then isn't there, with whatever your ovaries do umm and fractures ... the key is the oestrogen ... I got some information it did say that umm if you had a hysterectomy you were likely to be at high risk from heart disease because there was something, I think that occurs naturally for some reason that is removed, probably the oestrogen again ... I can see where HRT fits in on all of it and it is really quite helpful.' (316)

Table 3 Summary of findings

	Decision Chart	Clinical guidance programme
Expectations	Clarification of decisions Ensure 'right' decision made	Clarification of decisions Ensure 'right' decision made
Process of using decision aid	Awareness of complexity of issues. Use of risk factor information implicit. Too much information for some women	Most tasks completed by most women. Standard gamble and time trade off exercises found difficult because of the complexity of the tasks.
Reactions to the output	Positive, 'empowerment'. Ownership of knowledge	Surprise at specific guidance
Impact on decisions	Little change from previously held views – some decision clarification but women felt they had to 'go home and think about it'	Little change from previously held views – decision clarification – but not necessarily in line with guidance statement
Attitudes towards overall presentation of decision aid	Seen as offering 'time to think and talk.' Met information needs. Recommendations for improving layout suggested	Seen as offering 'time to think and talk.' Some negative attitudes to the technology apparent – 'grey box'.

Impact of Decision Chart on decisions

In general, women's reactions showed that they understood the information presented to them. However there were some signs that the Decision Chart had not served to sway women's original preferences regarding their ovaries (those women who were inclined to keep their ovaries were still inclined to do so, those who were inclined to have them removed had also not changed their minds). Some women appeared quite surprised by the amount of information they had received. Two women expressed a desire to go home and 'pore over it'.

'Well it showed me that I think that that shows me, if you keep the ovaries it might be better for you ... I mean its sort of a toss up, because there's not much difference between the charts, of what you've been giving me...I think my decision, that chart shows me, its better to keep your ovaries if you can.'

Reactions to the output from the Decision Chart

Some women appeared to derive a sense of empowerment from the information presented in the Decision Chart. In particular, women expressed a sense of ownership of the knowledge – it was concrete and something that they could see for themselves.

'everyday people don't know the pros and cons of having different things done to their body and this is and this, has helped me to understand. its sometimes there is only little difference and you needn't have worried so much'. 'I think it's really letting you have the decision and giving you the umm, the fors and against which is good and it's not pressurised.' (507)

In their discussions, it also became apparent that some women now felt better informed about the benefits and risks associated with their treatment options, and that the Decision Chart had outweighed their expectations.

'It's given me a lot more information than I thought, to be quite honest, I am very pleased, well I say, I haven't really had any information from anywhere else.' (325)

Attitudes towards the Decision Chart and its overall presentation

Women appreciated an opportunity to sit down and voice their feelings about the information presented and choices they were making and from the interviews it appeared that the Decision Chart played a role in facilitating this process. Although women also generally had positive attitudes concerning the comprehensibility and presentation of the information, a need for information was a recurring theme in women's comments.

'Well it's nice to have somebody to talk to and to actually see something on paper umm to sort of explain the pros and cons of things and umm also about the HRT ... it's been very helpful, it nice to know that there is at least somebody who will take the time to go through it with you.you know, you don't, you don't seem to get that opportunity to talk to somebody ... '(507)

The clinical guidance programme (CGP)

Expectations

Women felt that participating would help them clarify whether or not they had made the right decision concerning their ovaries. Further, they felt that they would be provided with information.

Process of using the CGP

Women began commenting on the impact of the oophorectomy decision on long-term health outcomes when they were presented with the introductory screens on the CGP, indicating an awareness of the issues to be considered and of the complexity of the decisions to be made.

'If I don't have HRT I am not getting it artificially so then I run the risk of ... (then again there's the) effect on breast cancer ... because I won't have HRT, so my risk of breast cancer ... right okay.' (121)

When presented with the standard gamble task (Fig. 3) some of the women found it hard to understand what the question was asking them to do. Despite this perceived difficulty however,

none of the women opted out of answering the question, although they were provided with that opportunity. In their comments, women expressed some evidence of understanding why they were completing this task. These comments also illustrate some of the difficulties that exist in thinking about risk, especially when related to hypothetical health states.

'I wouldn't want to die, you know, I wouldn't want to take that gamble and say right die, because my children are still quite young you know, ... on the other hand I do want quality of life to be able to enjoy life with them ... I am not too sure about the gambling bit. that sort of sways me ... I am not much of a risk taker.' (120)

Similarly some of the women also found the time-trade off exercise difficult at the outset, with two women needing additional explanations about how to complete the task. Practising effects were evident in that after being presented with one or two health states to value, most women became familiar with what was required of them and managed to complete the task satisfactorily. However some women remained uncomfortable with the idea of 'trading off' life years. Some found it difficult to imagine what a particular health state or combination of health states would be like. Thus some women tended to 'home in' on a particular health state that they could identify with, from a combination that was presented to them, in order to provide a valuation.

'I found it quite hard to think about pain and symptoms and weighing up things that aren't related to the condition that I don't really have ... I found that quite hard to picture, I couldn't, well I found it hard to see really ... , I don't know if you would actually do it, whether you would actually do that in your life, I don't know maybe you would, maybe you would later on in life' ... 'I hope this doesn't come back to haunt me.' (506)

Reactions to the output from the CGP

Unlike many decision interventions the CGP is explicitly designed to produce a definite guidance statement. For just under half the women the guidance was discrepant with their initial

inclinations and in all these cases women had initially chosen to keep their ovaries. Women reacted with surprise in the first instance followed by some nervousness. They used a variety of heuristic devices or rules of thumb to assimilate the guidance and justify their initial positions. Some women began to focus on the relatively small net gains or losses in life expectancy, which the CGP suggested, would accrue from either keeping or removing the ovaries. The difference in most cases was small (up to 26 weeks) and women used this information to justify their original position and reject the guidance.

'ooh, right! Ooh urnh!' (followed by nervous laugh.) 'There's not much in it really.' (506)

'Very muddled up person, I was fine until you brought this programme ... I don't see how it can come up with one week, a month or a year perhaps, but 1 week, it just seemed a bit odd.' (120)

These women expressed surprise not only because the guidance statement was discrepant with their inclinations but also because it was literally 'a guidance statement' telling them what the programme deemed 'best' for them given the evidence, their individual risk factors and their stated preferences. Although it had been made explicit throughout that the aim of the programme was that women should be provided with guidance as to the best option for them, it became evident that women had not envisaged what form the 'guidance' might take in the context of using the programme.

When the guidance presented was consistent with women's original inclinations they indicated relief. These women were not influenced by the small differences in gains in life expectancy between the options. Instead they were relieved that there were benefits to the choice towards which they had already been inclined, and that the guidance corresponded to this. Relief was also expressed in other ways; reference was made to the advice given by medical professionals.

'Right, exactly what my GP said ... well it has confirmed what my GP told me and she told me from a knowledge base, and personal as well, because she had the same thing.' (506)

Impact of CGP on decisions

The CGP appeared to clarify the decision for the women. It seemed to consolidate previously held views and what were once inclinations or uncertainties appeared to become firm decisions. These appeared to be reinforced regardless of the direction of the guidance. This reinforcement also occurred amongst women who received guidance, which was discrepant with their previously held views. The guidance statement not only failed to result in a change of position; it appeared to confirm the initial position.

'its almost like being told "you were right", I feel pleased with my decision.' (519)

'I thought it helped clarify in my mind what I was leaning towards anyway which was to have my ovaries removed.' (121)

Attitudes towards overall presentation

Overall there seemed to be a mixed attitude towards the CGP. Positive attitudes were most noticeable amongst women for whom the programme produced corresponding guidance. The CGP was thought to focus minds on important aspects, which women might not have otherwise considered. Positive attitudes were also influenced by the perception that the decision aid session as a whole provided an opportunity for the women to sit down and voice their feelings about the choices they were making. The whole experience of being interviewed and being taken through the programme was perceived as important.

'Very helpful because it was nice to be able to talk in a relaxed and unpressured situation, not with the best will in the world, when you go to the hospital and when you go to the GP, you are very conscious that time is not on your side ...' (121)

Women who received guidance that was discrepant with their original choices tended to view the programme negatively in the context of comparing it with traditional consultations. One woman describes the computer as a 'square grey box'. In particular, in their comparisons, women say that they would have considered changing

their mind about their choices had the guidance come from a doctor.

'I suppose with a doctor it seems to be reality and with a machine, I think it just a square grey box with a few bits of data fed into it ... I suppose the doctor is real, I can talk backwards and forwards with the doctor, the machine hasn't got as far as I can see, hasn't got feelings.' (519)

'Because it is an inanimate object isn't it, it's only, it can only deal with what I have told it' (121)

These comments illustrate a feeling of mistrust or suspicion in that women thought that the program might be designed to give a particular answer – for example to tell you to have your ovaries removed.

Lastly throughout their discussions, women expressed a need for information and advice. One commented that the CGP gave her a 'chance to talk' reflecting this. In addition women frequently asked questions illustrating a desire for more information.

Discussion

Summary of results

The majority of women taking part in the study were inclined to keep their ovaries rather than have them removed and to avoid using HRT and few women displayed absolute uncertainty. Most women in the study expected the decision interventions to provide them with clarification of their decision and of their previous inclinations. Their need for information became apparent in the frequency with which they asked questions throughout the sessions.

Women's reactions to the two very different decision interventions differed. Many of the women who used the Decision Chart found it valuable and the information proved, useful. However, not surprisingly, some women found it difficult to incorporate risk information to adjust their individual risk profiles when interpreting the charts. Many however, made attempts to weigh up the options indicating understanding of the relatively complex information provided. The Decision Chart appeared

to provide some clarification of the oophorectomy decision, but it also appeared to have little impact on treatment preferences. Women generally had a positive attitude to the Decision Chart, because it appeared to meet their information needs, provided them with a sense of empowerment and provided them with the opportunity to talk. However for some of the women there appeared to be too much information.

Many of the women who used the CGP tended to find the tasks difficult because of their complexity. The approach by some women to the valuation of health states is a concern – in some cases women appeared to be influenced by one particular item in the description of health state and this may have implications for the validity of their health state valuations. The CGP aims to offer precisely ‘individualized’ guidance – which was welcomed by women when it concurred with their previous view and was greeted with surprise when it disagreed. Although the programme’s guidance failed to result in a change of preferences, it did as with the Decision Chart appear to provide clarification of those preferences. Some women tended to be confused by the programme, and had mixed views about it. Some felt it was too much like a ‘grey box’ whilst others saw the experience of being taken through the programme as providing them with an opportunity to talk about their concerns.

Methodological issues in the design of interventions and methods of qualitative evaluation

The oophorectomy decision is a ‘one-off’ decision but it is particularly complex in that although there is one intended outcome – the prevention of ovarian cancer, there are important effects on three other major long-term health outcomes. This had implications for the design of the interventions. In the case of the Decision Chart we could not simply use a standard decision board³ to portray all the important information. In the case of the CGP it was necessary to be able to calculate risks and

benefits for a number of different outcomes – and this was another factor in the decision to use generic methods to ‘quality-adjust’ life expectancy in the CGP. Quality adjusted life years (QALYs) are well recognized as a method for summarizing the combined effects of changes in life expectancy and health-related quality of life, and their pros and cons and methods of measurement have been widely discussed particularly in the design of decision interventions.^{27,30,33} A number of decision interventions include individual patients’ utilities for health states and this is also a central tenet of the CGP – in order to be able to individualize the output as far as possible. The CGP has been configured to take account of anxieties about the use of QALYs. First, it is possible for valuations of health states to be undertaken using one of three methods: Time-trade off (TTO), standard gamble or visual analogue scale. Secondly, the output is presented both as QALE and as life expectancy, and lastly ‘opt-outs’ to population values are available for anyone who does not wish to value health states. Interestingly however, none of the women in this study took advantage of the possibility of using the ‘opt-outs.’ The interventions were developed and pre-piloted in conjunction with both patient and professional groups in order to increase validity and the inclusion of different methods of health state valuation was introduced as a result of this pre-piloting.

As far as the organization of the pilot evaluation was concerned, the timing of the PO decision is problematic. The decision is often taken as an adjunct to the decision to have a hysterectomy and this can make it difficult to find an appropriate time for a decision intervention to be used. From pre-pilot discussions with hospitals and consultants, it became clear that the PO decision was only thought to be finalized at the stage of admission to hospital and when the consent form was signed. As we were aiming to help women actually make the decision, we chose this timing to pilot our interventions. However it became clear that many women had already formed an intention with regard to whether or not they should undergo PO. This has both particular and

general implications. First, it appears that our particular decision interventions may therefore have been being used as a means of post-hoc rationalization after a decision had been taken. This may have made it more difficult for women to use the decision interventions as they were intended in this evaluation. We would have to take steps to try and ensure that women were able to use these interventions for actual decision-making in any further evaluation. Secondly, there are general implications of this finding, in that there may be a problem in 'locating' the actual decision-making point in usual health care practice, especially if there are long waiting lists for a particular treatment.

Both the decision chart and the CGP present a large quantity of complex information. The advantage of the CGP is that this information is individualized (although it is not necessarily clear to women going through the programme how this is achieved). The advantage of the Decision Chart is that women are able to see information on outcomes but the evident complexity of the decision makes individualizing the information difficult.

Our sample had a different educational background to the general population in that slightly more women had attended full time education to later ages. Although we were not aiming to achieve a representative sample of women to use the decision interventions for this pilot study, the fact that even these women found the interventions difficult is important, and we would need to take this into account in further development of the interventions. We had planned to recruit a 'convenience sample' of women facing the actual decision. Our aim was to assess whether the decision interventions could be used in a 'real' situation, and to assess the range of women's views of the decision interventions in this situation and we were able to do this.

Other situational variables, may have affected our findings, for example the context in which the decision interventions were administered, and the role of the facilitator also may have had some effect on women's views towards the decision interventions. The busy hospital setting

where time was limited, coupled with anxiety about imminent impending surgery may have affected women's ability to absorb information or to respond effectively to the tasks required. Hysterectomy is a major operation and oophorectomy can be seen as a small part of a larger decision. This too, may have overshadowed or downplayed the issue of decision-making about oophorectomy. Certainly this study confirms that there is an issue in general in the timing and practicalities of use and administration of decision interventions.

As far as analysis was concerned, transcripts were read and analysed by two researchers working first separately and then together, to agree themes. Transcripts were read and re-read to ensure that themes were appropriate and aptly described and summarized the data. Discrepancies in the data were noted and information about them included where appropriate, for example in the widely differing reactions of women to the guidance statements produced by the CGP.

Conclusions

Women were able to use both decision interventions and both appeared to provide decision clarification. Given O'Connor's stated dimensions of a good decision¹ each of the decision interventions appears to be of value in some, but not all respects.

In the case of the CGP, the women received precise individualized guidance as to the operation they should undergo. In the case of the Decision Chart many women felt empowered by the information they received. However there were some problems with both decision interventions. The explicit incorporation of individual risks and preferences is the biggest difference between the two interventions described in this paper. Whilst the CGP aims explicitly to incorporate as much individual information as possible – it is evident that its processes for making best use of this information were not necessarily trusted by the women who used it. The other intervention – the Decision Chart – was more widely trusted, but incorporation of risks and

preferences is implicit and it is not easy to compute the effects of different risk on a range of different outcomes.

Further developments may be beneficial for both decision interventions. It would be easy to computerize the Decision Chart so that women could see the effects of 'individualizing' their risks of the various outcome conditions. As far as the CGP is concerned, enhanced explanation of the tasks and a more 'user-friendly' interface would both help. and it is also possible that women need more reassurance about the provenance of the CGP because it gives such clear guidance. In principle the CGP sits well with patient involvement in decision-making – however, this method of involvement may not suit everyone.

The results of this paper will be useful in considering the next generation of decision interventions. The ideal might combine elements of both the CGP and the Decision Chart. However there is a growing realization that preferences both for involvement in decision-making and in preferred decision-making style vary.^{34,35} and it will be important to take account of these before undertaking further refinement and evaluation of the decision interventions under discussion here.

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Conflicts of interest

None.

References

- O'Connor AM, Tugwell P, Wells GA, Elmslie T, Jolly E, Hollingsworth G. *et al.* A decision aid for women considering hormone therapy after menopause: decision support framework and evaluation. *Patient Education and Counselling*, 1998; **33**: 267–279.
- Oliver S, Rajan L, Turner H. Informed choice for users of health services: views on ultrasonography leaflets of women in early pregnancy, midwives and ultrasonographers. *British Medical Journal*, 1996; **313**: 1251–1255.
- Whelan TJ, Levine MN, Gafni A, Lukka H, Mohide EA, Patel M. *et al.* Breast irradiation postlumpectomy: development and evaluation of a decision instrument *Journal of Clinical Oncology*, 1995; **13**: 847–853.
- Thomson R, Parkin D, Eccles M, Sudlow M, Robinson A. Decision analysis and guidelines for anticoagulant therapy to prevent stroke in patients with atrial fibrillation. *Lancet*, 2000; **355**: 956–962.
- Barry MJ, Fowler FJ, Mulley AG, Henderson JV, Wennberg JE. Patient reactions to a program designed to facilitate patient participation in treatment decisions for benign prostatic hyperplasia. *Medical Care*, 1995; **33**: 771–782.
- Shiloh S, Sagi M. Effect of framing on the perception of genetic recurrence risks. *American Journal of Medical Genetics*, 1989; **33**: 130–135.
- Brun W. Risk perception: main issues, approaches and findings. In: Wright G, Ayton P (eds) *Subjective Probability*. Chichester: John Wiley & Sons, 1994: 295–320.
- Greenhalgh T. Narrative based medicine: narrative based medicine in an evidence based world. *British Medical Journal*, 2000; **318**: 323–325.
- Edwards A, Hood K, Matthews E. The effectiveness of one-one communication interventions in health care; a systematic review. *Medical Decision Making*, 2000; **20**: 290–297.
- Thomson R, Parkin D, Eccles M, Sudlow M, Robinson A. Decision analysis and guidelines for anticoagulant therapy to prevent stroke in patients with atrial fibrillation. *Lancet*, 2000; **355**: 956–962.
- Llewellyn-Thomas HA, Williams JI, Levy L, Naylor C. Using a trade-off technique to assess patients' treatment preferences for benign prostatic hyperplasia. *Medical Decision Making*, 1996; **16**: 262–272.
- Molenaar S, Sprangers MA, Postma-Schuit FC, Rutgers EJ, Noorlander J, Hendriks J. *et al.* Feasibility and effects of decision aids. *Medical Decision Making*, 2000; **20**: 112–127.
- O'Connor AM, Rostom A, Fiset V, Tetroe J, Entwistle V, Llewellyn-Thomas H *et al.* Decision aids for patients facing health treatment or screening

- decisions: systematic review. *British Medical Journal*, 1999; **319**: 731–734.
- 14 Pell I, Dowie J, Clarke AE, Bhavnani, V, Kennedy, A. Development and preliminary evaluation of a computerised clinical guidance programme for the prophylactic oophorectomy decision. *Quality in Health Care*, 2002; **11**: 32–39.
 - 15 Levine MN, Gafni A, Markham B, MacFarlane D. A bedside decision instrument to elicit a patient's preference concerning adjuvant chemotherapy for breast cancer. *Annals of Internal Medicine*, 1992; **117**: 53–58.
 - 16 Whelan T, Levine M, Gafni A, Lukka H, Mohide E, Patel M. *et al.* Breast irradiation postlumpectomy: development and evaluation of a decision instrument. *Journal of Clinical Oncology*, 1995; **13**: 847–853.
 - 17 Whelan T, Gafni A, Charles C, Levine M. Lessons from the Decision Board: a unique and evolving decision aid. *Health Expectations*, 1999; **3**: 69–76.
 - 18 Luoto R, Hemminki E, Topo P, Uutela A, Kangas I. Hysterectomy among Finnish women: prevalence and women's own opinions. *Scandinavian Journal of Society of Medicine*, 1992; **20**: 209–212.
 - 19 Maresh M, Metcalfe M, McPherson K, Overton C, Hargreaves J, Bridgman S. *et al.* The VALUE National Hysterectomy Study. *BJOG* (in press).
 - 20 Clarke A, Black N, Rowe P, Mott S, Howle K. Indications for and outcomes of total abdominal hysterectomy for benign disease: a prospective cohort study. *British Journal of Obstetrics and Gynaecology*, 1995; **102**: 611–620.
 - 21 Sherwin B, Gelfland M. Sex steroids and affect in the surgical menopause: a double-blind, crossover study. *Psychoneuroendocrinology*, 1985; **10**: 325–335.
 - 22 Nathorst-Boos J, von Schultz BJ. Oophorectomy combined to hysterectomy – time for a re-evaluation? *Journal of the Swedish Medical Association*, 1994; **91**: 933–936.
 - 23 Sightler S, Boike G, Estape R, Averette H. Ovarian cancer in women with prior hysterectomy: a 14-year experience at the University of Miami. *Obstetrics and Gynecology*, 1991; **78**: 681–684.
 - 24 Grundsell H, Ekman G, Gullberg B, Johnsson JE, Larsson G, Lindahl B. Some aspects of prophylactic oophorectomy and ovarian carcinoma. *Annales Chirurgiae et Gynaecologiae*. 1981; **70**: 36–42.
 - 25 Pell I, Dowie J, Clarke A, E. Bhavnani V, Kennedy A. *An Expert at Your Fingertips? Design and Preliminary Evaluation of a Computerised Clinical Guidance Programme for the Prophylactic Oophorectomy Decision*. Conference Proceedings: Society for Social Medicine. Norwich: University of East Anglia, 2000.
 - 26 Pell IB. *The Design and Implementation of a Prototype Clinical Guidance Program*. Essex: Department of Computer Science, University of Essex, 1999.
 - 27 Cher DJ, Miyamoto J, Lenert LA. Incorporating risk attitude into Markov-process decision models: importance for individual decision. *Medical Decision Making* 1997; **17**: 340–350.
 - 28 Clarke AE, Dowie J, Pell I, Bhavnani V, Kennedy A. *Development and preliminary evaluation of decision interventions: a Clinical Guidance Programme, a Decision Chart and a Booklet for the Prophylactic Oophorectomy Decision*. London: National Co-ordinating Centre for Service Delivery and Organisation R & D, London School of Hygiene and Tropical Medicine, 2000.
 - 29 Speroff T, Dawson NV, Speroff L, Haber RJ. A risk-benefit analysis of elective bilateral oophorectomy: effect of changes in compliance with estrogen therapy on outcome. *American Journal of Obstetrics and Gynecology*, 1991; **164**: 165–174.
 - 30 Grann VR, Panageas KS, Whang W, Antman KH, Neugut AI. Decision analysis of prophylactic mastectomy and oophorectomy in BRCA1-positive or BRCA2-positive patients. *Journal of Clinical Oncology*, 1998; **16**: 979–985.
 - 31 Schrag D, Kuntz KM, Garber JE, Weeks JC. Decision analysis – effects of prophylactic mastectomy and oophorectomy on life expectancy among women with BRCA1 or BRCA2 mutations. *New England Journal of Medicine*, 1997; **336**: 1465–1471.
 - 32 Strauss A, Corbin J. *Basics of Qualitative Research: Grounded Theory Procedures and Techniques*. Newbury Park: Sage, 1990.
 - 33 Gafni A. The standard gamble method: what is being measured and how it is interpreted. *Health Services Research*, 1994; **29**: 207–224.
 - 34 Dowie J. Distinguishing patient's meta-preferences for relationship model and decision mode is essential in designing and evaluating physician-patient decision support systems. In: *Workshop Models of the Physician–Patient Relationship and Methods for Eliciting Patient's Preferences*, Institut National de la Sante et de la Recherche Medicale (INSERM). La Londe les Maures, France, 2000.
 - 35 Robinson A, Thomson R. Variability in patient preferences for participating in medical decision making. implications for the use of decision support tools. *Quality in Health Care*, 2001; **10** (Suppl. 1): 134–138.