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**Determining information for inclusion in a decision support intervention for clinical trial participation: a modified Delphi approach**

Katie Gillies PhD<sup>1</sup>, Zoë C Skea PhD<sup>1,2</sup>, Sara J MacLennan PhD<sup>2</sup>, Craig R Ramsay PhD<sup>1</sup>, Marion K Campbell PhD<sup>1</sup>

1. Health Services Research Unit, University of Aberdeen, Aberdeen, UK
2. Academic Urology Unit, University of Aberdeen, Aberdeen, UK

Reprint requests: Katie Gillies, Health Services Research Unit, University of Aberdeen, Aberdeen, UK, AB25 2ZD

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## Abstract

- **Background** The use of decision support interventions in the context of decisions about trial participation is an emergent field. There is a lack of evidence about what information is deemed important to support decisions about informed consent for clinical trials, and whether different groups agree on the information for inclusion.
- **Purpose** The overall objective was to determine the items which different stakeholder groups viewed to be important for inclusion in a decision support tool when making decisions about clinical trial participation; with a view to use these as a framework for developing decision support tools in this context. This is the first study to have addressed this issue.
- **Methods** A modified Delphi method was used to determine agreement on importance of items. The 'stakeholder' panel was made up of 49 individuals from 5 groups: 11 trialists; 6 research nurses; 7 ethics committee chairs; 9 decision support experts and 16 patients (9 trial experienced and 7 trial non-experienced). Two rounds of rating were completed. Items with a median of 7-10 with  $\geq 65\%$  of any one group (from aggregate ratings) in agreement were considered important for inclusion.
- **Results** The stakeholder panel achieved consensus on the majority of items included (60/66), agreeing that these were important for inclusion in a decision support tool for trial participation. These included items covering: information about trial participation and standard care; information on the likelihood of receiving different treatments; information to help patients' determine what matters most to them; ensuring the information is balanced; guidance on how to make a decision; disclosure of any conflicts

of interest; using plain language in the tool and guidance on the decision support development process. Some areas of divergence amongst the panel were also identified relating to the use of patient stories.

- **Limitations** Selection bias may be a limitation in this study due to the manner in which the participants were invited to take part and therefore the representativeness, and reproducibility with another group of stakeholders, may differ.
- **Conclusions** Agreement was obtained on a number of items, which we recommend should be used as a framework to develop useful tools to support decision making about participation in clinical trials.

(word count 358)

**Keywords:** Informed consent, clinical trial, decision aid, Delphi.

## Introduction

The process of gaining informed consent for participation in clinical trials has been established as a mechanism to protect potential participants against undue harm and aims to allow participants to make informed and autonomous choices about whether or not to participate in research trials.<sup>1</sup>

When invited to participate, potential participants are currently provided with a patient information leaflet (PIL) that contains required information about the trial and may form the basis of their decision about participation.<sup>2</sup> It is also likely that a member of the research team will engage in a conversation with the participant to answer any questions or concerns the participant may have before their informed consent is sought. Despite this process, there is evidence that some trial participants, both those considering participation and those who are actively enrolled, fail to understand key components of the trial processes and/or rationale, putting into question the adequacy of the current informed consent process.<sup>3, 4, 5, 6</sup>

Several studies have investigated the effects of changing the structure of the information provided during the informed consent process for clinical trials mostly with the aim of improving understanding or recruitment.<sup>3, 6, 7</sup> Yet to date, none of these studies have been able to determine optimal strategies, or outcome measures, in this context. Moreover, a recent review highlighted that little empirical evidence exists with regard to what information potential participants want to know when considering trial participation.<sup>8</sup>

Although provision of fact-based information is an important step for decision making, other influences on the process have been shown to be important.<sup>4, 9, 10</sup> For example, one study

found participants who are less satisfied with their decision to participate feel significant regret about their decision.<sup>11</sup> This provides further evidence that trial participants potentially require greater support during the decision making process to ensure that any decision is right for them.

There is an established evidence base in the treatment and screening decision making field that has investigated ways of facilitating and improving decisions.<sup>12</sup> This work has led to the development of tools (“decision aids”) to support decision making,<sup>13</sup> These decision aids are designed to promote a specific, deliberative process of decision making allowing people to make explicit choices about options and clarify what domains are important to them. <sup>13</sup> There is evidence to show that decision aids are effective at improving decision making in a variety of clinical contexts.<sup>13</sup> and preliminary studies have begun to explore their potential role in the informed consent process for clinical trials .<sup>14, 15, 16, 17</sup>

The International Patient Decision Aid Standards (IPDAS) is a set of quality criteria for decision aids.<sup>18</sup> They focus not only on information provision, but also on aspects of the process of decision making; as such the application of the IPDAS principles may be a potential way to improve the decision-support process for informed consent for clinical trials.

The main objective of this study, therefore, was to determine the items (informational and procedural) which different stakeholder groups viewed to be important for inclusion in a decision support tool when making decisions about clinical trial participation; with a view to use these as a framework for developing decision support tools in this context. This is the first study to have addressed this issue.

## Methods

The Delphi method seeks to gain consensus of opinion from a pre-selected group of stakeholders, often experts in the field, by using a series of self-completed questionnaires in 'rounds' of responses.<sup>19</sup> The method can be used as a means of achieving consensus but also exploring divergence between stakeholder. As the panel of stakeholders do not meet, individuals can express their opinions without being influenced by others. This study employed a 'modified' Delphi, in that the items generated for inclusion were generated through a systematic review process and not through the traditional interviews and discussion with the stakeholder group.<sup>19, 20</sup> Modified Delphi studies have been conducted by other health services researchers.<sup>21, 22</sup>

### *Establishing the Delphi panel*

Purposive stratified sampling was used to establish the Delphi panel. We considered 5 stakeholder groups to be relevant for this study: trialists, research nurses, ethics committee chairs, decision aid researchers and patients, who were further sub-divided into a trial experienced (defined by taking part in at least 1 clinical trial) and trial non-experienced group. These groups were deemed important as they may be involved in the design, development, delivery, ethical review or be potential users of this type of decision support tool. Potential participants were invited to take part through email distribution lists (trialists: UK Clinical Research Collaboration Trial Managers listserv; research nurses: Scottish Research Nurse and Coordinators Network listserv; ethics committee chairs: National Research Ethics Service committee chair listserv; decision aid researchers: Society for Medical Decision Making Shared Decision Making Interest Group listserv; and patients: National Institute for Health Research Patient and Public Involvement listservs) and were

asked to respond directly to the lead researcher (KG) if interested in participating. Individual participants were anonymised, in that they did not know the identities of the other individuals in the group or specific answers that any other individual gave.

### *Delphi item development*

We searched Medline and EMBASE (1974-2010) using key words and terms including 'informed consent', 'clinical trial', 'randomisation', and 'guideline' to identify relevant guidelines on informed consent for clinical trials. The search was supplemented with known guidelines on the topic from clinical or regulatory bodies such as the General Medical Council, the Research Governance Frameworks, and guidelines produced by the National Research Ethics Service (NRES). Data regarding information or process requirements for informed consent for clinical trials was abstracted from the identified guidelines. The abstracted data were compared to items included in the IPDAS standards, which were relevant for decisions about trial participation, and topics developed into items for inclusion in the questionnaire. All identified items were included in the questionnaire. Any items with considerable overlap were included as one item. The questionnaire was piloted with researchers (n=10) and patients (n=5)

### *Round One*

The final questionnaire contained 66 items divided into 10 sections, which were based on the results from the systematic review and supplemented with items from the IPDAS (questionnaire available on request). We also collected some information on demographics of respondents in order to describe the sample. A covering letter was included that explained: the purpose and aim of the Delphi study, including the proposal that the items would inform development of an intervention to replace existing patient information

leaflets (items included in the questionnaire covered all existing ethical standards for patient information for clinical trial participation); how the items had been developed; and instructions on how to rate using the likert scale. Participants were given the option of receiving the questionnaire by post or email, with the email option providing an electronic version of the questionnaire for completion.

Each of the 10 sections was prefixed by a short introduction describing the purpose of that particular section and participants were asked to rate the importance of each individual item for inclusion in a decision support tool for trial participation. Importance was rated on a scale of 1 = not important to 10 = very important, or no opinion, (figure 1). A 10 point scale was chosen as it may limit the bias of central tendency found in using scales with odd values. There is evidence that using a 10 point scale, over a 5 or 7, should introduce more variability (Dawes et al). Participants could also include any additional comments in a free text box at the end of each section. Two rounds of rating were completed.

### *Round Two*

Three new items were included in the Round Two questionnaire based on comments received from round one. Consistent with the Delphi method, second round participants were presented with feedback information from round one. Feedback of both qualitative and quantitative data between rounds has been recommended.<sup>23</sup> For each item, feedback included a frequency distribution of the group scores, the median and interquartile range, individual participant's previous scores and a summary of the qualitative comments for each section (Figure 1). The quantitative data allowed participants to reflect on their own position relative to the rest of the group. The qualitative comments made during round one

were summarised to include both positive and negative attitudes expressed in round one to provide a contextual background against which participants could base their ratings.

Email reminders, using text suggested by Sinha *et al* (2011),<sup>24</sup> were sent to non-responders in each round. Final data on importance of items presented in this paper are based on second round median ratings only.

### *Definition of 'consensus'*

As there is no general agreement on the level of predetermined measures of consensus, we defined agreement as. Although some researchers argue that there has to be 100% agreement for consensus to be achieved, it is more common and acceptable that consensus is reached when the majority of experts agree on items.<sup>25</sup> Agreement on items was defined as any item for which 65% or more of any individual stakeholder group were in agreement. Agreement was first investigated across all respondents, then at an individual stakeholder group level. Items were classified as demonstrating 'agreement' as follows: median of 7 to 10 important and required for inclusion; median of 5 to 6 undetermined and require further follow up; median of 1-4 not important and not required for inclusion. Disagreement on items was defined by 30% or more ratings, of any individual group, being scored as 1-4 and 30% or more of the ratings being scored as 7-10. Items which exhibited disagreement were deemed as requiring further follow up. Any items that did not fulfil these decision rules were classed as equivocal and requiring further follow up.

### *Research governance requirements*

This study was approved by the North of Scotland Research Ethics Committee (REC Reference Number 09/S0802/105) and NHS Grampian Research and Development department (Reference Number 2009HS002).

## Results

### *Stakeholder panel*

Table 1 describes the participants' response rate in the first and second rounds. We approached people who expressed an interest to participate in the Delphi process in response to the email invitation. (Of those who expressed an interest, 60/66 (92%) completed round one and 49/60 (82%) completed both rounds of rating. Table 2 details the characteristics of the participants who completed both rounds. There was no significant difference in the number of individuals in stakeholder groups in the final sample. The participants had a varied distribution of experience with decision support tools, with 53% having no previous experience, 29% having limited experience and 18% being experienced.

### *Consensus across items*

The median ratings achieved for each item after two rounds of rating are reported in supplementary information (Table S1). Of the 69 items, agreement was reached, at an entire group level, on 53 items with 9 given an overall median of 8, 18 a rating of 9 and 26 a rating of 10. These 53 items were encompassed by the following sections: 'The development process'; 'Providing information about trial participation and standard care'; 'Presenting information on the likelihood of receiving different treatments'; 'Determining what matters to patients'; 'Decision guidance'; 'Disclosing conflicts of interest'; 'Balancing

the presentation of options'; and 'Using plain language'. Nine items had equivocal ratings in that they did not fulfil the criteria for agreement or disagreement at the entire group level (Box 1). . However, each of these items showed agreement on importance within at least one of the individual 'stakeholder' group and as such were deemed important for inclusion according to the predefined decision rules. Disagreement was exhibited, at a whole group level, on 6 items, which were contained within one main section; using stories from other participants (41, 42, 43, 45) and two additional items; item 56. *Readability levels are reported*; and item 65. *The date the decision support tool was produced is reported*. However, agreement was shown to be present by at least one stakeholder group for all of these items (supplementary information Table S2). Therefore, no items exhibited disagreement within all individual groups, as defined by the pre-stated decision rules.

#### *Variability between stakeholder groups*

Although many of the items exhibited agreement at an entire group level, specific stakeholder groups showed more variation than others on some items (for example, items 12. *The decision support tool presents information about the advantages/benefits of non-participation* and 13. *The decision support tool presents information about the disadvantages/harms of non-participation*). Also, the items that were deemed as 'equivocal' by the entire group, (i.e. no agreement or disagreement on importance), illustrated variability between stakeholder groups. Of particular interest, was that some of these items clustered in the 'Basing included information on up to date scientific information' section. Five out of the six items were shown to be equivocal at the entire group level with the remaining item showing disagreement.

The section on 'Using stories from other participants' exhibited noteworthy variability and highlighted areas of divergence between the groups. This section contained 5 items (41. *The decision support tool provides stories of other participants' experiences of deciding to participate, or not, in a trial*; 42. *The decision support tool provides stories that represent a range of experiences (positive and negative) of taking part, or not, in a trial*; 43. *The decision support tool explains the processes used to select these stories*; 44. *The decision support tool explains how experts reviewed the information contained within the stories*; and 45. *The decision support tool states that the participants gave informed consent to include their stories*), which were rated as 6, 6, 5, 4, and 7, respectively, by the group and all exhibited considerable distribution across the interquartile ranges (minimum 6 point difference). However, the stakeholder groups differed in their median ratings with the trial experienced patient group agreeing that 41, 42, 43, and 45 were important items (rated 9, 8, 8, 9 respectively) and the research nurse group also agreeing that item 45 was important (rated 9) (supplementary information Table S2). Yet, trialists and ethics committee chairs deemed these items less important (trialists rated 3, 4, 2, 3 and ethics committee chairs 2, 2, 5, 3 for items 41, 42, 43, and 45). Several of the comments provided in the free text boxes offered some insight into the variability exhibited for this item (Box 1).

Overall, irrespective of agreement or disagreement on items, trialists and ethics committee chairs tended to rate items less important compared to the other groups. For example, at a group level a total of 28 items were rated as a median of 10, whereas the trialist group and ethics committee chair group scored only 18 and 15 items a median of 10, respectively (Table 3). These two groups were also the only groups to score any items a median of 3 or 2. In Contrast, patients, in particular the trial experienced patient group, rated more items of higher importance compared to other groups, as they scored a total of 49 items a median

of 10 and scored no item less than 6 (Table 3). Decision aid researchers generally rated items of higher importance, not rating any item less than a 5 (Table 3). No individual group produced a median of 1 for any item.

## **Discussion**

### *Principal findings*

This is the first study, to our knowledge, to use a stakeholder consensus based approach to determine the importance of items for inclusion in a potential decision support tool to facilitate decisions about participation in clinical trials. The Delphi process determined that the majority of items (53/69, 77%) were deemed important by all stakeholders for inclusion in such a tool. The Delphi also revealed areas of divergence between groups, which highlight areas for further research. Where stakeholder groups' ratings differed, trial-experienced patients and decision aid researchers tended to give higher ratings where as trialists and research ethics committee chairs tended to rate items lower.

As with the Delphi study to generate the IPDAS,<sup>18</sup> our study identified the use of patient stories as a contentious area for inclusion in decision support tools for trial participation. Several of the comments, from the decision aid researchers, ethics committee chairs and trialists, illustrated concerns about using this type of information due to the lack of empirical evidence of the effect of patient stories on decision making and the caution that their use may potentially bias some decisions depending on how stories are selected and presented, which has also been discussed in the literature.<sup>26</sup> Yet patients and research nurses largely felt this information was important and would be helpful in such a tool. The impact of this information on decision making for trial participation requires evaluation.

Three sections which have been previously shown to be important for inclusion in decision support tools,<sup>18</sup> but not core to informed consent guidance, were strongly endorsed by the group when considering their importance for inclusion in a decision support tool for trial participation. These items are: a) presenting information on the likelihood of receiving different treatments (patient information leaflets provide information on the chance of receiving a treatment based on random allocation, but the guidance does not detail specify how to present and format probabilistic information to assist understanding of risk); b) determining what matters to patients; and c) decision guidance. “Decision guidance”, which is a structured approach designed to help patients think about the best option for them (it can include worksheets or a structured set of questions for a person to address), might usefully be prioritised for future research. These sections are not currently included in informed consent guidance yet there is evidence in the literature that provides further impetus to consider their inclusion.<sup>14, 15,2719</sup>

### *Strengths and limitations*

The primary strength of this study is that it is the first, to our knowledge, that has empirically addressed the issue of importance of information and decision support processes in a tool for trial participation using a consensus based approach across a range of stakeholders. A further strength of the study was the high response rates achieved across both rounds with little attrition between rounds (responses of 92% and 82% for round 1 and 2 respectively). This is encouraging as, unlike other methods, Delphi requires a continued commitment from participants as they are questioned repeatedly about the same topic using a slightly modified questionnaire.. Moreover, the method explicitly addresses the interests and involvement of several key stakeholder groups. Each of these groups was

given equal weighting during the analysis so as to retain the representativeness in the final item set.

A recognised concern with the Delphi method is the selection of the stakeholder panel as there is no explicit guidance on sampling techniques for this purpose.<sup>28</sup> It is likely selection bias may be a limitation in this study due to the manner in which the participants were invited to take part and therefore the representativeness, and reproducibility with another group of stakeholders, is not assured. However it is accepted that having a heterogeneous group, where stakeholders are drawn from varied backgrounds, can ensure a wider knowledge base and may allow for consideration of different perspectives.<sup>29</sup> As such, our multidisciplinary panel may help to balance any bias introduced through sampling. Lastly, respondents were not explicitly asked to rank importance of Delphi items whilst considering contextual factors such as time, cost, resource, etc, all of which may have influenced their perceived importance when faced with making a trade-off. However, some of these factors, such as time, were identified in the open comments section of the questionnaire by some respondents. Therefore, it could be deduced that the Delphi participants considered such external factors implicitly when making their determinations of items of importance for inclusion.

### *Results in context*

To our knowledge no formally published data exist on eliciting stakeholder consensus on items important to facilitate decisions about clinical trial participation. The Delphi method was the appropriate method to use to answer this research question for its value in extracting and combining the views of many stakeholders. A further strength of the method

was the ability to analyse the data according to stakeholder group so as to reflect the priorities of individual groups as well as the entire group, in context.

The results may have implications for those recruiting potential participants to clinical trials as they suggest ways of improving the presentation of information, provide methods to allow personalisation of the information for the individual and provide suggestions for guidance through the decision. The purpose of the aggregated list is not to be prescriptive but more to provide potential solutions to improve the quality of decision making and better support the process in a trial context. However, these potential solutions require further analysis and empirical evidence to warrant use in practice.

Future research could explore the prioritisation of the items agreed as important by asking participants to rank the most important items, or sections, to give an indication of priority. Further work should also explore the lack of group consensus on specific items, such as the use of patient stories, amongst the different stakeholder groups.

## **Conclusions**

This study has used a robust approach to develop stakeholder consensus on items that could be included in decision aids for trial participation. We recommend that this list forms the framework to inform any future studies on the development of tools to support decision making about participation in a clinical trial. These tools should then be evaluated, against existing methods, for their ability to support the decision making process for clinical trial participation on a range of outcomes for decision quality and trial methodology.

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### **Declaration of conflict of interest**

The authors declare that there is no conflict of interest.

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