

Patient attitudes to clinical trials: development of a questionnaire and results from asthma and cancer patients

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Abstract

Objective To develop a questionnaire to assess patients' views of clinical trials, and to report the results from the questionnaire in two patient groups: asthma and cancer.

Design A 43 item questionnaire asking patients about their views to clinical trials was developed on the basis of interviews with trialists and focus groups with patients. The questionnaire was mailed to patients with a diagnosis of either asthma or cancer. A set of items was then selected, via statistical analyses, to form the core of the questionnaire.

Participants Patients with a diagnosis of cancer in one NHS Hospital Trust, and patients with a diagnosis of asthma in two NHS Hospital Trusts.

Results Completed questionnaires were received from 353 cancer patients and 578 asthma patients. Factor analyses of the data indicated that 22 items contributed to five dimensions: 'positive beliefs', 'safety', 'information needs', 'negative expectations' and 'patient involvement'. Differences between asthma and cancer patients on these dimensions were small. A regression of these dimension scores against a variable asking if patients would be willing to take part in trials found that 'safety' and 'information needs' did not contribute significantly to the model for either asthma or cancer patients.

Conclusions A questionnaire has been developed for use in assessing patients' views towards clinical trials. Results from the surveys reported here suggest that patient views about the importance of trials and beliefs about the value of patient involvement are likely to be predictive of whether or not patients will agree to take part in a study.

Introduction

Randomized controlled trials are widely accepted by the medical and scientific communities as the most rigorous method for evaluating interventions of health care. However, recruitment to trials can prove problematic.^{1–4} Evidence from cancer trials indicate that less than half of the patients eligible for inclusion and invited to take part agree to do so.⁵ Trials can fail in situations where insufficient patients are recruited, and so it is important to encourage participation. To do this an understanding of patients views of trials is essential.

A number of methodologies have been used to gain insight into patient views of trials. Focus groups, in-depth interviews and questionnaires have been adopted.^{6–10} However, no evidence was found of research papers explicitly outlining the development of questionnaires to assess patient attitudes to trials that had been based on both (i) patient reports for the derivation of items and (ii) psychometric testing to determine their operating characteristics. Such an approach is now regarded as the gold standard method for the construction of measures designed to elicit the views of patients.^{11–14} An instrument developed in such a way is desirable as it could be used to systematically assess patients views of trials across illness groups.

The purpose of this study was twofold. Firstly, to develop a questionnaire to assess patients views of trials and, secondly, to see if scores on the questionnaire could predict self reported willingness to take part in a trial. Two patient groups were selected: asthma and cancer. These conditions were selected to elicit the views of patients with a life-threatening illness as well as those with less severe problems, representing different groups likely to be involved in medicines evaluation. Items for inclusion in an initial pilot instrument were based on content analyses of transcripts of in-depth interviews with trialists and focus groups with patients. Surveys using the pilot instrument were then undertaken to determine the

items for inclusion in the final questionnaire. The psychometric properties of the resulting measure, and its ability to predict self-reported willingness to take part in a trial, were then assessed.

Methods

A three-stage strategy was used in order to develop and test the questionnaire.

Stage 1 – item generation

In the first stage of the research preliminary in-depth interviews were held with nine UK-based researchers with extensive knowledge and experience of running trials. The purpose of this part of the study was to gain professional judgement that could supplement that gained from searching the literature. These interviews were in part used to inform the topic guide for focus groups held with patients. Four patient focus groups were then undertaken with two illness groups: asthma and cancer. All interviews and focus groups were tape-recorded, transcribed and underwent content analysis.

Focus groups were conducted in a hospital in Oxfordshire and a hospital in Sheffield. These hospitals provided contact names for self-help/support groups and consequently three of the focus groups were formed from well-established asthma and cancer self-help groups which met regularly either within the hospital or a group member's home. Other asthma patients were recruited individually to form one focus group. Content analysis of transcripts of these discussions was used to identify issues of importance to the patients and to determine the ways in which they expressed their opinions. A list of issues relating to patient views of clinical trials was extracted from the transcribed interviews. Items for inclusion in the pilot questionnaire were devised from this list by three researchers. These were then discussed, scrutinized for repetition and ambiguity, and a final set of items agreed. Full documentation on the development of the item set is available from the senior author – this

paper reports stages 2 and 3 which are the surveys of patients with cancer and asthma.

Stage 2 – item reduction and scale generation

In the second stage of the research patient surveys were undertaken. The questionnaire developed in stages 1 and 2, above, was mailed to patients with a diagnosis of either cancer or asthma at three separate hospitals. A covering letter made clear that patients were not being asked to take part in a trial but being asked to complete a questionnaire about their attitudes to medical research and clinical trials in particular. A reminder card was sent after 2 weeks and a second copy of the questionnaire was mailed to non-responders 4 weeks after the original mailing. Analysis of these data using factor analytic techniques produced the final item pool for inclusion in the questionnaire.

Stage 3 – data completeness and internal reliability

In the third stage of the research data is reported on the data completeness of items and dimensions of the questionnaire, and the internal reliability of the dimensions. Some substantive findings from the final questionnaire are also reported, including the extent dimensions on the questionnaire predict the answer to a single item asking patients whether they would consider taking part in a trial in the future.

The questionnaire

The questionnaire was designed in the form of statements to be evaluated against a five-point agree–disagree scale. The initial survey instrument contained 43 items, each of which fell into one of three broad categories. These were:

- Knowledge and Beliefs – included statements that either reflected knowledge of trial methodology and the purpose of trials or beliefs about how they were conducted.
- Preferences and Expectations – included statements that reflected preferences on how people wished to be treated should they

themselves take part in a trial and expectations of how they thought they may be treated should they take part in a trial.

- Attitudes towards trials – included statements that broadly reflected general views about the purpose of trials. Statements on payment were also included in this group.

Twelve items were placed in the category ‘Knowledge and Beliefs’, 12 items in ‘Preferences and Expectations’ and 11 item in ‘Attitudes towards trials’. A copy of the original questionnaire indicating the items placed in these categories is available from the first author.

Statistical analyses

The target sample size was based on the assumption that factor analytical procedures require between three and ten times as many respondents as items.¹⁵ Thus, as a conservative (i.e. large) estimate, 400 completed questionnaires was the target for each group of patients, but with a minimum of 140 per group being acceptable. Principal component analyses were followed by factor analyses with varimax rotation of factors as a first step in reducing the available data to meaningful scales. Analyses were undertaken separately for each of the three categories into which items had originally been allocated. Only factors which gained an eigenvalue in excess of 1 were retained. Items with a loading of <0.4 for any of the factors were omitted.¹⁶

The resulting items for each factor were then assessed for internal consistency using item-total correlation corrected for overlap. Only items with a correlation of 0.3 or higher were included in the final item sets.¹⁷ Internal consistency reliability was then calculated for each set of items using the Cronbach’s alpha statistic. Linear regression analysis was then performed to see which of these domains was most predictive of the answer to a question asking if respondents would take part in a clinical trial. Differences between means were assessed by Mann–Whitney tests of statistical significance. Statistical significance was achieved if $P < 0.02$.

Ethical approval

Ethics Committee approval for this study was obtained from the South East Multi-centre Research Ethics Committee (ref: MREC 02/01/93).

Results

A total of 492 questionnaires were mailed to patients with a diagnosis of cancer. Of these 406 (82.52%) were returned, of which 53 (10.77%), were returned without being completed. There were thus 353 satisfactory questionnaires available for analysis. A total of 1659 questionnaires was mailed to patients with a diagnosis of asthma, of which 806 (48.58%) were returned. Of these 228 (13.74%) were returned without being completed. The total of completed questionnaires from asthma patients was therefore 578. Table 1 documents the reasons for the uncompleted returns for both disease groups. The mean age of respondents diagnosed with cancer was 61.87 years (SD 11.95; min = 27, max = 84; $n = 322$). Of those answering the question on sex 169 (52.2%) indicated they were male and 155 (47.8%) indicated they were female. The mean age of respondents with a diagnosis of asthma was 49.45 years (SD 16.90; min = 16, max = 91; $n = 561$). Of those answering the question on sex 208 (36.9%) indicated they were male and 356 (63.1%) indicated they were female. Respondents were asked whether they had ever been asked or taken part in a trial, as well as whether they would take part in one if invited (see Table 2). Of the 175 who had been asked to take part 123 (70.29%) said they had taken part in such a study. Of the sample as a whole 518

Table 1 Reasons for non-returns (percentage is percentage of questionnaires returned)

	Asthma	Cancer
Undeliverable	100 (12.41)	5 (1.23)
Deceased	14 (1.74)	2 (0.49)
Illness	5 (0.62)	2 (0.49)
Opted out/no reason given	109 (13.52)	44 (10.84)

Percentage values are given in parentheses.

Table 2 Respondents indicating whether they had ever been asked to take part in a trial, whether they had taken part in a trial, and willingness to take part in a trial

Respondents indicating they had been asked to take part in a trial	
Yes	175 (18.8)
No	694 (74.4)
Don't know	39 (4.2)
Respondents who had taken part in a trial	
Yes	131 (14.0)
No	733 (78.6)
Don't know	40 (4.3)
Willingness to take part in a trial	
Definitely	135 (14.5)
Probably	383 (41.1)
Unsure	250 (26.8)
Probably not	108 (11.6)
Definitely not	35 (3.8)

Percentage values are given in parentheses.

(55.6%) respondents indicated they would definitely or probably take part in a trial. These results suggest a generally positive view of trials.

Factor analysis was performed on items in each of the three broad categories included in the 43 item questionnaire. All data was included in this analysis (i.e. not broken down by condition). Principal component analysis of the 'Knowledge and Beliefs' questions produced four factors with eigenvalues greater than one. After rotation eight items had loadings of 0.4 or greater on two meaningful and interpretable factors, which accounted for 38.71% of the variance. These formed scales which measured: 'Positive Attitudes to Trials' and 'Safety'. For each dimension item total correlations were greater than 0.3 for each item. Consequently, no items were removed from either scale. Cronbach's alpha statistics for the two dimensions was found to be 0.73 and 0.64.

Principal component analysis of the 'Preferences and Expectations' questions produced five factors with eigenvalues greater than one. After rotation 12 items had loadings of 0.4 or greater on two meaningful and interpretable factors, which accounted for 38.71% of the variance. These formed scales which measured: 'Information Needs' and 'Negative Expectations'. For each dimension only items with item-total

correlations greater than 0.3 were retained. Consequently, two items were removed from the 'Information Needs' scale. Cronbach's alpha statistics for the two dimensions was found to be 0.70 and 0.72.

Principal component analysis of the 'Attitudes' questions produced four factors with eigenvalues greater than one. After rotation five items had loadings of 0.4 or greater on one meaningful and interpretable factor, which

accounted for 21.89% of the variance. These items formed a scale which measured: 'Patient Involvement'. Item total correlations were greater than 0.3 for all but one item, and consequently four items were retained in this scale. Cronbach's alpha statistics for this dimension was 0.64.

Item content, and item to total correlations for the five dimensions of the questionnaire is reported in Table 3.

Table 3 Questionnaire item content and item – total correlations (corrected for overlap) for each of the five dimensions of the questionnaire

	Correlation
Positive Beliefs scale ($\alpha = 0.73$)	
23. New and better treatments can only be produced if patients agree to take part in clinical trials	0.58
26. Without the results from clinical trials, doctors would be less able to select the best treatment	0.56
33. Pharmaceutical companies should ensure that valid clinical trials are conducted on every drug before it is generally available	0.38
37. If most patients refused to take part in clinical trials, important developments in medicine would be seriously delayed	0.57
Safety scale ($\alpha = 0.64$)	
31. Clinical trials are carried out according to strict rules to safeguard the interests of patients	0.45
36. I assume that drug treatments that have been prescribed for me have already been thoroughly tested in clinical trials	0.30
39. Clinical trials are only conducted on drugs for which there is already evidence to show that they are likely to be effective.	0.38
40. The conduct of all clinical trials is carefully regulated to ensure that the results are valid	0.53
Information Needs scale ($\alpha = 0.70$)	
7. I would want as much written information as possible about a clinical trial before I agreed to take part	0.48
11. I would want to know before agreeing to take part that I would be free to withdraw from the clinical trial at any time	0.50
15. I would want to know if I would be likely to get side effects by taking part in a clinical trial before I agreed to take part	0.53
22. I would only take part in a clinical trial if I thought I understood everything about it	0.47
Negative Expectations scale ($\alpha = 0.72$)	
4. I think I would find being in a clinical trial frightening	0.41
10. I would only take part in the clinical trial if I thought that my own health would benefit	0.51
14. I would only take part in a clinical trial if I thought that I would not be inconvenienced by doing so	0.37
16. I would only take part in a clinical trial if I knew which treatment I was going to receive	0.56
17. I would only take part in a clinical trial if I was sure that the doctor treating me knew which treatment I was getting	0.49
38. If I was satisfied with my current drug treatment, I would probably refuse to take a different drug in a clinical trial	0.42
Patient Involvement scale ($\alpha = 0.64$)	
5. It is important for people like me to take part in clinical trials to confirm the value of new treatments and/or medical techniques	0.48
12. I would take part in a clinical trial because the results should benefit patients like me in the future	0.48
18. I think all patients who are eligible should be asked to take part in clinical trials	0.42
32. Unless advised by their doctor to withdraw from a trial, all patients should co-operate fully until the trial is finished	0.34

Data completeness was high. For those cancer patients who responded and completed the questionnaire, 331 (93.76%) completed all 22 items enabling scores on all five dimensions to be calculated. Dimensions scores could be calculated for 338 (95.75%) respondents for the Negative Expectations score, 344 (97.45%) for the Safety scale, 347 (98.30%) for Positive Attitudes and Patient Involvement scales and 348 (98.58%) for the Information scale. For those asthma patients who responded and completed the questionnaire 534 (92.38%) completed all 22 items enabling scores on all five dimensions to be calculated. Dimensions scores could be calculated for 553 (95.68%) respondents for the Negative Expectations score, 557 (96.37%) for the Safety scale, 560 (96.89%) for the Patient Involvement scale, 563 (97.40%) for the Positive Attitudes scale, and 348 (97.40%) for the Information scale.

Descriptive statistics for the five dimensions of the questionnaire, broken down by illness group, are reported in Table 4. Scores on each dimension range from 0 (high level of disagreement) to 100 (high level of agreement). Interpretation of scores is shown in Table 5. Results between illness groups on the five domains of the questionnaire were compared, and statistically significant differences were only found on the mean scores between the two illness groups on the 'Information Needs' and 'Safety' scales ($P < 0.01$). Furthermore, whilst the differences were statistically significant they were small and unlikely to be meaningful.

Respondents were asked if they would, in principle, be willing to take part in a randomized trial of treatments. Responses were on a five point scale – 'Definitely', 'Probably', 'Unsure', 'Probably not' and 'Definitely not'. A total of 175 (36.5%) of cancer patients in the study said

Table 4 Descriptive statistics for domains of the questionnaire broken down by illness group

	<i>n</i>	Mean	SD	Median	Min	Max
Cancer respondents						
Positive attitudes	347	80.87	11.99	81.25	50.00	100.00
Safety*	344	74.06	19.93	75.00	31.250	100.00
Information*	348	83.51	12.96	87.50	37.50	100.00
Negative expectations	338	59.92	16.59	62.50	16.67	100.00
Patient involvement	347	70.25	16.44	75.00	0	100.00
Asthma respondents						
Positive attitudes	563	80.54	13.10	81.25	18.75	100.00
Safety*	557	72.24	13.25	68.75	37.50	100.00
Information*	568	85.64	12.49	87.50	0	100.00
Negative expectations	553	60.32	16.90	62.50	0	100.00
Patient involvement	562	69.45	17.23	66.67	8.33	100.00

*Mean scores were significantly different, $P < 0.01$.

Table 5 Interpretation of scores on the domains of the questionnaire

Dimension	Low score	High score
Positive Beliefs scale	Respondents hold negative views about trials	Respondents hold positive views about trials
Safety scale	Respondents assume safeguards may not be in place	Respondents assume safeguards in place
Information Needs scale	Respondents do not require information	respondents require information
Negative Expectations scale	Respondents do NOT have negative expectations of taking part	Respondents DO have negative expectations of taking part
Patient Involvement scale	Respondents believe patients should not be involved	Respondents believe patients should get involved

	Unstandardized coefficients		Std coeffs (β)	<i>t</i>	Sig.
	<i>b</i>	SE			
Oncology patients					
Constant	3.45	0.44		7.82	0.001
Positive Beliefs scale	0.12	0.005	0.15	2.54	0.01
Safety scale	0	0.004	0.05	0.89	NS
Information Needs scale	0	0.004	-0.03	-0.50	NS
Negative Expectations scale	-0.02	0.003	-0.38	-7.21	0.001
Patient Involvement scale	0.02	0.004	0.24	3.93	0.001
Asthma patients					
Constant	3.29	0.35		9.37	0.001
Positive Beliefs scale	0.01	0.004	0.12	2.39	0.02
Safety scale	0.01	0.003	0.07	1.69	NS
Information Needs scale	0	0.003	-0.02	-0.45	NS
Negative Expectations scale	-0.02	0.003	-0.32	-7.37	0.001
Patient Involvement scale	0.01	0.004	0.23	4.90	0.001

Adjusted $r^2 = 0.36$ (for cancer patients) and 0.26 (for asthma patients). Std coeffs, standardized coefficients.

they would 'probably' or 'definitely' take part in such a study, and a further 114 (32.1%) were unsure. A total of 343 (44.3%) of asthma patients said they would 'probably' or 'definitely' take part, and 136 (23.5%) were unsure. Linear regressions were undertaken, one on the data from cancer patients and one on the data gained from asthma patients, to determine which of the five domains of the new questionnaire was predictive of responses to the question as to whether respondents would take part in a trial. Strikingly, for neither group did the 'Information' or 'Safety' scale contribute significantly to either model (see Table 6). 'Positive attitudes' to trials, 'Negative Expectations' and 'Patient Involvement' scales contributed significantly in both groups.

Finally, descriptive data for the five domains of the questionnaire is presented broken down by responses to the question whether patients would take part in a trial. In this analyses respondents on the five-point scale were reduced to three groups – those indicating they would take part, those who were unsure and those who said they would not take part. Comparing those who said they would take part in a trial as opposed to those who said they would not revealed significant differences on each domain ($P < 0.001$ for each comparison) except for the

Table 6 Linear regression of questionnaire domains against dependent variable (stated willingness to take part in a trial. Response categories 'Definitely', 'Probably', 'Unsure', 'Probably Not' and 'Definitely Not')

'Information' scale (see Table 7). Thus, those who said they would take part in a trial had higher scores on the 'Patient Involvement', 'Positive Attitudes' and 'Safety' scales, and a lower score on the 'Negative Attitudes' scale than those who said they would not wish to take part.

Table 7 Descriptive statistics on the five scales of the questionnaire broken down by response to the question asking if patients would you take part in a clinical trial

	<i>n</i>	Mean	SD	CI
Positive attitudes				
Yes	511	83.78	11.89	82.7–84.8
Unsure	247	78.42	11.83	76.9–79.9
No	136	73.67	13.32	71.4–75.9
Safety				
Yes	507	74.82	12.66	73.7–75.9
Unsure	243	70.94	13.14	69.1–72.7
No	135	69.86	14.30	67.4–72.3
Information				
Yes	513	83.72	12.67	82.6–84.8
Unsure	249	86.27	11.26	84.9–87.7
No	139	86.46	14.85	84.0–89.0
Negative attitudes				
Yes	501	55.08	17.17	53.6–56.6
Unsure	244	65.04	13.06	63.4–66.7
No	132	70.57	13.62	68.2–72.9
Patient involvement				
Yes	511	74.59	15.69	73.2–76.0
Unsure	148	64.58	14.74	62.2–67.0
No	135	60.37	18.81	57.2–63.6

Discussion

The research reported in this paper has developed a questionnaire to assess peoples' knowledge, beliefs, preferences and attitudes to clinical trials. Analyses of results from the questionnaire indicated it to be multidimensional, and the internal reliability consistency of the domains was found to be acceptable.^{18–20} The quality and completeness of answers provided by respondents was high suggesting that the items both made sense to them and were appropriate.

The derivation of items for the questionnaire was primarily undertaken on the basis of focus groups with patients. Strikingly, the issues discussed by patients in these different groups were remarkably similar, despite diagnosis (of cancer or asthma). Groups were encouraged to discuss any aspect of health care evaluation they wished but questions were also posed by the moderator to ensure that all key issues were examined. Similarly, in the survey data reported here the results gained from the two illness groups were remarkably similar. This would tend to suggest that attitudes to trials are similar across diverse illnesses. The factors predicting willingness to take part were positive attitudes towards trials, negative expectations of being involved in such a study and beliefs about patient involvement.

The results reported here suggest that simply providing information and assuring patients that trials are safe is unlikely to influence them to take part: it seems likely that this is the least they expect and largely take for granted. Indeed one earlier study found that adapting the level of information to suit individual patients had no effect on accrual.⁴ More important are their own views towards trials, and patient involvement. Negative attitudes include expressed fears about being in a trial, not wishing to be in a study where patients do not know what treatment they are receiving, and not wishing to be inconvenienced. Positive attitudes to trials and patient involvement in research are likely to lead to a more positive attitude towards taking part. When recruiters are trying to encourage participation in a trial, their efforts are likely to be

more successful if they take account of the pre-existing views of patients in addition to explaining the purpose and requirements of the trial for which they are recruiting.

In the longer term efforts are clearly required to promote the benefits of trials by disseminating valid information about the purposes and benefits of trials as well as explanations of the methods used. Changing the views of those patients who hold negative opinions is a considerable challenge, and will require a shift in how patients perceive medical research and the importance of their involvement in it. However, the research reported here for asthma and cancer patients shows attitudinal profiles that are probably more favourable than many with an interest in the conduct of trials would have expected. Further research should determine whether this is true for patients with other conditions, as well as explore how well the dimensions of the questionnaire predict actual participation in trials.

Conflict of interest

All authors declare that the answer to the questions on your competing interest form are all No and therefore have nothing to declare.

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