

RESEARCH ETHICS

Patients' perceptions of information provided in clinical trials

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Background: According to the Declaration of Helsinki, patients who take part in a clinical trial must be adequately informed about the trial's aims, methods, expected benefits, and potential risks. The declaration does not, however, elaborate on what "adequately informed" might amount to, in practice. Medical researchers and Local Research Ethics Committees attempt to ensure that the information which potential participants are given is pitched at an appropriate level, but few studies have considered whether the patients who take part in such trials feel they have been given adequate information, or whether they feel able to understand that information.

Objectives: To explore trial participants' views (i) on the amount of information provided, and (ii) of their own understanding of that information.

Design: Structured interviews of patients participating in clinical trials for the treatment of chronic medical condition.

Findings: Patients generally felt they were given an appropriate amount of information, and that they were able to understand all or most of it. They felt they were given adequate time to ask questions before agreeing to take part. In comparison with treatment given outwith the research setting, patients generally felt they received more information when participating in a clinical trial.

Conclusions: Researchers sometimes complain that patients are given too much information during clinical trials, and have limited understanding of that information. The present study shows that this perception is not necessarily shared by patients. More research is needed in this area, particularly to gauge whether patient understanding is indeed accurate.

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A patient's consent to participate in a clinical trial can only be regarded as morally acceptable if he or she is competent and a genuine volunteer. Not only must potential participants be provided with adequate information on which to make a decision, they must also be able to understand that information. Despite this, several studies have found that the information provided to patients taking part in clinical trials is frequently too technical for the layperson to understand, or is pitched at a reading age which is too advanced for many patients. Priestley *et al*¹ compared the readability of 50 consent forms for clinical trials with that of ten British daily newspapers using the Gunning fog and Flesch-Kincaid indices. They found that the consent forms were "significantly more difficult to read than newspaper editorials". Several studies have subjected information leaflets to scrutiny: Tarnowski *et al*²; Grossman *et al*³ and Meade and Howser.⁴ More positive findings emerged in a study by Murphy *et al*.⁵ Other studies, such as that of Corbett, Oldham and Lilford,⁶ have asked potential trial participants to assess their information requirements in respect of hypothetical trials. Only a few studies have asked patients who are actually participating in clinical trials to assess the adequacy of the information they have received.⁷⁻¹² The aims of the present study were to explore the extent to which clinical trial participants feel that they are given adequate information, and whether they feel they have a reasonable understanding of that information. The study did not attempt to ascertain whether patients' understanding was, in fact, accurate, but rather it concentrated on the patients' own perceptions of this; the issue under investigation was not "are clinical trials patients adequately informed?", judged by some objective criterion, but rather "do patients themselves feel that they are adequately informed?"

METHODS

Participants

At the outset, 104 patients were interviewed by the investigator. The patients were each participating in one of 14 different clinical trials. It became apparent at an early stage in the data analysis that the responses of patients in one of the trials differed markedly from those in the other trial groups. It emerged that there were potential problems with the former group in that several of them felt they had been invited to participate at an inappropriate time, hence their responses were analysed separately. This comparison, between the responses of patients in the "problem group" and those of the remainder of patients, forms the subject matter of a separate paper.¹³ The views of the "problem group" have not been included in the present paper, since this would tend grossly to distort the findings, and give a false impression of the views of trial participants, generally. As a result, the present paper focuses on the responses of the 78 patients in the remaining 13 clinical trials (54% female). The numbers interviewed in each study ranged from one patient per study (in two cases) to 18 patients in the largest study. The nature of the clinical trials included phase II, III, and IV studies. These studies included research into hypertension, multiple sclerosis, motor neurone disease, hormone replacement therapies, diabetes, arthritis, and strokes. It should be noted that these are all chronic medical conditions, hence information-giving and the obtaining of patient consent could take place without the degree of urgency required in trials conducted during more traumatic situations, such as for the treatment of an acute cardiovascular episode.¹⁴ All trials were based in one geographical location, but comprised both hospital and general practitioner (GP) practices. Researchers were assured that their studies would not be identified other than in this very general fashion, hence no further details can be given about the trials.

Table 1 Patients' perceptions about the amount of information they received

	Too much n (%)	Right amount n (%)	Too little n (%)	Can't remember n (%)
The amount of information	2 (3)	73 (94)	2 (3)	1 (1)

Figures in tables are given to nearest whole number. n=78 in all cases.

Table 2 Patients' perceptions of their understanding of the information

	Understood all of it n (%)	Understood most of it n (%)	Understood very little n (%)	Don't remember getting any information n (%)
Understanding of information	39 (50)	38 (49)	–	1 (1)

Figures in tables are given to nearest whole number. n=78 in all cases.

Materials and procedures

The patient interviews formed part of a wider study into legal and ethical aspects of clinical trials, conducted by the author in 1997. In order to respect patient confidentiality, it was agreed with the Local Research Ethics Committee (LREC) that researchers would inform the investigator of the times of a patient's next appointment. The investigator attended the GP surgery or outpatient clinic at those times, and a researcher or member of the nursing staff then asked the patient if he or she was willing to be interviewed. This allowed patients to refuse to participate without their identities being revealed to the investigator. It was made clear to patients that this study was being conducted by an academic researcher, not a medical professional; that their answers would not be communicated to their doctors, and that any publication of results would not reveal their identities. Patients were advised that they were under no obligation to participate in this interview process. No questions were asked about a patient's medical condition or medical history. The terms of this preliminary information were approved by the LREC. The wording of the questions to be asked of patients during the interviews was discussed with a medical researcher who had a wealth of experience in drug studies, scrutinised by the LREC, then piloted with eight patients. Each patient in the pilot group was interviewed as normal, but was thereafter invited to comment on the clarity of the questions and on the range of available responses. This allowed the investigator to check for problems of ambiguity, and any difficulties patients experienced in answering. The interview questions were slightly modified in light of comments from the ethics committee, and from the pilot group. Each patient was interviewed in person by the investigator. These interviews lasted from 20 to 30 minutes.

As well as being asked to assess the amount of information they were given, and to comment on their understanding of that information, patients were asked whether they had been given an adequate opportunity to ask questions, before agreeing to participate. They were also invited to compare their experience as a clinical trial subject with the more common situation in which they were treated by their GP or hospital doctor, and to compare the amount of information they were given about the drug they were taking during the trial with the information that they were generally given about drug treatments. This question was asked in relation to a number of variables. The questions asked of participants, and the response options for each question, are shown in appendix 1.

RESULTS

As table 1 shows, the vast majority of patients (73 (94%)) felt they had received the right amount of information about the proposed trial; only two (3%) would have liked more, and two

patients less information. Comments from those who felt they received the right amount of information include:

It was about as much as you could take in. I might want more as it goes on, but initially it was fine.

It seemed to be enough for me. If I hadn't got enough or I'd been baffled, I wouldn't have bothered taking part.

The doctor went over everything thoroughly and the nurse phoned me at home to check I understood.

In terms of patient understanding, as table 2 shows, 39 patients (50%) felt they understood all of the information they had been given, and 38 (49%) that they understood most of it, but that there were some things they did not understand. One patient did not remember having received any information about the study.

One patient commented that he had to read the information leaflet "two or three times" in order to understand it. Another added:

On re-reading it and getting to know what I'm doing, it made sense.

A patient who had understood most, but not all, of the information commented that the information leaflet had contained "medical terms that were beyond me".

He also felt that some of the information was "too technical". He added:

I am probably above average intelligence . . . Others would surely struggle with the information.

Table 3 Time to ask questions, prior to agreeing to participate

	Plenty of time n (%)	Little opportunity n (%)	Can't remember n (%)
Adequate time to ask questions?	74 (95)	2 (3)	2 (3)

Figures in tables are given to nearest whole number. n=78 in all cases.

Table 4 Patient satisfaction with answers to questions

	Completely satisfied n (%)	Mostly satisfied n (%)	Not satisfied n (%)	Didn't ask questions n (%)	Can't remember n (%)
Satisfaction with answers to questions	40 (51)	10 (13)	–	21 (27)	7 (9)

Figures in tables are given to nearest whole number. n=78 in all cases.

Table 5 Comparison with treatment in non-trial setting

Information about:	Told much more about trial drug n (%)	Told a little more about trial drug n (%)	Told same amount n (%)	Told less about trial drug n (%)	Told far less about trial drug n (%)	Unable to compare n (%)	Not discussed n (%)	Not applicable n (%)
The way the drug works?	25 (32)	5 (6)	9 (12)	–	–	3 (4)	36 (46)	–
How to take the drug?	17 (22)	4 (5)	40 (51)	–	–	5 (6)	3 (4)	9 (12)
Possible side effects?	28 (36)	11 (14)	19 (24)	3 (4)	–	5 (6)	12 (15)	–
What to do if patient experienced side effect?	31 (39)	11 (14)	21 (27)	–	–	5 (6)	11 (14)	–

Figures in tables are given to nearest whole number. n=78 in all cases.

The frankness of this patient raises the possibility that some other patients may have been too embarrassed to admit to the investigator that they had not been able fully to understand the information.

A large majority of patients felt there had been adequate time to ask questions (74 (95%)), with only two (3%) feeling they would have liked more time (see table 3). As table 4 shows, more than a quarter did not ask any questions (21 (27%)). A further 40 (51%) were “completely” satisfied by the answers given to them by the researchers, with ten (13%) “mostly” satisfied. No patient was not satisfied with the medical team's responses to questions. Typical comments here include:

Everything was explained as it went along and I feel if I had needed more information, I would have got it.

Most potential questions were covered by the literature . . . the documentation really seemed to cover all the information that the layman would need to know.

What do potential trial participants ask? Questions about potential side effects were most common. Others asked about expenses for participation, and about the confidentiality of medical records, during the study. One patient in a five year study asked whether he would be told at the end of the trial whether he had been taking the drug or a placebo. Another asked if she would be able to keep taking the tablets after her six month long study ended.

When asked to compare the information they received as a clinical trial subject with the information they generally were given, as a patient, table 5 shows that in general, patients do receive more information when participating in trials. Several were keen to emphasise that the greater amounts of information they received during the trial was no reflection on their GPs' usual practices:

GPs don't have time to go into this—if you ask, they'll answer.

My GP is very good, but they don't have the time to go into that.

Only one patient expressed less than full confidence in his GP:

I don't have a lot of faith in my GP and the medical profession because of financial constraints in the health service . . .

Four patients (5%) pointed out that their local pharmacist was an alternative, and helpful, source of information about side effects, and how to take the drug. In relation to what to do if a suspected side effect did occur during a clinical trial, 11 patients (14%) stated that they had been told to get in touch with the hospital or GP “right away”. Interestingly, one of the patients who said that she “did not remember them mentioning side effects” then checked this recollection against the study's information leaflet, which she had kept in her handbag. She then found, to her surprise, that potential side effects had been explicitly mentioned. This raises the question of the accuracy of patient recollection, in general.

DISCUSSION

As Featherstone *et al* have pointed out, in the vast literature on medical research, “the patient's perspective is relatively neglected”.⁸ Only a few studies have asked patients to assess the information they receive. The present study suggests that patients who participate in clinical trials feel they are given adequate information. This finding is similar to that of Olver *et al*⁵ who found that out of 100 cancer patients, 68 felt they had been given the right amount of information, 14 felt there was insufficient information, and only five felt they received too much information. In a review of the literature, Edwards *et al*¹⁶ found four studies in which the experiences of patient participants were audited. At least 80% of patients in these studies reported that they had made an autonomous decision to take part.

Informed consent has been defined as requiring:

a full declaration of treatment options to any patient who has been invited to become a participant in a clinical study.... Together with the full description of any treatments there should be an explanation of the possible side effects of the new or standard treatments.¹⁷

This definition focuses very much on the giving of the information by the researcher, rather than on the understanding of the patient. It has been pointed out that, while the dictionary definition of the verb “to inform” is to describe, instruct or teach, a researcher could do each of these “and yet

Appendix 1

Question 1. *What do you think about the amount of information you were given about the test drug?*

Possible responses:

- "The information was too detailed. I didn't want to be told so much."
- "It was about the right amount of information."
- "I would have liked more information."
- "I can't remember."

Question 2. *Were you able to understand all of the information you were given?*

Possible responses:

- "I understood all of it."
- "I understood most of it, but there were some things I did not understand."
- "I understood very little of it."
- "I don't remember getting any information."

Question 3. *Were you given enough opportunity to ask your doctor questions about the drug study, prior to agreeing to participate?*

Possible responses:

- "Yes, there was plenty of time for questions."
- "No, there seemed little opportunity to ask questions."
- "I can't remember."

Question 4. *Were your questions answered to your satisfaction?*

Possible responses:

- "Yes, completely."
- "Yes, mostly."
- "No, I wasn't happy with the answers."
- "I didn't ask any questions"
- "I can't remember."

Question 5. *How did the amount of information you were given about the drug you would be taking during the research trial compare with what you had been told on earlier occasions about other drugs you have been given?*

This was asked in relation to each of the following:

- A. Information about the way the drug works?
- B. Information about how to take the drug?
- C. Information about possible side effects?
- D. Information about what to do if patient experience a side effect?

Possible responses:

- "I was told much more about the trial drug."
- "I was told a little more about the trial drug."
- "I was told about the same amount of information."
- "I was told less about the trial drug."
- "I was told far less about the trial drug."
- "I can't compare."
- "This was not discussed".
- "Not applicable".

fail to be understood by the listener or reader".¹⁸ Howard and DeMets have suggested that:

The literature repeatedly indicates that research subjects . . . do not adequately understand the programs involved.¹⁹

While this may well be the case, the current study shows that patients do believe they have understood the information they were given. As part of this process, it is imperative that patients who are being invited to participate in a clinical trial are given adequate opportunity to ask questions about the study, before agreeing to participate.²⁰ In the present study, patients did generally feel that they had adequate time to do so.

CONCLUSIONS

Although the present study found that in general patients felt they were given appropriate amounts of information, and reported a reasonable level of understanding of that information, this is not, of course, synonymous with a finding that

patients are in fact capable of assimilating the information they are given. Patients' perceptions are one thing—the reality of the situation could be quite different. Patients may feel they have a reasonable grasp of a concept, but if this were to be tested it might not in fact be correct. More research is needed in this area. In particular, researchers and ethics committees should attempt to ascertain whether patient perceptions are, in fact, accurate.

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