Patients’ perceptions of information provided in clinical trials

P R Ferguson

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.

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. 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: Tarnowsk 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 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.7-10 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?”
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 infor-
mentation 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 con-
tained “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 1 Patients’ perceptions about the amount of information they received

<table>
<thead>
<tr>
<th></th>
<th>Too much</th>
<th>Right amount</th>
<th>Too little</th>
<th>Can’t remember</th>
</tr>
</thead>
<tbody>
<tr>
<td>The amount of informa-</td>
<td>2 (3)</td>
<td>73 (94)</td>
<td>2 (3)</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>

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

Table 2 Patients’ perceptions of their understanding of the information

<table>
<thead>
<tr>
<th>Understanding of information</th>
<th>Understood all of it</th>
<th>Understood most of it</th>
<th>Understood very little</th>
<th>Don’t remember getting any information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Understanding of information</td>
<td>39 (50)</td>
<td>38 (49)</td>
<td>–</td>
<td>1 (1)</td>
</tr>
</tbody>
</table>

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

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

<table>
<thead>
<tr>
<th></th>
<th>Plenty of time</th>
<th>Little opportunity</th>
<th>Can’t remember</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adequate time to ask</td>
<td>74 (95)</td>
<td>2 (3)</td>
<td>2 (3)</td>
</tr>
</tbody>
</table>

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 investi-
ator. 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 agree-
ing 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

This patient commented that he had to read the infor-
mentation leaflet “two or three times” in order to understand it.
Another added:

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made sense.

A patient who had understood most, but not all, of the
information commented that the information leaflet had con-
tained “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.
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%) (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 GP’s usual practices:

GP’s 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”. 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 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 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.**

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

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**Table 4** Patient satisfaction with answers to questions

<table>
<thead>
<tr>
<th>Satisfaction with answers to questions</th>
<th>Completely satisfied n (%)</th>
<th>Mostly satisfied n (%)</th>
<th>Not satisfied n (%)</th>
<th>Didn’t ask questions n (%)</th>
<th>Can’t remember n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40 (51)</td>
<td>10 (13)</td>
<td>–</td>
<td>21 (27)</td>
<td>7 (9)</td>
</tr>
</tbody>
</table>

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

**Table 5** Comparison with treatment in non-trial setting

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

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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.

ACKNOWLEDGEMENTS

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REFERENCES AND NOTES

12. Snowdon C, Garcia J, Elbourne D. Making sense of randomisation: responses of parents of critically ill babies to random allocation of treatment in a clinical trial. Social Science Medicine 1997;45:1337-55. (The parents of infant patients were asked for consent.)
19. See reference 7: 300.
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