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Research papers

Informing patients about research: evaluation of an information leaflet

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ABSTRACT

Objectives To develop and evaluate an information sheet in order to effectively increase background knowledge about medical research, including reasons for participation, risks and benefits and the processes of recruitment and consent.

Design Recorded telephone questionnaire conducted at least 24 hours after receiving the information leaflet.

Setting Recruitment from antenatal/paediatric clinics and Newcastle-under-Lyme town centre.

Participants Fifty recruits of whom 37 gave interviews.

Main outcome measure Understanding of the leaflet as judged by answers to the specific questions.

Results In general the understanding of the leaflet was good and 90% of the participants indicated that they had understood most of it. It was thought to be generally informative. The question that caused greatest difficulty related to the correct explanation of informed consent, with only 65% giving a correct response. Other areas of difficulty related to questions about whether new treatments would be better or worse than standard treatments and details of consent in children. It was suggested that examples would be a helpful addition to the leaflet. Having read the leaflet, more than 70% of the participants would be prepared in principle to participate in research. Less than 10% felt that they would be less likely to participate in research after reading the leaflet.

Conclusion The idea of providing a general leaflet about research was supported by the results of the survey. A number of areas of improvement were identified. The leaflet has now been modified to take account of these suggestions.

Keywords: information leaflet, informed consent, patient involvement, research governance

Introduction

One of the most important aspects of modern ethical research is the taking of informed consent. In much of hospital-based research, patients are approached at a time when they are feeling unwell and are most vulnerable. One group of parents, reporting their experiences to the Griffith's Report, perceived that the conduct of research was secretive, despite the formal taking of signed consent, in accordance with the usual practice of the day (1990–1992).[1] Many

patients and parents have very little prior understanding of research. They may have given little thought to the reasons why they may, or may not, wish to take part. They know little of the process surrounding the review and approval of research projects, or the steps required to obtain informed consent.

The Department of Health currently recommends the involvement of consumers in research, and funding streams such as the National Programme on New and Emerging Applications of Technology (NEAT) require evidence of consumer involvement.[2,3] It has been argued that patients should be involved not only in determining research priorities, but also in the design and conduct of research projects.[4]

For these reasons a general information sheet entitled *Clinical Research: why get involved?* was developed. The idea was to increase awareness of research in general, so that patients would be better prepared to consider a specific research proposal, should they come to be eligible for a study. The information sheet was developed with the aim of piloting it in the Women and Children's Division of the North Staffordshire Hospital (NHS) Trust. Should the pilot prove successful then the plan was to roll it out across the local acute and community trust. At this point the information sheet would be made available to all patients whether outpatients or inpatients and it would also be available to the wider public on the web.

Before concluding the pilot, an evaluation was undertaken to determine whether the leaflet improves knowledge and understanding of medical research. In view of the recent thinking on consumer involvement, the evaluation sought to involve both patients and members of the public.

Methods

Preparation of the information sheet

The information sheet was initially drafted in order to cover the following areas:

- the importance of research
- how it may affect patients/parents
- why one should get involved
- research involving children
- consent in children
- how research studies are approved
- the research ethics committee
- informed consent
- whether one has to take part
- risks and benefits
- what about new information arising during a study
- questions you might want to ask.

The initial draft was developed with input from senior researchers, managers (with experience of complaints about research), nurses, parents and patients. There was consultation with the local Research Ethical Committee and the Hospital Trust Research and Development Board. The final version was modified to take account of the comments of the Plain English Campaign, and subsequently received a crystal mark of approval.[5] At the time that the original information leaflet was drafted, in North Staffordshire all research projects underwent a two-stage ethics approval procedure. The first stage evaluated scientific merit and the second stage evaluated the ethics of the project. This procedure was changed in the light of the new NHS Research Governance Framework.[6] This requires the investigator to take responsibility for providing the ethical committee with evidence of scientific merit, in the form of peer review.

Evaluation

An evaluation was undertaken with three objectives:

1 to determine whether the leaflet is comprehensible
2 to determine whether the leaflet is helpful and likely to be a positive influence on future research involvement
3 to obtain suggestions for the improvement of the leaflet.

Sample

The study groups consisted of patients/parents who were approached at random while waiting in either a paediatric or antenatal clinic, and members of the general public who were approached in Newcastle-under-Lyme town centre. The study was carefully explained to all the volunteers beforehand and confidentiality was assured. Each participant, when recruited, was issued with a sheet explaining the nature of the project and was offered the opportunity to ask any questions they might have. The study groups were complete when 25 people from each group agreed to read the leaflet and take part in a structured telephone interview a few days later. A recent graduate, familiar with research methodologies, conducted all the interviews.

Questions

The questions were of two types. The first set of questions was very specific to the information contained in the leaflet, in order to test understanding. The second set was of a more general nature, designed to canvas opinion about the leaflet.

Specific questions

1 Why do you think medical research might be important?
2 Do you know what an 'informed choice' is?
3 If yes, what is it?
4 Who consents when a child cannot do so?
5 Do you have to agree to participate in the research if your doctor asks you to think about it?
6 Would your treatment be any different if you decided not to take part in the research?
7 Explain what you think the risks and benefits of research might be.
8 Will the new treatment being researched be better or worse than the existing treatment?
9 When can you withdraw from the research?
10 Can you withdraw without giving a reason?

General questions

1 Did you understand the information in the leaflet?
2 If not, why not? How do you think it could be improved?
3 Do you have any questions as a result of reading it?
4 If you do, would you ask the doctor these questions if you were asked to join in some research?
5 If not, why not?
6 Are you more, or less, likely to consent to research as a result of reading the leaflet? Why is this? Do you have any other comments to make about the leaflet?

The interviews were all taped and transcribed in full. The study was designed primarily as a qualitative assessment. However, in order to summarise the results a judgement was made by an independent person, who had not been involved in designing the leaflet or evaluation, as to whether the answers to each of the specific questions showed an adequate level of understanding. Based on this process, the results were classified as positive or negative. Interesting observations from the more open-ended questions were also summarised as part of the results.

Results

In total 18/25 (72%) of the public group and 19/25 (76%) of the hospital group were successfully contacted and completed the telephone survey. The characteristics of the two groups are shown in Table 1. In general, the public had more educational qualifications than the patients and this seemed to be reflected in the responses given. The results are summarised in Table 2.

The results were very encouraging in that nearly 90% of the participants in both groups felt that they understood the leaflet. The answers to the specific questions suggested that the vast majority of participants did understand most of the leaflet. The question that posed most difficulty related to the correct explanation of informed consent, with only 65% giving a correct response.

Table 1 Number, age and qualifications of audit participants

	Hospital ($n = 19$)	Public ($n = 18$)
Age: mean (range)	28.1 (15–38)	37.8 (16–67)
No formal qualifications	12*	6
GCSE/A levels	5	5
Degree or postgraduate qualification	2	7

*Two participants were under the age of 16 years.

Although 73% of respondents did appreciate that study treatments could be either better or worse than the existing treatment, it was of concern that over a quarter of participants were not clear on this point.

With regard to the value of the leaflet, just over half the sample (19/36) indicated that they would be more likely to participate in research after reading it. Only 3/36 stated that reading the leaflet had made them less likely to be involved in the research. However, the details of the explanations given indicated that most respondents found it difficult to differentiate between the effect of reading the leaflet and the effect of their previously held opinion about research participation. Looking at the results from the 'willingness to participate' perspective, 25/34 were willing to participate in research with another five giving a more cautious assent. In total only four participants were against becoming personally involved in research. Eight participants volunteered helping others as a reason for getting involved.

In general, the public group scored more highly on understanding than the hospital group. They were also more willing to propose suggestions for the improvement of the leaflet.

The section discussing consent in children received the most specific comments. It was felt that this was unclear and potentially confusing.

One person raised the issue of whether an example of someone who had been involved in research might help. Two subjects appeared to be worried by one of the examples of research involvement, i.e. taking blood. They seemed to have formed the impression

Table 2 Participants' summarised responses to questions about the research leaflet

Responses	Total % (*n*) (*n* = 37)	Hospital % (*n*) (*n* = 19)	Public % (*n*) (*n* = 18)
Provided correct explanation of why medical research is important	97 (36/37)	95 (18/19)	100 (18/18)
Provided correct explanation of informed consent	65 (24/37)	53 (10/19)	78 (14/18)
Correctly stated that parents would give consent for a child	97 (36/37)	95 (18/19)	100 (18/18)
Correctly stated that they would not have to participate in research if a doctor asked them to	70 (26/37)	74 (14/19)	67 (12/18)
Correctly stated that their treatment would not be any different if they decided not to participate in research	86 (32/37)	84 (16/19)	89 (16/18)
Correctly stated that they would not know if a new treatment being researched would be better or worse than the existing treatment	73 (27/37)	68 (13/19)	78 (14/18)
Correctly stated that participants can withdraw from research studies at any time	92 (34/37)	89 (17/19)	94 (17/18)
Correctly stated that participants do not have to provide a reason for withdrawing	94 (35/37)	95 (18/19)	94 (17/18)
Stated that they understood the leaflet	89 (33/37)	89 (17/19)	89 (16/18)
Thought that the leaflet could be improved	40 (15/37)	21 (4/19)	61 (11/18)
Stated that they would be able to ask the doctor involved in the research questions	97 (35/36)	100 (19/19)	94 (16/17)
Stated that after reading the leaflet they would be more likely to consent to research	53 (19/36)	58 (11/19)	47 (8/17)

that they might be asked for a blood sample after reading the leaflet.

Subjects were not always clear about the overall purpose of the leaflet. They thought they were being asked to consent to research, not simply understand information relevant to research in general.

The question and answer format was commented on positively as was the use of bold headings. The leaflet was found to be generally informative.

Discussion

The evaluation was based on a questionnaire because this method is well tested and flexible.[7] The questionnaire developed specifically for this study incorporated two different sets of questions, specific and general, in an attempt to gain answers both relevant and specific to the three objectives of the study, within the bounds of a short telephone interview. The first, more specific, questions were used to determine understanding of the content of the leaflet and generate answers in a form that could then be analysed in a yes/no format. The more general questions were formulated in an open manner and were designed to encourage discussion and reflection. These questions were used to seek comment and suggestions about the leaflet; about attitudes towards research; and how these attitudes might have changed as a result of reading the leaflet.

In selecting a study population it is important to acknowledge that no consumer (patient/parent) can represent all the views and needs of the many diverse groups within the population. Using the term 'consumer perspective' might better represent what consumers can contribute. What is important is to try to

engage a range of people who may be affected by an initiative and this was the reason why the different study groups were chosen.[8]

The evaluation demonstrated that the majority of subjects clearly understood the main reasons for undertaking clinical research as stated in the leaflet. Furthermore, the majority of questions testing comprehension of the leaflet scored well.

Although the majority of respondents did understand the concept of informed consent, a significant minority of the hospital group did not (see Table 2). This is worrying in that the understanding of what is meant by an 'informed consent' is crucial to the whole point of the leaflet. It can be argued that if people cannot report what is meant by informed consent, then the provision of information to the general public through leaflets is fundamentally flawed. Support for such a view might also come from other published research on the difficulty of imparting information to patients.[9,10] However, the requirement to obtain a verbal explanation about what the phrase 'informed consent' means, requires a very high degree of comprehension. Such a high degree of comprehension might not be necessary when an individual consents to participate in a research project. At this time, the individual only needs to be able to understand the information relevant to the project, rather than needing to repeat back to an investigator what the concepts mean. This view is supported by the findings that those with higher levels of education found it much easier to correctly recall a definition of 'informed consent'. Notwithstanding these difficulties, it is also clear that a review of the wording of the leaflet in relation to the concept of 'informed consent' is also needed.

The answers offered to the question about 'who gives consent when a child can't' were mainly correct, which is not surprising, because the answer is a matter of general knowledge. However, the evaluation did reveal through specific comments that many of the subjects still found this area confusing. The problem mainly related to the issue of age and the concept of Gillick competence.[11] Therefore this aspect of the leaflet also needs improving, although there is a balance between simplicity and accuracy when dealing with more complex issues. One general lesson here might be that anyone engaging in research with children needs to take special care when preparing patient information sheets to clearly outline the issues in relation to consent for children.

The question attempting to elicit understanding of the issue of equipoise produced poor results. This issue is notoriously difficult to explain and is itself the subject of debate within the literature on research ethics, as to its status and legitimacy.[12,13] Although only 27 of the subjects thought that the new treatment would be better than the existing treatment, the detail in the answers suggests that the understanding was less good than this result would imply. For example, only a small number in each group were actually able to explain potential risks and benefits. Many of the subjects reported that there were relatively few risks involved in research or just seemed confused by the issue. The task of describing risks and benefits is one that requires a high degree of comprehension and reasoning ability.[14] It is possible that understanding would be improved by some examples, as was suggested by some of the subjects.

In retrospect, question 6 'would your treatment be any different if you decided not to take part in the research?' was confusing. The intention was to determine whether subjects would recognise that declining to take part in research would not lead to them being disadvantaged in any way. However, treatment might be different if a patient agreed to take part in a trial of a new treatment. Some participants clearly recognised this fact. Consequently this question needs a rethink before any further evaluations are undertaken.

On the question about whether reading the leaflet had made respondents more or less likely to participate in research, there was a very encouraging response. This suggests that information conveyed through a leaflet is likely to increase recruitment to research projects rather than act as a constraint. There was a strong belief from many subjects that medical research is important and that they want to participate. Some of those expressing willingness to participate actually suggested the leaflet itself was an important reason for this. Eight subjects suggested that they would be willing to be involved in research that was going to be beneficial to others. This is interesting in that it suggests that people may find it hard to talk about the risks and benefits of research without thinking of how this affects themselves, their families and friends.[15]

Although the sample sizes were quite small, the evaluation produced a wealth of useful information for redrafting of the leaflet. This has now been done, also taking into consideration recent changes in research governance procedures.[16] The rewrite includes a clear initial statement about the purpose of the leaflet, revised sections on children and informed consent and two examples to improve understanding about the risks and benefits inherent in research and clinical trials. Further modifications required by the Plain English Campaign have been incorporated.[5] The leaflet is presented as a colour glossy two-page leaflet, with photographs. The text of the latest version is provided in Appendix 1. The research and development consortium representing both the acute and community trusts has made a decision to adopt the leaflet, with the suggestion that is should also be made available in GP surgeries and community clinics.

Conclusions

While there were a few places where the phrasing of the leaflet could be improved, the majority of both groups appeared to understand the information in broad terms. Some people even suggested that they would like more information. Many suggested that they were more likely to participate as a result of reading the information provided. Therefore, the use of a general leaflet about research is supported by the results of this evaluation. The drafting of such leaflets is not easy and the survey suggested many improvements, despite the fact that extensive consultation went into the first draft. The latest version is available in text form in Appendix 1, so that a well-researched starting point is available for others wanting to provide such information. This evaluation proved to be both informative and useful.

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CONFLICTS OF INTEREST

None.

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Appendix 1

Clinical research: why get involved?

Information leaflet

If you were asked to help with medical research, what would you say?

This leaflet looks at some of the questions you may want to ask.

The researchers may be doctors, nurses, midwives or other staff. They will explain the research in detail, but you might still want to ask them questions.

Introduction

The aim of this leaflet is to help you understand what is involved in research. We hope this information will help you if you decide to take part in a research project while under our care. This leaflet is not about becoming involved in any particular research study. It just gives you background information about research.

Why do we need research?

Research is an essential part of healthcare. We need to carry out clinical (medical) research to develop new treatments, or to help us to decide which is the best available treatment or care. Such treatment might include medicines (such as antibiotics), interventions (such as operations) and tests (such as brain scans).

What will I have to do?

If you decide to take part in research, you might be asked to:

- fill in a questionnaire
- let us take extra blood samples for our research tests
- let us take simple measurements such as blood pressure
- let us review your medical notes for research into the effects of your past treatment
- have a new operation or take a new medicine.

Sometimes we also need to look at current treatments to find out which is most suitable for different groups of patients.

Why should I get involved?

Research is a way of helping us to understand the human body. It is also a way of testing new ideas and treatments. Your involvement is important to us and we appreciate your help. Research is the only way that medicine can improve and progress can be made. However, you don't have to get involved unless you want to.

How are research studies approved?

Before we can carry out research at either the North Staffordshire University Hospital or the Combined Healthcare Trust, we have to review all the studies to make sure that the research is worthwhile and practical. In other words, we need to make sure that there is a good chance that the information we get from the research will help patients in the future. We also check the research to make sure that:

- the research is properly funded
- we have suitably trained staff
- we have the right equipment
- we can carry out our research successfully
- the research is of a high quality.

All research studies have to be approved by the Research Ethics Committee before they can start.

Research Ethics Committee

This committee has a number of experts and members of the public who represent your interests as a patient or member of the public. In doing their job, the committee members need to be sure that:

- the planned research is worthwhile
- the risks of the research are kept as low as possible
- when there are risks, these are justified by the benefits to the patients taking part
- patients are given clear written information to help them decide whether to take part in the research
- there is a clear consent form for patients to sign.

The research study cannot begin until it meets all of these conditions.

What is informed consent?

Anyone involved in research needs to give their informed consent. Informed consent is when a patient agrees to take part in a research study after the details have been carefully explained to them. This explanation should help them to understand what they would have to do. They should understand any changes to treatment, whether the research will cause any pain or discomfort, and how they or patients in the future, will benefit. They will only be able to make an informed decision when they have understood all of these things.

To help patients or parents (in this leaflet 'parent' means anyone with parental responsibility for a child) make an informed decision, an information leaflet is provided for each research study. This information leaflet has to be approved by the Research Ethics Committee. Someone from the research team, normally a doctor, nurse or therapist, will explain the research using the leaflet. They will leave the leaflet with the patient so that they can think about whether they want to take part.

If you are ever asked to take part in a research study, you should take time to read the information leaflet carefully and think about what it means. You may want to talk to friends, relatives, another doctor or your general practitioner (GP). If you decide to take part in the research study, you will then be asked to sign a consent form. You, or your child, can only be included in any research project when the consent form has been signed and witnessed. You will be given a copy of the signed consent form to keep with the information leaflet.

In special circumstances where the research study involves emergency care, it may not be possible for the patient or parents to have enough time to think about everything that is involved before treatment starts. In these cases, the explanations will continue even after the consent form has been signed.

The patient, or parent on behalf of a child, can withdraw from a research study at any time even when a consent form has been signed.

Do I have to take part in the research?

No, taking part in research is voluntary. Take your time to decide whether or not you want to take part. If you do decide to take part, we will ask you to sign a consent form to show that you have understood what is involved.

We will give you the best possible care whether or not you decide to take part in the research. If you decide not to take part, we will give you the normal treatment for your condition. Please note that some new treatments are only available as part of a research project.

What are the possible risks and benefits of taking part?

The risks of research should be extremely low unless you are involved in testing a new treatment for a very serious disease. Below is an example of research, which does not involve a new treatment and where the risks are extremely low.

John is a 10-year-old boy with asthma. The doctors caring for John are doing some research to try and better understand how asthma is passed on through families. They have asked John and his parents whether they would be prepared to help. It would involve filling in a questionnaire giving details of John's asthma and taking a blood sample from John and his parents. The disadvantage in taking part is the time it will take to fill in the questionnaire and the discomfort involved in giving a blood test. There is no advantage for John, but if the research is successful it might help asthma sufferers in the future.

In the example that follows a new cancer treatment will be tried out. Studies like this are the only way to improve care for cancer sufferers. On the other hand, there is always a risk that the new treatment will not be as effective as the standard treatment.

Joan is a 55-year-old lady who has been diagnosed as having cancer. With the standard treatment, about half of patients with this type of cancer expect to survive for five years. The doctors looking after Joan are doing some research on a new drug that has been developed to treat Joan's condition. They have explained to Joan that the new drug makes patients feel worse during treatment, but they hope that more people will survive for five years. However, it is possible that patients receiving the new treatment will do less well. If Joan decides not to take part in the research she will have the standard treatment. If she decides to take part, she might still have the standard treatment or she might have the new treatment. In order to make a comparison between new and standard treatment, about half of the volunteers will have the new treatment and about half will have the standard treatment. This is decided by chance and even the doctor does not know which treatment Joan will have if she agrees to take part. If Joan decides to take part, she may do better if she has the new treatment. On the other hand, there is a risk that she will do worse and she is likely to feel worse during the early stages of the treatment. Taking part in the research study will benefit future patients with Joan's condition because after the research has been completed, the doctors will know which treatment is best.

Are new treatments always better than standard treatments?

No. When doctors know that a new treatment is definitely better than a standard treatment it is not ethical to do the research and patients should receive the new treatment whenever possible.

Will taking part in research affect my health insurance position?

This could happen, for example, if the research revealed that you had a problem you did not know about, like high blood pressure. On the other hand, this would also be a benefit because you could then get treatment for this problem. If you have any private medical insurance, you should check with your insurance company before you agree to take part in any research projects.

What if there is new information about treatment for my condition?

During the research, if new information about the treatment that we are testing becomes available then your research doctor or nurse will tell you about it. They will discuss with you whether you want to carry on with the research. If there is a major breakthrough, the research project may be stopped altogether so that all the patients can be given the most beneficial treatment that is available for them.

What about research involving children?

It is important for us to develop new treatments and techniques to improve the way we care for children. This means that some research studies must involve children. As with all research, we will fully explain the risks and benefits of any planned treatments.

Before we involve children in our research projects, we will discuss the matter fully with the parents and answer any questions they have. We will also involve the child whenever possible.

Consent for children

Once a child is old enough to fully understand the research that is planned, they can give consent themselves. In these cases, we would only enter a child into a research study if both the child and the parent agree. When a child is not old enough to give their consent, we must have the consent of at least one of their parents. Ideally, both parents should be involved in this process wherever possible.

Will I ever know about the results?

You should be offered the opportunity to receive a copy of any information that is published after the study has been completed. This may be a number of years after you have agreed to take part. Not all studies are published, but you should still be given a summary of the results.

Questions you may want to ask the researchers before you agree to take part

- What is this research for?
- What will happen to the research results?
- Can I have a copy of the results?
- What are the known risks and side-effects?
- Will I benefit from taking part in the research?
- What can you do to make me better if I become ill while taking part?
- What will I have to do if I take part?
- Will I have lots of hospital visits or forms to fill in?
- Why do you think that the new medicine or treatment will be better than the existing treatment?
- Can I have written details to take away with me?
- What will happen if I want to withdraw from the research before the end?

More information

For more information about research please contact:

Research & Development Department

This leaflet was produced by the Women and Children's Division of the North Staffordshire University Hospital (NHS) Trust.