BMJ open

What patients really want to know about research: a systematic review

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2011-000509
Article Type:	Research
Date Submitted by the Author:	15-Dec-2011
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Primary Subject Heading:	Ethics
Secondary Subject Heading:	Ethics
Keywords:	MEDICAL ETHICS, ETHICS (see Medical Ethics), GENERAL MEDICINE (see Internal Medicine)

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	3
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	3-5
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	6-7
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	7; 8
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	7
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	20
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8-9; 10; 11
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8-9
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	21
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	18
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	9
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	9

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	18
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	n/a
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	11
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	12-13
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	18
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	14-16
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	14-16
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	18
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	n/a
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	17
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	18-19
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	18-19
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	23

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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The Editor
British Medical Journal

19th October 2011

Dear Editor,

We hope that our paper entitled: **What patients really want to know about research: a systematic review** will be of general interest to your readership.

The paper reports a systematic review of what information potential participants want to know when they are deciding to participate in medical research compared to current guidance from the National Research Ethics Service (NRES). As a researcher, it is often difficult to decide how much information to include in a participant information sheet (PIS). PIS have become increasingly lengthy, especially for complex studies, and NRES guidance is not explicit in the level of detail recommended. This systematic review suggests that there is little evidence of what information potential participants want to know, but the available evidence shows that potential participants may have very different information needs. Our paper highlights the need for further research in this area and suggests a potential solution to tailored information provision.

We can confirm that the paper has not previously been published elsewhere. All authors declare they have no conflicts of interest and have read and approved this version of the manuscript. The requirements for authorship have been met by all authors.

Thank you for considering our work for publication.

Yours sincerely

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What patients really want to know about research: a systematic review

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ABSTRACT

Objective

To establish the evidence base for the information that participants want to know about medical research and to assess how this relates to current guidance from the National Research Ethics Service (NRES).

Data Sources

Medline, Web of Science, Applied Social Sciences Index and Abstracts (ASSIA), Sociological abstracts, Health Management Information Consortium (HMIC), Cochrane library, thesis index's, grey literature databases, reference and cited article lists, key journals, Google Scholar and correspondence with expert authors.

Study selection

Original research studies published between 1950 and October 2010 that asked potential participants to indicate how much or what type of information they wanted to be told about a research study or asked them to rate the importance of a specific piece of information were included.

Study appraisal and synthesis methods

Studies were appraised based on the generalisability of results to the UK potential research participant population. A meta-data analysis using basic thematic analysis was used to split results from papers into themes based on the sections of information that NRES recommends should be included in a participant information sheet.

Results

14 studies were included. Of the 20 pieces of information that NRES recommend should be included in patient information sheets for research pooled proportions could be calculated for seven themes. Results showed that potential participants wanted to be offered information about result dissemination (91% [95% CI 85%; 95%]), investigator conflicts of interest (48% [95% CI 27%;69%]), the purpose of the study (76% [95% CI 27%;100%]), voluntariness (39% [95% CI 2%; 100%]), how long the research would last (61% [95% CI 16%;97%]), potential benefits (57% [95% CI 7%; 98%]) and confidentiality (44% [95% CI 10%; 82%]). The level of detail participants wanted to know was not explored comprehensively in the studies. There was no evidence to support the level of information provision required by participants on the remaining 7 items.

Conclusions

There is limited evidence on what potential participants want to know about research. The existing evidence suggests that individuals may have very different needs and a more tailored evidence based approach may be necessary.

Article Summary

Article Focus:

- What information do potential participants want to know when they are deciding whether to take part in research?
- What is the established evidence base?
- How does the current evidence base relate to current guidance from the National Research Ethics Service (NRES)?

Key messages:

- There is little evidence of what information potential participants want to know about research when they are making the decision to take part.
- The limited evidence available suggests that potential participants may have very different information needs.
- Further research is required to determine what potential participants really want to know about research and how this can be delivered in a way that takes into account their different informational needs.

Study Strengths:

- An extensive search strategy ensured the review was systematic in capturing all available evidence.

Study Limitations:

- Papers included in the review differed in their methodologies and presentation of results, making comparisons between papers extremely difficult.

Introduction

Medical research is central to the advancement of treatments, services and technology.[1-3] Potential participants have the right to choose whether they participate in medical research[4;5] and individuals must give their consent prior to participating in research. As part of this ongoing process, potential participants must be provided with sufficient information to make a voluntary and informed decision.[2;6-11] In research settings, study information is usually conveyed to potential participants in the form of a written participant information sheet (PIS), which is later reinforced by a verbal consent interview with a member of the research team.[12]

In the UK, the National Research Ethics Service (NRES) provides extensive guidance on how a PIS should be written and presented. The guidance suggests that a PIS should be split into two parts where part one provides a brief and clear explanation of the essential elements of the specific study and allows participants to make an initial choice of whether the study is of interest. Part two should then contain additional information on matters such as confidentiality, indemnity and publication intentions.

There is some concern that PIS have become increasingly lengthy over recent years.[13-15] Complex studies, for example where the potential participant might, e.g. on the basis of test results be invited to participate in a further phase of the study, often use detailed and lengthy PIS's. This can lead to poor understanding by participants[16-18] and a corresponding concern that consent criteria are not always met. NRES guidance is not explicit in the level of detail to be included in a PIS and

there is disagreement amongst experts about how much information to include.[19] If PIS's become so complex that only the most confident and educated participants are able to digest all the information, this may result in selection bias meaning that research is less generalisable.[20] Further, there is a risk that healthcare researchers are becoming increasingly paternalistic in their information provision without recognising individual participant needs. In order to help address the problem of how much information to include in a PIS, we conducted a systematic review that aimed to establish the evidence base for the information that potential participants want to know when they are deciding about participation.

Methods

Selection Criteria and Literature Search

This systematic review included all studies that asked participants to indicate how much or what type of information they wanted to be told about a research study, or asked them to rate the importance of a specific piece of information. We included studies published between 1950 and 27th October 2010 with no limit to language or participant group. We only included studies of participant opinion and excluded studies of health care professional or other expert opinion.

We combined Mesh terms Patient, Research Subjects, Consent forms, Informed Consent and Research ethics with terms relating to information provision (Appendix 1). We conducted searches in Medline, Web of Science, ASSIA, Sociological abstracts, HMIC and the Cochrane Library electronic databases. We also searched thesis index's, grey Literature databases, reference and cited article lists, key journals and Google Scholar and we asked expert authors to identify relevant studies.

Data Extraction and Synthesis

One researcher (HK) extracted data from papers using a pre defined data extraction sheet and a second researcher (TK) checked it for accuracy with disagreements resolved by discussion between these two authors (

Table 1). A meta data analysis using basic thematic analysis was used to split results from the 14 papers into themes based on the sections of information that NRES recommends should be included in a PIS (with very similar headings combined to make one variable) (Table 2).[10] We coded individual results based on their relevance to each theme and then collated themes to report overall results. For themes where more than one quantitative study reported a proportion of participants wanting to know the information, pooled proportions with random effects were calculated using StatsDirect statistical software (StatsDirect Ltd, UK).

Results

The search yielded 11943 unique references. We discarded 11291 after reviewing the title, 620 after reviewing the abstract and a further 18 after reviewing the full paper (**Error! Reference source not found.**). HK conducted the citation screening and TK independently validated approximately 10% of the references identified from electronic databases (96.4% agreement rate).

TABLE 1 - SUMMARY OF STUDIES INCLUDED IN THE SYSTEMATIC REVIEW

Lead author / Country / Year	Inclusion/exclusion criteria	Participant illness	Total number of participants (response rate)	Study design	Sampling strategy	Analysis	Key Themes explored
Walkup[21] USA 2009	None provided	None	57 (not provided)	Exploration of conversation and questionnaire	Convenience	Descriptive summary statistics	Study purpose, voluntariness, study method, risks, benefits, confidentiality, review board approval
Bento[22] Brazil 2007	Female participants aged 18-49 who had taken part in a clinical trial of women's health in the previous 12 months and lived in Metropolitan area of Campinas, Sao Paulo, Brazil	Women's health	51 participants 8 focus groups (not provided)	Focus groups	Convenience	Framework analysis	Study methods, risks and benefits
Hutchinson[7] Australia 2008	Participants of clinical trials of COPD, asthma, diabetes, osteoporosis, rheumatoid arthritic and the influenza vaccine. Excluded if clinical trial for acute, life threatening or debilitating conditions with inadequate therapy	Chronic illness	259/324 (80%)	Questionnaire	Convenience	Descriptive summary statistics and multivariate logistic regression	Conflicts of Interest (CoI)/organisation and funding of the research
Gray[23] USA 2007	Participants enrolled onto a phase I research trial, spoke English, and were medically and mentally capable of participating	Phase I research trial	102/119 (86%)	Questionnaire	Consecutive participants enrolling onto parent trial	Descriptive summary statistics, Chi squared tests and Multivariate logistic regression	Conflicts of Interest (CoI)/organisation and funding of the research
Fernandez[24] Canada 2007	English speaking adolescent with cancer or parents of children with cancer. Excluded acutely unwell or recently relapsed	Cancer	40/43 - 10 adolescent, 30 parent participants, (93%)	Questionnaire	Random	Descriptive summary statistics and Chi squared tests	Return of study results
Grady[25] USA 2006	Participants of HIV, Hepatitis, Arthritis and Surgical Oncology Trials who were >18 years and English speaking	Various	33 (not provided)	Face to face semi structured interviews	Convenience	Transcripts coded and themes and major concepts identified	Conflicts of Interest (CoI)/organisation and funding of the research
Hampson[26] USA 2006	Participants with cancer and enrolled in a clinical trial who were English speaking and >18 years	Cancer	252/272 (93%)	Structured face to face interviews	Not provided	Descriptive summary statistics and Fishers exact test / Kruskal-Wallis test	Conflicts of Interest (CoI)/organisation and funding of the research
Weinfurt[27] USA 2006	Healthy adults or those with a mild chronic illness. Excluded if they had participated in another focus group within the previous 6 months or were working or had worked for an organisation involved in the conduct of clinical trials	Healthy	16 focus groups (not provided)	Focus groups	Convenience	Initial content codes based on transcripts developed that were summarised and reviewed to identify main themes	Conflicts of Interest (COI)/organisation and funding of the research
Partridge[28] USA 2005	All participants of the parent trial (chemotherapy trial)	Cancer	94/135 (69.6%)	Questionnaire	Convenience	Simple descriptive statistics	Return of study results
Kim[29]	Potential research participants >18 years,	Various	5478/20205	Online	Random	2-way ANOVA modified	Conflicts of Interest

USA 2004	diagnosed with heart disease, breast cancer or depression, and listed on the Harris Interactive Chronic Illness Database		(27%)	questionnaire		for ordinal data and multinomial logistic regression	(CoI)/organisation and funding of the research
Partridge[30] USA 2003	Any participant enrolled into the parent study (chemotherapy trial)	Cancer	51/55 (93%)	Questionnaire	Convenience	Simple descriptive statistics	Return of study results
Casarett[31] USA 2001	Participants with a current telephone number, enrolled at a pain clinic, who had chronic non-malignant pain, were taking scheduled opioids and had experienced the pain for at least 6 months	Chronic pain	40/86 (46.5%)	Semi structured telephone interviews	Convenience	Descriptive summary statistics and Bivariate analysis with non-parametric tests	Voluntariness, study methods, expenses, risks and the drug/device/procedure being tested
Maslin[32] UK 1994	Attending a breast unit and were patients with a breast cancer diagnosis or asymptomatic women with a family history of breast cancer	Cancer	213/300 (71%)	Postal questionnaire	Random	Simple descriptive statistics	Study purpose, voluntariness, study methods, risks, benefits and confidentiality
Sand[33] Norway 2008	Participants eligible for the parent study (all lung cancer patients)	Cancer	21/33 (64%)	Semi structured interviews	Convenience	Identification and categorisation of themes and analysis based on deductive and inductive categories	Voluntariness, study methods and treatment alternatives

TABLE 2 – EVIDENCE LINKED TO NRES PARTICIPANT INFORMATION SHEET RECOMMENDED HEADINGS

NRES Heading	What does NRES say should be included?	N studies	Evidence for inclusion in PIS from literature
What is the purpose of the study?	Purpose is an important consideration for subjects and should be included	2[21;32]	Pooled results showed that 76% (95% CI 27%;100%) participants wanted to know about study purpose
Why have I been invited?	Why and how participants have been chosen and how many will be in the study	0	No evidence
Do I have to take part? / What will happen if I don't want to carry on with the study?	The voluntary nature of the research should be included	4[21;31-33]	Pooled results from the 3 quantitative studies[21;31;32] showed that 39% (95% CI 2%; 100%) participants wanted to know about voluntariness The one qualitative study reported that it was the most important piece of information to be included in a participant information sheet[33]
What will happen to me if I take part? / What will I have to do?	How long the participant will be involved in the research / how long the research will last	3[21;31;32]	Pooled results from all three studies[21;31;32] showed that 61% (95% CI 16%;97%) participants wanted to know how long the research would last
	How often they need to attend a clinic	1[31]	68% (27/40; 95% CI 53%;82%) wanted to know the frequency of additional study visits[31]
	How long visits will be	0	No evidence
	Exactly what will happen to them	2[31;33]	Specific information types varied considerably between studies, so no meaningful pooled results could be calculated The proportion of people wanting to know what would happen to them ranged from 9.5% (2/21; 95% CI 0%;22.1%)[33] to 20% (8/40; 95%CI 7.6%;32.4%)[31] depending on what the specific information was. For example, 20% (8/40; 95% CI 7.6%;32.4%) wanted to know about burdens to friends or family caused by study participation,[31] 12% (5/40; 95% CI 2.3%;22.8%) wanted to know how much work they would miss because of study participation,[31] 10% (4/40; 95% CI 0.7%;19.3%) wanted to know how much time would be spent waiting in clinic during study visits,[31] and 9.5% (2/21; 95% CI -3%;22.1%) wanted to know practical information about trial procedures[33]
Expenses and payments	Expense claims available and if there is any kind of payment for participation	1[31]	25% (10/40; 95% CI 11.6%;38.4%) wanted to know if free medication would be available during or after trial[31]
What is the drug, device or procedure that is being tested?	Short description of the drug, device or procedure and give the stage of development, state the dosage of the drug and method of administration, and details of any contraindicated drugs included over the counter drugs	Two[22;31]	The one quantitative study[31] showed that specific questions about the medication regime ranged from 25% (10/40; 95% CI 11.5%;38.4%) that wanted to know what control they had over medication dose during the study to 70% (28/40; 95% CI 55.8%;84.2%) that wanted to know the frequency with which study medication must be taken.[31] The study also showed that 62% (25/40; 95% CI 47.5%;77.5%) wanted results of previous studies of safety and 45% (18/40; 95% CI 29.5%;60.4%) of efficacy, and 15% (6/40; 95% CI 3.9%;26.1%) wanted to know if study medication had been approved for clinical use[31] The one qualitative study showed that participants wanted to know how to use the intervention[22]
What are the alternatives for diagnosis or treatment?	What other managements/treatments are available and a list of all important comparative risks and benefit	1[33]	5% (1/21; 95% CI 0%;13.9%) wanted as much information about treatment alternatives as they received about the study medication[33]
What are the possible disadvantages and risks of	Any risks, discomforts or inconvenience should be outlined	4[21;321622]	Specific information types varied considerably between studies so no meaningful pooled results could be calculated. Results ranged from no participants that asked about study risks (0/57)[21] to 97% (207/213; 95%

taking part? / What are the side effects of any treatment received when taking part?			CI 95%;99.4%) who wanted to be informed about any possible emotional or physical discomforts and side effects[32]
Radiation and the Ionizing Radiation Regulations	If the use of additional ionizing radiation is required as part of the study then information must be given to the participant on the radiation involved	0	No evidence
Harm to the unborn child: therapeutic studies	Clear warnings must be given where there could be harm to an unborn child, if there was a risk in breast feeding, or if taking the medication is likely to cause fertility problems	0	No evidence
What are the possible benefits of taking part?	Benefits should be included, but where there is no intended clinical benefit it should be stated clearly	3[21;22;32]	Pooled results of the two quantitative studies[21;32] suggest that 57% (95% CI 7%; 98%) wanted to know about study benefits Two studies provided relevant data relating to specific benefits.[31;33] Specific requests ranged from 14% (3/21; 95% CI -0.7%;29.3%) that wanted to know about hopes for better treatment[33] to 55% (22/40; 95% CI 39.5%;70.4%) that wanted an opportunity to learn about condition or medication under study.[31] Specific information types varied considerably between studies so no meaningful pooled results could be calculated
What happens when the research study stops?	Arrangements for after the trial finishes must be given, and it must be clear if participants will have continued access to any benefits or intervention they may have obtained during the research. If treatment will not be available after the study, it should be explained what treatment will be available instead	1[31]	55% (22/40; 95% CI 39.6%;70.4%) wanted to know about the availability of medication after the study was over[31]
What if there is a problem?	How complaints will be handled and what redress may be available	0	No evidence
Will my taking part in the study be kept confidential?	How data will be collected, stored, what it will be used for, who will have access to it, how long it will be retained for and how it will be disposed of	2[21;32]	Pooled results showed that 44% (95% CI 10%; 82%) participants wanted to be given information about confidentiality and the protection of their privacy
Involvement of the GP/family doctor	If the participants GP needs to be notified of involvement or asked for consent	0	No evidence
What will happen to any samples I give?	Clear description of whether new samples will be taken, if excess samples will be taken, and if access to existing stored samples will be required. The same type of information as for data is required to be provided	0	No evidence
Will any genetic tests be done?	A separate consent form for genetic studies should be used	0	No evidence
What will happen to the results of the research study?	What will happen to the results of the research, if it is intended to be published and how results will be made available to participants, and that they will not be	3[24;28;30]	Pooled results showed that 91% (95% CI 85%; 95%) wanted to know about study results Specific information types varied considerably between studies, so no meaningful pooled results could be

	identified in any publication		calculated . Two studies provided relevant data relating to specific aspects of what they wanted to know about results.[24;30] 78% (31/40; 95% CI 64.6%;90.4%) of participants wanted a description of what researchers had learned that was important,[24] 35% (14/40; 95% CI 20.2%;49.8%) wanted it to include follow up contacts for the researcher[24] and 98% (29/40; 95% CI 58.7%; 86.3%) wanted a list of medical publications written as a results of the research.[24] 90% (46/51; 95% CI 82%;98.4%) wanted their family or loved ones to be informed of the results if they were unable to learn them[30]
Who is organising and funding the research?	The organization or company sponsoring the research and funding the research if these are different, and if the researcher conducting the research is being paid	6[23;25-27;29;34]	Pooled results from the four quantitative studies showed that 48% (95% CI 27%;69%) wanted to know about any type of CoI, but there was general disagreement over whether patients wanted to be told about financial CoI 3 studies provided relevant data relating to what participants wanted to know about specific aspects of COI.[26;29;34] When financial CoI were broken down into subcategories, 82.5% (4519/5478; 95% CI 81.48%;83.5%) wanted to be told about commercial funding,[29] 69% (3779/5478; 95% CI 67.8%;70.2%) about personal income,[29] between 41% (105/259; 95% CI 34.6%;46.5%) and 82% (4492/5478; 95% CI 81%;83%) about patents and stocks and shares[29;34] and 40% (101/253; 95% CI 34%;46%) thought researchers should have told participants only about the oversight system[26] One study reported that participants wanted to know specifically how money was spent, with proportions ranging from 25% (65/259; 95% CI 19.8%;30.4%) that wanted to know how much of the funding was spent on administration[34] to 38% (98/259; 95% CI 31.9%;43.8%) that wanted to know how spare accrued funds were used at study completion[34] One qualitative study reported that participants wanted to know the name of the sponsor[27] and one quantitative study reported that 57% (148/259; 95% CI 51.1%;63.2%)[34] wanted to know the name of the funder Some participants wanted help understanding the potential consequences of CoI, some did not[27] Specific information types varied considerably between studies so no meaningful pooled results could not be calculated
Who has reviewed the study?	Explain the role of the Research Ethics Committees and which Committee reviewed the current study	1[21]	No participants asked about institutional review board approval (0/57)[21]

Of the 14 studies included in the review, three specifically considered the return of research results to participants and six considered only investigator conflicts of interest (CoI). Five studies looked broadly at what information potential research participants wanted to know.

Of the 20 sections of information NRES suggest should be included in a PIS, there were seven categories where no research evidence was identified that suggested what information research participants wanted to know (Table 2). We were able to calculate pooled proportions for seven themes. Participants wanted to be told about dissemination of study results (91% [95% CI 85%; 95%]), investigator conflicts of interest (48% [95% CI 27%;69%]), the purpose of the study (76% [95% CI 27%;100%]), voluntariness (39% [95% CI 2%; 100%]), how long the research would last (61% [95% CI 16%;97%]), benefits (57% [95% CI 7%; 98%]) and confidentiality (44% [95% CI 10%; 82%]). Although the majority of participants appeared to want information for most of these themes, some participants did not, and the level of detail that participants wanted was not explored comprehensively.

Discussion

Of the 14 papers that met inclusion criteria, five looked broadly at what information research participants wanted to know. These studies focused on the category of information required rather than how much detail participants wanted. All 14 studies had substantial limitations to generalisability when applied to the wider research population because, for example, they focused on specific sub sections of the population, e.g. six studies included only cancer patients[24;26;28;30;32;33] and only one study conducted in the UK.[32]

In the absence of evidence to suggest what information potential research participants want, NRES have based their guidance on expert opinion. It does, however, mean that current information provision for research may not adequately address the informational needs of the general population, or 'hard to reach' groups such as socially deprived or black and minority ethnic groups. Whilst NRES recognise that one size does not fit all and that low risk studies with little or no intervention may need shorter information sheets, there is little evidence to identify what level of information provision should be made.[35] A potential difficulty in conducting research to determine what should be included in a PIS is that an individual's information preferences may change as they move from being a potential to actual participant.[36;37]

Responding to individuals' information needs may prove challenging, but the provision of high quality, appropriate information in a timely manner is crucial to the consent process. Electronic information provision may be one way to address different information needs. Recent research by Antoniou *et al.*[38] that allowed

participants to access three increasingly detailed levels of information electronically, found that the basic level of information was accessed by 70 to 82% of participants, but only 9 to 18% accessed the level of information currently recommended in NRES guidance, and only 3 to 12% accessed all three levels of information. Interestingly, 20% (93/552) participants said they wanted more information even though fewer than this (3-12%) read all of the information available to them.

The study by Antoniou *et al*[38]. is an important first step in determining what information potential research participants really want to know when they agree to take part in a study. Further research is required to assess the feasibility and acceptability of unfolding electronic information sheets.

Conclusions

There is limited evidence as to what information potential participants want to know at the time they are deciding whether or not to participate in research. Real time studies need to be conducted to explore what information potential participants access when given a choice. This will enable us to determine exactly what information research participants want to know, tailor PIS towards specific population sub groups and enable appropriate, high quality information to be provided to meet individual needs.

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Competing Interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) HK, MC, HD, TK, SW have support from the University of Birmingham for the submitted work; (2) HK, MC, HD, TK, SW have no relationships with any companies that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) HK, MC, HD, TK, SW have no non-financial interests that may be relevant to the submitted work.

Details of contributors

HK, MC, SW and HD conceived and designed the research. HK and TK collected, validated and extracted data. All authors made substantial contribution to the analysis and interpretation of the data. HK drafted the manuscript and SW, HD, MC and TK revised it.

Ethical approval

No identifiable personal information has been included in this study.

Ethical approval was not required for this systematic review.

Funding

The study was funded by the Medical Research Council Midland Hub for Trials Methodology Research (Medical Research Council Grant ID G0800808).

The study sponsor had no role in study design, collection, analysis or interpretation of data, in the writing of the report, or in the decision to submit the article for publication.

HK and TK are PhD students funded by and MC is Education Lead for the Medical Research Council Midland Hub for Trials Research Methodology.

Data

All authors had full access to all of the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Data sharing statement

Technical appendix and dataset available from the corresponding author at hmk592@bham.ac.uk.

Referenced Manager (Version 12) was used to analyse data. Stats Direct was used to calculate pooled proportions with random effects.

Supplemental files

Search strategy (appendix 1)

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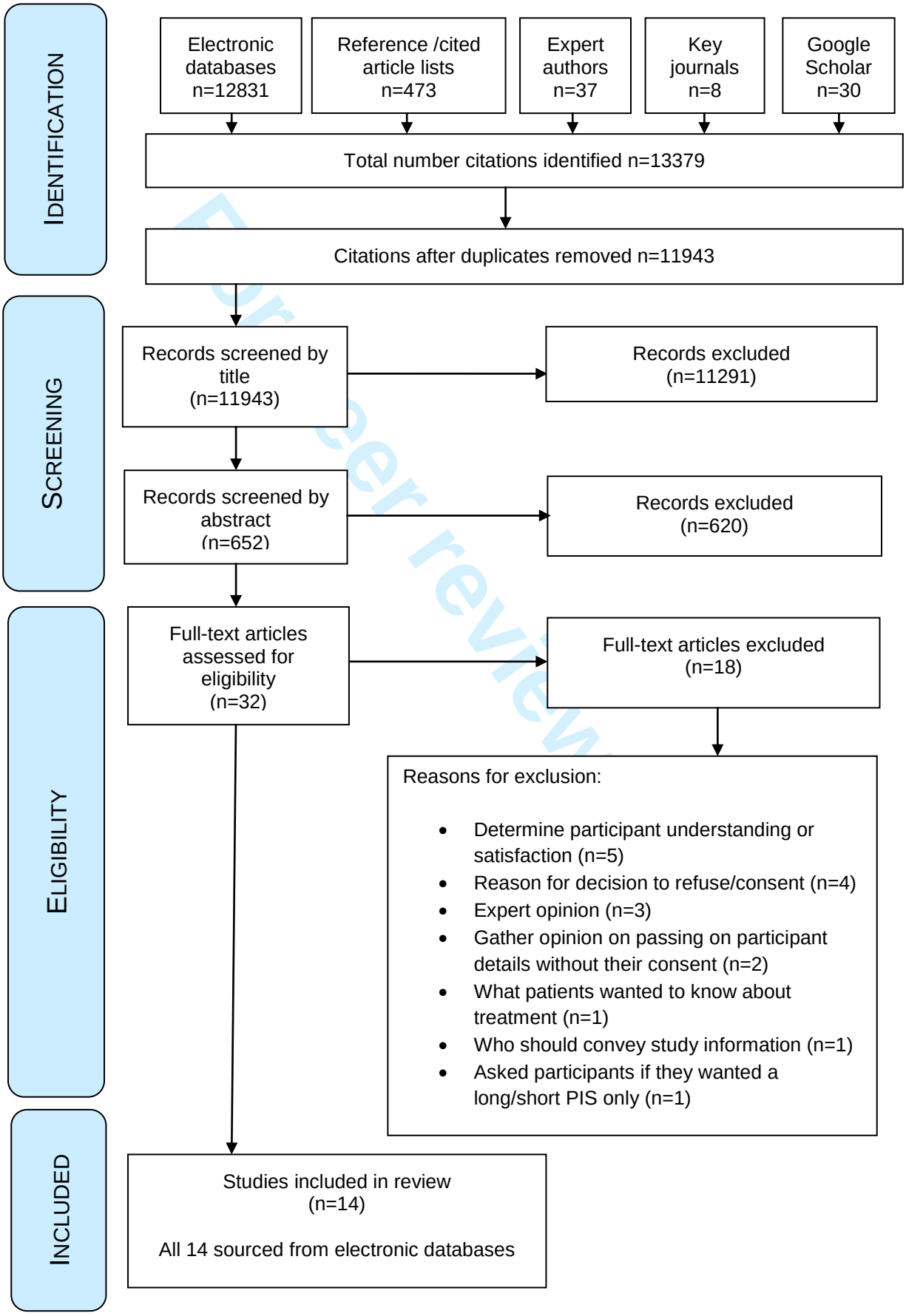
Figure 1 - Results of search strategy and identification of publications included in the review



Appendix 1 – Search strategy

1. "research patient*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
2. exp Patients/
3. "participant*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
4. exp Research Subjects/
5. 1 or 2 or 3 or 4 or 5 or 6
6. exp Consent Forms/
7. "information leaflet*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
8. "information sheet*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
9. (consent adj4 form*).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
10. 8 or 9 or 10 or 11
11. exp Informed Consent/
12. exp Ethics, Research/
13. "medico legal".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
14. "medicolegal".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15. exp Disclosure/
16. (informed adj4 consent*).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
17. (research adj4 ethic*).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
18. "disclos*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
19. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
20. "want to know".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
21. "want*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
22. "information*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
23. "require*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
24. "desire*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
25. "need*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
26. "choice*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
27. 23 or 24 or 25 or 26 or 27 or 28
28. 7 and 21 and 29
29. 12 or 22 or 30
30. 31 and "Humans" [Subjects]

BMJ open

What potential research participants want to know about research: a systematic review

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2011-000509.R1
Article Type:	Research
Date Submitted by the Author:	29-Mar-2012
Complete List of Authors:	Kirkby, Helen; The University of Birmingham, MRC Midlands Hub for Trials Methodology Research (HTMR) Calvert, Melanie; The University of Bimringham, MRC Midlands Hub for Trials Methodology Research (HTMR) Draper, Heather; The University of Birmingham, Centre for Biomedical Ethics Keeley, Thomas; The University of Bimringham, MRC Midlands Hub for Trials Methodology Research (HTMR) Wilson, Sue; The University of Bimringham, MRC Midlands Hub for Trials Methodology Research (HTMR)
Primary Subject Heading:	Ethics
Secondary Subject Heading:	Communication, Health services research, Patient-centred medicine, Qualitative research, Research methods
Keywords:	MEDICAL ETHICS, ETHICS (see Medical Ethics), GENERAL MEDICINE (see Internal Medicine)

what potential research participants want to know about research: a systematic review

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ABSTRACT

Objective

To establish the empirical evidence base for the information that participants want to know about medical research and to assess how this relates to current guidance from the National Research Ethics Service (NRES).

Data Sources

Medline, Web of Science, Applied Social Sciences Index and Abstracts (ASSIA), Sociological abstracts, Health Management Information Consortium (HMIC), Cochrane library, thesis index's, grey literature databases, reference and cited article lists, key journals, Google Scholar and correspondence with expert authors.

Study selection

Original research studies published between 1950 and October 2010 that asked potential participants to indicate how much or what types of information they wanted to be told about a research study or asked them to rate the importance of a specific piece of information were included.

Study appraisal and synthesis methods

Studies were appraised based on the generalisability of results to the UK potential research participant population. A meta-data analysis using basic thematic analysis was used to split results from papers into themes based on the sections of information that NRES recommends should be included in a participant information sheet.

Results

14 studies were included. Of the 20 pieces of information that NRES recommend should be included in patient information sheets for research pooled proportions could be calculated for seven themes. Results showed that potential participants wanted to be offered information about result dissemination (91% [95% CI 85%; 95%]), investigator conflicts of interest (48% [95% CI 27%;69%]), the purpose of the study (76% [95% CI 27%;100%]), voluntariness (39% [95% CI 2%; 100%]), how long the research would last (61% [95% CI 16%;97%]), potential benefits (57% [95% CI 7%; 98%]) and confidentiality (44% [95% CI 10%; 82%]). The level of detail participants wanted to know was not explored comprehensively in the studies. There was no empirical evidence to support the level of information provision required by participants on the remaining 7 items.

Conclusions

There is limited empirical evidence on what potential participants want to know about research. The existing empirical evidence suggests that individuals may have very different needs and a more tailored evidence based approach may be necessary.

Article Summary

Article Focus:

- What information do potential participants want to know when they are deciding whether to take part in research?
- What is the established empirical evidence base?
- How does the current empirical evidence base relate to current guidance from the National Research Ethics Service (NRES)?

Key messages:

- There is little empirical evidence of what information potential participants want to know about research when they are making the decision to take part.
- The limited empirical evidence available suggests that potential participants may have very different information needs.
- Further research is required to determine what potential participants really want to know about research and how this can be delivered in a way that takes into account their different informational needs.

Study Strengths:

- An extensive search strategy ensured the review was systematic in capturing all available empirical evidence.

Study Limitations:

- Papers included in the review differed in their methodologies and presentation of results, making comparisons between papers extremely difficult.

Introduction

Medical research is central to the advancement of treatments, services and technology.[1-3] Potential participants have the right to choose whether they participate in medical research [4, 5] and individuals must give their consent prior to participating in research. As part of this ongoing process, potential participants must be provided with sufficient information to make a voluntary and informed decision.[2, 6-11] In research settings, study information is usually conveyed to potential participants in the form of a written participant information sheet (PIS), which is later reinforced by a verbal consent interview with a member of the research team.[12]

In the UK, the National Research Ethics Service (NRES) provides extensive guidance on how a PIS should be written and presented. The guidance suggests that a PIS should be split into two parts where part one provides a brief and clear explanation of the essential elements of the specific study and allows participants to make an initial choice of whether the study is of interest. Part two should then contain additional information on matters such as confidentiality, indemnity and publication intentions.

There is some concern that PIS have become increasingly lengthy over recent years.[10; 13, 14] Complex studies, for example where the potential participant might, e.g. on the basis of test results be invited to participate in a further phase of the study, often use detailed and lengthy PISs. This can lead to poor understanding by participants [15-17] and a corresponding concern that consent criteria are not always met. NRES guidance is not explicit in the level of detail to be included in a

PIS and there is disagreement amongst experts about how much information to include.[18] If PISs become so complex that only the most confident and educated participants are able to digest all the information, this may result in selection bias meaning that research is less generalisable.[19] Further, there is a risk that healthcare researchers are becoming increasingly paternalistic in their information provision without recognising individual participant needs. In order to help address the problem of how much information to include in PIS, we conducted a systematic review that aimed to establish the empirical evidence base for the information that potential participants want to know when they are deciding about participation.

Methods

Selection Criteria and Literature Search

This systematic review included all studies that asked participants to indicate how much or what type of information they wanted to be told about a research study, or asked them to rate the importance of a specific piece of information. We included studies published between 1950 and 27th October 2010 with no limit to language or participant group. We only included studies of participant opinion and excluded studies of health care professional or other expert opinion.

We combined Mesh terms Patient, Research Subjects, Consent forms, Informed Consent and Research ethics with terms relating to information provision (Appendix 1). We conducted searches in Medline, Web of Science, ASSIA, Sociological abstracts, HMIC and the Cochrane Library electronic databases. We also searched thesis index's, grey Literature databases, reference and cited article lists, key journals and Google Scholar and we asked expert authors to identify relevant studies.

We did not conduct a formal quality assessment of included literature because there were both quantitative and qualitative studies, widely varied study methods and different types of results that were often not comparable between papers. Instead, we conducted a critical appraisal of each paper using five quality indicators (response rate, sample size, demographics, participant characteristics and strengths and limitations of study methods). The strengths and limitations of each study are presented in Table 1.

Data Extraction and Synthesis

One researcher (HK) extracted data from papers using a pre defined data extraction sheet and a second researcher (TK) checked it for accuracy with disagreements resolved by discussion between these two authors

Table 1). A meta data analysis using basic thematic analysis was used to analyse the data from the 14 papers. Themes were based on the sections of information that NRES recommends should be included in a PIS (Table 2).[10] Each paper was assessed to identify any further themes relating to what information research participants may want to know. A meta data analysis coded individual results based on their relevance to each theme and then themes were collated to report overall results. For themes where more than one quantitative study reported a proportion of participants wanting to know the information, pooled proportions with random effects were calculated using StatsDirect statistical software (StatsDirect Ltd, UK).

Results

The search yielded 11943 unique references. We discarded 11291 after reviewing the title, 620 after reviewing the abstract and a further 18 after reviewing the full paper (Figure 1). HK conducted the citation screening and TK independently validated approximately 10% of the references identified from electronic databases (96.0% kappa agreement rate). All 14 included studies were identified from searches of Medline and ASSIA. Expert authors identified 37 unique references; 13 were duplicates from the electronic searches and 24 did not meet the inclusion criteria.

TABLE 1 - SUMMARY OF STUDIES INCLUDED IN THE SYSTEMATIC REVIEW

Lead author / Country / Year	Inclusion / exclusion criteria	Participant illness	Participant demographics	Total number of participants (response rate)	Study design	Sampling strategy	Analysis	Key Themes explored	Study strengths	Study limitations
Walkup [31] USA 2009	None provided	None	Gender: Not reported Age: Not reported Education / deprivation: Not reported Ethnicity: Not reported	57 (not provided)	Exploration of conversation and questionnaire	Convenience	Descriptive summary statistics	Study purpose, voluntariness, study method, risks, benefits, confidentiality, review board approval	Participants approached in a public setting and invited to complete a questionnaire and researcher recorded study information spontaneously requested Did not specify a disease group	No inclusion/exclusion criteria Participant demographics not reported
Bento [21] Brazil 2007	Female participants aged 18-49 who had taken part in a clinical trial of women's health in the previous 12 months and lived in Metropolitan area of Campinas, Sao Paulo, Brazil	Women's health	Gender: Only women Age: 18-49 Education / deprivation: 4 focus groups 8th grade or less, 4 focus groups above 8th grade education Ethnicity: Not reported	51 participants 8 focus groups (not provided)	Focus groups	Convenience	Framework analysis	Study methods, risks and benefits	Participants of different ages and educational level likely to have different needs and opinions regarding topic Focus groups homogenous for age and educational level; suitable to ensure they were comfortable expressing opinions Recruitment continued until data saturation point	Demographics not representative of the general population as the study only included women and was limited to participants from a trial of a contraceptive intervention
Hutchinson [7] Australia	Participants of clinical trials of COPD, asthma,	Chronic illness	Gender: 52% male	259/324 (80%)	Questionnaire	Convenience	Descriptive summary statistics	Conflicts of Interest (CoI)/organisat		Demographics not representative of the general

2008	diabetes, osteoporosis, rheumatoid arthritis and the influenza vaccine. Excluded if clinical trial for acute, life threatening or debilitating conditions with inadequate therapy		Age: Median age 70 [range not reported] Education / deprivation: Range of backgrounds Ethnicity: Not reported				and multivariate logistic regression	ion and funding of the research		population as median age of 70
Gray [23] USA 2007	Participants enrolled onto a phase I research trial, spoke English, and were medically and mentally capable of participating	Phase I research trial	Gender: 52% male Age: Median age 61 [range 26-82] Education / deprivation: Range of backgrounds Ethnicity: 81% White	102/119 (86%)	Questionnaire	Consecutive participants enrolling onto parent trial	Descriptive summary statistics, Chi squared tests and Multivariate logistic regression	Conflicts of Interest (CoI)/organisation and funding of the research	Same interviewer conducted all interviews	Demographics not representative of the general population as the median age was 61 and was limited to cancer patients participating in an early phase clinical trial
Fernandez [32] Canada 2007	English speaking adolescent with cancer or parents of children with cancer. Excluded acutely unwell or recently relapsed	Cancer	Gender: Adolescents not reported Parents mostly female [23/30; 77%] Age: Adolescents median age 16 [range 13-20] Parents median age 40.9 [range 28-53] Education / deprivation: Adolescents predominantly in education [no figures reported] Parents 50% with post secondary education Ethnicity: Adolescents 80% White Parents 100% White	40/43 - 10 adolescent, 30 parent participants, (93%)	Questionnaire	Random	Descriptive summary statistics and Chi squared tests	Return of study results		Demographics not representative of general population as participants were well educated, mostly Caucasian and limited to adolescents with cancer/parents of children with cancer

Grady [21] USA 2006	Participants of HIV, Hepatitis, Arthritis and Surgical Oncology Trials who were >18 years and English speaking	Various	Gender: 61% male Age: Not reported Education / deprivation: Range of backgrounds Ethnicity: 70% White	33 (not provided)	Face to face semi structured interviews	Convenience	Transcripts coded and themes and major concepts identified	Conflicts of Interest (CoI)/organisation and funding of the research	Open questions used during interviews Data collection continued to saturation point Two authors independently conducted analysis	Used hypothetical scenario Demographics not representative of general population as participants were more often male and limited to adults participating in HIV, hepatitis, arthritis or surgical oncology trials
Hampson [27] USA 2006	Participants with cancer and enrolled in a clinical trial who were English speaking and >18 years	Cancer	Gender: 56% male Age: 24% < 50, 32% 50-59, 26% 60-69, 16% >70 Education / deprivation: Well educated and financially secure Ethnicity: 92% White	252/272 (93%)	Structured face to face interviews	Not provided	Descriptive summary statistics and Fishers exact test / Kruskal-Wallis test	Conflicts of Interest (CoI)/organisation and funding of the research	Validated interview questions	Demographics not representative of general population as the study population were well educated, financially secure and limited to adult participants of a clinical trial
Weinfurt [29] USA 2006	Healthy adults or those with a mild chronic illness. Excluded if they had participated in another focus group within the previous 6 months or were working or had worked for an organisation involved in the conduct of clinical trials	Healthy	Gender: 42% male Age: 12% 18-29, 51% 30-49, 37% >50 Education / deprivation: Well educated and financially secure Ethnicity: 56% White	16 focus groups (not provided)	Focus groups	Convenience	Initial content codes based on transcripts developed that were summarised and reviewed to identify main themes	Conflicts of Interest (COI)/organisation and funding of the research	Participants not limited to disease group	Only one moderator conducted focus groups Non-verbal communication not recorded Demographics not representative of general population as the study population were well educated, financially secure and the majority had previously shown interest in research

Partridge [24] USA 2005	All participants of the parent trial (chemotherapy trial)	Cancer	Gender: Only women Age: Mean age 55 [range not reported] Education / deprivation: Range of backgrounds Ethnicity: 96% White	94/135 (69.6%)	Questionnaire	Convenience	Simple descriptive statistics	Return of study results		Participant selection biased towards participants that wanted to know study results Demographics not representative of general population as the study population were mostly white, only included females and was limited to participants of a breast cancer trial
Kim [30] USA 2004	Potential research participants >18 years, diagnosed with heart disease, breast cancer or depression, and listed on the Harris Interactive Chronic Illness Database	Various	Gender: 50% male Age: 4% 18-29, 16% 30-44, 61% 45-64, 19% 65+ Education / deprivation: Range of backgrounds Ethnicity: 92% White	5478/20205 (27%)	Online questionnaire	Random	2-way ANOVA modified for ordinal data and multinomial logistic regression	Conflicts of Interest (CoI)/organisation and funding of the research	Validated questionnaire Participants chosen at random but from the subset of those registered on the Harris Interactive Chronic Illness Database	Demographics not representative of general population as it was limited to Internet users
Partridge [25] USA 2003	Any participant enrolled into the parent study (chemotherapy trial)	Breast cancer	Gender: Not reported Age: Median age 54 [range 29-82] Education / deprivation: Range of backgrounds Ethnicity: 84% White	51/55 (93%)	Questionnaire	Convenience	Simple descriptive statistics	Return of study results	Multicentre	Un-validated questionnaire Demographics not representative of general population as the study was limited to participants of a breast cancer trial. Gender was not presented but

										expect most were female given disease area
Casarett [20] USA 2001	Participants with a current telephone number, enrolled at a pain clinic, who had chronic non-malignant pain, were taking scheduled opioids and had experienced the pain for at least 6 months	Chronic pain	Gender: 40% male Age: Mean age 47 [range 30-86] Education / deprivation: Range of backgrounds Ethnicity: 85% White	40/86 (46.5%)	Semi structured telephone interviews	Convenience	Descriptive summary statistics and Bivariate analysis with non-parametric tests	Voluntariness, study methods, expenses, risks and the drug/device/procedure being tested	Validated interview topic guide Questions spontaneously asked by participants were recorded	Demographics not representative of general population as participants were more often male and limited to chronic pain patients
Maslin [33] UK 1994	Attending a breast unit and were patients with a breast cancer diagnosis or asymptomatic women with a family history of breast cancer	Cancer	Gender: Only women Age: Median 47 [range 24-81] Education / deprivation: Not reported Ethnicity: Not reported	213/300 (71%)	Postal questionnaire	Random	Simple descriptive statistics	Study purpose, voluntariness, study methods, risks, benefits and confidentiality	Participants chosen at random but from a subset of those attending a breast unit	Demographics not representative of general population as the study only included females and was limited those with breast cancer
Sand [22] Norway 2008	Participants eligible for the parent study (all lung cancer patients)	Cancer	Gender: 57% male Age: Median age 69 [range 44-84] Education / deprivation: Range of backgrounds Ethnicity: Not reported	21/33 (64%)	Semi structured interviews	Convenience	Identification and categorisation of themes and analysis based on deductive and inductive categories	Voluntariness, study methods and treatment alternatives		No inclusion/exclusion criteria stated but 11 potential participants were not invited Technical problems with 3 recordings Demographics not representative of the general population as participants were more often male, had a median age of 69 years and were limited to

lung cancer patients

TABLE 2 – EMPIRICAL EVIDENCE LINKED TO NRES PARTICIPANT INFORMATION SHEET RECOMMENDED HEADINGS

NRES Heading	What does NRES say should be included?	N studies	Empirical evidence for inclusion in PIS from literature
What is the purpose of the study?	Purpose is an important consideration for subjects and should be included	2[32;34]	Pooled results showed that 76% (95% CI 27%;100%) participants wanted to know about study purpose
Why have I been invited?	Why and how participants have been chosen and how many will be in the study	0	No empirical evidence
Do I have to take part? / What will happen if I don't want to carry on with the study?	The voluntary nature of the research should be included	4[21;23;32;34]	Pooled results from the 3 quantitative studies [20, 31, 33] showed that 39% (95% CI 2%; 100%) participants wanted to know about voluntariness The one qualitative study reported that it was the most important piece of information to be included in a participant information sheet [22]
What will happen to me if I take part? / What will I have to do?	How long the participant will be involved in the research / how long the research will last	3[21;32;34]	Pooled results from all three studies [20, 31, 33] showed that 61% (95% CI 16%;97%) participants wanted to know how long the research would last
	How often they need to attend a clinic	1[21]	68% (27/40; 95% CI 53%;82%) wanted to know the frequency of additional study visits [20]
	How long visits will be	0	No empirical evidence
	Exactly what will happen to them	2[21;23]	Specific information types varied considerably between studies, so no meaningful pooled results could be calculated The proportion of people wanting to know what would happen to them ranged from 9.5% (2/21; 95% CI 0%; 22.1%) [22] to 20% (8/40; 95%CI 7.6%; 32.4%) [20] depending on what the specific information was. For example, 20% (8/40; 95% CI 7.6%;32.4%) wanted to know about burdens to friends or family caused by study participation,[20] 12% (5/40; 95% CI 2.3%;22.8%) wanted to know how much work they would miss because of study participation,[20] 10% (4/40; 95% CI 0.7%;19.3%) wanted to know how much time would be spent waiting in clinic during study visits [20] and 9.5% (2/21; 95% CI -3%;22.1%) wanted to know practical information about trial procedures [22]
Expenses and payments	Expense claims available and if there is any kind of payment for participation	1[21]	25% (10/40; 95% CI 11.6%;38.4%) wanted to know if free medication would be available during or after trial [20]
What is the drug, device or procedure that is being tested?	Short description of the drug, device or procedure and give the stage of development, state the dosage of the drug and method of administration, and details of any contraindicated drugs included over the counter drugs	Two[21;22]	The one quantitative study [20] showed that specific questions about the medication regime ranged from 25% (10/40; 95% CI 11.5%;38.4%) that wanted to know what control they had over medication dose during the study to 70% (28/40; 95% CI 55.8%;84.2%) that wanted to know the frequency with which study medication must be taken.[20] The study also showed that 62% (25/40; 95% CI 47.5%;77.5%) wanted results of previous studies of safety and 45% (18/40; 95% CI 29.5%;60.4%) of efficacy, and 15% (6/40; 95% CI 3.9%;26.1%) wanted to know if study medication had been approved for clinical use [20] The one qualitative study showed that participants wanted to know how to use the intervention [21]
What are the alternatives for diagnosis or treatment?	What other managements/treatments are available and a list of all important comparative risks and benefit	1[23]	5% (1/21; 95% CI 0%;13.9%) wanted as much information about treatment alternatives as they received about the study medication [22]

What are the possible disadvantages and risks of taking part? / What are the side effects of any treatment received when taking part?	Any risks, discomforts or inconvenience should be outlined	4[32;34;16;22]	Specific information types varied considerably between studies so no meaningful pooled results could be calculated. Results ranged from no participants that asked about study risks (0/57) [31] to 97% (207/213; 95% CI 95%;99.4%) who wanted to be informed about any possible emotional or physical discomforts and side effects [33]
Radiation and the Ionizing Radiation Regulations	If the use of additional ionizing radiation is required as part of the study then information must be given to the participant on the radiation involved	0	No empirical evidence
Harm to the unborn child: therapeutic studies	Clear warnings must be given where there could be harm to an unborn child, if there was a risk in breast feeding, or if taking the medication is likely to cause fertility problems	0	No empirical evidence
What are the possible benefits of taking part?	Benefits should be included, but where there is no intended clinical benefit it should be stated clearly	3[22;32;34]	Pooled results of the two quantitative studies [31, 33] suggest that 57% (95% CI 7%; 98%) wanted to know about study benefits Two studies provided relevant data relating to specific benefits.[20, 22] Specific requests ranged from 14% (3/21; 95% CI -0.7%;29.3%) that wanted to know about hopes for better treatment [22] to 55% (22/40; 95% CI 39.5%;70.4%) that wanted an opportunity to learn about condition or medication under study.[20] Specific information types varied considerably between studies so no meaningful pooled results could be calculated
What happens when the research study stops?	Arrangements for after the trial finishes must be given, and it must be clear if participants will have continued access to any benefits or intervention they may have obtained during the research. If treatment will not be available after the study, it should be explained what treatment will be available instead	1[21]	55% (22/40; 95% CI 39.6%;70.4%) wanted to know about the availability of medication after the study was over [20]
What if there is a problem?	How complaints will be handled and what redress may be available	0	No empirical evidence
Will my taking part in the study be kept confidential?	How data will be collected, stored, what it will be used for, who will have access to it, how long it will be retained for and how it will be disposed of	2[32;34]	Pooled results showed that 44% (95% CI 10%; 82%) participants wanted to be given information about confidentiality and the protection of their privacy
Involvement of the GP/family doctor	If the participants GP needs to be notified of involvement or asked for consent	0	No empirical evidence
What will happen to any samples I give?	Clear description of whether new samples will be taken, if excess samples will be taken, and if access to existing stored samples will be required. The same type of information as for data is required to be provided	0	No empirical evidence

Will any genetic tests be done?	A separate consent form for genetic studies should be used	0	No empirical evidence
What will happen to the results of the research study?	What will happen to the results of the research, if it is intended to be published and how results will be made available to participants, and that they will not be identified in any publication	3[25;26;33]	Pooled results showed that 91% (95% CI 85%; 95%) wanted to know about study results Specific information types varied considerably between studies, so no meaningful pooled results could be calculated. Two studies provided relevant data relating to specific aspects of what they wanted to know about results.[25, 32] 78% (31/40; 95% CI 64.6%;90.4%) of participants wanted a description of what researchers had learned that was important,[32] 35% (14/40; 95% CI 20.2%;49.8%) wanted it to include follow up contacts for the researcher [32] and 98% (29/40; 95% CI 58.7%; 86.3%) wanted a list of medical publications written as a results of the research.[32] 90% (46/51; 95% CI 82%;98.4%) wanted their family or loved ones to be informed of the results if they were unable to learn them [25]
Who is organising and funding the research?	The organization or company sponsoring the research and funding the research if these are different, and if the researcher conducting the research is being paid	6[24;27-31]	Pooled results from the four quantitative studies showed that 48% (95% CI 27%;69%) wanted to know about any type of CoI, but there was general disagreement over whether patients wanted to be told about financial CoI 3 studies provided relevant data relating to what participants wanted to know about specific aspects of COI.[27, 28, 30] When financial CoI were broken down into subcategories, 82.5% (4519/5478; 95% CI 81.48%;83.5%) wanted to be told about commercial funding,[30] 69% (3779/5478; 95% CI 67.8%;70.2%) about personal income,[30] between 41% (105/259; 95% CI 34.6%;46.5%) and 82% (4492/5478; 95% CI 81%;83%) about patents and stocks and shares [28, 30] and 40% (101/253; 95% CI 34%;46%) thought researchers should have told participants only about the oversight system [27] One study reported that participants wanted to know specifically how money was spent, with proportions ranging from 25% (65/259; 95% CI 19.8%;30.4%) that wanted to know how much of the funding was spent on administration [28] to 38% (98/259; 95% CI 31.9%;43.8%) that wanted to know how spare accrued funds were used at study completion [28] One qualitative study reported that participants wanted to know the name of the sponsor [30] and one quantitative study reported that 57% (148/259; 95% CI 51.1%; 63.2%) [28] wanted to know the name of the funder Some participants wanted help understanding the potential consequences of CoI, some did not [29] Specific information types varied considerably between studies so no meaningful pooled results could not be calculated
Who has reviewed the study?	Explain the role of the Research Ethics Committees and which Committee reviewed the current study	1[32]	No participants asked about institutional review board approval (0/57) [31]

Of the 14 studies included in the review, three specifically considered the return of research results to participants and six considered only investigator conflicts of interest (CoI). Five studies looked broadly at what information potential research participants wanted to know.

Of the 20 sections of information NRES suggest should be included in a PIS, there were seven categories where no empirical evidence was identified that suggested what information research participants wanted to know (Table 2). No further themes, beyond the NRES categories, were identified. We were able to calculate pooled proportions for seven themes. Participants wanted to be told about dissemination of study results (91% [95% CI 85%; 95%]), investigator conflicts of interest (48% [95% CI 27%;69%]), the purpose of the study (76% [95% CI 27%;100%]), voluntariness (39% [95% CI 2%; 100%]), how long the research would last (61% [95% CI 16%;97%]), benefits (57% [95% CI 7%; 98%]) and confidentiality (44% [95% CI 10%; 82%]). Although the majority of participants appeared to want information for most of these themes, some participants did not, and the level of detail that participants wanted was not explored comprehensively.

Discussion

Of the 14 papers that met inclusion criteria, five looked broadly at what information research participants wanted to know. These studies focused on the category of information required rather than how much detail participants wanted. All 14 studies had substantial limitations to generalisability when applied to the wider research population because, for example, they focused on specific sub sections of the population, e.g. six studies included only cancer patients [22, 24, 25, 27, 32, 33] and only one study conducted in the UK.[33] A number of studies included only females [21, 24, 25, 33] and participants that were mostly white [24, 32] and well educated [27, 29, 32].

In the absence of empirical evidence to suggest what information potential research participants want, NRES have based their guidance on expert opinion. It does, however, mean that current information provision for research may not adequately address the informational needs of the general population, or 'hard to reach' groups such as socially deprived or black and minority ethnic groups. Whilst NRES recognise that one size does not fit all and that low risk studies with little or no intervention may need shorter information sheets, there is little empirical evidence to identify what level of information provision should be made.[34] A potential difficulty in conducting research to determine what should be included in a PIS is that an individual's information preferences may change as they move from being a potential to actual participant.[35, 36]

Responding to individuals' information needs may prove challenging, but the provision of high quality, appropriate information in a timely manner is crucial to the

consent process. Electronic information provision may be one way to address different information needs. Recent research by Antoniou *et al.*[37] that allowed participants to access three increasingly detailed levels of information electronically, found that the basic level of information was accessed by 70 to 82% of participants, but only 9 to 18% accessed the level of information currently recommended in NRES guidance, and only 3 to 12% accessed all three levels of information. Interestingly, 20% (93/552) participants said they wanted more information even though fewer than this (3-12%) read all of the information available to them.

The study by Antoniou *et al.*[37] is an important first step in determining what information potential research participants really want to know when they agree to take part in a study. Further research is required to assess the feasibility and acceptability of unfolding electronic information sheets.

Limitations

Ideally, differences in informational requirements for sub groups of the population would have been explored but the small numbers of studies identified and limited data extracted from papers meant this was not feasible.

Conclusions

There is limited empirical evidence as to what information potential participants want to know at the time they are deciding whether or not to participate in research. Real time studies need to be conducted to explore what information potential participants access when given a choice. This will enable us to determine exactly what

information research participants want to know, and could, in addition to other sources such as expert opinion, help tailor PIS towards specific population sub groups and enable appropriate, high quality information to be provided to meet individual needs.

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Competing Interests

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) HK, MC, HD, TK, SW have support from the University of Birmingham for the submitted work; (2) HK, MC, HD, TK, SW have no relationships with any companies that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) HK, MC, HD, TK, SW have no non-financial interests that may be relevant to the submitted work.

HD is an author of one of the papers included discussion [37]. SW was also acknowledged in this paper for comments on an early draft.

Details of contributors

HK, MC, SW and HD conceived and designed the research. HK and TK collected, validated and extracted data. All authors made substantial contribution to the analysis and interpretation of the data. HK drafted the manuscript and SW, HD, MC and TK revised it.

Ethical approval

No identifiable personal information has been included in this study.

Ethical approval was not required for this systematic review.

Funding

The study was funded by the Medical Research Council Midland Hub for Trials Methodology Research (Medical Research Council Grant ID G0800808).

The study sponsor had no role in study design, collection, analysis or interpretation of data, in the writing of the report, or in the decision to submit the article for publication.

HK and TK are PhD students funded by and MC is Education Lead for the Medical Research Council Midland Hub for Trials Research Methodology.

Data

All authors had full access to all of the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis.

Data sharing statement

Technical appendix and dataset available from the corresponding author at hmk592@bham.ac.uk.

Referenced Manager (Version 12) was used to analyse data. Stats Direct was used to calculate pooled proportions with random effects.

Supplemental files

Search strategy (appendix 1)

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Appendix 1 – Search strategy

1. "research patient*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
2. exp Patients/
3. "participant*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
4. exp Research Subjects/
5. 1 or 2 or 3 or 4 or 5 or 6
6. exp Consent Forms/
7. "information leaflet*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
8. "information sheet*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
9. (consent adj4 form*).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
10. 8 or 9 or 10 or 11
11. exp Informed Consent/
12. exp Ethics, Research/
13. "medico legal".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
14. "medicolegal".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
15. exp Disclosure/
16. (informed adj4 consent*).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
17. (research adj4 ethic*).mp. [mp=title, original title, abstract, name of substance word, subject heading word]
18. "disclos*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
19. 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20
20. "want to know".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
21. "want*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
22. "information*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
23. "require*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
24. "desire*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
25. "need*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
26. "choice*".mp. [mp=title, original title, abstract, name of substance word, subject heading word]
27. 23 or 24 or 25 or 26 or 27 or 28
28. 7 and 21 and 29
29. 12 or 22 or 30
30. 31 and "Humans" [Subjects]

Figure 1 - Results of search strategy and identification of publications included in the review