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Involving South Asian patients in clinical trials

M Hussain-Gambles,[1] B Leese,[1*] K Atkin,[1] J Brown,[2] S Mason[2] and P Tovey[1]

[1] Centre for Research in Primary Care, University of Leeds, UK
[2] Clinical Trials Research Unit, University of Leeds, UK

* Corresponding author

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Abstract

Involving South Asian patients in clinical trials

M Hussain-Gambles,[1] B Leese,[1*] K Atkin,[1] J Brown,[2] S Mason[2] and P Tovey[1]

[1] Centre for Research in Primary Care, University of Leeds, UK

[2] Clinical Trials Research Unit, University of Leeds, UK

* Corresponding author

Objectives: To investigate how South Asian patients conceptualise the notion of clinical trials and to identify key processes that impact on trial participation and the extent to which communication difficulties, perceptions of risk and attitudes to authority influence these decisions. Also to identify whether 'South Asian' patients are homogeneous in these issues, and which factors differ between different South Asian subgroups and finally how professionals regard the involvement of South Asian patients and their views on strategies to increase participation.

Data sources: A review of the literature on minority ethnic participation in clinical trials was followed by three qualitative interview studies. Interviews were taped and transcribed (and translated if required) and subjected to framework analysis. Face-to-face interviews were conducted with 25 health professionals; 60 South Asian lay people who had not taken part in a trial and 15 South Asian trial participants.

Results: Motivations for trial participation were identified as follows: to help society, to improve own health or that of family and friends, out of obligation to the doctor and to increase scientific knowledge. Deterrents were concerns about drug side-effects, busy lifestyles, language, previous bad experiences, mistrust and feelings of not belonging to British society. There was no evidence of antipathy amongst South Asians to the concept of clinical trials and, overall, the younger respondents were more knowledgeable than the older ones. Problems are more likely to be associated with service delivery. Lack of being approached was a common response. Lay-reported factors that might affect South Asian participation in clinical trials include age, language, social class, feeling of not belonging/mistrust, culture and religion. Awareness of clinical trials varied between each group. There are more similarities than differences in attitudes towards clinical trial participation between the South Asian and the general population. Important decisions, such as participation in clinical trials, are likely to be made by those family members who are fluent in English and younger. Social class appears to be more important than ethnicity, and older South Asian people and those from working class backgrounds appear to be more mistrustful. Approachable patients (of the same gender, social class and fluent in English) tend to be 'cherry picked' to clinical trials. This practice was justified because of a lack of time and resources and inadequate support. South Asian patients might be systematically excluded from trials owing to the increased cost and time associated with their inclusion, particularly in relation to the language barrier. Under-representation might also be due to passive exclusion associated with cultural stereotypes. Other characteristics such as gender, age, educational level and social class can also affect trial inclusion.

Conclusions: Effective strategies for South Asian recruitment to clinical trials include: using multi-recruitment strategies; defining the demographic and social profiles of the population to be included; using focus groups to identify any potential barriers; consulting representative community members to provide assistance in the study; ensuring eligibility criteria are set as wide as possible; developing educational and recruitment approaches to attract ethnic minority health professionals; ensuring health professionals are adequately trained in culturally and ethnically orientated service provision; determining the most effective mass media to use in study promotion and recruitment; and targeting inner-city, single-handed practices likely to have high ethnic minority populations. Future research should consider: responses when invited to participate; the role of methodological and organisational barriers to recruitment; the complexities of recruitment from a health professional perspective; developing culturally sensitive research methods; the magnitude of the problem of under-recruitment; strategies to encourage inner-city, single-handed GP participation; and other factors affecting trial inclusion, such as age, gender, educational level and socio-cultural background.

Contents

Glossary and list of abbreviations

Technical terms and abbreviations are used throughout this report. The meaning is usually clear from the context, but a glossary is provided for the non-specialist reader. In some cases, usage differs in the literature, but the term has a constant meaning throughout this review.

Glossary

Clinical trial Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.[1]

Controlled clinical trial A type of experiment that compares the effects of a new treatment on a patient group, with the effects of the standard treatment or a placebo on another group (the control group). See RCT

Culture A simple definition of culture is how we do and view things in our social grouping. Culture consists of a shared set of values, perceptions and assumptions, based on a shared history and language.

Ethnicity Ethnicity is not a neutral term and has come to embody language, religion, culture, nationality and a shared heritage.

Helsinki Declaration Recommendations guiding doctors in biomedical research involving human subjects, adopted by the 18th World Medical Assembly, Helsinki, Finland, 1964, and revised by the World Medical Assembly in Tokyo, Japan, 1975, in Venice, Italy, in 1983 and in Hong Kong in 1989.[2]

Institutional racism Institutional racism has gradually emerged as a helpful and productive idea to make sense of health inequalities and also inappropriate and inaccessible service provision. It is often called camouflaged racism, being not immediately obvious, but embedded in the assumptions informing organisational practices. It occurs when the policies of an institution lead to discriminatory outcomes for minority ethnic populations, irrespective of the motives of individual employees. In effect, it is the uncritical application of policies and procedures which ignore the needs of an ethnically diverse society.

Institutional review board US equivalent of research ethics committees.

Lay people The general public, or those not belonging to any particular professional group.

Nuremberg Code In 1947, an International Tribunal declared the Nuremberg Code, the standard by which a group of doctors in Nazi Germany should be judged.

Prejudice Prejudice refers to the negative opinions, judgments, beliefs and feelings we hold about individuals because of their membership in certain groups or categories. When these negative views lead us to act in certain ways toward these individuals and groups, the result is discrimination.

Race A biological construct, originated in relation to assumed differences on biological grounds, and defined as a group to which a person belongs as a result of physical features such as skin colour, bone structure and type of hair.

Randomised controlled trial A randomised controlled trial is a type of controlled clinical trial in which patients are assigned to the 'treatment' and 'control' groups at random.

South Asian people A term used to refer to people originating from India, Pakistan and Bangladesh.

List of abbreviations

CAM	complementary and alternative medicine
CONSORT	Consolidated Standards of Reporting Trials
COREC	Central Office for Research Ethics Committees
CSM	Committee for the Safety of Medicines
CTRU	Clinical Trials Research Unit
FDA	Food and Drug Administration
GCP	good clinical practice
HRT	hormone replacement therapy
IRB	institutional review board
LREC	Local Research Ethics Committee
MRC	Medical Research Council
MREC	Multicentre Research Ethics Committee
MRFIT	Multiple Risk Factor Intervention Trial
MRS	Medical Research Society
NIH	National Institutes of Health
NRR	National Research Register
ONS	Office for National Statistics
PHS	Physicians' Health Study
RCT	randomised controlled trial

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

Executive summary

Background

Many randomised controlled trials have fewer South Asian participants than expected. There is a lack of ethnic minority recruitment data in many trials, making assessment problematic. This study was prompted by a lack of knowledge about how South Asian people perceive trial involvement and the risks and benefits involved.

Objectives

1. Investigation of how South Asian patients conceptualise the notion of clinical trials.
2. Identification of the key processes that impact on trial participation and the extent to which communication difficulties, perceptions of risk and attitudes to authority influence these decisions.
3. Identification of whether 'South Asian' patients are homogeneous in these issues, and which factors differ between different South Asian subgroups.
4. Identification of how professionals regard the involvement of South Asian patients and their views on strategies to increase participation.

Design

A review of the literature on minority ethnic participation in clinical trials was followed by three qualitative interview studies. Interviews were taped and transcribed (and translated if required) and subjected to framework analysis.

Setting

The study took place in the Leeds and Bradford areas of England.

Subjects

Face-to-face interviews were conducted with 25 health professionals (consultants, GPs, nursing staff, academics, non-medically trained trial coordinators, Local Research Ethics Committee and Multicentre Research Ethics Committee members); 60 South Asian lay people (20 Indians, 20 Pakistanis and 20 Bangladeshis) who had not taken part in a trial and 15 South Asian trial participants.

Results

South Asian conceptualisation of trial participation

Motivations for trial participation were identified as follows: to help society, to improve own health or that of family and friends, out of obligation to the doctor and to increase scientific knowledge. Deterrents were identified as follows: concerns about drug side-effects, busy lifestyles, language, previous bad experiences, mistrust and feelings of not belonging to British society.

Key processes impacting on trial participation

There was no evidence of antipathy amongst South Asians to the concept of clinical trials and, overall, the younger respondents were more knowledgeable than the older ones. Problems are more likely to be associated with service delivery. Lack of being approached was a common response. Lay-reported factors that might affect South Asian participation in clinical trials include age, language, social class, feeling of not belonging/mistrust, culture (importance of families, gender issues, community gossip and health beliefs) and religion (modesty, meat-derived and non-Halal medicine).

Homogeneity of views about participation

Awareness of clinical trials varied between each group. Indian respondents were most likely to be aware and less than half of the Pakistani and Bangladeshi respondents were aware of clinical trials. There are more similarities than differences in attitudes towards clinical trial participation between the South Asian and the general population. Important decisions, such as participation in clinical trials, are likely to be made by those family members who are fluent in English and younger. Social class appears to be more important than ethnicity, and older South Asian people and those from working class backgrounds appear to be more mistrustful.

Professional views

Approachable patients (of the same gender, social class and fluent in English) tend to be 'cherry picked' to clinical trials. This practice was justified because of a lack of time and resources and inadequate support. South Asian patients might be systematically excluded from trials owing to the increased cost and time associated with their inclusion, particularly in relation to the language barrier. Under-representation might also be due to passive exclusion associated with cultural stereotypes. Other characteristics such as gender, age, educational level and social class can also affect trial inclusion.

Discussion

There are a number of reasons, identified from this study, why South Asians should not be excluded from clinical trials. Exclusion is inequitable since evidence suggests that people who take part in trials have better clinical outcomes. Unless South Asian people are routinely included in trials, the diseases to which they are disproportionately disposed (including diabetes and heart disease) will remain poorly understood and treated. Furthermore, exclusion of minority ethnic groups from trials undermines the government's NHS plan for tackling inequalities. It is also important to sustain the widespread applicability of trial findings to the whole population. Exclusion of a subset of the population could have implications regarding the safety and efficacy of new drugs. Finally, participation of minority ethnic groups in trials would help to reduce alienation and mistrust and emphasise that they are an integral part of British society.

Conclusions

The following suggestions may provide effective strategies for South Asian recruitment to clinical trials:

- use multi-recruitment strategies
- define the demographic and social profiles of the population to be included
- use focus groups to identify any potential barriers
- consult representative community members to provide assistance in the study
- ensure eligibility criteria are set as wide as possible to achieve wider applicability of results
- develop educational and recruitment approaches to attract ethnic minority health professionals
- ensure health professionals are adequately trained in culturally and ethnically orientated service provision
- determine the most effective mass media to use in study promotion and recruitment
- target inner-city, single-handed practices likely to have high ethnic minority populations.

Future research

The following areas of further research are recommended:

- responses when invited to participate
- role of methodological and organisational barriers to recruitment
- complexities of recruitment from a health professional perspective
- developing culturally sensitive research methods
- magnitude of the problem of under-recruitment
- strategies to encourage inner-city, single-handed GP participation
- investigation of other factors affecting trial inclusion, such as age, gender, educational level and socio-cultural background.

Chapter 1
Background

This report contains seven chapters, the first of which sets out some important definitions, the reasons for the research and the aims and objectives of the study. This is followed by a review of the literature and a chapter describing the methodology. The next three chapters present the results of interviews with healthcare professionals (Chapter 4), South Asian lay people (Chapter 5) and South Asian patients who have taken part in clinical trials (Chapter 6). The final chapter provides a discussion of the empirical findings, recommendations and suggestions for future research.

Clinical trials

Clinical trials are used to determine whether new interventions (drugs or treatments) are both safe and effective. A clinical trial uses human participants to generate scientific data and carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Patients are assigned either to the current intervention or to the experimental intervention so that the eventual outcome of each group can be compared. Experimental interventions may be compared with placebos (inactive pill, liquid or powder that has no treatment value) to assess the intervention's effectiveness.

Clinical trials are often conducted in phases. The trials at each phase have a different purpose and help scientists answer different questions. A Phase I trial is a first round of assessment of a drug's safety for human use and may or may not randomise patients. If randomised, the trial investigator uses either a computer-generated randomisation programme or one included in a statistics textbook to undertake the randomisation process. Phase II clinical trials are designed to determine the activity and efficacy of new drugs in specific diseases and may or may not involve the randomisation process. Phase III is a much larger randomised clinical trial, the purpose of which is to compare the new intervention with the conventionally accepted therapy in the management of a particular disease. Phase IV clinical trials compare the treatment's effectiveness with that of others already on the market, evaluate cost–benefit ratios and determine the drug's long-term effectiveness and impact on quality of life.[3]

Clinical trials provide data with more robust scientific rigour than surveys, clinical case studies or observational studies. They are increasingly becoming popular when informing clinical decision-making processes,[4] and randomised controlled trials (RCTs) are hailed as representing the 'gold standard' for scientific research.[5] As medical practice becomes more evidence based, they are considered to be the best way of evaluating new interventions. RCTs, however, are not without controversy.

A well-designed clinical trial also needs to satisfy the following criteria. It must address a highly focused question; employ a rational and feasible method; involve investigators expert in clinical care and research methodology; be conducted over an appropriate time frame; and must have clearly written protocols defining the plan of action and be readily understood by the participating investigators since strict adherence to the protocol is essential.[3] In addition, a number of ethical principles have to be incorporated into clinical trial design ensuring against exploitation of the participants.

Informed consent

According to the declaration of Helsinki 1964, a participant's decision to take part in clinical trials should depend on the information provided by the investigator.[6] Such information should contain the purpose of the study and the risks involved. The potential participants should then be encouraged to ask for explanations on any issues about which they are uncertain. This process is intended to provide the individual with sufficient clear information in order to allow them to make an informed choice about whether or not to take part in the trial. This process culminates in signing the consent form. Informed consent in clinical research is mandatory, whereas informed consent for routine therapy may be scanty or comprehensive, depending on the individual clinician.[7]

The simplest model of informed consent consists of four aspects, as specified in terms of the following criteria:[8,9]

1. Competence – the person giving consent must be mentally competent to do so.
2. Information – sufficient information must be received for the person to make an informed choice.
3. Understanding – the person's understanding must be sufficient for him or her to make a reasoned choice.
4. Voluntariness – the consent must be given voluntarily.

It should be noted that all these criteria specify a standard of perfection, which might never be completely met in practice. For instance, underlying the informed consent process is the notion of competence. Competence is the ability of the potential trial participant to understand the information provided and their capacity to make an informed decision. Assessment of competence, however, is a subjective process. Decision-making abilities can vary over time and under different circumstances. Studies suggest that as a result of illness, patients tend to feel that they must do whatever the doctor suggests, and tend to become less aggressive and passive out of a sense of powerlessness in the face of massive technical information. Patients also face uncertainties of outcome and, with time pressure to make a treatment decision, feel extreme psychological and physiological vulnerability, so that relevant information disclosed by the investigator may not be remembered by sick, anxious and sometimes frightened patients.[10]

Not understanding the disclosed study information does not necessarily mean that the patient is incapable of understanding or is incompetent, but could mean that the communication process involved in information disclosure was inadequate. Competence or the capacity to consent should be assessed individually in terms of the situation, circumstances or decision at hand.

South Asian demography

South Asian people (consisting of Indians, Pakistanis and Bangladeshis) embody the largest UK minority group, representing just over 1.9 million of the population.[11] There is a greater density of South Asian people in some parts of the UK than others and they are more likely to live in inner-city, densely populated areas, and in particular towns and cities. Bangladeshis live predominantly in the greater London area, one-third of the Indian community live in the outer London suburbs, with the remainder in the West Midlands and Leicester. Most of the Pakistanis live in the West Midlands and Yorkshire, with a smaller proportion living in London.[12] This geographical distribution is due to historical reasons, where South Asian people migrated to the UK (in the 1950s and peaked in the late 1960s) to fill the gaps in the post-War industrial British labour market, and are heavily concentrated in and around London, the cities of the industrial Midlands and the textile towns of the Pennine region. With regard to socio-economic background, there are substantial differences in the way in which South Asian people contribute to the labour market. According to the health education survey of 2000, Indian men are most likely to be in work, with Bangladeshi and Pakistani women least likely to be economically active. Very few South Asian people are in the professional class (social class I), the majority being in social classes III and IV (partly skilled). Over two-thirds of Pakistani and Bangladeshi women could not be classified into a social class owing to not having an occupation. Pakistani men had a slightly lower rate of economic activity than Indian men and only about one-third of Bangladeshi men were in work. Overall, unemployment rates for South Asian people are typically double that for the general population.[13]

The age structure of South Asian people also differs from that of the white population in being much younger (owing to patterns of migration). The ratio of males to females varies both by ethnic group and by age, and this is particularly evident amongst the Bangladeshis and Pakistanis. Among Pakistanis and Bangladeshis, men outnumber women by nearly 10%. These differing age structures have been ascribed to their recent migration trends.[12]

Patterns of socio-economic background are also reflected in the language abilities of these groups. The ability to read and write English is greatest in Indians, and nearly all Indian men and most Pakistani and Bangladeshi men can speak English. This is in sharp contrast to the women, where only three-quarters of Pakistani women and less than three-fifths of Bangladeshi women can speak English. Ability to speak English also declines dramatically with age, particularly for women. Almost all Indian and Pakistani men and women aged 16–30 can both speak and read English, but

the level of ability in English of Bangladeshi women aged 16–29 is the lowest. Of women aged 50–74, just over half of Indian and Pakistani women can speak English, compared with only 17% of Bangladeshi women.[13]

Reasons for the research

This research arose as a result of an exploratory empirical study investigating the ethnicity profile of six Phase III, multi-centre RCTs, conducted by the Clinical Trials Research Unit (CTRU).[14] The aim of the study was to ascertain the proportion of South Asian participants in five national and one regional trial. The findings showed that all trials had lower than expected South Asian population figures, suggesting their under-representation in clinical trials.

Owing to limited empirical evidence, a lack of ethnic minority recruitment data and the absence of inclusion/exclusion criteria in the published literature, it is very difficult to assess accurately the relative absence of South Asian people among clinical trial participants.[15] It is assumed that South Asian under-representation in clinical trials might be due to a number of factors, including patient attitudes, institutional/organisational barriers, resource issues, socio-cultural factors, investigator attitudes and culturally inappropriate recruitment strategies. There is relatively little qualitative work on ethnic minority peoples' attitudes to participation or their refusal to participate in clinical trials. A distinct lack of knowledge about how South Asian people perceive involvement in clinical trials, their reasons for involvement or refusal to participate in trials, their perceptions of risks and benefits of participating in trials and the concept of informed consent will make explicit any 'cultural factors' that may prevent them from participating in clinical trials.

Aims and objectives

The aim of the study was to extend knowledge of South Asian patients' understanding of trials and of the processes which facilitate or inhibit their involvement in them. In order to achieve this the following objectives were explored:

- Investigation of how South Asian patients conceptualise and understand the notion of clinical trials and the concepts (such as informed consent) which are central to their operationalisation.
- Identification of the key processes which impact on decision-making about whether or not to participate in trials (such as altruism and hope for better treatment) and the extent to which communication difficulties, varying perceptions of risk and diverse attitudes to authority influence these decisions.
- Identification of whether 'South Asian' patients are homogeneous in these issues, and which factors differ between the different South Asian subgroups.
- Identification of how professionals regard the involvement of South Asian patients, their views on the dangers of exclusion and the practical difficulties of inclusion and strategies to increase participation.

Chapter 2

Review of the literature

In order to provide background information to support the study, a literature review was carried out.

Methods

The purpose of this review was to identify gaps in existing literature and to evaluate critically and explore the reasons for ethnic minority under-representation in clinical trials. The literature search was based on the guidance proposed by the NHS Centre for Reviews and Dissemination.[16]

This search strategy[17] was used to draw together the relevant literature on:

- the conduct and reporting of clinical trials, including the use of explicit and implicit exclusion criteria
- the relationship between minority ethnic populations and medical research
- debates about the generalisability of data produced by clinical trials
- methods for ensuring diversity and representation in the samples used in clinical trials.

Searches were carried out for published and unpublished work in medical and social research. Articles were obtained initially by searching MEDLINE, CINAHL, PsyCLIT, Sociofile, Cochrane Library, Helmis, Library Thesis, and Science Citation Index. A number of specialised databases were also searched; these included The King's Fund Library database (London), Ethnicity Database (Bradford), the Centre for NHS Reviews and Dissemination (York) and UK OP, the catalogue of UK official publications (British Library, Boston Spa). Bibliographies were scanned for relevant articles and further papers identified through personal contacts with fellow researchers, and searching PubMed and the above-mentioned databases for prominent researchers in this field. Government official documents and official websites such as the National Research Register (NRR) and the Medical Research Council (MRC) were also searched for relevant information and any recent or ongoing research.

The extent of and reasons for ethnic minority under-representation in clinical trials

There is increasing interest in ethnic minority involvement in clinical trials in the USA, but there has been no comparable research exploring ethnic minority participation in the UK.

It is generally agreed that the RCT is the most effective method for evaluating healthcare treatments.[18] However, exclusion of minority ethnic patients from clinical trials is common and can result in trial findings being based on unrepresentative populations.[19] A review of the exclusion criteria used in trials found that many had blanket exclusions for ethnic minority participants, without any justification.[13] Ethnic minority populations have also been used frequently as exclusion criteria and control variables in regression analysis (treating ethnicity as a confounding variable), thus encouraging researchers to try and 'control for' its effects.[20]

It is prudent to include ethnic minority people in clinical trials in order to sustain the generalisability of the findings to the population as a whole and also to provide opportunities to undertake subgroup analyses to determine if ethnic origin influences how the intervention works.[21] Having said that, inclusion of ethnic minority people in clinical trials in order to allow subgroup analyses may not be so straightforward. There is concern amongst some statisticians about the validity of this process, which can be potentially misleading since there is a tendency to over-emphasise the results of subgroup analysis.[22] For accurate investigation of any differences in treatment responses and adverse effects across ethnicities, there is a need to specify subgroup analyses in advance and to take these into account when calculating sample size. Unplanned subgroup analyses have been shown to produce misleading results.[23]

A person's ethnic origin also plays an important role in their response to drugs. In public health, it is widely accepted that there are gender differences in drug metabolism[24] and in the

anatomical location and extent of disease for certain solid tumours.[25] Differences in drug metabolism are also attributed to complex interactions between genetic factors, the environment and culture.[26] Metabolism of drugs, concurrent diseases and counter-indications have been shown to vary considerably between different ethnic groups.[27] Despite this knowledge, subjects who typically participate in clinical trials tend to be white educated men, predominantly from middle-class backgrounds.[28]

Apart from poor science, exclusion from clinical trials also raises issues about equity in healthcare provision, since there is some evidence to suggest that people who take part in clinical trials fare better than those who do not.[29] Exclusion of ethnic minority people from clinical trials, it has been argued, also denies patients state-of-the-art treatment for diseases, frequent follow-up consultations and closer disease monitoring and management.[30]

More generally, ethnic minority exclusion from clinical trials also undermines the government's NHS plan for tackling inequalities and its core principle of providing culturally appropriate and accessible care for different groups and individuals.[31] Since there can be no scientific basis for excluding this group of people from clinical trials, exclusion suggests a form of discrimination in which minority ethnic populations are denied the same opportunities as the general population.

The reasons for ethnic minority under-representation in clinical trials might also be due to health professionals being unaware of the importance of representational sampling, and also historical or paternalistic reasons.[15] Traditionally, women of childbearing age have been excluded from clinical trials because of ethical considerations. Exclusion criteria that prevent older people from participating in clinical trials may be due to beliefs that they are fragile, vulnerable and have multiple illnesses, an assumption made regardless of their actual health status. It is also suggested that ethnic minority people and those from low socio-economic backgrounds may similarly be excluded from trials in order to protect them from potential manipulation and exploitation.[32] This belief is reflected by the recent good clinical practice (GCP) guidelines, which define ethnic minority people as 'vulnerable subjects', in need of protection from exploitation.[33] This has repercussions regarding the safety and the efficacy of new drug and medical interventions.

Although guidelines to improve the quality of undertaking and reporting clinical trials have been developed, e.g. the Consolidated Standards of Reporting Trials (CONSORT) statement,[18] there is evidence that they are still not being described adequately in publications.[34] Few peer-reviewed papers clearly stipulate exclusion criteria or the study population's ethnic background.[35] A UK-based review of RCTs of statins over the last decade showed that only eight out of 47 RCTs were specific about ethnicity, and these were all US based.[36] The paucity of ethnic minority recruitment data and the absence of inclusion/exclusion criteria in the published literature make it very difficult to assess accurately the relative proportion of ethnic minority groups involved in clinical trials. Exclusion from trials, based on an individual's ability to speak English, is a major barrier to South Asian participation in clinical trials, although the issue is wider than this.

Findings from an exploratory empirical study

We undertook an investigation of the ethnicity profile in six trials (chosen because of their broad recruitment in terms of size and number of centres), conducted by the Clinical Trials Research Unit (CTRU), to ascertain the proportion of South Asian participants. All the trials were Phase III, multi-centre RCTs; two were national breast cancer trials, two were national gynaecological trials (one a surgical, hysterectomy trial and the other for ovarian cancer); the fifth was a national, minimally invasive surgical trial of colorectal cancer and the sixth a regional study investigating *Helicobacter pylori* eradication in general practice. We found a range between 0% and 1.7% (mean, 0.6%) of South Asian (Indian, Pakistani and Bangladeshi) people in the six trials (*Table 1*). The highest recruiter of South Asian participants was a community trial which was based throughout Leeds and Bradford and targeted lower socio-economic, inner-city practices and therefore would be expected to have a higher than average ethnic minority recruitment. Even this trial's recruitment was lower than expected, when compared to the Office for National Statistics (ONS) latest estimates of South Asian populations in the Yorkshire and Humberside Region and the Great Britain South Asian population.[14]

This small survey used only the rather crude comparative data available for the expected South Asian population. We would have liked to compare

TABLE 1 *Proportion of South Asian participants in six multi-centre clinical trials*[a]

Trial type	Gender	Trial population age (years)	Recruitment	Recruitment figures	Number (%) of South Asian participants
Hysterectomy	Female	>18 [mean 41.2 (SD 8)]	National	1380 randomised	8 (0.6)
Colo-rectal cancer	Male and female	>18 [mean 69; range 25–94]	National	584 on whom ethnicity data are available	1 (0.2)
Breast cancer	Female	Mean 64	Regional	780 randomised	2 (0.3)
Breast cancer	Female	Most >55	Regional	133 randomised	0 (0)
Ovarian cancer	Female	>18[b]	Regional	480 registered (242 randomised)	3 (0.6)
			National	559 registered (300 randomised)	4 (0.7)
Helicobacter pylori eradication	Male and female	40–49	Regional	8407 participants	145 (1.7)

[a] ONS latest estimates of South Asian population figures are 3.8% for the Yorkshire/Humber Region and 3.4% for Great Britain as a whole.[11]
[b] Range and mean unknown.

more precisely the trials' inclusion criteria of age range and sex with those of the expected South Asian population, but this information is not currently available. Trials that recruited older patients would not be expected to comprise a percentage of South Asian people equal to the overall figures of the ONS because the number of elderly South Asian people in the UK population is small.

Medical research – a historical context

In the 1940s, widespread revulsion at Nazi experimentation on human subjects led to the development of an ethical code of research on medical subjects – the Nuremberg Code. This began a cascade of regulations emphasising the protection of human participants in medical experiments. The notion of 'protectionism' was beginning to be challenged by the American national commission for the protection of human subjects of biomedical and behavioural research in the Belmont report 1978. This report contained three basic ethical principles: respect for persons, beneficence and justice.

Adopting the provisions outlined in the Belmont report came too late for the 400 or so unknowing African-Americans who took part in the Tuskagee experiment (1932–72). The Tuskagee syphilis study was a long-term US government-funded experiment, looking at a cohort of African-American men who were diagnosed with syphilis but left untreated for many years, for the sole purpose of determining the course of untreated disease.[37] This was the longest non-therapeutic experiment on humans in the known history of medicine and is considered to be a key factor in creating a sense of mistrust and suspicion of the medical profession by African-Americans.

The legacy of the Tuskagee experiment is less relevant to the UK population compared with the thalidomide tragedy in the 1960s. The anti-nausea drug thalidomide, when prescribed to pregnant women, caused severe foetal abnormalities. This led the US Food and Drug Administration (FDA) to establish a policy in 1977, whereby pregnant and potentially pregnant women were routinely excluded from trials.[28] Both the Tuskagee experiment and the thalidomide tragedy made the institutional review boards (IRBs), the American equivalent of ethics committees, over-cautious and protective about including 'vulnerable' groups such as women and ethnic minorities in clinical trials. This view may have served the purpose of labelling women and ethnic minority groups as challenging or problematic in the minds of researchers.

With time, the international scientific community started to challenge and question the routine exclusion of women, ethnic minority groups and older people from biomedical research. Scientific

concerns were also being raised about the external validity or the appropriateness of applying trial findings from a homogeneous sample to a heterogeneous population. These issues led the US government to implement the National Institutes of Health (NIH) guidelines on inclusion of women and ethnic groups in clinical trials.[38]

The US experience

In an attempt to increase the external validity/generalisability of trial findings, the NIH Revitalization Act (1993) requires all NIH-supported research projects to include women, older people and ethnic groups, unless there is a clear and compelling justification not to do so.

The NIH guidelines on the 'blanket' inclusion of women, older people and ethnic minorities as participants in clinical trials have also opened up a Pandora's box of discussions around the definition of minority ethnic groups and the use of ethnicity as a variable. Since the introduction of the NIH Revitalization Act, investigators have been increasingly struggling to understand and implement these guidelines.[39] The guidelines categorise people into five groups: American Indian or Alaskan Native; Asian or Pacific Islanders; black, not of Hispanic origin; Hispanic; and white, not of Hispanic origin. This crude definition of ethnicity, coupled with the ambiguities surrounding the concept of race, ethnicity and culture, makes the recruitment of ethnic minority people appear more problematic to researchers.

It can be argued that NIH guidelines seem to imply that people of different races differ biologically, thus accentuating potential racial differences between ethnic and white groups, instead of recognising the effect of other equally important variables such as socio-economic and environmental factors that play an equally important role in disease. The NIH guidelines may also encourage some researchers to include ethnic minority people as a token gesture in order to secure funding from the NIH. There is, therefore, a danger that the NIH guidelines may unwittingly harbour and encourage the very beliefs that originally contributed to the Tuskagee experiment.

Methodological tensions

Clinical trials have evolved to test the efficacy and effectiveness of medical interventions and medications, requiring large subject numbers and multicentred trial sites. This has led to complex collaborations between medical professionals, support staff and clinical trial coordinators. Issues of ethics, feasibility and cost have to be addressed satisfactorily, all adding further to the complexity of the planning and conduct of clinical trials. Representative sampling, therefore, occurs against a backdrop of more general organisational and practical difficulties.

Cost issues

Running and recruiting into clinical trials is costly. Addition of 'extra variables' such as women and ethnic minority people, to perform subgroup analysis, means that more subjects have to be recruited into the trial. An analysis of different enrolment mixes in two American studies, the Physicians' Health Study (PHS) and the Multiple Risk Factor Intervention Trial (MRFIT), showed that inclusion of women and minority groups would almost double the cost of each trial.[40] This illustrates that the active inclusion of ethnic minority people in clinical trials has substantial resource implications, since a large number of persons eligible for the study are required to permit selecting subgroups in 'proper' proportions. There might also be additional costs of ethics committees' requirements that include translated information sheets in addition to employing staff with cultural and linguistic skills. Disregarding any additional expenditure on trials, owing to accommodating translation and interpreter cost, may mean that provisions are not made for those ethnic minority people for whom language is a barrier to communication.

Conceptualising ethnicity

Conventionally, epidemiologists and social scientists define populations using labels such as age, marital status, sex, race, ethnicity, religious affiliations, socio-economic status and educational level. At one end of the spectrum ethnic minority groups are defined in terms of demographic labels, and at the other end more specific markers for ethnicity are used, such as race, religion, migration status and other socio-cultural attributes. Defining ethnicity, therefore, is a challenge in itself, since there is no clear definition[41] and there is growing realisation that current definitions, largely based on a person's geographical heritage or origin, are increasingly inadequate in making sense of the experience of minority ethnic populations.[42] Diversity between ethnic groups further complicates the picture. South Asian people are a good example of a rich diversity within an ethnic group, including language, religion, socio-economic status, cultural

traditions, lifestyles and health beliefs, all determined by their experiences in the UK.

Inappropriate exclusion criteria

Designing a clinical study allows for considerable discretion on behalf of the professional, whose own belief systems and personal agendas may guide the design and recruitment for trials. For instance, if a researcher knows that the statistical power will be reduced and the cost increased by including women and ethnic minorities, or at some level believes that certain populations are not at risk for specific conditions and illnesses, then the study design might exclude those groups. Even altruistic beliefs, such as older patients or those with advanced stage disease not being able to tolerate the vigorous treatment regimes required for many studies, can skew the results by excluding such groups from the trial. It is also suggested that the Tuskagee experiment is a good enough reason to exclude ethnic minority groups from clinical trials in order to protect them from medical exploitation.[4,28]

A commonly used exclusion criterion, the ability to understand and speak English, could be a potential barrier to ethnic minority participation in clinical trials. The language barrier perhaps makes the greatest impact when obtaining consent from trial participants. Informed consent is the foundation of any clinical trial[43] but the process itself is fraught with dilemmas because of the potential for the participants to be exploited,[44] lack of understanding[45] and the limited time allowed for decision-making.[46] The increasing complexity of consent forms and information sheets may induce confusion and even fear in many people. However, there are barriers other than language, such as lack of cultural understanding, cultural myths and stereotypes, which can also undermine the communication process.

Socio-cultural barriers

Health research indicates that ethnic minority people are not treated equally.[47–52] There are also well-documented disparities in healthcare due to late presentation, inappropriate services, access difficulties, socio-economic background and racism.[53] A significant element of ethnic inequalities in health, therefore, relates to the disparities in socio-economic position within and among different ethnic minority groups.[52,54] This highlights that ethnic minority groups cannot be characterised as equally disadvantaged and that ethnicity should not be reduced to just a socio-economic variable.[55] Low ethnic minority recruitment to clinical trials might, therefore, be in part due to 'racially' constructed socio-economic factors that allow less utilisation of healthcare and hence a reduced opportunity to take part in trials. Since it is virtually impossible to disentangle issues relating to poverty from those related to ethnicity, low socio-economic status should be viewed as a potential barrier to ethnic minority participation in clinical trials.[56,57]

Cultural, linguistic and economic barriers have also been implicated as reasons for delayed early prognosis, prompt treatment and low ethnic minority participation in clinical trials.[58] Differences in health beliefs and behaviour are thought to influence the opportunity for clinical trial participation. It has been suggested that cultural beliefs or myths about disease or illness can vary considerably amongst different ethnic groups.[59] Illness may not be seen as a problem that needs sorting and this will affect the likelihood of such people participating in clinical trials. Similarly, issues concerning modesty, to do with religion and culture, in some ethnic minority women may result in low participation, and some may prefer to use alternative forms of medicine such as hakims (spiritual medical advisors) and herbal medicine, but evidence for this is conflicting.[60,61]

In conclusion, the documented evidence to support the common explanations for low ethnic minority recruitment rates in clinical trials include a history of exploitation of ethnic minority people by medical research, methodological/organisational factors and cultural and socio-economic barriers. Exclusion of ethnic minority people from clinical trials is not only poor science, because it challenges the external validity of trial findings, but also raises issues around equity in health provision.

The review also highlighted a lack of research on South Asian participation in UK trials and a poor understanding of their perspectives about participation in clinical trials. There is some speculation about how South Asian people make decisions about participation in clinical trials,[62] but otherwise there is a distinct lack of data in this area.

It is unclear from the literature whether low South Asian participation rates in clinical trials are a result of mistrust of medical research, the disproportionate effect of exclusion criteria or

TABLE 2 *Summary: extent of and reasons for ethnic minority under-representation in clinical trials*

1. Ethnic minority under-representation in clinical trials challenges the generalisability of trial findings and raises issues around equity in heathcare provision.
2. It is unclear from the literature (mainly US) whether low ethnic minority participation rates in clinical trials are a result of:
   (a) history of exploitation
   (b) mistrust of medical research
   (c) inappropriate exclusion criteria
   (d) organisational/structural issues
   (e) socio-cultural characteristics.
3. Findings from a small empirical study suggest that South Asian people might be under-represented in UK-based clinical trials, and reasons for this are unknown.
4. There is no evidence of researchers proactively ensuring a greater ethnic diversity in UK-based clinical trials.
5. There is poor understanding of South Asian people's perspectives on clinical trial participation.

organisational/structural barriers to participation. The literature also acknowledges that in addition to a participant's ethnicity, it is equally important to consider other socio-cultural characteristics such as gender, age, level of education, primary language and socio-economic background.

A summary of the extent of and reasons for ethnic minority under-representation in clinical trials is given in *Table 2*.

Lay perspectives on clinical trial participation

The general public may be losing confidence in medical research. Stories of human violations such as enrolment of ineligible patients, failure to follow the approved protocol and failure to protect the welfare of participants dominate the media.[63–64] Drug companies are perceived as failing to develop new drugs for diseases that affect predominantly the poorer nations, because they are not profitable enough, and people in the developing world as being exploited by pharmaceutical companies.[67] As a result, public confidence in clinical trials is undermined, and they are often stigmatised as 'human experimentation', owing to the exploitative use of some populations as research subjects and then failing to use the knowledge gained for the direct benefit of those populations.[68]

The current system for safeguarding people who volunteer to take part in clinical trials appears to be increasingly under stress, because of unprecedented growth in clinical research. Furthermore, the commercialisation of research is thought to be largely responsible for the public mistrust of science, where scientists are no longer perceived as guardians of objective truth, but as promoters of their own interests in a media driven market place.[69] As a result, there has been an increase in British efforts to inform the public understanding of science.[70]

Clinical trial participation in the UK

In the UK, the proportion of patients participating in clinical trials is relatively low and has declined further in recent years.[71,72] This might be because the NHS is becoming a less attractive place for pharmaceutical companies to conduct clinical trials, owing to Britain's poor record in trial recruitment, slow and confusing ethics committee processes or weak research management.[73] *Figure 1* shows that Britain has lower recruitment rates than other Western countries, and manages to recruit less than 80% of the patients promised for each trial.[73]

In the recent past, the reasons for poor recruitment rates in the UK have been blamed on factors associated with poorly trained clinicians, patient attitudes, and strict eligibility criteria.[74,75] Of more concern, health professionals obtaining informed consent are often not given appropriate training, and most ethics committees have no power or time, owing to their increasing workloads, to carry out their monitoring role.[5] The consequence of low participation rates not only means that clinical trials are taking longer to complete (because of extended recruitment periods) but also that the analysis of important results is delayed. This, according to Lara and colleagues, is unethical, because it denies future patients potentially superior treatments.[76] Low trial participant numbers also mean that the statistical power of the clinical trial is reduced and is one of the main reasons for early abandonment

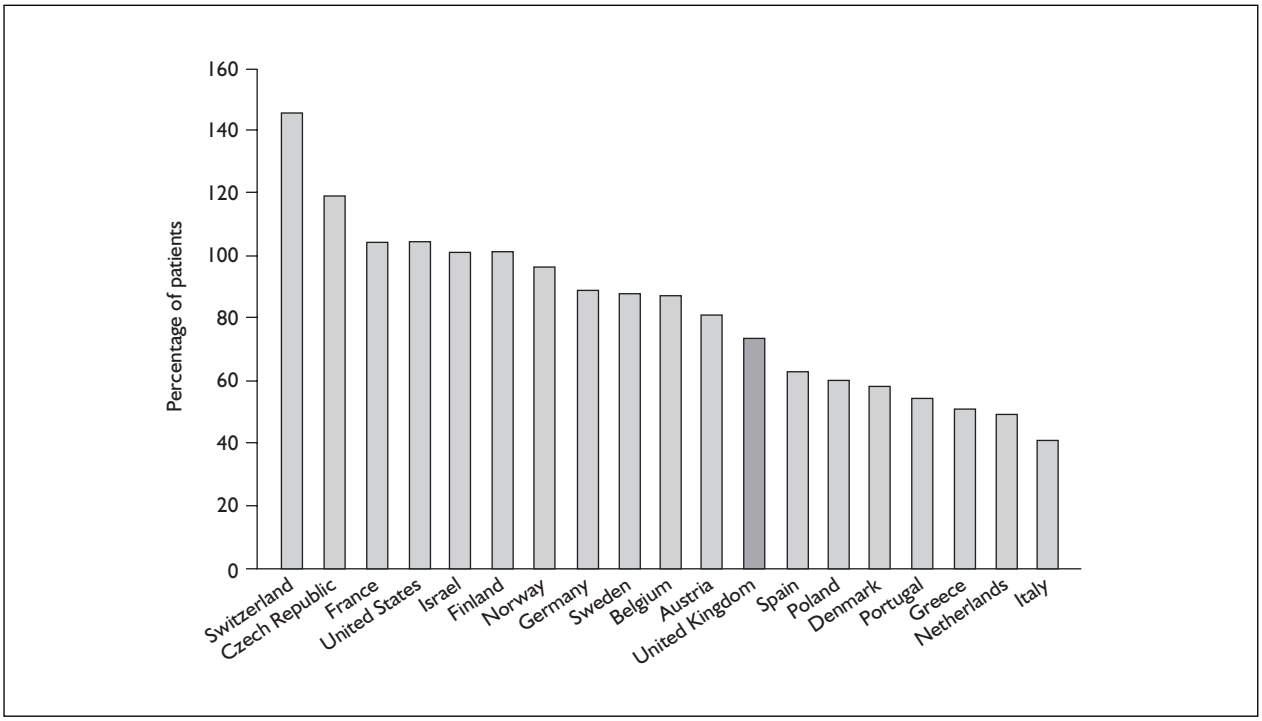

FIGURE 1 *Percentage of patients recruited against target for clinical trials*

of trials and increased costs associated with setting up large multicentre trials.[77] Studies have also been discontinued owing to poor recruitment of both patients and healthcare professionals.[78] Consequently, a lack of understanding of science, coupled with increasing consumerism of scientific research, can lead to mistrust of medical research by lay people.

However, it is estimated that more than 500,000 people volunteer for some form of medical research in the UK each year.[79] Little is known about why individuals participate and remain in clinical trials and about their views and experiences of taking part in them. Yet it is this population that constitutes potential participants for future clinical trials. A comprehensive literature identified a small number of studies that used hypothetical scenarios to explore public attitudes towards clinical trial participation. One UK survey of 1022 adults showed that 63% were prepared to be entered into an RCT to evaluate treatment for either a major illness or for cancer.[80] Cancer was also shown to be an important motivating factor for clinical trial participation in a US study, where a telephone survey of 489 lay people indicated that 46% were willing to take part in clinical trials with 29% being undecided and 25% unwilling. Half of those who were undecided said that they would take part if faced with cancer.[81]

It can be argued that lay perspectives on clinical trial participation might not necessarily be matched by action. When faced with the decision to take part in a trial, a host of factors come into play affecting a person's decision. Prospective participants may feel pressurised to take part in clinical trials for the fear of retribution, such as denial to future access to healthcare, or patients may not have other access to healthcare. However, a survey of two groups (cancer patients versus healthy controls) in the USA showed no significant differences in the attitudes of the two groups towards clinical trial participation.[82] Similarly, it was found there was very little difference between lay perspectives and the perspectives of actual trial participants.[83] Finally, it is important to recognise that clinical trials are a complicated phenomenon, involving institutional frameworks, socio-cultural variables, political considerations and the activities of many individuals. The context in which they are offered strongly influences a person's decision to participate or decline from taking part in them.[84]

Patient motivation to participate

Reasons why patients consider taking part in clinical trials are grouped together under four broad themes: altruistic factors, perceived or actual health benefits, clinician influence and favourable previous experiences. The types of

trials discussed here include prevention, screening/diagnosis and treatment trials. Owing to the limited literature in the UK, most studies are from the USA. *Table 3* summarises the main reasons for participating in clinical trials.

Altruistic factors

Altruism, advancing medical knowledge and contributing to scientific information were highly rated as motivators for taking part in clinical trials by patients.[77,85,86]

Health benefits

Many patients may also take part in clinical trials owing to the health benefits associated with participating in them.[62,87–89] Psychological factors such as potential or perceived health benefits were also cited as the main reason for trial participation among those already enrolled in trials,[90] and a UK-based cancer study of 78 patients showed that they were attracted to taking part in RCTs owing to being treated by a cancer specialist and encouraged by the prospect that their treatment would be closely monitored.[91] Reassurance provided by regular clinical examinations and the 'personal' nature of clinical care has also been used as a motivator.[88]

Clinician influence

The clinician responsible for recruitment has been shown to have a major influence on the decision to enter a trial[35,92] and trial participants included 'liking' the trial clinician as a motivator for taking part.[77,93] Trust in the doctor was also an important consideration in a UK-based questionnaire study of 204 patients.[74] Their findings showed that patients were generally willing to take part in RCTs but the type of trial and the communication style of the doctor/nurse exerted a considerable influence on their likelihood of participation. Clinician influence on the likelihood of participation in a clinical trial was, however, contradicted by a smaller UK study (n = 78), which showed that patients were not as susceptible to pressure to participate as had been proposed.[79]

Favourable previous experiences

Prior good experiences of taking part in clinical trials could motivate some patients. Surveys of patients who had previously participated in RCTs show that a general satisfaction with previous experiences was a strong motivational factor.[85,89,94] One large US cancer trial (n = 1949) showed that the majority of the trial participants had favourable attitudes towards medical research owing to positive experiences with clinical trial participation in the past. It appears that satisfaction with participating in clinical trials can improve a patient's likelihood of taking part in future trials.

TABLE 3 *Summary of patient motivations for clinical trial participation*

- Altruistic factors
- Health benefits
- Effective follow-up
- Clinician influence
- Communication style of doctor/nurse
- Satisfaction with previous experience

Reasons for non-participation

There are a number of barriers to clinical trial participations including trial burden, treatment preference, drug side-effects/fear of experimentation, randomisation process and informed consent. Hence declining to participate in clinical trials depends on a range of practical reasons and moral objections.

Trial burden

Participation in clinical trials can be demanding on patients as it can involve additional appointments and procedures, some of which cause discomfort, inconvenience or additional expense, including travel and childcare costs.[77]

Treatment preference

Withdrawal could be due to a belief that participants should be paid or a strong preference for or against a particular treatment regimen. Such preferences included reluctance to change medication, to take placebos, not to take any medication at all and issues around random allocation. Logistical factors, such as ease of access to services, have also been shown to influence patients' likelihood of participation in clinical trials.[88]

Drug side-effects and fear of experimentation

Limited research in this area shows that by far the most commonly cited barrier to clinical trial participation is concern about side-effects of drugs[95] and fear of experimentation.[90] This response was not shown to differ by ethnicity or gender and was dependent on educational level in the two US-based studies. Distrust of hospitals and fear of the unknown were also cited as barriers that prevented patients from entering clinical trials, and other factors highlighted by the same US study of cancer patients showed that reasons

for non-participation depended on the geographical location of the study site (i.e. too far away) and a fear of randomisation.[76] Concerns about drug side-effects and fear of experimentation should, therefore, be considered a major barrier to clinical trial participation.

Randomisation process

The randomisation process and its explanation appear to be another barrier to patient participation in RCTs.[85] Uncertainties and ignorance around the randomisation process can lead to 'fear of randomisation'.[96] The randomisation process or the method of treatment allocation was also shown to be unclear in a questionnaire study of 299 Finnish breast cancer patients, where almost 51% thought that the doctor had chosen the treatment and only 23% knew that they had been randomised and were able to explain what randomisation meant.[89]

Having evaluated some of the barriers to non-participation, it is clear that some patients find it difficult to comprehend the conceptual scientific basis of clinical trials. Furthermore, a University of Chicago study, showed that even though 90% of the patients stated that they understood all or most of the information provided in order to make an informed decision to participate in the trial, in reality only one-third of the patients could actually state the purpose of the trial.[43] Concern about drug side-effects, fear of experimentation and the randomisation process can be overcome by improving the process of information provision, which might lead to a better understanding of clinical trial concepts.[89] Since decision-making with regard to participation in clinical trials is dependent on the comprehension of often very technical medical terminologies, which might confuse many people, providing potential trial participants with appropriate study information should be considered an important aspect of obtaining informed consent. However, the literature rarely cites the actual process of informed consent as a barrier to clinical trial participation.

Informed consent

The concept of informed consent recognises the patient's right to participate voluntarily in clinical research. It exists because patients considering participation in clinical trials are viewed as potentially vulnerable and may be facing difficulties appreciating the difference between the therapeutic and research aspect of a given treatment. In addition, it takes into account the clinician/investigator's conflict of interest in their role as a clinician and a scientific investigator. Informed consent has, therefore, been set up to protect the potentially vulnerable research participant from harm,[43] and is a standard legal and ethical requirement, which is recognised internationally.[6]

Recently, informed consent forms have become increasingly unreadable, lengthy and uninformative.[43] Even though, in general, participants prefer to sign a consent form,[97] its purpose may not be totally clear to them.[77,98] Obtaining consent has been acknowledged as a barrier to patient participation in clinical trials and, if not required, clinicians would enter more patients in clinical trials.[35] Signing of the consent form is also dependent on the patient's relationship with their doctor.

Trust in the doctor

It was suggested that the doctor responsible for recruiting is likely to have an influence on the participants' decision to enter a clinical trial. One study showed that patients declining from signing the consent expressed less confidence in their doctor.[99] Trust in the doctor, therefore, must be the fundamental foundation underpinning the process of obtaining consent.

Level of information provision

Evidence about the provision of information on clinical trials is conflicting in the literature, and patients have been shown to suffer from either too little or too much being said. Some studies indicate that both participants and non-participants want more information about clinical trials,[87,97,100] whereas others suggest that giving patients more information is associated with lower recruitment rates.[77] Total disclosure of study information has also been shown to induce anxiety in some trial participants.[99] An insightful study by Myers and colleagues provides further evidence in support of this. In their study, some participants were informed that they might experience gastrointestinal irritation and some were not. Regardless of the treatment group to which they were assigned, those who were informed reported more frequent gastric side-effects causing them to withdraw from the study, compared with those who were not.[101] This suggests that there is a danger that informing patients of every conceivable side-effect could increase the likelihood of the patient developing a symptom through the power of suggestion.

Provision of written information has been shown to significantly improve patients' knowledge about

and attitudes toward RCTs.[102] This finding is contradicted, however, by a UK-based study, where the patients' decision to participate in trials may have been influenced by the verbal information provided, and the written information was difficult for them to understand.[103] Study information may not necessarily be provided to all trial participants.[87] Similarly, two other UK-based studies showed that 28 and 23% of patients were not provided with a written information leaflet despite the fact that this is a mandatory requirement for ethics approval of any RCT.[74] Finally, owing to the apparent paradox about the optimum level of information, the best solution might be to present the study information in a simple way, using a combination of both written and verbal information.

TABLE 4 *Summary of barriers to clinical trial participation*

1. Additional demands on the patient:
   (a) additional procedures and appointments
   (b) travel problems and childcare costs
2. Complexity of protocol causing problems with recruitment
3. Patient preference for a particular treatment or no treatment
4. Side-effects of drugs
5. Fear of experimentation
6. Poor comprehension of conceptual basis of clinical trials
7. Distrust of hospital or medicine
8. Geographical location of the study site
9. Process of gaining consent
10. Socio-cultural aspects

Trial participants' background

The willingness to participate and level of information required by the potential trial participant might also depend on their age, education and socio-economic background, and the limited literature on this topic is contradictory. A Finnish study investigating communication needs of patients found that the younger and more educated had a better understanding than the older patients and those who were less educated.[89] A desire to have more information and say in treatment was also shown to be strongest among young people and the more highly educated, as indicated by one UK survey.[80] These findings are contradicted by a UK study which suggests that the willingness to participate in a clinical trial is associated with being older and less educated and belonging to a lower socio-economic group.[88] The findings, nevertheless, indicate that the demographic characteristics of the potential trial participant must be borne in mind when obtaining informed consent.

Approach to decision-making

Attitudes to decision-making about participation in clinical trials can vary among individuals. The ethos within biomedicine, which advocates that patients should be encouraged to take an active role in medical decision-making, might not be easy to achieve. The potential trial participant's decision about whether to participate in a trial or not has been shown to be dependent on the 'important other' person's views (spouse, family member or close friend).[95] Similarly, one large US-based oncology study showed that nearly half of the patients made the decision to participate in the trial with the help of others.[92] An active role in medical decision-making has been shown to depend on a participant's age and educational background. Younger people were shown to be 'more independent' decision-makers than older patients, who preferred to leave the treatment decision to their doctors.[93] It is also possible that decision-making is dependent on an individual's cultural and ethnic background.

In summary, obtaining informed consent is a complicated process, which is dependent on a number of elements, including trust in the doctor, the level of information provided to the potential trial participant, the demographic characteristics of the trial participant and their approach to making decisions. The format of information provision may, therefore, have little impact on the potential trial participant's understanding of the subject. The consent process should focus on specific patient needs, including a greater sensitivity to trust and their socio-cultural background. *Table 4* summarises the barriers preventing patients from participating in clinical trials.

Poor understanding of science amongst lay people and the increasing commercialisation of clinical trials might lead to mistrust of medical research amongst the general population. This might partly explain poor clinical trial participation rates in the UK. Low recruitment rates in the UK might also be due to the barriers identified in *Table 4*, and any efforts to improve recruitment rates should concentrate on overcoming such barriers. The general barriers to recruitment are mostly generic in nature and, therefore, apply equally to the general population and to ethnic minority people.

The issues of patient information and consent also featured highly because these are particularly

contentious issues. Obtaining informed consent is a complicated process depending on trust in the doctor, how the information is provided and the potential trial participants' socio-cultural background. A breakdown in communication, due to a breach of any of these factors, might result in the patient refusing to participate in the clinical trial.

Finally, the findings reported here are mainly from cancer research and are hospital based. Any extrapolation of the findings to other clinical settings and geographical areas may not be ideal. It might be the case that owing to international differences in healthcare systems, UK citizens might be expected to differ from patients of other nationalities in their approach to participation in clinical trials. However, a UK study reported no clear differences between their findings and those reported in patient studies from the USA or Sweden.[87]

Table 5 summarises lay perspectives on clinical trial participation.

Professional perspectives on clinical trials

The health professional's 'willingness' to enter patients into clinical trials introduces another potential barrier to successful recruitment to clinical trials. Recruitment to clinical trials is complex and is dependent on the environment of the institution, the organisational framework, logistic barriers and health professionals' attitudes towards patients. A discussion of these follows.

TABLE 5 *Summary: lay perspectives on clinical trial participation*

- Poor understanding of science and increasing commercialisation of clinical trials means that the general population are just as likely as ethnic minority people to be mistrustful of medical research
- Britain, in the past, had a bad record of trial recruitment owing to slow and confusing ethics committee processes, weak research management and poorly trained clinicians
- Obtaining consent is a complicated process and depends on trust in the doctor, level of information provided and the potential trial participants' socio-cultural background. A breach of any of these factors can lead to a refusal to participate in clinical trials
- Barriers to clinical trial participation, identified in the literature, are generic and equally pertinent to ethnic minority people

Barriers to health professional involvement in clinical trials

Delays and problems with recruitment of health professionals to clinical trials are considered a major obstacle to successful completion of clinical research.[4] A number of barriers have been identified from the limited literature which might prevent health professionals from undertaking clinical trials themselves and recruiting patients to them. This is because health professionals face a dilemma where their traditional role as a caregiver is challenged by their conflicting and disparate role as a researcher/experimenter. Literature shows that those health professionals who take part in RCTs are often labelled as 'unfeeling', whereas those who do not participate in research are labelled 'unprofessional'.[75] The barriers presented next are grouped together and explored. *Table 6* provides a summary of health professional-reported barriers to participation in clinical trials.

Patient concerns

Undertaking clinical research can affect the doctor–patient relationship and concern about this has been shown to act as a barrier to health professional recruitment to RCTs.[75,77] Health professional concerns about recruiting patients to clinical trials have been found to be due to worries about treatment toxicity, the burden of the trial for the patients, travel costs, a reluctance to recruit more severely ill patients and a fear of feeling responsible if the patient did not receive the treatment which turned out to be best. In addition, loss of clinical autonomy and independence, where reporting to a third party, and an inability to individualise patient care were shown to be reasons for not recruiting all patients to trials.[77]

Such concerns about patients can result in not recruiting eligible patients to clinical trials. One study showed that 50–80% of eligible cancer

TABLE 6 *Health professional-reported barriers to participation in clinical trials*

- Concern for patients
- Worry about impact on doctor–patient relationship
- Time constraints
- Lack of rewards and recognition
- Insufficiently interesting question
- Loss of professional autonomy
- Lack of staff and training
- Difficulty with information provision and the consent procedure
- Prejudicial attitudes

patients were not enrolled in the clinical trial appropriate for their types and stages of disease because of their health professional's decision not to offer any trial. The reason for this patient exclusion might also be due to the health professional's perception of not having a study protocol which was appropriate for that patient's tumour site and stage.[76] This finding suggests that there might be a form of bias arising from the health professional's conception of an 'ideal' or an eligible patient. This can have ramifications for the recruitment of patients, especially ethnic minority people, who face additional barriers to participation due to language, cultural misconceptions and prejudicial attitudes.

Lack of incentives

Scientifically uninteresting clinical trials can also be a potential barrier to recruiting health professionals to run clinical trials. A major reason given for one failed trial was that the research question to be tested was not of sufficient interest to participating health professionals.[78] Benefit for health professionals' reputation and that of their institution was also shown to be an incentive for participating in clinical trials in a review by Ross and colleagues.[77] It was suggested that, owing to the additional work involved in running a clinical trial, lack of financial incentives should be viewed as a major barrier to health professional involvement in clinical trials.

Financial support

Studies have been discontinued owing to low health professional recruitment and it has been suggested that better compliance might have been obtained with economic incentives.[77] This is, however, a contentious issue. An American study of potential trial participants exploring pharmaceutical payments to doctors found that patients believed that such payments were wrong and that they had the right to be told about them.[104] If there are payments involved, these should be disclosed to potential trial participants as part of the process of gaining consent (www.corec.org.uk). Since patients who take part in clinical trials generally do so for altruistic reasons, it can be argued that non-disclosure of financial incentives is unethical.

Limited time

Clinical trials are becoming increasingly complex and the onus of identifying, providing information and recruiting potential trial participants lies primarily with the principal investigator, who in many cases is likely to be the patient's doctor. Owing to additional time required for recruitment, the consent process and follow-up appointments, lack of time is frequently cited as a major barrier preventing health professionals from undertaking clinical trials and recruiting patients to them.[77] In a survey of the UK members of the Medical Research Society (MRS), most respondents cited diminished research time to pursue clinical research as a problem for NHS-funded professionals. This is a situation that is expected to get worse.[72] In another UK survey of NHS clinicians involved in clinical trials, increasing management and additional administrative duties due to the NHS reforms were cited as a major barrier to their commitment to clinical trials.[105]

Lack of staff training

Health professionals have been shown to be ill-prepared for the demanding research role owing to inadequate research training and experience.[106] Complicated study designs can also deter health professionals from undertaking clinical research. This was found to be the case in a study where a complicated protocol was shown to act as a barrier to health professional recruitment, owing to the staff lacking the clinical skills required to perform trial treatments.[77] Studies indicate that clinical trials may be running in everyday clinical settings without any additional support[105] and health professionals obtaining informed consent are often not given appropriate training.[107] Inadequate education and poor training in clinical trial methodology also mean that some health professionals lack confidence in clinical trials.[108]

In addition to affecting patient recruitment, information provision and the consent process can also act as major barriers to clinician participation in clinical trials. Health professionals have been shown to struggle with giving information when describing clinical trials, with particular concerns about assessing the level of information required by patients.[75] Information provision becomes even more difficult when there are socio-cultural and linguistic differences between the health professional and the potential participant. A focus group study of cancer trials showed that US doctors (n = 73) considered information provision about clinical trials as the most important clinician-reported barrier to ethnic minority participation in clinical trials.[109] The authors also suggested that some doctors might not offer clinical trials to ethnic minority patients, and that 'racial bias' should be considered a barrier to African-American enrolment in clinical trials. The findings suggest that any attitudes or stereotypes about individuals or groups of people held by

health professionals are likely to affect their recruitment of those people.

Health professionals' attitudes

Health professionals, like the rest of the society, can harbour prejudice towards certain sections of the society, but there is limited literature on how such attitudes towards potential trial participants can affect their likelihood of being recruited to clinical trials. One US study showed that health professionals' perceptions of patients were influenced by the patients' socio-economic status and members of low socio-economic status groups were perceived more negatively on a number of dimensions than upper socio-economic status patients.[110] In the same study, patients' 'race' was also shown to be associated with clinicians' assessment of patient intelligence, and beliefs about patients' likelihood of adherence to medical advice. Other stereotypes and beliefs reported in the literature include ethnic minority and other people from low socio-economic backgrounds are difficult to reach, display deviant behaviour, cannot understand the research design[4] and that ethnic minority people have less interest in taking part in clinical trials.[111] It has also been proposed that an under-representation of women and ethnic minority people in AIDS clinical trials might partially result from the attitudes and perceptions of healthcare professionals.[112]

To conclude, stereotyping attitudes towards people from lower socio-economic backgrounds and ethnic minority people may contribute to some health professionals' reluctance to recruit these groups to clinical trials. It is not unrealistic to assume that ethnic minority people may respond to such attitudes with mistrust of health professionals and hence may be reluctant to participate in clinical trials. This dynamic is particularly important in the informed consent process during which a lack of trust often leads to the patient's refusal to enter a clinical trial.[113] Since most clinical trials are not designed to tackle stereotyping behaviour (owing to a lack of culturally sensitive training), inevitably it is possible that the population recruited rarely mirrors the full spectrum of patients who are likely to participate in them. Health professionals' discriminatory behaviour towards certain sections of society should, therefore, be viewed as a potential barrier to ethnic minority participation in clinical trials.

Recruiting patients to clinical trials is difficult because health professionals face a number of barriers, including patient concerns, poor incentives, lack of time and poor staff training. The difficulties facing health professionals in participating in clinical trials is a problem that needs to be addressed, and once these have been resolved the issues of patients' willingness to participate will become a key determinant of participation.

Since recruitment of eligible participants to clinical trials is often difficult, it can become very tempting to recruit clinic populations who are immediately at hand and who satisfy the entry criteria. Further, communication between the health professional and the patient largely reflects the class structure of British society, where health professionals (mainly from middle-class backgrounds and having the benefits of further education) have more in common with middle-class patients.[114] It is, therefore, not too unrealistic to assume that health professionals are likely to recruit those patients with whom they find it easier to communicate. This can explain why there is an over-representation of white, married, middle-class men in clinical trials.

Communication problems become more intensified when consent is sought (by white recruiters) from ethnic minority patients owing to the effect of racism, unsubstantiated beliefs about cultural or religious practices of the 'other', appropriate areas of discussion between men and women and the language barrier. Any logistical barriers due to lack of time and additional resources might mean that recruitment of this group of people becomes problematic.

Professional perspectives on clinical trials are summarised in *Table 7*.

TABLE 7 *Summary: professional perspectives on clinical trials*

1. Recruiting patients to clinical trials is difficult owing to health professionals facing a number of barriers due to:
   (a) patient concerns
   (b) poor incentives
   (c) lack of time
   (d) poor staff training
2. Owing to such barriers, it is not too unrealistic to assume that health professionals are likely to recruit those patients they find easier to communicate with, i.e. those from a similar social background
3. Stereotyping attitudes towards people from lower social class backgrounds and ethnic minority people may also contribute to some health professionals' reluctance to recruit these groups to clinical trials

Barriers to ethnic minority participation in clinical trials

Although a number of studies explore lay and professional motivations and barriers to clinical trial participation, there is limited research on ethnic minority perspectives. These tend to be all from the USA, and are mostly based on African-Americans' experiences, the largest ethnic minority group in the USA. Barriers to ethnic minority participation in clinical trials, as highlighted by the literature, include mistrust, language, lack of familiarity, cultural barriers, age, geographical location and social class.

Mistrust

Medical experiments in general can be a source of suspicion and confusion among the lay public, and the literature suggests that suspicion is more heightened in the case of ethnic minority people. Mistrust of the medical profession due to the Tuskagee experiment is the most commonly cited reason why African-American people do not wish to take part in government-sponsored medical research.[115] A focus group study consisting of African-American patients not only showed a mistrust of the doctors, scientists and the government, but the participants also saw signing the informed consent document as relinquishing their autonomy and as a legal protection for the clinicians.[113] Participants in another study thought that African-American people were pressured into participating in clinical trials and that medical research involved unreasonable risks.[92] The legacy of the Tuskagee experiment was also shown to be a major barrier to recruitment in AIDS clinical trials among African-Americans, where distrust was the strongest reason for non-participation among this group.[116]

Mistrust of medical research however, is not exclusive to African-American people. A small focus group study of 13 middle-class, professional African-American women refuted the claim that the Tuskagee study was a major reason for mistrust and low participation rates among African-American people.[21] The findings of this insightful study indicated that there is a poor understanding of the dominant white medical community concerning the beliefs and values of black patients, and that the Tuskagee experiment is often used as the rationale for the low recruitment of African-American people into clinical trials. Such lack of understanding not only potentially compromises their health and illness care but also, it can be argued, constitutes a form of discrimination where the needs of ethnic minority groups are either unmet or denied owing to misconceptions. The finding also touches upon another important point, the effect of social class on clinical trial participation.

Language also plays an important role in how individuals understand medical research and their participation in it.[117] In a study of white lay perspectives, 70% of the respondents thought that medical experimentation was riskier than medical research and that medical research was riskier than medical studies or clinical investigation/clinical trials.[92] The term medical study appears to have a more positive and benign connotation than medical experiment amongst both ethnic minority and the majority white population.

Differences in perceptions and attitudes between ethnic groups are governed by their past experiences. The fact that African-American people were enrolled in experiments without their prior knowledge is the reason why they might place mistrust as the most important barrier to clinical trial participation. Language, on the other hand, is more of a barrier to participation among Hispanic people and native-Americans, owing to communication difficulties in this group.

Language

Ethnic minority people, especially those whose first language is not English, have been traditionally excluded from research studies owing to language barriers.[62,111,118–120]

Provision of translated study information sheets might be a possible solution; however, they are not always provided in clinical trials and, when they are, the literature shows that they are not used very often in decision-making about clinical trial participation. Even if the resources were available to translate the study information sheets and the consent forms into a number of different languages, assumptions are still being made that they will be read and understood by potential trial participants.[121] High 'illiteracy' rates were highlighted in South Asian patients who attend Bradford hospitals. It was suggested that written translation of information in a variety of languages may prove to be ineffectual and that audio or video tapes may be more productive for the dispersal of information.[122] The idea of 'illiteracy' is also problematic when used in relation to South Asian languages. The relationship between oral speech and written language is not necessarily the same as it is for Western languages. For instance, the Gurmakhi Pubjabi script is used by Sikhs across the world, whereas Punjabi does

not have any particular script for Pakistani Muslims, who tend to write in Urdu.

A solution to alleviate the language barrier may be the provision of interpreters. This might be difficult to achieve since the NHS does not provide adequate language support for those whose first language is not English, and interpreters are often in short supply, difficult to get hold of and lack adequate training.[123] Even if interpreters are provided for recruitment to clinical trials, difficulties can still occur owing to lack of specialist medical training, which can result in patients acquiring misleading and erroneous information.[124] The ideal solution might be to provide bilingual health professionals who would recruit ethnic minority people to clinical trials. This strategy was found to be beneficial in one study, where the public favoured bilingual staff rather than non-medically trained interpreters, because it improved their access to GPs.[125]

Clinical trials are also based on Western research paradigms which not only fail to take into consideration non-Western cultural beliefs, but also do not translate well for members of other ethnic minority groups.[126] Although the literature suggests that the process of competency, information provision and the consent process are fraught with ambiguities, despite this, very little attention has been paid to ethical dilemmas that emerge in culturally diverse contexts, where conflicts among ethical principles are made even more complex by cultural and linguistic differences. Communication with a multilingual population can be further hampered owing to the nature of the technical medical terminologies used in clinical trials. It may be the case that clinical trial terminologies have not yet become part of the South Asian cultural repertoire.

The issue of informed consent becomes even more uncertain if the patient and the clinical trial investigator do not share the same language. Not understanding the disclosed study information, owing to the language barrier, does not necessarily mean that the individual is incapable of understanding or is incompetent. The language barrier should not be an excuse for incompetence and it is advisable that competence or the capacity to give consent should be assessed individually in terms of the situation, circumstances or decision at hand. It may be more important for the investigator who is obtaining informed consent not to overemphasise the content of information and the freedom of decision-making, but instead to concentrate on improving the communication process. It can be considered morally unjust to regard linguistic incompetence as equivalent to mental incompetence, and exclusion of ethnic minority people from clinical trials because of lack of translation facilities can be regarded as unethical and to constitute a form of 'economic discrimination'.[62]

Multicentre Research Ethics Committees (MRECs) in the UK have acknowledged that there may be potential problems in obtaining informed consent for patients for whom English is not the first language and they prefer 'special arrangements' to be made. However, no guidance is available to researchers on how to achieve this. The language barrier continues to be blamed for low ethnic minority participation in clinical trials, which masks more deep-seated difficulties of communication, some of which are related to racism.[52] There are barriers other than language, such as lack of cultural understanding, cultural myths and stereotypes, which can also undermine the communication process.

Cultural barriers

One of the problems with blanket statements about cultural patterns or cultural barriers is that they disguise any diversity that exists in most societies. South Asian people are a good example of this rich diversity, reflected by differences in social class, education and linguistic capabilities. There is a danger that indiscriminate use of 'cultural factors' can end up as myths and stereotypes. Some of the 'cultural' barriers to clinical trial participation may be due to factors other than culture, including age, gender and social class. How such 'cultural barriers' are manifest during a clinical trial encounter is what determines ethnic minority participation in them. This is an area that warrants further research.

The literature frequently cites cultural beliefs as possible barriers to ethnic minority participation in clinical trials.[4,26] Religion, language, cultural beliefs and folk medicine have been suggested as factors that may prevent ethnic minority people from taking part in clinical trials.[117] Findings from a small number of US studies (mainly based on Hispanics and American-Indians) offer a good starting point for discussion, where family dynamics, gender, modesty and different health beliefs have all been proposed as cultural barriers to clinical trial participation.

Importance of family

The literature suggests that a strong familial identification and attachment to nuclear and

extended families are likely to affect an ethnic minority participant's decision to take part in a clinical trial. Family was shown to play an important role in the lives of American-Indians, where many would consult their family members before deciding whether to take part in medical research. The same study also implied that it was not uncommon for family members to accompany patients to medical appointments and into the examination room.[127] The limited literature also suggests that occupying multiple roles of wife, mother, carer and employee is not uncommon amongst ethnic minority women. As such, their lifestyles might leave limited time for additional activities such as participating in clinical trials. This hypothesis is reinforced by the findings from a study that showed that Hispanic women refused to participate in one clinical trial owing to visiting family members who lived out of town. Such extended visits, it was claimed, could last up to 4–6 weeks at a time.[128]

However, it can be argued that it is not uncommon for other ethnicities to have strong familial identification, and people generally do not like making major decisions, such as participation in clinical trials, independently of their family. Similarly, it can be argued that occupying multiple roles of wife, mother, carer and employee is not uncommon amongst women in the general population from lower social class backgrounds. There is a problem in using culture, behaviour or beliefs to explain ethnic minority under-representation in clinical trials. Further exploration of these issues is needed. Studies that almost incriminate cultural aspects of ethnic minority people for their under-representation in clinical trials not only fail to acknowledge diversity in attitudes towards participation, but also ignore the effect of social class or standard of living gradients.[52]

Gender

A gender role is also implicated as contributing to ethnic minority refusal to participate in clinical trials. In one study a number of ethnic minority female potential participants indicated that their husbands would not allow them to participate in a trial.[129] Gender role in decision-making is likely to be part of the generic problem with communication and the role of women in society, who are often not taken seriously by men.[124]

Health beliefs

It has been suggested that concerns relating to illness and health can vary widely between different ethnic groups and this can potentially affect ethnic minority participation in clinical trials.[4] Hodge and colleagues argue that although most American-Indians accept the Western healthcare system, many still practise traditional tribal healing practices. Beliefs about certain illnesses and loss of body parts are also considered a taboo and many American-Indians believe that a diagnosis of cancer is a death sentence. Such attitudes and health beliefs may affect their participation in clinical trials.[127]

The consent process might also be perceived differently in various cultures. In cases where the individual is from a family- or community-orientated culture, as might be the case for some ethnic minority people, over-stressing the individual's role in decision-making may damage the informed consent process. Ashcroft and colleagues provide evidence where the quality of informed consent from American patients of Mediterranean origin was diminished because the patients were unable to consult their families.[62] Similarly, in Japan and Korea, there is a strong expectation that the doctor should tell the patient what to do, and that by being asked by the doctor what the patient wishes to do is not only disorientating for the patient, but in the long run diminishes the trust that the patient has in the doctor's ability to perform the doctor's role. Excluding patients' families from the consent process owing to the fear that the families may exert an improper influence upon the patient might not be an effective practice. It might mean that consent for clinical trials needs to be obtained in a different manner from some ethnic minority participants.

Modesty

Modesty in ethnic minority women is also presented as a cultural barrier to their participation in clinical trials. It was shown that American-Indian women placed a high value on sexual privacy and many were uncomfortable undergoing procedures such as Pap smear tests or breast examinations.[127] This was also reflected in another study which investigated four separate clinical trial studies and found no racial differences in study recruitment, apart from one study, which was a breast cancer treatment trial.[128] Modesty, however, is not exclusive to ethnic minority women, and some white women can also feel uncomfortable if intimate examinations are carried out by male doctors. Issues of modesty can be overcome by providing appropriately gendered medical staff.

Religion

Religion may be an important influence on ethnic minority participation in clinical trials. There is no literature concerning any religious barriers to clinical trial participation, apart from the suggestion that because the randomisation process might be linked to gambling, some cultural groups (e.g. Muslims) may object to participation in RCTs.[62] The sparse evidence about religious objections to participation in clinical trials is more likely to be due to an absence of research, rather than an absence of objections. There might be some dietary objections in certain religions such as Islam. Poor understanding due to the limited research activity in the area of ethnic minority participation in clinical trials could arguably be viewed as another barrier.

Age

Ethnic minority under-representation in clinical trials might also be related to age. Research shows that ethnic minority children with cancer are proportionately represented in cancer trials,[130] and that Asian-American children and young people (age group 0–22 years) had significantly higher participation rates than the older Asian-Americans (aged 65 years).[131] These studies suggest that an ethnic minority participant's age may be an important factor to consider in this debate, and that differences in participation rates may reflect a generational change in knowledge, attitudes and behaviours towards clinical trial participation.

Geographical location

Geographical location of the study site might be a potential barrier to clinical trial participation amongst the general population, especially those from lower social class backgrounds. It has been shown that location of the trial site might also be a barrier to ethnic minority participation. One study showed that recruitment rates of Asian-Americans in a clinical trial were affected by the geographical location of the study and that the numbers and locations of centres were related to the potential for recruitment.[131] Location of the trial site should, therefore, be viewed as a potential barrier to clinical trial participation among ethnic minority people.

Lack of familiarity

It has been suggested that ethnic minority people are denied equal participation in clinical trials because they are less likely to be informed about them.[15] Limited research in this area shows that when given appropriate information about clinical trials, African-American people were shown to participate at the same rate as white people.[109] Appropriate information provision about the research process and specific clinical trials was also an important factor in determining whether or not ethnic minority women participated in three trials.[128] It can be argued that the general population might also not be aware of clinical trials owing to their specialist nature. Nevertheless, in view of the limited research in this area, lack of knowledge and awareness of clinical trials might be a potential factor contributing to low ethnic minority participation in clinical trials.

Socio-economic barriers

Structural barriers embedded in the medical and social system may work to deny access to medical care because clinical trial participation is dependent on the location, type of institution, trial design, and is also sometimes associated with increased costs. Access to clinical trials, for these reasons, may therefore be limited for the socio-economically disadvantaged.[130] In addition, hidden costs, associated with participation in clinical trials, such as lost time at work and childcare costs, weigh more heavily on the poor.[126] Statistics show that ethnic minority people tend to be self-employed or employed in low-paid jobs. This might mean that their lifestyles would allow them little flexibility to participate in clinical trials and for some, taking part in a clinical trial may mean losing wages. Any out-of-pocket expenses can be a particular problem amongst those ethnic minority people who occupy low-paid jobs.

Table 8 summarises barriers to ethnic minority participation in clinical trials which are similar to those facing the general population. Additional barriers due to language, culture, religion, age and socio-economic status have been identified as particularly relevant to ethnic minority people.

There are a number of barriers to ethnic minority participation in clinical trials, including fear and mistrust (more pertinent to African-Americans), concerns about side-effects of drugs, barriers due to healthcare professionals, language, lack of familiarity, cultural barriers, complexity of forms and procedures, age, socio-economic barriers and geographical location of the study. Although mistrust of the healthcare system is a major

TABLE 8 *Summary: barriers to ethnic minority participation in clinical trials*

1. Fear and mistrust (more pertinent to African-Americans)
2. Concerns about side-effects of drugs
3. Barriers due to healthcare professionals
4. Language
5. Cultural barriers
   (a) importance of family
   (b) gender
   (c) modesty
   (d) health beliefs
6. Religion
7. Age
8. Lack of familiarity
9. Social class
10. Geographical location of the study site
11. South Asian people in the UK might be facing similar barriers with regard to their participation in clinical trials

barrier to African-American participation in clinical trials, this might not be true for South Asian people, where language is a more important barrier to their participation. Furthermore, any generic barriers to participation are intensified if there are cultural differences between the health professional and the patient. This might lead to a breakdown in the communication process, which is not just limited to language differences but also dependent on health professionals' attitudes towards the patient. In addition to a potential trial participant's ethnicity and associated cultural beliefs, it is equally important to consider other socio-cultural characteristics such as gender, primary language, social class and age. Lack of elderly ethnic minority people in clinical trials also indicates a need for more promotional activities for this age group.

Institutional racism to explain South Asian under-representation in clinical trials

South Asian people have a higher than national average morbidity rate due to heart disease, stroke, hypertension, asthma and diabetes and generally have poorer health outcomes.[133–135] Difficulties with access and use of health services by South Asian people are found in almost all sections of the NHS.[134–136] Findings also indicate treatment inequalities in prescribing habits for South Asian patients[137,138] and poor healthcare offered to ethnic minority people compared with other population groups, particularly in terms of meeting language needs and preferences for the gender of doctors consulted.[139]

There is also diversity within South Asian people. Not all South Asian people uniformly share the greater risk of heart disease[140] and hypertension.[141] Indians have been shown to have a health profile comparable to that of white adults, with Pakistanis and Bangladeshis being the worst off.[54] High rates of mortality from ischaemic heart disease among South Asian people have also been shown to be the highest in Pakistanis and Bangladeshis, who are more socio-economically disadvantaged than Indians.[142] Similar ethnic variations in disease incidence were reported by a US study, where socio-economic status was shown to be strongly linked to breast cancer incidence, but this effect was stronger for Hispanics and Asians (lower social class) than for whites or African-Americans.[143] Low socio-economic status, poor housing and higher rates of unemployment have also been shown to be positively associated with illness and, according to Nazroo,[142] substantial improvements in ethnic minority health will only come from addressing such socio-economic inequalities that exist between different ethnic minority groups. Acknowledging socio-economic diversity in order to tackle discrimination might only be part of the solution.

There is a need to acknowledge how health inequalities and discrimination interrelate with other areas of disadvantage such as socio-economic background, gender and age. Socio-economic inequality can account for a sizeable proportion of the health disadvantage experienced by minority ethnic men and women, but gender inequality in minority ethnic health remains after adjusting for socio-economic characteristics.[52] South Asian elderly are a particularly vulnerable group because of the compounding of disadvantages due to their relatively weak position in society, language barriers and lack of access to healthcare. With a growing South Asian elderly population in the UK, there is a real danger that with time, health inequities in this group of people will become more apparent.[144]

It may be the case that what appears to be a lack of enthusiasm among South Asian people for prevention and other research programmes such as clinical trials is due to lessons learned from previous experiences with the health service. One US study found that the health experiences of African-Americans were negative compared with the experiences of whites, and that such

experiential differences may play an important role in the formation of beliefs and attitudes towards the medical establishment.[145] Previous bad experiences of the NHS might also affect some South Asian people's attitudes towards health professionals, and consequently may dictate their likelihood of participating in clinical trials.

Institutional racism has been identified as one of the main reasons for inequality in access to services to South Asian communities.[146] As a result of the Stephen Lawrence Inquiry into evidence of institutional racism in Britain's major public services, the government decided to tackle this issue by augmenting the Race Relations legislation of 1976, which requires all public bodies in the UK (including the NHS) to have a general duty to promote good race relations, to end discriminatory practices and to ensure racial equality.[147] Promoting race equality is particularly important in the health sector, because the NHS has a major role to play in reducing ethnic health inequalities.

Institutional racism

Institutional racism is associated with organisations where there is racism in relation to policies, procedures and practices, many of which are part of the 'unthinking operation of a system'.[148] In this context, the term is perhaps most useful when referring to actual policies and practices in the NHS, which have been shown to have a discriminatory effect on disadvantaged groups. Fundamental to the understanding of institutional racism is the notion that the same service for all means an equal service for all. This results in services that fail to meet the needs of ethnic minority people since it assumes that everyone is the same, thus ignoring diversity, dietary and linguistic needs, religion and cultural practices.

Institutional racism is very often hidden, and is entrenched in taken-for-granted assumptions that inform organisational practices and policies. Institutional racism is referred to as camouflaged racism, meaning that it is not immediately obvious.[149] Institutional racism operates in the healthcare of people from different ethnic and cultural backgrounds, owing to culturally unacceptable and inflexible services and care based on cultural stereotypes. Institutional racism has been described as a form of discrimination which occurs when service provision is the same for everyone but people from various ethnic groups cannot access or gain maximum benefit because of language, religious or cultural reasons, because staff lack skills and knowledge about specific needs, because of lack of positive action, professional expertise, training and consultation and lack of information.[150]

Operationalising institutional racism

Institutional racism takes place in subtle ways. Institutionally racist policies often seem non-discriminatory to the people who are used to them. A good example illustrating this is the provision of a male gynaecologist, which means a loss of utility for those who have a preference for a female gynaecologist such as some ethnic minority women. The inability of the NHS to provide adequate language support for those whose first language is not English is another good example of the failure to recognise cultural diversity. Not providing appropriate linguistic services for South Asian people, for whom language is a barrier to trial participation, may mean loss of an opportunity to take part in clinical trials. In addition, this notion also ignores the fact that ethnic minority people do not have the same opportunities as the majority population, since they experience greater socio-economic disadvantages and racism. Conceptually, institutional racism explains these disparities in service provision. Since the power of institutional racism is deeply rooted in the taken-for-granted nature of organisational practices and policies, when such institutional processes are reviewed and new structures put in (e.g. allocating extra resources for translation/interpretation), there are often complaints of 'special treatment' or unfair diversion of resources. This highlights a lack of understanding of existing and unquestioned power structures, which have long privileged white males and those from middle-class backgrounds.

In terms of under-representation of South Asian people in clinical trials, institutional racism may be operating at a number of levels, including poor conceptualisation of ethnicity, race and culture, cultural myths and stereotypes, structural and organisational barriers to access and lack of positive action. A discussion of these follows.

Ethnicity versus race

The terms ethnicity and race are frequently used as synonyms in health and related sciences. Ethnicity is specifically to do with the person's place of origin or ancestry, cultural heritage, religion and language, whereas the term race originated in relation to assumed differences on

biological grounds and is defined as a group a person belongs to as a result of physical features such as skin colour, bone structure and type of hair.[151] The visible differences between different ethnic groups are adaptations to different climates and do not necessarily imply any deeper genetic differences. Races are based on a few physical features of small importance to health, compared with ethnicity, which, it can be argued is of greater importance to health because it encompasses a mix of cultural factors such as language, diet, religion and ancestry.

There are some biological differences between the old and the young and between women and men. Biological differences are, therefore, not all due to an individual's ethnicity. The issue is the emphasis on racial/ethnic differences and the racist discourses in which they occur. Jones argues that much of the discourse on the genetics of race is nothing more than prejudice dressed up as science.[152] Although scientific research has established flaws in the biological underpinnings of the construct of race, the reality remains that strong political and social forces are still linked with the concept of race.[153] The close historical link between eugenics and racism is a good enough reason why researchers should be critical of studies demonstrating genetic differences between races, and it is important to exercise caution in interpreting such findings. Only when the term ethnicity is fully divorced from race will it become possible to report ethnic differences in health without racist overtones.

Culture

A simple definition of culture is how we do and view things in our social grouping. Culture consists of a shared set of values, perceptions and assumptions, based on a shared history and language.[148] Difficulties can often arise in health research when ethnic minority health disparities are blamed on cultural differences between ethnic minority groups and the majority population. Such an attitude distracts attention from "wider power relationships within society, and fails to recognise that the dominant culture and the minority ethnic culture do not meet on equal terms".[148] It also ignores the role that political, socio-economic factors play in this debate.[154]

Ethnicity and culture are a complicated interaction of traditions, religion, socio-economic status, language and health behaviour, all shaped by personal or collective experiences. Ethnic minority cultural identities are continually changing and being reinvented through fusion with majority cultures.[155] The health beliefs and behaviour of South Asian people are shaped by their experiences in the UK, and are likely to be different to those of second-generation South Asian people. Nearly 50% of all ethnic minority people are born in the UK,[156] and the children of migrants in contact with different cultural values retain a part of their parents' culture, in addition to developing their own cultural identities in time.[157] Ethnicity, religion and socio-economic status are, therefore, all important factors influencing South Asian people's lifestyles and experiences.

Dimensions within groups, such as age, gender and socio-economic status, further complicate the picture. Misconstruing the concepts of race and ethnicity perpetuates their use to accentuate differences and provides the potential for abuse.[158,159] Making sense of diversity is part of the process of tackling institutional racism, but there is also a need to recognise that South Asian people may not be all that different from the general population. This argument is further supported by a study that showed similar concerns and needs of patients with end-stage cancer. This was irrespective of their ethnic backgrounds.[160] Differences in health as highlighted by morbidity and mortality statistics can also exist owing to differences in socio-economic status, age, gender and geographical location. Ethnicity therefore is not the only explanation for social exclusion and disadvantage.

Racism

The US literature shows that stress, especially due to racism, directly impacts on the health of ethnic minority people through physiological mechanisms such as those associated with blood pressure[161] and indirectly through methods used by individuals as coping mechanisms such as smoking, overeating and substance abuse.[162] It has been argued that racism, rather than race, may be the actual risk factor for many diseases owing to under-utilisation of preventive care and delays in seeking treatment, which results in higher levels of presentation with later-stage disease.[163]

Those who experienced racism are more likely to have respiratory illness, hypertension, chronic illness, anxiety and depression, and that ethnic identity is one of the risk factors associated with ill health.[164] A large proportion of South Asian people live in inner cities and experience unemployment, unequal opportunity and street racism.[155] Such characteristics of urban environments are the main sources of psychosocial factors that determine ill health, and poverty

further exacerbates this problem through its role in restricting individual freedom of choice. Racism should therefore be considered an important causative factor when developing research agendas for ethnic minority health.[165]

It can also be argued that South Asian women are doubly disadvantaged in this respect owing to racism and sexism, both inherent in the society they live in, and in their culture.[150] The relationship between the two is complicated since in some circumstances gender may be more important in making sense of a situation than an individual's ethnicity. Assumptions about the passivity of South Asian women is a good example, where South Asian women sometimes struggle to convince doctors that their child is seriously ill, and are dismissed as 'neurotic' or 'over-protective'.[149] Similarly, South Asian women are viewed as being incapable of making decisions to participate in clinical trials. Such a treatment of South Asian women might not be wholly due to their ethnicity, but also owing to the doctor's sexist attitudes. The challenge for researchers is to know when ethnicity makes a difference and when it does not. It is for this reason essential that policy and practice recognise how ethnicity relates to other aspects of an individual's identity.

Researching ethnic minority health provides useful opportunities for research into aetiological factors. Illnesses such as cardiovascular disease, diabetes and cancer and their incidence are viewed not as random occurrences, but are linked to particular risk factors such as genetics, diet, susceptibility and exposure. Many of the risk factors associated with chronic illnesses, such as obesity, sedentary lifestyle, smoking and alcohol abuse, are also frequently associated with ethnicity and socio-economic status.[166] Consequently, research findings that adjust for race and socio-economic status or compare across ethnic and socio-economic groups seem to imply that the risks under investigation are to be expected from the populations in question, instead of discussing explicitly the multifaceted social circumstances that lead to such risk factors.

Cultural myths and stereotypes

Stereotyping is common to all humans and generalisations are made all the time in order to make sense of the world. According to Eagley and Chaiken,[167] stereotypes are oversimplified or untrue generalisations about social groups, and refer to shared beliefs about others with respect to their personality traits, attitudes and behaviours. Psychologists agree that stereotypes are essential components of prejudices and it is the acting out of prejudice that leads to discrimination.[168]

Stereotyping to explain the attitudes and behaviour of Asian people is widespread within the NHS and many authors report health professionals as holding negative stereotypes of South Asian patients.[169–171] Not offering Muslim couples prenatal diagnosis for thalassaemia, based on the cultural myth that Muslims do not condone abortions owing to religious objections, is such an example.[170] Medical conditions are also sometimes misdiagnosed if the person does not fit ethnic stereotypes and at-risk groups.[124] Other examples include the stereotype that South Asian women need to be told what to do and that they have lower pain thresholds,[172] and that South Asian families 'look after their own', which denies services for disabled or chronically ill individuals or their families.[173] Such stereotypes not only serve to condemn the South Asian culture, but also create mistrust between health professionals and their South Asian patients. Stereotyping South Asian people is likely to affect the health professional's practice of recruiting them to clinical trials, although at present there is no published research on the effect of stereotyping attitudes on South Asian participation in clinical trials.

Structural and organisational barriers to access

Another way that institutional racism manifests itself in the processes of South Asian participation in clinical trials is through structural and organisational barriers. Most clinical trials in the UK take place in secondary care or tertiary/specialist centres. It has been suggested that a small proportion of South Asian people make use of such services.[174] Given the available literature on access difficulties amongst this group, it will not be unrealistic to infer that a large number of South Asian people, as a result of limited access to secondary/tertiary care, may never get an opportunity to take part in clinical trials. South Asian people also tend to be more concentrated in inner-city locations and have a propensity to visit single-handed practices where the GP is likely to speak their language.[139] Single-handed inner-city practices are often under-resourced and overstretched and as such are unlikely to have the time and resources required for conducting clinical research. For those South Asian people who manage to gain access to secondary and tertiary care, institutional racism further limits their opportunity of participating in clinical trials.

Lack of positive action

To rectify this, there needs to be a more proactive approach in changing policy and practice. Research without commitment can lead to disillusionment and estrangement of South Asian people from research.[175] Since clinical trials are not designed to tackle the different facets of institutional racism, lack of positive action could be considered as another barrier to South Asian participation in clinical trials.

The debates informed by the model of institutional racism explain how healthcare needs of South Asian people are either ignored or, when recognised, are viewed as a problem, blamed on cultural and religious differences and subjected to various cultural myths and stereotypes.

In summary, much of the published literature is US-based and applicable to the African-American population, but a number of barriers to ethnic minority inclusion in trials were identified, many of which are faced by the UK South Asian population, including mistrust, concern about drug side-effects, health professional-related barriers, language, cultural barriers, religion, age, lack of familiarity, social class and geographical location of the study site. All of these issues are explored in depth in the interviews conducted in this study with professionals, South Asian lay people and South Asians who have taken part in a trial.

A summary of the institutional racism aspect is given in *Table 9*.

TABLE 9 *Summary: institutional racism to explain South Asian under-representation in clinical trials*

1. Clinical trials are a political process, reflecting values of the society in which they take place
2. Institutional racism has been used as a framework to explain the failings of public institutions to respond to the needs of ethnic minority people. The framework of institutional racism is used here to systematically explore the problematic conceptualisation of ethnicity, culture and racism as a means of understanding the processes of social exclusion
2. South Asian people may be actively excluded from clinical trials as a result of different facets of institutional racism, including:
   (a) lack of cultural sensitivity and awareness of specific needs
   (b) discriminatory behaviour at point of recruitment due to cultural myths/stereotypes
   (c) lack of positive action and professional expertise
   (d) organisational/structural barriers, due to poor access to 'trial-rich' sites, e.g. secondary/tertiary care.

Chapter 3
Methods

Choice of research methodology

Research methodology is concerned with both the detailed research methods through which data are collected and the more general philosophies upon which the collection and analysis of data are based.[176] Broadly, research methodology defines a research problem and how research should proceed, and research method is the actual technique or tools of investigation adopted.[177] Research methodology is also determined by a number of practical considerations including time, financial resources required to conduct the study and the requirements of the research funder and, therefore, is a balance between feasibility and desirability. In social research, methodologies may be defined very broadly, for example qualitative or quantitative research.

The majority of the literature on ethnic minority participation in clinical trials is dominated by quantitative methods ranging from surveys/questionnaires to structured interviews, with very small numbers utilising qualitative semi-structured interviews. There are limits to the type of data that can be gathered using surveys and questionnaires and such methods may fail to provide complex details behind a phenomenon. Quantitative research based on statistical analysis of numerical data is primarily aimed at hypothesis testing and evaluating the efficacy, safety and cost-effectiveness of diagnosis and therapy. A dependence on purely quantitative methods may therefore neglect the social and cultural construction of the 'variables' which quantitative research seeks to correlate.

Qualitative research is difficult to define and does not have a distinct set of methods that are entirely its own.[178] Qualitative researchers use narratives, content, discourse, archival and even statistical analysis. In essence, qualitative research involves the systematic collection, organisation and interpretation of textual data gained from talk or observation and explores meanings of social phenomena as experienced by individuals themselves.[179] Such research conceptually analyses narratives and descriptions in order to uncover and understand what lies behind phenomena about which little is yet known, or to gain novel and fresh slants on things about which something is already known. It is therefore appropriate to use qualitative methods to understand perceptions, motives and actions of individuals and organisation.[180] Broadly, qualitative research seeks to answer the 'what' and not the 'how often' question, and it can be argued that it is more concerned with the process itself, rather than the outcome. This is different from quantitative research, which usually emphasises measurement and analysis of causal relationships between variables and not processes.

For the purpose of this study, a quantitative method is not suitable owing to the exploratory nature of the topic. A qualitative methodological approach is the most appropriate to achieve the aims of the study.[181] The basis for this approach is drawn from the interpretation by Hammersley and Atkinson (Ref. 181, p. 7):

> "Human actions are based upon, or infused by, social meanings: intentions, motives, attitudes and beliefs … people interpret stimuli and these interpretations, continually under revision as events unfold, shape their actions. The same physical stimulus can mean different things to different people and, indeed to the same person at different times."

For example, gathering data in a variety of contexts by including health professional, lay and trial participant perspectives allows the collection of a rich, contextual and detailed dataset to help provide a clearer picture of the issues facing South Asian people with regard to participation in clinical trials. Further, one-to-one interviews will make it possible to recount the range of experiences described by different respondents in response to similar situations so that emergent patterns become more apparent. Such information will allow not only the identification of diversity, but also convergence in beliefs and behaviours amongst health professionals and the different South Asian ethnic and religious groups, thus allowing for the creation of possible typologies (the relationship between categories or particular strategies adopted by particular people in particular circumstances).[182]

Outline of choice of methods

The choice of a qualitative design allows for several options such as structured, semi-structured

and unstructured interviews. Interviews provide data on understanding, attitudes, opinions, what people remember and feelings that people have, and are exploratory in nature. They also have the advantage over questionnaires because of their flexibility in both scope and depth of material covered and because they represent individual rather than aggregate concerns. Generally, structured interviews, commonly used in survey studies, allow a limited data collection; semi-structured interviews allow for fixed topics of discussion and in unstructured interviews the interviewer may have a list of broad topics but the direction is largely set by the respondent.

For the present study, a semi-structured interview method was adopted, using qualitative interviewing techniques.[183] Utilising this method enables respondents' experiences and views on participation in clinical trials to be explored by allowing a deeper understanding of their subjective perceptions. Adopting a semi-structured interview approach would further provide an in-depth exploration of the varying agendas, expectations and priorities of the three groups (lay people, health professionals and trial participants) in a way which fully contextualises that data within an understanding of broader influences such as professional judgements and culturally specific norms.

One of the methodological difficulties facing a qualitative researcher is the cumbersome task of applying structure and making coherent a large data set of information. One systematic approach to synthesising and interpreting qualitative data is a matrix-based approach (a series of related themes under which data are ordered) described by Ritchie and Spencer.[182] Framework analysis was developed as a methodological approach, which uses strategies of data analysis to improve the reliability and theoretical depth of analysis. Particular attention is paid to the process entailed in coding data. The coded data are placed in different categories that are then examined and compared within and across categories. Informed by the theoretical ideas developed during the research process, these categories are further reassembled and reduced in number by grouping them together into themes and the narratives are compared to identify common themes. Framework analysis is designed to make the analytical process more explicit so that it can be viewed and assessed by people other than the primary researcher.[184]

Methodological rigour

The methodology took into account a number of techniques to ensure rigour and these included careful sampling, a thorough description of the study sample allowing the generalisability of the study to be assessed, and data collection. Data analysis involved identifying and documenting recurrent, accurate and consistent themes and patterns as they emerged from the data, achieved by using framework analysis. In addition, negative cases were explicitly pursued, that is, those which ran counter to expectation, as a means of enhancing the validity of the developing propositions.[185]

Ethics

Leeds and Bradford Local Research Ethics Committees (LRECs) granted ethical approval for the study on 21 January and 12 February 2002, respectively. Trial participants included in the study had to have first-hand experience of taking part in a clinical trial and inclusion was not restricted to RCTs only. This allowed for a wider sampling frame. All people interviewed had to be over 18 years old and reside in either Leeds or Bradford. The respondents were provided with study information sheets explaining the research, which were individualised for lay people, health professionals and trial participants. To minimise the risk of exploitation and coercion, respondents were also informed that refusal to participate would in no way jeopardise their healthcare.

Each interview commenced with a discussion on confidentiality and anonymity, where it was made clear to the respondents that anything discussed in the interview would be kept confidential from any third party except the study team members. Respondents were also informed that they were free to stop the interview at any time or to refuse to answer any question. At the end of each interview, the respondents were asked if they were happy with the interview process and if so to sign the consent form, which formed part of the ethics committees' requirements. All tapes were given a code number as soon as the interview was completed, prior to handing the tapes to the transcribers. Initials were used in transcripts and where possible, other identifying details were altered.

Research methods

Using semi-structured interviews, lay respondents' views and experiences of clinical trials were explored in depth. In order to review the processes and potential barriers to South Asian recruitment throughout the whole life cycle of a clinical trial, healthcare professionals involved in

clinical trials, and South Asian trial participants were concurrently interviewed as part of the same process. This was undertaken in order to explore, understand and explain the range and diversity in attitudes and behaviour. This approach is designed to produce a rounded, rather than one-sided or partial treatment of the research themes, thus embracing data drawn from all three key stakeholder groups.

Interview schedules (topic guides)

The findings from the literature review, the aims of the study and the views of key stakeholders were instrumental in identifying relevant themes to underpin the study and to inform the three separate interview schedules. An initial pilot study consisting of 11 key stakeholder interviews (health professionals, lay people and South Asian trial participants) was undertaken to fine-tune each interview schedule. In the case of South Asian lay respondents, some probing was necessary because it was a topic with which most were unfamiliar.

Although the interviews were based around pre-established topics, they remained flexible enough to provide the opportunity for the respondents to shape discussion and to establish new themes or subthemes, which could be pursued subsequently. The themes of the three interview schedules were continually reviewed and revised on the basis of emerging findings, and were individually tailored to the situation of each sample group.[186] This approach is useful given the under-researched nature of the study theme.

The health professional interview schedule (Appendix 1) explored awareness of and perspectives on clinical trial participation amongst South Asian people. Health professionals were asked to describe their experiences of involving South Asian people and, more broadly, minority ethnic patients in trials. They were further encouraged to identify barriers to clinical trial participation facing South Asian people, dangers of exclusion and the practical difficulties of inclusion. Health professionals were also asked to identify strategies for increasing participation and to talk about any approaches taken by ethics committees to improve South Asian participation in clinical trials.

A different interview schedule was used with South Asian lay people (Appendix 2). Here, their awareness of and perspectives on clinical trial participation were explored, in addition to their perceptions of the risks and benefits of participation in trials. They were further asked to identify any factors or circumstances that might affect their decision to take part or to decline participation. The lay interview schedules were also designed to investigate the awareness and understanding of the informed consent process. South Asian patients who had been involved in trials were also interviewed using similar topic guides to the lay interview schedule, but particularly focused on their experiences of taking part in clinical trials and their decision-making processes (Appendix 3).

Process of semi-structured interviews

Interviews were conducted in an informal manner and were governed by the direction of the discussion rather than a formal question and answer format. Such interviews according to Bryman and Burgess, are referred to as "conversations with a purpose", and tend to be structured around a particular set of topics, and discuss themes that need to be explored in detail.[187] Probing was used to achieve a deeper exploration and also to prevent people from digressing, thus ensuring that a sufficient level of detail was acquired from the respondents. In the interviews with trial participants, greater use was made of probes to encourage them to remember significant events and the process of recruitment.

Owing to the nature of the topic, few South Asian lay people were aware of clinical trials or the possibilities of participating in them. In order to set the scene, they were supplied with some background to the study and the nature of clinical trials, which was provided in the form of a study information sheet. They were also provided with an opportunity to discuss the rationale underpinning clinical trials prior to the commencement of the interview. Interviews were conducted in the interviewees' own homes or, in some cases, their places of work. Each respondent was given the opportunity to be interviewed in a language of their choice and, if preferred, by a same-sex interviewer. Most of the lay people interviews were conducted in the evenings or the weekends owing to work commitments and typically lasted between 45 and 90 minutes. Interviews were audio taped (using standard compact cassette recording equipment) and then either transcribed or translated and transcribed by a professional secretary verbatim if conducted in English or a South Asian language, respectively. Most of the transcripts were validated against the original tape recording. All lay people and trial participants were sent a hand-written thank you card and the health professionals were sent a letter thanking them for their views and time.

Sampling frame and selection

Sampling and selection of respondents are strategically crucial elements of qualitative research and, according to Mays and Pope, an appropriate and justifiable sampling is critical in ensuring methodological rigour.[188] In contrast to statistical sampling in quantitative research, which is used to generate empirically representative samples, sampling in qualitative research uses non-probability methods, including 'purposive' sampling, in which individuals with particular characteristics are deliberately and systematically selected to explore emerging themes. Qualitative studies are, therefore, generally based on small samples so that issues can be investigated in-depth. The choice of sampling approach is usually driven by the research objectives, extent of prior knowledge (from the literature review) and the size, diversity and location of the researched population.

In qualitative research, it is difficult to predict in advance the number of interviews needed to generate good data. Ideally, data collection should be continued until 'saturation' is reached, i.e. no new themes emerge from the data. For this study, it was estimated that three samples consisting of 60 South Asian lay people (of whom 20 were Pakistani, 20 Indian and 20 Bangladeshi), 25 health professionals and 40 South Asian patients, who had taken part in clinical trials, would be sufficient.

Process of respondent recruitment

During the recruitment phase, various hospitals, ethics committees, general practices and South Asian health and charity organisations in Leeds and Bradford were contacted and briefed about the study objectives. Information sheets and contact details were left with the managers/responsible persons within the organisations and names and telephone numbers of respondents were requested if they had agreed to be interviewed. The respondents were initially contacted by telephone and followed up with a written confirmation of date and time of interview and the study information sheet. Assurance of anonymity and confidentiality was made to all participants.

Health professionals

The opinions and experiences of principal investigators, clinicians and members of ethics committees were all relevant to the research questions. Respondents were identified through a range of mechanisms, including personal contacts, 'snowballing' and through national networks of trialists. All chairs of MRECs in the UK were also approached by telephone and email (as specified in the original protocol), but difficulties were encountered with regard to most of them being unsure as to the ethics involved in the process of being interviewed. The Central Office for Research Ethics Committees (COREC) proposed that all MRECs should be applied to individually and even then there was a chance that chairs would not agree to interviews since they are frequently inundated with such requests. Eventually, five members of ethics committees were interviewed. The target for the study was to interview 25 professionals and this was successfully achieved. Of those 25 interviewed, 11 (44%) were male, 11 (44%) were consultant or GP recruiters, six (24%) were nursing and allied staff and eight (32%) were academics/non-medical trial co-ordinators or LREC/MREC members.

South Asian lay people

The respondents were purposively sampled in order to achieve representation from areas of high and low ethnic concentration, a spread of ages, religious groups (Muslims, Hindus and Sikhs), English and non-English speakers and equal numbers of men and women, according to the specifications provided in the sampling matrix (*Table 10*). The matrix represents the numbers aimed for in recruitment. The sample is representative since it takes into account socio-economic status, educational background and duration of stay in the UK. In total 60 South Asian lay people were initially recruited by selection from the records of GPs in Leeds and Bradford, thus allowing a methodologically respectable subsample of equal numbers (20) each of Bangladeshi, Indian and Pakistani respondents.

Table 11 gives a further breakdown of the respondents according to location and interview language.

Recruitment of trial participants

Although the original proposal stated that 40 interviews would be undertaken with trial participants selected from the trials database of CTRU and supplemented through contacts with national networks of trialists, only 15 South Asian patients who had been involved in clinical trials were interviewed. This was because it proved to be extremely difficult to find any more South Asian patients who had been a trial participant, a finding in its own right. In addition to respondents identified from the *H. pylori* trial, further recruitment was achieved by directly contacting the cancer centre, organ transplant unit, gastroenterology, midwifery, coronary heart

TABLE 10 *Sampling matrix for South Asian lay people*

	Bangladeshi numbers	Indian numbers	Pakistani numbers
Gender			
Male	9–11	9–11	9–11
Female	9–11	9–11	9–11
Age (years)			
18–30	2–4	2–4	2–4
31–40	2–4	2–4	2–4
41–50	2–4	2–4	2–4
51–60	2–4	2–4	2–4
60+	2–4	2–4	2–4
Language			
English speaking	9–11	9–11	9–11
Non-English speaking	9–11	9–11	9–11
Born in UK/moved to UK before age 11 years	9–11	9–11	9–11
Moved to UK after age 11 years	9–11	9–11	9–11
Religion			
Muslim	–	18–22	18–22
Sikh	6–7	–	–
Hindu	6–7	–	–
Other	6–7	–	–
Total	20 (18–22)		20 (18–22)

TABLE 11 *Lay people interviewed in language of choice in Leeds and Bradford*

	Leeds	Bradford	English	Urdu/Hindi	Punjabi	Bengali/Sylehti	Mirpuri	Gujarati
Pakistani	12	8	11	5	1	–	3	–
Indian	14	6	13	2	2	–	–	3
Bangladeshi	5	15	9	–	–	11	–	–
Total	31	29	33	7	3	11	3	3

disease and diabetes centres in both Leeds and Bradford. Attempts were also made to recruit respondents by talking about clinical trial participation on Radio Sunrise (the local Asian radio station) on two separate occasions. Although the listeners showed much interest, none of the people who telephoned in had ever taken part in a trial, the reality being that there are very few South Asian people who have taken part in clinical trials in West Yorkshire.

Even though 66 *H. pylori* trial participants were identified, they were either unwilling to take part, had moved away or did not respond. A considerable amount of time was spent on this and all the possibilities were exhausted. Clearly this is a finding for this study.

A total of 15 South Asian trial participants were interviewed, made up of seven (47%) from the *H. pylori* eradication study, two (13%) from cancer trials, three (20%) from a midwifery trial and one each (7%) from a CHD, a diet and a hormone replacement therapy (HRT) trial.

Process of recruiting trial participants from the H. pylori *study*

Once the lists of names for all South Asian participants had been provided by CTRU, they were checked by GPs and the names of patients (not of South Asian origin/no longer alive/not living in Leeds/chronically ill/severe communication difficulties) deemed unsuitable for participation in the study were removed. The names of all participants who took part in the *H. pylori* trial in West Yorkshire were initially put in Nam Pehchan, a computer programme developed by Bradford Health Authority which identifies South Asian names.[189] Colleagues further checked the list generated by Nam Pehchan for any discrepancies since the package was found to be not very efficient in the identification of South Asian names.

TABLE 12 *Response rate of South Asian trial participants in* H. pylori *study*

Total number contacted by letter	66
Final number of replies received by post	17
Number agreeing to be interviewed	3
Number not wishing to be interviewed	14
Number contacted by telephone (1 month later)	49
Number agreeing to the interview (following call)	4
Final interview response rate	7

Response rates

A total of 66 South Asian people were identified from eight general practices in Leeds, located equally in high and low areas of ethnic minority concentration. Strategies to maximise response rate such as personalised University letter-headed invitation letters, self-addressed envelopes, reminders and telephone follow-up calls (evenings and weekends) were employed,[190,191] but the response rate remained lower than expected. *Table 12* shows the breakdown by response rate.

The reasons for this poor response rate were due to a number of factors identified in *Table 13*. The greatest problem was due to incorrect addresses/non-contacts (40%) rather than with refusal to participate. The majority of the non-contacts lived in South Leeds, an area associated with high deprivation levels. Studies have shown a strong link between non-response and deprivation.[192] The only contact that was made in South Leeds declined to take part owing to visitors from abroad taking up her time. Around 8% of the respondents could not recall taking part in the trial because it took place 3 years earlier and a further 13% were incorrectly identified by the Nam Pehchan package. In addition, low response rates to written invitations (in English language) to participate in research are known to be higher for ethnic minority people as literacy rates are not high in some migrant groups, especially in women and older people.[193]

Data analysis – the framework approach

The framework approach was chosen as the method of analysis. This methodological approach pays particular attention to the process entailed in coding data. The coded data are placed in different categories, which are then examined and compared within and across categories. Informed by the theoretical ideas developed during the research process, these categories are further reassembled and reduced in number by grouping them together into themes and the narratives are compared to identify common themes. The data were coded using a detailed scrutiny of the transcripts to identify concepts and more specific themes and patterns. The emergent themes and the coding structure were discussed at regular meetings between the researchers in order to ensure a shared understanding of the key themes and analytic frameworks. Reading and re-reading the transcripts and applying the final themes and models to each transcript refined the analysis. A clear and explicit strategy for analysis was established and used with each set of data. The framework approach therefore consists of a highly rigorous process of sifting the data, charting and sorting out material according to key issues and themes. A five-staged approach to analysis was adopted[182] and is described in *Table 14*.

TABLE 13 *Reasons for non-response*

Number unavailable/ex-directory/unlisted	26 (40%)
Too busy/family commitments/work	9 (12%)
Could not recall taking part in the trial	5 (8%)
Husband did not want wife to take part	1 (1%)
Not South Asian in origin (Iraqi/Saudi Arabian)	3 (13%)

Translation of transcripts

Interviews were conducted in the interviewees' own homes or in some cases their places of work. Each respondent was given the opportunity to be interviewed in a language of their choice and, if preferred, by a same-gender interviewer. Most of the lay people interviews were conducted in the evenings or the weekends owing to work commitments and typically lasted between 45 and 90 minutes. Interviews were audio taped (using standard compact cassette recording equipment) and then either transcribed by a professional secretary verbatim if conducted in English or translated and transcribed according to guidelines developed by the authors, thus ensuring a degree of homogeneity between the transcripts.

Although using in-depth interviews provided a rich source of information for the study, there were a number of drawbacks to this approach. Cross-cultural communication is especially susceptible to problems in interpreting interview responses, but as Denzin and Lincoln (1998) suggest, the quality of data generation is largely dependent on the skills and expertise of the interviewer. In order to screen out any potential interview bias, all interviewers (Gujarati, Mirpuri,

TABLE 14 *Key processes of framework analysis*

- **Familiarisation:** or immersion in the raw data by listening to the tapes and reading the transcripts in order to highlight key ideas and recurrent themes
- **Identification of framework:** key themes and issues were identified around which the data were organised and referenced. The aims and objectives of the study and the interview schedule and recurrent issues raised by the respondents informed this process
- **Indexing:** this involved application of themes identified (identification of framework) to the text, in the form of annotating the transcripts with numerical codes
- **Charting:** headings and subheadings were used to build up a picture of the data as a whole
- **Mapping and interpretation:** associations were clarified between themes with a view to finding explanations for the findings and typologies identified if present

and Sylheti – variant of Bengali) were briefed on the study background, trained in interviewing skills, then observed conducting one interview, before being left on their own. Similarly, all translators and transcribers followed set guidelines, thereby minimising any biases due to translation or transcription. Saturation of categories in analysis still occurred, that is, the last few interviews added little to the insights gained from earlier interviews.

Process of data analysis

Following a detailed scrutiny of the transcripts to identify concepts and specific themes and patterns (familiarisation), the themes or categories were further refined to construct a thematic framework that represented the variety of perceptions, influences, experiences and attitudes towards clinical trial participation among the three samples. The thematic framework not only covered the main themes and barriers identified by the literature search and the interview schedule, but also related to issues that emerged from interviews conducted. The first version of the index is, therefore, largely descriptive and rooted in *a priori* issues/concepts.

The thematic framework or the final index was systematically applied to all the transcripts by annotating the margins of each transcript by a numerical code that linked back to the index. Indexing the transcripts involved making judgements about the meaning and significance of the data as they stood in the context of the interview as a whole, a somewhat subjective process, since the data were open to different interpretations. The process of indexing provides the researcher with a mechanism for labelling data in manageable 'bites' for subsequent retrieval and exploration.

Following the application of the thematic framework to individual transcripts, the next stage in framework analysis involves building up a picture of the data as a whole by 'lifting' the data from their original context and rearranging them according to the appropriate thematic reference.

Chapter 4 provides the results of the interviews with health professionals who had been involved in clinical trial recruitment. Chapter 5 sets out the results of the interviews with South Asian people who had not been involved in a clinical trial. The experiences of South Asian trial participants are presented in Chapter 6.

Chapter 4

Health professionals' views and experiences of involving South Asian people in clinical trials

Introduction

This chapter explores the perspectives of key stakeholder health professionals regarding South Asian participation in clinical trials and the reasons underpinning their under-representation. The analysis is based on data collected from 25 health professionals. The interviews began by asking the respondents to provide some information on their backgrounds, their personal experiences and beliefs about clinical trial participation. Their views on South Asian participation in clinical trials were explored next and barriers to their participation highlighted. The final part of the findings identifies strategies for improving South Asian participation in clinical trials.

Data were collected using semi-structured in-depth interviews using a checklist of topics to guide the discussion. Each interview lasted from 30 to 90 minutes and was fully transcribed. In total, 25 interviews were undertaken, involving 11 male and 14 female respondents; all respondents were involved in some aspect of clinical trials with ethnic minority patients. The respondents were anonymised and their views presented in order of interview and professional status (C = consultant, D = GP/registrar, E = ethics committee member, I = non-medical investigator, N = nurse), gender and transcript page number.

Results

The following presentation of results examines health professional reported-barriers to South Asian participation in clinical trials. Their perspectives regarding South Asian involvement in clinical trials and possible reasons for their exclusion are explored. Cultural and religious barriers to participation are next reported, followed by a discussion of strategies to improve the recruitment rates. To set the scene, the results begin by providing a background to common recruitment problems in the NHS, and the respondents' philosophies on involving South Asian people in clinical trials.

The nature of recruitment

Limited time for recruiting to clinical trials (regardless of the trial participant's ethnic background) was perceived as a major problem. One respondent felt irritated about lack of time and considered recruitment to clinical trials to be a real chore:

> "And then, you know, if the worst comes to the worst and you actually have to recruit them it's even more work, you know, and the telephone call and forms and. …" (21NF-10)

The time required for recruiting to clinical trials depended on the type of trial. Additional time allowed for providing patients with the study information to take home was not always possible for certain types, such as transplant and neonatal trials. This was due to the 'unpredictable nature' of the clinical trial. A small number of respondents felt that clinical trials are not essential, since in every-day practice treatment decisions are made without any evidence based on trials. One respondent viewed clinical trials as 'just red tape', a situation made worse by additional work required by the ethics committees, complicated study protocols and lack of incentives. Others felt that there was a need to change the culture of clinical trials because they were perceived as separate from routine treatment. Those respondents wanted patients to see clinical trials not only as a choice of treatment, but also as a normal pattern of care. Overall, the general consensus was that there was a need for clinical trials, but the extra effort involved in providing patients with information and in obtaining consent was viewed as time consuming and, therefore, a 'hassle'. In addition to the extra work involved in recruiting to clinical trials, a substantial number of the respondents felt that lack of incentives did not help the situation.

> "… but we'd prefer to do it in a trial but we're gonna put all these obstacles in for a trial, then people [health professionals] don't bother. There's no incentive, you see, other than peer pressure or getting a publication." (5CM-12)

The principal investigators appeared more enthusiastic and motivated about trial recruitment

than those not directly involved in initiating the trials. This was due to incentives such as their personal reputation, publications and invitations to meetings.

> "But for the ordinary clinician, the ordinary midwife who finds herself trying to recruit someone to a trial, the incentives are very much against it. It's a lot of work." (1CM-1)

Other incentives for recruiting patients to clinical trials included the belief that taking part in them was beneficial for trial participants since they were more carefully monitored than non-participants. There were also altruistic reasons. One respondent thought that there were advantages for patients from lower socio-economic backgrounds because they would receive free state-of-the-art treatments and prescriptions. A number of respondents felt that patients were more of a guinea pig outside the trial than in because clinical trials offer carefully controlled patterns of care from which nobody could deviate.

The belief in the importance of the clinical trial was another incentive for the respondents to recruit. Although financial incentives were generally viewed negatively (one respondent thought that it might cloud his judgement), others recognised that commercial studies can motivate some recruiters. Getting paid by the number of patients recruited to a clinical trial was, however, viewed as potentially encouraging the recruitment of anyone, rather than making sure that the patient population in the study represented the population as a whole.

> "They are paying me a quarter of a million quid [to do this trial] so you know, I'm not going to turn my nose up at it but my heart is not in that trial. The staff just don't believe the trial is really supportive. It's not just laziness, it's a genuine disbelief in the importance of the thing." (1CM-3)

In addition to lack of time and incentives, it was also perceived that owing to increasing consumerism and patient choice, recruiting to clinical trials was becoming increasingly problematic. This was due to the general public increasingly having 'a voice' and a preference for treatment choice, which sometimes caused problems with recruitment. One of the respondents thought that patients were generally more knowledgeable about clinical trials and the 'concept of tossing a coin to choose the treatment was not double Dutch to them'. Others believed that negative views of clinical trials (where they are labelled as experimentation) meant that the general public does not like being used as guinea pigs. This distrust of clinical trials was blamed on the media, in terms of how the NHS was portrayed, and the general public's poor understanding of science. Overall, the respondents believed that suspicion and mistrust of research existed across all ethnicities, including the South Asian population. This finding is in keeping with those of Ethier and colleagues.[90]

Socio-economic background and patient education level came up frequently as a barrier to recruitment, where it was suggested that clinical trial concepts might be difficult to understand for patients from lower social classes (who are also likely to be less compliant owing to their lack of understanding). Debates in the literature suggest that working-class patients find it more difficult to communicate with doctors. This has been attributed to the social class position of the doctor and class variation in communication.[114] In addition, it was implied that people from lower social class backgrounds were more suspicious about research as a result of picking up negative information from the tabloid press. There was uncertainty as to whether the negative media portrayal of the NHS, and clinical trials in particular, affected South Asian perceptions of clinical trials, as illustrated in the following quotation:

> "… they [patients] pick up more from the news and, you know, maybe the papers and things, particularly the red tops, will have a suspicion about research and doctors, whereas a lot of the South Asian patients, maybe because they don't pick up that type of information, are still very much more trusting of what medical staff will say." (8CM-8)

Others suggested that barriers to clinical trial recruitment included poor compliance with trials due to extra visits and additional procedures, drug side-effects and the detrimental effect of providing too much study information (for instance, too much information on drug side-effects).

Owing to lack of time, poor incentives, patient choice and mistrust of clinical trials, recruitment is becoming increasingly difficult. Even though, in theory, the respondents acknowledged the importance of representational sampling, in practice, when faced with such limitations, it comes as no surprise that patients tended to get 'cherry picked' to clinical trials. The following quotation encapsulates this phenomenon:

> "… we are often aware of the fact that it is very easy to sort of almost like cherry pick the patients that go into studies … it's very easy to approach the patients that you know will comply, will be easy to deal with, will probably make our job easier by the fact that they can understand, and so the very nature of that you are cherry picking the group of patients and it's something that we are aware of all the time, that we shouldn't be excluding people from studies to make our job easier." (7NF-13)

Excluding people from clinical trials for ease of recruitment is recognised; however, cherry-picking participants is an everyday practice and is not considered to be a form of discrimination. This process was justifiable according to one respondent, who argued that it was in human nature to go for the path of least resistance, and that investigators were no different from the rest of the society by going for the easy option.

Philosophies on South Asian participation in clinical trials

Less than half of the respondents were aware of South Asian under-representation in clinical trials and of the significance of representational sampling. This is a good example of institutional racism at its most fundamental level. Nearly one-quarter of the respondents did not think that representational sampling was important and that trials should be specifically designed for South Asian diseases. Concerns were also raised about the practicalities of achieving representative sampling; it was argued by one respondent that this might be a pointless exercise in regular trials (owing to the small numbers of South Asian people), unless the whole trial was enormous. One respondent believed that there should not be any requirement to include South Asian people in clinical trials for the sake of having the same ethnic mix as the population, and that scientists should decide whether there was a scientific reason to include them. The scientific reasons for inclusion, according to another respondent, should depend on evidence that there is a biological difference between the majority population and the ethnic minority population. This view was challenged by another respondent, who argued that, unless South Asian people were routinely included in clinical trials, it would be virtually impossible to determine any ethnic differences in drug response.

Those who were aware of the significance of representational sampling believed that equal representation was crucial in determining ethnic differences in drug response and in the investigation of those diseases that are prevalent in South Asian people. In addition, a small number believed that ethnic health inequalities would continue to persist if South Asian people are routinely excluded from clinical trials. Although most of the respondents stated that they would be 'shocked' to come across deliberate exclusion of South Asian people from clinical trials, nevertheless, they agreed that exclusion was likely to be due to a 'passive lack of inclusion' because of organisational/institutional barriers, including limited resources, lack of time and inappropriately trained staff.

Barriers to South Asian participation in clinical trials

A number of barriers, specific to South Asian participation in UK-based clinical trials, were identified by the respondents. These included lack of awareness about the importance of representational sampling, the language barrier, lack of resources for translation/interpreters, lack of culturally similar staff and culturally appropriate tools, poor training in cultural sensitivity, stereotyping attitudes and geographical barriers. All of these barriers were identified as having an impact on the informed consent process, which is crucial to clinical trial participation. Health professional-reported barriers to South Asian participation in clinical trials are set out in *Table 15*.

Lack of awareness

It was suggested that exclusion of South Asian people from clinical trials was due to a genuine lack of awareness of the importance of representational sampling. It was suggested that

TABLE 15 *Health professional-reported barriers to South Asian participation in clinical trials*

1. Lack of awareness about the importance of representational sampling
2. Language barrier
3. Lack of available resources for translation/interpretation
4. Lack of culturally similar staff and culturally appropriate tools
5. Poor training in cultural sensitivity
6. Stereotyping attitudes
7. Geographical barriers
8. Consent process
9. Cultural barriers
   (a) non-compliance due to socio-economic background
   (b) lack of decision-making in some South Asian women
   (c) modesty
10. Religion – dietary restrictions

unless health professionals are specifically trained in such matters, owing to their busy work schedules the issue might never cross their minds.

> "I'm sure there are a lot that don't even think about it [why South Asians should be included in trials] … if you are stressed in an under-staffed ward and you are running around, … all you want to do is get to the end of that shift, get home, take your shoes off and relax. You are just so focused on I've got to get this done and this done that you don't start looking at the wider picture." (6NF-11)

Currently, ethnic backgrounds of most trial participants are not stipulated in published findings. It was suggested that such information should be routinely monitored, collected and disseminated, in order to formally evaluate South Asian under-representation. Overall, the present findings indicate that there is confusion amongst some health professionals about the significance of representational sampling, and educational programmes might be needed. Although there is a will to include South Asian people in clinical trials, the reality remains that unless there are adequate resources within the infrastructure of a trial, representational sampling may not be so easy to achieve.

Language barrier

Nearly half of the respondents suggested that the inability to speak the English language was a major barrier to South Asian participation in clinical trials. Language provision was further hampered by the variety of different South Asian languages and lack of available resources to cope with such linguistic diversity. In addition, it was suggested that children whose parents cannot speak English are also excluded from clinical trials as part of the same process. The following two quotations from different respondents (illustrating their reactions to potential trial participants, who are non-English speakers) clearly highlight the effect of language barrier on an individual's likelihood of being approached to take part in clinical trials.

> "… I want the next patient into my trial and she's a, a lady from, from Bengal or, or East Pakistan and you know that she doesn't speak English and she doesn't read very well. And in the past translation's been done by her son or by her nephew, you think 'ooh this, no, no, I'll leave her out'." (13EM-5)

> "… the nurses say 'Oh, no, she speaks no English' or 'He speaks no English.' And then you think 'Oh, well, should we enter them into the trial and should we approach?' and there probably is a drive that says 'Probably not.' Cos it just makes it more difficult." (5CM-12)

Having a good rapport with the patient was another important factor in clinical trial recruitment. A number of respondents felt that it was easier to recruit 'approachable' patients. The gender and the language of the patient were also seen as affecting the doctor–patient relationship and consequently the patient's likelihood of being asked to take part in the trial. This is likely to have a negative impact on the recruitment of some South Asian people, in particular the women.

> "… because of the language barrier and because the majority of South Asian people that I see are women, I feel sometimes that there is a little bit of a barrier between us." (15DM-1)

The language barrier also deters the clinical trial recruiter from building up a good relationship with the potential trial participant.

> "… you need to build up a relationship with people, and the only way they come back is by building up a relationship with you and that would be very difficult if somebody's first language was different to the researcher's first language. It would be a barrier definitely." (10IF-10)

These findings suggest that some clinical trial recruiters may actively exclude South Asian people from clinical trials because of what they view as 'pragmatic' reasons. This is a good example of institutional racism in operation, where there is a lack of awareness of discriminatory practices. Institutionally racist policies are often seen as non-discriminatory to those people who are used to them. One respondent, however, argued that the language barrier is frequently used as an excuse by some health professionals, who do not want to put in the extra effort involved in recruiting South Asian patients.

> "… I think the problem sometimes is from, in our side, it's not them. It's that they [South Asians] either don't get the opportunity to even consider it [taking part in trials] because it's not discussed with them, or it's the way that it's said to them. And sometimes the language is part of that, you know, it either puts people off totally from mentioning it and they'll sort of defend that by saying, 'Well she doesn't speak English and she's had such a lot to take in anyway I didn't want to, you know, burden her with the extra', that's frequently said to me… but where women don't speak English I think it's highlighted even more than it is normally." (21NF-9)

Translating information sheets and consent forms for non-English-speaking patients (due to ethics

committees' requirements) was also viewed as an extra burden by nearly half of the respondents.

> "Oh, it irritates researchers, yes I know it does … I don't think there is any sort of objection in principle, it's just a matter of the effort involved." (1CM-4)

There was a universal concern about the additional cost associated with actively including South Asian people in clinical trials. As a consequence of the extra work involved and lack of organisational support (interpreters and cost of translation), some investigators find loopholes to get around the ethics committees by stating that language provision will be addressed if resources allow. Others set the inability to speak English as an exclusion criterion in their study protocols. Two of the respondents believed that exclusion due to language barriers was justifiable from a safety perspective, since inability to speak or understand English affected drug compliance and patient safety. This was especially pertinent if the treatment regimen was complicated and dangerous, for example chemotherapy trials. Most of the respondents in principle did not agree with having language as a justifiable exclusion criterion. However, in their current working environment, logistical barriers such as lack of time, resources and poor organisational support for language provision meant that they had little choice in this matter. This resulted in routine exclusion of those South Asian people for whom English language was a barrier to communication. The following quotation captures the essence of this dilemma:

> "... you've got a certain time in which to recruit and if you don't recruit then you won't achieve the success of the trial and so on, and that will affect, you know, whether you get any more money through and all those sorts of thing, … I think there is certain level of logistic problems that tend to mean for ease of trial recruitment, and you try and avoid those [recruiting non-English speakers], cos otherwise you end up not being able to recruit." (5CM-4)

In trials where recruitment takes place via postal mail or telephone, the language barrier is further complicated owing to issues of patient confidentiality. One respondent in particular experienced difficulties recruiting older South Asian women to a menopause trial because the older women could not speak English and the trial nurse could not explain the study to them over the telephone. Even if the resources were available for translators, it was generally felt across the board that there was a lack of interpreters who were trained in clinical trial terminologies and concepts. This led to concerns about the level and quality of information provided to the non-English speaking trial participants.

> "I never know whether in fact that the person who is doing the interpreting is actually giving an exact representation of the words that I'm using … if there are some concerns about people not getting correct information it's better not to involve myself at all, that was one barrier." (15DM-1)

Two of the respondents suggested that interpreter provision for clinical trials could be networked within the existing hospital interpreter system. This view was contradicted by another respondent, who suggested that unless interpreter provision was funded within a clinical trial, it might be pointless to use hospital interpreters because special training in clinical trial terminologies was essential. The general concern about interpreter provision was that there was a lack of trained interpreters, who were familiar with clinical trial terminologies.

> "If you had an interpreter who was able to understand what it is we were trying to achieve, then maybe … but we haven't, and therefore one tends to avoid it [recruiting South Asian patients]." (5CM-5).

The respondents also viewed using family members as interpreters as unacceptable. The following example highlights the difficulties of using family members as interpreters:

> "… I discuss life-threatening events with chemotherapy. I don't think relatives will feel always comfortable mentioning that. And how, how it comes across, it may, I don't know how it'd be interpreted, it could, you know, it could kill you." (3NM-14)

With regard to provision of written translated material to South Asian patients, it was felt that all patients should be fully informed before entering into clinical trials. This requires being able to understand the trial details both verbally and in writing. Verbal information, it was argued, is not always easy to retain, and it was recommended that verbal information should be backed up with written information. In practice, a small number of the respondents made use of both translated sheets and interpreters. However, one of the respondents suggested that the use of translated information sheets might be unnecessary, since people who can read a South Asian language are also likely to read or understand English, because they are both correlates of being educated. A solution proposed by one of the respondents was the provision of a free on-call interpreting service that could be accessed instantaneously.

Lack of time, resources for the additional work involved in recruiting South Asian people and poor organisational support were consistent themes. The respondents recognised lack of resources within the trial framework as effectively leading to an active exclusion of non-English-speaking South Asian people from clinical trials. Not providing appropriate linguistic services for South Asian people denies them the opportunity to take part in clinical trials. The inability of the NHS to provide adequate language support for those whose first language is not English is an example of institutional racism. The findings also suggest that pragmatic barriers due to language and additional costs were viewed as problems that the respondents could not overcome. Lack of positive action is another facet of institutional racism. A quotation by one of the respondents sums up the essence of the difficulties facing investigators with regard to the routine inclusion of South Asian patients in clinical trials:

> "… you know, they're [researchers] looking for an easy way out really, and they're looking for the easiest way to be able to do their piece of work without creating too much aggravation for themselves, … if you really wanted to put into place all of the different issues with, relating to language, culture, etc. etc. and employing somebody to be an interpreter, making sure that everything's translated up, making sure that that's transcribed as well afterwards, converted into English, it costs more money and that is a good reason for not doing it." (2EM-4)

Lack of resources for translation

Owing to increasing pressures on trial investigators to secure funding for clinical trials, it was suggested that clinical trials had to be as cost-effective as possible. In order to make the trial more economically viable, provisions for additional resources (translation, interpreters and for outreach/community efforts) tend to get missed out of grant applications. One respondent believed that in the current competitive environment of research funding, such additional costs might reduce her chances of getting funding:

> "… we wouldn't have got the funding, because the trial would be too expensive … and in a way we're scared to do because if we did manage to recruit people it would have huge financial [implications] … ." (10IF-4-12)

Extra resource allocation for language support might not be a high enough priority to 'justify special measures'. Two respondents argued that it could be judged unethical to use scarce resources on something that would yield very few results.

Although it was acknowledged that good research should be about providing meaningful data and not about cost-effectiveness of clinical trials, in practice there is usually a 'trade-off' between trial efficiency and knowledge sought. Such a trade-off will also depend on the type of trial; for instance, representational sampling may not be necessary in certain surgical interventions. The respondents felt that there should be a will at the government/funding level to allocate extra resources for including South Asian people in clinical trials. The role of funding bodies in addressing this inequality, therefore, came up frequently.

> "… I think this has to come through the funding agencies because if they're not gonna fund it, you're not gonna be able to afford to do it and that's the thing that I've been thinking about for ages, is how you persuade funding agencies to do it." (18IF-15)

In order to convince the funding agencies to allocate additional resources for recruiting South Asian people to clinical trials, one respondent suggested using the 'science card' instead of the 'political card'. She suggested that funding agencies might be more interested in good science rather than fighting for equity, and more effort should be made to increase their awareness of the importance of the generalisability of trial findings. There was a consensus that the respondents wanted to be proactive in recruiting more South Asian people to clinical trials; however, they were limited in their efforts owing to financial restrictions. A small number were also concerned about getting their grant proposals rejected if they took the initiative to incorporate the additional resources needed to overcome communication barriers.

Lack of culturally similar staff and culturally appropriate tools

Even if provision were made for extra resources for translation and interpreting, there was a feeling amongst some respondents that, since the majority of the clinical trial investigators are white, logically, it would be easier for them to recruit members of their own ethnic group. Also highlighted were the logistic difficulties in identifying ethnically similar researchers owing to the variety of languages and religions of the South Asian populations. Respondents shared concerns regarding the applicability of increasingly used 'quality of health questionnaires' to South Asian people.

> "… despite the fact that we've got a large South Asian population …, a lot of the studies specifically exclude

> that group because, who can't speak English, and that's not all the South Asian patients, but it's a large chunk of them, because they can't translate the questionnaires, because they can't translate various aspects of the study." (8CM-6)

The importance of translating and validating questionnaires into the different South Asian languages was acknowledged, but the increased costs associated with this exercise were suggested to act as a major barrier to South Asian participation in clinical trials.

> "… so I just don't know whether the resources would allow people like me doing research on the kind of subjects I'm doing to actually do that. I would, I would be very happy to use the tools if they were there, but there's more work needed to validate those tools in those communities." (10IF-2)

Other potential barriers cited by the respondents included lack of a clear definition of an ethnic minority group, lack of ethnic monitoring in clinical trials and the complicated South Asian naming system.

Lack of training in cultural sensitivity

"South Asian patients are perfectly capable of participating in research and are not difficult to recruit"; a suggestion made by one respondent. However, they may not be approached to participate in clinical trials, owing to uncertainties about what recruiting such a group would entail. In the experience of one respondent, in areas of low ethnic minority concentrations researchers may feel anxious about recruiting South Asian people owing to not being able to cope with language needs and cultural differences. As a consequence of this 'fear of the unknown', South Asian people were being excluded all over the UK, in one large multi-centre trial:

> "… I know when I speak to other people at other centres or trial centres, they're always a bit sort of, they're not as keen because they think it's gonna be a problem recruiting somebody that doesn't speak English, and … how will they follow them up and questionnaires and that sort of thing, and I think that's ... that's a bit of a barrier still." (21NF-12)

Lack of training in cultural sensitivity, coupled with a language barrier, makes communication processes between the health professional and the patient difficult. However, if health professionals were unfamiliar with South Asian culture, many might be afraid of offending their patients. This was the case in one trial:

> "… there's an anxiety there … if your research, for example, is about babies dying or something that is culturally specific to, to, to Muslims apparently, then people might feel very reluctant to do it. Particularly if they know that the communication is the problem, you know they can't get the person, they think, to understand what they're saying and vice versa. And people will be frightened of offending." (13EM-4)

Lack of familiarity with South Asian culture, to the point of being almost fearful, can sometimes lead to the development of cultural myths and stereotypes about the 'other'. Health professionals, like the rest of the society, have been shown to harbour such beliefs. Cultural myths and stereotypes about South Asian people are common in the NHS and an aspect of institutional racism.

Stereotyping attitudes

A number of stereotypes and cultural myths about South Asian people were revealed. It was suggested that the existence of stereotypes in the NHS might have an impact on South Asian recruitment to clinical trials. These stereotypes could be overcome by providing training in cultural sensitivity to the NHS staff.

> "I think training is important, I think you are going to have people with very set certain ideas who are, I don't think racist is the right word to use, but ... stereotyping." (6NF-6)

Stereotyping is not exclusive to South Asian people, since other groups such as women, older people and those from lower socio-economic backgrounds are also stereotyped. The respondents recollected some stereotypes they had come across at work and these included the following: women tend to look after their family and therefore might not be able to come for appointments; older people are likely to be on several different medicines which will affect their drug metabolism; and patients from lower social class backgrounds are less compliant. Some believed that social class was a barrier to clinical trial participation in general.

> "Yes there is a difference in social class … patients of a lower social class may well not be as good at being followed up, about attending for follow-up interviews or follow-up sessions, they lose interest quickly and they maybe don't understand the importance of the trial work and therefore may well not comply with all the things that are necessary." (15DM-4)

Others held similar beliefs about South Asian people.

> "… Asian people in trials can be less compliant and less willing to turn up for visits, so you may have a schedule to trial visit and they may not turn up or

> when they do turn up you find that they haven't taken their medication." (9IF-7)

Lack of compliance in South Asian people might also be due to their social class background. One respondent, who recalled a study where she tried to recruit people from a number of sections of the society and found that even in the white European community the response rate differed due to class differences, shared this conviction.

Another stereotype with regard to South Asian people included the belief that older women lacked interest in research:

> "… the older age group, women between 49 and 69, and we've found that they often just don't respond … Yeah, they don't, they often will, despite sending several letters, very rarely do we get a response." (7NF-1)

This stereotype was unpicked by one respondent, who suggested that lack of interest in this group might be because a number of older South Asian people are not fluent in English. Inability to speak or read English was believed to be more common amongst Bangladeshi and Pakistani women. Sending letters in English, therefore, might not be an ideal way of engaging with this population.

Lack of time-keeping amongst South Asian people was another stereotype mentioned by three respondents. One of the respondents did acknowledge that this might also be linked to their social class backgrounds.

> "… coming to the surgery at a fixed time. I think that is a problem for a lot of South Asian families … I think anybody from social class 5, you know, they all have that sort of issue. But white patients would do that as well. So it's not specifically South Asian patients … ." (2EM-9)

Poor time-keeping in South Asian patients may also be due to unfamiliarity with the appointment system in the NHS (which can be confusing), and the absence of translated signs in hospital wards.

> "… I think often they're not late, they're just … They're just lost, they don't understand the system, … they might just come in and sit down and not know that they've got to go and do anything or say, 'I'm here', or d'you know what I mean? Especially here, because it's very confusing here, cos they've got to check in at the main doors, and then they also have to check in at the desk in clinic, so a lot of people go to the first window and then come and sit down because they don't realise that they've got to do anything else. And I think it's more of a fault of the clinic system than people coming late, to be honest." (21NF-7)

Gender stereotyping (male domination and lack of decision-making in South Asian women) was also frequently cited by the respondents as a major barrier to female South Asian participation in clinical trials. Although the inability of South Asian women to make decisions on their own (for consent) was at first attributed to the role of male domination in their culture, on probing it became apparent that decision-making was dependent on whether the female patient could speak English or not.

> "… a lot of the women come with an English-speaking female relative and often then it'll be the English speaking female relative that will indicate the decision." (8CM-8)

Another stereotype mentioned by two of the respondents was that if a person doesn't speak English, then they are not intelligent.

> "I think assumptions are probably made that if you can't speak English, you're not intelligent … that myth needs to be sort of, sort of broken down, because I think that does happen." (3NM-4)

The stereotype that South Asian people have extended families 'who look after their own' may be a barrier to participation in certain types of trials. This stereotype is illustrated by a quotation from one of the respondents:

> "… cos most of the elderly Asian patients do go home to their families, they don't go in, don't look at … rehab or long-term care somewhere else … . They've got their extended family usually and, who look after them rather than needing nursing home care or continuing care or intermediate care (laughing) or whatever the care the label is." (7NF-10)

One respondent recalled another stereotype she had come across, which was about South Asian people having different health beliefs and views about preventive health. Such a misconception about South Asian health beliefs may prevent them from being approached to take part in preventive trials.

> "I guess I've heard people talk about people from South Asian background particularly not having the same feelings about preventative health care as people from White English backgrounds, … so they think this is a trial about preventing ill health and maybe people from the South Asian background wouldn't be so interested in getting involved in that." (10IF-7)

Geographical barriers

In addition to barriers to participation facing South Asian people discussed so far, the respondents also suggested that the effect of geographical location of clinical trials should not be overlooked. This view was based on the premise that the majority of South Asian people are registered with inner-city, single-handed practices, which usually do not get involved in clinical trials. The majority of the practices that get involved in clinical research are situated in suburban and affluent areas. Large proportions of South Asian people tend to live in inner-city areas, and consequently registered with inner-city practices or single-handed GPs. It was proposed that lack of participation in research by the smaller inner-city practices meant that a large percentage of their predominantly South Asian patients might not get the opportunity to take part in clinical trials.

Hospital referrals were also viewed as a barrier to South Asian participation. Three of the respondents believed that South Asian people might not be referred to specialist sites (where a large proportion of clinical trials take place) and might be selectively 'filtered' out. Such selective filtration might be due to preconceived ideas and stereotypes about South Asian patients (illustrated by the following quotation), or to genuine and paternalistic reasons, where the specialist may assume that lack of transport and family support would make it difficult for the patient to have access to the specialist site.

> "… because people could think they [South Asians] are not going to understand so it's not worth referring them to Cookridge [cancer trials]. You could get two patients and they would say 'Oh we will send that lady, she has her own transport, articulate, everything like that, up to Cookridge.' You could perhaps have a South Asian and they would say, 'Well she doesn't speak English and she has no transport, they are not going to take her up there, she won't go on that trial.' Well okay, she might not go on the trial, the other lady might not go on the trial, but she has not been given that option." (6NF-10)

Obtaining informed consent by potential trial participants can be a cumbersome task. Factors affecting cross-cultural communication (untrained interpreters, lack of translated information sheets, cultural stereotypes) make this crucial process even more problematic.

The consent process

All respondents acknowledged the importance of obtaining fully informed consent from trial participants. A number believed that, regardless of the ethnic background of the trial participant, the consent process should be viewed as a major barrier to recruitment. This was due to the use of technical and often very complex medical terminologies which most lay people would find difficult to comprehend. One respondent illustrated this point by providing an example of a female lawyer's reaction to the explanation of the randomisation process.

> "… I just sat with somebody upstairs for quite a while discussing it and explaining randomisation, and then she said to me at the end, 'So I can just pick, can't I?' ... . Which is the opposite of what I'd just been explaining." (21NF-5/6)

Owing to the increasing distrust and litigation in society, the need for consent becomes a necessity in order to protect the investigators. This results in the consent form being viewed as protection against getting sued. The respondents also highlighted the difficulties of obtaining a balance between protecting the trial participant against potential abuse and putting them off taking part in the trial owing to the complicated and often 'scary' nature of the consent form.

> "… I think sometimes the official form is a bit threatening to people, they think because they've got this written form they've got to sign, … And sometimes I think that makes people nervous, because they think, 'God, this must be something really big if I've got to do this. I get asked about all sorts of things and I don't have to do this'… and that's sometimes a bit scary for people, I think." (21NF-4)

Obtaining informed consent often depends on whether or not the investigator considers the potential trial participant to be competent enough to go through the trial. Such an evaluation is subjective and was considered a problem by one of the respondents:

> "… are they competent to be able to give consent? If they are, how do you ascertain that they're competent? Is it simply by them saying yes, or do you have to go through a better process than that? … I think what you end up doing is assessing whether you think they can understand the language, and you feel comfortable with that, and if you don't, you don't ask for consent." (5CM-1/4)

Translation of information sheets into different South Asian languages was not viewed as productive since information provision was seen as one part of the consent process. It was therefore suggested that written information sheets might be futile because the crux of the investigator's job

was to make sure that their patients understood what they were being told and what to do if there were any problems. Having a language barrier meant that the intricate details of the trial would be difficult to convey to the potential trial participant.

Another barrier to the consent process was the stereotype that South Asian women were unable to make decisions on their own. It was suggested that as a result, many South Asian women might not be approached to take part in clinical trials. One respondent elaborated this sentiment by suggesting that in his experience lack of decision-making amongst women was common, and this was regardless of the woman's ethnic background:

> "There's a special barrier in some South Asian groups … women won't be able to make a decision for themselves and will need to seek advice from the family and things before they decide. To be honest, we make a big thing of that but quite honestly that applies to English women just as much. Not many of them can allow themselves to be randomised without talking to their husbands." (1CM-5)

Poor education was also given as an explanation for lack of autonomous decision-making amongst South Asian women.

> "… I mean certainly amongst the South Asians, I think the women are less likely to be literate than the men which is also a major issue." (20CF-6/7)

Decision-making might be different in different cultures and is dependent on the individual's educational background and life experiences. It was suggested that most people do not make important decisions in isolation, and that autonomous decision-making (underpinning the informed consent process) was a Western concept, where the doctor and the patient exist as two separate people, and 'nothing around them matters'. The same respondent also argued that there was a need to change the 'individualist culture' of the consent process. Her views were contradicted by another respondent, who found it very difficult to have South Asian family members present during the informed consent process:

> "… how difficult it is sometimes with some cultural groups to have a private interview because often erm, somebody whether it's a mother, mother-in-law or a partner wants to sit in and in maternity care that's a very big issue because we're trying to reach women, and usually it's women who have a hard time getting private space erm." (18IF-14)

Another barrier to the consent process was identified as too much trust. There were concerns that some South Asian patients allowed their doctors to be paternalistic and that patient loyalty could easily turn into dependency. Some of the consultants, and GPs in particular, felt that too much trust in the doctors was counterproductive to the informed consent process. These respondents felt that the issue of the patient wanting to please the doctor is particularly applicable to South Asian patients who were generally viewed as being too trusting.

> "… I'm far more likely to get the response from an Asian patient, 'Yes doctor, we'll do what you think is best.' Whereas from a white patient they will generally have a fixed view … a lot of the Asian patients are quite happy to go into trials because they accept that we think that's a reasonable thing to do, and that's where we find with Asian patients that probably they're more willing to go along in that direction." (8CM-2)

The respondents also discussed the practice of coercing patients to take part in clinical trials. It was suggested that it was naive to assume that coercion (either deliberate or accidental) does not take place in clinical trial recruitment. It was acknowledged that health professionals are in a position of relative power since patients want to please and maintain a good relationship with them. As a consequence of this power relationship, patients may be more inclined to agree to get involved in clinical trials.

> "… there's a power thing certainly. You come along and see your consultant and it's difficult to say no. I mean I quite shamelessly do that, I use that because I am often trying to recruit patients to trials that are difficult, the recruitment is slow … I am very persuasive. You know, 'It's your choice my dear, but it will really please me if you do'." (1CM-7)

In addition to the barriers identified above, health professionals also described a number of patient-centred or cultural barriers to explain South Asian under-representation in clinical trials.

Cultural barriers to clinical trial participation

Cultural barriers to clinical trial participation, identified by respondents included non-compliance, male domination resulting in lack of decision-making in women, issues around modesty amongst South Asian women and religious obligations.

Non-compliance

Lack of compliance was frequently presented as a 'cultural' barrier to explain low South Asian

participation rates in clinical trials. One respondent had problems retaining and recruiting younger South Asian men (owing to their work commitments). Another faced difficulties recruiting older South Asian men because of their unusual working patterns.

> "… an amazing number of them actually do work night-shifts and I couldn't recruit those, or they had commitments that they couldn't come at the time of day, say like early morning with fasting blood samples and they couldn't come for those." (7NF-8)

When probed further on the issue of South Asian non-compliance, it became apparent that non-compliance was related to an individual's social class background – their busy lifestyles rather than their culture.

> "… our white women from [ ], who live in a very socially deprived area, don't take tablets, just as our Asian women from [ ]. So I don't think that's a cultural thing, I think that's a social class." (8CM-8)

Another example also illustrated that non-compliance was likely to be related to social class background and not the patient's ethnicity:

> "… one study that we did where they had to take a course of tablets for a week, and we did have a number of people who didn't comply with that, but none of those were Asian. They were white, they were from lower socio-economic groups, if you like, but they were the ones that didn't comply." (21NF-6)

The potential trial participant's inability to understand the technical nature of the clinical trial, due to the language barrier, was also discussed. Understanding clinical trial terminologies was argued to be dependent on the patients' social class, and not necessarily their ethnicity.

> "… I think it's fair to say we found it easier to recruit in more middle-class areas … I suspect that social class, education is actually what most matters. At least I would, I mean that's my impression from running these trials that actually ethnic minority is not of itself an issue." (20CF-3)

Lack of time-keeping (mentioned earlier as a stereotype) according to one respondent was also likely to be class driven, rather than due to the patient's ethnicity or culture:

> "… it depends on socio-economic factors, do they have transport? You know, can they get here easily? Are they allowed out? The Asian group tend to have more children, gotta juggle bringing them as well, and that generates problems." (5CM-7)

These findings suggest that non-compliance in South Asian people is likely to be due to social class rather than their culture or ethnicity. What is of interest is the fact that some of the respondents could not distinguish between cultural and social class factors. The effects of age, gender and social class can be as important as ethnicity in explaining South Asian under-representation in clinical trials. Lack of discernment can lead to cultural myths and stereotypes.

Male domination

There was some confusion amongst the respondents with regard to the belief that South Asian women were dominated by their husbands. The inability of some South Asian women to make decisions on their own (with regard to the informed consent process) was frequently given as a barrier to their participation in clinical trials. This, according to a number of respondents, was thought to lead to some recruiters not approaching them in the first instance.

> "Asian women, they are very dominated by the males and they are not able to make their own decisions and that is very sad when a man makes a decision and she is not allowed to make the decision and I feel those women do lose out on a lot of things." (6NF-11)

It was also suggested that lack of decision-making might be related to the patient's educational background. Pakistani and Bangladeshi women in particular were viewed as being less educated and, therefore, lacking the confidence to make decisions on their own. The respondents suggested that those South Asian women who were successfully recruited to clinical trials tended to be younger or Sikhs. This was due to their ability to speak fluent English.

> "… we have successfully recruited some Asian patients but they do tend to, we have, they tend to have been either the younger ones or perhaps erm, Sikhs who often tend to speak English, so we haven't had a huge amount of success with recruiting from other groups … ." (7NF-2)

On the issue of lack of decision-making amongst some women, one of the respondents suggested that this might be because 'traditional families' tend to be male dominated, where women have less freedom to take part in things. In such families, 'feeding the man' might take priority over taking part in clinical trials. Such 'traditional families', it can be argued, also exist in the majority population, and lack of decision-making among some women might be due to their relatively weak position in society.

Modesty

Low participation in 'embarrassing trials' (such as gynaecological, breast and bowel) was thought to act as a barrier for some South Asian females, who, owing to concerns about modesty, seem to have a preference for female doctors in relation to such problems. The respondents considered certain topics as 'taboo subjects'.

> "… and talking about sex for example, you know, if you were to go to, again Asian women, and started asking about sex, I don't think that would go down terribly well." (13EM-7)

One respondent recalled a clinical trial on irritable bowel syndrome in which South Asian women were particularly reluctant to come forward to enrol due to the 'embarrassing' nature of the trial:

> "… because it was almost seen as sort of an embarrassing thing that you just didn't talk about." (9IF- 2)

Religion

An exploration of religious barriers to participation amongst South Asian people, revealed very little. The following quotation from one respondent sums up this line of investigation:

> "… I've never had anybody say to me 'I'm a religious fundamentalist, I disagree with the scientific method.' (Laughs) Ever." (4DM-9)

Vegetarianism was thought to prevent some Hindus and Sikhs from ingesting meat-derived medication. Similarly, it was suggested that alcohol, gelatine and products containing pork would put Muslims off taking part in clinical trials. Some difficulties were encountered with Muslim patients fainting whilst obtaining blood samples during the fasting month of Ramadan, and accepting medication during this period. The religious practice of not shaving body hair by some Sikh men posed one respondent with some difficulty:

> "… I have had difficulties sometimes dealing with ECGs on Sikh gentlemen … Because they're very hairy (laughs) and the electrodes don't stick and you can't shave their hair so." (7NF-9)

One respondent believed that some South Asian patients might hold a fatalistic view towards illness that might affect their likelihood of participating in clinical trials:

> "… the phrase that they use is [Inshallah] it's God's will and whatever will be will be and that's, I mean that affects trials and it affects clinical care as well … ." (8CM-4)

TABLE 16 *Strategies to improve South Asian under-representation in clinical trials*

- Educational programmes aimed at investigators, ethics committees and funding bodies to increase awareness of under-representation of ethnic minority people in clinical trials
- Additional resource allocation for language support
- Patient education and advance awareness of clinical trials
- Culturally sensitive training
- Recruiting more ethnic minority health professionals
- Need for guidelines and ethics committee policing
- Improved reporting of ethnic background in published trial findings and a greater sensitivity in reporting research findings
- Mandatory inclusion of ethnic minority people
- Culturally sensitive communication and culturally sensitive approaches to the consent process
- Promoting trust
- Developing innovative patient education materials
- Improving the informed consent process

Apart from these points, there was very little forthcoming about religious objections to clinical trial participation in South Asian people.

Strategies for improving South Asian recruitment to clinical trials

Having identified a number of barriers thought to be responsible for South Asian under-representation in clinical trials, the respondents also suggested some strategies to improve their recruitment to clinical trials. These are presented in *Table 16* and include improving awareness of clinical trials, building trust, employing culturally similar staff, need for guidelines and policing and novel recruitment strategies. A discussion of these strategies follows.

Improving patient awareness

Overall, the respondents felt that there was a need to change the public's negative image of clinical trials – where they are viewed as a form of experimentation. One of the respondents argued that the first time a patient hears about clinical trials is when they are asked to participate in them, and that usually occurs when the patient is either ill or under stress. Providing advance knowledge about the benefits of taking part in clinical trials was considered a way around this barrier. This was achieved in one department by producing patient information leaflets and by giving patients ample time to consider participation, should they be asked to take part in

the trial. The leaflets also included information on the reasons for randomisation and educated patients on the importance of undertaking research and clinical trials generally.

It was also suggested that improving public awareness could also be achieved via the popular media, for instance discussions in women's magazines. Some respondents proactively pursued the advanced awareness strategy in their units by training their translators in clinical trial terminologies, so that potential South Asian trial participants would have a better understanding of clinical trials. Increasing public awareness about clinical trial participation, according to one respondent, could also begin at school level.

> "I think you've gotta educate the people about trials and what they're about and why they're necessary. I think you could do that for the whole population, not just the Asians, but I think you might have to target them because they often don't understand why these things are happening, they're not aware that trials take place, generally, as are not many other people as well, although it's been in the media a lot more recently." (5CM-10)

Only one respondent stressed the importance of making doctors aware of the importance of representational sampling, even though a large number stated that lack of awareness on this issue was a barrier to South Asian participation. With regard to health professional training, it was suggested that this should take place whilst in training.

> "… education should be at the stage where people are training, or the nurse training or doctor training. You see I don't think much doctors get much training on anything like that at all and certainly working with nurses who have trained in other areas, I don't think they got that. We got that because of the area that I trained in [clinical trial recruitment]." (6NF-6)

Building trust

Building trust in the South Asian community was suggested as an important strategy for improving recruitment rates to clinical trials. Half the respondents suggested trust as a very important element of the doctor–patient relationship, where any barriers due to trial complexity can be overcome if the patients trusted their clinicians.

> "… the more complicated the trial the more trust is involved in that. If you're taking blood sample after blood sample after blood sample from patients they don't like that. They don't trust, you know, they have to have a lot of trust in you in order for them to take that on board and to accept it." (2EM-6)

As part of this process, some of the respondents were increasingly using ethnic minority lay representatives on their trial steering committees. This strategy was found to be of limited value in one respondent's experience, where the South Asian lay representative was not viewed as substantially contributing to raising patient awareness.

Nurses' supportive input into clinical trial recruitment was also acknowledged, where it was suggested that they play an important role in patient recruitment (by identifying patients, talking to them, preparing them and discussing the implications of the trial) before the patient talks to the lead investigator. This supportive role extended to the nurses becoming patient counsellors.

> "… sometimes the doctor will explain something to them, they go off and then they ring you back and say 'Well I don't really understand what the doctor said, can you explain that again to me.' … I think patients that are in clinical trials, having a named clinical nurse like that, is much more easy for them to ring us and tell us." (6NF-7)

Employing culturally similar staff

Culturally matched health professionals would not only help overcome the language barrier but may also promote trust between the patient and the recruiter, a suggestion made by some respondents. Matching investigators, who were of the same ethnic group as the target population, was tried in one trial to ease recruitment difficulties. This strategy was found to be ineffective and the respondent could not explain this. It was suggested that matching might not be sufficient as a strategy on its own.

> "… the investigators that were the same religion as well, because obviously if you have Hindus and Muslims there maybe a problem there, so we tried to get the investigator to be of the same religion. Also to speak the same language … We still found it hard to recruit patients. Some investigators recruited better than others, but it was still harder, it seemed to be harder than recruiting from white population, even then." (9IF-2)

Need for guidelines and policing

Although increased awareness through education was recommended, a number of respondents also thought that it might be more effective to construct clear guidelines which will prevent 'investigators from abdicating' recruiting South Asian people to clinical trials. Suggestions included NHS run trials should make it mandatory for researchers to include ethnic

minority populations (reflecting the local demography), and that guidelines should stipulate that South Asian people are part of the society and therefore should not be excluded from clinical trials owing to limited resources. It was also suggested that ethics committees could play a more proactive role in monitoring trial protocols. Funding bodies could also allocate adequate resources to meet the costs involved in recruiting South Asian people.

> "… ethics committees to make it formal in their procedure that they do not allow these people [investigators] to get round it by having various loopholes [e.g. inability to speak English], and the third thing is that for that to be recognised when people are putting resources into clinical trials, that this is an additional expense, and to make sure that, you know, there are enough interpreters or relevant people." (2EM-11)

Strategies for lobbying for guidelines included targeting the Committee for the Safety of Medicines (CSM), the MRC and the Welcome Foundation in the UK. Nearly one-quarter of the respondents also suggested compulsory inclusion of South Asian people in clinical trials, a scheme similar to the US NIH guidelines on compulsory inclusion of women, older people and ethnic minority people. Two respondents, however, contradicted this viewpoint, by arguing that ethnic minority inclusion should be based on science and not political reasons.

Novel recruitment strategies

The NHS language line, which allows investigators to gain access to an interpreting service for most languages, was mentioned by one of the respondents. The language line was recently set up to let researchers book the time and the translator of their choice. Although the language line cannot substitute an interpreter in person, nevertheless, it is a facility that is perhaps under-utilised because researchers might be unaware of its existence.

Another novel strategy included specialist clinical trial information centres offering around the clock localised facilities for translation and interpreters for all ethnic minority languages. Such centres could provide investigators with resource packs or information guiding them on how to go about recruiting different ethnic minority groups. Another respondent recommended providing mobile phones, for the 'mobile' population with no fixed address for the duration of the clinical trial. Such a scheme was found invaluable in a chemotherapy trial where, for safety reasons, it was essential that the trial participants had 24-hour access to a telephone. Financial incentives for participation in clinical trials were suggested by one of the respondents, along with making clinical trials more user friendly so that people felt more comfortable participating in them.

Direct community recruitment was also suggested as a good strategy for improving clinical trial participation rates. This might involve targeting South Asian communities through Prime TV, Zee TV and South Asian radio stations and identifying newspapers that were widely read. It was further suggested that because religion was important to the older generation in particular, it might be useful to build contacts with mosques, temples and gurdwaras, promoting clinical trial participation.

Conclusion

Lack of time, scarce resources, poor incentives, increasing patient choice and mistrust of clinical research mean that recruitment to clinical trials is becoming increasingly problematic. As a consequence, those patients who are approachable, perceived as being compliant, are the same gender as the recruiter and fluent in English tend to get 'cherry picked'. This practice, however, was not viewed as discriminatory and was justified because of lack of time, resources and inadequate NHS support structures.

In order not to fall into essentialised notions of ethnicity, there is a need to recognise that in addition to a participant's ethnicity, it is equally important to consider other socio-cultural characteristics such as gender, age, level of education, primary language and social class – all of which also affect the communication process. Differences in access to healthcare (including clinical trial participation) appear to reflect the class structure of British society and health professionals, who have more in common with middle-class patients. This finding could partially explain why, typically, trial participants tend to be white educated men from predominantly middle-class backgrounds.[28]

One of the interesting findings of this study is illustrated by the confusion amongst some of the respondents in separating cultural barriers from social class or gender issues. Lack of compliance, for instance, was given as a 'cultural' reason for low South Asian participation in clinical trials. Such an attitude fails to consider structural barriers embedded in the medical and social system which work to deny access to medical care for the disadvantaged. Similarly, lack of decision-

making amongst South Asian women was perceived to be the result of male domination in the South Asian culture, rather than due to lack of fluency in the English language. Ethnicity, therefore, is operationalised in several different ways in clinical trial participation, and the key to good policy development is to know and understand when ethnicity makes a difference and when it does not.

Perhaps the most important finding of this study is that South Asian patients might be systematically excluded from clinical trials owing to the increased cost and time associated with their inclusion. The language barrier was frequently given as a reason for low participation rates amongst South Asian people. These findings are somewhat paradoxical in the sense that nearly 50% of South Asians are born in the UK and therefore fluent in English.[156] The assumption that South Asian women (in particular Pakistani and Bangladeshi) are illiterate is also an inaccurate stereotype. The literacy (in any language) of South Asian adults varies from 32% in elderly Pakistani women to virtually 100% in Indian of both sexes under the age of 30 years.[194] It might be the case that the respondents experienced recruiting older South Asian people, those from predominantly lower social class backgrounds, and those new to the UK – all of whom are likely to have English language as a barrier to communication. The present findings are, therefore, in agreement with the literature that suggests that ethnic minority people, especially those whose first language is not English, have been traditionally excluded from research studies[119] and a limited command of the English language is a major reason for non-participation in clinical trials.[118]

Other explanations for South Asian under-representation in clinical trials might be due to their passive exclusion as a result of cultural myths and stereotypes, held by some health professionals. Respondents' accounts suggest that South Asian doctors also held stereotypes. Although linguistic barriers between South Asian health professionals and their patients may not be present, there are other barriers of social class and education. Like all professionals, South Asian health professionals are socialised into particular ways of perceiving patients; internalisation of stereotypes, therefore, is not surprising.[195] Class difference may also explain why matching trial recruiters (same ethnicity as the target population) was found to be an ineffective strategy in the experience of one respondent. It might also be the case that white investigators are afraid to approach South Asian trial patients owing to misunderstandings and confusion about their culture. Such misunderstandings can be overcome by providing training in cultural sensitivity and by deconstructing cultural myths and stereotypes.

Finally, the findings suggest that organisational policies and practices within the NHS effectively discriminate against those people for whom language is a barrier to communication. Exclusion from clinical trials due to the inability of the NHS to provide a culturally sensitive service suggests a form of institutional racism in which minority ethnic populations are denied the same opportunities as the general population. Similarly, lack of positive action amongst health professionals in recruiting South Asian people to trials is another facet of institutional racism. Other

TABLE 17 *Summary of Chapter 4*

- Findings suggest that approachable patients (of the same gender, social class and fluent in English) tend to get 'cherry picked' to clinical trials
- This practice was not viewed as discriminatory and was justified because of lack of time and resources and inadequate NHS support structures
- South Asian patients might be systematically excluded from clinical trials owing to the increased cost and time associated with their inclusion, and the language barrier was frequently given as a reason for low participation rates amongst this group of people
- South Asian under-representation in clinical trials might also be due to their passive exclusion as a result of cultural myths and stereotypes held by some health professionals. Such misunderstandings can be overcome by providing training in cultural sensitivity and by deconstructing cultural myths and stereotypes
- Clinical trial participation appears to reflect the class structure of British society and health professionals, who have more in common with middle-class patients
- In addition to a participant's ethnicity, other socio-cultural characteristics such as gender, age, level of education, primary language and social class can also affect recruitment to trials
- This suggests that ethnicity is operationalised in several different ways in clinical trial participation, and the key to good policy development is to know and understand when ethnicity makes a difference and when it does not
- Institutionally racist organisational policies and practices within the NHS, including provision of a culturally insensitive service, lack of positive action, staff poorly trained in the recruitment of culturally diverse population, poor structure and organisational support for running clinical trials and discriminatory attitudes, effectively result in the exclusion (either directly or indirectly) of South Asian people from clinical trials

aspects of institutional racism identified in this study include staff poorly trained in the recruitment of culturally diverse populations, poor structure and organisational support for running clinical trials and discriminatory attitudes. An accusation that institutional racism operates in the recruitment of South Asian people to clinical trials does not imply that the health professionals are racist. However, non-racist individuals can unwittingly perpetuate racist practices by their uncritical participation in racist institutional structures. It is not unreasonable to deduce that NHS policies and practices that lack cultural sensitivity are discriminatory. Such practices effectively result in the exclusion (either directly or indirectly) of certain members of society. The findings presented here suggest that institutionally racist policies within the NHS may be more of a barrier to South Asian participation in clinical trials than the South Asian individual's reluctance itself.

A summary of the discussion in this chapter is given in *Table 17*.

Chapter 5

South Asian lay perspectives on clinical trials

Introduction

Through an analysis of South Asian lay perspectives on clinical trial participation, this chapter highlights any similarities and differences between South Asian and the general population. It also explores any different perspectives of the various South Asian subgroups towards clinical trials. The findings presented here, for the first time, also highlight specific cultural or religious barriers to South Asian participation in clinical trials. The South Asian population in the UK is not heterogeneous in terms of ethnicity, religion, languages and cultural practices. As a way of reflecting this diversity, the analysis is based on data collected from 60 South Asian lay people (of whom 20 were Pakistani, 20 Indian and 20 Bangladeshi), purposively sampled from Leeds and Bradford in West Yorkshire. The sample was drawn from a variety of urban and inner-city locations to cover a wide social spectrum, age, areas of wealth/deprivation and gender as specified in the sampling matrix (*Table 10*). The respondents were anonymised in order of ethnic background (LP = lay Pakistani, LI = lay Indian, LB = lay Bangladeshi), order of interview, gender and transcript page number.

Results

The interviews began with asking the respondents if they knew what clinical trials were and their personal experiences (if any) and beliefs about participating in them. The respondents were then asked to identify any specific factors thought to have an effect on a South Asian person's decision to participate in a hypothetical clinical trial. An exploration of motivating factors and any potential barriers to clinical trial participation followed this discussion. Finally, there is an exploration of strategies recommended for improving South Asian recruitment to clinical trials.

Awareness of clinical trials

Awareness of clinical trials varied between each group. Indian respondents were most likely to be aware (80%), with less than half of the Pakistani and Bangladeshi respondents (30 and 40%, respectively) being aware of clinical trials. Those who were aware tended to be familiar with the term 'medical research' rather than 'clinical trials'. This finding is in keeping with that of Sugarman and colleagues' study, which showed varying levels of understanding of clinical trials amongst the majority population, and that the general public is more familiar with the term 'medical research' than 'clinical trial'.[82]

There was no evidence of antipathy to the concept of clinical trials and, overall, the younger respondents were more knowledgeable than the older ones. Three of the younger respondents (new arrivals in the UK) had heard of clinical trials from their country of origin (Pakistan, India and Bangladesh). Across all three groups, older South Asian females were least knowledgeable about clinical trials. Awareness was mainly through newspapers, television, radio and poster advertisements. A small number of respondents had heard of clinical trials through 'cancer charity donation envelopes'. One young Bangladeshi female had heard about clinical trials through a GMTV morning chat show. Five of the respondents had heard of the term through either family members being ill or friends who had taken part in clinical trials. Only one Indian respondent had first-hand experience of participating in a trial, which was a long time ago when he was a student. An older Pakistani respondent had first heard of clinical trials when he was asked to take part in one during a consultation with a heart specialist, a few years ago.

Lack of being approached was a common response across the three groups. This is reflected by the literature, which suggests that ethnic minority people are less likely to be informed about clinical trials because they are least likely to be approached to participate in them.[15,111]

> … If somebody had brought it up to me like you have now, and something came across, I think I would give it a go." (LI8M1) [translated from Punjabi]

The respondents were also of the opinion that 'news travels fast in the Asian community' and if they were asked to participate in clinical trials, most would. They believed that South Asian

people should be made aware of how clinical trials are 'relevant to the South Asian community' owing to the prevalence of diseases such as diabetes and heart disease. Even for those respondents who wanted to be more proactive in 'current medical affairs', lack of translated information leaflets in different South Asian languages meant that such information was not easily accessible. It was also suggested that because clinical trials are a 'Western concept', they have not yet become part of the South Asian cultural repertoire.

Those respondents who were familiar with clinical trials were not aware of concepts such as randomisation, equipoise and treatment choices. The very few who had a good understanding of these terms had close friends or family members who had been involved in clinical trials in the past. When asked how they would react to being randomised in a hypothetical clinical trial, three Indian respondents stated that they would prefer not to be randomised and would want to know which treatment they were receiving. One respondent did not consider randomisation to be an issue for him, and his decision to take part in a clinical trial would depend on how desperate his situation was. Another Indian respondent recalled her experiences when her father, who was terminally ill with cancer, was offered the opportunity to take part in a clinical trial. The family decided not to participate in the trial owing to the time factor (terminal cancer) and also because they preferred the father to have the treatment rather than the placebo.

> "… I suppose it would be very different if somebody suggested that there was a new drug about which you need and you were unsure about as part of the medication, but you knew that you were at least getting it so you feel that you're doing something that needs to be done." (LI16F1/2)

Lack of general understanding about clinical trials also meant that most of the respondents knew very little about the informed consent process. Studies show that the purpose of the consent form is not totally clear to the general public.[77,98] Those respondents who had a good understanding of consent spoke fluent English, and understood informed consent to mean 'free will', and the consent form as a protection for both the patient and the health professional. Others had heard of consent forms because of prior experiences as outpatients, through childbirth and having surgery. Older respondents, in all three groups, generally did not appear too knowledgeable on the topic, and held the general attitude that, if it will help them, they would sign the consent form.

One older person thought that consent was a legally binding document of some sort; another saw the consent form as a legal document, which protected doctors against public liability.

> "… you have to give consent to them if something goes wrong then you cannot take action against them." (LP20M5) [translated from Mirpuri]

General factors affecting clinical trial participation

The respondents were asked to discuss any specific factors which might impact on a South Asian person's likelihood of participating in a clinical trial. A summary of these factors is presented in *Table 18*. Age, language, social class, feelings of not belonging, culture and religion came up as important factors.

The likelihood of a South Asian person participating in a clinical trial, according to most respondents, would depend on their age. The respondents could see no reason why younger South Asian people would not want to participate in clinical trials, because they were perceived as more knowledgeable, educated and therefore capable of making their own decisions.

Older South Asian people were also alleged not to want to visit hospitals. An older Gujarati male respondent suggested that 'fear' of hospitals was due to lack of translated information sheets and he perceived older white people as being 'more knowledgeable' owing to the availability of information material in English.

> "… whereas the white population … They have more reading material in their language and they are in touch with the new developments." (LI20M3) [translated from Gujarati]

It was also suggested that travelling can be a barrier to older South Asian people, in particular

TABLE 18 *Factors thought to affect South Asian participation in clinical trials*

1. Age
2. Language
3. Social class
4. Feeling of not belonging/mistrust
5. Culture
   (a) importance of families
   (b) gender issues
   (c) community gossip
   (d) health beliefs
   (e) modesty and gender segregation
6. Religion (meat derived and non-Halal medicine)

the women, who would 'get nervous' about using public transport on their own. Two other respondents suggested that there would be an anxiety about visiting hospitals because older people could be worried in case they were suffering from a serious disease. One older Indian respondent recalled a situation where his wife would not go for a chest X-ray in case the doctors found something wrong with her.

The findings suggest, therefore, that old age could be an important factor likely to impact on South Asian recruitment to clinical trials. Old age has also been cited as a barrier to the recruitment of the general population.[80,89] Older South Asian people were viewed as being 'uneducated', lacking in confidence and not fluent in English. Similar beliefs and stereotypes about older people also exist amongst the general population (with the exception of language). Nevertheless, the present findings indicate that old age might be as important as ethnicity in explaining South Asian under-representation in clinical trials. Lack of confidence and anxiety about hospital visits also suggest that older South Asian people are less likely to be approached about clinical trial participation, since the bulk of NHS trials take place in secondary and tertiary care settings. The 'language barrier' was mentioned universally, and was believed to be more common in older and working class South Asian people. Frustration, with regard to routine medical consultations, was apparent in the accounts of those respondents who could not speak English.

> "… it's hard to understand the language because it's complicated in the words that they [doctors] use. And we don't know any different or how to go about arguing with him." (LI18M1) [translated from Gujarati]

A substantial number of respondents believed that 'education raises a person's awareness and knowledge about science, current issues and the world', that 'educated people are more likely to be familiar with research' and that being educated 'makes a person more articulate and gives them the confidence to ask questions'. An older Indian respondent, who suggested that a person's educational level does not necessarily indicate his or her ability to understand, contradicted these views. He argued that people have different levels of understanding, and being uneducated does not necessarily equate to being unintelligent. Fear of the 'unknown' was another factor associated with clinical trial participation, where it was suggested that this 'fear' could be overcome with education and by improving South Asian people's understanding of clinical trials. This view is somewhat paradoxical, since the only respondent who was most 'fearful' of participating in clinical trials was also the highest educated of the whole sample.

> "Well I mean it's just, you know, sort of fright, that's all I can think of really, fright. Fright and the dangers I can associate with it, that's all. I mean, okay, it's selfish in a way because other people try it, trial themselves for me." (LI4M2)

Overall, the general feeling was that illiteracy should not be equated with lack of intelligence. Examples were provided about how some 'uneducated' South Asian women single-handedly run businesses, bring their children up and look after their husbands and homes. This is encapsulated in the following quotation:

> "… I know women who are running shops, they can't read and write, they're running shops, they're plastering their kitchens, they're, they're doing all sorts of innovative things that show they've got intelligence, but they just haven't had the benefit of formal education … being illiterate does not mean that you're unintelligent." (LP1F11/12)

Such beliefs fail to recognise that clinical trials are a Western scientific concept and have not yet become part of the cultural repertoire of South Asian people (or the general public for that matter).

Social class was also believed to have an impact on the likelihood of South Asian participation in clinical trials. It was argued that middle-class people and 'white-collar workers' are more likely to be exposed to 'current affairs' and therefore likely to be 'more knowledgeable about developments in science'. Working-class South Asian people, on the other hand, were perceived as lacking such awareness. Some respondents were of the opinion that South Asian people from working-class backgrounds would be suspicious of clinical trials because 'they would not trust authority in any form'. Analogies were provided with the general working-class population, who, it was argued, would react to authority and medical research in a similar way. One respondent suggested that government initiatives, aimed at tackling inequalities amongst the general working-class population, should also extend to include South Asian people:

> "… depressed working class kind of poor white working class family, they would shun things, wouldn't they? … Medicine, huh, we're not guinea pigs." (LI9M13)

A small number of respondents suggested that some people could be 'just purely selfish'. One respondent believed that, similar to the general population, some South Asian people might have a 'let somebody else do it' mentality, which means that they would not take part in trials. The 'what's in it for me' attitude was mentioned by another respondent:

> "… I think a lot of people probably you would find 'what's in it for me'. I'm just thinking if my mum and dad were approached, I don't think they would get involved." (LI5F3)

Others talked about 'cultural mindset', which was perceived as being related to age and social class. According to one Pakistani male, although his wife would not have any objections to him taking part in a clinical trial, his parents would object because of their 'mindset'. Such a 'cultural mindset', according to another Pakistani respondent, depended on a person's upbringing, which might also be linked to a feeling of 'not belonging to the British community':

> "… I might be being a bit biased here, but Bengalis sort of tend not to go over stuff like this, and women tend not to go for things like this … it all boils down to I think education and the mindset that they've been brought up in … they don't feel part of the community [British] … So, I think that's what I basically mean by mindset." (LP4F5/7)

These feelings of 'not belonging' might also apply to some of the older South Asian people, who came to the UK in the 1960s and worked in factories, with little opportunity to 'mingle' with people from the general population.

> "… I could see my Gran coming out with something like that, 'Why should I do it?' and help the goras [white people] whatever. I think the older generations have got that attitude." (LI5F5)

Such a prejudicial outlook might be due to perceptions that South Asian people are taken advantage of or have experienced racism. A number of respondents therefore suggested that there was a need to build a trust of other groups within the population, in particular amongst older and working class South Asian people.

The respondents also suggested a number of 'cultural reasons' which might influence South Asian participation in clinical trials. These include the importance of families, gender issues, health beliefs and religion.

Participation in clinical trials was viewed as an important decision, and the respondents were of the opinion that South Asian people like to involve their families when making major decisions. One Pakistani respondent argued that South Asian men are more likely to make decisions because they were more likely to be educated than their wives:

> "Majority of our women are uneducated, it is a problem for them to understand to make a decision. There is a big difference between educated and uneducated people, as you know. The difference being the uneducated person would not fully understand the concept." (LP11M5) [translated from Urdu]

Decision-making also depended on the severity of the condition; the degree of reliance on family members depended on whether the respondents had small children, a spouse to provide for and, in a small number of cases, respect for elders' wishes. This was viewed as part of South Asian culture.

> "… you know in our culture, not just the family come together but the extended family and all the elders get together. What can you do?" (LP11M3) [translated from Urdu]

Others said that they would consult their children because they are educated in the UK and are fluent in English. A large number of male respondents interviewed also thought that they would consult their wives before deciding to take part in clinical trials. This is a finding that contradicts the stereotype that South Asian women cannot make decisions. Those male respondents with a limited command of the English language were likely to leave decision-making to their UK-educated wives.

> "… it's to do with ability of … ability in the language and understanding. I think it happens other way round as well where husbands are from abroad and the wife makes decisions for them." (LP13M7)

It was also argued that there is a myth amongst the general population that South Asian men make all the decisions, especially with regard to health matters. One Indian respondent stated that his 'wife would shoot him down' if he was to make a decision without her. Others stated that 'Asian women were more powerful' than people think. The present findings suggest that most South Asian people would want to involve their family members when making important decisions such as participation in clinical trials. Although this was given as a 'cultural factor', involving family members in important decisions is not uncommon amongst the general population. In the case of some South Asian people, however, it appears that important decisions are being made

by those family members who are fluent in English, and are likely to be young people or even children.

Gender inequalities and male domination in some South Asian families was also proposed as a 'cultural' barrier to participation in clinical trials.

Traditional families were stereotyped as being male dominated, where the men prevented the women from learning English as a means of 'controlling them'.

> "… you know most of the time daughter-in-law has to stay at home and they are not allowed … They are not allowed to go to the English class … Their mother-in-law doesn't allow them … And also their husband thought if they go out maybe they can't control them." (LB5F5/6)

Another Bangladeshi respondent provided the example of her community centre, which has been struggling to gain the trust of the local Bangladeshi community. This was due to the fear that Bangladeshi men had about their wives 'been taken off them and brain washed against their religion and culture'. The commonly held stereotype that South Asian women are incapable of making decisions on their own could be explained by the 'woman's low status' in traditional families. A number of Indian respondents suggested that Pakistani and Bangladeshi people tend to be more traditional than Indians, and women in such traditional families were viewed as 'chapatti makers'.

> "… if it makes their wife better and she's going to make the chapattis again, then yes they'll sign it [consent forms] … and again that's from education and that's from their family background, and also what sort of job they do in this country." (LI3F6)

Two of the Pakistani female respondents argued that 'it is a man's world' and women are dominated in certain families. Male domination was not, however, exclusive to South Asian people, since some men from other groups also dominate their wives.

> "Being a Pakistani mother, lady or a wife our upbringing is such that making any decision, I become anxious and don't want to be blamed for anything … We can only pray and hope for the change … It is a man's world. You cannot blame just Asian women, in the West some women are pressurised by the men. The English men are educated but ignorant some men beat their wives and hospitalise them. It is a man's world." (LP15F4/5) [translated from Urdu]

Male domination in the South Asian community, according to a number of respondents, might be generational and with time women would be treated as equal to men.

Community gossip was also thought to act as a 'cultural' barrier to South Asian participation in clinical trials. A suggestion made by the respondents from all three groups was that 'South Asian people tend to live in close-knit communities', and because the majority of the Bangladeshi families in Leeds and Bradford live very close to each other, such 'extended families' tend to 'know each other's business'.

> "… You only have to sneeze in one house and it's travelled three streets before you actually wipe your nose clean, and that is the way it is within the community." (LB8F5/6)

It was suggested that those South Asian people who live in close-knit communities always have a 'fear in the back of their minds' that somebody would find out. That somebody could be an interpreter working in the hospital or the setting where the clinical trial was taking place.

> "… if they know the interpreter and they're from a close-knit community and they are likely to know them, they might think, 'Oh God I might be compromised', and, of course, you know, on one point they'd think, 'Everything is confidential', but they might think, 'Oh God she's gonna blab this to everybody and it's our personal business'." (LP13M)

As a result of this, it was suggested that some South Asian people tend to avoid going to doctors and hospitals, and 'suffer in silence' instead. Some families might also have concerns that any gossip would give their families a 'bad name' and this was of particular concern if they had daughters of 'marriageable age'.

> "… if the daughters are of marriageable age they would be concerned there is nothing negative said or anything made up or gossip made up. If somebody is coming for medication somebody may falsify the reasons for that medication. … People use that especially in the villages area in the cities it is a different lifestyle but I would assume I wouldn't put anything past them." (LP6F4) [translated from Urdu]

When probed about why community gossip would have an impact on clinical trial participation, gender came up as particularly important, and female reputation was viewed as more easily damaged and harder to repair in South Asian communities. Families, therefore, placed more

restrictions on young women, as illustrated by a quotation from a male Bangladeshi respondent:

> "I mean prestige is like, I mean if my girl and my wife doing something openly or doing some research on anything, right, and sure some community people they gossip behind. They say, 'Oh, his daughter doing this', or 'his wife doing this', and that is it … In terms of marriage as well because if they don't live in their own boundary right, they might find it's hard to find a husband or find, hard to find a girl for him or her. So these sort of concern in the community, so it might effect the trial, you see. So I'm not 100% sure, but it could effect decision." (LB7M3)

Superstition and ignorance were also believed to prevent some South Asian people from participating in clinical trials. It was argued that owing to 'ignorance' and lack of education, some South Asian people do not believe in taking drugs of any kind, because they would be worried about tempting fate. Such a fatalistic attitude, according to two Bangladeshi respondents, meant that some South Asian people would rather go to religious priests and herbalists than medical doctors. This was due to their belief that using 'pharmaceutical drugs was like playing God' and that 'herbs were natural and Islamic'.

> "… they'd rather go to a priest who, you know, they have more faith in hakims [herbalist] and things like that. D'you know, things like fate you know, they'll say, 'It's written to happen'." (LB1M9)

One Indian respondent argued that fatalism was often 'dubbed a cultural factor', and that there was a danger that this could develop into a stereotype and be used against South Asian people. She argued that some non-Asian doctors might have a misunderstanding that there is something innate in the South Asian culture which prevents them from participating in medical research or refusing treatment due to 'notions of fatalism and notions of destiny or fate'. Notions of fatalism also exist amongst the general population, and should not be considered exclusive to South Asian people.

Complementary and alternative medicine (CAM) was suggested as another possible factor influencing some South Asian people's decision whether or not to participate in a clinical trial. Use of CAM, according to an Indian respondent, was traditional amongst 'villagers back home', and more likely to be common amongst older people and more traditional families. Herbalism and homeopathy were viewed as 'natural' and free from side-effects.

With regard to religion as a barrier to clinical trial participation, respondents from all different religious backgrounds (Islam, Hinduism and Sikhism) agreed that there were no religious objections to taking part in clinical trials. Some Muslim respondents argued that it was 'Islamic to help others' and that taking part in clinical trials would be advocated by Islam. Others stated that they did not use religion as a 'reference point', and believed that if anything helped people, 'it must be the right thing to do'.

> "No it isn't no, no. But the thing is, but you know Islam actually does encourage you to educate yourselves and to, you can go to the other side of the world for your, for your knowledge. So it's, it wouldn't hinder you at all." (LP2F9)

There were however, concerns amongst some of the older South Asian Muslims about 'gora [white] medicine'. This was because such medicine might contain 'haram' [forbidden] products such as alcohol, gelatine and other pork derivatives.

Often religion was confused with culture; for example, a number of Bangladeshi respondents argued that it was 'un-Islamic' for men to allow their wives or female members of their family to take part in clinical trials owing to issues of Purdah and the gender of the doctor.

> "… men won't agree to allow their wives to take part in the research, you see. Is part of Purdah like, and also our custom and culture." (LB7M3)

Examples were also provided which illustrated that, owing to the gender of the doctors, some Muslim women were unable to seek medical care, sometimes for serious medical conditions.

> "… those who do the breast screening if you go there the X-ray is taken by a woman but afterwards if they suspect something then you will see a doctor who is a man then a woman cannot be willing to come forward." (LP20M12) [translated from Mirpuri]

One female Bangladeshi respondent felt very strongly about how 'cultural reasons' often get confused with religion, and how Muslim women tend to get stereotyped about wearing Purdah and being subservient.

> "… people saying it's all to do with Islam, all to do with your Muslim faith, people out there to understand it's not … it's a more cultural thing … it's all to do with culture and not religion." (LB8F7)

To summarise, stereotyping attitudes are not exclusive to those from the general population and stereotypes only become an issue if used

against South Asian people by those in power. The findings indicate that South Asian people, owing to socialising to Western ideas and values, also hold cultural myths and stereotypes. Stereotyping due to class, status and educational snobbery was particularly evident in the accounts of Indian respondents and a small number of Pakistani and Bangladeshi respondents from more middle-class professional backgrounds. Such stereotypes fail to acknowledge diversity in South Asian people, and also fall short of recognising that the South Asian population in Leeds and Bradford may be very different to that in other parts of the UK.[12,13]

The findings also indicate that religion is very difficult to distinguish from culture and is frequently used as a surrogate for cultural practices such as gender segregation. Although there are no major religious objections to taking part in clinical trials, religion was often implicated as having an effect on a Muslim person's decision about participation, where modesty, for example, was associated with religion.

Motivations and deterrents to clinical trial participation

The following section presents respondents' views on how they would react if they were asked to take part in a hypothetical clinical trial which was testing out a new drug or intervention.

Sense of responsibility

The majority of respondents stated that they would consider taking part in a clinical trial to 'help humanity' and for the 'betterment of mankind'. By far the most common reason for taking part in a clinical trial was due to altruistic reasons and a sense of responsibility to help others.

> "… Everyone has a responsibility to participate in such matters, our community is not aware, we should bring them in level with the rest, inform them." (LP19M5) [translated from Mirpuri]

Others acknowledged that taking part might not be directly beneficial to them, but might help their children and the future generation.

> "We should not think that something does not benefit us now and why should we participate, humans should not think like this if it has not benefited my generation but the third generation it may benefit them, then I should take a part." (LP18M11) [translated from Mirpuri]

There was, however, a tension between responsibility to society and personal responsibility to family members. Most of the younger respondents, across all three groups, thought that family responsibilities were more important than responsibilities to society. Respondents with young children, in particular, viewed looking after their families as taking priority over participation in clinical trials, which was perceived as potentially risky. The following quotation from the wife of an Indian taxi driver illustrates this concern:

> "He has a family to look after at the end of the day. He has to think about us. Even me if I was to do [clinical trial] I have to think about the children." (LI8M2) [translated from Punjabi]

Busy lifestyles and lack of time due to work commitments and family obligations were of particular concern amongst those respondents who held manual jobs.

> "After work you get tired you go home. At the weekends you spend time with your family or friends. In the evening around 7 the clinics are closed … I feel that if I had the time I would participate in the health issues, as you know it is very important. I feel it is important for everyone to be aware of issues around health. … If you are not aware how can you help anyone else?" (LP14M3)[translated from Urdu]

Lack of childcare facilities and issues around travel meant that one Pakistani female respondent was unable to take part in a clinical trial in the past:

> "But I would have participated but it's just at that time my situation, cos we had a business and the children were very young. It was very hard to get child care and so I wouldn't have minded but it was difficult to travel and parking." (LP2F2)

The respondents often suggested that South Asian people had more commitments than others, owing to their customs and culture. Such commitments included looking after their children, visiting family members in the UK and abroad, family weddings and the extra work associated with living in larger families. One Indian male contradicted this viewpoint by arguing that not all South Asian families are large. Having a big family depends on a person's education and upbringing. Larger families and busy lifestyles were perceived as being directly associated with inner-city living and lack of money. The findings suggest that there is a will to take part in clinical trials amongst those South Asian who are socio-economically disadvantaged; however, owing to lack of child care support and loss of income, participation in clinical trials might become difficult for this group of people.

Personal/family involvement

Other motivations for taking part in a hypothetical clinical trial included either having an illness themselves or family members or close friends suffering from an illness. Responsibility to their loved ones was a strong motivating factor for clinical trial participation.

> "… my son was born with a hole in his heart and we were constantly in and out for the first year and then the hospital asked me if I could put my child forward for the student's exams and assessments. And I was happy to help because I knew that we needed to train these doctors to get them out …" (LP10F12)

A clinical trial which might improve scientific knowledge about an illness from which the respondents 'suffered' was another motivating factor. One Indian respondent, who had asthma, said that he would have no qualms about taking part in a clinical trial that was testing new drugs for asthma. He would, however, think twice about taking part in a trial for an illness that he did not have, unless his family members or friends suffered from it. Others suggested that South Asian people might be more motivated to take part in clinical trials for those illnesses which were more common in their community. These included trials on heart disease, thalassaemia and diabetes.

Summing up, the findings indicate that a strong sense of responsibility to society, family and friends was a strong motivation to take part in clinical trials. Personal responsibilities towards looking after their families can sometimes challenge responsibility to society. This is particularly true of those South Asian people who are socio-economically disadvantaged.

Obligation to doctors

There was a general agreement across all three groups that South Asian people have a tendency to hold doctors in high esteem. This was because in the sub-continent, doctors have a high social status. Such a mentality, according to an Indian respondent, is brought over to the UK by the older generation and also transferred to some of the younger people.

> "I have been taught this is a noble profession. And the ethics of the profession to conserve, as you know, conserve life, and I would never even dream of suspecting a doctor, I wouldn't." (LP16M8)

There is a danger that having such a high opinion of doctors might make some South Asian people feel obliged to take part in clinical trials, and this was viewed as 'unethical' by a number of respondents.

> "… well I think especially the ones that are uneducated, they're easily persuaded, easily persuaded because I mean, okay, I regard my GP pretty highly, okay, but I also realise that GP just offer an opinion. Whereas if I was uneducated, GP's God … the Asian community always looks at, well doctors being the top profession, the top everything. Whatever they said they will believe they will do it, you know. I mean I would possibly be inclined, but they would definitely do it, I reckon." (LI4M6)

All South Asian people, however, do not share such a strong 'loyalty' to doctors. The more educated respondents argued that they would not be influenced by 'doctor status', and that the decision to participate in a trial would be their personal choice. A combination of good experience, wanting to add to 'scientific knowledge' and to please their doctors meant that some South Asian people would feel obliged to take part in clinical trials.

> "I'd be obliging, I'd be obliging. I mean like the times I've been up at hospital for outpatients appointments and things like that … ." (LB8F1)

With regard to placing too much trust in doctors, there was a sense of unease amongst the younger respondents who were concerned about their older relatives getting exploited. Older South Asian people were perceived as being vulnerable, owing not only to the language barrier but also to their 'unconditional' trust in doctors. One Pakistani respondent suggested that because some South Asian people 'place so much trust in the medical profession', their decision to participate in a clinical trial was likely to be biased. Some might even sign the consent form without understanding or reading it.

> "Sometimes they end up signing through bad influence and they don't know what they've signed." (LI18M 2) (translated from Gujarati)

With regard to whether the ethnic background of the doctor would have an influence on a South Asian person's likelihood of taking part in a clinical trial, the majority of the respondents said it would not. The doctor's ethnicity only made a difference to those respondents who were not fluent in English. This was because Asian doctors were perceived as being able to speak the same language as the respondents, and were viewed as being familiar with South Asian religions and customs.

> "Doctor is a doctor. There are issues of zaban [language] that you need to know what is happening. There is nothing else a doctor is a doctor. Black makes no difference." (LP20M4) [translated from Mirpuri]

To summarise, although enthusiasm to take part in clinical trials might not always be matched by action, the majority of the respondents believed that they would take part in clinical trials, for altruistic reasons. These findings mirror the literature that suggests that altruism is a major motivating factor to clinical trial participation amongst the general public. Some respondents were concerned about taking part in clinical trials. This was because they thought that taking part might mean that their health would be compromised in a way that would prevent them from looking after their families. Such concerns were more vocalised by those South Asian people who had young families to support, and potential drug side-effects were viewed as preventing them from carrying out their family obligations. *Table 19* presents a summary of motivations for participation amongst South Asian people.

Drug concerns

Although the respondents were made aware that there are many different types of clinical trials and not all involved testing out new drugs, concerns about side-effects came up as the most important deterrent to clinical trial participation. Most respondents said that they had no objections in principle to taking part in a clinical trial; others, however, wanted 'guarantees' that there would be no long-term drug side-effects.

> "… But guarantee that there's going to be no harm to yourselves or whatever, you know, there's not going to be any reaction … That's why you are researching, so you are using them as a form of guinea pig to be honest. You know, so there will be reaction and I wouldn't be impressed with that." (LP17M5)

A small number believed that it was not 'natural' to take pharmaceutical drugs and that there was a chance that taking any drugs would have side-effects. It was considered 'unnatural' to 'mess with your body', and one respondent stated that the body was like a 'machine which could break down':

> "… the body is like a machine if it breaks down it is not a good thing. Therefore, to participate in any research you have to think it through deeply. It is not easy to decide. … If you experiment about an unknown subject you do not know how it will turn out." (LP11M2) [translated from Urdu]

There was definite unease about the long-term, harmful side-effects of new drugs amongst some respondents. Concerns were also raised about getting addicted to the trialled drug.

> "… sometimes if you take too many drugs after a few months you are habituated to it, and you want the higher power one so that'd be the bad things." (LB4F 2/3)

Some of the older respondents were worried about drug–drug interactions because they were already on a cocktail of multiple drugs for different illnesses.

> "Personally only because of my health, because I'm on other medication and I think that might affect it … it might react adversely to the drugs I'm taking so many that would be another reason why I personally wouldn't do it, but I can't see any other ethical or religious or any reasons, in my case, where I wouldn't do it." (LI3F1)

The findings presented here are in agreement with those in the literature, showing that drug side-effects are also a major barrier to clinical trial participation amongst the general population.[87]

Language

Language was frequently presented as a major barrier to clinical trial participation, especially in older South Asian people and those from socio-economically disadvantaged backgrounds. Those respondents who believed that they were too old to learn English argued that they had their children and grandchildren to interpret for them. However, a number mentioned that owing to school and normal working hours, they were unable to see doctors because their children were unavailable to interpret.

> "Young people are not always available to take with you. Who's going to go with you every day? The young people are at school and they are not available." (LB11M4) [translated from Sylehti]

In addition, it was argued that, increasingly, children are unable to speak their parent's

TABLE 19 *Summary of motivations for clinical trial participation*

- To help society
- If related to own health
- If related to family and friends
- Out of obligation to doctor (especially in older South Asian respondents)
- To increase scientific knowledge

language. This was given as a reason why so many South Asian people who lived in socially deprived parts of Leeds and Bradford preferred to see South Asian doctors. The diversity in South Asian languages, however, means that registering with a South Asian GP does not guarantee the 'right language', as one Bangladeshi respondent's quotation illustrates:

> "… they have people speaking Urdu and they assume that all Bangladeshis can speak and understand Urdu." (LB17F3/4) [translated from Sylehti]

One Indian respondent argued that language might not be the main issue, and that it might be the nature of the 'technical terms', which would be equally confusing for other people also:

> "… it's the level at which you give the information … whether it's appropriate to the people you're dealing with, which is probably exactly the same in the white community if you're dealing with people with different education levels." (LP1F6)

During obtaining consent, confusion can arise owing to the use of often perplexing medical terminologies. Research shows that the general public also finds clinical trial concepts and medical terminologies confusing.[43,79] The language barrier only complicates an already difficult communication process involved in obtaining consent from South Asian trial participants. Signing of the consent form was also believed to depend on the person's level of education.

Some respondents were concerned that their parents and relatives, who are not fluent in English, might be put at risk if the consent forms and the information sheets on clinical trials were not translated. According to one Pakistani respondent, lack of fluency in English meant that some South Asian people are likely to say no to participation in clinical trials since saying yes would imply further communication:

> "… perhaps this is a good strategy, saying you can't speak English when you can, to get out of things … 'Okay me no English'." [Laughs] (LP13M8)

Lack of fluency in English and not being able to understand clinical trial methodology can lead to insecurities and doubts. This is of particular concern during obtaining consent, since under stressful conditions, consent might not be entirely voluntary. The area of concern is the fact that some South Asian people might be consenting without completely understanding the full implications of the medical intervention.

> "My feelings were that they were investigating the cause of the pain so I accepted this and agreed and signed the form." (LP9M2)[translated from Urdu]

The inability of the NHS to cater for the linguistic needs of South Asian people can lead not only to distress, but also, as illustrated by the following quotation, to expensive legal action:

> "… Cos a lady, Asian lady … she'd made a complaint about that, and she said that she wasn't told that, when she was, in the initial consultation, but they realised that she couldn't speak English." (LP7F5)

Although a number of respondents had used the interpreter service in the NHS, the majority of those stated that interpreters were not readily available and were difficult to organise in emergencies and acute medical consultations. Others felt 'guilty' about using NHS resources on interpreters and suggested involving community advocates as 'clinical trial interpreters'. Community advocates were viewed as being familiar with the linguistic requirements of the community. However, another respondent, who was a community worker, argued that it should not be the community's responsibility to cater for such needs, and that the NHS should provide resources for interpreting and increasing South Asian awareness of clinical trials.

> "… I mean hospitals, NHS they used to ride on us before. Not any more, because we're not going to provide interpreters because we don't have the resources." (LP17M11)

Mistrust

Another potential barrier to South Asian participation in clinical trials was the issue of mistrust, where some examples of 'mistreatment' of South Asian people by the NHS staff were provided. The findings suggest that mistrust of research and clinical trials might not be a major concern amongst South Asian lay people. This is contrary to the findings in the literature, which suggest mistrust as the most important barrier to ethnic minority participation in clinical trials.[113] Mistrust was an issue amongst a small number of respondents who believed that 'research was a bit of a dodgy process back home', or those who had heard stories of exploitation of the poor and the vulnerable in the Indian sub-continent. Some South Asian people, therefore, might be suspicious of medical research, due to unethical conduct of clinical trials in their country of origin.

> "In Pakistan what is research? In Pakistan you don't have research … the big hospital doctors are only

> involved in the hospitals if they want to do any research they will carry it out without obtaining consent." (LP20M13) [translated from Mirpuri]

A number of respondents stated that they would only consider taking part in government-funded, NHS-based clinical trials.

> "… I think if it was something that was funded through the NHS I might be happier, if it was something privately funded by a pharmaceutical company or, I'm not, I know this sounds awful, but I'm not very trustful of private medicine." (LP1F2)

One Indian female respondent suggested that in the case of pharmaceutical run trials, it was very important to have a third person who was not directly involved with the pharmaceutical company; such a neutral person could be the GP in charge of the patient:

> "… there should be someone, a middle person. I mean GP can be one where, I mean neutral person because he, he's not gaining anything out of this trial." (LI1F6)

Two respondents thought that clinical trials were morally wrong because they did not agree with animal experimentation.

> "The way the animals are used and the way it is done is cruelty. I don't think it is right because it has also a right to live in the world." (LB12M4) [translated from Sylehti]

Although most of the respondents had good previous experiences of the NHS, a small number did not trust the NHS owing to bad experiences in the past. One Indian respondent felt that hospital doctors looked down on South Asian people:

> "… I've noticed when you go to the hospital, doctors sometimes treat you like an idiot when they see the colour of the skin and maybe they don't want to waste their time and sometimes you feel as if you're wasting their time, so they give you the impression that they're doing you a favour by even, you know, agreeing to consult with you." (LI3F7)

Examples were provided where nurses in hospital wards (owing to their busy workload) do not have time for non-English speaking patients.

> "I think sometimes doctors are not very open as well with patients who can't speak English. Also in, especially in the wards, nurses not … able to communicate with them, and they haven't got time. Mainly in the ward, hospitals, there's no time for nurses to do anything with non-language speaker." (LI12F8)

Such bad experiences with the NHS might put some South Asian people off taking part in clinical trials. Previous bad experiences of the NHS, according to the present findings, might also affect South Asian people's attitudes towards health professionals, and consequently would dictate their likelihood of participating in clinical trials. Trust is also crucial during obtaining informed consent, and studies show that signing of the consent form is dependent on the patient's relationship with their doctors.[97] Although the respondents predominantly trusted the consent forms and the medical profession, there were three who did not. These three respondents were educated in the UK and spoke fluent English, thus highlighting that mistrust of medical research is not exclusive to those from a socially disadvantaged background, as suggested by some of the respondents.

> "I sometimes think that, that you know people have other motives rather than the hundred per cent sort of benefit to patients, and I think whenever there's money involved, and I know doctors take the Hippocratic oath, but I don't know … I'm just a little bit …" (LP1F3)

Some South Asian people might be mistrustful of signing legally binding documents in general, and this might have an impact on obtaining consent for clinical trials.

> "They feel it's gonna come back and be flung in their face a couple of years down the line in court to do with like something or other, you know, whatever it's like. I don't know, benefits or something or tax or god knows what like, you know. But that's a class issue, isn't it? It's a class thing, you know." (LI9M19)

It was also suggested that mistrust of signing legal documents might be due to lack of understanding and prior bad experiences with 'bogus salesmen'.

> "… I mean I'm scared of signing forms and also binding documents, you see, because they might know, could be small print anywhere and somewhere, you see. So in that way our community people are very aware of it, right. So they're most concerned to sign legal document and forms." (LB7M7)

In summary, the findings suggest that lack of trust is generally about how people view their position in society and how society treats them. These findings indicate that social class might be more important than ethnicity and that South Asian people from a lower socio-economic background (similar to other working class families) are likely to be mistrustful of authority in any form and this might affect their decision to sign consent forms.

TABLE 20 *Summary of deterrents to clinical trial participation*

- Concerns about drug side-effects
- Busy lifestyles (family and work obligations)
- Language barrier
- Previous bad experiences in the NHS
- Mistrust of research and pharmaceutical sponsored trials
- Feelings of not belonging to British society

In the case of South Asian people, racism or the feeling that 'they're not welcome here' or 'do not belong' further compounds such experiences. These feelings can inevitably lead to the mentality 'why should we lift a finger to make progress for which we may not benefit, and other people might benefit'.

A summary of deterrents to clinical trial participation is given in *Table 20*.

Financial incentives

There was a degree of confusion amongst some respondents about payments for participation in clinical trials. This confusion appeared to have arisen from advertisements from companies such as Covance, who pay for participation in early-phase clinical trials. This gave rise to the perception that poorer South Asian people might want to take part in clinical trials because of money and the well-off ones would not.

> "Sometimes I have heard that they use the medicines on poor people and offer them some money. If there were complications they would not be able to do anything. I don't think somebody who is wealthy would bother to participate." (LI15F6) [translated from Hindi]

One respondent believed that financial incentives might legitimise research:

> "I think if money would … I think they would. You know. But they think 'I'm doing something free that could risk my life, so why should I do it?'." (LP8F4)

Only one respondent said that he would take part in the trial for financial reasons, and that would only be if he 'were a poor destitute student'. Overall, the general feeling about getting a payment for taking part in clinical trials was that, owing to South Asian people's busy lifestyles, financial incentives were not enough of a motivating factor.

The respondents further identified a number of strategies that might help improve South Asian recruitment to clinical trials.

TABLE 21 *Summary of strategies for improving South Asian recruitment to clinical trials*

- Targeting community centres and religious institutions such as mosques and Hindu and Sikh temples
- Targeting people from lower socio-economic backgrounds including outreach work with women and older people and 'door-to-door calling' to target more 'insular' groups
- A combination of translated information sheets and verbal information would take into consideration non-English speakers and those who are illiterate. Educational/promotional videos, which the respondents could take home and watch, would be the best solution for those South Asian people who were either illiterate or lacked fluency in English
- Mail shots that could be sent out with utility bills such as the council tax, gas and electricity bills, putting posters up in community and job centres, local libraries, Mailas (festivals) and GPs' surgeries
- Other information media included the radio and television, which could be used to invite doctors to talk about the benefits of participating in clinical trials
- In order to 'appeal' to the more altruistic side of South Asian people, efforts could also be aimed at making them aware of how clinical trial participation can improve medical knowledge about those diseases which are prevalent in the South Asian community
- Ethnic minority GPs, who are likely to speak South Asian languages, could recruit patients to clinical trials
- Strategies to improve South Asian people's awareness of clinical trials need to be ongoing, and there is a need to monitor progress and to evaluate those strategies that are most effective

Strategies for improving South Asian recruitment to clinical trials

A number of different strategies to improve awareness and participation rates were suggested. These are presented in *Table 21*. Targeting community centres was the most frequently given strategy, followed by religious institutions such as mosques and Hindu and Sikh temples. It was suggested that some South Asian people might not be religious, and some of the more 'traditional' families might not visit community centres. Different strategies were therefore suggested for 'traditional' families including outreach work with women and older people and 'door to door calling' to target more 'insular' groups.

> "… it's like if I go to some of the houses round here, because they know me, you know, they're likely to, you know, welcome me. And if you're somebody from, you know, Leeds or somewhere else, then they don't know them basically, they don't recognise the face, then they think, you know, you'll have a problem." (LB1M4)

With regard to information provision about clinical trials, it was suggested that this should be provided in a form that would take into consideration non-English speakers and those who are illiterate. A combination of translated information sheets and verbal information was proposed as the ideal solution. Information leaflets could be translated into the more common South Asian languages and leaflets could be sent out via postal mail. One respondent suggested mail shots that could be sent out with utility bills such as council tax, gas and electricity bills. Even if the information sheets could not be translated into the different South Asian languages owing to lack of resources, it was suggested that younger family members who were likely to be educated and fluent in English could read and translate for their parents. Other suggestions included putting posters up in community and job centres, local libraries, Mailas (festivals) and GPs' surgeries.

One Indian respondent suggested that many South Asian people get their knowledge on 'medical matters' through TV soaps. It was also suggested that doctors could be invited to talk about clinical trials on Asian radio stations and TV channels and that external speakers could be invited to give talks at community centres, including those people who have had first-hand experiences of taking part in clinical trials. Many community centres hold regular health education classes where health visitors, dieticians and dentists are invited to give talks. Clinical trials could be promoted in a similar way. Educational/promotional videos, which the respondents could take home and watch, were also mentioned.

> "My parents are a prime example. They can't really read Bangla … A video might be a good idea …" (LB4F 7/8)

In order to 'appeal' to the more altruistic side of South Asian people, efforts could also be aimed at making them aware of how clinical trial participation can improve medical knowledge about those diseases which are prevalent in the South Asian community.

> "… most Asians or Indians are taking medicines of some sort, diabetes, heart problems, they're two big things amongst Indians, I know. And you know, if you tell them, 'Look, you know the tablet you're taking, well, that was actually trialled on, let's say on someone, and the only reason you're taking it now is because we've proved it on the trials that it works.' I think that would open their eyes up and therefore I wouldn't find any of them not willing to take part in a trial." (LI2M8)

Religious institutions could also be targeted. It was suggested that because people of varying ages and socio-economic backgrounds visit the mosque on Fridays, there might be an opportunity there to hand out leaflets to improve awareness and importance of medical research.

> "We have a good community spirit at the Mandir and sometimes they organise specialists to come in so we can talk about our health problems. If they talked about clinical trials and medical research I think many people would take an interest and be willing to participate." (LI20M3) [translated from Gujarati]

Doctors can also play an important role in the recruitment of South Asian people to clinical trials. One Indian respondent suggested that because 'hospital doctors don't have a lot of time', South Asian patients, especially those with a linguistic barrier, tend to feel 'brushed off'. GPs, on the other hand, were perceived as having a better relationship with their South Asian patients.

> "And I don't think that any media coverage or anything like that is going to affect it directly. I think it's got to be a one to one with somebody they trust like, like a GP to say, well you should do that and you should have been involved in that, all right." (LP3M2/3)

Other strategies to improve South Asian recruitment to clinical trials included having more ethnic minority doctors who were capable of understanding South Asian culture and religions and who were likely to speak the South Asian languages. Finally, as one Indian respondent pointed out, strategies to improve South Asian people's awareness of clinical trials need to be ongoing in order to keep their interest going. There is a need to monitor progress and to evaluate those strategies that are most effective. With time, enough South Asian people would become aware of the importance of taking part in clinical trials.

Conclusion

The findings presented in this chapter suggest a lack of antipathy among South Asian lay people towards clinical trial participation. However, there is a general lack of awareness of clinical trials amongst this group of people. The findings also suggest that South Asian people have different levels of awareness and that attitudes vary between and within South Asian people, as in the general population. Indian respondents were most likely to be aware (80%) and less than half of the Pakistani

and Bangladeshi respondents (30 and 40%, respectively) were aware of clinical trials. Degree of awareness also appeared to be related to levels of education and age. The findings also suggest that older respondents, and women in particular, across all three groups, were least likely to be knowledgeable about clinical trials. A lack of decision-making is related to a patient's educational background, and Pakistani and Bangladeshi women lacked the confidence to make decisions on their own as opposed to those who are younger, of Indian origin and fluent in English. Poor awareness of clinical trials might also be because they are a Western concept and have not yet become part of the South Asian cultural repertoire, and familiarity only comes with engaging with it. Lack of education, although frequently given as a barrier to South Asian participation in clinical trials, is a myth that is often used as a scapegoat in such debates.

The presence of diverse attitudes in the sample suggests that the relevance of ethnicity should not be exaggerated, and although significant in some aspects of clinical trial participation, the effect of ethnicity and culture needs to be kept in perspective. Ethnicity is important in relation to discussing cultural influences on decision-making about clinical trial participation (e.g. the importance of family in decision-making and gender segregation) but is not the sole explanation for South Asian under-representation.

No major religious objections to participation in clinical trials, in principle, were identified apart from objections to using non-Halal medication, alcohol and any meat-derived products (in the case of vegetarian South Asian people). The findings also suggest that culture, religion and gender segregation cannot be separated and that lack of education, as an explanation for ethnic minority under-representation in clinical trials, is a myth. These findings therefore deconstruct essentialised notions of ethnicity by illustrating that South Asian participation in clinical trials is equally dependent on age, gender, language and social class. With the exception of language, it can be argued that such factors are equally applicable to the general population.

The significance of ethnicity is further brought into perspective by findings that suggest that South Asian lay people's views about participation in clinical trials are mirrored by the general population. When asked how the respondents would react to taking part in a hypothetical clinical trial, responsibilities to society, family and doctors were given as motivating factors. These motivations are similar to those identified in the literature about the majority white population. Enthusiasm might not always be matched by action and when faced with a decision to participate in a trial a host of other factors come into play that affect a person's decision. For example, tensions can develop between

TABLE 22 *Summary of Chapter 5*

- Awareness of clinical trials varied between each group. Indian respondents were most likely to be aware and less than half of the Pakistani and Bangladeshi respondents were aware of clinical trials
- There was no evidence of antipathy to the concept of clinical trials and, overall, the younger respondents were more knowledgeable than the older ones
- Lack of being approached was a common response across the three groups
- Lay-reported factors affecting South Asian participation in clinical trials include age, language, social class, feeling of not belonging/mistrust, culture (importance of families, gender issues, community gossip and health beliefs) and religion (modesty, meat-derived and non-Halal medicine)
- There are more similarities than differences in attitudes towards clinical trial participation between the South Asian and the general population. The presence of diverse attitudes suggests that the relevance of ethnicity should not be exaggerated, and although significant in some aspects of clinical trial participation, the effect of ethnicity and culture needs to be kept in perspective
- Ethnicity is important in relation to discussing cultural influences on decision-making about clinical trial participation (e.g. the importance of family in decision-making, modesty in women, the month of Ramadan, dietary restrictions on alcohol and pork-derived products) but is not the sole explanation for South Asian under-representation in clinical trials
- Important decisions, such as participation in clinical trials, are likely to be made by those family members who are fluent in English and younger
- Social class appears to be more important than ethnicity, and older South Asian people and those from working-class backgrounds appear to be more mistrustful owing to experiencing racism or the feeling that 'they're not welcome here' or 'do not belong'
- Lack of education was frequently given as a barrier to South Asian participation in clinical trials; however, education is a myth that is often used as a scapegoat in such debates. Clinical trials are a Western concept and familiarity only comes with engaging with it

responsibility to society and responsibility to one's own family (most pronounced in those respondents who were from working-class backgrounds). Barriers to clinical trial participation identified by the respondents included side-effects of drugs, family and work commitments, language and mistrust. A small number of respondents recalled situations where South Asian people had had bad experiences in the NHS. Negative health experiences of ethnic minority people may play an important role in their attitudes towards health professionals and consequently may dictate their likelihood of participating in clinical trials.

Some health professionals were found to hold stereotypes about South Asian people, which can have a negative impact on their recruitment to clinical trials. One of the interesting findings of this study is that some respondents also held stereotypes about South Asian people. Such stereotyping might be due to socialising to Western ideas and values. Stereotyping due to class, status and education was particularly evident in the accounts of respondents from middle-class professional backgrounds. Participation in clinical trials also depends on how South Asian people view their position in society and how society treats them. Social class emerges above ethnicity, age and gender and poorer South Asian people might have similar experiences, views and attitudes to other working class families. In the case of South Asian people, however, experiences of racism or the feeling that 'they're not welcome here' or 'do not belong' is an added disadvantage, likely to act as a barrier to their participation.

A summary of the discussion in this chapter is given in *Table 22*.

Chapter 6

South Asian patients' experiences of clinical trial participation

Introduction

The views and experiences of South Asian patients about clinical trial participation, their reasons for involvement, their understanding of informed consent and potential barriers to their participation are explored in this chapter. In order to review the processes and potential barriers to South Asian participation throughout the whole life cycle of a clinical trial, health professionals' views and lay perspectives will be drawn upon to ground further the findings presented here. The analysis is based on data collected from 15 South Asian trial participants. Data were collected using semi-structured in-depth interviews, using a checklist of topics to guide the discussion. The respondents were anonymised and their views presented in order of interview, gender and transcript page number.

Results

It was originally anticipated that it would be possible to interview 40 trial participants from a local *H. pylori* trial (selected from the trials database of CTRU). Even though 66 *H. pylori* trial participants were identified, most could not recall the study which took place over 3 years earlier, and others were either unwilling to be interviewed, had moved away or did not respond. In addition to respondents identified from the *H. pylori* trial, further recruitment was achieved by directly contacting the cancer, gastroenterology, gynaecology/midwifery, cardiovascular and diabetes centres and organ transplant units in both Leeds and Bradford. Attempts were also made to recruit trial participants by talking about clinical trial participation on Radio Sunrise (the local Asian radio station) on two separate occasions. Although the listeners showed much interest, none of the people who phoned in had ever taken part in clinical trials. The reality is that there are very few South Asian people who have taken part in clinical trials in West Yorkshire, and clearly this is a finding for this study.

A total of 15 patients were interviewed from Leeds and Bradford – eight women and seven men. The types of clinical trials the respondents had taken part in included *H. pylori* (7 respondents); cardiovascular (1); cancer (2); diet (1); gynaecological/obstetrics (3); and HRT (1). Only four of the respondents were aware of clinical trials prior to being approached to take part in them. Eleven of the respondents were aged 40–60 years and four were aged 20–30 years. The respondents were predominantly from social classes III and IV (partly skilled), except for one primary school teacher. All respondents were fluent in English, with the exception of two who preferred to be interviewed in Urdu and Punjabi. Contrary to the beliefs held by health professionals and South Asian lay people, the sample clearly indicates that older South Asian people, and those from lower socio-economic backgrounds, are perfectly capable of taking part in clinical trials. The sample also shows that South Asian women do participate in HRT and gynaecological trials; however, this assumption needs to be supported by statistically larger samples. South Asian trial participants' experiences and reasons for participation are examined next in relation to various patient characteristics including gender, social class and age. No clear patterns were apparent, other than a fluency in English. Although the sample is small, some interesting findings have been identified.

Reasons for participation

Altruism was a prominent feature in the majority of the interviews. The respondents believed that taking part in the trial would benefit society at large and they considered it their responsibility to help others.

> "Because we're here to help each other, that's the main thing." (TM3-6)

Some of the respondents (in particular the older ones) believed that it was important to take part in those trials that would help people of their age, and that they would consider taking part in future trials including preventative trials of osteoporosis, Alzheimer's disease, stroke and arthritis. Others thought that taking part in diabetes or

cardiovascular trials would be directly beneficial to the South Asian community, since they shared a greater disease burden.

> "… in this country, our people suffer more by these diseases, good for them to take part … More of them have heart problems, some of them have strokes, asthma, most [South Asian people] are ill." (TM15-6)

An older female took part in an HRT trial because the trial nurse told her that South Asian women were under-represented in HRT trials. Having this knowledge motivated her to contribute to 'scientific knowledge' and to 'help her community'.

> "Well if it's solved my problem, if it's cured the problem, then I can tell people, 'Oh, yes, why don't you go for this test? This might done good for you'. You know, so I can tell the people." (TM11-4)

Having prior knowledge about the benefits of taking part in trials motivated one female respondent who read the study information and the importance of taking part in a gynaecological trial on a poster displayed in her local maternity ward. Although she did not feel comfortable with the frequent gynaecological examinations, nevertheless, her main motivation was to 'help research'. Despite having a busy lifestyle, 'being able to help society' was a strong motivating factor for an older female respondent, who took part in the *H. pylori* trial:

> "I have a lot of responsibilities looking after my five children, looking after my husband, looking after the home, keeping up appearances as well. Somebody like me who can't even write my name. I have managed to stand on my feet." (TF10-5) [Translated from Punjabi]

The findings clearly highlight the importance of educating South Asian lay people about the benefits of trial participation, although any trial information presented in the English language may miss out those who are unable to read or understand English. Similar to the general population, respondents' accounts also identify altruism as the main motive for trial participation.[43,77] Although it would be naive to assume from the present findings that altruism is the primary motivation in South Asian people's decision to take part in clinical trials, the desire to help others appears to be a strong motivating factor. It might be the case that altruism was secondary to the hope that the trial might benefit the patient.

> "Yes, well they said it works much better, so that's why I tried it, as well as I thought it will be beneficial to other patients at the same time." (TM2-3)

Apart from altruism, another reason for participation was the hope of finding an answer to chronic illnesses. A female respondent believed that taking part in the trial 'might make somebody listen' and help her make sense of her illness. Similarly, a male respondent took part in the *H. pylori* trial to help 'cure' his indigestion:

> "Well they asked me, and I said, 'Why not? Go for it', because the main reason was I used to have indigestions, and I wanted to find out why do I have indigestions … so I thought if it'll cure, if they can find out why not have a go and have a trial, that was the main reason." (TM3-1)

Two of the younger females who took part in gynaecological/obstetrics trials did so to help their unborn babies, despite finding the procedures 'painful and embarrassing'.

> "It took a lot of courage on my part to go ahead with the trial, the swabs were awful and painful and embarrassing, I did it for my unborn baby, if anything had happened to her I would have never forgiven myself." (TF13-1)

Other reasons for participating in clinical trials included curiosity, to help the doctor and absence of an alternative treatment.

A majority of the trial participants had good or partial recall of the major features of the trial and were generally pleased with all aspects of participation. They felt that they were provided with sufficient time to decide whether to take part or not. Some respondents chose to discuss the details of the trial with their spouses and friends, and were provided with written information (in English) to take home. Trial staff were perceived as 'knowledgeable', which gave the respondents 'the confidence' to participate in the trial. The respondents were particularly impressed with the 'friendliness' of the trial staff, who were generally viewed as being helpful, who made the respondents 'feel at ease' and 'talked to them nicely'. The respondents' views about trial staff are encapsulated in the following quotation.

> "When I first came here I was a bit nervous, you know. I'd never been in such a place but the doctors, like all the nurses, everybody, the staff was just excellent. They treat me really good and talked to me nicely … it was perfect. He gave me plenty of time to think about it, a week or two weeks before. He explained to me step by step what it was and he also

said, if you would like to bring any friend or any member of your family, you can explain to them and discuss it with them and talk about." (TM2-5/8)

An older female respondent was especially moved by the tolerant and sympathetic nature of her trial nurse whilst she struggled with one of the procedures of the trial:

"And they did very good, very good, if you can't blow. But them, they don't force, you know, like they don't say, 'Oh, you can't', they were very good, yeah." (TF5-7)

Clinical trial nurses were viewed as being patient and giving freely of their time, so that the respondents had adequate opportunities to ask questions.

Again these findings are very similar to those in the literature on white trial participants, where trial recruiters' friendliness is considered an important motivating factor in trial participation. The only bad trial experience recollected was that of a young female respondent who felt that her male consultant did not provide her with any trial information, and coerced her into taking part in a gynaecological trial:

"I don't know, he said, 'You're going to have some swabs taken' and said to the midwife who was in charge of me, and said, 'She's going to talk to you about it and going to do the swabs' and that was it, and I didn't know it was a trial, and he didn't say … he didn't ask me if I wanted to have the swabs taken or not and I thought I didn't have a choice." (TF12-1)

The same respondent did, however, end up taking part in the trial, but only because she viewed her midwife as 'nicer' and 'understanding':

"… I suppose if the midwife wasn't as nice as she was, then I wouldn't have, no, I would have thought, 'oh God, she's not very understanding', but she was really nice, sort of encouraged me and everything … she used to joke about the little baby after she's born and stuff like that, she was really nice." (TF12-6)

These findings clearly illustrate the detrimental effect of poor communication skills on trial recruitment and compliance.

Framing of information and decision-making

Initial information about trial participation varied from letters of invitation (in English), to a direct approach by the consultant or the trial nurse. In the case of *H. pylori* trials, respondents received letters at home asking them to contact their surgeries, which caused a degree of confusion amongst some. One of the *H. pylori* respondents thought he had been called for a routine health check and another felt that he was 'summoned' and was not given a choice.

"I thought because when I go to doctors, you know for a general checking … once a year or once in two years' time, I always go for check-up. So when I got the letter I thought oh it's only the practice and, just checking for the body … So I says, 'Yes, no problem' … That's why I go for a test … So it's just the normal test for any test on the body, I never say 'no'. So I just says, 'Carry on straight then'." (TM11-2)

An older female respondent took her daughter (who was fluent in English) to the surgery with her, because she wanted more clarification about the purpose of the trial. Once the respondents had had their initial meeting with the trial nurse, and were given opportunities to ask questions about different aspects of the *H. pylori* trial, they were all happy to participate.

Who provided the information was not viewed to be as important as how it was provided. A female respondent who took part in an HRT trial recalled her initial experiences with two younger GPs in her surgery, whom she felt did not take enough time to explain adequately the nature and the reason for the trial. It was only after one of the older GPs in the same practice intervened that she decided to take part in the trial. Her reason for agreeing to take part was because she did not feel 'undermined' by the older GP, who patiently went through the trial details with her and answered all her questions. For this respondent, 'being listened to' was important.

"I actually saw three different doctors from the same practice, and one of the doctors, he was, he's the elderly, he's the oldest, and he was very good how he explained and how he put everything in context. I think he's the only one who actually listened to all my questions and I didn't feel undermined by him cos he looked at my lifestyle and he, and then he put everything in perspective." (TF9-4/5)

Difficulties with understanding clinical trial terminologies was an issue that came up frequently, in particular for the older South Asian respondents, who showed a preference for 'simple information'.

"I understood bits of it, some things I didn't understand. The second time I went I took my daughter with me. She explained what he said and that they will offer to get somebody to translate for

> me. When I visit the doctor I occasionally take my daughter because of the terminology used." (TF10-2) [translated from Punjabi]

Only one respondent preferred to have more technical knowledge and was not satisfied with the 'basic' information provided in the *H. pylori* trial. This suggests a degree of diversity in South Asian trial participant expectations of the type of information required.

> "… I would have expected it to be more specific about what they're actually doing and why they're doing it. Basically details that, you know, you would get in the *New Scientist*." (TM8-2)

Evidence about the provision of information on clinical trials (in the general population) is conflicting in the literature, and there is some ambiguity with regard to the amount, level and type of information provided to potential trial participants. Research examining informed consent suggests that even when trial recruiters adhere to strict informed consent procedures and ensure that 'simple language' is used, this does not guarantee that participants will fully understand the implications of participation.[98] The present findings indicate that in the case of English-speaking South Asian trial participants, similar issues around information provision and understanding might be in operation.

A critical look at the findings did not identify any patterns in information provision and decision-making process, except for trial recruiters' 'friendly nature', degree of fluency in the English language and same-gendered staff for more intimate trials. Three of the respondents had decided to take part in the trial on their own, and this was regardless of their age, gender or social class.

> "It's my body and at the end of the day the decision is mine and no-body else's." (TF13-2)

Others had decided with the help of their partners and knowledgeable friends.

> "I did ask my husband, yeah, and he said it was up to me." (TF12-6)

One respondent believed that he was not given a choice in the matter and the decision to take part in the trial was made by his GP. He did, however, suggest that the trial was not imposed on him, and he took part out of 'obligation' to his GP:

> "I was almost told, you know, 'Will you come down?' … And I think people feel more obliged, you know, if you say, 'Can I talk to you for two minutes?' or you just say, 'Look, I'm asking you', put them on the spot … No, it wasn't imposed, but it was more like obliged, I felt obliged to do it, and I did it. And it wasn't such a terrible thing." (TM7-7)

When probed further on how he felt about being almost coerced into taking part in the trial, he argued that the trial was 'not a big inconvenience' for him, and he had the philosophy that clinical trials were beneficial and being coerced to take part in them should not be viewed as violating people's rights, because 'at the end of the day it is for their own good'.

Decision to take part in the trial also depended on the gender of the trial recruiter, especially in those trials that were viewed as 'embarrassing'. A female respondent agreed to participate in a gynaecological trial, only because the trial nurse was a woman:

> "… because there was a female who was doing it all, so I suppose that was good." (TF12-3)

Modesty has been specified as a 'cultural' barrier to clinical trial participation amongst South Asian women. Both health professionals and South Asian lay people suggested that certain types of trials might not attract South Asian women who have a preference for female staff. This is also supported by the present findings, where three of the female respondents stated that they would not have taken part in the gynaecological trials if it involved members of the opposite gender. This was because these women considered 'showing their parts to men' as unacceptable. This finding is also in keeping with the literature, which suggests that concerns about modesty, in British ethnic minority women, resulted in poor participation in gynaecological procedures.[137] As the present findings indicate, modesty, although considered a barrier to participation, might not be an issue for all South Asian women. The views of one Indian female respondent (who took part in an HRT trial) illustrates this point:

> "For something like HRT it would be a gender issue as well, not for me, for most South Asian women it would be a gender issue." (TF9-10)

This suggests that there is a need to recognise that not all South Asian females have a preference for female staff and there is a degree of diversity in attitudes amongst this group of women. A similar case can be argued for other women who may also have reservations about the gender of the staff for intimate medical examinations.

Finally, the respondents were briefed on some of the beliefs and stereotypes held by health professionals and South Asian lay people about clinical trial participation amongst South Asian people. These included lack of autonomous decision-making in women and expecting doctors to be paternalistic. With the exception of one older respondent, who suggested that asking a GP would be a good starting point, all others argued that their decision to take part in the trial was drawn from talking to trial recruiters, family members and friends who they considered more knowledgeable on medical matters. An older female respondent argued that in her experience, some Asian women only ask their husbands 'because they think their husband will have better knowledge than them'. An active role in decision-making has been shown to depend on participants' age and educational level, in a study where white older patients were shown to prefer to leave decision-making to their doctors.[93] The present findings indicate a mix of paternalistic, shared and family decision-making with regard to South Asian participation in clinical trials, and the respondents' accounts clearly illustrate that patterns of decision-making about trial participation are not dissimilar to that of the majority population.

Trial burden

The decision to take part in a clinical trial also appeared to be dependent on the trial burden. Sometimes, owing to extra visits and complicated and often uncomfortable medical procedures, some trial participants found it a struggle to comply with the more demanding trials. Logistic barriers to participation were discussed where respondents contextualised their experiences in relation to other South Asian people by arguing that those who worked long hours, occupied manual or low-paid jobs, were unable to take time off work and had no transport would not be able to take part in clinical trials. This view was illustrated by a female respondent's experience, who found it difficult to make frequent trips to the hospital for the trial, as a result of extra cost.

> "… because I used to have to go to hospital nearly every week with to see my consultant and for the [x] trial as well, it was quite costly, sometimes even twice a week by taxi." (TF12-6)

Lack of financial support for childcare was also recognised as a barrier to trial participation, where one respondent stated that although she would not mind taking part in future trials, since having a child she is unable to participate due to extra costs associated with trial participation. An older trial participant very nearly had to pull out of a heart trial due to a stroke, which made him unable to use his own transport. His trial nurse had to organise hospital transport for him so that he could continue to complete the trial.

> "I can't go anywhere, I am sorry, I stay home all the time. Sometimes … I can't walk or do anything … I go there in hospital transport, they take me there and bring me back." (TM15-3/4)

All respondents were aware that if they were not fluent in the English language, they might not have been able to participate in clinical trials. This is a contradictory finding in the sense that two of the trial participants were not fluent in English, but still took part in clinical trials.

Lack of fluency in English was also believed to lead to the discrimination of those South Asian patients for whom language is a barrier to communication. This was illustrated by an example provided by a female respondent, who shared a ward with a non English-speaking patient during her chemotherapy trial:

> "There was an Asian woman who couldn't speak English and I could see she was treated differently. Not only just by the staff, also the other patients. She was a lovely woman, she was really nice, but I felt it was just her lack of English. She was a friendly person and everything, so yes people do treat differently if you don't speak the language." (TF1-4)

The presence of such discriminatory practices in the NHS was thought to lead to mistrust of health professionals amongst South Asian people and this was suggested as a potential barrier to South Asian participation in clinical trials. One respondent argued that because South Asian people are treated as 'outsiders', they might not want to 'contribute' to medical knowledge because they are not made to feel a part of British society:

> "And even though we're here and we've tried to get in with the people, we're still treated as an outsider, and then we tend to think, 'Well it's nothing to do with us'. You know, if something's going on it doesn't affect us, it's nothing to do with us, we have to get on with our business, or run our little shop or whatever and that's it. So there's that, the fact that we are treated as aliens or we feel alien, that's why." (TM7-3)

Lay respondents also argued that older South Asian people or those from lower socio-economic backgrounds might not take part in clinical trials owing to experiencing racism and because of a 'feeling of not belonging'.

The role of trust in consent

Trust in the doctor or nurse involved in the clinical trial was apparent in many of the accounts. Trust was expressed in terms of the health professional being an expert, which extended to trust in the trial itself.

> "At the moment I have not come across a point where I don't trust my doctor. So whatever the doctor says I agree, you know, that's it, that's a trust, and I trust her information … And because I've been with that doctor for a while, so that's, so I say, 'Yes, I trust her'." (TM3-9)

Although none of the respondents interviewed had personally experienced breaches of trust, some recalled bad experiences of their friends and close relatives at the hands of the NHS.

> "… he said the nurses and the doctors, they didn't treat me right … he couldn't speak English. 'Look, I have lost confidence in that, I don't want to go to hospital.' I used to tell him you should go and he said no. So he is scared to go back in case something else might happen." (TM2-7)

On the issue of trust, one respondent argued that although some South Asian people have had bad experiences in the NHS, such experiences were considered insignificant compared with the breaches of trust 'back home'.

Trust in the doctor and the trial nurse, along with 'openness' about all aspects of the trial, was universally acknowledged as an important factor contributing to their participation in clinical trials.

> "So he [trial recruiter] would have to be open about it. There's no point just showing the positive side, but the negative, because they don't know, that's why they are doing the trial and your doctor should explain to you and you have to have total faith in your doctor, and trust." (TF1-7)

Again, this finding is mirrored by the general population, who have also been shown to participate in clinical trials owing to confidence and trust in trial recruiters.[99] In addition, the present findings seem to suggest that humane qualities of honesty, compassion and empathy foster trust and can increase South Asian patients' willingness to participate in clinical trials.

With regard to informed consent, although the majority of the respondents stated that they were happy to sign the consent form, not all fully understood the reasons for signing it. Three of the 'middle-class' respondents (teacher, property developer and driving instructor) could understand the concept of consent. Others had varying levels of understanding. It was suggested that only those people who have had surgery in the past would know about consent. The respondents could not see a reason why South Asian people would be any different from the general population in their level of understanding of consent. Some viewed consent as a Western formality, which they were happy to go along with. An older female respondent remembered signing consent for the trial because another lady in the trial did the same:

> "I'm not sure. There was another Asian women who signed the form so I copied her. I thought if she's signed it, it must be okay. The other lady understood English I didn't know that much." (TF10-5) [Translated from Punjabi]

In the experience of two younger female respondents, signing the consent form for the trial was a cause for concern.

> " 'Well you have to sign this informed' … I think that's where the risk comes in. That's when I'll start thinking, 'Is there something that this person's not telling me?'." (TF9-8)

This concern might be due to either unfamiliarity with the concept of informed consent or poorly informed assumptions, where consent was seen as a form of protection for the health professionals, in case 'something went wrong'.

> "Informed consent form basically is a legal right, I think, you know, to protect professionals." (TM8-7)

Another reason why consent can be of concern is due to mistrust of small print. This was a cause for concern by one of the respondents:

> "I am generally very wary of signing anything, it's the small print, you never know what you are signing these days." (TF13-1)

Similar issues were discussed by South Asian lay people, where mistrust of signing official documents was identified as a potential barrier to obtaining consent for clinical trials. This mistrust was due to previous bad experiences with bogus salesmen and the generic mistrust of signing anything official in an increasingly litigious society.

Finally, the findings suggest that South Asian trial participants face some uncertainties with regard to the consent process. Similar ambiguities about consent are also common amongst the general population, where the purpose of the consent

form may not be totally clear to trial participants.[98] The difference is that such ambiguities facing South Asian people have their foundation in experiencing discriminatory practices in the NHS.

Strategies for improving South Asian participation in clinical trials

Apart from reiterating the strategies already identified in earlier chapters (pictorial information, videos, advance awareness through community work, posters in surgeries and hospital, etc.), the respondents also suggested a number of approaches that they found to be effective in their personal experience. These included appealing to the trial participants' altruistic nature. It was suggested that if South Asian people were made aware of the fact that clinical trials could be beneficial for those illnesses which are prevalent in their community, many would take part to 'stop suffering'. GPs and practice nurses were identified as the perfect vehicle for disseminating this information. One respondent believed that clinical trial information was better if provided by nurses, who tend to have a better relationship with patients in general:

> "I think one thing I would say, because when I was asked to participate, if rather than coming from doctor, if it had, although my practice nurse initiated conversation that she wanted at least half a dozen Asian women between the age of 40 and 50 to come forward and try HRT because there's very, very, even one, not even 1% women on this treatment. But I still had to go through my GP before I was like medically approved. If it had come from nurses rather than GP, you know, where you do feel that relationship, you see more, primary healthcare rather than the GPs." (TF9-9)

Experiences of trial participants also indicate that support groups, where trial participants can meet to discuss their experiences and vent any anxieties they might have about clinical trials, would be beneficial.

> "… getting to know the people who were in the same situation as me, or who were taking part in the trial … it would have been interesting hearing about other people's experiences as well with the trial, how they, you know, dealt with it … ." (TF12-7)

> "Sometimes information is presented technically but it would be more helpful if I knew somebody who had gone through a trial, that practical experience is more important than numbers and figures." (TF1-2)

It was also felt that trial recruiters should have the 'right attitude', which meant that they should not make trial participants feel 'fobbed off'.

> "More friendly kind and answering your questions, taking it right, if he doesn't know anything so I don't have to tell anything. Not that sort of attitude, the right attitude. No, just the attitude and the correct information, not fobbing off." (TF1-11)

Only one respondent mentioned ethnically similar staff, since they could overcome any communication barriers due to linguistic differences. Other approaches included educating school children about clinical trial participation, so that they can take the information home and educate their parents (who might not get the opportunity to find out about trials by other means). It was also suggested that for those South Asian people who are from a lower socio-economic background, payment for travel costs and crèche facilities might reduce their trial burden.

> "If travel was paid for such as taxi fares and crèches should be provided if they couldn't get baby sitters." (TF13-2)

Conclusion

It is important to consider the potential limitations of this study because only a small number of South Asian trial participants were interviewed and the data presented here may not necessarily be representative of other South Asian trial participants' experiences. The very fact that this group of people successfully participated in clinical trials also suggests that they may already be sympathetic to clinical trials or have a different understanding of science than that of other South Asian people. This needs exploring in more detail in future studies. The qualitative nature of this study also revealed a vast amount of rich data on their experiences, how they overcame barriers to their participation, and their unique perspectives and recommendations on how to improve South Asian participation rates. This has not been previously examined elsewhere. There are also a number of themes from this study that find echoes not only in earlier chapters, but also in the literature, thus adding to the reliability of the findings.

One of the important findings has to be the acknowledgement that, in a similar manner to the general population, there is much diversity in attitudes and experiences amongst the respondents. South Asian trial participants' attitudes and experiences of clinical trial participation also appear to be very similar to those of the general population. It will be important for future research to investigate

whether such experiences are reflected in other trials and with a bigger patient group. The only differences identified in the present study appear to be due to modesty in South Asian women (a cultural factor) and socio-economic background of trial participants (trial burden bears heavily on the poor). Although the respondents in the present study were fluent in English, their experiences suggest that trial participation would have been difficult for them were this not the case. Lack of language support should therefore be considered as a major barrier to participation, along with discriminatory practices in the NHS. Future policy and practice should focus on tackling institutional racism in the NHS.

The findings also suggest that, contrary to health professional and lay beliefs, those South Asian people who are older, from lower socio-economic backgrounds and women are perfectly competent to take part in and comply with clinical trials. Most of those who were interviewed were either fluent or had a reasonable level of spoken English. For English-speaking South Asian people, inclusion in clinical trials should be easier and this study, for the first time, bears out this assumption.

Factors such as clear and concise trial information, provided by caring and understanding trial staff, were very important to the respondents. Appealing to a South Asian person's altruistic nature by informing them that South Asian people are frequently under-represented in those clinical trials which investigate illnesses prevalent in South Asian people was also identified as a strong motivational reason for clinical trial participation. Altruism, in order to contribute to science and society, should be recognised and the contribution that the trial participant makes through involvement in the trial should be acknowledged and fed back. This could provide a sense of purpose and 'belonging to society' to South Asian trial participants. A possible way in which this feedback can be achieved is for patients to receive reports of the findings of the study to which they have contributed.

One conclusion that can be drawn from this study might be that translated information should be provided to those trial participants who prefer to have the information in a South Asian language. The findings clearly suggest that some participants did not fully understand what they were taking on when first approached to participate by letter. Providing translated information sheets might diminish the possibility that patients are consciously or unconsciously coerced into participation in clinical trials. Providing patients with information is a challenging area because of the framing of information and problems with readability and language. Consideration needs to be given to ways of providing accurate and straightforward information to South Asian trial participants. A clinical trial protocol can be summed up in three or four pages of easy-to-read language, so long as the necessary translation is made available. The use of videos and pictures was one of the ways put forward by the respondents, combined with a system of checking understanding and on-going education and training in communication skills for health professionals.

A summary of the discussion in this chapter is given in *Table 23*.

TABLE 23 *Summary of Chapter 6*

- South Asian-reported motivations for trial participation are very similar to those reported for the general population. These include:
  (a) altruism
  (b) hope for a better treatment
  (c) to improve scientific knowledge/curiosity
  (d) clinician influence
- Women and older and socio-economically disadvantaged South Asian people are capable of participating in clinical trials, if they are fluent in English
- South Asian women do participate in gynaecological trials if undertaken by female trial staff
- Lack of language support in the NHS makes participation in clinical trials difficult for those South Asian people for whom language is a barrier to communication
- There is diversity within the South Asian population in terms of views and experiences
- Strategies proposed to facilitate South Asian participation in clinical trials include clear and concise information delivered by caring and understanding staff, the knowledge that South Asian people are under-represented in clinical trials investigating illnesses more prevalent in South Asian people and same-gendered staff for more 'intimate' trials

Chapter 7

Discussion

A summary of the main findings of this study is presented below, followed by implications for future research and recommendations for policy and practice.

Background

Ethnic minority under-representation in clinical trials is frequently addressed in the USA. However, it is difficult to assess accurately the extent of South Asian under-representation in clinical trials owing to lack of information on the ethnic background of trial participants and an absence of inclusion/exclusion criteria in the published literature.[35] Findings from our initial exploratory study suggest that there is South Asian under-representation in UK-based clinical trials. There is also a gap in knowledge about the effect of inter-group differences such as age, gender and socio-economic status and how these variables affect South Asian trial participation. Lack of evidence of their under-representation, absence of guidance for researchers (to ensure proactively a greater ethnic diversity in UK-based clinical trials) along with poor understanding of South Asian people's perspectives on clinical trial participation make this a fertile ground for research. The reasons why it is important to include South Asian people in clinical trials are set out below:

- Exclusion from clinical trials is inequitable, since evidence suggests that people who take part in clinical trials have better health outcomes.
- Unless South Asian people are routinely included in clinical trials, then the illnesses from which they disproportionately suffer (such as diabetes and heart disease) will remain poorly understood and treated.
- Ethnic minority exclusion from clinical trials undermines the government's NHS plan for tackling inequalities and its core principle of providing culturally appropriate and accessible care for different groups and individuals.[31]
- To sustain the widespread applicability of the trial findings to the population as a whole (since a person's ethnic origin plays an important role in their response to drugs).
- Exclusion of a subset of the population from clinical trials has repercussions regarding the safety and the efficacy of new drugs and medical interventions.
- More generally, ethnic minority participation in clinical trials would reduce any alienation and mistrust amongst this group, and would help to emphasise that they are an integral part of British society.

The main findings

The literature highlights tensions that exist in clinical trial participation amongst ethnic minority people, how their participation might be affected within the current context of service organisation and delivery, and that the conduct of clinical trials occurs within a historical and socio-political context. The documented evidence to support the common explanations for poor ethnic minority participation rates in clinical trials includes mistrust due to a history of exploitation by medical research, inappropriate exclusion criteria, methodological and structural factors and socio-cultural barriers. Socio-cultural barriers reported in the literature tend to centre on discrimination experienced by ethnic minority people at the point of recruitment, cultural factors and poor access to healthcare due to economic constraints.

The literature review suggests that clinical trials take place within a wider social context in which disparities in ethnic health provision exist. From the perspectives of South Asian people, experiences with healthcare provision and clinical trial participation may not be that different. Therefore, efforts to bring about equal participation in clinical trials need to take into account the effect of racism, discrimination and social exclusion. However, the ethnic minority participation literature rarely addresses these issues. Not only does a lack of understanding of such issues encourage racist service delivery,[194] but also policies based on poorly contextualised accounts of ethnicity can end up as cultural myths and stereotypes.

A critical evaluation of attitudes and barriers to clinical trial participation suggests that South Asian people may not be all that different from

the general population, and that such barriers are generic and equally pertinent to ethnic minorities and the general population. For instance, poor understanding of science and increasing commercialisation of clinical trials mean that the general population is just as likely as ethnic minority people to be mistrustful of medical research. Empirical evidence also illustrates more similarities than differences in attitudes towards clinical trial participation between South Asian lay and the general population. There was little evidence of antipathy to the concept of clinical trials amongst South Asian lay people and awareness of trials appears to be a correlate of social class, education and youth. Overall, Indian respondents were more likely to be aware than Pakistani and Bangladeshi respondents (reflected in the social class/education gradient amongst British South Asians). These findings are in agreement with the literature, which shows that social class can affect a person's likelihood of participating in clinical trials.[195,196] Older South Asian people and those from working-class backgrounds tended to be more mistrustful of medical research owing to experiencing racism or the feeling that 'they're not welcome here' or 'do not belong'.

Ethnicity appears to be important in relation to cultural influences on decision-making about clinical trial participation; for instance, the importance of family in decision-making, modesty in women and dietary restrictions on alcohol and pork-derived medicine. The tendency in the literature to emphasise cultural reasons for poor ethnic minority participation rates may partly be true. However, the presence of diverse attitudes suggests that the relevance of ethnicity (although significant in some aspects of clinical trial participation) needs to be kept in perspective. Lay respondent accounts clearly demonstrate that social class, gender and age might be as important as ethnicity in making sense of South Asian under-representation in clinical trials. Furthermore, diversity occurs within the South Asian population itself.

Similarly, South Asian trial participants' experiences and motivations for trial participation are very similar to those reported in the literature about white trial participants. The only points of difference identified were due to language and discriminatory behaviour, leading to mistrust of health professionals and by proxy medical research. The findings also showed that contrary to health professional and South Asian lay beliefs about the inability of older people, women and those South Asians from more traditional/lower social classes to take part in clinical trials, these groups are perfectly capable of participating if adequate provisions are made. These include caring and trustworthy staff, same-gender staff for more intimate trials and availability of free transport (in one instance).

Institutional racism can be used to explain the failings of public institutions to respond to the needs of ethnic minority people. At the heart of institutional racism is the premise that 'same service for all equates with an equal service for all'. This either results in ethnic minority people getting their needs ignored (for example, disregard of dietary, linguistic and cultural needs) or their needs are misinterpreted and used against them (owing to poorly informed assumptions about cultural differences, race and ethnicity). Health professionals' accounts indicate that South Asian people may be actively excluded from clinical trials owing to different facets of institutional racism which manifest themselves as lack of cultural sensitivity and awareness of specific needs, discriminatory behaviour at point of recruitment, structural barriers (due to poor access to trial-rich sites) and lack of positive action by health professionals. These issues are discussed next.

Lack of cultural sensitivity and awareness of specific need

Organisational barriers and poor resources in the NHS affect recruitment processes. In everyday clinical practice, those patients who are easier to communicate with, that is, those who are fluent in English and those from a similar social background to health professionals, tend to get recruited to clinical trials. Health professionals were often unaware of the significance of South Asian under-representation in clinical trials or were impeded by their unfamiliarly with South Asian culture and lack of culturally appropriate tools. Stereotypes about people from lower socio-economic backgrounds and South Asian people may also contribute to some health professionals' reluctance to recruit these groups. Any generic barriers to recruitment are further intensified if there are cultural differences between the health professional and the patient.

The findings suggest that currently clinical trials are organised according to a 'white norm', which does not recognise cultural difference and diversity. Further, medical research is a Western concept that has not yet fully become part of the South Asian cultural repertoire.[124] Ethical issues

can arise from fundamental contradictions between Western biomedical perspectives and the norms and values of other cultures. Any deviance from this norm creates notions of difference in the minds of health professionals. This deviance, according to the empirical findings, was described as an inability to make autonomous decisions, and some health professionals felt awkward about having South Asian family members present when seeking informed consent.

Rather than recognising a strong familial identification as an important cultural aspect of South Asian people, some health professionals may be deterred from obtaining consent from this group of people. The challenge for the NHS is, therefore, to develop culturally appropriate methods of obtaining consent, while at the same time meeting the requirements of ethics committees. There is also a need to understand that decision-making is not necessarily an autonomous process and that important decisions, such as participation in clinical trials, is a matter that concerns significant members of the family. It is not uncommon for other ethnicities to have strong familial identification, and major decisions such as participation in clinical trials are usually negotiated within families. The 'inability of South Asian women to enter a clinical trial without first consulting their husbands' was another issue which a number of health professionals found frustrating. In fact, some women would consult their English-speaking husbands because they were acting as interpreters.

Decision-making is a very complex issue and is dependent on the person's socio-cultural background, age and family dynamics. It is therefore inappropriate to adopt the generalised notion that South Asian men take control of decisions and that women are completely compliant. Adopting such an attitude gives rise to stereotyping of South Asian women.

The lack of routine language support in the NHS for non-English speaking South Asian people means a loss of opportunity to participate in trials. This was evident in health professionals' accounts, which showed that South Asian people may be systematically excluded from clinical trials owing to the increased cost and time associated with language support. These findings, although in keeping with the US literature, are somewhat paradoxical since a large proportion of British South Asians are fluent in English.[13] In addition, the proportion of South Asian people who speak English increases with length of settlement in the UK (although there are exceptions, for instance, those new to Britain as a result of arranged marriages). It may be the case that the language barrier is used as an excuse in a situation where considerable technical medical information is exchanged across cultural, socio-economic and linguistic boundaries.

According to the findings, fluency in the English language appears to be strongly linked in a South Asian individual's socio-economic background. This is supported by the statistics that show that the ability to read and write English is greatest in Indians and that most Pakistani and Bangladeshi men can speak English. This is in contrast to the women, where only three-quarters of Pakistani women and less than three-fifths of Bangladeshi women could speak English. Ability to speak English also declines dramatically with age.[13] This pattern was recognised by all respondents who believed that older South Asian people, Pakistani and Bangladeshi women and those from a lower socio-economic background are least likely to participate in clinical trials as a result of poor fluency in English.

Learning a language as an adult can be particularly difficult for those South Asian people who are from lower socio-economic backgrounds. Their domestic and work responsibilities may leave little or no time, and learning English may be seen as less of a priority in terms of the day-to-day needs of family and home. Some South Asian people may have a basic command of the English language, sufficient to enable them to cope with routine demands, but this may be lost when they need to discuss medical problems, or when communication occurs with people in authority or in frightening situations. This was evident from the accounts of a number of trial participants who, although 'fluent' in English, did not appear to understand fully the complexities of trial participation.

Providing an interpreting service may not be the ideal solution for improving South Asian recruitment to clinical trials. Communication through an interpreter, however good, is never likely to be as effective as direct communication between a health professional and a patient who share the same language and cultural understanding. Health authorities serving a multi-ethnic population could employ ethnic minority health professionals at all levels. With time, barriers due to language will be surmounted. In the meantime, special considerations may need to be made in the NHS to train health professionals

in the generic skills needed to respond flexibly to a diverse patient population and time allowed for the extra workload involved. However, perhaps too much attention is placed on the language barrier instead of focusing on the process of communication between the patient and the health professional. Starting with the perception that recruiting and obtaining consent from South Asian people is a problem, rather than finding ways to overcome the language barrier, inevitably results in exclusion of South Asian people from clinical trials. Most health professionals did not consider the exclusion of this group from clinical trials for pragmatic reasons as discriminatory.

An important first step for health professionals is to be sensitive to a patient's socio-cultural beliefs and perspectives and not to become involved in cultural stereotyping. It is also essential that health professionals recognise individual differences, because people of the same ethnicity can vary enormously in their beliefs and practices. South Asian under-representation might also be due to a mixture of the particular requirements of groups not being met (e.g. cultural and language needs) but equally, also, that some people choose not to participate in trials because they mistrust the healthcare system owing to previous bad experiences in the NHS.

Discriminatory behaviour at point of recruitment

Empirical findings suggest that unfamiliarity with the South Asian culture means that some health professionals tend to adhere to stereotypes concerning South Asian people. The current findings are also endorsed by US literature, which suggests that clinical trials recruiters discriminate against ethnic minority groups and that ethnic background negatively influences access to clinical trials. Fear of the unknown or a lack of familiarity with South Asian culture on the part of some health professionals is one of the explanations for South Asian under-representation in clinical trials.

Respondents' accounts also suggest that South Asian doctors may also hold stereotypes and, although linguistic barriers between them and their patients may not be present, there are other barriers of social class and education. Differences in access to clinical trials may reflect the class structure of society and of health professionals who have more in common with middle-class patients. Any class differences are further intensified in communication between people of different cultural origins. Differences in social class have been shown to distort the doctor–patient communication process and it is likely that class differences also play a role in South Asian under-representation in clinical trials.

The majority of the South Asian respondents viewed doctors to be in a higher social class than themselves, and this was expressed in terms of the doctor's greater education and position of specialist knowledge. Findings from the present study, therefore, suggest that socio-economic variations in the decision to take part in clinical trials are important and future research is needed to test this hypothesis. Social exclusion and discrimination may have a major impact on the economic and social well-being of ethnic minority people and may ultimately be expressed as inequalities in health.[197]

Although the empirical evidence suggests that mistrust of research and clinical trials might not be a major concern amongst South Asian lay people (contrary to the findings in the literature, which suggest mistrust as the most important barrier to ethnic minority participation in US clinical trials), mistrust was an issue amongst a small number of respondents as a result of suspicions about medical research, owing to unethical conduct of clinical trials in their country of origin. Some respondents also recalled situations where South Asian people in the UK had bad experiences in the NHS (in particular those South Asians who lacked fluency in the English language). Such negative health experiences may play an important role in their attitudes towards health professionals and, consequently, may dictate their likelihood of participating in clinical trials. Those South Asian respondents who were from a lower socio-economic background appeared to be generally more mistrustful of authority and viewed signing the consent form for clinical trials with a degree of suspicion (a situation that might equally apply to others from working-class backgrounds). In the case of South Asian people, however, experiences of racism or the feeling that 'they're not welcome here' or 'do not belong' further compound mistrust.

Structural barriers

Clinical trial participation is dependent on the location of the trial site. Access to clinical trials, for this reason, may be limited for the socio-economically disadvantaged. Most clinical trials in the UK take place in secondary care or tertiary/specialist centres and only a small proportion of South Asian people make use of such services.[174] Given the literature on access difficulties facing South Asian people, it is likely

that a large proportion of this group may never get an opportunity to participate in clinical trials. South Asian people also tend to be more concentrated in inner-city locations and are likely to be registered with single-handed practices where the GP is more likely to speak their language.[139] Single-handed inner-city practices are often under-resourced and overstretched and as such are unlikely to have the time and resources required for conducting clinical research.

Lack of positive action

The findings reported here stress the need for funding bodies to take into consideration the increased cost implications of translation/validation of health questionnaires, training staff in cultural sensitivity, outreach efforts to improve ethnic minority participation in research and reimbursement for expenses or costs of bilingual staff/translators. Such resources should be included and justified as part of the necessary and routine components of research if South Asian recruitment rates in clinical trials are to improve. Ideally, economic considerations should not be used as an excuse for the exclusion of South Asian people from clinical trials.

Valuing diversity in healthcare research and acknowledging an individual's culture in its broadest sense (including taking into account a patient's ethnicity, age, gender, education, social class, religion and prior health experiences) are all important factors which should not be overlooked when conducting any type of research. Recognising these aspects and acknowledging their influence on health in reported findings may also prevent stereotyping and exclusion.

The presence of diverse attitudes amongst South Asian respondents also suggests that the relevance of ethnicity and culture needs to be kept in perspective. Ethnicity is important in relation to discussing cultural influences on decision-making about clinical trial participation (e.g. the importance of family in decision-making and gender segregation) but is not the sole explanation for South Asian under-representation in clinical trials. No major religious objections to participation in clinical trials, in principle, were identified apart from objections to using non-Halal medication, alcohol and any meat-derived medicine (vegetarianism). The significance of ethnicity is further brought into context by the fact that South Asian respondents' views are mirrored by the general population. These findings therefore illustrate that South Asian participation in clinical trials is equally dependent on language, social class, age and gender. With the exception of language, such factors are equally applicable to some sectors of the general population.

Future research

Researching South Asian under-representation in clinical trials could have beneficial outcomes for the health service, including improving trial participation in those illnesses that are more prevalent in South Asian people, fulfilling the NHS equality policy, overcoming mistrust and improving relationships between health professionals and patients. A summary of areas for future research follows:

- Although a positive attitude towards clinical trial participation amongst South Asian lay people was indicated, a crucial area requiring further research must be to establish whether such a response reflects actual behaviour when people are invited to take part in the trials. Similarly, interviewing those people who refuse to participate in clinical trials may provide invaluable information which could be used to establish guidelines for improving participation rates.
- A lack of empirical evidence about the role that methodological or organisational barriers play in South Asian under-representation in clinical trials suggests that there is a need to understand the process of how clinical trials are undertaken and how trial information is provided and understood by this group. Qualitative studies 'nested' within an ongoing clinical trial have been shown to help clarify recruitment difficulties, and changes to information and presentation have resulted in improved recruitment rates.[198] Adopting a similar methodology may highlight methodological/organisational barriers to trial participation amongst South Asian people by exploring the process of information provision, assimilation and, ultimately, decision-making. This can be achieved through in-depth interviews with South Asian trial participants and those who declined to participate, in order to elicit interpretations of study information, experiences of the study, including understanding of treatment options and reasons for refusal. The outcome would be to develop and implement policy and practice guidance that would ultimately result in improved recruitment and retention of South Asian people in clinical trials. Future research could also explore the effect of trial burden (in terms

of time, lost income, travel and crèche facilities) on socio-economically disadvantaged South Asian people.
- Language, mistrust and culturally insensitive and inappropriate strategies among the majority white recruiters can form powerful barriers to the collection of data. Complexities of recruitment processes for South Asian people, from the perspectives of health professionals, also need exploring in order to devise and implement appropriate recruitment strategies. This has implications for the training and education of health professionals. There is also a need to determine how investigator behaviour, attitudes, stereotypes and cultural beliefs affect minority enrolment in clinical trials. Factors relating to organisation and utilisation of services may also need to be explored in greater depth.
- Research is required to devise guidelines for promoting greater cultural sensitivity in the recruitment of trial participants.
- Although there are some studies concerning the various approaches to recruitment of ethnic minority populations in the USA, there is a need to carry out similar research in the UK. Research is also required into developing and validating culturally sensitive research methods, materials and data collection instruments. This knowledge will inform the design of culturally sensitive studies, allow appropriate enrolment of ethnic minority people and ensure that the benefits of the research are made available to all ethnic minority communities.
- Some potential participants expressed concern that research findings generated from amongst their local South Asian population resulted in little in the way of tangible health benefits. Future research should focus on implementing and evaluating effective dissemination strategies amongst this group of people. This would help to ensure that the benefits of taking part in research are apparent and could improve future recruitment.
- Further studies need to be undertaken to have a better picture of the magnitude of the problem of South Asian under-representation in clinical trials.

Recommendations for policy and practice

The findings in this study have implications for both policy and practice and provide the basis for effective trial recruitment strategies to be established in the NHS and the private sector. Although focusing on the South Asian population, many of the recommendations that follow are relevant for other types of health-related research studies. Recommendations for policy are described next. Although we believe that all of the following recommendations are of equal importance, we have attempted to prioritise them by giving higher priority to those that are likely to have the widest impact and which can provide the basis on which the other recommendations can build.

Role of ethics committees

MRECs and LRECs can play their role in redressing South Asian under-representation in clinical trials by acting as watchdogs and by ensuring that the investigators are satisfactorily addressing the inclusion policy in the proposal. When examining research proposals, ethics committees could look for evidence that includes information on the population characteristics of the disease or condition under study, national and local demographics of the population and knowledge and understanding of the ethnic/cultural characteristics of the population. Such knowledge incorporated in the early design and implementation of clinical trials will ensure that barriers to participation are appropriately addressed. Having this information will also allow the development of culturally sensitive research methods/materials and data collection instruments. Research ethics committees can, in this way, ensure that a study design is culturally sensitive and permits appropriate enrolment of participants and that the benefits of the research are made available to all ethnic minority communities. *Table 24* provides some recommendations for ethics committees.

Improved reporting of ethnic background in published trial findings

There is a need for an increased awareness and monitoring of recruitment and retention of ethnic minority people in clinical trials. Peer-reviewed journals have an important part to play in this process, and it is recommended that the CONSORT statement should take steps to ensure that the ethnic make-up of trial participants is specified in all trials. Published trials should report inclusions and refusals in order to highlight areas where further efforts are needed. Similarly, pharmaceutical companies and other private institutions that take part in clinical trials should make efforts to increase the enrolment of ethnic minority people in their trials and to report their findings.

TABLE 24 *Recommendations to ethics committees*

- The inclusion of ethnic minority people should be determined by the scientific questions under examination and their relevance to ethnic groups. It is not anticipated that every study will include all minority groups and subgroups. There must be a scientifically acceptable justification for limiting the study to only one gender, age or ethnic group, such as high prevalence of the condition, unique disease characteristics or gap in knowledge in the selected population
- Exclusion of any groups should be based on science and not the convenience of the investigator
- Ethics committees should look for evidence that the principal investigator has satisfactorily addressed the inclusion policy in the proposal. Such evidence may include:
  (a) information on the population characteristics of the disease or condition under study
  (b) awareness of the proportion of each minority group, which should be included in the study population and the denominator used in determining this proportion
  (c) a knowledge and understanding of the ethnic/cultural characteristics of the population
  (d) culturally sensitive research methods, materials and data collection instruments
  (e) logistic plans and letters of commitment from relevant community groups and organisations for the planned study
  (f) justification made in support of appropriate staffing needs for outreach plans
  (g) the costs of outreach efforts to improve ethnic minority participation in research, such as reimbursement for expenses or bilingual staff/translators, and whether these are covered

Health equality and culturally sensitive training

It is difficult to achieve equality in health by treating everyone exactly the same and considerations need to be made for lack of familiarity with the health service, language, cultural differences and the presence of discrimination in the NHS. At its most straightforward, derivatives from meat products are sometimes used in the coating of medicines. These are unlikely to be Halal and therefore would be unacceptable to Muslim people. Awareness of these issues amongst trial managers and recruiters would also help to ensure that recruitment and consent procedures reflect the experiences of South Asian populations, which may be different from Western assumptions and values.

A greater awareness of and understanding of the cultural diversity of people from different ethnic minority groups can be achieved by actively involving such groups in the education of health professionals. Health professionals should also learn to feel comfortable in asking patients about their language and dietary needs, religious practices and cultural customs. Education and training of all clinical trial staff are critical in ensuring that they interact with the study participants in a positive, reassuring manner, exhibiting understanding of the factors that study participants often experience in the unfamiliar setting of a trial.

TABLE 25 *Guidelines for health professionals to promote greater cultural sensitivity*

- Acknowledgement of cultural diversity of patients
- Awareness of issues of generation, gender and power relationships, both within the family itself and in any communication between the patient and the healthcare professional
- Sensitivity to the patient's political and historical background such as refugee status, new to the country, past discrimination and lack of access to healthcare
- Determination of whether decisions are made by the patient or the family
- Assessment of provisions for the language required to discuss the protocol
- Evaluation of the importance of religious beliefs to the patient
- Utilise available resources, including family members and trained interpreters
- Ask the patient about their needs

Stereotyping and having preconceived ideas about individuals or populations to be recruited into clinical trials fail to take into account or respect the cultural and economic diversity of ethnic minority populations. Achieving 'cultural competence', however, requires additional resources and organisational support. The NHS should aim to provide appropriate provision for this purpose. Guidelines for health professionals to promote greater sensitivity are set out in *Table 25*. Further information can be obtained from Chattoo and colleagues.[199]

Recruiting more ethnic minority health professionals

Patients might be more satisfied with care from doctors of the same ethnicity because they feel more comfortable and trust a health professional who is from a culturally similar background.[200] Training of bicultural/bilingual researchers has been reported as an effective strategy in recruiting ethnic minority people.[126] It is further suggested that matching gender and ethnicity is helpful,

especially for those members of more traditional cultures where issues of modesty are significant factors. Consequently, an effective method of recruiting South Asian people into clinical trials would be to include the participation and collaboration of health professionals who provide care for the populations to be included in the trial. Involving ethnic minority health professionals in the planning and design of clinical trials has also been shown to help overcome barriers of discrimination and stereotyping.[4] Equal opportunity policies can ensure that more people from ethnic minority backgrounds are recruited into health professional roles. Such individuals could play a major role in clinical trial organisation and recruitment.

Participation of nurses as recruitment coordinators, patient educators and patient counsellors has been found to be essential in successful clinical trial recruitment of the general population.[201] Nurses have also been shown to recruit successfully women from ethnic minorities and low social class backgrounds by providing study information in settings where women are found as patients, such as family planning clinics and gynaecology and paediatric departments.[202]

Language support

Modification of the usual approaches to research protocols, procedures and trial management may enhance ethnic minority recruitment to clinical trials. This includes carefully assessing the exclusion criteria for each trial and ensuring the study information sheets are as user friendly as possible. There is a need to evaluate the process of obtaining informed consent from non-English-speaking ethnic minority participants, since too much attention may be being placed on the forms themselves, instead of focusing on the process of communication between the patient and the health professional. The challenge is to develop culturally appropriate methods while at the same time meeting the requirements of ethics committees.

Ethics committees require that informed consent and the study information sheets be written in the patient's language at their level of comprehension. However, not only is translation of the informed consent/study information sheets into a number of languages expensive, but also in a multi-ethnic and multi-lingual environment, many patients may not speak the language that is translated. It can also be argued that South Asian people who can read and write in their own language are very likely to read in English, which is a second language in most parts of South Asia. Translation of information sheets, therefore, remains a major problem since in reality it may never be possible to translate clinical trial information into the hundreds of languages that exist in the UK. If illiteracy is a problem for the potential study population, then study materials should not rely on reading ability and study staff could assist with filling in forms. Information could also be provided by videotape or in graphical or pictorial representations.[203]

The use of translators trained in clinical trial terminologies may be a more appropriate alternative. Ethics committees may need to be more flexible about the informed consent process and trial coordinators may need to ensure that translators are available where required. A practical solution may lie in translating a small number of the main spoken/written languages of the target population and by providing translators for those who may not be able to read or who are not 'captured' by the language translated. Health advocates and link workers may have an important role to play in information provision and access, but they appear to be under-utilised and many healthcare professionals are not aware of the range of available resources.[204]

Additional resource allocation

Although recruitment strategies such as health professional or clinic referrals (mostly from secondary and tertiary care) may be cost-effective, they may have a low yield in terms of South Asian participation, owing to poor access and other barriers. Inner-city, single-handed practices and health centres providing services for ethnic minority communities can be a rich source of potential trial participants. There are, however, time and resources implications. Providing small grants and additional resources directed at conducting trials, along with appropriate support staff, should enable single-handed practices to be more actively involved in clinical research.

Additional resources are also required for more community-based recruitment strategies. Population-based strategies such as door-to-door neighbourhood recruiting, direct mailings and telephone recruiting have been successful in terms of recruitment rates, but are more expensive. Media recruitment (television, posters, radio and newspapers) is less expensive but has a lower yield than more direct methods.[4,205] The cost associated with media recruitment can be reduced by receiving donated materials and services such as free media, local radio stations, sponsorship by

local or national/international celebrities or leaders, volunteer time, small gifts for participants or promotional brochures and posters.

Participation in clinical trials may also mean that some patients may have to support considerable expenses to participate and this restriction results in offering clinical trial benefits only to those who have the time and transport facilities and can afford time off work. Funders, ethics committees and investigators should appreciate the increased costs associated with successful recruitment of ethnically diverse people into clinical trials and need to ensure that budget constraints will not interfere with recruitment rates and methods.

Raising community awareness

Community recruitment has been shown to be more effective than recruitment from the healthcare system.[4] Raising community awareness about the need for and the importance of clinical trials, through educational programmes, could be a useful strategy. This could be achieved by approaching managers of community centres, community groups, women's centres, religious institutions and charitable organisations that work with ethnic minority groups before undertaking a trial. Social gatherings organised by community groups, including youth, elderly and women's groups and health awareness programmes, can be ideal for promoting clinical trials and for recruiting participants. Provision of appropriate educational programmes and presentations to such groups to highlight the benefits of taking part in clinical trials has been shown to be an effective strategy in the US.[202]

Promoting trust

It is likely that if patients experience untrustworthy situations in clinical encounters, then their decision whether or not to participate in clinical trials will be affected. Efforts to educate patients and the South Asian community about clinical trials should be directed at overcoming mistrust in addition to explaining the purpose of clinical trials and their potential value in medical research. Special advocacy or community link workers, who are independent of the medical profession, could provide a bridge on which to build trust. Other schemes to improve trust might include the use of patient support groups.[4] This was also one of the strategies suggested by a female South Asian trial participant.

Clinical trial recruiters should also be encouraged to look within their own research environments and organisational/institutional structures to identify sources that may potentially promote a mistrust of their institution.[206] Qualities such as compassion, empathy and honesty should form a natural repertoire of any health professional. This, coupled with culturally sensitive training, would ensure that if lack of trust is a barrier to South Asian recruitment in clinical trials, then with appropriate educational programmes, this barrier can be surmounted.

Mandatory inclusion

In the USA, mandatory inclusion of ethnic minority people in clinical trials has received legislative backing through the NIH Revitalisation Act of 1993. Similar compulsory inclusion of ethnic minority people in the UK trials may also prove to be an effective strategy. It is not clear, however, whether the notion of social fairness with regard to mandatory inclusion of ethnic minority people in clinical trials would receive much support in the UK. Health professionals in the UK may assume that the existence of the NHS automatically ensures equity and fairness in every aspect of healthcare provision, including clinical trial participation. More research is suggested in this area.

It is strongly recommended that medical students should be trained early on about these issues. Having more ethnic minority people in leadership roles in medicine and research would also help to advance justice in research for ethnic minority people. Further, the greater diversity there is among medical decision-makers, the more likely it is that the needs of all ethnic groups will be recognised. The attitudes of recruiters are important in bringing about change, but management backing and the development of policy relating to resources, staff recruitment and working practices must be made at every level of the organisation if meaningful progress is to be achieved.

A summary of effective recruitment strategies is given in *Table 26*.

Conclusions

The conclusions to this study are set out below in relation to each of the four main objectives.

Objective 1: investigation of how South Asian patients conceptualise the notion of clinical trials

One of the important findings has to be the acknowledgement that, in a similar manner to the

TABLE 26 *Summary of effective strategies for South Asian recruitment to clinical trials*

- Use multi-recruitment strategies
- Define demographic and social profiles of the population to be included in the trial
- Use focus group interviews to identify and understand any potential barriers to participation
- Consult or recruit representative community members, social organisations and other groups to provide service in the development and implementation of the study
- Conduct pilot studies of specific recruitment strategies for specific populations
- Ensure that the eligibility criteria are set as wide as possible in order to achieve wider applicability of results
- Develop educational programmes and recruitment approaches to attract ethnic minority health professionals and social workers
- Gauge level of literacy and spoken language capabilities
- Determine the most effective mass media to use in study promotion, education and recruitment
- Targeting single handed, inner-city practices, likely to have high ethnic populations, may also be useful
- Develop support groups and sites for study participants that will enable them access to the trial
- Implement a dissemination strategy

general population, there is much diversity in attitudes and experiences amongst the respondents. In some ways, South Asian trial participants' attitudes and experiences of clinical trial participation also appear to be very similar to those of the general population. The only differences identified in the present study appear to be due to modesty in South Asian women (a cultural factor) and socio-economic background of trial participants (trial burden bears heavily on the poor). Although many respondents in the present study were fluent in English, their experiences suggest that trial participation would have been difficult for them were this not the case. Lack of language support should therefore be considered as a major barrier to participation, along with discriminatory practices in the NHS. Future policy and practice should focus on tackling institutional racism in the NHS.

The findings also suggest that, contrary to health professional and lay beliefs, those South Asian people who are older, from lower socio-economic backgrounds and women are perfectly competent to take part in and comply with clinical trials. Most of those who were interviewed were either fluent or had a reasonable level of spoken English. For many, English was their first language. For English-speaking South Asian people, inclusion in clinical trials should be easier and this study, for the first time, bears out this assumption.

Factors such as clear and concise trial information, provided by caring and understanding trial staff, were very important to the respondents. Appealing to a South Asian person's altruistic nature by informing them that South Asian people are frequently under-represented in those clinical trials which investigate illnesses prevalent in South Asian people was also identified as a strong motivational reason for clinical trial participation. Altruism, in order to contribute to science and society, should be recognised and the contribution the trial participant makes through involvement in the trial should be acknowledged and fed back. This could provide a sense of purpose and 'belonging to the society' to South Asian trial participants. A possible way in which this feedback could be achieved is for patients to receive reports of the findings of the study to which they have contributed.

One conclusion that can be drawn from this study might be that translated information should be provided to those trial participants who prefer to have the information in a South Asian language. The findings clearly suggest that some participants did not fully understand what they were taking on when first approached to participate by letter. Providing translated information sheets might diminish the possibility that patients are consciously or unconsciously coerced into participation in clinical trials. Providing patients with information is a challenging area because of the framing of information and problems with readability and language. Consideration needs to be given to ways of providing accurate and straightforward information to South Asian trial participants. A clinical trial protocol can be summed up in three or four pages of easy-to-read language, so long as the necessary translation is made available. The use of videos and pictures were some of the ways put forward by the respondents, combined with a system of checking understanding and on-going education and training in communication skills for health professionals.

Ethnicity appears to be important in relation to cultural influences on decision-making about clinical trial participation; for instance, the importance of family in decision-making, modesty in women and dietary restrictions on alcohol and pork-derived medicine. The tendency in the literature to emphasise cultural reasons for poor

ethnic minority participation rates may partly be true. However, the presence of diverse attitudes suggests that the relevance of ethnicity (although significant in some aspects of clinical trial participation) needs to be kept in perspective. The majority of the South Asian respondents viewed doctors to be in a higher social class than themselves, and this was expressed in terms of the doctor's greater education and position of specialist knowledge. Findings from the present study, therefore, suggest that socio-economic variations in the decision to take part in clinical trials are important and future research is needed to test this hypothesis.

In summary, there was no evidence of antipathy amongst South Asians to the concept of clinical trials and, overall, the younger respondents were more knowledgeable than the older ones. Problems are more likely to be associated with service delivery. Lack of being approached was a common response across the three groups. Lay-reported factors that might affect South Asian participation in clinical trials include age, language, social class, feeling of not belonging/mistrust, culture (importance of families, gender issues, community gossip and health beliefs) and religion (modesty, meat derived, and non-Halal medicine).

Objective 2: identification of the key processes which impact on trial participation and the extent to which communication difficulties, perceptions of risk and attitudes to authority influence these decisions

Although the empirical evidence suggests that mistrust of research and clinical trials might not be a major concern amongst South Asian lay people (contrary to the findings in the literature, which suggest mistrust as the most important barrier to ethnic minority participation in US clinical trials), mistrust was an issue amongst a small number of respondents as a result of suspicions about medical research, owing to unethical conduct of clinical trials in their country of origin. Some respondents also recalled situations where South Asian people in the UK had bad experiences in the NHS (in particular those South Asians who lacked fluency in English). Such negative health experiences may play an important role in their attitudes towards health professionals and, consequently, may dictate their likelihood of participating in clinical trials. Those South Asian respondents who were from a lower socio-economic background appeared to be generally more mistrustful of authority and viewed signing the consent form for clinical trials with a degree of suspicion (a situation that might equally apply to other people from working-class backgrounds). In the case of South Asian people, however, experiences of racism or the feeling that 'they're not welcome here' or 'do not belong' further compound mistrust.

The significance of ethnicity is brought into perspective by findings that suggest that South Asian lay people's views about participation in clinical trials are mirrored by the general population. When asked how the respondents would react to taking part in a hypothetical clinical trial, responsibility to society, family and doctors were given as motivating factors. These motivations are similar to those identified in the literature about the general population. Barriers to clinical trial participation identified by the respondents included side-effects of drugs, family and work commitments, language and mistrust. Negative health experiences of ethnic minority people may play an important role in their attitudes towards health professionals and consequently may dictate their likelihood of participating in clinical trials.

In addition to a participant's ethnicity, it is equally important to consider other characteristics such as gender, age, level of education, primary language and socio-economic background – all of which also affect the communication process. Differences in access to healthcare (including clinical trial participation) appear to reflect the class structure of British society and health professionals, who have more in common with middle-class patients. This finding could partially explain why, typically, trial participants tend to be white educated men from predominantly middle-class backgrounds.

Organisational barriers and poor resources in the NHS affect recruitment processes. In everyday clinical practice, those patients who are easier to communicate with, that is, those who are fluent in English and those from a similar social background to health professionals, tend to get recruited to clinical trials. Any generic barriers to recruitment are further intensified if there are cultural differences between the health professional and the patient.

The lack of routine language support in the NHS for non-English-speaking South Asian people means a loss of opportunity to participate in trials. This was evident in health professionals' accounts, which showed that South Asian people may be systematically excluded from clinical trials owing

to the increased cost and time associated with language support. These findings, although in keeping with the US literature, are somewhat paradoxical since a large proportion of British South Asians are fluent in English. In addition, the proportion of South Asian people who speak English increases with length of settlement in the UK (although there are exceptions, for instance those new to Britain as a result of arranged marriages). It may be the case that the language barrier is used as an excuse in a situation where considerable technical medical information is exchanged across cultural, socio-economic and linguistic boundaries.

Learning a language as an adult can be particularly difficult for those South Asian people who are from lower socio-economic backgrounds. Their domestic and work responsibilities may leave little or no time, and learning English may be seen as less of a priority in terms of the day-to-day needs of family and home. Some South Asian people may have a basic command of the English language, sufficient to enable them to cope with routine demands, but this may be lost when they need to discuss medical problems or when communication occurs with people in authority or in frightening situations. This was evident from the accounts of a number of trial participants who, although 'fluent' in English, did not appear to understand fully the complexities of trial participation.

Providing an interpreting service may not be the ideal solution for improving South Asian accrual to clinical trials. Communication through an interpreter, however good, is never likely to be as effective as direct communication between a health professional and a patient who share the same language and cultural understanding. However, perhaps too much attention is placed on the language barrier instead of focusing on the process of communication between the patient and the health professional. Starting with the perception that recruiting and obtaining consent from South Asian people is a problem, rather than finding ways to overcome the language barrier, inevitably results in exclusion of South Asian people from clinical trials.

Clinical trial participation is dependent on the location of the trial site. Access to clinical trials, for this reason, may be limited for the socio-economically disadvantaged. Most clinical trials in the UK take place in secondary care or tertiary/specialist centres and a small proportion of South Asian people make use of such services. South Asian people also tend to be more concentrated in inner city locations and are likely to be registered with single-handed practices where the GP is more likely to speak their language. Single-handed inner-city practices are often under-resourced and overstretched and as such are unlikely to have the time and resources required for conducting clinical research.

Objective 3: identification of whether 'South Asian' patients are homogeneous in these issues, and which factors differ between different South Asian subgroups

The study findings suggest that South Asian people have different levels of awareness and that attitudes vary between and within South Asian people, as in the general population. Indian respondents were most likely to be aware (80%), and less than half of the Pakistani and Bangladeshi respondents (30 and 40%, respectively) were aware of clinical trials. Degree of awareness also appeared to be related to levels of education and age. The findings also suggest that older respondents, and women in particular, across all three groups, were least likely to be knowledgeable about clinical trials. Health professionals suggested that a lack of decision-making is related to a patient's educational background, and Pakistani and Bangladeshi women may lack the confidence to make decisions on their own as opposed to those who are younger, of Indian origin and fluent in English. Poor awareness of clinical trials might also be because they are a Western concept and have not yet become part of the South Asian cultural repertoire and familiarity only comes with engaging with it.

Fluency in the English language appears to be strongly linked in a South Asian individual's socio-economic background. This is supported by statistics that show that the ability to read and write English is greatest in Indians and that most Pakistani and Bangladeshi men can speak English. This is in contrast to the women, where only three-quarters of Pakistani women and less than three-fifths of Bangladeshi women could speak English. Ability to speak English also declines dramatically with age. This pattern was recognised by all respondents who believed that older South Asian people, Pakistani and Bangladeshi women and those from a lower socio-economic background are least likely to participate in clinical trials as a result of poor fluency in English.

Ethnicity is important in relation to discussing cultural influences on decision-making about

clinical trial participation (e.g. the importance of family in decision-making and gender segregation) but is not the sole explanation for South Asian under-representation. No major religious objections to participation in clinical trials, in principle, were identified apart from objections to using non-Halal medication, alcohol and any meat-derived products (in the case of vegetarian South Asian people). South Asian participation in clinical trials is equally dependent on age, gender, language and social class. With the exception of language, it can be argued that such factors are equally applicable to the general population, although they might find a different expression.

In summary, awareness of clinical trials varied between each group. Indian respondents were most likely to be aware and less than half of the Pakistani and Bangladeshi respondents were aware of clinical trials. Ethnicity is important in relation to discussing cultural influences on decision-making about clinical trial participation but is not the sole explanation for South Asian under-representation in clinical trials. Important decisions, such as participation in clinical trials, are likely to be made by those family members who are fluent in English and younger. Social class appears to be more important than ethnicity, and older South Asian people and those from working-class backgrounds appear to be more mistrustful.

Objective 4: identification of how professionals regard the involvement of South Asian patients and their views on strategies to increase participation

Perhaps the most important finding of this study is that South Asian patients might be systematically excluded from clinical trials owing to professional perceptions of the increased cost and time associated with their inclusion. The language barrier was frequently given as a reason for low participation rates amongst South Asian people. It might be the case that the health professionals experienced recruiting older South Asian people, those from predominantly lower socio-economic backgrounds and those new to the UK – all of whom are likely to have English language as a barrier to communication.

Other explanations for South Asian under-representation in clinical trials might be due to their passive exclusion as a result of cultural myths and stereotypes, held by some health professionals. Although linguistic barriers between South Asian health professionals and their patients may not be present, there are other barriers of social class and education. Like all professionals, South Asian health professionals are socialised into particular ways of perceiving patients; internalisation of stereotypes, therefore, is not surprising. Class difference may also explain why matching trial recruiters (same ethnicity as the target population) was found to be an ineffective strategy in the experience of one respondent. It might also be the case that white investigators are afraid to approach South Asian trial patients owing to misunderstandings and confusion about their culture. Such misunderstandings can be overcome by providing training in cultural sensitivity and by deconstructing cultural myths and stereotypes.

It is also possible that organisational policies and practices within the NHS effectively discriminate against those people for whom language is a barrier to communication. Exclusion from clinical trials due to the inability of the NHS to provide a culturally sensitive service suggests a form of institutional racism in which minority ethnic populations are denied the same opportunities as the general population. Similarly, lack of positive action amongst health professionals in recruiting South Asian people to trials is another facet of institutional racism. Other aspects of institutional racism identified in this study include staff poorly trained in the recruitment of a culturally diverse population, poor structure and organisational support for running clinical trials and discriminatory attitudes. An accusation that institutional racism operates in the recruitment of South Asian people to clinical trials does not imply that the health professionals are racist. The findings presented here suggest that institutionally racist policies within the NHS may be more of a barrier to South Asian participation in clinical trials than the South Asian individual's reluctance itself.

Institutional racism can be used to explain the failings of public institutions to respond to the needs of ethnic minority people. At the heart of institutional racism is the premise that 'same service for all equates with an equal service for all'. This either results in ethnic minority people getting their needs ignored (for example, disregard of dietary, linguistic and cultural needs) or their needs are misinterpreted and used against them (owing to poorly informed assumptions about cultural differences, race and ethnicity). Health professionals' accounts indicate that South Asian people may be actively excluded from clinical trials owing to different facets of institutional racism, which manifest themselves as

lack of cultural sensitivity and awareness of specific needs, discriminatory behaviour at point of recruitment, structural barriers (due to poor access to trial-rich sites) and lack of positive action by health professionals.

Rather than recognising a strong familial identification as an important cultural aspect of South Asian people, some health professionals may be deterred from obtaining consent from this group of people. The challenge for the NHS is, therefore, to develop culturally appropriate methods of obtaining consent, while at the same time meeting the requirements of ethics committees. There is also a need to understand that decision-making is not necessarily an autonomous process and that important decisions, such as participation in clinical trials, are a matter that concerns significant members of the family. It is not uncommon for other ethnicities, including the majority white, to have strong familial identification, and major decisions such as participation in clinical trials are usually negotiated within families. The 'inability of South Asian women to enter a clinical trial without first consulting their husbands' was another issue which a number of health professionals found frustrating. In fact, some women would consult their English-speaking husbands because they were acting as interpreters.

An important first step for health professionals is to be sensitive to a patient's socio-cultural beliefs and perspectives and not to become involved in cultural stereotyping. It is also essential that health professionals recognise individual differences, because people of the same ethnicity can vary enormously in their beliefs and practices. South Asian under-representation might also be due to a mixture of the particular requirements of groups not being met (e.g. cultural and language needs) but equally, also, to some people choosing not to participate in trials because they mistrust the healthcare system owing to previous bad experiences in the NHS.

Empirical findings suggest that unfamiliarity with the South Asian culture means that some health professionals tend to adhere to stereotypes concerning South Asian people. Fear of the unknown or a lack of familiarity with South Asian culture on the part of some health professionals is one of the explanations for South Asian under-representation in clinical trials.

Respondents' accounts also suggest that South Asian doctors may also hold stereotypes and although linguistic barriers between them and their patients may not be present, there are other barriers of social class and education. Differences in access to clinical trials may, therefore, reflect the class structure of society and of health professionals who have more in common with middle-class patients. Differences in social class have been shown to distort the doctor–patient communication process and it is likely that class differences also play a role in South Asian under-representation in clinical trials.

Valuing diversity in healthcare research and acknowledging an individual's culture in its broadest sense (including taking into account a patient's ethnicity, age, gender, education, socio-economic status, religion and prior health experiences) are important factors which should not be overlooked when conducting any type of research. Recognising these aspects and acknowledging their influence on health in reported findings may also prevent stereotyping and exclusion.

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Contributions of authors

Mah Hussian-Gambles (Research Fellow, Healthcare Studies) conducted the literature review; recruited participants; conducted the face-to-face interviews; analysed the data; contributed to report writing and checking; responded to referees' comments; and met on a regular and ongoing basis during the study, with formal meetings held at least monthly to discuss study progress.

Dr Brenda Leese (Reader in Primary Care Research) managed the project; contributed to the intellectual development of the study; advised on methodology and analysis; met on a regular and ongoing basis during the study, with formal meetings held at least monthly to discuss study progress; took the major role in writing the HTA report; and coordinated response to referees' comments.

Dr Karl Atkin (Senior Lecturer, Primary Care) contributed to the intellectual development of the project; advised on methodology and analysis; met on a regular and ongoing basis during the study, with formal meetings held at least monthly to discuss study progress; contributed to report writing; and responded to referees' comments.

Julia Brown (Head of Unit Clinical Trials Research Unit) contributed to the intellectual development of the project; advised on methodology; discussed study progress; and contributed to the revision of the report.

Dr Su Mason (Principal Research Fellow, Clinical Trials Research Unit) contributed to the intellectual development of the project; advised on methodology; discussed study progress and contributed to the revision of the report.

Dr Philip Tovey (Principal Research Fellow, Healthcare Studies) led project design, monitoring form and content of initial interviews; advised on methodology and analysis; had *ad hoc* meetings with lead researcher during fieldwork; checked final report and responded to referees' comments.

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Appendix 1

Involving South Asian Patients in Clinical Trials

Interview Schedule for Professionals

RESEARCH OBJECTIVES

- **Investigate dangers of exclusion and the practical difficulties of inclusion**
- **Identify strategies for increasing participation**
- **Explore approaches taken by ethics committees to improve participation**

Introduction: (fill in consent form)

- **Interviewer to introduce themselves and CRPC.**
- Introduce study *(we are trying to find out about health professionals' experiences, views, beliefs and ideas about involving South Asian patients in clinical trials. This research will help us to recommend better ways of giving information to Asian people about taking part in medical research and also give health professionals guidance for improving recruitment rates.)*
- **Assure confidentiality (whatever you say will be confidential and no names will be used in our final report).**
- **Ask permission to use tape recorder.**

1. Background information

Could we start by asking you to say a bit about yourself …

- **Could you start by telling us about your role and involvement with clinical trials in general?**
  What types of trials, are some more successful than others?

- Have you been involved in trials in which ethnic minorities have participated?

2. Clinical trial participation

- **Are you aware of any differences in the level of recruitment of older people, women and ethnic minorities to clinical trials?**
  Your personal beliefs/ideas about under-representation, older people and osteoporosis trials

- Do you think that's an issue that needs to be addressed?

  (a) Is that because there are differences in the way drugs behave in different groups?

  (b) Are there biological differences between races?

3. Barriers to recruitment

The next two questions are about all groups, not just ethnic minorities

- **Do you think there are any barriers which prevent physicians from recruiting patients to participate in clinical trials?**

- **Do you think there are any barriers which prevent patients from participating in clinical trials?**

- **Do you think there are any barriers which prevent ethnic minority physicians from recruiting patients to participate in clinical trials?**

- **Do you think there are any barriers which prevent South Asian patients from participating in clinical trials?**

- **Is distrust of the medical profession an issue for the patients, do you think?**

- **In your experience, do you think there is anything in the beliefs or practices of researchers, which act as barriers to South Asian patients entering trials?**
  Such as the belief that South Asian patients are non-compliant, takes too long to explain the study to them.

- Do you think there is a difference in the way different health professionals communicate with patients in general, when recruiting for a trial?
  For example, are South Asian patients more likely to respond to an invitation by a nurse or a consultant?

  (a) If nurse, is it something about the way they behave?

4. South Asians and clinical trial participation

- **Can you think of any reasons why South Asians will be less willing to participate in trials than the white population or other ethnic groups (ACs)?**
  For example, distrust, logistical difficulties or just simply, they don't get to know about trials.

- Do you think there are differences between the South Asian community, other ethnic groups (ACs) and the white population in terms of the level of and type of information required about them participating in clinical trials?
  For example, need to explain what a trial is, consent forms, etc.

- Do you believe that there is anything in the way of life of South Asian patients which influences their decision to participate or not in trials?
  For example, do they look at illness and health in a different way to the white population, time keeping, social class?

- Do you think religious influences play a role in the decision to participate or not in clinical trials?
- **What do you think are the most important things to think about in terms of methods of recruitment from South Asian communities?**
  For example, staff who are racially similar, presence of interpreters, etc.

5. Personal beliefs

- What consensus of opinion is there between your colleagues; are there any issues they disagree with regarding recruitment of South Asian people in trials?
  Have you ever come across interesting beliefs or been concerned by the views of other health professionals with regards to South Asian recruitment into trials

- **Can you think of any instances in the past which would make you reluctant to recruit South Asian patients in trials?**
  Such as cultural barriers, lack of support from peers, lack of ethnic minority patients, language problems

- Do you think that recruitment of South Asians is dependent on organisational structure within the NHS or departmental bureaucracy?
  For instance, does it depend on political views and actions of principal investigators rather than the availability of interpreters.

6. Finishing off

- **Do you think there are any differences between Leeds and Bradford when it comes to recruiting South Asian patients?**
  In what way are they different?

- Do you know of any interventions which increased or improved recruitment of patients?
  How have you gone about doing that?
  How applicable is it to South Asian patients?
  In what way?

7. The Way Forward

Thinking now about all that we have discussed, what messages would you like to give the HTA about South Asian involvement in clinical trials?

Thank you very much for giving your time and telling me about your views and experiences, do you mind if we keep in touch with you during the course of this research? I might need some contacts.

If you think of anything else please email me or call, you have my details on the information sheet.

I will be sending you a copy of the report when it is all finished, by the end of 2003.

Appendix 2

Involving South Asian Patients in Clinical Trials

Interview Schedule for Lay People

RESEARCH OBJECTIVES

- **Explore awareness of and perspectives on clinical trial participation**
- **Investigate awareness and understanding of the informed consent process**
- **Explore perceptions of risks and benefits of participation in trials**
- **Identify factors and circumstances affecting decision-making**

Introduction: (fill in consent form)

- **Interviewer to introduce themselves and CRPC.**
- Introduce study *(we are trying to find out about South Asian people's experiences, views, beliefs and ideas about getting involved in clinical trials. This research will help us to recommend better ways of giving information to Asian people about taking part in medical research and also give health professionals guidance for improving recruitment rates.)*
- **Assure confidentiality (whatever you say will be confidential and no names will be used in our final report).**
- **Ask permission to use tape recorder.**

1. Background information

Could we start by asking you to say a bit about yourself …

- **What comes to your mind when you hear the term clinical trials or medical research? What does the term medical research mean to you? If new concept to them then explain.**
- **What are your general feelings about medical research?** *Do you think it is a good thing or a bad thing? Are there any benefits or dangers of taking part in trials?*
- Do you know anyone who was asked to participate or did participate in medical research?
- Would you consider taking part in medical research?
- What are the reasons why you might participate?
- What are the reasons you might not participate?

- Would your decision to participate depend on factors like how you get on with your doctor?
  Is trust in the medical profession an important issue for you?

- Is there anything the doctors should do to make it easier to take part in trials?
  In relation to clinical trial process, consent form, information sheet etc.

2. Informed consent

- *Have you heard of informed consent? Are you aware of legal protections for participants in medical research?*
  Do you know the purpose of informed consent? Explain if need to.

  Probe: Informed consent
  Adequate disclosure of information
  Patient's ability to understand information
  Voluntary choice.

- Can the process of informed consent or information sheets be made more user friendly in any way?

- *Do you feel that language is a problem? (e.g. access to interpreters, use of jargon)*
  If relevant who provides interpreting for you?
  why do/don't you use professional interpreters?

3. Decision-making

- Would you make the decision to take part in the trial yourself?
  How involved is your family in making decisions in general?
  Any gender differences, e.g. wife and husband?

- Are you more or less likely to enter a trial if it was somebody you knew?
  Coercion by doctor, should doctors make that decision for you?

4. South Asians and clinical trial participation

- **Can you think of any reasons why South Asians will be less willing to participate in trials than the white population?**
  For example, distrust, logistical difficulties or just simply, they don't get to know about trials.

- Do you think there are differences between the South Asian community and the white population in terms of the level of and type of information required for them to participate in clinical trials?
  For example, need to explain what a trial is, consent forms, etc.

- Do you believe that there is anything in the way of life of South Asian patients which influences their decision to participate, or not in trials?
  For example, do they look at illness and health in a different way to the white population, time keeping, social class.

- Do you think religious influences play a role in the decision to participate or not in clinical trials?

- **What do you think are the most important things to think about in terms of methods of recruitment from South Asian communities?**
  For example, staff who are racially similar, presence of interpreters, etc.

5. The Way Forward

Thinking now about all that we have discussed, what messages would you like to give the HTA about South Asian involvement in clinical trials?

What recommendations do you have for researchers to improve South Asian participation in research?

Thank you very much for giving your time and telling me about your views and experiences, do you mind if we keep in touch with you during the course of this research? I might need some contacts. If you think of anything else please email me or call, you have my details on the information sheet.

Appendix 3

Involving South Asian Patients in Clinical Trials

Interview Schedule for Trial Participants

CENTRE FOR PRIMARY RESEARCH IN CARE

RESEARCH OBJECTIVES

- **Explore perspectives on clinical trial participation**
- **Investigate awareness and understanding of the informed consent process**
- **Explore perceptions of risks and benefits of participation in trials**
- **Identify barriers and motivation for involvement in trials**
- **Identify factors and circumstances affecting decision-making**

Introduction: (fill in consent form)

- Interviewer to introduce themselves and CRPC.
- Introduce study *(we are trying to find out about your experiences, views, beliefs and ideas about taking part in clinical trials. I would particularly like to know about how you were treated when first approached and during the trial. This research will help us to recommend better ways of giving information to Asian people about taking part in medical research and also give health professionals guidance for improving recruitment rates.)*
- **Assure confidentiality (whatever you say will be confidential and no names will be used in our final report).**
- **Ask permission to use tape recorder.**

1. Background information

Could we start by asking you to say a bit about yourself …

- Could you start by telling us about your involvement and experience of taking part in a clinical trial?
  starting with your initial diagnosis …
  Explain if not sure what a CT is.

- Were you aware of clinical trials before your (illness)?

- Did you understand what was going on when approached to enter a trial?
  How was the subject raised, what were your initial reactions?
  Did you understand the doctor's explanation about the trial?

- What was your response, were you given enough time to think about your decision?
  Did you ask questions? (what kind, why not?)

- Where specifically were you recruited?
  A hospital or a cancer centre, were there any differences in the way you were treated there?
  For instance, what were the health professionals like, their attitudes to you?
  What was the service like, how long did you have to wait?

- What are your general feelings about medical research?
  Are there any benefits or dangers of taking part in trials?
  Explore if they would participate again?

- Is trust in the medical profession an important issue for you?
  Would your decision to participate depend on factors like how you get on with your doctor?

- Is there anything the doctors should do to make life easier?
  In what respect?
  In relation to clinical trial process, consent form, information sheet, etc.

2. Informed consent

- *Have you heard of the term informed consent (giving permission to take part), or understand what it means?*
  Explain if need to.
  Did you have any problems with the idea, what kind of information or advice have you been given?
  How easy or difficult has it been to get the information you need?
  Where were you given the information? (Surgery, hospital, home, community centre)

Who gave you this information?
How was the information given to you (verbal/written/audiotape/videotaped)

Has this information been helpful?

- *Are you aware of legal protections for participants in medical research?*
  Probe: *Informed consent*

Adequate disclosure of information
Patient's ability to understand information
Voluntary choice

- Did you have enough time to consider your participation in the trial?

- Can the process of informed consent or information sheets be made more user friendly in any way?

Did you know what you were agreeing to, what was good what was bad?

- *Do you feel that language is a problem? (e.g. access to interpreters, use of jargon)*
  If English was not good, how was this overcome?
  Understand and unpick barriers to understanding
  If relevant who provides interpreting for you?
  why do/don't you use professional interpreters?

- Have you heard of the randomisation process in clinical trials?
  If appropriate.

3. Decision-making

- Did you make the decision to take part in the trial yourself?

How involved was your family in deciding whether to participate in the trial?
Any gender differences, e.g. wife and husband? If such advice, what was it?

- Are you more or less likely to enter a trial if it was somebody you knew?
  Coercion by doctor, should doctors make that decision for you?

- About your decision to participate, were you influenced by anything or anyone?
  Coercion by doctor, should doctors make that decision for you?

- Would you wish (based on the information that you receive) to decide about participation on your own, or would you wish the doctor to decide about participation on your behalf?

4. Barriers to recruitment

Mention statistical under-representation in trials, ask what they think the reasons may be for this?

- Do you think there is a difference in the way different health professionals communicate with patients in general, when recruiting for a trial?
  For example, are South Asian patients more likely to respond to an invitation by a nurse or a consultant?

  (a) If nurse, is it something about the way they behave?

  (b) Do you think there are any reasons which prevent physicians from recruiting South Asian patients to participate in clinical trials?

5. South Asians and clinical trial participation

- **Can you think of any reasons why South Asians will be less willing to participate in trials than the white population?**
  For example, distrust, logistical difficulties or just simply they don't get to know about trials.

- Do you think there are differences between the South Asian community and the white population in terms of the level of and type of information required for them to participate in clinical trials?
  For example, need to explain what a trial is, consent forms, etc.

- Do you believe that there is anything in the way of life of South Asian patients which influences their decision to participate, or not in trials?
  For example, do they look at illness and health in a different way to the white population, time keeping, social class?

- Do you think religious influences play a role in the decision to participate or not in clinical trials?

- **What do you think are the most important things to think about in terms of methods of recruitment from South Asian communities?**
  For example, staff who are racially similar, presence of interpreters, etc.

6. The Way Forward

Thinking now about all that we have discussed, what messages would you like to give the HTA about South Asian involvement in clinical trials?

Thank you very much for giving your time and telling me about your views and experiences, do you mind if we keep in touch with you during the course of this research? I might need some contacts.

If you think of anything else please email me or call, you have my details on the information sheet.

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CRC Professor and Director of Medical Oncology, Christie CRC Research Centre, Christie Hospital NHS Trust, Manchester

Professor F D Richard Hobbs,
Professor of Primary Care & General Practice, Department of Primary Care & General Practice, University of Birmingham

Professor Allen Hutchinson,
Director of Public Health & Deputy Dean of ScHARR, Department of Public Health, University of Sheffield

Dr Duncan Keeley,
General Practitioner (Dr Burch & Ptnrs), The Health Centre, Thame

Dr Donna Lamping,
Research Degrees Programme Director & Reader in Psychology, Health Services Research Unit, London School of Hygiene and Tropical Medicine, London

Mr George Levvy,
Chief Executive, Motor Neurone Disease Association, Northampton

Professor James Lindesay,
Professor of Psychiatry for the Elderly, University of Leicester, Leicester General Hospital

Professor Rajan Madhok,
Medical Director & Director of Public Health, Directorate of Clinical Strategy & Public Health, North & East Yorkshire & Northern Lincolnshire Health Authority, York

Professor David Mant,
Professor of General Practice, Department of Primary Care, University of Oxford

Professor Alexander Markham,
Director, Molecular Medicine Unit, St James's University Hospital, Leeds

Dr Chris McCall,
General Practitioner, The Hadleigh Practice, Castle Mullen

Professor Alistair McGuire,
Professor of Health Economics, London School of Economics

Dr Peter Moore,
Freelance Science Writer, Ashtead

Dr Andrew Mortimore,
Consultant in Public Health Medicine, Southampton City Primary Care Trust

Dr Sue Moss,
Associate Director, Cancer Screening Evaluation Unit, Institute of Cancer Research, Sutton

Professor Jon Nicholl,
Director of Medical Care Research Unit, School of Health and Related Research, University of Sheffield

Mrs Julietta Patnick,
National Co-ordinator, NHS Cancer Screening Programmes, Sheffield

Professor Robert Peveler,
Professor of Liaison Psychiatry, University Mental Health Group, Royal South Hants Hospital, Southampton

Professor Chris Price,
Visiting Chair – Oxford, Clinical Research, Bayer Diagnostics Europe, Cirencester

Ms Marianne Rigge,
Director, College of Health, London

Dr Eamonn Sheridan,
Consultant in Clinical Genetics, Genetics Department, St James's University Hospital, Leeds

Dr Ken Stein,
Senior Clinical Lecturer in Public Health, Director, Peninsula Technology Assessment Group, University of Exeter

Professor Sarah Stewart-Brown,
Director HSRU/Honorary Consultant in PH Medicine, Department of Public Health, University of Oxford

Professor Ala Szczepura,
Professor of Health Service Research, Centre for Health Services Studies, University of Warwick

Dr Ross Taylor,
Senior Lecturer, Department of General Practice and Primary Care, University of Aberdeen

Mrs Joan Webster,
Consumer member, HTA – Expert Advisory Network

Feedback

The HTA Programme and the authors would like to know your views about this report.

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We look forward to hearing from you.

The National Coordinating Centre for Health Technology Assessment,
Mailpoint 728, Boldrewood,
University of Southampton,
Southampton, SO16 7PX, UK.
Fax: +44 (0) 23 8059 5639 Email: hta@soton.ac.uk
http://www.ncchta.org

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