Engaging patients from minority ethnic groups with clinical trials for blood cancer

Dr Andrew Smart

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About the author

Andrew Smart is a Reader in Sociology at Bath Spa University. His work explores the intersection between ethnicity and biomedical science, including the participation of minority ethnic groups in biomedical research (www.bathspa.ac.uk/our-people/andrew-smart/).

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Introduction

Long standing concerns about ethnic disparities in medical research have been brought to the forefront by prominent public protest about racial discrimination and the unequal impact of the Covid-19 pandemic on people from minority ethnic groups. Clinical trials are centrally important to the process of developing new treatments and can give some patients access to treatments that they would not otherwise have. However, many clinical trials struggle to enrol patients, and people from minority ethnic groups appear to be particularly underrepresented. Ensuring that clinical trials are representative of ethnic diversity has the potential to improve the validity and generalisability of studies and address ethnic inequalities and discrimination. This report examines these issues in the context of blood cancer, explaining both the potential barriers and solution for addressing the underrepresentation of patients from minority ethnic groups in UK clinical trials.

Blood cancers

Approximately 40,000 people are newly diagnosed with blood cancer in the UK each year,[1] and a total of around 240,000 people are living with blood cancer.[2] It is the commonest form of cancer in children, teenagers and young people, and the fifth commonest in adults.[3]

There are more than 100 types of blood cancer, including various sub-types of lymphoma, leukaemia and multiple myeloma. Some blood cancers have a rapid onset and are often diagnosed in Accident and Emergency; others are monitored, potentially for many years, before treatments are started.[4] A variety of factors may cause or contributing to blood cancer, and there are differences in treatments, responses and outcomes.[5]

Approximately 15,000 people with blood cancer die each year.[6] Increasingly, however, people are living for many years after diagnosis; some are cured while others have ongoing treatment.[7] Patients with chronic blood cancer require treatment for the rest of their lives.[8] 6 in 10 of people diagnosed with blood cancer survive for 10 or more years.[9]

Blood cancers and minority ethnic groups

The is ethnic diversity in blood cancer (see chapter 'Ethnic variations in disease incidence and clinical trials participation'). People from some minority ethnic groups appear to have higher rates of some sub-types of blood cancer. Rates of multiple myeloma are higher among Black African and Black Caribbean men and women.[10] Rates of leukaemia are slightly higher among Pakistani men, women and children, and Black African women.[11] The risks of 'lymphomas and reticulendothelial neoplasms' is higher for children in the 'Asian' and 'Black' groups,[12] and rates of some lymphomas are slightly higher among Pakistani and Black African men and women, and Indian men.[13] The true extent of ethnic variations in blood cancer in the UK, however, remains somewhat unclear because of limitations in the data that has been collected and published.

Population variation can also become relevant in some treatments for blood cancer. A donor stem cell (allogeneic) transplant can be used to treat some types of leukaemia, lymphoma, and multiple myeloma. While initiatives to encourage stem cell donors from minority ethnic groups[14] mean that the UK stem cell registry now broadly matches UK demographics,[15] efforts to increase the number of such donors continue as this will improve the likelihood that patients will be able to find a suitable match.

The importance of clinical trials

Clinical trials are an essential part of the medical research process that test the safety and efficacy of new medicines and other health interventions. For patients whose treatment options are limited, clinical trials may take on an added importance. Some blood cancers are not treatable using surgery or radiotherapy, so the development of new drugs and access to them can be especially important.[16] As such, the boundary between research and treatment can be blurred.[17] For some patients, participating in a clinical trial can be the only, and may be the best, treatment option.[18] Being part of a clinical trial may present a patient with the opportunity to have access to a new treatment before it is approved.[19] Patients with blood cancer in some clinical trials have had better health outcomes than those who did not participate,[20] although there is disagreement about whether it can be claimed that trial treatments are generally superior to 'standard' care.[21]

Underrepresentation of patients from minority ethnic groups

Work to improve rates of participation in clinical trials is ongoing,[22] as many UK clinical trials fail to reach their original targets for patient enrolment.[23]

An underrepresentation of people from minority ethnic groups in UK clinical trials has been recognised for many years,[24] including in cancer research.[25] In US cancer research, concerns have existed for even longer and remain unresolved despite efforts to increase rates of participation.[26] Only 20% of clinical trial results published in leading oncology journals analyse results by race or ethnicity, and only 2% of research is focused on cancer sub-types that disproportionately affect minority ethnic groups.[27]

Why ethnic diversity in clinical trials is important

Ensuring that clinical trials are ethnically diverse can improve the quality of research and help to create a body of evidence that reflects the UK population. Enrolling patients from diverse ethnic groups can enhance the validity and generalisability of studies[28] and enable analysis that explores differences between groups, if such differences exist.[29]

The unwarranted exclusion of people from minority ethnic groups from research risks perpetuating health inequalities,[30] may contradict legal duties that aim to prevent discrimination,[31] and can lead to claims of institutional racism.[32]

Barriers and solutions

Various factors influence the enrolment of any patient into a clinical trial, with overlaps between issues that are patient-related and those that relate to professional practice. Some factors, like understanding and access, can become relevant to some patients from minority ethnic groups in particular ways, while others, namely mistrust and cultural and language difference, are specific to some patients from minority ethnic groups. Discussions of the 'barriers' to clinical trials often focus on patient-related concerns, although one US review found that 'structural and clinical' issues like eligibility criteria and access to trial settings made participation unachievable for more than three quarters of patients.[33]

The cancer research community has developed strategies for improving enrolment to clinical trials,[34] and general initiatives have been developed in relation to minority ethnic groups.[35] In the context of cancer research, there appears to be a 'correspondence' between health professional and Black Britons about the barriers that are hampering participation.[36] This correspondence suggests that the concerns of potential participants are understood, but that effective solutions have not yet been implemented.

Some patients with blood cancer report uncertainty, distress and anxiety in connection to issues such as the complexity and 'invisibility' of the disease, accessing care and living with a long-term condition.[37] These problems might plausibly exacerbate the barriers to clinical trials faced by some patients from minority ethnic groups. As such, blood cancer patients from minority ethnic groups may experience particular intersections of difficulties in relation to clinical trials participation.

Scope of the report

This project aims to support Blood Cancer UK's Clinical Trials Support Service by investigating the underrepresentation of minority ethnic groups in the context of UK clinical trials for blood cancer. The research examined existing information on:

- ethnic variations in disease incidence and clinical trials participation.
- reasons for ethnic differences in rates of participation in clinical trials.
- strategies for increasing rates of clinical trials participation among patients from minority ethnic groups.

The project was supported by an Advisory Group of patient representatives and professionals from healthcare and health charities. Advisory Group members participated in a private capacity, not as representatives of their employers or other organisation. The group met twice, first to discuss key barriers and then to discuss potential solutions. Involving a range of stakeholders in the project generated invaluable insights from particular perspectives and provided feedback on the direction and development of the work. Advisory Group members have commented on issues and findings that they think are particularly important (see chapter 'Advisory Group Comments').

Sources

There is very little information that directly addresses questions about clinical trial participation among patients with blood cancer from minority ethnic groups in the UK. As such, this report drew together information about the participation of UK patients from minority ethnic groups in medical research,[38] especially in relation to clinical trials[39] and patients with cancer.[40] However, even in this wider field there is a paucity of academic literature. As much of the research in this area has occurred in the US,[41] including in relation to clinical trials for patients with cancer,[42] information from US studies was used to provide a wider context.

While this report identifies key barriers and potential solutions, the shortage of UK research highlights that there are gaps in knowledge and evidence. There is great diversity between and within ethnic groups, and patient experiences may differ depending on their health context. As such, it is difficult to draw broad conclusions from the existing body of knowledge. More research is needed to better understand the nature, extent and impact of ethnicity on decisions to participate in UK clinical trials.

Terminology: underrepresentation and enrolment

This report will use the term 'underrepresentation' but recognises that there are variations in how to judge population-level differences in rates of participation in medical research. There are debates about whether representativeness should be judged based on the proportion of an ethnic group in the general population, or relative to particular disease risk.[43] Being 'available' to be involved in some clinical trials may differ between ethnic groups due to differences in the age profile of groups relative to the general population[44] and differences in disease prevalence.[45]

The report will use the term 'enrolment' to refer to the whole process of facilitating patient participation in clinical trials but recognises that this may blur distinctions between activities that may be separately viewed as 'recruitment' and 'retention'.

Terminology: ethnicity and minority ethnic groups

The ideas of race and ethnicity, and the terms and categories that describe racial or ethnic groups can be contentious. While race and ethnicity are distinct concepts, they are often used in indeterminate, interchangeable and overlapping ways in medical research, policy-making and everyday life. For example, the census categories for England and Wales are described as 'ethnic' and yet use racialised terms – While, Black, Asian – for a primary categorisation that frames finer-grained choices (eg, 'White/White British', 'Black/Black African', 'Asian/Pakistani'). These categories are commonly used in health research, and when the finer-grained distinctions are not reported, this leaves apparently 'racial' difference between White, Black and Asian patients. This is problematic for reasons that extend beyond the scope of this report. Suffice to say that if differences in health outcome between such racialised groupings are simplistically interpreted as reflecting biological differences between 'races' they will likely misrepresent the realities of genetic ancestry, meaningful social group boundaries and the role of cultural and socio-environmental factors in health.

The report will favour the term ethnicity, or racial/ethnic if this better represents what is being described. It will use specific ethnic group labels where possible, and if a more general grouping is needed, it will use terms such as Black British, Black Britons or people from minority ethnic groups. However, in order to accurately describe the work of others, it will also replicate the terms and categories used by the original authors (relatively common examples are 'South Asian' or 'British South Asian', and 'White', 'Black' and 'Asian' group).

Endnotes

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Executive Summary

Ethnic variations in disease incidence and clinical trials participation

- The available data shows ethnic variations in the rates of cancer, including in blood cancers where higher risks of myeloma, and slightly higher risks of leukaemia and lymphoma have been reported among particular minority ethnic groups.
- Rates of participation of patients with cancer in clinical trials have risen, and variability exists according to factors like age, location and form of cancer.
- In 2018-19 over 107000 patients with cancer were involved in research, about 45% of whom were in 'interventional' studies.[46] This included 12012 patients with blood cancer, 3019 of whom (25%) were in 'interventional' studies. Based on the numbers of people involved in 'interventional' studies, haematology was the 6th largest speciality area. Given that approximately 40,000 people are newly diagnosed with blood cancer in the UK each year, it can be estimated that participation rates in clinical trials for blood cancer patients are about 7.5% of incident cases in 2018-19.
- Participation in medical research and clinical trials may be influenced by a range of demographic, attitudinal and experience factors, and may also differ relating to the study design, the form of cancer and location of treatment
- There is evidence to suggest an underrepresentation of people from minority ethnic groups in medical research and clinical trials, including in relation to clinical trials for patients with blood cancer.
- Some evidence suggests that there are not racial/ethnic differences in levels of willingness to participate in research or in rates of participation once people are deemed 'eligible', leading to calls for the research community to be more effective in addressing potential barriers to participation.
- More accessible and up-to-date data could improve understanding of ethnic variations in patterns of illness, and the absence of consistent and available data on the ethnicity of participants in clinical trials makes it impossible to conclusively judge patterns of involvement as a whole.

Reasons for ethnic differences in rates of participation in clinical trials

- Altruistic and personal motivations, and interpersonal relationships with health professionals, are key drivers of participation in clinical trials.
- Many factors influence the enrolment of patients into clinical trials, with intersections between those issues facing patients and those issues facing health professionals.
- Factors that may influence patients in general include awareness, preferences about treatment, concerns (about randomisation, safety, etc.), understanding, perceptions (of benefits, trust and the clinicians' views) and practical or financial matters.
- Factors that may influence health professionals in general include awareness and availability of trials, workload, eligibility criteria, views on the trial and suitability of patients, awareness of patient preferences and concerns and communicating about uncertain balances of risks and benefits.

- Some of the above-listed factors may become particularly relevant to some patients from minority ethnic groups, while other, namely, mistrust and cultural and language difference, are specific to some patients from minority ethnic groups.
- Factors relating to health professions that limit the participation of patients from minority ethnic groups include eligibility criteria (comorbidities and language restrictions); the impact of prejudices, biases and stereotypes on patient enrolment; the availability and appropriateness of information about research; access to healthcare sites where trials are occurring; and the commitment to meaningfully address the problem in research policy and practice.
- In terms of patient-related factors, mistrust appears to be broad-based and related to historical and contemporary patterns and experiences of discrimination; it seems to be clearest (but not exclusively or universally) among Black Britons.
- Issues of cultural, including religious, difference may relate to perceptions of health, disease, medicine, treatment and mortality, including issues of stigma; familial or communal approaches to decision-making; concerns about modesty, medical ingredients or the giving of body parts; and interpretations of practices surrounding research ethics.
- English language proficiency creates issues in the interactions between patients and professionals, in the use of interpreters or translated written materials and in the involvement of family members in clinical encounters. It may make trials participation and research ethics procedures awkward. Issues of English proficiency seems to be clearest (but not exclusively or universally) among British South Asian patients.
- Patients with blood cancer have varied experiences, but some report uncertainty, distress and anxiety in connection to: the complexity of blood cancer (including in diagnosis, terminology, treatment options and experiences of care); feelings of invisibility due to relatively low public awareness of blood cancer and the absence of obvious signs of ill health for some patients; the practical and psychological burdens of living with a long-term condition; and difficulties in accessing care.

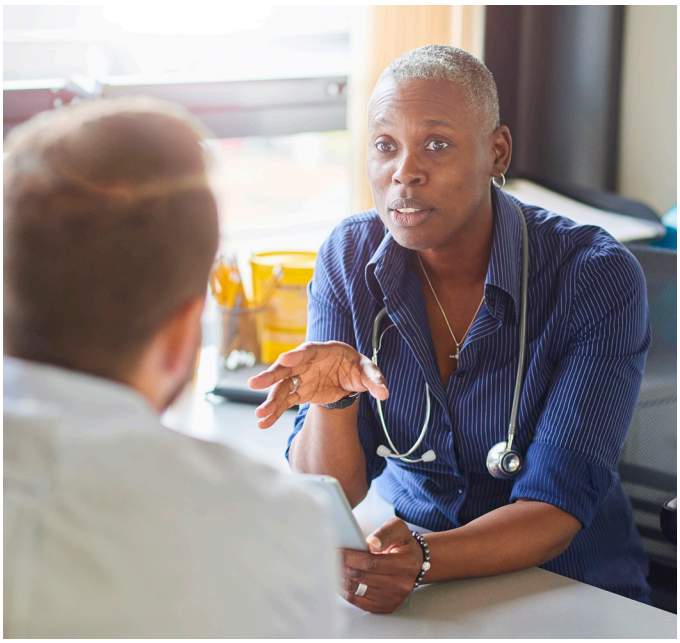
- The above-noted problems that can face patients with blood cancer might exacerbate the barriers to clinical trials faced by some patients from minority ethnic groups. Issues of mistrust, language difference and understanding may be exacerbated by the complexity of blood cancer, and by feelings of anxiety, isolation and uncertainty connected to coping with long-term health conditions, especially ones that might not be obviously visible and well-recognised. Psychological concerns about clinical trials may by exacerbated by the anxieties and uncertainties related to feelings of invisibility, or to living with a chronic condition. Financial or logistical problems may be exacerbated if people experience fragmented healthcare, or if services are not locally available. Research is needed to understand if these issues are affecting participation in clinical trials for blood cancer patients from minority ethnic groups.
- When considering the representation of people from minority ethnic groups in clinical trials, it is important to remember that significant differences exist between minority ethnic groups and within them (including in relation to age, gender, socio-economic status, religiosity, etc.).
- Given the paucity of research in the UK, understanding about the extent, nature and impact of ethnicity on participation in clinical trials is limited and care should be taken not to generalise from the limited evidence that does exist.

Strategies for increasing rates of clinical trials participation among patients from minority ethnic groups

- Successfully encouraging patients to participate in clinical trials has been associated with various practices, although health context, trial designs and socio-demographic factors (ethnicity, age, gender and education) may affect the effectiveness of different strategies for different groups of people.
- Strategies for improving enrolment to clinical trials for patients with cancer include checklists built around recurrent themes and issues, and a process for identifying barriers and addressing them through training.
- Suggestions for increasing participation among patients from minority ethnic groups were reported around the following themes: building trust, cooperation and understanding; appropriate and accessible information; trial design and practice; developing person-centred research and researcher competences; and research system issues
- With respect to building trust, cooperation and understanding, suggestions centred on meaningful practices of community engagement (both for specific trials and for medical research more broadly) and thinking about who patients perceive to be trustworthy communicators (including people such as GPs or other trial participants).
- Providing appropriate and accessible information must involve attending to language issues (eg, thinking about translation, interpreters, format, support and inclusive language and images). Providing more information about the study drug or procedure and greater transparency about available treatment options could also help to address issues of mistrust. Patient support groups, especially those regarded as trustworthy by people from minority ethnic groups, could be well placed to provide general information and support.
- In terms of trials design and processes, there should be clarity about the study population, why people from minority ethnic groups should be involved in the research and how to reach them. Also, trial designs should avoid restrictive eligibility criteria (eg, comorbidities and language restrictions) and burdensome study protocols, and consider how to address potential barriers around finance, logistics and research ethics processes.

“Suggestions for increasing participation among patients from minority ethnic groups were reported around the following themes: building trust, cooperation and understanding; appropriate and accessible information; trial design and practice; developing person-centred research and researcher competences; and research system issues.”

- With respect to person-centred research, framing research as a cooperative endeavour could help to address issues of mistrust and cultural and language difference. Developing health professionals' interpersonal and communication skills could support them to manage situations that can be emotional and difficult, to reflect on their own attitudes or biases and to enable patients to be fully, actively and sensitively engaged in discussions. This should include considerations about cultural and structural competence to ensure interactions between patients and professional are sensitive to, and able to address, potential differences in outlooks and experiences. Large research organisations should consider ways to ensure all their trials activities are appropriately supported and advised.
- At the level of over-arching research systems and policymaking, the lack of reliable and consistent data has been long-recognised, and a range of organisational level recommendations have previously been made to support and incentivise change. While the UK does not have specific legislation like that developed in the US to support the inclusion of minority ethnic groups in health research, research organisations should be ensuring that their activities meet to the requirements of the Equalities Act 2010.
- Practices for facilitating the involvement of people from minority ethnic groups in clinical trials are in use in the UK, although these appear to be limited in scope and the effectiveness of different strategies remains unclear.



- Initiatives and resources to support health researchers have been developed. These place the onus on researchers to tailor strategies for engagement and participation that reflect the needs and concerns of the people that they wish to enrol in their studies.
- Blood Cancer UK's Clinical Trials Support Service could support patients and their carers by developing culturally and linguistically appropriate information; facilitating access to networks of trusted individuals and organisation; and developing a person-centred approach to enrolment based on cultural and structural competence and relational communication. It could support health professionals involved in clinical trials by developing awareness about ethnic disparities and strategies for improving clinical trial designs and patient enrolment; by promoting and supporting community engagement; and by sharing knowledge and networks for key skills and support. It could raise awareness of clinical trials through community engagement activities and by sharing information about ethnic disparities.
- Blood Cancer UK could also address ethnic disparities in blood cancer research by advocating for a central resource of material to support public and professional awareness, understanding and action; for policies that incentivise appropriate attention to issues of ethnic diversity in the health sector; for improved data collection and sharing to facilitate understanding of ethnic differences relating to blood cancer; for health research organisations to be accountable for addressing ethnic disparities; and for research to better understand the extent, nature and impact of ethnicity on participation in clinical trials.

Endnotes

46 NIHR CRN nd

1. Ethnic variations in disease incidence and clinical trials participation

To understand questions about the participation of people from minority ethnic groups in clinical trials, this chapter will consider:

1. ethnic variations in the rates of cancer, particularly blood cancers
2. rates of participation of patients with cancer in clinical trials
3. factors that influence participation in medical research and clinical trials
4. ethnic variability in participation in medical research and clinical trials, especially in relation to cancer studies

1. Ethnic variations in rates of cancer

- Reports using data about cancer incidence and survival from England have shown ethnic variations in the rates of cancer.[47] Finding from these data need to be treated with caution due to limitations in the collection and reporting of ethnicity data,[48] and a lack of analysis of the different age structures of ethnic groups.[49]
- Taken as a whole, rates of cancer are lower in minority ethnic groups compared to the 'White group',[50] although men in both 'Black' and 'White' groups have equal risk,[51] and Black Caribbean, Black African and Pakistani children have higher risks than those in the 'White' group.[52] Furthermore, some forms of cancer are more common in patients from minority ethnic groups:
    - rates of colorectal cancer are higher among men in the 'Black' group.[53]
    - rates of stomach cancer are higher among those in the 'Black' group.[54]
    - rates of liver cancer are higher among those in the 'Asian' group.[55]
    - women in the 'Asian' group have higher rates of mouth cancer, and higher rates of cervical cancer in over 65-year-olds.[56]

Blood cancers

- Similarly, the risk of most sub-types of blood cancer is higher among those in the 'White' group[57] but there are instances where people from minority ethnic groups are at greater risk.

Multiple myeloma

- Multiple myeloma (from here on in, myeloma) is more common among those in the 'Black' group compared to those in the 'White' and 'Asian' groups.[58] It has been estimated that Black Britons have 2 - 2.5 times higher rates of myeloma, while British South Asian men have lower rates than those in the 'White' group.[59] The risks are higher for both men and women identifying as Black African and Black Caribbean.[60]
- This finding corresponds with US experience, where black Americans comprise 20% of patients with myeloma, but only 13% of the US population.[61] Myeloma is the commonest form of blood cancer among black Americans; they are 2-3 times more likely than white Americans to develop the disease and its precursor condition; and they are more likely to be diagnosed at a younger age.[62]

> "The available data shows ethnic variations in the rates of cancer, including in blood cancers where higher risks of myeloma, and slightly higher risks of leukaemia and lymphoma have been reported among particular minority ethnic groups."
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Leukaemia

- Using the broad 'race' categories, Leukaemia is more common in men in the 'White' and 'Black' groups than for men in the 'Asian' group.[63]
- However, analysis using the more finely grained ethnic group categories shows Pakistani men and women and Black African women have slightly higher risks compared to those in the 'White' group.[64]
- Looking specifically at children, all those in the 'Asian' group have a 30% increased risk compared to those in the 'White' group, with those identifying as Pakistani being at the greatest risk (almost 60%).[65]

Lymphomas

- Some sources say the risks of lymphomas do not appear to vary by ethnicity,[66] while others report that British South Asians have lower rates of non-Hodgkin lymphomas and higher rates of Hodgkin lymphomas.[67]
- Analysis using the more finely grained ethnic group categories suggests that, when compared to the 'White' group:
  - Pakistani men and women and Indian men (and to a lesser extent, Black Caribbean men) have slightly higher rates of Hodgkin lymphoma.[68]
  - Black African men and women and Pakistani men have slightly higher rates of non-Hodgkin lymphoma.[69]
- Looking specifically at children, compared to those in the 'White' group, the risks of 'lymphomas and reticulendothelial neoplasms' are 50% higher in the 'Asian' group and 75% higher in the 'Black' group.[70]

2. Rates of participation of patients with cancer in clinical trials

- Prior to 2001, participation rates in clinical trials for cancer patients were less than 3.5% of incident cases, and a National Cancer Research Network (NCRN) was created to facilitate UK cancer research.[71] Participation rates 'in clinical trials and other well-designed studies' in 2008-2010 were 'reaching 17% of the incident cancer population'.[72]
- In 2018-19 over 107000 patients with cancer were involved in research, about 45% of whom were in 'interventional' studies. In terms of the numbers of people involved in research, haematology was the 6th largest speciality area (after breast, urology, head and neck, colorectal and upper gastrointestinal). In terms of the numbers of people involved in 'interventional' studies, haematology was the 6th largest speciality area (after colorectal, upper gastrointestinal, breast, urology, and lung).[73]

- In 2018-19, 12012 patients with blood cancer were involved in research, 3019 of whom (25%) were in 'interventional' studies.[74] Given that approximately 40,000 people are newly diagnosed with blood cancer in the UK each year,[75] it can be estimated that participation rates in clinical trials for blood cancer patients are about 7.5% of incident cases in 2018-19.
- The 2012-13 National Cancer Patient Experience Survey (NCPES) found that 30.4% of patients had had discussions about research and 18.9% had taken part in research (generally, not specifically clinical trials).[76] In 2019, 30% of respondents were still reporting that they had had discussions about research, but the question about participation is no longer asked.[77]
- There is some variability in participation in clinical trials in oncology. For example, in terms of age, there are 'higher accrual rates of paediatric patients', but teenagers over 15 and young adults with cancer have lower rates of participation.[78] There is also variability within the UK, with lower rates of participation in Northern Ireland (2.2%), although it should be noted that this is specifically for participation in 'an interventional cancer clinical trial'.[79] In Northern Ireland, participation was higher in clinical trials for patients with haematological malignancies (4.5%).[80]

3. Factors influencing participation in medical research and clinical trials

- While the focus of this report is on minority ethnic groups, it should be recognised that a range of factors are associated with engagement with medical research and clinical trials.
- It is useful to offer some context using research from the US where the factors that play a role can include income, education, age, the presence of chronic conditions, previous participation, having a friend or relative with an illness, favourable attitudes toward medical research and study design.[81] In relation to clinical trials for cancer interventions, older patients[82] and women with some forms of cancer (head and neck, colorectal and lung)[83] are less likely to participate.
- In the UK, the 2012-13 NCPES found[84]:
  - older patients and those with some additional long-standing conditions were less likely to be asked to take part in research and less likely to be taking part in research.
  - women were less likely to have been asked to take part in research, but not less likely to participate in research.
  - patients with haematological cancer had the highest proportions of research participation (71.7% of 3842 patients) and were most likely to participate in research (almost twice as likely as patients with breast cancer).
  - patients' willingness to participate in research can change over time.
  - discussions about research participation and also rates of participation were greater in particular healthcare settings (specialist or teaching hospital trusts).
- With respect to clinical trials more specifically:
  - UK patients with cancer were more likely to express a willingness to participate in a hypothetical trial if they had previous experience of trials, if they were male and if they were younger (70 or under).[85]
  - patient uptake of specific clinical trials for a variety of cancers, in contrast to the above finding, did not find associations between accepting a place on the trial and gender or age, or on disease stage or tumour type.[86]

- association between participation and trial design or setting was not found in one study,[87] but was found in another, where people were more likely to decline a trial that compares standard treatment to a novel therapy and different treatment duration, and more likely to accept a trial that compares a standard treatment to a standard treatment plus a new treatment.[88]
- the 'timing' of an invitation to participate in a trial has also been linked to decision-making, with a risk of adding to patient anxiety if an approach is made too soon after diagnosis.[89]

4. Ethnic variability in participation in medical research and clinical trials, especially in relation to cancer studies

- While we know that 732,176 participants took part in 6052 medical research studies in England in 2019/20,[90] the NIHR does not systematically collect or report on data that disaggregates participation by ethnic group.
- Concerns about a lack of inclusion of participants from minority ethnic groups has been reported in medical research[91] and in clinical trials:
  - people from minority ethnic groups comprise 13.8% of the population, yet only comprised 9.58% of participants in COVID-19 intervention studies and 5.72% of participants in vaccine studies.[92]
  - South Asian patients were underrepresented in six clinical trials covering a range of conditions.[93]
  - South Asian patients were more likely to be excluded from a clinical trial for cardiac rehabilitation.[94]
  - mental health trials in the UK and other European countries have a lack of participation from minority ethnic groups.[95]
- The 2012-13 NCPES found ethnic variation in research participation (after controlling for other relevant factors). Patients from minority ethnic groups were not less likely to have had discussions about research, but Asian/ Asian British and Black/ Black British patients were less likely to have taken part in research (29% and 37% respectively).[96] This is participation in 'research' generally, not specifically clinical trials. The NCPES 2019 no longer asks if people took part in research, but it shows that people from minority ethnic groups are more likely to be asked to take part in research (White 24.6%, Asian 30.9%, Black 34.8%). However, it also shows that, having been asked, they are also more likely to have been deemed ineligible (White 3.7%, Asian 4.1%, Black 5.2%).[97]
- There is evidence that patients with cancer from minority ethnic groups are less likely to participate in clinical trials, for example:
  - an analysis of 64 studies found the 'odds of being in a trial were 30% lower for a member of a minority ethnic groups compared to a white cancer patient' after controlling for gender, age and diagnosis/ disease. It was specifically patients identifying as black or Chinese that had less likelihood of involvement.[98]
  - a multi-national trial, including 9 UK trials centres, comparing three treatments for prostate cancer on over 1500 men reported that 'less than 1% of the participants enrolled in this trial were of African–Caribbean ancestry'.[99]
- With respect to blood cancers in particular it is necessary to look at data from the US. It has been shown that found that African Americans make up 20% of patients with myeloma but only 4.5% of those in clinical trials.[100] Two recent multi-national myeloma trials for treatments both had less than 3% of trial participants who identified as black.[101] One review of US myeloma clinical trials found that the racial/ethnic composition of the trial sample was reported in less than 40% of studies, and that in those that did report their sample, 'the proportion of minority individuals was half the expected'.[102] Another review of 9 large myeloma trials found the enrolment of patients from minority ethnic groups had decreased over time.[103]
- Some caution should be exercised when interpreting this evidence, and again it is useful to look at research from the US for context. Ethnic differences in participation rates in clinical trials for cancer treatments have been long recognised.[104] Research has revealed that, compared to white respondents, African Americans have more

negative attitudes towards clinical trials, particularly trials for medications, and express less willingness to participate in research.[105]

- However, other studies find racial/ethnic differences in rates of participation but not differences in levels of willingness to participate.[106] Furthermore, they find that once people are deemed 'eligible' for research, there are not racial/ethnic disparities in rates of participation.[107] Similar findings have been found in the UK.[108] It has been argued that the research community may be reducing opportunities for patients from minority ethnic groups to participate and that it needs to more effective in addressing the known barriers to participation.[109]

Key findings

- The available data shows ethnic variations in the rates of cancer, including in blood cancers where higher risks of myeloma, and slightly higher risks of leukaemia and lymphoma, have been reported among particular minority ethnic groups.
- Rates of participation of patients with cancer in clinical trials have risen, and variability exists according to factors like age, location and form of cancer.
- In 2018-19 over 107000 patients with cancer were involved in research, about 45% of whom were in 'interventional' studies. This included 12012 patients with blood cancer, 3019 of whom (25%) were in 'interventional' studies. Based on the numbers of people involved in 'interventional' studies, haematology was the 6th largest speciality area. Given that approximately 40,000 people are newly diagnosed with blood cancer in the UK each year, it can be estimated that participation rates in clinical trials for blood cancer patients are about 7.5% of incident cases in 2018-19.
- Participation in medical research and clinical trials may be influenced by a range of demographic, attitudinal and experience factors, and may also differ relating to the study design, the form of cancer and location of treatment.
- There is evidence to suggest an underrepresentation of people from minority ethnic groups in medical research and clinical trials, including in relation to clinical trials for patients with blood cancer.
- Some evidence suggests that there are not racial/ethnic differences in levels of willingness to participate in research or in rates of participation once people are deemed 'eligible', leading to calls for the research community to be more effective in addressing potential barriers to participation.
- More accessible and up-to-date data could improve understanding of ethnic variations in patterns of illness, and the absence of consistent and available data on the ethnicity of participants in clinical trials makes it impossible to conclusively judge patterns of involvement as a whole.

Endnotes

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2. Reasons for ethnic differences in rates of participation in clinical trials

To understand the reasons for participation rates and the variability in them, this chapter will consider:

1. motivations to participate in clinical trials
2. barriers to enrolling patients into clinical trials
3. barriers to clinical trials for patients from minority ethnic groups
    a. factors related to health professionals
    b. patient-related factors
4. the experiences of patients with blood cancer that might exacerbate the barriers to participation

1. Motivations to participate in clinical trials

- People participate in clinical trials because of the potential personal benefits (ie, improved health outcomes, or incentives) and the potential social benefits of supporting medical research,[110] including in interventions for cancer.[111] These broadly instrumental and altruistic motivations are similarly evident among South Asian people discussing asthma research[112] and Black Britons discussing myeloma research.[113] South Asian trial participants also view their contribution as 'particularly beneficial to the South Asian Community' when involved in trials where South Asian patients were underrepresented or in disease areas that disproportionately affect South Asians.[114]
- Interpersonal relationships with health professionals, including trust in them and a desire to help them, are also an important motivation for participation in clinical trials among patients with cancer.[115] Similarly, in research on minority ethnic groups, some Bangladeshi participants regarded involvement in medical research as a 'favour' to the researcher,[116] while one South Asian patient reported taking part in a clinical trial 'out of an 'obligation' to his GP'.[117]

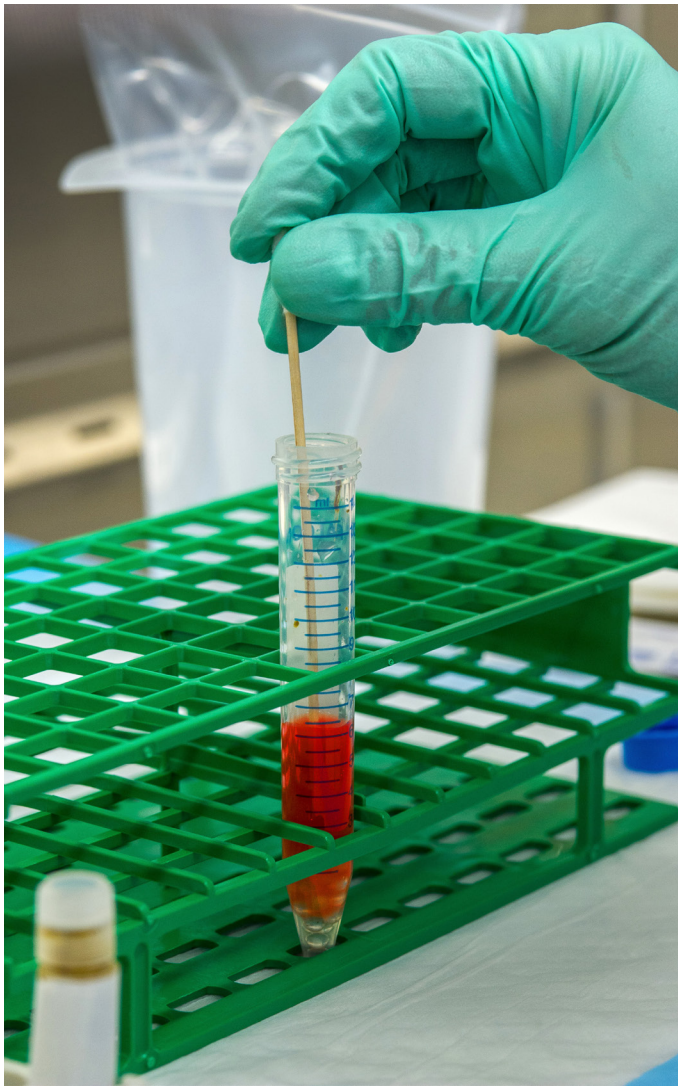
2. Barriers to enrolling to clinical trials

- The factors influencing participation in clinical trials are multiple, complex and overlapping,[118] with intersections between issues that are patient-related and those that relate to professional practice. The factors noted below are drawn from studies that focus partially or largely on research involving cancer patients in the UK.
- In relations to patients, barriers can include:
    - having a treatment preference.[119]
    - worries or concerns about
        - uncertain outcomes, including safety.[120]
        - randomisation and the experimental nature of trials, including not wanting a study drug, placebo or additional procedures.[121]
        - confidentiality.[122]
        - the impacts on their treatment.[123]

    - stigmatisation during the trial (of smokers).[124]
    - the disease or treatment in general.[125]
    - participation being upsetting.[126]
  - not wanting more treatment.[127]
  - understanding trial design, including equipoise.[128]
  - perceptions of a lack of personal benefit (especially in a phase 1 trial).[129]
  - distrust of the doctor.[130]
  - practical, logistical or financial issues, including accessing trial locations.[131]
- Research on US patients with cancer shows a similar pattern of issues[132] but also include not being informed of trials, concerns about their relationship with their physician and their perception of the physician's attitude towards the trial.[133]
- In relation to health professionals, barriers can include:
  - workload, time and resources relating to enrolment.[134]
  - identifying patients that meet eligibility criteria.[135]
  - their views about the trial.[136]
  - their views about the suitability of patients for the trial.[137]
  - awareness about trials.[138]
  - awareness of patients' treatment preferences and concerns about randomisation.[139]
  - concern that a trial might imply a criticism of their current practice.[140]
  - juggling research and clinical roles when dealing with patient eligibility, the effectiveness of interventions and equipoise.[141]
- Research on US practitioners echoes these issues and also includes communicating about the uncertain balance of risks and benefits of cancer clinical trials,[142] and problems with the availability of trials in particular healthcare settings or in the context of health insurance.[143]

3. Barriers to clinical trials for patients from minority ethnic groups

- Many barriers to participation in clinical trials are common regardless of ethnicity,[144] but some can be especially relevant to some patients from minority ethnic groups, or they may be expressed in particular ways for those patients. Other barriers, namely those surrounding mistrust and culture and language difference, are specific to some patients from minority ethnic groups.
- It is important to note diversity within and between ethnic groups. Difference in participation have been found within and between the groups compressed into the 'South Asian' category, with variations noted in relation age, gender, socioeconomic status, culture, religion, spoken language and language proficiency.[145]
- Given this diversity, and the lack of research in this area, it is difficult to generalise from the findings reported below. Further research is necessary to better understand the nature, extent and impact of ethnicity on participation in clinical trials.



3.1 Factors related to health professionals

Eligibility

- Clinical trial exclusion criteria can be a general barrier to clinical trials enrolment that can be expressed in specific way for patients for minority ethnic groups. Diabetes mellitus, hypertension and heart disease exist in higher rates in some minority ethnic groups.[146] Some argue that the unequal rates of such disease are themselves - in part - explained by socio-structural inequalities and systemic racism.[147] Regardless of the causes, when clinical trials for cancer treatments exclude potential participants if they have these comorbidities, patients from some minority ethnic groups are more likely than other patients to be excluded.[148]
- Inappropriate exclusion from clinical trials due to language ability is claimed to be a 'major barrier' for British South Asian patients.[149] One survey of the National Institute for Health Research (NIHR) portfolio of mental health studies found that 64% 'completely excluded participants unable to communicate in English'.[150] Such exclusions are linked to the additional costs of employing translators, interpreters or staff with specific 'cultural or linguistic skills',[151] or costs of additional targeted enrolment activities.[152]

Judgments about enrolling patients

- Some general issue about judging who to invite and who is 'suitable' for a clinical trial may be exacerbated by factors relating to ethnicity. Such judgements are shaped by a combination of 'the values, norms and mores of healthcare professionals' and the prejudices, biases and stereotypes they hold about people from minority ethnic groups.[153] This may include assumptions about a patient's willingness to be involved in a trial and their ability to comply with a trial regime,[154] which may mean that some people are simply not asked.[155]
- Furthermore, awareness of potential cultural difference among health professionals (eg, that Black Britons might mistrust the medical establishment) can actually manifest (consciously or unconsciously) as a reluctance to try to enrol black patients.[156]
- Interviews with UK health professionals involved in blood cancer care and trials reveal a 'reticence in talking about ethnicity within a clinical research or clinical trial context' and an assumption that ethnicity was not 'immediately relevant outside of London'.[157]

Information provision

- The availability and appropriateness of information about trials is a general issue that may include factors relating to ethnicity. Black Britons discussing clinical trials for blood cancer reported that access to information was partial, with patients at larger trials centres or with connections to patient networks being 'more in the know'.[158] This included information about treatment and trials generally, and information that was relevant to all patients, including those from minority ethnic groups.[159]

Access to trials sites

- Access to trials sites is a general issue that may include factors relating to ethnicity. People from minority ethnic groups in the UK are more likely to live in urban centres and particular towns and regions.[160] Furthermore, those identifying as Pakistani, Bangladeshi, Black Caribbean and Black African are more likely to be among those in lower socio-economic status groups.[161] Given the socio-economic disparities between ethnic groups, the underrepresentation of minority ethnic groups in clinical trials can be seen as 'caused in part by 'racially' constructed socio-economic factors'.[162]
- The problem of 'access' is thus connected to the geographical proximity of healthcare settings that are offering clinical trials and the availability and costs of transportation. This has been reported among British South Asians[163] and by Black Britons discussing clinical trials for blood cancer.[164]

Meaningfully addressing the problem in research policy and practice

- Research that examined underrepresentation of minority ethnic groups in the 100000 Genomes Project highlighted a range of shortfalls in service planning and delivery.[165] These included: 'assumptions about the way things are done; a lack of investment of time in community engagement; adopting a tick-box approach to engagement and failing to see that there is an equality vacuum where decision making becomes culturally bound due to a lack of diversity in organisations.'[166] In the context of myeloma research it has been argued that the voices of people from minority ethnic groups 'are still missing from the agenda'.[167]

3.2 Patient-related factors

Mistrust

- Among African Americans, mistrust in clinical trials[168] can be specifically linked to a 'history of exploitation and mistreatment'[169] and continuing experiences of racism and social marginalisation. The Tuskegee Syphilis Study and the case of Henrietta Lacks are the most well-known examples that implicate medical research in this wider pattern of discrimination.[170] African Americans have greater knowledge of the Tuskegee Syphilis Study, lower levels of trust in medical research, and a greater belief that minorities bear most of the risks of medical research.[171]
- Similar outlooks and concerns exist among Black Britons.[172] Research on participation in clinical trials for blood cancer found positive associations with the idea of clinical trials and a generally high level of respect for medical professionals. However, associations 'between clinical trials and negative historical or current events' were common.[173] Knowledge of the Tuskegee Syphilis Study or the Henrietta Lacks case was not always detailed but it was linked to fears including unwitting involvement in experimentation or removal of bodily materials (although such knowledge was not always a barrier to participation in trials). Clinical trials were thus linked to ideas of vulnerability, exploitation and discrimination that extended beyond a general sense of the potential harms of involvement and into the idea that black people were 'absorbing a higher level of risk'.[174] Participants saw themselves as being part of 'less influential' social group who were 'at a higher risk of mistreatment'; a view that was common even among those who trusted their doctors.[175] Such concerns also related to blood donation, bone marrow donation, organ donation and fears regarding the purpose, use and privacy of medical data.[176] Doubts about the motives of the scientists and concerns about whether black patients would receive the claimed benefits of research were also expressed.[177]
- Issues of trust have also been found among respondents identifying as Arabic and Chinese, with the former related to concerns about group exploitation, and the latter related to concern about data usage.[178]
- Trust in medical research might be influenced by knowledge, perceptions or experiences of medical research in other countries. For example, British South Asians may have been negatively influenced by perceptions of medical research practices on Indian subcontinent.[179] When declining trial participation, mistrust of trial organisations is a main factor for Indians, both in India and elsewhere.[180]
- British South Asian can have good level of trust in clinical trials teams.[181] British South Asian and White British cancer patients have similarly high levels of trust for health professionals,[182] but British South Asian patients prefer to have sensitive information communicated to them by someone of a 'similar religion or background' (BSA 38.1% versus WB 7.4%).[183]

> "Issues of mistrust, language difference and understanding may be exacerbated by the complexity of blood cancer, and by feelings of anxiety, isolation and uncertainty connected to coping with long-term health conditions, especially ones that might not be obviously visible and well-recognised."
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Understanding study design and concepts: randomisation and placebo

- Key ideas in study design, like randomisation and placebo, are not always understood by patients in general, which can give rise to concerns about safety and efficacy. This issue has been reported among African Americans[184] and Black Britons.[185] The term 'clinical trials' sometimes had negative connotations for Black Britons, including concerns that they were 'haphazard', that new drugs might be unsafe or that placebos might be given instead of treatment.[186] It is important to recognise that 'general' concerns might be experienced differently by those in minority ethnic groups due to the above-noted issues of mistrust, and issues of culture and language discussed below.
- The cultural specificity of clinical trials research may also be an issue as '[t]he concept of clinical trials is a Westernised one, and as yet, may not have become part of the 'cultural repertoire' of the ethnic minority communities in the UK, or that of the general population'.[187] While unfamiliarity with the concepts and practices of clinical trials is not exclusive to minority ethnic groups, it may be exacerbated by the above-noted issues of mistrust, and issues of culture and language discussed below.

Ethno-cultural or ethno-religious issues

- Trial participation may be influenced by perceptions of disease, treatment benefits and mortality that are ethnically variable. Outlooks that equate cancer with death, and show fatalism about potential interventions, have been reported among South Asians.[188] A study of British South Asian patients found they were more likely than White British patients to view cancer as incurable and more likely to attribute it to fate.[189]
- British South Asian patients are also more likely than those who are White British to want to restrict knowledge about a cancer diagnosis to people within the family, suggesting that it is seen as a stigma for an individual and their family.[190] This may relate to perceptions about fertility and marriage found in the context of other illnesses.[191] However, patients who had migrated directly from the Indian subcontinent were much more likely to report a desire to restrict information about a diagnosis than so-called 'African Indians' who arrived in the UK after first migrating to Africa.[192] Indian trial participation, both in India and elsewhere express worries about confidentiality in relation to employment, insurance, personal life and marriage.[193]
- While discussing blood cancer trials, Black Britons expressed ethno-cultural understandings of health and the body connected to herbalism or holism.[194] There is also evidence that alternative medicine shapes the outlooks of people identifying as Arabic and Chinese,[195] and conflicting findings about its influence on the views of British South Asian patients.[196]
- Muslim participants in medical research may have concerns related to the ingredients of medicinal products, or the giving of body parts.[197]
- British South Asians patients have expressed concerns about gender and modesty.[198] Among clinical trial participants, these issues were more like to arise in trials related to gynaecological and breast health, and social class also influenced patient decision-making.[199] Other gendered issues about autonomy in decision-making and practices of chaperoning have been found in respondents identifying as Indian, Pakistani and Arabic. [200]
- Potential cultural variability may impact on the interpretation of administrative practices surrounding research ethics.[201] For example, a requirement 'to sign a consent form may imply a lack of trust' and hinder participation among people originating from an oral culture.[202] While disquiet and ambiguities about consent processes can be general, the uncertainties aired by South Asian patients may relate to issues of mistrust,[203] culture and language.[204]

- Decisions to participate in research are guided by an individualistic conception of the patient. Patients from minority ethnic groups may have more familial or communal approaches, which might constrain decision-making or act as source of positive encouragement.[205] Among Black Britons, decisions to participate in a trial could be influenced by the 'wider community'.[206] British South Asian patients may see participation in a clinical trial as a 'collective decision taken by the family',[207] although research has also found that some patients made decisions alone and others discussed them with their families.[208]

Language and literacy (including in research ethics practices)

- In the context of cancer care, it has been found that language issues exist in relation to sharing information in families, the clinical interaction between health professional and patient, and clinical interactions involving interpreters.[209] Where healthcare interactions involve family members as translators or supporters this may have implications for what information is shared and how it is communicated (which may be shaped by cultural or religious expectations).
- The provision of information for decision about participation in research relies on written and verbal communication, which raises issues about patient literacy. Addressing concerns about literacy are not exclusive to patients from minority ethnic groups (or universal to them).[210] However, 'general' literacy concerns might be experienced differently by those in minority ethnic groups, again related to potential issues of mistrust and culture. Among South Asian patients, the lack of language appropriate information has been perceived as showing a lack of respect.[211]

- English language competency is 'a major barrier to South Asian participation in clinical trials'.[212] It can make participation in clinical trials 'uncomfortable or intimidating'.[213] Aspects of the consent process, for example the 'what if something goes wrong' section of the information sheet, can create confusion and wariness for some patients.[214] Older South Asian patients have reported confusion and uncertainty during trial participation, with some requiring the support of family members.[215] There is concern that this leads to discrimination against such patients.[216]
- The availability and appropriateness of translators or translated materials can be a problem. For example, Hindi translations that are classical rather than colloquial may be ineffective, Gujarati translations may be unhelpful as it 'is largely a spoken language' and some direct translations for technical terms do not exist.[217] Understanding the idea of research itself can be a main barrier to participation where interpreters have difficulty finding a suitable translation for the word 'research'.[218] There is a concern that where a person's 'main language does not have a widely agreed written form', research ethics processes that centre on written information provision and informed consent are a barrier to participation.[219]

Financial concerns and 'trial burden'

- Financial concerns are not specific to patients from minority ethnic groups, but some minority ethnic groups are more likely to be among those in lower socio-economic status groups and as such it is hard to 'disentangle issues relating to poverty from those related to ethnicity'.[220]
- British Social Asian trial participants have expressed concerns about potential loss of income or additional costs (eg, extra travel),[221] and various 'trial burdens' related to employment, financial issues (such as childcare, travel and disruptions to daily life),[222] education or family commitments.[223]

Experiences of discrimination

- It has been shown that health-related beliefs, attitudes and behaviour can be influenced by the sense of social isolation associated with being in a minority group.[224] Interviews with British Social Asian trial participants revealed that some 'believed 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.'[225]

Psychological factors

- While psychological factors are not specific to patients from minority ethnic groups research on minority ethnic groups has noted issues of stress, denial and avoidant behaviour,[226] lack of confidence, fear of the unknown,[227] fear of treatment and anxiety that something 'new' might be found.[228] These 'general' concerns might be experienced differently by those in minority ethnic groups due to issues of mistrust and issues of language and cultural difference.[229]

4. The experiences of patients with blood cancer that might exacerbate the barriers to participation

- The experiences of patients with blood cancer are varied, but some report uncertainty, distress and anxiety in connection to:
    - the complexity of diagnosis in some blood cancer, including misdiagnosis, especially for myeloma.[230]
    - the variety and complexity of types of blood cancer, including the fact that the word cancer does not appear in the name of disorders.[231]
    - the complexity of treatments that can sometimes involve multiple drugs.[232]
    - the visibility, or invisibility, of blood cancer: obvious signs of ill health are absent in some patients, who can report feeling 'fake'[233]; also, the relatively low public awareness of blood cancer may contribute to feelings of anxiety and isolation.[234]
    - the duration of 'the patient journey', which can be long or even life-long: patients might be required to 'watch and wait' until treatment starts, which can be distressing; many patients relapse, which creates ongoing anxiety and uncertainty tied to medical appointments.[235]
    - the fragmented experience of care, which may involve navigating a range of different services and professionals[236] in haematology and oncology, and in primary and secondary care.[237]
    - the local availability of care for haematology.[238]
- Such problems might exacerbate the barriers to clinical trials faced by some patients from minority ethnic groups. Problems for patients from minority ethnic groups related to trust, language and understanding may be increased by the complexity of blood cancer (including in diagnosis, terminology, treatment options and experiences of care), and by feelings of anxiety, isolation and uncertainty connected to coping with long-term health conditions, especially ones that might not be obviously visible and well-recognised.
- Such problems may also exacerbate the psychological and financial or logistical barriers to clinical trials that can face patients from minority ethnic groups. Psychological concerns about clinical trials may by increased by the anxieties and uncertainties related invisibility, or to coping with long-term health conditions. Furthermore, if blood cancer patients from minority ethnic groups are worried about taking part in a clinical trial because of financial or logistical problems, these may be worsened if they experience fragmented healthcare, or if services are not locally available.
- However, these suggested intersections between the context of blood cancer and the barriers facing some patients from minority ethnic groups remain speculative. Further research is needed to better understand the factors that may limit participation in clinical trials for various types of blood cancer, not only those relating to the concerns of patients, including patients from a variety of minority ethnic groups, but also the barriers that may exist within the research community.

Key findings

- Altruistic and personal motivations, and interpersonal relationships with health professionals, are key drivers of participation in clinical trials.
- Many factors influence the enrolment of patients into clinical trials, with intersections between those issues facing patients and those issues facing health professionals.
- Factors that may influence patients in general include awareness, preferences about treatment, concerns (about randomisation, safety, etc.), understanding, perceptions (of benefits, trust and the clinicians' views) and practical or financial matters.
- Factors that may influence health professionals in general include awareness and availability of trials, workload, eligibility criteria, views on the trial and suitability of patients, awareness of patient preferences and concerns and communicating about uncertain balances of risks and benefits.
- Some of the above-listed factors may become particularly relevant to some patients from minority ethnic groups, while other, namely, mistrust and cultural and language difference, are specific to some patients from minority ethnic groups.
- Factors relating to health professions that limit the participation of patients from minority ethnic groups include eligibility criteria (comorbidities and language restrictions); the impact of prejudices, biases and stereotypes on patient enrolment; the availability and appropriateness of information about research; access to healthcare sites where trials are occurring; and the commitment to meaningfully address the problem in research policy and practice.
- In terms of patient-related factors, mistrust appears to be broad-based and related to historical and contemporary patterns and experiences of discrimination; it seems to be clearest (but not exclusively or universally) among Black Britons.
- Issues of cultural, including religious, difference may relate to perceptions of health, disease, medicine, treatment and mortality, including issues of stigma; familial or communal approaches to decision-making; concerns about modesty, medical ingredients or the giving of body parts; and interpretations of practices surrounding research ethics.

- English language proficiency creates issues in the interactions between patients and professionals, in the use of interpreters or translated written materials and in the involvement of family members in clinical encounters. It may make trials participation and research ethics procedures awkward. Issues of English proficiency seems to be clearest (but not exclusively or universally) among British South Asian patients.
- Other patient-related issues like understanding of trials processes and concepts and psychological factors are also important, and these can be experienced differently by patients from minority ethnic groups because of the issues of mistrust and cultural and language differences. Financial and logistical concerns can be experienced by patients from minority ethnic groups as they may be more likely to be among those in lower socio-economic status groups.
- Patients with blood cancer have varied experiences, but some report uncertainty, distress and anxiety in connection to: the complexity of blood cancer (including in diagnosis, terminology, treatment options and experiences of care); feelings of invisibility due to relatively low public awareness of blood cancer and the absence of obvious signs of ill health for some patients; the practical and psychological burdens of living with a long-term condition; and difficulties in accessing care.
- The above-noted problems that can face patients with blood cancer might exacerbate the barriers to clinical trials faced by some patients from minority ethnic groups. Issues of mistrust, language difference and understanding may be exacerbated by the complexity of blood cancer, and by feelings of anxiety, isolation and uncertainty connected to coping with long-term health conditions, especially ones that might not be obviously visible and well-recognised. Psychological concerns about clinical trials may by exacerbated by the anxieties and uncertainties related to feelings of invisibility, or to living with a chronic condition. Financial or logistical problems may be exacerbated if people experience fragmented healthcare, or if services are not locally available. Research is needed to understand if these issues are affecting participation in clinical trials for blood cancer patients from minority ethnic groups.
- When considering the representation of people from minority ethnic groups in clinical trials, it is important to remember that significant differences exist between minority ethnic groups and within them (including in relation to age, gender, socio-economic status, religiosity, etc.).
- Given the paucity of research in the UK, understanding about the extent, nature and impact of ethnicity on participation in clinical trials is limited and care should be taken not to generalise from the limited evidence that does exist.

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3. Strategies for increasing rates of clinical trials participation among patients from minority ethnic groups

To understand the reasons for participation rates and the variability in them, this chapter will consider:

1. Successful enrolment to clinical trials, and overarching strategies for improving enrolment to clinical trials for patients with cancer
2. Facilitating increased participation among patients from minority ethnic groups
    a. Building trust, cooperation and understanding
    b. Appropriate and accessible information
    c. Trial design and practice
    d. Developing person-centred research and researcher competences
    e. Research system issues
3. The current use of solutions in clinical trials practices, and recent initiatives to support the participation of patients from minority ethnic groups
4. Lessons for Blood Cancer UK

1. Successful enrolment to clinical trials, and overarching strategies for improving enrolment to clinical trials for patients with cancer

- Successful enrolment to clinical trials has been associated with:
    - timely intervention to key clinical questions.[239]
    - using dedicated research staff.[240]
    - training research staff about the trial process and intervention.[241]
    - straightforward data collection.[242]
    - prioritising the convenience of participants.[243]
    - effective communication about the benefits of the study to individuals, families and the common good.[244]
    - using incentives.[245]

- Strategies to improve enrolment have focused on potential participants, those enrolling participants or on the trial design or process. Successful approaches have been shown to be:
    - multiple contacts with potential participants.[246]
    - telephone reminders.[247]
    - 'opt-out' procedures for contacting potential participants.[248]
    - using 'open' trial designs, where participants are aware of which treatment they are receiving.[249]
- However, the effectiveness of different strategies may vary.[250] The health context, research design (eg, clinical trials using placebos or randomisation) and socio-demographic factors (ethnicity, age, gender and education) may all affect which strategies work and whether they work for some groups of people and not others.[251]
- Strategies have been developed to facilitate more inclusive clinical trials,[252] including in oncology in the UK,[253] such as:
    - checklists of specific issues facing patients and professionals,[254] or of broad themes which promote a multi-stakeholder approach.[255]
    - the QuinteT Recruitment Intervention process which first seeks to understanding the context-specific barriers to enrolment, and then develops training and support to help to address these.[256]

2. Facilitating increased participation among patients from minority ethnic groups

- Attempts to increase participation in clinical trials among patients from minority ethnic groups have focused on issues that are patient-related and those that relate to professional practice.[257] As there are substantial overlaps in some aspects of the proposed strategies, this section will be organised by 5 key themes: building trust, cooperation and understanding; appropriate and accessible information; trial design and practice; developing person-centred research and researcher competences; and research system issues.

a. Building trust, cooperation and understanding

Community engagement – specific and general

- Engagement can be specific to a research project or more general outreach activities. Approaching engagement in a spirit of dialogue, rather than 'education', may promote mutual understanding. This could allow medical researcher to acknowledge the concerns that people may have and gain insights into how trust can be established; it may prompt thinking about how medical research activities can fit alongside a range of values and beliefs. Engagement activities may need to consider timing (in relation to cultural or religious activities) and may require translators.[258]
- Engagement about specific projects is recommended throughout the research process, from initial planning through to honest and appropriate feedback at the end of the study.[259] Engagement can help to build trust[260] and to shape study design and implementation.[261] For example, focus groups with community representatives or advisory boards can provide insights into potential barriers to participation and offer feedback on the appropriateness of study information materials, effective means of communication (eg, local newspapers, radio, social media, posters and word of mouth) and locations for enrolment activities.[262] Engaging with community leaders (including faith leaders) and community advocates can be useful to gain understanding about the

potential influence of cultural or religious beliefs and help build support from trusted authority figures.[263] Engagement activities that are promoting research may benefit from emphasising the individual and community benefits.[264] It can be useful to raise awareness about a research project within the whole community, not just among potential research participants.[265]

- General community engagement activities can build public awareness, understanding and trust, including among minority ethnic groups.[266] By collaborating with community leaders or advocates, general engagement activities can be tailored to the need of different groups to promote dialogue around key issues.[267] Outreach events in community settings[268] and in centres of medical research could help build a sense of inclusion and cooperation.
- Mass media campaigns have been used to raise awareness about clinical research,[269] including (in the US) campaigns directed toward minority ethnic groups.[270]
- Specialist research groups and national organisations that fund medical research are well-placed to create and share general resources that could support the medical research community in its engagement activities. Existing resources that present 'patient perspectives' and encourage and support researchers[271] could be further developed. For example, an online repository of written and audio-visual materials about clinical trials concepts and processes that address common concerns, such as randomisation, using inclusive language and imagery and translated for different audiences (see below 'Appropriate and accessible information'). It may be beneficial to involve production companies with specialist knowledge of the target audiences. To underline the clinical importance of having patients from minority ethnic groups included in research,[272] a general awareness raising campaign aimed at health professional and patients could be deployed in centres of medical research.

Trustworthy communicators

- Doubts about motives of the scientists are connected to the extent to which information from medical researchers is believed.[273] Where there is potential mistrust, the perceived trustworthiness of information sources is important.
- It was found that South Asian patients were more likely to participate in a trial if they have a 'personal invitation from a trusted GP, hospital consultant or community/faith leader', whereas general communications such as posters, leaflets and newspaper adverts were less described as 'distant'.[274] Indian patients may be reassured by research linked to organisations or professionals perceived to be authoritative.[275] In oncology trials, senior male doctors had greater success in enrolling British South Asian patients than 'persons of perceived lesser hierarchical status (senior nurses and radiographers)'.[276] GP involvement in trial enrolment may be beneficial as British South Asian patients show a greater desire to interact with their GP, rather than hospital specialists.[277]
- Involving appropriately trained health professionals from minority ethnic groups in the clinical trials process, perhaps as community champions or ambassadors, may help some potential participants to have confidence in the research.[278] However, involving researchers who have experience working with minority ethnic groups and who are linguistically and culturally competent is more important than simply seeking ethnic correspondence between researchers and patients (see below 'Study information provision: language, culture and trust' and 'Cultural and structural competence').[279]
- While discussing blood cancer research, Black Britons noted that healthcare professionals can 'sometimes come across as overzealous', which can 'erode trust and confidence'.[280] In contrast, stories of peoples' experiences of trial participation (positive or negative) were considered an 'important and credible source of information and reassurance'.[281] These stories did not necessarily have to be from people of a shared ethnicity.

- Health charities can play an important role in support and information sharing (see below 'Patient support groups'). In the context of blood cancer, some information about clinical trial experiences is shared online.[282] Charitably funded initiatives to support clinical trials like the Trials Acceleration Programme and IMPACT partnership, and Blood Cancer UK's Clinical Trials Support Service have employed specialists to support and advocate for patients and their carers.[283]
- Health charities that draw particular attention to ethnic disparities surrounding blood cancer are especially well positioned to act as a trustworthy source of support and advice for patients.[284] Such charities also play important roles in promoting awareness, encouraging participation in donor programmes and representing the needs of patients from minority ethnic groups.[285]
- The growth of social media presents opportunities for building effective communications through trusted sources. However, it also poses risks for the spread of misinformation, and thought needs to be given to who will and will not be reached through various social media channels.

b. Appropriate and accessible information

Study information provision: language, culture and trust

- Commonplace terms like 'trial' and 'experimental' reflect the world of medical science, but they can create negative perceptions which can be magnified by issues of mistrust and cultural and language difference.[286] When communicating with patients, the appropriateness of this terminology, and potential alternatives could be given consideration.
- Improved information and communications materials, including about research ethics processes, may be needed to better explain clinical trials to patients from minority ethnic groups.[287] Study communications materials should use inclusive language and images, should be straightforward and accessible, and may require alternative formats (eg, DVDs).[288] There may be a need to develop new study materials or use previously translated materials if appropriate.[289] Research in the US suggests that the format of information (eg, the length of information sheets) and tailored support for understanding are also likely to be important where language competency is a concern.[290] To ensure quality and appropriateness there is an argument for standardising key communications materials, or standardising the processes for developing them (such as a 'multi-staged approach' that includes community engagement[291]).
- The availability of appropriately translated information or interpreters can be the most important 'facilitator' of participation in research for some South Asian patients.[292] This highlights the need for language choice and the need for support staff with language competency.[293]
- In the context of blood cancer, 'recruitment strategies and communication tools'[294] encouraging patients from minority ethnic groups to participate in myeloma research are 'often not culturally appropriate' and do not 'target those at highest risk, particularly black people.'[295]
- Black British respondents discussing blood cancer research wanted clearer information about the implications of being in a trial, and 'the processes and procedures any drugs or medicines had previously been through'.[296] They were keen to know that they were 'not the first to take part in a particular trial' and if there were guarantees about harm.[297] This is similar to other UK patients with cancer, who would prefer to be given more detail about study drugs or procedure,[298] and more information on available research (rather than the treatment team deciding what they should know about).[299] It has also been found that providing additional information (about rights to withdraw and treatment details) can help address concerns about randomisation.[300] Where mistrust can be an issue, greater transparency might be beneficial.

Patient support groups

- Health charities can support patients by providing access to appropriate information. In the context of blood cancer, patient support organisations have resources about participation in clinical trials. In the US, the Leukaemia and Lymphoma Society has guidance that addresses questions about the organisation of trials, the trials experience, safety, participation in different types of trial, access to trials and decision-making.[301] In the UK, organisations like Blood Cancer UK and the Anthony Nolan Trust have online content to explain clinical trials, addresses some common misunderstandings and directs people to particular trials.[302] There is, however, concern that patients may not be finding such information.[303]
- Patient support groups in North America are far more likely to provide information about clinical trials and other forms of medical knowledge (eg, causes, diagnosis, etc.) compared to those in Europe (78% vs 29%).[304] Arguably, European patient groups could provide more information about these issues.[305]
- To ensure information provided by patient support groups is made appropriate to patients from minority ethnic groups, consideration should be given to the above-noted ways to improve information and communication, and to community engagement activities.

c. Trial design and practice

Clarity on who to include, why and how to reach them

- To guide their thinking about sampling and enrolment, researchers need to define the populations that should be involved in their research[306] and recognise the structure and locations of UK ethnic minority groups.[307] This can help to set expectations and promote thinking about what groups might not be adequately represented.[308] It is also recommended that researchers have a clear sense of why people from minority ethnic groups should be involved in the research, either as a representative part of the general population, or as a focal element of the study.[309] This can impact on thinking about sampling strategies, such as selecting trials sites that have a high proportion of people from minority ethnic groups,[310] or using 'snowball sampling' that utilises community social networks (eg, religious leaders, community organisations, advocate organisations, and carers or family members).[311]

Pragmatic trial designs (including ethics processes and access)

- The appropriateness and acceptability of trial design has been questioned in the context of enrolling young patients with cancer to clinical trials.[312] This has been framed as a call for 'pragmatism in trial design' to facilitate much-needed research for a patient population that is disadvantage and suffering 'discrimination in care'.[313] Key issues in this context included restrictive eligibility criteria and the impact of study protocols on potential participants.[314]
- In the context of patients from minority ethnic groups, it has also been argued that eligibility criteria should be set as widely as possible to avoid 'case selection biases that tend structurally to exclude patients'.[315] Also, there are calls to removal of language barriers to participation by making reasonable adjustments to informed consent processes (see below 'Ethics processes'). To ensure that study 'assessment tools' (eg, questionnaires) are appropriate, a flexible approach to the collection of data, or the use of language support, may be required.[316]
- Consideration may need to be given to research ethics processes where language and cultural barriers are an issue.[317] This

could include creating patient information documents that address issues that may be concerning to particular minority ethnics groups, working to overcome the limitations of written translations, thinking about the consent process in a context of family decision making, and exploring the potential for using audio-recorded rather than written consent.[318] The use of audio-recorded consent from South Asian patients has been argued to be an acceptable alternative written consent in health services research.[319]

- In terms of financial and logistical barriers to access (ie, additional costs, childcare, working commitments and transport), solutions can include reimbursements, accessible trial sites or alternative locations, arranging travel and providing flexibility around participation.[320] Where people from minority ethnic groups are underusing health services, invitations to take part in research could happen outside of the healthcare system.[321] Recognising and addressing these issues can require consideration of the wider social contexts that may affect the decisions of patients (see below 'Cultural and structural competence').
- Access can be particular issue the context of blood cancers, both because of the rarity of some disorders and because some treatments are only available in specialist centres. In this context, initiatives like the Trials Acceleration Programme and IMPACT partnership have created a national network for clinical trials.[322]

d. Developing person-centred research and researcher competences

Reimagining research as a cooperative relationship

- There may be a need to re-conceptualise the relationship between researchers and patients, with involvement viewed as an act of 'cooperation' rather than 'participation'.[323] This may better reflect how patients perceive their decision to be involved, which relies not only on a sense of contributing to a public good, but also on being able to justify their choice as 'safe and sensible'.[324] Such justifications rely on judgments about the trustworthiness of health professionals and the organisations overseeing their activities.[325] For patients from minority ethnic groups - mistrust is a clear concern for some – developing a co-operative relationship may require researchers to understand the reasons for mistrust and seek potential ways for building trust. This could be connected to community engagement activities discussed above, and also to issues of communication discussed below.

Communications processes

- Enrolling patients into clinical trials can be 'complex and fragile' process, with some professionals acknowledging 'emotional and intellectual challenges' around equipoise and role conflicts.[326] Despite good intentions, some practitioners' communication can be unclear and lead to patient confusion.[327] Research on a bladder cancer trial found that patients did not 'feel fully included in the trial enterprise',[328] and recommended that professionals should help patients to feel 'attached' to the trial by developing relationships based on 'trust and respect' and by recognising 'vulnerability'.[329] Training on trials principles and how to engage with patients could help support the communications process.[330]
- For patients from minority ethnic groups, shortfalls in communication can relate to potential issues of mistrust and language and cultural difference. Any patients could experience having too little information, a lack of clarity, unanswered or unacknowledged concerns, rushed encounters, poorly timed invitations and insensitive language; however, some patients from minority ethnic groups may view such interactions as reflecting a lack of care and respect that is consistent with experiences of discrimination. Arguably, patients who feel under-appreciated or disempowered will be less inclined to seek the extra information that they might need in order to decide to take part.
- One solution in US cancer research has focussed on the patient, the professional and on their interaction.[331] To address patient attitudes and communication skills, a 'question-prompt' list was developed with the input of patients, families, professionals and community members, focused on issues like the purpose of the trial and its risk. Professional communications are addressed by focusing not only on information communication, but also relational communication. This entails using plain language, offering empathetic responses

that acknowledge and validate concerns and building shared decision-making (also see NHS England guidance on the language used by healthcare professionals[332]). The issue of professional biases and attitudes are addressed by prompts for pre-emptive thinking about the potential benefits for the patient and strategies for discussing these, designed to increase the likelihood that such discussion will take place.

Cultural and structural competence

- Cultural competency involves combining cultural knowledge with self-awareness, and using these insights to develop strategies, skills and practices that promote inclusivity.[333] Awareness of one's own stereotypes and biases, and of the potential role of cultural difference in communication and interpersonal relations, could improve understanding and allow differences to be addressed.[334] As such, it may be beneficial for health professionals to have training to ensure services are sensitive to cultural and ethnic difference,[335] including in the context of enrolment to clinical trials.[336]
- Involving culturally competent staff may help to address issues such as: engaging with decision-making within familial contexts (by offering support for discussing information or engaging with families); being sensitive to diverse models of health and illness (by using a 'stepped' approach to introducing the study) and stigma (by avoiding stigmatising or embarrassing terms); judging the appropriateness of incentives for participation (using tokens of gratitude rather than money); and the potential for cultural or religious activities to affect peoples' ability to participate.[337] Also, it may help to identify situations where the gender of clinical trials staff is important to a potential trial participant.[338]
- Cultural competence also involves awareness of differences between ethnic groups and the diversity within ethnic groups.[339] This is important to recognise because it highlights that strategies to address barriers may need to be tailored to fit the specific context of the research and the people that it hopes to enrol.[340]
- Furthermore, being sensitive to variation can be an antidote against assumptions. Being aware of potential ethnic difference risks feeding into health professionals' perceptions and stereotypes about patients from minority ethnic groups, and thus become a reason why they deem them unsuitable for a trial or why they may be reticent about inviting them to participate. Recognising the variability within and between ethnic groups can avoid creating or reinforcing potentially damaging stereotypes.
- A 'structural competence' framework is emerging in the US that highlights for example, inequalities rooted in institutional policies and practices or in ethnic patterns of deprivation. It criticises 'cultural competency' solutions because they focus interpersonal communications and individual biases, rather than the broader social factors that result in ethnic health disparities.[341] Structural competence training initiatives have been developed that aim to foster awareness of the societal level 'economic and political condition that produce inequalities'.[342]
- In the context of blood cancer trials in the US, it has been suggested that a specific 'diversity officer' could provide the competencies necessary for enrolling of black patient into myeloma trials.[343] Identifying an individual with similarly responsibility in UK research settings could also provide researchers in those organisations with support and advice.

e. Research system issues

Lack of clear data on ethnicity

- A long-standing barrier to clear understanding of the true nature and scale of minority ethnic group representation in UK medical research is the non-existent, unreliable or inconsistent data on the ethnicity of study subjects.[344] Requirements to report clinical trial enrolment data have been described as 'minimal'.[345]
- In the context of UK blood cancer, it has been argued that trial data, and health data more generally, needs to be disaggregated by ethnicity to understand 'the outlook, outcomes and treatment responses specific for black patients', and also to begin addressing questions about the reasons for any differences.[346]

Organisational level policy changes

- The challenges of enrolling participants from minority ethnic groups are regarded by some researchers as a 'major hassle' and others as surmountable obstacles,[347] and it is important to recognise the difficulties that researchers face with when seeking to include participants from underserved groups.[348] While strategies to improve ethnic diversity in enrolment to clinical trials certainly exist, attempts to apply them happen in working contexts that either do not incentivise change, or which create barriers to change. Professionals face competing pressures on their time and resources, which raises questions about how to prioritise the inclusion of patients from minority ethnic groups in clinical trials.
- Overcoming some of the barriers to improving enrolment requires thinking about the funding, organisation, governance and dissemination of research. Scholars in the US and UK have made various recommendations for policy changes aimed at research funders, ethics committees, professional bodies, and academic journals, including:
    - funding for the additional costs of translation, interpreters and community engagement and increased sample sizes if sub-group analysis is required;[349] research review criteria that judge and incentivise appropriate inclusion, and the training of reviewers to adequately judge this;[350] and funders prioritising trials based on the sampling of underrepresented racial/ ethnic groups.[351]
    - research ethics committees to review clinical trial design[352] and to recognise the potential variations in culture and language that may impinge on the suitability of research ethics practices.[353]
    - academic journal standards for appropriately detailed reporting and analysis about populations, samples and sampling practices that use consistent terminology.[354]
    - initiatives to increase ethnic diversity in the biomedical research community, including in scientific organisations, professional associations and governing bodies.[355]
    - funders to support studies to investigate enrolment of participants from minority ethnic groups;[356] and research among underrepresented groups who have declined to participate, including on how opinions are formed and how these opinions could be shaped.[357]
- In the context of clinical trials, consideration should also be given to how questions about ethnic diversity should be factored into the approval and assessment of medicines and health technologies.

Law

- In the US, the appropriate inclusion of people from minority groups in National Institute of Health funded clinical trials has been legally required since 1993.[358] Legislation requiring federal agencies to address barriers preventing people from minority ethnic groups participating in cancer clinal trials, the Henrietta Lacks Cancer Research Act 2019, was signed into law in January 2021.[359] There is no comparable legalisation in the UK,[360] but questions could be asked about the extent to which the practices of research organisations are meeting the requirements of the Equalities Act 2010.

3. The current use of solutions in clinical trials practices, and recent initiatives to support the participation of patients from minority ethnic groups

Solutions in use in clinical trials practice

- A recent review tried to establish if the above strategies are being used in the UK.[361] It identified study materials, such as the 'screening and outcome measures' on health questionnaires, that had been translated or culturally adapted, and found examples of staff training on cultural sensitivity and language difference. In relation to enrolment, it found social networks being used to gain support, promote awareness and facilitate engagement; considerations about location informing sampling decisions; the use of translations, interpreters or participation in a preferred language; 'follow-up' activities, including telephone calls or home visits; sensitivity to 'culturally appropriate' incentives and religious and cultural festivals; and the use 'recruitment staff from same cultural background' and, in fewer instances, gender.[362] Despite finding these examples, the researchers expressed concern about the limited range of strategies that had been employed; the lack of detail about the methods used; the 'lack of tailored approaches'; and the lack of assessments of effectiveness.[363]

Initiatives to support the participation of patients from minority ethnic groups

- The Centre for BME Health (CBMEH) work in partnership with representatives from minority ethnic groups to create culturally sensitive resources, methodologies, training and engagement activities.[364] The CBMEH offers practical solutions for a range of issues including a staged process for developing translated information and AV materials to support public engagement.[365] CBMEH has also created a 'Toolkit'[366], 'checklist', training[367] and AV materials[368] to guide the work of health researchers. The Toolkit focuses on issues like sampling, recruitment, cultural competence and community engagement.

- The INCLUDE programme aims to improve research design so that it better addresses underserved populations, such as minority ethnic groups; it develops guidance, resources and initiatives aimed at policy makers, funders, regulators and researchers.[369] INCLUDE's Ethnicity Framework guides researchers to think about who the trial results should apply to and how to ensure those people are involved in the trial process.[370] It focuses on questions about potential group differences in benefits and harms; responses and engagements; access; eligibility, recruitment and consent. Further sets of questions in the framework prompt thinking about the impacts of differences related to disease factors and cultural factors; how group differences might affect data analysis; how to enable community involvement and what it might it cost; and the impacts of trial design, processes and dissemination on participation.

- Woven throughout the CBMEH 'Toolkit' and INCLUDE's Ethnicity Framework are recurrent reminders about stakeholder involvement in decision-making, and diversity within and between ethnic groups. This advice highlights the need to tailor strategies for engagement and participation to reflect the needs and concerns of the people that researchers wish to enrol in their studies.

4. Lessons for Blood Cancer UK

- This review of ways to facilitate clinical trials participation for patients from minority ethnic groups may have implications for the work of Blood Cancer UK.
- The Blood Cancer UK Clinical Trials Support Service aims to support and advocate for blood cancer patients who are enrolled on clinical trials, and their carers; impartially advise patients with blood cancer, and their carers about clinical trial opportunities by providing information, advocacy and liaison between clinicians and trial sites; support health professionals involved in clinical trials for blood cancer; and raise awareness of clinical trials for blood cancer.[371]
- In order to advise, support and advocate for patients and their carers the service could:
    - develop culturally and linguistically appropriate material to share with patients enrolled on or considering clinical trials, and/or liaise with other organisations to create and share these. This should include explanations of key concepts and processes, and of the potential benefits of ethnic diversity in research; a 'question-prompt' list to support clinical interactions; and patient experience stories.
    - develop, and facilitate access to, its networks of individuals and organisation that can be regarded as trustworthy information sources and who can provide language support.
    - develop a person-centred approach to enrolment based on cultural and structural competence and relational communication.
- In order to liaise with and support health professionals involved in clinical trials, the service could:
    - develop awareness about ethnic disparities in blood cancers and clinical trials participation and the clinical benefits of addressing these issues, and/or liaise with other organisations to undertake this work.
    - recommend strategies and resources that can be used to improve clinical trial designs and facilitate enrolment of patients from minority ethnic groups.
    - promote and support the use of community engagement.
    - share its networks of trusted source and language support.
    - liaise with trial designers to design clinical trial protocols and practices that are less likely to exclude patients from minority ethnic groups and that recognise and address potential barriers.
    - liaise with patient-facing professionals to encourage a person-centred approach to enrolment based on cultural and structural competence and relational communication.
- In order to raise awareness of clinical trials, the service could:
    - arrange and/or participate in community engagement activities.
    - share information about ethnic disparities in blood cancers and clinical trials participation using culturally and linguistically appropriate resources (eg, on its website).
- Blood Cancer UK could also help to address ethnic disparities in blood cancer research by advocating for:
    - a central resource of culturally and linguistically suitable material to support patient awareness and understanding and professional awareness and action.
    - policies that incentivise appropriate attention to issues of ethnic diversity in the funding of health research, in research ethics processes, in academic publishing, and in the approval and evaluation of medicines.
    - improvements to data collection and sharing that could reveal ethnic patterning in the incidence of cancer and participation in medical research in general and clinical trials in particular.
    - health research organisations to be accountable for ethnic disparities in their activities by identifying where they are happening and how they will address them.
    - research to better understand the extent, nature and impact of ethnicity on participation in clinical trials for blood cancers.

Key findings

- Successfully encouraging patients to participate in clinical trials has been associated with various practices, although health context, trial designs and socio-demographic factors (ethnicity, age, gender and education) may affect the effectiveness of different strategies for different groups of people.
- Strategies for improving enrolment to clinical trials for patients with cancer include checklists built around recurrent themes and issues, and a process for identifying barriers and addressing them through training.
- Suggestions for increasing participation among patients from minority ethnic groups were reported around the following themes: building trust, cooperation and understanding; appropriate and accessible information; trial design and practice; developing person-centred research and researcher competences; and research system issues
- With respect to building trust, cooperation and understanding, suggestions centred on meaningful practices of community engagement (both for specific trials and for medical research more broadly) and thinking about who patients perceive to be trustworthy communicators (including people such as GPs or other trial participants).
- Providing appropriate and accessible information must involve attending to language issues (eg, thinking about translation, interpreters, format, support and inclusive language and images). Providing more information about the study drug or procedure and greater transparency about available treatment options could also help to address issues of mistrust. Patient support groups, especially those regarded as trustworthy by people from minority ethnic groups, could be well placed to provide general information and support.
- In terms of trials design and processes, there should be clarity about the study population, why people from minority ethnic groups should be involved in the research and how to reach them. Also, trial designs should avoid restrictive eligibility criteria (eg, comorbidities and language restrictions) and burdensome study protocols, and consider how to address potential barriers around finance, logistics and research ethics processes.
- With respect to person-centred research, framing research as a cooperative endeavour could help to address issues of mistrust and cultural and language difference. Developing health professionals' interpersonal and communication skills could support them to manage situations that can be emotional and difficult, to reflect on their own attitudes or biases and to enable patients to be fully, actively and sensitively engaged in discussions. This should include considerations about cultural and structural competence to ensure interactions between patients and professional are sensitive to, and able to address, potential differences in outlooks and experiences. Large research organisations should consider ways to ensure all their trials activities are appropriately supported and advised.
- At the level of over-arching research systems and policymaking, the lack of reliable and consistent data has been long-recognised, and a range of organisational level recommendations have previously been made to support and incentivise change. While the UK does not have specific legislation like that developed in the US to support the inclusion of minority ethnic groups in health research, research organisations should be ensuring that their activities meet to the requirements of the Equalities Act 2010.

> "Practices for facilitating the involvement of people from minority ethnic groups in clinical trials are in use in the UK, although these appear to be limited in scope and the effectiveness of different strategies remains unclear."
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> page 41

- Practices for facilitating the involvement of people from minority ethnic groups in clinical trials are in use in the UK, although these appear to be limited in scope and the effectiveness of different strategies remains unclear.
- Initiatives and resources to support health researchers have been developed. These place the onus on researchers to tailor strategies for engagement and participation that reflect the needs and concerns of the people that they wish to enrol in their studies.
- Blood Cancer UK's Clinical Trials Support Service could support patients and their carers by developing culturally and linguistically appropriate information; facilitating access to networks of trusted individuals and organisation; and by developing a person-centred approach to enrolment based on cultural and structural competence and relational communication. It could support health professionals involved in clinical trials by developing awareness about ethnic disparities and strategies for improving clinical trial designs and patient enrolment; by promoting and supporting community engagement; and by sharing knowledge and networks for key skills and support. It could raise awareness of clinical trials through community engagement activities and by sharing information about ethnic disparities.
- Blood Cancer UK could also address ethnic disparities in blood cancer research by advocating for a central resource of material to support public and professional awareness, understanding and action; for policies that incentivise appropriate attention to issues of ethnic diversity in the health sector; for improved data collection and sharing to facilitate understanding of ethnic differences relating to blood cancer; for health research organisations to be accountable for addressing ethnic disparities; and for research to better understand the extent, nature and impact of ethnicity on participation in clinical trials.

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4. Advisory Group Comments

Advisory Group members were invited to represent the views of patients and professionals from health charities and healthcare. Advisory Group members were asked to reflect on their involvement on the project and offer a brief comment on the issues or findings that they considered to be particularly important.

Patient Representatives

Ruchi Shrivastava

Biography

I am a British Indian and took part in a clinical trial after being diagnosed with Hodgkin Lymphoma at the age of 24.

Comment

Barriers to participation in clinical trials that I can identify from my personal experience of being diagnosed with Hodgkin Lymphoma are mostly linked with appropriate information: Finding an appropriate time to discuss clinical trials and also the terminology used.

I felt overwhelmed with information whilst attempting to process the staging of the cancer and also being given information about a suitable clinical trial. Due to my family attending the appointment with me, they were able to later explain to me what I had been told. But finding an appropriate time to discuss clinical trials, when the patient isn't distressed and is able to process the information and ask questions would be a solution to feeling bombarded with information.

Recruitment of clinical trials can be dealt with more sensitively with staff empathising with the individual. I initially felt like staff were more focussed on the results of the clinical trial rather than reassuring me of any concerns and focussing on my cancer treatment. I think terminology used when discussing clinical trials with patients' needs to be considered to ensure patients still feel that their health is the priority when participating in a trial. Additional barriers exist around terminology used in research, such as 'experimental drugs'. It may seem scary if the patient doesn't have an understanding of the process of clinical trials and lead to unnecessary anxiety which may also impact participation.

Hinna Salam

Biography

I am 29-year-old British Pakistani female; I was diagnosed with Hodgkin's lymphoma at 23 years old and am currently in remission. I was contacted by Blood Cancer UK regarding this project as someone from a BAME background who has been diagnosed and treated for blood cancer.

Comment

Whilst my personal experience did not involve clinical trial, I reflected on my journey and whether my race or any other factors had any impact and how I felt about this.

Through the discussions I was involved with, the themes that resonated with me were around awareness and access to a trial. Before becoming involved in this project, I did not really understand what a clinical trial was, and it was not something was discussed with me at any stage of my treatment. Whether my ethnicity, favourable prognosis, or my location (I was treated in a local hospital as an outpatient) played a role in this, it is difficult to say. Equally it was not something that I considered or thought to ask about. Whilst I would like to think, if I had been approached to partake in a clinical trial that I would have been willing, that period of time felt like a whirlwind. I remember it being a series of never-ending appointments and anxiety and I was very much led by the support and advice of my consultant at the time as to what to do.

The other themes that were explored were around trust, which were a predominate part of our discussions. My family sought the advice from a close family friend, despite not being in the relevant field, for reassurance and a second opinion that I was receiving the appropriate treatment. Whilst I was confident in with advice from consultant, my family felt it was important to seek reassurance from someone they knew and trusted. The other theme that resonated with me were the ethno cultural/religious issues. I was not surprised with the information provided by Andrew around stigmas of cancer diagnosis in the south Asian community. Whilst the opinion of a family friend, who was a medical professional, was sought, my diagnosis and treatment were largely kept hidden from my extended family and community so it would not adversely impact my future marriage prospects. This would involve not disclosing my diagnosis as well as hiding visual symptoms of hair loss from chemo with a headscarf and/or wig so people would not talk.

Health Charity Professional Representatives

Beverley De-Gale

Biography

I am the co-founder of the 44 times award winning leading UK Blood Cancer & Healthcare charity, ACLT (African Caribbean Leukaemia Trust). The ACLT was founded in June 1996, after we received the devastating news that our 8-year-old son Daniel De-Gale, needed a life-saving stem cell (bone marrow) transplant to win his three-year battle against leukaemia. When confronted by heart-wrenching facts and figures it became the need for an organisation to galvanise awareness and increase the number of stem cell donors became apparent to me. The racially specific characteristics of bone marrow meant that compatible donors (for African/Caribbean sufferers), can only be found within the African and Caribbean population. I channelled the anxiety of discovering my son had blood cancer with the goal of creating a better future for people suffering from leukaemia and other blood-related disorders. The charity was started to raise awareness to enable potential donors to come forward and donate, making them, potentially a lifesaver.

Comment

There is no doubt a lack of empathy during the initial diagnosis stage and during subsequent treatments, alongside little or no cultural understanding by some healthcare providers may result in a lack of understanding and trust from patients and families.

A new patients' initial allotted appointment, when receiving the life changing diagnosis from healthcare professionals, should allow more time for that sensitive conversation to take place. Professionals should be mindful of how much the patient has understood about their diagnosis and then being able to gently move forward discussing all treatment options, the prognosis and all the while answering any questions that may arise. They should allow the patient and loved ones to express their fears and being able to sensitively react. Extending the time given to each person at the initial diagnosis stage will help to develop better relationships and greater trust for all. It will allow questions to be asked, the patient's options better explained and discussed, and ensure the patient and loved ones better understand the intended road map.

Language barriers - if an English-speaking patient struggles to really understand what's happened and the timetable of treatments, can you imagine what it would be like if English is not your 1st language. It must be terrifying beyond words not being able to properly understand or being able to communicate back clearly. The words 'Clinical Trial' could make the patients feel like guinea pigs, and that would of course be a problem.

Short, informative videos for patients to watch about the importance of clinical trials, answering all, or at least most common, questions about taking part and the benefits of taking part for the patient and for future treatments for all patients could be a very helpful tool. It could encourage patients to seriously consider a clinical trial as benefitting not only their lives but also other patients that come behind them.

This would also work the other way around – a short, informative video for Consultants, Nurses and all healthcare professionals about how to better communicate with Black or Asian patients and their families about all of the above. This will certainly assist the discussion around Clinical Trials with Black and Asian patients. Also, videos need to take into account the distinctions within each community.

We always say that in Black and Asian healthcare it's all about having a high degree of trust in the words of the messenger (the doctors). If there is no trust, which could be simply down to a lack of empathy being shown, allotted time, lack of communication skills and language barriers, it's most likely a non-starter.

Verity McLelland

Biography

I have worked in the charity sector for over twelve years in criminal justice and health organisations focusing on programme design and delivery and public and volunteer involvement, most recently at Diabetes UK. I have a strong interest in reducing health inequalities and in 2019 led a project to better understand potential barriers to people from Black and South Asian communities accessing health information and support in the South West region.

Comment

During the Advisory Panel meetings, I felt that a common theme emerged across many of the issues that were raised as to what barriers exist to people accessing clinical trials and research, and that was around a lack of a person-centred approach towards those patients who may be eligible to take part. We heard experiences of patients who had been offered a place on a clinical trial and it seemed that at many stages of the process, from designing the trial to the person being given information about the trial by a health care professional (HCP), the process was not taking into account the patient, their and their families feelings and also the practicalities of how the trial could impact their day to day lives. It felt hugely important that in terms of increasing involvement in trials patients were enabled to fully understand what was involved in the trial and to ask any questions they or their family may have, and for the information to be shared with them in a way they will understand.

One potential solution which I felt could help was around improving the understanding and awareness of these factors with the HCP's who may offer the trial to a patient to try to encourage them to take a more individualised and person-centred approach when discussing access to a trial. By providing a practical document or focused training video with real patients experiences where they can share the factors which either encouraged or discouraged them being involved in a trial, I think it could help HCP's involved to hear patient voices, perhaps for the first time, and to understand the impact that their words and the way they present a trial can be hugely significant in someone's decision making process. We also discussed a leaflet with a glossary to help patients and their families understand some of the terms used when talking about trials which I think would be helpful as people may not always wish to say that they don't understand something, or they may have pre-conceived ideas about what something means. All of the possible solutions must be made accessible through either verbal or written translation if patients don't speak English as their first language.

Chiara De Biase

Biography

I am Director of Patient Services at Anthony Nolan, with responsibility for the development of clinical and supportive care pathways that help patients before and after transplant, including palliative and end of life care. I lead the delivery of patient information as well as funding NHS posts to support patients going through transplant. My interest in the research project stems from a commitment to see more stem cell transplant patients involved in clinical research which can improve outcomes for this group of patients.

Comment

Two important considerations:

1. The impetus should be on researchers and clinicians to involve a diverse group of patients in research (rather than asking more of patients themselves).
2. Reluctance to take part in research reflects broader and complex issues to do with health literacy, relationships with, and treatment by, health systems and the circumstances of patients' lives.

Healthcare Professional Representatives

Surabhi Chaturvedi

Biography

I am a psychological therapist specialising in supporting patients and their families affected by blood cancers. I offer psychological therapy to patients/ caregivers from diagnosis onwards throughout their treatment pathway, in addition to training and consultation to professionals on psychological aspects of cancer care. I am based in the department of Haematology at King's College Hospital, London.

Comment

Increasing representation of patients from BME communities in clinical trials starts with care providers reflecting on whether and why this issue matters to them. In addition to systemic national initiatives mandating changes, change will come when professionals recognise the value of this for their clinical areas. Changing the status quo often requires investment of time and effort, and we invest this time and effort if we think the cause is worthwhile. That is when we will not settle for, or accept as 'given', some of the things that may currently prevent BME patients accessing research (language barriers; financial constraints preventing patients accessing trial centres; misunderstandings about what clinical trials mean; or stereotypes/ assumptions about patients from BME communities). These can be overcome if there is a commitment to finding solutions, which includes investing financially in appropriate services. Second, because mistrust rooted in histories of oppression and exclusion could be a factor preventing participation, it is incumbent on professionals to start by acknowledging this as valid and engage with it at a relational level when reaching out to BME communities with a view to rebuilding trust. Coming at this from positions of 'I really care about you having access to the best research', 'I understand why you might be hesitant' and 'What can I do to help?' can all be helpful. Third, using persons from BME communities in promotional campaigns can make a difference, because it can make historically disenfranchised people feel that this is something that includes and applies to 'people like me'. Finally, tailoring the trial recruitment process to make it more person centred can provide patients opportunities to ask questions, have multiple conversations and include the views of family members/ trusted community leaders in their decision making if this is important to them.

Sanjay Gandhi

Biography

I am the Lead Radiologist for North Bristol Haematology Cancers for the past 18 years and have helped more than a dozen multicentre cancer research trials. I am also the founding member of the North Bristol NHS Trust (NBT) equality and diversity group and Vice-Chair of BAME Staff Network. My roles also include 4-year tenure as the Corporate BAME Champion at NBT. I am one of the Specialist Advisor to BAME Healthcare Charity (BHC).

Comment

My input to the discussion was wide, particularly emphasising barriers such as language, appropriateness of the information about the trial, risk averseness, worries about financial security, the role of the family. Some also think 'What is in it for me by participating in the trial?'. The discussion also included potential solutions: the role of community leaders, visibility of BAME in videos/promotional material, Engagement Officers/Ambassadors. I believe that the information regarding clinical trials should be standardised (both for leaflets as well as any videos). A good translation/language interpretation service can play an important role in getting the right message across people from diverse backgrounds.

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