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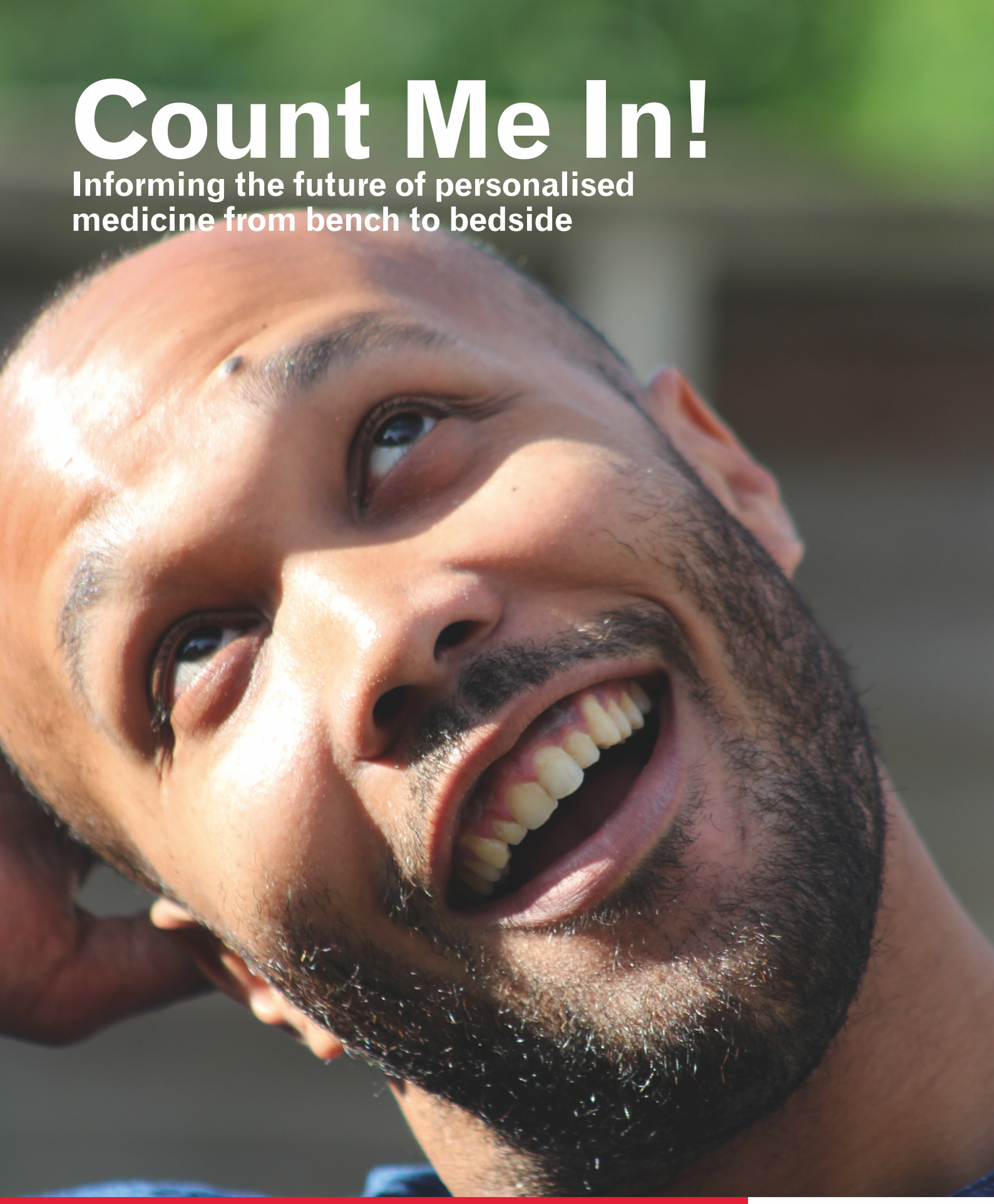

A qualitative inquiry into the views of black Caribbean and black African communities on clinical trials, clinical trial enrolment, and clinical research

Report Authors: Dr Sophia Skyers, Campbell Kerr and Pauline Johnson

September 2017

THE BASIL SKYERS MYELOMA FOUNDATION
supporting people with Multiple Myeloma

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Thank you to all the patient organisations that supported this research.

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The authors would also like to thank Amgen UK, and Nottingham Hospitals Charity, for responding positively to our request for financial support. It has helped enormously in making the inquiry both feasible and possible and the views expressed are ours entirely. Thank you also to the following patient and community organisations: BME Cancer Communities (BMECC), the Sickle Cell Society (SCS), the Black Health Initiative (BHI) – BME Cancer Voice, Bexley African Caribbean Community Association (BACCA), and Greenwich African Caribbean Forum (GACF), for providing access to patients and to carers, and the wider community, and to Myeloma UK for its support. These organisations, individually and collectively do unstinting and imaginative work in the community, and the Foundation is pleased and proud that they agreed, without hesitation, to work with us on this project, exploring an inequality in clinical trial participation.

The authors would like to specifically acknowledge the support of Beverley De-Gale OBE and Orin Lewis OBE. They are the co-founders of the African Caribbean Leukaemia Trust (ACLT), set up in memory of their son Daniel De-Gale who was diagnosed with acute lymphoblastic leukaemia in 1993, at the age of six. ACLT has supported this inquiry from the outset, identifying and facilitating access to patients across a range of haematological malignancies, benign haematology's and also, to carers. It is absolutely true to say that this project would not have been possible without the commitment and support of ACLT, and their signposting of participants to the researchers. We cannot stress enough how profoundly grateful we are to the staff and volunteers at ACLT, and in particular to Beverley and to Orin.

There are a number of individuals we would also like to say thank you to for their support in the recruitment process: Mary Tsindides, Trustee, Basil Skyers Myeloma Foundation, and Kathryn Hope and Beverley Hutchinson, Basil Skyers Myeloma Foundation volunteers. Thank you to Professor Frank Chinegwundoh, Consultant Urologist, Barts and Chairman of Black Cancer Care for his support, and for highlighting the similarity of the issues raised in clinical research inclusion in relation to prostate cancer, multiple myeloma, and other blood cancers. Thank you to the following volunteers from the Sickle Cell Society who helped with the facilitation of a national event: Craig Lloyd, Laura McCloskey, Kalpna Sokhal, Valerie Oldfield and Kye Gbangbola. Thank you also to two Nottingham business owners, Chris Sampson owner of A Touch of Class hair salon, and Richard Newland, owner of Jamaica Ways restaurant, who allowed access to their customers to conduct impromptu interviews. Finally, thank you to Kate Morgan, Policy Manager, Myeloma Patients Europe, Dr Monica Taylor, Leader of the Jamaica Multiple Myeloma Support Group, the team at Hayward Medical Communications, and Linda Kelly, Pirate Dog Design.

Editorial Board

This inquiry has been carried out by Dr Sophia Skyers, Chair of the Basil Skyers Myeloma Foundation, and Mr Campbell Kerr, and Ms Pauline Johnson, both Trustees of the Basil Skyers Myeloma Foundation, and patient representatives. They were, supported by an editorial board whose members are as follows:

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Table of Contents

About the Basil Skyers Myeloma Foundation

The Basil Skyers Myeloma Foundation is a mainstream registered charity set up in 2010. It is run entirely by volunteers, and is overseen by a board of trustees comprised of patients, carers, myeloma clinical nurse specialists, and consultant haematologists.

The Foundation's focus is practical support for all patients, carers, and families affected by multiple myeloma. Multiple myeloma, or myeloma as it is more commonly known is an incurable blood cancer, affecting almost 5,000 newly diagnosed people in the UK each year. As well as having a central focus on practical patient support, the Foundation also seeks to influence current thinking about policy, and practice as it relates to myeloma patients. This includes leading research and developing conversations in areas that hitherto, have not been explored. The work of the Foundation starts from the premise that being for example, a patient, a carer, or a healthcare professional, does not denote a single identity. As an illustration, the experiences of a patient can traverse many boundaries, and may also embody the roles of healthcare professional, policy analyst, carer, or all three. So too, a healthcare professional may, at some stage, intersect or permeate the boundaries of patient and/or carer. In this sense, knowledge about myeloma services, research, policy, and practice, is ubiquitous. As knowledge is in all of us, harnessing this diversity of thought and opinion has a particular salience. It means that as patient organisations and statutory agencies, we can and should work across patient, carer and professional boundaries to jointly examine some of the wider and taken for granted assumptions that underline *what* we do, *how* we do what we do, *why* we do what we do, *who* is included in conversations about *what* is emphasised in healthcare service delivery and clinical research, and who is not. We can then begin to posit new ideas, and contribute to developing new insights.

The ethos and objectives of the Basil Skyers Myeloma Foundation as set out in its governing document and agreed by the Charity Commission are as follows:

The relief of sickness and preservation of health for people living with multiple myeloma, their families and carers, in particular but not exclusively:

1. *To provide resources for people living with multiple myeloma and charities that are involved in providing direct services to multiple myeloma sufferers which enhance the quality of their lives and the lives of their families, carers and those who provide support to them.*
2. *To work with public, private and voluntary organisations at a strategic level to raise awareness of multiple myeloma and its impact on sufferers, family members, carers and the wider community.*
3. *To support and fund medical research in multiple myeloma to the intent that the useful results of such research be disseminated for the public benefit.*

As patient organisations and statutory agencies, we can and should work across patient, carer and professional boundaries to jointly examine some of the wider and taken for granted assumptions that underline *what* we do, *how* we do what we do, *why* we do what we do, *who* is included in conversations about *what* is emphasised in healthcare service delivery and clinical research, and who is not.

Executive Summary

Clinical trials, clinical research equality and inclusion: At the axis of the planning and delivery of healthcare and other public services is the principle of equality and inclusion. It integrates a focus on disadvantaged groups where health outcomes are not keeping pace with the general population and addressing inequality is positioned as central to improving performance in the health and care system. The randomized clinical trial is seen as the unassailable *gold standard* and the centerpiece of evidence for testing whether safety and therapeutic efficacy is due to a particular intervention, rather than to chance, or to some other unrelated cause. There is however evidence from recent randomized blood cancer trials and genomic studies that black and minority ethnic groups and in particular, black people are not represented. This pattern of under representation also mirrors that found in disease areas where black people have a disproportionate risk of diagnosis.

A number of inter-related factors impact the health of populations. Indeed, just as blood cancers as a group are multifactorial, that is, they are not *one* disease but *many*, and diseases such as multiple myeloma and other blood cancers do not follow a single clinical course in all patients but *many*, so too, the contours of risk, disparities, response, recovery, and survivorship are not articulated against a neutral genetic backdrop. They are shaped by a constellation of factors operating contemporaneously, social, economic, environmental, clinical, and which include our genetic endowment, epigenetic effects, and our epigenetic inheritance. This underlines the need for clinical trials and clinical research to be inclusive, and for our thinking and our narratives to be extended and unfettered by engaging in active multi-stakeholder collaboration and partnerships that span professional boundaries.

This study was prompted by the work of the Basil Skyers Myeloma Foundation on myeloma inequalities, and wider calls for more inclusive clinical trials and clinical research. There are few studies that are aware of or acknowledge the under representation of black and minority ethnic communities in clinical trials, particularly in the UK, the reasons for it, and the implications for clinical research, services and support. This is a significant omission given that blood cancer inequalities are manifest in incidence and prevalence between, within, and across population groups. The thinking that underpins blood cancer trials is anchored in genomics and biotechnology as the overarching intellectual fabric, but it does not take account of the fact that clinical trials and clinical studies mirror the social relations in society.

Widening participation: The case for widening participation in clinical trials and clinical research and reframing how we look at them is an inclusive agenda. It is also important for reasons of ethics, and because widening trial participation can potentially bring benefits in terms of further enlightenment and perspicacity to understanding more about disease pathogenesis. This study does point out however that it is important to understand *what* we mean by *race* and *ethnicity*, and to understand *how* these concepts may be translated in a clinical trial or clinical research setting given that race and/or ethnicity are social constructs, not inherent biological categories. As social constructs they nevertheless do have biological consequences that arise from social and economic inequalities. This inquiry seeks to initiate a conversation about clinical trial participation in black communities, as part of an inclusive agenda in order to understand more about the aetiology of blood cancers to inform clinical research, linking with wider strategies and approaches for tackling health inequalities in disadvantaged groups.

Research themes, approach and sample: The inquiry was carried out between February and May 2017 and was supported by a multi-disciplinary board comprised of patients' groups within the voluntary and community sector, consultant haematologists, and clinical nurse specialists. A convenience sample of 150 participants comprising: haematology patients, non-haematology patients, and non-patients, took part in the inquiry via a mixture of in-depth telephone interviews and focus groups (see Appendix A and B). A sample of 12 healthcare professionals and stakeholders were also interviewed (see Appendix C).

Discussion of findings: The study found that the notion of a *'clinical trial'* was both positive and negative and that it centered on both positive and negative ideas of being a *'guinea pig'* or a *'lab rat'*. Interestingly, whether the response was positive or negative, views of clinical trials were entwined with the particular historical experiences of black communities, and the economic position of black people. This was seen as aligning them with the experiences of disadvantaged groups perceived to be at risk of being used in clinical trials or clinical research in ways not always appropriate. These views were seen to impact perceptions about clinical trials, and things that are medical. At the same time, a lack of relevant patient information provides a fertile ground for these ideas to flourish.

Alongside concerns about clinical trials and clinical research, the study did find a genuine desire to know more, and to engage. It did not find any differences between black African and black Caribbean groups, or differences among members of the second and third generation in terms of positive or negative perceptions of clinical trials. They were both.

The study found that clinical trials are not routinely ethnically monitored but are monitored on other important dimensions, for example, gender and age. The fact that ethnic monitoring does not take place appears to be due, in part, to historical concerns about issues of race and ethnicity in a scientific context. It is also due to a lack of awareness and a lack of recognition of ethnicity as having any salience in a clinical research context. Where clinical trial participation figures are available, for whatever reason, they clearly show a skewed selection operating in the recruitment process. Indeed, alongside the views of patients and non-patients, this study also found that there is unconscious bias operating in consultations where clinicians sometimes make *'judgement calls'* about who, in their view, will be able to comply with a clinical trial regimen. In addition, the timeframe for recruitment and the pressure to recruit swiftly brings added pressure.

While this study did not examine the views of other minority ethnic groups or other disadvantaged groups, it may also be the case that they are similarly underrepresented as inequality does intersect and fragment along lines of social class, gender, location and so forth. This study therefore argues that it is important to explore broader inequalities using an equality framework.

The production of this report, and the following recommendations, mark the beginning of an attempt to highlight the relevance of social constructions of ethnicity, in the context of wider discussions about inequality, and the way in which it is relevant to clinical trials and clinical research, as this does not currently feature in discussions in the UK.

Recommendations

It is recommended that:

1. The report be disseminated to organisations with key influence such as the National Institute for Health and Care Excellence (NICE), the National Cancer Research Institute (NCRI), the Wellcome Trust, Public Health England, NHS England, and those involved in the sponsoring of clinical trials including blood cancer charities and industry.

2. The report is disseminated to the National Cancer Taskforce as evidence to support the on-going implementation of the National Cancer Strategy in relation to the black and minority ethnic patient experience, and cancer inequalities, as this is specifically mentioned in the Strategy.

3. Patient organisations, NCRI, industry and statutory health agencies engage in a joint dialogue centred on the collection of data to ensure that ethnicity is mandated within the remit of all sponsored clinical trials and clinical research, coupled with the identification of incentives.

4. Opportunities be explored for widening the current involvement of black and minority ethnic patient organisations and service users through different participatory practices, so that they can play an active role in the oversight and governance of clinical research, and clinical trials, through membership of expert panels and advisory groups, ensuring that research issues reflect the priorities of a broad spectrum of patients and researchers.

5. An interactive roundtable event be developed and organised jointly by all of the patient organisations and NHS Trusts directly involved in the production of this report. This should mark the start of a continuing multi-stakeholder dialogue on blood cancers and understanding the relevance of broader health inequalities and disparities in relation to ethnicity and other economically disadvantaged groups, and the implications for diagnosis, incidence, prevalence, and access to clinical trials, and access to services, information, and support.

6. A close examination of major trial centres in the UK should be conducted. This should focus on recruitment to myeloma clinical trials as a blood cancer that disproportionately impacts black communities. This can inform an understanding of the pool of patients that are referred, and the views of healthcare professionals. This information will be valuable for other blood cancer clinical trials.

7. Alongside biological and quantitative clinical trial data collection, the invisible and unrecognised contribution of all blood cancer patients should be captured qualitatively as part of the process of reporting on clinical trial outcomes. This is in terms of the patient experience of clinical trials: emotional, practical, and social, along with their reflections, thus bringing symmetry, balance, and visibility as part of an inclusive exchange to inform clinical research, policy and practice.

8. The views of other minority ethnic groups and other disadvantaged communities in relation to clinical trials, clinical research, and access should be examined as a priority. This is important given that as well as ethnicity, inequality does fragment and intersect along lines of social location, language, social class, gender and so forth, and understanding the experiences of all patients that are seldom heard is critical to addressing inequalities, and ensuring that the benefits of clinical research and healthcare services are evenly distributed.

Blood cancers as a group are multifactorial, that is, they are not one disease but *many*, and diseases such as multiple myeloma do not follow a single clinical course but *many*. This underlines the need for us to reframe how we look at clinical trials and clinical research, and for them to be inclusive of all communities.

Foreword: Dr Matthew Streetly, Consultant Haematologist, Guy's and St Thomas

Myeloma is a malignant disease of the bone marrow, and is one of 137 blood cancers. Despite the introduction of new treatments that have significantly improved responses it remains an incurable disease for the vast majority of patients. However, genetically, biologically and clinically, myeloma is a heterogeneous disease. Whilst for some patients chemotherapy treatments can lead to responses lasting many years, other patients have very short lived disease control and this results in observed survival for patients that can range from <2 years to >10 years. Whilst significant advances have been made in understanding the disease and patient related factors that contribute to this variability, stratification and treatment selection on this basis is in its infancy, with limited evidence to suggest selecting one treatment over another.

An area that has become of increased interest for myeloma research is the influence of ethnicity on the diagnosis, biology and treatment of myeloma. It is well recognised that myeloma occurs with almost double the frequency in the black population compared to the white population and the average age at diagnosis is about 5 years younger in the black population. There are also suggestions that ethnicity has an influence on the biology of the disease and subsequent therapy response. However, understanding of the factors both internal, for example genetic, and external, for example social, and environmental, is currently limited.

A large amount of myeloma research is focused on bringing new drugs from the laboratory bench to the bedside for the benefit of the patients. Clinical trials are the cornerstone of ensuring that these new drugs are at least as effective and safe as existing therapies, and remain a mandated requirement to gain approval by regulatory bodies. Clinical trials are also a route for patients to potentially access newer treatments before they are licensed or have gained regulatory approval. It is therefore of critical importance that we have an understanding of the outcomes of clinical trial research in the context of ethnicity, and that all groups have the opportunity to take part in clinical trials. We know that some medications for the treatment of other illnesses such as hypertension have variable efficacy dependent on ancestry, so it is not implausible that similar effects may be the case for myeloma and other blood cancer therapies.

The work presented in this report raises some extremely important issues regarding the way that ethnicity data are collected, analysed and reported in clinical trials but much more critically, explores the awareness, understanding and access of clinical trials in black patient populations. Implementation of the recommendations has the potential to have far reaching consequences for the improvement of outcomes for all blood cancer patients, as well as helping move towards equality of access to the best possible therapies. Importantly whilst myeloma and other blood cancers are the main diseases discussed within the report, the key messages have relevance to all cancer clinical trials and to the eventual development of personalised treatment approaches.

Dr Sophia Skyers, Mr Campbell Kerr and Ms Pauline Johnson: The Researchers

Dr Sophia Skyers

Sophia Skyers is Chair of the Basil Skyers Myeloma Foundation, and one of its founders. The Foundation was set up in memory of Basil Skyers, Sophia's only sibling. Basil was diagnosed with the incurable blood cancer multiple myeloma in 2008 and after various treatments, including a stem cell transplant he died on 2 August 2010, following relapse. Sophia was the main carer for Basil following his diagnosis, up until his death age 49. Sophia is of the view that a major asset we have as individuals is our particular ways of seeing and doing, borne of our combined personal and professional experience. Whilst it is an asset, it does mean that we can become inured. Sophia is keen to use her personal experience as someone who has been and continues to be deeply affected by myeloma, and her professional experience as a health researcher with social, economic, and biological concerns for health, to positive effect. This is by working with others to challenge the boundaries of current thinking, and developing conversations on issues in relation to myeloma and other cancer inequalities where they have not been examined, and where the interests of patients, carers, healthcare professionals, and patient organisations abut, intersect, and converge.

Mr Campbell Kerr

Campbell Kerr was diagnosed with multiple myeloma in January 2014. The illness started with what he thought was a simple case of a trapped nerve, or slipped disc. Following a visit to the hospital to have exploratory scans, he was admitted on the same day for a spinal operation, and did not see the outside of a hospital again for six weeks. A diagnosis of multiple myeloma followed shortly after this, and resulted in the standard CTD (Cyclophosphamide, Thalidomide, and Dexamethasone) treatment combination, and subsequent stem cell transplant. Campbell is now two years post stem cell transplant and is currently on the Myeloma XI Clinical Trial. Campbell Kerr was appointed to the Board of the Basil Skyers Myeloma Foundation in 2015 and has a committed interest in diversity and engagement issues across a wide range of patient experiences. Campbell has spoken to national audiences of patient organisations and healthcare professionals about the experience of having myeloma, and the importance of learning by embracing different patient and carer perspectives.

Ms Pauline Johnson

Pauline Johnson was diagnosed with multiple myeloma in 2009 and has been a Trustee of the Basil Skyers Myeloma Foundation since 2011. Before her diagnosis, Pauline had never heard of multiple myeloma and when she was initially told, did not realise that it was a blood cancer. That realisation came when, after delivering the news, her consultant said that she needed to begin chemotherapy immediately. After extensive chemotherapy, followed by a stem cell transplant, Pauline was in remission for five years, relapsing in 2015, and then undergoing a second successful stem cell transplant in 2016. As an active Trustee, Pauline has assisted in raising the profile of myeloma and inequalities with parliamentarians, clinicians, patients, carers, and policymakers, and has been instrumental in developing research for the Foundation centred on diverse patient experiences and the importance of the patient voice in myeloma research, policy, and practice. Pauline is of the view that we need to begin to think differently, and to do things differently, as part of a fresh approach, in order to embrace a wider range of patient and carer views and experiences.

1. Introduction and background to the inquiry

1.1 Blood cancers and risk between and within ethnic groups: Multiple myeloma, most often referred to as myeloma, is the second most common of the blood cancers, of which, there are 5,000 new diagnoses in the UK each year.[1] There are in fact 137 different blood cancers, of which, chronic lymphocytic leukaemia, also known as CLL is the most common. As a group, blood cancers have the fifth highest incidence of all cancers and in the UK, 38,000 people each year are diagnosed with a blood cancer.[2] The UK is ethnically and culturally diverse and where clinical trials are conducted, it is important that steps are taken to ensure that sample populations reflect this. This is because blood cancers affect all of humanity, and some groups disproportionately. As an illustration, the white group has the highest rates for most blood cancer subtypes, and blood cancers overall. At the same time, black people, particularly black men, compared with the population generally, have for example, more than double the incidence of plasma cell malignancy associated with myeloma.[3] Moreover mature T-cell malignancy, one of a group of aggressive non-Hodgkin lymphomas, is higher in the black population, particularly among black women.

It is also the case that not only does the risk of haematological malignancy vary between ethnic groups, but there are also differences within ethnic groups. There is evidence for example of a disparity in the incidence of Hodgkin lymphoma and mature B-cell malignancies in the South Asian population, with a disproportionately higher incidence among men in the South Asian group as a whole. Within the South Asian group, the incidence of Hodgkin lymphoma and mature B-cell malignancies is however significantly higher among Indians and Pakistanis, than among Bangladeshis. Similarly, in the black group, we also see a pattern within an overall pattern, in that the incidence of mature B-cell malignancies is almost three times higher in black Africans compared with black Caribbean people.[4]

1.2 The heterogeneity of blood cancers and the importance of multi-stakeholder collaboration: The current therapies to treat blood cancers are powerful and offer immense hope to patients and to their families. It is important however to pay attention to blood cancer disparities as overall figures obscure important differences that are germane to blood cancers, and the way in which we look at them. A greater understanding of difference potentially has benefits for the entire community of people living with a blood cancer. Just as blood cancers as a group are multifactorial, that is, they are not *one* disease but *many*, and diseases such as myeloma do not follow a single clinical course in all patients but *many*, so too, the contours of risk, disparities, response, recovery, and survivorship are not articulated against a neutral genetic backdrop. They are shaped by a constellation of factors operating contemporaneously, social, economic, environmental, clinical, and which include our genetic endowment, epigenetic effects, and our epigenetic inheritance.[5] This underlines the need for clinical trials and clinical research to be inclusive, and for our thinking to be unfettered by engaging in active multi-stakeholder collaboration and partnership.

By coming together, we can jointly begin to question many of the assumptions that underline what we do, what we take for granted, areas where we think differently about the same things, and areas where we think similarly about many different things. This is the most crucial component of being imaginative and inventive, bringing greater perspicacity, as this type of knowledge and experience has the potential to contribute, to addressing unidentified and seemingly intractable issues.

1.3 Aims, purpose, scope and themes for the inquiry: At the axis of the planning and delivery of healthcare and other public services is the principle of equality and inclusion. It integrates a focus on disadvantaged groups where health outcomes are not keeping pace with

the general population and positions tackling inequality as central to improving performance in the health and care system.[6] A number of cross-linking and inter-related factors including organisational barriers to services, clinical, social, economic, environmental, and cultural, impact the health of populations and have biological consequences. A better understanding of the inter-play between these factors will lead to a better understanding of the aetiology of blood cancers.

1.4 This report is an account of a qualitative inquiry into the views of black African and black Caribbean communities on clinical trials and clinical research. The focus on black communities is because, of all ethnic groups, black people have the lowest level of clinical trial participation, and as a group are persistently under represented in genomic studies.[7] The inquiry has also been prompted by the work of the Basil Skyers Myeloma Foundation on myeloma inequalities, and wider calls for more inclusive clinical research. While there is an emerging body of evidence about diversity and service access issues generally, there are limited inquiries about black and minority ethnic communities and blood cancer disparities. There are also few studies that examine the reasons for the under representation of black and minority ethnic communities in clinical trials, particularly in the UK, and the implications for clinical research, services and support.

This inquiry seeks to initiate a conversation about clinical trial participation in black communities. It was supported by an editorial board comprised of interested patients' organisations, consultant haematologists, and clinical nurse specialists, and was structured around a sample of black African and black Caribbean haematology patients, non-haematology patients and non-patient participants.

1.5 The focus of the inquiry

Qualitative Research Themes

1. An exploration of what is understood or attached to the terms 'clinical trial' and 'clinical research' in the black African and black Caribbean haematology patient and non-patient population.
2. An exploration of whether there are intra-group differences within the black African and black Caribbean haematology patient and non-patient population in terms of what is understood or attached to the terms 'clinical trial' 'clinical research' and 'clinical study' (e.g. first, second, and third generation differences, country of birth, origin, age, gender).
3. An exploration of views within the black African and black Caribbean haematology patient and non-patient population on clinical trial participation.
4. An exploration of whether there are intra-group differences in views about clinical trial participation in the black African and black Caribbean haematology patient and non-patient population (e.g. first, second and third generation differences, country of birth, origin, age, gender).
5. An exploration of the views of clinicians and researchers about clinical trial recruitment and the reasons for the under representation.

1.6 The All Parliamentary Party Group (APPG) on Blood Cancer had its inaugural meeting in January 2017, at the House of Commons, to which the Basil Skyers Myeloma Foundation and other blood cancer charities were invited. The focus of the APPG is on understanding the particular needs of all blood cancer patients and the particular needs of black and minority ethnic cancer patients is absolutely fundamental to this as it is specifically mentioned in the National Cancer Strategy.[8] The Association of Medical Research Charities (AMRC) and the Association of the British Pharmaceutical Industry (ABPI) Patient First Conference on 28 November 2016, put out a call

for suggestions on how to improve diversity in clinical research, especially in relation to black and minority ethnic inclusion.

It is the intention that this report, in conjunction with other work undertaken by the Foundation, alongside evidence of other patient organisations, will stimulate debate, discussion and action. This is through joint alliances, and the work of other organisations such as the National Cancer Research Institute (NCRI), as well as organisations with key influence such as National Institute for Health and Care Excellence (NICE) which develops guidelines for research, and identifies gaps in evidence.

1.7 Organisation of the report: This report is organised as follows: section two sets the wider context in terms of explaining what clinical trials are, and points to some conflicting evidence about the reasons for the underrepresentation of black communities. This is followed by section three, which examines the terms *race* and *ethnicity* as dynamic socially constructed concepts, and what this implies in the context of clinical trials and clinical research. This section also explores the notion of *ancestry,* and the tendency, although not precisely, for genetic markers to cluster in particular populations based on geographic evolutionary history. This is a critical consideration in the case of tissue typing for successful bone marrow donation for example, given the tendency for certain genetic markers to be present in some ethnic groups more than in others. Section four sets out the approach to the inquiry and section five presents evidence from the qualitative inquiry, organised on a thematic basis, and as it relates to the views of haematology patients, non-haematology patients and non-patient participants about clinical trials and clinical research. It also incorporates views from healthcare professionals. The final section six synthesises the findings arising from the inquiry, and sets out a series of recommendations.

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2. Blood cancers clinical trials and clinical research

2.1 What is a clinical trial and clinical research? Clinical trials informed by epidemiological studies are important to understanding blood cancers. They enrol individuals as volunteers, and provide a critical base of evidence for evaluating clinical safety and efficacy, before the introduction of a novel therapy, a medical device, or a medical procedure. The underlying objective of a clinical trial is to increase medical knowledge, and to improve future patient care, and outcomes, by bringing forward new treatments. They fall into two categories both of which are governed by the Medicines and Healthcare Products Regulatory Agency (MHRA), and fall within the NHS Research Governance Framework.[9] The first is a Clinical Trial of Investigational Medicinal Product (CTIMP). It involves the testing of new drug therapies, medicines, and the use of placebos, and may often involve a combination of an existing drug therapy with a new trial drug.

The randomised CTIMP is generally regarded as the unassailable *gold standard* and the centerpiece of evidence for testing, whether safety and therapeutic efficacy is due to a particular intervention, rather than to chance, or to some other unrelated cause. This is supposed to be through statistically representative samples of research participants. The second category is non-CTIMP, which encompasses studies or research that do not use investigational medicinal products as defined by the MHRA. Non-CTIMP trials cover a wide spectrum and include, for example, the trialling of a medical shampoo, a surgical procedure, different types of tests, scans, exploration of risk, genetics, screening, exploration of the psychological or social impact of disease and so forth.

2.2 Clinical trials can be sponsored by a variety of organisations including universities, charities, NHS Trusts, NHS Healthcare Foundation Trusts, pharmaceutical companies, biotechnology companies, and companies in the medical devices and diagnostics industry. Moreover, patient organisations that vary in the extent to which they are vocal and are heard engage with statutory agencies and industry, and are actively engaged in campaigns and partnerships to increase access to clinical trials across specific disease areas. The early phase 1 and phase 2 trials look at safety and mainly tend to be run by the pharmaceutical companies who develop a particular medication and look to see if it is something that can be used in clinic. The Clinical Trial Network run by Myeloma UK however also oversees phase 1 and phase 2 trials. The majority of phase 3 trials are non-industry sponsored, and are for drugs that are already licensed. There is a phase 4 trial period known as post market surveillance, which is of no fixed duration, once a drug is available on the market. The risk of teratogenicity with Thalidomide for example, which is routinely used today in the treatment of myeloma, only became apparent in the 1950s after the drug was actually on the market and being used to treat pregnancy associated emesis.[10]

In terms of patient confidentiality and ethics approval the requirements for CTIMP and non-CTIMP trials are largely the same but there are some additional requirements for CTIMPs. CTIMP studies must receive Clinical Trials Authorisation to proceed, and at the time of writing, they are also required to register for a European Clinical Trials Database (EudraCT) number, and are subject to mandatory inspections. It is the CTIMP studies that tend to be in the popular imagination of a clinical trial involving the testing of new drug therapies, medicines, and the use of placebos. In this study, the terms clinical trial and clinical research are used interchangeably to mean any study, whether CTIMP or non-CTIMP.

2.3 What does the existing evidence on trial enrolment tell us? A small body of qualitative evidence in the US and a very limited body of qualitative evidence in the UK seeks to explain the low enrolment levels of black people in clinical trials. At one level, put simply, the legacy of negative past experiences is seen as forming part of a collective historical cultural

memory among black people, and as therefore giving rise to a factually grounded distrust of clinical trials, clinical research, and clinical researchers.[11] At another level, the factors shaping clinical trial enrolment are seen as being rooted in far more complex phenomena. This includes: a lack of access to clinical trials; a lack of knowledge about them; a lack of opportunity to participate, which includes not being asked; practical exigencies on the part of both clinicians and patients, and the values, norms and mores of healthcare professionals, and the perceptions they have of patients. This includes culturally informed judgements and assumptions about who will be able to comply with a clinical trial regimen.[12]

2.4 The recent global registration trial data for ASPIRE and ENDEAVOR which tested Kyprolis for refractory multiple myeloma, has given added impetus to the work of the Basil Skyers Myeloma Foundation on myeloma and inequalities. The trial data revealed that black African and black Caribbean people, despite having double the risk of myeloma, had very low rates of trial enrolment at 2.9% and 2% respectively. This is illustrated in the table below.

2.5 In other myeloma and blood cancer trials, ethnic data is either not routinely recorded or where it is recorded, it is not routinely published, or acted on. The Myeloma UK Clinical Trial Network, which, as already stated, runs early phase 1 and 2 myeloma trials, examines the effect that different drug combinations have on patients at different points in their journey. One of the long-term purposes of this is to tease out whether certain sub-groups benefit more or less, whether there is an impact on patients with particular cytogenetic abnormalities and so forth. While diagnosis or dual diagnoses are recorded, along with age and gender, the ethnicity of patients is not or if it is recorded it is not used. Given that the black population has a disproportionate risk of myeloma, this is a significant omission, as is the under representation of black patients on trials. Moreover, this is not a deviation from a normally inclusive pattern of clinical research as there are parallels with non-haematological cancers such as prostate cancer where the same pattern of trial enrolment is in evidence.

There are 40,000 prostate cancer diagnoses each year, and black men who have twice the risk of developing the disease, compared with the population generally, have a very low rate of clinical trial participation.[15] The largest prostate cancer study, the Protec-T Study, which ran for 14 years across nine trial centres in the UK, and reported its initial results in September 2016, enrolled very few black patients.[16]

2.6 Equality, equity and inclusion: The case for widening participation in clinical trials and reframing how we look at them is an inclusive agenda. It is also important for reasons of ethics, and because widening trial participation can potentially bring benefits in terms of further enlightenment and acuity to understanding more about disease, by drawing on a wider sample population that

Clinical Trial	Ethnic Distribution in the total study population	Geographic region distribution of patients
ASPIRE[13] Carfilzomib+lenalidomide +dexamethasone versus lenalidomide+dexamethasome in relapsed multiple myeloma	N=792 White 95.2% Black 2.9% Asian 0.5% Other 1.4%	N=792 Europe 74.5% North America 21.6% Rest of the world 3.9%
ENDEAVOR[14] Carfilzomib+dexamethasone versus bortezomib+dexamethasone in relapsed multiple myeloma	N=929 White 75% Black 2% Asian 12% Not reported 11%	N=929 Eastern Europe 29% Western Europe 38% North America 9% South America 3% Asia Pacific 22%

reflects all of society and not only part of it.[17] The *'embodied'* experience of patients, which is currently missing from discussions about clinical trial participation is crucial to this understanding and is integral to the future of stratified medicine.[18] As the *State of the Nation in Multiple Myeloma for example makes clear,* translational research that engages patients, healthcare professionals and industry will add to the existing armamentarium of therapies.[19] In terms of *equality* and *equity*, it is important that we examine this issue. A focus on *equality* is important in terms of ensuring that everyone has equal access to any treatment, service or support, but a focus on *equity* is critically important in ensuring that we understand why certain groups are underrepresented or have restricted access, and can inform targeted action and approaches to address this where necessary. It is important however to understand *what* we mean by *race* and *ethnicity*, and *how* these concepts may be translated in a clinical trial or clinical research setting.

9. www.ec.europa.eu 'Definition of Investigational Medicinal Products (IMPs) Definition of Non Investigational Medicinal Products' (NIMPs) and see also www.mhra.gov.uk
10. More commonly known as morning sickness in pregnancy
11. J A Fisher, C A Kalbaugh, Challenging Assumptions About Minority Participation in US Clinical Research, American Journal of Public Health, 2011; 101 (12): 2217-2222.
12. K L Pariera, S T Murphy, J Meng, and M L McLaughlin, Exploring willingness to participate in clinical trials by ethnicity, Journal of Racial and Ethnic Health Disparities, 2016.
    Alondra Nelson, The Social Life of DNA: Race, Reparations and Reconciliation After the Genome, Beacon Press, 2016.
    D Wendle, R Kington, J Madans, Are racial and ethnic minorities less willing to participate in health research? PLoS Med, 2006: 3 (2): e19.
    M Van Ryn, J Burke, The effect of patients' race and socio-economic status on physicians' perceptions of patients. Soc Sci. Med. 2000: 50 (6): 813-828.
    IDEA, Warwick University, Improving the Delivery of Ethnically Appropriate Research, Services and Policy, Ethnicity and Clinical Trials, IDEA Workshop Papers, 2013.
    Steven Epstein, Inclusion: The Politics of Difference in Medical Research, The University of Chicago Press, 2007.
13. A K Stewart, Vincent Rajkumar et al.; Carfilzomib, Lenalidomide, and Dexamethasone for Relapsed Multiple Myeloma, New England Journal of Medicine 2015; 372:142-152.
14. Meletios A, Dimopoulos, Phillipe Moreau, et al., Carfilzomib and dexamethasone versus bortezomib and dexamethasone for patients with relapsed or refractory multiple myeloma (ENDEAVOR): a randomized, phase 3, open-label, multicenter study, Lancet Oncol. 2016; 17:27-38.
15. Prostate cancer affects 1 in 4 black men and 1 in 8 white men and therefore black men have double the risk, which is the same as the risk of myeloma in black people.
16. Freddie C Hamdy, Jenny L Donavan, et al, 10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer, New England Journal of Medicine, October 2016; 375:1415-1424.
    Interview with Professor Frank Chinegwundoh, Consultant Urological Surgeon, Barts Health NHS Trust, November 2016.
17. See discussion in the report for the use of race and ethnicity as important social constructs.
    Alice B. Popejoy and Stephanie M. Fullerton, Op Cit 7.
18. Anne Kerr, and Sarah Cunningham-Burley, Embodied innovation and regulation of medical technoscience: transformations in cancer patienthood
19. The Basil Skyers Myeloma Foundation, Myeloma UK, Bloodwise, and NHS Trusts from across England, provided expert advice at a roundtable meeting convened by Hayward Medical Communications that informed the production of the State of the nation in multiple myeloma – a UK perspective, Amgen and Hayward Medical Communications, 2016.

3. Race, ethnicity, ancestry – How is it relevant?

3.1 Social constructions of race and ethnicity: In recent years, the discussion about equality and inclusion has encompassed a focus on nascent biomedical technologies and the shift towards more targeted cancer therapies.[20] The Human Genome Project which mapped the entire human genetic code demonstrated that in biological terms, humans share 99.9% of their DNA and that the remaining 0.1% cannot be attributed to race.[21] The terms race and/or ethnicity do not therefore denote inviolate biological or naturally occurring categories rooted in the genetic script of individuals or groups sharing physical and/or social attributes. They are self-assigned, imprecise, socially constructed classifications. They are often employed uncritically in scientific, medical and social research, and their pedigree is a long and contested one.

3.2 Interpreting official hallmarks of race and ethnicity over time, by geography, and by race and ethnic classification: As self-assigned and contested concepts, what we understand by race and ethnicity is dynamic and it changes over time. This dynamism has included seismic shifts in how the terms are defined and interpreted, even during the lifetime of the three authors of this report. Added to variations in definition and interpretation over time are variations by country.[22] As self assigned categories, it is the case that how individuals self identify, or whether they choose to identify at all, also changes with time as individual notions of identity and the expression of it change.[23] There is also an added layer of complexity in practically applying broad race and ethnic categories. Given the 200,000 year history of humans has been one of constant migration, cultural exchange, cultural fusion, and the mixing of DNA, illimitable diversity is not reducible to a few ascribed groupings that have an administrative imprimatur. The groupings are not able to accurately account for identity or experience either at a group level, or at an individual one. This has important implications in terms of the way race and ethnicity potentially shape and inform clinical trials, and clinical research and practice, with all the methodological constraints this implies for: data collection and comparison; comparisons over time; comparisons between continents, and critically, understanding how and why patients self-identify, the social location of patients and the patient experience, and how aggregate data inform individual patient care.[24]

3.3 In clinical research, the available data on the recorded participation of black patients mirrors the pattern of exclusion we see at other institutional sites including access to other healthcare services. While race and ethnicity are not biological categories, the terms are nevertheless valuable in research as broad social constructs. They add to our understanding of patterns of inequality and this includes inequalities in health, and health outcomes. These inequalities are based on shared social attributes and experiences, and shared connection by geographic ancestry that have biological consequences, and a focus on inequality is critical to the framing, understanding, and contextualizing of risk and group disparities in health.

As clinicians, researchers, patient, carers, and policy advisers begin to understand more about the complex interaction of variables: genetics and genetic inheritance; epigenetics and epigenetic inheritance; environmental signals; high risk cytogenetics, and the contours of response, response variation and so forth, a different set of questions arise from the myriad factors that correlate or intersect the social categories of race and ethnicity, and other social groupings. This has implications for broader coalitions of organisations coming together to identify and to address disparities in the incidence and prevalence of blood cancers across all communities, and to identify and address disparities in survivorship.[25]

3.4 The questions that are posed in clinical trials and clinical research and who poses those questions, obviously informs the type of evidence that is collected, and the boundaries of knowledge that is curated. Therefore, including sets of questions that have been informed by *varied* rather than *unified* perspectives is fundamental to innovation, to the collection and production of robust evidence, to guarding against subtle and persistent bias, and therefore to the external validity of knowledge. The trial population in blood cancer trials currently reflects a partial view of the patient population. It is anchored in genomics and biotechnology as the overarching intellectual fabric, but it does not take account of the fact that clinical trials and clinical studies mirror the social relations in society. This ultimately begs the question of the extent to which the knowledge produced is also parochial and therefore incomplete, and the implications of this for those groups that are not included in clinical research, as well as the implications for those that are in terms of understanding more about the aetiology of blood cancers.

As blood cancers affect all of us, it is unclear why a diverse patient population and the broader patient experience, is not also reflected in the design and at the participatory level in clinical trials. This is an issue that does concern all of us since the knowledge that would be gained from a diverse recruitment pool could more justifiably be extended to the patient population as a whole, as it would mirror society as a whole. This is in contrast to the current practice of deriving knowledge from a limited clinical trial patient pool that is then extended to diverse treatment groups. A broader base for knowledge construction as well as wider participation is intellectually more rigourous, and therefore, potentially has hugely beneficial effects for the entire blood cancer patient population, their families and carers.

3.5 Ancestry: While there is no genetic basis in our DNA to identify race and ethnic categories, variation in DNA, as already stated, can reveal something about ancestry in a geographical sense. As an illustration, notwithstanding significant variation within groups sharing a common ancestry, certain genetic mutations, for example sickle cell, haemoglobin C, and thalassemia, carry the hallmarks of our journey as humans across the globe over millennia. They also bear the footprint of our adaptations as a common human species to environmental threats.[26]

In blood cancer and its treatment, ancestry is important and currently, nowhere is this seen with greater clarity than in the Human Leukocyte Antigen (HLA) typing that is used to match stem cell donors to patients. HLA is a protein or marker found in most of the cells in the human body. The immune system uses HLA markers to determine which cells belong in a particular body and which do not. HLA matching is important in allogenic bone marrow transplantation to prevent graft rejection and other serious complications. Ancestry is pivotal to this because patients are more likely to find a match among potential donors from their own ethnic group so black and minority ethnic patients in the UK for example, face more obstacles in finding suitable donors. This is because of their smaller numbers in the donor pool, and because black and minority ethnic donors are under represented on the donor registry. Moreover, black and minority ethnic patients who are of dual heritage, for example African and European or other ancestry, have a rarer HLA variation and therefore have an even smaller chance of finding a suitable stem cell donor.

3.6 Ancestry may also have implications for personalised medicine in that genetic variants of blood cancers or some of its biological features may show variation by geographic ancestry. This in turn may have implications for the extent to which certain treatments may or may not be effective across or within populations, or for understanding the precursors of disease. In the absence of wider study populations, a statement either way is speculative and it remains an important issue but an unexamined one.

While race and ethnicity are not biological categories, the terms are valuable in research as broad social constructs. They add to our understanding of patterns of inequality and this includes inequalities in health and health outcomes. These inequalities are based on shared social attributes and experiences, and shared connection by geographic ancestry.

20. M Lock, and V K Nguyen, An Anthropology of Biomedicine. Chichester: Wiley-Blackwell, 2010.
    Epstein, Steven, Op Cit 12
21. M W Foster and R R Sharp, Race, ethnicity, and genomics: social classifications as proxies of biological heterogeneity. Genome Rs 2002; 12:844-850.
22. To illustrate these points further, the UK Population Census has a number of ethnic categories. This includes the white and the black group, both of which are defined principally by colour. The South Asian group by contrast is defined not by colour, but by reference to an entire continent. The Chinese group is defined by reference to an ethnicity, and included in the overall Chinese category is the culturally distinct Vietnamese group. This is a radical departure from the 1991 UK Population Census, which is illustrated in the Office of National Statistics, A Guide to Comparing 1991 and 2001 Census Ethnic Group Data, which had different categories of ethnicity in the two periods, and different questions were asked in England, Scotland, Wales, and Northern Ireland during this same period. In terms of other variations by country, in the UK, the Asian and Chinese groups are distinct Census categories whereas in the US, the Asian Census category includes the South Asian and Chinese population in one group.
23. See for example JRF and Manchester University, Dynamics of Diversity: Evidence from the 2011 Census, ESRC Centre on Dynamics of Ethnicity, March 2014 which, through anonymous records linking responses to 2001 and 2011 Census, was able to track how individuals express their ethnic identity across time, with significant proportions choosing a different ethnic group in 2011 to the one they selected in 2001.
    Alice B. Popejoy and Stephanie M. Fullerton, Op Cit 7.
24. A patient from Jamaica for example, who has Indian or Chinese ancestry will share an identity as an African Caribbean, or black Caribbean. Therefore, group based notions or probabilities should not to be employed in making judgments about individual patients on the basis of group membership because individuals do not confirm to group assumptions.
    Jill A Hollenbach, Aliya Saperstein et al Race Ethnicity and Ancestry in Unrelated Transplant Matching for the National Marrow Donor Program: A Comparison of Multiple Forms of Self Identification with Genetics, PLoS ONE 10(8): e0135960, 19 August, 2015.
25. Steven Epstein, Op. Cit. 12.
    Dorothy Roberts, Fatal Invention: How Science, Politics and Big Business Recreate Race in the Twenty-First Century, the New Press, 2011
    Michael Marmot, Op. Cit. 5.
    Peiter Sonneveld, Hervé Avet-Loiseau, Sagar Lonial, et al, Treatment of multiple myeloma with high-risk cytogenetics: A consensus of the International Myeloma Working Group, Blood 2016, 127:2955-2962.
    See for example, K Dimopoulos, P Gimsing and K Grønbæk, The role of epigenetics in the biology of multiple myeloma, Blood Cancer Journal, 2014, 4, which points to several recent studies that have highlighted the biological complexity of multiple myeloma for example and epigenetic changes have been revealed to be critical players in its development.
26. Sophia Skyers, one of the authors of this report has haemoglobin C trait and it is seen disproportionately, but not exclusively in people whose ancestors are from West Africa, the Caribbean, Italy, Greece, and Latin America. People with the haemoglobin C trait have red blood cells that have normal haemoglobin A and an abnormal haemoglobin which is called haemoglobin C. Having the haemoglobin C trait means that individuals with it have slightly more normal haemoglobin A than the abnormal haemoglobin C, and it does not therefore pose any health difficulty. Haemoglobin C does however offer some protection against malarial parasite and is an evolutionary adaptation for people originating from those parts of the world where malaria and malarial parasites are common. It quite clearly confers no evolutionary advantage to someone like Sophia who was born in and lives in the UK.
    Christine Kenneally, The Invisible History of the Human Race: How DNA and History Shape Our Identities and our Futures, Penguin Books, 2016.
    Catherine Bliss, Race Decoded: The Genomic Fight for Social Justice, Stanford University Press, 2012.
    Alondra Nelson, Op. Cit. 12

4. Approach to the inquiry

4.1 Development of a sample frame, qualitative approach, collection of data and analysis: The focus for the study was exploratory in seeking to understand the views of the black population about clinical trials. The form data takes can include numbers and/or qualitative narrative accounts, depending on the research questions being posed. This research, which was exploratory, justifiably suggested a research strategy centred on a qualitative approach to data collection.

A sample of 150 participants comprising: haematology patients, non-haematology patients, and non-patients, took part in the inquiry between February and May 2017. The approach was structured around a mixture of one-to-one and paired face-to-face interviews, and one-to-one telephone interviews, lasting between 20 and 60 minutes. The African Caribbean Leukaemia Trust (ACLT), Bexley African Caribbean Community Association (BACCA), and the Black Health Initiative (BHI) - BME Cancer Voice, directed interviewees to the researchers. A focus group and two deliberative workshops each lasting for an hour were also included in the approach. The focus group was with a patient support group, Sistas Against Cancer in Nottingham and was organised by BME Cancer Communities (BMECC). As part of a national conference to support its continuing programme of work on clinical trials and the future of sickle cell, the Sickle Cell Society (SCS) convened a deliberative workshop with patients and carers, which the researchers were asked to facilitate. The outcomes of that workshop will support the Sickle Cell Society in developing its national programme of clinical trial inclusion, and at the same time has informed this research. Finally, the Greenwich African and Caribbean Forum (GACF) offered the Foundation a dedicated space in which to run a deliberative workshop at one of its monthly meetings as part of its *Audience With* series which provides a platform for bringing together the community with healthcare and business professionals, on a variety of issues and topics.

4.2 To ensure that the sample did not only reflect those actively willing to engage with the subject matter, participants were also recruited through impromptu drop-ins at a black hairdresser, a Caribbean café, and at places where black people come together socially. The sample was a diverse one that took account of age, place of birth, including African countries, Islands in the Caribbean, and gender, and where possible, whether participants were first, second, or third generation, and recruited from Leeds, Manchester, Nottingham, Derby, Essex, Kent, Bedford and London (See Appendix A and B for details). The participants were given assurances that what was discussed would remain confidential, and that they would not be identified. It was also made clear to participants that they were under no obligation to answer any question. A series of telephone interviews were also held with healthcare professionals who impart information about clinical trials to patients, and recruit to them, and researchers who engage with clinical trials at a strategic level. A total of 12 interviews were held with healthcare professionals and researchers (See Appendix C).

4.3 It was made clear to everyone that as well as having specific lines of inquiry to inform the study, issues that participants saw as relevant should also be introduced. Indeed, the essence of the qualitative method and other forms of appreciative inquiry is in the term *inter-view*, which denotes an exchange of views. In this sense, knowledge is not solely about the researcher mining for and extracting information, but is about an exchange of views where knowledge is created and informed through the active participation of interviewer and interviewee during conversation and interaction.[27] In line with best practice in qualitative research, the lines of inquiry were continually refined as the research proceeded. This ensured that the process remained exploratory, and at the same time, focused on the deliverables of the project.

4.4 A technique known as *thematic saturation* was employed and this is where there is correspondence with the themes coming through from the fieldwork and there are no new data emerging.[28] A system of framework analysis was used to identify and categorise emerging themes. The process of framework analysis involves an in-depth familiarisation with the interview data; the coding of the data; the identification of themes; a review of the themes, and the organisation of themes. This is the process that informed the production of the report. There were 5 classification headings generated from the data and under these headings, all of the data were accounted for.

27. Jane Ritchie, Jane Lewis et al, Qualitative Research Practice: A Guide for Social Science Students and Researchers, Sage (Second Edition) 2014.
28. Jill Francis, Marie Johnson, Clare Robertson et al, What is an adequate sample size? Operationalising data saturation for theory-based interview studies, Psychology and Health, Volume 25, 2010, 1229 – 1245, 2010.
A.J OPnwuegbuzie, and N.L. Leech, Sampling Designs in Qualitative Research: Making the Sampling Process More Public, The Qualitative Report, 12 (2), 238 – 254, 2007.

5. Themes emerging from the inquiry

5.1 The following themes were identified and have been elaborated on in the ensuing paragraphs:

a) Associations and meanings attached to the terms clinical trial and clinical research.

b) Clinical trials, historical and current associations, and conflation with blood, organ, and donor registration.

c) Decisions about participating in a clinical trial and experiences of them.

d) Clinical trials and structural barriers to participation.

e) Widening participation and views on how we might be more inclusive.

5.2 Associations and meanings attached to the terms clinical trial and clinical research: The prevailing narrative and a continually recurring theme in the discussions with haematology, non-haematology, and non-patient participants, was the concept of a clinical trial as signifying *'experimentation'* and *'research'* to test ideas, specifically in relation to the ingestion of medicines or the injection of drugs. A minority of participants did envisage a clinical trial as a medical procedure involving for example, the drawing of a venous blood sample for use in laboratory tests, as experimentation on biopsied tissue that would otherwise be discarded, or as involving use of a machine or external device. The majority however saw a clinical trial as involving human populations in the testing of new drugs and medicines to assess safety and efficacy, and to identify potentially harmful side effects.

The clinical trial was seen, variously as: something that was positive and of benefit to humankind; as being centered on *'experimental treatments' for 'terminally ill patients'* when *'they are running out of ideas'*; as involving a process of *'trial and error'*, and as spanning patients with a range of diagnoses. It was also seen as *'scientific research'*, in non-patient healthy population groups such as students, or the general public, through self-selection and choice for monetary reward; as a *'medical experience lacking certainty'*, but nevertheless as representing *'progress'*, and *'future medicine' and also less positively in being seen* as invoking *'fear'*, and as having the potential to take advantage of vulnerable groups without their knowledge or consent, the defining hallmark being use as a *'guinea pig'* or a *'lab rat'*.

5.3 Across the entire cohort, haematology, non-haematology, and non-patient participants were concerned that in a clinical trial, after having received a cancer diagnosis for example, they might be randomized and solely receive a placebo and therefore no active treatment at all. The concept of randomization, as employed in clinical trials, is not clearly understood. The notion of randomization as understood by some study participants denoted something that was *'haphazard'* and *'not thought through'*. There also appeared to be concern about the level of risk involved, and the safety of drugs being tested, and this includes experimental drugs and drugs that have passed through previous trial phases. The study participants explained how they understood clinical trials in this way:

'Clinical trial conjures up to my mind a guinea pig for a new drug. There is a drug that is not on the market yet and you're a guinea pig and there might be placebos and the actual drug and the reactions of the people will be tested in terms of safety….So, you would have the drug that is being trialed and then you would have the dummy drug and would compare effects' (Interviewee 1, Female, Age 45, Nigeria, Second Generation, London).

At the clinical trial design and recruitment stages, while diagnosis, co-morbidities, age and gender are seen as relevant, and data are collected on that basis, there is no mandating the collection of ethnic data. In other words, for all disease areas, and this includes for example, myeloma and prostate cancer where black people have a higher disease risk burden, clinical trial data are not routinely collected on grounds of ethnicity. This contributes to an in-built partiality.

'My father in law died of myeloma last year and he was actually on some trial drugs but he was 89 and he had myeloma. He was diagnosed three years ago…um to be honest, we don't know if he had a placebo or the actual thing because he wasn't told. We think he had the actual drug because he had an adverse reaction. He became confused. Basically, he didn't react to it very well….The risk of clinical trials is that people don't get any drug at all. That is the only way they would be able to test it. I wouldn't have thought it would be an older drug against a new drug. I would have thought with old drugs they would have established what they can do so that's why they are introducing new drugs.' (Interviewee 5, Age 51, Female, Jamaica, Second Generation, London).

'Obviously I am a bit more aware of what this means as a result of being diagnosed. My interpretation is that there are medications being considered in addition to what's already in existence but not officially rubber stamped in the UK and my understanding is that if you tick all the boxes, you will be offered the chance of medication that has not been considered. As a person being diagnosed with myeloma I would consider it as a positive in my case. For example, now I am on medication and for whatever reason two or three months down the line the haematologist says "we have done everything in our power", and I am waiting to die, knowing clinical trials are in existence, who's to say that what they have in existence would assist me or help prolong my life or whatever the case may be' (Interviewee 19, Male, Age 56, Multiple Myeloma, St Lucia, Second Generation, Bedfordshire).

'Clinical trials, what comes in my mind is that it is experimenting and researching, into various illness and disease...I see it as positive, you got to do some trial or investigation for helping to combat diseases' (Interviewee 26, Male, Age 77, Prostate Cancer, Jamaica, First Generation, Leeds).

'I am part of one at the moment where anytime I go to the hospital they take my blood because me having kidney cancer and my age so the trial and all is taking my blood. I'm not having any special medication. I don't have a problem with that if it's going to aid and benefit people in the future but I'm not being a guinea pig for any reason' (Interviewee 34, Female, Age 53, Kidney Cancer, Jamaica, Second Generation, Nottingham).

5.4 The term *'guinea pig'* as used by participants had two seemingly contradictory and dual meanings, sometimes held simultaneously by the same individual. The term could be used critically on the one hand to signify potential misuse of the body and in particular, the bodies of black people and other disadvantaged groups. At the same time, the term *'guinea pig'* could be used affirmatively, in a way that implied treating people as *'special'*, showing them *'extra care'*, and at the same time, moving medicine forward, providing hope for existing and future patients. Allied to these views was also the notion that whilst being a *'guinea pig'* in a clinical trial might imply individual benefits and wider benefits for society through improved access to more effective treatments, it might also mean black people absorbing a higher level of risk. This is because risks, harms, and benefits, and the ability to influence are seen as being unequally distributed in society. In these circumstances, less influential groups can be seen as being at a higher risk of mistreatment, even among those patients who place trust in their clinician. The following remarks exemplify these views:

'….one of the things is that us as people, we are all very different, no one is the same, everyone's body is different so even going down the normal route there is a risk that things can happen to you but in a clinical trial, it is even a bigger risk. No two people are the same….In a way everything is a trial because they are probably researching everything and how everyone reacts. I feel they were open with me and that they never knew it could happen (adverse effects in a clinical trial) which is why what happened to me was such a shock. Their main issue is curing the cancer and not people's quality of life. If someone does not like black people though, they are not going to give them the best options' (Interviewee 8, Female, Age 26, Acute Lymphoblastic Lymphoma, Jamaica, Third Generation, Essex).

'It is trial and error but that's the way it is. If we didn't have this, how would we know to treat what we got? I mean my grandmother ed to give me bush "tek dis and tek dis". we know more information than we ever fore' (Interviewee 18, Male, Rare Eye Age 51, Jamaica, Second Generation,

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nd awful. The first thing I pig and to be honest, these trials because they that whereas black ep back. So, the first g a guinea pig and e do. Um, I say linical trials I periment for ? Don't get ative way ons and ve tive.

5.5 A minority of study participants saw the terms *clinical trial* and *clinical research* as being interchangeable. The majority however said that they saw a clear distinction between the two. Whereas a clinical trial was seen as involving people in the testing of pharmacologically active agents or placebos, clinical research was seen as being more theoretical, often a stage before or after a clinical trial that does not involve the physical testing of drugs in humans. Clinical research was therefore seen as innocuous, and as a less loaded concept, precisely because it was seen as having very limited potential to cause direct harm to individuals. The following remarks typify this view:

'…they are trying something out. This research is also clinical research….I'm talking to you and giving you my opinion but you are not asking me to inject anything or try anything that's the difference. I can talk until whenever because I'm giving you my opinion you ask but for you to tell me to sit down do this injection there or wherever, that's different. I'll talk to you yes' (Interviewee 21, Age 50, Female, Jamaica, First Generation, Nottingham).

'One is a trial and one is researching into the background' (Interviewee 23, Female, Age 86, Jamaica, First Generation and has participated in two clinical trials, Son died of Multiple Myeloma in 2010, age, 49, 2010, Nottingham).

5.6 Clinical trials, historical and current associations, and conflation with blood, organ, and donor registration: While the concept of a clinical trial was viewed as positive among some of the study sample, albeit with risks attached, and negative among others, the term clinical trial was at the same time conjoined with negative historical and current associations. This was the case among the majority of study participants, including those who held positive views about clinical trials. The negative associations related principally to the Tuskegee experiments, and to the Henrietta Lacks story.[29] Their knowledge was not always detailed, and whilst it sometimes translated into being seen as an actual or potential barrier to participation, this was not always the case. Rather, these experiences were viewed in the context of broader historical and continuing social and economic inequalities between various groups in society, and inequalities between developing and developed nations. A direct link was made between socially and economically disadvantaged groups, which included but was by no means limited to black people, and the potential for injury and mistreatment. There was only a very small minority of study participants who did not make any association between clinical trials and negative historical or current events.

It was explained in this way:

'It could be anybody, black white, green blue but I have heard people say clinical trials are only carried out on, not necessarily black people, but people from minority groups, it could be poor, it could be uneducated people, it could be homeless people etc etc. I know certain things this mind set that people have that historically everything bad gets dumped on black people. Take for example medication in West Africa for example, medication that has expired is sent to African countries where pharmaceutical guidance is not as rigid as it should be and if people want a prescription on the market place, they buy it and self medicate and it can lead to disaster. So, whether it is something like that that has poisoned the minds so they got this idea that all the rubbish gets dumped on Africa….So if someone comes along and says they want you to take part in this trial, I think something from way back holds them back' (Interviewee 3, Female, Age 59, Lupus, Sierra Leone, First Generation, Kent).

'There is a fear factor of exploitation, a general fear factor of what they gonna do to me. I honestly think it's a cultural thing. There is a basis for it. It is how the majority who are white, because you've got this perspective of hierarchy where all these people are the professionals, the high uppers and so on and they will extract things or take things that they need and actively use things in an inappropriate way possibly and you can't control it' (Interviewee 22, Male, Age 80, Jamaica, First Generation, Nottingham).

'Clinical trial as a black person, it conjures up a level of brutality in terms of not sure what they're doing to me so its not physical, its psychological and are they going to give me something that is not going to kill me but damage me so a lot of it is psychological. I think history dictates that when they have done clinical trials on black people as much as it is to find out what is going on it is not to cure them, it is experimental. It's not for our good, always for somebody else's good. Just historical when they were doing the trial on the American soldiers, can't remember what it was for you know, I think that is the one that sticks in my head to be honest but to be honest, even myself, I have rheumatoid arthritis, they wanted to put me on a combination of drugs or a placebo and when they talked me through it the side effects were horrendous and it would make my arthritis better but it could affect my blood, it could affect my kidneys, I would rather take Ibubrufen and deal with the pain and discomfort I'm in' (Interviewee 29, Female, Age 50, Jamaica, Second Generation, Rheumatoid Arthritis, Leeds).

'I think the first thing I read before I knew a great deal about research was about the Tuskegee. It was something that happened in America. It was a horrible thing. It went on until the 70s and they were letting them go home and infect their wives' (Focus Group Participant 33, Female, Age 61, Breast Cancer, Jamaica, Second Generation, Nottingham).

5.7 This study found that documented historical experiences and current views about clinical trials are also conflated with fears about blood and bone marrow donation. These fears are all part of a generalised concern about being used as a *'guinea pig'*, in a position of powerlessness. As with any social group, black communities are a diverse group and it is therefore impossible to pin down precisely, a particular stance that accords with this view in every case. As illustrated haematology, non-haematology, and non-patient participants viewed clinical trials as important in pushing forward the frontiers of medical knowledge, and as having wider public benefit. At the same time, there was recognition that while there are risks involved, these risks are seen as being higher for those of lower socio-economic status. These concerns about risks and harms also morph into concerns about procedures involving blood donation and testing for bone marrow donation, as well as organ donation. As is the case with clinical trials, these procedures are seen as being part and parcel of the same set up, in having the potential to expose black people to unwitting experimentation and the taking of their body parts through their use as *'guinea pigs'*. Moreover while participants in the sample talked generally in terms of a high level of respect for healthcare professionals, organisational practice in relation to data capture, data management, and data use is seen by some as lacking transparency. This gives rise to additional concerns about loss of control over personal data, and concerns about whom the data will be shared with, and the use to which data will be put.[30] These deeply held fears are ingrained with individual cultural beliefs, cultural practices, and historical associations, and contemporary group experiences of discrimination.

The following remarks typify these views:

'My wife worked as a volunteer with ACLT and during the drive the companies were prepared to hold drives and a lot of the black people they would help me to sign up but not be on the register for anyone else and when I asked them why, they said they mistrust the authority with the information and people have said it direct to me but in my case, the more people on the register, the better….I have been in hospital, I have not noticed many black people coming forward to say sign up and this is from personal experience also people from African background will say they can use it for voodoo and can use it for x y z so people are very mistrustful of what they do with information. It is cultural influence. I come from Nigeria, people feel that you can use it to do some kind of medicine against them or people being killed for their body parts so people are scared to offer up anything they feel could be used against them' (Interviewee 6, Male, Age 60, Myelofibrosis, Nigeria, First Generation, London).

'Black people back home hold doctors in very high esteem so it is a contrast reasons in what I have found here and what I see back home. Back home people trust doctors completely whatever the doctor gives you is OK but I have come here and seen people who are wary of doctors in case they are treated badly. But I do know that people trust medical doctors they are educated and know what they are doing but when it comes to clinical trials, that is where our belief system would kick in with: "am I being used here from the stories I have heard". I know when we asked people to register I hear "I didn't want to sign" that "the doctor will kill you to harvest your organs" and things like that and you think my goodness, where did you hear that from?' (Interviewee 15, Female, Age 50, Kenya, First Generation, Son Diagnosed Leukaemia, 2012, at 22, Died in 2014 at 24, London).

'Fear is a big one. Perhaps it stems back going back to days of slavery, perhaps it goes back to that. People don't trust the system that we are in, understandably, I think they have done the black community wrong but when it is for our benefit, they should get on board, they think you are not doing something to help us, you are doing something to harm us'
(Interviewee 17, Male, Age 53, St Kitts and Barbados, Second Generation, Multiple Myeloma, 12 Years Post Stem Cell Transplant, Manchester).

5.8 Decisions about participating in a clinical trial and experiences of them: The factors influencing the decision of participants who indicated that they might be willing to take part in a clinical trial were varied and interconnected. There were those who said that receiving payment for taking part would be a consideration, and others who said their age would be a factor. There were those who said lifestyle issues would be important in terms of the level of personal commitment required, logistical arrangements and so forth, and others who said that any decision would need to be informed by clear information, a full understanding of the implications of taking part, coupled with knowledge about the processes and procedures any drugs or medicines had previously been through. There were some participants who stated that they would need an assurance that they were not the first to take part in a particular trial, and that they would want an absolute guarantee that they would not be harmed as a result of taking part, as well as those who said that offering a trial at diagnosis of a serious illness might be too much for some patients to take in, as well as those who said that they would like to see clinical trials offered earlier. There were others who said positive and negative stories about the experiences of people, both black and white, who had taken part in a trial would be an important and credible source of information and reassurance, and there were those who said it would be important to hear stories from the experiences of black people, *'who are like me'*.

The prime mover for the majority of participants in taking part in a trial was the chance of recovery, however infinitesimal, of extended life expectancy, or at the very least, making a contribution towards the progress of medicine that might not benefit them, but might, at some point in the future, benefit their children, other family members, and ultimately, wider humanity. The views of participants were more positive in cases where they or a close family member had taken part in a clinical trial and the outcome had been a favourable one, or where the treatment offered to them had been successful and less invasive than their existing regimen. These views were expressed in the following ways:

'If I was particularly diagnosed with an illness and the doctor said to me, we are not sure, we have not got a cure, the doctor said to me and I accepted my fate moving forward because number one it might save me, if it doesn't save me, it might save my son, my daughter, anyone in my community and outside. There must have been lots of guinea pigs in my family for diabetes, blood pressure, and yes it might be apprehension in that case and I might actually get worse by something you have given me… I might not have one that works, but for my husband it has. I have had a marriage for 17 years whereas if he hadn't been on it (a trial for AML), I wouldn't have' (Interviewee 2, Female, Age 56, Antigua, Husband diagnosed with AML, Second Generation, London).

'…been on a clinical trial for a new medicine it is Glivec Inmatinb and been on the trial from 2001 as I was lucky, it worked very well for me and personally after being on that thing for six months, it showed signs of improvement…. Everybody is different, with me, after nine months, I had showing signs of remission so then the thing is leaving me and some people it took a little longer….Clinical trials I have to say yes, honest to God especially 18, 19 years ago with leukaemia, the success rate was very poor …I was on an injection called Interferon B, and I don't' think there is one person on earth who likes injections so coming from an injection to a tablet I say yes. If it was injections, I don't know what I would do, I would probably say yes too but once it is a tablet, rather than an injection I say yes please!' (Interviewee 4, Male, Age 55, Chronic Myeloid Leukaemia, Dominica, Second Generation, Kent).

'I listen to them but at the end I make that decision about whether I'm gonna be doing it. I listen to your point how you put yourself across….I listen to the stranger if it is somebody who is working on the drugs and he probably know a little bit more than my normal doctor that I'm seeing day in and day out. He probably would be able to put a bit more across to me than a normal somebody every day doctor won't, but then at the end of the day, I make that decision, but he's probably giving me a bit more food for thought' (Interviewee 20, Female, Age 58, Sickle Cell, Second Generation St Kitts, Nottingham).

'We are less trusting of everything really because when it comes to things like cancer, black people associate it to be a white disease and the minute you are diagnosed with it and then you want to give me a trial, no, too much, all in one go….Before I was diagnosed 100 per cent thought it was a white disease but when I was diagnosed I literally thought I was the only person ever of my age to be diagnosed with it but when you go to hospital and see people and read things, you realize it is not a colour disease….Yeah, I think trial should be available 100 per cent because the medications that I am on that have got me to the point where I am now healthy and living my life, these treatments have to be tried on someone so I think it is good to try medications and treatment because our bodies are changing and the cancers are becoming more aggressive. The Tablet, Gleevec and Imatinnib that I was on, had to be tried on somebody because if I had been diagnosed early than that, I have would have had to go through transplant and chemotherapy and all I had to take, one tablet. I know someone who has been on the tablet for fifteen years but I know this was because of so many trials with people for me to benefit from it'
(Interviewee 14, Female, Age 31, Rawanda, Diagnosed with CML, at 21, and ALL at 26, London).

Clinical trials are a route for patients to potentially access newer treatments before they are licensed or have gained regulatory approval. It is therefore of critical importance that we have an understanding of the outcomes of clinical trial research in the context of ethnicity, and that all groups have the opportunity to take part in clinical trials.

'My husband was diagnosed in 2007 and died in 2012 of myeloma. I would have liked for him to have it (clinical trial) at the end but he was too ill. They should offer it earlier' (Interviewee 41, Female, Age 64, First Generation Jamaica, London).

5.9 In those cases where the outcome of treatment is considerably less than optimal, or where a loved one has died, views about taking part in a clinical trial lean towards being seen as conferring limited benefit, or as resulting in damage to quality of life. This was most often the case where patients had consented to a treatment, not necessarily as part of a clinical trial, or where carers had given consent to a particular treatment, or to a trial, but in hindsight, did not feel that they had been sufficiently apprised of the nature of the risks, and the availability of other treatment options:

'I had ATG treatment which is basically not stem cells but is using a type of rabbit treatment they also use a horse….At the time I didn't have a choice because when I was diagnosed, October 2008, and by January 2009 I had the ATG treatment because they explained you don't have to go through chemo, we haven't found your bone marrow match, you are needing blood and platelets every week so it would be good to try this treatment so I agreed not really understanding what I was getting myself into. It was not the best reaction, I had lock jaw my mouth was swollen, my lips turned outwards, I had paralysation, literally my hands were locked and after a day or two I made a recovery but I had pains in my joints… I wouldn't (go on a clinical trial) because I've had a bad experience with different types of treatment, I wouldn't be quick to run into a clinical trial. If you are at the point where you have no other options then I suppose yeah, you haven't got much to lose' (Interviewee 7, Female, Age 28, Aplastic Anaemia, Jamaica, Third Generation, London).

'I was diagnosed in 2007 December and was on a new protocol of drugs for my treatment so instead of being two years or two and a half years, I had 18 months of treatments but in March 2008 I had a rare side effect that they had never seen and my whole nervous system shut down and I couldn't walk, talk and was paralysed and because they had never seen this before, they didn't know whether I would be able to walk again and I have mobility problems now but clinical trials, I personally am quite against them….because of what happened to me, my views have totally changed on clinical trials. Everything is based on surviving the cancer and not the quality of life afterwards…. I was 17 and I had my life ahead of me and yeah I am surviving and I am very grateful for that and sometimes in my mind I wonder how it would have been if I didn't get these side effects. If I had just gone on the normal treatment because when it happened to me I had to go on the other protocol and I was on that treatment for two years anyway….you need to understand the pros and cons because what happened to me was very rare, over 1 in a million so I wouldn't want people to be frightened from my experience but equipping yourself with the right information and preparing yourself for anything that could happen' (Interviewee 8, Female, Age 26, Acute Lymphoblastic Lymphoma, Jamaica, Third Generation, Essex).

'He had a couple of clinical trials but when he first went I just didn't care what they gave him I just wanted them to just fix him so in the beginning, I didn't even care and even though they were trials, I didn't hear that word "trial", all I just heard: "this is what we give them, this is what works" but it was only after the third chemo didn't work I started to listen in a different way and it was in remission for a while, and then it came back and the doctor talked about a new trial and it was a new drug....But for me, I think because maybe because the way my head works or whatever I was more open to it than my family were because they say, "guinea pig, guinea pig, you don't know what is going to happen to him"…. So he was refused that drug first and the doctors put quite a bit of pressure on...he had an allergic reaction to it and he was the fifth person to try it and when he had the reaction, that was really worrying because I thought you are just trying, you don't know what you are doing and physically seeing what happened, it just puts everyone's mind in a different place and that's what happens when you are

experimenting. No one ever says what the trials were, this is what they can do' (Interviewee 13, Female, Age 48, Dual Heritage Nigeria and Irish, Son Diagnosed Hodgkin Lymphoma age 21, Died Age 23).

5.10 The wider community can and do seek to influence decisions about trial participation at critical junctures along the treatment pathway and this influence is centered on views of the clinical trial as placing an additional and unnecessary burden on an already *'sick body'*, or as identifying a medical problem that they would prefer to ignore. As patients and carers move on in their journey, they may also become more knowledgeable, and make retrospective assessments about the treatment and advice they have been given. These assessments can focus on concerns about the treatment options put forward, and not being made aware of the range of patient groups that can provide assistance and support in decision-making at an enormously challenging time. The trust placed in healthcare professionals clearly plays an important role in influencing and informing the treatment decisions of patients, but in relation to clinical trials, this may sometimes come across as over zealous. The recruitment and retention targets, and the small window of opportunity to enrol, means that there is systemic pressure on healthcare professionals to do so swiftly. In circumstances, where the individual outcome on the trial is not as desired, patients and carers may account for this in the context of there being no guarantees about anything. Alternatively, it can erode trust and confidence:

'I think he did go on a clinical trial because sometimes looking back I wonder if we should have agreed with that clinical trial without searching for bone marrow I think he went for clinical trial because he had the cord transplant and he had to sign a form to agree to go to a clinical trial. Because I think I was not given enough information about the options that we had because I think they should have given us some options, the information I now know, they should have given us the options of treatment, they should have said, the reasons for going for the cord transplants and if I had been given the information, it would have helped me and my son to make an informed decision…He was relying on me and you know when you are unwell you rely on someone and in our most vulnerable moments we should have been given all the options to help us make an informed decision….What I learned and know now is he relapsed after the cord transplant and when he relapsed ACLT came to do a presentation and when they did the presentation I learned about the bone marrow match and didn't know that and didn't know we could have tried because we have a very big family back home and were not given the option of getting the family back home tested and there was not a chance of getting my family back home and the ACLT mobilized for donor drive so many Kenyans turned up' (Interviewee 15, Female, Age 50, Kenya, First Generation, son diagnosed Leukaemia, 2012, at 22, died in 2014 at 24, London).

'I have taken part in a clinical trial before and just expressing this to people I got negative answers back. It was basically um to do with lupus which I suffer from and it just involved lots and lots of questions, blood tests etc and um people felt I shouldn't have taken part in it….It was an experiment and they felt I would be given medication, which I wasn't, which would have a negative effect on me. They felt with the condition I have that I was ill and that I suffered as a result of the condition so why should I put extra burden on myself. To me, those thoughts came out of ignorance because they did not understand what was involved. They have this idea that I was being given medication which was going to harm me….I took part because there is no cure for lupus at the present time and I thought if I could do my little bit you never know what is going to happen in 20 or 30 years time. You never know what is going to come out of a trial which is going to benefit people in the future' (Interviewee 3, Female, Age 59, Lupus, Sierra Leone, First Generation, Kent).

There are different conceptions of health and the body among different communities. In these circumstances, the space in which a conversation about a clinical trial takes places is not a neutral space in which information is transmitted, received, understood, and necessarily believed.

'I put my name down for a clinical trial a while ago, probably coming up about four years now because I donate blood and one of the Cambridge biotechnics ones said "we'll register you, we'll let you know" so I'm still waiting….I have a certain blood which means I can donate to everyone and I was asked if there was anybody else in my family and I asked them and they said "Oh no" they don't have time, a lot of them it's a case of um, as I say, "I don't want to know" or "I can't do it. If I do it they might find something wrong with me". I rather they do it and they find something wrong with me rather than going through the motions and then I find out it's too late' (Interviewee 10, Female, Age 57, St Kitts, First Generation, London).

5.11 Clinical trials and structural barriers to participation: Notwithstanding the illimitable diversity of views and experience within black communities, there are some clearly identifiable issues in relation to clinical trial participation. As illustrated, negative views about clinical trials may arise from knowledge, either complete or partial, which is anchored in documented experiences at particular historical moments where black people have engaged with the research community. These concerns are in turn linked to fears about the potential to harm black people and other groups who experience disadvantage, and the idea of a clinical trial as only being offered as a last resort. There may also be different conceptions of health and the body. In these circumstances, the space in which a conversation about a clinical trial takes place is not a neutral space in which information is transmitted, received, understood, and necessarily believed. Moreover, because the underlying issues are not always articulated in the patient/practitioner space, healthcare professionals may be entirely unaware that there may be a subtext to the consultation. In fact, what is being communicated by a healthcare professional may become part of a broader narrative that is woven into an intricate web of varied interpretations and meanings, moving beyond the immediate imperatives of a particular trial or treatment. Indeed, this may also be the case where patients are receptive to the idea of a clinical trial and knowledgeable about them. The following remarks provide a vivid illustration of this complex dynamic at work:

'I have a strong belief that patient outcomes are better on clinical trials if they are on them rather than not on them because we get a lot of good clinical trials….When I see a patient at diagnosis and relapse, I will try to outline the off-trial option that is the best and the trial option if it is available at that point. So, I will always want to offer a clinical trial option….I had not appreciated it until you raised the data so my impression would have been that there wasn't an issue that needs to be resolved. I would say anything that is going to encourage any patient to consider a clinical trial would be beneficial because as I said at the start, I think patients going onto clinical trials is the way forward for them' (Dr Dean Smith, Consultant Haematologist, Nottingham Centre for Clinical Haematology).

'I trust herbal doctors if for broken bones, but internally we use herbs, holistic doctors. We don't get cancer because we eat vegetarian and alkaline, we don't feed up on certain things. I'm not bringing that one (cancer) on me… You know how much things they have to go through? Trial and error. No, let me enjoy my few days or whatever I have. Just go in peace. My sister had cancer and went though all the stupidness….after coming up through slavery, would you trust them with your life?!' (Interviewee 25, Female, Age 63, First Generation, Nevis, Rastafarian, Nottingham).

'One of the same reasons why they won't go on the bone marrow register or the organ donor is that they are not guinea pigs….They don't really understand what they are getting themselves into. They think they are going to be harvested for their organs and they like to deal in speculation and rumours rather than facts. I do believe it is ignorance and fear' (Interviewee 7, Female, Age 28, Aplastic Anaemia, Jamaica, Third Generation, London).

'…things in history that you've read the stories that's been told and I feel that they'll use the poorest of the poor to get, you know, formation. I believe they are doing it to um, ill us off. It's another form of getting rid k people, reducing population. That's about. The world can't cope can it? many people here. They class us not human….I've been asked I am diabetic but I refused to cause I don't know what, I'm ld be a risk helping me or 'm not prepared to take that er way round. It could of thing' (Focus Group 52, Diabetes Type 2, Nottingham).

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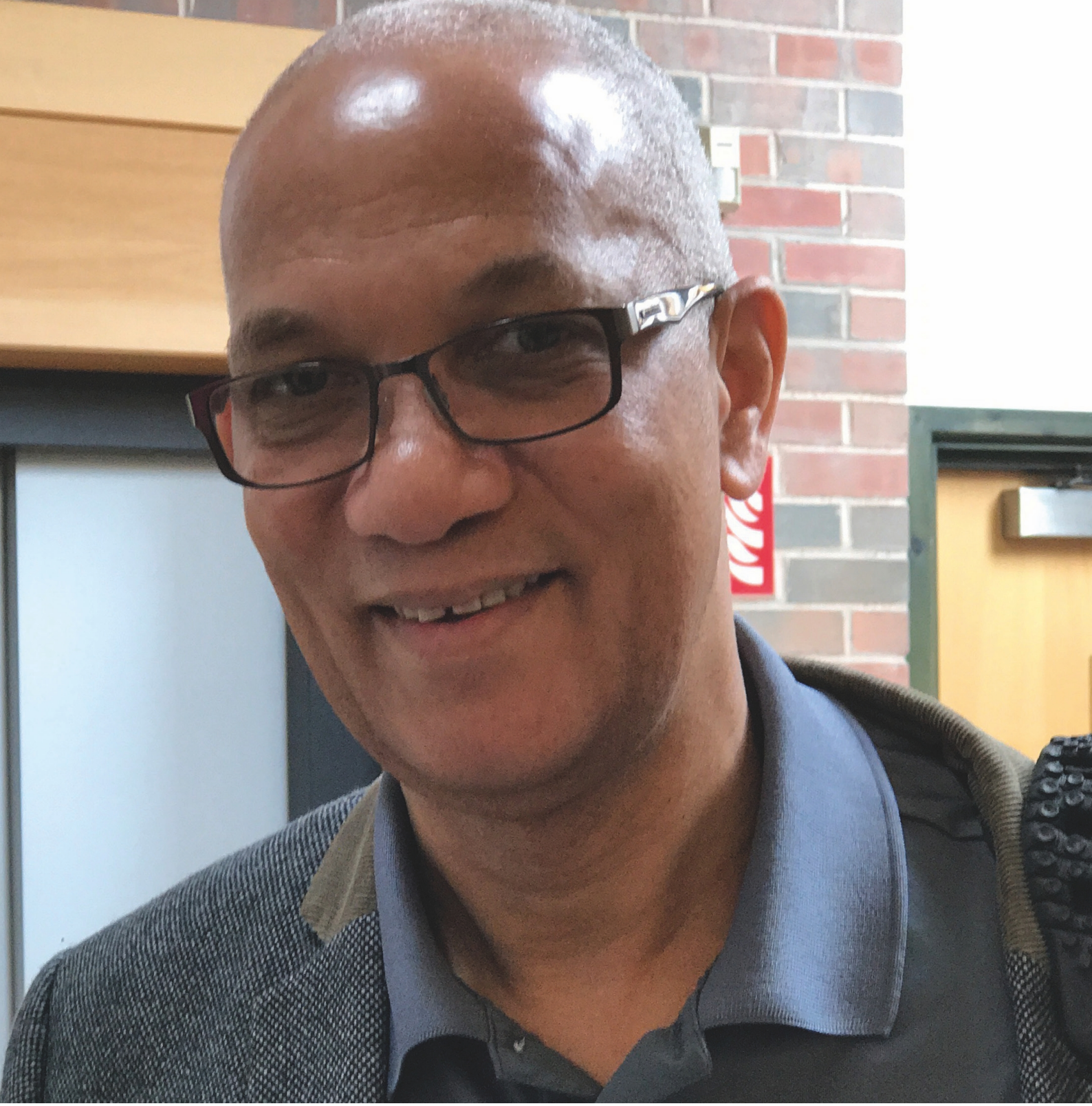
higher disease risk burden, clinical data are not routinely collected on grounds of ethnicity.

The absence of a holistic equality focus in the design of research protocols, and in the oversight of research ethics committees thus gives rise to an in-built partiality. This pivots on unquestioned and unexamined assumptions about the design of clinical trials, how clinical trials should be routinely executed, and the data that are viewed as important for monitoring performance and patient outcomes:

'One of my concerns would be not all patients are offered trials. So, because if they are elderly black patients there might be a concern about them not showing an interest in trials and if they are not aware of trials they might not bring it up and there might be a reluctance for clinicians to bring it up….Some people love the idea of trials and it depends on how it is portrayed, the options displayed. What I tell a patient is different to what they take on board and making sure that they understand. We might think we have done a great job and they might think I've got cancer and I'm going to die. But, people of all races can be suspicious' (Dr Fran Wadelin, Consultant Haematologist, Nottingham Centre for Clinical Haematology).

'I guess I think they may not be sure of the reactions they might get so they don't approach black people. Research can be quite difficult to do and when you are trying to recruit somebody, if you think they might not understand what you are saying or they may be resistant….It is because research is hard enough you may say to yourself they may not be suitable, you want to find somebody that is easy to talk to so there is an in-built bias when you are recruiting so you chose people who will make it easy for you….In terms of professionals, I think the research ethics committees should mandate that ethnicity is taken into account. I think also that in the same way we could not do a study that is all male unless it was for prostate cancer, you could not do a colon study and recruit all men so in the same way, the research ethics committees should be asking specifically what is your strategy for being inclusive and also there should be a mechanism in six months or a year, there should be an oversight of the ethnicity composition. At the present time there



Documented experiences at particular historical moments where black people have engaged with the research community and current views about clinical trials are often conflated with fears about blood and bone marrow donation. These fears are all part of a generalised concern about being used as a *guinea pig*, in a position of powerlessness. These underlying issues are not always articulated in the patient/practitioner space.

is no come back if you don't have any ethnic minority people in your research. You still get the research income. There is no incentive to do better. It is "hard to reach" versus "need to reach", otherwise the results are not generalislable' (Professor Frank Chinegwundoh, MBE, Consultant Urologist, Barts Health NHS Trust, Chairman of Cancer Black Care).

'Large genome wide association studies of particular diseases have tended to focus on Caucasian populations and there's a recognition that this is wrong for a number of reasons but scientists may also be trying to tread carefully here too….within research there is not enough diversity among the people doing the research and addressing this will likely improve diversity in the research participants as well' (Dr Simon Ridley, Director of Research, Myeloma UK).

'We do make a judgement call in clinic when recruiting patients into trials. Be it consciously or subconsciously, there are some patients whom on paper might fulfil the criteria but you would not offer a trial to for a variety of reasons, so we do pre-select a bit. The rationale, maybe you don't think the patient can cope with the trial protocol or visits etc. I think from the patient's point of view, trust in the relationship with their physician is most important. My area of speciality involves chronic disease management so I have an on-going relationship and we build a degree of trust, they know me well enough to trust. I would not be recommending it if I thought it would do them harm. If people understand the background of trials and what they aim to achieve, it makes it easier to recruit, and when patients have taken part in trials before, they seem to understand it better, they see that patients get excellent care on trials and are encouraged to volunteer for more in the future. I have patients actively asking in clinic if we have trials running they can take part in after they have been on one. In my Sickle cell patient cohort, with largely people of African and African-Caribbean ethnicity, it can be a mixed bag because some are aware of the issues from the past relating to historical "testing" on minorities which can create a barrier but I think where the trial and its aims are well and honestly explained, taking in some cultural differences in involvement, recruitment improves. Involving other allied specialists like a Clinical Nurse Specialist for example, who can spend time and further explain and dilute the language can be very beneficial.' (Dr Rachel Kesse-Adu, Consultant Haematology and Sickle Cell Disease, Guy's and St Thomas NHS Foundation Trust).

5.13 The availability of clinical trials is also germane to the discussion in that it is only possible to offer clinical trials to patients at sites where they are available. Added to this are clinical trial inclusion and exclusion criteria, which may exclude patients with co-morbidities such as hypertension, diabetes, and in the case of myeloma for example, renal failure, which can occur in up to 40% of patients with myeloma.

From the patient and carer perspective, there is also a lack of patient information about clinical trials generally, and this lack of availability of information and knowledge about where to go to get information is also linked to a lack of patient information seen as relevant to the patient community as a whole. Those patients that are more in the know or who have access to active patient networks, or who are at larger trial centres with access to more trials and dedicated trial nurses, have access to more information about treatments generally and clinical trials specifically. The issue here is that views about the availability and accessibility of trials do vary for a variety of reasons, across and within organisations as the following remarks make clear:

'The problem they have is that they have inclusion and exclusion criteria and co-morbidities often pose a problem. They set the bar very high so a normal myeloma patient with an element of renal failure is often excluded when they represent the standard population and trials are looking at a fitter population….Renal exclusion (which can accompany myeloma) affects the Afro Caribbean population more' (Dr Cathy Williams, Myeloma Clinical Lead, Nottingham Centre for Clinical Haematology).

The recruitment and retention targets, and the small window of opportunity to enrol to a clinical trial means that there is systemic pressure on healthcare professionals to do so swiftly. There is also a reticence in talking about ethnicity within a clinical research or clinical trial context, and clinicians also make their own judgement calls when recruiting to a clinical trial.

'I can only speak from my experience in both specialities that I have been in…I have to tell you that 100 per cent of the patients that I have seen on trials have been white and I don't know if that happens to be the ones who come to us because trials are in different locations but I haven't seen any….I'm in an area with a very diverse population but then it also attracts patients from other areas because they (the hospital she works at) are a centre for clinical trials for a whole range of things and the patients that have come in have not been local so that might be one of the factors. But does that mean that those patients in those areas outside are more likely to be made aware?...So, having said that, my son is frequently involved in that, and he has been involved in quite a few sleep studies and it is a bit inconvenient for me but I am quite keen that whatever we can do to progress developments that affect us, we should get involved so personally I have no problem with it' (Interviewee 40, Female, Age 50, Second Generation, Nigeria and Haematology Nurse, large trial centre, son has sickle cell, London).

'We have a large clinical trial unit here at Barts Cancer Centre, so it is usual for large numbers of our patients to be screened for and entered into clinical trials. Maybe this is because we have comparative ease of access to trials, maybe it's the dedicated approach of our medics and how much time they take to clearly outline all treatment options to all patients (inclusive of trial options available here and at neighbouring centres), or maybe it's because we have very experienced Myeloma Consultants who are heavily focused on improving outcomes and are involved in research themselves. Equally, maybe it's because we serve a population of East London, which is densely populated with people of black and minority ethnic backgrounds who happen to represent the groups with the highest incidence of myeloma. Whatever the actual reason(s), I don't get a sense of there being less black people on trials than others at this centre. All patients are informed about trial options and are put forward for screening if they choose. In terms of people's attitudes and willingness to go on trials or to perhaps view themselves as 'a guinea pig', I'd say it is varied across all ethnicities and age groups. Our clinicians will allow as much time as they safely can, giving patients time to explore the options. There has been so much international research and development in myeloma in recent years that we sometimes have access only via trials to regimens, which are used routinely in the States. Some patients do their own research and are aware of drugs used in the States that are only available in the UK on a trial. Patients on trials have access to a dedicated trials nurse (who delivers each treatment) as well as their CNS. The overlap between CNS and the trial nurse can vary hugely depending on individual patient's needs. Variables affecting this include whether the trial is first line therapy for a newly diagnosed patient or occurs later as a subsequent line of treatment.' (Andrea Guy, Myeloma Clinical Nurse Specialist, Barts Health NHS Trust).

5.14 Widening participation and views on how we might be more inclusive: The participants who were positive about clinical trials, as well as those who had a measure of reluctance made it clear that they would be keen to engage in more in depth discussions to inform themselves. This was also tied up with access to information and knowledge about health issues affecting the community, about where to go to find information about clinical trials, and what taking part means on a personal level. What is clear is that, in common with the population generally, no one approach will suit everyone, and neither is it a question of incorporating black communities into existing ways of doing things. Rather, it is about examining existing ways of doing things and actively engaging; modifying existing approaches where it can potentially broaden engagement, and seeing the diversity in black communities and applying different communication styles and approaches.
The patient organisations that have supported this research all have a tried and tested record of working with and supporting patients and carers nationally, and running successful information and awareness raising engagement health related events, in partnership with statutory, voluntary, and other health agencies including NHS Trusts.

5.15 A key component in moving from the rhetorical level to action is recognising the need to make general patient information about events and the design and promotion of them both relevant and inclusive in cultural and visual content, in tone and in style. Among the successful approaches employed by patient organisations are: community health events at national and local venues; deliberative and participative spaces that engage communities in a discussion about a range of health issues and treatments; information dissemination and interaction through community radio stations, targeted shows on mainstream radio, and via social media, and engagement through existing community forums and educators. Moreover, working with and through church pastors of faith organisations, accessing faith conventions, and faith health groups is an important way of engaging black communities on important health issues.

Indeed, despite a general decline in overall church attendance and a projected continued decline to 2020, available figures on black church attendance for 2008 and 2013 reveal that, what is true for the population generally, is not true for the black population specifically. In the black population, church membership has not followed the general pattern of decline, but has actually increased to a point where it has, to some extent, slowed down an overall projected decline in church membership that was envisaged. In the UK there were 700 mostly new Pentecostal churches, established between 2005 and 2014, at least 400 of which had black majority congregations. Moreover, the Redeemed Christian Church of God set up 296 churches in the UK between 2010 and 2014 and this represents the largest number for any single denomination. This is part of what is known as the 'fresh expressions movement'.[32]

5.16 There is therefore no single organisation that has all of the answers, and no single approach that will work, but forming coalitions and connections, working in ways, for example, that has made the production of this report possible, offers one avenue for doing things differently, working jointly across professional and organisational boundaries as it enables us all to look beyond our immediate horizons.

All organisations, and this includes research ethics committees could inform more inclusive approaches by engaging in a wider interpretive dialogue about clinical trial participation, and at the same time, examining operations and activities in general from a strategic equality perspective. We already have the recognition that there is an issue that needs to be addressed, what we need now is an on-going commitment, and the investment of time and resources to make change happen:

'…I honestly don't think that black people themselves think that they get particular diseases, it is only when it is highlighted like say, more black men getting prostate cancer for instance but generally, that is the only one I can think of, apart from myeloma, but not of the others' (Interviewee 22, Male, Age 80, Jamaica, First Generation, Nottingham).

'….it has to be from the community from the level that you can actually sit down so I think that if there is more awareness of what it can do, why it can do it, the fact that cancer is on the rise, if you've got it you are actually making a difference for your children, grandchildren, people would take it on board, if it's not about themselves, its about their future kids. It's like promotions, you have to get the right people in place, make it appealing and it has its pros and cons so if you do it right and it is promoted sensitively, it has to be community sensitive…. More thinking in community venues needs promoting on local radio and I think just general awareness' (Interviewee 27, Male, Age 43, Second Generation, St Kitts, Leeds).

'It may be that there is a lack of awareness. Are these things advertised? If you want to include black people you have to meet black people where they are likely to be. For example, I went to an event that was on black health, specifically targeted at black people and it was all about diseases that are common to black people….So we probably need events targeted at black people and then they would take notice. Combine it with an event' (Interviewee 1, Female, Age 45, Nigeria, Second Generation, London).

…we talk in descriptive, "dem juk yuh wid a needle" and "God in heaven, dem tek too much blood" so put it in a language that we will say I will get involved, and know what the benefits are…. look at the language that they are writing, it is very clinical, very cold, and if you don't get past that…. I think if you partner with an organisation that can say this is going to be your approach and this is the language you need to speak it in. It's not taking them away from their profession, its actually if people knew you, they would take it. They have got to come out of their ivory towers and partner with grass roots organisations and come out and get somebody to look at the literature and how we are going to engage. We are not going to engage with three sides of A4' (Interviewee 29, Female, Age, 50, Female, Jamaica, Second Generation, Rheumatoid Arthritis, Leeds).

'A community event would be the kind of thing…if they don't know you and you are running an event, you are not gonna get many and that fact is not because the colour, it is the fact that when we came to this country we were not classed as accepted' (Interviewee 26, Male, Age 77, Jamaica, First Generation, Prostate Cancer, Leeds).

'I think the black community need to open up and come together. An event to attract people if you were to say you'll get a plate of rice and peas and chicken incentive to turn up….and I think if we had more community drives and presentations and yes if we could entice them with a bit of food that might help' (Interviewee 17, Male, Age 53, St Kitts and Barbados, Second Generation, Manchester, 12 Years Post Stem Cell Transplant).

'Look to raise the issue to the younger generation and get it through to schools and also look to changing perceptions of the younger generation to change perceptions and get more buy in to trials and acceptance' (Interviewee 44, Female, Age 21, Guyana and Nigeria, Mother diagnosed with Multiple Myeloma 2009).

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29. The notorious Tuskegee Syphilis Study carried out between 1932 and 1972 by the United States Public Health Service is one example. In that study, poor black sharecroppers in Alabama were recruited to a clinical trial to study the natural progress of syphilis. While the study was in progress, penicillin was discovered to treat syphilis but the study continued and the men were not treated with penicillin that could have cured them.

    The Henrietta Lacks story, known in the scientific community as HeLa, refers to a poor black tobacco farmer who was diagnosed with cervical cancer, and whose cancer cells were taken without her knowledge and are now one of the key tools in clinical research.
30. This may partly explain the low response rate for example on the Patient Experience Survey
31. This point was made by a healthcare professional during interview. Also, for example, see Stockton-on-Tees Joint Health and Well Being Strategy, 2012 – 2018 which illustrates this point in terms of the higher rate of hospital emergency admissions for black people compared with their population generally and the average for England which shows that even in areas with very small black populations, health outcomes are not keeping pace with the population generally, or the average for England.
32. Peter Brierley, UK Church Statistics, 2014, Brierley Consulting

6. Discussion of findings and recommendations

6.1 Discussion of findings: This study has centred on the views of black African and black Caribbean communities on clinical trials. This is because the evidence points to a significant underrepresentation of black people in clinical trials. This is the case, even in those disease areas where black people have a disproportionate risk of diagnosis.

6.2 The notion of a clinical trial was found to be positive among some, and negative among others, as were ideas of being a *'guinea pig'*. Interestingly, whether the response was positive or negative, views of clinical trials were entwined with the particular historical experiences of black communities, and the economic position of black people was seen as aligning them with the experiences of other disadvantaged groups also perceived to be at risk of being used in research, in ways not always appropriate. These views not only impact perceptions about clinical trials, but also spill over into fears about things that are medical. At the same time, a lack of relevant patient information provides a fertile ground for these ideas to flourish. Alongside these views, this study did find a genuine desire to know more, and to engage. It did not find any differences between black African and black Caribbean groups, or among members of the second and third generations in terms of whether their perceptions of clinical trials were positive or negative. They were both. That is not to say that there are not such differences, rather that this study did not find any among its cohort.

6.3 It is unclear why clinical trials are not routinely ethnically monitored given that they are monitored on other dimensions. This is likely due in part to concerns, given the historical record in relation to discussions about ethnicity in clinical research. It is also likely due to a lack of awareness and a lack of recognition of ethnicity as having any particular salience in a clinical research context. Where figures are available on black and minority ethnic participation, they clearly show that there is a skewed selection operating in the recruitment process. The study also found that there may be unconscious bias operating in consultations where clinicians sometimes make *'judgement calls'* about who, in their view, will be able to comply with clinical trial requirements.

While this study did not examine the views of other minority ethnic groups, or other disadvantaged groups, it may also be the case that they are similarly underrepresented as inequality does fragment and intersect along lines of social class, gender, location and so forth. It is therefore important to explore these broader inequalities, using an equality framework. The production of this report, and its recommendations, is therefore the beginning of an attempt to highlight the relevance of social constructions of ethnicity, in the context of wider discussions about inequality, and its relevance to clinical trials and clinical research, as this is currently absent in discussions in the UK.

6.4 Recommendations: It is recommended that:

1. The report be disseminated to organisations with key influence such as the National Institute for Health and Care Excellence (NICE), the National Cancer Research Institute (NCRI), the Wellcome Trust, Public Health England, NHS England, and those involved in the sponsoring of clinical trials including blood cancer charities and industry.
2. The report is disseminated to the National Cancer Taskforce as evidence to support the on-going implementation of the National Cancer Strategy in relation to the black and minority ethnic patient experience, and cancer inequalities, as this is specifically mentioned in the Strategy.
3. Patient organisations, NCRI, industry and statutory health agencies engage in a joint dialogue centred on the collection of data to ensure that ethnicity is mandated within the remit of all sponsored clinical trials and clinical research, coupled with the identification of incentives.
4. Opportunities be explored for widening the current involvement of black and minority ethnic patient organisations and service users through different participatory practices, so that they can play an active role in the oversight and governance of clinical research, and clinical trials, through membership of expert panels and advisory groups, ensuring that research issues reflect the priorities of a broad spectrum of patients and researchers.
5. An interactive roundtable event be developed and organised jointly by all of the patient organisations and NHS Trusts directly involved in the production of this report. This should mark the start of a continuing multi-stakeholder dialogue on blood cancers and understanding the relevance of broader health inequalities and disparities in relation to ethnicity and other economically disadvantaged groups, and the implications for diagnosis, incidence, prevalence, and access to clinical trials, and access to services, information, and support.
6. A close examination of major trial centres in the UK should be conducted. This should focus on recruitment to myeloma clinical trials as a blood cancer that disproportionately impacts black communities. This can inform an understanding of the pool of patients that are referred, and the views of healthcare professionals. This information will be valuable for other blood cancer clinical trials.
7. Alongside biological and quantitative clinical trial data collection, the invisible and unrecognised contribution of all blood cancer patients should be captured qualitatively as part of the process of reporting on clinical trial outcomes. This is in terms of the patient experience of clinical trials: emotional, practical, and social, along with their reflections, thus bringing symmetry, balance, and visibility as part of an inclusive exchange to inform clinical research, policy and practice.
8. The views of other minority ethnic groups and other disadvantaged communities in relation to clinical trials, clinical research, and access should be examined as a priority. This is important given that as well as ethnicity, inequality does fragment and intersect along lines of social location, language, social class, gender and so forth, and understanding the experiences of all patients that are seldom heard is critical to addressing inequalities, and ensuring that the benefits of clinical research and healthcare services are evenly distributed.

Appendix A – Interview and Focus Group Participants

Participant Profile							
Int.*	**Male/ Female**	**Age**	**Diagnosis**	**Ethnicity**	**Generation**	**Place of Birth**	**Place of Residence**
1	Female	45	None	Africa, Nigeria	Second	Nigeria	London
2	Female	56	None	Caribbean, Antigua	Second	London	London
3	Female	59	Lupus 2008	Africa, Sierra Leone	First	Sierra Leone	Kent
4	Male	55	Chronic Myeloid Leukaemia, 1999	Caribbean, Dominica (born in UK but raised in Dominica)	Second	Kent	Kent
5	Female	51	None Father in law died of multiple myeloma	Caribbean, Jamaica	Second	London	London
6	Male	60	Myelofibrosis, 2005	Africa, Nigeria	First	London	London
7	Female	28	Aplastic Anaemia, 2008	Caribbean, Jamaica	Third	London	London
8	Female	26	Acute Lymphoblastic Lymphoma, 2007	Caribbean, Jamaica	Third	Essex	Essex
9	Male	67	None	Caribbean, Dominica	First	Aruba	London
10	Female	57	None	Caribbean, St Kitts	First	St Kitts	London
11	Female	48	None	Dual Caribbean, Jamaica and Irish	Second	London	London
12	Female	-	Lymphoma Daughter (26)	Dual Thai and Italian	Second	Thailand	London
13	Female	48	Son Lymphoma died diagnosed 21 died 23	Dual Irish and Africa	Second	London	London
14	Female	31	Diagnosed CML age 21 and ALL age 26	Africa, Kenya	First	Rawanda	London
15	Female	50	Son died Leukaemia diagnosed 2012, died 2014	Africa, Kenya	First	Kenya	London
16	Female	50	Son sickle cell	Africa, Nigeria	First	Nigeria	London and Nigeria
17	Male	53	Multiple Myeloma, 12 years post stem cell transplant	Caribbean, St Kitts and Barbados	Second	Manchester	Manchester
18	Male	51	Rare Eye Disease	Caribbean, Jamaica	Second	London	London
19	Male	56	Multiple Myeloma	Caribbean, St Lucia	Second	Bedfordshire	Bedfordshire
20	Female	58	Sickle Cell	Caribbean, St Kitts	Second	St Kitts	Nottingham
21	Female	50	None	Caribbean, Jamaica	Second	Jamaica	Nottingham
22	Male	80	None	Caribbean, Jamaica	First	Jamaica	Derby

***Interviewee**

Participant Profile							
Int.*	**Male/ Female**	**Age**	**Diagnosis**	**Ethnicity**	**Generation**	**Place of Birth**	**Place of Residence**
23	Female	86	Son died of multiple myeloma age 49	Caribbean, Jamaica	First	Jamaica	Nottingham
24	Female	48	None	Ben Nevis	Second	Nottingham	Nottingham
25	Female	64	None	Bahamas	First	Bahamas	Nottingham
26	Male	77	Prostate cancer	Caribbean, Jamaica	First	Jamaica	Leeds
27	Male	43	None	Caribbean St Kitts and Jamaica	Second	Leeds	Leeds
28	Female	45	None	Trinidad and Tobago and Jamaica	Second	Leeds	Leeds
29	Female	50	Rheumatoid Arthritis	Caribbean, Jamaica	Second	London	Leeds
30 FG	Female	53	Breast Cancer	Caribbean, Jamaica	Second	Nottingham	Nottingham
31 FG	Female	51	Diabetes Type 2	Caribbean, Jamaica	Second	Jamaica	Nottingham
32 FG	Female	54	None	Caribbean, Jamaica	Second	Nottingham	Nottingham
33 FG	Female	61	Breast Cancer	Caribbean, Jamaica	Second	Nottingham	Nottingham
34 FG	Female	53	Kidney Cancer	Caribbean, Jamaica	Second	Nottingham	Nottingham
35 FG	Female	-	None	Caribbean, Jamaica	Second	Nottingham	Nottingham
36 FG	Female	-	None	Caribbean, Jamaica	Second	Nottingham	Nottingham
37	Female	43	Oncology Researcher, London	Caribbean, Jamaica	Second	Manchester	London
38	Female	63	In clinical trial for condition called HTLV-1 (Human T Cell Lymphotropic Virus)	Caribbean, Jamaica	Second	Jamaica	Kent
39	Male	56	In clinical trial for keloid scarring (frostbite treatment)	Caribbean, Jamaica	Second	Jamaica	Nottingham
40	Female	50	Haematology nurse, son has sickle cell	Africa, Nigeria	Second	Nigeria	London
41	Female	64	Husband died of multiple myeloma in 2012	Caribbean, Jamaica	First	Jamaica	London
42	Female	74	Son died of multiple myeloma age 49	Caribbean, Jamaica	First	Jamaica	London
43	Female	63	Husband diagnosed with multiple myeloma 2017	Caribbean, St Lucia	First	St Lucia	London
44	Female	21	Mother diagnosed with multiple myeloma, 2009	Guyanese and Nigeria	Third	London	Winchester
45	Female	53	None	Caribbean, Barbados	Second	London	London

***Interviewee**

Appendix B – Deliberative Workshops

Sickle Cell Society Clinical Trials and the Future of Sickle Cell Workshop		
Total Numbers	**Men**	**Women**
52	14	38

Greenwich African and Caribbean Forum An Audience With the Basil Skyers Myeloma Foundation Part its Audience With…. Series		
Total Numbers	**Men**	**Women**
54	16	38

Appendix C: Healthcare Professional Interviews

Name	Designation
Professor Frank Chinegwundoh, MBE	Consultant Urologist, Barts Health NHS Trust
Ms Maresa Farell	Clinical Nurse Specialist, Barts Health NHS Trust
Dr Jayne Galinsky	Health Services Researcher, Myeloma UK
Ms Andrea Guy	Clinical Nurse Specialist, Barts Health NHS Trust
Dr Charlotte Kallmeyer	Consultant Haematologist, United Lincolnshire Hospitals NHS Trust
Dr Rachel Kesse-Adu	Consultant, Haematology and Sickle Cell Disease, Guy's and St Thomas NHS Foundation Trust
Ms Jane Mills	Clinical Psychologist, Nottingham University Hospitals NHS Trust
Dr Simon Ridley	Director of Research, Myeloma UK
Dr Dean Smith	Consultant Haematologist, Nottingham University Hospitals NHS Trust
Dr Matthew Streetly	Myeloma Clinical Lead, Guys and St Thomas NHS Foundation Trust
Dr Fran Wadelin	Consultant Haematologist, Nottingham University Hospitals NHS Trust
Dr Cathy Williams	Consultant Haematologist, Myeloma Clinical Lead, Nottingham University Hospitals NHS Trust

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