Study Protocol: Participatory Approaches to Support Patient-centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Version 2 January 2023

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1. Background

Sickle cell disease (SCD) is a genetic disorder of red blood cells. The abnormal sickle-shaped cells become trapped in the circulation creating blockages, often triggered by infections. Around 50% of deaths in the under-5s with SCD are due to infection.[1] Blockages of blood vessels by sickle cells is associated with sudden episodes of severe, intractable pain particularly affecting the bones. A complex sequence of events follows which culminates in organ damage so that later in life SCD patients experience failure of the heart, lungs, brain, kidneys and other organs. SCD detrimentally affects growth and intellectual development which, coupled with unpredictable episodes of pain and hospitalisations, impacts on schooling, employment and mental health. For SCD patients, each life stage—childhood, adolescence, adulthood—brings its own challenges.

The World Health Organization (WHO) has declared SCD a public health priority; 75% of the 300,000 annual global SCD births occur in Sub-Saharan Africa (SSA).[2-4] Although accurate data are lacking, around 6 million Africans are living with SCD and 50–80% will die before adulthood, predominantly in the first 5 years of life.[5] The vast majority of patients in SSA with SCD are never diagnosed so addressing this inequity is key to achieving the SDGs "Leave No One Behind" agenda and WHO's revamped commitment to Universal Health Coverage.[6] WHO estimates that 70% of SCD deaths are preventable with: a) appropriate clinical management (see below); b) early identification of SCD; and c) patient-centred care. The introduction of such interventions have enabled high-income countries to reduce SCD deaths from 3 to 0.13 per 100 person years of observation.[7] This means up to 94% survive to 18 years in the USA and 99% to 20 years in the UK.[8] Our research will focus on these aspects of SCD care.

1.1 Clinical mainstays for SCD

Penicillin prophylaxis: People with SCD are particularly susceptible to infections, especially of the respiratory tract and blood (i.e. septicaemia). This is partly because their spleens are damaged by the sickle-shaped red blood cells and splenic function is important for the immune system to clear infections. Lifelong antibiotic prophylaxis is therefore recommended for all people with SCD.[9] Though the benefits in adults are equivocal, it is particularly important that there is full adherence to prophylactic penicillin up to 5 years of age. A Cochrane systematic review of three randomized trials (n = 857) assessed the effects of prophylactic antibiotics for preventing pneumococcal infection in children with SCD. It concluded that prophylactic penicillin significantly reduces the risk of pneumococcal infection in children with SCD <5 years of age, and is associated with minimal adverse effects.[10] Penicillin prophylaxis should start by 3 months of age (recommended doses are: for children <1 year, 62.5 mg twice a day; children aged 1–5 years, 125 mg twice a day; for adults and children >5 years of age, 250 mg twice a day). If the person is allergic to penicillin, oral erythromycin should be given. Standards and guidelines recommend that 90% of infants should have been offered and prescribed penicillin (or alternative) by 3 months and 99% by 6 months. It is important to start by 3 months of age, as this is when the level of semi-protective foetal haemoglobin (HbF) starts to decline and the risk of splenic hypofunction increases.[7] Although not the main focus of our research, vaccinations against infections (e.g. pneumococcus, influenza, meningitis, hepatitis B, papilloma virus - adults only) are also recommended for SCD patients.

Hydroxyurea (also known as hydroxycarbamide) reduces anaemia in SCD, increases haemoglobin levels (which improve the oxygen-carrying capacity of the blood), reduces anaemia, lessens blood transfusion requirement and reduces mortality.[11] It also reduces the 'stickiness' of red cells thereby improving blood flow, though its maximal effect may take several months. In a randomised control trial it reduced mortality by 40% after 9 years and in a non-randomised study from Greece, the probability of 10-year survival was 86% for those on hydroxyurea, compared with 65% for those not on hydroxyurea even though the treated group had more severe disease.[7] Hydroxyurea also reduces painful episodes and chest crises, and reduces pain, transfusions, hospitalisations and hospital stay in children and young adults with SCD.[12-14] It can be used as an alternative to transfusions in stroke prevention.[15] The use of hydroxyurea translates into public health cost benefits.[16] It has clinical value at all ages, even in asymptomatic young children, and guidelines advise it should be offered to all children, even those with no symptoms.[17] It is well tolerated with few side effects and no chromosome damage (i.e. no risk of mutagenicity or carcinogenicity).[18]

Blood transfusion is recommended in SCD for strokes, acute chest syndrome and peri-operatively. Blood transfusion is life-saving for acute complications or to prevent the development or progression of chronic complications.[19] The major goals of transfusion in SCD are to (i) improve oxygen-carrying capacity by correcting anaemia and (ii) prevent or reverse complications of SCD-related blood vessel blockages and red cell breakdown. It can be given either as a top-up (as in routine transfusions) or exchange transfusion (to replace simultaneously-removed patient's sickle cell blood). Complications of transfusion in SCD include allo-immunisation, iron overload, haemolytic transfusion reactions and transfusion-transmitted infections. Ideally all SCD patients should be immunised against hepatitis B whether or not they are on regular transfusions and annual testing should be undertaken for transfusion-transmitted viruses for recipients of transfusions.[20]

The decision to transfuse a patient with SCD must be taken by a trained clinician with expertise in managing patients with SCD because they need to consider the degree of anaemia relative to the patient's steady state haemoglobin concentration and overall clinical condition. In high income countries all SCD patients must have extended red cell antigen typing performed to prevent the development of antibodies after transfusion. However, such typing is not widely available in SSA.[21] In SSA, shortages of blood and facilities able to provide a transfusion, mistrust of the health system, lack of understanding about blood donation and the transfusion process, and poor uptake of care mean that when blood is available it is mostly used in SCD for treatment of acute anaemia.[22, 23]

1.2 The unmet needs and gaps our study will address

Improving early detection and uptake of care, use of the clinical mainstays for SCD, and patient-centred care will be the focus of our research, as these three areas constrain SCD care in SSA, exacerbating morbidity and mortality.

Poor early detection and uptake of care: Failure to diagnose SCD means it is very difficult to provide evidence about the burden and gravity of problem to policy makers so they can implement appropriate programmes. At least 50% of individuals with SCD in SSA are never diagnosed and therefore do not take up care.[24] For example, Nigeria's SCD prevalence is ~4 million among its population of 202 million; only ~30,000 patients (<1%) are registered in health facilities (co-principal investigator (Obiageli Nnodu) personal communication).

Consequently, there are very limited data from SSA on morbidity and mortality. In Tanzania, the average life expectancy of SCD patients managed in high-quality facilities is 33 years compared to 52 years among their national healthy peers.[24] The overall mortality rate of 1,725 SCD patients in Tanzania from 2004 to 2009 was 1.9/100 person years of observation and was highest in those under 5-years old (7.3/100 person years).[24] In Nigeria SCD accounts for 5.6% of national under-five mortality. **These deaths rates are similar to those in high-income countries prior to the routine implementation of clinical mainstays for SCD**.

Inadequate clinical management and continuity of care: In addition to poor implementation of clinical interventions for SCD that are known to work there are particular failures in health service delivery for SCD patients so they are marginalised and 'left behind'. These are: failure to identify most babies born with SCD; a potentially difficult transition for adolescents from paediatric to adult clinics; and emphasis on crisis management rather than chronic, preventative care. Deriving solutions from high-income country contexts and attempting to apply them in SSA in a 'one size fits all' approach is not likely to work because of the nuances of local culture and context, and the scale of the problem in SSA. To navigate this complexity, our research puts the perspective and voices of SCD patients (working together with healthcare providers) at the heart of all our activities, actively involving them in identifying local, context-specific problems linked to the clinical mainstays and in implementing solutions.

Lack of patient-centredness: The traditional focus on management of SCD from a clinical perspective has dominated SCD care resulting in lost opportunities to understand, respond to and mitigate barriers (e.g. education, economics, geography) that limit access, uptake and adherence to clinical care. Lack of patient-centredness means health care services do not span the continuum of care and the life-course of patients. Patient-centred care sees health care as a partnership between providers and users. It facilitates provision of care that engages patients in defining what is appropriate, accessible and of good quality, and in health providers being responsive to this.

2. Purpose of the Research

There is a clear need to improve early detection and uptake of SCD, to increase use of clinical mainstays, and, throughout, to provide care that is patient-centred. To do so, we will deploy participatory approaches in order to drive both supply- and demand-side factors affecting each of these three components. We will then study implementation and outcomes of these approaches with the overall aim of influencing policy and practice for SCD in our three study contexts: Ghana, Nigeria, Zambia.

Within each country, we will work with six health facilities with known SCD care provision. In these facilities we will identify a team of healthcare providers with responsibility around SCD care. We will also work with a community group from within the catchment area of each health facility. This group will be comprised of (adolescent/adult) individuals with SCD, carers of patients with SCD, and community influencers.

The **community group** will use **participatory action cycles** (PACs) in order to drive community sensitisation around SCD to improve earlier detection and uptake of care, and also to overcome access barriers. The **facility group** will carry out **standards-based audit**

(SBA) in order to drive uptake of the clinical mainstays and also to promote earlier detection of SCD in newborns, which facilitates earlier uptake of clinical mainstays for reduced morbidity and mortality (see section 3.5 on recruitment of both of these teams). The facility and community groups will come together in order to co-develop a model for patient-centred SCD care in **learning collaboratives**, which should be reflected in the care provided at each facility. From this combination of activities, we draw our overall study title: Patient-centred management of sickle cell disease in Africa (**PACTS**).

2.1 PACs implementation (months 18–42)

PACs follow ***plan-act-observe-reflect cycles***.[25, 26] Each PAC team will **identify key barriers** to early identification (e.g. due to gaps in local knowledge) and uptake of SCD care. Teams will rank the barriers and **plan** which barriers would be feasible and impactful and which to tackle first. They will then brainstorm possible solutions, agree on one and enumerate local assets and resources that need to be mobilised to implement the solution. These will not be provided through the project since that would undermine sustainability and ownership. All the PACs teams will implement their chosen solution over 2-3 months ('**act'**) and then appraise ('**observe**') whether the solution has worked or if it needs adjusting. They will **reflect** on the overall strengths and weaknesses of their approach, evaluate the impact, and determine whether to adapt, adopt (embed), or abandon their approach, determining next steps needed. Finally, they will, after an approach has been determined to be successful and has been embedded, identify the next barrier they will address in a new cycle.

2.2 SBA implementation

SBA teams will be established and healthcare and transfusion providers will be orientated about its steps. Like PACs, it is a cyclical problem-solving approach. It begins with identifying a specific standard of care to uphold (e.g. penicillin prophylaxis for children, hydroxyurea maintenance, guidelines for transfusion in SCD).[27] They then collect a baseline measurement of performance against that standard, carrying out a root cause analysis to understand why the standard is not being met and identify and implement a solution to tackle root causes. A second measurement is then taken after approximately 2–3 months to determine if improvements have been made and to reflect on why (or why not) and to adjust the solution if needed.

Overall, each cycle will sequentially address priority barriers (8-12 barriers each per PACs and SBA team). In total, up to 48-72 patient/carer/community solutions (to overcome access constraints to patient-centred care) and up to 48-72 clinician-generated solutions (to implementing evidence-based standards for SCD care) will be tested, refined and adopted. Where teams across countries are tackling similar barriers, we may establish WhatsApp groups or Teams check-in meetings to foster cross-country learning.

PAC and SBA teams will be supported by a PACTS study SBA and PAC lead. A research coordinator in each country will offer logistical support to these leads. These individuals will support the formation of each team, capacity strengthening to use each approach, and will carry out intensive monthly **mentoring and coaching** to help teams overcome any implementation challenges they may be facing and to facilitate continuous learning opportunities. PhD students may support some implementation, but will largely be

responsible for carrying out independent study of different aspects of the intervention, which will be determined by them, but aligning with the priorities of each country study team.

2.3 PAC and SBA learning collaboratives

Each country PAC and SBA team will meet monthly. The SBA and PAC leads (with support from PhD students in our PACTS research consortium) will facilitate larger collaborative meetings every three months for all PACs and SBA teams associated with each health facility to come together. *In addition, members from community-based organisations supporting SCD patients/carers of people living with SCD and higher-level stakeholders from blood services and the ministry of health will be invited to at least one learning collaborative each year.*

Representatives from all PAC and SBA teams from the three partner countries will attend the biennial workshops. All these meetings will be used to reflect and for peer learning—to develop capacities and technical skills, to share good practices that might be adopted elsewhere, to help overcome common challenges using PACs and SBA, and to engage in "friendly competition". An additional central purpose of these learning collaboratives will be for community- and facility-based teams to work together to share their experiences to identify what **patient-centred SCD care** in each context entails and to collaboratively develop guidance for supporting patient-centredness in SCD care. Part of the SBA activities will then also entail moving this guidance into practice. We will learn about the practicality of these guidelines through the SBA activities and will refine them to ensure they are fit-for-purpose. We will promote their incorporation into national guidelines through dissemination activities throughout the life of the study.

Learning from these approaches around characteristics of patient-centred SCD care, barriers and facilitators of routine use of clinical mainstays, core constraints around early uptake of care and access to care more generally, key activities that can support improved access of SCD care, and approaches to broader community SCD sensitisation will be captured through intensive implementation research. Key insights will be collated and shared with policymakers with the aim of influencing policy improvements for patient-centred, evidence-based SCD care.

3. Methods

3.1 Research Question, Aim, and Objectives

Research Questions

i. Why are proven interventions for SCD that save lives in high-income countries not being widely used in SSA?
ii. What, according to patients, carers and SCD healthcare providers, constitutes patient-centred SCD care?
iii. What constraints do patients experience when trying to access proven interventions for SCD at different stages of their lives?
iv. What solutions devised by patients and healthcare providers can advance patient-centred care and sustainably overcome constraints to both uptake of care and implementation of clinical mainstays?

Aim

To improve wellbeing and health outcomes for SCD patients in SSA through earlier and improved detection of SCD and optimised implementation of known evidence-based clinical interventions, using a patient-centred approach.

Objectives

1. To understand the barriers SCD patients face in accessing and adhering to care at different life stages.
2. Use participatory actions cycles (PACs) as platforms for SCD patients/carers and community members to together support community sensitisation for earlier uptake of SCD care and to overcome access barriers.
3. To work with SCD patients/carers, their communities, healthcare providers and policy makers to generate and implement guidelines for patient-centred SCD care .
4. To work with SCD patients/carers, their communities, healthcare providers and policy makers to consistently use successful patient-centred solutions and evidence-based SCD care.
5. Use a realist evaluation to explore barriers preventing a) uptake of SCD care, b) implementation of evidence-based practice, and c) patient-centred care in terms of what worked, for whom, under which conditions, and why.

3.2 Study Design

To study implementation of the intervention in-depth, we will carry out a realist evaluation (see section 3.3 below). As this is implementation research, implementation of the intervention and study of the implementation process will occur simultaneously in a phased approach as detailed below. However, of note is that though PACs and SBA introduction, capacity-strengthening, and support to community and clinical teams is our intervention, they too can be considered as approaches to implementation research, generating rich insights around local barriers and how to overcome these, all of which will be captured.

In months 0–6, the study team will be established, staff members (PAC and SBA leads) hired and trained, and community entry established.

3.3 Data Collection

Phase 1: Situational analysis; selection of facilities and PACs and SBA teams (months 7–18)

Situational analysis: The purpose of the situational analysis is familiarisation with current knowledge on: social factors affecting access to SCD care[*]; patient/carer expectations of patient-centred care; and key barriers constraining implementation of evidence-based SCD clinical mainstays and adopting patient-centredness in care provision.

Information from **a *scoping (literature, policy), and media review*** summarising what is known about SCD and accuracy of public information (from the media review), and a ***patient***

[*] Please note that this will be complemented by research into geographical and financial factors that are part of an epidemiological and mapping study (for which a separate ethics application will be submitted). This will be an ongoing study that will also be designed to detect changes in clinical mainstays and patient outcomes.

survey about barriers to accessing care will be used to brief the PACs and SBA research teams (see Phase 2). Additional information will be obtained from a ***qualitative study***.

Scoping and media reviews

A scoping review involving peer-reviewed and grey literature (including policy and guidelines for SCD in each country and in SSA more broadly) will be conducted to synthesise current global knowledge about barriers to accessing and implementing SCD care in SSA and to collate current guidelines on SCD management. Public misperceptions about SCD that exacerbate stigma are common and can be countered by more sensitive and accurate reporting, so we will also undertake a review of media reports[†] (i.e. media content analysis) from 2019–2022 to identify trends and gaps in knowledge and possible opportunities for sensitisation. To enhance quality, these reviews will involve systematic identification of articles, independent extraction of data, and coding of data by two researchers with arbitration by a third researcher.

Baseline patient survey

Using information from the scoping review and media content analyses, a baseline survey will be designed and administered to consenting SCD patients aged 15 and older (or, for children, their carers) attending clinics at the teaching hospitals in Abuja, Lusaka, and Kumasi—"active" patients. To understand SCD care provided and perceptions of access to care and quality of care, we will sample 300 participants (either a patient or their carer) in each teaching hospital. The tool will be administered electronically by a research assistant, and built on Microsoft Forms. Responses will be password protected and automatically sent—or queued to be sent—to cloud storage depending on internet connectivity. A similar survey will be administered to individuals with SCD who do not access SCD care from the formal national health service—"inactive patients" (see Appendix 1 for *drafts* of both tools—these will likely change with scoping review/media content analysis inputs). They will be identified through snowball sampling (by peer-SCD patients) and local community-based organisations who support SCD-affected persons. This information will provide a broad understanding of the socio-cultural and health system barriers they face in accessing of SCD care.

Qualitative study

To explore and explain findings from the review and the survey, we will carry out additional qualitative data collection. This will involve three **focus group discussions** (FGDs) per country focussing on:

1. *Patients/carers* to help us to understand what SCD patients/carers need and expect from care, their perceptions of the quality of care received, their ideals for "patient-centred SCD care", and constraints they face in accessing care.
2. *Community members* more broadly (religious and other community members, traditional healers, other influential community members) to establish localised understanding of SCD and perceptions around community access to health facilities.

[†] We are planning to follow this with research into how best to support journalists to engage more effectively with SCD patients and researchers. We will also apply for separate ethics for this activity.

3. *Health facility staff* providing SCD care to establish standards of care currently in place, typical approaches in SCD care, their views on what "patient-centred SCD care" would entail, and perceptions around quality of SCD care and areas for improvement (see Appendix 1 for FGD guides).

Key informant interviews: 5–10 will take place with policymakers who play a role in SCD and community health decision-making in order to determine which policies guide SCD in each country, resource allocation for SCD care, and higher-level facilitators and barriers of SCD care. These key informants may include Directors of Clinical Services/Public Health and National/Zonal Blood Services and senior facility and university officials responsible for training in SCD care (e.g. Medical Directors, Deans). We will also carry out key informant interviews with representatives from community-based or national-level organisations supporting patients with SCD and carers of children living with SCD to understand their perspectives around uptake of care, common misconceptions, patient-centredness in SCD care, and facilitators and barriers of uptake and delivery of quality SCD care.

Findings from the situational analysis will by synthesised and shared with PAC and SBA teams as a springboard for discussion and to inform priority topic areas for each group.

Realist evaluation

Information from the literature, media, and policy reviews and the qualitative study will be synthesised and analysed retroductively, applying "realist logic"—we will look for relationships in any data that speak to patterns around the provision and uptake of patient-centred, evidence-based SCD care.[28] In particular we will generate hypothesised "context, mechanism, outcome configurations" and will hypothesise what we think within the *context* is likely to drive (as in, what will our participants be likely to respond to in the intervention and why—these are the *mechanisms*)[29] patient-centred, evidence-based SCD care, and what the *outcomes* of that will be.[30] We will then develop a programme theory from combining these "context-mechanism-outcome configurations". We will reflect on this theory within our study team (as each country Principal Investigator and other members of the study team are instrumental in driving SCD in each country) and a selection of stakeholders (community and clinical) in a half-day *participatory workshop* and refine it to develop an **initial programme theory.**

Intervention start-up

Simultaneously during this phase, we will be **recruiting health facilities** in our three study areas (6 facilities/country) **and building SBA and PACs teams** associated with these facilities (1 each/facility = 6 SBA teams total per country) and community (6 PAC teams total per country). We will also begin capacity strengthening with each team. In each country, a SBA and PAC lead will be appointed. These individuals will recruit and capacitate SBA and PAC teams and support their activities through mentoring and coaching.

Throughout all aspects of implementation across phases, we will carry out **detailed documentation of processes**, which will feed into the realist evaluation**.** In this phase, processes of facility and community entry will be documented, as will all capacity strengthening activities, *including study team reflections* on challenges and opportunities around capacity strengthening.

Phase 2: **Intervention and study of its implementation (months 18–42)**

To overcome barriers identified in Phase 1—and perhaps others that might be raised by each team—solutions to early identification and uptake of SCD care will be identified and tested through **repeated PACs** with teams of SCD patients/carers and other influential community members, and **SBA cycles** will be carried out with health facility teams to drive routine use of evidence-based SCD care, centred around clinical mainstays. Finally, PAC and SBA teams will be brought together in learning collaboratives to **co-create guidance for patient-centred SCD care**.

Documentation of processes

Again, there will be detailed documentation of processes throughout, often accompanying by structured observation (either carried out by trained research assistants or PhD students) guided by a template. This will include:

- PAC team members/turnover
- Details of capacity strengthening activities for each member
- PAC meetings: attendees, main discussion points, decisions made
- Outcomes of PACs: changes resulting
- SBA team members/turnover
- Details of capacity strengthening activities for each member
- SBA meetings: attendees, main discussion points, decisions made
- Outcomes of PACs: changes resulting in standards of care

In particular, meeting discussion points and decisions will be a rich source of data about challenges and facilitators around the aim of each cycle. With member permission, these meetings will be recorded and transcribed. Detailed **observation notes, transcripts of meetings, and reflections from the SBA and PAC leads from reflective implementation diaries** will be generated and collated on a monthly basis (see Appendix 1 for some of these tools). Additionally, PAC and SBA **team documentation** (meeting minutes, any graphical information or tables outlining the outcomes of their activities) will also be reviewed by the SBA and PAC leads and photographed/scanned to ensure a digital record is kept.

In addition, **learning collaboratives will be recorded** in detail, collecting similar content as meetings including attendees, key discussion points, and decisions made. Prominent and promising solutions will be described, as well as those that tried and failed. Structured observation templates will guide data collection during learning events. Some discussions will, with permission, also be recorded and transcribed.

Mentoring and coaching will be facilitated by guidance of what to review with each team (e.g. actions taken, progress made, challenges, successes) with space for commentary. These will be collated on a monthly basis. **PACTS study team meetings** will also be recorded and minutes will be taken. These meetings—and mentoring and coaching guidance—will be a good opportunity for the SBA and PAC leads to offer their reflections and insights on the processes.

All of these data will provide comprehensive insights around many of our study questions.

Outcomes from the PAC and SBA activities, for example, changes in indicators that reflect the clinical mainstays (e.g. number of outpatient visits and inpatient days; haemoglobin levels; number of infections and transfusions/year) will also be independently evaluated by our study team in an ongoing epidemiological study which is described in a separate protocol.

Realist evaluation

Throughout this phase, the objective of the realist evaluation is to test and refine the initial programme theory from Phase 1. This programme theory will underscore the relationship between PACs and SBA activities, how participants respond to them, what outcomes they produce, and how the process and outcomes are moderated by contextual factors. To test and refine the "context-mechanism-outcome" configurations originally generated, additional data alongside the process data from above will be collected and analysed in three "rounds" ***at months 18, 30, and 42***.

Data will include ***qualitative data*** from PACs and SBA participants and other key stakeholders about their activities and perceptions and ***contextual*** data (e.g. collating documents such as relevant policies and national strategies, health management plans, documentation of health facility changes).

Qualitative data will include an FGD with each PAC team and SBA team (12 FGDs per country per round) and 5-10 in-depth interviews with other stakeholders (e.g. leaders of each participating health facility, relevant blood services staff, community leaders who may not be part of the PAC team, SCD community-based organisation representatives) (see Appendix 1 for tools). The intention of these will be to generate insights around what is working (or not) through the PACs and SBA cycles and why. Insights around contextual factors moderating each teams' activities will also be garnered. In-depth interviews will also be carried out with the SBA and PAC lead.

Additional **contextual data** will be updated monthly, but summarised and analysed against other data within each round. It is likely that PAC and SBA team members may be able to provide these insights, but if not, a check-in with the facility in-charge or local leaders may be needed. As these stakeholders are very likely to be interviewed as part of the qualitative data collection, additional questions about contextual factors may be added there. These data will include: information about each participating health facility (e.g. changes to staffing, infrastructure, availability of medicines or equipment that may affect SCD care); policy changes; broader social/cultural changes or events (e.g. conflict, an election); and any other factors that arise that the study team feels might impact upon either the implementation of the interventions, or their outcomes on SCD care uptake and provision.

Process, qualitative, and contextual data will be synthesised in each round of data collection. Again, realist logic will be applied and we will explore the data retroductively. The aim will be to test and refine the context-mechanism-outcome configurations and, ultimately, the programme theory that results. This will always be done through participatory workshops with the study team and key stakeholders—as for the initial programme theory.

Phase 3: Knowledge translation and close-out (months 42–48)

In this final phase, three "rounds" of the realist evaluation will have been completed, after which a **final, transferrable programme theory** will be generated for each country to highlight how and under which conditions SBA and PACs can be used together to drive patient-centred, evidence based SCD care provision and uptake. Importantly, this final programme theory will be compared/tested across all three countries for homogeneity (meaning that it is robust and "holding up" across three very different contexts) or heterogeneity (likely highlight the role of critical moderating contextual factors unique to each country). This programme theory—or its iteration from each country—will be of use to other research or implementation teams seeking to replicate this intervention elsewhere.

However, key insights gained through the processes of the PACs and SBA themselves and the most successful solutions generated will be packaged into policy briefs (or other relevant outputs as decided by the consortium—possibly with inputs from journalists (see footnote on page 9)—intended to influence SCD policy. A close-out workshop (year 4) will be held for all PACTS consortium members to collate these findings and to identify key recommendations and appropriate audiences for these. The aim is threefold: i) to support **community health policy change** through guidance that will improve community understanding of SCD, encourage earlier diagnosis and uptake of care, and facilitate access to care; ii) to support the **introduction of standards of care reflecting clinical mainstays** (and supporting guidance on their routine implementation generated from SBA cycles); and iii) to **introduce guidance patient-centred SCD care**, also with guidance around its implementation. Throughout the consortium's lifetime there are embedded dissemination events at which there will be interim updates provided. However, during this final stage a much more intensive push to influence policy change will take place.

Table 1 below summarises the primary data collection throughout phases 1 and 2, as there will be no data collection in Phase 3. Of note is that some of the participants from the situational analysis are likely to be engaged in the intervention and repeated. Therefore, the total number of participants likely reflects an overestimate.

Table 1. Summary of primary data collection for the study of implementation within PACTS

Data collection method	Activity	Total participants
Phase I		
Baseline survey	300 patients actively receiving care at each of the three main teaching hospitals (one per country); we will aim to find 100 SCD-affected persons/carers of children living with SCD who do not access care	900 active patients 300 inactive patients
Focus group discussions	Three per country (community FGD, SCD patient/carer FGD, and SCD healthcare provider FGD), each with 6–8 participants = 18–24 participants per country x3 countries	54–72
Key informant interviews	5–10 per country x3 countries	15–30
Process documentation	- Capacity strengthening activities (what took place, where, who attended) - Reflections on key gaps and strengths	N/A

Phase II		
Process documentation	- Detailed log of all activities led by the study team (what took place, when, where, who attended) - SBA and PAC monthly meeting minutes - SBA and PAC monthly meeting observation notes - SBA and PAC monthly meeting transcripts (from audio recordings) - SBA and PAC monthly mentoring checklists/comments - SBA and PAC run charts/other tables or visuals capturing improvement - Learning collaborative observation notes - Learning collaborative transcripts (from audio recordings) - SBA and PAC lead reflective implementation diaries - Minutes/recordings from PACTS study team meetings	N/A
FGDs	With each PAC and SBA team, per round (12 per country, 36 across all three rounds) = 108 FGDs, however, participant numbers remain constant across rounds as the same participants will be repeating. 12 FGDs per country, each with approximately 10 participants = 120 per country	360
In-depth interviews	5–10 per round = 15–30 per country And SBA and PAC lead each round (assume no turnover and participant repeats)	47–92
Contextual data	Will be informed by existing qualitative data collection	N/A
	TOTAL	1676–1754

3.4 Data Analysis

The situational analysis review of activities will draw only from secondary data. We will carry out a thematic analysis to identify core drivers or inhibitors of SCD care provision and uptake. The media review will involve a media content analysis—identifying and summarising core content (key SCD messages shared, misinformation, correct information).

The baseline study will simply generate categorical data. We will use Stata 13 to generate descriptive statistics. Open text responses will be coded and analysed thematically.

For qualitative data (from focus group discussions and in-depth or key informant interviews, as well as transcripts from SBA and PAC meetings or learning collaboratives), we will carry out a framework analysis. The framework will be generated following creation of the initial programme theory and will be designed to collate key aspects of implementation, but also to test context-mechanism-outcome configurations. All coding and analysis will be assisted using NVivo.

Process documentation will be collated and updated in an Excel file for each country, with a sheet generated for each PAC or SBA team to document member activities and turnover and key happenings (from observations or SBA and PAC lead reflective implementation diaries) from each meeting. A separate Excel file will be used to collate mentoring and coaching data. A final file will be used to collate attendance and observation data from learning collaboratives.

3.5 Participant Sampling and Recruitment

The **study areas** for our research cover the catchment populations of the teaching hospitals in Abuja (Nigeria), Kumasi (Ghana) and Lusaka (Zambia). We will liaise with the Ministry of

Health in each country to secure their endorsement for the study. In Nigeria, a representative from the Ministry of Health is part of our external advisory board. We will use invitation/permission letters from the Ministry to support entry into each health facility.

Six health facilities/country within these study areas will be selected to participate (with support from the existing SCD community engagement officers in each site). Selection criteria for facilities will include a) they provide care (including blood transfusions) for and have a substantial pool of SCD patients; and b) they represent diversity in location (urban, semi-urban, rural). Study information will be provided to the facility in-charge and after one week, they will have the responsibility of consenting to their facility's participation or declining their facility's participation. As PAC and SBA teams are built based on the facility, these will not be selected until the facilities have been confirmed.

Participants for the patient/carer survey will be identified in two ways. Those who are *actively* receiving care will be known to the three teaching hospitals that we are working with. Study materials will be posted in the waiting rooms where SCD-affected persons and carers of children living with SCD may wait. Here, members of the study team will also approach prospective participants whilst they wait giving them information about the study and answering questions that they might have. At the conclusion of the visit, if the SCD patient/their carer is willing, an informed consent process will be carried out and they will be guided through a research assistant-administered survey taking no more than 30 minutes of their time. Recruitment will continue until 300 unique SCD patients/ carers of children living with SCD have participated in the survey. For SCD-affected persons/ carers of children living with SCD who are *not* receiving care, we will work through community-based organisations who provide support around SCD to whom these individuals may be known. Research assistants will identify prospective participants with the help of these organisations and will follow-up participants first by phone and will then arrange to do the survey at their home or at another preferred location. An informed consent process will take place before any data collection begins. We will also deploy snowball sampling with identified participants to determine if they may be aware of other SCD-affected persons/ carers of children living with SCD who are not receiving care. Recruitment will continue until 100 participants who are not receiving SCD care have been identified. For both types of participants (those receiving care, and those not), informed consent will also have provisions should the participant not be literate (see more in section 5.1).

Please note that sample size calculations have not been made, as we are not making statistically significant inferences, but simply carrying out this survey in an exploratory way to gain insights from a broad cross-section of SCD-patients and carers of children living with SCD. At each teaching hospital (one in Abuja, one in Lusaka, one in Kumasi), there are approximately 2000–3000 SCD patients who receive care regularly throughout the year. Given our timeline, we estimate that it would therefore be plausible over a three-month period to obtain survey responses from 300 unique patients/carers. The numbers of SCD-affected persons/ carers of children living with SCD who do not receive care is unknown in all contexts, and we anticipate that it will may be much more challenging to identify these participants, however, their perspectives are incredibly important. As such, we will continue to recruit until we reach 100 unique participants, though this may need to be adjusted down if this is simply not possible within the three months allotted for this survey.

In **months 15–18**, each **PACs team (1/facility)** will be drawn from communities within the catchment area of each participating health facility. Each team will comprise ***SCD patient/carers and influential community members/decision-makers (which may also include traditional healers)*** for approximately 10 people per team. Inclusion of community members will improve the community's understanding of the challenges faced by SCD patients. Community team members will be accessed first by identifying and liaising with community-based organisations that support SCD-affected persons, who will serve as community gatekeepers in addition to providing suggestions for possible participants. Discussions with community leaders to identify prospective participants as well as snowball sampling (e.g. an identified carer may be aware of another carer in their community) will also take place. Inclusion criteria will be: aged 18 and older (unless a person living with SCD, in which case they must be at least 15 years of age); a carer of someone (alive or deceased) with SCD or someone living with SCD or a community leader or a traditional healer; must be literate; must be willing to consent. Each prospective participant will be approached by the study team and given study materials (the participant information sheet). They will be given at least one week to decide their participation.

Simultaneously, at each participating health facility, all staff with a role in providing SCD care will be invited to participate in a **SBA team** (1/facility). 6-10 members will be selected to maximise diversity in knowledge and experience (e.g. by cadres, years of experience, responsibilities). These staff will be identified by the facility in-charge, and by speaking to staff on relevant units to identify those staff members with SCD responsibilities. Inclusion criteria will be: those staff working for at least one year providing SCD disease, aged 18 and older, speaking English, and consenting to participate. Each prospective participant will be approached by the study team and given study materials (the participant information sheet). They will be given at least one week to decide their participation.

Key informants (e.g. ministry officials, medical education leaders, community-based organisation representatives) will be identified through our PACTS consortium's extensive network. Where we may not have knowledge of the right person, most of these individuals will have an online presence for the role that we seek and will be approached accordingly. As for other participants, each prospective participant will be approached by the study team and given study materials (the participant information sheet). They will be given at least one week to decide their participation. Key informant interviews may take place in their office or another private space of their choosing. For informants who might be at a distance, the interviews will be arranged online.

Other **in-depth interview participants** (e.g. other community members, other members of staff at participating health facilities) will be identified as intervention implementation progresses and we learn more about who is influential in community and facility-based SCD issues. They will be approached, as for all other participants, by a member of the study team and given study materials (the participant information sheet). They will be given at least one week to decide their participation.

3.6 Dissemination

As described in Phase 3 above, the final part of this study is dedicated to dissemination. However, it is important to note that throughout, SBA and PAC teams will be disseminating their activities and achievements to their health facilities and communities respectively.

Learning collaboratives are also a critical point for dissemination by each team and will be expanded to include a wider group, including policymakers, annually.

4. Timeline

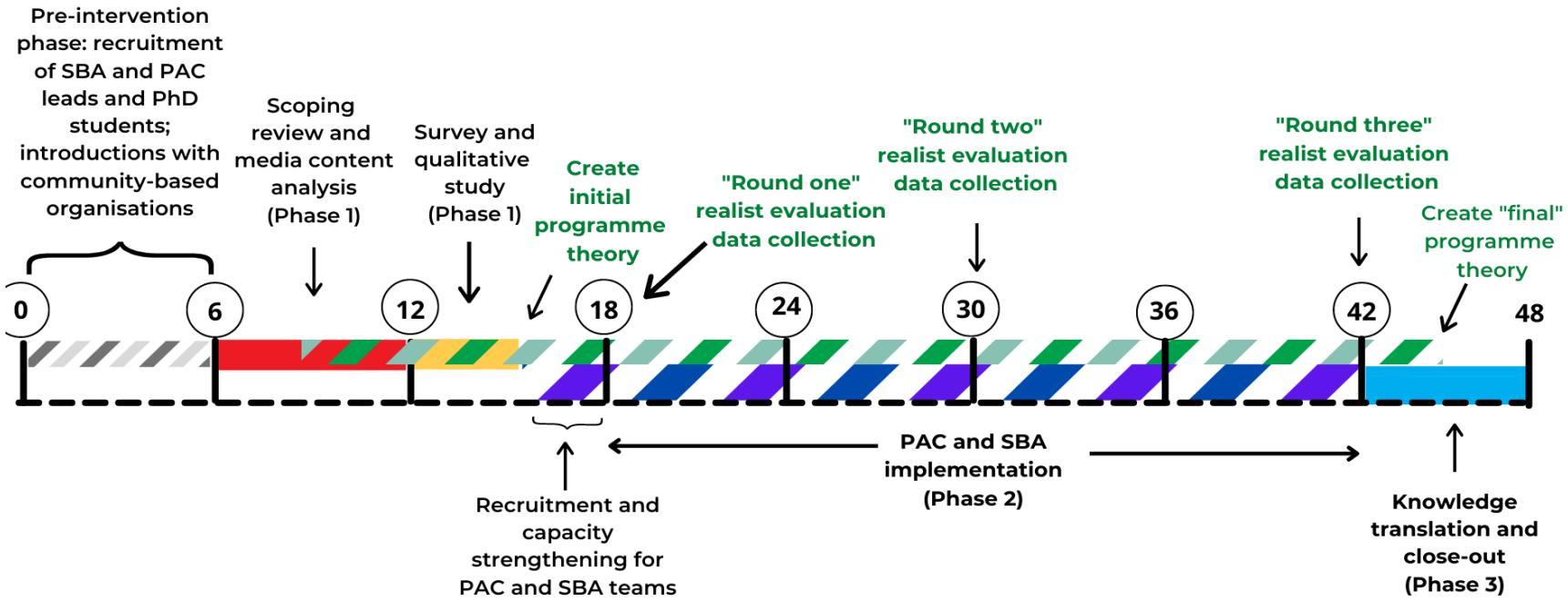

Figure 1. Study timeline showing implementation research aspects and intervention implementation across three phases

The first six months of the study are dedicating to recruiting study staff—primarily the PAC and SBA leads who will be supporting the teams in each country and to working closely with community-based organisations supporting SCD, as they will be essential in both the recruitment of survey respondents and PAC team members. The scoping review (policy and literature) will take place from months 6–12, alongside the media content analysis. The SCD patient/carer survey will take place simultaneously with the qualitative study in months 12–15. These will be analysed and used to inform PAC and SBA activities in Phase 2, but will also be used to create the realist evaluation's initial programme theory in month 15. During months 15–18, PAC and SBA teams will be established and capacitated, and from months 18–42, they will carry out activities (Phase 2). In months 18, 30, and 42, data for the realist evaluation will be collected and analysed, each producing a further iteration of the programme theory until a "final" one is developed by month 45. Phase 3, which is primarily for dissemination, will take place from months 42–48, with the aim of informing SCD policy and guidance in each country.

5. Ethical Considerations

Ethics approval will be sought from the University of Abuja Teaching Hospital in Nigeria, the Committee on Human Research and Publication Ethics at KNUST in Ghana, and ERES Converge in Zambia. Approval will also be sought from LSTM, but this will be contingent on first obtaining approvals from African partners.

The main anticipated ethical risks are associated with potential identification of individuals contributing to surveys and interviews, and possibly triggering recall of negative events among participants. Before taking part in the research, participants will be given information about the study and will be given at least one week to consider whether they want to participate. All survey and interview responses will be anonymised so participants cannot be identified. All transcripts from qualitative data will have participant names replaced with pseudonyms or participant numbers, and all identifying information will be removed.

5.1 Informed Consent

All participants will undergo a process of written informed consent (see **appendices 2 and 3** for participant information sheets and informed consent forms). An individual informed consent process will take place with each participant. Where they may not be literate, a literate witness will ensure that the participant has understood and has had the opportunity to ask questions before signing or providing a thumb print. They will be free to end their participation at any time.

Outside of the patient survey, our research is primarily qualitative and does not involve biological samples, but it does involve human participants–SCD patients (or carers of children with SCD), community members and healthcare providers. This will also likely include some adolescent participants (aged 15 and older) with SCD. They and their parent/guardian will both provide consent to participate.

All PAC and SBA participants will be literate as this is an inclusion criteria. This is to ensure that they can participate fully in all activities, which will involve a lot of learning and sharing of written information. The contents of the participant information sheet will be explained to each participant and they will have the opportunity to ask questions directly. Again, after one week, they will be re-approached to be consented into the study if they wish. They will again have the opportunity to ask questions or seek clarifications at this time.

For the situational analysis community FGDs, there may be non-literate participants, for whom an informed consent process with a literate witness present will take place. The participant will provide a thumbprint and the witness will provide their signature.

Key informants and other interview participants will have the contents of the participant information sheet explained to them and they will have the opportunity to ask questions. A minimum of one week will be given to ensure that the participant has had time to consider their participation fully. Following this, an appropriate time and date for data collection will be organised and prior to the start of the interview written informed consent will be taken. If the interview is by telephone, verbal informed consent will take place in the presence of a witness and will be audio recorded. However, if the participant can access emails they will

be emailed the informed consent form and will be asked to complete it and return it electronically (encrypted) as well.

5.2 Privacy and Confidentiality

Privacy and confidentiality will be upheld throughout this study. To uphold privacy, all discussions and/or data collection that may involve private information will be carried out in a private, secure space in which participants cannot be overheard. Data collectors will maintain the highest level of confidentiality during all interactions with participants and through all forms of data collection. No identifying information will be shared beyond the study team under any circumstances.

At the outset of focus group discussions, all group members will be reminded that they will hear disclosures from others, and that they should keep these private. We will establish a set of “ground rules” led by participants from the outset of the discussion to reinforce this. Further, participants will be reminded that they should not share any personal information that they are not comfortable with the group knowing. However, as none of the questions posed during the focus group discussion are personal, so we will hopefully avoid this scenario. The facilitator will regularly remind them of their commitment to privacy and confidentiality throughout, as needed.

Key informant and other interviews will be carried out in a private space. Though all efforts will be made to anonymise transcripts and any published information, by nature of key informants occupying a unique position, it may still be possible that some key informants might be identifiable. This risk will be communicated to all key informants during the informed consent process.

All transcripts will have identifying details redacted and only anonymised transcripts will be shared with the study team.

5.3 Data Management

All participant data—including hard copies of informed consent forms, and any stored digital information—will be kept securely. Files will be password-protected and stored on a secure cloud storage established for the purpose of secure data sharing within our study team. This cloud storage will only be accessible to invited study team members, and each file (or folder) can have added password or access protections as needed. The cloud storage is backed up through LSTM and is supported by IT services at LSTM, ensuring security in the event of any breach.

For **qualitative data,** raw audio data will be uploaded as soon as possible to the cloud storage. Immediately thereafter, they will be deleted from any recording devices. Interview recordings will be transcribed using a denaturalised approach—transcripts will be non-verbatim, with repeated words, pauses and stutters removed. Transcription will be performed by the interviewers, with a second person checking the transcript for accuracy. All personal identifiers will be removed and the transcripts anonymised, with unique ID numbers used to protect participants’ privacy and confidentiality. It is these anonymised, verified transcripts that will be uploaded to cloud storage. During the period of transcription, the files will be maintained in a password-protected file on a secure project laptop.

For **quantitative data**, participants will also be given unique ID numbers that will be linked to the data. Data will thus be anonymised at the point of upload to cloud storage. Any hard copy forms of quantitative data collection will have the participant's name redacted and will be scanned and uploaded into cloud storage, alongside the electronic version of the data, and then destroyed.

For both qualitative and quantitative data, a master file containing the participant/facility/organisation names and their corresponding ID numbers will be password protected and only available to the study principal investigators. This will be in a file with additional access and password protections in cloud storage.

Process documentation in Excel files and scanned SBA and PAC documents will be uploaded into the cloud storage. These will also have identifying information removed. Informed consent forms will be scanned, named, and immediately saved in password-protected files. Paper copies will be stored in a GCP compliant space in a locked drawer in an office space with locked doors that are only accessible to members of the study team.

After 10 years (following the requirements of the funder), these data will be deleted.

5.4 Safeguarding

Though this is generally a low-risk study, we acknowledge that persons living with SCD—especially adolescents—are vulnerable. As such, we will have a rigorous approach to safeguarding:

- A **safeguarding lead will be appointed** in each study country.
- The SBA and PAC leads and all members of data collection teams will undergo **safeguarding training** led by TT.
- Given that sexual and gender-based violence are prominent safeguarding concerns, whether as a result of our study activities or not, **emergency sexual and reproductive health services within our study area will be mapped out**—all country principal investigators are senior clinicians who will identify and document suitable services, which will be communicated to each country safeguarding lead and the SBA and PAC leads**,** should there be any need to support a participant or study team member in accessing care.
- Prior to starting any activities, as a study team, we will carry out a **risk assessment of potential safeguarding concerns**. Primarily, the possibility of interviews or focus group discussions resulting in disclosure of inappropriate care or interactions with staff from health facilities/NGOs/other local organizations.
- Study principal investigators will **map out available services and networks** of mental and medical support, should, for example, inappropriate care be identified and a person living with SCD need to be referred elsewhere.
- Data will only be collected from participants (especially adolescents) in an accessible setting, during daytime hours, in a location that is known to the participants and which is communicated to their parent/caregiver.

If a participant discloses any safeguarding concerns (e.g. abusive treatment from health facility staff), our process is as follows: study team member to inform the study principal investigator and safeguarding focal person → safeguarding focal person to follow-up directly with the participant to fully understand their experience as well as their boundaries in terms of what they deem acceptable in terms of next steps → safeguarding focal person (with

support from principal investigator) to initiate next steps. Whistle-blowers will always be protected and supported. If needed, LSTM's safeguarding lead, Phil Tubb, will be contacted and engaged.

In addition to protecting participants, our researchers will be expected to undertake field activities with at least one other person present, in daytime hours, with clear communication of when and where they will be. There is a budget for "communication support" to ensure that the study team members have access to data/airtime as needed.

At LSTM TT is a Departmental safeguarding focal person and a member of LSTM's Safeguarding Oversight Committee. LSTM has a comprehensive safeguarding policy (2019) with components that include: roles and responsibilities; safeguarding procedures; forms of harm/abuse; dealing with suspicions or allegations of harm or abuse; safeguarding in overseas research settings; safe recruitment and selection of staff; and allegations of staff misconduct. We will be compliant with this policy throughout this study.

5.5 Special Considerations Around Participants' Emerging Needs

At the end of the baseline survey for people living with SCD who are NOT accessing care/ carers of children living with SCD, we will let them know the contact details of the outreach services officers from their local SCD health care providers.

For anyone we encounter who has additional medical or psychosocial needs we will ask for advice from the lead co-Investigators in each country about appropriate referral mechanisms.

5.6 Anticipated COVID-19 Risks and Mitigation Strategies

We cannot assume that **COVID-19** will not be affecting the communities where we intend to carry out study activities. As such, we are mindful of the need to be aware of and responsive to changing guidance. We will always work within the confines of the guidance from national and local governments. To ensure safety of facilitators and participants, the following measures will always be in place should COVID-19 transmission increase in any of our study settings:

- Study staff (SBA and PAC leads, any data collection team members) will be encouraged to have two COVID-19 vaccinations (and boosters, if eligible).
- Study staff will be equipped with a "COVID-19 kit", which will include hand sanitizer, disinfectant wipes, and disposable masks.
- Study staff will be trained to thoroughly wash their hands immediately prior to interacting with participants.
- Study staff will be required to wear a face mask for the duration of their contact with participants, and will be trained on the appropriate way to wear a face mask.
- Study staff will always maintain a minimum of 2m of distance from participants, and, unless it is unavoidable, study activities will take place in a sheltered space outdoors.
- Participants will also be asked to sanitise their hands and to wear face masks (which we will provide).
- If interactions must occur indoors, we will ensure that only well-ventilated spaces are used.
- For qualitative data collection, interviews will take place in private outdoor spaces, or if necessary, in well-ventilated indoor spaces. As above, hand hygiene, social

distancing of at least 2m, and wearing of masks will take place. However, as previously mentioned, these interviews may simply take place over the phone if it is determined that they pose too much risk.

5.7 Quality Assurance

To ensure that all data collected are of the highest quality possible, there are a number of steps that will be taken. In the first instance, given the nature of this work SBA and PAC leads will complete daily debriefs in their reflective implementation diaries after spending time with participants in order to capture their emerging thoughts and feelings, and to maintain reflexivity.

Qualitative data that are collected will have rigour maintained throughout. To ensure questions are clear and that there are no missing questions that should be added in, all instruments will be piloted in populations in each country similar to those who will be involved in the main study and identified in collaboration with country principal investigators. Where carried out in local languages, discussion prompt guides will be translated and back-translated to ensure that the appropriate meaning of the questions and prompts is retained. Any transcribed materials will be checked against the original audio by a second person, and the quality of translation (where appropriate) will also be ensured by reviewing the translated script against the original audio.

All quantitative data from the baseline survey will also be piloted to ensure all questions are clear and all responses are mutually exclusive and exhaustive. During data collection, 10% of all data will be checked for completeness and correctness each day, and if needed, mop-up data collection will take place, collecting data from additional participants, as follow-up data collection will likely be a challenge.

6. References

1. Leikin SL, Gallagher D, Kinney TR, et al. Mortality in children and adolescents with sickle cell disease. *Pediatrics* 1989; 84: 500-508.
2. World Health Organization. Management of birth defects and haemoglobin disorders: report of a joint WHO-March of Dimes meeting, Geneva, Switzerland, 17-19 May 2006. 2006.
3. Piel FB, Hay SI, Gupta S, et al. Global burden of sickle cell anaemia in children under five, 2010–2050: modelling based on demographics, excess mortality, and interventions. *PLoS medicine* 2013; 10: e1001484.
4. Piel FB, Patil AP, Howes RE, et al. Global epidemiology of sickle haemoglobin in neonates: a contemporary geostatistical model-based map and population estimates. *The Lancet* 2013; 381: 142-151.
5. Weatherall D, Akinyanju O, Fucharoen S, et al. Inherited disorders of hemoglobin. *Disease Control Priorities in Developing Countries 2nd edition* 2006.
6. Nelson E, Bloom G and Shankland A. Accountability for health equity: galvanising a movement for universal health coverage. 2018.
7. Cnaan A and Ryan L. Survival analysis in natural history studies of disease. *Statistics in medicine* 1989; 8: 1255-1268.
8. Telfer P, Coen P, Chakravorty S, et al. Clinical outcomes in children with sickle cell disease living in England: a neonatal cohort in East London. *haematologica* 2007; 92: 905-912.
9. Novelli EM. Sickle Cell Disease: Prevention of Complications. *Nonmalignant Hematology*. Springer, 2016, pp.63-73.
10. Hirst C and Owusu-Ofori S. Prophylactic antibiotics for preventing pneumococcal infection in children with sickle cell disease. *Cochrane Database of Systematic Reviews* 2014.
11. Qureshi A, Kaya B, Pancham S, et al. Guidelines for the use of hydroxycarbamide in children and adults with sickle cell disease: A British Society for Haematology Guideline. *British journal of haematology* 2018; 181: 460-475.
12. Charache S, Terrin ML, Moore RD, et al. Effect of hydroxyurea on the frequency of painful crises in sickle cell anemia. *New England Journal of Medicine* 1995; 332: 1317-1322.
13. Smith WR, Ballas SK, McCarthy WF, et al. The association between hydroxyurea treatment and pain intensity, analgesic use, and utilization in ambulatory sickle cell anemia patients. *Pain medicine* 2011; 12: 697-705.
14. Wang WC, Ware RE, Miller ST, et al. Hydroxycarbamide in very young children with sickle-cell anaemia: a multicentre, randomised, controlled trial (BABY HUG). *The Lancet* 2011; 377: 1663-1672.
15. Estcourt LJ, Kohli R, Hopewell S, et al. Blood transfusion for preventing primary and secondary stroke in people with sickle cell disease. *Cochrane Database of Systematic Reviews* 2020.
16. Wang WC, Oyeku SO, Luo Z, et al. Hydroxyurea is associated with lower costs of care of young children with sickle cell anemia. *Pediatrics* 2013; 132: 677-683.
17. DiMartino LD, Baumann AA, Hsu LL, et al. The sickle cell disease implementation consortium: Translating evidence-based guidelines into practice for sickle cell disease. *American journal of hematology* 2018; 93: E391.
18. McGann PT, Flanagan JM, Howard TA, et al. Genotoxicity associated with hydroxyurea exposure in infants with sickle cell anemia: results from the BABY-HUG Phase III Clinical Trial. *Pediatric blood & cancer* 2012; 59: 254-257.
19. Davis BA, Allard S, Qureshi A, et al. Guidelines on red cell transfusion in sickle cell disease. Part I: principles and laboratory aspects. *British journal of haematology* 2017; 176: 179-191.

20. Howard J. Sickle cell disease: when and how to transfuse. *Hematology 2014, the American Society of Hematology Education Program Book* 2016; 2016: 625-631.
21. Boateng LA, Schonewille H, Ligthart PC, et al. One third of alloantibodies in patients with sickle cell disease transfused with African blood are missed by the standard red blood cell test panel. *haematologica* 2021; 106: 2274.
22. Asamoah-Akuoko L, Hassall OW, Bates I, et al. Blood donors' perceptions, motivators and deterrents in Sub-Saharan Africa–a scoping review of evidence. *British Journal of Haematology* 2017; 177: 864-877.
23. Tshilolo L, Mukendi R and Wembonyama S. Blood transfusion rate in Congolese patients with sickle cell anemia. *The Indian Journal of Pediatrics* 2007; 74: 735-738.
24. Makani J, Cox SE, Soka D, et al. Mortality in sickle cell anemia in Africa: a prospective cohort study in Tanzania. *PloS one* 2011; 6: e14699.
25. Baum F, MacDougall C and Smith D. Participatory action research. *Journal of epidemiology and community health* 2006; 60: 854.
26. Bennett S, Whitehead M, Eames S, et al. Building capacity for knowledge translation in occupational therapy: learning through participatory action research. *BMC medical education* 2016; 16: 1-11.
27. Weeks A, Lightly K and Ononge S. *Let's Do Audit!: A Practical Guide to Improving the Quality of Medical Care Through Criterion-based Audit*. Cambridge University Press, 2010.
28. Gilmore B, McAuliffe E, Power J, et al. Data analysis and synthesis within a realist evaluation: toward more transparent methodological approaches. *International Journal of Qualitative Methods* 2019; 18: 1609406919859754.
29. Dalkin SM, Greenhalgh J, Jones D, et al. What's in a mechanism? Development of a key concept in realist evaluation. *Implementation science* 2015; 10: 1-7.
30. De Brún A and McAuliffe E. Identifying the context, mechanisms and outcomes underlying collective leadership in teams: building a realist programme theory. *BMC health services research* 2020; 20: 1-13.

7. Appendices

Appendix 1. Data Collection Instruments

Situational Analysis: Patient Survey: Active Patients

	Prompt	Response
1	**Date**	[dd/mm/yy]
2	**Participant ID**	[######]
3	**Country**	Ghana Nigeria Zambia
4	**Participant/ dependent age at last birthday**	[Age in years]
5	**Participant/ dependent age of SCD diagnosis**	[Age in months—e.g. three years = 36 months]
6	**Do other members of your family have SCD?**	Yes [number] No I don't know
7	**Number of health facilities at which SCD care has been sought**	1 2–3 4–5 More than 5 I don't know N/A—I have never sought care at a health facility
8	**How long did it take you to travel to access care today?**	Less than 30 minutes 30–60 minutes 1–2 hours More than two hours
9	**Do you face any barriers accessing care?**	Yes No I don't know
9a	**[If yes to 9] What type of barriers?**	*Select all that apply* Costs Transportation Permission to access care Other [please indicate]
10	**What do you feel would make it easier for patients to access SCD care?**	[Open text]
11	**Do you/your dependent face stigma or discrimination as a result of your/their SCD diagnosis?**	Yes No I don't know

11a	**[If yes to 11]** **Please explain why you stated yes**	[Open text]
12	**Do you feel that there are misconceptions about SCD in your community?**	Yes No I don't know
12a	**[If yes to 12] What do you think those are?**	[Open text]
13	**Type of care provided *today***	*Select all that apply* Counselling Pain management Blood transfusion Prevention of infection Vaccinations Mental health/psychosocial support Treatment for chronic organ dysfunction Hydroxycarbamide/hydroxyurea Stem cell therapy Other [Please indicate] I don't know Nothing
14	**Types of care received *to-date***	*Select all that apply* Counselling Pain management Blood transfusion Prevention of infection Vaccinations Mental health/psychosocial support Treatment for chronic organ dysfunction Hydroxycarbamide/hydroxyurea Stem cell therapy Other [Please indicate] I don't know Nothing
15	**Are you satisfied with the quality of care provided *today*?**	Very dissatisfied Somewhat dissatisfied Neither satisfied nor dissatisfied Somewhat satisfied Very satisfied
16	**Can you please explain why you indicated that level of satisfaction?**	[Open response]
17	**Do you feel that SCD care should improve at this health facility?**	Yes No I don't know
17a	**[If yes to 16]** **How do you feel it should improve?**	[Open response]

Situational Analysis: Patient Survey: Inactive Patients

	Prompt	Response
1	**Date**	[dd/mm/yy]
2	**Participant ID**	[#######]
3	**Country**	Ghana Nigeria Zambia
4	**Participant/ dependent age at last birthday**	[Age in years]
5	**Participant/ dependent age of SCD diagnosis**	[Age in months—e.g. three years = 36 months]
6	**Do other members of your family have SCD?**	Yes [number] No I don't know
7	**Number of health facilities at which SCD care has been sought**	1 2–3 4–5 More than 5 I don't know N/A—I have never sought care at a health facility
8	**Do you feel that it is important to receive care for SCD?**	Not at all important Somewhat important Very important Not sure
9	**[If "not at all important", "somewhat important", or "very important" to 8] Can you please explain why you feel that it is/is not/is somewhat important to receive SCD care?**	[Open text]
10	**Why are you/your dependent not undertaking care for SCD?**	*Select all that apply* Costs Transportation Permission to access care Other [please indicate]
11	**What do you feel would make it easier for patients to access SCD care?**	[Open text]
12	**Do you/your dependent face stigma or discrimination as a result of your/their SCD diagnosis?**	Yes No I don't know
12a	**[If yes to 12] Please explain why you stated yes**	[Open text]

13	**Do you feel that there are misconceptions about SCD in your community?**	Yes No I don't know
13a	**[If yes to 13] What do you think those are?**	[Open text]
14	**Have you/your dependent ever received care for SCD?**	Yes No I don't know
14a	**[If yes to 14] Type of care ever received**	*Select all that apply* Counselling Pain management Blood transfusion Prevention of infection Vaccinations Mental health/psychosocial support Treatment for chronic organ dysfunction Hydroxycarbamide/hydroxyurea Stem cell therapy Other [Please indicate] I don't know Nothing
15	**What would make you/your dependent regularly access care?**	[Open text]

Situational Analysis: FGD with Patients/Carers

Introduce yourself, explain the purpose of the FGD, take informed consent. Remind participants about confidentiality.

1. Please describe your/your dependent's current experiences of SCD care.
    a. Probe: Where do you/your dependent receive care?
    b. Probe: Is this care good quality? (Why or why not?)
    c. Probe: Do you feel that you/your dependent's needs in terms of SCD management are being met? (Why or why not?)
2. What treatment(s) do you/your dependent receive?
    a. Probe: Hydroxyurea? Penicillin? Blood transfusion? Pain management?
    b. Probe: How often?
    c. Probe: Are you given information about what these treatments do?
3. Do you incur any costs for SCD care?
    a. Probe: Indirect costs (e.g. transportation, meals, accommodation)?
4. What is most important to you in terms of SCD care?
    a. Probe: Being treated with respect? Open communication? The ability to ask questions?
    b. Probe: Receiving medication?
5. Are there any barriers that you/your dependent face in terms of accessing SCD care? (Please explain)
6. Does anything make it easier for you/your dependent to access SCD care?
    a. Probe: Outreach services?
    b. Probe: Community-base or other non-governmental organisations?
7. What aspects of how SCD care is provided do you think are positive?
8. How would you improve SCD care?
9. Do you have any further comments?

Please thank the participants for their time.

Situational Analysis: FGD with SCD Clinicians

Introduce yourself, explain the purpose of the FGD, take informed consent. Remind participants about confidentiality.

1. Please describe how someone is diagnosed with SCD in your health facility/ies.
2. Do you feel that most patients have a timely diagnosis? (Why or why not?)
    a. What do you feel constrains early diagnosis of SCD care?
    b. What do you feel facilitates early diagnosis of SCD care?
3. Please describe how SCD is treated at your health facility/ies.
    a. Probe: Hydroxyurea? Penicillin prophylaxis? Blood transfusion? Pain management?
4. What do you feel are positive aspects of the SCD care provided?
5. What do you feel could be strengthened in the SCD care provided?
6. What do you think “patient-centred” SCD care would include?
    a. Probe: Communication with patient? Dialogue? Involvement of the patient in decision-making? Empathy?
7. What do you feel constrains uptake of SCD care?
8. What do you feel facilitates uptake of SCD?
    a. Probe: Outreach services?
    b. Probe: Partnerships with local organisations?

Please thank the participants for their time.

Situational Analysis: FGD with Community Members

Introduce yourself, explain the purpose of the FGD, take informed consent. Remind participants about confidentiality.

1. Please describe what you understand “sickle cell disease” to mean.
    a. Do you think most people in this community understand what SCD is?
    b. Do you know the difference between carrying a SCD trait versus having SCD?
2. Do you know anyone with (or who had) SCD?
3. Do you know how people get SCD?
4. Do you know what happens when someone has SCD?
5. Do you think that someone with SCD can live a normal life?
6. Do you know where people with SCD/their carers can access treatment?
7. Do you think it is challenging for people in this community to access healthcare? (Why or why not?)
    a. Probe: Expenses?
    b. Probe: Transportation?
8. When do you think people with SCD should be diagnosed?
9. Do you think that people with SCD face stigma in this community? (Why or why not?)
10. Any further comments?

Please thank the participants for their time.

Situational Analysis: KII with Decision-makers

Introduce yourself, explain the purpose of the interview, take informed consent. Remind participant about privacy.

1. Please describe your role.
2. What do you think is the burden of SCD in this [country/district/state]?
    a. Probe: Are there good estimates of incidence/prevalence? From where?
    b. Probe: Are there "pockets" where you see more SCD than others? Why?
3. Do you feel that SCD is a priority in this [country/district/state]? (Why or why not?)
4. What policies are in place that dictate clinical care for SCD?
    a. Probe: Are these adequate?
    b. Probe: Do you know when these were last updated?
5. Are there any policies in place to support community (demand-side) factors influencing SCD care? (Please describe)
    a. Probe: Anything to support community sensitisation for SCD?
    b. Probe: Anything to support early diagnosis of SCD?
    c. Probe: Anything to support uptake of SCD care?
6. Are you aware of specific resources that are earmarked to support SCD care? (Please explain)
7. What are some of the biggest barriers in this [country/district/state] to providing effective SCD care?
    a. How do you feel these might be resolved?
8. Are there any forthcoming changes to SCD policy/guidelines/resource allocation that you are aware of? (Please describe if so)
9. Any further comments?

Please thank the participant for their time.

Situational Analysis: KII with SCD Community-based Organisation/Non-governmental Organisation Representatives

Introduce yourself, explain the purpose of the interview, take informed consent. Remind participant about privacy.

1. Please describe your role.
2. Please describe the activities of your organisation with respect to SCD.
    a. Probe: Community sensitisation?
    b. Probe: Support accessing care?
    c. Probe: Support in provision of care?
3. What do you think is the burden of SCD in this community?
    a. Probe: Are there good estimates of incidence/prevalence? From where?
    b. Probe: Are there "pockets" where you see more SCD than others? Why?
4. Do you think there is a problem of SCD stigma in this community? (Please explain)
5. What are some common community misconceptions about SCD, if any?
    a. Probe: Does your organisation do anything to redress these misconceptions?
6. What do you think patients with SCD/their carers want from SCD care?
    a. Probe: Do you think that current care available meets those expectations? (Why or why not?)
7. What do you feel "patient-centred SCD care" would look like?
    a. Probe: Greater empathy? More communication and information provided? Patient involvement in decision-making?
8. What do you think constrains early diagnosis of SCD in this community?
9. What do you think might facilitate early diagnosis of SCD in this community?
    a. Probe: Is your organisation doing anything to support this?
10. What do you tin constrains access to SCD care in this community?
11. What do you think might facilitate access to SCD care in this community?
    a. Probe: Is your organisation doing anything to support this?
12. Any further comments?

Please thank the participant for their time.

Realist Evaluation: Observation Template

Date	
Location	
Activity	
Attendees	
Discussion points (e.g. challenges/problems arising; solutions and implementation; decisions made; information discussed)	
Observations about team/group dynamics	
Other observations	

Realist Evaluation: Reflective Diary Template

Date	
Activity/ies	
Reflections (e.g. Positive points, challenges, questions arising, reflections on context, etc.)	
Points to discuss with supervisor	

Realist Evaluation: FGD with PAC Team Members

Introduce yourself, explain the purpose of the FGD, take informed consent. Remind participants about confidentiality.

1. Please describe the role of this team.
2. Please describe your team's activities over the past [months/year]
    a. Probe: problems established?
    b. Probe: Actions generated?
    c. Probe: Anything implemented?
    d. Probe: Success of what was implemented? (Please explain how you knew it was successful or not)
3. What do you feel is working well within this team?
4. What are some of the challenges that this team is facing?
5. Do you think that this team is making an impact? (Please explain)
6. Do you feel confident that you can introduce positive change in this community? (Please explain)
7. Please describe what has happened during learning collaboratives.
8. Is it useful to come together with other community teams in learning collaboratives? (Please explain)
9. Have you found it useful to work with the clinical teams during learning collaboratives? (Please explain)
    a. What are some challenges to working with the clinical teams?
    b. What are some advantages to working with the clinical teams?
10. Are there any further skills or knowledge that you feel you need, as a team, to work more effectively?
11. Any further comments?

Please thank the participants for their time.

Realist Evaluation: FGD with SBA Team Members

Introduce yourself, explain the purpose of the FGD, take informed consent. Remind participants about confidentiality.

1. Please describe the role of this team.
2. Please describe your team's activities over the past [months/year]
    a. Probe: problems established?
    b. Probe: Actions generated?
    c. Probe: Anything implemented?
    d. Probe: Success of what was implemented? (Please explain how you knew it was successful or not)
3. What do you feel is working well within this team?
4. What are some of the challenges that this team is facing?
5. Do you think that this team is making an impact? (Please explain)
6. Do you feel confident that you can introduce positive change in this health facility? (Please explain)
7. Please describe what has happened during learning collaboratives.
8. Is it useful to come together with other clinical teams in learning collaboratives? (Please explain)
9. Have you found it useful to work with the community teams during learning collaboratives? (Please explain)
    a. What are some challenges to working with the community teams?
    b. What are some advantages to working with the community teams?
10. Are there any further skills or knowledge that you feel you need, as a team, to work more effectively?
11. Any further comments?

Please thank the participants for their time.

Realist Evaluation: In-depth Interview with SCD Stakeholders

Introduce yourself, explain the purpose of the interview, take informed consent. Remind participant about privacy.

1. Please describe your role.
2. Have you heard of the PACTS intervention? [*May need to briefly describe and re-ask if they are not familiar with the acronym*]
    a. If yes: Can you briefly describe what the intervention involves?
    b. If yes: Do you think the intervention has resulted in any changes in this [community/health facility]? (Please explain)
3. In the past [months/year], have you noticed any changes in [community perception/diagnosis/uptake] of SCD? Please explain.
    a. Probe: Why do you think those changes are occurring?
4. In the past [months/year], have you noticed any changes in SCD care? Please explain.
    a. Probe: Why do you think those changes are occurring?
5. Are there any other interventions or organisations active in SCD in this [community/health facility]?
    a. Probe: Can you describe what they do?
6. What do you feel is needed in this [community/health facility to support better [uptake/provision] of SCD care? (Please explain)
7. Any further comments?

Please thank the participant for their time.

Realist Evaluation: In-depth Interview with PAC and SBA Leads

Introduce yourself, explain the purpose of the interview, take informed consent. Remind participant about privacy.

1. Please describe your role.
2. Please describe, generally, what the teams you have been supporting have been working on over the past [months/year].
    a. Probe: problems established?
    b. Probe: Actions generated?
    c. Probe: Anything implemented?
    d. Probe: Success of what was implemented? (Please explain how you knew it was successful or not)
3. What do you feel is working well within this intervention?
    a. What do you feel you are carrying out well in supporting teams?
4. What are some of the challenges that the teams face?
5. What are some challenges that you have faced in supporting the teams in this intervention?
6. Do you think that these teams are making an impact? (Please explain)
7. Do you feel confident that the teams can introduce positive change in their [communities/health facilities]? (Please explain)
8. Please describe what has happened during learning collaboratives.
9. Do you think that learning collaboratives are useful? (Why or why not?)
    a. How could these be strengthened?
10. Are there any further skills or knowledge that you feel the teams you support need to work more effectively?
11. Any further comments?

Please thank the participant for their time.

Appendix 2. Participant Information Sheets

PARTICIPANT INFORMATION SHEET: Patients Living with Sickle Cell Disease/ Carers of Children Living with Sickle Cell Disease Accessing Care (Survey)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called “PACTS”.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the “PACTS” intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are a person living with sickle cell disease, or a carer to a child with sickle cell disease, receiving care at [teaching hospital name]. You therefore have very important insights about your experiences of living with sickle cell disease or caring for someone with sickle cell disease.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. In no way will your medical care/your dependent’s care be affected if you decline to participate. If you do decide to take part and later change your mind, that is absolutely okay. You can withdraw your

participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

At the end of your/your dependent's appointment today, we will ask you to sit with a research assistant and complete a survey. Before answering any questions, we will go through this information sheet and you will be given the opportunity to ask any questions you might have. They will ask you some questions and record your responses on a tablet. This will take a maximum of 30 minutes of your time. The questions will be about your experience living with sickle cell disease/caring for someone with sickle cell disease and accessing health care.

5. Expenses and payments

There are no payments for participating and you will not incur any expenses.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, as we are only asking you to reflect on your experiences and what you feel some community perceptions might be. However, if you have had some unpleasant experiences, this might be difficult for you to talk about. We are not asking about these experiences directly but if at any point the questions are upsetting to you, we can pause the survey or stop it altogether. You can decline to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

There will be no direct benefit to you but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care.

8. Will my taking part in the study be kept confidential?

All survey data will be kept confidential. On the survey response itself, there is no identifying information—you will be given a unique number instead. As such, there will be no way to link your survey responses back to you. Signed consent forms will have your name but will be unlinked to your survey responses. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. A brief with key findings from this survey will be shared with the hospital for participants to view. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

12. Safeguarding

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM/[University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] code of conduct. This means that they must not ask you for any financial, physical or sexual favours in return for taking part in this research. If you experience any abuse, harassment or neglect by a study team member you can contact the study Safeguarding Lead [local safeguarding focal person name and contact details to be added] or Tara Tancred at tara.tancred@lstmed.ac.uk. You may also raise a safeguarding concern directly with LSTM Designated Safeguarding Officer Philippa Tubb on +44 (0)151 705 3744/safeguarding@lstmed.ac.uk. LSTM's safeguarding commitment is described on LSTM Safeguarding webpage.

13. What will happen to my data?

All survey data will be anonymous. This anonymous data may be shared with specific members of the study consortium outside of the country where the data were collected to support analysis. Study documents will be kept for 10 years, after which time they will be destroyed.

Other key points about how your data are handled:

- Your data will be handled in accordance with UK Data Protection Act 2018.

- You can find out more about how we use your information at https://www.lstmed.ac.uk/privacy-statement.
- The LSTM Data Protection Officer can be contacted if you have any concerns about the collection or storage of your personal data: dataprotection@lstmed.ac.uk
- If you have any complaints about the handling of your personal data, you can contact the UK Information Commissioners Office: https://ico.org.uk/make-a-complaint/
- If you do not have internet access, please ask someone you trust to assist you in making a complaint.

Thank you for considering taking the time to read this sheet

You will be given a copy of the information sheet to keep

CONTACT INFORMATION

Please get in touch with the research ethics committee contacts below if you have questions about your rights as a study participant or if you have other concerns:

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Liverpool School of Tropical Medicine Research Ethics Committee:

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If you have any questions, comments, or concerns about this study, now or at any point, you may contact the study principal investigators:

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PARTICIPANT INFORMATION SHEET: Adolescent (15–17-year-old) Patients Living with Sickle Cell Disease and Accessing Care (Survey)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss your participation with a parent or caregiver if they are with you today.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are a person living with sickle cell disease receiving care at [teaching hospital name]. You therefore have very important insights about your experiences of living with sickle cell disease or caring for someone with sickle cell disease. As an adolescent, you represent a very important group of sickle cell patients, as you transition out of paediatric care into adult care—this is a time when a lot of patients stopped engaging with healthcare services.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. In no way will your medical care be affected if you decline to participate. If you do decide to take part and later change your mind, that is absolutely okay. You can withdraw your participation at any time

with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

At the end of your appointment today, we will ask you to sit with a research assistant and complete a survey. Before answering any questions, we will go through this information sheet and you will be given the opportunity to ask any questions you might have. They will ask you some questions and record your responses on a tablet. This will take a maximum of 30 minutes of your time. The questions will be about your experience living with sickle cell disease and accessing health care.

5. Expenses and payments

There are no payments for participating and you will not incur any expenses.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, as we are only asking you to reflect on your experiences and what you feel some community perceptions might be. However, if you have had some unpleasant experiences, this might be difficult for you to talk about. We are not asking about these experiences directly but if at any point the questions are upsetting to you, we can pause the survey or stop it altogether. You can decline to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

There will be no direct benefit to you but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care. This is especially important for adolescents living with sickle cell disease.

8. Will my taking part in the study be kept confidential?

All survey data will be kept confidential. On the survey response itself, there is no identifying information—you will be given a unique number instead. As such, there will be no way to link your survey responses back to you. Signed consent forms will have your name but will be unlinked to your survey responses. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. A brief with key findings from this survey will be shared with the hospital for participants to view. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

12. Safeguarding

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM/[University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] code of conduct. This means that they must not ask you for any financial, physical or sexual favours in return for taking part in this research. If you experience any abuse, harassment or neglect by a study team member you can contact the study Safeguarding Lead [local safeguarding focal person name and contact details to be added] or Tara Tancred at tara.tancred@lstmed.ac.uk. You may also raise a safeguarding concern directly with LSTM Designated Safeguarding Officer Philippa Tubb on +44 (0)151 705 3744/safeguarding@lstmed.ac.uk. LSTM's safeguarding commitment is described on LSTM Safeguarding webpage.

13. What will happen to my data?

All survey data will be anonymous. This anonymous data may be shared with specific members of the study consortium outside of the country where the data were collected to support analysis. Study documents will be kept for 10 years, after which time they will be destroyed.

Other key points about how your data are handled:

- Your data will be handled in accordance with UK Data Protection Act 2018.

- You can find out more about how we use your information at https://www.lstmed.ac.uk/privacy-statement.
- The LSTM Data Protection Officer can be contacted if you have any concerns about the collection or storage of your personal data: dataprotection@lstmed.ac.uk
- If you have any complaints about the handling of your personal data, you can contact the UK Information Commissioners Office: https://ico.org.uk/make-a-complaint/
- If you do not have internet access, please ask someone you trust to assist you in making a complaint.

Thank you for considering taking the time to read this sheet

You will be given a copy of the information sheet to keep

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Zambia:

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Liverpool School of Tropical Medicine Research Ethics Committee:

Telephone: +44(0)151 702 9551

Email: lstmrec@lstmed.ac.uk

If you have any questions, comments, or concerns about this study, now or at any point, you may contact the study principal investigators:

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PARTICIPANT INFORMATION SHEET: Patients Living with Sickle Cell Disease/ Carers of Children Living with Sickle Cell Disease Not Accessing Care (Survey)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS".

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are a person living with sickle cell disease, or a carer to a child with sickle cell disease. You therefore have very important insights about your experiences of living with sickle cell disease or caring for someone with sickle cell disease.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. In no way will your medical care/your dependent's care be affected if you decline to participate. If you do decide to take part and later change your mind, that is absolutely okay. You can withdraw your participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

At a time that is convenient with you, we will ask you to sit with a research assistant and complete a survey. Before answering any questions, we will go through this information sheet and you will be given the opportunity to ask any questions you might have. They will ask you some questions and record your responses on a tablet. This will take a maximum of 30 minutes of your time. The questions will be about your experience living with sickle cell disease/caring for someone with sickle cell disease and accessing health care.

5. Expenses and payments

There are no payments for participating and you will not incur any expenses.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study as we are only asking you to reflect on your experiences and what you feel some community perceptions might be. However, if you have had some unpleasant experiences, this might be difficult for you to talk about. We are not asking about these experiences directly but if at any point the questions are upsetting to you we can pause the survey or stop it altogether. You can decline to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

There will be no direct benefit to you but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care.

8. Will my taking part in the study be kept confidential?

All survey data will be kept confidential. On the survey response itself, there is no identifying information—you will be given a unique number instead. As such, there will be no way to link your survey responses back to you. Signed consent forms will have your name but will be unlinked to your survey responses. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study our key findings will be shared as part of a series of study dissemination meetings. A brief with key findings from this survey will be shared with the

hospital for participants to view. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

12. Safeguarding

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13. What will happen to my data?

All survey data will be anonymous. This anonymous data may be shared with specific members of the study consortium outside of the country where the data were collected to support analysis. Study documents will be kept for 10 years, after which time they will be destroyed.

Other key points about how your data are handled:

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Professor Imelda Bates

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PARTICIPANT INFORMATION SHEET: Adolescent Patients (aged 15–17-years-old) Living with Sickle Cell Disease Not Accessing Care (Survey)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss your participation with a parent or caregiver if they are with you today.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are a person living with sickle cell disease receiving care at [teaching hospital name]. You therefore have very important insights about your experiences of living with sickle cell disease or caring for someone with sickle cell disease. As an adolescent, you represent a very important group of sickle cell patients that we would like to ensure receive appropriate care.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. If you do decide to take part and later change your mind, that is absolutely okay. You can withdraw your participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

We will ask you to sit with a research assistant and complete a survey. Before answering any questions, we will go through this information sheet and you will be given the opportunity to ask any questions you might have. They will ask you some questions and record your responses on a tablet. This will take a maximum of 30 minutes of your time. The questions will be about your experience living with sickle cell disease and accessing—or not accessing—health care.

5. Expenses and payments

There are no payments for participating and you will not incur any expenses.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, as we are only asking you to reflect on your experiences and what you feel some community perceptions might be. However, if you have had some unpleasant experiences, this might be difficult for you to talk about. We are not asking about these experiences directly but if at any point the questions are upsetting to you, we can pause the survey or stop it altogether. You can decline to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

There will be no direct benefit to you but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care. This is especially important for adolescents living with sickle cell disease.

8. Will my taking part in the study be kept confidential?

All survey data will be kept confidential. On the survey response itself, there is no identifying information—you will be given a unique number instead. As such, there will be no way to link your survey responses back to you. Signed consent forms will have your name but will be unlinked to your survey responses. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. A brief with key findings from this survey will be shared with the hospital for participants to view. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

12. Safeguarding

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13. What will happen to my data?

All survey data will be anonymous. This anonymous data may be shared with specific members of the study consortium outside of the country where the data were collected to support analysis. Study documents will be kept for 10 years, after which time they will be destroyed.

Other key points about how your data are handled:

- Your data will be handled in accordance with UK Data Protection Act 2018.
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Professor Imelda Bates

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PARTICIPANT INFORMATION SHEET: Patients Living with Sickle Cell Disease/ Carers of Children Living with Sickle Cell Disease (Focus Group Discussion)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss this study with others to help you make a decision about whether to participate or not. You will have one week to decide whether you would like to participate or not.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are a person living with sickle cell disease, or a carer to a child with sickle cell disease. You therefore have very important insights about your experiences of living with sickle cell disease or caring for someone with sickle cell disease.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. In no way will your medical care/your dependent's care be affected if you decline to participate. If you do decide to take part and later change your mind, that is absolutely okay. You can withdraw your participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

You will be asked to take part in a group discussion with other people living with sickle cell disease/ carers of children living with sickle cell disease. Before any discussion begins, we will ensure you have gone through an informed consent process. After this, as a group, you will be asked questions about experiences and expectations of sickle cell disease care, including reflecting on some reasons why care might be difficult to access and what might make it easier. This will take a maximum of 90 minutes of your time.

5. Expenses and payments

There are no payments for participating, but you will be given a transportation allowance to cover any expenses arising from coming to the discussion today. There will also be refreshments (water and other drinks, biscuits, fruits) provided.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, as we are only asking you to reflect on your experiences and what you feel some broader perceptions might be. However, if you have had some unpleasant experiences, this might be difficult for you to talk about. We are not asking about these experiences directly but if at any point the questions are upsetting to you, we can pause the discussion and you can step out, or you can withdraw your participation altogether if you do not wish to continue. You do not have to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

There will be no direct benefit to you but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care.

8. Will my taking part in the study be kept confidential?

The study team will keep all responses entirely confidential. You will never be referred to by your name, but only by a unique study number. However, for group-based activities, it is not possible to guarantee confidentiality, though we will remind all participants to keep any discussions or admissions in the strictest confidence. Please refrain from mentioning anything that you do not wish the group to know—you can tell the facilitator separately at the end of the discussion if there is something important that you wish to raise privately. Signed consent forms will have your name, but will be unlinked to any of your responses in the

discussion. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

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PARTICIPANT INFORMATION SHEET: Adolescent Patients (aged 15-to-17-years-old) Living with Sickle Cell Disease (Focus Group Discussion)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss this study with others, especially your parents or caregivers, to help you make a decision about whether to participate or not. You will have one week to decide whether you would like to participate or not.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are an adolescent living with sickle cell disease. You therefore have very important insights about your experiences of living with sickle cell disease or caring for someone with sickle cell disease. As an adolescent, you represent a very important group of sickle cell patients that we would like to ensure receive appropriate care, especially as you transition from paediatric care into adult care.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. In no way will your medical care/your dependent's care be affected if you decline to participate. If you do decide

to take part and later change your mind, that is absolutely okay. You can withdraw your participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

You will be asked to take part in a group discussion with other people living with sickle cell disease/carers of children living with sickle cell disease. Before any discussion begins, we will ensure you have gone through an informed consent process. After this, as a group, you will be asked questions about experiences and expectations of sickle cell disease care, including reflecting on some reasons why care might be difficult to access and what might make it easier. This will take a maximum of 90 minutes of your time.

5. Expenses and payments

There are no payments for participating, but you will be given a transportation allowance to cover any expenses arising from coming to the discussion today. There will also be refreshments (water and other drinks, biscuits, fruits) provided.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, as we are only asking you to reflect on your experiences and what you feel some broader perceptions might be. However, if you have had some unpleasant experiences, this might be difficult for you to talk about. We are not asking about these experiences directly but if at any point the questions are upsetting to you, we can pause the discussion and you can step out, or you can withdraw your participation altogether if you do not wish to continue. You do not have to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

There will be no direct benefit to you but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care.

8. Will my taking part in the study be kept confidential?

The study team will keep all responses entirely confidential. You will never be referred to by your name, but only by a unique study number. However, for group-based activities, it is not possible to guarantee confidentiality, though we will remind all participants to keep any discussions or admissions in the strictest confidence. Please refrain from mentioning anything that you do not wish the group to know—you can tell the facilitator separately at the

end of the discussion if there is something important that you wish to raise privately. Signed consent forms will have your name, but will be unlinked to any of your responses in the discussion. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

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PARTICIPANT INFORMATION SHEET: Community Members (Focus Group Discussion)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss this study with others to help you make a decision about whether to participate or not. You will have one week to decide whether you would like to participate or not.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are living in a community in which there are also some people living with sickle cell disease. We are trying to understand more about community perceptions of sickle cell disease—your insights are very important.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. There are no consequences for declining to participate. If you do decide to take part and later change your mind, that is absolutely okay. You can withdraw your participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

Today, you will be asked to take part in a group discussion with other community members. Before any discussion begins, we will ensure you have gone through an informed consent process. After this, as a group, you will be asked questions about community understanding and perceptions of sickle cell disease, including reflecting on some reasons why care might be difficult to access and what might make it easier. This will take a maximum of 90 minutes of your time.

5. Expenses and payments

There are no payments for participating, but you will be given a transportation allowance to cover any expenses arising from coming to the discussion today. There will also be refreshments (water and other drinks, biscuits, fruits) provided.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, as we are only asking you to reflect on your experiences and what you feel some broader perceptions might be. Though it is very unlikely, if, at any point, the questions are upsetting to you we can pause the discussion and you can step out or you can withdraw your participation altogether if you do not wish to continue. You do not have to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

There will be no direct benefit to you but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care.

8. Will my taking part in the study be kept confidential?

The study team will keep all responses entirely confidential. You will never be referred to by your name, but only by a unique study number. However, for group-based activities, it is not possible to guarantee confidentiality, though we will remind all participants to keep any discussions or admissions in the strictest confidence. Please refrain from mentioning anything that you do not wish the group to know—you can tell the facilitator separately at the end of the discussion if there is something important that you wish to raise privately. Signed consent forms will have your name but will be unlinked to any of your responses in the discussion. Consent forms will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

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Throughout the study our key findings will be shared as part of a series of study dissemination meetings. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

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12. Safeguarding

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Zambia:

Dr Catherine Chunda

Email: catherinechunda@yahoo.co.uk]

Professor Imelda Bates

Telephone: +44 0151 705 3115

Email: Imelda.bates@lstmed.ac.uk

PARTICIPANT INFORMATION SHEET: Clinicians proving SCD Care (Focus Group Discussion)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called “PACTS”. You may wish to discuss this study with others to help you make a decision about whether to participate or not. You will have one week to decide whether you would like to participate or not.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the “PACTS” intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are a clinician who has provided care to persons living with sickle cell disease. You have important insights around how sickle cell disease is managed and what some constraints in providing appropriate care might be.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. There are no consequences for declining to participate and in no way will your relationship with your employing facility be affected. If you do decide to take part and later change your mind, that

is absolutely okay. You can withdraw your participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

Today, you will be asked to take part in a group discussion with other clinicians. Before any discussion begins, we will ensure you have gone through an informed consent process. After this, as a group, you will be asked questions about sickle cell disease care and how you feel this could be improved. This will take a maximum of 90 minutes of your time.

5. Expenses and payments

There are no payments for participating, but you will be given a transportation allowance to cover any expenses arising from coming to the discussion today. There will also be refreshments (water and other drinks, biscuits, fruits) provided.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, as we are only asking you to reflect on your experiences and what you feel some broader perceptions might be. Though it is very unlikely, if, at any point, the questions are upsetting to you we can pause the discussion and you can step out or you can withdraw your participation altogether if you do not wish to continue. You do not have to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

There will be no direct benefit to you but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care.

8. Will my taking part in the study be kept confidential?

The study team will keep all responses entirely confidential. You will never be referred to by your name, but only by a unique study number. However, for group-based activities, it is not possible to guarantee confidentiality, though we will remind all participants to keep any discussions or admissions in the strictest confidence. Please refrain from mentioning anything that you do not wish the group to know—you can tell the facilitator separately at the end of the discussion if there is something important that you wish to raise privately. Signed consent forms will have your name but will be unlinked to any of your responses in the discussion. Consent forms will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

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10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

12. Safeguarding

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PARTICIPANT INFORMATION SHEET: Key Informant Interviews (Decision-makers, NGO representatives)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss this study with others to help you make a decision about whether to participate or not. You will have one week to decide whether you would like to participate or not.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You have unique insights around sickle cell disease resource allocation and decision-making and how people living with sickle cell disease are supported in this [community/district/state/country].

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. There are no consequences at all for declining to participate. If you do decide to take part and later change your mind, that is absolutely okay. You can withdraw your participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

We will go through an informed consent process, after which we will begin an interview in which we will ask you several questions about how sickle cell disease is supported in this [community/district/state/country]. We will re-contact you for 3 follow-up interviews (one approximately three months from now, one in 15 months from now, and a final one 27 months from now). These interviews will be to assess any changes in sickle cell disease care and changes in sickle cell disease support over time. If you participate in one interview but do not wish to participate in others, that is completely fine. Each of these interviews will take a maximum of 60 minutes. These will take place in a private location of your choosing, including your office, if you wish. However, if it is difficult to carry out this interview face-to-face, we will arrange a meeting online using Teams or Zoom. You will be provided with a link to that interview at least 24 hours before it is scheduled.

5. Expenses and payments

There are no payments for participating and you will not incur any expenses.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, as we are only asking you to reflect on your experiences and perceptions. Though it is very unlikely, if, at any point, the questions are upsetting to you we can pause the interview or stop it altogether. You do not have to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

There will be no direct benefit to you but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care.

8. Will my taking part in the study be kept confidential?

All interview data will be kept confidential. However, as you are a “key informant”, this means that you occupy a unique position. We will make the greatest effort to ensure that no identifying information remains in any study materials, but this may not always be 100% possible. We will share with you any materials we intend to report to ensure you are comfortable with the information being shared.

If recordings of any interviews are made, these, and any transcripts made from these, will be stored securely in an online cloud storage, managed through the Liverpool School of

Tropical Medicine, and only the study team will be able to access them. We will always anonymize transcripts, removing all identifying information and using a unique participant ID number. Whatever we write about this project will never refer to you by name or with any information that you could be identified with.

We will keep all anonymised data (transcripts, meeting notes) for 10 years after the conclusion of the study, after which they will be destroyed. Signed consent forms will have your name, but will be unlinked to your interview responses. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

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10. What will happen to the results of the research study?

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PARTICIPANT INFORMATION SHEET: Participatory Action Cycle Group Members

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss this study with others to help you make a decision about whether to participate or not. You will have one week to decide whether you would like to participate or not.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are a person living with sickle cell disease, a carer to a child with sickle cell disease, or an influential member of a community in which people with sickle cell disease are living. You therefore have very important insights about experiences of living with sickle cell disease, caring for someone with sickle cell disease, or community perceptions around sickle cell disease.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. There is no consequence to declining to participate. If you do decide to take part and later change your mind, that is absolutely okay. You can withdraw your participation at any time with no

negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

We are forming six teams across six communities. On these teams will be: people living with sickle cell disease (aged 15 and older); carers of people living with sickle cell disease; and other influential community members (e.g. community leaders, traditional healers). You will be brought together monthly to carry out something called “participatory action research”. With the help of a facilitator, you will be guided through a process in which you will identify problems or barriers in your community linked to knowledge and understanding of sickle cell disease and uptake of care. As a group, you will also design and implement “solutions” to tackle some of these problems, with the broader goal of community sensitisation and improved access to care. Every six months, there will also be day-long “learning collaborative” meetings, in which all six community teams will be brought together to share their experiences. At one of these meetings each year, clinical teams and some decision-makers and local non-governmental organisation representatives will also be invited so that there can be shared creation of guidelines to support “patient-centred” sickle cell disease care.

You will be given training to support your ability to carry out these activities, and supported through close mentorship from your facilitator. This will take approximately 3–5 hours of your time each month, with two additional days for the collaborative meetings every six months. Altogether, about 10 days each year will be required. These activities will carry on for two years. Once you have agreed to take part, you can change your mind at any point within the two years.

The facilitator will take notes during activities and some discussions may be—with the group’s permission—(audio) recorded. The larger learning collaborative meetings will be observed by other members of the study team, and parts of those meetings may also be (audio) recorded.

5. Expenses and payments

There is a small payment of [insert in local currency] for participating, and all expenses will be covered including provision of a transportation allowance. For the learning collaborative meetings, meals and, if necessary, accommodation will be provided.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, but we do appreciate that it may take a considerable amount of your personal time. The facilitator will work with the group to ensure that all activities are planned to accommodate everyone's schedules and commitments to the greatest extent possible.

Additionally, throughout you will likely reflect on your experiences and what you feel some community perceptions might be. If you have had some unpleasant experiences, this might be difficult for you to talk about. We are not asking about these experiences directly, but if, at any point, the discussions are upsetting to you we can pause the activity or you can withdraw your participation for the day, or completely, if you wish. You do not have to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

This study will help us to understand many things, including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care. We are hoping that your activities may directly lead to improvements in policy and guidance for sickle cell disease.

A direct benefit to you will be capacity strengthening in the use of participatory action cycles, which is a highly transferrable skill set.

8. Will my taking part in the study be kept confidential?

All data generated through the activities of your team will be kept confidential. Any notes, observations, or transcripts from meeting discussions will be anonymised and not linked to any participants by name. However, for group-based activities it is not possible to guarantee confidentiality, though we will remind all participants to keep any discussions or admissions in the strictest confidence. Please refrain from mentioning anything that you do not wish the group to know—you can tell the facilitator separately at the end of the discussion if there is something important that you wish to raise privately. Signed consent forms will have your name but will be unlinked to study data. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

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10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. Your own team meetings and learning collaborative meetings will also be a time when emerging study findings will be shared. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

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13. What will happen to my data?

Any data from audio files will be deleted once the files have been transcribed. Any observation notes will be recorded electronically and anonymized. Any data collected from your activities within the participatory action cycles will be collated electronically and anonymised. Anonymised data may be shared with specific members of the study consortium outside of the country where the data were collected to support analysis. Study documents will be kept for 10 years, after which time they will be destroyed.

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PARTICIPANT INFORMATION SHEET: Adolescent (aged 15–17-years-old)
Participatory Action Cycle Group Members

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss this study with others—especially your parents or caregivers—to help you make a decision about whether to participate or not. You will have one week to decide whether you would like to participate or not.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are an adolescent living with sickle cell disease. You therefore have very important insights about experiences of living with sickle cell disease. Your insights are particularly valuable, as we know that many adolescent patients are lost to care when they transition from paediatric care to adult care, and we would like to understand and, if possible, help to address this loss.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. There is no consequence to declining to participate. If you do decide to take part and later change your

mind, that is absolutely okay. You can withdraw your participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

We are forming six teams across six communities. On these teams will be: people living with sickle cell disease (aged 15 and older); carers of people living with sickle cell disease; and other influential community members (e.g. community leaders, traditional healers). You will be brought together monthly to carry out something called “participatory action research”. With the help of a facilitator, you will be guided through a process in which you will identify problems or barriers in your community linked to knowledge and understanding of sickle cell disease and uptake of care. As a group, you will also design and implement “solutions” to tackle some of these problems, with the broader goal of community sensitisation and improved access to care. Every six months, there will also be day-long “learning collaborative” meetings, in which all six community teams will be brought together to share their experiences. At one of these meetings each year, clinical teams and some decision-makers and local non-governmental organisation representatives will also be invited so that there can be shared creation of guidelines to support “patient-centred” sickle cell disease care.

You will be given training to support your ability to carry out these activities, and supported through close mentorship from your facilitator. This will take approximately 3–5 hours of your time each month, with two additional days for the collaborative meetings every six months. Altogether, about 10 days each year will be required. These activities will carry on for two years. Once you have agreed to take part, you can change your mind at any point within the two years.

The facilitator will take notes during activities and some discussions may be—with the group’s permission—(audio) recorded. The larger learning collaborative meetings will be observed by other members of the study team, and parts of those meetings may also be (audio) recorded.

5. Expenses and payments

There is a small payment of [insert in local currency] for participating, and all expenses will be covered including provision of a transportation allowance. For the learning collaborative meetings, meals and, if necessary, accommodation will be provided.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, but we do appreciate that it may take a considerable amount of your personal time. The facilitator will work with the group to ensure that all activities are planned to accommodate everyone's schedules and commitments to the greatest extent possible.

Additionally, throughout you will likely reflect on your experiences and what you feel some community perceptions might be. If you have had some unpleasant experiences, this might be difficult for you to talk about. We are not asking about these experiences directly, but if, at any point, the discussions are upsetting to you we can pause the activity or you can withdraw your participation for the day, or completely, if you wish. You do not have to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

This study will help us to understand many things, including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care. We are hoping that your activities may directly lead to improvements in policy and guidance for sickle cell disease.

A direct benefit to you will be capacity strengthening in the use of participatory action cycles, which is a highly transferrable skill set.

8. Will my taking part in the study be kept confidential?

All data generated through the activities of your team will be kept confidential. Any notes, observations, or transcripts from meeting discussions will be anonymised and not linked to any participants by name. However, for group-based activities it is not possible to guarantee confidentiality, though we will remind all participants to keep any discussions or admissions in the strictest confidence. Please refrain from mentioning anything that you do not wish the group to know—you can tell the facilitator separately at the end of the discussion if there is something important that you wish to raise privately. Signed consent forms will have your name but will be unlinked to study data. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. Your own team meetings and learning collaborative meetings will also be a time when emerging study findings will be shared. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

12. Safeguarding

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM/[University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] code of conduct. This means that they must not ask you for any financial, physical or sexual favours in return for taking part in this research. If you experience any abuse, harassment or neglect by a study team member you can contact the study Safeguarding Lead [local safeguarding focal person name and contact details to be added] or Tara Tancred at tara.tancred@lstmed.ac.uk. You may also raise a safeguarding concern directly with LSTM Designated Safeguarding Officer Philippa Tubb on +44 (0)151 705 3744/safeguarding@lstmed.ac.uk. LSTM's safeguarding commitment is described on LSTM Safeguarding webpage.

13. What will happen to my data?

Any data from audio files will be deleted once the files have been transcribed. Any observation notes will be recorded electronically and anonymized. Any data collected from your activities within the participatory action cycles will be collated electronically and anonymised. Anonymised data may be shared with specific members of the study consortium outside of the country where the data were collected to support analysis. Study documents will be kept for 10 years, after which time they will be destroyed.

Other key points about how your data are handled:

- Your data will be handled in accordance with UK Data Protection Act 2018.

- You can find out more about how we use your information at https://www.lstmed.ac.uk/privacy-statement.
- The LSTM Data Protection Officer can be contacted if you have any concerns about the collection or storage of your personal data: dataprotection@lstmed.ac.uk
- If you have any complaints about the handling of your personal data, you can contact the UK Information Commissioners Office: https://ico.org.uk/make-a-complaint/
- If you do not have internet access, please ask someone you trust to assist you in making a complaint.

Thank you for considering taking the time to read this sheet

You will be given a copy of the information sheet to keep

CONTACT INFORMATION

Please get in touch with the research ethics committee contacts below if you have questions about your rights as a study participant or if you have other concerns:

[Ghana:

Chair, Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics

Telephone: +233 3220 63248

Email: admin@smsknust-kath.org; chrpe@knust.edu.gh

Nigeria:

Chair, University of Abuja Teaching Hospital Health Research Ethics Committee

Telephone:+234 0988 21228

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Zambia:

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Telephone: +260 955 155633/ +260 955 155634

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Liverpool School of Tropical Medicine Research Ethics Committee:

Telephone: +44(0)151 702 9551

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If you have any questions, comments, or concerns about this study, now or at any point, you may contact the study principal investigators:

Study Principal Investigators:

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Zambia:

Dr Catherine Chunda

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Professor Imelda Bates

Telephone: +44 0151 705 3115

Email: Imelda.bates@lstmed.ac.uk

PARTICIPANT INFORMATION SHEET: Standards Based Audit Group Members

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

You are being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss this study with others to help you make a decision about whether to participate or not. You will have one week to decide whether you would like to participate or not.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why have I been chosen?

You are a clinician supporting people living with sickle cell disease. You therefore have very important insights about experiences of providing care to people living with sickle cell disease and how this care might be improved.

3. Do I have to take part?

You do not have to take part in this study if you do not wish to do so. There is no consequence to declining to participate. If you do decide to take part and later change your mind, that is absolutely okay. You can withdraw your participation at any time with no negative consequences at all—we will delete any data that we have collected from you at that point.

4. What will happen to me if I take part?

We are forming six teams across six health facilities that provide care to people living with sickle cell disease. On these teams will be all clinicians providing care to people living with sickle cell disease in the facility, as well as the facility in-charge, and other influential persons who are necessary to include for decision-making. You will be brought together monthly to carry out something called a “standards-based audit” (this is sometimes referred to as clinical or criterion-based audit). With the help of a facilitator, you will be guided through a cyclical process in which you will identify problems or barriers in your facility linked to key clinical mainstays of sickle cell disease care (infection prevention, blood transfusion, and use of hydroxyurea). As a group, you will also design and implement “solutions” to tackle some of these problems, with the broader goal of improving evidence-based practice in sickle cell disease care. Every six months, there will also be day-long “learning collaborative” meetings, in which all six clinical teams will be brought together to share their experiences. At one of these meetings each year, community teams and some decision-makers and local non-governmental organisation representatives will also be invited so that there can be shared creation of guidelines to support “patient-centred” sickle cell disease care.

You will be given training to support your ability to carry out these activities, and supported through close mentorship from your facilitator. This will take approximately 3–5 hours of your time each month, with two additional days for the collaborative meetings every six months. Altogether, about 10 days each year will be required. These activities will carry on for two years. Once you have agreed to take part, you can change your mind at any point within the two years.

The facilitator will take notes during activities and some discussions may be—with the group’s permission—(audio) recorded. The larger learning collaborative meetings will be observed by other members of the study team, and parts of those meetings may also be (audio) recorded.

5. Expenses and payments

There are no payments for participating, but all expenses will be covered including provision of a transportation allowance. For the learning collaborative meetings, meals and, if necessary, accommodation will be provided.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study, but we do appreciate that it may take a considerable amount of your personal time. The facilitator will work with the group to ensure that all activities are planned to accommodate everyone's schedules and commitments to the greatest extent possible.

Additionally, throughout you will likely reflect on your experiences and what you feel some community perceptions might be. If you have had some unpleasant experiences, this might be difficult for you to talk about. We are not asking about these experiences directly, but if at any point the discussions are upsetting to you we can pause the activity or you can withdraw your participation for the day, or completely, if you wish. You do not have to answer any questions you are not comfortable answering.

7. What are the possible benefits of taking part?

This study will help us to understand many things, including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care. We are hoping that your activities may directly lead to improvements in policy and guidance for sickle cell disease.

A direct benefit to you will be capacity strengthening in the use of standards-based audit, which is a highly transferrable skill set.

8. Will my taking part in the study be kept confidential?

All data generated through the activities of your team will be kept confidential. Any notes, observations, or transcripts from meeting discussions will be anonymised and not linked to any participants by name. However, for group-based activities, it is not possible to guarantee confidentiality, though we will remind all participants to keep any discussions or admissions in the strictest confidence. Please refrain from mentioning anything that you do not wish the group to know—you can tell the facilitator separately at the end of the discussion if there is something important that you wish to raise privately. Signed consent forms will have your name but will be unlinked to study data. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. Your own team meetings and learning collaborative meetings will also be a time when emerging study findings will be shared. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

12. Safeguarding

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM/[University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] code of conduct. This means that they must not ask you for any financial, physical or sexual favours in return for taking part in this research. If you experience any abuse, harassment or neglect by a study team member you can contact the study Safeguarding Lead [local safeguarding focal person name and contact details to be added] or Tara Tancred at tara.tancred@lstmed.ac.uk. You may also raise a safeguarding concern directly with LSTM Designated Safeguarding Officer Philippa Tubb on +44 (0)151 705 3744/safeguarding@lstmed.ac.uk. LSTM's safeguarding commitment is described on LSTM Safeguarding webpage.

13. What will happen to my data?

Any data from audio files will be deleted once the files have been transcribed. Any observation notes will be recorded electronically and anonymized. Any data collected from your activities within the standards-based audit cycles will be collated electronically and anonymised. Anonymised data may be shared with specific members of the study consortium outside of the country where the data were collected to support analysis. Study documents will be kept for 10 years, after which time they will be destroyed.

Other key points about how your data are handled:

- Your data will be handled in accordance with UK Data Protection Act 2018.
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Dr Catherine Chunda

Email: catherinechunda@yahoo.co.uk]

Professor Imelda Bates

Telephone: +44 0151 705 3115

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PARTICIPANT INFORMATION SHEET: Facility In-charge (Permission for standards-based audit to take place)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Your facility is being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called "PACTS". You may wish to discuss the participation of this facility with other members of staff. You have one week to decide whether you would like this facility to participate or not.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the "PACTS" intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why has this health facility been chosen?

This health facility provides care to people living with sickle cell disease.

3. Does the facility have to take part?

No, if you decline this facility's participation, that is absolutely fine and will have no consequences. If you do decide that it is okay for the facility to take part and later change your mind, that is absolutely okay. You can withdraw the facility's participation at any time with no negative consequences at all—we will delete any data that we have collected from the facility at that point.

4. What will happen if this health facility takes part?

We will be forming a team of clinicians and perhaps some other relevant members of staff who support the provision of care for people living with sickle cell disease. This team will meet monthly to carry out audit processes linked to improving evidence-based practice for sickle cell disease, and also to improving the patient-centredness of sickle cell disease care. Twice per year, outside of working hours, some members of the team will be asked to attend a day-long learning collaborative meeting, in which team members from other health facilities carrying out these audit processes are also present. At one of these meetings per year, decision-makers and community members will also be present with the aim of supporting learning around patient-centredness in sickle cell disease care.

Activities will be observed, notes will be taken, and—with the team's permission—some discussions may be (audio) recorded.

5. Expenses and payments

There are no payments for participating and the facility will not incur any expenses.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study for the health facility, though we do appreciate this may cause some disruption. We will arrange activities with the members of the audit team such that no disruption to care occurs.

7. What are the possible benefits of taking part?

There will be no direct benefit to the health facility but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care. These findings will be shared with ministry-level officials with the aim of improving policies and guidelines for sickle cell disease.

Further, participants within the audit cycles will gain invaluable and transferrable skills around standards-based audit.

8. Will taking part in the study be kept confidential?

All study data will be kept confidential. There is no identifying information linked to the health facility—it will be assigned a unique ID number in any observation forms, notes, or transcripts. Signed consent forms will have your name but will be unlinked to data from this health facility. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings, to which you will be invited. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

12. Safeguarding

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM/[University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] code of conduct. This means that they must not ask you for any financial, physical or sexual favours in return for taking part in this research. If you experience any abuse, harassment or neglect by a study team member you can contact the study Safeguarding Lead [local safeguarding focal person name and contact details to be added] or Tara Tancred at tara.tancred@lstmed.ac.uk. You may also raise a safeguarding concern directly with LSTM Designated Safeguarding Officer Philippa Tubb on +44 (0)151 705 3744/safeguarding@lstmed.ac.uk. LSTM's safeguarding commitment is described on LSTM Safeguarding webpage.

13. What will happen to my data?

No data will be collected from you directly. There will be some data collection activities surrounding the standards-based audit team. From this team: any data from audio files will be deleted once the files have been transcribed. Any observation notes will be recorded electronically and anonymized. Any data collected from activities within the standards-based audit will be collated electronically and anonymised. Anonymised data may be shared with specific members of the study consortium outside of the country where the data were

collected to support analysis. Study documents will be kept for 10 years, after which time they will be destroyed.

Other key points about how data are handled:

- Data will be handled in accordance with UK Data Protection Act 2018.
- You can find out more about how we use information at https://www.lstmed.ac.uk/privacy-statement.
- The LSTM Data Protection Officer can be contacted if you have any concerns about the collection or storage of data: dataprotection@lstmed.ac.uk
- If you have any complaints about the handling of data, you can contact the UK Information Commissioners Office: https://ico.org.uk/make-a-complaint/
- If you do not have internet access, please ask someone you trust to assist you in making a complaint.

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Liverpool School of Tropical Medicine Research Ethics Committee:

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If you have any questions, comments, or concerns about this study, now or at any point, you may contact the study principal investigators:

Study Principal Investigators:

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Professor Imelda Bates

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PARTICIPANT INFORMATION SHEET: Facility In-charge (Survey)

Study title: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Your facility is being invited to participate in a study in which we would like to understand how to best implement an intervention which aims to support the improvement of access to and uptake of quality care for people living with sickle cell disease. This study will run from January 2023–2026 and is called “PACTS”.

1. What is the purpose of the study?

With the Liverpool School of Tropical Medicine, the [University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] with support from Syracuse University and Imperial College London is carrying out the “PACTS” intervention. We believe this intervention has a lot of potential to improve how people living with sickle cell disease are cared for to increase the quality and length of their lives. Therefore, to make this research as impactful as possible, we are studying its implementation in detail to try to gain insights that will support learning that can enable our research findings to be taken up into policies and clinical practice.

2. Why has this health facility been chosen?

This health facility provides care to people living with sickle cell disease.

3. Does the facility have to take part?

No, if you decline this facility’s participation, that is absolutely fine and will have no consequences. If you do decide that it is okay for the facility to take part and later change your mind, that is absolutely okay. You can withdraw the facility’s participation at any time with no negative consequences at all—we will delete any data that we have collected from the facility at that point.

4. What will happen if this health facility takes part?

We will be carrying out exit-interviews with patients (aged 15 and older) receiving care for sickle cell disease, or carers of patients, using an electronic survey. We will be posting study materials—with your permission and departmental permission—in areas where

patients/carers commonly wait. Members of the study team will approach prospective participants whilst they are waiting for care to give them basic details of the study. Once their appointment is finished, we will then carry out informed consent with the participant and will continue to the survey. Surveys will be administered in a private location nearby that is agreed upon by you. Each survey will take a maximum of 30 minutes to administer. We will be aiming to recruit 300 participants at this health facility.

5. Expenses and payments

There are no payments for participating, but the facility will not incur any expenses.

6. What are the possible disadvantages and risks of taking part?

This is a very low-risk study for the health facility, though we do appreciate this may cause some disruption. We will arrange with you and other members of the clinical team supporting patients with sickle cell disease how to best share study information and to approach participants in a way that is as minimally disruptive as possible. We will not interrupt clinical care at all.

7. What are the possible benefits of taking part?

There will be no direct benefit to the health facility but this study will help us to understand many things including key factors that will help to support better quality care for people living with sickle cell disease, earlier diagnosis of sickle cell disease, and better uptake of care. These findings will be shared with ministry-level officials with the aim of improving policies and guidelines for sickle cell disease.

8. Will taking part in the study be kept confidential?

All survey data will be kept confidential. On the survey itself, there is no identifying information linked to the health facility—it will be assigned a unique ID number. Signed consent forms will have your name but will be unlinked to survey responses from this health facility. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

9. Who is organizing and funding the research?

This study is being funded by the National Institute for Health Research in the UK. It is being led by [the Kwame Nkrumah University of Science and Technology/the University of Abuja/ the Ministry of Health] in partnership with the Liverpool School of Tropical Medicine.

10. What will happen to the results of the research study?

Throughout the study, our key findings will be shared as part of a series of study dissemination meetings. A brief with key findings from this survey will be shared with the hospital for you, other clinical staff, and participants to view. We will also aim to publish our findings in scientific journals so that people in other contexts might benefit.

11. Who has reviewed the study?

This study has been reviewed and has been allowed to proceed by [The Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics/ University of Abuja Teaching Hospital Health Research Ethics Committee/ Excellence in Research and Science (ERES) Institutional Review Board] and at the Liverpool School of Tropical Medicine.

12. Safeguarding

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM/[University of Abuja/The Ministry of Health, Zambia/the Kwame Nkrumah University of Science and Technology] code of conduct. This means that they must not ask you for any financial, physical or sexual favours in return for taking part in this research. If you experience any abuse, harassment or neglect by a study team member you can contact the study Safeguarding Lead [local safeguarding focal person name and contact details to be added] or Tara Tancred at tara.tancred@lstmed.ac.uk. You may also raise a safeguarding concern directly with LSTM Designated Safeguarding Officer Philippa Tubb on +44 (0)151 705 3744/safeguarding@lstmed.ac.uk. LSTM's safeguarding commitment is described on LSTM Safeguarding webpage.

13. What will happen to my data?

No data will be collected from you directly. Survey data will be obtained from patients/caregivers accessing this facility. Anonymised survey data may be shared with specific members of the study consortium outside of the country where the data were collected to support analysis. Study documents will be kept for 10 years, after which time they will be destroyed.

Other key points about how data are handled:

- Data will be handled in accordance with UK Data Protection Act 2018.
- You can find out more about how we use information at https://www.lstmed.ac.uk/privacy-statement.

- The LSTM Data Protection Officer can be contacted if you have any concerns about the collection or storage of data: dataprotection@lstmed.ac.uk
- If you have any complaints about the handling of data, you can contact the UK Information Commissioners Office: https://ico.org.uk/make-a-complaint/
- If you do not have internet access, please ask someone you trust to assist you in making a complaint.

Thank you for considering taking the time to read this sheet

You will be given a copy of the information sheet to keep

CONTACT INFORMATION

Please get in touch with the research ethics committee contacts below if you have questions about your rights as a study participant or if you have other concerns:

[Ghana:

Chair, Kwame Nkrumah University of Science and Technology Committee on Human Research Publication and Ethics

Telephone: +233 3220 63248

Email: admin@smsknust-kath.org; chrpe@knust.edu.gh

Nigeria:

Chair, University of Abuja Teaching Hospital Health Research Ethics Committee

Telephone:+234 0988 21228

Email: uathmrec@yahoo.com

Zambia:

Chair, Excellence in Research and Science (ERES) Institutional Review Board

Telephone: +260 955 155633/ +260 955 155634

Email: eresconverge@yahoo.co.uk]

Liverpool School of Tropical Medicine Research Ethics Committee:

Telephone: +44(0)151 702 9551

Email: lstmrec@lstmed.ac.uk

If you have any questions, comments, or concerns about this study, now or at any point, you may contact the study principal investigators:

Study Principal Investigators:

[Ghana:

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Zambia:

Dr Catherine Chunda

Email: catherinechunda@yahoo.co.uk]

Professor Imelda Bates

Telephone: +44 0151 705 3115

Email: Imelda.bates@lstmed.ac.uk

Appendix 3. Informed Consent Forms

PARTICIPANT CONSENT FORM: Key Informants

Title of Study: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Name of Principal Investigators: [Dr Alex Osei-Akoto/Professor Obiageli Nnodu/ Dr Catherine Chunda] and Professor Imelda Bates

	Please initial box
1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and any questions I have asked have been answered to my satisfaction.	
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason.	
3. I agree for this interview to be recorded.	
4. I agree to my quotations being used anonymously in publications or reports released on the study.	
5. I agree to take part in the above study.	

Name _____ Signature _____ Date _____

Person taking consent _____ Signature _____ Date _____

PARTICIPANT CONSENT FORM: Standards-based Audit/Participatory Action Cycle Team Members

Title of Study: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Name of Principal Investigators: [Dr Alex Osei-Akoto/Professor Obiageli Nnodu/ Dr Catherine Chunda] and Professor Imelda Bates

	Please initial box
1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and any questions I have asked have been answered to my satisfaction.	
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason.	
3. I agree for study activities (interviews, meetings, discussions) to be recorded if needed.	
4. I agree for meetings and learning collaboratives to be observed.	
5. I agree to my quotations being used anonymously in publications or reports released on the study.	
6. I agree to take part in the above study.	

Name	Signature	Date

Person taking consent	Signature	Date

PARTICIPANT ASSENT FORM: Adolescent (aged 15-to-17-years-old) Participatory Action Cycle Team Members

Title of Study: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Name of Principal Investigators: [Dr Alex Osei-Akoto/Professor Obiageli Nnodu/ Dr Catherine Chunda] and Professor Imelda Bates

	Participant initials	Parent/ caregiver initials
1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and any questions I have asked have been answered to my satisfaction.		
2. I understand that my [dependent's] participation is voluntary and I am free to withdraw at any time, without giving any reason.		
3. I agree for study activities (interviews, meetings, discussions) [my dependent will participate in] to be recorded if needed.		
4. I agree for meetings and learning collaboratives [my dependent will participate in] to be observed.		
5. I agree to my [dependent's] quotations being used anonymously in publications or reports released on the study.		
6. I agree [for my dependent] to take part in the above study.		

Participant name	Signature	Date
Parent/ caregiver name	Signature	Date
Witness	Signature	Date
Person taking consent	Signature	Date

PARTICIPANT CONSENT FORM: Focus Group Discussion Participants

Title of Study: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Name of Principal Investigators: [Dr Alex Osei-Akoto/Professor Obiageli Nnodu/ Dr Catherine Chunda] and Professor Imelda Bates

	Please initial box
1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and any questions I have asked have been answered to my satisfaction.	
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason.	
3. I agree for the focus group discussion to be recorded.	
4. I agree to my quotations being used anonymously in publications or reports released on the study.	
5. I agree to take part in the above study.	

Name	Signature	Date
Witness	Signature	Date
Person taking consent	Signature	Date

PARTICIPANT ASSENT FORM: Adolescent (aged 15-to-17)Focus Group Discussion Participants

Title of Study: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Name of Principal Investigators: [Dr Alex Osei-Akoto/Professor Obiageli Nnodu/ Dr Catherine Chunda] and Professor Imelda Bates

	Participant initials	Parent/ caregiver initials
1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and any questions I have asked have been answered to my satisfaction.		
2. I understand that my [dependent's] participation is voluntary and I am free to withdraw at any time, without giving any reason.		
3. I agree for the focus group discussion [attended by my dependent] to be recorded.		
4. I agree to my [dependent's] quotations being used anonymously in publications or reports released on the study.		
5. I agree [for my dependent] to take part in the above study.		

Participant name	Signature	Date
Parent/ caregiver name	Signature	Date
Witness	Signature	Date
Person taking consent	Signature	Date

PARTICIPANT CONSENT FORM: Patient Survey

Title of Study: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Name of Principal Investigators: [Dr Alex Osei-Akoto/Professor Obiageli Nnodu/ Dr Catherine Chunda] and Professor Imelda Bates

	Please initial box
1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and any questions I have asked have been answered to my satisfaction.	
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason.	
3. I agree to take part in the above study.	

Name	Signature	Date
Witness	Signature	Date
Person taking consent	Signature	Date

PARTICIPANT ASSENT FORM: Adolescent (aged 15-to-17) Patient Survey

Title of Study: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Name of Principal Investigators: [Dr Alex Osei-Akoto/Professor Obiageli Nnodu/ Dr Catherine Chunda] and Professor Imelda Bates

	Participant initials	Parent/ caregiver initials
1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and any questions I have asked have been answered to my satisfaction.		
2. I understand that my [dependent's] participation is voluntary and I am free to withdraw at any time, without giving any reason.		
3. I agree [for my dependent] to take part in the above study.		

Participant name	Signature	Date
Parent/ caregiver name	Signature	Date
Witness	Signature	Date
Person taking consent	Signature	Date

HEALTH FACILITY CONSENT FORM: Patient Survey (Health Facility In-charge Consent)

Title of Study: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Name of Principal Investigators: [Dr Alex Osei-Akoto/Professor Obiageli Nnodu/ Dr Catherine Chunda] and Professor Imelda Bates

	Please initial box
1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and any questions I have asked have been answered to my satisfaction.	
2. I understand that the participation of this health facility in the survey is voluntary and I am free to withdraw consent for this facility to participate at any time, without giving any reason.	
3. I agree to this health facility taking part in the above study.	

Name	Signature	Date
Person taking consent	Signature	Date

HEALTH FACILITY CONSENT FORM: Standards-based Audit (Health Facility In-charge Consent)

Title of Study: Participatory Approaches to Support Patient-Centred Sickle Cell Disease Management in Africa (PACTS): A Study of Implementation

Name of Principal Investigators: [Dr Alex Osei-Akoto/Professor Obiageli Nnodu/ Dr Catherine Chunda] and Professor Imelda Bates

	Please initial box
1. I confirm that I have read and understood the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and any questions I have asked have been answered to my satisfaction.	
2. I understand that the participation of this health facility in the survey is voluntary and I am free to withdraw consent for this facility to participate at any time, without giving any reason.	
3. I agree to this health facility taking part in the above study.	

Name	Signature	Date
Person taking consent	Signature	Date