Study Protocol: Exploring the design and operation of community health and wellbeing sickle cell hubs (‘sickle hubs’) to relieve pressure on GPs and hospital services

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Abstract

Aim: With patients, we will co-design sickle cell disease (SCD) resource centres ('sickle hubs') ready for an implementation study across Liverpool. The hubs' advice and support will facilitate patients' timely and appropriate access to NHS and social services, thereby relieving NHS pressure. Cultural appropriateness is woven throughout since our participants are predominantly from ethnic minorities.

Background: SCD is a chronic, complex blood condition causing lowered life expectancy and requires regular hospital appointments punctuated by emergency admissions due to painful episodes, infections and anaemia symptoms. It is compounded by stigma, social and mental health problems and reduced income through unemployment. A 2021 national SCD review highlighted NHS failings resulting in unnecessary SCD deaths and inequitable underfunding including in our north-west region. Community-based care for social and health issues in chronic conditions can reduce hospitalisations and improve patients' wellbeing but examples for SCD are scarce. Our proposal complements the review's recommendations for better community SCD care and NHS-community linkages. It builds on current initiatives including NIHR's 'research ready communities', our institution's 'knowledge exchange' network with local diaspora, our NIHR-funded community SCD project in Africa, and upcoming SCD service peer reviews and pilots of 'hyper-acute' units.

Design/methods: In our 15-month project, 'research champions' from our local community will be trained by RDN team and supported by our researchers to engage our SCD community (patients and families/carers) in our participatory research. Over three discussions rounds, 8-10 people from the SCD community and NHS professionals will gradually build a consensus on what SCD hubs should do, where they should be based and how to evaluate their impact. Information from workshops, surveys, interviews and consultations will feed into discussions. Through this process, the participants will design an intervention for a subsequent study where 4-5 Liverpool hubs will be tested in practice. Inputs from monthly management and 3-monthly advisory team meetings will ensure we on track with timelines/outputs and consider the wider local/national context.

Patient/public involvement: Our 'hub' idea was proposed by our SCD community to streamline their access to NHS services, and to provide socio-culturally appropriate support for wellbeing and resilience. They have contributed to every stage of the proposal and our public co-applicant brings personal experience of living with SCD. The SCD community will be key drivers of change and their inputs are essential to optimise our research design and ultimately reduce health disparities. We have incorporated RDN's community 'research champions' approach which has proven successful in our region for engaging marginalised populations in research.

Dissemination: We will expand our existing list of relevant local and national audiences and will map the type and timing of materials needed to share our findings with each one, including through social media, blogs/briefs, presentations/workshops and conferences/papers.

Abbreviations

EDI	Equality Diversity and Inclusion
FGD	Focus group discussion
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
KII	Key Informant Interview
LUHFT	Liverpool University Teaching Hospital Foundation Trust
NHS	National Health Service
NIHR	National Institute for Health Research
NIHR-RfPB	NIHR Research for Patient Benefit
RRDN	NIHR Research Delivery Network
PAT	Patient Advisory Team
PPI	Patient and Public Involvement
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
SCD	Sickle Cell Disease
SSA	Sub-Saharan Africa
SSSN	Liverpool Sickle Cell and Thalassaemia Support Group
UKRI	UK Research and Innovation

Research Team

Name	Organization/country	Qualification	Role in study
Imelda Bates (IB)	LSTM – UK	MBBS, MD, Professor	Principal Investigator
Motto Nganda	LSTM – UK	MD, MSc	Co-investigator, PPI lead
Ayombo Akinmolayan (AA_1)	N/A	Person living with SCD	Public Co-investigator
Annmarie Allt (AA_2)	Northwest NIHR Research Delivery Network (RDN) – UK	NA	Research Engagement Officer: Recruit, train and oversee activities of 'research champions' relating to engaging communities in research
Funmi Dairo (FD)	Liverpool Sickle Cell and Thalassaemia Support Group (SSSN) - UK	Vice chair Sickle Cell and Thalassaemia Support Group	Provide access to SCD networks/members, and relevant advice and resources
Sabrina Emanual-Malins (SE)	Liverpool Sickle Cell and Thalassaemia Support Group (SSSN) - UK	Alder Hey SCD patient representative Sickle Cell and Thalassaemia Support Group	Provide access to SCD networks/members, and relevant advice and resources
Jessica Bradbury (JB)	Liverpool University Hospitals NHS Foundation Trust (LUHFT) - UK	SCD Specialist Nurse	Clinical guidance and liaison with NHS clinical and administrative services
Adama Ladu (AL)	Consultant SCD specialist Haematologist – Nigeria	MBBS, PhD	Lead culturally appropriate mutual learning on community-based SCD initiatives between UK and SCD networks in SSA

Research champions	To be recruited	To be recruited	Promote community engagement; design and delivery team for all research activities and workshops
Susie Crossman (SC)	LSTM – UK	PRINCE2 in Project Management	Project management
Zena Parker (ZP)	LSTM – UK	APM Project Fundamentals	Project administration
Project Advisory Team (PAT)	Global	To be recruited	The PAT will guide the project's strategic direction and help put the findings into academic, NHS and cultural context.

Background and Rationale

What is the problem being addressed?

Lack of community support for the SCD community creates more work for hospitals and GPs

We will address the lack of support in the community to meet the holistic needs of patients with sickle cell disease (SCD) and their families. This leads to inappropriate use of NHS health services unnecessarily increasing the workload on hospitals and GPs. Our proposal will explore the concept of non-medical **community health and wellbeing hubs ('hubs')** for SCD across the Liverpool area[a]. There is evidence from other chronic conditions that better community support can improve patients' quality of life and relieve pressure on health services. Although there are a few SCD community hubs in the UK, they are generally not in areas where SCD burden is low (as in Liverpool). We are not proposing to adopt the same approach as in high SCD-burden cities (i.e. we will not replicate an existing health service intervention): this would be inappropriate given the differences in SCD burden and the limited resources available for SCD in Liverpool, and the lack of evidence about how community SCD hubs should function in our low-prevalence context.

Our SCD community's priorities for the services to be provided through community hubs include culturally appropriate health and social advice, encouraging adherence to routine appointments to avoid emergency admissions, and smoothing the transition from paediatric to adult SCD hospital services. Hubs could also signpost local resources, agencies and NHS access pathways, as a 'one-stop shop' to link those affected by/at risk of SCD, into medical and social services.

Medicalised approach to SCD care does not fully address social and clinical barriers

The current healthcare approach to SCD emphasizes lifestyle changes and counselling for preventing disease related complications - it does not fully address the social and clinical barriers that prevent health equity.[1] After receiving standardised care in hospital, patients return home and pre-existing multifactorial environmental stressors (e.g. financial, housing) that contributed to the initial hospitalization.[2,3] Health and social factors interact and should be addressed to make sure medical treatment benefits are fully realised.

SCD patients are marginalised and underserved

SCD patients in the UK come almost exclusively from ethic minority communities, and are disproportionately affected by poverty, stigma and other negative determinants of health. Community SCD hubs are of particular benefit to

underserved communities because they can improve health and social outcomes and therefore contribute to reducing health inequalities. Through a community hub, SCD patients and their families will have easy access to support from a team of volunteers with whom they are culturally and socially aligned.

Evidence about the activities and operation of community SCD hubs is lacking

The proposal is research rather than a service evaluation because although there is evidence of hub benefit in other chronic conditions, there is little evidence available to indicate how they should operate for SCD patients and what they should do. This is especially so for areas such as Liverpool where SCD prevalence is relatively low and SCD services are particularly poorly resourced compared to larger cities with higher SCD prevalence (e.g. Manchester).

Our proposal is to collaboratively design with patients an intervention (i.e. community hubs) and evaluation metrics ready for trialling in a larger (tier 2) application. The extent to which published evidence about the benefit of such community centres for other chronic conditions can be extrapolated to our setting is unclear because much of the published evidence is from the USA where the healthcare system is different from that in the UK.

Why is our research important for healthcare services and the health/wellbeing of SCD patients?

Community SCD hubs have the potential to improve patients'/families'/carers' wellbeing and resilience, to reduce the pressure on hospital/GP facilities and to improve the appropriate use of health services. They could reduce the excessive delays currently experienced when those with SCD trying to access formal health services. Relieving GPs/hospitals of some of these educational, advisory and support functions, means NHS resources for SCD can be better targeted towards streamlining routine and emergency primary and hospital care. Our proposal will contribute to improved healthcare efficiency and effectiveness and therefore aligns closely with the remit of the R4PB programme.

SCD is a disabling but neglected chronic disease

In England there are ~17,000 people living with SCD with 250 new cases a year.[4] It is more common in people of Black African, Caribbean, Middle Eastern and South Asian heritage and is due to a mutation in the beta-globin gene. This causes red blood cells to become irreversibly sickle shaped which can lead to red cell breakdown and eventually to severe organ damage (e.g. strokes, sight loss). SCD causes chronic ill health with episodes of intense pain due to the damaged red blood

cells blocking vessels and restricting oxygen supply, often requiring emergency hospitalisations.

Patients need regular hospital follow-ups to pre-empt and treat complications and to monitor hydroxyurea therapy. Health issues are compounded by stigma, social and mental health problems. The All-Party Parliamentary Group report[5,6] was scathing about NHS failings and unnecessary deaths and near misses from SCD. Our proposal aligns with recommendations in this report concerning 'inadequate or non-existent' community care, and poor joined-up care between primary and secondary care levels. Our proposed community hubs would address gaps highlighted in the report including insufficient awareness and training about SCD, negative attitudes towards patients and under resourcing of SCD services.[2]

Our Liverpool-based research will help redress national inequities for SCD patients

The 'No one's Listening' report[5] (p47) noted significant disparities in resources for SCD across the UK. Funding is disproportionately concentrated in major centres leaving areas such as Liverpool especially underserved. Liverpool hospitals provide specialist care for our increasing population of SCD patients (currently 132 adult and 102 children). There are dedicated SCD clinics in Alder Hey (paediatrics) and the Royal Liverpool (adults) hospitals and services are linked with the north-west SCD coordinating centre in Manchester.[7] At present we have no community provision in Liverpool for SCD patients except that offered by the volunteers in our local sickle cell support network (SSSN) and patient support group. They can only give limited support, such as providing advice on access to local paediatric and adults health services and for some social issues.

The adult clinic nursing support across Liverpool has recently been increased from 50% to 100% (JB). Although she does have a community liaison role, in practice she needs to spend most of her time on clinical service delivery. There are no plans to increase the community outreach activities by healthcare professionals though the hospital staff are very willing and keen to support the activities of a community SCD. Despite having emergency telephone triage of SCD patients to facilitate rapid hospital admission in Liverpool, increasing bed shortages mean that many SCD patients are delayed in A+E. Consequently, as reflected in the Liverpool 2022-3 audit of 34 acute hospital episodes of adult SCD crises against NICE standards (QS58), is that time to receive analgesia has doubled in the last 10 years.

Early identification and enrolment in a long-term care programme is critical for reducing deaths and complications in SCD, and for reducing patients' high overall healthcare resource utilisation, yet some of those at risk are unaware of their sickle status or of the importance of regular monitoring. Although all newborns with SCD are detected through the national ante-natal screening programme, those born outside the UK (e.g. students at our five Liverpool universities; refugees and asylum-

seekers) need education, advice and encouragement to understand and take-up screening, and subsequent hospital referral if they have SCD or are carriers.

Anticipated outcomes and impact for SCD patients

Our proposal is for a preliminary exploratory study so it will not have immediate benefit for patients or the NHS. Our longer-term goal within the next 4-6 years is to create a bridge to the community-health service interface for the SCD community which will improve holistic care thereby increasing their resilience and reducing the burden on health services (see figure 1 Theory of Change). We have **three activity themes**: i) the design and function of the hubs; ii) community research participation; and iii) knowledge sharing. We anticipate that the outputs from these will lead to the outcomes of: a) a network of community hubs for the sickle cell community; b) effective engagement of the SCD community in hub functions and in research; and c) strengthened capacity among the community for SCD outreach and advocacy.

Review of existing evidence and how it supports this proposal

Our research is timely and needed

Our proposal is a timely response to recommendations in the 'No-ones listening report'.[5] The report highlights "shocking failures" and a "call for major changes into care for sickle cell patients". To address the need for better education of health staff, and patients with SCD and their families, NHS England launched a new campaign in 2022[8] to raise awareness of the signs of a SCD crisis and to provide education on SCD and its related health inequalities (e.g. resources available for Trusts; free e-learning module for healthcare professionals). Our research will contribute to this effort.

There is an ongoing **UK peer review of SCD services** (Sept 2023-25)[9] and through collaborators FD and SE findings from this will be taken into account as hubs develop. Through our project advisory team (PAT) we can also incorporate learning emerging from the new **NHS-England pilot scheme (2024-) for hospital-based 'hyper-acute units'** that provide rapid access SCD care.[10]

Existing evidence on community health and wellbeing hubs for SCD

Our initial review of the literature did not highlight any publications specifically relating to non-medical community centres for SCD in the UK. Much of the evidence concerning community care for those living with SCD and other chronic conditions that need holistic care is from the USA and/or embedded in research about health inequities and the social determinants of health.

Populations affected by SCD and social consequences

SCD is a complex chronic disease which disproportionately affects the poorest members of our society; 46% of the 900,000 people in families with an ethnic minority household head are in poverty, compared to 19% (10.7 million) with a White household head.[11] Many SCD patients struggle to remain employed or attend school regularly because of frequent hospital admissions. SCD patients experience marginalisation and stigma, and cultural mismatches between healthcare providers and families creates mistrust and jeopardises their care. These factors hinder life and career opportunities and exacerbate poverty.[12] A study of the role of community health workers – who were aligned socially and culturally with the population they served – indicated they can provide social support, navigation of health systems and resources, and lay counselling.[12] These can improve patient-centred outcomes in underserved communities and, although they have not been evaluated in SCD, the authors suggest that this approach may improve care outcomes for those living with SCD.

Provision and benefits of community services for patients, the NHS and for reducing health disparities

Holistic care is important for improving the quality of life of people affected by chronic conditions such as SCD. Working together, hospitals and community and voluntary agencies can raise awareness of SCD and provide health focused, non-clinical wellbeing support in the community. Examples include culturally-appropriate mediation, informal counselling, social support, health and SCD education, advocacy for individual and community needs, and advice on local services, housing and benefits. Although examples of community services for SCD are rare,[12-14] evidence from other chronic conditions indicates they can assist with navigating appropriate access to health services and resources, support patients at medical consultations and promote appropriate use of health services.

The benefits of enhanced community support for SCD include improved patients' health,[12,15] reduced hospital readmissions and earlier detection and treatment of complications thereby reducing the number and length of hospital admissions,[16] and improving health and social outcomes. It is especially effective for those with chronic diseases from underserved communities since they help to foster trust in health services and reduce stigmatisation. They can also encourage those affected by SCD to take greater control of their own lives thereby improving resilience.[16] In addition to direct patient benefits, better community services also benefit the health services by avoiding inappropriate medical consultations and demands on health professionals, enabling more resources to be targeted on services improvements for SCD patients.

A review from the USA[17] indicates that community-based centres and organisations that provide health education and counselling, in addition to antenatal and dental services, can make access to care more equitable for those living with SCD.

Addressing some of these social determinants of health can help to reduce the reliance of patients on emergency care and shift disease management to a more chronic care, preventative model.[18]

Disproportionate under-funding for SCD

In the UK, SCD services are markedly under-resourced compared to other complex chronic conditions that also need a multifaceted approach (e.g. haemophilia, cystic fibrosis)[5]. The situation is similar in the USA where cystic fibrosis prevalence is less than half that of SCD but has 3.5 times the funding from government and 440 times the funding from national foundations.[19] In the UK, with its haematology "workforce crisis", SCD is disproportionately under-resourced and "neglected in comparison to blood cancers". Hydroxyurea treatment is free for cancer patients but not for SCD patients[5], and specialist SCD nurse numbers are "inadequate" especially community nursing support and counselling.

Building on our current work and existing initiatives

The involvement of patients is critical to our project but, in common with other marginalised groups, it is challenging to engage the SCD community in research. We will build on the networks, skills and knowledge in community-delivered research gained by our co-applicants' (RDN[20]) from their four NIHR-funded '**research ready communities'**[21] projects and the Phoenix Way project.[22]

The RDN team found that lack of awareness, misinformation and language are important barriers hindering ethnic minority groups' participation in research. We will create a new research partnership between RDN and the Liverpool SCD support network through RDN's community research engagement team. MN (co-applicant and PPI lead) has already engaged with several ethnic minority communities in Liverpool through LSTM's '**knowledge exchange' network**[23] and affirmed their interest to be involved in projects.

For mutual learning, particularly on screening/diagnostic, cultural and social aspects, we will also forge links with the NIHR-funded, LSTM-hosted **PACTS project** based in UK, Ghana, Nigeria and Zambia (2022-6).[24] PACTS is a patient-centred, implementation research project to improve healthcare for SCD patients at the community-facility interface and partners have extensive experience of SCD including providing counselling and novel near-patient testing. Collaboration among medical institutions from resource-rich and low-resource countries will help to improve the research infrastructure and lead to a better understanding of SCD. Manchester (NW SCD coordinating centre) has a larger population of patients with SCD and thalassaemia than Liverpool, currently around 1,200 adults and children. The Manchester community nursing service only conduct hydroxycarbamide monitoring and review patients undergoing acute admission. Manchester has a community hub[25] which is a registered charity run by volunteers who receive

compensation for their travel/subsistence. Their activities include befriending, home visits, partner and pre-conception screening, housing support, exercise classes, community and maternity groups, and fundraising. We will consult and learn from Manchester's experience in developing Liverpool hubs intervention.

Justification for research

Sickle cell disease (SCD) primarily affects ethnic minorities so in addition to having a chronic health condition requiring lifelong medical care and frequent hospitalisations, patients experience stigma and poverty, with consequent marginalisation and disparities in healthcare. Our research responds to a highly critical UK government report highlighting the neglect of SCD and recommending improvements in community provision. In the UK, funding for SCD is disproportionately low compared to other chronic diseases and resources are concentrated in high-prevalence areas. There is very little evidence to guide the design and function of community SCD hubs that is transferable to the Liverpool area where prevalence is low. Evidence from the USA, from non-SCD chronic conditions and from studies of social determinants of health, indicate that community hubs can reduce hospital visits and improve quality of life, resilience and patient outcomes. Examples of potential SCD hubs' functions include health education, counselling and advice on screening and 'buddies' for hospital appointments.

Our research questions focus on exploring the functions, operation and locations of community SCD health and wellbeing hubs that bridge the community-health service interface. The questions have been articulated by our Liverpool sickle cell patients and their carers to reflect their need for more holistic, patient-centred care in their communities. These hubs could provide holistic and culturally appropriate support, thereby improving SCD patients' wellbeing and resilience. This would also benefit health services by reducing workload and helping patients navigate NHS access pathways more effectively.

Aims and Objectives

Our research approach is novel because it engages our marginalised SCD communities in research to design patient-centred health and wellbeing hubs. The hub intervention will be based on lived experiences, patients' needs, and current best evidence combined with extensive consultations and consensus building (Delphi process – see figure 1), and the research will be led and conducted by Liverpool community members.

Aim

To **co-design with patients the components of an intervention** (i.e. Liverpool community SCD hubs) for improving patients' wellbeing, resilience and interactions with health services for trialling in a larger study. Our focus is on adults with SCD and the paediatric-adult transition stage rather than on children's services, since adults are less well-served in Liverpool. Our aim will contribute to our **vision** - to improve wellbeing and resilience and reduce health disparities for our SCD patients - while simultaneously strengthening their research engagement and trust in health services to reduce their marginalisation.

Objectives

1- Review published evidence about the role and operation of community centres to support SCD patients and their families

2- Determine SCD prevalence across our region; identify hot-spots to locate future SCD hubs

3- Train community 'research champions' to advocate for and contribute to patient-designed participatory research

4- Use the patient-designed research to identify key SCD hub functions that will improve access and adherence to healthcare, smooth the paediatric-adult care transition, and provide socio-cultural support; explore how these functions can be implemented and integrated with existing initiatives

5- Identify feasible and scalable metrics for evaluating the impact of the hubs

6- With stakeholders, jointly reflect on our results and finesse the Theory of Change (figure 2) and intervention for future trialling

Our aim and objectives will answer our co-designed **research questions:**

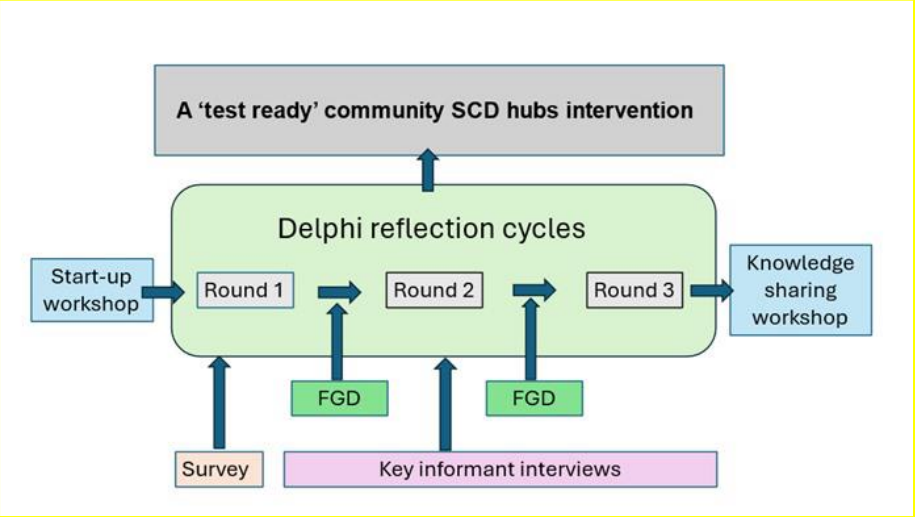
- Can community SCD hubs bridge the community-health service interface, improve patients' wellbeing, resilience and provide holistic social and culturally appropriate SCD care?
- Where should hubs be located, what functions and services should they provide, how can these be coordinated and their impact on SCD patients and NHS evaluated?

Research plan / Methods

Approach / Study Design

Our formative research project has been developed **with and for our SCD community to meet their needs** to improve its scientific rigour, acceptability and usefulness. With our community co-researchers and based on published literature on community interventions for SCD and other chronic diseases, we will use a Delphi framework to explore what the community SCD hubs should do, what would be feasible and acceptable from the perspectives of the community and healthcare professionals, and how hubs can streamline access to, and relieve pressure on, the NHS. As relevant information emerges from our scoping review of the literature, survey, FGD and KIIs, this will be incorporated into our consultations (figure 1).

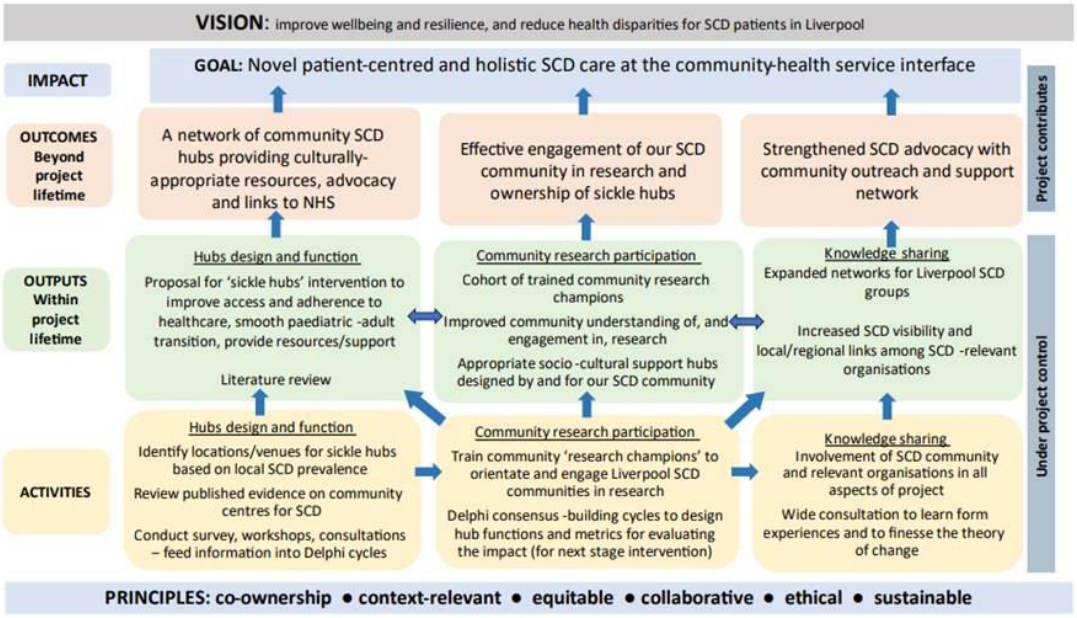
Figure 1: Outline of research approach



Our exploratory project will explore what the hubs should do and how they link with existing NHS, local government and civil society platforms in preparation for a subsequent intervention study. It is not designed to set up operational community SCD hubs. Through participatory research, our research team (i.e. community research champions and person living with SCD, supported by researchers) will identify the SCD community's proposed hub functions, and explore how they can be operationalised and their impact measured (effectiveness, feasibility and acceptability).

Our integrated workstreams reflect the three themes in our Theory of Change (figure 2) and are interdependent. The design and function of the hubs (theme 1) will be determined through community research participation (theme 2). Knowledge sharing within and beyond the project (theme 3) is cross-cutting and throughout the project and will be co-delivered by SSSN volunteers and the research team.

Figure 2: Theory of change



Research activities / Data Collection

Our activities are in two phases

Phase 1 (0-7 months)

Start-up activities (months 1-2)

- ***Management processes***

Finalising contracts/partner agreements, preparing and submitting ethics, establishing a research data management platform, establishing Project Advisory Team (PAT)

- ***Start-up workshop***

This workshop follows RDN's well-established format and will be led by their community research engagement team. It aims to sensitise the public about the project, identify four suitable volunteers as research champions, seek volunteers as Delphi participants and for focus groups, and identify key individuals for interviews. An example of the workshop format is attached. It will be adapted for our SCD context and covers understanding research, challenges communities face in participating in research, and understanding topics that are of importance to them.

Initial consultations and published literature have already indicated some potential hub functions (Box 1). Although we are not proposing a clinical trial, the workshop will promote engagement in all types of research including clinical trials. The workshop will be in a convenient central venue, that can accommodate up to 70-80 participants. It will be advertised to SCD patients and their families and communities, and relevant organisations/individuals through **appropriate local networks**.

Box 1: Suggestions for possible community SCD hub functions

- Educational SCD resources
- Advice/encouragement for adherence to medications (e.g. folic acid, hydroxyurea), immunizations and follow-up appointments
- Liaison with/outreach from hospital and GP services (e.g. psychologist/nurse-led counselling) and citizen's advice (re housing, benefits, immigration)
- Advocacy and counselling, including for SCD screening
- Cultural support
- Language translations

❖ ***Identify local SCD 'hotspots'***

Postcodes from anonymised hospital records of SCD patients attending hospitals in the Liverpool region will be used to map SCD patients' addresses to see where patients are concentrated. To ensure confidentiality these postcodes will not be shared but will be rated hotter or cooler depending on the concentration of SCD patients within them. Potential venues/locations for future SCD hubs within or close to hotter areas will be discussed among the research team and PAT and explored through Delphi feedback discussions.

Training and research preparation (months 3-7)

❖ ***Scoping review***

This will use standard methodology and be conducted with specialist assistance. We will specify the research question, identify relevant literature in databases (e.g. PubMed, SCOPUS, CINAHL, PsycINFO and Web of Science), select studies (with screening by two independent reviewers), map the data and summarise the results (including any hard data on e.g. cost/time savings and patient outcomes). The search strategy will follow the PRISMA checklist for Scoping Reviews to identify the highest possible number of relevant articles and minimize publication bias. Preliminary findings from the scoping review will feed into the development of the initial survey and guides for the key-informant interviews and focus group discussions.

❖ ***Initial survey***

After **ethical approval,** the research team will prepare, conduct and analyse **an anonymous survey** across the SCD community (~200 respondents) to collect views from patients/carers/families about potential hub functions, operation, feasibility, acceptability and potential measures of success. The recruitment target of 200 is based on an estimated conservative survey response rate of ~30-40%.[29] We have over 200 sickle cell adult and paediatric patients in our area. They and their carers and family members (total 400-500) will be invited to participate in the survey through the SSSN networks, relevant organisations and our hospitals' system for surveying patients. This will ensure a diverse representation in age, gender, disease severity and frequency of hospital visits/admissions. The survey questionnaire will be developed by the research team fed by preliminary findings from the scoping review. To ensure we have enough volunteers as champions and participants in the Delphi, FGD and KII processes, our survey will ask those interested in volunteering to provide their contact details. Findings from the initial survey will feed into the development of guides for focus group discussions and key-informant interviews.

- ***Training for research champions***

Training for the research champions will be based on RDN's well-established model but adapted for our project (Box 2). RDN's engagement team will lead the training through 4-5 face-to-face sessions totaling ~24 hours over ~ 4-5 months. Our two workshops will be co-designed and co-delivered with trained community champions and their training sessions are opportunities to reflect, share learning and contribute to detailed planning for each Delphi round.

Box 2: Training for community research champions comprises:
***How to undertake community conversations*:** To find out what people know and feel about health research, and the places and services they visit in the community for support with their health needs (i.e. for SCD). Techniques learnt include interviewing, focus group discussions and delivering workshops.
***Reviewing community conversations*:** To reflect on the activities and conversations to understand what people know about health research and their views towards it. Over several rounds of conversations about potential hub functions they can build a picture of the most important support needed for health.
Making a collective action plan: Together with the RDN and research team the champions make a plan for the activities and functioning of the hubs while also continuing to improve access to health research opportunities for our SCD community and local public.
Taking action in the local community: As our project is exploratory we have not included training for the champions in actions to implement hubs. This will be included in our subsequent proposal which will highlight the champions role at the centre of the implementation activities.
Reflections workshop: Together with Research Champions involved in other local projects to celebrate achievements, to reflect on the programme overall and to suggest possible improvements.

Phase 2 (months 7-14)

Methodological framework: Delphi process to determine hub functions

Our methodological framework is the Delphi process, a structured technique in three phases (preparing, conducting, and analysing) that facilitates iterative cycles of decision-making by a small group on a complex problem. Delphi is widely used in healthcare settings to generate group consensus (e.g. on hub functions) and to formulate and prioritise recommendations for action (e.g. design of hub intervention).

The Delphi process will be led by the research champions supported by researchers. Each discussion round involves providing controlled feedback of relevant information (including from the survey, literature review, focus group discussions and key informant interviews – see below), joint reflections and refinement of the hub intervention to generate consensus while also avoiding 'groupthink'. Various techniques will be used for the discussions (e.g. initially idea generation with ranking/prioritisation as the focus narrows) which will be a combination of face-to-face and virtual. Participants will gradually build up an agreed prioritised and justified list of hub functions, potential venues where they could be located, and evaluation metrics (Box 3).

There is little evidence to guide the optimal number of participants for the Delphi process, but to minimise bias and gain multiple perspectives, the Delphi participants will be 8-10 individuals drawn from health service users (SCD community), health providers and academics to maximise the participants' diversity. We propose 3-4 Delphi consultation rounds because at least three rounds are needed to check the stability of the responses.

Box 3: Published examples of potential evaluation approaches for measuring hubs' impact and changes in research engagement by the SCD community

- Emergency hospital SCD admission trends
- Adherence to scheduled appointments/medications/tests
- Quality of life questionnaire ((e.g. lifestyle ASCQ-Me and function SF-36)
- Adapt published evaluation approaches for SCD community projects (e.g. 'community SCD health ambassadors', i.e. research champions) *toolkit* (measuring engagement in research and self-management) and a *framework* for assessing community based participatory research41 covering participants' diversity, community SCD contacts, extent and duration of patients involvement, and diversity of engagement methods.

Enhancing Delphi information through focus group discussions (FGD) and key informant interviews (KII

To achieve a broader range of inputs to our research questions and to extend the opportunity for more community members to be engaged in the research, we will hold group FGDs and ~5-6 KIIs - e.g. SCD clinicians, GPs, social services, local government, citizens advice, clinical educators). Information from these will feed into the Delphi process. **Two sets of FGDs** will be held – one between Delphi rounds 1 and 2, and one between rounds 2 and 3. Each set of FGDs will involve **four focus groups** constituted as follows: parents of older transitioning children; students; male and female SCD patients (total ~24 participants).

The qualitative data from our FGDs and KII will be analysed jointly by the research champions and academics and summarised for feeding into the rounds of Delphi discussions. Quantitative data (e.g. from the survey) will be presented as summary descriptive statistics.

End-of-project activities (months 13-14)

Final activities will be a co-analysis and reflection of all findings among the champions and research team, and production of the consensus hub intervention for trialling and scaling up in a future tier 2 study. Materials will be prepared and disseminated in diverse formats, and reports and publications drafted. The project process and agreed hub intervention (e.g. potential sickle hubs' locations, functions, operation and evaluation) will be shared at an **interactive end-of-project workshop**. This will include a wide range of stakeholders including the project advisory team, all Delphi, FGD and KII participants, and other local research champions and 'research ready communities' project teams, GP practice managers, local government representatives and SCD healthcare professionals.

Equality, diversity and inclusion (EDI)

We will welcome all potential research participants irrespective of age, gender, ethnicity, disability and religion. We will document participant and research team EDI data. Research champions will be representative of the diversity of our SCD

community and bring their own lived experience. Once confident, they can design and deliver materials in their own languages which will improve equity and accessibility. Our institutions have EDI policies, standards and good practice. All our applicants and collaborators will abide by these and will have opportunities for training on EDI, research integrity, safeguarding, data management, ethics, general data protection regulation (GDPR) and other research-related topics.

Our proposal has been co-developed with our SCD community, NHS staff and RRDN team. It aligns closely with UK government recommendation5 for better community support to benefit patients and reduce pressure on the NHS. Our focus on Liverpool's SCD community and the north-west (a UK low-income region) complements the UKRI 2022-7 strategies, especially sub-themes on **health inequalities and community connectedness.**

Data Analysis

The scoping review will draw only from secondary data. A narrative synthesis – a summary of key findings within each document and resonant findings emerging across all documents – of documents arising from the rapid scoping review will be carried out.

The patient/carers survey will simply generate categorical data. We will use Stata 15 to generate descriptive statistics. Open text responses will be coded and analysed thematically.

A thematic framework analysis will be carried out for all qualitative data (FGDs, KIIs, Delphi session notes). FGDs and KIIs will be transcribed using a denaturalised approach—transcripts will be non-verbatim. Any data collected in a language other than English will be translated to English and back translated to ensure accuracy of the translated content. The framework will be generated from data collection guides designed to collate key aspects around functioning of the hubs. Inductive codes will be added from reading and familiarisation of the transcripts and notes. All coding and analysis will be assisted using NVivo version 14

Participant sampling and recruitment

The start-up workshop will be advertised through appropriate local networks including hospital SCD clinics, GP practices, student health centres, asylum link RDN local network, SSSN, the Afro-Caribbean centre and Mary Seacole house. The advert will contain relevant study information pertaining to the workshop. Research team members affiliated to these networks will be the first point of contact for workshop attendees replying to the invitation. For example, JB and SE will be the

contact for hospital SCD clinics, GP practices and student health centres; ID will be the contact for asylum link RDN network, FD and SE will be the contact for SSSN and FD, AA_2 and MN will be the contact for the Afro-Caribbean centre and Mary Seacole house. We will be able to accommodate ~ 70-80n workshop participants. This workshop will be informative, no data will be collected, therefore, no informed consent is required.

Participants of the patient/carer survey will be identified and recruited through the LUHFT's system of sending out surveys direct to patients by JB, the SSSN networks and their personal contacts by FD and SE and other relevant, pre-identified organisations by AA_2 and MN. We will invite ~ 200 SCD adult and paediatric transition (15 years and over) patients and their carers and family. This will ensure a diverse representation in age, gender, disease severity of SCD and frequency of hospital visits/admissions. Written informed consent will be obtained before administration of the survey.

Please note that sample size calculations have not been made, because 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 their carers. The recruitment target of 200 is based on an estimated conservative survey response rate of ~30-40%, because we have over 200 sickle cell adult and paediatric patients in our area, and they and their family members (total 400-500) will be invited to participate in the survey.

Participants for the Delphi process, key-informant interviews and focus group discussions will be approached by study team (MN and IB) during the start-up workshops. We will maximise diversity to include SCD health service users, health workers, academics (including clinical educators), the social services, representatives from citizens advice and local councils for the Delphi (~ 8-10) and KIIs (~ 5-6). Where diversity is not reached, we will also carry out a snowball search of participants for further recruitment. Participants for FGDs will include parents of older transitioning children, students, male and female SCD patients (total ~ 24 participants). Written informed consent will be obtained form all potential participants before any data collection by MN and 'research champions'. All participants will be given at least one week to decide on their participation. Delphi, FGDs and KIIs will take place in a private space of choosing of participants or will be conducted online.

Dissemination

How our research will lead to outputs, outcomes and longer-term impact is depicted in our Theory of Change (figure 2) in which **knowledge sharing** is a key cross-cutting theme.

Research outputs ('products')

Our **primary output will be a 'test ready' scalable intervention *i.e. community SCD hubs, with***

recommendations for potential locations and evaluation metrics ready to be trialled across our region (tier 2 application - NIHR-RfPB 2026). Important **secondary outputs** will include:

- A scoping review of the relevant literature
- A cohort of trained and experienced community research champions with sharable training resources relevant for SCD
- A collaboratively-refined Theory of Change (figure 2) to underpin future testing of the intervention
- Improved awareness of SCD across the region and expansion of connections among SCD-relevant community organisations/stakeholders.

Research outcomes

Our anticipated **primary research outcome** is a ***network of community SCD hubs informed by evidence from a subsequent implementation research study*** *(tier 2 proposal)* managed by volunteer coordinators who act as SCD ambassadors and health service 'navigators'.

Secondary outcomes include a ***strengthened SCD advocacy and community outreach and support network*** and ***effective engagement of our SCD community in research.*** The hubs can also be platforms for add-on community-based SCD research such as evaluation of near-patient/self-testing for SCD).

Our **5-year goal** after trialling the hubs is a novel patient-centred and holistic approach to SCD care at the community-health service interface.

Sharing our work and engaging patients, NHS and the wider population

Through the workshops, survey, Delphi participants, FGDs, KIIs and our research team and PAT, we will expand our existing list of potential audiences for our work and determine the most appropriate way and timing for engaging each of them (i.e. a dissemination plan). Many key audiences (e.g. patients, carers, NHS professionals, community organisations) have already been identified through the SSSN and RDN's previous work with our region's marginalized communities (also see 5) and through SSSN's awareness-raising events including local radio, National Museums Liverpool and newsletters.

Target organisations and networks for recruitment and knowledge sharing

Opportunities for participating in various project activities will be shared with the following:

a. Research participation (e.g. research champions, survey, Delphi process, FGDs and KII)

- Organisations/communities identified through RDN's previous mapping exercise for reaching local ethnic minority groups including Asylum link, Liverpool Afro-Caribbean centre, Mary Seacole House, and the Phoenix Way.
- Liverpool Citizen's Advice.
- Members and contacts of the SSSN, SCD patient support group and LSTM's 'knowledge exchange' network of ethnic minority communities in Liverpool.
- Health professionals involved with SCD patients (hospital and GP practices)

b. Final knowledge sharing workshop: those listed in a) plus

- Manchester SCD coordinating centre staff
- Local authority staff involved in NIHR's Health Determinants Research Collaborations
- Academics in clinical haematology and public health across the north-west/nationally

c. **wider dissemination** for mutual learning and sharing of experiences: all those in a) and b) plus

- National SCD support organisations
- RRDN nationally
- UK policy makers
- Internationally through PACTS partners' networks, the SickleinAfrica community and the UK Haemoglobinopathy forum
- British Society for Haematology annual conference49 and peer-reviewed journal publications (e.g. Brit J Haem; HemoSphere)
- Reciprocal representation at meetings of this 'hub' project and the PACTS SCD project in sub-Saharan Africa
- NIHR's initiated research group/centre networking events

How outputs will enter the health system/society

We will use a variety of strategies tailored to each audience listed above including written briefs, social media, training aids, blogs, webinars and conference presentations. We will also engage with our local authority because our outputs are relevant for NIHR's national 'Health Determinants Research Collaborations' programme. This aims to create an evidence-informed culture within local government through collaborations between academics and local authorities (including Liverpool) to improve health outcomes for the public.

Sharing progress and findings with study participants

Study participants are central to our project and engaged throughout as they will be involved in generating and refining our findings through Delphi rounds, focus group discussions and key informant interviews, and in reflective workshops to review progress.

Further funding requirements

The next step will be a tier 2 proposal to test the hub intervention in practice.

Timeline

Gantt Chart - Timeline with key milestones (M) and deliverables (D)

Activity	Months														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Phase 1 (months 0-7)															
Start up															
Contracts and agreements finalised	x	x	D												
Establish project advisory team (PAT)	x	x	x												
Identify SCD 'hot spots'	x	x	x												
Ethics preparation and submission	x	x	x	x	x	x									
Prepare survey/data collection tools/platform	x	x	x	x	x	x									
Scoping review	x	x	x	x	D										
Prepare for designing hub functions															
Survey SCD community				x	x										
Start-up workshop – sensitise public; select research champions, Delphi participants and focus group members			M												
Training of research champions				M											
Delphi rounds				x				x				M			
Review of Delphi and preparation for next round			x	x	x	x	x	x	x	x	x	x			
Phase 2 (months 7-15)															
Survey analysis and report							D								
Prepare for and convene FGDs x4					x	x				x	x				
KII					x	x	x	x	x	x	x	x			
Final knowledge sharing workshop														M	
Management activities															
Monthly management team meetings	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
3-monthly PAT meetings				x			x			x			x		
Dissemination															
Reports, briefs, blogs etc and publication writing				x	x	x	x	x	x	x	x	x	x	x	D

Ethical considerations

NHS Approval has been sought from the NHS Royal Liverpool hospital. Research ethics approval is being sought from the LSTM's Research ethics committee.

The main anticipated ethical risks are associated with potential identification of individuals contributing to surveys and FGDs 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, interview, and FGD 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.

Informed consent

All participants will undergo a process of written informed consent (see **appendices 1 and 2** 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.

Key informants 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.

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, we will hopefully avoid this scenario. The facilitator will regularly remind them of their commitment to privacy and confidentiality throughout, as needed.

Key informant 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.

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. Qualitative data will be transcribed with a second person checking the transcript for accuracy. All personal identifiers will be removed and the transcripts anonymised, with unique identification 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 identification numbers that will be linked to the data. Data will thus be anonymised at the point of upload to cloud storage. No hard copy forms of quantitative data will be collected.

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

Informed consent forms will be scanned, named, and immediately saved in password-protected files. Paper copies will be stored in a good clinical practice (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.

Safeguarding

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

- Our study PI, IB will serve as **safeguarding lead** for the study.
- All members of data collection teams will undergo **safeguarding training** led by IB.
- 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 organisations.
- Study PI, IB and LUHFT liaison, JB will be aware of processes to follow in case any safeguarding concerns are raised during the study including how to access support for gender-based violence, or mental health and medical support, should, for example, inappropriate care be identified and a person living with SCD needs medical or mental health assessment.
- 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.

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. All members of the LSTM team (IB, MN, JP, SC, and ZP) have undergone training on this policy. We will be compliant with this policy throughout this study.

Anticipated risks

To participants

- Asking considerable amounts of time/causing disruption to work patterns, especially for carers, health workers, and other stakeholders (from citizens advice, local councils, academics). Research activities are spread out across 8-10 months, demanding about 4 half-days for Delphi, KII and FGD participants, and 45 – 60 min for survey participants. All activities will be planned with participants to ensure that they are as minimally disruptive as possible.

- People may be identified who are *not* accessing appropriate care. Any person found to not be accessing appropriate care will be liaised with our PI, IB and our LUHFT Liaison, JB who are experts in SCD management for appropriate clinical care.

- Participants discussing/listening to experiences living with/caring for someone with SCD may be distressing. For anyone we encounter who has additional medical or psychosocial needs we will ask for advice from the PI and LUHFT liaison who are experts in SCD management in Liverpool, for appropriate referral mechanisms.

- It is not possible to always maintain confidentiality in focus group discussions and other participatory activities. Participants will be made aware of this, and this will be reflected in the participant information sheets. At the start of group activities, participants will be reminded of the importance of confidentiality, but also not to state things that they may not want the group to be aware of.

- It is not possible to always maintain anonymity for key informants. Participants will be made aware of this, and this will be reflected in the participant information sheets. Key informants will be referred to with the most general titles we can use wherever we may report findings from them. We will confirm with them that they are happy with specific quotations being used.

- Risk of transmission of infectious diseases including COVID-19. We will take all necessary precautions to minimize the risk of transmission of infectious diseases. For example, we will ask anyone with cold symptoms not to attend any group activities in person.

To investigators

- Risk to the investigators will be minimal. Data collection activities will be limited to daylight hours. Research champions will always inform a supervisor where they

will be collecting data. A WhatsApp group will be created between research champions and their supervisor and research lead, to support tracking of activities and check-ins.

To members of the public

- Time required for advert for the start-up workshop and recruitment for the patient/carers survey which will be done through the LUHFT's system of sending out surveys direct to patients may be disruptive to services. We will make arrangements ahead of time with LUHFT to ensure these are done within routine service delivery to make the process as minimally disruptive as possible.

- Poor practices carried out in terms of SCD care may arise. Concerns will be addressed to the study PI and LUHFT liaison who will channel these to the clinical teams.

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, research champions will complete daily debriefs with the RRDN and research lead, MN, after every research activity 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 with SCD patients/carers who are part of the study team. 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.

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Appendices

Appendix 1. Participant Information Sheets

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

Study title: Exploring the design and operation of community health and wellbeing sickle cell hubs ('sickle hubs') to relieve pressure on GPs and hospital services

You are being invited to participate in a study in which we would like to understand how to best design sickle cell disease resource centres or hubs for improving SCD patients' wellbeing, resilience and interaction with health and social services, while also relieving NHS pressures. This study is being carried out by the Liverpool School of Tropical Medicine (LSTM), supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT) and SCD networks that include SCD patients and carers in the Liverpool health area catchment. This study will run from April 2025 to July 2026.

1. What is the purpose of the study?

We believe resource centres or hubs for people living with sickle cell disease will improve their wellbeing and resilience, thereby reducing hospitalizations or hospital visits while relieving pressure from the NHS. Therefore, we are trying to understand how the hubs will look like, where they will be located, what their key functions will be and how they will be run. Our findings will be used to subsequently test the hubs to determine how the hubs can be supported to function optimally.

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 in the Liverpool catchment area. 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 recognizable data that we have collected from you at that point.

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

We will like you to complete a short online survey about your experience living with sickle cell disease/caring for someone with sickle cell disease; and how a community resource centre or hub would be useful to you. Please go through this information sheet and if you wish to participate, sign (or initiate) the consent form before you start answering any questions. You have at least 1 week to make up your mind, during which you can ask any questions you might have. The questions will take a maximum of 30 minutes of your time.

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 how you feel community resource centres or hubs for SCD patients will be helpful to you. 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, you 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 improve the wellbeing and resilience of people living with SCD, and how resource centres can help to realize this.

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 stored in a protected cloud server and only accessible to the principal investigators of this study.

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 Liverpool School of Tropical Medicine (LSTM) supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT).

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 LUHFT 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 Research Ethics Committee of the Liverpool School of Tropical Medicine (LSTM).

12. **Safeguarding**

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM and LUHFT 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, Prof Imelda Bates on Imelda.Bates@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 team in the UK 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 Liverpool School of Tropical Medicine research ethics committee contact below if you have questions about your rights as a study participant or if you have other concerns:

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 investigator and co-investigator:

Study Principal Investigator:

Professor Imelda Bates

Telephone: +44 0151 705 3115

Email: Imelda.bates@lstmed.ac.uk

Study co-investigator:

Doctor Motto Nganda

Telephone: +44 0151 705 3276

Email: Motto.Nganda@lstmed.ac.uk

PARTICIPANT INFORMATION SHEET: Adolescent (15–17-year-old) Patients Living with Sickle Cell Disease/ Carers of Children Living with Sickle Cell Disease (Survey)

Study title: Exploring the design and operation of community health and wellbeing sickle cell hubs ('sickle hubs') to relieve pressure on GPs and hospital services

You are being invited to participate in a study in which we would like to understand how to best design sickle cell disease resource centres or hubs for improving SCD patients' wellbeing, resilience and interaction with health and social services, while also relieving NHS pressures. This study is being carried out by the Liverpool School of Tropical Medicine (LSTM), supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT) and SCD networks that include SCD patients and carers in the Liverpool health area catchment. This study will run from April 2025 to July 2026.

1. What is the purpose of the study?

We believe resource centres or hubs for people living with sickle cell disease will improve their wellbeing and resilience, thereby reducing hospitalizations or hospital visits while relieving pressure from the NHS. Therefore, we are trying to understand how the hubs will look like, where they will be located, what their key functions will be and how they will be run. Our findings will be used to subsequently test the hubs to determine how the hubs can be supported to function optimally.

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 in the Liverpool catchment area. 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/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 recognizable data that we have collected from you at that point.

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

We will like you to complete a short online survey about your experience living with sickle cell disease/caring for someone with sickle cell disease; and how a community resource centre or hub would be useful to you. Please go through this information sheet and if you wish to participate, sign (or initiate) the consent form before you start answering any questions. You have at least 1 week to make up your mind, during which you can ask any questions you might have. The questions will take a maximum of 30 minutes of your time.

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 how you feel community resource centres or hubs for SCD patients will be helpful to you. 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, you 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 improve the wellbeing and resilience of people living with SCD, and how resource centres can help to realize this.

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 stored in a protected cloud server and only accessible to the principal investigators of this study.

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 Liverpool School of Tropical Medicine (LSTM) supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT).

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 LUHFT 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 Research Ethics Committee of the Liverpool School of Tropical Medicine (LSTM).

12. **Safeguarding**

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM and LUHFT 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, Prof Imelda Bates on Imelda.Bates@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 team in the UK 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
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Email: Imelda.bates@lstmed.ac.uk

Study co-investigator:

Doctor Motto Nganda

Telephone: +44 0151 705 3276

Email: Motto.Nganda@lstmed.ac.uk

PARTICIPANT INFORMATION SHEET: Patients (non-students) Living with Sickle Cell Disease

(Focus Group Discussion)

Study title: Exploring the design and operation of community health and wellbeing sickle cell hubs ('sickle hubs') to relieve pressure on GPs and hospital services

You are being invited to participate in a study in which we would like to understand how to best design sickle cell disease resource centres or hubs for improving SCD patients' wellbeing, resilience and interaction with health and social services, while also relieving NHS pressures. This study is being carried out by the Liverpool School of Tropical Medicine (LSTM), supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT) and SCD networks that include SCD patients and carers in the Liverpool health area catchment. This study will run from April 2025 to July 2026.

1. What is the purpose of the study?

We believe resource centres or hubs for people living with sickle cell disease will improve their wellbeing and resilience, thereby reducing hospitalizations or hospital visits while relieving pressure from the NHS. Therefore, we are trying to understand how the hubs will look like, where they will be located, what their key functions will be and how they will be run. Our findings will be used to subsequently test the hubs to determine how the hubs can be supported to function optimally.

2. Why have I been chosen?

You are a person living with sickle cell disease receiving care in the Liverpool catchment area. You therefore have very important insights about your experiences of living 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 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 recognizable 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. 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 how a community resource centre or hub would be useful to you. 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. 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 improve the wellbeing and resilience of people living with SCD, and how resource centres can help to realize this.

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 Liverpool School of Tropical Medicine (LSTM) supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT).

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 LUHFT 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 Research Ethics Committee of the Liverpool School of Tropical Medicine (LSTM).

12. **Safeguarding**

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM and LUHFT 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, Prof Imelda Bates on Imelda.Bates@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 data will be anonymous and stored securely in an online cloud storage, managed through the Liverpool School of Tropical Medicine. Only specific members of the study team in the UK will access this data for analysis. 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 FGD responses. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

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Study co-investigator:

Doctor Motto Nganda

Telephone: +44 0151 705 3276

Email: Motto.Nganda@lstmed.ac.uk

PARTICIPANT INFORMATION SHEET: Patients (students) Living with Sickle Cell Disease

(Focus Group Discussion)

Study title: Exploring the design and operation of community health and wellbeing sickle cell hubs ('sickle hubs') to relieve pressure on GPs and hospital services

You are being invited to participate in a study in which we would like to understand how to best design sickle cell disease resource centres or hubs for improving SCD patients' wellbeing, resilience and interaction with health and social services, while also relieving NHS pressures. This study is being carried out by the Liverpool School of Tropical Medicine (LSTM), supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT) and SCD networks that include SCD patients and carers in the Liverpool health area catchment. This study will run from April 2025 to July 2026.

1. What is the purpose of the study?

We believe resource centres or hubs for people living with sickle cell disease will improve their wellbeing and resilience, thereby reducing hospitalizations or hospital visits while relieving pressure from the NHS. Therefore, we are trying to understand how the hubs will look like, where they will be located, what their key functions will be and how they will be run. Our findings will be used to subsequently test the hubs to determine how the hubs can be supported to function optimally.

2. Why have I been chosen?

You are a student living with sickle cell disease receiving care in the Liverpool catchment area. You therefore have very important insights about your experiences of living with sickle cell disease. As a student, you represent a very important group of sickle cell patients, as you face unique academic challenges — 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 recognizable 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. 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 how a community resource centre or hub would be useful to you. 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. There will also be refreshments (water and other drinks, biscuits, fruits) provided.

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

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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 improve the wellbeing and resilience of people living with SCD, and how resource centres can help to realize this.

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?

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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. A brief with key findings from this survey will be shared with the LUHFT 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?

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12. **Safeguarding**

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13. **What will happen to my data?**

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Study co-investigator:

Doctor Motto Nganda

Telephone: +44 0151 705 3276

Email: Motto.Nganda@lstmed.ac.uk

PARTICIPANT INFORMATION SHEET: Adolescents (15–17-year-olds) Living with Sickle Cell Disease

(Focus Group Discussion)

Study title: Exploring the design and operation of community health and wellbeing sickle cell hubs ('sickle hubs') to relieve pressure on GPs and hospital services

You are being invited to participate in a study in which we would like to understand how to best design sickle cell disease resource centres or hubs for improving SCD patients' wellbeing, resilience and interaction with health and social services, while also relieving NHS pressures. This study is being carried out by the Liverpool School of Tropical Medicine (LSTM), supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT) and SCD networks that include SCD patients and carers in the Liverpool health area catchment. This study will run from April 2025 to July 2026.

1. What is the purpose of the study?

We believe resource centres or hubs for people living with sickle cell disease will improve their wellbeing and resilience, thereby reducing hospitalizations or hospital visits while relieving pressure from the NHS. Therefore, we are trying to understand how the hubs will look like, where they will be located, what their key functions will be and how they will be run. Our findings will be used to subsequently test the hubs to determine how the hubs can be supported to function optimally.

2. Why have I been chosen?

You are a person living with sickle cell disease receiving care in the Liverpool catchment area. You therefore have very important insights about your experiences of living 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 recognizable 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. 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 how a community resource centre or hub would be useful to you. 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. 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 improve the wellbeing and resilience of people living with SCD, and how resource centres can help to realize this.

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 Liverpool School of Tropical Medicine (LSTM) supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT).

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 LUHFT 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?

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12. **Safeguarding**

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13. **What will happen to my data?**

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Study co-investigator:

Doctor Motto Nganda

Telephone: +44 0151 705 3276

Email: Motto.Nganda@lstmed.ac.uk

PARTICIPANT INFORMATION SHEET: Parents of older (15–17-year-olds) transitioning children Living with Sickle Cell Disease

(Focus Group Discussion)

Study title: Exploring the design and operation of community health and wellbeing sickle cell hubs ('sickle hubs') to relieve pressure on GPs and hospital services

You are being invited to participate in a study in which we would like to understand how to best design sickle cell disease resource centres or hubs for improving SCD patients' wellbeing, resilience and interaction with health and social services, while also relieving NHS pressures. This study is being carried out by the Liverpool School of Tropical Medicine (LSTM), supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT) and SCD networks that include SCD patients and carers in the Liverpool health area catchment. This study will run from April 2025 to July 2026.

1. What is the purpose of the study?

We believe resource centres or hubs for people living with sickle cell disease will improve their wellbeing and resilience, thereby reducing hospitalizations or hospital visits while relieving pressure from the NHS. Therefore, we are trying to understand how the hubs will look like, where they will be located, what their key functions will be and how they will be run. Our findings will be used to subsequently test the hubs to determine how the hubs can be supported to function optimally.

2. Why have I been chosen?

You are a parent of a child living with sickle cell disease who is transitioning from paediatric to adult care (15–17-year-olds) in the Liverpool catchment area. You therefore have very important insights about your experiences caring for children with sickle cell disease transitioning from paediatric to adult care. Adolescents represent a very important group of sickle cell patients, as they transition out of paediatric care into adult care—this is a time when a lot of them stop 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 the medical care of your adolescent child 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 recognizable 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 parents of children living with sickle cell disease transitioning from paediatric to adult care. 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 how a community resource centre or hub would be useful to you and your child. 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. 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 improve the wellbeing and resilience of people living with SCD, and how resource centres can help to realize this.

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 Liverpool School of Tropical Medicine (LSTM) supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT).

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 LUHFT 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 Research Ethics Committee of the Liverpool School of Tropical Medicine (LSTM).

12. **Safeguarding**

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM and LUHFT 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, Prof Imelda Bates on Imelda.Bates@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 data will be anonymous and stored securely in an online cloud storage, managed through the Liverpool School of Tropical Medicine. Only specific members of the study team in the UK will access this data for analysis. 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 FGD responses. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

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 Liverpool School of Tropical Medicine research ethics committee contact below if you have questions about your rights as a study participant or if you have other concerns:

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 investigator and co-investigator:

Study Principal Investigator:

Professor Imelda Bates

Telephone: +44 0151 705 3115

Email: Imelda.bates@lstmed.ac.uk

Study co-investigator:

Doctor Motto Nganda

Telephone: +44 0151 705 3276

Email: Motto.Nganda@lstmed.ac.uk

PARTICIPANT INFORMATION SHEET: Delphi process

Study title: Exploring the design and operation of community health and wellbeing sickle cell hubs ('sickle hubs') to relieve pressure on GPs and hospital services

You are being invited to participate in a study in which we would like to understand how to best design sickle cell disease resource centres or hubs for improving SCD patients' wellbeing, resilience and interaction with health and social services, while also relieving NHS pressures. This study is being carried out by the Liverpool School of Tropical Medicine (LSTM), supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT) and SCD networks that include SCD patients and carers in the Liverpool health area catchment. This study will run from April 2025 to July 2026.

1. What is the purpose of the study?

We believe resource centres or hubs for people living with sickle cell disease will improve their wellbeing and resilience, thereby reducing hospitalizations or hospital visits while relieving pressure from the NHS. Therefore, we are trying to understand how the hubs will look like, where they will be located, what their key functions will be and how they will be run. Our findings will be used to subsequently test the hubs to determine how the hubs can be supported to function optimally.

2. Why have I been chosen?

You have unique insights around sickle cell disease management, resource allocation or decision-making and how people living with sickle cell disease are supported in the Liverpool catchment.

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 recognizable 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 series of group discussion and reflections with other stakeholders in the Liverpool area. Before any discussion/reflections begin, we will ensure you

have gone through an informed consent process. After this, as a group, you will be presented with summaries from survey and group discussions on the experiences of people living with sickle cell disease and their carers; and on their reflections on how community resource centres would be useful to them. Based on this, you will be asked to reflect on how such community resource centres or hubs could be used to improve the wellbeing and resilience of people living with sickle cell disease and their carers. This will also include how such hubs would be funded and operated, what their functions would be and what measures should be put in place to assess their impact. This will take a maximum of 90 minutes of your time. We will re-contact you for 2 follow-up discussion/reflection sessions in 4- and 8-months 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. 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 the experiences of people living with sickle cell disease and their carers; and how you feel community resource centres could be implemented to improve wellbeing and resilience of people living with sickle cell disease. 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 improve the wellbeing and resilience of people living with SCD, and how resource centres can help to realize this.

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/reflections 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 Liverpool School of Tropical Medicine (LSTM) supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT).

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 LUHFT 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 Research Ethics Committee of the Liverpool School of Tropical Medicine (LSTM).

12. **Safeguarding**

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM and LUHFT 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, Prof Imelda Bates on Imelda.Bates@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 data will be anonymous and stored securely in an online cloud storage, managed through the Liverpool School of Tropical Medicine. Only specific members of the study team in the UK will access this data for analysis. 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 contribution in the Delphi process. These will be locked in cabinet in a secure office space to which only the study team principal investigators have access.

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
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Telephone: +44 0151 705 3115

Email: Imelda.bates@lstmed.ac.uk

Study co-investigator:

Doctor Motto Nganda

Telephone: +44 0151 705 3276

Email: Motto.Nganda@lstmed.ac.uk

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PARTICIPANT INFORMATION SHEET: Key-informant interviews

Study title: Exploring the design and operation of community health and wellbeing sickle cell hubs ('sickle hubs') to relieve pressure on GPs and hospital services

You are being invited to participate in a study in which we would like to understand how to best design sickle cell disease resource centres or hubs for improving SCD patients' wellbeing, resilience and interaction with health and social services, while also relieving NHS pressures. This study is being carried out by the Liverpool School of Tropical Medicine (LSTM), supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT) and SCD networks that include SCD patients and carers in the Liverpool health area catchment. This study will run from April 2025 to July 2026.

1. What is the purpose of the study?

We believe resource centres or hubs for people living with sickle cell disease will improve their wellbeing and resilience, thereby reducing hospitalizations or hospital visits while relieving pressure from the NHS. Therefore, we are trying to understand how the hubs will look like, where they will be located, what their key functions will be and how they will be run. Our findings will be used to subsequently test the hubs to determine how the hubs can be supported to function optimally.

2. Why have I been chosen?

You have unique insights around sickle cell disease management, resource allocation or decision-making and how people living with sickle cell disease are supported in the Liverpool catchment.

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 recognizable 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 to reflect on how community resource centres or hubs could be used to improve the wellbeing and resilience of people living with sickle cell disease and their

carers. This will also include how such hubs would be funded and operated, what their functions would be and what measures should be put in place to assess their impact. This will take a maximum of 60 minutes of your time and will be carried out in a private location of your chosen, including in 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 how you feel community resource centres could be implemented to improve wellbeing and resilience of people living with sickle cell disease. 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 improve the wellbeing and resilience of people living with SCD, and how resource centres can help to realize this.

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. 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 Liverpool School of Tropical Medicine (LSTM) supported by the Royal Liverpool University Teaching NHS Foundation Trust (LUHFT).

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 LUHFT 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 Research Ethics Committee of the Liverpool School of Tropical Medicine (LSTM).

12. **Safeguarding**

The study team and data collectors are expected to behave ethically and responsibly at all times and follow the LSTM and LUHFT 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, Prof Imelda Bates on Imelda.Bates@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 data will be anonymous and stored securely in an online cloud storage, managed through the Liverpool School of Tropical Medicine. Only specific members of the study team in the UK will access this data for analysis. 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.

Other key points about how your data are handled:

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- 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

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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 investigator and co-investigator:

Study Principal Investigator:

Professor Imelda Bates

Telephone: +44 0151 705 3115

Email: Imelda.bates@lstmed.ac.uk

Study co-investigator:

Doctor Motto Nganda

Telephone: +44 0151 705 3276

Email: Motto.Nganda@lstmed.ac.uk

Appendix 2. Informed Consent Forms

PARTICIPANT CONSENT FORM: Key Informants

Title of Study: Exploring the design and operation of community health and wellbeing sickle cell hubs to relieve pressure on GPs and hospital services

Name of Principal Investigator: Professor Imelda Bates

	Please initiate 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

NHS
Liverpool University Hospitals
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PARTICIPANT CONSENT FORM: Focus group discussion (patients, students, parents of adolescents)

Title of Study: Exploring the design and operation of community health and wellbeing sickle cell hubs to relieve pressure on GPs and hospital services

Name of Principal Investigator: 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

NHS
Liverpool University Hospitals
NHS Foundation Trust

LSTM
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PARTICIPANT ASSENT FORM: Focus group discussion (adolescents15-17-year-olds)

Title of Study: Exploring the design and operation of community health and wellbeing sickle cell hubs to relieve pressure on GPs and hospital services

Name of Principal Investigator: 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 [my dependent will participate in] 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 ASSENT FORM: Survey (adolescents15-17-year-olds)

Title of Study: Exploring the design and operation of community health and wellbeing sickle cell hubs to relieve pressure on GPs and hospital services

Name of Principal Investigator: 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

PARTICIPANT CONSENT FORM: Survey (patients and carers)

Title of Study: Exploring the design and operation of community health and wellbeing sickle cell hubs to relieve pressure on GPs and hospital services

Name of Principal Investigator: 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