Evaluation of pilot hyperacute units to deliver acute sickle cell disease care as part of a wider programme of quality improvement

Protocol

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Evaluation Summary

Title	Evaluation of pilot hyperacute units to deliver acute sickle cell disease care as part of a wider programme of quality improvement
Background	In response to recognition of avoidable deaths and failures of care for people with sickle cell disease (SCD), NHS England is funding a transformation programme to respond to areas of identified need and clinical risk for people affected by sickle cell disease. Nested in this programme is a pilot to implement hyperacute units that people with sickle cell disease can attend when they are in vaso-occlusive crisis. The pilot units aim to be operational 24 hours a day for seven days a week and to operate a triage line (also operating 24/7). These hyperacute units will also interface with other service developments aiming to optimise care for people with sickle cell disease, including the provision of digital care plans (called universal care plans or UCPs). The aim of these units is to deliver optimal care more quicky via contact with specialist health professionals who can ensure the correct level of treatment is administered, preventing further escalation. The pilot will run for two years with implementation and management to be led by local health systems who will be responsible for decisions on on-going service support following the conclusion of the pilot period.
Aims	To meet evidence user requirements, we will conduct a phased evaluation starting in October 2023. An initial six-month scoping period will explore the planned organisation and delivery of hyperacute units. This will be followed by a Phase 1 evaluation of service implementation in which we will gather early insights to maximise learning opportunities and to support early commissioning decisions. Specifically, we will seek to: • Understand the local development of pilot hyperacute units. • Understand how hyperacute unit provision links with other service developments such as digital care plans. • Assess early implementation including professional experience and acceptability. • Assess patient experience and engagement with the new units. • Identify barriers and enablers to patient access and flow. • Map relevant existing data sources and assess data quality for future evaluative focus. We propose a phased approach with phase 1 will allow us to explore early implementation and process outcomes whilst establishing the most suitable source of data for quantitative analysis. Phase 2 will focus on outcomes and will be conditional on the availability of suitable data and successful implementation of the pilot units and through-put of patients.
Design	Multi-site, multi-method evaluation of up to six pilot sites (currently four in London, one in Manchester and one in Sheffield and Leeds (single site)
Timelines	Sense-making, mapping of case sites and governance approvals: Oct 2023 to Mar 2024 Phase 1 evaluation of implementation: March to June 2025 Phase 2 will overlap with Phase 1 and, with agreement could run until December 2025 with the potential of further additional analyses.

Funding	This research is an independent evaluation undertaken by the NIHR Rapid Service Evaluation Team (REVAL). REVAL is funded via a competitive review process by the NIHR Health and Social Care Delivery Research (HSDR) Programme (NIHR151666). The views expressed in this protocol are those of the author(s) and not necessarily those of the NIHR, NHS England or the Department of Health and Social Care.

Evaluation context

Sickle cell disease (SCD) is a genetic condition that affects haemoglobin molecules, in turn impacting the formation of red blood cells. People with SCD have misshaped red blood cells that have difficulties passing through blood capillaries, which can result in them getting stuck. If this happens the red blood cells form clusters that can block the capillaries, resulting in tissue hypoxia and intense pain, referred to as a vaso-occlusive crisis (Bender, 2003). The latest Annual Data Report by the United Kingdom (UK) National Haemoglobinopathy Registry reported that in 2021 there were 12,913 registrations of people with SCD in the UK (Foster, 2021). Most people with SCD in the UK are registered in London (n=8158), with the next largest population in the West Midlands (n=1198), followed by the Northwest (n=908) (Foster, 2021).

In 2021 the All-Party Parliamentary Group on Sickle Cell and Thalassaemia (SCTAPPG) published the 'No One's Listening' report, an inquiry into avoidable deaths and failures for people affected by SCD in secondary care (SCTAPPG, 2021). This report was triggered by the coroner's report into the death of SCD patient Evan Nathan Smith in North Middlesex hospital. The report concluded that the 21-year-old would not have died if medical staff had recognised his SCD symptoms and treated him appropriately sooner. The SCTAPPG report emphasised a pattern of ingrained and longstanding sub-standard care for people with SCD, with health systems accused of stigmatisation and failure to prioritise SCD health and care services. These on-going issues were cited as leading people with SCD to have lost trust in the healthcare system (SCTAPPG, 2021). These issues have been identified in the United States of America (USA) as well, where a 2019 review regarding health disparities in SCD care showed that access to appropriate care was a major challenge, with people with SCD experiencing more difficulties in obtaining medication for pain relief than people with other chronic diseases (Lee, 2019).

In the UK there are National Institute for Health and Care Excellence (NICE) quality standards covering the management of acute painful episodes of sickle cell disease in hospital (NICE, 2012). Standards include the timely provision of pain medication during crisis. A purported factor inhibiting the meeting of standards is a lack of coordinated SCD care from staff with appropriate knowledge, and failure to alert haematology teams to the arrival of people with SCD in crisis in emergency settings (SCTAPPG, 2021). A 2019 qualitative UK study reported that people with SCD have no problems with routine haematology clinic appointments, but when patients attended emergency departments or general wards, they experienced delays in receiving analgesia and felt ignored and abandoned by staff who seemed to disregard their pain (Lee, 2019). In a 2018 study, less than half of participants, all of whom had SCD or cared for someone with SCD, thought healthcare professionals in planned care settings have sufficient knowledge about SCD or that staff in emergency settings knew enough about their condition (Chakravorty, 2018). In another UK study, people with SCD described situations where they felt forced to exacerbate already severe symptoms to ensure they received the pain medication that the need (Renedo, 2019). Negative previous experiences have also been reported to contribute to people with SCD delaying care-seeking; with people trying to manage their condition at home for as long as possible (Jenerette, 2014; Evensen, 2016).

While NICE highlight that people with SCD and their carers should be regarded as experts in their own condition, this often does not happen (SCTAPPG, 2021; NICE 2012). Failure to listen to SCD patients, especially when seeking pain relief for acute vaso-occlusive episodes, is a longstanding

concern (Maxwell, 1999). With SCD primarily affecting people with African or Caribbean heritage, racism is regarded by many to be a key factor in sub-standard care SCD patients receive (SCTAPPG, 2021). Patients report facing scepticism and feel that their pain is downplayed, overlooked, or straight up ignored. Furthermore, people with SCD and the people who care for them report experiences of stigmatisation when seeking pain relief, for example being viewed by health professionals as drug addicts or being treated as a low priority even when suffering extreme pain.

Specialised acute-care focused centres could potentially improve care for those with SCD. NHS England's Sickle Cell Disease Quality Improvement Programme is now intending to address the issues described above through the introduction of up to six pilot hyperacute units for people affected by SCD. The aim of these units is to reduce response times for delivery of pain assessment and medication and enable contact as required with a specialist haematologist who can ensure the correct level of treatment is administered, preventing further escalation. These units are to be rolled out as part of a pilot for a period of two years. The implementation and management of changes to service delivery will be led and overseen by the selected Integrated Care Boards (ICBs) who remain responsible for commissioning acute and community care pathways and will be responsible for the service continuation following the conclusion of the pilots.

The hyperacute unit pilot sits within the transformation programme alongside other core elements, each responding to an area of clinical risk for people affected by sickle cell disease (see Table 1).

Table 1: Summary of risk areas and corresponding core programme delivery elements

Clinical risks for people with sickle cell disease	Responsive programme delivery element
Lack of appropriate care when having a vaso-occlusive crisis	Pilot programme of service transformation to sickle cell disease hyperacute units
Lack of access to optimised and consistent care protocols	Development of accessible digital care plans, called universal care plans
The high cost of prescriptions	Providing support to raise awareness of and access to existing support with prescription costs

REVAL has been commissioned by the National Institute for Health and Care Research (NIHR) to develop and conduct an independent evaluation of the implementation of this SCD work programme, with a primary focus on the pilot hyperacute units for people with sickle cell disease when they are in vaso-occlusive crisis. Given the relevance of accessible digital care plans for the patient group, the evaluation will also consider this element where it seems appropriate. Furthermore, contemporaneously with implementation of these three elements (Table 1), new local activities for people with sickle cell disease are planned for some pilot sites e.g., specialised community nursing provision and peer-to -peer mentoring in London. These additional activities will not be the focus of our evaluation but as they are part of a single transformation programme, we will capture contextual information and any important interactions between the hyperacute units and these wider elements.

Evaluation ethos and guiding principles

Evaluating the implementation of major system change

The introduction of hyperacute units alongside other facets of the SCD transformation programme is considered a major system change as, collectively, there is significant alterations to the way existing care pathways are configured, delivered and experienced with the objective of improving outcomes. Any evaluation of the implementation of a major system change, or elements within this, requires exploration of four core elements – see Figure 1 (text boxed in red), proposed by Fulop et al, 2015. Our evaluation focus will be on boxes 1 to 3 with exploration of elements of box 4.

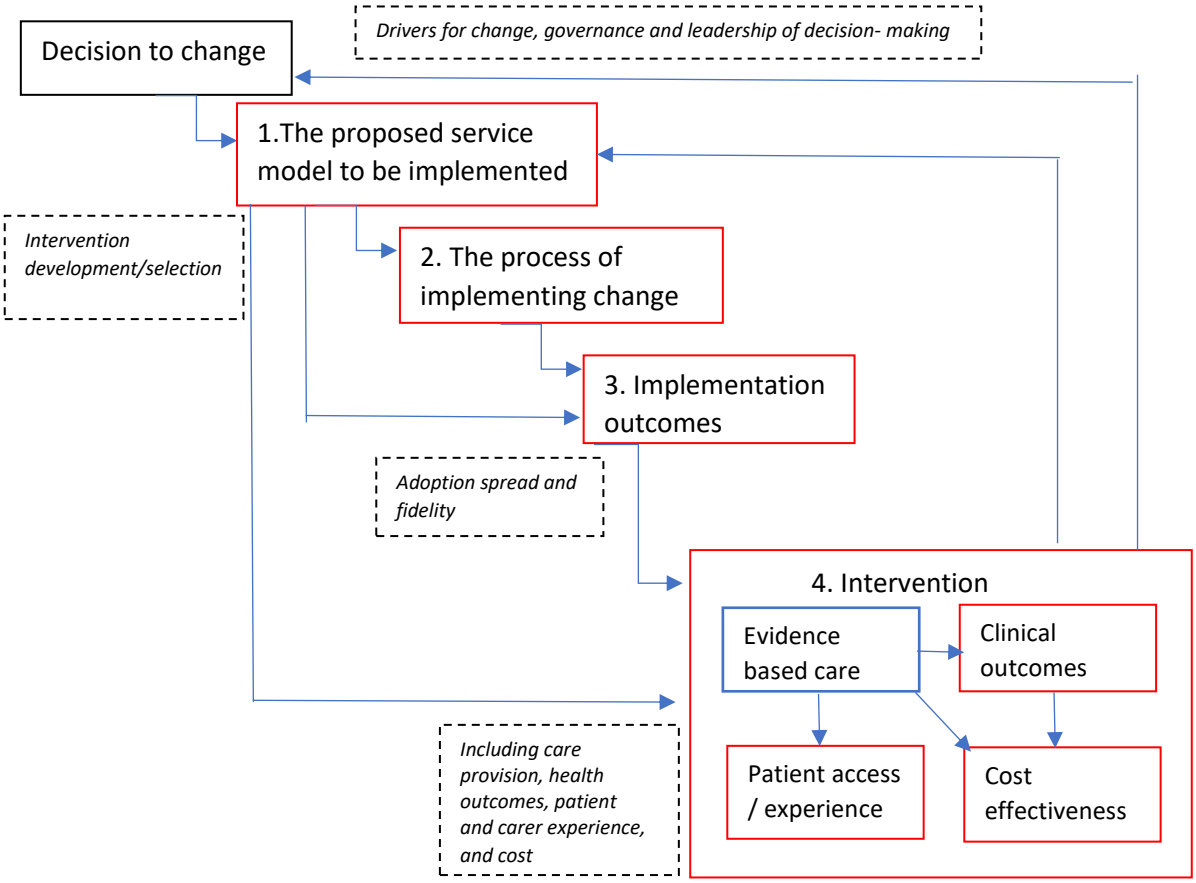


Figure 1: Key components of major system change, adapted from Fulop et al 2015

Theoretically informed evaluation

We undertake theoretically informed evaluation; this approach enables us to offer a more efficient and meaningful method to generalise and predict outcomes and provides a framework to aid replication in other settings. At this stage, we have not pre-specified a single underlying theory or theoretical approach: rather, we will draw on theories relating to major system change (Best et al, 2012), the process of implementation (Consolidated Framework for Implementation Research (CFIR)) and to access and equity (Health Disparities Framework).

Public and community involvement and engagement

We recognise the importance of securing public and community involvement and engagement in the development of this evaluation from the earliest stages. In the very short-term we propose involving one of our programme patient and public facilitators and representatives from the SCD Programme Patient Advisory Group, the Sickle Cell Society, and the Caribbean and African Health Network. This will be the first step and more involvement and engagement will be a priority.

Maximising impact and knowledge mobilisation

To ensure relevance to the needs of the SCD work programme and to maximise the impact and use of evaluation findings, our preference is to actively engage with key stakeholders at all stages of the evaluation process. This ensures we can maximise the relevance of the work, provides opportunities to iteratively feedback insights to inform decision making processes and ensures efficient use of NIHR resources.

Proposed plan of investigation

We are proposing a two-phased evaluation that will:

- provide timely insights into the initial implementation of hyperacute units for people with SCD and
- support quantitative assessment of access and clinical outcome data.

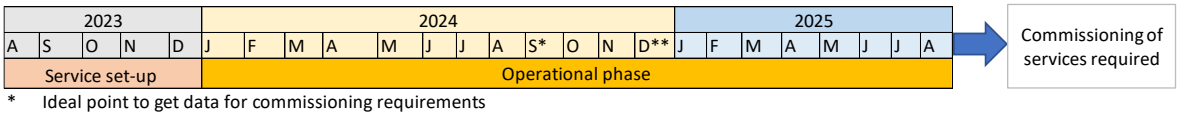
This phased approach recognises that evaluative activity is conditional on (a) successful early implementation of services and (b) availability of relevant quantitative patient-level data.

This protocol details Phase 1 and 2 of the evaluation, which focuses on implementation outcomes, and exploration of available patient level quantitative data needed to explore clinical and cost outcomes.

We suggest this phased approach as it will maximise timely insights and learning opportunities and protects against planning speculative analyses that are not possible given available data. It also allows us to support data collection to allow future evaluation that will be required. This phased approach will ideally produce a single final report but will allow interim findings to be delivered during the evaluation. See also the timetable section for more detail.

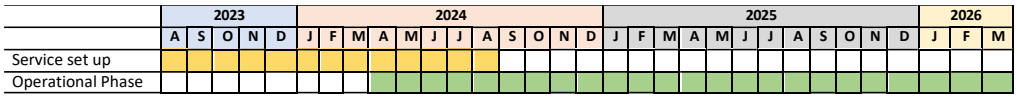
We note that NHS England's timetable at the time of protocol development means that evaluation insights would, from this stakeholder's perspective, before the end of the pilot to inform commissioning decisions. For reference, the current implementation timetable for the pilot hyperacute units is detailed in Figure 2.

Figure 2: Summarises the pilot plans linked to the timing of insights required to inform post-pilot commissioning submissions.



* Ideal point to get data for commissioning requirements

** Last useful date to get data for comissioning requirements



Commissioning of services required.

Evaluation summary

We suggest a mixed methods evaluation. The overarching aim of this evaluation is to explore how hyperacute units for people with sickle cell disease are being implemented in up to six UK sites and the impacts of this.

We have seven overarching questions we will aim to address. These questions have been informed by the approach taken in the evaluation of reconfigurations of acute stroke services (Fulop, 2013) whilst recognising that this was a large piece of research conducted over several years in contrast with the initial evaluative work being proposed currently.

1. What are the factors influencing the implementation of hyperacute units for people with sickle cell disease in vaso-occlusive crisis?
2. Are hyperacute units offering the model of service delivery that was anticipated and is this acceptable to staff and service users?
3. Are there any unintended consequences or benefits from the implementation of hyperacute units?
4. How does hyperacute activity interface with other service developments such as: staff training and education, enhanced cross setting care communication (including the use of universal digital care plans and other community initiatives)?
5. Can we access or develop a robust quantitative dataset to assess the impact of hyperacute units in terms of clinical impact and a return on investment?
6. Do hyperacute units improve the timely access of people with sickle cell disease in vaso-occlusive crisis to acute care?
7. Do hyperacute units improve people with sickle cell disease's timely access to appropriate pain assessment and medication?

Evaluation plan

Sense-making and mapping of case sites

Timeframe: 6 months – October 2023 to May 2024

We will meet with local leads and other relevant stakeholders for each pilot site to understand the local context for implementation. These sense-making discussions will establish the timelines for implementation and explore local intentions for the design, organisation and delivery of the pilot hyperacute units and surface any local contextual information relating to geographical spread and populations targeted.

These consultations are not formal interviews and are in-confidence for internal purposes only. The information provided will help us (REVAL) shape and frame the data collection for the evaluation phases that follow. We will ask to record the discussions, which will be via Teams, Zoom or the phone, but if individuals would prefer to talk without a recording this will also be possible. If an individual is uncomfortable with the recording process at any time during the discussion, then we will stop the recording. All audio files will be deleted after our note taking process is complete.

To compliment these sense making consultations, we will identify any publicly available documents on SCD generally and on the proposed case sites specifically, including any documents detailing

service specification. We will engage with representatives of the NHS England Sickle Cell Disease Quality Improvement (SCD QI) Programme and other relevant parties to ensure that the evaluation meets future commissioning needs and will maximise the impact and use of findings as they emerge.

This mapping phase will also have a strong focus on speaking with a range of Voluntary, Community and Social Enterprise (VCSE) groups and civil society partners as well as implementation of our standard PCIE plans. This is a clinical area with an established and important VCSE network which is closely engaged with service transformation plans. It is important that mapping reaching into these stakeholder groups to both inform the evaluation and raise awareness of its conduct.

As part of the mapping work, we will also develop a draft logic model (see Appendix 1 for outline draft) for the hyperacute unit element of the service transformation. The model has scope to information elements of the evaluation design as we progress. Whilst we have not noted this further in the protocol, it is implicit that such iteration can occur.

Phase 1a: Service user and staff insights into the implementation and impact of hyperacute units for people with sickle cell disease

Addresses overarching questions 1 to 4

Timeframe: March 2024 to December 2025
In phase 1a we will:

- Describe hyperacute service delivery models including wider active elements such as universal care plans.
- Investigate whether service implementation is being achieved (compared with service specifications and expectations about links with additional elements) and in a way that is acceptable to staff and service users, exploring possible unintended consequences.
- Explore cross working and training and education activity linked to service development and delivery.
- Examine service users' early perceptions and experiences of hyperacute units for their sickle cell disease care?

To understand implementation, experience and acceptability of the pilot hyperacute units from a range of perspectives (as well as exploration of potential spillover effects) we plan to undertake qualitative interviews with a purposive sample of professionals involved in the commissioning, organisation and delivery of hyperacute units and, with a purposive sample of service users accessing and experiencing the new care pathway.

Interviews will be guided by the SCD QI programme service specifications, from sense making discussions with the SCD programme team and other key stakeholders and by relevant theory.

Recruitment of professionals and data collection

The contact details of key informants involved in the delivery of each pilot hyperacute unit will be provided by NHS England's SCD QI programme team. This information is publicly available but as the national programme team hold the most up to date details, this reduces the risk of unnecessary/inappropriate contacts.

Potential participants will then be approached initially by an e-mail invitation from the evaluation team that will include a copy of the participant information sheet and consent form. Those indicating interest in participation will then contact the evaluation team and a dialogue opened to answer any questions and arrange interviews where agreeable, at a time to suit the participant. Verbal consent will be recorded at this point (see below). Snowball sampling will be used to recruit other participants who meet our criteria and are thought to have a perspective on the implementation, delivery or the future commissioning of each hyperacute unit.

Participant interviews will be guided by a topic guide. Broadly, areas covered will be informed by role and the underpinning frameworks and theories guiding the work, including those shaping the exploration of implementation i.e., the CFIR (Damschroder et al. 2022) and the Health Disparities Framework and those supporting or expanding exploration of the implicit or explicit theories of change that have shaped service model delivery.

Service user interviews

We will carry out interviews with service users in each site. These interviews will focus on understanding awareness of, access to and the acceptability and experience of receiving care via this new pathway. The number of service users to be included and the nature and focus of the questions will be further developed and refined in conjunction with our PPI facilitators, third sector organisation representatives and individuals affected by sickle cell disease. Initially we plan to work with the Sickle Cell Society, especially given their involvement in the No-one Listens report alongside local organisations at pilot sites. Areas for exploration informed by information to date are outlined below but will be developed and finalised with patients and public members:

- *How aware are local service users and their families of new service availability?*
- *How acceptable are the new services to local service users and their families?*
- *Are there any perceived positive or negative impacts of new services aimed at people affected by sickle cell disease e.g. in terms of raising awareness and confidence around condition management and navigating services or increasing time taken to access services?*
- *Do people experience barriers to accessing hyperacute units when they are in crisis, and if so, what are these?*
- *What are the experiences of people receiving care in hyperacute units?*
- *What elements of the new service have worked well, not so well and the reasons why?*

Recruitment of service users and data collection

For service users, potential participants will be identified via the pilot hyperacute units. As our evaluation will be time limited, there will be service users who present elsewhere, who can't access hyperacute units, as well as those affected by the service changes but who may not need to present at the pilot units during the evaluation timelines. Given this, we will also explore opportunities to elicit service users' awareness of access to and perceived acceptability of the service change via community routes, as this will allow us to access perceptions of people eligible to use the unit – but who do not during the evaluation's timelines. There may also be value in soliciting interviews with service users from non-pilot sites to reflect, comparatively, on experiences based on the types and level of service access. We will also explore opportunities for this during the mapping phase.

For those identified via the pilot hyperacute units, the local teams will identify those eligible to take part in service user interviews. Eligible service users (those experiencing vaso-occlusive crisis) will be

approached via the local clinical teams, who will pass on information about the study through an invitation letter and ask patients to complete a consent-to-contact form. Once the consent-to-contact form has been completed and returned, the research team will contact the service user and participants to discuss the study and potential participation further.

The interviews, themselves, are likely to be conducted remotely but, where necessary (considering social risk factors), we will facilitate face-to-face interviews. Where interpreters are required, we will assess the cost of local interpretation services to explore the feasibility of using these, ensuring that all required confidentiality and data protection requirements are met.

Each service user interview will be guided by a specific topic guide that will cover topics relevant to the research questions. This will include both positive and negative experiences of the local service, how the model has impacted on service perceptions, experiences and anticipated future service use.

Data analysis and integration

We will adopt a rapid approach to data analysis that is consistent across the proposed pilot sites. Interviews will be audio-recorded with consent, transcribed and thematically analysed using a modified framework approach (Gale 2013). This will involve:

- creating a summary template based on the topic guide, with space provided for other observations, unexpected findings and "key quotations"
- completing the summary template following each interview, using field notes from the interviewer; discussing the analysis as a research team
- iterative refinement of the template as the data collection progresses
- transferring the summary templates to a matrix

The matrix of summarised data provides a structure for analysis and interpretation which is useful for policy research and is well suited to managing large datasets such as this (Gale 2013). This will be iteratively developed as the interviews continue, through discussion at regular analysis meetings, discussions with the SCD programme team and with reference to relevant theory (see guiding principles). Overlaps and distinctions across all groups of participants and across sites will be considered through iterative analysis and constant comparison.

Development of logic model to guide further evaluation

Using insights from the above analysis, we will refine the logic model for the hyperacute unit element of the service transformation developed in the mapping phase. We would seek to do this in a way that takes account of the multiple perspectives of those involved in delivering and accessing the pilot hyperacute units. This will then be used to guide the outcomes analysis to be undertaken in phase 2 and any future assessment and or evaluation beyond the auspices of this current work.

Phase 1a Deliverables

We will maximise the impact and use of the evaluation findings and will iteratively feedback insights to inform decision making processes as they occur. Deliverables at the end of Phase 1 should include:

- Learning from the process of implementation and service refinement at each of pilot site
- Service user perspectives on awareness of, access to and experience of the new units
- Professional experience and acceptability of and on optimising new models of care delivery
- Wider impacts of the units on staff interactions, education and training
- Any identified barriers and enablers to patient access and flow

Ethics and governance for Phase 1a

Informed consent

All potential research respondents who are recruited for interviews will receive verbal and written information (participant information sheet) regarding the study and will be encouraged to ask questions prior to taking part. It will be made clear that participation is purely voluntary and respondents are able to withdraw from the study at any time, without giving a reason. We will obtain verbal consent before undertaking the telephone or Teams/Zoom interview which we will audio-record separately to the interview audio-recording.

Confidentiality, anonymity and data protection

With consent, all interviews will be audio-recorded using a secure University provided encrypted audio device. We will follow the University of Manchester's standard operating procedure for taking recordings of participants for research purposes: http://documents.manchester.ac.uk/display.aspx?DocID=38446). Recordings of the consent process and interviews will be transferred from the device as soon as possible to secure University servers (so that de-identified data is stored separately to consent data) and then deleted from the device. Consent recordings will be stored on the University's secure servers for 5 years. Transcription of audio-recordings will be undertaken by a University of Manchester approved external transcription company. Audio recordings will be uploaded to the transcription company via a secure server. We will remove any personal identifying information (such as names, places) from transcriptions once they are returned. We will securely destroy the audio-recording of each interview, once an interview has been transcribed and the research team has checked the transcription for accuracy.

Once a respondent enters the study, they will be provided with a unique identifier. This means that data including field notes, audio recordings, transcriptions and demographic data will be identified only by their unique identifier and not the name of the respondent. The 'pseudonymisation key' to the unique identifier and respondent's details (name, contact details, site and job title), will only be accessible to members of the research team and stored electronically on a University of Manchester secure server, separate to the de-identified data. Data will not be fully anonymised for the duration of the study and the psuedo-anonymisation key will remain in place for the duration of the study. Electronic data (such as digital audio-recordings, transcriptions, field notes, and demographic data) will be stored on a University of Manchester secure server. Hard copies of consent forms and demographic data will be kept in a locked cabinet in a locked room on University premises. Once the study is finished, data will be archived securely for 10 years, after which time it will be securely destroyed.

We are aware of the sensitive nature of this research. The research team has experience in conducting research on similar sensitive topics. We will maintain the anonymity of the participating organisations and individuals and will publish findings that are anonymised and aggregated. Individual participants are assigned a unique numerical identifier and in this instance each organisation will be given a pseudonym.

Service user engagement is necessary to help alignment with national policy drivers and help ensure patient voice and experience remains central to the research. However, this needs to be balanced with a maintenance of confidentiality of potential participants. We will ensure that confidentiality around potential service user involvement is ensured.

Monitoring and Quality Assurance
The study will be subject to the NIHR Evaluation, Trials and Studies Coordinating Centre audit and monitoring requirements stated in the agreed research contract between the Secretary State for Health and Social Care and the University of Manchester. The study will be subject to the audit and monitoring regime of the University of Manchester.

Ethics and governance approvals
The research team will gain appropriate ethical and governance approvals for Phase 1a of the evaluation. The study will be conducted in full conformance with all relevant legal requirements and the principles of the Declaration of Helsinki, Good Clinical Practice (GCP) and the UK Policy Framework for Health and Social Care Research 2017.

Phase 1b: Exploration of quantitative clinical activity and outcome data

Addresses overarching question 5

In Phase 1b we will:

- Assess existing relevant patient-level quantitative data to understand the suitability of data to address questions 5 and 6 (related to clinical access and outcomes).
- Consider whether a minimum data set is needed, and if so, the feasibility and structure of this.
- Consider a suitable measure of service user experience and where in the care pathway this will be given to service users.
- Explore the feasibility of comparative analyses, conditional on the type of quantitative patient-level data that can be secured.
- Consider how available outcome data guide the type of value of investment analyses that may be possible in phase 2.

As part of the planned sense making phase (Oct 2023 to March 2024) and into Phase 1b we will continue exploration with the NHS England SCD QI programme team and other relevant individuals about suitable data sources and access to these. Where possible we will map existing potential data sources and consider data quality and the availability of baseline data for future evaluative focus of this phase.

Below we present early considerations that have informed the decision to include this data feasibility work as part of Phase 1.

Exploration of potential quantitative data sources: routinely collected data

There are two main avenues regarding data sources to address the questions above. The first involves the use of existing routinely collected data. There may be scope to access required data from the Specialised Services Quality dashboard (SSQD) but intelligence from early scoping suggests that this may not be a good data source because of data quality. Other data sources include NHS Hospital Episodes Statistics (HES) data, NHS emergency care dataset (ECDS) and secondary uses service (SUS) data with potential links to Office of National Statistics data i.e., mortality data (see Table 2a). These sources are likely to have data on service access but not about clinical outcomes.

We note that the REVAL team cannot access HES or ECDS now after a hold on our application for programme level access. This application is now active but may take several months to come to fruition. As part of the mapping work, we will continue to explore whether a REVAL analyst can have a short-term honorary contract with NHS England and access data at a local hub e.g. in Leeds, to facilitate data access as required.

An advantage of the use of these routinely collected sources of data is the availability of pre-unit and post-unit data that means assessment of change over time is possible. Analysis of these datasets, if possible, may also facilitate **comparative analysis** with some potential pilot sites that are unable to implement over this time-period or with patients with SCD in geographies not covered by the pilot site.

Exploration of potential quantitative data sources: minimum dataset

The second option is to specify a minimum dataset. There are issues with this option, but during the development of this protocol and the discussions that supported it – a linked draft minimum dataset based on our suggested items has been included in the memorandum of understanding between pilot sites and NHS England (Appendix 2). It is likely that this route of data collection may be the only way to access the information required to inform future decision making about on-going service support. The feasibility of this needs to be assessed with pilot sites.

A further important limitation with a minimum dataset is a potential lack of baseline, or pre-intervention, data, or of non-pilot sites collecting these data. This may limit the assessment of change over time or between comparators. Again, an understanding of any data currently collected at pilot sites will add insights here.

Exploring value of investment

There is a need to consider the return on investment resulting from hyperacute units. This service development will require estate and staff resources – that may not be offset from other areas – thus there may be a net cost to deliver the service. This scenario means the impact of the service on clinical outcomes will be crucial to assess – focusing attention again on the measurement of robust quantitative individual patient-level data. The availability of comparative data is also important here. Thus, exploration in Phase 1b will also consider feasible economic analyses alongside clinical analyses.

Deliverables from phase 1b

- Information required to inform decision making about initiation of phase 2: analyses of quantitative clinical activity and outcome data based on there being an agreed, acceptable and accessible data source to capture clinical activities and outcomes from pilot sites.
- A decision on feasibility of comparative analyses with areas not piloting hyperacute units.
- Where required the development of an extension to the study protocol with a full data analyses plan around how questions 5 and 6.
- Understanding about the value on investment analyses that can be undertaken.

Table 2: Summary of granular Phase 2 questions and requirements of potential data sources

Questions	**Routine data requirements**	**Minimum dataset requirements (used to inform MDS – see appendix 2)**

Individual characteristics of people accessing hyperacute units	**Requirements** Would need to be able to identify people with sickle cell disease in crisis alongside various descriptors.	Standard details
Date and Time of triage	**Requirements** Would need local sites to keep call logs and other triage routes.	**Requirements** Record date and time of call
Nature of triage advice and decision on clinical need	**Requirements** Would need local datasets to record count data on nature of advice/ decision on clinical need.	**Requirements** Count data of standard categories that may include: Ambulance dispatch Attend HAU Refer to primary or community care services Recommend self-care Other
How many people are accessing hyperacute units	**Requirements** Would need HES/SUS/ED datasets to have count data on people with sickle cell disease accessing hyperacute units as a separate setting from ED. Could use postcode to calculate distance travelled. Although would be limited by assumption that patient travelled from home. **Baseline data to assess change** If above data available, could compare these data over time (pre-unit and post unit) in relevant areas. Potential for comparative analyses with contemporaneous controls without units if areas can be identified.	**Requirements** Count data by date and time of people in crisis attending hyperacute units and their postcode.
How many patients seen in an hyperacute unit come via the emergency department, and what are waiting times?	**Requirements** As above. Would require HES/SUS/ED to record point of initial acute presentation and, where this is in ED, track patients to hyperacute unit if redirection takes place. **Baseline data** n/a	**Requirements** Record whether patients attending the hyperacute unit went to ED first: information would come from asking patient or family member directly. Ideally with some assessment of arrival and wait time.
Are patients with sickle cell disease still being treated in emergency departments rather than available hyperacute units?	**Requirements** As above. Would require HES/SUS/ED to record point of initial acute presentation and, where this is in ED, track patients to hyperacute unit if redirection takes place (or does not). As for all these questions, the ability of the datasets to distinguish ED and the hyperacute unit is crucial. **Baseline data** n/a	**Requirements** Ideally to ask ED in areas to record all sickle cell disease crisis contacts. The feasibility of this, as will all elements of the suggested minimum dataset, would need consideration. May rely on patients reporting this in request/health professional knowledge of pathway to HAU.
Do hyperacute units reduce the time taken for a patient to	**Requirements** Would need HES/SUS/ED datasets to hold data that can count people with sickle cell disease accessing hyperacute units, record time of	**Requirements** Time of meds received. This can be combined with presentation time data.

receive pain medications? In what settings are people being given their emergency pain relief?	presentation or triage and time of pain prescription. **Baseline data** If above data available could compare these data over time (pre-unit and post unit) in relevant areas. Potential for comparative analyses with contemporaneous controls without units if areas can be identified.	Also need setting of delivery
How many people are admitted to hospital from hyperacute units, does this figure change over time?	**Requirements** Would need HES/SUS/ED datasets to count admissions for people with sickle cell disease, ideally following hyperacute unit visit. **Baseline data** If above data available could compare these data over time (pre-unit and post unit) in relevant areas. Potential for comparative analyses with contemporaneous controls without units if areas can be identified.	**Requirements** Count data of patients in hyperacute units admitted to hospital
What proportion of people with an acute painful sickle cell episode have their pain relief assessed at least every four hours until discharge or the end of the episode?	**Requirements** Would need HES/SUS/ED datasets to count admissions for people with sickle cell disease, ideally following hyperacute unit visit. **Baseline data** If above data available could compare these data over time (pre-unit and post unit) in relevant areas. Potential for comparative analyses with contemporaneous controls without units if areas can be identified.	**Requirements** Pain score data with frequency of assessment
How long do people admitted from hyperacute units stay in hospital and where in hospital are they admitted to? If not admitted, information on discharge	**Requirements** Length of stay for relevant patients from HES. **Baseline data** If above data available could compare these data over time (pre-unit and post unit) in relevant areas. Potential for comparative analyses with contemporaneous controls without units if areas can be identified.	**Requirements** Date of admission and date of discharge. If not admitted – details of where people discharged to

Once available data are mapped, and an approach decided we will seek approval from NIHR at the noted decision point in the evaluation about the further development and enactment of Phase 2.

Added May 2024 following conduct of phase 1b.

Phase 2: Clinical activity and outcome analysis

In phase 1b we explored the question '*Can we access or develop a robust quantitative dataset to assess the impact of hyperacute units in terms of clinical impact and a return on investment?*' by investigating five areas as detailed in Appendix 3. Exploration suggests that we need to and can develop the required dataset. Based on these insights and associated activities we outline a proposed set of activities for phase 2.

Time frame: 2024 to June 2025, with proposed later analyses in October 2025 once data are available:

In phase 2 we aim to address the following questions, with questions 2.1 and 2.2 included in the original plans (with a change to wording proposed here) and questions 2.3-2.5 added to the protocol at this stage:

2.1 Do hyperacute units **support** the timely access of people with sickle cell disease in vaso-occlusive crisis to acute care?
2.2 Do hyperacute units **support** people with sickle cell disease's timely access to appropriate pain assessment and medication?
2.3 What are inpatient admission rates, length of stay and readmissions rates for people with sickle cell-related vaso-occlusive crisis across England before the introduction of hyperacute units? How can we best analyse changes in these metrics following the introduction of hyperacute units, using hospital episode statistics data?
2.4 What are service user experiences of hyperacute units in terms of general care and timely access to effective pain relief?
2.5 What are the costs of delivering hyperacute units and how do these relate to the consequences (outcomes) observed?

Questions 2.1 and 2.2

These questions will be addressed using distribution of an agreed minimum dataset across pilot sites. (see Appendix 4 for the current version). We recognise that without comparators it will be difficult to quantitatively show improved timely access and pain relief, so we have amended the wording of questions to assess support (rather than improvement). We will, however, continue to explore whether each site has historical data that could allow informal comparison of pre and post hyperacute unit activity e.g., audit data, but is not currently clear that this will be feasible in a consistent way.

Data collection and analyses

Sites will be provided with the minimum dataset data collection tool; this contains material relevant to the evaluation and wider data important for services and NHS England to collect beyond the evaluation. The requirement to complete the dataset forms part of the agreement between NHS England and the pilot sites: thus, the data is routinely collected NHS data rather than research data being collected specifically for this evaluation. Data transfer agreements will be set up with the individual sites, and until such an agreement is in place, sites will provide aggregated information every two months on: number of patients seen in their hyperacute unit, number of research packs distributed, and any challenges experienced with completing the minimum dataset. Challenges will be discussed with sites, and if needed the dataset amended to ensure data collection.

These data will be summarised within and across sites using descriptive statistics to report:

- Numbers and characteristics of those accessing the hyperacute units;
- Routes of access to hyperacute units;
- For those directed to the hyperacute unit: We will present the proportion of patients meeting agreed quality standards for timely access to pain relief and assess the use of effective pain relief by summarise changes in pain scores from triage to ED bypass admission, administration of first analgesia dose and at subsequent pain assessment after 30 minutes;
- We will also summarise where triage processes have been circumvented and people arrive directly at the hyperacute unit from emergency departments and time taken for this to occur and the impact on timely and effective pain-relief;
- We will summarise next steps in the care pathway for those seen in the hyperacute unit.

Question 2.3

We have added in this question as there is interest in how the new hyperacute units may impact on people's wider use of acute services. As outlined in the logic model guiding this work (Appendix 1), a reduction in admission rates and length of stay when admitted as an inpatient are potential medium terms outcomes for the hyperacute units. We propose to use our rapid access to hospital episodes statistics (HES) data to explore this as far as we can within this current evaluation. We have now received most of the HES data we requested, and we are just organising this into accessible and usable sets internally.

The analyses we would ***like*** to do is to compare outcome data on these key metrics before and after the introduction of the hyperacute units. However, we will only get data for 2024/25 after this has been collected, collated, and released to us (likely Sept 2025, although we will continue to monitor this). To lay the groundwork for a future evaluation we will generate the 'before' data and outline the protocol for the comparative 'after' work – exploring the potential use of interrupted time series. We will then look to return to continue the planned 'after' analyses whilst delivering other key findings from phase 1 and 2 activity.

Data collection and analyses

We will access HES data using our approved internal process, which will allow rapid access as these data are now stored at the University of Manchester.

Identification of relevant patient episodes will be primarily via the ICD-10/11 code of D57.1, sickle-cell anaemia with crisis. Index episodes of admission related to this code will be isolated and mapped by time and provider organisation (we currently have access to data from 2017/18 to 2022/23). We will not restrict the cohort by any procedural OPCS-4 code. In the HES cohort, outcomes described will be: duration of index admission; time to first subsequent admission with a sickle cell related diagnosis; rate of subsequent admissions with a sickle cell-related diagnosis. We will then explore data by providers over time and group data into current pilot and non-pilot providers to demonstrate the feasibility of this.

We will explore use of the HES data to examine if there are any differences in outcomes for pilot sites before and after the introduction of the hyperacute units. We will do this using interrupted time

series analyses, using patient level outcomes and clustering at the hospital level. We will also compare relevant data from the minimum dataset with the 'before' HES data.

We will then explore the feasibility of a future analyses to examine differences in outcomes between sites with and without hyperacute units during the pilot period. We will do this by exploring the feasibility of examining patient level outcomes with indicator variables for whether or not the hospital has a hyperacute unit. We will then design an analysis that adjusts for other patient and hospital level confounders in a multivariable multilevel regression analysis, with clustering at the hospital level.

Question 2.4

We will explore this question in part from qualitative data collection in phase 1 of the proposed work. This will be supplemented with questionnaire data from an experience questionnaire that will be distributed by pilot sites in the hyperacute units. See Appendix 5 for a copy of the questionnaire.

Data collection and analyses

The patient experience survey was developed based on the CQC Urgent and Emergency Care Survey for patient experience, the Adult Sickle Cell Quality of Life - Quality of Care (ASCQ-Me QOC), and input from our lived experience advisory panel. It will be distributed to patients upon discharge of the hyperacute unit. The questionnaire can be completed online or in paper format in the participants own time. Return envelopes will be provided, as part of the research information pack, for those completing the survey on paper.

We will present a descriptive analysis (number and percentage of SCD episodes) of questionnaire responses to describe:

- Route to the hyperacute unit and time taken to get to the unit
- Self-reported time taken to receive assessment at the unit
- Patient-reported wait times for pain relief and experience in pain management
- Experience with unit staff
- Overall experiences at the unit

As well as reporting of questionnaire findings, data will be triangulated with minimum dataset information to add additional insight around self-reported access times for units and patient numbers having timely pain relief and pain-relief experiences.

Question 2.5

We have considered several factors in deciding on the most suitable approach to assess costs and how these relate to outcomes that can be measured in this evaluation. We propose undertaking a cost-consequences analysis. Cost-consequence analysis is a form of economic evaluation where disaggregated costs and a range of appropriate outcomes are presented to allow decision makers to make informed judgements on relevance and relative importance to their decision-making context. Outcomes are not limited to health or service utilisation and can include measures of staff and patient experience.

Data collection and analyses

Capturing costs of delivering the service

The costs of the service will cover staff inputs. Staff inputs will be collected from each pilot site. These data will be collected through discussion with lead staff at each site and supported with a survey to gather information if this is required.

Estimates of additional staff time for setting up the service in the first year will also be collected. The staff role and where possible an agenda for change grade will be gathered and expressed in terms of whole-time equivalents for each staff category. Costs will be applied to these resources using the most recent Personal Social Services Research Unit (PSSRU) Cost of Health and Social Care publication and uplifted to current prices.

We will also assess the use of health care resources associated with the service. For example, medications.

The costs of delivering the service will provide insights into the resources required for commissioning whilst also informing any future (patient-level) economic evaluation of the service.

Consequences of the service

Consequences of the service will be reflected using the data presented in response to questions 2.1, 2.2 and 2.4). Consequences here are in the broad sense of measures impacted by the service rather than clinical outcomes.

Integration of costs and consequences

The costs will be summarised and listed together with the consequences identified from questions 2.1, 2.2 and -2.4. The methods and limitations therein will vary accordingly in line with the approaches taken in these parts of the evaluation. This cost-consequences approach will help facilitate understanding of the implications of commissioning the service. This work will also inform the design of a future fuller economic evaluation.

Phase 2 deliverables

Key deliverables from phase 2 are:

- Important insights into hyperacute unit activity in terms of patient numbers and proportions of patients getting timely access to effective pain relief.
- Insights into sickle-cell crisis related inpatient admissions and length of stay across England, prior to the introduction of hyperacute units and an analyses plan for exploration of the impact of hyperacute units on these outcomes when data are available.
- Detailed insights into self-reported patient experience of hyperacute units including timeliness of access, care received and effective and timely pain relief.
- Early insights in the cost of services mapped against the consequences of this investment in term of outcomes assessed across the evaluation in terms of timely access to effective pain relief, patient and staff experiences and in-patient activities.

PCIE

As a team we have committed to ensure that we actively listen to and involve citizens in all aspects of our work. A public, patient involvement and engagement plan for the evaluation has been developed in partnership with our REVAL public contributors.

The research team has formed an initial Public Advisory Panel. Members bring a range of skills, knowledge, and expertise and will ensure that a diverse public voice informs the evaluation that we do and the methods we use. The Advisory Panel model will be iteratively formed reflecting the nature of the evaluation, and we will re-visit the model throughout the course of the evaluation to include additional representation and expertise as necessary. We will consult with the Advisory Panel at regular points during the evaluation lifespan to facilitate ongoing collaboration for input and feedback into the evaluation process, including in the early stages of the evaluation seeking ongoing advice on recruitment approaches, and development of interview topic guides.

Research Team

Jo Dumville/Paul Wilson	**Leads**
Stephanie Gillibrand	**Qualitative and mixed methods oversight**
Maartje Kletter	**Research Associate**
Elaine Harkness	**Data Analysis**
Luke Munford	**Data Analysis**

Proposed advisory panel

Toby Bakare	**Chair**
Marie-Claire Kofi	**Advisory Group Member**
Laurel Brumant	**Advisory Group Member**
Colin Sandiford	**Advisory Group Member**
Lewis Thomas	**Advisory Group Member**
Sabrina Emanuel	**Advisory Group Member**
Patrish Zea	**Advisory Group Member**
Ade Sawyer	**Advisory Group Member**
Anthony Mason	**Advisory Group Member**
Reia Costa	**Advisory Group Member**

Other regular stakeholder meetings

Dr Dianne Addei	Senior Public Health Advisor	Monthly (and more frequently as required)
Ranjit Senghera	Senior Healthcare Inequalities Improvement Policy Delivery Lead	Monthly (and more frequently as required)
John James	Chief Executive, Sickle Cell Society	On request

Zoe Hamilton	Lead commissioner for the Haemoglobinopathies Clinical Reference Group	On request
Sickle Cell Review Phase 2 Steering Group	n/a	On request
NHS England Sickle Cell Disease Patient Advisory Group	n/a	On request

Dissemination and knowledge mobilisation

To ensure relevance to national decision-making need and to maximise the impact and usefulness of findings, we intend to actively engage with key stakeholders at all stages of the research process, not only to ensure efficient use of NIHR resources, but also to maximise the impact and use of findings as they emerge. Our preference is to facilitate this relationship, to provide timely feedback loops to inform decision-making and to provide insights from the evaluation as they emerge during the life of the study. We will do this through maintaining regular contact with the NHS England NHSE Sickle Cell Disease Quality Improvement Programme, and local service providers and the wider system that they are delivering care into as part of the pilot. We will also liaise with relevant VCSE partners. We will maximise opportunities to share early insights with the NHS England team and evidence users more widely throughout the evaluation.

Timeline

Timelines have been amended (Figure 3) in line with the shift in NHS England timelines detailed in Figure 2: as the implementation of the services has been delayed there has been a shift to a later start of data collection. The timeline below details the planned phases – with a decision point about continuation to phase 2 at the end of March 2024. This decision was informed by the pace of service implementation and the insights gathered into available data.

The decision was made to proceed to phase 2 and details have been added to this revised timeline alongside an extension of the main study to December 2025 and scope for additional analyses following this as data continue to accrue.

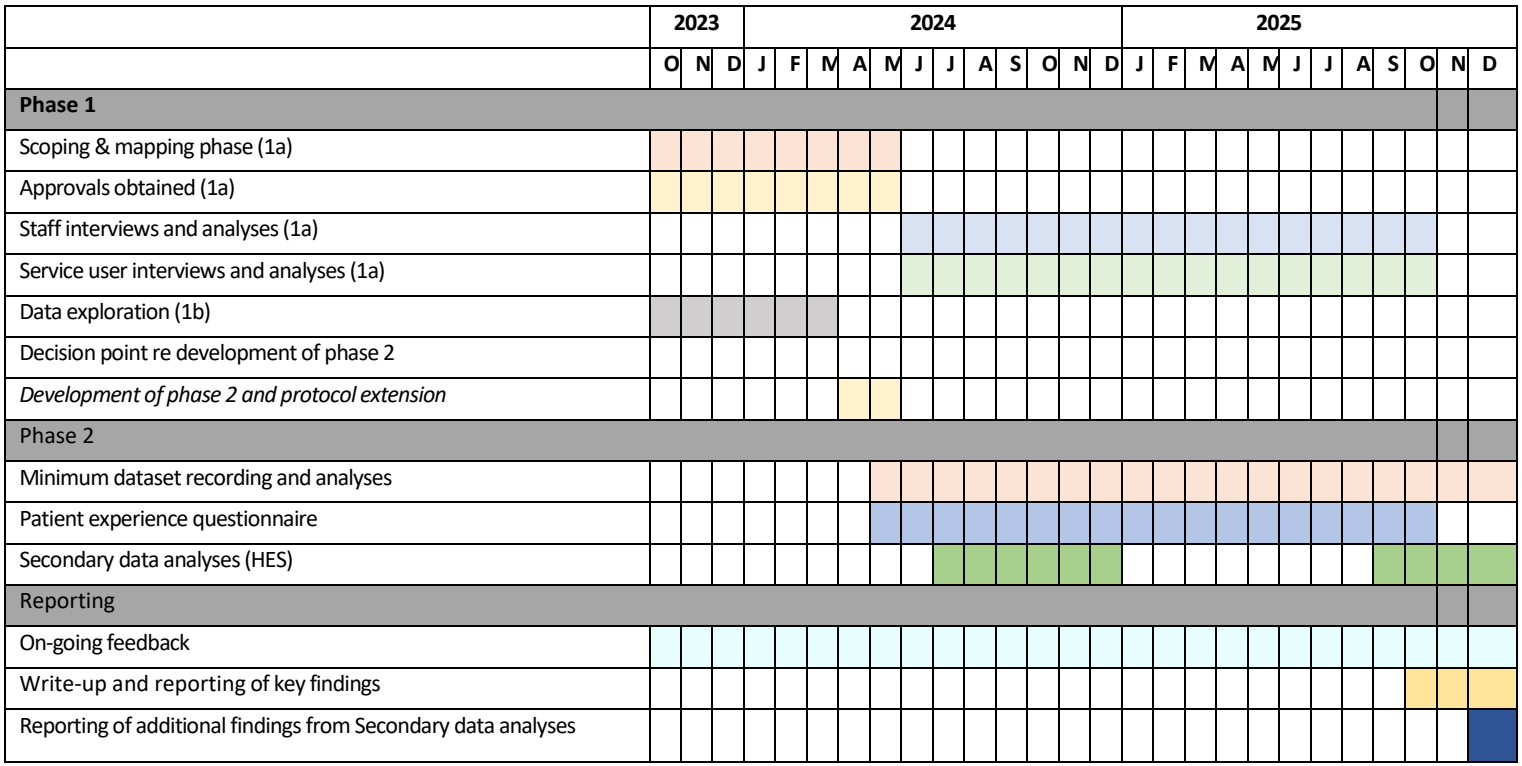


Figure 3: Revised timelines

Statement of Indemnity

The University of Manchester has insurance available in respect of research involving human subjects that provides cover for legal liabilities arising from its actions or those of its staff or supervised students. The University also has insurance available that provides compensation for non-negligent harm to research subjects occasioned in circumstances that are under the control of the University.

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Appendix 1: Working draft of hyperacute unit logic model at time of protocol submission

Assumptions: On-going HAU service funding. Local funding of relevant community-based services. Recruitment of suitable staff. Patient flow into hyperacute units. ICB support. Successful implementation with 24/7 coverage. Service user engagement.

Direct input	Activities	Outputs	Short-term outcomes	Medium/long term
Clinical staff who are knowledgeable about caring for people in VOC 24/7 triage phone line for people in VOC Estate outside A&E (space and beds) to house hyperacute unit VOC care plan and technical capacity to share this across health setting	24/7 emergency advice and support for people in VOC delivered via the triage telephone line 24/7 hyperacute unit, which bypasses of A&E, for people in VOC Accessible, digitally held care information that can be accessed in the hyperacute unit Timely mobilisation of hyperacute unit staff in response to incoming people in VOC Systems that allow rapid administration of pain relief for people in VOC and on-going regular patient assessment Access to timely patient admission as required Engagement with people and communities affected by sickle cell disease	24/7 triage telephone line and in-hospital hyperacute unit are the usual, and direct, point of contact and care for people in VOC. Knowledgeable clinical staff present through the care of people in VOC. Environment that builds staff knowledge of VOC care and the capacity to deliver this Use of digital care plans to support care of people in VOC People in VOC receiving acceptable and appropriate advice and support for home self-care whilst via the triage phone line. People in VOC receiving appropriate assessment, pain relief and wider emergency care, including admission where required.	People in VOC use the triage telephone line as anticipated. Decrease number of noncomplicated VOC patients requiring in-person emergency care People in VOC requiring in-person emergency care bypass A&E and attend the hyperacute unit. People in VOC receive appropriate pain relief within 30 min of care contact People in VOC receive regular assessment of pain and other relevant symptoms Reduced number of people in VOC admitted to hospital because of better earlier management Reduced length of stay for people admitted to hospital Improved patient experience	Improved continuity of care Building of improved service user and community trust in services Reduce risk of death for people in VOC

Appendix 2: Draft minimum dataset developed by REVAL and NHE England – currently undergoing further consultation

Data item	**Definition** From national data source databases dictionaries where appropriate	**Response Options** From national data source databases dictionaries where appropriate
Patient Identifiers		
Patient ID	Pseudonymised NHS Number	
Site ID	Project site code	
Age	Age (10-year bands)	
Patient Post Code	Post Code	
NHS Number		
GP Practice Code	GP Practice Code	
CCG Code	CCG Code at invite	
Patient demographics		
Sex	Sex	Male Female Other
Ethnicity	Ethnicity (as specified by the patient)	White Mixed Asian or Asian British Black or Black British Other Ethnic Groups Prefer not to say
Main Language		Use Main Preferred Language SNOMED CT Codes
Triage		
Referral type		Self-referral Primary care Other community setting Via ambulance ED (or other secondary care)

Triage date		
Triage time		
Triage type		Telephone In-person
Symptoms on triage		Hypoxia Fever Jaundice Nausea
Pain score on triage		VAS or equivalent
Triage outcome		Advised to attend: -HAU -ED -Hot clinic -Other community setting HAU Admission Virtual ward Other
Does patient have a SCD identifying patient card		Yes No Unsure
HAU admission		
Date of HAU admission		
Time of HAU admission		
Did patient present at ED prior to HAU?		Yes No Unsure
If patient did present ED prior to HAU, time of arrival at ED		

Treatment		
Pain score prior to 1st analgesia dose		VAS or equivalent
Setting of Initial pain score assessment		Ambulance ED HAU Other
Patient care plan reviewed to determine treatment?		Yes No Care plan not available
Time initial pain medication administered		
Type of initial pain medication received		List possible analgesia options
Method for administration		IV Oral Patient controlled
Setting where initial pain medication administered		Ambulance ED HAU Other
Pain score 30 minutes after 1st dose analgesia received		VAS or equivalent
Number of pain score reviews during HAU admission		
Other medication received		Laxatives Paracetamol NSAIDS Anti-emetics Anti-diuretics etc
HAU outcome		

Hyperacute unit outcome		Admitted to IP bed Admitted to ICU Discharged to primary care Admitted to virtual ward Discharged to community setting
Date of inpatient hospital admission		
Date of inpatient hospital discharge		
Patient experience questionnaire and consent to contact pack given?		Yes No
Subsequent Treatment/Monitoring Outcomes		
Death within 30 days of hyperacute unit admission		Date
Date of death	From death certificate	
Primary Cause of death	From death certificate	
Placeholder – other (attendance at community settings/ re-admission data)		

Appendix 3: Summary of areas explored in phase 1b, and insights gained

Area explored in phase 1b	Insights and related activities
Assess existing relevant patient-level quantitative data to understand the suitability of data to address questions 5 and 6 (related to clinical access and outcomes).	Through mapping work and a workshop with stakeholders, there was agreement that there was not a current process of data collection embedded in sites that would allow a consistent set of information relevant to this evaluation and wider service-level insights to be collected. It was agreed that specialised services quality dashboard data were partial and not tailored to unit activity. NHS digital-held routine data were also not suitable to record hyperacute unit activity: hospital episode statistics is only relevant for in-patients and there is scope here to explore certain outcomes – but not about unit activity or pain relief. This information is also unlikely to be captured via emergency care data.
Consider whether a minimum data set is needed, and if so, the feasibility and structure of this.	Based on the activities above, it was decided that a minimum dataset was required, and it would be feasible to collect these data at each participant site. The original minimum dataset developed by NHS England has been adapted with a range of stakeholders via a workshop and individual meetings. This is now with NHS England for sign-off and all sites have agreed to collect these data (see Appendix 4 for revised version) We are in the process of obtaining the agreements required for us to access these data.
Consider a suitable measure of service user experience and where in the care pathway this will be given to service users	All stakeholders considered that a measure of patient experience was important. In response to this we have drafted a patient experience questionnaire for use as part of the evaluation, this has been approved as part of ethical review. The questionnaire draws content from existing validated questionnaires, with further input from those with lived experience and adaptions to fit the context we are evaluating. The questionnaire will be given to patients at sites by staff. We have adapted the questionnaires to also contain a consent to contact section, so it will

	support identification and potential recruitment for interview elements of the study. (See appendix 5 for questionnaire)
Explore the feasibility of comparative analyses, conditional on the type of quantitative patient-level data that can be secured.	Our assessment is that comparative analyses will be challenging in the timeframes we have. We are working with one Trust, which does not have a hyperacute unit planned currently, to support data collection using elements of the minimum dataset, but this will only provide a small amount of data. One avenue we where we think we can prepare the ground for comparative analyses is with use of hospital episode statistics data for specific outcomes. We can use these data to explore admission rates, hospital length of stay and short-term, readmission rates following an initial crisis 'before' the introduction of the hyperacute units and develop the approach that can be taken when further 'after' data are available.
Consider how available outcome data guide the type of value of investment analyses that may be possible in phase 2.	Within the current timelines of the rapid evaluation we cannot undertake a full economic evaluation, we propose to present a cost-consequence analyses.

Appendix 4: Revised minimum dataset, under-going final revisions

Data item	Format & length	Definition (from national data source databases dictionaries where appropriate)	Response options (from national data source databases dictionaries where appropriate)
Date of submission	an11 (DD/MM/CCYY)	Date of submission	
Patient Identifiers of people attending the bypass unit			
Patient ID	Numeric	Sequential numbering within site, data will be anonymised	
Site ID	Numeric	Project site code	
Age	select option	Age (in 10-year age band) at time of arrival to ED bypass	<20 20-29 30-39 40-49 50-59 60-69 70-79 80+
Post Code	min an6 max an8	POSTCODE OF USUAL ADDRESS is the POSTCODE of the ADDRESS nominated by the PATIENT where the ADDRESS ASSOCIATION TYPE is National Code 'Main Permanent Residence' or 'Other Permanent Residence'.	
NHS number	n10	The NHS NUMBER, the primary identifier of a PERSON, is a unique identifier for a PATIENT within the NHS in England and Wales.	
GP practice code	an6	Valid ODS code – see the NHS Digital ODS Portal for valid codes. If planned activity has not been agreed at this level, monthly monitoring will not be at this level and the data element should be left blank. Where the POINT OF DELIVERY CODE is one of the non-activity codes or is DRUG or DEVICE this should be left blank.	

ICB code	min an3 max an5	Integrated Care Board (ICB) code. Valid ODS code – see the NHS Digital ODS Portal for valid codes.	
Patient demographics of people attending the bypass unit			
Gender	select option	Gender	Male Female Other
Ethnicity	select option	Ethnicity (as specified by the patient)	White Mixed Asian or Asian British Black or Black British Other Ethnic Groups Prefer not to say
Main Language			Use Main Preferred Language Snomed CT Codes
Does the patient have any communication difficulties	select option	Communication difficulties e.g. learning disability, deaf, blind	Yes No
Is the patient known to the service?	select option		Yes No, out of area No, visiting the UK
Route of access to the bypass unit			
How people accessed the bypass unit	select option	bypass unit access route	Via ED bypass triage line Emergency department GP self-referral/walk-in Ambulance drop off (not via triage line)
***Triage data (for those patients directed to the bypass unit)**			
Triage date	an11 (DD/MM/CCYY)	Date patient triaged	Date

Triage time	an5 (00:00)	Time patient triaged, record using 24-hour clock	time: 24-hour clock
Triage type	select option	Triage type	Telephone In-person Virtual via Local ambulance service
Neurological symptoms	select option	Neurological symptoms e.g. headache, local weakness or numbness, sudden confusion or speech disturbance	Yes No
Respiratory symptoms	select option	Respiratory symptoms e.g. severe chest pain/tightness, shortness of breath, cough	Yes No
Pain score at triage, verbal assessment	n4 (XX.X)	Pain rated from 0 (no pain) to 10 (extreme pain) **at triage**	Rated from 0 to 10 or not recorded
Site of pain	select option	Bodily location of pain	Back Chest Abdomen Limb Other
SCD ID card /alert	select option	Does patient have a Sickle Cell Disease identifying patient card/ alert in any format?	Yes No Unsure
Emergency Department bypass admission			
ED bypass arrival date	an11 (DD/MM/CCYY)	Date patient arrived at ED bypass	Date
ED bypass arrival time	an5 (00:00)	Time patient arrived at ED bypass, record using 24 hour clock	time: 24-hour clock
ED presentation prior to ED bypass	select option	Did the patient present to the Emergency Department prior to ED bypass?	Yes No Unsure
ED arrival time	an5 (00:00)	If patient presented at the Emergency Department prior to Emergency Department bypass enter time of arrival at Emergency Department using 24-hour clock	time: 24-hour clock

Readmission to bypass	select option	Is this a readmission for a previous SCD crisis?	Yes, < 24 hours Yes, > 24 hours but < 1 week No Don't know
New admission	select option	Is this a new admission for a SCD crisis	Yes No Don't know
Pain score on admission to bypass unit, verbal assessment	n4 (XX.X)	Pain rated from 0 (no pain) to 10 (extreme pain) **at admission**	Pain rated from 0 to 10 or not recorded
Symptoms / diagnostics at bypass			
Hypoxia	select option	Low levels of oxygen causing confusion, bluish skin, changes in breathing and heart rate	Yes No
Fever	select option	High temperature over 38C	Yes No
Worsening jaundice	select option	Worsening yellowing of skin or whites of eyes	Yes No
Nausea or vomiting	select option	Nausea or feeling sick or vomiting	Yes No
Respiratory	select option	Respiratory symptoms e.g. chest pain, shortness of breath, cough	Yes No
Other symptoms	free text	Any other symptoms	Please enter as free text
Pain assessment and treatment			
Initial pain score assessment (prior to analgesia)	n4 (XX.X)	Pain rated from 0 (no pain) to 10 (extreme pain) **prior to first analgesia dose**, taken verbally	Pain rated from 0 to 10 or a not recorded option

Location of initial pain score assessment	select option	Setting where initial pain score was assessed	Ambulance Emergency department Emergency department bypass unit Other
Other, location of initial pain score assessment	Free text	Other setting where initial pain score assessed	Other, please specify
Was patient assessed as requiring pain relief?	select option	Need for pain relief	Yes;no
Time initial pain medication	an5 (00:00)	Time initial pain medication administered, record using 24-hour clock	time: 24-hour clock
Initial pain medication type	select option	Type of initial pain medication received (record all relevant)	Morphine Oxycodone Other
Other medication (inititial)	Free text	Give details of any other medication given	Free text
Method for administration (initial administration)	select option	How was medication administered to patient?	IV Subcutaneous Intramuscular Orally Other
Other administration method (initial adminsitration)	Free text	Give details of other administration methods	Other, please specify
Where pain medication administered (initial administration)	select option	Setting where initial pain medication was administered	Ambulance Emergency department Emergency department bypass unit Home Other
Other where administered (initial administration)	free text	Details of other settings where initial pain medication was administered	Other, please specify

Patient care plan reviewed	select option	Was patient care plan reviewed to determine treatment?	Yes No Care plan not available
Pain score 30 minutes after intital analgesia	n4 (XX.X)	Pain rated from 0 (no pain) to 10 (extreme pain) **30 minutes after first analgesia dose**	Pain rated 0 to 10 or not recorded
Time of second administration of pain relief, if relevant	00:00 (24 hour clock)	Time of recorded pain relief	Time 24-hour clock
Pain score assessment (prior to second administration of analgesia)	n4 (XX.X)	Pain rated from 0 (no pain) to 10 (extreme pain) **prior to second analgesia dose**, taken verbally	Pain rated from 0 to 10 or a not recorded option
Location of second administration of pain relief	select option	Location of pain administration	Ambulance Emergency department Emergency department bypass unit Home Other
Type of pain relief (second administration)	Select option	Type of pain relief	Morphine Oxycodone Other
Method for administration (second administration)	select option	How was medication administered to patient?	IV Subcutaneous Intramuscular Orally Other
Pain score 30 min after second administration of pain relief	n4 (XX.X)	Pain rated from 0 (no pain) to 10 (extreme pain) **30 min after second does of analgesia**	Pain rated from 0 to 10 or not recorded

Total number of doses of analgesia given to patient during episode	Number	Number of dose of pain medication given whilst in ED bypass (also including those given in ambulance)	Whole number
No. of pain score assessments whilst in ED bypass	Number	Record the number of pain score assessments during Emergency Department bypass episode	Whole number
Other medications during by pass stay	select option	Record any other medications received whilst in the Emergency Department bypass	Laxatives Paracetamol NSAIDS Anti-emetics Anti-pruritics Other, please specify
Other medications specified	free text	Give details of any other medications administered while in Emergency Department bypass	Free text
ED bypass outcome			
ED bypass outcome	select option	Record outcome of visit to Emergency Department bypass	Inpatient bed: haematology Inpatient bed: general medicine Inpatient bed: other Admitted to critical care Discharged to primary care Admitted to virtual ward Discharged to community setting Discharged home without follow-up Other
Inpatient admission, other	free text	Record other inpatient ward type if admitted	Free text
Date decision discharge	an11 (DD/MM/CCYY)	Date decision made to discharge patient from ED bypass unit	Date
Time decision discharge	an5 (00:00)	Time decision made to discharge patient from ED bypass unit	time: 24-hour clock

Date discharged ED bypass unit	an11 (DD/MM/CCYY)	Date actual discharge from ED bypass unit	Date
Time discharged ED bypass unit	an5 (00:00)	Time actual discharge ED bypass unit	time: 24-hour clock
Date inpatient admission	an11 (DD/MM/CCYY)	Date patient admitted as an inpatient to hospital (if applicable)	Date
Date inpatient discharge	an11 (DD/MM/CCYY)	Date patient discharged from hospital (if applicable)	Date
REVAL pack	select option	REVAL pack containing patient experience questionnaire and consent to contact given to patient?	Yes No
Subsequent Outcomes			
Death within 30 days ED bypass	select option	Record date of death if within 30 days of Emergency Department bypass	Yes No Unsure
Date of death	an11 (DD/MM/CCYY)	Record date of death from death certificate	Date
Cause of death		From death certificate, please list all parts as recorded on the death certificate	ICD codes for all parts of the death certificate
Placeholder – other (attendance at community settings/ re-admission data)			

Appendix 5: Draft service user questionnaire and related introductory materials

Evaluation of emergency department bypass units to deliver sickle cell care.

Questionnaire

Dear Sir/Madam,

We are conducting research to find out how changes in care delivery for people with sickle cell impacts on service user experiences.

We are inviting you to complete this questionnaire about your recent hospital care for a sickle cell related vaso-occlusive crisis.

The questionnaire is focused on your experiences of care, and recent experiences of an emergency department bypass unit for people with sickle cell. This is a service that means you do not go to the emergency department (A&E) but are directed to a separate area in the hospital that is focused on emergency sickle cell care.

The questionnaire will take approximately 20 minutes to complete. Before you decide whether to take part, it is important that you understand what you are being asked to do. Please read the attached Participant Information Sheet carefully.

If you chose to, there are 2 ways you can complete the questionnaire, and you can pick the one that suits you best:

Paper	Online
1. Read the attached Participant Information Sheet	1. Read the attached Participant Information Sheet.
2. Using a pen or pencil, fill in the questionnaire on pages 8-13	2. Using your mobile device, scan the QR Code on page 7
3. If you choose to, add your contact details in the 'Consent to Contact' form	3. Follow the link.
4. Fold the questionnaire, place it inside the pre-paid envelope, and seal it.	4. Follow the onscreen instructions to complete the questionnaire.
5. Post the envelope containing the questionnaire at any post box.	4. If you choose to, add your contact details in the 'Consent to Contact' box.
	5. Click submit.

Who is conducting this research?

This research is being conducted by the REVAL team. The REVAL team are an independent team of researchers based at The University of Manchester, led by Professor Jo Dumville (https://research.manchester.ac.uk/en/persons/jo.dumville).

What is the purpose of this research?

Emergency department bypass units are being tested to see if they improve care for people with sickle cell who are experiencing a vaso-occlusive crisis. These units should allow people to receive timely and appropriate care.

We would like to find out more about your care experiences during your recent visit to the unit. We are collecting data in several ways, including this questionnaire.

What happens if I do not want to take part?

It is up to you to decide whether to take part. You are under no obligation to take part in this questionnaire, and whether you take part or do not take part will have no bearing on the care that you receive. If you do not want to take part you do not need to do anything further.

If I take part, what would I be asked to do?

We would like you to complete the questionnaire that is included with this letter. You can complete the questionnaire at a time of your choosing, either online, or on paper.

If you have received this questionnaire during a previous visit within the last 4 weeks and returned it to us there is no need to do so again. If it has been over 4 weeks since you completed a questionnaire, please consider completing and returning another one to us.

We would like to receive your questionnaire as soon as is possible after your visit. We understand that it might be difficult to remember some details from your visit, especially about how long things took. Any information you can recall is useful. If you were accompanied on your visit, it may be that the friend or family member can recall some of the details about how long it took to access care.

Will I be compensated for taking part?

There will be no paid compensation for taking part in this questionnaire.

What information will you collect about me?

We will collect your responses to the questionnaire. We do not need to collect any information that could identify you, called “personal identifiable information”. If you choose to, you can provide your contact details, specifically, your name, and email address in the ‘Consent to Contact form/box. If you prefer to remain anonymous, simply do not fill the ‘Consent to Contact’ form/box.

Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following ways:

All data is stored in protected areas (both in offices and on computers), which can only be accessed by the REVAL researchers, with approval. You can choose whether you would like to provide your name and contact details. If you do provide these, to protect your personal details we will assign a unique identification number to you straight away, and store these separately from the questionnaire.

What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you. If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research, and our Data Protection, Confidentiality and Further Details page on Data protection and Confidentiality – NHS surveys [ADD LINK]

What happens if I change my mind?

If you decide to take part you are still free to withdraw without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. Therefore, if you have completed the questionnaire and submitted it to us, but then change your mind and do not wish to participate, it will not be possible to remove your data from the project. This does not affect your data protection rights.

Further research activity

There are two research activities that people living with sickle cell can take part in for this project:

1. This questionnaire
2. Interview

If you would like to, you can also take part in an interview with a member of the research team. These individual interviews are an opportunity to discuss your experiences of care on the emergency department bypass unit. The interview would take place at a time of your convenience, over the phone, or using a video call on Teams or Zoom. The interview would last around 60 minutes.

If you would like to find out more information about the interviews, so that you can decide whether it is something you may like to do, please provide your contact details in the consent to contact form attached. A member of the research team will be in touch within *eight* weeks of receiving your form. Please note that if you do supply your personal details, the questionnaire will no longer be anonymous.

If you do not want to take part in the interview, please do not complete the ‘Consent to contact’ form. You can simply complete the questionnaire and return it to us without providing your personal details. This is still very useful to us.

Thank you for helping with our research,

Yours faithfully,

The REVAL Team

Maartje Kletter

maartje.kletter@manchester.ac.uk

How to Complete this Questionnaire

Please answer each question to the best of your ability, based on your recollection of your experience of care during your *most recent* admission to the emergency department bypass, during a sickle cell crisis.

If you have used the bypass unit more than once during the period in which we are conducting this research, you may be offered the opportunity to complete this questionnaire on multiple occasions. Please only complete this questionnaire if you have not done so within the last *4 weeks*.

You may choose from 2 ways to complete the questionnaire:

1. <u>Paper</u>

   Complete the attached questionnaire on paper, using a pen or pencil. Once you have completed the questionnaire, use the attached pre-paid envelope to post your questionnaire to the research team. Please do not hand this questionnaire to the staff at reception, as they will be unable to return it to us.

2. <u>Online</u>

   Complete this questionnaire online by scanning the QR code. This link will take you to the questionnaire on Qualtrics. Fill in your responses, and click submit.

QR CODE

Please only complete this questionnaire once per visit. If you have completed the questionnaire online, you do not need to also complete a paper copy, and vice versa.

Questionnaire

1. **What was the date of your visit to the Emergency Department Bypass unit (dd/mm/yy)?**

   ……/……/……

2. **Before going to this Emergency Department Bypass unit, where did you go to, or contact, for help with your condition? (Cross ALL that apply)**

   ☐ 999 emergency service

   ☐ Emergency Department Bypass unit sickle cell telephone service

   ☐ An A&E department

   ☐ No other contact

   ☐ Somewhere else, (please note)

   ……

   ……

3. **Before your most recent visit to the Emergency Department Bypass unit, had you previously been to the same unit to be treated for a vaso-occlusive crisis? (Please select one response)**

   ☐ Yes

   ☐ No

4. **How long did you have to travel to access the Emergency Department Bypass unit? (Please select one response)**

   ☐ Less than 15 minutes

   ☐ 16-30 minutes

   ☐ 31-60 minutes

   ☐ More than an hour

<u>Access to a health care professional</u>

5. **From the time you arrived at the Emergency Department Bypass unit, how long did you wait before being examined by a doctor or nurse? (Please select one response)**

☐ Less than 15 minutes

☐ 16-30 minutes

☐ 31-60 minutes

☐ More than an hour

<u>Management of your pain</u>

6. **Did you have any pain relief before arriving at the Emergency Department Bypass unit? (Please select all relevant responses)**

☐ No

☐ Yes, at home

☐ Yes, in an ambulance

☐ Yes, other, (please note)

……

……

7. **How long after arriving at the Emergency Department Bypass unit did you have to wait before your sickle cell pain was treated? (Please select one response)**

☐ Less than 15 minutes

☐ 16-30 minutes

☐ 31-60 minutes

☐ More than an hour

8. **To what degree were the doctors and nurses able to help your sickle cell pain? (Please select one response)**

☐ Not at all

☐ A little bit

☐ Somewhat

☐ Quite a bit

☐ Very much

9. Do you think the UEC/ED Bypass unit staff did everything they could to help control your sickle cell pain? (Please select one response)

☐ Yes, definitely

☐ Yes, to some extent

☐ No

☐ Can't say/ don't know

☐ I was not in pain while I was in the Emergency Department Bypass unit

Experience with health care staff in the Emergency Department Bypass unit

10. Were the doctors and nurses in the Emergency Department Bypass unit aware of your personal care plan requirements? (Please select one response)

☐ Yes, definitely

☐ Yes, to some extent

☐ No

☐ I don't have a care plan in place/I don't know about a care plan

11. Did the doctors and nurses listen to what you (or your carer) had to say? (Please select one response)

☐ Yes, definitely

☐ Yes, to some extent

☐ No

☐ I was not well enough discuss my care needs with doctors and nurses

12. If you (or your carer) had any anxieties or fears about your sickle cell crisis, were you able to discuss these with a doctor or nurse? (Please select one response)

☐ Yes, completely

☐ Yes, to some extent

☐ No

☐ I did not have any anxieties or fears

13. Did you have confidence and trust in the doctors and nurses in the Emergency Department Bypass unit examining and treating you? (Please select one response)

☐ Yes, definitely

☐ Yes, to some extent

☐ No

14. Did doctors or nurses in the Emergency Department Bypass unit talk to each other about you as if you weren't there? (Please select one response)

☐ Yes, definitely

☐ Yes, to some extent

☐ No

15. If you needed medical attention, were you able to get a member of the Emergency Department Bypass unit team help you? (Please select one response)

☐ Yes, always

☐ Yes, sometimes

☐ No, I could not find a member of staff to help me

☐ A member of staff was with me all the time

☐ I did not need attention

16. Sometimes, a member of staff will say one thing, and another will say something quite different. Did this happen to you in the Emergency Department Bypass unit? (Please select one response)

☐ Yes, definitely

☐ Yes, to some extent

☐ No

17. **Were you involved as much as you wanted to be in decisions about your care and treatment in the Emergency Department Bypass unit? (Please select one response)**

- ☐ Yes, definitely
- ☐ Yes, to some extent
- ☐ Yes, my carer was involved in decisions about my treatment
- ☐ No
- ☐ I was not well enough to be involved in decisions about my care

Overall experience

18. **During your time in the Emergency Department Bypass unit, did you get enough to drink? (Please select one response)**

- ☐ Yes
- ☐ No, because I did not get enough help to drink
- ☐ No, because I was not given enough to drink
- ☐ No, for another reason
- ☐ I had a hydration drip

19. **During your time in the Emergency Department Bypass unit were you kept warm and comfortable? (Please select one response)**

- ☐ Yes, all of the time
- ☐ Yes, some of the time
- ☐ No

20. **Overall, did you feel you were treated with respect and dignity regarding pain relief requirements while you were in the Emergency Department Bypass unit? (Please select one response)**

- ☐ Yes, all of the time
- ☐ Yes, some of the time
- ☐ No

21. Overall, did you feel you were treated with respect and dignity regarding non pain-related medical care needs while you were in the Emergency Department Bypass unit? (Please select one response)

☐ Yes, all of the time

☐ Yes, some of the time

☐ No

22. Overall... (*please circle one number*) I had a very poor experience/ I had a very good experience

Poor Good

1 2 3 4 5 6 7 8 9 10

<u>After your visit to the Emergency Department Bypass unit</u>

23. Were you admitted to hospital from the Emergency Department Bypass unit?

☐ Yes **(please go to question 23)**

☐ No **(please go to question 24)**

24. If you were admitted to the hospital after attending the Emergency Department Bypass unit, were you offered a pain-relief pump (sometimes called a PCA pump) during your stay?

☐ Yes, all of the time

☐ Yes, some of the time

☐ No

25. In the last 12 months have you had enough support from local services and organisations to help you manage your condition?

☐ Yes, (please note)

☐ No

☐ I did not expect any further care or support after I left the hyperacute unit.

……

……

Thank you for completing this questionnaire.

Please don’t forget to complete the consent to contact form if you are interested in participating in an interview.