Summary Project Outcome

Acute Pain in Sickle Cell Disease: developing a clinical trial protocol to assess treatments for improving care, equity, and equality in care

Project group

- Professor Paul Telfer (PT): Haematologist, Bart's Health NHS Trust and Queen Mary University of London
- Dr Sanne Lugthart (SL): Haematologist, University Hospitals of Bristol
- Dr Kofi Anie (KA): Clinical Psychologist, Brent Sickle Cell & Thalassaemia Centre, London North West University Healthcare NHS Trust
- Dr Stella Kotsiopoulou (SK): Haematologist, Croydon University Hospital
- Dr Sara Stuart-Smith (S S-S): Haematologist, Kings College Hospital
- Ms Carol Burt (CB): Sickle Cell Society and patient representative
- Professor Richard Hooper (RH): Statistician, Pragmatic Clinical Trials Unit, Queen Mary University of London
- Dr Jo Haviland (JH): Statistician, Pragmatic Clinical Trials Unit, Queen Mary University of London
- Professor Borislava Mihaylova (BM): Health Economics, Wolfson Institute of Population Health, Queen Mary University of London
- Dr Esubalew Aseef (EA): Health Economics, Wolfson Institute of Population Health, Queen Mary University of London
- Dr Ben Bloom (BB), Consultant in Emergency Medicine at Royal London Hospital and Honorary Senior Lecturer, Queen Mary University of London
- Dr Laura Aiken (LA), Clinical trials fellow and Haematology SpR, Royal London Hospital
- Dr Stephen Hibbs (SH), PhD student, Queen Mary University of London and Haematology SpR, Royal London Hospital

Patients with sickle cell disease often experience severe pain episodes that require hospital care, including pain relief. However, pain medication is not always administered promptly, leading to poor patient experiences in the hospital. This issue was notably highlighted in the All Party Parliamentary Group report 'No one's listening'.

To address this, the Clinical Reference Group (CRG) for Haemoglobinopathies, which covers red blood cell disorders including sickle cell disease and thalassaemia, established a team of healthcare professionals to investigate ways to improve urgent pain management for sickle cell patients. From this team, a core research group was formed, consisting of four doctors and a psychologist from various NHS hospitals and a patient representative from the Sickle Cell Society. Our project is titled 'Acute Pain in Sickle Cell Disease: Developing a Clinical Trial Protocol to Evaluate Treatment Interventions for Improving Care, Equity, and Equality in Delivery of Care.' We received funding from the NHS Race and Health Observatory.

The primary goals of this project were to create a clinical trial protocol aimed at enhancing the urgent management of sickle cell pain and to identify social and economic factors that impact the health of individuals with sickle cell disease.

We completed several national questionnaires and projects in 2023:

1. We organised a national conference in May 2023 with two experts from the USA to discuss their experience of urgent care for sickle cell disease. One expert, Dr Sophie Lanzkron, MD, MHS, Director, Sickle Cell Centre for adults, The Johns Hopkins Hospital and Professor of Medicine, provided her experience with 'infusion units' which sickle cell patients could attend when in sudden severe pain. The other expert, Dr Paula Tanabe, RN, PhD, Laurel B. Chadwick Distinguished Professor in the Schools of Nursing and Medicine at Duke at the Duke University School of Nursing, clinical and health services researcher, shared results of her Emergency Department protocols and results of a clinical trial of pain management in the Emergency Department. Five UK centres shared details of their day units and Emergency Departments, including the time from the patient arriving at the hospital to receiving the first dose of effective pain relief. Heath care commissioners and patients contributed to the conference. Slides are provided in Appendix 5.

2. We confirmed that urgent pain management often fails to meet the national standard of 100% of patients receiving effective pain relief within 30 minutes of arriving at the hospital (Appendix 6).

3. We found that illness significantly affects the lives of patients and their carers or families, primarily due to income loss, childcare costs, and other external factors like education and employment. This information was collected during a patient focus group in November 2023. In the focus group, ten patients or parents shared their experiences with hospital admissions, career development, and the impact of their illness on their families and loved ones. This information will be utilised in a future study to measure loss of income and quality of life. (Appendix 3 and 4).

4. We completed a literature review of opioid and non-opioid pain relief, as well as supportive treatments that could be offered to patients when experiencing a pain episode. This review was published in 'Blood Reviews' an international scientific journal with the aim to educate doctors worldwide. The review summarised available treatments and pain relief which can be to be offered to patients with sickle cell disease presenting in pain. We included details of how patients experience the health care settings when in pain. The review is a landmark article available to health care workers worldwide (Appendix 1).

5. With support from the Pragmatic Clinical Trial Unit, we developed a draft clinical trial protocol to investigate and compare two health care settings; the Emergency Department and the day unit (or hyper-acute unit) (Appendix 2). We consider that sickle patients cared for in a day unit setting will receive faster and more effective pain relief and have their pain controlled more quickly, and be able to go home or have only a short hospital inpatient stay. We will compare day unit care to the current 'standard' of care, which is the Emergency Department. The trial protocol has been completed by our project group and we hope to get funding to progress with this trial in the near future.

   We have reached out to several hospitals in England, and six have shown interest in participating in our randomised multi-centre clinical trial (Appendix 8). If our findings indicate that care is better in a day unit setting, it could lead to a nationwide shift in practice. This would involve developing specialist day-care units for managing pain episodes in patients with sickle cell disease, particularly in regions with high sickle cell prevalence, instead of relying on Emergency Departments. (Appendix 9).