ISRCTN19529224 https://doi.org/10.1186/ISRCTN19529224

Serial pulse oximetry measurements in primary care to improve triage and referral decisions for children

Submission date
01/10/2026

Recruitment status
Not yet recruiting

Registration date
05/10/2026

Overall study status
Ongoing

Last Edited
05/10/2026

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
To improve child survival, the World Health Organisations Integrated Management of Childhood Illnesses guidelines need to balance inpatient treatment of higher risk moderately hypoxaemic children, whilst not overwhelming the health system with unnecessary referrals of children from primary care. This study will establish how often hypoxaemia spontaneously resolves and describe factors that lead to either spuriously low SpO2 measurements or temporary desaturation that can be managed in outpatient settings. Ultimately, this will facilitate more specific guidelines that minimise burdens associated with referrals and preserve resources within the healthcare system without compromising on access to oxygen for those in need. The aim of the "Serial Oximetry for Improved Triage and Referral" (SOfTeR) study is to improve care and management of children with hypoxaemia who present to primary care facilities in Nigeria and Malawi. This aim will be addressed through answering these specific research questions:
1. What proportion of children who present to outpatient settings with an SpO2 <95% return to a normal oxygen saturation (SpO2 95-100%) within 1 hour?
2. What demographic and clinical factors identify children who present with an SpO2 <95% that returns to normal within 1-hour and within 3-hours?
3. How can triage and referral pathways be adapted to safely manage children in primary care settings who present with an SpO2 <95%?
4. Is a prolonged period of SpO2 monitoring for children in LMIC outpatient settings acceptable to healthcare workers and caregivers?

Who can participate?
The study will involve two types of participants, children and wider healthcare stakeholders. Children will be eligible if they are ≥2 months to <10 years, present to primary care with an acute condition, and have an SpO2<95% as measured by study staff. For wider stakeholders will include caregivers of recruited children, healthcare workers from study facilities, practitioners and implementers, and decision makers, including facility managers, district/LGA or State level decision makers.

What does the study involve?
We will conduct three sub-studies: a) a prospective cohort of children with severe and moderate hypoxaemia who present to primary care facilities; b) a quality-of-care assessment for medical oxygen at the referral facility; c) a qualitative study of the acceptability and potential design of different triage approaches for primary care.

What are the possible benefits and risks of participating?
There are three potential risks for participants, but overall, this should be outweighed by the potential benefit to children and healthcare systems. The first is the conduct of malaria and haemoglobin testing, that requires an invasive blood prick. Malaria RDTs are commonly conducted in both settings, and we estimate that up to 50% of children would have this done as part of routine care (when tests are available). For these children, the study would not pose any additional pain or distress than could be expected as part of standard care. The second risk is the duration of the observation period within primary care, as we will ask caregivers and their child to remain for 1-3hours. We will not stop any child from being immediately referred, but are aware that even in cases of referrals, children can stay at the facility for over an hour. The final is the time-burden on clinical and facility staff, and the risk of taking them away from clinical tasks. To mitigate this we will plan the data collection for a time that is convenient, and will allow for returning visits.

Where is the study run from?
The study will be conducted in Sweden, Malawi and Nigeria, as a research collaboration between Karolinska Institutet Sweden, Oxygen for Life Initiative Nigeria and Centre for Research and Development Institute Malawi.

When is the study starting and how long is it expected to run for?
Recruitment for the study is expected to start in March 2027, and finish by December 2029.

Who is funding the study?
The Swedish Research Council (reference: 2025-02236)

Who is the main contact?
Prof Carina King (carina.king@ki.se, ck2031@bath.ac.uk)

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Prof Carina King

ORCID ID
https://orcid.org/0000-0002-6885-6716

Contact details
Department of Global Public Health,
Tomtebodevägen 18a
Stockholm
Sweden
171 65

+46 793134756
carina.king@ki.se

Additional identifiers

Study information

Scientific Title
Serial oximetry for improved triage and referral of children presenting to primary care

Acronym
SOfTeR

Study objectives
The aim of the “Serial Oximetry for Improved Triage and Referral” (SOfTeR) study is to improve care and management of children with hypoxaemia who present to primary care facilities in Nigeria and Malawi. This aim will be addressed through answering these specific research questions:
1. What proportion of children who present to outpatient settings with an SpO2 <95% return to a normal oxygen saturation SpO2 95-100%) within 1-hour?
2. What demographic and clinical factors identify children who present with an SpO2 <95% that returns to normal within 1-hour and within 3-hours?
3. How can triage and referral pathways be adapted to safely manage children in primary care settings who present with an SpO2 <95%?
4. Is a prolonged period of SpO2 observation for children in LMIC outpatient settings acceptable to healthcare workers and caregivers?

Ethics approval required
Ethics approval required

Ethics approval(s)
Not yet submitted

Primary study design
Observational

Secondary study design
Cohort study

Study type(s)

Health condition(s) or problem(s) studied
Oxygen saturation levels in children a≥2 months to <10 years with an acute illness presenting to primary care

Interventions
We will conduct two sub-studies: a) a prospective cohort of children with severe and moderate hypoxaemia who present to primary care facilities; b) a qualitative study of the acceptability and potential design of different triage approaches for primary care.

a) A prospective cohort of children aged ≥2 months to ≤10 years old, presenting to primary care outpatient settings with an oxygen saturation <95% will be followed to determine if their SpO2 returns to normal (i.e. 95-100%) and how long that takes. Recruited children will be monitored by study staff within facilities for 1-3 hours and then followed-up at 3-days and 14-days to ascertain onward care and survival. The purpose of this cohort is to try and understand which children were incorrectly classified as being hypoxaemic, which children had transient hypoxaemia, and which have persistent of worsening SpO2 values and need referral and hospitalisation.

b) We will use multiple qualitative methods to understand whether a prolonged triage approach or alternative monitoring and referral patient pathways are acceptable, feasible to implement and desirable for healthcare workers, caregivers and wider stakeholders. We will start with stakeholder mapping and consultations, to understand how the process of guideline modifications and revisions are done in each country, and who is involved in the process. This serves multiple purposes: to ensure the right people are invited to co-design, to generate buy-in for the idea of differentiated care pathways, and to provide legitimacy when we discuss with healthcare workers and caregivers. We will then conduct in-depth interviews with caregivers and focus group discussions (FGDs) with healthcare workers, that will inform (alongside findings from sub-study 1), a co-design workshop with key stakeholders in oxygen systems and child health in Nigeria and Malawi.

Intervention Type
Not Specified

Primary outcome(s)
1. Proportion of children who present with an SpO2 <90% who return to a normal oxygen saturation (SpO2 95–100%) measured using study staff measurements with a pulse oximeter at 1-hour

Key secondary outcome(s)
1. Proportion of children who present with an SpO2 90-94% who return to a normal oxygen saturation (SpO2 95–100%) measured using study staff measurements with a pulse oximeter at 10 minutes

2. Proportion of children who present with an SpO2 90-94% who return to a normal oxygen saturation (SpO2 95–100%) measured using study staff measurements with a pulse oximeter at 1-hour, and 3-hours

3. Proportion of children who clinically deteriorate (i.e. develops a new danger sign, or their SpO2 drops by 3% or more) measured using study staff clinical assessment at 1-hour, and 3-hours

4. Proportion of children admitted to hospital measured using follow-up caregiver phone call at day 14

5. Proportion of children treated with oxygen measured using follow-up caregiver phone call at day 14

6. Mortality measured using follow-up caregiver phone call at day 14

Completion date
31/12/2030

Eligibility

Key inclusion criteria
1. Aged ≥2 months to ≤10 years
2. Presenting with an acute suspected infectious illness
3. An SpO2 <95% as measured by trained study staff

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Months

Upper age limit
10 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Aged <2 months or >10 years
2. Presenting for growth monitoring or vaccinations
3. Presenting with trauma
4. An SpO2 95-100% as measured by trained study staff
5. Clinically unstable at the point of recruitment (convulsing, unconscious)

Date of first enrolment
01/03/2027

Date of final enrolment
31/12/2029

Locations

Countries of recruitment
Malawi

Nigeria

Sweden

Study participating centre

Centre for Research and Development Initiative (Ceradi)
Mchinji
Malawi

Study participating centre
Oxygen for Life Initiative
Ibadan
Nigeria

Sponsor information

Organisation
Karolinska Institutet

ROR
https://ror.org/056d84691

Funder(s)

Funder type

Funder Name
Vetenskapsrådet

Alternative Name(s)
Swedish Research Council, VR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Results and Publications

Individual participant data (IPD) sharing plan

Anonymised individual patient level data will be deposited in an open access data repository (details to be added later), with access approved through researcher requests for the first 36 months of study completion to allow for project publications to be completed, and then made fully accessible.

IPD sharing plan summary

Stored in publicly available repository