# **BMJ Open** Technology to improve reliable access to oxygen in Western Uganda: study protocol for a phased implementation trial in neonatal and paediatric wards

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#### ABSTRACT

chnology<br/>access to<br/>Uganda:<br/>a phased<br/>al in neonatal<br/>ds. *BMJ Open*<br/>doi:10.1136/Introduction<br/>Oxygen is an essential medicine for children<br/>and adults. The current systems for its delivery can be<br/>expensive and unreliable in settings where oxygen is<br/>most needed. FREO2 Foundation Australia has developed<br/>an integrated oxygen system, driven by a mains-<br/>powered oxygen concentrator, with the ability to switch<br/>automatically between low-pressure oxygen storage<br/>device and cylinder oxygen in power interruptions. The<br/>aim of this study is to assess the clinical impact and cost-<br/>effectiveness of expanding this system to 20 community<br/>and district hospitals and level IV facilities in Western

Uganda. Methods and analysis This will be a phased implementation with preintervention and postintervention comparison of outcomes. Standardised baseline data collection and needs assessment will be conducted. followed by implementation of the FREO, Oxygen System in combination with pulse oximetry in 1-2 facilities per month over a 16-month period, with a total 23-month data collection period. The primary outcome will be the proportion of hypoxaemic children receiving oxygen pre and post oxygen system. Secondary outcomes will assess clinical, economic and technical aspects. Pre and post oxygen system primary and secondary outcomes will be compared using regression models and standard tests of significance. Useability will be guantitatively and qualitatively evaluated in terms of acceptability, feasibility and appropriateness, using standardised implementation outcome measure tools.

Ethics and dissemination Ethics approval was obtained from Mbarara University of Science and Technology (MUREC 1/7) and the University of Melbourne (2021-14489-13654-2). Outcomes will be presented to the involved facilities, and to representatives of the Ministry of Health, Uganda. Broader dissemination will include publication in peer-reviewed journals and academic conference presentations.

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#### INTRODUCTION

Pneumonia is the single largest infectious cause of death in children worldwide.<sup>1</sup> Children who are poor, malnourished and living in

## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ We will evaluate the use of novel technology to overcome the oxygen access gap in resource constrained settings and add to the toolkit of available technology for affordable and sustainable oxygen access.
- $\Rightarrow \mbox{This expanded programme builds on previous} \label{eq:response} implementation of the $FREO_2$ system in Mbarara Regional Referral Hospital, Western Uganda, and will be managed by a multidisciplinary team of clinicians, engineers and health workers.}$
- ⇒ Implementation will be phased but not randomised. Outcomes are compared within and between facilities at different time points pre and post oxygen system. This allows assessment of the influence of confounders, including time.
- ⇒ The programme has a strong emphasis on strengthening the use of pulse oximetry, training and standardised clinical guidelines for oxygen therapy.

remote areas are most at risk and the burden placed by pneumonia on families and health systems aggravates existing inequalities.<sup>2</sup>

Hypoxaemia-low oxygen levels-complicates respiratory and non-respiratory illness in newborns and children, and significantly increases the risk of a child dying.<sup>34</sup> Pulse oximetry can non-invasively diagnose hypoxaemia, and has been shown to reduce mortality rates and improve measures of quality of care when implemented systematically.<sup>5</sup> Oxygen systems—a suite of interventions aimed at improving the diagnosis and management of hypoxaemia-is a proven intervention shown to reduce pneumonia mortality by up to 35%-50%.<sup>67</sup> Oxygen is included in WHO's essential medicines list,<sup>8</sup> and there is evidence that interventions aimed at detecting and treating hypoxaemia are economically competitive compared with other pneumonia interventions.910

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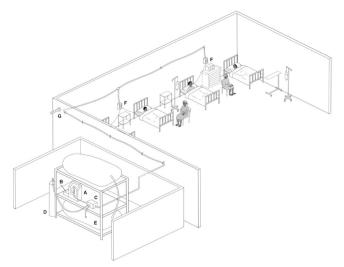
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**Figure 1** FREO<sub>2</sub> oxygen system, consisting of an oxygen concentrator (A), PROTECT—power conditioning system (B), Prioritiser—pneumatic switch that automatically controls oxygen source (C), back-up cylinder (D), low-pressure oxygen storage (E), patient flow-metres (F) and Stack Lamp—traffic light display that communicates the status of the system (G). image reprinted from Peake *et al*, and inspired by a similar illustration by David Woodroffe.<sup>20</sup>

However, the availability and use of oxygen and pulse oximetry continues to be limited globally. A survey of 231 health centres and hospitals in 12 African countries, found only 44% of facilities reporting uninterrupted oxygen access.<sup>11</sup> In Nigeria, while 11/12 studied facilities had some access to oxygen, the majority of this was produced by faulty concentrators and below the recommended oxygen purity.<sup>12</sup> In the same study, because of limitations in use of pulse oximetry, and substandard oxygen, 90% of children who had evidence of hypoxaemia did not receive appropriate oxygen therapy. Globally, there are insufficient detailed data on oxygen access and pulse oximetry to fully understand the breadth and depth of these problems.<sup>13</sup>

Oxygen concentrators, in appropriate settings, can improve the reliability, and reduce ongoing costs of oxygen when compared with cylinders.<sup>14</sup> <sup>15</sup> However, a systematic review of electricity supply in sub-Saharan facilities found that up to 72% of facilities do not have reliable access.<sup>16</sup> Poor-quality grid electrical supply can damage concentrators and shorten their life span.<sup>17</sup> More recent programmes have trialled solar-powered systems, demonstrating cost-effectiveness<sup>10</sup> and mortality reductions in more rural and remote settings.<sup>18</sup>

As an additional tool to improve the applicability, cost and efficiency of concentrators, particularly in rural and isolated facilities, the  $FREO_2$  oxygen system (figure 1) combines a robust oxygen concentrator with a lowpressure oxygen storage (LPOS) device able to store 1400 L of oxygen.<sup>19</sup> When the concentrator stops producing oxygen during a power cut the oxygen begins automatically flowing from the stored oxygen. Should the LPOS Store be emptied during a prolonged power cut, oxygen is automatically recruited from a high-pressure cylinder to continue supply. This control of oxygen source is achieved by a 'Prioritizer device': a pneumatic switch that can automatically switch between concentrator, LPOS and cylinder oxygen without additional intervention from health workers. A traffic light (Stack Lamp) display communicates the status of the system to nursing staff (green=concentrator oxygen, orange=LPOS oxygen, red=back up cylinder oxygen). The oxygen concentrator is connected to a PROTECT device, that conditions the mains power to meet the specific electrical requirements of the concentrator. This system has been recently field tested at the Mbarara Regional Referral Hospital in Uganda.<sup>20</sup>

The  $FREO_2$  oxygen system is designed to require a minimum of maintenance and no direct input from the health workers (other than controlling the flow rate of oxygen to individual patients).

The aim of this study is to expand and evaluate the  $FREO_2$  technology and sustainability model in 20 midlevel facilities in Western Uganda.

#### **METHODS AND ANALYSIS**

This protocol has been written in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement 2013.<sup>21</sup>

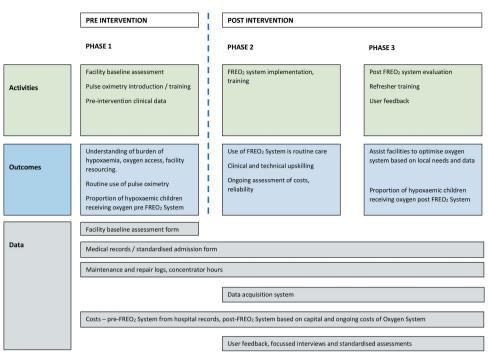
## **Site selection**

Health facilities will be selected based on a number of considerations: (1) oxygen availability in facilities can be improved; (2) facility oxygen needs are significant, and cannot be met sustainably and affordably with primary oxygen sources; (3) there is enthusiasm and supportive leadership within the facility for the programme; (4) geographical proximity to FREO<sub>2</sub> Uganda base and (5) are representative of the type of facilities in Western Uganda (public, private not-for-profit and private for profit).

A facility-selection questionnaire will be sent out by email to 60 facilities, within 90 min driving distance from the  $FREO_2$  office (online supplemental appendix 1). Facility administrators are asked to provide information on case load, infrastructure, human resources and willingness to participate. Eligible facilities are visited, and a baseline assessment (online supplemental appendix 2), using a standardised tool is completed. The assessment collects more detailed information on admissions numbers, pneumonia burden, pre-existing oxygen supplies, access to pulse oximetry, oxygen costs, staffing and biomedical support. Selection and recruitment of facilities is unblinded and non-randomised.

#### Inclusion criteria and enrolment

All neonatal and paediatric (<12 years) admissions to selected health facilities will be included and screened with pulse oximetry. Information on oxygen therapy is collected for admitted children on oxygen. Hypoxaemia,



**Figure 2** Project outline. Blue dotted line represents oxygen system installation. Phase 1 - pre-existing oxygen supplies with improved pulse oximetry and training; phase  $2 - \text{FREO}_2$  oxygen system installation and training; phase 3 - programme evaluation.

and need for oxygen, is defined as oxygen saturation by pulse oximetry  $(\text{SpO}_2) < 90\%$ , based on WHO clinical guidelines.<sup>22</sup> Oxygen administration will follow local guidelines, based on WHO recommendations. We will not exclude children on the basis of age or diagnosis. We will however note when a child presents with a condition that causes non-oxygen responsive hypoxaemia (eg, cyanotic congenital heart disease).

## Consent

The level of intervention is at a health facility level and not at an individual patient level, and all individual patient data are deidentified. Consent will be sought from the health facility administrator/director to eventually augment or replace the existing oxygen supplies with the FREO<sub>2</sub> system. Plain language statements will be made available to all staff and patients using the system.

#### Implementation

## Phase 1: improved detection of hypoxaemia; use of pre-existing oxygen supplies

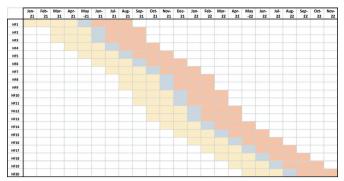
Figure 2 summarises the three project phases. Following baseline assessment, staff will receive refresher training in the diagnosis of hypoxaemia (±provision of pulse oximeters). Prior knowledge and training will be assessed, including a brief pretraining quiz with clinical questions on pulse oximetry and oxygen therapy based on WHO guidelines.<sup>23</sup> Clinical data collection will commence following this training. A standardised admission form (online supplemental appendix 3) is completed by the admitting officer for all admissions (whether or not they require oxygen), with emphasis on documenting whether a child receives oxygen and why, and the presence of any

oxygen and/or power interruptions. Collecting data on all admissions, rather than only for children receiving oxygen, will provide a denominator for calculating hypoxaemia prevalence (overall and disease specific) that can be used by facilities to estimate oxygen requirements moving forward. This phase will occur over the first 3 months for each enrolled facility, with allowance for an additional month for the first enrolled facility to allow learning and adjustment of the data collection tools.

#### Phase 2: FREO<sub>2</sub> oxygen system and oxygen therapy training

The FREO<sub>2</sub> oxygen system will then be installed in each facility. Timing will be staggered to accommodate resource constraints, and to allow for lessons to be learnt (figure 3), with roll-out in 1–2 facilities per month. The project team will combine installation with training in equipment use, refresher of pulse oximetry and oxygen therapy training, and training in data collection.

Equipment installation will be supported by study technicians working alongside health facility staff. The  $FREO_2$  oxygen system will be located away from the patient beds, with low pressure oxygen tubing piped to the bed-side of each patient. Flow is split, with individual patient flow metres at the bed-side, such that one  $FREO_2$  system can supply up to four children simultaneously. The number of systems required by facilities is determined by the case-load, and projected number of hypoxaemic admissions. Based on admission numbers of the level IV facilities in Uganda, and a hypoxaemic prevalence of 10% of all admissions, we expect that one system per facility will be sufficient.



**Figure 3** Projected implementation timeline. Phased implementation of  $FREO_2$  oxygen system in 20 health facilities: yellow (pre oxygen system), blue (installation), red (post oxygen system). Roll-out presented over 15 steps—sequence and timing may be differ from plan. HF, health facility.

Clinical data will continue to be collected for all admissions, using the standardised admission form. In addition, a previously described data acquisition system<sup>19 20</sup> will be deployed at each health facility to enable remote monitoring of oxygen flow rate and purity, pressure within the LPOS and the backup oxygen cylinder, and temperature and humidity. Data will be uploaded to a remote server to assess system performance and facilitate preventative maintenance.

## Phase 3: impact evaluation

Post oxygen system data will be collected for 3 months, in the same way as for the preintervention period, and will begin 2 weeks following equipment installation to account for a 'wash-out' period. The postintervention period for the last enrolled facility is expected to complete in November 2022 (figure 3).

In addition, usability assessments using the described standardised tools (online supplemental appendix 4), and semistructured interviews will be conducted in focused group interview format.<sup>24</sup> Postintervention data collection will be accompanied by refresher training in oxygen therapy.

## **Data collection and management**

Clinical data will be prospectively collected for each facility using the standardised patient admission form for the duration of the study. The form will be filled-in by attending clinicians on the day of admission. On discharge, study personnel will use routine medical records to complete a discharge section, which details discharge diagnosis, duration of oxygen therapy and frequency of pulse oximetry measurements.

Clinical data will be extracted from medical records, deidentified and entered and managed using Research Electronic Data Capture (REDCap) hosted at the University of Melbourne.<sup>25 26</sup> Data are double entered and screened for data entry errors monthly by the study coordinator. Discrepancies are first investigated by referring to the paper form, and if required, by retrieving the child's medical record.

Deidentified paper forms (admission forms) will be stored in a central research facility in Uganda.

On completion the study, finalised, deidentified data will be available from the corresponding author (RS), on reasonable request.

## **Outcomes**

## Health outcomes

There is evidence from large implementation trials for reductions in childhood mortality with implementation of pulse oximetry, and improved oxygen systems. This study does not aim to duplicate these, but rather test whether the FREO<sub>2</sub> oxygen system can improve getting oxygen to children who need it. To test this hypothesis, the primary outcome will be the proportion of hypoxaemic children receiving oxygen pre and post oxygen system. Hypoxaemia is defined as SpO2 <90% either on admission or during hospital stay.

Secondary clinical outcomes will be compared pre and post oxygen system:

- Overall, pneumonia and neonatal (age <28 days) mortality pre and post FREO<sub>9</sub> oxygen system.
- Duration of oxygen therapy per patient pre and post FREO<sub>9</sub> oxygen system.
- ► Length of stay pre and post FREO<sub>9</sub> oxygen system.
- Estimated amount of oxygen used per patient pre and post FREO<sub>2</sub> oxygen system.

## **Technical and systems outcomes**

- Pre-FREO<sub>9</sub> oxygen system:
  - Number and duration of power and/or oxygen outages or interruptions, and reasons.
  - Estimated oxygen use and amount of cylinders used.
  - Oxygen purity produced by concentrators.
  - Capacity for replenishment, maintenance and repair of existing oxygen supplies.
- Post-FREO<sub>9</sub> oxygen system:
  - Number and nature of failure events that could compromise oxygen access to a hypoxaemic child.
  - Frequency, extent and duration of power outages/ overvoltage.
  - Amount of oxygen delivered from LPOS device.
  - Equipment malfunctioning, maintenance and repair.
  - Amount of oxygen use and estimated amount of cylinder oxygen use.
  - Delivered oxygen purity.

#### Economic outcomes

All costing data for each given facility will be logged to project-specific forms by the person making the expenditure at the time the expense is incurred and recorded. The project will aim to collate initial outlay, running costs, and incidental costs. The cost to avert one hypoxaemic child not receiving oxygen because of unavailability will be calculated by dividing the total cost of the system by the additional number of hypoxaemic children accessing oxygen.

Secondary outcomes:

- Cost of oxygen per litre and per patient pre and post oxygen system.
- Cost of oxygen per litre over time.
- ► Capital expenditure.
- Running costs.

## Usability assessment

Standardised implementation outcome measure tools will be used: the acceptability of intervention measure, intervention appropriateness measure and the feasibility of intervention measure in the postintervention phase (online supplemental appendix 4).<sup>27</sup>

In addition, semistructured interviews will be conducted with health workers and health administrators in the post implementation period. Health worker interviews will capture user attitudes towards the intervention and the implementation model, including the training modules.

#### Sample size

Although the study design is non-randomised, sample size and power calculations were based on methods for stepped wedge cluster randomised trials, using the Stata17 program 'stepped wedge' to calculate power based on our anticipated timeline.<sup>28 29</sup> We assumed baseline oxygen deliver to at least 50% of hypoxaemic children and an improvement in this proportion to at least 80% post introduction of the FREO<sub>9</sub> system. We conservatively assumed a baseline hypoxaemia prevalence of 10% in all paediatric and neonatal admissions, based on a previous systematic review and a prospective study from Nigeria.<sup>3 30</sup> Recruitment of 4 hypoxaemic admissions per facility per month (or 40 total neonatal and paediatric admissions per month) would be able to detect a 30% improvement in oxygen access with a p value 0.01 and power 0.9. Preliminary facility data shows that these admissions numbers should be achievable.

#### **Statistical analysis**

We will use mixed-effects regression for primary and secondary analyses of effect of the oxygen system enabling comparison between facilities preintervention and postintervention and across time periods. We will analyse individual patient data, with fixed effects for time and intervention and random effects for facility and facility time interaction. Intervention effects will be expressed as an odds ratio with 95% confidence intervals. For the primary outcome, this analysis will aim to detect whether there has been a change in the proportion of hypoxaemic children receiving oxygen pre and post oxygen system. Similarly, we will analyse the impact on overall, pneumonia and neonatal mortality as secondary outcomes. For other economic and technical outcomes, pooled data from all facilities preintervention and postintervention will be compared using standard tests of significance.

## Study personnel

Implementation will be led by an oxygen team, consisting of a paediatric nurse, biomedical engineer, doctor and programme manager. Training is coordinated by clinicians with the Babies and Mother Alive programme of the Brick by Brick Uganda group. Funding is provided to each facility to support clinical staff in assisting with data collection and management.

## Timeline

The study covers a period of 23 months. Data collection will end 3 months after implementation of the Oxygen System in the final facility (projected November 2022; figure 3).

## ETHICS AND DISSEMINATION

Ethics approval was obtained from Mbarara University of Science and Technology (MUREC 1/7) and the University of Melbourne (2021-14489-13654-2).

Results will be shared with participating health facilities in the form of reports and presentations. Facility representatives will be involved in the publication of manuscripts. Outcomes will be presented to the involved facilities, and to representatives of the Ministry of Health. We will also aim for broader dissemination, including publication in peer-reviewed journals and academic conference presentations.

## Patient and public involvement

Patients and the public were not involved in the study design. The Ministry of Health and facility leadership are involved in site selection. Regular informal contact between the study team and involved facilities (clinical and technician staff) will allow adaptation of training and implementation to meet specific needs.

#### **Ethical considerations**

There is a risk that the FREO<sub>2</sub> oxygen system may displace existing oxygen systems (cylinders or concentrators) and deskill facility staff in routine upkeep and maintenance of these systems. To mitigate this, this project will prioritise facilities with poor baseline oxygen supplies, where the intervention is not detracting from already functioning oxygen systems. Pulse oximeters provided in the course of the programme will be the property of health facilities and available to them beyond the programme duration. The FREO<sub>2</sub> system will be supported for an additional 12 months after project completion, while facilities (or the Ministry of Health) choose to either enter into an agreement with FREO2 Uganda to provide ongoing maintenance, training and support for a fee or transition to a different system.

The clinical data collected as part of this project represent information that is expected to be recorded in a thorough routine clinical assessment (eg, vital signs such as heart rate), and is therefore unlikely to represent additional workload on staff. On discharge, study personnel

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will extract relevant clinical data by chart review with no direct interaction with patients. Data collection forms will be deidentified when data are extracted, and all analysis and publication will use the data in deidentified form.

To study the risk of technology failure on oxygen availability, the FREO2 oxygen system has been trialled in Mbarara Regional Referral Hospital.<sup>20</sup> It has proven safe and reliable. To add further layers of safety, embedded within the system is a back-up oxygen cylinder, and an automatic mechanism to shift between oxygen supplies.

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