Evaluating the impact of paediatric operating rooms in low- and middle-income countries: a protocol for a global, multi-centre, prospective and retrospective database study

**KidsOR Research Collaboration:** A global, multi-centre research partnership committed to locally driven and evidence-based collaboration to close the gap in the provision of safe and accessible paediatric surgery in low- and middle-income countries.

**Primary contact**
Please address any study correspondence to the team member listed below

<table>
<thead>
<tr>
<th>Name</th>
<th>Hailey Zislis, MPH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Health Program Evaluation Specialist</td>
</tr>
<tr>
<td>Organisation</td>
<td>Kids Operating Room (KidsOR)</td>
</tr>
<tr>
<td>Address</td>
<td>4th Floor, 107 George Street, Edinburgh, EH2 2ES, United Kingdom</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:hailey@kidsor.org">hailey@kidsor.org</a></td>
</tr>
</tbody>
</table>

**Study Protocol v2**
03 February 2020
# Contents

1. *Introduction*
   1.1. Background
   1.2. Rationale
   1.3. Aim
   1.4. Objectives
   1.5. Ethos

2. *Methodology*
   2.1. Study design
   2.2. Study sites
   2.3. Collaborator recruitment
   2.4. Study duration
   2.5. Scope of data collection
   2.6. Pre-intervention inclusion criteria
   2.7. Post-intervention inclusion criteria
   2.8. Study variables
   2.9. Outcome measures
   2.10. Data collection and management
   2.11. Site variations in data collection
   2.12. Identification of consecutive patients
   2.13. Data collectors
   2.14. Data quality
   2.15. Data validation

3. *Data analysis*

4. *Ethical approvals*

5. *Authorship and dissemination*

6. *Funding*

7. *Limitations*

8. *Benefits*

*References*

*Appendices*

A. Memorandum of understanding for data collection
B. Data collection tool
C. Study definitions
D. Participant information and informed consent
E. Data collector role responsibilities
F. Letter from Yale University Institutional Review Board: Pilot site approval
G. Letter from Yale University Institutional Review Board: Multi-site approval
Abstract

Problem: It is estimated that there are 1.7 billion children lacking access to surgical care in low- and middle-income countries (LMICs), yet there is a paucity of data severely limiting targeted infrastructure development and thoughtful capacity building.

Intervention: Kids Operating Room (KidsOR) is a global health charity based in Scotland enabling high-quality, safe surgical services for children in LMICs by providing surgeons and their teams with the infrastructure needed to transform the care available for their nation’s children.

Objective: KidsOR has established a global research collaboration to carry out a multi-centre, prospective and retrospective database study evaluating the impact of KidsOR-funded interventions in LMICs.

Methods: This study aims to create a database of paediatric surgical cases performed one year before and three years after the institution of dedicated, KidsOR-funded operating theatres. Audit data will be collected on patient demographics, surgery, anaesthesia, and discharge. Research data will be collected from the family of paediatric patients to further explore the socio-economic burden of paediatric surgery. A local data collector will capture all data electronically using Research Electronic Data Capture (REDcap), a secure online data collection tool.

Outcomes: The primary outcome will be all-cause, in-hospital mortality and the secondary outcomes will be in-hospital, post-operative complications at the time of discharge. Analysis will be performed retrospectively and focused initially on epidemiology and outcomes. Subsequent cost data will be used in an economic model in order to determine cost-effectiveness and disability-adjusted life years.

Benefits: Once completed, this project will be the largest ever study of the impact of surgical systems intervention for children in LMICs to date. At the local, regional, and global levels, this research is essential to improve quality of care, support surgical teams, strengthen the knowledge base, advocate for further investment, sustain political will, and provide donors with transparency.
## Sponsor

### Sponsor Details

<table>
<thead>
<tr>
<th>Name</th>
<th>Yale University – Yale School of Medicine, Department of Surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>PO Box 208062, New Haven Connecticut, 06520-8062, United States of America</td>
</tr>
<tr>
<td>Telephone</td>
<td>+12037852697</td>
</tr>
</tbody>
</table>

## Primary Investigator

<table>
<thead>
<tr>
<th>Name</th>
<th>Doruk Ozgediz, MD, MSc, FACS, FAAP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Assistant Professor of Surgery (Pediatrics) and of Pediatrics</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:doruk.ozgediz@yale.edu">doruk.ozgediz@yale.edu</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Kokila Lakhoo PhD, FRCS, FCS, FCS, MRCPCH, MBCHB</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Associate Professor of Paediatric Surgery</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:kokila.lakhoo@nds.ox.ac.uk">kokila.lakhoo@nds.ox.ac.uk</a></td>
</tr>
</tbody>
</table>

## Co-investigator

<table>
<thead>
<tr>
<th>Name</th>
<th>Maija Cheung, MD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Resident, General Surgery</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:maija.cheung@yale.edu">maija.cheung@yale.edu</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Sarah Ullrich, MD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Resident, General Surgery</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:sarah.ullrich@yale.edu">sarah.ullrich@yale.edu</a></td>
</tr>
</tbody>
</table>
## Funder

### Funder Details

<table>
<thead>
<tr>
<th>Name</th>
<th>Kids Operating Room (KidsOR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>4th Floor, 107 George Street, Edinburgh, EH2 2ES, United Kingdom</td>
</tr>
<tr>
<td>Telephone</td>
<td>+441312970090</td>
</tr>
</tbody>
</table>

### Co-Investigator

<table>
<thead>
<tr>
<th>Name</th>
<th>Hailey Zislis, MPH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Health Program Evaluation Specialist</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:hailey@kidsor.org">hailey@kidsor.org</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>David Cunningham, LLD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Chief Executive Officer</td>
</tr>
<tr>
<td>Email</td>
<td><a href="mailto:david@kidsor.org">david@kidsor.org</a></td>
</tr>
</tbody>
</table>
**Collaborators**
All partner hospitals participating in the global study at the time of publication

**West Africa**

<table>
<thead>
<tr>
<th>Country</th>
<th>City</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burkina Faso</td>
<td>Ouagadougou</td>
<td>CHU Pédiatrique – Charles DeGaulle</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Abuja</td>
<td>National Hospital</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>Freetown</td>
<td>Connaught Hospital</td>
</tr>
</tbody>
</table>

**East Africa**

<table>
<thead>
<tr>
<th>Country</th>
<th>City</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethiopia</td>
<td>Addis Ababa</td>
<td>Menelik II Hospital</td>
</tr>
<tr>
<td>Kenya</td>
<td>Tenwek</td>
<td>Tenwek Hospital</td>
</tr>
<tr>
<td>Malawi</td>
<td>Blantyre</td>
<td>Mercy James Institute – Queen Elizabeth Hospital</td>
</tr>
<tr>
<td>Malawi</td>
<td>Blantyre</td>
<td>Pediatric ENT – Queen Elizabeth Hospital</td>
</tr>
<tr>
<td>Malawi</td>
<td>Lilongwe</td>
<td>Kamuzu Central Hospital</td>
</tr>
<tr>
<td>Mozambique</td>
<td>Maputo</td>
<td>Hospital Central de Maputo</td>
</tr>
<tr>
<td>Rwanda</td>
<td>Kigali</td>
<td>Centre Hospitalier Universitaire de Kigali</td>
</tr>
<tr>
<td>Tanzania</td>
<td>Dar Es Salaam</td>
<td>Muhumbili National Hospital</td>
</tr>
<tr>
<td>Uganda</td>
<td>Kampala</td>
<td>Mulago National Referral Hospital</td>
</tr>
<tr>
<td>Zambia</td>
<td>Lusaka</td>
<td>University Teaching Hospital</td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>Bulawayo</td>
<td>United Bulawayo Hospital</td>
</tr>
</tbody>
</table>

**Central America**

<table>
<thead>
<tr>
<th>Country</th>
<th>City</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haiti</td>
<td>Port-au-Prince</td>
<td>St Damien’s Hospital</td>
</tr>
</tbody>
</table>

**South America**

<table>
<thead>
<tr>
<th>Country</th>
<th>City</th>
<th>Hospital</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecuador</td>
<td>Quito</td>
<td>Hospital de Los Valles</td>
</tr>
<tr>
<td>Peru</td>
<td>Lima</td>
<td>Instituto Nacional de Salud del Niño</td>
</tr>
</tbody>
</table>
1. Introduction

1.1. Background

The unmet need
It is estimated that 30% of the global burden of disease is treatable with surgery, yet in LMICs as much as 87% of the surgical need remains unmet\(^1,^2\), and 1.7 billion children lack access to surgical care.\(^3\) The most common causes of death in children under age five include pre-term birth complications and congenital anomalies, while injury is the most common cause of death among children aged 5 to 14.\(^4\) Surgical intervention has the potential to improve outcomes in each of these areas, however the burden of paediatric surgical diseases remains largely unknown.\(^5\) Globally, profound improvements in child mortality have been observed over the past few decades.\(^6\) Nonetheless, children living in areas such as Sub-Saharan Africa remain 15 times more likely to die before the age of five compared with their counterparts in high-income countries.\(^7\) In contrast to the improvements in childhood mortality that have been witnessed overall, the rate of decline in deaths in LMICs due to surgical conditions has not been as pronounced as the rates of decline in conditions due to infectious causes.\(^8\)

1.2. Rationale

Closing the gap
Many countries, even those with better economic indicators than their neighbours, have severe gaps in infrastructure inhibiting their ability to provide safe and accessible paediatric surgery.\(^9,^10\) KidsOR is a global health charity based in Scotland that enables high-quality, safe surgical services for children in LMICs by providing surgeons and their teams with the infrastructure needed to transform the care available for their nation’s children. At the time of writing, KidsOR has installed 19 paediatric operating rooms (ORs) across 10 countries in Africa and South America, with a commitment to deliver at least five further ORs globally in 2019. Starting in 2020, KidsOR will also begin to invest in the training of paediatric surgeons and anaesthetists in Africa to address the workforce deficit and increase local capacity for operative interventions. An audit evaluating the impact of a KidsOR installation of two dedicated paediatric ORs in Tanzania found a 90% increase in surgical volume post-intervention — allowing the local team to clear a several year backlog in a few months.\(^11\) An economic evaluation of a KidsOR intervention in Uganda showed that the installation of a dedicated paediatric operating theatre fell comfortably within accepted thresholds for cost-effectiveness in LMIC contexts — and was found to be more cost-effective than anti-retroviral therapy treatment for HIV in Sub-Saharan Africa.\(^12\) KidsOR recognises that support in the form of theatre infrastructure, while effective in the short-term, must be supplemented by dedicated research to have an even greater impact.

The paucity of data
There is sparse data in most LMICs regarding the distribution of surgical conditions, options, and outcomes, but this paucity of data is especially pronounced in paediatric surgery.\(^5\) Across global surgery more broadly, prospectively collected databases are almost non-existent and the heavy burden of clinical care often takes priority over research. This lack of data severely limits targeted infrastructure development and thoughtful capacity building; and thus, has been identified as a research area to prioritise by the Lancet Commission on Global Surgery.\(^13\) Characterisation of disease burden can provide an opportunity to advocate for research allocation to specific areas, as well as the establishment of training programmes and educational platforms aimed at addressing specific pathologies and infrastructure gaps. This is
especially true of paediatric surgical conditions where congenital malformations, tumours, injuries, and infectious diseases can be fatal if left untreated. Additionally, caring for paediatric and neonatal patients suffering from congenital malformations for example, often requires multiple operations, multidisciplinary teams, and advanced coordination of long-term care to achieve optimal outcomes. To capture the burden of paediatric surgical conditions and outcomes, and evaluate the impact of KidsOR-funded interventions, this study will establish a database of baseline and post-intervention data collected from paediatric surgical cases.

The financial burden
Though evidence has demonstrated the cost-effectiveness of surgical intervention, many families are at-risk of accruing out-of-pocket (OOP) medical costs at a level of more than 10% of their total annual household income, or 40% of their annual household expenditure after food expenses.14,15 This phenomenon is termed ‘catastrophic healthcare expenditure’ (CHE), and is a key indicator of the sustainability of surgical delivery.16 These OOP expenditures include direct medical costs – such as hospital stay, procedures, medical and diagnostic tests, medications, and supplies – and indirect medical costs – such as lost wages, transport, and food.14 Nearly one quarter of individuals who undergo surgery each year face financial hardship, and 90% of this burden is felt in LMICs.15,17 The first ever study of OOP spending from the patient’s family’s perspective in an LMIC paediatric surgical setting took place in Kampala, Uganda in 2018 and found that almost one-third of households incurred CHE for a paediatric surgical procedure even though paediatric surgical services in Uganda are provided for free at the point of delivery.15 To further explore the socio-economic aspect of the burden of families of paediatric surgery patients, this study will also collect data via a brief quantitative survey with the family of paediatric patients.

1.3. Aim

KidsOR is sponsoring a dedicated research project to evaluate the impact of the interventions it funds. To this end, KidsOR has partnered with Yale University to lead an independent global research study investigating key factors in clinical output alongside exploring the social, geographic, and economic factors influencing access to safe surgery for children in LMICs.

1.4. Objectives

1) Establish a database of paediatric surgical cases performed one year before and three years after the institution of any KidsOR-funded dedicated paediatric operating suite.

2) Categorise the epidemiology, burden of disease, surgical interventions performed, risk-adjusted post-operative outcomes, and surgical and anaesthetic resource use and availability for children who undergo an operation at KidsOR installation sites.

3) Assess the level of OOP spending and CHE for families of paediatric patients who underwent surgery at KidsOR partner hospitals.

4) Perform a cost-effectiveness analysis of building and maintaining KidsOR operating theatres in LMIC settings.

1.5. Ethos
The conditions of KidsOR funding stipulate that it must only be used for locally driven action that is focused on sustainability and capacity building in paediatric surgery. In line with this commitment, this study has been iteratively developed from the ground-up through regular consultation with locally based paediatric surgeons and anaesthetists working in LMICs across the globe. A key consideration in the design of this study has been to ensure that this research minimises the burden on local surgical teams insofar as possible.

2. **Methodology**

2.1. **Study design**

This is a global, multi-centre, prospective and retrospective database study evaluating the impact of installing dedicated paediatric ORs in LMICs. This is an observational phase and therefore no interventions are being performed with regard to this study.

2.2. **Study sites**

All participating hospitals are one at which a KidsOR-funded OR has been, or is planned to be, established.

2.3. **Collaborator recruitment**

In order to transparently establish the partnership between KidsOR and each collaborating centre, KidsOR send the local primary investigator (PI) at each site a Memorandum of Understanding (MoU) before the intervention takes place. The MoU is not contractually-binding for either signatory but outlines how both partners plan to work together through the course of the agreed installation, maintenance, and research activities. To this end, the MoU includes an appendix addressing in further detail the partnership as it pertains to the matters of data collection, research guidance, and publication – attached as Appendix A.

2.4. **Study duration**

This study seeks to develop a prospectively and retrospectively collected database of paediatric surgical cases performed one year before and three years after the institution of dedicated paediatric operating suites at multiple sites worldwide, listed on [Page 6 of this Research Protocol](#).

2.5. **Scope of data collection**

This study will involve:

1) The collection of baseline, pre-installation audit data from the operating room logbook and the patient’s medical records;

2) The collection of post-installation audit data from the operating room logbook and patient’s medical records; and

3) The prospective collection of quantitative research data from the parent or guardian of the patient.
2.6. Pre-intervention inclusion criteria

All paediatric patients, including neonates, undergoing an operation at a KidsOR partner hospital will be included in this study. At the global level, this will include children from 0 – 18 years of age. In cases where study sites define their paediatric populations differently, the inclusion criteria will be adjusted to suit the local context.

2.7. Post-intervention inclusion criteria

Only paediatric patients, including neonates, undergoing an operation taking place in a KidsOR-funded OR will be included in this study. At the global level, this will include children from 0 – 18 years of age. In cases where study sites define their paediatric populations differently, the inclusion criteria will be adjusted to suit the local context.

2.8. Study variables

Data will be collected on:

- **Patient demographics** – area where patient lives; date of birth; gender; weight; admission date; surgery date; whether patient was transferred; whether patient previously had an operation in this OR; whether planned or staged; time of operation; prematurity.

- **Surgery** – whether emergent or elective; diagnosis; procedures performed; cadre of most senior surgery provider; whether surgical trainee was present; surgical resource use and availability.

- **Anaesthesia** – cadre of most senior anaesthesia provider; anaesthesia type; whether anaesthesia trainee was present; anaesthetic resource use and availability; perioperative indicators for risk factor stratification; use of surgical safety checklist.

- **Discharge** – date of discharge; perioperative indicators for risk factor stratification; need for re-intervention during hospital stay; status at discharge.

- **Socio-economics** – wait time; direct cost of hospitalisation; indirect cost of hospitalisation; annual family income before hospitalisation; socioeconomic burden of hospitalisation; length of journey to hospital.

The data collection tool is attached in Appendix B.

2.9. Outcome measures

**Primary outcome**
All-cause, in-hospital mortality

**Secondary outcomes**
In-hospital, post-operative complications at the time of discharge:
• Surgical site infection (SSI)
• Sepsis
• Need for re-intervention during hospital stay
• Length of hospital stay
• CHE for hospitalisation

The definitions of outcome measures are attached in Appendix C.

2.10. Data collection and management

An individual data collection record should be created for each operation meeting the inclusion criteria. A local data collector will capture all data electronically using the data collection tool on REDCap. REDCap is a secure, Health Insurance Portability and Accountability Act (HIPAA) compliant, user-friendly, and widely used web application designed for data collection within research studies. The study database will be housed on secure, encrypted Yale University servers where it is backed up daily by their REDCap team.

Access to data is password-protected, and user rights are set based on the collaborator’s role and institution. Data will be automatically de-identified at export, and local PIs will be able to access data from their collaborating centre at all times. REDCap can be accessed through any internet browser, though it also supports data collection via its own mobile device application. This means that data collectors have the option to collect data on an encrypted tablet or smartphone. The REDCap mobile application is optimised for offline data capture, which may bolster the feasibility of electronic capture in some LMIC contexts.

For the collection of audit data, verbal consent will be obtained from the patient’s parent or guardian at the time the surgical consent is obtained. The collection of research data from the parent or guardian of the patient will only take place if the individual gives informed consent to participating in this research after being fully informed by the data collector, and if there are no present circumstances that would make it ethically unjustifiable to approach the family for research purposes. The participant information and informed consent statements are attached in Appendix D – these statements will be translated into relevant local languages as required.

2.11. Site variations in data collection

The collection of quantitative research data will only be carried out prospectively. How much of the pre- and post-installation audit data collection will be carried out prospectively versus retrospectively will vary by site depending on multiple contextual factors, including but not limited to the time it takes to obtain study approval. It is understood that the medical records being abstracted for retrospective data collection may not contain a number of variables included in this study. In these cases, study sites should only populate the data collection tool with the data that has already been recorded in the patient records and theatre logbook.

2.12. Identification of consecutive patients
In order to identify and adjust for consecutive treatments, the data collection tool contains a field querying whether this is a new entry for an existing patient who has previously had an operation in this OR.

### 2.13. Data collectors

KidsOR appreciates that the risk of collecting insufficient and/or inadequate data must be weighed against the potential resource burden of recording and collecting in excess, which may in turn produce non-compliance and incomplete data secondary to collection fatigue. In line with this understanding, KidsOR will fund a local data collector in each partner hospital. Their key responsibility is to record and monitor the number of children treated in KidsOR-funded facilities over 20 days per month.

KidsOR also recognises the importance of reducing the burden of this study on local PIs where possible and appropriate, since their primary commitment is to deliver essential paediatric surgical care in LMIC settings. To this end, KidsOR appointed a Scotland-based Health Program Evaluation Specialist (HPES) in early 2019. Their key responsibility is to assist both the local and global study teams in all aspects of research delivery from end-to-end.

The HPES will provide ongoing training and support to the data collectors throughout all stages of the study, as well as arrange for the payment of their monthly fee. To assist with the recruitment of the data collector, a description of the responsibilities of the role will be provided to each local PI – attached as Appendix D. The individual of best fit for this position varies depending on the context; the HPES can discuss with local PIs examples of what the right candidate might look like by sharing the experiences of existing study sites.

### 2.14. Data quality

The following measures have been introduced to ensure a high quality of data:

- **Initial consultation**
  - Alongside the annual conferences of the West African College of Surgeons (WACS) and the College of Surgeons of East, Central, and Southern Africa (COSECSA) in 2018, early stage plans for this research project were presented for consultation to local paediatric surgeons working in KidsOR partner hospitals across Africa.

- **Study guidance**
  - A comprehensive study protocol has been produced and distributed across the research collaboration. The protocol has been updated and recirculated based on insights from study piloting and feedback from local PIs and other relevant experts.
  - The protocol and data collection tool contain clear and succinct instructions and definitions. The data collection tool is available in English, Spanish, and French – all translations have been checked by native speakers for accuracy.
• **Onboarding and communications**
  
  - An initial onboarding meeting takes place between the local study team and the HPES at KidsOR, who will introduce the study, detail the data collection process, and address any questions or concerns. The HPES then leads a focused discussion about implementation, current data collection practices, data collector recruitment, and study approvals. At this time local PI communication preferences are identified, and next steps are agreed in collaboration.
  
  - KidsOR maintains two separate WhatsApp groups for collaborators – one for local PIs and one for data collectors. These are only used for global team updates; at least once a month, the HPES at KidsOR posts a study-wide update video in each group. If required, local PIs and/or data collectors can contact the HPES directly by WhatsApp for site-specific support with data collection.

• **Study piloting**
  
  - Initial piloting is currently underway in seven countries across West Africa, East Africa, and South America. The earliest pilot phase focused on study onboarding processes and the implementation of electronic, prospective data capture – and the data collection tool was amended following feedback on study definitions and variables, and questionnaire routing and translations. The next phase of piloting is expected to focus more on reporting, quality assurance, retrospective collection, and analysis.

2.15. **Data validation**

**Monthly**

At the end of each month, the HPES will extract a list of study records entered and the date of operation for each of these records. The resulting figures will be imported into a spreadsheet template which charts the operation dates into a table by month and year, and also highlights whether any operation dates are missing.

Each month, the local study team will be provided with a snapshot of data collection progress across the relevant date range. At this time, if any record is missing a date, or has a clear error in the date field, the data collector will be asked to correct this, and then review the patient file again to make sure there are no other data entry errors in the record.

**Quarterly**

Over one week per quarter, data collectors will be asked to validate all cases collected against the theatre logbook for accuracy. On a quarterly basis, approximately 5% of all cases at each centre will be selected at random for a review of accuracy by local PIs.

3. **Data analysis**
Analysis will be performed on the collected data retrospectively and will be focused initially on epidemiology and outcomes. At this time, sample size calculations will be undertaken to ensure the statistical relevance of any results. Subsequent cost data will be used in an economic model in order to determine cost-effectiveness and disability-adjusted life years.

4. Ethical approvals

Global

Titled Evaluating the Impact of Paediatric Operating Rooms in LMICs, this study was granted initial approval by the Institutional Review Board (IRB) of the Human Research Protection Program (HRPP) at Yale University on January 17, 2019 – attached as Appendix E. This earliest approval was granted to pilot the study at Muhimbili National Hospital (Dar es Salaam, Tanzania) and has a renewable expiry date of January 16, 2020. A subsequent request was made to extend the data collection sites to all those listed on Page 7 of this research protocol. The updates to this study were granted approval by the IRB of the HRPP at Yale University on April 5, 2019 – attached as Appendix F.

Local

All research activity emanating from KidsOR itself will be formed according to accepted research methods. In-country standards of study permissions will be obtained, and this includes all aspects of ethical and/or administrative approval where required. KidsOR will defer to local PIs to lead the project down the most appropriate route to the necessary approvals according to local regulations and institutional bodies. In order to obtain access to REDCap, evidence of local study approval must be emailed to the HPES at KidsOR. Where possible and appropriate, the HPES can be contacted to assist with applications for study approval.

5. Authorship and dissemination

- Any journal publishing a KidsOR study will be asked to make all collaborators PubMed citable co-authors. The authorship of the article will read “KidsOR Research Collaboration”. All author’s names and roles will be listed at the end of the paper. Please contact the HPES at KidsOR for a current list of authors relevant to your submission for publication.

- Local PIs will have access to the REDCap data collected at their own hospital, so that this data can be used for their own publication and quality improvement purposes. There will be no expectation of automatic inclusion of KidsOR and/or Yale University in any and/or all research taking place within KidsOR-funded operating theatres.
  - Notification of such research projects would be considered a matter of courtesy however and made by the clinicians concerned.
  - Publications derived from such research projects should include KidsOR in the attribution and acknowledgement sections.
  - If KidsOR and/or Yale University staff are directly involved in the research project, they should be included in the relevant authorship.
• Research projects, however, investigating or reporting on aspects of the design and/or functionality (including economic elements of performance) of KidsOR-funded operating theatres should involve dialogue with KidsOR.

6. Funding

KidsOR has secured funding to provide a monthly fee of $300 USD to the local data collector at each partner hospital for the duration of the study. The charity will also support any fees incurred for individual ethics applications; however, for the purposes of fee status this project may be considered to be a locally driven study being carried out in collaboration rather than internationally led research.

7. Limitations

• This is not a population-based study; only children who present for treatment and undergo an operation will be captured in the database. This will not fully characterise the epidemiology of paediatric surgical conditions in LMICs, where many children may never reach a health centre equipped to provide the level of surgical care required. In addition, it is expected that the operations performed will vary depending on the expertise of the local team.

• This study will likely underestimate post-operative complications. Follow-up for these patients will be limited to the duration of their hospital stay, so this study will not capture longer-term outcomes that can be particularly important for understanding the long-term disability and quality of life of patients with certain diagnoses – including but not limited to complex trauma and congenital anomalies. The data collection tool will capture if patients undergo another operation in the same KidsOR operating theatre, however it will not capture readmission to the ward or repeat clinic visits.

• The estimation of OOP and CHE will be limited by recall bias, as the study relies on participants’ memories and has no way of verifying responses. In addition, this study may also underestimate the costs of hospitalisation since the questionnaire does not capture the costs of discharge medications and supplies, follow-up clinic visits, or home care.

8. Benefits

Once completed, this project will be the largest ever study of the impact of surgical systems intervention for children in LMICs to date. The data collected will provide substantial benefit to both local collaborators in the immediate setting with regard to outcomes and resource allocation, as well as the broader community of paediatric surgery providers – including but not limited to health workers, governments, scientists, and economists. These data will allow for the better characterisation of the burden of disease, perioperative risk factors, surgical outcomes, and financial difficulties for children and their families. At the local, regional, and global levels, this research is essential to improve quality of care, support surgical teams, strengthen the knowledge base, advocate for further investment, sustain political will, and provide donors with transparency. It will show the real cost, and benefit, of saving a child’s life, of preventing a life of pain and disability, and of transforming children’s futures.
References


Appendix A

Memorandum of Understanding
Data collection, management systems and research guidance

Appendix A – Data Collection

1. Use of data

   a. Data collected from all KidsOR theatres will be used for the following purposes

      i. Evaluating return on investment and matching expenditure (start-up and maintenance) with patient outcomes will be a regular requirement of units both individually and collectively.

      ii. Outcome analysis: as part of the governance process, KidsOR units will be required to be aware of condition-specific, as well as overall, mortality in each unit. Data analysis will also allow trend analysis in relation to outcomes for the purpose of comparative studies across the units, as well as comparison with national and international standards.

      iii. Each unit will be committed to quality improvement initiatives and any documented deviated (positive or negative) from baseline activity should prompt further analysis to correlate the change in practice with outcome (e.g. introduction of endoscopic surgery ensures progress in patient care and is not detrimental to patient outcome).

2. Data collection

   The risk of collecting insufficient and inadequate data needs to be set against the potential burden of recording and collecting excessively, which in turn may produce non-compliance and incomplete data secondary to collection fatigue. KidsOR will therefore fund a data clerk in each partner hospital, to a maximum budget, to support the transfer of data into the REDCap software.

   REDCap is a mature, secure web application for building and managing online surveys and databases. While REDCap can be used to collect virtually any type of data, it is specifically geared to support capture for research studies. REDCap meets all the requirements for collection of protected health information as laid out by the United States Government. While hardcopy data capture will be the preserve of individual units, data transfer will be carried out electronically.

3. Datasets

   Datasets will include the following categories: demographics, diagnostic and procedural data, and outcome and discharge data.

   a. Demographic data

      i. Name, parent’s phone number, date of birth, age, gender, weight, admission date, discharge date, operation date, readmission date, and referral source.

   b. Diagnostic data
i. Up to five diagnoses with diagnostic coding will be selected from a drop-down list of diagnoses.

c. **Procedural data**

   i. Up to five surgical procedures carried out (selected from drop-down menu), operator status, assistant status, contamination status of wound, anaesthetic given, urgency, outcomes, complications, and risk factors.

d. **Outcome data**

   i. Outcome and follow-up data will be recorded, as well as mortality and major complications.

Data capture format (electronic or hardcopy) will be at the discretion of the individual units, but the data collector will use REDCap to electronically upload their data.

4. **Data ownership**

Ownership of data will be shared between individual hospitals and KidsOR, as will be the intellectual property on use of that data. The implications of such an arrangement are that there will be attribution of source and ownership of data during publication procedures, and the same with presentations. Collated datasets, however, will be the intellectual property of KidsOR.

5. **IT governance and security**

Data should conform to the new European regulations – general data protection regulation (GDPR) and as such patient identity should be protected and anonymised, recognising that rare conditions being treated in specific locations will occasionally result in indirectly identifiable information being collected. Datasets will also require storage on mobile devices and desktops in an encrypted manner. Loss of any devices containing patient information will be reported immediately to KidsOR.

6. **Data output**

Units will be requested to contribute their activity data on a daily basis via the data collector and through REDCap. That data may be serially manipulated for audit research and clinical reporting purposes by either the donor unit or the central administration of KidsOR.

There will be an implicit understanding that the publication of collated data by KidsOR should be able to proceed without express authorisation or permission being requested from the donor unit. The exception to this policy will be when there is a prospect of directly or indirectly identifiable information leading to the identity of the source hospital. In that unlikely event, direct discussion will be had with the relevant clinician(s) and permission for further dissemination of clinical information and/or images requested.

Exporting data from individual units to international databases (e.g. GICS registry on anorectal anomalies) will not require the explicit permission of KidsOR. Similarly, KidsOR will not submit data to such databases unless authorised by the donor unit.

7. **Exporting data for non-medical uses**
Exporting data to other destinations (e.g. commercial interests) will not take place without the explicit permission of both parties.

8. Research guidance

- There will be no expectation of automatic inclusion of KidsOR in any/all research projects taking place within KidsOR operating rooms. Notification of such research projects would be considered a matter of courtesy however and made by the clinicians concerned.

- Research projects, however, which are investigating or reporting on aspects of the design/functionality (including economic elements of performance) of Kids Operating Rooms should involve dialogue with KidsOR.

- Research projects emanating from KidsOR itself will be formed according to accepted research methods. This includes all aspects of ethical and/or administrative approval (if required) an in-country standards of ethical permission will be obtained.

- Publications derived from such research projects will include KidsOR in the attribution/acknowledgement sections. If KidsOR staff are directly involved in the research project they will be included in the relevant authorship.
## Appendix B

### Data Collection Tool

#### Demographics

<table>
<thead>
<tr>
<th>Field</th>
<th>Choices</th>
</tr>
</thead>
<tbody>
<tr>
<td>First name</td>
<td>-</td>
</tr>
<tr>
<td>Last name</td>
<td>-</td>
</tr>
<tr>
<td>Phone number</td>
<td>-</td>
</tr>
<tr>
<td>Area where the patient lives</td>
<td>Drop-down list of the administrative regions in the country where the patient lives. Select ‘other’ if the patient is presenting from outside the country of treatment, and a drop-down list of other countries will be shown subsequently.</td>
</tr>
<tr>
<td>Date of birth</td>
<td>D-M-Y</td>
</tr>
<tr>
<td>Is the exact birthdate known?</td>
<td>Yes</td>
</tr>
<tr>
<td>Age (years)</td>
<td>Calculated automatically based on DOB</td>
</tr>
<tr>
<td>Gender</td>
<td>Female; Male; Other</td>
</tr>
<tr>
<td>Weight (kilograms)</td>
<td>On the day of presentation, to one decimal place</td>
</tr>
<tr>
<td>Date of admission</td>
<td>D-M-Y</td>
</tr>
<tr>
<td>Date of surgery</td>
<td>D-M-Y</td>
</tr>
<tr>
<td>Was the patient transferred from another health centre?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Is this a new entry for an existing patient who has previously had an operation in this OR?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Is this operation part of a planned or staged procedure?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Time of operation</td>
<td>Daytime (normal hours M-F); Night (5pm-6am M-F); Weekend (Sat or Sun)</td>
</tr>
<tr>
<td>Was the patient born prematurely? (born before 37 weeks of gestation)</td>
<td>Yes; No; Unknown</td>
</tr>
</tbody>
</table>

#### Surgeon

<table>
<thead>
<tr>
<th>Field</th>
<th>Choices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Was this an elective (planned) operation?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Diagnosis codes</td>
<td>Drop-down list of diagnosis codes for relevant conditions. If the condition is listed as ‘not otherwise specified’ (NOS), please briefly describe the code on the line. At least one diagnosis code must be included but up to five can be added. Try to list the codes in order of relevance with Diagnosis Code 1 as most relevant and Diagnosis Code 5 as least relevant.</td>
</tr>
<tr>
<td>Procedure codes</td>
<td>Drop-down list of procedure codes for relevant procedures. If the procedure is listed as NOS, please briefly describe the code on the line. At least one procedure code must be included, but up to five can be added. Try to list the codes in order of relevance with</td>
</tr>
</tbody>
</table>
### Primary surgeon type
- Paediatric/specialist surgeon; Paediatric surgery fellow; General surgeon; Medical officer; Surgery resident

### Assistant surgeons (select all that apply)
- Paediatric/specialist surgeon; General surgeon; Surgery resident; Paediatric surgery fellow; Medical officer

### Was a surgical trainee present?
- Yes; No; Unknown

### Were necessary surgical resources missing?
- Yes; No
  
  If ‘yes’ is selected, routing queries what resources were not available.

### Was laparoscopy available for this operation?
- Yes; No
  
  If ‘yes’ is selected, routing asks whether laparoscopy was used for this operation. If laparoscopy was available but not used, routing queries the main reason for this decision. If laparoscopy was available and used, routing asks whether any problems were encountered using laparoscopy in this case.

  If ‘no’ is selected, routing asks whether laparoscopy would have been considered whether it was available.

### Anaesthetist

<table>
<thead>
<tr>
<th>Field</th>
<th>Choices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anaesthesia provider (select all that apply)</td>
<td>Paediatric/specialist anaesthetist; Paediatric Anaesthesia fellow; Physician anaesthetist; Anaesthesia resident; Non-physician anaesthetist</td>
</tr>
<tr>
<td>Anaesthesia type (select all that apply)</td>
<td>Local anaesthesia; Regional anaesthesia; General anaesthesia; Monitored anaesthesia care or sedation; No anaesthesia</td>
</tr>
<tr>
<td>Was an anaesthesia trainee present?</td>
<td>Yes; No; Unknown</td>
</tr>
<tr>
<td>Were necessary anaesthesia resources and/or drugs missing?</td>
<td>Yes; No</td>
</tr>
<tr>
<td></td>
<td>If ‘yes’ is selected, routing queries what resources were not available.</td>
</tr>
<tr>
<td>ASA Class</td>
<td>I – Healthy person; II – Mild systemic disease; III – Severe systemic disease; IV – Severe systemic disease that is a constant threat to life; V – A moribund patient who is not expected to survive without the operation</td>
</tr>
<tr>
<td>Pre-operative temperature (Celsius)</td>
<td>To one decimal place</td>
</tr>
<tr>
<td>Sepsis in 48 hours prior to surgery?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Blood transfusion in 48 hours prior to surgery?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Were antibiotics given pre-operatively?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Safety checklist used in OR?</td>
<td>Yes; No</td>
</tr>
</tbody>
</table>

### Discharge

<table>
<thead>
<tr>
<th>Field</th>
<th>Choices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of discharge</td>
<td>D-M-Y</td>
</tr>
<tr>
<td>Antibiotics given post-operatively?</td>
<td>Yes; No</td>
</tr>
</tbody>
</table>
Post-operative sepsis? Yes; No
Post-operative surgical site infection (SSI)? Yes; No
Did the patient need another operation this admission? Yes; No
Status at discharge Recovered; Ran away; Transferred; Died

If ‘died’ is selected, routing queries whether this was an on-table death.

<table>
<thead>
<tr>
<th>Socioeconomics</th>
<th>Choices</th>
</tr>
</thead>
<tbody>
<tr>
<td>Field</td>
<td>Choices</td>
</tr>
<tr>
<td>Participant information</td>
<td>Routing only shows further questions if ‘yes’ is selected.</td>
</tr>
<tr>
<td>Informed consent</td>
<td>Routing only shows further questions if ‘yes’ is selected.</td>
</tr>
<tr>
<td>How long did the child wait to have the operation?</td>
<td>Less than 2 weeks; 2-4 weeks; 1-3 months; 3-6 months; 6 months - 1 year; 1 - 2 years; More than 2 years</td>
</tr>
<tr>
<td>Out-of-pocket DIRECT medical cost of hospitalisation (hospital stay, procedures, medical and diagnostic tests, medications, supplies, etc.)</td>
<td>$0-25 USD; $26-50 USD; $51-100 USD; $101-200 USD; $201-500 USD; $501-1,000 USD; Greater than $1,000 USD</td>
</tr>
<tr>
<td>Currency exchange rate guide given to each data collector to standardise conversions.</td>
<td></td>
</tr>
<tr>
<td>Out-of-pocket INDIRECT medical cost of hospitalisation (transportation, feeding, employing an attendant, etc.)</td>
<td>$0-25 USD; $26-50 USD; $51-100 USD; $101-200 USD; $201-500 USD; $501-1,000 USD; Greater than $1,000 USD</td>
</tr>
<tr>
<td>Currency exchange rate guide given to each data collector to standardise conversions.</td>
<td></td>
</tr>
<tr>
<td>Did your household have to borrow money to pay for this hospitalisation?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Did your household have to sell any land or possessions to pay for this hospitalisation?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Did your household lose wages as a result of this hospitalisation?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>Annual family income BEFORE this hospitalisation</td>
<td>$0-25 USD; $26-50 USD; $51-100 USD; $101-200 USD; $201-500 USD; $501-1,000 USD; Greater than $1,000 USD</td>
</tr>
<tr>
<td>Currency exchange rate guide given to each data collector to standardise conversions.</td>
<td></td>
</tr>
<tr>
<td>Did your child receive any government subsidy to help pay for this operation?</td>
<td>Yes; No</td>
</tr>
<tr>
<td>If ‘yes’ is selected, routing queries the queries the approximate value of this subsidy.</td>
<td></td>
</tr>
<tr>
<td>How long did it take you to reach the hospital when you started traveling?</td>
<td>Duration in hours</td>
</tr>
<tr>
<td>Additional comments</td>
<td>-</td>
</tr>
</tbody>
</table>
## Appendix C

### Study Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Surgical site infection (SSI)</strong></td>
<td>The Centre for Disease Control and Prevention define this as including one or more of the following:</td>
</tr>
<tr>
<td></td>
<td>1) Purulent drainage from the wound;</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>2) At least <strong>TWO</strong> of the following are present: pain or tenderness, localised swelling, redness, heat, fever <strong>AND</strong> the incision is opened deliberately to manage infection or spontaneously dehisces <strong>OR</strong> the clinician diagnoses an SSI;</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>3) There is an abscess within the wound.</td>
</tr>
<tr>
<td><strong>Sepsis</strong></td>
<td>Defined as meeting 2 or more age-appropriate systemic inflammatory response syndrome (SIRS) criteria, with a suspected or documented source of infection.</td>
</tr>
</tbody>
</table>

### SIRS criteria by age group

<table>
<thead>
<tr>
<th>Age group</th>
<th>Heart rate (beats/minute)</th>
<th>Respiratory rate (breaths/minute)</th>
<th>Leukocyte count (leukocytes x 10^9/mm³)</th>
<th>Systolic blood pressure (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborn (0 days to 1 week)</td>
<td>&gt;180</td>
<td>&lt;100</td>
<td>&gt;50</td>
<td>&gt;34</td>
</tr>
<tr>
<td>Neonate (1 week to 1 month)</td>
<td>&gt;180</td>
<td>&lt;100</td>
<td>&gt;40</td>
<td>&gt;10.5 or &lt;5</td>
</tr>
<tr>
<td>Infant (1 month to 1 year)</td>
<td>&gt;180</td>
<td>&lt;90</td>
<td>&gt;34</td>
<td>&gt;12.5 or &lt;6</td>
</tr>
<tr>
<td>Toddler (&gt;1 to 15 years)</td>
<td>&gt;140</td>
<td>NA</td>
<td>&gt;22</td>
<td>&gt;13.5 or &lt;6</td>
</tr>
<tr>
<td>School age (&gt;5 to 12 years)</td>
<td>&gt;130</td>
<td>NA</td>
<td>&gt;18</td>
<td>&gt;13.5 or &lt;4.5</td>
</tr>
<tr>
<td>Adolescent (&gt;12 to &lt;18 years)</td>
<td>&gt;110</td>
<td>NA</td>
<td>&gt;14</td>
<td>&gt;11 or &lt;4.5</td>
</tr>
</tbody>
</table>
Participant Information and Informed Consent

Participant information

You are being invited to take part in a research study. Before making your decision, it is important to know why the research is being done and what the study will involve.

This study is sponsored by Yale University. You have been asked to take part because you are the parent or guardian of a child who has been treated in an operating room funded by KidsOR.

KidsOR is a charity based in Scotland working to make sure every child in the world can get surgery if they need it. This study is about the ways that your child’s operation has impacted your family when it comes to things like money, work and travel.

The survey has 11 short questions and should not take more than 5 to 10 minutes of your time. There will be no compensation for participating in this study.

I will read the questions out to you and record your answers directly into a secure place. We will not collect any of your personal information, so that your answers cannot be traced to you.

It is up to you whether you decide to take part in this survey. You can skip questions that you do not want to answer, and if wanted you can stop the interview at any time.

There will be no added risk to your child if you choose to take part in this study. Should you choose not to take part in this study, it will not have any impact on the care your child will receive.

If you have any questions, I am happy to answer these for you now.

Informed consent

- I confirm that I understand the information provided for this survey.
- I confirm that I have had the opportunity to ask questions and am satisfied with any answer that I have received.
- I understand that my participation in this study is voluntary and that I am free to stop at any time without saying why.
- I understand that there will be no compensation for taking part in this study.
- I agree to participate in this study.
Appendix E

Data Collector Role Responsibilities

KidsOR is a global health charity focused on bringing equitable access to safe surgery for all children. Working across Africa, Latin America and Southeast Asia, KidsOR provides surgical infrastructure to local surgeons; allowing more children to access the care they need.

Recording and monitoring the number of children treated in KidsOR facilities, the impact surgery has on the child, and the cost of this to the family is crucial to our long-term goal of securing wider funding for investment in surgery.

You will be an important part of the team, accurately recording data from your hospital and entering it into the database. You will be part of a global team helping to transform access to safe surgery for future generations.

**Category of work**
You will be a contractor, submitting monthly invoices for payment of your fees

**Fee**
$300 per calendar month

**Duration**
20 days per month

**Reports to**
Health Program Evaluation Specialist, KidsOR (based in the UK)

**IT**
You will need your own computer, smartphone or table compatible with REDCap – further information and training will be provided

**Purpose**
The data collector will be responsible for recording all the paediatric surgical cases done in their hospital – including the operating rooms and the wards. These will be recorded directly on to a computer or REDCap-compatible device.

**Responsibilities**

- Works closely with all paediatric surgeons of the hospital.
- Registers all paediatric surgical procedures carried out in the hospital and records all additional information required.
- Enters data securely and directly into the REDCap database.
- Provides monthly reports to the hospital on activity, as well as any such other reports the hospitals require.
• Will participate in a monthly check-in with the KidsOR Health Program Evaluation Specialist, by teleconference or WhatsApp

• Will attend in-hospital training by the KidsOR team and will participate in regular KidsOR online meetings, team events and training events.

• Will act as the local contact for KidsOR in the hospital, supporting with any visits or other activities.

• Will ensure that the local surgical teams are kept informed of KidsOR developments and that they are regularly updated on project progress and activity opportunities emerging from KidsOR.
Pilot site IRB approval
January 17, 2019

APPROVAL OF SUBMISSION VIA EXPEDITED REVIEW

Approval Date: 1/17/2019
Expiration Date: 1/16/2020

Investigator: Doruk Ozgediz
Type of Review: Initial Study
Title of Study: Evaluating the Impact of Pediatric Operating Rooms in LMICs
IRB Protocol ID: 20000024126
Submission ID: 2000024126

Research activities associated with this submission are approved and may begin consistent with the terms of IRB approval.

The HIC has determined that this protocol presents minimal risk to subjects.

The IRB found this study to meet the requirements of 45 CFR § 46.404 in that it presents no more than minimal risk to the minor subjects.

The IRB acknowledges that HIPAA regulations do not apply to this protocol, as this research is conducted internationally. The Principal Investigator is reminded that if protected health information is intended to be brought back to Yale, HIPAA regulations will apply. If so, you must include provisions for requesting research authorization from foreign subjects, or justify a request for a waiver of HIPAA authorization to the IRB.

The HIC notes that the PI is sponsoring this multi-center study and that Yale serves as coordinating center. The HIC reminds the Investigator of their obligations as a sponsor coordinating a multi-center trial. These responsibilities include, but are not limited to, ensuring ongoing IRB approval at other study sites, monitoring adverse events and reporting to the HIC, the FDA, Sponsor, and other bodies that monitor the conduct of the study and retaining copies of this documentation.

IRB approval from Muhimbili National Hospital must be obtained and submitted to the HIC for approval before research can take place at that location.
See the next pages for important reminders and the list of IRB approved documents.
IMPORTANT REMINDERS:

- By 11/17/2019, you are to submit documentation for a continuing review.

- You can submit a request to close research (end the IRB’s oversight) when:
  - The protocol is permanently closed to enrollment,
  - All subjects have completed all protocol related interventions and interactions, and
  - Analysis of private identifiable information is completed.

- Changes must be submitted with a modification and approved by the IRB prior to implementation except to eliminate immediate hazards to participants. This includes changes to study procedures, informed consent documents, recruitment activities or study personnel.

- Information that requires prompt reporting to the IRB must be done so within 5 days of the PI becoming aware of the event (see Policy 710: Reporting Unanticipated Problems Involving Risks to Subjects or Others, including Adverse Events). This includes potential serious noncompliance, continuing noncompliance, and unanticipated problems to subjects or others.

- In conducting this activity, you should refer to and follow the Investigator Manual (HRP-103) as applicable, which can be found in the IRB Library within the IRB system.
IRB REVIEW REFLECTS:

- KidsOR Data Collection form.docx, Category: Study questionnaires, measures, focus groups/interview questions;

Please keep this letter with your copy of the approved protocol documents.
Appendix G

Multi-site IRB approval
April 5, 2019

APPROVAL OF SUBMISSION VIA EXPEDITED REVIEW

Approval Date: 4/5/2019
Expiration Date: 1/16/2020

Investigator: Doruk Ozgediz
Type of Review: Modification/Update
Title of Study: Evaluating the Impact of Pediatric Operating Rooms in LMICs
IRB Protocol ID: 2000024126
Submission ID: MOD00019067

Research activities associated with this submission are approved and may begin consistent with the terms of IRB approval.

The modification request includes: expanding data collection sites to Centre Hospitalier Universitaire de Kigali (CHUK), Muhimbili National Hospital, Kamuzu Central Hospital, Hospital Central de Maputo, Menelik II Hospital, Mulago National Referral Hospital, University Teaching Hospital (UTH), Tenwek Hospital, Connaught Hospital, Hospital Centre University Pediatric – Charles DeGaulle, National Hospital, Abuja, Nigeria, The Edward Francis Small Teaching Hospital, Mercy James Institute, Queen Elizabeth ENT and United Bulawayo Hospital.

The IRB finds the modification does not affect subjects’ rights or welfare or change subjects’ willingness to participate in the study, therefore, reconsenting of subjects is not required.

See the next pages for important reminders and the list of IRB approved documents.
IMPORTANT REMINDERS:

- By 11/17/2019, you are to submit documentation for a continuing review.

- You can submit a request to close research (and the IRB’s oversight) when:
  - The protocol is permanently closed to enrollment,
  - All subjects have completed all protocol related interventions and interactions, and
  - Analysis of private identifiable information is completed.

- Changes must be submitted with a modification and approved by the IRB prior to implementation except to eliminate immediate hazards to participants. This includes changes to study procedures, informed consent documents, recruitment activities or study personnel.

- Information that requires prompt reporting to the IRB must be done so within 5 days of the PI becoming aware of the event (see Policy 710: Reporting Unanticipated Problems Involving Risks to Subjects or Others, including Adverse Events). This includes potential serious noncompliance, continuing noncompliance, and unanticipated problems to subjects or others.

- In conducting this activity, you should refer to and follow the Investigator Manual (HRP-103) as applicable, which can be found in the IRB Library within the IRB system.
IRB REVIEW REFLECTS:

- KidsOR Data Collection Tool (Burkina Faso).docx, Category: Study questionnaires, measures, focus groups/interview questions;

Please keep this letter with your copy of the approved protocol documents.