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Outcomes after surgery for children in Africa

A fourteen-day prospective observational cohort study (ASOS-Paeds)

The ASOS-Paeds Investigators

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Research in context

Evidence before this study

Access to safe and affordable anaesthesia and surgery is a public health priority. Children in Africa constitute approximately 40% of the total population compared to a global average of 25%, resulting in a much greater burden of surgical disease in children in Africa. It is reported that 85% of children in Africa will need a surgical intervention by the age of 15. We know that adult surgical outcomes in Africa are poor, with a postoperative mortality twice the global average. However, there are few data reporting the surgical outcomes of children in Africa. As we could not identify any previous evidence synthesis describing surgical outcomes for children in Africa, we conducted a systematic review and meta-analysis as part of this report (PROSPERO CRD42022357658). The meta-analysis of perioperative mortality for children following surgery was defined as death occurring within 30 days of a surgical procedure. We included studies published after 2011 which included ≥ 200 children in the cohort, and reported perioperative mortality for a range of surgical procedures. One hundred and fifty-eight reports had full text review for eligibility from 13258 abstracts. Ten studies were included in the meta-analysis. The meta-analysis showed that the current data from Africa were biased as all studies were conducted in single African countries, South Africa accounted for 10517 of the 16349 included patients (64%), and a large paediatric specialist hospital accounted for more than half of cases reported (8493/16349 [52%]). These data suggested that the outcomes in Africa are potentially poor (16 deaths per 1000 children, 95% confidence interval (CI) 9-24 in Africa compared to 2 deaths per 1000 children in high-income countries, 95% CI 1-3 respectively). This meta-analysis suggests that there is insufficient data currently to inform the provision of safe anaesthesia and surgery for children in Africa.

Added value of this study

This study provides much needed data on outcomes in children having surgery in Africa. In children undergoing surgery in Africa, postoperative complications occurred in 18% of children which is threefold greater rate than high-income countries. The 30-day in-hospital surgical mortality was 2.3%, 11 times higher than in high-income countries in a crude, unadjusted comparison. Death following a postoperative complication, also known as ‘failure to rescue’, occurred in 1 in 9 children in Africa, fourfold higher than high-income countries. The children most likely to die following postoperative complications had co-existing disease and underwent intermediate and major emergency surgery. The high mortality and failure to rescue rates were aggravated by an unsafe environment for anaesthesia and surgery. Clinician researchers in many participating sites prospectively reported their hospitals as

unable to provide safe anaesthesia and surgery for children under 6 years of age. This difficulty was compounded by unreliable oxygen and electricity supplies, a lack of essential emergency drugs needed to manage cardiovascular complications, and a lack of protocols and procedures to promote safe and effective patient care.

Implications of available evidence

This study provides robust data describing outcomes for children undergoing surgery in African hospitals. The findings demonstrate that the outcomes for children in Africa are even worse than that reported for adults, with mortality rates eleven times greater than for children in high-income countries. These data reveal a neglected public health crisis in Africa and the healthcare inequity for children in Africa. This study demonstrates that there is a need to improve surgical outcomes for children in Africa, health system strengthening (which focuses on access, resources and training for anaesthesia and surgery), provision of environments which are safe for the conduct of anaesthesia and surgery, and strategies to address the high rate of 'failure to rescue'. This will require cross-sectoral cooperation and long-term planning involving health leaders, policymakers, and funders.

Abstract

Background

Safe anaesthesia and surgery is a public health imperative. There are few data describing outcomes for children undergoing anaesthesia and surgery in Africa.

Methods

International 14-day prospective, observational cohort study of children (<18 years) undergoing surgery in African countries. We aimed to recruit as many hospitals as possible across all levels of care providing surgical treatment. Each hospital recruited all eligible children for a 14-day period between January and December 2022. The primary outcome was in-hospital postoperative complications within 30 days of surgery. The secondary outcome was in-hospital mortality within 30 days after surgery. We also collected hospital-level data describing equipment, facilities and protocols available.

Findings

We recruited 8625 children from 249 hospitals in 31 African countries. The mean age was 6·1 (4·9) years. 5675/8600 children (66%) were male. Most children were healthy (American Society of Anesthesiologists' Class I, 6110/8579 [71%]) undergoing elective surgery 5325/8604 (62%). Postoperative complications occurred in 1532/8515 (18·0%) of children, predominated by infections (971/8538, 11·4%). There were 199/8596 deaths (2·3%), 169/199 (84·9%) following emergent surgeries. Deaths following postoperative complications occurred in 166 of 1530 complications (10·8%). Operating rooms were reported as safe for anaesthesia and surgery for neonates, infants, and children <6 years in 121/223 (54·3%), 147/223 (65·9%), and 188/223 (84·3%) of hospitals respectively.

Interpretation

Outcomes following anaesthesia and surgery for children in Africa are poor, with complication rates up to fourfold higher (18% versus 4·4-14%) and mortality rates 8-fold higher than high-income countries in a crude, unadjusted comparison (17·9 deaths versus 2·18 deaths per 1000 children). To improve surgical outcomes for children in Africa, we need health system strengthening, provision of safe environments for anaesthesia and surgery, and strategies to address the high rate of 'failure to rescue'.

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99	Funding
100	Jan Pretorius Research Fund of the South African Society of Anaesthesiologists (SASA)
101	Association of Anesthesiologists of Uganda
102	
103	Registration
104	This study was registered on ClinicalTrials.gov (NCT05061407).

Introduction

Access to safe and affordable surgery is a public health priority.^{1,2} Children in Africa constitute approximately 40% of the total population compared to the global average of 25%, and consequently children bear a larger proportional burden of the surgical disease.³ In our previous work, we have shown adult surgical outcomes in Africa are poor with a mortality of twice the global average, driven by increased mortality following postoperative complications, which is known as ‘failure to rescue’.^{2,4} However, there are few data describing surgical outcomes for children in Africa. Current reports are limited by small sample sizes or poor generalisability.⁵⁻¹⁰ There are limited multinational studies of outcomes of children following anaesthesia and surgery across the African continent. However, it is likely that children undergoing surgery in Africa are exposed to similar limitations in perioperative care, and poor patient outcomes that have been documented in adult surgical patients.²

Robust epidemiological data are needed to describe patient care and outcomes for children undergoing anaesthesia and surgery in hospitals in Africa. These data are needed to inform national and international healthcare policy, and to define the ongoing research agenda. Given the specialist nature of paediatric anaesthesia and surgery, access, resources, and staff training are likely to create even greater challenges in the provision of safe, effective perioperative care to children than we know exist for adults in African hospitals. We hypothesized that the surgical outcomes following surgery in children in Africa would therefore be worse than reported elsewhere. To ensure safe surgery and anaesthesia for children in Africa, it is therefore important to understand the morbidity and mortality associated with surgical care.

The objectives of this study were therefore to determine: i) the incidence of in-hospital postoperative complications and death up to 30 days after surgery, and ii) the association between pre-operative, and intra-operative risk factors with postoperative complications and death amongst children undergoing surgery in Africa. These epidemiological data will inform health policy at a national and international level in African health systems, and define a research agenda to ensure safe, and effective anaesthesia and surgical care for children in Africa.

Methods

Study design, setting, and participants

ASOS-Paeds was a fourteen-day, international prospective, observational cohort study of children (<18 years) undergoing surgery in hospitals in Africa. This study was registered on ClinicalTrials.gov (NCT05061407). Our study is reported in accordance with the STROBE statement.¹¹ Research ethics and regulatory approvals were in place before starting the study at each site, in accordance with their national research regulations. The primary ethics approval was from the Health Research Ethics Committee of the Faculty of Health Sciences, University of Cape Town (HREC 466/2021). The study was undertaken as an international clinical audit with no significant risk to the study population. We expected that in most countries there would be no requirement for individual patient consent as all data were recorded as part of routine clinical care and anonymised before being uploaded to the study database. This precedent had already been set in previous national and international studies of adults and children undergoing surgery in Africa and Europe.^{2,8,9,12} Only two ethics committees required informed consent, both in South Africa, affecting seven hospital sites. ‘Broadcasting’ signage, as an infographic poster with pictures and words, and as a poster with words only, were placed in participating hospitals to ensure that all patients and parents/guardians were aware that the hospital was participating in the study (Supplementary Material S1).

We aimed to recruit as many hospitals as possible, of all sizes, providing surgical services for children. Eligibility included all consecutive patients <18 years admitted to participating hospitals during the study period who had elective and non-elective surgery. This included day case surgery and operative procedures outside of operating theatres requiring local or general anaesthesia. Exclusion criteria were: i) patients undergoing radiological or other procedures not requiring general anaesthesia, or where general anaesthesia was performed but no procedure was performed e.g., general anaesthesia to facilitate radiological imaging, ii) patients having obstetric surgery, and iii) prior participation in ASOS-Paeds. Patient recruitment at a site ran for fourteen days, commencing on the date chosen by each participating hospital within the study recruitment period of 15 January 2022 to 23 December 2022. Recruitment started at 07h00 on day one and finished at 06h59 on the fourteenth day. Follow up was until discharge, censored at 30 days if the patient was still alive and in hospital. Our study website provided open access to all study documents and frequently asked questions (<https://www.asos.org.za/index.php/asos-paeds>), training videos, and virtual meetings were conducted to provide training for patient recruitment, and data collection and management. Data were collected by study investigators who included medical doctors, anaesthesia providers, surgery providers, medical students and research assistants.

Variables and data

Hospital-specific data included the DCP-3 hospital level of care (first, second, third),¹³ reimbursement status of the hospital, number of operating rooms, number of specialists, number and level of critical care beds, resources and equipment appropriate to paediatric surgery and anaesthesia (e.g. oxygen, electricity, paediatric airway trolleys etc.), and on-site availability of blood (Supplementary Material S2). The study design and data collected was informed by a previous national study in South Africa (SAPSOS).⁸ Data included co-existing disease, indication for surgery, urgency, severity and type of surgery, and level of care immediately postoperatively. Complications were assessed according to predefined criteria (the case record form (CRF) and definitions are shown in Supplementary Materials S3- S5) and were graded as mild, moderate, or severe. All sites had to provide a screening log of eligible study patients on each of the 14 days of recruitment. Data were collected on paper CRFs and then anonymised during the transcription process using Research Electronic Data Capture (REDCap) tools hosted by Safe Surgery South Africa. Soft limits were set for data entry, prompting investigators when data were entered outside these limits. There were therefore two data entry checks at the time of electronic submission, and the soft limits set on REDCap. In countries with poor internet access, mobile phones were used for data entry, or paper CRFs were securely submitted via WhatsApp or e-mailed to Safe Surgery South Africa for data entry. National lead investigators confirmed the face validity of the unadjusted outcome data for their countries.

Patient outcomes

The primary outcome measure was postoperative complications in hospital up to 30 days after surgery. The secondary outcome measures included in-hospital mortality up to 30 days after surgery. Severe intraoperative critical incidents were also a secondary outcome which will be presented in a separate peer-reviewed paper.

Statistical analysis

To provide generalisable data and minimise sample bias we aimed to recruit as many sites as possible, including all eligible consecutive patients. A statistical analysis plan was written before data analysis (Supplementary Material S6). Categorical variables are described as proportions. Continuous variables are described as mean and standard deviation if normally distributed or median and interquartile range (IQR) if not normally distributed. Missing data was assessed by inspection of the proportion of complete data submitted per variable, the pattern of missing data (assessed by univariate statistics, t-tests, cross tabulations with chi-square tests of independence) and

Little's missing completely at random (MCAR) test. The results of Little's MCAR tests showed that the data are likely MCAR. With less than 1.5% data missing respectively on the two variables with missing data exceeding 1%, the proportion of missing data were small enough to ignore. No imputation was done. Hierarchical multi-level generalised linear mixed models (GLMM), with patients, hospitals and countries at the first, second and third levels respectively were constructed to identify factors independently associated with postoperative in-hospital complications and mortality. All risk factors were considered for entry into the models as the number of reported deaths exceeded 10 events (deaths) per variable,¹⁴ provided there was no evidence of collinearity. Collinearity was assessed using the variance inflation factor. If collinearity was detected, then variables would either be excluded or combined. It was planned that, if necessary, statistical models would be adapted to the event rate provided by the sample recruited, in order to prevent overfitting of any logistic regression models¹⁴ based on their univariate relation to outcome ($p < 0.05$), biological plausibility and low rate of missing data. The following variables were entered into the models: age, sex, American Society of Anesthesiologists (ASA) category, preoperative co-existing diseases (cardiac disease, chronic respiratory disease, neurological disorder, HIV/AIDS, cancer, current respiratory tract infection, other comorbidity), urgency of surgery (elective or emergency), severity of surgery (minor, intermediate, or major), indication for surgery (non-communicable disease, infection, trauma, congenital), type of surgery (neurosurgery, cardiac surgery, gynaecological surgery, thoracic surgery, ear, nose and throat surgery, hepatobiliary surgery, orthopaedic surgery, maxillofacial and dental surgery, gastrointestinal surgery, kidney and urological surgery, ophthalmology, plastic and cutaneous surgery, burns surgery, and other), anaesthesia induction after hours, and surgery duration. All analyses were complete case analyses due to a low rate of missing data. Variance partition coefficients (VPC) were derived for county and hospital for both complications and mortality.¹⁵ Residuals plots were inspected to assess for any outlying cases and potential influential cases. The impact of these cases on the models was further assessed by refitting the models with these cases excluded.

The following pre-specified sensitivity analyses were conducted for the analysis for the primary outcome of postoperative complications: elective, and emergency surgical cohorts, and a cohort excluding patients with a current or recently diagnosed Covid-19 infection (defined as confirmed Covid-19 infection from 7 weeks preoperatively to 30 days postoperatively). The results of the analysis are reported as adjusted odds ratios (OR) with 95% confidence intervals (CI). Post hoc sensitivity analyses requested by the reviewers included the inclusion of the following variables in the GLMM: country human development index classification (middle versus low-income countries), hospital level, provider level and use of the surgical safety checklist.

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The meta-analysis of perioperative mortality following paediatric surgery (defined as death occurring within 30 days following a surgical procedure) was updated to include ASOS-Paeds (PROSPERO CRD42022357658). The study inclusion criteria were studies published after 2011 with ≥ 200 patients in the study cohort and reporting perioperative mortality in paediatric surgical patients.

Role of the funding source

This study was funded by Jan Pretorius Research Fund of the South African Society of Anaesthesiologists (SASA) and Association of Anesthesiologists of Uganda. Funding was used to pay for ethics fees. No individual was compensated for collecting data. The funders had no role in the study design, data collection, data analysis, data interpretation, writing of the paper, or the decision to submit. All members of the writing committee had access to all the data in the study. AT and BMB had final responsibility for the decision to submit for publication.

Results

Hospital-level data

We recruited 8625 of 8757 (98·5%) children eligible for the study from 249 hospitals in 31 countries (Figure 1). The countries included 14 low-income countries (Burkina Faso, Democratic Republic of Congo, Ethiopia, Gambia, Madagascar, Malawi, Mali, Niger, Rwanda, Sierra Leone, Somalia, Somaliland, Sudan, Uganda), 16 middle-income countries (Algeria, Cameroon, Congo, Egypt, Ghana, Guinea, Kenya, Libya, Mauritius, Morocco, Namibia, Nigeria, Senegal, South Africa, Tunisia, Zimbabwe) and one high-income country (Seychelles). Seven hospitals in South Africa were required to take informed consent for participation, and 25 eligible patients were excluded who did not consent. The recruitment per country was a median of 127 patients [IQR 54-359] (Supplementary Material S7). Hospital level recruitment was a median of 24 patients [IQR 11-47]. Hospital level data were provided for 240 (92·0%) of the 249 hospitals. There were 41 (17·1%) level 1, 52 (21·7%) level 2, and 147 (61·3%) level 3 hospitals. 169 (79·3%) of 213 hospitals were government funded, 22 (10·3%) of 213 were privately funded, and 22 (10·3%) of 213 were non-governmental organisations, mission or charity hospitals. There were 69/249 (27·7%) university affiliated hospitals. The hospitals had a median of 300 beds (IQR 150-500), five operating rooms (IQR 3-8) and two paediatric critical care beds allowing invasive ventilation (IQR 0-6). There was a median of seven full time specialist surgeons (IQR 3-16·5), three full time specialist anaesthesiologists (IQR 1-6) and five full time specialist paediatricians (IQR 1-10). 32/182 (17·6%) of the hospitals had a median of two full time specialist anaesthesiologists that practiced only paediatric anaesthesia (IQR 1-4). The reported total surgical volume per month was a median of 200 (IQR 80-400) cases, of which a median of 35 (17·5%) (IQR 20-88) were children <18 years of age. Data describing operating room preparedness, equipment, drugs and protocols necessary for safe paediatric surgery were available from 233/249 (93·6%) sites (Supplementary Material S8). Operating rooms were reported as safe for anaesthesia and surgery for neonates in 121/223 (54·3%), for infants in 147/223 (65·9%) and for children <6 years in 188/223 (84·3%). Electricity, and oxygen were unreliable at 48/221 (21·8%) and 42/221 (19·0%) of hospital sites respectively. The emergency drugs: epinephrine and atropine were not always at 33/221 (14·9%) and 26/221 (11·8%) of hospital sites respectively. Many sites did not have protocols and administrative data collection to support safe surgery (Supplementary Material S8).

Patient-level data

The patient cohort characteristics are shown in Table 1. The mean age was 6·1 years, with 5675 (66%) of 8600 children being male. Most children were ASA category 1 (6110/8579, 71·2%) having elective surgery (5325/8604,

61·9%). The most common comorbidity was a neurological disorder (383/8612, 4·4%) followed by cardiac disease (259/8612, 3·0%) and a current respiratory tract infection 252/ 8612 (2·9%). There were 184/8600 (2·1%) children with a current or recently diagnosed Covid-19 infection. The most common primary indication for surgery was congenital disease (3397/8590, 39·5%). The three most common types of surgery were gastrointestinal (2158/8600, 25·1%), kidney and urology (1505/8600, 17·5%) and orthopaedic (1216/8600, 14·1%). 1516/8506 (17·8%) of surgeries were performed after hours. The World Health Organisation (WHO) surgical safety checklist was used in 4817/8580 cases (56·1%).

Most children (7166/8625, 83·9%) went to a ward postoperatively, and 436/8625 (5·1%) were admitted to a critical care unit postoperatively. Postoperative length of stay was 2 (IQR 1-4) days, and 1717/8371 (20·5%) children were discharged on the day of surgery. The postoperative outcomes are shown in Table 2. 199 of 8596 children died (2·3%) following surgery and 23 of these children (11·6%) died on the day of surgery. Postoperative complications occurred in 1532/8515 (18·0%) of children, of which 166/1530 (10·8%) deaths followed postoperative complications. Most complications occurred in the ward (944/1520, 62·1%), but most deaths occurred in high-care wards and critical care units (128/193, 66·3%). Nearly half of the complications occurred in elective surgical patients (699/1530, 45·7%), but most of the deaths occurred in urgent and emergency surgeries (169/199, 84·9%). Most deaths occurred in children who underwent gastrointestinal surgery (105/199 (52·8%). A post hoc analysis showed that the majority of these deaths occurred in neonates (43/105, 41·0%), and infants (25/105, 23·8%). The most common group of postoperative complications were infections (971/8538, 11·4%) (Table 3). The most common complications were bleeding (467/8552, 5·5%) and superficial surgical site infections (549/8562, 6·4%). The mortality was highest following cardiovascular complications (120 deaths following 216 cardiovascular complications, 55·6%). The outcomes by facility level are shown in Supplementary Material S9. All complications and mortality were most common in level 3 hospitals (1213/1445 (83·9%) complications, and 154/184 (83·7%) deaths).

The missing data for risk factors and outcomes are shown in Supplementary Material S10. Data completeness was good with no variable having more than 1·4% of the data missing. The factors independently associated with postoperative complications included: age of 0-28 days, a higher ASA category, co-existing diseases (neurological disorder, chronic respiratory disease, cancer, current respiratory tract infection, and ‘other’ comorbidities), emergency surgery, intermediate and major surgery, infection as an indication for surgery, burns surgery, and an

increasing duration of surgery (Table 4). Estimates of VPC for all complications were 0·008 and 0·237 for country and hospital respectively, indicating a correlation in complications between individuals within the same hospital of 0·237 suggesting that 23·7% of the total variance in complications was attributable to differences between hospitals within countries. Estimates of VPC for mortality were 0·167 and 0·328 for country and hospital respectively. Excluding cases where the residuals deviated from the cohort, did not change the model. The sensitivity analyses of elective surgical patients, emergency surgical patients, and exclusion of patients with recent Covid-19 were consistent with the overall generalised linear mixed model of the primary analysis. A post hoc decision to conduct a sensitivity analysis excluding the two countries providing more than 10% of the patients to the dataset (Egypt and South Africa) was also consistent with the overall analysis (Supplementary Material S11-S14 respectively). Neither the country human development index, hospital level, provider level, nor the use of the surgical safety checklist were independently associated with postoperative complications in the adjusted model (Supplementary Material S15-S18).

The factors independently associated with postoperative mortality included: age < 1 year, ASA category ³3; co-existing diseases (neurological disorder, cardiac disease, current respiratory tract infection); emergency surgery; burns surgery and an increasing duration of surgery (Table 5). No sensitivity analyses were conducted for mortality, as there were an insufficient number of outcome events to conduct robust analyses.¹⁴

The updated meta-analysis including of mortality following surgery in children which includes ASOS-Paeds is shown in Supplementary Materials S19-S23. The 30-day mortality following paediatric surgery is 10·6 times higher in Africa than high-income countries (23 deaths per 1000 children, 95% CI 20-27 and 2 deaths per 1000 children, 95% CI 1-3 respectively) in a crude, unadjusted comparison.

Discussion

This was a prospective, observational study of surgical outcomes for children undergoing surgery in 31 African countries. The principal findings were that postoperative complications occurred in 18% of children with an in-hospital mortality rate of 2.3%. Complication rates were up to fourfold higher,¹⁶⁻¹⁹ and mortality was 11-fold higher than high-income countries.^{18,20-22} The main risk factors for postoperative complications were co-existing disease, intermediate and major surgery, and emergency surgery. Neonates and infants were independently associated with postoperative complications and mortality. Factors contributing to the difficulty in providing safe anaesthesia and surgery included unreliable oxygen and electricity supplies, a lack of essential emergency drugs needed to manage cardiovascular complications, and a lack of protocols and procedures to support safe clinical surgical practice. These findings suggest that poor outcomes following surgery for children in Africa are an even more serious public health problem than amongst adults. There is an urgent need to improve the safety and effectiveness of anaesthesia and surgery for children in African hospitals.

The strength of this study is that it provides a comprehensive presentation of outcomes for children having surgery from 31 African countries, with data completeness exceeding 98% for all prognostic risk factors, and the outcomes of postoperative complications and mortality. Furthermore, missing data appeared to be missing at random, suggesting no systemic bias to the data submitted. The sensitivity analyses support the primary analysis suggesting that the findings are potentially generalisable across the participating countries. The VPC suggests that the complications and mortality attributed to differences between countries is limited (0.8% and 16.7% respectively). However at the level of the hospital, between a ¼ and 1/3 of the complications and mortality is attributable to differences between hospitals (23.7% and 32.8% respectively). This study overcomes the limitations of previous studies of postoperative complications in children having surgery in Africa which were limited in recruitment, scope, and standardisation of outcomes, and follow up.²³⁻²⁵ The incidence of postoperative complications following paediatric surgery is 30% higher in Africa than reported in the United States American College of Surgeons National Surgical Quality Improvement Program: Pediatric (NSQIP: Pediatric) which also reported on a mixed cohort of in-patient paediatric surgical patients.¹⁹ Failure to rescue reported in the United States sample was 3%¹⁹ compared to nearly fourfold increase in Africa of 10.8%. In summary, although adult surgical outcomes in Africa are poor,² outcomes following surgery in children in Africa are even poorer.

The large number of postoperative complications occurring in healthy children (over 50% occur in ASA category 1 patients) in Africa, and the high postoperative mortality, and failure to rescue suggests that there is an opportunity to provide safer surgery for healthy, elective children, as well as for children having emergency surgery in Africa. Unfortunately, in many cases the clinicians report that the environment for anaesthesia and surgery does not support the delivery of safe anaesthesia and surgery, or the management of complications following surgery. Previous studies have also identified similar challenges in providing surgery for children in district hospitals in Malawi, Tanzania, and Zambia. Surgeries were performed by general medical officers with inadequate surgical equipment and supplies, in an environment with unreliable electricity and access to running water.²⁶ Our data is in keeping with studies reporting on hospital infrastructure and equipment where the available continuous oxygen supply ranges from 22 to 61% of hospitals, an unreliable electricity supply is present in 50-70%, availability of pulse oximeters in 48-75% in hospitals in Africa.²⁷ This suggests that there is a need for a comprehensive approach to provide environments which are safe for anaesthesia and surgery for children in Africa by addressing the limitations in resources (physical and human), education and minimum standards of practice, and improved safety practices. We therefore echo the call for including children in National Surgical Obstetric and Anaesthesia Plans (NSOAPs), and support baseline assessment using the Global Initiative for Children's Surgery (GICS) modified Children's Surgical Assessment Tool (CSAT) tool and the Optimal Resources for Children Surgical Care (OReCS),²⁸ or the Anesthesia Facility Assessment Tool (AFAT) developed by the World Federation of Societies of Anaesthesiologists (WFSA). The current NSOAP Surgical Assessment Tool (SAT) does not capture data on number of specialists providing anaesthesia or surgery for children. Providing a scaffolding for safe anaesthetic practice and surgery for children must be a priority for Africa. OReCS provides a roadmap to inform NSOAPs and for improving anaesthesia and surgical care in children.²⁸ Healthcare expenditure needs to prioritise providing equipment, drugs and infrastructure necessary for safe anaesthesia and surgery for children. High quality training and education is needed for all healthcare workers providing paediatric surgical care, including both physicians and non-physician providers.

Limitations of this study may include the inability to extrapolate the findings to the African countries which were not represented. It is likely, however, that the non-participating countries may have worse outcomes than presented here due to insufficient infrastructure and resources necessary for participation. This is evident by the inability of 12 countries to obtain ethical approval despite willing collaborators (Figure 1). There is also an over-representation of level 3, well-resourced hospitals in this study. This limitation may however present a broader problem in that

level 1 hospitals may be under-represented because they cannot provide anaesthesia and surgery for children. Most hospitals which participated but did not recruit a single patient into the study (11/14 [78·6%]) were level 1 hospitals suggesting that these are the hospitals with insufficient resources for safe anaesthesia and surgery in children. The inability to provide anaesthesia and surgery at level 1 hospitals would decrease access to surgical care for children further compromising outcomes for surgical pathology.¹ We are unable to determine the proportion of patients who received surgery outside of operating theatres in this study. We are therefore unable to determine the frequency or safety of this practice in Africa. Although, the reports that sites were unsafe for anaesthesia and surgery in children is a subjective assessment by clinicians, and the reporting of unreliable electricity and oxygen resources, shortages of emergency cardiovascular drugs, and a lack of functional incubators was not done with a validated tool, these data are supported by other studies of available equipment and facilities at hospitals in Africa. These factors further strengthen the call for providing the resources to deliver safe anaesthesia and surgery appropriate to each level of care. It is likely that with under resourced level 1 hospitals, less complex, minor surgery in healthy children occurs in higher level hospitals. Due to the pragmatic nature of this study, data were not collected regarding perioperative nursing care which is a further limitation. Perioperative outcomes are also dependent on levels of nursing care. This topic would be a useful future research project of perioperative outcomes in children.

Conclusions

Outcomes following anaesthesia and surgery for children are poor in Africa, with one in five children experiencing a postoperative complication and one in 50 children dying in-hospital within 30 days. To improve these outcomes we need health system strengthening (which focuses on access, resources and training for anaesthesia and surgery), provision of environments which are safe for the conduct of anaesthesia and surgery, and strategies to address the high rate of ‘failure to rescue’.

405 **Other information**

406 *Contributors:*

407 AT, RP and BB were responsible for conception and design of the work.

408 AT and BB were responsible for acquisition, analysis, or interpretation of data for the work; drafting the work and
409 revising it critically; and agreement to be accountable for all aspects of the work in ensuring that questions related
410 to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

411 BB and AH accessed and verified the underlying data of this manuscript and were responsible for analysis and
412 interpretation of data.

413 All authors were responsible for acquisition of data at their sites, critically revising the work, final approval of the
414 version to be published, and agreement to be accountable for all aspects of the work.

415 AT and BB made the final decision to submit for publication.

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417 *Registration*

418 ClinicalTrials.gov (NCT05061407): African Surgical Outcomes Study in Paediatric patients (ASOS-Paeds)

419

420 *Protocol*

421 The protocol and statistical analysis plan are posted at ClinicalTrials.gov (NCT05061407)

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425 Anaesthesiologists (SASA) and the Association of Anesthesiologists of Uganda.

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427 *Data Sharing Statement*

428 Data will be disclosed only upon request and approval of the proposed use of the data by the Steering Committee.

429 Data are available to the journal for evaluation of reported analyses. Data requests from other non-ASOS-Paeds
430 investigators will not be considered until 2 years after the close out of the study. Data will be de-identified for
431 participant, hospital and country, and will be available with a signed data access agreement.

432

433 *Declaration of interests:*

434 AT received a grant from the South Africa Society of Anaesthesiologists for funding the ethical clearances in
435 various countries and for funding for study administrator Safe Surgery South Africa

436 AH-S and MN received funding to pay for ethical clearance of the study in Uganda from the Association of
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438 RP has received grants from Edwards Lifesciences and Intersurgical UK, and consulting fees and honoraria from
439 Edwards Lifesciences.
440 All other authors declare no competing interests.
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1 **Table 1. Baseline characteristics of the African Surgical Outcomes Study in Paediatric patients (ASOS-Paeds) patient cohort**

2

	All patients (n=8625)	Patients with complications (n=1532)	Patients with no complications (n=6983)	Patients who died (n=199)	Patients who survived (n=8397)
Age					
Mean (SD)	6.1 (4.9)	5.5 (5.1)	6.2 (4.8)	3.4 (5.0)	6.2 (4.9)
Median (IQR)	5.0 (1.9-10.0)	3.9 (1.0-9.3)	5.03 (2.0-10.0)	0.5 (0.3-6.0)	5.0 (2.0-10.0)
Sex					
Male	5675/8600 (66%)	958/1529 (62.7%)	4647/6964 (66.7%)	120/197 (60.9%)	5538/8375 (66.1%)
Female	2925/8600 (34%)	571/1529 (37.3%)	2317/6964 (33.3%)	77/197 (39.1%)	2837/8375 (33.9%)
Age category					
0-28 days	310/8591 (3.6%)	130/1528 (8.5%)	170/6954 (2.4%)	68/198 (34.3%)	240/8364 (2.9%)
29-364 days	1168/8591 (13.6%)	243/1528 (15.9%)	911/6954 (13.1%)	49/198 (24.7%)	1112/8364 (13.3%)
1-3 years	2072/8591 (24.1%)	339/1528 (22.2%)	1702/6954 (24.5%)	24/198 (12.1%)	2041/8364 (24.4%)
4-12 years	3948/8591 (46.0%)	602/1528 (39.4%)	3305/6954 (47.5%)	40/198 (20.2%)	3900/8364 (46.6%)
13- <18 years	1093/8591 (12.7%)	214/1528 (14.0%)	866/6954 (12.5%)	17/198 (8.6%)	1071/8364 (12.8%)
ASA Category					
1	6110/8579 (71.2%)	784/1519 (51.6%)	5272/6969 (75.6%)	47/197 (23.9%)	6054/8368 (72.3%)
2	1588/8579 (18.5%)	357/1519 (23.5%)	1210/6969 (17.4%)	40/197 (20.3%)	1546/8368 (18.5%)
3	741/8579 (8.6%)	289/1519 (19.0%)	440/6969 (6.3%)	72/197 (36.5%)	667/8368 (8.0%)
4 and 5	140/8579 (1.6%)	89/1519 (5.9%)	47/6969 (0.7%)	38/197 (19.3%)	101/8368 (1.2%)
Urgency of surgery					
Elective	5325/8604 (61.9%)	699/1530 (45.7%)	4578/6978 (65.6%)	30/199 (15.1%)	5288/8389 (63.0%)
Expedited	941/8604 (10.9%)	192/1530 (12.5%)	737/6978 (10.6%)	30/199 (15.1%)	908/8389 (10.8%)
Urgent	1912/8604 (22.2%)	479/1530 (31.3%)	1406/6978 (20.1%)	98/199 (49.2%)	1810/8389 (21.6%)
Immediate	426/8604 (5.0%)	160/1530 (10.5%)	257/6978 (3.7%)	41/199 (20.6%)	383/8389 (4.6%)
Emergency (all together)	3279/8604 (38.1%)	831/1530 (54.3%)	2400/6978 (34.4%)	169/199 (84.9%)	3101/8389 (37.0%)

Grade of surgery					
Minor	2996/8594 (34.9%)	287/1532 (18.7%)	2672/6972 (38.3%)	19/199 (9.5%)	2972/8381 (35.5%)
Intermediate	3890/8594 (45.3%)	646/1532 (42.2%)	3214/6972 (46.1%)	57/199 (28.6%)	3830/8381 (45.7%)
Major	1708/8594 (19.9%)	599/1532 (35.5%)	1086/6972 (15.6%)	123/199 (61.8%)	1579/8381 (18.8%)
Primary indication for surgery					
Non-communicable	2231/8590 (26.0%)	381/1532 (24.9%)	1829/6967 (26.3%)	45/199 (22.6%)	2184/8376 (26.1%)
Traumatic	1455/8590 (16.9%)	267/1532 (17.4%)	1171/6967 (16.8%)	23/199 (11.6%)	1429/8376 (17.1%)
Infective	1507/8590 (17.5%)	320/1532 (20.9%)	1176/6967 (16.9%)	36/199 (18.1%)	1468/8376 (17.5%)
Congenital	3397/8590 (39.5%)	564/1532 (36.8%)	2791/6967 (40.1%)	95/199 (47.7%)	3295/8376 (39.3%)
Type of surgery					
Neurosurgery	442/8600 (5.1%)	138/1531 (9.0%)	301/6976 (4.3%)	17/199 (8.5%)	425/8385 (5.1%)
Cardiac	160/8600 (1.9%)	61/1531 (4.0%)	98/6976 (1.4%)	11/199 (5.5%)	149/8385 (1.8%)
Gynae	100/8600 (1.2%)	17/1531 (1.1%)	81/6976 (1.2%)	1/199 (0.5%)	98/8385 (1.2%)
Thoracic	107/8600 (1.2%)	47/1531 (3.1%)	58/6976 (0.8%)	14/199 (7.0%)	93/8385 (1.1%)
Ear nose and throat	888/8600 (10.3%)	104/1531 (6.8%)	781/6976 (11.2%)	5/199 (2.5%)	883/8385 (10.5%)
Hepatobiliary	61/8600 (0.7%)	20/1531 (1.3%)	40/6976 (0.6%)	3/199 (1.5%)	58/8385 (0.7%)
Orthopaedic	1216/8600 (14.1%)	164/1531 (10.7%)	1038/6976 (14.9%)	6/199 (3.0%)	1207/8385 (14.4%)
Maxillofacial and dental	216/8600 (2.5%)	30/1531 (2.0%)	186/6976 (2.7%)	2/199 (1.0%)	214/8385 (2.6%)
Gastrointestinal	2158/8600 (25.1%)	494/1531 (32.3%)	1638/6976 (23.5%)	105/199 (52.8%)	2047/8385 (24.4%)
Kidney/ Urology	1505/8600 (17.5%)	217/1531 (14.2%)	1270/6976 (18.2%)	10/199 (5.0%)	1491/8385 (17.8%)
Ophthalmology	332/8600 (3.9%)	11/1531 (3.4%)	317/6976 (4.5%)	0/199 (0.0%)	332/8385 (4.0%)
Plastics/ cutaneous	570/8600 (6.6%)	92/1531 (6.0%)	474/6976 (6.8%)	7/199 (3.5%)	562/8385 (6.7%)
Burns	153/8600 (1.8%)	54/1531 (3.5%)	96/6976 (1.4%)	14/199 (7.0%)	139/8385 (1.7%)
Other	692/8600 (8.0%)	82/1531 (5.4%)	598/6976 (8.6%)	4/199 (2.0%)	687/8385 (8.2%)
Comorbidity					
Cardiac disease	259/8612 (3.0%)	94/1532 (6.1%)	160/6983 (2.3%)	31/199 (15.6%)	228/8397 (2.7%)
Chronic respiratory disease	168/8612 (2.0%)	54/1532 (3.5%)	113/6983 (1.6%)	8/199 (4.0%)	160/8397 (1.9%)

Neurological disorder	383/8612 (4.4%)	116/1532 (7.6%)	262/6983 (3.8%)	27/199 (13.6%)	356/8397 (4.2%)
HIV/AIDS	40/8612 (0.5%)	4/1532 (0.3%)	36/6983 (0.5%)	0/199 (0.0%)	40/8397 (0.5%)
Cancer	171/8612 (2.0%)	53/1532 (3.5%)	111/6983 (1.6%)	5/199 (2.5%)	165/8397 (2.0%)
Current Respiratory Tract Infection	252/8612 (2.9%)	93/1532 (6.1%)	157/6983 (2.2%)	18/199 (9.0%)	234/8397 (2.8%)
Other	213/8612 (2.5%)	67/1532 (4.4%)	141/6983 (2.0%)	15/199 (7.5%)	198/8397 (2.4%)
None	6850/8612 (79.5%)	1204/1532 (66.8%)	5760/6983 (82.5%)	105/199 (52.8%)	6732/8397 (80.2%)
Covid-19 diagnosis	184/8584 (2.2%)	33/1532 (2.2%)	150/6972 (2.2%)	6/184 (3.3%)	78/8385 (0.9%)
After hours operation	1516/8506 (17.8%)	386/1505 (25.6%)	1116/6909 (16.2%)	75/197 (38.1%)	1440/8294 (17.4%)
Not after hours	6990/8506 (82.2%)	1119/1505 (74.4%)	5793/6909 (83.8%)	122/197 (61.9%)	6854/8294 (82.6%)
Surgery checklist	4817/8580 (56.1%)	915/1529 (59.8%)	3850/6959 (55.3%)	116/199 (58.3%)	4694/8369 (56.1%)
No checklist	3763/8580 (43.9%)	614/1529 (40.2%)	3109/6959 (44.7%)	83/199 (41.7%)	3675/8369 (43.9%)
Most senior anaesthetist					
Specialist	5750/8589 (66.9%)	1098/1532 (71.7%)	4588/6962 (65.9%)	152/199 (76.4%)	5592/8375 (66.8%)
Non-specialist physician	1888/8589 (22.0%)	269/1532 (17.6%)	1608/6962 (23.1%)	23/199 (1.6%)	1863/8375 (22.2%)
Nurse	529/8589 (6.2%)	83/1532 (5.4%)	427/6962 (6.1%)	17/199 (8.5%)	505/8375 (6.0%)
Non-physician	422/8589 (4.9%)	82/1532 (5.4%)	339/6962 (4.9%)	7/199 (3.5%)	415/8375 (5.0%)
Most senior surgeon					
Specialist	6698/8594 (77.9%)	1254/1531 (81.9%)	5357/6968 (76.9%)	158/199 (79.4%)	6526/8380 (77.9%)
Non-specialist physician	1828/8594 (21.3)	259/1531 (16.9%)	1564/6968 (22.4%)	39/199 (19.6%)	1788/8380 (21.3%)
Nurse	35/8594 (0.4%)	11/1531 (0.7%)	21/6968 (0.3%)	1/199 (0.5%)	34/8380 (0.4%)
Non-physician	33/8594 (0.4%)	7/1531 (0.5%)	26/6968 (0.4%)	1/199 (0.5%)	32/8380 (0.4%)
Post-op location					
Ward	7166/8625 (83.9%)	944/1520 (62.1%)	6164/6951 (88.7%)	65/193 (33.7%)	7095/8341 (85.1%)
High care	941/8625 (11.0%)	309/1520 (20.3%)	623/6951 (9.0%)	45/193 (23.3%)	895/8341 (10.7%)
Critical care	436/8625 (5.1%)	267/1520 (17.6%)	164/6951 (2.4%)	83/193 (43.0%)	351/8341 (4.2%)

- 3 Data are n/N (%). Denominators vary with the completeness of the data. SD standard deviation, IQR interquartile range, ASA American Society of Anesthesiologists, HIV
- 4 human immunodeficiency virus, AIDS acquired immunodeficiency syndrome

Table 2. Postoperative outcomes in the African Surgical Outcomes Study in Paediatric patients (ASOS-Paeds)

Postoperative outcomes (whole cohort)	n (%)
Complications	1532/8515 (18·0%)
Mortality	199/8596 (2·3%)
Mortality on the day of surgery	23/199 (11·6%)
Death following a postoperative complication	166/1530 (10·8%)
Elective surgery cohort	5325/8604 (61·9%)
Complications	699/5325 (13·1%)
Mortality	30/5318 (0·6%)
Mortality on the day of surgery	7/30 (23·3%)
Death following a postoperative complication	23/698 (3·3%)
Emergency surgery cohort	3279/8604 (38·1%)
Complications	831/3231 (25·7%)
Mortality	169/3270 (5·2%)
Mortality on the day of surgery	16/169 (9·5%)
Death following a postoperative complication	143/830 (17·2%)

Data are n/N (%). Denominators vary with the completeness of the data.

Table 3. Postoperative complications in the African Surgical Outcomes Study in Paediatric patients (ASOS-Paeds)

COMPLICATIONS	Patients (n)	Mild (n, %)	Moderate (n, %)	Severe (n, %)	Patients with complications (n, %)	Deaths following complications (n, %)
All complications	8515	1193	883	538	1532/8515 (18·0%)	166/1530 (10·8%)
Infection	8538				971/8538 (11·4%)	107/970 (11·0%)
Superficial surgical site infection	8562	299 (3·5%)	194 (2·3%)	56 (0·7%)	549/8562 (6·4%)	28/549 (5·1%)
Deep surgical site infection	8553	52 (0·6%)	88 (1·0%)	76 (0·9%)	216/8553 (2·5%)	31/216 (14·4%)
Body cavity infection	8553	36 (0·4%)	54 (0·6%)	42 (0·5%)	132/8553 (1·5%)	16/132 (12·1%)
Bloodstream infection	8552	52 (0·6%)	104 (1·2%)	83 (1·0%)	239/8552 (2·8%)	59/239 (24·7%)
Pneumonia	8552	116 (1·4%)	102 (1·2%)	64 (0·7%)	282/8552 (3·3%)	57/281 (20·3%)
Other infection	8544	61 (0·7%)	51 (0·6%)	24 (0·3%)	136/8544 (1·6%)	14/136 (10·3%)
Cardiovascular	8543				216/8543 (2·5%)	120/216 (55·6%)
Cardiac arrest	8571			133 (1·6%)	133/8571 (1·6%)	113/133 (85·0%)
Arrhythmia	8554	60 (0·7%)	32 (0·4%)	35 (0·4%)	71/8554 (1·5%)	43/127 (33·9%)
Other	8545				809/8545 (9·5%)	99/808 (12·3%)
Bleeding	8552	340 (4·0%)	105 (1·2%)	22 (0·3%)	467/8552 (5·5%)	29/466 (6·2%)
Acute kidney injury	8554	39 (0·5%)	37 (0·4%)	29 (0·3%)	105/8554 (1·2%)	40/105 (38·1%)
Other	8551	138 (1·6%)	116 (1·4%)	107 (1·3%)	361/8551 (4·2%)	65/361 (18·0%)
Re-operation	8565				347/8565 (4·1%)	

Data are n/N (%). Denominators vary with the completeness of the data.

Table 4. Generalised linear mixed model factors independently associated with postoperative complications.

Model Term	Intercept (odds)	95% confidence interval	P-value
Intercept	0.041	0.023-0.074	<0.001
Age 0-28 days	2.301	1.594-3.322	<0.001
29-364 days	1.261	0.966-1.647	0.088
1-3 years	1.065	0.838-1.355	0.605
4-12 years	0.953	0.772-1.177	0.654
Age 13-<18 years	Reference		
Female	1.061	0.921-1.222	0.414
Male	Reference		
ASA 4 and 5	6.161	3.947-9.616	<0.001
3	2.626	2.040-3.381	<0.001
2	1.446	1.200-1.743	<0.001
ASA 1	Reference		
Cardiac disease	1.130	0.722-1.767	0.593
Chronic respiratory disease	1.885	1.235-2.877	0.003
Neurological disorder	1.704	1.188-2.444	0.004
HIV/AIDS	0.376	0.121-1.165	0.090
Cancer	1.952	1.251-3.046	0.003
Current respiratory tract infection	2.080	1.492-2.898	<0.001
Other	1.556	1.061-2.282	0.024
Emergency	1.473	1.240-1.749	<0.001
Elective	Reference		
Major	2.075	1.630-2.640	<0.001
Intermediate	1.386	1.149-1.673	<0.001
Minor	Reference		
Congenital	0.968	0.793-1.182	0.752
Infective	1.517	1.211-1.899	<0.001
Traumatic	1.320	1.009-1.727	0.043
Non-communicable	Reference		
Other	1.178	0.663-2.090	0.576
Burns	2.315	1.191-4.500	0.013
Plastics/cutaneous	1.656	0.944-2.903	0.078
Ophthalmology	0.311	0.137-0.703	0.005
Kidney/urology	1.336	0.784-2.276	0.287
Gastrointestinal	1.141	0.678-1.919	0.620
Orthopaedic	0.955	0.554-1.647	0.869
Hepatobiliary	1.437	0.618-3.343	0.400
Ear nose and throat	0.903	0.516-1.579	0.721

Thoracic	1·684	0·832-3·408	0·148
Gynae	0·873	0·377-2·020	0·750
Cardiac	1·450	0·674-3·121	0·342
Neurosurgery	0·968	0·534-1·755	0·916
Maxillofacial and dental	Reference		
Surgery after hours	1·188	0·984-1·435	0·074
Surgery not after hours	Reference		
Duration of surgery (per 15 minute increase)	1·078	1·059-1·098	<0·001

ASA American Society of Anesthesiology; HIV/AIDS human immunodeficiency virus/ acquired immunodeficiency syndrome

Table 5. Generalised linear mixed model factors independently associated with in-hospital mortality.

Model Term	Intercept (odds)	95% confidence interval	P-value
Intercept	0.002	0.000-0.010	<0.001
Age 0-28 days	10.657	4.768-23.822	<0.001
29-364 days	4.398	2.128-9.091	<0.001
1-3 years	1.331	0.613-2.889	0.470
4-12 years	0.975	0.496-1.916	0.942
Age 13-<18 years	Reference		
Female	0.926	0.644-1.331	0.678
Male	Reference		
ASA 4 and 5	14.133	7.120-28.052	<0.001
3	3.912	2.268-6.747	<0.001
2	1.546	0.920-2.598	0.100
ASA 1	Reference		
Cardiac disease	2.178	1.036-4.579	0.040
Chronic respiratory disease	2.048	0.760-5.517	0.156
Neurological disorder	6.083	2.846-13.004	<0.001
HIV/AIDS*	-	-	0.992
Cancer	1.500	0.428-5.264	0.527
Current respiratory tract infection	2.208	1.125-4.333	0.021
Other	2.228	1.068-4.645	0.033
Emergency	3.952	2.393-6.525	<0.001
Elective	Reference		
Major	1.848	0.972-3.511	0.061
Intermediate	0.920	0.500-1.694	0.790
Minor	Reference		
Congenital	0.858	0.494-1.492	0.588
Infective	0.851	0.466-1.553	0.598
Traumatic	0.848	0.359-2.002	0.706
Non-communicable	Reference		
Other	0.648	0.098-4.272	0.652
Burns	10.430	1.722-63.178	0.011
Plastics/cutaneous	2.140	0.364-12.571	0.400
Ophthalmology*	-	-	0.980
Kidney/urology	0.961	0.175-5.290	0.964
Gastrointestinal	1.475	0.300-7.265	0.633
Orthopaedic	0.594	0.098-3.594	0.571
Hepatobiliary	2.017	0.250-16.294	0.511
Ear nose and throat	1.002	0.161-6.223	0.998

Thoracic	1·642	0·277-9·722	0·585
Gynae†	-	-	0·988
Cardiac	0·628	0·090-4·371	0·638
Neurosurgery	0·296	0·050-1·753	0·180
Maxillofacial and dental	Reference		
Surgery after hours	1·248	0·821-1·896	0·299
Surgery not after hours	Reference		
Duration of surgery (per 15 minute increase)	1·043	1·013-1·074	0·004

ASA American Society of Anesthesiology; HIV/AIDS human immunodeficiency virus/ acquired immunodeficiency syndrome; * `no deaths; † 1 death

Figure 1. African Surgical Outcomes Study in Paediatric patients (ASOS-Paeds)

recruitment

