Outcomes after surgery for children in Africa (ASOS-Paeds): a 14-day prospective observational cohort study

*The ASOS-Paeds Investigators**

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See Online for appendix

Summary

Background Safe anaesthesia and surgery are a public health imperative. There are few data describing outcomes for children undergoing anaesthesia and surgery in Africa. We aimed to get robust epidemiological data to describe patient care and outcomes for children undergoing anaesthesia and surgery in hospitals in Africa.

Methods This study was a 14-day, international, prospective, observational cohort study of children (aged <18 years) undergoing surgery in Africa. We recruited as many hospitals as possible across all levels of care (first, second, and third) providing surgical treatment. Each hospital recruited all eligible children for a 14-day period commencing on the date chosen by each participating hospital within the study recruitment period from Jan 15 to Dec 23, 2022. Data were collected prospectively for consecutive patients on paper case record forms. The primary outcome was in-hospital postoperative complications within 30 days of surgery and the secondary outcome was in-hospital mortality within 30 days after surgery. We also collected hospital-level data describing equipment, facilities, and protocols available. This study is registered with ClinicalTrials.gov, NCT05061407.

Findings We recruited 8625 children from 249 hospitals in 31 African countries. The mean age was 6·1 (SD 4·9) years, with 5675 (66·0%) of 8600 children being male. Most children (6110 [71·2%] of 8579 patients) were from category 1 of the American Society of Anesthesiologists Physical Status score undergoing elective surgery (5325 [61·9%] of 8604 patients). Postoperative complications occurred in 1532 (18·0%) of 8515 children, predominated by infections (971 [11·4%] of 8538 children). Deaths occurred in 199 (2·3%) of 8596 patients, 169 (84·9%) of 199 patients following emergency surgeries. Deaths following postoperative complications occurred in 166 (10·8%) of 1530 complications. Operating rooms were reported as safe for anaesthesia and surgery for neonates (121 [54·3%] of 223 hospitals), infants (147 [65·9%] of 223 hospitals), and children younger than 6 years (188 [84·3%] of 223 hospitals).

Interpretation Outcomes following anaesthesia and surgery for children in Africa are poor, with complication rates up to four-fold higher (18% *vs* 4·4–14%) and mortality rates 11-fold higher than high-income countries in a crude, unadjusted comparison (23·15 deaths *vs* 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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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 with the global average of 25% and, consequently, bear a larger proportional burden of the surgical disease.[3] In our previous work,[2,4] we have shown that 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 small numbers of multinational studies of outcomes of children following anaesthesia and surgery across the African continent. It is likely that children undergoing surgery in Africa are exposed to similar limitations in perioperative care, in addition to poor patient outcomes as documented in adult surgical patients.[2]

We aimed to get robust epidemiological data 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 health-care 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 and effective perioperative care to children than we know exist for adults in African hospitals. We hypothesised that the surgical outcomes following surgery in children in Africa would be different from those reported elsewhere. To ensure safe surgery and anaesthesia for children in Africa, it is important to understand the morbidity and mortality

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 with 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 years. 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 (registered in PROSPERO [CRD42022357658]) as part of this report on July 5, 2022. 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 between Jan 1, 2012, to July 5, 2022 with no language restrictions that included at least 200 children in the cohort and reported perioperative mortality for a range of surgical procedures. 158 reports had full-text review for eligibility from 13 258 abstracts (appendix p 77). Nine 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, that South Africa accounted for 10 517 (64·3%) of 16 349 included patients, and that a large paediatric specialist hospital accounted for more than half of cases reported (8493 [51·9%] of 16 349 patients). These data have suggested that the outcomes in Africa are potentially poor (16 deaths per 1000 children [95% CI 9–24] in Africa compared with two deaths per 1000 children [95% CI 1–3] in high-income countries). This meta-analysis suggests that there is insufficient data 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, postoperative complications occurred in 18% of children, which is a three-fold greater rate than high-income countries. The 30-day in-hospital surgical mortality was 2·3%, which is 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 one in nine children in Africa, which is four-fold 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 younger than 6 years. 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 all the available evidence

This study provides robust data describing outcomes for children undergoing surgery in African hospitals. The findings show that the outcomes for children in Africa are even worse than that reported for adults, with mortality rates 11 times greater than for children in high-income countries. These data reveal a neglected public health crisis in Africa and the health-care inequity for children in Africa. This study shows 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 that are safe for the conduct of anaesthesia and surgery, and strategies to address the high rate of failure to rescue. Improvement of surgical outcomes for children will require cross-sectoral cooperation and long-term planning involving health leaders, policy makers, and funders.

associated with surgical care. The objectives of this study were therefore to determine the incidence of in-hospital postoperative complications and death up to 30 days after surgery, and the association between pre-operative and intra-operative risk factors with postoperative complications and death among children undergoing surgery in Africa.

The 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 and participants

This study was a 14-day, international, prospective, observational cohort study of children (aged <18 years) undergoing surgery in hospitals in African countries. The study was undertaken as an international clinical audit with no significant risk to the study population. We aimed to recruit as many hospitals as possible, of all sizes, providing surgical services for children.

Eligibility criteria were all consecutive patients aged younger than 18 years admitted to participating hospitals from Jan 15 to Dec 23, 2022 who had elective and non-elective surgery, which included day case surgery and operative procedures outside of operating theatres requiring local or general anaesthesia. Exclusion criteria were: (1) patients undergoing radiological or other procedures not requiring general anaesthesia, or when general anaesthesia was performed but no procedure was performed (eg, general anaesthesia to facilitate radiological imaging); (2) patients having obstetric surgery; and (3) previous participation in the ASOS-Paeds trial. Patient recruitment at all sites ran for 14 days commencing on the date chosen by each participating hospital within the study recruitment period. Recruitment started at 0700 h on day 1 and finished at 0659 h on the 14th 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 were sent via email and WhatsApp, and virtual meetings took place on Zoom 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.

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.[2,8,9,11] Three ethics committees required informed consent, two in South Africa and one in Malawi, affecting seven hospitals (appendix p 82). At these sites, consent was obtained from parents for all children in the study. Assent was obtained from all children aged 12–17 years, and from children aged 7–11 years if they were deemed able to understand. If any child was not capable of understanding, then assent was waivered. 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 or guardians were aware that the hospital was participating in the study (appendix pp 37–38).

This study was registered with ClinicalTrials.gov, NCT05061407. This study is reported in accordance with the STROBE statement.[12] 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).

Procedures

Hospital-specific data included the Disease Control Priorities Project-3, which defines hospital levels of care (first, second, and 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 (eg, oxygen, electricity, and paediatric airway trolleys), and onsite availability of blood (appendix pp 39–41). The study design and data collected were informed by a previous national study in South Africa (the SAPSOS trial).[8] Data included co-existing disease, indication for surgery, urgency, severity and type of surgery, and level of care immediately postoperatively (appendix p 51). Complications were assessed according to predefined criteria (the case record form and definitions are in the appendix [pp 42–52]) and were graded as mild, moderate, or severe. All sites had to provide a screening log of eligible patients on each of the 14 days of recruitment. Data were collected on paper on the case record forms and then anonymised during the transcription process using Research Electronic Data Capture tools hosted by Safe Surgery South Africa, a research-driven non-profit organisation. Soft limits were set for data entry, prompting investigators when data were entered outside these limits; therefore, there were two data entry checks at the time of electronic submission, and the soft limits were set on the Research Electronic Data Capture tool. In countries with poor internet access, mobile phones were used for data entry or paper-based case record forms 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.

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 reported in a separate study.

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 (appendix pp 53–54). Categorical variables have been described as proportions, and continuous variables have been described as mean and standard deviation if normally distributed, or median and interquartile range 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, and cross tabulations with χ^2 tests of independence) and Little's missing completely at random (MCAR) test. The results of Little's missing completely at random tests showed that the data were likely missing completely at random. With less than 1·5% data missing 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 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 ten 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 to prevent overfitting of any logistic regression models[14] based on their univariate relation to outcome ($p<0 \cdot 05$), biological plausibility, and low rate of missing data. The following variables were entered into the models: age, sex, American Society of Anesthesiologists category, preoperative co-existing diseases (ie, cardiac disease, chronic respiratory disease, neurological disorder, HIV/AIDS, cancer, current respiratory tract infection, or other comorbidity), urgency of surgery (elective or emergency), severity of surgery (minor, intermediate, or major), indication for surgery (non-communicable disease, infection, trauma, or congenital), type of surgery (ie, 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 were derived for country and hospital for both complications and mortality.[15] Residual plots were inspected to assess for any outlying cases and potential influential cases. The effect of these cases on the models was further assessed by refitting the models with these cases excluded.

Pre-specified sensitivity analyses were elective and emergency surgical cohorts, and a cohort excluding patients with a current or recently diagnosed COVID-19 infection (defined as confirmed infection from 7 weeks preoperatively to 30 days postoperatively), which were conducted for the analysis for the primary outcome of postoperative complications. The results of the analysis are reported as adjusted odds ratios (ORs) with 95% CIs. Post-hoc sensitivity analyses included the inclusion of the following variables in the generalised linear mixed models: country human development index classification (middle-income countries *vs* low-income countries), hospital level, provider level, and use of the surgical safety checklist.

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 (registered in PROSPERO [CRD42022357658]). The study inclusion criteria were studies published after 2011 with 200 or more patients in the study cohort and reporting perioperative mortality in paediatric surgical patients.

Role of the funding source

The funders of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the paper or the decision to submit.

Results

Between Jan 15 and Dec 23, 2022, we recruited 8625 (98·2%) of 8782 children eligible for the study from 249 hospitals in 31 countries (figure). Six hospitals in South Africa and one hospital in Malawi 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; appendix p 55). Hospital level recruitment was a median of 24 patients (IQR 11–47), and hospital level data were provided for 240 (92·0%) of 249 hospitals. There were 41 (17·1%) of 240 level 1 hospitals, 52 (21·7%) level 2 hospitals, and 147 (61·3%) level 3 hospitals. 169 (79·3%) of 213 hospitals were government funded, 22 (10·3%) were privately funded, and 22 (10·3%) were non-governmental organisations, mission, or charity hospitals. There were 69 (27·7%) of 249 university affiliated hospitals. The hospitals had a median of 300 beds (IQR 150–500), five operating rooms (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 (1–6), and five full-time specialist paediatricians (1–10). 32 (17·6%) of 182 hospitals had a median of two full-time specialist anaesthesiologists who practised 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%)

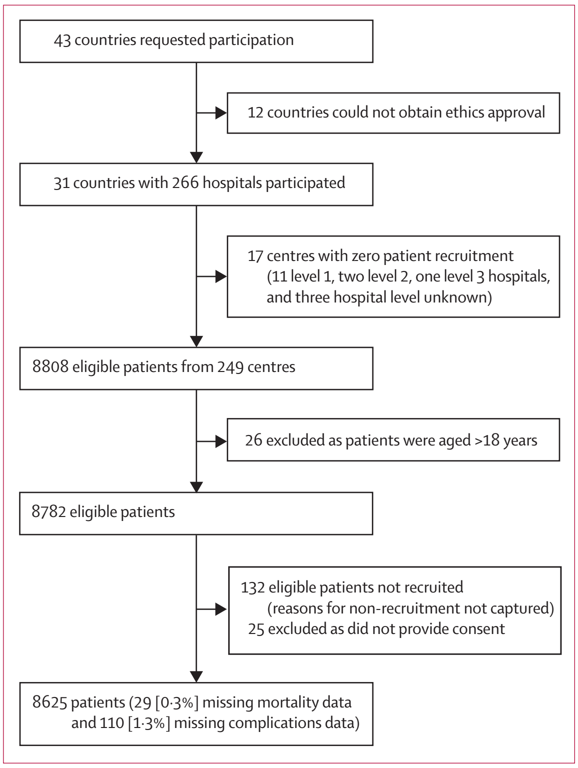

Figure: **African surgical outcomes study in paediatric patients (ASOS-Paeds) recruitment** of 200 cases (IQR 20–88) were children younger than 18 years. Data describing operating room preparedness, equipment, drugs, and protocols necessary for safe paediatric surgery were available from 233 (93·6%) of 249 sites (appendix p 56). Operating rooms were reported as safe for anaesthesia and surgery for neonates (121 [54·3%]

	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 (66·0%)	958/1529 (62·7%)	4647/6964 (66·7%)	120/197 (60·9%)	5538/8375 (66·1%)
Female	2925/8600 (34·0%)	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%)
American Society of Anesthesiologists Physical Status 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 (1·0%)	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%)
Gynaecology	100/8600 (1·2%)	17/1531 (1·1%)	81/6976 (1·2%)	1/199 (1·0%)	98/8385 (1·2%)
Thoracic	107/8600 (1·2%)	47/1531 (3·1%)	58/6976 (1·0%)	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 (1·0%)	20/1531 (1·3%)	40/6976 (1·0%)	3/199 (1·5%)	58/8385 (1·0%)
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 and 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%)	332/8385 (4·0%)
Plastics and 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%)

(Table 1 continues on next page)

	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)
(Continued from previous page)					
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 (<1·0%)	36/6983 (1·0%)	0/199 (0%)	40/8397 (1·0%)
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 (2·1%)	33/1532 (2·2%)	150/6972 (2·2%)	6/184 (3·3%)	78/8385 (1·0%)
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 (<1·0%)	11/1531 (1·0%)	21/6968 (<1·0%)	1/199 (1·0%)	34/8380 (<1·0%)
Non-physician	33/8594 (<1·0%)	7/1531 (1·0%)	26/6968 (<1·0%)	1/199 (1·0%)	32/8380 (<1·0%)
Post-operation 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%)

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

Table 1: **Baseline characteristics**

of 223 hospitals), infants (147 [65·9%]), and children younger than 6 years (188 [84·3%]). Electricity and oxygen were unreliable at 48 (21·7%) of 221 hospital sites for the first and 42 (19·0%) of 221 hospital sites for the latter. The emergency drugs, epinephrine and atropine, were not always available. Epinephrine was not always available at 33 (14·9%) of 221 hospital sites, and atropine was not always available at 26 (11·8%) hospital sites. Many sites did not have protocols and administrative data collection to support safe surgery (appendix p 56).

The mean age was 6·1 (SD 4·9) years, with 5675 (66·0%) of 8600 children being male. Most children (6110 [71·2%]of 8579 patients) were from category 1 of the American Society of Anesthesiologists Physical Status score undergoing elective surgery (5325 [61·9%] of 8604 patients). The most common comorbidity was a neurological disorder (383 [4·4%] of 8612 patients) followed by cardiac disease (259 [3·0%] of 8612 patients), and a current respiratory tract infection (252 [2·9%] of 8612 patients). There were 184 (2·1%) of 8584 children with a current or recently diagnosed COVID-19 infection. The most common primary indication for surgery was congenital disease (3397 [39·5%] of 8590 patients). The three most common types of surgery were gastro-intestinal (2158 [25·1%] of 8600 patients), kidney and urology (1505 [17·5%] of 8600 patients), and orthopaedic (1216 [14·1%] of 8600; table 1). 1516 (17·8%) of 8506 surgeries were performed after hours. The WHO surgical safety checklist was used in 4817 (56·1%) of 8580 cases.

Most children (7166 [83·9%] of 8625 patients) went to a ward postoperatively, and 436 (5·1%) of 8625 patients were admitted to a critical care unit postoperatively. Postoperative length of stay was 2 (IQR 1–4) days, and 1717 (20·5%) of 8371 children were discharged on the day of surgery. 199 (2·3%) of 8596 children died following surgery and 23 (11·6%) of these children died on the day of surgery. Postoperative complications occurred in 1532 (18·0%) of 8515 children, of which 166 (10·8%) of 1530 deaths followed postoperative complications (table 2). Most complications occurred in the ward (944 [62·1%] of 1520 patients), but most deaths occurred in high-care wards and critical care units (128 [66·3%] of 193 patients; table 1). Nearly half of the complications occurred in elective surgical patients (699 [45·7%] of 1530 patients), but most of the deaths occurred in urgent and emergency surgeries (169 [84·9%] of 199 patients). Most deaths occurred in children who underwent gastrointestinal surgery (105 [52·8%] of 199 patients; table 1). A post-hoc analysis showed that most of these deaths occurred in neonates (43 [41·0%] of 105 patients), and infants (25 [23·8%] of 105 patients).

	n/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 (1·0%)
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%)

Denominators vary with the completeness of the data.

Table 2: **Postoperative outcomes for the whole cohort**

The most common group of postoperative complications were infections (971 [11·4%] of 8538 patients). The most common complications were bleeding (467 [5·5%] of 8552 patients) and superficial surgical site infections (549 [6·4%] of 8562 patients). The mortality was highest following cardiovascular complications (120 [55·6%] of 216 deaths following 216 [2·5%] of 8543 cardiovascular complications; table 3). The outcomes by facility level are shown in the appendix p 58. All complications and mortality were most common in level 3 hospitals (1213 [83·9%] of 1445 complications and 154 [83·7%] of 184 deaths).

The missing data for risk factors and outcomes are shown in the appendix (p 60). 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 American Society of Anesthesiologists 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 variance partition coefficients for all complications were 0·008 for country and 0·237 for hospitals, 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 variance partition coefficients for mortality were 0·167 for country and 0·328 for hospitals. Excluding cases in which the

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

Data are n (%) or n/N (%). Denominators vary with the completeness of the data. NA=not applicable.

Table 3: **Postoperative complications**

	Odds ratio	95% CI	p value
Intercept (odds)	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
13–<18 years	1 (ref)	1 (ref)	1 (ref)
Sex			
Female	1·061	0·921–1·222	0·414
Male	1 (ref)	1 (ref)	1 (ref)
American Society of Anesthesiologists Physical Status category			
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
1	1 (ref)	1 (ref)	1 (ref)
Comorbidity			
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 comorbidities	1·556	1·061–2·282	0·024
Urgency of surgery			
Emergency	1·473	1·240–1·749	<0·001
Elective	1 (ref)	1 (ref)	1 (ref)
Grade of surgery			
Major	2·075	1·630–2·640	<0·001
Intermediate	1·386	1·149–1·673	<0·001
Minor	1 (ref)	1 (ref)	1 (ref)
Primary indication for surgery			
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	1 (ref)	1 (ref)	1 (ref)
Type of surgery			
Other types of surgery	1·178	0·663–2·090	0·576
Burns	2·315	1·191–4·500	0·013
Plastics and cutaneous	1·656	0·944–2·903	0·078
Ophthalmology	0·311	0·137–0·703	0·005
Kidney and 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
Gynaecology	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	1 (ref)	1 (ref)	1 (ref)
Surgery after hours	1·188	0·984–1·435	0·074
Surgery not after hours	1 (ref)		
Duration of surgery (per 15 min increase)	1·078	1·059–1·098	<0·001

(Table 4 continues in next column)

(Continued from previous column)

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

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 (appendix pp 61–68). 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 (appendix pp 69–76).

The factors independently associated with postoperative mortality included age younger than 1 year, American Society of Anesthesiologists category 3, co-existing diseases (neurological disorder, cardiac disease, and 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 of mortality following surgery in children that includes the ASOS-Paeds trial is shown in the appendix (pp 77–81). In the updated meta-analysis, the 30-day mortality following paediatric surgery is eight times higher in Africa than high-income countries (17·91 deaths per 1000 children, 95% CI 20–27 *vs* 2·18, 1–3) in a crude, unadjusted comparison.

Discussion

For this study, the principal findings were that postoperative complications occurred in 18% (1532 of 8515) of children with an in-hospital mortality rate of 2·3% (199 of 8596). Complication rates were up to four-fold 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

	Odds ratio	95% CI	p value
Intercept (odds)	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
13–<18 years	1 (ref)	1 (ref)	1 (ref)
Sex			
Female	0·926	0·644–1·331	0·678
Male	1 (ref)	1 (ref)	1 (ref)
American Society of Anesthesiologists Physical Status category			
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
1	1 (ref)	1 (ref)	1 (ref)
Comorbidity			
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 comorbidities	2·228	1·068–4·645	0·033
Urgency of surgery			
Emergency	3·952	2·393–6·525	<0·001
Elective	1 (ref)	1 (ref)	1 (ref)
Grade of surgery			
Major	1·848	0·972–3·511	0·061
Intermediate	0·920	0·500–1·694	0·790
Minor	1 (ref)	1 (ref)	1 (ref)
Primary indication for surgery			
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	1 (ref)	1 (ref)	1 (ref)
Type of surgery			
Other types of surgery	0·648	0·098–4·272	0·652
Burns	10·430	1·722–63·178	0·011
Plastics and cutaneous	2·140	0·364–12·571	0·400
Ophthalmology*	··	··	0·980
Kidney and 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
Gynaecology†	··	··	0·988
Cardiac	0·628	0·090–4·371	0·638
Neurosurgery	0·296	0·050–1·753	0·180
Maxillofacial and dental	1 (ref)	1 (ref)	1 (ref)
Surgery after hours	1·248	0·821–1·896	0·299
Surgery not after hours	1 (ref)	1 (ref)	1 (ref)
Duration of surgery (per 15 min increase)	1·043	1·013–1·074	0·004

(Table 5 continues in next column)

(Continued from previous column)

*No deaths. †One death.

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

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 among adults. There is an urgent need to improve the safety and effectiveness of anaesthesia and surgery for children in African hospitals.

A 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 variance partition coefficients suggest that the complications and mortality attributed to differences between countries is limited (0·8% for complications and 16·7% for mortality). However, at the level of the hospital, between one-quarter of the complications (23·7%) and one-third of mortality (32·8%) were attributable to differences between hospitals. This study overcomes the limitations of previous studies of postoperative complications in children having surgery in Africa, which were low recruitment, different scope, different outcomes, and different follow-up.[23–25] The incidence of postoperative complications following paediatric surgery was 30% higher in Africa than reported in the American College of Surgeons National Surgical Quality Improvement Program: Pediatric, which also reported on a mixed cohort of in-patient paediatric surgical patients.[19] Failure to rescue reported in the USA sample[19] was 3% compared with nearly a four-fold 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 (>50% occur in American Society of Anesthesiologists 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, and 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[25–27] 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 other studies reporting on hospital infrastructure and equipment in Africa. The reported available continuous oxygen supply ranges from 22% to 61% of hospitals, an unreliable electricity supply is present in 50–70% of hospitals, and pulse oximeters are available in 48–75% of hospitals in Africa.[27] The inadequate infrastructure, equipment, and supplies suggest that there is a need for a comprehensive approach to provide environments that are safe for anaesthesia and surgery for children in Africa by addressing the limitations in resources (physical and human), education, minimum standards of practice, and improved safety practices. We therefore echo the call for including children in National Surgical Obstetric and Anaesthesia Plans, and support baseline assessment using the Global Initiative for Children's Surgery modified Children's Surgical Assessment Tool and the Optimal Resources for Children Surgical Care,[28] or the Anaesthesia Facility Assessment Tool developed by the World Federation of Societies of Anaesthesiologists. The current National Surgical Obstetric and Anaesthesia Plans Surgical Assessment Tool 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. Optimal Resources for Children Surgical Care provides a roadmap to inform National Surgical Obstetric and Anaesthesia Plans and for improving anaesthesia and surgical care in children.[28] Health-care 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 health-care workers providing paediatric surgical care, including both physicians and non-physician providers.

Limitations of this study include the inability to extrapolate the findings to the African countries that were not represented. It is likely, however, that the non-participating countries might have worse outcomes than presented here due to insufficient infrastructure and resources necessary for participation. This lack of resources is evident by the inability of 12 countries to obtain ethical approval despite willing collaborators (figure). There is also an over-representation of level 3, well-resourced hospitals in this study; however, this limitation could present a broader problem in that level 1 hospitals could be under-represented because they cannot provide anaesthesia and surgery for children. Most hospitals that participated but did not recruit a single patient into the study (11 [78·6%] of 14 hospitals) 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 are a subjective assessment by clinicians, and we did not use a validated tool to assess electricity and oxygen resources, shortages of emergency cardiovascular drugs, and a lack of functional incubators, 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 and 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. Levels of perioperative nursing care and how they affect outcomes for children would be a useful future research project. 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 (that focuses on access, resources, and training for anaesthesia and surgery), provision of environments that are safe for the conduct of anaesthesia and surgery, and strategies to address the high rate of failure to rescue.

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Contributors

AT, RP, and BMB conceived and designed the study. AT and BMB did the acquisition, analysis, and interpretation of the data; drafting and revising the study critically; and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. BMB and AH accessed and verified the underlying data and were responsible for the analysis and interpretation of the data. All authors did the acquisition of data at their sites, critically revised the study, approved the final version to be published, and agreed to be accountable for all aspects of the work. All members of the writing committee had access to all the data in the study. AT and BMB made the final decision to submit for publication.

Declaration of interests

AT received a grant from the South African Society of Anaesthesiologists. This money was used to pay for ethical clearances in Democratic Republic of the Congo, Cameroon, Sierra Leone, Senegal, Burundi, and Kenya, and to pay for study administrator, Safe Surgery South Africa. AH-S and MTN received funding to pay for ethical clearance of the study in Uganda from the Association of Anesthesiologists of Uganda. RP received grants from Edwards Lifesciences and Intersurgical UK, and consulting fees and honoraria from Edwards Lifesciences. All other authors declare no competing interests. BMB, RP, AH-S, HK, AH, and FKB are all partially funded by the National Institute for Health and Care Research (NIHR) Global Health Group on Perioperative and Critical Care, NIHR133850.

Data sharing

Data will be disclosed only upon request and approval of the proposed use of the data by the steering committee. Data requests from other non-ASOS-Paeds investigators will not be considered until 2 years after the closeout of the study. Data will be de-identified for participants, hospitals, and countries, and will be available with a signed data access agreement.

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