Study Results Summary for Registry Submission

ISCRTN 71392921

IMPALA

1. Participant Flow

Flow diagram of participants at each stage:

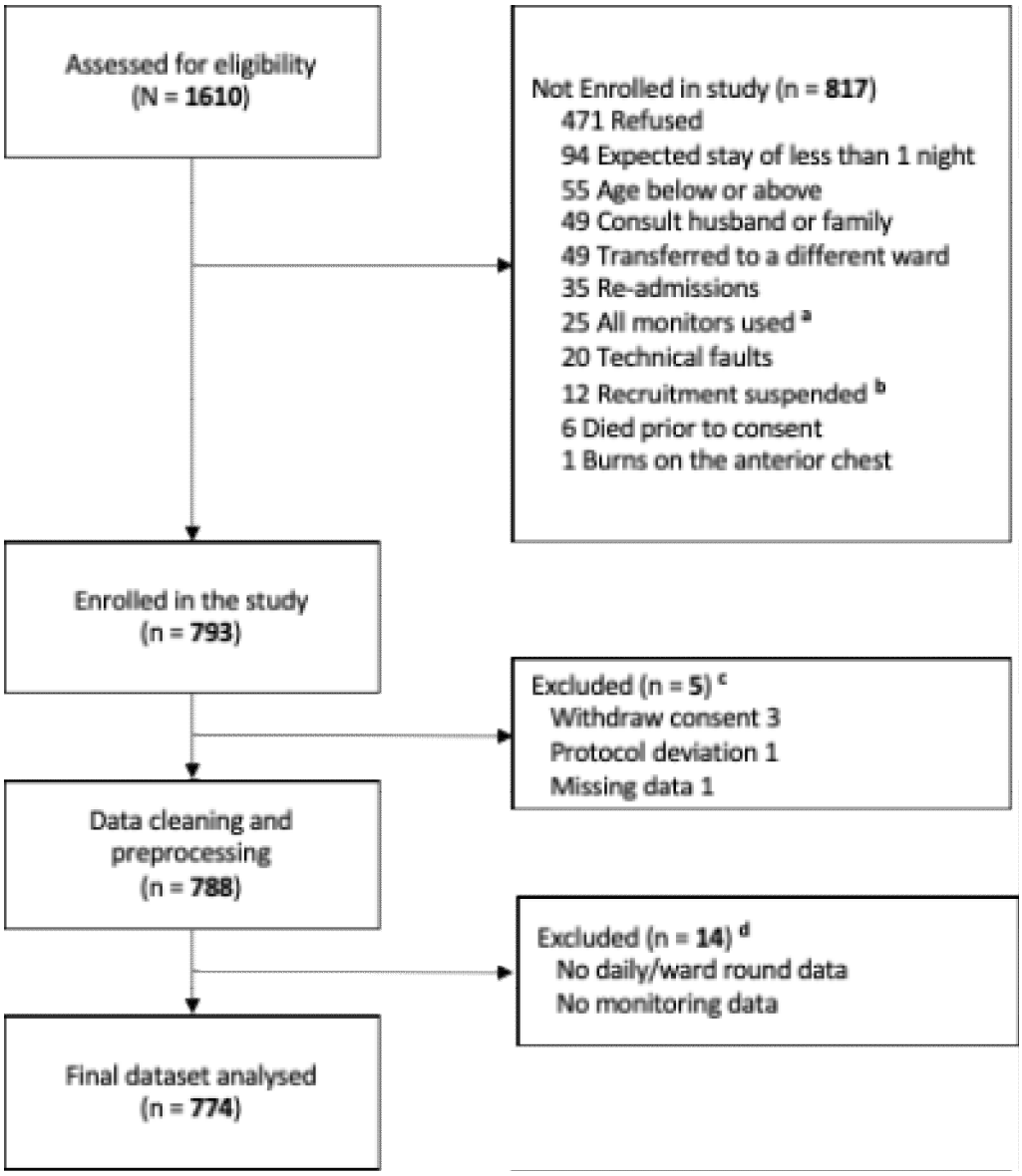

Figure 1. Flowchart of patients included in the analysis

2. Baseline Characteristics

Characteristic	**Total (N=774)**
DEMOGRAPHICS	Participant, No (%)
Child age (Months) - mean (SD)	19.1 ± (15.4)
Sex (Male)	440 (56.8%)
Siblings	536 (69.3%)
Hospital	
QECH	391 (50.5%)
ZCH	383 (49.5%)
PATIENT HISTORY	
Previous hospital admission	163 (21.1%)
Chronic conditions disability	50 (6.5%)
Convulsions (seizures)	213 (27.5%)
CLINICAL OBSERVATIONS	
Increased work of breathing	378 (48.8%)
Pallor	221 (28.6%)
Underweight (waz<-2)	256 (33.1%)
Reduced consciousness (VPU, Alert as ref)	116 (15.0%)
Fever on admission	142 (18.3%)
Multiple diagnoses	654 (84.5%)
HDU Admission reasons	
Respiratory	588 (76.0%)
Circulatory	121 (15.6%)
Neurological	182 (23.5%)
Need for intensive nursing care	243 (31.4%)

Table 1 : Participant characteristics

3. Outcome Measures

Primary Outcome:

- In hospital deaths occurred in 55 children as displayed in table 1

Secondary Outcomes:

- Severe outcome occurred in 71 patients as displayed in table 1.
- Since this is a composite score of three events we further specified the overlap in the figure below.

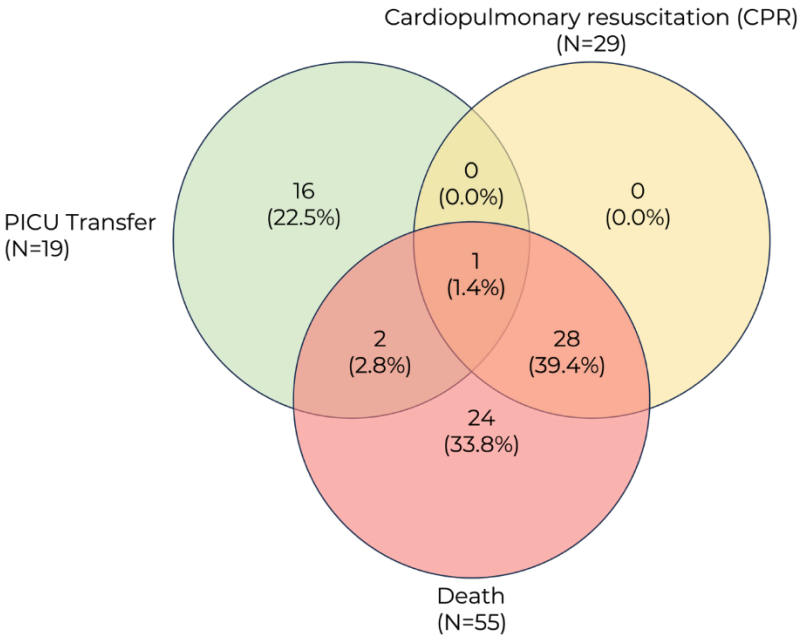

Figure 2. Overlap of events for the secondary outcome measure: severe outcome (any of the above) and primary outcome: in-hospital death

OUTCOME	Total (N=774)
Deaths (in hospital)	55 (7.1%)
Severe outcome (any of below)	71 (9.2%)
Cardio-Pulmonary Resuscitation	29 (3.7%)
ICU transfer	19 (2.5%)
Death	55 (7.1%)

Table 2 : Outcome of the patients

4. Adverse Events

This study was not an intervention trial, yet an observational study. We did report two events to our scientific advisory board, the ethical committee and sponsor. The first event was a potential electric current leakage, investigations showed this was harmless and the cause was taken away. The second event concerned loss of patient data in case the monitors battery would run out of power. This was caused due to a software update which was fixed, and the implementation process of future updates was changed. No serious harms occurred to the study participants.