Supplementary Online Content

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This supplementary material has been provided by the authors to give readers additional information about their work.

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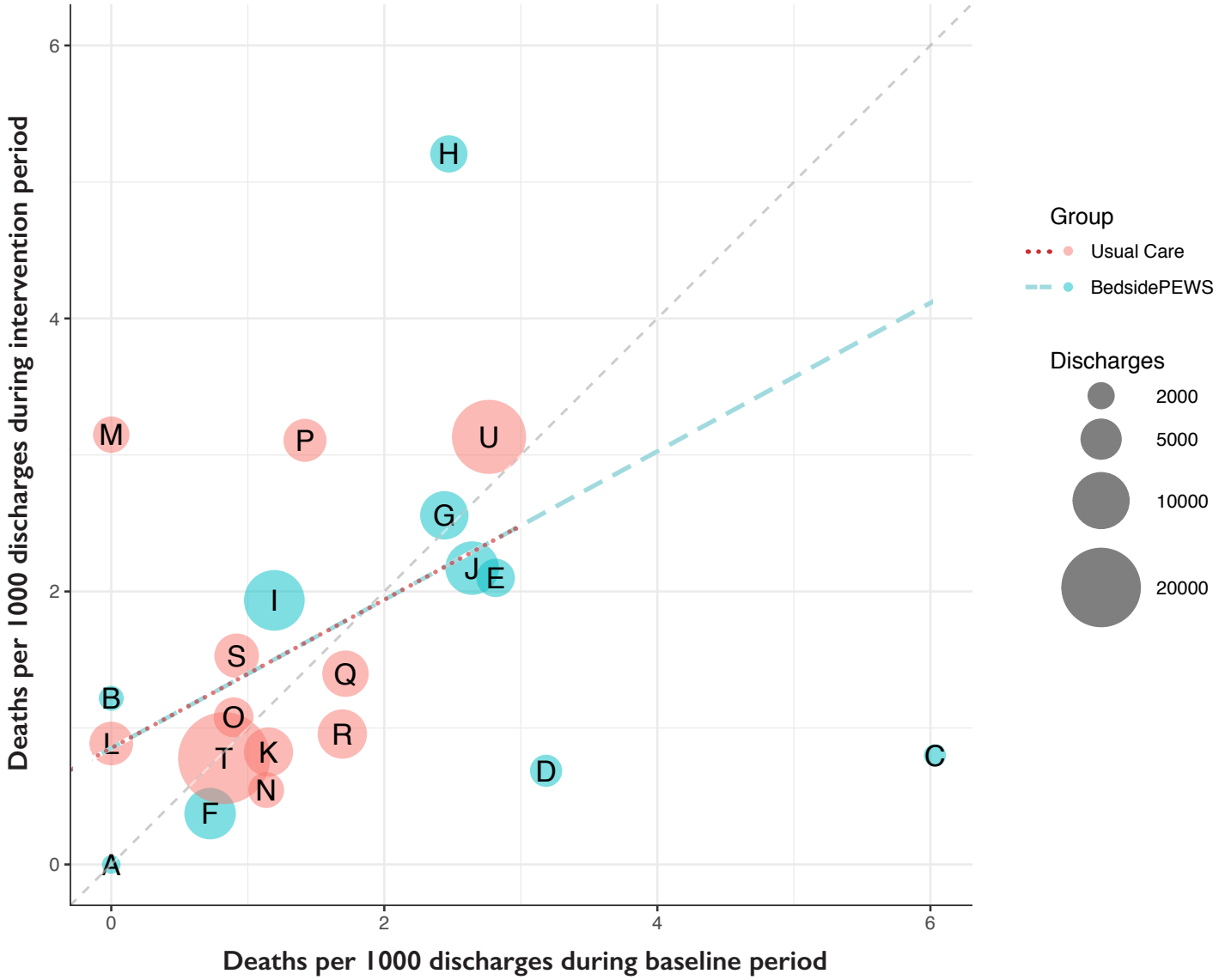
Figure S1 **Hospital mortality per thousand hospital discharges**



All cause hospital mortality rates in baseline and post-randomization periods are presented by hospital. The letter in centre of each circle is an identifier that can be used to link to other cluster-level (hospital) data in Table S3 and Table S4. Hospitals A to J inclusive were randomized to the BedsidePEWS and amongst these Hospital A, C and H had extended run-in phases. Hospitals K to U inclusive were randomized to usual care.
The dashed line is the line of identity where the baseline and post-randomization period mortality rate are the same. Hospitals implementing the BedsidePEWS are marked in salmon and usual care hospitals are in blue. Each circle represents a hospital. The circle center reflects the co-ordinates of the baseline and post-randomization mortality rates. The circle size is proportional to the number of discharges during the intervention period of that hospital. Thus hospital with larger circles are contributing more data and will have narrower 95% confidence intervals for the true values of their mortality rates.
The colored lines represent the linearized fitted relationships between mortality in baseline and post-randomization phases in intervention (dotted salmon line) and usual care hospitals (dashed blue line). These lines are visually co-incident - consistent with the finding of no significant difference in the primary analysis and the baseline adjusted absolute difference of 0.01 per thousand patient discharges.

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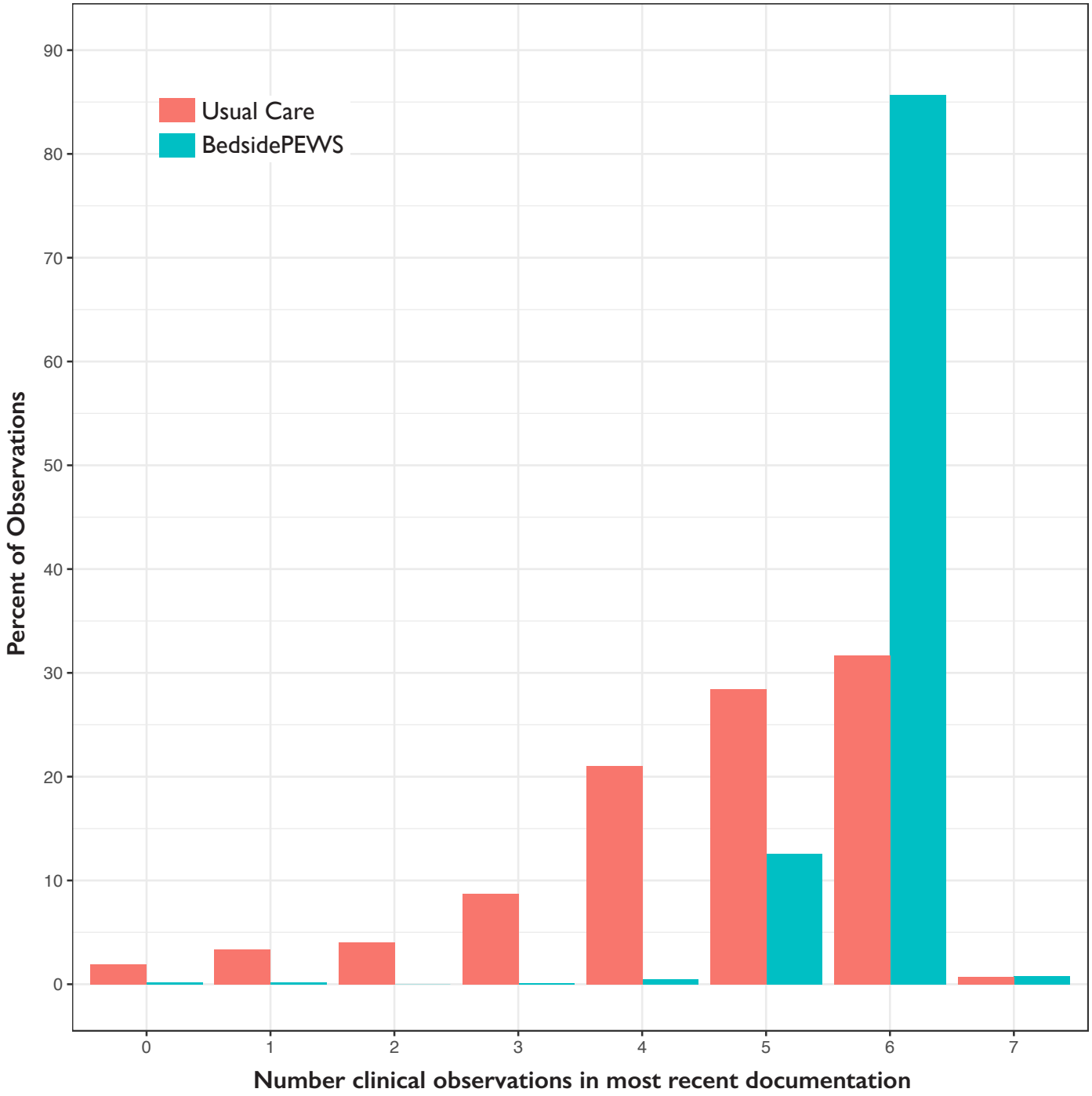
Figure S2 **Documented clinical observations in randomly selected patients**



Each study week at each hospital, five patients who had been admitted to an inpatient ward for at least 24-hours were randomly selected for documentation review. Documentation of Heart Rate, Respiratory Rate, Systolic Blood Pressure, Saturation, Respiratory Effort, Capillary Refill, and Oxygen Therapy measurements were reviewed by trained study co-ordinators. The most recent set of clinical observations was identified and the number of different types of these clinical observations was abstracted. A set of clinical observations was regarded as those that were documented as being from the same time. The minimum number of clinical observations from the seven in the BedsidePEWS score was zero (for example if only temperature was documented) and the maximum was seven (if all clinical observation types in the BedsidePEWS score were used).

The figure describes the last set of clinical observations taken from 5420 randomly selected patients in the post-randomization period. The histogram shows the relative frequency distributions in 2588 patients in BedsidePEWS hospitals and 2832 patients in usual care hospitals. Few of these randomly selected patients had 7 clinical observation types documented, however the proportion of observation sets with 5 or more clinical observation types was significantly greater in BedsidePEWS hospitals than usual care hospitals.

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eTable 1. Study outcome definitions

Study Outcome	Definition
Hospital Mortality	Death of an eligible inpatient as determined by local practice. This definition intentionally included children with Do Not Resuscitate orders (DNR), to ensure that we did not exclude children who had survived earlier resuscitation events that may have been impacted by the intervention.
Mortality without Not For Resuscitation Order	Death in an eligible patient where there was not a documented Do Not Resuscitate order at the time of death.
Significant Clinical Deterioration Event (Late ICU Admission)	Late ICU Admission was defined using the Children's Resuscitation Intensity Scale. It was a composite measure comprised of one or more of: [a] Intubation and/or receiving endotracheal ventilation at the time of ICU admission or intubated within 1 hour after Urgent ICU admission [b] >60 ml/kg intravenous or intraosseous fluid resuscitation given in the 12 hours before transfer, and/or administration of any intravenous or intraosseous inotrope or vasopressor at the time of transfer or at any stage in the 12 hours before transfer. [c] Chest compressions (cardiopulmonary resuscitation) before transfer from ward area or within 1 hour of ICU admission or ECMO instituted before or within 1 hour of ICU admission. [d] Death on an inpatient ward, or within an hour of urgent ICU admission in patients without DNR order. Death may have occurred despite cardiopulmonary resuscitation or if there was the intent to perform cardiopulmonary resuscitation and patient was pronounced dead without cardiopulmonary resuscitation.
Cardiac Arrest	The provision of chest compressions for clinical signs of low or absent cardiac output in eligible patients without a Do Not Resuscitate Order. Cardiac arrest could also occur in eligible patients without DNR, with vital signs absent, where chest compressions were not started, and the patient was determined to have died. Cardiac Arrest was a subset of the above clinical deterioration event, and included events occurring within in the first hour of urgent ICU admission.
Potentially Preventable Cardiac Arrest	The potential preventability of cardiac arrest events was the degree to which 'events may have been avoided given the application of reasonable current standards of practice by an average practitioner and system anticipated to manage the condition in question' Assessment of the potential preventability of cardiac arrest was made for all cardiac arrests. Anonymized, delinked clinical data was presented in a standardized format and potential preventability was rated by two blinded physician reviewers. Potential preventability ratings of 4: 'more than likely (more than 50/50, but "close call");' 5: 'strong evidence of preventability;' 6: 'virtually certain evidence of preventability' were defined as 'potentially preventable' cardiac arrest events.
Urgent ICU Admission	Was an admission to the Pediatric ICU with departure from the event location in less than six hours from the time the ICU admission was initiated. Initiation was defined as the time when the ICU admission was confirmed, or confirmed as a 'definite possibility following surgery' in cases where post-operative care in the ICU might be required. ICU admissions initiated intra-operatively or from the recovery room were regarded as urgent ICU admissions, irrespective of the time between initiation and departure from the Operating room.
Unplanned ICU Readmission	Re-admission before midnight of the second full calendar day after ICU discharge. Thus, re-admission occurred before the 3rd midnight following ICU discharge.
Unplanned Hospital Readmission	Re-admission to any inpatient area in the hospital before midnight of the second day full calendar day after discharge. Thus, re-admission occurred before the 3rd midnight following hospital discharge.
Ventilator-free Days	Days alive and without invasive mechanical ventilation in the 28 days beginning at ICU

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Study Outcome	Definition
	admission. This was recorded for the first ICU admission during each of the baseline and the post-randomization periods.
Urgent Consultations to the ICU or Rapid Response team	New urgent consultations were the consultation to ICU expertise – as one or both of an ICU consultation or formal rapid response team for an eligible patient in an eligible inpatient unit. Consultations were requested to occur in less than 15 minutes. Planned reviews of patients previously consulted were excluded. Patients who have been previously consulted on were regarded as having a new consult if an urgent call was made that resulted in an unplanned or earlier than planned review.
Immediate ('Stat') Calls to Physicians	Calls for immediate specific physician attendance to provide patient care to an eligible patient admitted to an inpatient ward.
Immediate Call to Resuscitation Team	Calls for immediate medical assistance from the resuscitation team and equipment for an eligible patient in an eligible inpatient unit.
Documentation Frequency	The frequency with which each of the clinical observations of the BedsidePEWS score (heart rate, respiratory rate, systolic blood pressure, transcutaneous oxygen saturation, respiratory effort, oxygen therapy, capillary refill) were documented in 24 hours. These data were abstracted from five randomly selected eligible patients each week in each hospital.
ICU Length of Stay	The number of whole or part study days (00:00:00 – 23:59:59) a given patient was in the ICU.
ICU Mortality	Death in ICU of an eligible patient, either during the course of an urgent or elective ICU admission
Mechanical Ventilation Days	The number of whole or part calendar days of invasive mechanical ventilation provided during the ICU stay
Dialysis Days	The number of whole or part calendar days of dialysis provided during the ICU stay. 'Dialysis' included hemo-filtration and hemodialysis techniques used either intermittently and continuously (or both), peritoneal dialysis, plasmaphersis and red-cell exchange.
ECMO Days	The number of whole or part calendar days of extracorporeal membrane oxygenation therapy provided during the ICU stay
Nitric Oxide Days	The number of whole or part study days of inhaled nitric oxide therapy provided during the ICU stay.
PELOD	The Pediatric Logistic Organ Dysfunction score was calculated for the first 24 hours after ICU admission and for the ICU stay. Scores for Pediatric Logistic Organ Dysfunction (PELOD) can range from 0 to 71; higher PELOD score describes more severe organ dysfunction.
Pediatric Index of Mortality	The Pediatric Index of Mortality (version 2) was calculated from diagnosis and physiologic data from the first 12 hours of urgent ICU admission. A greater PIM-2 score indicates greater probability of death. The minimum possible score of -8.4137 corresponds to 0.02% predicted ICU mortality. Technically the PIM-2 score has no upper bound due to the possible inputs for Base Excess and PaO2. However, with Pa02 of 40 and BE at -35 the PIM score is +9.7778 and predicted mortality is 99.9%.

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The study outcomes are presented with the definitions applied at each site. Data were collected by research coordinators trained by the research team at the data coordinating center (Center for Safety Research). Data quality review included review for completeness of case report forms, source data verification, and electronic review for internal consistency of submitted data. The pre-specified outcomes not reported here are those from the perception surveys of frontline staff and hospital administrators.

ICU: Intensive Care Unit; DNR Do Not Resuscitate; ECMO: Extracorporeal Membrane Oxygenator Therapy.

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eTable 2. Hospital level outcomes: mortality, mortality without 'do not resuscitate' order

	Discharges			Mortality		Mortality without DNR	
	Baseline n	Post-randomization n	Total n	Baseline n (/10^3 discharges)	Post-randomization n (/10^3 discharges)	Baseline n (/10^3 discharges)	Post-randomization n (/10^3 discharges)
Hospitals with Bedside Paediatric Early Warning System							
A	467	837	1304	0 (0)	0 (0)	0 (0)	0 (0)
B	677	1643	2320	0 (0)	2 (1.22)	0 (0)	0 (0)
C	663	1250	1913	4 (6.03)	1 (0.8)	2 (3.02)	1 (0.80)
D	1256	2915	4171	4 (3.18)	2 (0.69)	2 (1.59)	0 (0)
E	2131	4287	6418	6 (2.82)	9 (2.10)	5 (2.35)	6 (1.4)
F	4143	8049	12192	3 (0.72)	3 (0.37)	1 (0.24)	1 (0.12)
G	3689	7037	10726	9 (2.44)	18 (2.56)	3 (0.81)	3 (0.43)
H	2022	4034	6056	5 (2.47)	21 (5.21)	0 (0)	13 (3.22)
I	6698	11370	18068	8 (1.19)	22 (1.93)	8 (1.19)	14 (1.23)
J	4918	8751	13669	13 (2.64)	19 (2.17)	5 (1.02)	4 (0.46)
All	26664	50173	76837	52 (1.95)	97 (1.93)	26 (0.98)	42 (0.84)
Hospitals with Usual Care							
K	3472	7285	10757	4 (1.15)	6 (0.82)	1 (0.29)	1 (0.14)
L	2526	5642	8168	0 (0)	5 (0.89)	0 (0)	2 (0.35)
M	1978	3811	5789	0 (0)	12 (3.15)	0 (0)	2 (0.52)
N	1762	3672	5434	2 (1.14)	2 (0.54)	1 (0.57)	0 (0)
O	2232	4638	6870	2 (0.90)	5 (1.08)	0 (0)	1 (0.22)
P	2819	5471	8290	4 (1.42)	17 (3.11)	1 (0.35)	7 (1.28)
Q	3497	6440	9937	6 (1.72)	9 (1.4)	1 (0.29)	4 (0.62)
R	3545	7327	10872	6 (1.69)	7 (0.96)	1 (0.28)	2 (0.27)
S	3266	5886	9152	3 (0.92)	9 (1.53)	0 (0)	6 (1.02)
T	13308	26956	40264	11 (0.83)	21 (0.78)	7 (0.53)	8 (0.30)
U	8313	17238	25551	23 (2.77)	54 (3.13)	4 (0.48)	14 (0.81)
All	46718	94366	141084	61 (1.31)	147 (1.56)	16 (0.34)	47 (0.50)

Data are from 21 hospitals in the EPOCH Cluster Randomized Trial of the Bedside Paediatric Early Warning System (BedsidePEWS) versus usual care. The participating hospitals were in Belgium (Queen Fabiola Children's University Hospital, Brussels); Canada (Alberta Children's Hospital, Calgary; British Columbia Children's Hospital, Vancouver; Children's Hospital – London Health Sciences Centre, London; CHU de Quebec – Universite Laval, Quebec city; CHU Sainte-Justine, Montréal; Izaak Walton Killam Health Centre, Halifax; McMaster Children's Hospital, Hamilton; Montreal Children's Hospital, Montreal; Saint John Regional Hospital, Saint John; SickKids, Toronto; Stollery Children's Hospital, Edmonton; Victoria General Hospital, Victoria); Ireland (Temple Street Children's University Hospital, Our Lady's Children's Hospital, both in Dublin); Italy (Bambino Gesù Children's Hospital, IRCCS, Rome); New Zealand (Starship Children's Hospital, Auckland); The Netherlands (Erasmus MC Sophia, Rotterdam); and United Kingdom (St Georges University Hospitals NHS Foundation Trust, Kings College Hospital NHS Foundation Trust , Imperial College Healthcare NHS Trust, Bart's Health NHS Trust, The Royal Brompton & Harefield NHS Trust all in London).

The letter in the first column is an identifier that can be used to link to other cluster-level (hospital) data in Table S3 and Figure S1. Hospitals A to J inclusive were randomized to the BedsidePEWS and are ranked from least to greatest number of pediatric ward beds. Hospitals K to U inclusive were randomized to usual care. They are ranked from the least to the greatest number of pediatric ward beds.

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The numbers of discharges from the baseline and post-randomization periods are used as denominators to calculate mortality rates per thousand hospital discharges. These data were reviewed and approved by site investigators at each site.

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eTable 3. Hospital-level outcomes: significant clinical deterioration, cardiac arrest, potentially preventable cardiac arrest

	Patient Days		**Significant Clinical Deterioration**		**Cardiac Arrest**		**Potentially Preventable Cardiac Arrest**	
	Baseline	Post-Randomization	Baseline	Post-Randomization	Baseline	Post-Randomization	Baseline	Post-Randomization
	N	N	n/10^3 patient-days	n/10^3 patient-days	n/10^3 patient-days	n/10^3 patient-days	n/10^3 patient-days	n/10^3 patient-days
Hospitals with Bedside Paediatric Early Warning System								
A	1133	2270	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
B	1876	5135	1 (0.53)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
C	5283	10443	4 (0.76)	8 (0.77)	2 (0.38)	1 (0.10)	2 (0.38)	1 (0.10)
D	4965	9555	11 (2.22)	11 (1.15)	1 (0.20)	2 (0.21)	1 (0.20)	2 (0.21)
E	8662	17779	9 (1.04)	15 (0.84)	0 (0)	1 (0.06)	0 (0)	1 (0.06)
F	10392	23522	5 (0.48)	7 (0.30)	2 (0.19)	3 (0.13)	1 (0.10)	2 (0.09)
G	17238	34438	19 (1.10)	23 (0.67)	5 (0.29)	9 (0.26)	4 (0.23)	8 (0.23)
H	23244	47145	13 (0.56)	21 (0.45)	2 (0.09)	3 (0.06)	1 (0.04)	2 (0.04)
I	30571	56231	10 (0.33)	23 (0.41)	2 (0.07)	5 (0.09)	1 (0.03)	3 (0.05)
J	26336	45341	8 (0.30)	19 (0.42)	1 (0.04)	3 (0.07)	1 (0.04)	2 (0.04)
All	129700	251859	80ß(0.62)	127(0.50)	15 (0.12)	27(0.11)	11 (0.08)	21 (0.08)
Hospitals with Usual Care								
K	10164	22431	5 (0.49)	8 (0.36)	1 (0.10)	0 (0)	1 (0.10)	0 (0)
L	6655	13034	13 (1.95)	27 (2.07)	1 (0.15)	0 (0)	0 (0)	0 (0)
M	8941	16388	4 (0.45)	18 (1.10)	0 (0)	3 (0.18)	0 (0)	3 (0.18)
N	8917	16888	1 (0.11)	1 (0.06)	1 (0.11)	0 (0)	1 (0.11)	0 (0)
O	11705	22810	6 (0.51)	13 (0.57)	1 (0.09)	2 (0.09)	1 (0.09)	1 (0.04)
P	12126	22113	3 (0.25)	5 (0.23)	2 (0.16)	2 (0.09)	2 (0.16)	2 (0.09)
Q	13335	25093	11 (0.82)	10 (0.4)	2 (0.15)	4 (0.16)	1 (0.07)	4 (0.16)
R	16077	33678	9 (0.56)	17 (0.5)	2 (0.12)	4 (0.12)	2 (0.12)	4 (0.12)
S	14304	24762	1 (0.07)	5 (0.20)	0 (0)	0 (0)	0 (0)	0 (0)
T	28698	49117	41 (1.43)	62 (1.26)	2 (0.07)	5 (0.10)	1 (0.03)	4 (0.08)
U	31575	61270	50 (1.58)	93 (1.52)	6 (0.19)	12 (0.20)	3 (0.10)	11 (0.18)
All	162497	307584	144 (0.89)	259 (0.84)	18 (0.11)	32 (0.10)	12 (0.07)	29 (0.09)

Data are from 21 hospitals in the EPOCH Cluster Randomized Trial of the Bedside Paediatric Early Warning System (BedsidePEWS) versus usual care. The letter in the first column is an identifier that can be used to link to other cluster-level (hospital) data in Table S2 and Figure S1. Hospitals A to J inclusive were randomized to the BedsidePEWS and are ranked from least to greatest number of pediatric ward beds. Hospitals K to U inclusive were randomized to usual care. They are ranked from the least to the greatest number of pediatric ward beds. The numbers of patient days from the baseline and post-randomization periods are used as dominators to calculate event rates per thousand patient days. These data were reviewed and approved by site investigators at each site.

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eTable 4. Per patient analysis of ICU resource use

	BedsidePEWS		Usual Care			
	Baseline	Post-Randomization	Baseline	Post-Randomization	Difference (95% CI)	p-value
Urgent ICU Admission N	393	686	531	967	-	-
Mortality (%)[a] N (%)	31 (7.9%)	42 (6.1%)	28 (5.3%)	67 (6.9%)	-1.55 (-4.90 to 1.80)	0.36
PIM-2 Predicted Mortality[b] N (%)	21 (5.4%)	38 (5.5%)	25 (4.8%)	44 (4.6%)	0.69 (-0.54 to 1.92)	0.27
PIM-2[c] mean (std dev)	-4 (1.6)	-3.9 (1.5)	-3.9 (1.4)	-3.9 (1.3)	0.13 (-0.11 to 0.37)	0.29
ICU Total LOS mean (std dev)	8.6 (14.6)	9.4 (14.2)	9.4 (14.5)	9 (15)	1.28 (-0.97 to 3.53)	0.27
ICU Total LOS median (IQR)	4 (2, 8)	4 (2, 9)	5 (2, 9.5)	4 (2, 9)	-	-
ICU Mean LOS mean (std dev)	7.4 (12.3)	7.8 (11.2)	8 (12.4)	7.4 (12)	1.04 (-0.91 to 2.99)	0.29
ICU Mean LOS median (IQR)	4 (2 -8)	4 (2 -8)	4 (2-8)	4 (2-8)	-	-
Ventilator free days mean (std dev)	23.7 (8.0)	23.9 (7.8)	24.3 (7.0)	24 (7.6)	0.26 (-1.04 to 1.57)	0.69
Ventilator free days median (IQR)	28 (23, 28)	28 (24, 28)	28 (24, 28)	28 (24, 28)		-
MV Days mean (std dev)	3.9 (10.6)	4.1 (10.1)	4 (10.3)	3.7 (10.3)	0.69 (-0.99 to 2.36)	0.42
MV Use N (%)	164 (41.7%)	287 (41.8%)	220 (41.4%)	400 (41.4%)	-0.93 (-7.46 to 5.61)	0.78
HFOV Use N (%)	23 (5.9%)	25 (3.6%)	15 (2.8%)	30 (3.1%)	-1.17 (-2.52 to 0.19)	0.09
Nitric Oxide Use N (%)	19 (4.8%)	27 (3.9%)	20 (3.8%)	29 (3%)	-0.38 (-1.91 to 1.15)	0.63
ECMO Use N (%)	10 (2.5%)	9 (1.3%)	6 (1.1%)	17 (1.8%)	-1.03 (-2.45, 0.38)	0.15
Dialysis Use N (%)	9 (2.3%)	27 (3.9%)	12 (2.3%)	27 (2.8%)	0.96 (-1.25 to 3.17)	0.40
ICU Technology Days mean (std dev)	4.6 (12.2)	5.1 (13.9)	4.5 (11.4)	4.1 (11.3)	1.13 (-0.99 to 3.25)	0.30
ICU Technology Days median (IQR)	0 (0-5)	0 (0- 4)	0 (0- 4)	0 (0- 4)	-	-
PELOD ICU[d] mean (std dev)	9.3 (9.4)	9.6 (9)	10.2 (9.9)	10 (9.4)	-0.12 (-1.62 to 1.37)	0.87
PELOD 24h[d] mean (std dev)	6.7 (7.7)	6.6 (7.4)	6.9 (7.5)	7 (7.6)	-0.29 (-1.06 to 0.49)	0.47

Analyses of Urgent ICU admission were performed using patient-level data. The 55 patients (3.2%) who had admissions in both periods were removed from this analysis. For proportions of patients the denominators were the number of patients admitted in each period. Both the per-patient total and per-patient mean duration of ICU stay were calculated to account for patients with more than one admission in a particular period (baseline or post-randomization). The per-patient mean values

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of PIM-2 and PELOD across all ICU stays were used for patients with more than one admission. The number of Ventilator Free Days was calculated for the first ICU admission only.
Data are presented as mean and standard deviations, and for ICU length of stay, Ventilator Free Days and the Number of ICU Technology days per patient the median and interquartile range data are also presented. All comparisons adjusted for the hospital-specific baseline value of each outcome and used generalized estimating equation approach to account for clustering within hospital. Comparisons for continuous variables (including those that count numbers of days) used a linear model to estimate mean differences (and their 95% CIs) and comparisons for binary variables used a binomial model with an identity link to estimate risk differences (and their 95% CIs).

BedsidePEWS; Bedside Paediatric Early Warning System; ICU Intensive Care Unit; PIM-2: Pediatric Index of Mortality version 2; MV Mechanical Ventilation; HFOV High Frequency Oscillatory Ventilation; ECMO Extra Corporeal Membrane Oxygenator therapy; PELOD: pediatric logistic organ dysfunction; 95%CI: Ninety-five percent Confidence Interval for the associated estimate. IQR Interquartile range; Std. dev.; Standard deviation.

a. Eight patients without Do Not Resuscitate Orders Died before urgent ICU admission. There were 4 in each group.
b. PIM-2 predicted total mortality was calculated by summing the inverse logit (1/(1+exp(-PIM)) of the PIM-2 score from each patient. Predicted numbers were rounded to the nearest integer and also shown as a percentage of the total number of patients.
c. Severity of illness at ICU admission used the Pediatric Index of Mortality (PIM-2). A greater PIM-2 score indicates greater probability of death. The minimum possible score of -8.4137 corresponds to 0.02% predicted ICU mortality. Technically the PIM-2 score has no upper bound due to the possible inputs for Base Excess and PaO2. However, with Pa02 of 40 and BE at -35 the PIM score is +9.7778 and predicted mortality is 99.9%.
d. In-ICU organ dysfunction used the PEdiatric Logistic Organ Dysfunction (PELOD) score for the first 24 hours and for the duration of ICU. Scores for PELOD can range from 0 to 71; higher PELOD score describes more severe organ dysfunction.

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eTable 5. Study sample pre-trial assumptions and post-trial calculations

	Anticipated	**Actual**
Hospitals	20	21
Pediatric Beds (ward)	2397	2085
Patient discharges	99,389	144,539
Patient days	397,556	559,443
Inter-cluster coefficient of variation (k)	0.15	0.43
Between cluster standard deviation (σc)	0.00076	0.00071
Mortality /1000 patient discharges	5.1	1.7
Deaths	507	244
SCDE (Late ICU admission) /1000 patient days	2.0	0.69
SCDE events	795	386

Post-hoc tabulation of assumptions used for the power calculation (baseline rates, constant cluster size, inter-cluster variation) showing important differences between the best available 2009 calculations and those derived from the trial data. The k (CV) and its 95% confidence interval were recalculated using Bayesian methods to be 0.43 (0.17-0.77).
Amongst the studied hospitals there were fewer pediatric ward (non-ICU) beds, and more patient-discharges and patient-days than were initially anticipated. Amongst study outcome events, there were fewer events than anticipated – with half the number of deaths and significant clinical deterioration events.

SCDE; Significant Clinical Deterioration Event. ICU; Intensive Care Unit.

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