EPOCH
Evaluating Processes of care and Outcomes of Children in Hospital

a cluster-randomised trial
of a documentation-based
system of care  NCT01260831

Christopher S Parshuram
staff physician Department of Critical Care Medicine senior scientist Child Health Evaluative Sciences Program. The Research Institute. Hospital for Sick Children. director Centre for Safety Research. professor Interdepartmental Division of Critical Care Medicine & Departments of Pediatrics & Health Policy. Management and Evaluation. faculty Patient Safety Centre, Faculty of Medicine, University of Toronto, Canada.

and the EPOCH Investigators
for the Canadian Critical Care Trials Group
Named inventor: Patent Bedside Paediatric Early Warning System (BedsidePEWS).
Owner the Hospital for Sick Children.

Shareholder: Bedside Clinical Systems - a clinical decision support company in part owned by the Hospital for Sick Children.
Does the BedsidePEWS...

improve early detection of critical illness
reduce mortality &
improve processes of care

without increasing healthcare utilization?
Do outcomes vary according to the source of admission to the pediatric intensive care unit?*

Folafoluwa O. Odetola, MD, MPH; Andrew L. Rosenberg, MD; Matthew M. Davis, MD, MAPP; Sarah J. Clark, MPH; Ronald E. Dechert, RRT, DrPH; Thomas P. Shanley, MD

8000 patient single center study urgent ward admissions ‘do worse’

Unadjusted length of stay and mortality according to the sources of admission

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Emergency Department n = 1,949</th>
<th>Operating Room n = 4,596</th>
<th>Ward n = 1,010</th>
<th>Non-PICU Transfer n = 1,105</th>
<th>Inter-PICU Transfer n = 237</th>
</tr>
</thead>
<tbody>
<tr>
<td>PICU length of stay</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>3.1 (9.7)</td>
<td>4.0 (10.1)</td>
<td>8.1 (18.9)</td>
<td>6.2 (17.7)</td>
<td>11.1 (14.6)&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Median (IQR)</td>
<td>1 (1–3)</td>
<td>2 (1–4)</td>
<td>3 (1–9)</td>
<td>2 (1–7)</td>
<td>7 (2–13)&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>PICU mortality, %</td>
<td>3.7</td>
<td>2.2</td>
<td>9.8</td>
<td>6.7</td>
<td>12.7&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

Table 5. Multivariable logistic regression analysis of mortality in the pediatric intensive care unit (PICU) according to the sources of admission

<table>
<thead>
<tr>
<th>Source of Admission</th>
<th>Odds of Mortality</th>
<th>95% Confidence Interval</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Emergency department</td>
<td>Referent category</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Operating room</td>
<td>0.51</td>
<td>0.28–0.94</td>
<td>.03</td>
</tr>
<tr>
<td>Ward</td>
<td>1.65</td>
<td>1.08–2.51</td>
<td>.02</td>
</tr>
<tr>
<td>Non-PICU transfer</td>
<td>0.80</td>
<td>0.51–1.25</td>
<td>.33</td>
</tr>
<tr>
<td>Inter-PICU transfer</td>
<td>1.43</td>
<td>0.80–2.56</td>
<td>.23</td>
</tr>
</tbody>
</table>

<sup>a</sup> Significantly different from ED admissions (95% confidence interval [CI], 2.6 – 4.6)
JOURNAL CLUB

Reduction in Hospital Mortality Over Time in a Hospital Without a Pediatric Medical Emergency Team

Limitations of Before-and-After Study Designs

Ari R. Joffe, MD; Natalie R. Anton, MD; Shauna C. Burkholder, MD

significant reductions in time periods of Sharek & Tibballs studies effective intervention with ‘business as usual’

you can’t stop progress
here the intervention was time - not MET

...... need cluster randomized design
rapid ‘response’

Rapid Response Teams

A Systematic Review and Meta-analysis

Paul S. Chan, MD, MSc; Renuka Jain, MD; Brahmajee K. Nallmothu, MD, MPH; Robert A. Berg, MD; Comilla Sasson, MD, MS

Study
Bristow et al (hospital 1 vs 2)20
Bristow et al (hospital 1 vs 3)20
Buist et al28
Bellomo et al27
Priestley et al34
Kenward et al33
Hillman et al31
Dacey et al13
Jones et al32
Chan et al9
Baxter et al12

Figure 4. Cumulative pooled estimate for hospital mortality after rapid response team (RRT) implementation in adults. The cumulative effect of each additional study on the pooled mortality estimate in adults is depicted. Because of significant findings in earlier studies, there was a suggestion that RRTs may reduce hospital mortality rates. After inclusion of recent adult studies, however, implementation of RRTs was not found to be associated with lower hospital mortality rates. Dotted vertical line denotes the overall pooled mortality estimate in adults. CI indicates confidence interval; RR, relative risk.

initial mortality benefit ‘resolved’ over time
Bedside PEWS

Bedside Paediatric Early Warning System

1. validated score to quantify severity of illness & risk of deterioration
2. documentation record representation, score calculation & decision support
3. score matched recommendations a safety-net that describes reasonable care
4. implementation program educator-designed, frontline expert tested

Kristen L Middaugh, James S Hutchison, David Wensley, Nadeene Blanchard, Joseph Beyene, Patricia C Parkin

Full list of author information is available at the end of the article.

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design

eligible
Hospital with PICU
>200 hospital admissions /year
willing to be randomized

Control

<table>
<thead>
<tr>
<th>Standard Care</th>
<th>Standard Care</th>
</tr>
</thead>
</table>

Intervention

<table>
<thead>
<tr>
<th>Standard Care</th>
<th>run in BedsidePEWS implemented</th>
</tr>
</thead>
</table>

26 weeks 52 weeks

hospitals randomized 1 : 1 ratio
concealment until week one
analyses account for clustering, baseline rates, volume
primary outcome

all-cause hospital mortality

objective in an inherently unblinded study is independent of care limitations (DNR)

estimated 5/1000 patient discharges

>>> power 80% alpha 0.05 for ARR 0.1%
## late ICU admission

### main secondary outcome

<table>
<thead>
<tr>
<th></th>
<th>Early</th>
<th>none of the below</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Pos. Press. V</td>
<td>unplanned bag mask, CPAP or BIPAP</td>
<td>&lt;12 h before</td>
</tr>
<tr>
<td>3</td>
<td>Intubation</td>
<td>intubation</td>
<td>&lt;12 h before or &lt;1 h after</td>
</tr>
<tr>
<td>4</td>
<td>Circulatory</td>
<td>≥60 ml /kg or inotropes or pressors</td>
<td>&lt;12 h before</td>
</tr>
<tr>
<td>5</td>
<td>Circ. &amp; Resp.</td>
<td>Circulatory intervention <strong>and</strong> Intubation</td>
<td>&lt;12 h before or &lt;1 h after (ETT)</td>
</tr>
<tr>
<td>6</td>
<td>CPR/ECMO</td>
<td>cardiac massage or ECMO</td>
<td>&lt;12 h before or &lt;1 h after</td>
</tr>
<tr>
<td>7</td>
<td>Death</td>
<td>irrespective of other interventions</td>
<td>no ICU admission</td>
</tr>
</tbody>
</table>
369 patients urgent ICU transfer from inpatient ward
5 deaths before transfer

15% overall mortality
22% ‘Late’ ICU admission
secondary outcomes

1. late ICU admission
2. severity of clinical deterioration
3. potentially preventable cardiac arrest
4. unplanned hospital readmission
5. unplanned PICU readmission

urgent ICU admission

6. PIM score (predicted mortality)
7. PICU mortality
8. PELOD score day 1 & all PICU
9. VFD first ICU admission
operations

Center for Safety Research team

EPOCH Executive Steering Committee
C Parshuram J Hutchison
K Dryden-Palmer A Joffe
C Farrell J LaCroix
R Gottesman V Nadkarni
M Gray P Parkin
M Helfaer D Wensley
E (B) Hunt A Willan
oversight processes

1. dual study oversight:
   - Executive Steering Committee
   - Canadian Critical Care Trials Group
2. delegated randomization
3. data safety & monitoring board
4. site data confirmation & sign off
5. independent statistician review
6. writing committee
7. independent pre-submission review
results

21 hospitals | 3 continents | 3 languages | 21 cultures

## Participants

<table>
<thead>
<tr>
<th></th>
<th>all</th>
<th>control</th>
<th>BedsidePEWS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospitals</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sites</td>
<td>21</td>
<td>11</td>
<td>10</td>
</tr>
<tr>
<td>Rapid Response Team</td>
<td>9</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>&gt;200 Beds</td>
<td>3</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Staffed Beds</td>
<td>2085</td>
<td>1148</td>
<td>937</td>
</tr>
<tr>
<td><strong>Patients</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>*Hospital Discharges</td>
<td>144,539</td>
<td>94,366</td>
<td>50,173</td>
</tr>
<tr>
<td>*Ward Patient Days</td>
<td>559,443</td>
<td>307,584</td>
<td>251,859</td>
</tr>
<tr>
<td>*ICU Days</td>
<td>15,961</td>
<td>9,293</td>
<td>6,668</td>
</tr>
</tbody>
</table>

* post-randomization period
mortality outcomes

<table>
<thead>
<tr>
<th>mortality outcome</th>
<th>control</th>
<th>BedsidePEWS</th>
<th>Odds or Rate Ratio (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>all-cause hospital</td>
<td>147 (1.56)</td>
<td>97 (1.93)</td>
<td>1.003 (0.77-1.32)</td>
<td>0.98</td>
</tr>
<tr>
<td>N (/1000 hospital discharges)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>+do not resuscitate</td>
<td>100 (0.84)</td>
<td>55 (1.09)</td>
<td>1.041 (0.75-1.45)</td>
<td>0.81</td>
</tr>
<tr>
<td>N (/1000 hospital discharges)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>after urgent ICU</td>
<td>73 (6.2%)</td>
<td>43 (5.2%)</td>
<td>0.81 (0.57-1.15)</td>
<td>0.24</td>
</tr>
<tr>
<td>N (/100 urgent ICU discharges)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>predicted urgent ICU</td>
<td>58 (4.9%)</td>
<td>46 (5.4%)</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>N (/100 urgent ICU discharges)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All-cause hospital mortality was <40% of rate anticipated before study. We sought a difference of 1/1000 hospital discharges: mortality was similar observed > predicted mortality after Urgent ICU admission in control hospitals 1.3% higher in control hospitals vs 0.2% lower in BedsidePEWS hospitals.
### Timeliness of ICU Admission

<table>
<thead>
<tr>
<th>ICU admission</th>
<th>control</th>
<th>BedsidePEWS</th>
<th>Rate Ratio (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>late ICU</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N (/1000 hospital days)</td>
<td>259 (0.842)</td>
<td>127 (0.504)</td>
<td>0.763 (0.61-0.95)</td>
<td>0.0164</td>
</tr>
<tr>
<td><strong>urgent ICU admission</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N (/1000 hospital days)</td>
<td>1178 (3.83)</td>
<td>828 (3.29)</td>
<td>0.973 (0.88-1.07)</td>
<td>0.55</td>
</tr>
<tr>
<td><em>cardiac arrests</em></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N (/1000 hospital days)</td>
<td>32 (0.104)</td>
<td>27 (0.107)</td>
<td>1.001 (0.60-1.69)</td>
<td>0.97</td>
</tr>
<tr>
<td>pot. preventable arrest</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N (/1000 hospital days)</td>
<td>29 (0.094)</td>
<td>21 (0.083)</td>
<td>0.875 (0.50-1.54)</td>
<td>0.64</td>
</tr>
</tbody>
</table>

Similar rate of urgent ICU admission.
Infrequent cardiac arrest ~1/10000 hospital days
Less late ICU admission with BedsidePEWS
16% of urgent admissions with BedsidePEWS vs 24% in control hospitals
& early ICU

most deteriorating children admitted to ICU had no major ICU intervention
cardiac arrest & death before transfer were uncommon & similar rates

0 10 20 30 40 50 60 70 80 90 100

Percent of Urgent ICU admissions

no major intervention:
65% control
77% BedsidePEWS

783 BedsidePEWS
1079 Usual Care

clinical deterioration events and interventions

0 10 20 30 40 50 60 70 80 90 100

Percent of Urgent ICU admissions

None Pos. Press. V Intubation Circulatory Circ. & Resp. CPR/ECMO Death
## care processes

<table>
<thead>
<tr>
<th>process outcome</th>
<th>control</th>
<th>BedsidePEWS</th>
<th>Rate Ratio (95%CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>resuscitation team call</td>
<td>179 (0.58)</td>
<td>126 (0.50)</td>
<td>0.97 (0.77-1.23)</td>
<td>0.82</td>
</tr>
<tr>
<td>N ( /1000 patient days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ICU/RRT consultation</td>
<td>1694 (5.51)</td>
<td>1015 (4.03)</td>
<td>1.050 (0.965-1.142)</td>
<td>0.26</td>
</tr>
<tr>
<td>N ( /1000 patient days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>‘stat’ call</td>
<td>1157 (3.76)</td>
<td>1727 (6.86)</td>
<td>1.170 (1.085-1.261)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>N ( /1000 patient days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>heart rate measurements /24 hours</td>
<td>6.45</td>
<td>7.40</td>
<td>0.49 (0.09-0.89)</td>
<td>0.027</td>
</tr>
<tr>
<td>systolic blood pressure measurements /24 hours</td>
<td>3.58</td>
<td>5.05</td>
<td>0.96 (0.62-1.29)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

- similar ‘code-blue’ & ICU consult calls
- better documentation
- more ‘we need the Dr. now’ with BedsidePEWS
## resource utilization

<table>
<thead>
<tr>
<th>resource outcome</th>
<th>control</th>
<th>BedsidePEWS</th>
<th>Odds Ratio (95% CI)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICU days</td>
<td>9293 (2.93%)</td>
<td>6668 (2.58%)</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>N (% of hospital days)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ventilation days</td>
<td>267</td>
<td>264</td>
<td>23</td>
<td>0.42</td>
</tr>
<tr>
<td>/1000 ICU days</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECMO use</td>
<td>1.61%</td>
<td>1.09%</td>
<td>0.30 (0.12-0.75)</td>
<td>0.01</td>
</tr>
<tr>
<td>% urgent ICU admit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HFOV use</td>
<td>2.89%</td>
<td>3.26%</td>
<td>0.52 (0.24-1.10)</td>
<td>0.09</td>
</tr>
<tr>
<td>% urgent ICU admit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>technology-days</td>
<td>302</td>
<td>304</td>
<td>-29 (-93-35)</td>
<td>0.39</td>
</tr>
<tr>
<td>/1000 ICU days</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**similar ICU resource utilization**

**suggestion less ‘advanced’ technology use with BedsidePEWS**
interpretation

BedsidePEWS vs usual care:

1. similar hospital mortality
   40% initially anticipated rate -> power vs. no difference
   zero asymptote... more controlled end of life?

2. decreased late ICU admission
   main secondary, prev. original main outcome
   but similar cardiac arrest / death before ICU (n=8)

3. changed processes of care
   more vital signs taken, same resuscitation team calls

4. similar ICU resource utilization
limitation

larger academic hospital focus
  unclear generalizability to community hospitals
  no US hospitals

major events were infrequent
  primary outcome in retrospect perhaps not ideal
  smaller regional hospitals had zero mortality
  69 cardiac arrests ... many judged as preventable

culture change challenging
  adherence needs review - physician & nurse actions

more data and analyses to complete
  main work + planned sub-studies
questions addressed

in our first look @ 36,000 data forms

Does the BedsidePEWS...

Yes  improve early detection of critical illness
No   reduce mortality
Yes/No improve processes of care &
Yes  not increase healthcare resources
Arianne Willems
Malika Hazim
Bernard Wenderickx
Paul Mourlhou
Afrothite Kotsakis
Sarah Gander
Wendy Harris
Joanne Holland
Julie MacLean
Darlene Boliver
Stephanie Cajolais
Samara Zavalkoff
Maryse Dagenais
Sarah Shea
Marc-Andre Dugas
Josee Gaudreault
Louise Gosselin
Catherine Farrell
Caroline Cler-Proulx
Laurence Bertout
Isabelle Grisoni
Jonathan Duff
Jodie Pugh
Denise Capito
Amanda Barclay
Fiona Auld
Laurie Robson
Jonathan Gilleland
Lois Saunders
Douglas Fraser
Paige Bechard
Colleen Martin
Lindsay Spear
Kathleen Tobler
Kimberly Kulbaba
Nicola Robertson
Dermot Doherty
Emma Ladewig
Suja Somanadhan
Louise Greensmith
Cormac Breatnach
Cathal O’Rourke
Corrado Cecchetti
Orsola Gawronski
Aryanna Rusucitto
Ester Pagaduan Cabillon
Gabrielle Nutall
Gregory D. Williams
Claire Sherring
Tracey Bushell
Miriam Rea
Louise Armriding
Greta Olykan
Cynthia Van der Starre
Angelique Hogeboom
Andrea De Oude-Lubbers
Martin Martin
Nargis Hemat
Simon Broughton
Sarah Harris
Emily Downing
David Inwald
Ruchi Sinha
Sophie Raghunanan
Mamta Vaidya
Leanne Reardon
Margarita Burmester
Kanwarjit Kailay
Loredana Haidu
Susan Ferri
Jessica Grillo
Nida Shahid
Sarah Ashley
Simran Singh
Kate Byrne
Aarthi Kamath
Kristen Middaugh
Michael-Alice Moga
Nelly Thwaites
Critical Care Colleagues@SickkIds