

Supplementary Appendix II: **“Handoff improvement and adverse events-reduction program implementation in paediatric intensive care units in Argentina: a stepped-wedge trial”**

Figure 1. Study sample in stepped wedge cluster randomized trial, showing health records reviewed in each cluster and period.

PICUs	Month of the study										
	Jul-18	Aug-18	Sep-18	Oct-18	Nov-18	Dec-18	Jan-19	Feb-19	Mar-19	Apr-19	May-19
1	27	21	15	18	10	13	22	8	11	14	14
2	30	29	24	17	12	12	14	16	12	15	24
3	12	16	13	14	25	22	15	13	14	18	17
4	30	30	30	30	30	30	30	30	30	30	29
5	30	30	30	30	30	30	30	30	30	30	29
6	27	24	27	24	24	21	17	21	18	17	30

Control

Intervention

Table 1. Preventable adverse event per site and per period.

Site	Rates for 1000 days of hospitalization (95% CI)		Rate of rates (Intervention/Control) (95% CI)	p-Value*
	Intervention	Control		
1	27.6 (20.8;36.7)	37.4 (29.5;47.4)	0.74 (0.51;1.07)	0.109
2	21.3 (14.2;32.1)	32.2 (23.3;44.4)	0.66 (0.39;1.11)	0.122
3	84.5 (66.1;108.0)	84.4 (65.7;108.3)	1.00 (0.71;1.42)	0.995
4	82.7 (65.4;104.5)	73.5 (61.8;87.4)	1.12 (0.84;1.51)	0.430
5	112.8 (87.9;144.6)	139.8 (106.2;184)	0.81 (0.56;1.17)	0.257
6	42.2 (28.6;62.2)	28.9 (15.8;52.8)	1.46 (0.71;2.98)	0.304

*p-value was obtained from the generalized mixed linear model adjusted by the time effect.

Table 2: Total amount of adverse event and preventable adverse event by type and group

	Adverse events		Non preventable adverse events	
	Intervention (N=698)	Control (N=767)	Intervention (N=698)	Control (N=767)
Health-care-associated infections				
Central line-associated blood stream infection	11	19	10	19
Sepsis/bacteremia unrelated to catheter	18	30	17	30
Ventilator-associated pneumonia	59	57	59	56
Nosocomial pneumonia, not ventilator-related	8	13	5	8
Catheter-associated UTI	43	74	43	74
Hospital-acquired viral illness	11	17	10	17
Surgical site infection	9	3	9	2
Endometritis	0	0	0	0
C. difficile colitis	2	1	2	1
Respiratory				
Acute respiratory failure (RR elevated or depressed)	19	17	16	14
Respiratory distress, not acute failure	2	0	0	0
Pneumothorax/hemothorax/SQ air	12	15	11	13
Barotrauma	3	0	3	0
Atelectasis (CXR findings with increased [A-a] O ₂ gradient)	11	5	7	4
Bronchospasm	0	2	0	0
Aspiration (witnessed, with or without CXR changes)	1	1	1	1
Pulmonary Embolus	0	0	0	0
Post extubation stridor	13	22	2	3
R mainstem bronchus intubation	1	1	1	1
Unplanned extubation	0	0	0	0
Reintubation within 24 hrs of planned extubation	23	18	23	18
Other Respiratory (note: ventilator-associated pneumonia and other pneumonia is under infections section)	35	37	7	9
Gastrointestinal				
Nausea / vomiting	0	1	0	0
Diarrhea	0	1	0	1
Constipation	6	2	4	2
Gastric distension	0	0	0	0
Pancreatitis	0	0	0	0

Jaundice / hepatic insult (elevated bilirubin / elevated ALT and/or AST)	9	4	0	0
Ileus	0	2	0	2
Other GI	1	4	1	3
Surgical / Obstetrical				
Post-operative hemorrhage	8	6	3	4
Post-operative hematoma	2	0	1	0
Laceration or other injury of organ	0	2	0	1
Unplanned removal of organ due to intra-operative injury	0	0	0	0
Vascular injury	1	2	0	0
Nerve injury	0	0	0	0
Surgical anastomosis failure	0	1	0	1
Wound dehiscence	4	5	1	1
Retained foreign instrument or sponge	0	0	0	0
Failed procedure (e.g., need for revision)	5	3	5	0
Unplanned return to surgery	8	3	5	0
Uterine rupture	0	0	0	0
Major placental abruption	0	0	0	0
Unplanned / emergency hysterectomy	0	0	0	0
Fetal / neonatal complications associated with delivery (e.g. stillbirth, birth trauma, dystocia, unplanned NICU admission)	0	0	0	0
Other surgical or obstetrical	10	5	2	4
Renal/Fluids/Endocrine				
Fluid overload (new CHF, severe edema or increased [A-a] O ₂ gradient associated with IV fluids)	6	4	6	4
Dehydration / Oliguria (urine output <0.5cc/kg TBW > 4 hrs; or CVP < 5 or PAWP < 8 with signs of dehydration)	0	0	0	0
Acute renal failure (increased Creat > 50% with or without oliguria)	12	16	6	8
Metabolic acidosis (HCO ₃ < 20)	1	2	0	1
Metabolic alkalosis (HCO ₃ > 30)	0	1	0	1
Adrenal insufficiency (Low baseline or ACTH stimulation test cortisol and / or responds to corticosteroid Rx)	0	0	0	0
Hyperglycemia	3	4	1	4
Hypoglycemia	7	14	7	10
Hyperkalemia	1	1	0	1
Other Renal / Fluids / Endocrine	13	13	10	8
Neurologic				

Oversedation (drug related)	2	8	2	6
Delirium / Encephalopathy	0	5	0	1
Seizures	6	3	3	2
CVA / Intracerebral hemorrhage	0	1	0	1
Paralysis / Neuromuscular blocker excess	0	0	0	0
Obtundation (not drug-related)	13	1	13	1
Inadequate sedation/anxiolysis	0	0	0	0
Inadequate analgesia	0	0	0	0
Withdrawal symptoms	17	17	13	15
Other neurologic	6	7	2	5
Cardiovascular				
Cardiac Arrest	31	23	8	15
Hypotension	9	10	3	5
Hypertension	4	2	4	1
Low cardiac output	4	1	4	1
Shock (non-cardiogenic) (hypotension and oliguria or altered sensorium or peripheral hypoperfusion)	5	3	4	1
Arrhythmias / Conduction abnormality (new VT, VF, AF, SVT, bradycardia or heart block)	5	13	3	5
Myocardial infarction/ischemia (ECG changes and/or increased troponin or CK-MB)	0	0	0	0
Pulmonary edema (Increased [A-a] O ₂ gradient or new CXR clinical findings or PCWP≥18)	0	3	0	3
Peripheral (extremity) ischemia (absent pulses or skin color and temperature changes)	0	3	0	1
Other cardiovascular	6	0	4	0
Hematologic				
Hemorrhage (Hct ↓ > 5% or needs RBC transfusions)	28	22	17	15
Thromboembolic event - venous	9	21	4	16
Thromboembolic event - arterial	3	3	0	1
Hematoma	2	2	2	2
Other Hematologic, Specify	9	9	6	5
Other Categories				
Hypothermia (Temperature < 35° C)	2	5	0	5
Pyrexia (Temperature > 39° C)	0	0	0	0
Alcohol or drug withdrawal	8	6	7	3
Allergic reaction (e.g. rash, hives, anaphylaxis)	3	5	1	2
Fall	0	0	0	0
Pressure Ulcer	10	19	10	19

Death	21	9	5	2
Rash (non-allergic)	1	0	0	0
Line complication	41	38	37	36
Tube complication (chest tube, foley, etc.)	6	4	6	4
Other harm type not listed above	37	37	26	31

Table 3. Proportion of compliance on the key elements of verbal handoffs in each site

Verbal Site	Illness severity		Patient summary		Action list		Situation awareness and contingency plans		Synthesis by the receiver	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
1	81.7%	0.0%	93.3%	10.5%	63.3%	4.0%	10.0%	0.0%	93.3%	2.6%
2	73.8%	4.0%	100.0%	81.6%	96.7%	36.8%	16.4%	9.2%	62.3%	0.0%
3	65.4%	0.0%	99.0%	65.5%	81.2%	0.0%	53.5%	0.0%	85.2%	0.0%
4	83.3%	0.0%	93.8%	61.9%	83.3%	22.6%	58.3%	4.8%	95.8%	36.9%
5	83.8%	34.7%	100.0%	91.7%	36.3%	12.5%	2.5%	1.4%	90.0%	0.0%
6	73.7%	63.3%	96.8%	90.0%	95.8%	83.3%	99.0%	73.3%	67.4%	46.7%

Table 4. Proportion of compliance on the key elements of written handoffs in each site

Written Site	Illness severity		Patient summary		Action list		Situation awareness and contingency plans		Synthesis by the receiver	
	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control
1	98.3%	0.0%	95.0%	1.3%	68.3%	15.8%	10.0%	0.0%	96.7%	1.3%
2	98.4%	1.3%	100.0%	61.8%	45.9%	7.9%	37.7%	1.3%	16.4%	0.0%
3	93.1%	1.7%	97.0%	46.6%	93.1%	13.8%	71.3%	0.0%	88.1%	0.0%
4	95.8%	0.0%	100.0%	86.9%	91.7%	10.7%	83.3%	0.0%	95.8%	0.0%
5	86.1%	0.0%	88.6%	0.0%	13.9%	0.0%	1.3%	0.0%	8.7	0.0%
6	82.1%	20.0%	87.4%	60.0%	92.6%	73.3%	94.7%	70.0%	66.3%	16.7%