


# Quality improvement project to reduce unplanned extubations in a paediatric intensive care unit

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## ABSTRACT

**Background** Unplanned extubations are recurrent adverse events in mechanically ventilated children and have been the focus of quality and safety improvement in paediatric intensive care units (ICUs).

**Local problem** To reduce the rate of unplanned extubation in the paediatric ICU by 66% (from 2.02 to 0.7).

**Methods** This is a quality improvement project that was conducted in a paediatric ICU of a private hospital at the quaternary level. All hospitalised patients who used invasive mechanical ventilation between October 2018 and August 2019 were included.

**Interventions** The project was based on the Improvement Model methodology of the Institute for Healthcare Improvement to implement change strategies. The main ideas of change were innovation in the endotracheal tube fixation model, evaluation of the endotracheal tube positioning, good practices of physical restraint, sedation monitoring, family education and engagement and checklist for prevention of unplanned extubation, with Plan–Do–Study–Act, the tool chosen to test and implement ideas for change.

**Results** The actions reduced the unplanned extubation rate to zero in our institution and sustained this result for a period of 2 years, totalling 743 days without any event. An estimate was made comparing cases with unplanned extubation and controls without the occurrence of this adverse event, which resulted in savings of R\$955 096.65 (US\$179 540.41) during the 2 years after the implementation of the improvement actions.

**Conclusion** The improvement project conducted in the 11-month period reduced the unplanned extubation rate to zero in our institution and sustained this result for a period of 743 days. Adherence to the new fixation model and the creation of a new restrictor model, which enabled the implementation of good practices of physical restraint were the ideas of change that had the greatest impact in achieving this result.

## INTRODUCTION

Unplanned extubation (UE) is defined as any unexpected or UE due to patient agitation or patient handling by the team.<sup>1 2</sup>

UEs are considered a recurrent adverse event in mechanically ventilated children<sup>3</sup> and have been the focus of improvement of quality and safety in paediatric intensive care

## WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Unplanned extubations events increase morbidity and actions led by improvement projects reduce the occurrence of these events.
- ⇒ So far, the focus of the vast majority of studies has been the patient sedation level, and nursing staff/patient sizing, and those that point to actions aimed at endotracheal tube fixation do not provide enough details for them to be implemented reliably.

## WHAT THIS STUDY ADDS

- ⇒ Our study was conducted with a focus on six primary drivers and the highlight were the implementation of a new fixation model and the development in our country of a new movement restrictor which was a great differential in the way of providing adequate restriction.

## HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ The other differential of our study was that we brought the innovations implemented with detailed photos, which allows the implementation by other institutions.
- ⇒ The quality improvement project conducted in the 11-month period reduced the unplanned extubation rate to zero in our institution and sustained this result for a period of 2 years.

unit (PICU). UE requiring reintubation is an adverse event with the potential for severe damage and is associated with airway complications, cardiorespiratory impairment and even death, in addition to an increased duration of mechanical ventilation,<sup>4</sup> an increased length of stay in the ICU and hospitalisation<sup>5 6</sup> and, consequently, a significant financial impact. In this improvement project, any UEs were included and monitored, regardless of the need for reintubation.

In the paediatric population, several factors have been associated with a higher risk for UE, including patient age, type of endotracheal tube fixation, patient sedation level and nursing staff size.<sup>7 8</sup>

Thus, attempts at improvements related to UE indicators mainly focus on the adequacy of sedation and effective restraint, thus avoiding periods of patient agitation and factors related to the monitoring of endotracheal tube fixation and positioning. The current debate focuses on improving processes to prevent UEs involving paediatric patients.<sup>9 10</sup>

In the period from January 2017 to October 2018, a significant increase in the UE rate was identified in the PICU. As these events are preventable, it is important to carry out an improvement project to reduce their incidence.

The aim of study is UE rate in the PICU was reduced by 66% (from 2.02 to 0.7) from October 2018 to August 2019. This target was established based on our historical series as recommended by the quality improvement model.

## METHODS

This is a quality improvement project that uses the Improvement Model methodology of the Institute for Healthcare Improvement to test and implement change strategies.<sup>11</sup> It was conducted in a PICU of a private hospital with a quaternary level with approximately 3000 hospitalisations/year. All patients admitted to the PICU who used invasive mechanical ventilation between October 2018 and August 2019 were included, and any UE was UE, regardless of the need for reintubation. Tracheostomised patients were excluded from the study.

The UE was defined as any unexpected or UE due to patient agitation or patient handling by the team.

### Formulation of the multidisciplinary team

We formed a multidisciplinary team composed of nurses, nursing technicians, physical therapist, physicians and specialists in quality and health economics. The project team identified which causes were related to the increase

in UE in the PICU through the fishbone diagram (online supplemental figure), then reviewed the current process and opportunities for improvement, identified key processes where changes were needed and created a guiding diagram (figure 1), with the main ideas for change being innovation in the endotracheal tube fixation model, evaluation of endotracheal tube positioning, good practices of physical restraint, sedation monitoring, family education and engagement and checklist for prevention of UE.

### Interventions

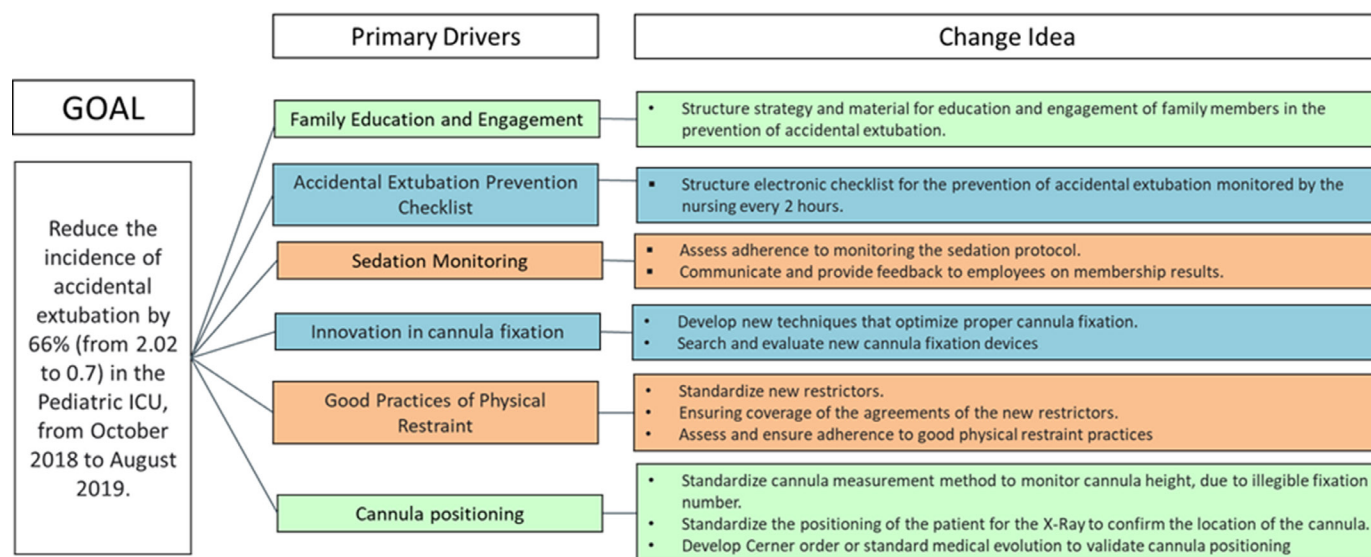
The main interventions (ideas for change) that were implemented after the tests (Plan–Do–Study–Act, PDSA) are described below.

### Innovation in the endotracheal tube fixation model

Initially, a search was made in the market for new endotracheal tube fixation devices available that did not present effective fixation alternatives for the paediatric population.

We then introduced a new orotracheal endotracheal tube fixation technique with Tensoplast (no latex free) following the model of the Rainbow Babies and Children Hospital, replacing the ‘H fixation’ method (online supplemental figure), which reduced the detachment of the endotracheal tube fixation, increased the fixation durability on average from 24 hours to 7 days and reduced the number of fixation changes. The idea of the new fixation model was approved in the tests and adopted, and the entire physical therapist and nursing team was trained to perform the new fixation method (online supplemental figure).

For patients transferred from other services, the fixation was changed as soon as the patient was admitted to the unit.



**Figure 1** Guiding diagram with the main change ideas named the primary drivers and the change ideas describing the actions that were tested. ICU, intensive care unit.

## Evaluation of endotracheal tube positioning

Alternative ways to monitor the endotracheal tube depth were suggested, especially in situations where the number of fixations presented in the endotracheal tube was illegible. The method used to evaluate the external measurement of the endotracheal tube from the lip to the end of the endotracheal tube was tested and adopted, without considering the connector, as well as standardising the medical records for monitoring. Another idea of change was to insert the positioning number of the tracheal endotracheal tube in the digital image of the X-ray. The idea was tested by inserting the abbreviation LS (upper lip), followed by the number corresponding to the endotracheal tube fixation in the X-ray. This action facilitated the evaluation of the positioning with the corresponding number, optimising the decision making for possible adjustments in the positioning of the endotracheal tube. A standard medical evolution was also developed to validate the positioning of the endotracheal tube. The entire physical therapist and nursing team was trained to perform the evaluate the external measurement of the endotracheal tube.

## Good practices of physical restraint

Restrictive alternatives were developed in partnership with a national company, whose model consists of gloves and limb restraints (online supplemental figure) that limit movement, as alternatives to physical restraint or the use of limb restraint (online supplemental figure) unavailable in the Brazilian territory, in a safe and comfortable way, as they do not tie the patient to the bed. These new restrictors were developed from the benchmarking conducted with international companies. After testing and approval of the new devices, the product was registered in the National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária), and commercial negotiation was conducted to ensure the coverage of the new restrictors by the agreements. In addition, the electronic medical records of mechanical restraint and monitoring of restraint were standardised in the electronic medical record to ensure the surveillance, quality and safety of minimally contained patients, in accordance with good practices in PICUs and the legislation of the Regional Nursing Council. The quality of the restriction process was constantly monitored, and all employees received feedback regarding good restriction practices.

## Monitoring of sedation

A form for monitoring compliance of sedation goals was established, tested and implemented in the medical prescription through the COMFORT-B scale<sup>12</sup> (goal between 11 and 22). In addition, we sought to achieve nursing monitoring every 2 hours of the COMFORT-B scale and corrections when necessary, both recorded in medical records.

## Education and family engagement

A verbal orientation guide for the prevention of UE developed by the nurse with the care partner was elaborated and tested, indicated in the patient orientation chart with a specific field for prevention of UE and filled out the educational plan in the electronic medical record.

## Checklist for prevention of UE

The UE Prevention Checklist was developed and tested in the electronic medical record and included the following: fixation condition, exchange of fixation and positioning of the circuit. In addition, an electronic medical record task was created, whose reminder required the evaluation of the checklist by the nursing technician every 2 hours, ensuring continuous surveillance of intubated paediatric patients.

## Study of interventions

To evaluate the results, data were collected on the number of patients ventilated day, UE event and date of the event. The preintervention data (February 2017 to September 2018) were surveyed retrospectively and prospectively in the intervention phase (October 2018 to August 2019) and postintervention (September 2019 to December 2021).

The data to evaluate the process measures, including adherence to UE prevention good practices, were collected through a process and medical record audit, through a standardised checklist, prospectively in the intervention phases (October 2018 to August 2019).

Data to assess balance measures, including adverse events and late clinical complications related to the UE and costs related to reintubation, were collected through the reporting of occurrences and cost analysis through the expert panel, prospectively in the intervention phases (October 2018 to August 2019) and postintervention (September 2019 to December 2021).

## Measures

The primary outcome was to reduce the UE rate by 66% from 2.02 to 0.7 per 100 ventilations/day. To evaluate this result, the UE rate (ratio between the number of accidental extubated paediatric patients and the number of ventilated patients-day) was calculated. In addition, as a result indicator, the days between UE events in the PICU were also calculated, with the goal of reaching at least 76 days without any occurrence, also based on our historical series which was 51 days.

The events were monitored through an electronic notification system but were also shared on daily Safety Huddle.

The data related to the process indicators included the evaluation of the adherence of the multidisciplinary team of the PICU to the ideas of change tested, which were performed through audits of medical records to monitor the percentage of adherence to the following processes: monitoring of the endotracheal tube depth, fixation of the endotracheal tube, sedation scale monitoring score,

good practices of physical restraint, education of the family to prevent UE measures with a goal of 95% adherence to good practices. From this perspective, the process indicators did not have preintervention baseline data and were collected from December 2018 to June 2019 during the intervention period of the improvement project.

The process measures were based on the team's adherence to good practices for the prevention of UE. For this purpose, compliance was evaluated in the following processes: monitoring of the endotracheal tube depth, adequate endotracheal endotracheal tube fixation, adequate inflated cuff pressure, monitoring score of the sedation scale, good physical restriction practices, education of the family to preventive measures and UE. All these process measures had a target of 95% adherence.

As an indicator of balance, the occurrence of adverse events and late clinical complications related to UE and the costs related to reintubation were evaluated. To estimate the cost balance indicator related to reintubation after UE, the consumption of hospital resources of the 15 patients in whom the adverse event occurred was compared with the consumption of 60 patients who used the PICU and used mechanical ventilation, with a profile age similar to the cases.

### Analysis

The monthly UE rate was plotted on a control Uchart, and the number of days between events was plotted on a control Tchart. The control charts were created using QI Macros for Excel software. The rules for the analysis and identification of special causes in the variation in the

control graphs were as follows: points outside the limits, trends and deviations.

The estimation of incremental costs and incremental length of stay was performed, following the propensity score methodology, according to a study that evaluated costs and incremental length of stay related to extubation,<sup>13</sup> the comparison between cases with adverse events from UE and controls was performed based on the variables age in months, sex, acute renal failure and non-invasive ventilation, all variables collected prior to intubation. For the control population, paediatric patients exposed in the PICU who used mechanical ventilation during hospitalisation were eligible for matching. A ratio of 4:1 was performed, that is, for each case of accidental extubation, it was compared with four controls without accidental extubation. Resulting in a total of 15 cases of accidental extubation and 60 controls of patients admitted to the PICU who used Mechanical Ventilation. The hospital consumption of the hospitalisations analysed was extracted from the dispensing of items at the patient level and dollarised according to the average dollar for the year 2021 (R\$5.319675).

### RESULTS

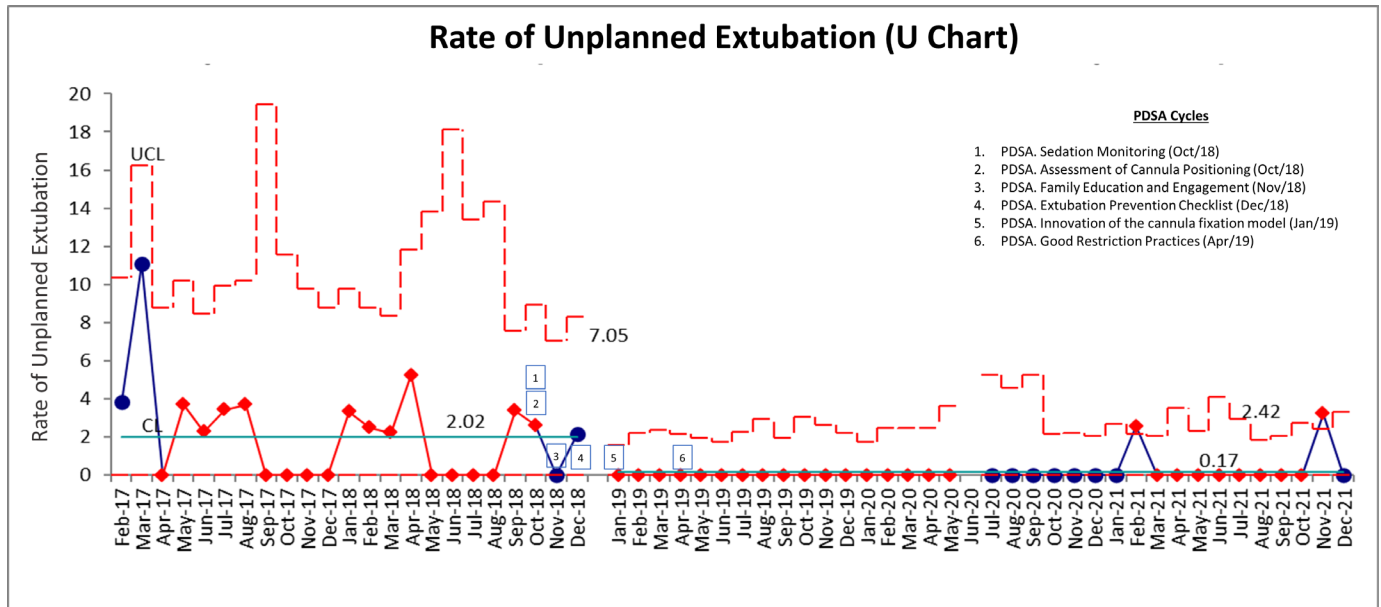
The demographic characteristics of the patients included in the study are presented in [table 1](#).

The number of children who used mechanical ventilation through an orotracheal tube during the preintervention period (February 2017 to September 2018) was 91, with an average of 54.6 children/year. During this

**Table 1** Demographic characteristics and major diagnostic of paediatric patients

Demographic characteristics	Extubation unplanned		P value
	Yes (n=15)	No (n=60)	
Age (month)	28, 73 (49.06)	28, 00 (32.73)	0.9456
Gender (male)	7 (46.67%)	38 (63.33%)	0.2386
Acute renal failure	4 (26.67%)	18 (30.00%)	0.7998
Non-invasive ventilation (previously)	3 (20.00%)	15 (25.00%)	0.6851
CASEMIX (APR-DRG) (dp)	5, 11 (4.80)	5, 55 (6.06)	0.7962
Major diagnostic category			
Disorders of the ears, nose, throat	1 (6.67%)	4 (7.41%)	
Nervous system disorders	3 (20%)	5 (9.26%)	
Neoplasm disorders	2 (13.33%)	4 (7.41%)	
Newborn conditions originating perinatal period	1 (6.67%)	7 (12.96%)	
Circulatory system disorders	2 (13.33%)	8 (14.81%)	
Respiratory system disorders	4 (26.67%)	15 (27.78%)	
Digestive system disorders	1 (6.67%)	0 (0%)	
Blood and immune disorders	1 (6.67%)	3 (5.56%)	
Infectious and parasitic diseases	0 (0%)	4 (7.41%)	
Disorders of the kidneys and urinary tract	0 (0%)	2 (3.7%)	
Endocrine disorders	0 (0%)	1 (1.85%)	
Spleen trauma	0 (0%)	1 (1.85%)	

Values presented in percentage, mean and SD.



**Figure 2** Accidental extubation rate in the paediatric ICU from February 2017 to December 2021 presented by UChart chart. ICU, intensive care unit; PDSA, Plan–Do–Study–Act.

period, the rate of use of mechanical ventilation was 537 ventilated/day, with an average of 322 ventilated/day per year. During the intervention period (October 2018 to August 2019), 65 children required orotracheal intubation, totaling 511 ventilations/day in 11 months. In the postintervention period (September 2019 to December 2021), the number of intubated children was 99 children, an average of 42 children/year, with a mechanical ventilation rate of 809 ventilated/day or 347 ventilated/day/year.

The reintubation rate among patients who had an UE event was zero in the pre intervention period and 2.0% during the project period.

The monitored outcome indicators corresponded to the monthly UE rate, as well as the days between UE events.

From this perspective, the UE rate in the PICU in the preintervention period corresponded to an average of 2.02 UE per 100 ventilations/day, according to the UChart graph (figure 2).

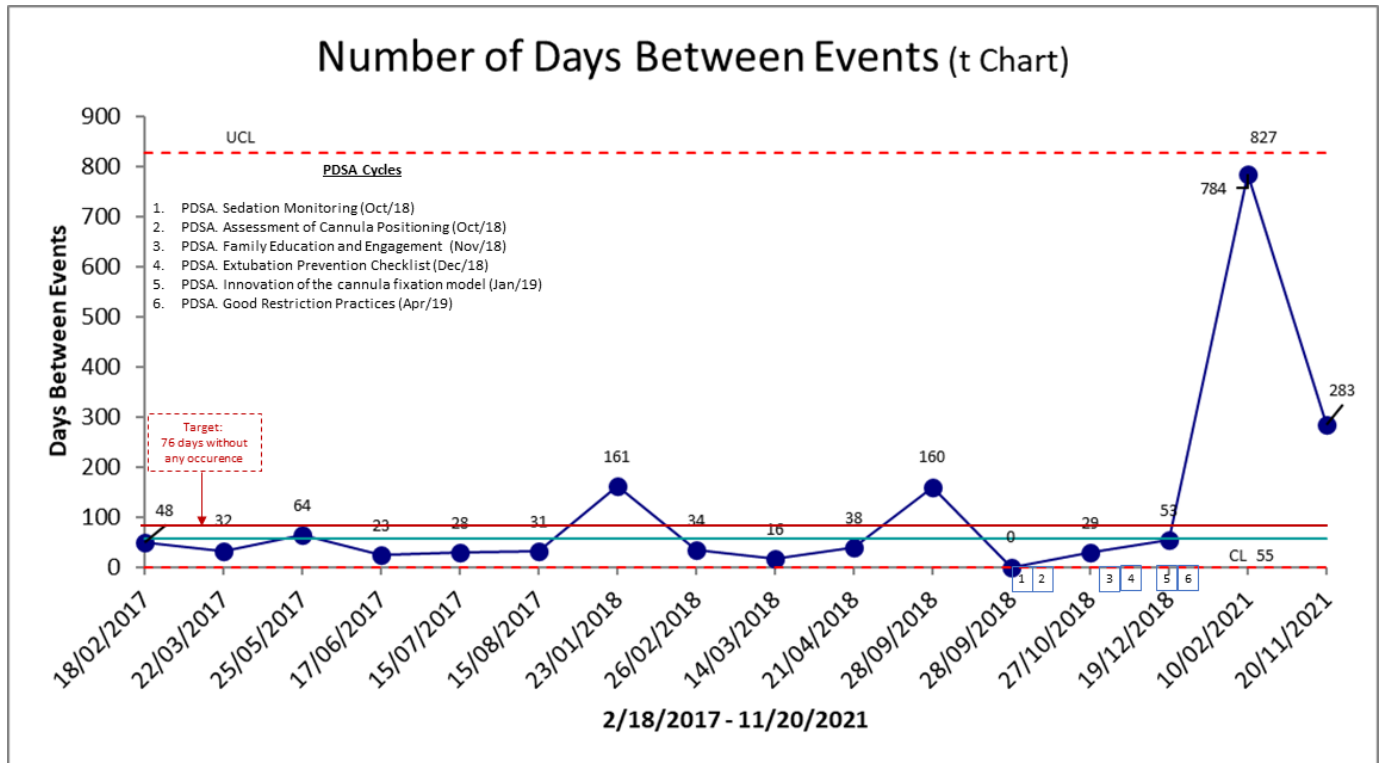
In the intervention phase, several PDSAs were initiated from October 2018, namely, monitoring of sedation (October 18), evaluation of endotracheal tube positioning (October 18), education and family engagement (November 18), and checklist prevention of UE (December 18). Since January 2019, there has been a reduction in the rate of UE to zero (0.00) concomitant with the test and implementation of the new endotracheal tube fixation model and subsequent standardisation of the new restrictors (April 2019). The results show that we achieved a 100% reduction in the UE rate in the sustained PICU during the 2-year period, as there was no occurrence of this event from January 2019 to December 2020.

Thus, we surpassed the established goal of the improvement project, which was a 66% reduction in the extubation rate (from 2.02 to 0.7 per 100 ventilated/day), and the results were sustained in the postintervention period. In 2021, two events of UE were reported, and in both cases, there was no need for reintubation. These events were related to low surveillance in the direct care of the professional in the extubation planning stage (figure 3).

In the preintervention period, the mean number of days between UE events in the PICU was 59 days. In the intervention phase, the six change ideas were implemented, and the mean number of days between UE events corresponded to 108 days. As of January 2019, concomitant with the implementation of the new endotracheal tube fixation model, there was no sustained UE event during the 2-year period, reaching a total of 784 days without any UE event in the postintervention phase, and in the postintervention phase, the mean number of days between UE events corresponded to 288 days. Therefore, comparing the preintervention and postintervention periods, there was a 488% increase in the number of days between events (figure 3).

The process indicators did not reach the goal of 95%, and the best percentages were monitoring of the endotracheal tube depth, endotracheal tube fixation and family education, reaching average adherence of 75.8%, 77.4% and 76, 1%, respectively. Regarding adherence to the monitoring of the sedation scale and good practices of physical restraint, compliance was between 35% and 40% (online supplemental figure).

The balance indicator evaluated the occurrence of adverse events and late clinical complications related to UE as well as the costs related to reintubation. During the intervention period, in June 2019, an adverse event related to a lesion



**Figure 3** Days between accidental extubation events in the paediatric ICU from February 2017 to December 2021 presented by a graph presented by a TChart graph. ICU, intensive care unit; PDSA, Plan–Do–Study–Act.

caused by pressure of the labial mucous membrane associated with the endotracheal tube was identified, and the laser was applied with temporary damage reversal. The professionals were revalidated in the new treatment about method of fixation and implanted checklist of safe prone positioning with repositioning of the endotracheal tube for pressure relief. No skin lesions related to the adhesive or latex of the tensoplast were observed.

The estimate of the incremental financial impact of the adverse event obtained through the mean incremental difference between cases with adverse extubation events and controls without adverse events was R\$63673.11 (US\$11,969.36) per hospitalisation with the occurrence of UE. A mean time of incremental stay of 8 days was observed in the group of patients accidentally extubated, and the mortality rate of extubated cases was 5% higher than in cases without adverse events.

From this perspective, the improvement project reached zero UEs in the PICU during the 2-year period. Thus, it is estimated that, according to the number of patients ventilated-day, these improvement actions were able to achieve the prevention of 15 extubations unplanned in the postintervention period, when we consider the historical rate of 2.02, providing an estimated savings of R\$955096.65 (US\$179540.41).

## DISCUSSION

This improvement project, developed in the period of 11 months, achieved a reduction in the UE rate from 2.02 to 0.0, and these results were sustained for 24 months. The

days between events exceeded the initial goal of 76 days by 877%, reaching 743 days ago.

Our findings are consistent with other authors who report an UE rate between 0.74 and 3.19,<sup>14 15</sup> and the literature has reinforced the importance of improvement projects for the reduction of UE conducted by multidisciplinary teams. The results obtained by other studies range from 20% to 80% reduction in the incidence of UEs.<sup>8 16 17</sup>

Our study was conducted by a multidisciplinary team using the Improvement Model of the Institute for Healthcare Improvement.<sup>11</sup> The project was conducted with a focus on six primary drivers: innovation in the endotracheal tube fixation model, assessment of endotracheal tube positioning, good practices of physical restraint, sedation monitoring, family education and engagement and checklist for prevention of UE.

The literature describes the main risk factors associated with UE, including age, inadequate fixation, patient sedation level and nursing staff/patient sizing.<sup>7–9 18 19</sup> In other improvement projects, the adequacy of fixation and monitoring of adequate levels of sedation and restriction are the main drivers,<sup>18–20</sup> and in this improvement project, our primary drivers also represent these risk factors.

In our study, the replacement of the fixation model was one of the changes that had a high impact on the prevention of UE. ‘Compared with the previous ‘H’ model with single tape, referenced by other studies,<sup>8 21</sup> the current model increased the duration and periodicity of fixation replacement.’ The fixation model adopted by our study was also described by Rachman *et al* in a study that evaluated the

incidence of UE during the period of 9 years after the implementation of an improvement project. The replacement of the fixation model was implemented in this current project in addition to the educational plan of the entire care team on the importance of the prevention of UE in the PICU environment.<sup>21</sup> In our service, we use it as a reference for fixing the upper lip and not the tooth. This point seems to be quite controversial since most authors do not cite the reference used in their studies.<sup>22–25</sup> Ahmed and Boyer describe both possibilities of references<sup>22</sup> but Agnes *et al* clearly point out that the reference for the endotracheal tube depth formula is referenced by the distance between the tooth and the carina.<sup>25</sup>

Adequacy of sedation is a subject that presents many challenges because sedation for the prevention of agitation and consequently the prevention of UE can lead to excessive levels of sedation, increasing the duration of mechanical ventilation and length of hospital stay.<sup>26</sup> According to Society of Critical Care Medicine Clinical Practice Guidelines Finding a balance between oversedation and undersedation is paramount. That guideline suggests the use of COMFORT-B scale to evaluate the ideal depth of sedation, the same scale used for our study.<sup>27</sup> Our study based the adequacy of sedation on the COMFORT-B scale (goals 11–22) in an attempt to minimise the extremes of agitation or deep sedation, both with harmful effects for the patient. da Silva *et al* also used the COMFORT-B scale to establish the sedation goal; however, in this study, the sedation goal tolerated the patient slightly more alertly, with a score between 17 and 26.<sup>8</sup>

The development of restrictors that were not available in our country was a key point in the improvement project. The containment of patients with band restraint was already prohibited in our institution and strongly criticised in the literature about its use.<sup>26 28 29</sup> The project team was in search of a model that would provide a less restrictive alternative, and the challenge was to find a national company that would manufacture a model similar to those used internationally, which was a great differential in the way of providing adequate restriction and comfortable in the paediatric population, that is, effective according to best practices. These new models provide limitations in movements with restriction of elbow flexion and pinch of the fingers with comfort and prevention of accidental exit of the traction devices. The choice of this restrictor model aimed to balance between patient safety and preventing the unwanted removal of a vital support device (tube and catheters) and a restriction that allowed a certain degree of mobility and even playing. Some precautions were incorporated into the protocol for using this restriction, such as monitoring the restrictor every 2 hours to assess perfusion, skin condition.<sup>30</sup>

In events considered rare, such as the case of UE, the monitoring of process indicators is extremely important because they change earlier with the changes than the outcome indicators.

Our results in the process indicators, whose evaluation sought to guide the adherence of the multidisciplinary team of the PICU to the ideas of change tested,

indicate percentages of adherence above 75% in the data related to the monitoring of the endotracheal tube depth, endotracheal tube fixation and education of the family. Regarding the adherence to the monitoring of the sedation scale and good practices of physical restraint, compliance was between 35% and 40%. As these indicators were obtained through medical records audits, they were perceived as not consistent with the care practice and must have been a consequence of deficient records in the medical records. Direct observations estimated higher levels of adherence. Certainly, in future studies, the collection of process indicators should be performed by the direct observation method.

Regarding endotracheal tube fixation, the conformity of fixation was evaluated with respect to the fixation conditions and not the technique. Our attention was drawn to the fact that, in relation to the new fixation technique, after it was implanted, it was used in 100% of intubated patients during and after the improvement project and was therefore incorporated into the work routine of the multidisciplinary team.

The results of the actions of this improvement project, in addition to reducing the UE events to zero, promoted an improvement in the operational efficiency of the PICU. Cost estimates show a reduction in the consumption of resources in the PICU, length of stay and systemic hospital impact. Previous studies in adults and children corroborate our results because they showed that UE is associated with increased length of hospital stay and, in the ICU<sup>18 16</sup>; however, studies that performed cost analysis associated with UE are rare. Roddy *et al*, in a retrospective study analysing 48 UE, showed an increase in hospital costs compared with controls of US\$36 692/case, in addition to an increase in hospitalisation time of 6.5 days/case.<sup>13</sup>

Our study has some limitations. The first is related to the low number of ventilated patients/day, with an average of 32 ventilated patients/day. Our ICU has 20 beds, but the vast majority have low complexity, which is characterised by a small number of patients using mechanical ventilation.

The second, the lack of approval in certain countries of this restriction model may be a limiting factor for its implementation.

The third, the completion time of the checklist. Our checklist was adapted to the nursing controls. Since the intensive care nursing controls are every 2 hours, we adjusted the checklist evaluation for these moments, so there was no overload for the care team. But this is an important point to consider.

The fourth, we were unable to identify the effect of the interventions in isolation. The methodology used is not designed to identify which measure alone would have the greatest impact on the results, but rather how to effectively implement a set of measures (equivalent to a bundle) that are known to have an impact on reducing UE and that should be implemented together.

The fifth, unfortunately, we did not monitor the mean values of the COMFORT-B scale, only we only established a target that did not exist before the project.

Another significant limitation was our way of evaluating the process indicators, which was not performed through direct observation but through analysis of medical records.

## CONCLUSIONS

The improvement project conducted in the 11-month period reduced the UE rate to zero in our institution and sustained this result for a period of 2 years. The set of implemented measures during this quality improvement project allowed of this result.

**Contributors** JCDF, MSN and SB made substantial contributions to study conception and design, data acquisition, analysis and interpretation of the data and has been involved in drafting the manuscript and revising it critically for important intellectual content; CdP, DTM, CdCC and JFA made substantial contributions to study conception and design and acquisition, analysis and interpretation of the data and has been involved in drafting the manuscript and revising it critically for important intellectual content; AC made substantial contributions to study conception and design and analysis and interpretation of the data and have been involved in drafting the manuscript and providing final approval of the version to be published. JCDF, Guarantor.

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**Patient consent for publication** Not applicable.

**Ethics approval** The project was approved by the Research Ethics Committee and authorised to be exempted from signing the informed consent form (ICF).

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