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ORIGINAL RESEARCH

Key process and outcome indicators on quality and safety of care for critically ill pediatric patients according to international standard organization protocols: a four-year follow-up study

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Abstract

The European Society of Intensive Care Medicine (ESICM) suggests nine quality and safety indicators of care for critically ill patients. The aim of the present study was to examine the Key Process and Outcome Indicators (KPOIs) chosen according to International Standard Organization (ISO) protocols in a Greek Pediatric Intensive Care Unit (PICU). Two structure, one process, and four outcome indicators were examined in a stepwise approach according to Observe-Plan-Do-Study-Act (OPDSA) cycles, in an observational four-year cohort study (2017–2020). Two structure indicators—that ICUs fulfil national requirements to provide intensive care and 24-h consultant availability were requirements for the creation of the PICU and considered standards of care. One process indicator—Standardized Handover Procedure was transformed from handwritten (2017–2018) into electronic form (2019–2020) and 100% compliance rates throughout the four years were recorded. 96, 85, 103 and 94 patients were admitted in 2017, 2018, 2019 and 2020 with median (IQR) Pediatric Risk of Mortality III-24 h scores of 10 (6.25–17), 10 (6–13), 8 (5–13) and 8 (6.75–12), respectively. Mortality rates were 24%, 11.8%, 17.5%, 16%, and Standardized Mortality Ratio (SMR) were 1.42, 0.92, 1.56 and 1.33, correspondingly. No early (<48 h after PICU discharge) readmissions were recorded for 2017 and 2018, only 1 in 2019 (0.8%) and none in 2020. Catheter Related Bloodstream Infection rates were 1.37:1000, 1.37:1000, 1.26:1000 and 1.39:1000 catheter days, respectively. Unplanned extubation rate was 10.30% in 2019 and 5.72% and 3.91:1000 ventilation days in 2020. In conclusion, ISO implementation of our unit was the trigger for internal PICU audit and external benchmarking. OPDSA cycles, following small steps at a time, in an iterate cycle of evolution, facilitated our actions. The majority of the KPOIs examined in our study was within international PICUs reference values.

Keywords

Pediatric intensive care unit—PICU; Quality; Safety; Key process and outcome indicators—KPOIs; Pediatric risk of mortality—PRISM III; Standardized mortality ratio—SMR

1. Introduction

The International Organization for Standardization (ISO), founded in 23 February 1947, in Geneva from standards organizations from 25 countries, currently consists of 167 participants. ISO takes its name from the Greek word *isos* (*ίσος*, meaning "equal"), and this universal term is used worldwide to avoid different acronyms in different countries (ISO in English, Organisation Internationale de Normalisation—OIN in French). "*Whatever the country, whatever the language, the short form of our name is always ISO*", was stated about its name by their founders [1].

Reports from ISO today, as of April 2022, have announced 24,261 standards covering almost all aspects of technology and manufacturing with the aid of 804 technical committees and subcommittees. Healthcare has not been left behind. ISO 9000 family, is the world's most well-known quality management standard for companies and organizations of any size. ISO 9000 is complemented by ISO 26000, that assesses and addresses social responsibilities. Together they contribute also to the 17 Sustainable Development Goals to promote prosperity and protecting the planet, adopted by all United Nations Member States in 2015, as part of the 2030 Agenda for Sustainable Development [2]. Especially, goal 3 for good health and well-being, which ISO contributes with 3068 standards [3, 4].

Having its fundamentals in the scientific methods of hypothesis—experiment—evaluation, Shewhart introduced Plan-Do-Check-Act (PDCA) cycle in the 1920s, as an iterative cycle for improving processes and outcomes. Later, Deming in the 1950s revised Check to Study and renamed to Plan-Do-Study-Act (PDSA), as he felt that the term "check" was closely to the concept of inspection and "success/failure" instead of "study" which would put more emphasis on data and learning [5]. Finally, other scholars added "O" which stands for Observation of baseline current conditions, and turned to OPDSA [6]. OPDSA cycle is an iterative five-step management method for the control and continuous improvement of processes, products and outcomes. The concept is to define the process you want to optimize by (1) measuring how it currently performs, (2) analyzing how it can be optimized, (3) deciding how to improve it, (4) implementing the new process and creating a plan to measure it, and (5) reviewing it again in future in a continually improvement effort. Small steps are followed initially to reach significant future results [7–9].

The task force on safety and quality of the European Society of Intensive Care Medicine (ESICM), starting its actions since 2009, released in 2012 a number of indicators to improve the safety and quality of care for critically ill patients. Eighteen experts from 11 European countries, concluded in nine indicators reaching 90% level of consensus, after five rounds of considerations, and agreed that, the set of nine indicators should be applicable for any unit and not specific to any individual disease process or specialty. It is worth mentioning that major difficulty was anticipated with indicators describing processes of care than on the structures and outcomes (**Supplementary Table 1**) [10]. Choosing among the ESICM suggestions the most relevant Key Process and Outcome Indicators (KPOIs) in PICUs and applying the OPDSA principles could allow the identification and removal of inefficiencies and establish the basis for process and outcome improvement.

The aim of the present study was to examine the stepwise approach and the performance of the KPOIs chosen for ISO implementation in a PICU, in an observational cohort four-year study (01 January 2017—31 December 2020). In fact, it will represent an internal four-year audit which could enable external benchmarking as well as the comparison of our results with literature, and the identification of the topics for future improvement.

2. Methods

2.1 Setting

An eight-bed tertiary PICU at Hippokration General Hospital of Thessaloniki, Greece, founded in 1999, to serve all critically ill children aged 35 days to 16 years old, from the wider region of Northern Greece. All diagnostic categories are admitted, apart from cardiac surgery patients and patients with severe burns (>10% Body Surface Area), due to lack of support of the corresponding surgical specialties, serviced by one director and seven consultants, four of whom are certified in intensive care, with 24/7 consultant presence. All PICU modalities are available in the unit, apart from Extra Corporeal Membrane Oxygenation. Nurse to patient ratio ranges from 1:2 in morning shifts to 1:3 or 1:4 in rest shifts, according to PICU occupancy rate which fluctuates around 70%.

2.2 Key Process and Outcome Indicators (KPOIs)

On occasion of PICU ISO implementation, ESICM indicators were adopted as part of PICU performance evaluation. Seven out of nine ESICM indicators were chosen. Two structure indicators—that ICUs fulfil national requirements to provide intensive care and 24 h consultant availability—were requirements for the creation of the PICU and considered standards of care. As a result, we focused our study on five KPOIs; one process indicator—Standardized Handover procedure for discharging patients, and four outcome indicators; namely (a) reporting and analysis of Standardized Mortality Ratio (SMR), *e.g.*, the ratio of the observed to predicted mortality rate, (b) ICU readmission rate within 48 h of ICU discharge, (c) the rate of central venous Catheter Related Blood Stream Infection (CRBSI), and (d) the rate of unplanned endotracheal extubations.

2.3 Definitions

2.3.1 Pediatric Risk of Mortality III (PRISM III-24) and SMR

For SMR evaluation a suitable illness severity score, appropriately calibrated on the population under investigation, is necessary, to calculate the probability of death, in order to compare observed to predicted mortality rate [11, 12]. In our case, in contrast to adult mortality prediction models that calculate mortality at hospital discharge, we used PRISM III-24 which predicts mortality at PICU discharge [13]. PRISM III-24 was chosen among the illness severity scores for pediatric intensive care patients because it was previously examined in our population and was found to have a very good performance with high discrimination and calibration abilities. The Area under the Receiver Operating Curve (AUC) showed very good discrimination of PRISM III-24h score (AUC 0.892, 95% CI 0.821–0.963) and PRISM III-24 predictive model (AUC 0.900, 95% CI 0.836–0.964). Hosmer-Lemeshow goodness-of-fit test showed good calibration of PRISM III-24 score (χ^2 (8) = 1.716, p = 0.989) and PRISM III-24 predictive model (χ^2 (8) = 8.294, p = 0.405) [14].

2.3.2 Readmission rate

The readmission rate within 48 h of PICU discharge were calculated as the percentage (%) of initial admissions per year.

2.3.3 Catheter Related Blood Stream Infection (CRBSI) and Central Line Associated Blood Stream Infection (CLABSI)

According to 2008 Centers for Disease Control (CDC) criteria, a patient has primary BSI if he has at least: (a) one positive blood culture for a recognized pathogen and infection not related to another site, (b) at least one of the following signs or symptoms: fever (>38 °C), chills, or hypotension and two positive blood cultures for a common skin contaminant (such as diphtheroids (*Corynebacterium* spp), *Bacillus* (not *B anthracis*) spp, *Propionibacterium* spp, coagulase-negative staphylococci (including *S epidermidis*), viridans group streptococci, *Aerococcus* spp, *Micrococcus* spp) in two separate blood samples, within 48 h, and infection not related to another site, (c) patient <1 year of age has at least one of the following signs or symptoms: fever (>38 °C, rectal), hypothermia (<37 °C, rectal), apnea or bradycardia and two positive blood cultures for a common skin contaminant as described above and infection not related to another site [15]. Primary bloodstream infections (BSI) include CRBSI and BSI of unknown origin. CRBSI was characterized as a BSI occurring 48 h before or after catheter removal and positive culture with the same microorganism of either (a) quantitative Central Venous Catheter (CVC) tip culture $\geq 10^2$ Colony Forming Units (CFU)/mL or semi-quantitative CVC tip culture >15 CFU, (b) quantitative blood culture ratio CVC blood sample/peripheral blood sample >3 fold (blood samples drawn at the same time), (c) differential time to positivity (DTP) of blood cultures: CVC drawn blood sample culture positive two hours or more before peripheral blood culture (blood samples drawn at the same time), and (d) positive culture with the same microorganism from pus from insertion site [16]. Evaluation whether primary BSI fulfilled the criteria for CRBSI was done, and the rate of CRBSI infections:1000 catheter days (CD) was calculated.

CRBSI criteria with strict microbiological confirmation has been gradually replaced in the literature since 2011 by another surveillance definition as Central Line Associated Blood Stream Infection (CLABSI), proposed by CDC/National Healthcare Safety Network (NHSN). CLABSI is a primary BSI with CVC use (even intermittent) in the 48 h preceding the onset of the infection. It is calculated the same way, as rate of CLABSI:1000 CD [17–19]. Because the two terms are used with different frequencies and interchangeable worldwide, we used both definitions to have more comparable data.

CVC use was defined as Device Utilization Ratio (DUR) and evaluated as total Catheter Days per total days of Length of patient Stay (LOS) in the unit [18].

2.3.4 Unplanned extubation rate

The rate of unplanned endotracheal extubations was calculated as the percentage (%) of mechanically ventilated patients for 2019, and both as the percentage and also the more detailed index of number of unplanned extubations:1000 days of mechanical ventilation (MV) in 2020.

2.4 Study design

The study was designed as an observational four-year (01 January 2017—31 December 2020) cohort study. Three indicators; namely SMR, PICU readmission rate within 48 h of discharge, and the rates of CRBSI/CLABSI were examined during the first two years (2017–2018) to set baseline values, and their performance were continually evaluated (2019–2020) as well. Two more indicators, the standardized electronic handover procedure for discharging patients and the rate of unplanned extubations were prospectively added in 2019 and the more detailed index of number of unplanned extubations:1000 days of mechanical ventilation was further assessed for 2020.

2.5 Exclusion criteria

Readmissions were excluded as happened in SMR evaluation of PRISM III-24 and ESICM indicators. However, early readmissions only, were included for the evaluation of readmission rate within 48 h of discharge, as the ESICM indicator.

2.6 Data collected

Demographic data, reasons for admissions, PRISMIII-24, the presence of comorbidities, the need for mechanical ventilation and mechanical ventilation days, the need for inotropic support, LOS, CRBSI and CLABSI rate, readmission <48 h rate, unplanned extubations, the outcome at discharge and the SMR were collected for the above time periods.

2.7 Statistical analysis

Categorical variables were described as percentages (%), while continuous variables as mean ± SD or median (IQR), as appropriate, according to normal Kolmogorov-Smirnoff testing. Differences between patients who died or survived were sought with *t*-test for independent samples and/or Mann Whitney test for continuous variables, whereas for the univariate analysis between categorical variables and the dependent variable (death), the χ^2 test was applied. The 2-tailed significance level was set at 0.05. Data were analyzed using IBM SPSS Statistics 22.0 (Armonk, NY, USA).

3. Results

3.1 Overall evaluation of the population studied

Among 441 consecutive admissions during the study period, 63 were excluded as readmissions, and 378 children remained for evaluation. There were 208 boys (55%) and 170 girls (45%) with a median (IQR) age of 46 (10–108) months (Table 1). The main reasons for admission were: respiratory failure (21.2%), postoperative care (20.9%), neurologic failure (12.7%), trauma (11.1%), Status Epilepticus (10.8%), sepsis (7.4%), cardiac arrest—Return of Spontaneous Circulation (ROSC) (6.3%), metabolic diseases (3.4%), other diseases (3.7%) and cardiac diseases (2.4%). The median PRISM III-24 score was 9 (6–13). More than half (51.9%) suffered from complex chronic conditions. A big proportion (40.5%) received inotropic support. The MV rate (2019–2020) was 93.4% and the median MV duration (2021) was 7 (3–21) days. The median LOS was 9 (4–23) days. Overall, 66 patients died, given a discharge mortality rate of 17.5%. Patients who died had a greater (mean ± SD) PRISM III-24 score (20.07 ± 11.61 *vs.* 9.14

TABLE 1. Patient characteristics per year.

	2017	2018	2019	2020	Total
Patients (N)	96	85	103	94	378
Age	40 (14–102)	48 (12–102)	42 (8–96)	67 (9–133)	46 (10–108)
Boys, %	51	50	60	59	55
PRISM III-24 score	10 (6–17)	10 (6–13)	8 (5–13)	8 (7–12)	9 (6–13)
Surgical, %	15	24	21	23	21
Comorbidities, %	64	53	42	48	52
Inotropes, %	47	46	34	39	40
MV rate, %	NA	NA	94	93	93[1]
MV days	NA	NA	NA	7 (3–21)	7 (3–21)
MV days sum	NA	NA	NA	1278	1278[2]
LOS	9 (3–22)	10 (5–24)	8 (3–21)	10 (5–27)	9 (4–23)
LOS sum	1644	1699	1760	1583	6686
CD	13 (6–23)	12 (6–29)	12 (5–23)	11 (5–28)	12 (5–25)
CD sum	1458	1458	1582	1435	5933
DUR	0.89	0.86	0.90	0.92	0.89
CLABSI, N	19/1458	11/1458	12/1582	15/1435	57/5933
CLABSI rate	13:1000	7.5:1000	7.6:1000	10.4:1000	9.6:1000
CRBSI, N	2/1458	2/1458	2/1582	2/1435	8/5933
CRBSI rate	1.4:1000	1.4:1000	1.3:1000	1.4:1000	1.3:1000
Mortality, discharge, %	24.0	11.8	17.5	16.0	17.5
Mortality, predicted	16.8	12.8	11.2	12.0	13.6
SMR	1.4	0.9	1.6	1.3	1.3

PRISM III-24: Pediatric Risk of Mortality; MV: Mechanical Ventilation; NA: Not applicable; LOS: Length of Stay; CD: Catheter days; DUR: Device Utilization Ratio; CLABSI: Central Line Associated Blood Stream Infection; CRBSI: Catheter Related Blood Stream Infection; SMR: Standardized Mortality Ratio. All parameters followed non parametric distribution, values are given as median (IQR). [1]for 2019–2020 only; [2]for 2020 only.

± 5.09, $p < 0.001$), were more likely to receive inotropic support (38.6% *vs.* 3.1%, $p < 0.001$), to be girls (22.4% *vs.* 13.5%, $p = 0.023$) and suffered from different reasons at admission ($p < 0.001$). On the contrary, they did not show significant differences in age ($p = 0.726$), comorbidities ($p = 0.306$), MV days ($p = 0.482$) and LOS ($p = 0.777$), compared to patients who survived. The worst mortality rate within diagnosis was recorded in sepsis (42.9%) and in cardiac arrest patients resuscitated with ROSC (41.7%), followed by cardiac (33.3%), respiratory (23.8%), neurologic (22.9%), other (21.4%), metabolic (7.7%), postoperative (6.3%), and trauma (4.8%). Interestingly, no deaths were recorded in Status Epilepticus patients.

3.2 Standardized Electronic Handover Procedure (SEHOP) for discharging patients

The previous handwritten discharge instructions were transformed to a standardized electronic preformed document (SEHOP) that accompanied each patient at PICU discharge. This enabled the electronic record keeping of each patient as well. We recorded a 100% compliance rate since the beginning of the evaluation period from 01 January 2019 to 31 December 2020.

3.3 Reporting of Standardized Mortality Ratio (SMR)

96, 85, 103 and 94 patients were admitted in 2017, 2018, 2019 and 2020 with median (IQR) PRISM III-24 h scores of 10 (6.25–17), 10 (6–13), 8 (5–13) and 8 (6.75–12) respectively. Mortality rates were 24%, 11.8%, 17.5%, 16%, and SMR were 1.42, 0.92, 1.56 and 1.33 correspondingly (Table 1).

3.4 ICU readmission rate within 48 of ICU discharge

No early readmissions were recorded for 2017 and 2018, only 1 in 2019 and none in 2020. Readmission rate for 2019 was 0.8%.

3.5 CRBSI and CLABSI rates

424 temporary CVCs for 3870 CD and 85 semi-permanent Hickman catheters for 2063 Hickman CD, were evaluated. Overall DUR was 0.89, fluctuating between 0.868 and 0.929. Eight CRBSIs were documented in 5933 CD, given an overall

CRBSI rate of 1.34:1000 CD. 57 CLABSIs were recorded in 5933 CD, setting an overall CLABSI rate of 9.60:1000 CD. Analytically, CLABSI and CRBSI rates per year are exposed in Table 1. LOS were significantly higher in patients with CLABSI (37.44 ± 32.93 *vs.* 14.88 ± 19.39 days, $p < 0.001$) and CRBSI (47.25 ± 54.11 *vs.* 17.04 ± 21.29 days, $p < 0.001$). Mortality, although not significantly, was higher both in CLABSI (25.50% *vs.* 16.30%, $p = 0.119$) and CRBSI patients (25% *vs.* 17.30%, $p = 0.570$).

3.6 The rate of unplanned endotracheal extubations

Ten unplanned extubations were recorded in 97 MV patients in 2019 (10.30%) and 5 in 87 MV patients in 2020 (5.72%). The total duration of MV in 2020 was 1278 days, given an unplanned 2020 extubation rate of 3.91:1000 MV days. All unplanned extubations were self-extubations during the weaning period, and only one patient needed re-intubation.

4. Discussion

We present a one center quality initiative study in the context of ISO implementation. The fulfillment of the two structure ESICM indicators on safety and quality of care of intensive care patients at a 100% level since the creation of our tertiary PICU, laid the foundations to go on with the evaluation of the other KPOIs [20–22]. Starting with the OPDSA cycle, we firstly observed PICU performance for the years 2017–2018 to set the baseline values for the three initial indicators chosen. Then, analyzing each indicator, we tried to keep up with the good results, sought for weak points, plan their improvement, study their application and act accordingly, going into an iterate cycle of continuous assessment. Gradually, we added the rest indicators in small steps each following year, approaching them with the same manner, as demonstrated in Table 2. Due to the nature of our study, we will discuss each KPOI separately.

4.1 Standardized Electronic Handover Procedure (SEHOP) for discharging patients

SEHOP is an effectiveness and efficiency indicator that should accompany every PICU patient on discharge including standardized documentation of the reasons for admission and the forthcoming diagnosis made, the on-going problems, the full list of the recent medications and alterations of previous if any, and the issues that need to be resolved [23–26]. The diagnosis should follow a recognized system of classifying disease and the information should be available to all clinical teams caring for the patient post discharge. In our case, handwritten discharge instructions were given to all patients since the origin of the PICU. The improvement made after ISO implementation was the commencement of the SHEOP following a predetermined form, beginning in 01 January 2019. The International Classification of Diseases, Tenth Revision (ICD 10) system was used for disease classification [27, 28]. The standardized form helped avoiding errors due to bad handwriting while the predetermined pattern allowed all the critical information to be included without omissions. According to the OPDSA proposal, we observed the discharging process, planned a SEHOP form and applied it for the years 2019 and 2020. Studying our actions, we found a 100% compliance rate. Our future efforts will be focused on maintaining this performance level.

4.2 Analysis of Standardized Mortality Ratio (SMR)

Mortality at PICU discharge (observed mortality) is a raw indicator of effectiveness and quality of care as it doesn't take into consideration the severity of critical illness and the case mix. SMR evaluation allows internal audit and external PICU benchmarking, and enables the performance of reflective practice and quality improvement [12]. As depicted in Table 2, according to the OPDSA cycle, firstly, we observed the SMR for the years 2017 (1.42) and 2018 (0.92) compared to ESICM ICU standards of 0.75–1.25 [10], the international PICU SMR levels of 0.92–1.39 [13, 29–31], and the national SMR for Greek PICUs of 1.54 [32]. In the literature, better outcomes are reported in populations with more surgical patients, less severity of illness and lower proportion of MV [13, 31, 33–37]. Although the characteristics of our cohort could justify our results, a better outcome was sought. As understaffing, especially nursing, is related to poor outcome, an initiative for better medical and nurse staffing was carried out [21, 22, 38–41]. Two more MD doctors and five nurses were added to PICU workforce. Better internal allocation of nurses' shifts was planned as well, moving from the minimum 1:4 nurse to patient ratio during night shifts when it was sometimes necessary, to the least acceptable ratio of 1:2.66 (minimum three nurses in each shift to maximum of eight patient beds). In the parallel, the better education of medical stuff was pursued; four doctors started post graduate studies and three more consultants were certified in intensive care. Furthermore, under continuing educational programs, we updated all medical protocols. The prospective 2019 (SMR 1.56) and 2020 (SMR 1.33) evaluations were still relatively high, showing that more actions are required. The fact that we managed to contain our SMR values during the first year of the severe acute respiratory syndrome coronavirus 2 SARS-CoV-2 pandemic could serve as an indication that our efforts started to flourish.

4.3 ICU readmission rate within 48 h of ICU discharge

Early (<48 h) readmissions could be related to poor discharge decision making, *e.g.*, earlier than anticipated discharge, gaps in the communication regarding patient needs to the step down facility, deficient handover procedure, poor ward patient care, and serve as an ICU safety and quality indicator worldwide [29, 42–45]. Patients with early readmissions are associated with increased hospital stay, cost, morbidity and mortality. Lower early readmission rate is typically reported for discharged pediatric PICU patients (1.2–3.7%) [46–50] compared to the target of 4% set by ESICM for adults [10]. Ensuing the OPDSA cycle, we observed readmission rates for the years 2017 and 2018 which were zero (0), as demonstrated in Table 2.

TABLE 2. Observation plan do study act (OPDSA) yearly cycles.

	2017	2018	2019	2020
Structure				
ICU fulfils national requirements to provide intensive care—Standard of Care 100% 24 h availability of a consultant level—Standard of Care 100%				
Process				
Standardized Electronic Handover Procedure (SEHOP) for discharging patients	Observation-Baseline handwritten HO Plan set for electronic procedure SEHOP Do measure compliance rate (CR) Study compliance rate Action if needed		Observation Plan SEHOP Do CR 100% Study CR Action no needed	Observation Plan SEHOP Do CR 100% Study CR Action no needed
Outcome				
SMR ESICM Standard 0.75—1.25 [10] PICUs 0.92–1.39 [13, 29–31] Greek PICUs 1.54 [32]	Observation Plan to measure Do SMR 1.42 Study SMR Action if needed	Observation Plan to measure Do SMR 0.92 Study SMR Action if needed	Observation Plan to reduction Do SMR 1.56 Study SMR Action needed	Observation Plan to reduction Do SMR 1.33 Study SMR Action needed
Readmission <48 h (RE) ESICM Standard Adults 4% [10] PICUs 1.2–3.7% [46–50]	Observation Plan to measure Do RE 0% Study RE Action if needed	Observation Plan to measure Do RE 0% Study RE Action if needed	Observation Plan to reduce LOS Do RE 0.8% Study RE Action needed?	Observation Plan to reduce LOS Do RE 0% Study RE Action needed?
CRBSI ESICM Standard 4:1000 CD [10]	Observation Plan to measure Do CRBSI 1.37:1000 Study CRBSI Action if needed	Observation Plan to measure Do CRBSI 1.37:1000 Study CRBSI Action if needed	Observation Plan to measure Do CRBSI 1.26:1000 Study CRBSI Action needed?	Observation Plan to measure Do CRBSI 1.39:1000 Study CRBSI Action needed?
CLABSI USA PICUs <3.1:1000 CD [60, 62, 63] International 3.7–18.8:1000 CD [61, 64–68] Greek PICUS 6.09–16.67:1000 CD [69, 70]	Observation Plan to measure CLABSI 13.03: 1000 Study CLABSI Action if needed	Observation Plan to measure CLABSI 7.54: 1000 Study CLABSI Action if needed	Observation Plan to reduction CLABSI 7.58: 1000 Study CLABSI Action needed	Observation Plan to reduction CLABSI 10.43: 1000 Study CLABSI Action needed
Unplanned extubation (UEX) ESICM Standard UEX both Adult + Pediatrics (P) <10:1000MV days [10, 79] UEX P 3.4–14.7% [29, 76–78]	Not applicable	Not applicable	Observation Plan to measure Do UEX rate 9.7% Study UEX Action needed?	Observation Plan to measure MV days Do UEX rate 5.37% Do UEX 3.91:1000 Study UEX Action needed?

SMR: Standardized Mortality Ratio; ESICM: European Society of Intensive Care Medicine; PICU: Pediatric Intensive Care Unit; CRBSI: Catheter Related Bloodstream Infection; CD: Catheter days; CLABSI: Central Line Associated Bloodstream Infection.

Our low numbers were not realistic compared to the literature and an action was started to examine and determine the reasons behind the data. We decided to check the hypothesis that the patients stayed too long in the PICU, until they had better health than is normal for discharge. This course of action, increased, on the one hand, the patient's safety, but, on the other hand, keeping patients too long in the PICU is inefficient [42, 51]. The prolonged need for PICU care is intertwined to illness severity, case mix, discharge policies and existence of step-down facilities. As mentioned, the majority of our population suffered from comorbidities (51.7%) and had all the characteristics that inevitably, mandated a prolonged PICU stay. The lack of step-down pediatric units in our country complicates further the equation on LOS. An initiative was started in 2019 to examine whether an earlier discharge policy is feasible with the concept of having a shorter LOS with acceptable anticipated readmission rates; protocols for less sedation and faster weaning from MV and increased use of Non-invasive Ventilation (NIV) were incorporated as well [52]. A shorter, although not significantly, LOS was recorded for 2019 (17.08 $\pm$ 24.06) and 2020 (16.84 $\pm$ 17.70) days compared to 2017 (17.12 $\pm$ 24.36) and 2018 (19.98 $\pm$ 24.99). Despite that, early readmission rates remained very low, 0.8% for 2019 and 0% for 2020, suggesting that probably other reasons behind PICU management are to be sought.

4.4 CRBSI and CLABSI rates

Bloodstream infections are the first Hospital Acquired Infections (HAI) infections in pediatrics [53] and CRBSI and CLABSI are considered device related preventable HAI that increase LOS and cost whereas their role in mortality remains controversial [18, 54–56]. The last decade an effort has started worldwide to keep their rate as low as possible, and their control is considered not only a safety and a quality indicator, but a reimbursement one as well [57]. DUR is inseparably related to CVC infection rates and reduction in CVC use is among the first bundles of care to be taken under their control [9, 58]. DUR in our occasion was 0.89, very high compared to international ICU values of around 0.70 [59] and PICU values which are even lower, about 0.50 [60, 61], and are another confirming factor regarding high illness severity in our population. Higher patient's acuity necessitates CVC presence, which inevitably expose them to higher infection rates. As exposed in Table 2, CRBSIs baseline rates for 2017 and 2018 found them within ESICM limits (<4:1000 CD) [10], and our plan was to maintain those high result standards for the following years, which we succeeded in doing. Conversely, baseline CLABSI rates were higher than reported USA pediatric values which are below 3.1:1000 CD [60, 62, 63]. Our results approached other international values ranging from 3.7–18.8:1000 CD [61, 64–68] and were found within national PICU CLABSI rates of 6.09 to 16.67:1000 CD [69, 70]. Actions were indicated with focused efforts in increasing compliance with the insertion and prevention CLABSI bundles of care [18, 71, 72]. A stabilization was recorded in 2019, with an unfortunate relapse in 2020, despite our efforts, probably due to the burden of the 2020 pandemic, where less experienced personnel had to deal with increased PICU workload. In accordance with the literature, CRBSIs and CLABSIs increased LOS, whereas they did not play a role in the mortality.

4.5 The rate of unplanned endotracheal extubations

Unplanned extubation (UEX) rate is an indicator of poor patient care and related to patient safety as it is associated with the need for re-intubation, and increased risk for nosocomial pneumonia and death [10, 73, 74]. UEX are defined as accidental, due to accidental removal of endotracheal or tracheostomy tube during nursing or medical handling, or as self-extubations, due to patient movements, happening usually during awakening or weaning periods. Reference values are recorded as percentage of mechanically ventilated patients of 2–16% for adults [74, 75] and 3.4–14.7% for children [29, 76–78] and/or with the more accurate index of unplanned extubations:1000 days of MV with standards lower than 10:1000 MV days, both for adults and children [10, 79]. As small steps to our OPDSA cycles, UEX were added in 2019 and their rate per 1000 MV days in 2020 (Table 2). The first recorded rate in our study was 9.70% for 2019, and subsequently 5.37% and 3.91:1000 MV days for 2020, all values being well within international references. Interestingly, all UEX were self-extubations during the weaning period and only one patient in 2020 needed re-intubation, which could indicate an unnecessary prolonged weaning period. Our plans are to maintain these good standards into the future with the use of bundles of care, including better fixation of the endotracheal and/or tracheostomy tubes, use of anatomical and arithmetic reference points, which are to be checked at least every shift, and protocols for high risk situations [79, 80]. Our goals will be enhanced by less use of invasive MV, increasing the use of noninvasive ventilation and shorten, as much as possible, the weaning period.

5. Study limitations

This is a one-center study which precludes the generalization of our results. National policies concerning PICU availability, dictating the admission of very sick patients with almost universal need for MV and CVCs, and the lack of step-down units, inevitably played a role in our outcomes. Despite those restrictions, we tried to assess the actions of our PICU both internally and externally, and applied the OPDSA cycles on five KPOIs, in a four-year follow-up study, to improve our performance. The strengths of our study are the use of an illness severity score for SMR estimation, validated for our population. Moreover, the evaluation of the strict CRBSI microbiological rate in parallel with the surveillance CLABSI rate, together with the analytical description of dwell catheter time, on a patient per patient basis, are scarcely mentioned in the literature.

6. Conclusions

ISO implementation in our unit was the beginning for the establishment of five KPOIs on quality and safety of care for critically ill pediatric patients, and the trigger for internal PICU evaluation and external benchmarking. The OPDSA cycle facilitated our actions, to observe initially baseline values of the indicators chosen, to plan the indicated actions, to apply the necessary changes, to study the results and to identify the weak points for further improvement, one small step at a time, in an iterate cycle of evolution. We found that the majority of the KPOIs examined in our study was within international PICUs reference values. Our future goals are to maintain the well performed actions, to improve those that lag behind and to integrate new ones such as the adverse event reporting system, and the presence of routine multi-disciplinary clinical ward rounds, in an effort to keep up with the international standards on quality and safety of care of intensive care medicine.

AVAILABILITY OF DATA AND MATERIALS

The data presented in this study are available on reasonable request from the corresponding author.

AUTHOR CONTRIBUTIONS

EV, AV and MSD—designed the research study. EV, MSV and PEM—performed the research; analyzed the data. EC, SK, EK, PG, MK, VA and EK—collected the data and uploaded them electronically. EV, AV and MSD—wrote the manuscript. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Patients were treated with the standard protocols of care according to their diagnosis. No intervention was done for the purposes of the study. The Institutional Review Board of Hippokration Hospital of Thessaloniki approved our study (reference 24854/07-27-2021), and due to its observational character, the need for informed consent was waived.

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CONFLICT OF INTEREST

The authors declare no conflict of interest. Eleni Volakli, Asimina Violaki, Maria Sdougka are serving as the Guest editors of this journal. We declare that Eleni Volakli, Asimina Violaki, Maria Sdougka had no involvement in the peer review of this article and has no access to information regarding its peer review. Full responsibility for the editorial process for this article was delegated to SG.

SUPPLEMENTARY MATERIAL

Supplementary material associated with this article can be found, in the online version, at https://oss.signavitae.com/mre-signavitae/article/1699969874638323712/attachment/Supplementary%20material.pdf.

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