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## **ORIGINAL ARTICLE**

# Reformulating real-time random safety analysis during the SARS-CoV-2 pandemic

s o2 Gonzalo Sirgo<sup>a,2</sup>, Manuel A. Samper<sup>a,\*,1,2,3</sup>, Julen Berrueta<sup>a</sup>, Joana Cañellas<sup>a</sup>,

Alejandro Rodríguez<sup>a,b</sup>, María Bodí<sup>a,b</sup>

<sup>a</sup> Hospital Universitari de Tarragona Joan XXIII, Universitat Rovira I Virgili, Institut d'Investigació Sanitària Pere I Virgili,

8 Tarragona, Spain

<sup>9</sup> <sup>b</sup> CIBERES, Spain

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## KEYWORDS

### Abstract

11		Abstract
12	AASTRE;	Introduction: From a safety perspective, the pandemic imposed atypical work dynamics that
13	Patient safety;	led to noticeable gaps in clinical safety across all levels of health care.
14	Critical care;	Objectives: To verify that Real-Time Random Safety Analyses (AASTRE) are feasible and useful
15	COVID-19;	in a high-pressure care setting.
16	Pandemics;	Design: Prospective study (January-September 2022).
17	Information System	Setting: University Hospital with 350 beds. Two mixed ICUs (12 and 14 beds).
18		Interventions: Two safety audits per week were planned to determine the feasibility and
19		usefulness of the 32 safety measures (grouped into 8 blocks).
20		Main variables of interest: 1) Feasibility: Proportion of completed audits compared to sched-
21		uled audits and time spent. 2) Utility: Changes in the care process made as a result of
22		implementing AASTRE.
23		Results: A total of 390 patient-days were analyzed (179 were Non-COVID patients and 49 were
24		COVID patients). In the COVID patient subgroup, age, ICU stay, SAPS 3, and ICU mortality were
25		significantly higher compared to the Non-COVID patient subgroup. Regarding feasibility, 93.8%
26		of planned rounds were carried out with an average audit time of $25\pm8\text{min}$ . Overall, changes
27		in the care process were made in 11.8% of the measures analyzed.
28		Conclusions: In a high-complexity care environment, AASTRE proved to be a feasible and useful
29		tool with only two interventions per week lasting less than 30 min. Overall, AASTRE allowed
30		unsafe situations to be turned safe in more than 10% of the evaluations.
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E-mail address: masamper.tgn.ics@gencat.cat (M.A. Samper).

- Q3 <sup>1</sup> Doctorando por la URV.
  - <sup>2</sup> Gonzalo Sirgo y Manuel A. Samper son primeros coautores.
  - <sup>3</sup> ORCID ID: Manuel Samper: 0000-0001-5858-9653.

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02

## **ARTICLE IN PRESS**

G. Sirgo, M.A. Samper, J. Berrueta et al.

#### Reformulación de los Análisis Aleatorios de Seguridad en Tiempo Real durante la 33 PALABRAS CLAVE pandemia SARS-CoV-2 34 AASTRE; Seguridad del Resumen 35 paciente; Introducción: Desde el punto de vista de la seguridad la pandemia impuso dinámicas de tra-36 Cuidados intensivos; bajo atípicas que provocaron visibles brechas en la seguridad clínica en todos los niveles de la 37 COVID-19; atención sanitaria. 38 Pandemia: Objetivos: Comprobar que los Análisis Aleatorios de Seguridad en Tiempo Real (AASTRE) son 39 Sistema de factibles v útiles en un escenario de elevada presión asistencial. 40 información clínica Diseño: Estudio prospectivo (enero y septiembre de 2022). 41 Ámbito: Hospital Universitario con 350 camas. Dos UCIs polivalentes (12 y 14 camas). 42 Intervenciones: Se planificaron 2 auditorías de seguridad a la semana para determinar la 43 factibilidad y la utilidad de las 32 medidas de seguridad. 44 Variables de Interés principales: 1) Factibilidad: proporción de auditorías completadas 45 respecto a las programadas y el tiempo empleado; 2) Utilidad: cambios en el proceso de atención 46 realizados como resultado de la aplicación de AASTRE. 47 Resultados: Se analizaron un total de 390 pacientes día (179 fueron pacientes No-COVID y 49 48 COVID). En los pacientes COVID la edad, el SAPS 3, la estancia y la mortalidad en UCI fueron 49 significativamente mayores respecto a los pacientes No-COVID. En cuanto a la factibilidad, el 50 93.8% de las rondas planificadas fueron realizas con un tiempo promedio empleado por auditoría 51 de 25 $\pm$ 8 minutos. Globalmente se produjeron cambios en el proceso de atención en el 11.8% 52 de las medidas analizadas. 53 Conclusiones: AASTRE, en un ambiente de elevada complejidad asistencial, resultó ser una 54 herramienta factible y útil con sólo dos intervenciones semanales de menos de 30 minutos. 55 Globalmente, AASTRE permitió revertir situaciones inseguras a seguras en más del 10% de las 56 57 evaluaciones. © 2024 Publicado por Elsevier Espa?a, S.L.U. 58

## 59 Introduction

500 Still recent, it is easy to recall the strain exerted by 511 the pandemic triggered by SARS-CoV-2 virus on the health 522 care systems everywhere.<sup>1</sup> Long before, in Intensive Care 533 Medicine, there was already a strong association between 544 high care pressure and a lack of adherence to clinical 555 practice guidelines, which secondarily led to a worsening 566 prognosis, including increased mortality.<sup>2-4</sup>

From a safety perspective, the pandemic imposed atypical work dynamics that caused gaps in clinical safety at all levels of health care.<sup>5</sup> Specifically, significant changes in the perception of safety culture were described, associated with structural, leadership, and communication deficits.<sup>6</sup> Other authors highlighted inefficiencies in the system due to a lack of process standardization.<sup>7</sup>

In the ICU setting, incidents related to patient safety 74 (IRSP) during the pandemic led to an increase in pri-75 mary bacteremia,<sup>8</sup> central venous catheter-associated 76 bacteremia,<sup>9</sup> ventilator-associated pneumonia, catheter-77 associated urinary tract infections, renal failure, and 78 thromboembolic and vascular events, all of which were asso-79 ciated with increased mortality.<sup>10,11</sup> In response to these 80 IRSPs, health care professionals were further strained as 81 82 they were forced to adapt to new safety standards.<sup>12</sup> Simul-83 taneously, during this period, IRSP reporting systems were underutilized. 13-15 84

<sup>85</sup> Our group has developed a proactive safety tool called <sup>86</sup> Real-Time Random Safety Audits (AASTRE), which has been associated with improvements in structure, process, and outcome quality indicators. AASTRE has proven particularly useful in situations of high care pressure and for the more severe critically ill patients.<sup>16,17</sup> This tool is based on a set of evidence-based measures that are considered mandatory during ICU care activities. Randomization refers to the fact that neither the measures nor the patients audited can be known in advance of the safety rounds, as both are randomized on the day of the audit.

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Emphasizing the importance of clinical safety and considering the paradox of its neglect during the pandemic, the objectives of this study are: 1) To describe the adaptation of AASTRE to the pandemic work dynamic; 2) To demonstrate that AASTRE is feasible and useful in a real pandemic scenario; 3) To build a web platform that makes the results visible in a simple, continuous, and intuitive way for clinicians.

## Materials and methods

## Design

We conducted a prospective study in a teaching hospital with Q4 106 350 beds and 2 multipurpose ICUs (12 and 14 beds). During 107 the study period, both units treated COVID and non-COVID 108 patients interchangeably. The ICU has a Clinical Information 109 System (CIS) where data from patient bedside devices, information generated in other departments, and information

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PMR-AASTRE

generated/recorded by professionals during patient care are

stored. These data were extracted for analysis in the present Q5

113 study.

114 Intervention period

From January 2022 through September 2022, coinciding withthe 6th and last wave of the pandemic.

## 117 Description of AASTRE

AASTRE is a validated proactive safety tool<sup>18,19</sup> that allows 118 unsafe situations to be detected and converted into safe 119 ones in real-time. In its version 2.0,<sup>20,21</sup> it checks a total 120 of 32 mandatory safety measures, distributed across 8 dif-121 ferent blocks: 1) mechanical ventilation, 2) hemodynamics, 122 3) renal function and continuous renal replacement tera-123 phies, 4) analgesia and sedation, 5) treatment, 6) nutrition, 124 7) nursing care and structure, and 8) clinical information 125 system. Each safety measure has a specific definition, evalu-126 ation criteria, and a specific methodology for its verification. 127 AASTRE was scheduled twice weekly in each unit for a total 128 of 9 months. On evaluation days, 30% of ICU patients and 50% 129 of the safety measure blocks were randomized. All patients 130 admitted to the ICU are eligible for AASTRE. However, only 131 measures for which the selected patient meets the evalua-132 tion criteria will be assessed. The possible responses during 133 audits are: (1) Yes<sup>--</sup> when the measure analyzed was per-134 formed/taken during the daily ICU round; (2) Yes, after 135 AASTRE- when the safety audit detected an omission error 136 that was corrected; (3) No- when the analyzed measure 137 could not be changed despite the audit; (4) Not applica-138 ble" when the patient does not meet the evaluation criteria. 139 The checklist and audit responses are entered into a web 140 platform (https://v2.aastre.es/web/index.php). A senior 141 professional (Prompter)-who was not directly responsible 142 for the care of any of the selected patients on the evaluation 143 dav-conducted the AASTRE at the bedside using a mobile 144 device (Tablet), along with the treating nurse and physician 145 (attending or resident), acting as a facilitator and providing 146 feedback to the professionals during the entire process. The 147 amount of changes in the process of health care as a result 148 of verification was considered. 149

## 150 Definition of variables and indicators

- 1 Patient-days: Number of patients evaluated on all days
   when safety audits were conducted.
- <sup>153</sup> 2 Feasibility: Number of patients for whom AASTRE was
   <sup>154</sup> completed in relation to those scheduled and the mean
   <sup>155</sup> evaluation time.
- 3 Utility: Number of changes in the health care processes 156 implemented as a result of the verification. Specifically, 157 for each safety measure, a quantitative variable was 158 159 defined to analyze it (improvement proportion related to AASTRE, PMR-AASTRE). PMR-AASTRE is defined as a 160 process indicator such that there can be a PMR-AASTRE 161 for each measure, for each block of measures (PMR-162 AASTRE-B), or overall, for the entire set of measures 163

(PMR-AASTRE-G). Its calculation was performed using the following formula:

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No. of "Yes, after AASTRE"  $\times$  100 No. of evaluations conducted (Total – "Not applicable")

A PMR-AASTRE  $\geq$  10% was considered clinically relevant.  $^{17,20}$ 

- 1 Outcome indicators: ICU mortality, mean length of stay, and rates of central venous catheter-related bacteremia (CRB), ventilator-associated pneumonia (VAP), ventilatorassociated tracheobronchitis (VAT), catheter-associated urinary tract infections (CAUTI), self-extubation of the endotracheal tube (ETT), reintubations, or barotrauma, using definitions and metrics published in former studies.<sup>21,22</sup>
- 2 Multivariate analysis: A selection of variables was made to determine their independent impact on a significant PMR-AASTRE-G. These variables included demographics (sex, age, patient type, and admission type), severity (SOFA, APACHE-II, SAPS-3), care burden (Nursing/Patient and Doctor/Patient ratios in addition to NAS – Nursing Activities Score), and those derived from the disease, severity, and vital support during their stay (COVID, length of stay and days on mechanical ventilation, RASS scale, presence of shock or need for continuous renal replacement techniques, and nutritional risk).

## Data mining

Demographic data and variables necessary to assess care process measures and quality indicators were extracted from the CIS, using a previously defined extract, transform, and load process.<sup>21–23</sup>

## Statistical analysis

To describe baseline characteristics, continuous variables were expressed as median (Q1-Q3 range) and categorical ones as number of cases (percentage).

For patient demographic characteristics, clinical characteristics, care process measures, and quality indicators, inter-group differences were evaluated using the chi-square test and Fisher's exact test for categorical variables, and the Mann-Whitney *U* test or Wilcoxon test for continuous variables. This was performed using Python and the Tableone module, applying the chi-square test for each variable.

We conducted a multivariate analysis to determine the relationship between selected independent variables and a significant PMR-AASTRE-G  $\geq$  10%. To adjust for potential confounding effects, multiple logistic regression analysis, fixed model, and likelihood ratio method were used for potential confounding effects. Results were expressed as odds ratios with 95% confidence intervals. The acceptable level of statistical significance was set at p < 0.05. Data analysis was performed using R software (cran.r-project.org).

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obal				Desde:	Hasta:
	=			01/01/2022	0 30/09/2022 0
PMR: 12.05%				SOFA Min.	SOFA Max.
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ariable groups					
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Aechanical ventilation		Hemodynamics			Datio Enformaria:
	=		-	1: Mayor o igual	1: Menor o igual
PMR: 22.41%		PMR: 8.01%			Ratio Medicina:
				۲ Mayor o igual	1: Menor o igual
tenal		Sedation and analgesia			Filtrar
	=		-		
PMR: 17%		PMR: 6.95%			Restablecer datos
reatment		Nutrition			
	=		-		
PMR: 6.75%		PMR: 31.66%			
are and structure		Clinical Information System			
	=		-		
PMR: 11.1%		PMR: 15.68%			

Figure 1 Plataforma de indicadores de proceso de AASTRE.

## 216 Construction and implementation of process

### <sup>217</sup> indicators platform

For more efficient, automated, and real-time use of the 218 data obtained from the AASTRE safety rounds, a web appli-219 cation was developed using free software (Python, Django, 220 HTML, CSS, JavaScript) to access AASTRE results in the form 221 of graphs that allow filtering by date, SOFA, patient type, 222 staff type, nursing/patient ratio, and doctor/patient ratio, 223 in addition to selecting PMR-AASTRE, whether for each vari-224 able, PMR-AASTRE-B, or PMR-AASTRE-G (Fig. 1). 225

## 226 Results

During the study period, a total of 390 patient-days were 227 analyzed, 179 of whom were non-COVID patients and 49, 228 229 COVID patients (Table 1). The latter were significantly younger [61 vs 66 years (p = 0.011)] than the non-COVID ones. 230 Additionally, COVID patients had significantly longer lengths 231 of stay, higher SAPS 3 scores, and higher ICU mortality rates 232 vs non-COVID patients [18.5 vs 10.97 days (p < 0.001); 52 233 vs 49 (p = 0.039); and 34.7% vs 15.2% (p = 0.004), respec-234 tively]. Moreover, COVID patients remained many more days 235 on mechanical ventilation and with a urinary catheter than 236 no-COVID patients [14.94 vs 4.45 days (p < 0.001); 17.87 vs 237 8.6 days (p = 0.001), respectively]. No significant differences 238 were found between the 3 groups in the outcome indicators 239 under consideration (Table 2). 240

### 241 Feasibility

Audits were conducted in 93.8% of the patients for whom they were scheduled. The most common reasons for failing to conduct the audits in 6.2% of cases were lack of time from the Prompter and the patient's absence from the ICU at the time of the audit (e.g., in the operating room or undergoing imaging modalities). The median time spent on audits was  $25\,\text{min}\pm8\,\text{min}.$ 

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## Utility

The PMR-AASTRE-G was 11.8% (Tables 3a and 3b). No significant differences in PMR-AASTRE-G were observed between COVID and non-COVID patients. A PMR-AASTRE-B  $\geq$  10% was observed in the same measure blocks in both subgroups (5 out of 8 blocks). When the 2 patient subgroups were compared only the nutrition block showed significant differences, being PMR-AASTRE-B significantly higher in COVID patients (48.7% vs 25.0%; p = 0.012).

Regarding specific measures, the review of mechanical ventilation (MV) alarms (66.7% vs 43.0%; p = 0.032) and enteral nutrition monitoring (45.5% vs 24.4%; p = 0.046) were significantly higher in COVID patients. However, the evaluation of mobilization and evaluation of ICU-acquired muscle weakness (26.0% vs 7.0%; p = 0.018) was significantly higher in non-COVID patients.

Table 4 shows the impact of selected independent variables on PMR-AASTRE-G. The Nursing Activities Score (NAS) < 50 (normal workload) was associated with a higher likelihood of meeting mandatory measures (OR, 0.24 -std 0.46-; p = 0.0019). On the other hand, both the days on MV (OR, 2.78 -std 0.48-; p = 0.032) and SOFA  $\geq$  8 (OR, 4.73 - std 0.63-; p = 0.013) were factors independently associated with higher overall tool utility (PMR-AASTRE-G  $\geq$  10%).

## Discussion

This is the first study ever conducted during the pandemic274that evaluated the effect of a safety intervention that275allowed converting unsafe situations into safe ones in real-276time. Its feasibility and utility were demonstrated for both277COVID and non-COVID patients.278

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#### Table 1Patient characteristics. P < 0.05.</th> 01

Characteristic	Non-COVID ( <i>n</i> = 179)	COVID ( <i>n</i> = 49)	р
Age	66 (58.00-72.00)	61 (48.5–69.5)	0.011
Male gender (%)	125 (69.8)	36 (73.5)	0.75
Mortality	27 (15.1)	17 (34.7)	0.004
APACHE II score	21.0 (16-27.5)	20.5 (16-27)	0.85
SOFA score	3 (1-5)	3 (2-5)	0.09
SAPS 3 score	49 (38.0-58.0)	52 (45.75-58.0)	0.039
Charlson Index	3 (1-5)	3 (2-5)	0.571
Patient type			
Medical	102 (57.0)	41 (83.7)	0.001
Surgical	77 (43.0)	8 (16.3)	
Type of admission			
Emergency	164 (91.6)	48 (98.0)	0.221
Scheduled	15 (8.4)	1 (2.0)	
MV	125 (69.8)	41 (83.7)	0.08
Days on MV	4.45 (0.0-12.7)	14.94 (6.68-29.85)	<0.001
Days off MV	4.29 (2.64-7.44)	4.22 (1.95-7.65)	0.583
Days on CVC	4.8 (0–13)	8 (0-22)	0.169
Days on UC	8.6 (3.05-17.76)	17.87 (9.14-35.48)	0.001
Length of ICU stay (days)	10.97 (5.05-21.15)	18.5 (11.09-35.49)	<0.001

COVID: COronaVIrus Disease; APACHE II: Acute Physiology and Chronic Health disease Classification System II at admission; SOFA: Sepsisrelated Organ Failure Assessment in the first 24h; SAPS 3: Simplified Acute Physiology Score III at admission; MV: mechanical ventilation; CVC: central venous catheter; UC: urinary catheter; UCI: intensive care unit.

#### Table 2 Outcome indicators.

Indicators	Non-COVID ( <i>n</i> = 179)	COVID (n = 49)	р
Self-extubation	8.76	5.70	0.65
Reintubation	5.60	4.88	1.00
Barotrauma	0.55	0.00	1.00
Catheter-related bacteremia (CRB)	1.84	6.52	0.14
Ventilator-associated Pneumonia (VAP)	9.39	16.49	0.14
Ventilator-associated Tracheobronchitis (VAT)	2.21	5.82	0.22
Catheter-associated urinary tract infections (CAUTI)	0.79	4.1	0.07

COVID: COronaVIrus Disease; CRB: catheter-related bacteremia; VAP: ventilator-associated pneumonia; VAT: ventilator-associated tracheobronchitis; CAUTI: catheter-associated urinary tract infections.

The lack of studies on clinical safety during the pan-279 demic is notable.<sup>24</sup> Some authors describe patient safety 280 incidents (PSIs) associated with treatment delays or the performance of inappropriate procedures, suggesting that proactive safety tools could have been useful in that context.<sup>25</sup> Concurrently, the safety gap has been explained by the need to reallocate personal resources: many safety 285 experts returned to purely clinical activities, preventing 286 many functional units from maintaining or promoting their 287 activities.<sup>26</sup> 288

Of note that AASTRE is a tool deeply embedded in 289 the culture of our organization. This fact likely relates to 290 the feasibility described in this study. AASTRE is based on 291 the interaction between health care professionals (some 292 responsible for patient care and others facilitating measure 293 verification - prompters)16. This moves away from the idea 294 of safety rounds led by managers or safety experts. In fact, 295 in our own experience, the presence of trainees and nursing 296 staff during audits makes interaction a space for organiza-297

tional learning17 focused on processes. It has been reported that the one factor that significantly improves audit acceptance is building a shared sense of the results.<sup>27</sup>

A particularly striking result was the high utility of the tool during the analyzed period (PMR-AASTRE-G of 11.8%), which is significantly higher than the results obtained by AASTRE in previous pre-pandemic periods (5.4% and 6.7%).<sup>16,17</sup> The utility of AASTRE is directly associated with real-time improvements in safety since the evaluated measures, if not performed at the time of the audit (omission errors), were taken immediately (real-time). Former studies17 associated AASTRE's utility with times of higher clinical workload. In this study, the health care team managed both COVID and non-COVID patients, so the clinical workload was evenly distributed among all professionals. During the pandemic, this sustained workload-translated into physical and cognitive fatigue-has been associated with omission errors through its influence on decision-making and task prioritization.<sup>28,29</sup> In relation to utility, Arabi et al.<sup>30</sup> con-

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Table 3a	PMR-AASTRE results by evidence-based mandato	y measures. PMR-AASTRE-B $\geq$ $^{\circ}$	10%. PMR-AASTRE $\geq$ 10%. <i>P</i> < 0.05
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Blocks and measures	Total PMR (%)	PMR non-COVID (%)	PMR COVID (%)	D
PMR-AASTRF-G	549 (11.8)	385 (11 4)	164 (13.0)	0 136
Mechanical ventilation	108 (22.4)	78 (23.6)	30 (19.9)	0.432
Alveolar pressure limit, $n$ (%)	16 (24.6)	14 (33.3)	2 (8.7)	0.057
Mechanical ventilation alarms, $n$ (%)	58 (50.4)	34 (43.0)	24 (66.7)	0.032
Spontaneous ventilation test, $n$ (%)	2 (4.7)	2 (6.5)	0 (0)	1.000
Adequate tidal volume	2 (1.8)	1 (1.3)	1 (2.7)	1.000
Assessment of mobilization and acquired muscle	30 (20.4)	27 (26.0)	3 (7.0)	0.018
weakness at the ICU setting	· · ·	· · ·	( )	
Hemodynamics	33 (8.0)	25 (8.3)	8 (7.3)	0.924
Monitor Alarms	30 (17.0)	22 (16.8)	8 (17.8)	0.938
Fluid administration in initial shock phase, $n$ (%)	0 (0)	0 (0)	0 (0)	1.000
Fluid administration in clinical stability phase, $n$	1 (0.7)	1 (0.9)	0 (0)	1.000
(%)	. ,			
Adequate hemodynamic monitoring, $n$ (%)	2 (3.4)	2 (4.7)	0 (0)	1.000
Renal	34 (17.0)	21 (14.2)	13 (25.0)	0.116
Acute renal dysfunction assessment (ARDA), n (%)	32 (16.9)	20 (14.5)	12 (23.5)	0.211
Daily prescription and adequate monitoring of	2 (18.2)	1 (10.0)	1 (100.0)	0.182
continuous renal replacement therapy (CRRT), n		· · ·	, , , , , , , , , , , , , , , , , , ,	
(%)				
Sedation and analgesia	29 (7.0)	24 (7.4)	5 (5.4)	0.677
Pain management, n (%)	3 (1.7)	3 (2.2)	0 (0)	1.000
Control of agitation and prevention of	8 (8.2)	5 (6.8)	3 (12.5)	0.401
oversedation, n (%)	. ,		( )	
Delirium prevention and management, $n$ (%)	18 (12.5)	16 (14.0)	2 (6.7)	0.365

cluded that, in situations like those experienced during the
 pandemic, a fundamental lesson that needed to be learnt
 was the need to prioritize the use of measures exclusively
 based on scientific evidence, an aspect guaranteed by AAS TRE.

Reportedly, high clinical workload (high nursing and 322 physician-to-patient ratios) has been associated with lower 323 quality of care, a higher number of adverse events, longer 324 lengths of stays, and higher mortality.<sup>31,32</sup> Margadant et al.<sup>33</sup> 325 showed that a high NAS was associated with in-hospital mor-326 tality. Consequently, our study demonstrated that avoiding 327 nursing workload overload (defined by NAS<sup>34</sup>) was associ-328 ated with proper adherence to evidence-based measures 329 and, therefore, fewer omission errors. 330

Consistent with what Ilan et al.<sup>35</sup> described and what 331 has been shown in former studies, <sup>16,17</sup> our study found that 332 patient severity was associated with significant tool util-333 ity. This is explained by the fact that high patient severity 334 makes many medical care efforts to be focused on measures 335 necessary for prompt patient resuscitation, while other less 336 urgent but also important evidence-based measures are 337 sidetracked. 338

It is of note that despite the COVID group being a more
 severe group, with longer lengths of stay, days on mechan ical ventilation, and days with a urinary catheter, there
 were no significant differences in outcome indicators, such
 as rates of NAVM, tracheobronchitis, BRC, and catheter associated urinary tract infections, as described by other
 authors.<sup>8-10</sup>

The goal of any health care system is to strive for excellence while prioritizing the patients' best interests. For this reason, health care professionals should first aim to understand how they perform their roles, regardless of contextual complexity. In this regard, AASTRE has become a solid support for quality of care, not only because of its utility (as discussed) but also because it provides a form of quantitative feedback that has proven essential for driving any improvement in care quality.<sup>36</sup>

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### Limitations

This study has several limitations: 1) It was conducted at a single center; 2) The study took place during the 6th wave of the pandemic, when clinical pressure was still high, though lower compared with other periods during the pandemic (although still far from normal clinical conditions, Moreno-Mulet et al.<sup>37</sup>). In any case, the reduced clinical pressure undoubtedly favored the implementation of AAS-TRE. 3) The study was conducted at a time when there was no longer collaboration with other specialties (Cardiology, Pediatrics, Emergency Medicine, Anesthesia) as had been the case in previous waves. This aspect would have been interesting to analyze as, under those circumstances, the use of AASTRE creates an interaction between the prompter and the trainee physician that allows for the formation of a learning space,<sup>20</sup> which would have probably had more repercussions as a tool for information transmission and learning. 4) Finally, reactive tools, such as adverse event notifications were not considered, which would have helped analyze the safety situation of our ICU during the study period.

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Table 3b	PMR-AASTRE results by	v evidence-based mandatory	measures PMR-B-AASTRE	> 10% PMR-AASTRE >	> 10% P<0.05
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Blocks and measures	Total PMR (%)	PMR non-COVID (%)	PMR COVID (%)	р
Treatment	89 (6.7)	66 (6.9)	23 (6.4)	0.845
Checking for drug and food allergies/intolerances in the patients' medical history (MH), <i>n</i> (%)	18 (9.0)	13 (9.0)	5 (9.1)	1.000
Correct prescription of daily treatment orders, <i>n</i> (%)	7 (3.5)	5 (3.4)	2 (3.6)	1.000
Appropriate indication and dosage of prescribed medication, $n$ (%)	15 (7.6)	10 (6.9)	5 (9.3)	0.558
Correct administration of prescribed treatment, <i>n</i> (%)	22 (11.1)	16 (11.2)	6 (10.9)	0.844
Adequate maintenance of blood glucose levels, <i>n</i> (%)	9 (4.5)	8 (5.6)	1 (1.8)	0.449
Assessment of antibiotic treatment, $n$ (%)	5 (3.9)	4 (4.2)	1 (3.2)	1.000
Nutrition	44 (31.7)	25 (25.0)	19 (48.7)	0.012
Monitoring of enteral nutrition (EN), <i>n</i> (%)	35 (30.4)	20 (24.4)	15 (45.5)	0.046
Monitoring of parenteral nutrition (PN), n (%)	9 (37.5)	5 (27.8)	4 (66.7)	0.150
Care and structure	122 (11.1)	91 (11.1)	31 (11.0)	0.966
Oral hygiene with chlorhexidine (0.12%), n (%)	0 (0)	0 (0)	0 (0)	1.000
Daily assessment of pressure ulcer risk, n (%)	2 (0.9)	0 (0)	2 (3.4)	0.066
Semi-sitting position, n (%)	57 (38.8)	40 (38.1)	17 (40.5)	0.936
Unambiguous patient identification, $n$ (%)	4 (1.7)	4 (2.3)	0 (0)	0.575
Updated limitation of life support treatment (LLST), <i>n</i> (%)	51 (22.3)	42 (24.6)	9 (15.5)	0.212
Daily assessment of catheter necessity, n (%)	8 (4.2)	5 (3.7)	3 (5.2)	0.700
Clinical information system	90 (15.7)	55 (13.8)	35 (20.1)	0.071
Information validation from devices, $n$ (%)	8 (17.4)	5 (13.2)	3 (37.5)	0.129
Correct compliance with medical information, <i>n</i> (%)	18 (9.5)	10 (7.6)	8 (13.8)	0.281
Correct integration with other hospital departments, <i>n</i> (%)	64 (33.3)	40 (29.9)	24 (41.4)	0.165

Table 4 Multivariate analysis for PMR-AASTRE-G  $\geq$  10%. Data expressed as OR and std between brackets. P < 0.05.

Variables	OR (Std)	р
Age	1.35 (0.28)	0.29
Gender	1.66 (0.32)	0.11
Type of patient	1.61 (0.32)	0.35
Type of admission	0.74 (0.55)	0.58
COVID	1.81 (0.34)	0.082
$SOFA \ge 8$	4.73 (0.63)	0.013
SAPS-3	0.91 (0.36)	0.80
APACHE II (>30)	1.88 (0.48)	0.19
Lengt of ICU stay (>14 days)	0.55 (0.43)	0.17
Days on MV (7–14 days)	2.78 (0.48)	0.032
RASS (-4 to -5)	0.92 (0.54)	0.88
Shock	1.12 (0.44)	0.80
CRRT	0.65 (0.41)	0.30
Nurse-to-patient ratio (>2:1)	1.39 (0.28)	0.24
NAS (Normal nursing activity score)	0.24 (0.46)	0.0019
Doctor-to-patient ratio (>3:1)	0.96 (0.31)	0.90
Nutritional risk (NUTRICm score)	1.03 (0.35)	0.93

Age:  $\leq 65$ ; >65; Gender: Male/Female; type of patients: medical/surgical; type of admission: emergency/scheduled; COVID: Yes/No; SOFA: <4, 4–7, 8–12, >12; SAPS-3: <60, 60–80, >80; APACHE II:  $\leq 14$ , 15–29,  $\geq 30$ ; Length of ICU stay (days): <7, 7–14, >14; Days on MV: <7, 7–14, >14; RASS: (-1, -2, -3) and (-4, -5); Shock: On noradrenaline, vasopressin, or dobutamine; CRRT: Yes/No; Nursing ratio:  $\leq 2:1$ , >2:1; NAS (Nursing Activities Score):  $\leq 50$  (Normal workload), >50 (High workload); doctor ratio:  $\leq 3:1$ , >3:1; nutritional risk: Low nutritional risk (0–4), high nutritional risk (5–9).

## Q2

## 374 Conclusions

## AASTRE proved to be a feasible and useful tool during the last phase of the pandemic (characterized by moderate clinical pressure) with only 2 weekly interventions of approximately 30min each. The clinical complexity in an environment of COVID and non-COVID patients may explain the utility of

AASTRE in both patient groups, with a notable increase in PMR-AASTRE-G compared with previously analyzed periods.

## 382 CRediT authorship contribution statement

MB, GS, MS, and AR contributed to the study design. MB, 383 GS, and MS conducted the safety rounds. JB and JC con-384 tributed to the configuration of the SIC and the calculation 385 of metrics for indicators and process measures. JC, AR, 386 and JB contributed to data analysis and statistical anal-387 ysis. JC and MB developed and implemented the process 388 indicators platform. All authors contributed to the drafting 389 of the manuscript. All authors read and approved the final 390 manuscript. 391

## 392 Ethical aspects

This study was approved by the Ethics and Clinical Research Committee (CEIC) of Institut d'Investigació Sanitària Pere Virgili. Reference: 3/2021. Given the nature of the study and the anonymity of the data, obtaining informed consent was deemed unnecessary.

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## <sup>403</sup> Declaration of competing interest

404 None declared.

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## 411 References

- 4121. Barbash IJ, Kahn JM. Fostering hospital resilience-lessons413from COVID-19. JAMA. 2021;326(8):693-4, http://dx.doi.org/41410.1001/jama.2021.12484.
- 2. Bagshaw SM, Opgenorth D, Potestio M, Hastings SE, Hepp SL, Gilfoyle E, et al. Healthcare provider perceptions of causes and consequences of ICU capacity strain in a large publicly funded integrated health region: a qualitative study. Crit Care Med. 2017;45(4):e347-56, http://dx.doi.org/10
   .1097/CCM.0000000002093.

3. Weissman GE, Gabler NB, Brown SE, Halpern SD. Intensive care unit capacity strain and adherence to prophylaxis guidelines. J Crit Care. 2015;30(6):1303-9, http://dx.doi.org/10. 1016/j.jcrc.2015.08.015.

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487

- 4. Gabler NB, Ratcliffe SJ, Wagner J, Asch DA, Rubenfeld GD, Angus DC, et al. Mortality among patients admitted to strained intensive care units. Am J Respir Crit Care Med. 2013;188(7):800-6, http://dx.doi.org/10.1164/rccm.201304-06220C.
- 5. Fournier JP, Amélineau JB, Hild S, Nguyen-Soenen J, Daviot A, Simonneau B, et al. Patient-safety incidents during COVID-19 health crisis in France: an exploratory sequential multi-method study in primary care. Eur J Gen Pract. 2021;27(1):142–51, http://dx.doi.org/10.1080/13814788.2021.1945029.
- 6. Brborović O, Brborović H. Hrain 19 pandemic crisis and patient safety culture: a mixed-method study. Int J Environ Res Public Health. 2022;19(4):2237, http://dx.doi.org/10. 3390/ijerph19042237.
- 7. Mills P, Louis RP, Yackel E. Delays in care during the COVID-19 pandemic in the Veterans Health Administration. J Healthc Qual. 2023;45(4):242–53, http://dx.doi.org/10. 1097/JHQ.00000000000383.
- 8. Buetti N, Ruckly S, de Montmollin E, Reignier J, Terzi N, Cohen Y, et al. COVID-19 increased the risk of ICU-acquired blood stream infections: a case-cohort study from the multicentric OUTCOMEREA network. Intensive Care Med. 2021;47(2):180-7, http://dx.doi.org/10.1007/s00134-021-06346-w.
- 9. Fakih MG, Bufalino A, Sturm L, Huang RH, Ottenbacher A, Saake K, et al. Coronavirus disease 2019 (COVID-19) pandemic, central-line-associated bloodstream infection (CLABSI), and catheter-associated urinary tract infection (CAUTI): the urgent need to refocus on hardwiring prevention efforts. Infect Control Hosp Epidemiol. 2022;43(1):26-31, http://dx.doi.org/10.1017/ice.2021.70.
- Luz MV, Silva JF, Ceccato HD, de Souza Júnior PJ, Villar PM, Mendes PRA, et al. Cohort study of hospitalized patients with COVID-19 at Brazilian tertiarycare hospital: occurrence of adverse events and mortality. Braz J Infect Dis. 2023;27(4):102791, http://dx.doi.org/10. 1016/j.bjid.2023.102791.
- 11. Piazza G, Campia U, Hurwitz S, Snyder JE, Rizzo SM, Pfeferman MB, et al. Registry of arterial and venous thromboembolic complications in patients with COVID-19. J Am Coll Cardiol. 2020;76(18):2060–72, http://dx.doi.org/10. 1016/j.jacc.2020.08.070.
- 12. Berggren K, Ekstedt M, Joelsson-Alm E, Swedberg L, Sackey P, Schandl A. Healthcare workers' experiences of patient safety in the intensive care unit during the COVID-19 pandemic: a multicentre qualitative study. J Clin Nurs. 2023;32(19–20):7372–81, http://dx.doi.org/10.1111/jocn.16793.
- Griffeth EM, Gajic O, Schueler N, Todd A, Ramar K. Multifaceted intervention to improve patient safety incident reporting in intensive care units. J Patient Saf. 2023;19(7):422-8, http://dx.doi.org/10.1097/PTS.000000000001151.
- Gil-Aucejo A, Martínez-Martín S, Flores-Sánchez P, Moyano-Hernández C, Sánchez-Morales P, Andrés-Martínez M, et al. Valoración de la cultura de seguridad del paciente en la UCI de un hospital de segundo nivel al finalizar la tercera oleada de COVID-19. Enferm Intensiva. 2022;33(4):185-96, http://dx.doi.org/10.1016/j.enfi.2021.09.006.
- 15. Impact of the COVID-19 pandemic on patient safety incident and medication error reporting systems. J Healthc Qual Res. 2022;37(6):397-407, http://dx.doi.org/10.1016/j.jhqr.2022.03.003.
- 16. Bodí M, Olona M, Martín MC, Alceaga R, Rodríguez JC, Corral E, et al. Feasibility and utility of the use of real time random safety audits in adult ICU patients: a multicentre study. Intensive Care Med. 2015;41(6):1089–98, http://dx.doi.org/10.1007/s00134-015-3792-3.

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- 489 17. Bodí M, Oliva I, Martín MC, Gilavert MC, Muñoz C, Olona M, et al. Impact of random safety analyses on structure, process and outcome indicators: multicentre study. Ann Intensive Care. 2017;7(1):23, http://dx.doi.org/10.1186/s13613-017-0245-x.
- 18. Sirgo Rodríguez G, Olona Cabases M, Martin Delgado MC,
  Esteban Reboll F, Pobo Peris A, Bodí Saera M, et al. Audits
  in real time for safety in critical care: definition and
  pilot study. Med Intensiva. 2014;38(8):473-82, http://dx.doi.
  org/10.1016/j.medin.2013.11.008.
- 19. Bodí M, Oliva I, Martín MC, Sirgo G. Real-time random safety audits: a transforming tool adapted to new times. Med Intensiva. 2017;41(6):368-76, http://dx.doi.org/10
  .1016/j.medin.2016.09.006.
- Sirgo G, Olona M, Martín-Delgado MC, Gordo F, Trenado J, García M, et al. Cross-cultural adaptation of the SCORE survey and evaluation of the impact of Real-Time Random Safety Audits in organizational culture: a multicenter study. Med Intensiva. 2021, http://dx.doi.org/10.1016/j.medin.2021.03.015.
- Soviet Strain Str
- 22. Bodí M, Claverias L, Esteban F, Sirgo G, De Haro L, Guardiola JJ, et al. Automatic generation of minimum dataset and quality indicators from data collected routinely by the clinical information system in an intensive care unit. Int J Med Inform. 2021;145:104327, http://dx.doi.org/10.
  1016/j.ijmedinf.2020.104327.
- 23. Sirgo G, Esteban F, Gómez J, Moreno G, Rodríguez A, Blanch L, et al. Validation of the ICU-DaMa tool for automatically extracting variables for minimum dataset and quality indicators: the importance of data quality assessment. Int J Med Inform. 2018;112:166-72, http://dx.doi.org/10
  .1016/j.ijmedinf.2018.02.007.
- 24. Evans LV, Ray JM, Bonz JW, Joseph M, Gerwin JN, Dziura JD,
   et al. Improving patient and clinician safety during COVID-19
   through rapidly adaptive simulation and a randomised con trolled trial: a study protocol. BMJ Open. 2022;12(5):e058980,
   http://dx.doi.org/10.1136/bmjopen-2021-058980.
- 25. Yackel EE, Knowles R, Jones CM, Turner J, Pendley Louis
   R, Mazzia LM, et al. Adverse patient safety events during the COVID-19 epidemic. J Patient Saf. 2023;19(5):340-5, http://dx.doi.org/10.1097/PTS.00000000001129.
- 26. Kagan I, Arad D, Aharoni R, Tal Y, Niv Y. Crisis management for Patient Safety Officers: lessons learned from the Covid-19 pandemic. Isr J Health Policy Res. 2023;12(1):29, http://dx.doi.org/10.1186/s13584-023-00577-6.

27. Hut-Mossel L, Ahaus K, Welker G, Gans R. Understanding how and why audits work in improving the quality of hospital care: a systematic realist review. PLoS One. 2021;16(3):e0248677, http://dx.doi.org/10.1371/journal.pone.0248677. 536

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- Avansino J, Leu MG. Effects of CPOE on provider cognitive workload: a randomized crossover trial. Pediatrics. 2012;130(3):e547-552, http://dx.doi.org/10.1542/peds .2011-3408.
- 29. Aziz S, Arabi YM, Alhazzani W, et al. Managing ICU surge during the COVID-19 crisis: rapid guidelines. Intensive Care Med. 2020;46(6):1303–12, http://dx.doi.org/10. 1007/s00134-020-06092-5.
- Arabi YM, Myatra SN, Lobo SM. Surging ICU during COVID-19 pandemic: an overview. Curr Opin Crit Care. 2022;28(6):638–44, http://dx.doi.org/10.1097/MCC.00000000001001.
- 31. Tarnow-Mordi WO, Hau C, Warden A, Shearer AJ. Hospital mortality in relation to staff workload: a 4-year study in an adult intensive-care unit. Lancet. 2000;356(9225):185-9, http://dx.doi.org/10.1016/s0140-6736(00)02478-8.
- Stone PW, Mooney-Kane C, Larson EL, Horan T, Glance LG, Zwanziger J, et al. Nurse working conditions and patient safety outcomes. Med Care. 2007;45(6):571–8, http://dx.doi.org/ 10.1097/MLR.0b013e3180383667.
- 33. Margadant C, Wortel S, Hoogendoorn M, Bosman R, Spijkstra JJ, Brinkman S, et al. The nursing activities score per nurse ratio is associated with in-hospital mortality, whereas the patients per nurse ratio is not. Crit Care Med. 2020;48(1):3–9, http://dx.doi.org/10.1097/CCM.000000000004005.
- 34. Miranda DR, Nap R, de Rijk A, Schaufeli W, Iapichino G, TISS Working Group. Nursing activities score. Crit Care Med. 2003;31(2):374–82, http://dx.doi.org/10.1097/01.CCM.0000045567.78801.CC.
- 35. Ilan R, Fowler RA, Geerts R, Pinto R, Sibbald WJ, Martin CM. Knowledge translation in critical care: factors associated with prescription of commonly recommended best practices for critically ill patients. Crit Care Med. 2007;35(7):1696–702, http://dx.doi.org/10.1097/01.CCM.0000269041.05527.80.
- 36. Brown B, Gude WT, Blakeman T, van der Veer SN, Ivers N, Francis JJ, et al. Clinical Performance Feedback Intervention Theory (CP-FIT): a new theory for designing, implementing, and evaluating feedback in health care based on a systematic review and meta-synthesis of qualitative research. Implement Sci. 2019;14(1):40, http://dx.doi.org/10.1186/s13012-019-0883-5.
- 37. Moreno-Mulet C, Sansó N, Carrero-Planells A, López-Deflory C, Galiana L, García-Pazo P, et al. The impact of the COVID-19 pandemic on ICU health care professionals: a mixed methods study. Int J Environ Res Public Health. 2021;18(17):9243, http://dx.doi.org/10.3390/ijerph18179243.