Impact of the coronavirus pandemic on the patterns of vital signs recording and staff compliance with expected monitoring schedules on general wards

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ABSTRACT

Introduction: Coronavirus disease 2019 (COVID-19) placed increased burdens on National Health Service hospitals and necessitated significant adjustments to their structures and processes. This research investigated if and how these changes affected the patterns of vital sign recording and staff compliance with expected monitoring schedules on general wards.

Methods: We compared the pattern of vital signs and early warning score (EWS) data collected from admissions to a single hospital during the initial phase of the COVID-19 pandemic with those in three control periods from 2018, 2019 and 2020. Main outcome measures were weekly and monthly hospital admissions; daily and hourly patterns of recorded vital signs and EWS values; time to next observation and; proportions of 'on time', 'late' and 'missed' vital signs observations sets.

Results: There were large falls in admissions at the beginning of the COVID-19 era. Admissions were older, more unwell on admission and throughout their stay, more often required supplementary oxygen, spent longer in hospital and had a higher in-hospital mortality compared to one or more of the control periods. More daily observation sets were performed during the COVID-19 era than in the control periods. However, there was no clear evidence that COVID-19 affected the pattern of vital signs collection across the 24-h period or the week.

Conclusions: The increased burdens of the COVID-19 pandemic, and the altered healthcare structures and processes required to respond to it, did not adversely affect the hospitals' ability to monitor patients under its care and to comply with expected monitoring schedules.

INTRODUCTION

The adherence to expected vital signs monitoring schedules on hospital wards is sensitive to nurse staffing levels,[1] and is likely modified by the complexity of patients' clinical care, nurses' competing clinical priorities and staff skill mix.[2-4] The impact of many of these is likely to have been amplified by the ongoing pandemic of coronavirus disease 2019 (COVID-19), a novel viral infection caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). In response to the emerging pandemic, the National Health Service (NHS) wrote to NHS hospital Chief Executives (CEOs) on 17th March 2020 instructing them to discharge all medically fit, hospital in-patients, wind-down elective activity over the following 30 days, postpone all non-urgent elective operations from 15/04/20, and expand critical care capacity.[5]

In response, the study hospital modified staff shift patterns, deployed existing staff to more acute and often unfamiliar clinical settings (e.g. surgeons were responsible for the care of some medical patients), cancelled staff annual leave, ceased the use of temporary or 'locum' staff, expanded critical care services outside its intensive care unit (ICU), used wards differently (e.g. patients with COVID-19 infection were cared for in cohorts within ward bays; surgical wards were used for medical admissions). By mid-April 2020, UK hospitals had admitted almost 20,000 patients with COVID-19 infection,[6] many of them critically ill, and much of the clinical work, including the measurement of patients' vital signs, was undertaken with staff wearing personal protective equipment (PPE) such as gowns, gloves, masks and face visors.

The aim of the current research was to investigate if and how the burdens of the initial phase of the COVID-19 pandemic, and the altered healthcare structures and processes required to respond to it, affected the patterns of vital signs recording and staff compliance with the vital signs monitoring schedules in the general wards of the study hospital.

METHODS

Study setting

The study took place in a large NHS acute general hospital in the south of England, which has approximately 7,900 staff and provides all acute services excluding burns, spinal injury, neurosurgical and cardiothoracic surgery to a population of approximately 640,000 people. The study was performed under Isle of Wight, Portsmouth and South East Hampshire Research Ethics Committee approval (ref 08/02/1394).

Methods and participants

<u>Vitalpac and vital signs documentation</u>

Routine documentation and charting of all vital signs at the bedside is undertaken in real-time in adult in-patient areas of the hospital using commercially available, electronic software (Vitalpac) running in handheld devices.[7] Whenever vital signs are measured at the bedside, the software demands that the following are recorded: date/time of observation set (automatically set by the handhelds); breathing rate (RR); pulse rate (HR); systolic blood pressure (sBP); body temperature (T); neurological status using either the Alert-Verbal-Painful-Unresponsive (AVPU) scale; and peripheral oxygen saturation (S_pO_2). A record of the inspired gas (i.e., air or oxygen) being breathed by the patient at the time of S_pO_2 measurement is also required, together with the patient's target S_pO_2 range. Vitalpac is not used in the maternity unit or intensive care unit.

For each set of vital signs, Vitalpac automatically calculates and displays an early warning score (EWS), which reflects the patient's severity of illness. Until 05/02/19, the EWS integrated in Vitalpac was the National Early Warning Score (NEWS).[8] Thereafter, in line with national guidance, Vitalpac was gradually updated to accommodate a modification of NEWS, NEWS2,[9] which includes two additional elements: 1) a S_pO_2 scale for use in patients with hypercapnic respiratory failure and 2) the addition of 'new confusion' (C) to the AVPU scale.[9] For most patients, NEWS and NEWS2 are effectively identical. In our analysis, we did not distinguish between NEWS and NEWS2 values and used whichever EWS value was exported from the Vitalpac software.

The EWS value also determines the time to the next vital signs observation (TTNO), i.e. when the patient should next be monitored. Observation intervals vary between 6-12 hours for the least ill patient to 30 minutes for the most severely ill. Once a patient's vital sign observations haven been entered by the hospital staff, Vitalpac automatically displays the EWS value and when the next set of observation should be taken, based on the hospital's clinical escalation protocol (Table 1). Two slightly different escalation protocols were in operation within Vitalpac during the study period – one until the end of January 2019 and another commencing February 2019 (Table 1).

Vital signs database

We extracted the vital signs, EWS values and TTNO data of consecutive adults (≥16 years) admitted to Portsmouth Hospitals University NHS Trust between 01/01/18 and 30/04/20, inclusive, from the hospital database server. The end date of the study was arbitrary. The following were excluded: data from patients discharged from hospital before midnight on the day of admission and from those transferred directly at admission to a critical care area; and vital sign sets for which any measurements were absent or out-of-range. Where duplicate sets existed at a given date/time, we assumed that the last recorded set was 'correct' and removed all others. Vital sign measurements and EWS values recorded after midnight on 30/04/20 were removed, as were observations without a follow-up set within 24h to avoid artefacts due to patients being transferred to ICU where Vitalpac is not used.

The study database also included patient demographic (e.g. patient gender and age) and admission specialty (i.e. medical, surgical, other) data, and a range of patient outcomes (e.g. length of stay (LoS), in-hospital mortality).

Study periods

As major changes were made to NHS healthcare structures and processes following the NHS letter to hospital CEOs on 17/03/20,[5] we chose to compare four study periods:

- COVID-19 era [17/03/2020 to 30/04/2020, inclusive] [total of 45 days]. This cohort includes all hospital admissions during the period, irrespective of whether the patients were tested for SARS-CoV-19 virus, and whether they were found to be positive or negative.
- CONTROL 2018 [17/03/2018 to 30/04/2018, inclusive] [total of 45 days]
- CONTROL 2019 [17/03/2019 to 30/04/2019, inclusive] [total of 45 days]
- CONTROL 2020 [01/01/2020 to 16/03/2020, inclusive] [total of 76 days]

Data storage and analysis

All data were stored in Microsoft SQL Server 2019, and analysed using Microsoft Excel, and R v3.6.0 statistical computing and graphics software.[10] Each vital signs set was allocated to an hour of the day, with the time for each set being labelled as the current hour at the moment of the timestamp, e.g. timestamps between 07:00 and 07:59 were labelled as 07:00. We calculated the number of vital signs sets collected each hour, stratified by EWS value grouped from 0 to $\geq$9, and expressed them as both a proportion of the total number of vital signs sets collected in the 24-h period and as a proportion of the total number for that EWS value in the 24-h period. We also calculated the number of vital signs sets collected each hour, expressed as a proportion of the total collected in the day, stratified by day of the week. We plotted the mean TTNO for each hour of the day, categorised by EWS value in the COVID-19 era and the three control periods.

Definition of 'late' and 'missed' vital signs observations

We defined vital signs sets as 'late' if overdue by more than 33% of the expected TTNO calculated and displayed by Vitalpac. Sets were defined as 'missed' if overdue by more than 67% of the expected TTNO. For example, where TTNO was 60 min, the next observation was classified as 'late' if recorded >80 min after the previous set and 'missed' if recorded >100 min later.

Statistical analysis

Descriptive statistics were calculated including counts, means (± SD), medians (IQR), percentages and proportions. Count data were tested for significance using Fisher's exact test (Bonferroni correction for pairwise comparison). Proportions were compared using the chi squared test (Bonferroni correction). Mean values were compared with one-way ANOVA and Scheffe's test, and median values were compared using Kruskal-Wallis and Dunn's test (Bonferroni correction).

RESULTS

After exclusions, the data extract from 01/01/2018 to 30/04/20 contained a total of 96,650 hospital admissions aged $\geq$16 years with vital signs. The admission pattern over these sixteen months demonstrates a sudden large fall in total admissions and in all admission groups (medicine, surgery, other) at the beginning of March 2020 (Figure 1).These falls are emphasised in Supplementary Figure 1, which displays the weekly admissions from 01/01/2020 to 30/04/20 and shows that the fall during March 2020 was followed by a small rebound in mid-April 2020.

Table 2 shows the admissions and observation data for the four study periods: COVID-19 era, CONTROL 2018, CONTROL 2019 and CONTROL 2020. Comparing the admissions numbers in the COVID-19 era with the mean for the CONTROL 2018 and CONTROL 2019 periods, there were falls of 27.6% (total admissions) 15.8% (medicine), 44.1% (surgery) and 76.4% (other). When compared to the CONTROL 2018 and CONTROL 2019 periods, admissions in the COVID-19 era had a similar gender distribution. However, COVID-19 era admissions had a higher median age at admission, higher admission HR and RR, higher admission EWS value and more received supplemental oxygen. During the hospital stay, admissions during the COVID-19 era had more observation sets performed per day, different physiology (higher HR and RR; lower sBP and S_pO_2), a higher mean EWS, a longer stay in hospital, and increased 24 h and in-hospital mortality (Table 2).

When vital signs sets were stratified by EWS value and collection hour and expressed as a proportion of the total collected during the 24-h period, the pattern of vital sign recording seemed uninfluenced by the onset of COVID-19 (Figure 2). All four periods exhibited peaks of activity at 06:00, 11:00 and 16:00, and between 20:00 and 23:00. Similarly, when vital signs sets were stratified by EWS value and collection hour and expressed as a proportion of the total number for that EWS value during the 24-h period, there appeared to be no discernible difference (Supplementary Figure 2). Equally, the patterns of observations on each day of the week were similar and uninfluenced by the onset of COVID-19 (Supplementary Figure 3).

The pattern of the mean TTNO for each EWS value and collection hour shows groupings that reflect the escalation protocols deployed in Vitalpac throughout 2018, 2019 and 2020 (Supplementary Figure 4). After December 2019, the median TTNO for higher EWS values ($\geq$ 6) was longer ($p<0.001$). Comparing the patterns in the COVID-era and CONTROL 2020 period shows no additional influence of COVID-19.

When the total number of vital signs sets recorded monthly from 01/03/2018 to 30/04/20 is categorised by EWS value, the proportion of admissions who were less severely ill during admission (EWS values 0 and 1) fell at the onset of the COVID-19 era (Figure 3). In addition, there was a gradual small reduction in the proportion of 'on time' observations over time from March 2018 to March 2020 (Supplementary Figure 5), accompanied by gradual and small rises in the proportions of 'late' and 'missed' observations in the same period. However, from the start of the COVID-19 era, the proportion of 'on time' observations seemed to rise slightly. Figure 4 and Supplementary Table 1 show that the proportions of 'on time' sets were lower for the COVID-era across all EWS value ranges compared to the CONTROL 2018 period and for EWS values of 3-5 in the CONTROL 2019 period ($p<0.001$). Compliance was better for the COVID-era across all EWS value ranges compared to the CONTROL 2020 period ($p<0.001$).

DISCUSSION

The COVID-19 pandemic and the resulting necessary altered healthcare structures and processes were associated with a marked reduction in the number of daily admissions to all specialty groups. Overall, admissions were older, more ill on admission and throughout their stay, more often required supplementary oxygen, spent longer in hospital and had a higher in-hospital mortality compared to one or more of the control periods. More observation sets were performed daily during the COVID-19 era than during control periods. However, overall, we could find no evidence that COVID-19 affected the pattern of vital signs collection across the 24-h period or the week. There was a significant fall in 'on time' vital sign sets in the higher EWS group (≥6) between the CONTROL 2018 and all subsequent study periods (Figure 4 and Supplementary Table 3), although we believe this is due to a decaying effect of a prior local patient safety quality improvement initiative aimed at reducing late and missed vital sign sets. Nevertheless, from the start of the COVID-19 era, the proportion of 'missed' and 'late' observations fell slightly, suggesting improved adherence to the vital signs monitoring protocol.

Major strengths of the study were that vital signs data were extracted from a large dataset of routinely collected observation sets entered directly into electronic devices at the bedside as part of the patients' clinical management. In all four periods, the database comprised complete vital signs datasets from all patients across all specialities, with each dataset having an accurate date/time stamp. In addition, the TTNO data used in the analyses was based on the observation intervals determined and displayed by Vitalpac. Finally, the start of the COVID-19 era of the study was clearly defined, commencing on the day the NHS wrote to hospital CEOs regarding the necessary NHS response to COVID-19.[5]

The main limitations are that the study is observational, relies on data from a single hospital and excludes vital signs data from specialist wards (i.e. critical care, maternity). Additionally, where patients are monitored continuously, the hospital's escalation protocol dictates that a full vital sign is entered into Vitalpac using the "minimum interval" algorithm. Should staff fail to do so, missing data could influence the overall results. However, as Vitalpac provides the electronic record of vital signs on general wards and the focus of the current research is the pattern of *documentation* of vital signs, this should not materially affect our findings. The escalation protocol in Vitalpac changed in February 2019; however, we feel that this is of minor importance given that this occurred many months before the NHS letter to CEOs and because we analysed against the real-time escalation algorithm embedded in Vitalpac in each of the four study periods. Another limitation is that the underlying health informatics nature of our research precludes the direct, detailed comparison of bedside clinical practice (e.g., time taken to perform vital signs measurements, impact on the response to deterioration) or specific details of organisational changes (e.g. numbers of staff on duty, staff-to-patient ratios) in the CONTROL and COVID-19 eras.

There is limited published data on the adherence of hospital staff to expected monitoring schedules[11-15] and none focuses on the impact of COVID-19. However, research prior to the COVID-19 pandemic shows that adherence is poor, [12-14] often being reduced at weekends, on national holidays and during night-time hours.[11,12] The frequency of night-time measurements may be unrelated to the patient's EWS value[15] and higher EWS values are associated with reduced protocol compliance.[12,13] Previous research in the study hospital showed only partial adherence to expected monitoring schedules, with several monitoring peaks and similar patterns for patients with different levels of physiological derangement.[12] Essentially, we found little difference between these earlier patterns and those observed in the current COVID-19 study.

The COVID-19 pandemic has resulted in considerable changes to the numbers and case-mix of patients admitted to hospital. Dealing with an emergent, potent infectious disease with good human-to-human transmission and the ability to produce critical illness of rapid onset has also created significant difficulties for hospital clinical and administrative practice. Therefore, it could be expected that these burdens would hamper the study hospital's capacity to monitor patients' vital signs adequately and for its staff's ability to comply with the expected monitoring schedules. For instance, the fact that patients with COVID-19 in our study were sicker on admission and required more complex care than in matched periods in 2018 and 2019; the deployment of existing staff to often unfamiliar, acute clinical settings; and the need for staff to deliver care wearing PPE might all be expected to worsen compliance in the study hospital. On the other hand, the reduced total hospital population due to the discharge of medically fit hospital in-patients; reduced elective clinical activity; and cancelled staff leave might all be expected to release staff time that could be directed, at least partially, towards improved patient monitoring. Overall, our findings suggest that the aggregate impact of these competing sets of circumstances has resulted in little observable overall change in patient monitoring, although the slight fall in the proportion of 'missed' and 'late' observations during the pandemic ~~may~~ might just reflect a small improvement.

We cannot know whether our study results are generalisable to future outbreaks of COVID-19, or other epidemics or pandemics, as their circumstances may be very different. However, whilst the reduced hospital patient throughput did not apparently lead to improved monitoring, it seems that it was not adversely impacted by the pandemic, and this is useful knowledge for planning future services. The study leaves many questions unanswered. For instance, we were unable to compare monitoring practices for admissions proven to have COVID-19 infection and those without, and this could form the basis of future research. In addition, a recent systematic literature review has demonstrated insufficient robust evidence to quantify the nursing time and workload involved in measuring and documenting patients' vital signs.[16] Although work is currently underway to fill this knowledge gap,[17] it would be useful to study the time taken to complete these tasks with and without the use of PPE as this is relevant to determining practicable monitoring schedules. Moreover, there are significant barriers to efficient vital signs measurement and documentation, including when electronic systems are utilised.[18-20] It is possible that COVID-19 has influenced these barriers further or, indeed, introduced new ones. Consequently, qualitative research would be beneficial in defining specific barriers and facilitators to vital sign measurement and recording during the COVID-19 pandemic.

CONCLUSIONS

The increased burdens of the COVID-19 pandemic, and the altered healthcare structures and processes developed in response, did not adversely affect the hospital's ability to monitor patients under its care and to comply with expected monitoring schedules.

CONFLICT OF INTEREST: The following potential conflicts of interest are declared by the authors and the other members of the PACIFIC-19 team. Professor Chauhan, Dr Meredith, Dr Schmidt, Dr Spice, Dr Fox, Dr Mortlock, Dr Fleming, Dr Pilbeam, Dr Rowley and Dr Poole are employees of Portsmouth Hospitals University NHS Trust (~~PHT~~ PHUNT), which had a royalty agreement with The Learning Clinic (TLC) to pay for the use of ~~PHT~~ PHUNT intellectual property within the Vitalpac product that expired before the commencement of this study. Professors Prytherch and Smith are former employees of ~~PHT~~ PHUNT. Dr Schmidt, and the wives of Professors Prytherch and Smith, held shares in TLC until October 2015. Dr Schmidt and Professors Smith and Prytherch were unpaid research advisors to TLC and received reimbursement of travel expenses from TLC for attending symposia in the United Kingdom. Professor Briggs' research has previously received funding from TLC through a Knowledge Transfer Partnership. Professor Smith was a topic expert for the National Institute for Clinical and Health Excellence's clinical guideline surveillance process for Clinical Guideline 50 (Acutely ill patients in hospital. Recognition of and response to acute illness in adults in hospital) in 2007 and 2016, and a member of the Royal College of Physicians of London's National Early Warning Score (NEWS) Development and Implementation Group, which developed NEWS and NEWS2. Dr Kostakis, Mr Price, Dr Scott, Dr Mortlock, Dr Spice, Dr Fox, Dr Fleming, Dr Pilbeam, Dr Rowley and Dr Poole declare no conflict of interests.

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LEGENDS FOR FIGURES

Figure 1: Monthly hospital admission numbers (total and specialty) during the period 01/03/18 to 30/04/20.

Figure 2: Recorded vital signs sets, stratified by EWS value and collection hour and expressed as a proportion of the total number collected during the 24 h period.

Figure 3: Monthly proportions of vital signs sets for each EWS from 01/03/18 to 30/04/20.

Figure 4: Proportions of ‘on time’, ‘late’ and ‘missed’ observations, categorised by EWS value groups, in the four study periods. [‘late’ = overdue by more than 33% of the expected TTNO calculated and displayed by Vitalpac; ‘missed’ = overdue by more than 67% of the expected TTNO]. TTNO = Time to next observation.

Table 2: Demographic and observation data regarding admissions in each of the four study periods

	CONTROL 2018 (a)	CONTROL 2019 (b)	CONTROL 2020	COVID-19 era (c)	p value	post-hoc tests (p value <0.05)
Days in period	45	45	76	45		
Admissions, N	5916	6171	10242	4375		
Admissions to medical specialties, N (%)	3,871 (65.4%)	3,961 (64.2%)	6,793 (66.3%)	3,299 (75.4%)		
Admissions to surgical specialties, N (%)	1,723 (29.1%)	1,835 (29.7%)	2,849 (27.8%)	994 (22.7%)		
Admissions to other specialties, N (%)	322 (5.4%)	375 (6.1%)	600 (5.9%)	82 (1.9%)		
Admissions per day, N	131	137	135	97		
Admissions to medical specialties per day, N	86	88	89	73		
Admissions to surgical specialties per day, N	38	41	37	22		
Admissions to other specialties per day, N	7	8	8	2		
Female, N (%)	3,130 (52.9%)	3,261 (52.8%)	5,445 (53.2%)	2,214 (50.6%)	0.011	
Age [years], median (IQR)	67.2 (19.5)	67.7 (19.5)	67.7 (19.7)	68.4 (19.1)	0.004	(c) different from (b)
Admission observations						
Admission HR [bpm], mean (SD)	80.9 (16.7)	80.7 (16.6)	81.4 (16.7)	82 (16.5)	<0.001	(c) different from (a) & (b)
Admission RR [1/min], mean (SD)	17.4 (2.9)	17.6 (2.9)	17.9 (2.9)	18 (2.9)	<0.001	all different from each other
Admission temperature [ºC], mean (SD)	36.8 (0.5)	36.8 (0.5)	36.7 (0.5)	36.8 (0.6)	0.938	
Admission S_pO_2 [%], mean (SD)	96.3 (2.3)	96.3 (2.3)	96.2 (2.3)	96.2 (2.3)	0.151	
Admission sBP [mmHg], mean (SD)	130.7 (23.8)	131 (24.3)	131.2 (24.3)	130.8 (23.7)	0.711	
Admission supplemental O2, N (%)	1,044 (17.6%)	1,011 (16.4%)	1,844 (18.0%)	811 (18.5%)	0.015	(c) different from (b)
Admission AVPU						
Alert, N (%)	138,256 (99.2%)	153,602 (99.3%)	280,666 (99.6%)	95,329 (99.2%)	0.042	
Responds to voice, N (%)	704 (0.5%)	632 (0.4%)	652 (0.2%)	462 (0.5%)	0.150	
Responds to pain, N (%)	201 (0.1%)	151 (0.1%)	245 (0.1%)	131 (0.1%)	0.037	(c) different from (b)
Unresponsive, N (%)	124 (0.1%)	85 (0.1%)	111 (0%)	53 (0.1%)	0.046	
Admission EWS value, mean (SD)	1.6 (1.9)	1.6 (1.9)	1.7 (1.9)	1.7 (2)	0.001	(c) different from (a) & (b)

All observations during stay						
No of observations, N	139318	154679	281828	96059		
Observation sets / day, median (IQR)	3.9 (3-5)	4 (3.2-5)	4.2 (3.6-5)	4.5 (3.8-5.8)	<0.001	all different from each other
HR [bpm], mean (SD)	80.2 (15.6)	80.3 (15.4)	79.9 (15.3)	80.7 (15.1)	<0.001	(c) different from (a) & (b)
RR [1/min], mean (SD)	17.3 (2.8)	17.5 (2.8)	17.7 (2.7)	18.1 (3.1)	<0.001	all different from each other
Temperature [^oC], mean (SD)	36.8 (0.5)	36.7 (0.4)	36.7 (0.5)	36.8 (0.5)	<0.001	all different from each other
S_pO_2 [%], mean (SD)	96.1 (2.3)	96.1 (2.3)	95.9 (2.3)	95.8 (2.4)	<0.001	(c) different from (a) & (b)
sBP [mmHg], mean (SD)	126.1 (22.7)	126.2 (22.2)	126.5 (22.1)	126.8 (21.9)	<0.001	(c) different from (a) & (b)
Supplemental O2, N (%)	24,595 (18%)	26,468 (17%)	53,166 (19%)	23,857 (25%)	<0.001	all different from each other
AVPU						
Alert, N (%)	138,256 (99.2%)	153,602 (99.3%)	280,666 (99.6%)	95,329 (99.2%)	0.061	
Responds to voice, N (%)	704 (0.5%)	632 (0.4%)	652 (0.2%)	462 (0.5%)	0.001	(a) different from (b)
Responds to pain, N (%)	201 (0.1%)	151 (0.1%)	245 (0.1%)	131 (0.1%)	0.001	(a) different from (b)
Unresponsive, N (%)	124 (0.1%)	85 (0.1%)	111 (0%)	53 (0.1%)	0.001	(a) different from (b)
EWS value, mean (SD)	1.7 (2)	1.6 (1.9)	1.7 (1.9)	1.9 (2.1)	<0.001	all different from each other
Outcomes						
Length of stay [days], median (IQR)	4 (2-12)	4 (2-12)	4 (2-10)	3 (1-8)	<0.001	all different from each other
ICU admission within 24h, N (%)	83 (1.4%)	92 (1.5%)	128 (1.2%)	86 (2.0%)	0.070	
Death within 24h, N (%)	151 (2.6%)	146 (2.4%)	254 (2.5%)	183 (4.2%)	<0.001	(c) different from (a) & (b)
In-hospital deaths, N (%)	294 (5%)	286 (4.6%)	530 (5.2%)	323 (7.4%)	<0.001	(c) different from (a) & (b)

HR = heart/pulse rate; RR= respiratory rate; sBP = systolic blood pressure SpO2 = peripheral oxygen saturation; EWS, Early Warning Score.
Count data has been tested for significance using Fisher's exact test and Bonferroni correction for pairwise comparison\
Proportions were compared using the chi squared test (Bonferroni correction)
Mean values were compared with one-way ANOVA and Scheffe's test
Median values were compared using Kruskal-Wallis and Dunn's test (Bonferroni correction)

Table 1

Table 1: Escalation protocols for the study hospital from November 2017 onwards

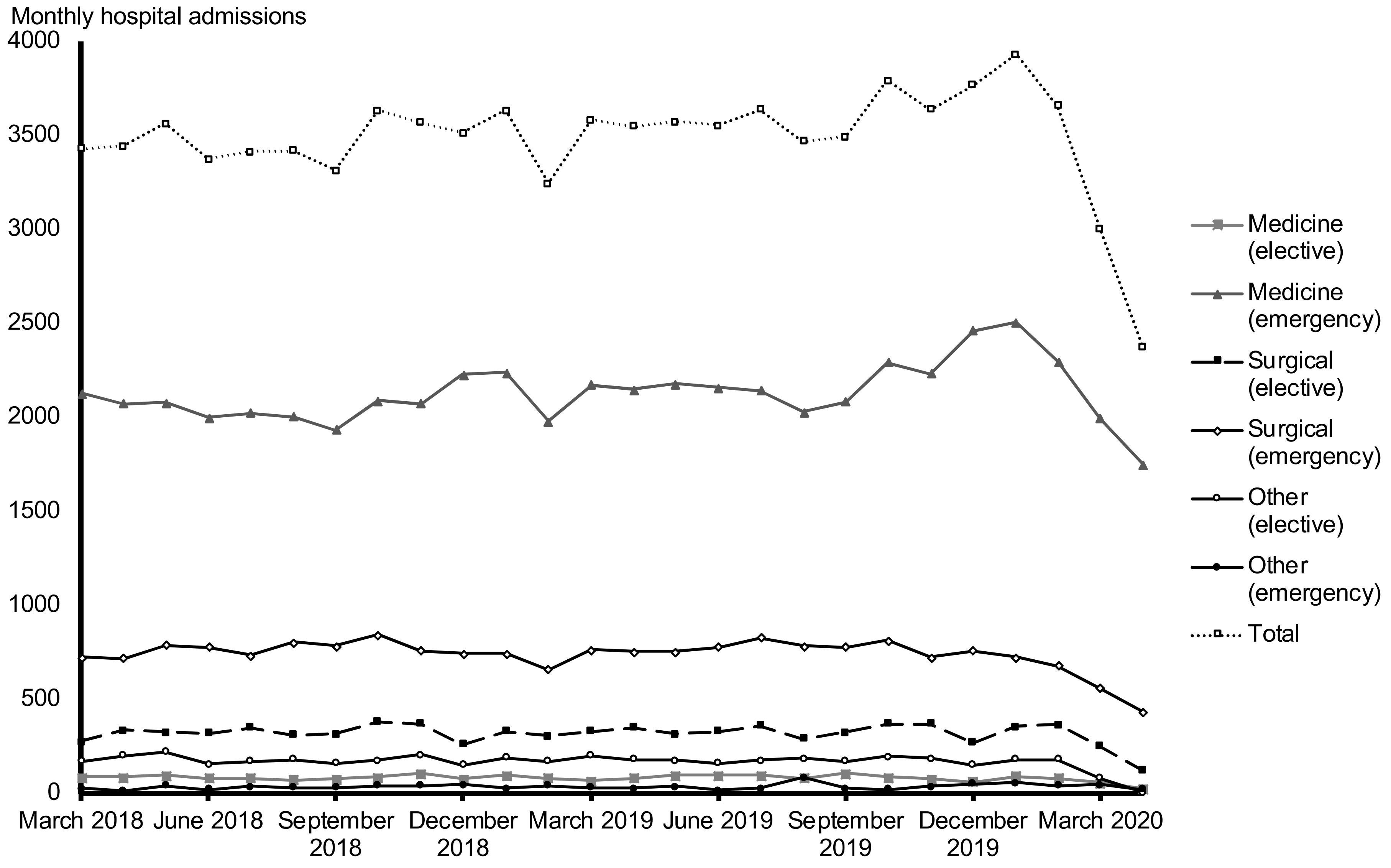
a. November 2017 – January 2019, inclusive

EWS value	Minimum interval between observations (minutes)
0 – 1	360, or 720 if stable
2	360
3 – 5	240
6	120
7 – 8	60
>=9	30

b. From February 2019

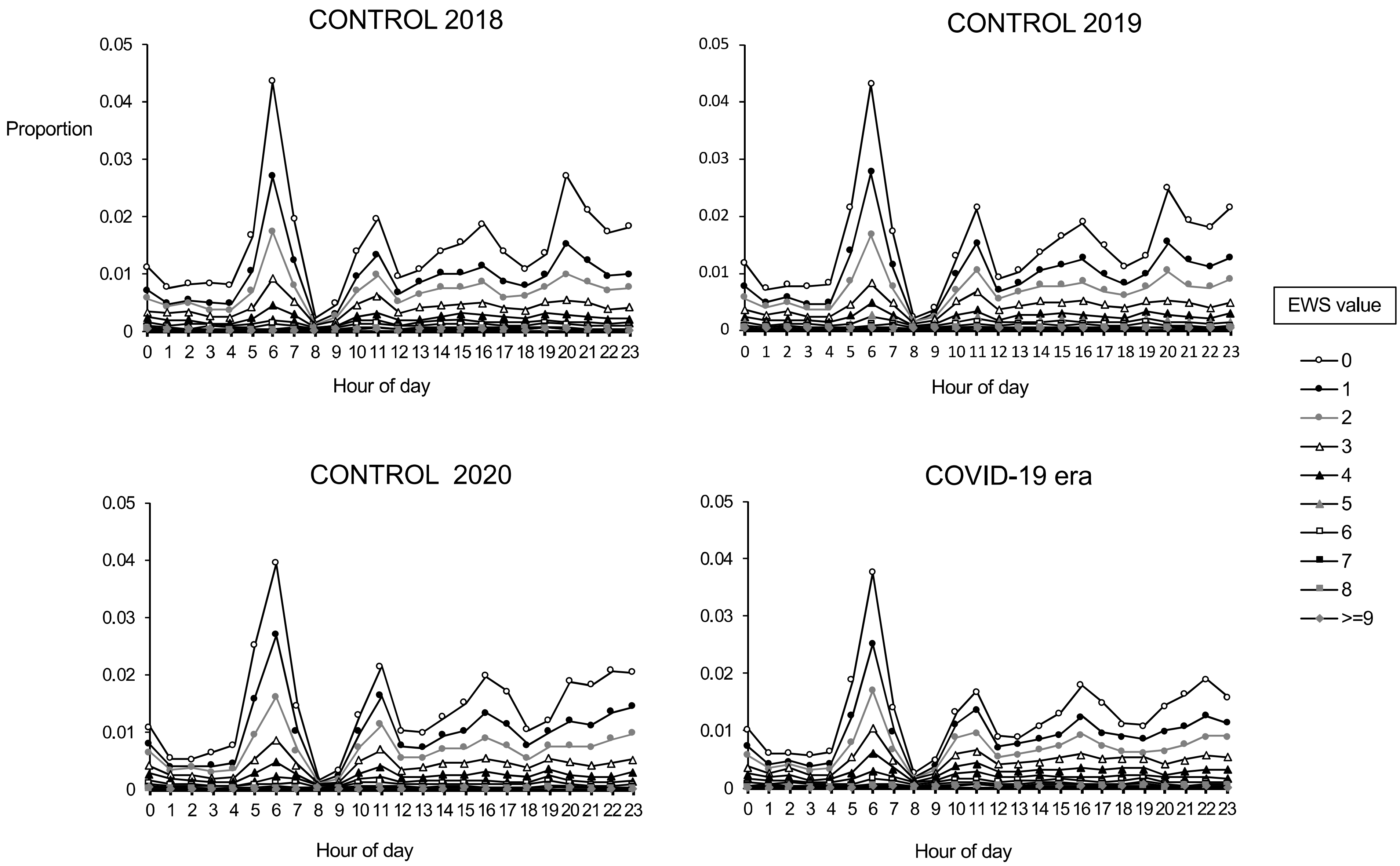
EWS value	Minimum interval between observations (minutes)
0	360
1-2	360
Single EWS parameter scoring 3	240
3 – 4	240
5	60
6	60
7 – 8	30
>=9	30

Figure 1



Monthly hospital admissions
4000
3500
3000
2500
2000
1500
1000
500
0
March 2018
June 2018
September 2018
December 2018
March 2019
June 2019
September 2019
December 2019
March 2020
Medicine (elective)
Medicine (emergency)
Surgical (elective)
Surgical (emergency)
Other (elective)
Other (emergency)
Total

Figure 2



CONTROL 2018
CONTROL 2019
CONTROL 2020
COVID-19 era
Proportion
0.05
0.04
0.03
0.02
0.01
0
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23
Hour of day
EWS value
0
1
2
3
4
5
6
7
8
>=9

Figure 3

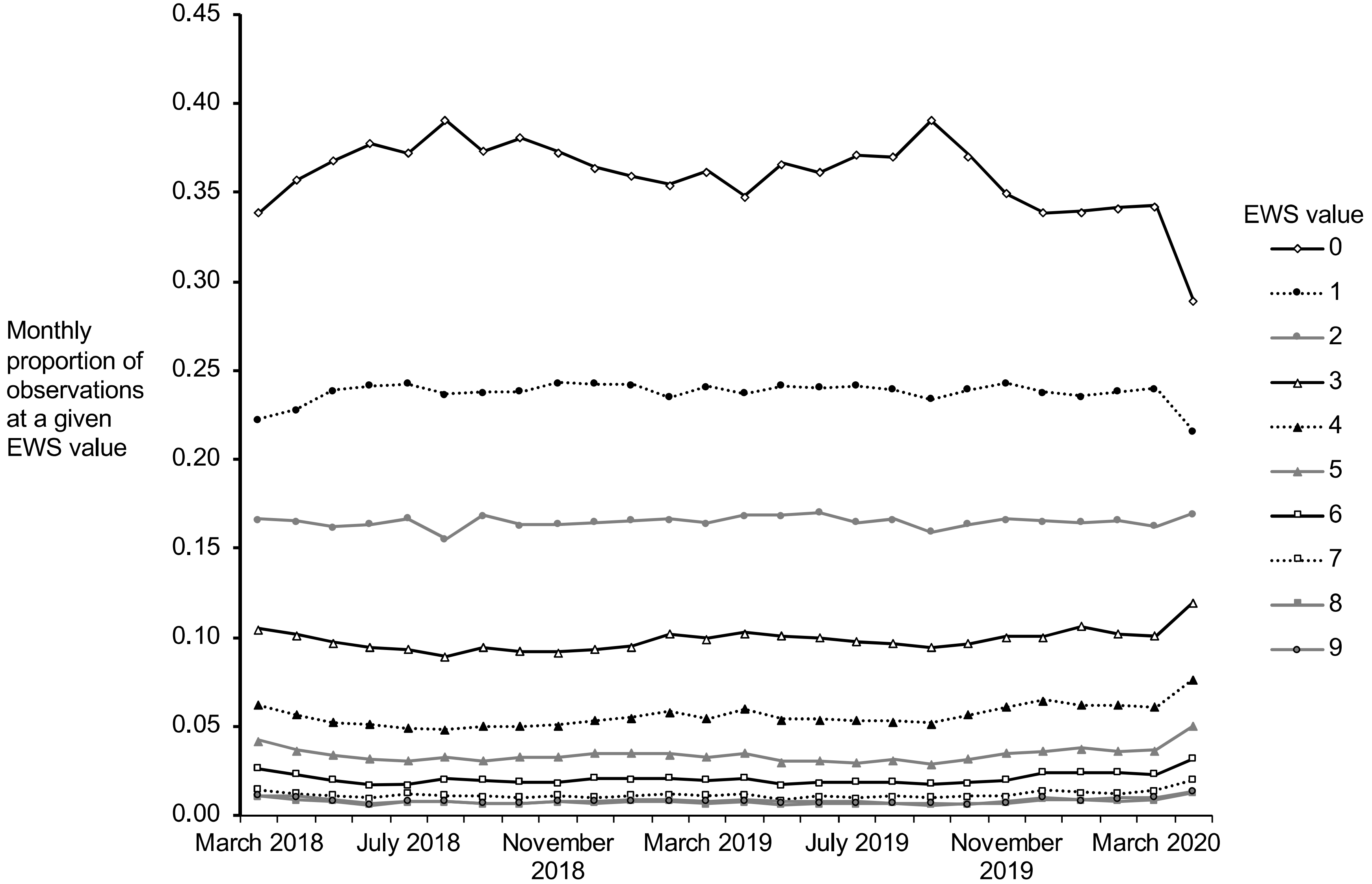
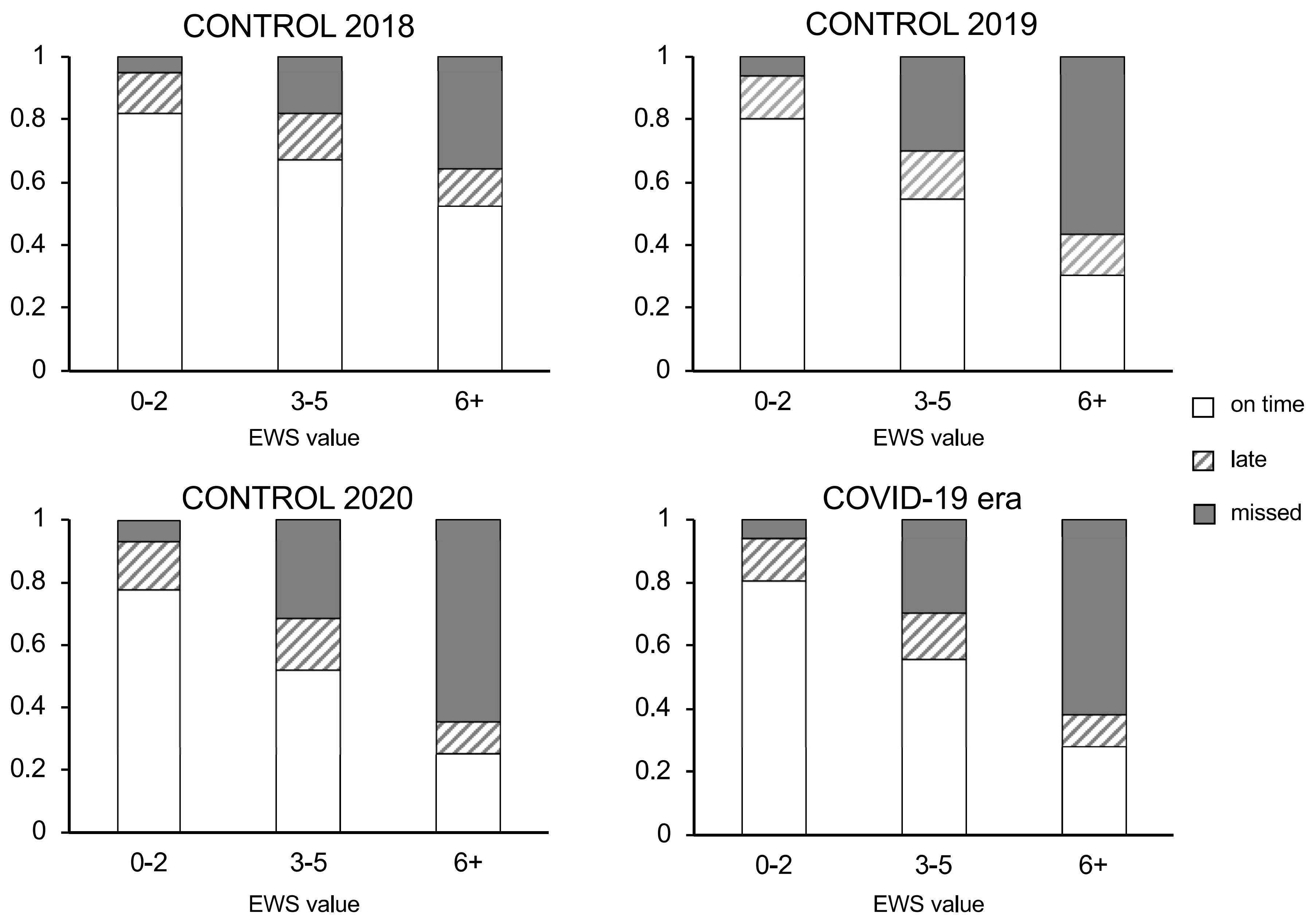

Monthly proportion of observations at a given EWS value
0.45
0.40
0.35
0.30
0.25
0.20
0.15
0.10
0.05
0.00
March 2018
July 2018
November 2018
March 2019
July 2019
November 2019
March 2020
EWS value
0
1
2
3
4
5
6
7
8
9

Figure 4


CONTROL 2018
CONTROL 2019
CONTROL 2020
COVID-19 era
1
0.8
0.6
0.4
0.2
0
0-2
3-5
6+
EWS value
on time
late
missed

CONFLICT OF INTEREST: The following potential conflicts of interest are declared by the authors and the other members of the PACIFIC-19 team. Professor Chauhan, Dr Meredith, Dr Schmidt, Dr Spice, Dr Fox, Dr Mortlock, Dr Fleming, Dr Pilbeam, Dr Rowley and Dr Poole are employees of Portsmouth Hospitals NHS Trust (PHT), which had a royalty agreement with The Learning Clinic (TLC) to pay for the use of PHT intellectual property within the Vitalpac product that expired before the commencement of this study. Professors Prytherch and Smith are former employees of PHT. Dr Schmidt, and the wives of Professors Prytherch and Smith, held shares in TLC until October 2015. Dr Schmidt and Professors Smith and Prytherch were unpaid research advisors to TLC and received reimbursement of travel expenses from TLC for attending symposia in the United Kingdom. Professor Briggs' research has previously received funding from TLC through a Knowledge Transfer Partnership. Professor Smith was a topic expert for the National Institute for Clinical and Health Excellence's clinical guideline surveillance process for Clinical Guideline 50 (Acutely ill patients in hospital. Recognition of and response to acute illness in adults in hospital) in 2007 and 2016, and a member of the Royal College of Physicians of London's National Early Warning Score (NEWS) Development and Implementation Group, which developed NEWS and NEWS2. Dr Kostakis, Mr Price, Dr Scott, Dr Mortlock, Dr Spice, Dr Fox, Dr Fleming, Dr Pilbeam, Dr Rowley and Dr Poole declare no conflict of interests.

CRediT author statement

Ina Kostakis: Methodology, Software, Validation, Formal analysis, Investigation, Writing – Review & editing, Visualisation.
Gary Smith: Conceptualization, Methodology, Validation, Investigation, Writing – Original draft, Validation, Formal analysis, Investigation, Visualisation, Project administration.
David Prytherch: Conceptualization, Methodology, Software, Validation, Formal analysis, Investigation, Data curation, Writing – Review & editing, Supervision.
Paul Meredith: Conceptualization, Methodology, Software, Validation, Formal analysis, Data curation, Writing – Review & editing.
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Anoop Chauhan: Conceptualization, Methodology, Writing – Review & editing, Supervision.