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Evaluating associations between Patient-to-Nurse ratios and mortality, process of care events, and vital sign documentation on pediatric wards: A secondary analysis of data from the EPOCH cluster randomized trial

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Title: Evaluating associations between patient-to-nurse ratios and mortality, process of care events, and vital sign documentation on pediatric wards: A secondary analysis of data from the EPOCH cluster-randomized trial

ABSTRACT

Objective: to describe the associations between patient-to-nurse staffing ratios and rates of mortality, clinical deterioration events, processes and perceptions of care.

Design: Secondary analysis of data from the EPOCH cluster-randomized trial.

Setting: 22 Hospitals caring for children in Canada, Europe, and New Zealand.

Participants: Eligible hospitalized patients were aged >37 weeks and <18 years.

Primary and secondary outcome measures: the primary outcome was all cause hospital mortality. Secondary outcomes were five events reflecting process of care also collected on all EPOCH patients; the frequency of documentation for each of eight vital signs on a random sample of patients; four measures describing nursing perceptions of care. The timeliness of urgent PICU admissions was classified using the Children Resuscitation Intensity Scale.

Results: A total of 217,714 patient admissions for 849,798 patient days over the course of the study were analyzed. The overall mortality rate was 1.65/1000 patient discharges. Univariate Bayesian models estimating the rate ratio (RR) for the patient-nurse ratio and the probability that the RR was less than one found that a higher patient-nurse ratio was associated with fewer clinical deterioration events (RR=0.88, 95% CrI 0.77, 1.03; P(RR < 1) = 95%) and late ICU admissions (RR=0.76, 95% CrI 0.53, 1.06; P(RR<1)=95%). In adjusted models, a higher patient-to-nurse ratio was associated with lower hospital mortality (odds ratio (OR) =0.77, 95% CrI=0.57, 1.00; P(OR < 1)=98%). Nurses from hospitals with a higher patient-to-nurse ratio had lower ratings for their ability to influence care, and reduced documentation of most individual vital signs and of the complete set of vital signs.

<u>Conclusions</u>: The data from this study challenge the assumption that pediatric care is less safe or of lower quality with higher patient-to-nurse ratios. The mechanism of these effects warrants

further evaluation including unmeasured factors, such as nursing skill mix, experience, education, and physician staffing ratios.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- A strength of this study is the multicenter international prospective data collection including > 210,000 patient-discharges in 22 hospital sites in 7 high-income countries improving the generalizability of the findings.
- Our measure of patient-to-nurse staffing was from a randomly selected sample of beds in the inpatient ward areas where studied patients received care. Ideally the nurse staffing would have been recorded for all patients on all study days to increase the precision of our description of staffing.
- Unmeasured factors may be confounding the association between patient-to-nurse ratio and the study outcomes including physician staffing ratios, the availability of licensed practice nurses or vocational nurses, differences in nurse education and skill-mix and other patient confounding variables such as case-mix, age and comorbidities.

INTRODUCTION

Nurses are the primary human resource for clinical observation and the delivery of patient care in pediatric hospitals. They are essential components of Rapid Response Systems with roles that include monitoring clinical condition, communicating to others in the primary care team, and escalating the intensity of care as determined by the child's severity of illness (1). Low patient-to-nurse ratios are a well-accepted strategy to mitigate already identified patient risk in intensive care units (ICU) (2–6). In observational studies, lower patient-to-nurse ratios have been associated with lower mortality in adult patients (7,8) and with lower hospital readmission at 15-30 days in children (9). Standards of pediatric nursing care on hospital wards require comprehensive and continuous patient assessments, vital signs measurement, and documentation (10,11) to provide information on early signs of clinical deterioration (12). High patient-to-nurse ratios increase workload for each nurse, which may reduce the frequency of vital signs monitoring, and compromise the effectiveness of interventions and communication (13–15).

While there is evidence on the association of nurse staffing levels and patient mortality in the adult inpatient setting, in pediatric settings this evidence is limited. A study using nurse staffing administrative data in California from 1996-2001 examining 3.65 million discharges from 286 general and children's hospitals reported no association of patient-to-nurse staffing and mortality in children (4). Another study performed in Korea including over 600,000 children admitted to 46 tertiary care hospitals showed an increased risk of failure to rescue associated with lower patient-to-nurse staffing ratios (Grade 1 (beds/nurse<2), OR 1.39; 95% CI 1.15, 1.70; compared to grade 3 (2.5 ≤ beds/nurse < 3). Also, an association with a better composite outcome of cardiac arrest, shock, or respiratory failure was found with lower patient-to-nurse ratios (grade 1 compared to grade 3 OR 0.48; 95% CI 0.40, 0.58) (3). In the Neonatal ICU setting there is some evidence of an association between patient-to-nurse staffing levels or increased proportions of nurses with neonatal certifications and reduced neonatal mortality (16). In Pediatric ICU (PICU) an association with lower mortality and lower odds of complications was found with increased years of nursing experience and nurses with Bachelor or higher degrees (17–20). Current evidence on safe patient-to-nurse ratios for the pediatric setting is limited and much needed to support future nursing workforce planning (21). Therefore, the objective of this study was to determine the association between patient-to-nurse staffing and rates of clinical deterioration events, and processes and perceptions of care on in-hospital pediatric wards.

METHODS

We performed a secondary analysis of data from 217,714 patient admissions in acute care pediatric wards the 22 hospitals included in the “Evaluating processes of care and outcomes of children in hospital” (EPOCH) cluster randomized trial (22). Outcomes were available for all patients without loss to follow-up. The hospitals were located in Belgium, Canada, England, Ireland, Italy, New Zealand, and the Netherlands and had a total of 2085 eligible inpatient unit beds (Parhsuram 2018). Three hospitals (14) had >200 beds, 10 (45%) had a 24/7 Rapid Response Team and 20 (91%) were University affiliated. Eleven hospitals were randomized to implement the Bedside Pediatric Early Warning System (BedsidePEWS).

The main exposure of interest was patient-to-nurse staffing on inpatient wards of participating hospitals. Within each of three 26-week study periods at each hospital, we recorded the total number of patients cared for by the primary nurse of five randomly selected patients. The mean value of the (5 patients) $\times$ (26 weeks) = 130 measurements collected in each 26-week period was used to represent typical staffing levels on the inpatient wards of each hospital for that period.

The primary outcome was hospital mortality. This was also the primary outcome of the EPOCH trial. Secondary outcomes were (a) five events reflecting process of care, also collected on all

EPOCH patients: clinical deterioration events, late ICU admissions, resuscitation team calls, stat calls and PICU consultations; (b) the frequency of documentation for each of eight vital signs on the random sample of patients; and (c) four measures describing nursing perceptions of care. Amongst secondary outcomes reflecting process of care, clinical deterioration events were defined as deaths on the ward or urgent admission to a PICU, which itself was defined as an admission with departure from the event location in less than six hours from the time the PICU admission was initiated (22). The timeliness of urgent PICU admissions was classified using the Children Resuscitation Intensity Scale (CRIS), with scores that range from 1 (no major interventions) to 7 (death before or within the first hour after ICU admission); a score >2 was classified as a late ICU admission (23). Vital signs were documented on the randomly selected patient records. We abstracted the number of documented measurements over a 24-hour period for each patient for each of eight clinical observations: heart rate, respiratory rate, systolic blood pressure, oxygen therapy, oxygen saturation, capillary refill time, respiratory effort, and temperature. We defined vital sign recording as complete when the first seven of these (the clinical indicators in the BedsidePEWS) were documented. We also calculated the BedsidePEWS score (if at least five of the seven measurements were available) from these vital signs of the last hour evaluated. Nurses' perceptions of quality of patient care were recorded once in each study period using a Documentation and Interaction Survey. This survey had the aim of exploring the perception of the documentation system and quality of care. Responses to the communication quality question "How do you rate communication about patients on your team?" were on a 9-point scale from 1, (extremely poor) to 9 (excellent). Responses to the timely care question "Please indicate your agreement/disagreement with the statement: 'Patients have received the care that they needed when they needed it'" were on a 5-point scale from 1 (strongly disagree) to 5 (strongly agree). Responses to the apprehension question "When calling a physician after-hours to review the patient or their management plan, how apprehensive did you feel?" were on a 9-point scale from

1 (extremely apprehensive) to 9 (not at all apprehensive). Responses to the influence on care question “How confident did you feel that you could influence the plan of care?” were on a 9-point scale from 1 (extremely confident) to 9 (not at all confident), which we reversed, so that a 9 became “extremely confident”.

In recognition of the modest number of site-by-period observations in the study data set, we carefully considered options for adjustment variables. After consideration of seven options describing the hospital resources – (1) the proportion of full-time (>90% full-time equivalent) registered nurses, (2) number of pediatric beds, (3) presence of a transplant program, (4) overnight in-house consultant pediatrician, (5) overnight in-house senior trainee (fellow), (6) 24/7 medical emergency team, and (7) mean severity of illness – four were used. Two reflected patient risk for deterioration – the presence of a transplant program and the average patient severity of illness (measured as the mean BedsidePEWS score at the site in the period). Two reflected non-nurse staffing resources – the presence of in-house overnight senior trainee (fellow) and having a medical emergency team. We also adjusted by a fifth variable indicating whether the period was assigned to the EPOCH intervention .Table 1A in the supplement summarizes the sources and roles of all variables included in our analyses.

Statistical analysis

Clinical outcomes were aggregated over each 26-week period and represented as rates. Mortality was summarized as deaths per 1000 patient discharges. Five process of care outcomes (clinical deterioration events, late PICU admissions, immediate calls to a physician to attend at the bedside of a patient, resuscitation team calls, and PICU consultations) were summarized as events per 1000 patient days. To assess the dependence of hospital mortality on the patient-to-nurse ratio, we entered aggregate death and admission data for each site in each period into a random effects logistic regression, with site-specific random effects and site-and-time specific predictors (EPOCH intervention, patient-nurse ratio, presence of transplant team, the presence of in-house overnight senior trainee presence of a medical emergency team, and the mean BedsidePEWS). Similar analyses were used for process of care events, except that random effects negative binomial models were used, with event counts as the outcome, and the logarithm of site-period totals of patient ward-days as an offset. Analyses of documentation of vital signs also used a random effects negative binomial models, with aggregated counts of documentation as the outcome and logarithm of the total number of assessments on the randomly selected patients as the offset. A random effects proportional odds regression model was used to assess the dependence of nurse-reported perceptions of quality of care on the patient to nurse ratio, with site-specific random effects and the same site-and-time specific predictors as above. All models were fitted using Bayesian models in the brms package in R and measures of association are presented with a 95% credible interval (CrI) and the Bayesian posterior probability of a reduction in the outcome with a higher patient-to-nurse ratio. After inspection of the data a post-hoc sensitivity analysis was performed in which we excluded a hospital that was an outlier (site 21) with respect to the patient-nurse ratio.

This study was approved by the Human Research Ethics Board at the Hospital for Sick Children, Toronto, Canada (Approved REB # 1000062622).

RESULTS

Data from 22 hospitals participating in the EPOCH trial (22) included 217,174 patients and 849,798 patient days. Random sampling selected 8282 patients on whom we assessed vital sign documentation and patient-nurse ratios. The median (IQR) number of patients cared for by an individual nurse was 3.0 [2.8, 3.6]. Three hospitals (14%) had a mean patient-to-nurse ratio greater than 4, with one outlier having a patient/nurse ratios of 6.5-7.0 over the three study periods. (Figure 1).

Hospital mortality occurred in 360 patients with an overall rate of 1.65/1000 patient discharges (1.57 in period 1), and other events occurred at rates 0.53 to 5.9/1000 patient days in period 1 (Table 1).

Table 1: Model-based estimates for associations between average patients per nurse and clinical outcomes. Multivariable models were adjusted for EPOCH intervention, transplant hospital, medical emergency team hospital, overnight In-house fellow trainee, and mean BedsidePEWS score.

Outcome	Period 1 Rate	Univariable		Multivariable			
				All Sites		Excluding Site 21	
		OR (95% CrI)	P(OR <1)	OR (95% CrI)	P(OR <1)	OR (95% CrI)	P(OR <1)
Hospital Mortality (deaths per 1000 discharges)	1.57	0.82 [0.59, 1.08]	92.1%	0.77 [0.57, 1.00]	97.7%	0.6 [0.35, 0.97	98.2%
Outcomes measured as a rate per 1000 ward-days							
Outcome	Period 1 Rate	RR (95% CrI)	P(RR <1)	RR (95% CrI)	P(RR <1)	RR (95% CrI)	P(RR <1)
Clinical Deterioration	3.49	0.88 [0.77, 1.03]	95.4%	0.90 [0.78, 1.05]	92.0%	1.04 [0.83, 1.3]	37.4%
Late ICU admission (i.e., CRIS ≥ 3)	0.74	0.76 [0.53, 1.06]	94.9%	0.81 [0.56, 1.14]	89.7%	0.63 [0.36, 1.11]	94.6%
Stat Call	5.91	1.16 [0.55, 2.43]	34.6%	1.34 [0.61, 2.95]	77.8%	0.98 [0.32, 2.93]	51.6%
Resuscitation Team	0.53	0.82 [0.60, 1.10]	91.3%	0.82 [0.59, 1.14]	89.0%	0.77 [0.44, 1.33]	82.9%
PICU Consultation	4.79	0.95 [0.71, 1.29]	62.7%	0.92 [0.69, 1.23]	71.4%	0.98 [0.66, 1.44]	55.2%

Legend: CRIS=Children resuscitation intensity scale; ICU=intensive care unit; OR=odds ratio per 1 unit increase in the patient nurse ratio; PICU=pediatric ICU; RR=rate ratio per 1 unit increase in the patient nurse ratio; CrI=credible interval. Multivariable, all sites: The multivariable model including all sites. Multivariable, excluding site 21: Multivariable model excluding site with an outlying patient-nurse ratio.

In univariate analyses we found a higher number of patients per nurse was associated with lower odds of hospital mortality, and lower rates of clinical deterioration events, late ICU admissions, and resuscitation team calls. In multivariable models, point estimates for these four associations were similar to the estimates from univariate analyses; the probability of a reduction in mortality with a higher patient-nurse ratio increased, but other probabilities of associations decreased (Table 1).

Figure 2 plots the association of each of these study outcomes with nurse staffing by 26-week study period, with the estimated univariate association overlaid. In the sensitivity analysis excluding the hospital with a high patient-nurse ratio, the associations with hospital mortality and late ICU admissions were stronger, but the evidence for all other associations with clinical events was weaker (Right-hand columns of Table 1 and supplementary Figure 1).

In multivariable models, nurse perceptions tended to be less favorable in hospitals where nurses were caring for more patients: point estimates of ORs were all < 1, meaning that the odds of more favorable perceptions decreased as the patient-nurse ratio increased. However, it was only for influence on care that there was a high probability (> 95%) that the OR was < 1 in either the univariate or multivariable model. (Table 2).

Table 2: Model-based estimates of the odds ratio for a better score on the Documentation and Interaction Survey (DIS) Outcomes with increasing values of average patients per nurse

DIS Item	Univariable		Multivariable			
			All Sites		Excluding Site 21	
	OR (95% CI)	P(OR<1)	OR (95% CI)	P(OR<1)	OR (95% CI)	P(OR<1)
Communication Quality	0.97 [0.84, 1.15]	65.9%	0.95 [0.81, 1.19]	68.5%	1.02 [0.78, 1.37]	43.5%
Apprehension	1.10 [0.89, 1.34]	18.1.%	0.94 [0.79, 1.12]	78.6%	1.01 [0.76, 1.33]	47.0%

Care is Timely & Quality	0.95 [0.79, 1.17]	68.2%	0.87 [0.71, 1.11]	87.9%	0.82 [0.59, 1.17]	87.3%
Influence Care	0.87 [0.74, 1.01]	97.0%	0.85 [0.73, 0.98]	98.5%	0.78 [0.58, 1.01]	97.1%

Legend: DIS= Documentation and Interaction Survey. Data were extracted from the Documentation and Interaction Survey (DIS). Multivariable proportional odds models were adjusted for transplant program hospital, medical emergency team hospital, overnight in-house fellow coverage, mean BedsidePEWS score and EPOCH intervention. OR: odds ratio, the relative change in the odds of a better DIS outcome for a one unit increase in the patient-nurse ratio. An OR < 1 means that the DIS score worsens with an increasing patient-nurse ratio.

Findings were largely unchanged in the sensitivity analysis. Supplementary figure 2 shows the nurse perceptions for surveys from site-periods where the patient nurse ratio was in the bottom quartile, middle two quartiles and top quartile.

Documentation of several clinical observations was also related to nurse staffing. Adjusted analyses found, as the patient-nurse ratio increased, greater than 95% probability of reduced documentation for each vital sign, with two exceptions, temperature and respiratory effort. Documentation of the complete set of vital signs was also reduced with increased patient-nurse ratio (Table 3).

Table 3: Model-based estimates of the association between average patients per nurse and vital signs documentation

Outcome	Period 1 Mean Number of Measurements/ Patient/24hrs	Univariable		Multivariable	
		RR (95% CI) (per patient to-nurse)	P(RR<1)	RR (95% CI) (per patient to-nurse)	P(RR<1)
Heart Rate	6.59	0.87 [0.76, 1.00]	97.6%	0.83 [0.72, 0.95]	99.6%

Respiratory Rate	6.14	0.87 [0.73, 1.03]	94.3%	0.81 [0.68, 0.96]	99.2%
Systolic blood pressure	3.8	0.88 [0.73, 1.06]	91.7%	0.80 [0.68, 0.95]	99.4%
Oxygen saturation	5.84	0.93 [0.76, 1.13]	77.8%	0.83 [0.68.1.02]	96.4%
Capillary refill time	1.63	1.1 [0.31, 3.97]	43.8%	0.37 [0.09, 1.19]	95.2%
Oxygen therapy	6.16	0.81 [0.62, 1.08]	92.9%	0.73 [0.55, 0.96]	98.7%
Respiratory effort	2.38	0.98 [0.67, 1.53]	53.9%	0.83 [0.46, 1.45]	75.0%
All of above collected	3.93	0.93 [0.63, 1.34]	65.6%	0.72 [0.51, 0.99]	97.8%
Temperature	5.47	0.95 [0.87, 1.05]	83.8%	0.98 [0.88, 1.1]	66.8%

Legend: RR: rate ratio, the relative change in the rate of documentation for a one unit increase in the patient-nurse ratio; P(RR<1) = posterior probability that there is a reduction in the rate of documentation with an increasing patient-nurse ratio. The multivariable model adjusted for transplant program hospital, medical emergency team hospital, overnight in-house fellow coverage, hospital severity of illness (mean BedsidePEWS score) and EPOCH intervention. With the exclusion of the outlying site, only capillary refill [RR 0.27; 95% CrI 0.06, 1.18; Pr(RR<1)=95.8%] and "all of the above" [RR 0.78; 95% CrI 0.57, 1.07; Pr(RR<1)=94.1%] had strong evidence of associations. For all other vital signs, probabilities of reductions with a higher patient-nurse ratio were 83% or lower.

With the exclusion of the outlying hospital, there were reductions in documentation with an increased patient-nurse ratio, but the probabilities of reductions were lower (Supplementary table A2).

DISCUSSION

We evaluated the associations of nurse staffing with mortality, clinical process measures (clinical deterioration events, resuscitation team calls, stat calls and PICU consultations), documentation of vital signs, and nurse perceptions of care in a secondary analysis of prospective clinical trial data from 217,174 patient-discharges in 22 hospital sites in 7 high-income countries (21). To our knowledge, this is the first study reporting on the association of patient-to-nurse ratios on acute care pediatric wards with in-hospital mortality, unplanned admissions, or failure to rescue. There are 3 main findings and related implications.

First, we found that higher patient-to-nurse ratio was associated with lower mortality and fewer process of care events, including resuscitation team calls, clinical deterioration events, and late ICU admission. Urgent ICU consultations were also less frequent, although not convincingly reduced. The robustness of our findings is suggested by consistency of observed effects in univariable and multivariable models (adjusted for patient risk and non-nurse staffing variables), by concordance of the direction of effects for different related process of care outcomes, and by workload-related findings. Our results contrast with evidence from other observational studies in adult hospital settings linking higher patient-to-nurse ratio with in-hospital mortality and failure to rescue (8,24–29). While there is some evidence of the association of nurse staffing levels with critical deterioration events for the neonatal and pediatric intensive care settings (2–6), current literature for pediatric wards shows no association with in-hospital mortality (4) or an association of increased nurse staffing levels with increased failure to rescue, which is consistent with our results (3). The data from this study challenge the assumption that care is less safe or of lower quality when there are higher patient-to-nurse ratios, or that more nurses are needed for patient safety on pediatric wards, and that having higher patient-to-nurse ratios invariably leads to adverse clinical and process outcomes. On the other hand, different issues, such as simultaneity of the observed associations may be at stake. As measures of patient acuity influence nurse staffing decision making, the outcome can causally influence staffing levels the same as staffing levels can influence the outcome. As patients with higher acuity at risk of worse outcomes will have higher staffing levels, this may underestimate the true effect of nursing staffing (30). In fact, the results of this study may show that the allocation of nurse staffing ratios in pediatric wards are in accordance with patient's risk of mortality, not a casual relationship between the two. More studies are needed to understand what other factors, such as nurse staffing characteristics or other healthcare professionals ratios might possibly contribute to determine a casual relationship between nurse staffing and mortality in pediatrics. Factors protective of child mortality on the wards such as parent's presence at the child's bedside should also be explored (31).

Second, documentation of vital signs was less frequent with higher patient-to-nurse ratio. Adjusted analyses found that documentation of heart rate, respiratory rate, systolic blood pressure, oxygen saturation, capillary refill time, and oxygen therapy, as well as the entire set of vital signs, were documented less often with higher patient-to-nurse ratio. While the association or higher level of nurse staffing and the completeness and timeliness of vital signs monitoring is reported in the adult setting, the effect of increased nurse staffing on this process is small (32).

Third, nurses working in hospitals with higher patient-to-nurse ratios reported greater apprehension when calling a physician after hours, and perceived worse communication quality, timeliness of care, and reduced ability to influence care; the finding was strongest for influence of care. This result is consistent with published observational studies suggesting worse patient outcomes and quality of care in hospitals with less staffing in adult inpatient wards (7,28,29,33,34), neonatal ICU (14,16,35,36), and paediatric ICUs (17–20), and of studies linking less favourable perceptions of quality and safety with lower nurse staffing (24,37,38). Our findings of less favorable nurse perceptions associated with higher patient-to nurse ratio is consistent with our finding of reduced documentation; however, this contrasts with our objective data of lower mortality and fewer clinical events with less intensive nurse staffing. It is possible that increased workload in hospitals with higher patient-to-nurse ratio may be influencing perceptions of care quality. It is likely that for most respondents their frame of reference is dominated by the hospital in which they work; that is, the local culture may lead to different expectations of quality and safety that is separate from the objectively observed trial data. We hypothesize that greater expectations of frontline staff may be mitigating any adverse consequences of higher patient-to-nurse ratio and contributing to lowered rates of adverse outcomes. Further research is needed.

Limitations

There are several limitations of this study. First, our measure of patient-to-nurse staffing was from a randomly selected sample of beds in the inpatient ward areas where studied patients received care. Ideally the nurse staffing would have been recorded for all patients on all days of the 78 weeks of the study. Other approaches, including aggregating nurse staffing each patient day, or sampling a larger sample, may have increased the precision of our description of staffing. Our finding of relative stability of estimates from the 130 patients sampled from each 26-week period in the study suggests the approach used was not subject to major random variation. Second, unmeasured factors may be confounding the association between patient-to-nurse ratio and the study outcomes. Possible factors include physician staffing ratios (39) that may be related to a 'teaching hospital' effect; the availability of licensed practice nurses (LPNs) or vocational nurses to moderate the nursing workload; and other patient confounding variables such as case-mix, age and comorbidities. It is possible that higher patient-to-nurse ratios were tailored to lower acuity patients, although random sampling should have minimized this potential bias. The effects of these factors should be evaluated in further research. Third, unaccounted differences in nurse education and skill-mix might have confounded our results. Increased rates of Registered Nurses and nursing support staff (33,34), nurses with Bachelor degrees (8,40,41), nurses with higher levels of education (42), or improved working environments (24) were found to be essential in reducing safety failures, in-hospital failure-to-rescue and deaths in the adult patient population (29).

Strengths

The multicenter international prospective data collection including 217,174 patient-discharges in 22 hospital sites in 7 high-income countries is a strength of this study. This improves the generalizability of the results of the findings.

CONCLUSIONS

Our 22 -hospital evaluation found that mortality, clinical deterioration, and resuscitation team activation were about 10-20% less frequent with each additional patient per nurse. Our findings were consistent across multiple analyses and in six related measures, and contrast with prior observational data in the adult population showing increased nurse staffing was associated with reduced events. Our prospective data are hypothesis generating and may help reinforce consideration of other factors, including skill mix, education requirements, experience, and physician ratios before implementing well-intentioned decisions to increase nurse staffing to improve patient safety and quality of care.

Figure 1: Average patients per nurse and total number of ward-days by hospital.
This figure plots the total number of ward days in a period at a site against the average patient-nurse ratio in that period at that site, with periods at the same site plotted in the same colour. The boxplots in the margin show the 25^{th} and 75^{th} percentiles and medians across site-periods.

Figure 2: The association of the mortality and process of care study outcomes and nurse staffing.
Each of the 6 panels plots the rate of the outcome in a period at a site against the average patient-nurse ratio in that period at that site, with the areas of the circles being proportional to the

number of patient discharges or number of ward days. The fitted values from the univariate random effects models are shown by the solid line (mean) and shaded area (95% CrI).

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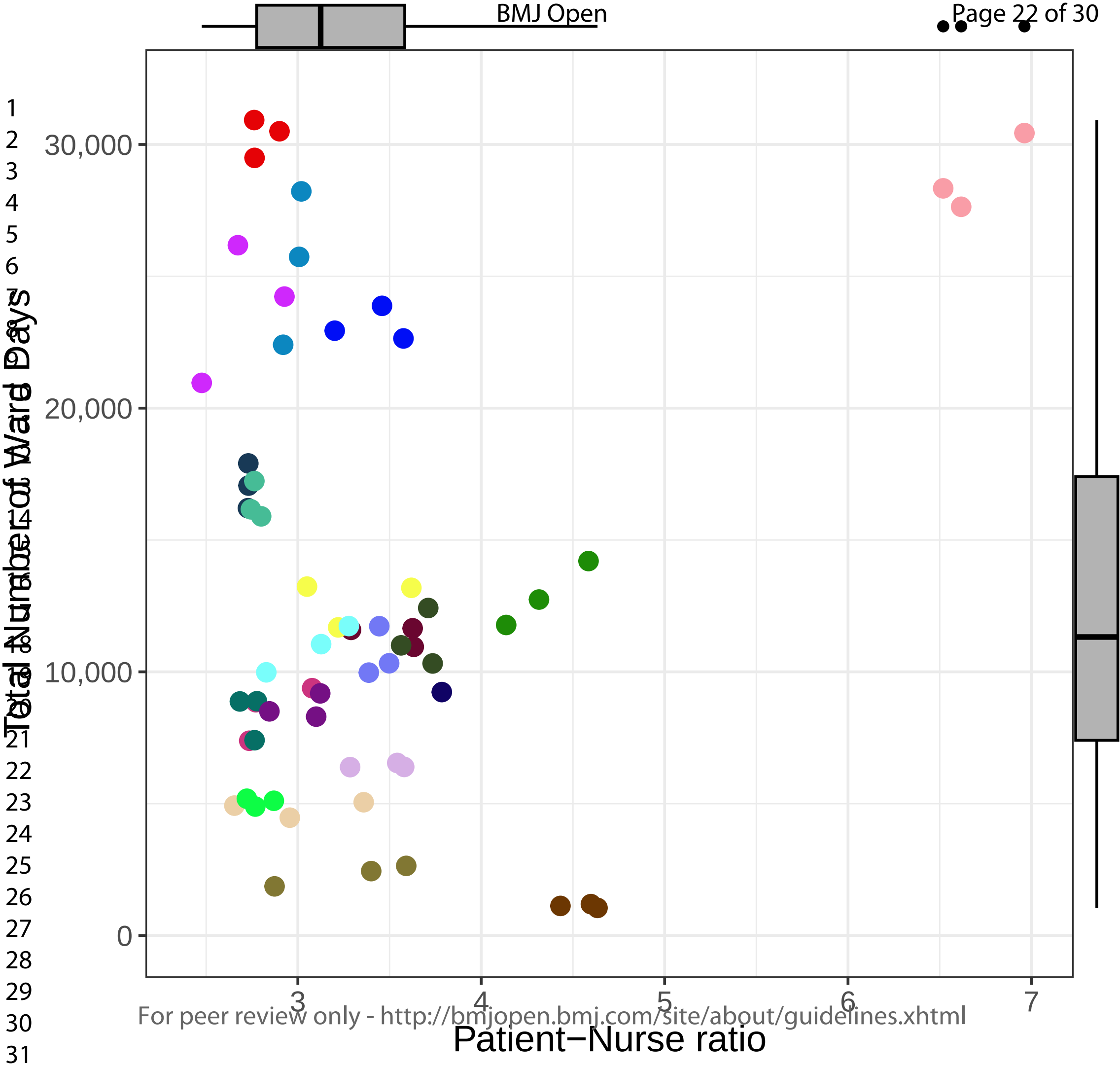
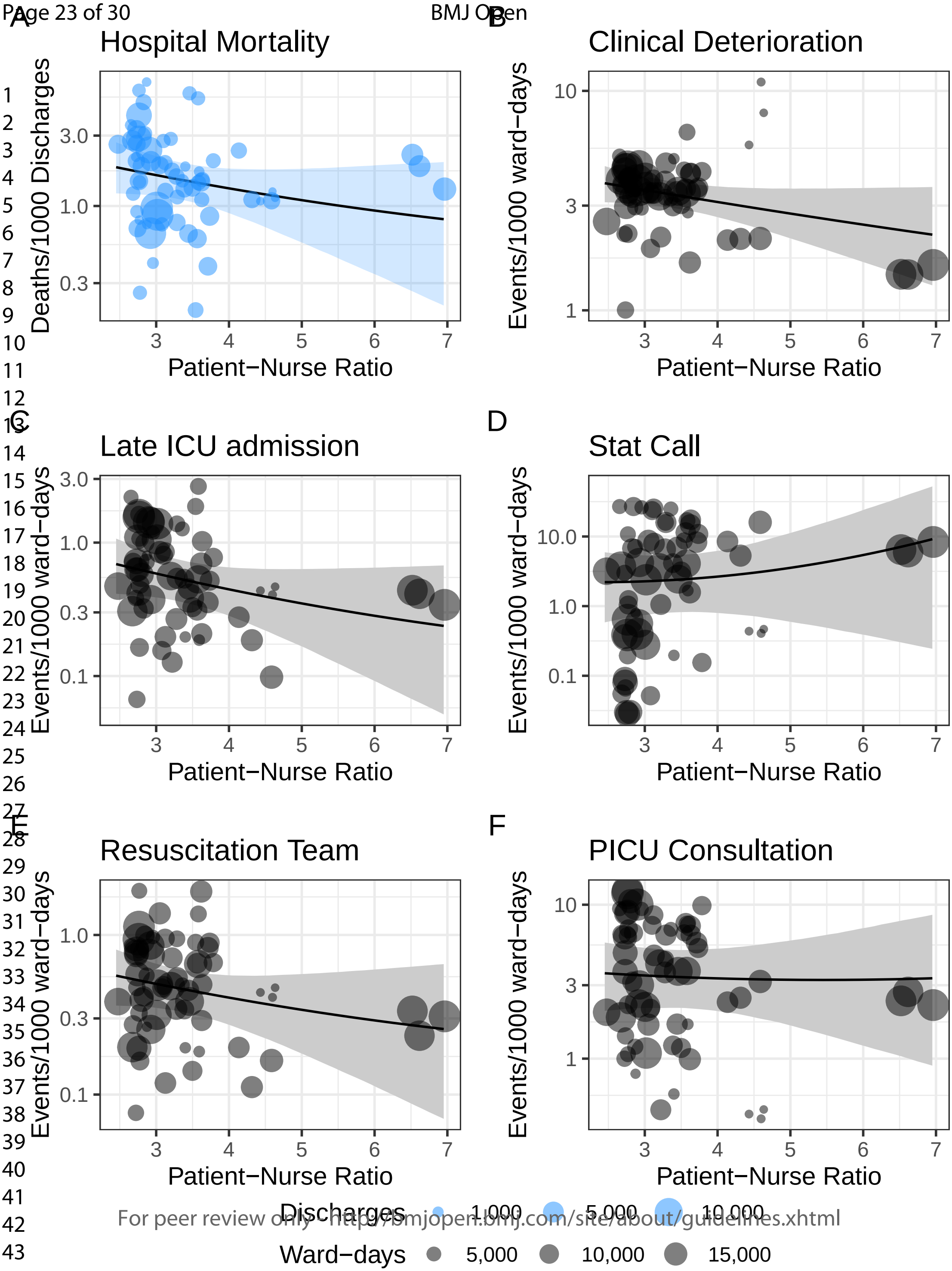

Total Number of Ward Days
30,000
20,000
10,000
0
3
4
5
6
7
Patient−Nurse ratio

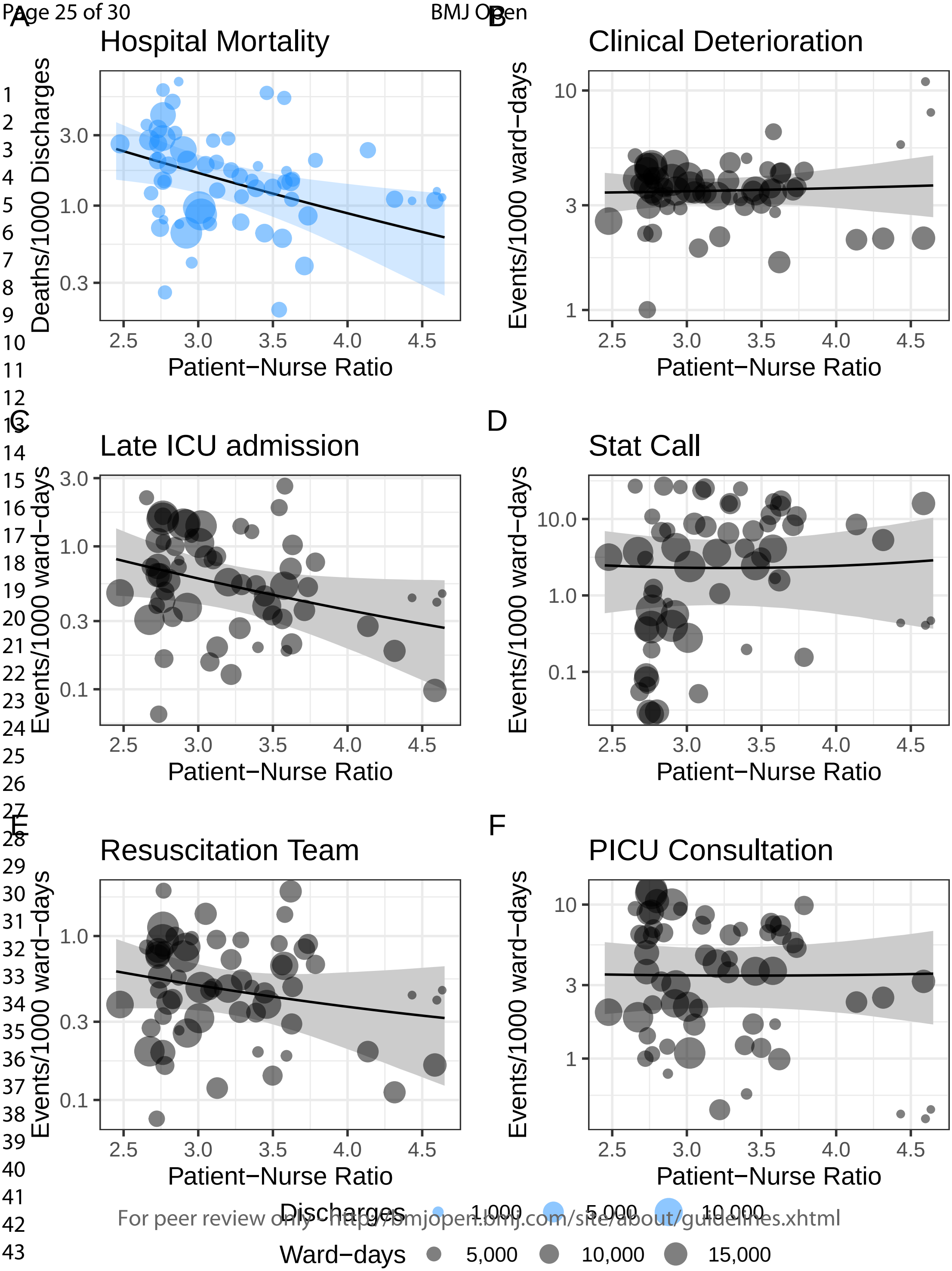


A
Hospital Mortality
Deaths/1000 Discharges
3.0
1.0
0.3
Patient−Nurse Ratio
B
Clinical Deterioration
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
C
Late ICU admission
Events/1000 ward−days
3.0
1.0
0.3
0.1
Patient−Nurse Ratio
D
Stat Call
Events/1000 ward−days
10.0
1.0
0.1
Patient−Nurse Ratio
E
Resuscitation Team
Events/1000 ward−days
1.0
0.3
0.1
Patient−Nurse Ratio
F
PICU Consultation
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
3 4 5 6 7
Discharges 1,000 5,000 10,000
Ward−days 5,000 10,000 15,000

Supplementary Figure 1A

The association of the study outcomes and nurse staffing by study period, excluding site 21 (sensitivity analysis)

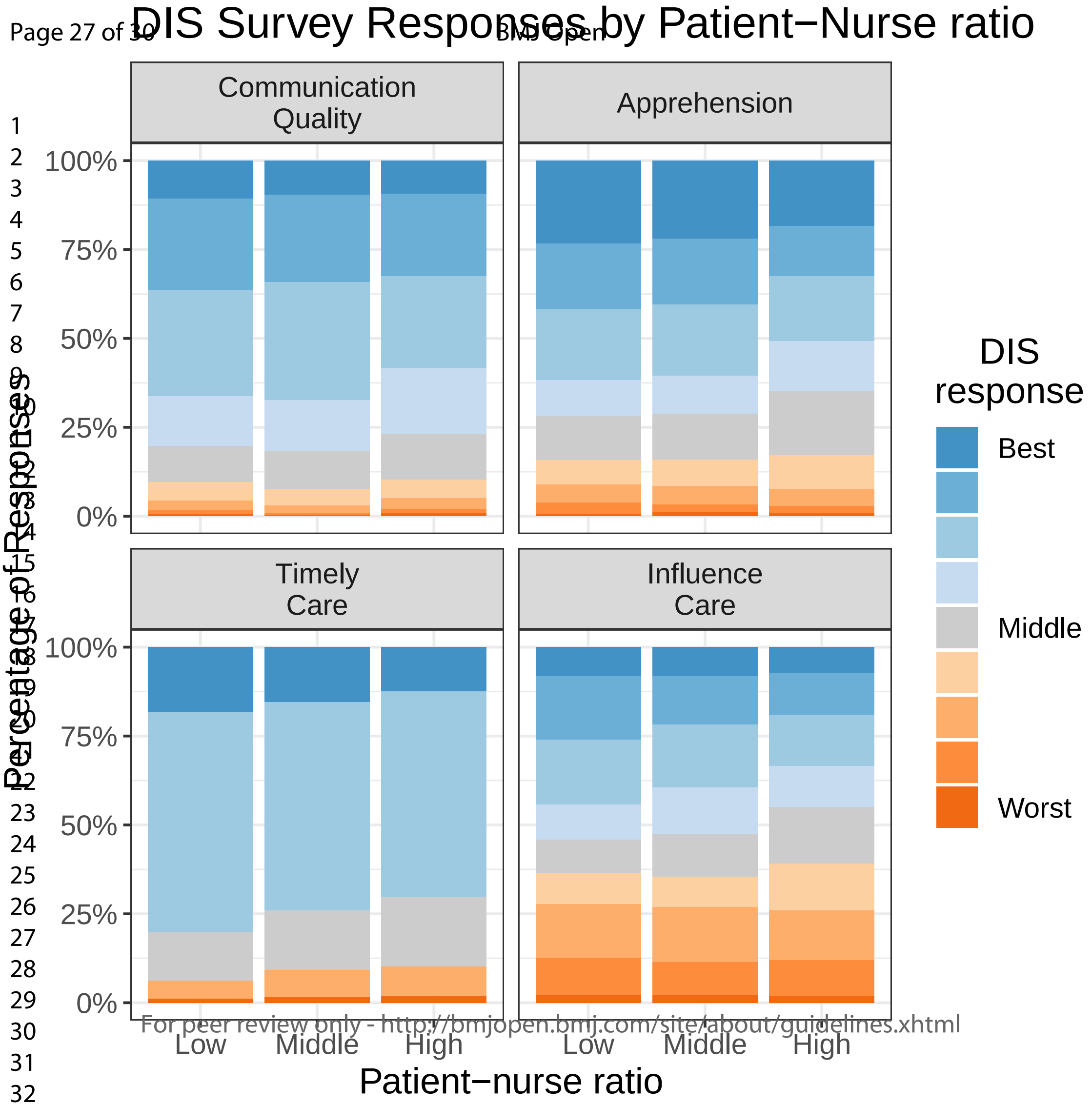
Figure 1A: After excluding the site with outlying patient-nurse ratios in all three period, the association of the mortality and process of care study outcomes and nurse staffing. Each of the 6 panels plots the rate of the outcome in a period at a site against the average patient-nurse ratio in that period at that site, with the areas of the circles being proportional to the number of patient discharges or number of ward days. The fitted values from the univariate random effects models are shown by the solid line (mean) and shaded area (95% CrI).


A
Hospital Mortality
Deaths/1000 Discharges
3.0
1.0
0.3
Patient−Nurse Ratio
2.5 3.0 3.5 4.0 4.5
B
Clinical Deterioration
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
C
Late ICU admission
Events/1000 ward−days
3.0
1.0
0.3
0.1
Patient−Nurse Ratio
D
Stat Call
Events/1000 ward−days
10.0
1.0
0.1
Patient−Nurse Ratio
E
Resuscitation Team
Events/1000 ward−days
1.0
0.3
0.1
Patient−Nurse Ratio
F
PICU Consultation
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
Discharges 1,000 5,000 10,000
Ward−days 5,000 10,000 15,000

Supplementary figure 2A: nurse perceptions of quality of care (sensitivity analysis, excluding site 21)

Figure 2A: Distributions of DIS responses for communication quality (9-point scale), apprehension (9-point scale), timely care (5-point scale) and influence care (9-point scale) from nurses, where higher scores are better perceptions. The responses are grouped according to whether they were collected from a site-period with a nurse -patient ratio in the lowest quartile, middle two quartiles, or highest quartile. The 5 point scale was coded so that 5 was "best", 3 was "middle" and 1 was "worst" (with 4 mapping onto 7, and 2 mapping onto 3 on the 9-point scale). As the ratio increases, there are proportionally more orange bar segments (worse perceptions) and fewer blues ones (better perceptions).

Legend: DIS=Documentation and Interaction Survey


DIS Survey Responses by Patient−Nurse ratio
Communication Quality
Apprehension
Timely Care
Influence Care
100%
75%
50%
25%
0%
Percentage of Responses
Low
Middle
High
Patient−nurse ratio
DIS response
Best
Middle
Worst

Appendix

Table 1A: Sources of data

Data role	Data	Measurement level	Source within EPOCH	Comment
Outcomes	Clinical outcomes (mortality, clinical deterioration events, late ICU admissions, duration of hospital stay, etc.)	One outcome per patient	Clinical trial outcomes database	All 217,174 patients in the trial had these outcomes documented
	Vital signs documentation	One value per patient	Random selection of 5 patients each week for the 26 weeks of each study period at each site	8,282 patients were assessed for documentation of vital signs
	Documentation and Interaction Survey	One survey per nurse	Nurses at enrolled hospitals	All nurses were approached
Predictors	Patient to nurse ratio	One value per site per time period	Random selection of 5 patients each week for the 26 weeks of each of three study periods at 22 sites	The ratio was based on the average number of patients being cared for by nurses of the selected 8,282 patients.
	Site-specific descriptors (Mean BP,Medical team,PM MD/Fellow,Transplant)	One value per site per time period	Clinical trial site descriptors database	Mean BP could vary by study period. Other descriptors were constant

Table 2A: Vital Signs Monitoring sensitivity analysis (excluding site 21)

Outcome	Univariable		Multivariable	
	RR (95% CrI)	Pr(RR<1)	RR (95% CrI)	Pr(RR<1)
Heart Rate	0.98 [0.86, 1.13]	60.4%	0.96 [0.83, 1.10]	74.0%
Respiratory Rate	1.01 [0.88, 1.17]	43.3%	0.98 [0.83, 1.14]	62.5%
Systolic blood pressure	1.01 [0.79, 1.31]	45.6%	0.89 [0.71, 1.13]	83.4%
Oxygen saturation	1.06 [0.89, 1.27]	25.7%	0.98 [0.81, 1.19]	57.8%
Capillary refill time	0.97 [0.17, 4.77]	52.0%	0.27 [0.06, 1.18]	95.8%
Oxygen therapy	0.92 [0.73, 1.15]	77.8%	0.89 [0.70, 1.14]	81.8%
Respiratory effort	1.04 [0.52, 2.32]	45.6%	0.86 [0.34, 2.01]	63.3%
All of above collected	1.11 [0.76, 1.62]	28.9%	0.78 [0.57, 1.07]	94.1%
Temperature	0.99 [0.89, 1.09]	60.3%	1.00 [0.89, 1.13]	51.3%

Vital signs monitoring -random effects negative binomial models. Estimates are rate ratios (RR) for the relative change in the rate of documentation with one additional patient per nurse, 95% CrIs and P(RR < 1), the probability that the rate of documentation is reduced with an increasing patient-nurse ratio.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5-7*
Bias	9	Describe any efforts to address potential sources of bias	7-8
Study size	10	Explain how the study size was arrived at	In original EPOCH trial
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	N/A
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	7-8

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	/
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*9-12*
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-12
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	N/A

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

BMJ Open

Evaluating associations between Patient-to-Nurse ratios and mortality, process of care events, and vital sign documentation on pediatric wards: A secondary analysis of data from the EPOCH cluster randomized trial

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Secondary Subject Heading:	Health services research, Paediatrics, Nursing
Keywords:	PAEDIATRICS, Mortality, Nurses, Hospitals, Human resource management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Title: Evaluating associations between patient-to-nurse ratios and mortality, process of care events, and vital sign documentation on pediatric wards: A secondary analysis of data from the EPOCH cluster-randomized trial

ABSTRACT

Objective: to describe the associations between patient-to-nurse staffing ratios and rates of mortality, process of care events, and vital sign documentation.

Design: Secondary analysis of data from the EPOCH cluster-randomized trial.

Setting: 22 Hospitals caring for children in Canada, Europe, and New Zealand.

Participants: Eligible hospitalized patients were aged >37 weeks and <18 years.

Primary and secondary outcome measures: The primary outcome was all cause hospital mortality. Secondary outcomes were five events reflecting process of care also collected on all EPOCH patients; the frequency of documentation for each of eight vital signs on a random sample of patients; four measures describing nursing perceptions of care.

Results: A total of 217,714 patient admissions for 849,798 patient days over the course of the study were analyzed. The overall mortality rate was 1.65/1000 patient discharges. Univariate Bayesian models estimating the rate ratio (RR) for the patient-nurse ratio and the probability that the RR was less than one found that a higher patient-nurse ratio was associated with fewer clinical deterioration events (RR=0.88, 95% CrI 0.77, 1.03; P(RR < 1) = 95%) and late ICU admissions (RR=0.76, 95% CrI 0.53, 1.06; P(RR<1)=95%). In adjusted models, a higher patient-to-nurse ratio was associated with lower hospital mortality (odds ratio (OR) =0.77, 95% CrI=0.57, 1.00; P(OR < 1)=98%). Nurses from hospitals with a higher patient-to-nurse ratio had lower ratings for their ability to influence care, and reduced documentation of most individual vital signs and of the complete set of vital signs.

Conclusions: The data from this study challenge the assumption that lower patient-to-nurse ratios are the solution for making pediatric care more safe. The mechanism of these effects warrants

further evaluation including factors, such as nursing skill mix, experience, education, work environment and physician staffing ratios.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study is based on a multicenter international prospective data dataset of > 210,000 patient-admissions in 22 hospital sites in 7 high-income countries
- The measure of patient-to-nurse staffing was from a randomly selected sample of beds in the inpatient ward areas where studied patients received care.
- Staffing levels and clinical outcomes represent an average over three six month periods.
- Individual patient-level risk adjustment and a wider range of variables to control for case mix and general hospital resources would have increased the precision of our results.
- Unmeasured factors may be confounding the association between patient-to-nurse ratio and the study outcomes.

INTRODUCTION

Nurses are the primary human resource for clinical observation and the delivery of patient care in pediatric hospitals. They are essential components of Rapid Response Systems with roles that include monitoring clinical condition, communicating to others in the primary care team, and escalating the intensity of care as determined by the child's severity of illness (1). Low patient-to-nurse ratios are a well-accepted strategy to mitigate already identified patient risk in intensive care units (ICU) (2–5). In observational studies, lower patient-to-nurse ratios have been associated with lower mortality in adult patients (6,7) and with lower hospital readmission at 15-30 days in children (8). Standards of pediatric nursing care on hospital wards require comprehensive and continuous patient assessments, vital signs measurement, and documentation (9,10) to provide information on early signs of clinical deterioration (11). High patient-to-nurse ratios increase workload for each nurse, which may reduce the frequency of vital signs monitoring, and compromise the effectiveness of interventions and communication (12–15).

While there is evidence on the association of nurse staffing levels and patient mortality in the adult inpatient setting, in pediatric settings this evidence is limited (16,17). A study using nurse staffing administrative data in California from 1996-2001 examining 3.65 million discharges from 286 general and children's hospitals reported no association of patient-to-nurse staffing and mortality in children (18). Another study using the Healthcare Cost and Utilization Project Kids' Inpatient Database (KID) in California showed no association of nurse ratios and Registered Nurses (RN) FTEs with lower risk-adjusted mortality, risk-adjusted complications and risk-adjusted resource utilization for pediatric cardiac surgical services (19). Moreover, a study performed in Korea including over 600,000 children admitted to 46 tertiary care hospitals showed an increased risk of failure to rescue associated with lower patient-to-nurse staffing ratios (Grade 1 (beds/nurse<2), OR 1.39; 95% CI 1.15, 1.70; compared to grade 3 (2.5 ≤ beds/nurse < 3). In the same study, in addition, an association with a better composite outcome of cardiac arrest, shock, or respiratory failure was found with lower patient-to-nurse ratios (grade 1 compared to grade 3 OR 0.48; 95% CI 0.40, 0.58) (20). In the Neonatal ICU setting there is some evidence of an association between patient-to-nurse staffing levels or increased proportions of nurses with neonatal certifications and reduced neonatal mortality (21). In Pediatric ICU (PICU) an association with lower mortality and lower odds of complications was found with increased years of nursing experience and nurses with Bachelor or higher degrees (22–25). Current evidence on safe patient-to-nurse ratios for the pediatric setting is limited and much needed to support future nursing workforce planning (17). Therefore, the objective of this study was to determine the association between patient-to-nurse staffing and rates of clinical deterioration events, and processes and perceptions of care on in-hospital pediatric wards.

METHODS

We performed a secondary analysis of data from 217,714 patient admissions in acute care pediatric wards the 22 hospitals included in the "Evaluating processes of care and outcomes of children in hospital" (EPOCH) cluster randomized trial (26). Outcomes were available for all patients without loss to follow-up. The hospitals were located in Belgium (n=1), Canada (n=11), the United Kingdom (n=5), Ireland (n=2), Italy (n=1), New Zealand (n=1), and the Netherlands (n=1) and had a total of 2085 eligible inpatient unit beds (26). Three hospitals had >200 beds, 10 (45%) had a 24/7 Rapid Response Team and 20 (91%) were University affiliated. Eleven hospitals were randomized to implement the Bedside Pediatric Early Warning System (BedsidePEWS).

Main exposure

The main exposure of interest was patient-to-nurse staffing on inpatient wards of participating hospitals. Within each of three 26-week study periods at each hospital, we recorded the total number of patients cared for by the primary nurse of five randomly selected patients, who were eligible on an inpatient ward for more than 24 hours. The mean value of the (5 patients) × (26 weeks) = 130 measurements collected in each 26-week period was used to represent typical staffing levels on the inpatient wards of each hospital for that period (26).

Primary and secondary outcomes

The primary outcome was hospital mortality. This was also the primary outcome of the EPOCH trial. Secondary outcomes were (a) five events reflecting process of care, also collected on all EPOCH patients: clinical deterioration events, late ICU admissions, resuscitation team calls, stat calls and PICU consultations; (b) the frequency of documentation for each of eight vital signs on the random sample of patients; and (c) four measures describing nursing perceptions of care.

Clinical deterioration events

Amongst secondary outcomes reflecting process of care, clinical deterioration events were defined as deaths on the ward or urgent admission to a PICU, which itself was defined as an admission with departure from the event location in less than six hours from the time the PICU admission was initiated (26). The timeliness of urgent PICU admissions was classified using the Children Resuscitation Intensity Scale (CRIS), with scores that range from 1 (no major interventions) to 7 (death before or within the first hour after ICU admission); a score >2 was classified as a late ICU admission (26).

Vital signs documentation

Vital signs were documented on the randomly selected patient records. We abstracted the number of documented measurements over a 24-hour period for each patient for each of eight clinical observations: heart rate, respiratory rate, systolic blood pressure, oxygen therapy, oxygen saturation, capillary refill time, respiratory effort, and temperature. We defined vital sign recording as complete when the first seven of these (the clinical indicators in the BedsidePEWS) were documented. We also calculated the BedsidePEWS score (if at least five of the seven measurements were available) from the last available set of vital signs.

Nurses perceptions of quality of patient care

Nurses' perceptions of quality of patient care were recorded once in each study period using a Documentation and Interaction Survey, developed and used extensively in the parent study. This survey had the aim of exploring the perception of the documentation system and quality of care. Questions were judged to have high face validity by the study group, although not formally validated. Responses to the communication quality question "How do you rate communication about patients on your team?" were on a 9-point scale from 1, (extremely poor) to 9 (excellent). Responses to the timely care question "Please indicate your agreement/disagreement with the statement: 'Patients have received the care that they needed when they needed it'" were on a 5-point scale from 1 (strongly disagree) to 5 (strongly agree). Responses to the apprehension question "When calling a physician after-hours to review the patient or their management plan, how apprehensive did you feel?" were on a 9-point scale from 1 (extremely apprehensive) to 9 (not at all apprehensive). Responses to the influence on care question "How confident did you feel that you could influence the plan of care?" were on a 9-point scale from 1 (extremely confident) to 9 (not at all confident), which we reversed, so that a 9 became "extremely confident".

Adjustment variables

In recognition of the modest number of site-by-period observations in the study data set, we carefully considered options for adjustment variables. After consideration of seven options describing the hospital resources – (1) the proportion of full-time (>90% full-time equivalent) registered nurses, (2) number of pediatric beds, (3) presence of a transplant program, (4) overnight in-house consultant pediatrician, (5) overnight in-house senior trainee (fellow), (6) 24/7 medical emergency team, and (7) mean severity of illness – four adjustment variables were used. Two reflected patient risk for deterioration – the presence of a transplant program and the average patient severity of illness (measured as the mean BedsidePEWS score at the site in the period). Two reflected non-nurse staffing resources – the presence of in-house overnight senior trainee (fellow) and having a medical emergency team. We also adjusted by a fifth variable indicating whether the period was assigned to the EPOCH intervention. Table 1A in the supplement summarizes the sources and roles of all variables included in our analyses.

Statistical analysis

Clinical outcomes were aggregated over each 26-week period and represented as rates. Mortality was summarized as deaths per 1000 patient discharges. Five process of care outcomes (clinical deterioration events, late PICU admissions, immediate calls to a physician to attend at the bedside of a patient, resuscitation team calls, and PICU consultations) were summarized as events per 1000 patient days. To assess the dependence of hospital mortality on the patient-to-nurse ratio, we entered aggregate death and admission data for each site in each period into a random effects logistic regression, with site-specific random effects and site-and-time specific predictors (EPOCH intervention, patient-nurse ratio, presence of transplant team, the presence of in-house overnight senior trainee presence of a medical emergency team, and the mean BedsidePEWS).

Similar analyses were used for process of care events, except that random effects negative binomial models were used, with event counts as the outcome, and the logarithm of site-period totals of patient ward-days as an offset. Analyses of documentation of vital signs also used a random effects negative binomial models, with aggregated counts of documentation as the outcome and logarithm of the total number of assessments on the randomly selected patients as the offset.

A random effects proportional odds regression model was used to assess the dependence of nurse-reported perceptions of quality of care on the patient to nurse ratio, with site-specific random effects and the same site-and-time specific predictors as above. All models were fitted using Bayesian models in the brms package in R and measures of association are presented with a 95% credible interval (CrI) and the Bayesian posterior probability of a reduction in the outcome with a higher patient-to-nurse ratio. After inspection of the data a post-hoc sensitivity analysis was performed in which we excluded a hospital that was an outlier (site 21) with respect to the patient-nurse ratio.

This study was approved by the Human Research Ethics Board at the Hospital for Sick Children, Toronto, Canada (Approved REB # 1000062622).

RESULTS

Data from 22 hospitals participating in the EPOCH trial (26) included 217,174 patients and 849,798 patient days. Random sampling selected 8282 patients on whom we assessed vital sign documentation and patient-nurse ratios. The median (IQR) number of patients cared for by an individual nurse was 3.0 [2.8, 3.6]. Three hospitals (14%) had a mean patient-to-nurse ratio greater than 4, with one outlier having a patient/nurse ratios of 6.5-7.0 over the three study periods. (Figure 1).

Hospital mortality occurred in 360 patients with an overall rate of 1.65/1000 patient discharges (1.57 in period 1), and other events occurred at rates 0.53 to 5.9/1000 patient days in period 1 (Table 1).

Table 1: Model-based estimates for associations between average patients per nurse and clinical outcomes. Multivariable models were adjusted for EPOCH intervention, transplant hospital, medical emergency team hospital, overnight In-house fellow trainee, and mean BedsidePEWS score.

Outcome	Period 1 Rate	Univariable		Multivariable			
				All Sites		Excluding Site 21	
		OR (95% CrI)	P(OR <1)	OR (95% CrI)	P(OR <1)	OR (95% CrI)	P(OR <1)
Hospital Mortality (deaths per 1000 discharges)	1.57	0.82 [0.59, 1.08]	92.1%	0.77 [0.57, 1.00]	97.7%	0.6 [0.35, 0.97]	98.2%
Outcomes measured as a rate per 1000 ward-days							
Outcome	Period 1 Rate	RR (95% CrI)	P(RR <1)	RR (95% CrI)	P(RR <1)	RR (95% CrI)	P(RR <1)

Clinical Deterioration	3.49	0.88 [0.77, 1.03]	95.4%	0.90 [0.78, 1.05]	92.0%	1.04 [0.83, 1.3]	37.4%
Late ICU admission (i.e., CRIS ≥ 3)	0.74	0.76 [0.53, 1.06]	94.9%	0.81 [0.56, 1.14]	89.7%	0.63 [0.36, 1.11]	94.6%
Stat Call	5.91	1.16 [0.55, 2.43]	34.6%	1.34 [0.61, 2.95]	77.8%	0.98 [0.32, 2.93]	51.6%
Resuscitation Team	0.53	0.82 [0.60, 1.10]	91.3%	0.82 [0.59, 1.14]	89.0%	0.77 [0.44, 1.33]	82.9%
PICU Consultation	4.79	0.95 [0.71, 1.29]	62.7%	0.92 [0.69, 1.23]	71.4%	0.98 [0.66, 1.44]	55.2%

Legend: CRIS=Children resuscitation intensity scale; ICU=intensive care unit; OR=odds ratio per 1 unit increase in the patient nurse ratio; PICU=pediatric ICU; RR=rate ratio per 1 unit increase in the patient nurse ratio; CrI=credible interval. Multivariable, all sites: The multivariable model including all sites. Multivariable, excluding site 21: Multivariable model excluding site with an outlying patient-nurse ratio.

In univariate analyses we found a higher number of patients per nurse was associated with lower odds of hospital mortality, and lower rates of clinical deterioration events, late ICU admissions, and resuscitation team calls. In multivariable models, point estimates for these four associations were similar to the estimates from univariate analyses; the probability of a reduction in mortality with a higher patient-nurse ratio increased, but other probabilities of associations decreased (Table 1).

Figure 2 plots the association of each of these study outcomes with nurse staffing by 26-week study period, with the estimated univariate association overlaid. In the sensitivity analysis excluding the hospital with a high patient-nurse ratio, the associations with hospital mortality and late ICU admissions were stronger, but the evidence for all other associations with clinical events was weaker (Right-hand columns of Table 1 and supplementary Figure 1).

In multivariable models, nurse perceptions tended to be less favorable in hospitals where nurses were caring for more patients: point estimates of ORs were all < 1, meaning that the odds of more favorable perceptions decreased as the patient-nurse ratio increased. However, it was only for influence on care that there was a high probability (> 95%) that the OR was < 1 in either the univariate or multivariable model. (Table 2).

Table 2: Model-based estimates of the odds ratio for a better score on the Documentation and Interaction Survey (DIS) Outcomes with increasing values of average patients per nurse

DIS Item	Univariable		Multivariable			
			All Sites		Excluding Site 21	
	OR (95% CI)	P(OR<1)	OR (95% CI)	P(OR<1)	OR (95% CI)	P(OR<1)
Communication Quality	0.97 [0.84, 1.15]	65.9%	0.95 [0.81, 1.19]	68.5%	1.02 [0.78, 1.37]	43.5%
Apprehension	1.10 [0.89, 1.34]	18.1.%	0.94 [0.79, 1.12]	78.6%	1.01 [0.76, 1.33]	47.0%
Care is Timely & Quality	0.95 [0.79, 1.17]	68.2%	0.87 [0.71, 1.11]	87.9%	0.82 [0.59, 1.17]	87.3%
Influence Care	0.87 [0.74, 1.01]	97.0%	0.85 [0.73, 0.98]	98.5%	0.78 [0.58, 1.01]	97.1%

Legend: DIS= Documentation and Interaction Survey. Data were extracted from the Documentation and Interaction Survey (DIS). Multivariable proportional odds models were adjusted for transplant program hospital, medical emergency team hospital, overnight in-house fellow coverage, mean BedsidePEWS score and EPOCH intervention. OR: odds ratio, the relative change in the odds of a better DIS outcome for a one unit increase in the patient-nurse ratio. An OR < 1 means that the DIS score worsens with an increasing patient-nurse ratio.

Findings were largely unchanged in the sensitivity analysis. Supplementary figure 2 shows the nurse perceptions for surveys from site-periods where the patient nurse ratio was in the bottom quartile, middle two quartiles and top quartile.

Documentation of several clinical observations was also related to nurse staffing. Adjusted analyses found, as the patient-nurse ratio increased, greater than 95% probability of reduced documentation for each vital sign, with two exceptions, temperature and respiratory effort. Documentation of the complete set of vital signs was also reduced with increased patient-nurse ratio (Table 3).

Table 3: Model-based estimates of the association between average patients per nurse and vital signs documentation

Outcome	Period 1 Mean Number of Measurements/ Patient/24hrs	Univariable		Multivariable	
		RR (95% CI) (per patient to-nurse)	P(RR<1)	RR (95% CI) (per patient to-nurse)	P(RR<1)
Heart Rate	6.59	0.87 [0.76, 1.00]	97.6%	0.83 [0.72, 0.95]	99.6%
Respiratory Rate	6.14	0.87 [0.73, 1.03]	94.3%	0.81 [0.68, 0.96]	99.2%
Systolic blood pressure	3.8	0.88 [0.73, 1.06]	91.7%	0.80 [0.68, 0.95]	99.4%
Oxygen saturation	5.84	0.93 [0.76, 1.13]	77.8%	0.83 [0.68.1.02]	96.4%
Capillary refill time	1.63	1.1 [0.31, 3.97]	43.8%	0.37 [0.09, 1.19]	95.2%
Oxygen therapy	6.16	0.81 [0.62, 1.08]	92.9%	0.73 [0.55, 0.96]	98.7%
Respiratory effort	2.38	0.98 [0.67, 1.53]	53.9%	0.83 [0.46, 1.45]	75.0%
All of above collected	3.93	0.93 [0.63, 1.34	65.6%	0.72 [0.51, 0.99]	97.8%
Temperature	5.47	0.95 [0.87, 1.05]	83.8%	0.98 [0.88, 1.1]	66.8%

Legend: RR: rate ratio, the relative change in the rate of documentation for a one unit increase in the patient-nurse ratio; P(RR<1) = posterior probability that there is a reduction in the rate of documentation with an increasing patient-nurse ratio. The multivariable model adjusted for transplant program hospital, medical emergency team hospital, overnight in-house fellow coverage, hospital severity of illness (mean BedsidePEWS score) and EPOCH intervention. With the exclusion of the outlying site, only capillary refill [RR 0.27; 95% CrI 0.06, 1.18; Pr(RR<1)=95.8%] and "all of the above" [RR 0.78; 95% CrI 0.57, 1.07; Pr(RR<1)=94.1%] had strong evidence of associations. For all other vital signs, probabilities of reductions with a higher patient-nurse ratio were 83% or lower.

With the exclusion of the outlying hospital, there were reductions in documentation with an increased patient-nurse ratio, but the probabilities of reductions were lower (Supplementary table A2).

DISCUSSION

We evaluated the associations of nurse staffing with mortality, clinical process measures reflecting failure to rescue, documentation of vital signs, and nurse perceptions of care in a secondary analysis of prospective clinical trial data from 217,174 patient-discharges in 22 hospital sites in 7 high-income countries (26). There are 3 main findings and related implications.

First, we found that higher patient-to-nurse ratio was associated with lower mortality and fewer resuscitation team calls, clinical deterioration events, and late ICU admission. The robustness of our findings is suggested by the consistency of observed effects across [i] single variable analyses, [ii] multivariable analyses that include adjustment for severity of illness, and some organizational factors, [iii] a sensitivity analysis where a potential outlier hospital was excluded and [iv] by concordance of the direction of effects for different related process of care outcomes. Our results contrast with observational studies in adult hospital settings (7,27–31) and in the Neonatal Intensive Care Units where more patients per nurse has been associated with worse outcomes – including mortality (21,32–35).

Differences between paediatric wards settings and adult inpatient wards, paediatric and neonatal ICU settings are numerous. Our review of studies found 2 studies evaluating the nurse staffing in paediatric inpatient wards: one in California (3.65 million admissions in 286 hospitals) found no association of staffing with mortality (18) and another from Korea (608,017 admissions in 46 hospitals) found more nurses per patient was associated with increased rates of failure to rescue (36). An additional study evaluating pediatric cardiac surgical services in California showed no association of nurse ratios and RN FTEs with lower risk-adjusted mortality (19). All used coarse methods to calculate nurse-staffing, used administrative data and may not have been able to discern patient location (ICU or ward) at the time of events from the administrative data that was used to identify selected events.

Common practice is for sicker patients – those of higher acuity – to be assigned to nurses who are caring for a smaller number of other patients. This practice may lead to an underestimation of the true effect of nursing staffing in unadjusted analyses (37). Another interpretation of the study results is that they illustrate that (at hospital level) the allocation of nurses to the patients in pediatric wards is matched to the patient's risk of mortality. Thus nurse-staffing is a consequence of expected patient risk of mortality – rather than being its determinant. More studies are needed to understand what other factors related to the work environment, inter-professional collaboration, staffing of other professions, communication, parental advocacy and escalation processes may contribute to failure to rescue and may help identify effective solutions (38–41).

Second, adjusted analyses found that documentation of heart rate, respiratory rate, systolic blood pressure, oxygen saturation, capillary refill time, oxygen therapy, and complete sets of vital signs was less frequent with higher patient-to-nurse ratio. While the association or higher level of nurse staffing and the completeness and timeliness of vital signs monitoring is reported in adult settings, the effect of increased nurse staffing on this process is small (15). We note that in unadjusted analyses the observed effect of staffing was less than found in adjusted analyses – suggesting that overall documentation was similar and that once acuity and patient complexity were accounted for then documentation was reduced more if the nurse was looking after a greater number of other patients.

Third, nurses working in hospitals with higher patient-to-nurse ratios reported greater apprehension when calling a physician after hours, and perceived worse communication quality, timeliness of care, and reduced ability to influence care; the finding was strongest for influence of care. This result is consistent with published observational studies suggesting worse patient outcomes and quality of care in hospitals with less staffing in adult inpatient wards (6,28,29,31,42), neonatal ICU (21,32,33,43), and paediatric ICUs (22–25), and of studies linking less favourable perceptions of quality and safety with lower nurse staffing (44–46). Our findings of less favorable nurse perceptions associated with higher patient-to nurse ratio is consistent with our finding of reduced documentation. It also contrasts with our objective data of lower mortality and fewer clinical events with less intensive nurse staffing. We hypothesize that increased workload in hospitals with higher patient-to-nurse ratio may be influencing perceptions of care quality. It is likely that for most respondents their frame of reference is dominated by the hospital in which they work; that is, the local culture may lead to different expectations of quality and safety that is separate from the objectively observed trial data. We hypothesize that greater expectations of frontline staff may be mitigating any adverse consequences of higher patient-to-nurse ratio and contributing to lowered rates of adverse outcomes.

Limitations

There are several limitations of this study. First, our measure of patient-to-nurse staffing was from a randomly selected sample of beds in the inpatient ward areas where studied patients received care. Ideally the nurse staffing would have been recorded for all patients on all days of the 78 weeks of the study. Other approaches, including aggregating nurse staffing each patient day, or sampling a larger sample, may have increased the precision of our description of staffing. This limitation is shared with other studies of inpatient paediatric care (18,36). Our finding of relative stability of estimates from the 130 patients sampled from each 26-week period in the study suggests the approach used was not subject to major random variation. Second, unmeasured factors may be confounding the association between patient-to-nurse ratio and the study outcomes. Possible factors include physician staffing ratios (47) that may be related to a 'teaching hospital' effect; the availability of licensed practice nurses (27) or vocational nurses to moderate the nursing workload; and other patient confounding variables such as case-mix, age and comorbidities. The parent study was performed in relatively well staffed tertiary care hospitals, where the mean patient-to-nurse ratio was relatively low and may have concealed reduced risk from a higher baseline risk in the most acute and complex patients. Third, unaccounted differences in nurse education and skill-mix might have confounded our results. Increased rates of Registered Nurses and nursing support staff (31,42), nurses with Bachelor degrees (7,48,49), nurses with higher levels of education (50), or improved working environments (44) have been found to be essential in reducing safety failures, in-hospital failure-to-rescue and deaths in the adult patient population (29).

Strengths

The multicenter international prospective data collection including 217,174 patient-admissions in 22 hospital sites in 7 high-income countries is a strength of this study. This improves the generalizability of the results of the findings.

CONCLUSIONS

Our 22 -hospital evaluation found that mortality, clinical deterioration, and resuscitation team activation were about 10-20% less frequent with each additional patient per nurse. Our findings were consistent across multiple analyses and in six related measures, and contrast with prior observational data in the adult population showing increased nurse staffing was associated with reduced events. Our prospective data are hypothesis generating and emphasize the value of considering other factors, including skill mix, education requirements, experience, and physician: patient ratios before implementing well-intentioned decisions to increase nurse staffing to improve patient safety and quality of care.

Figure 1: Average patients per nurse and total number of ward-days by hospital.
This figure plots the total number of ward days in a period at a site against the average patient-nurse ratio in that period at that site, with periods at the same site plotted in the same colour. The boxplots in the margin show the 25th and 75th percentiles and medians across site-periods.

Figure 2: The association of the mortality and process of care study outcomes and nurse staffing. Each of the 6 panels plots the rate of the outcome in a period at a site against the average patient-nurse ratio in that period at that site, with the areas of the circles being proportional to the number of patient discharges or number of ward days. The fitted values from the univariate random effects models are shown by the solid line (mean) and shaded area (95% CrI).

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Competing interests: C Parshuram is a named inventor of the Bedside Paediatric Early Warning System and has shares in a decision support company in part owned by SickKids that was established to commercialize the Bedside Paediatric Early Warning System. All other authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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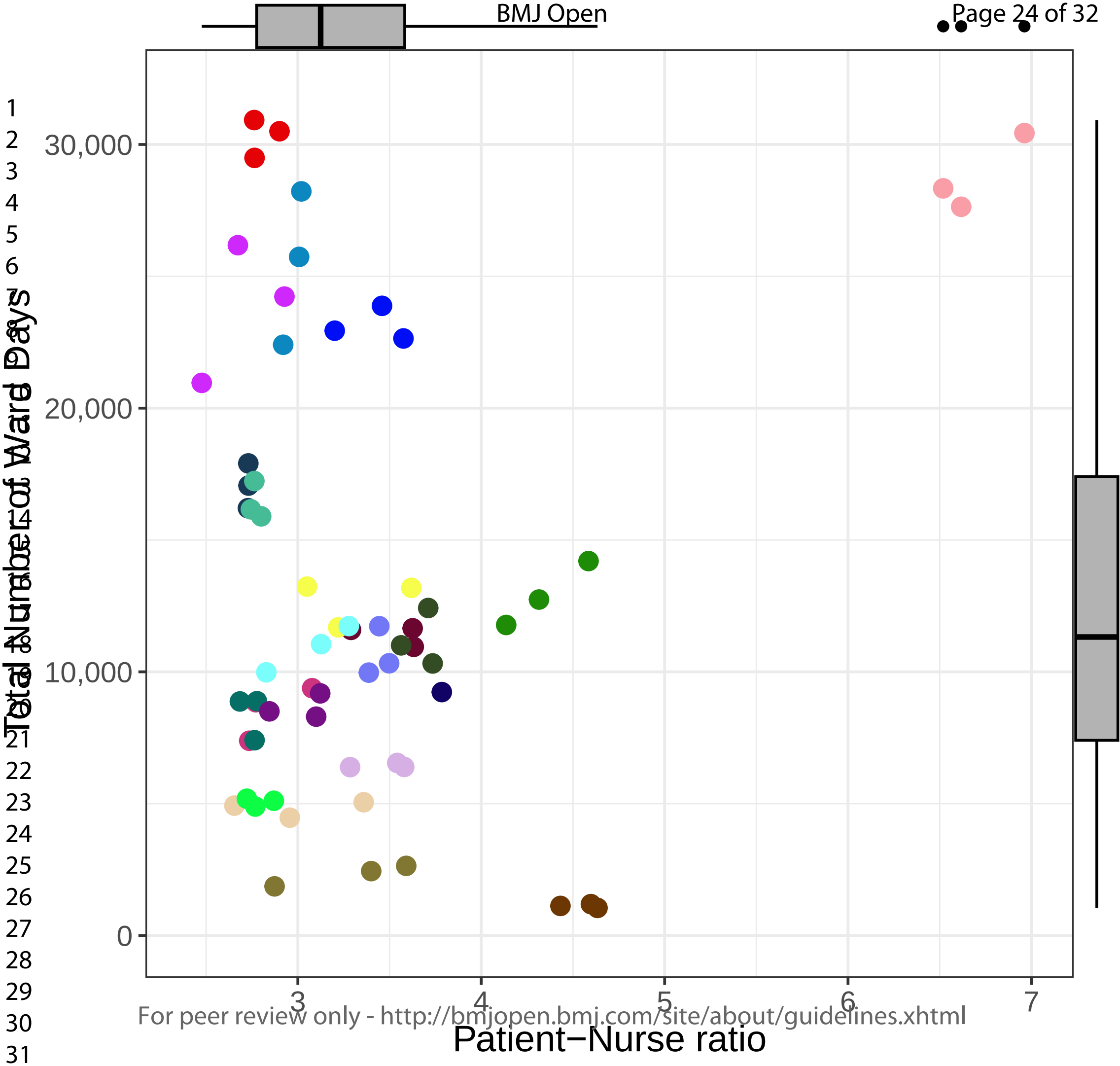
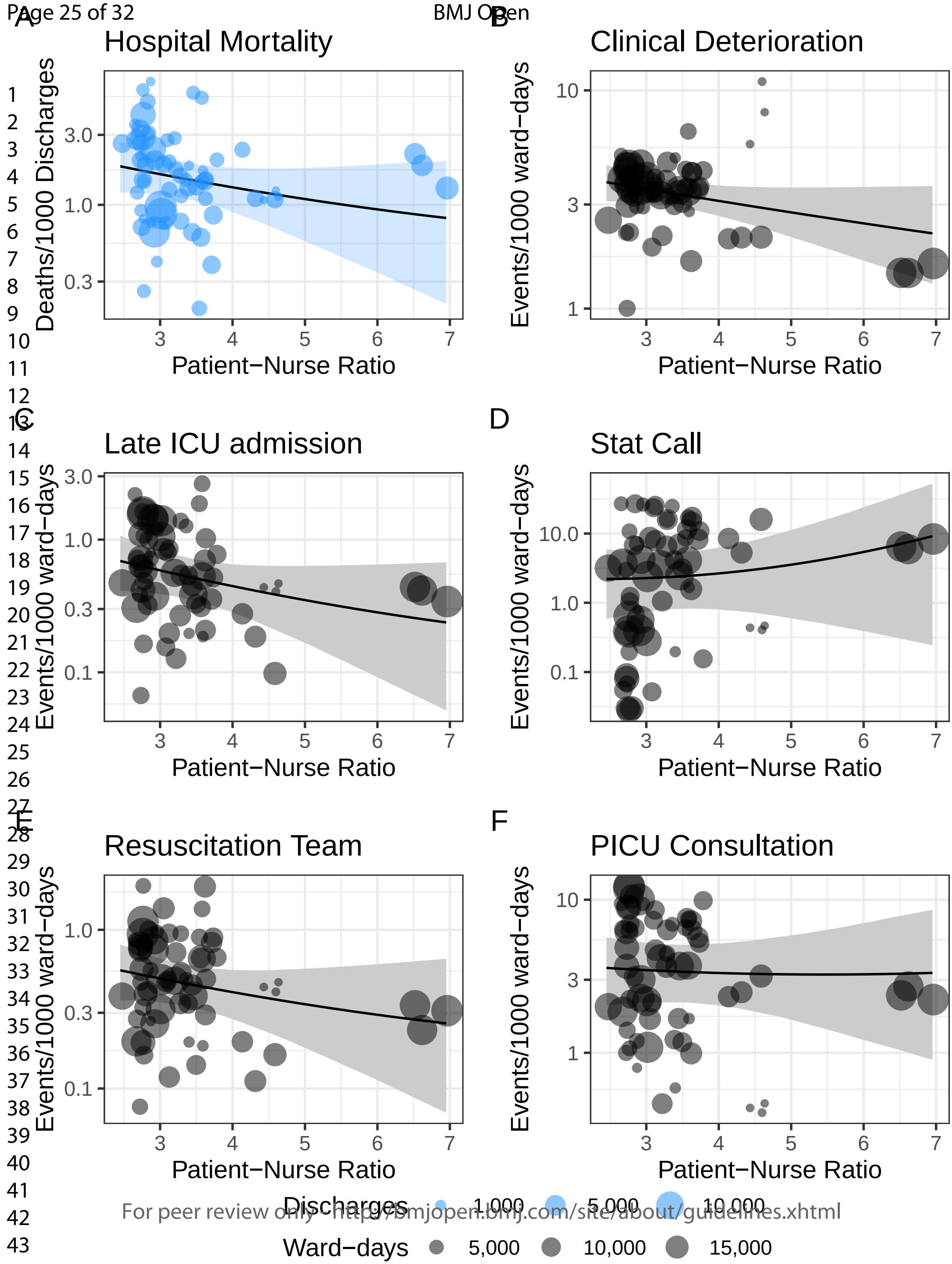
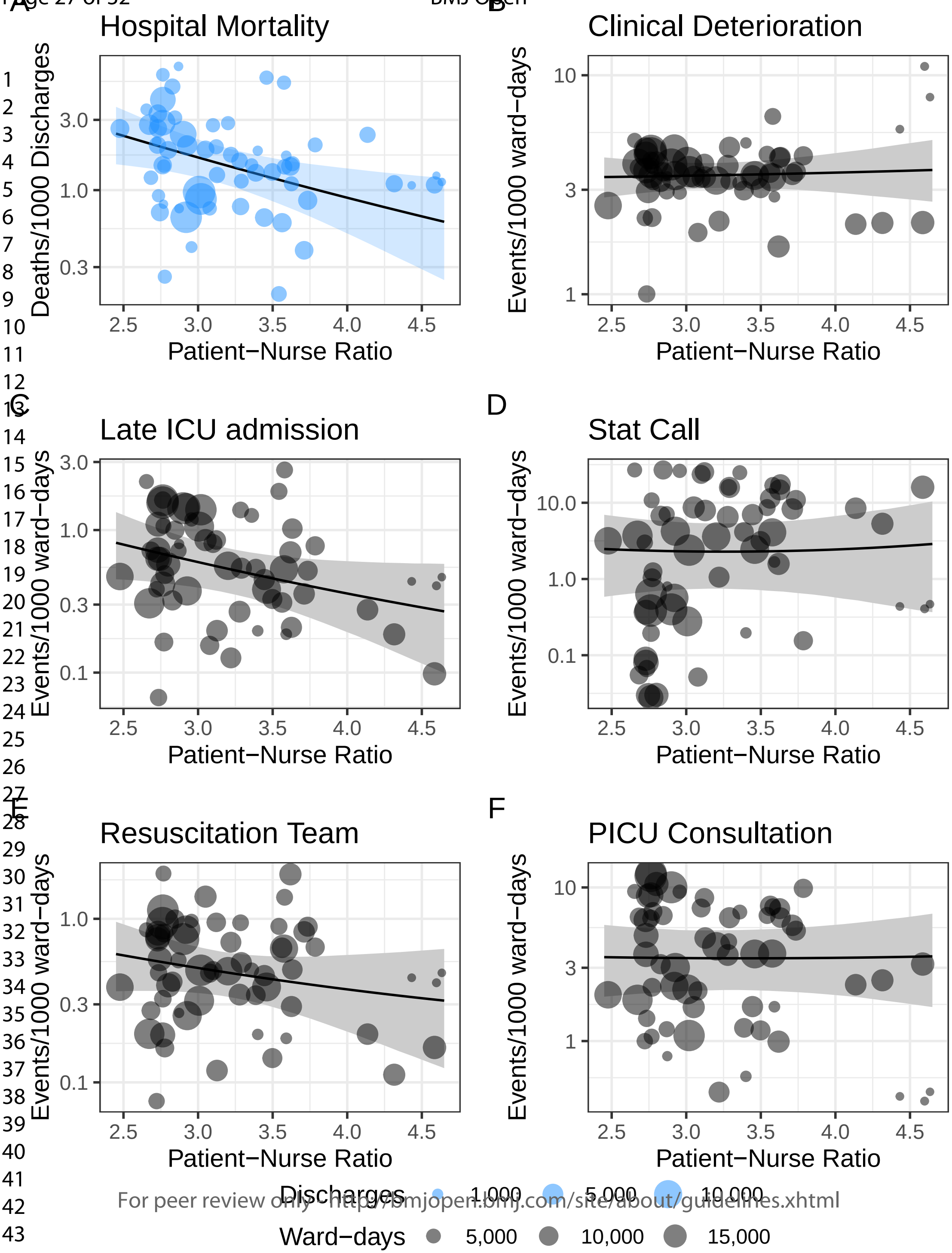

30,000
20,000
10,000
0
Total Number of Ward Days
3
4
5
6
7
Patient−Nurse ratio


A
Hospital Mortality
Deaths/1000 Discharges
3.0
1.0
0.3
3 4 5 6 7
Patient−Nurse Ratio
B
Clinical Deterioration
Events/1000 ward−days
10
3
1
3 4 5 6 7
Patient−Nurse Ratio
C
Late ICU admission
Events/1000 ward−days
3.0
1.0
0.3
0.1
3 4 5 6 7
Patient−Nurse Ratio
D
Stat Call
Events/1000 ward−days
10.0
1.0
0.1
3 4 5 6 7
Patient−Nurse Ratio
E
Resuscitation Team
Events/1000 ward−days
1.0
0.3
0.1
3 4 5 6 7
Patient−Nurse Ratio
F
PICU Consultation
Events/1000 ward−days
10
3
1
3 4 5 6 7
Patient−Nurse Ratio
Discharges 1,000 5,000 10,000
Ward−days 5,000 10,000 15,000

Supplementary Figure 1A

The association of the study outcomes and nurse staffing by study period, excluding site 21 (sensitivity analysis)

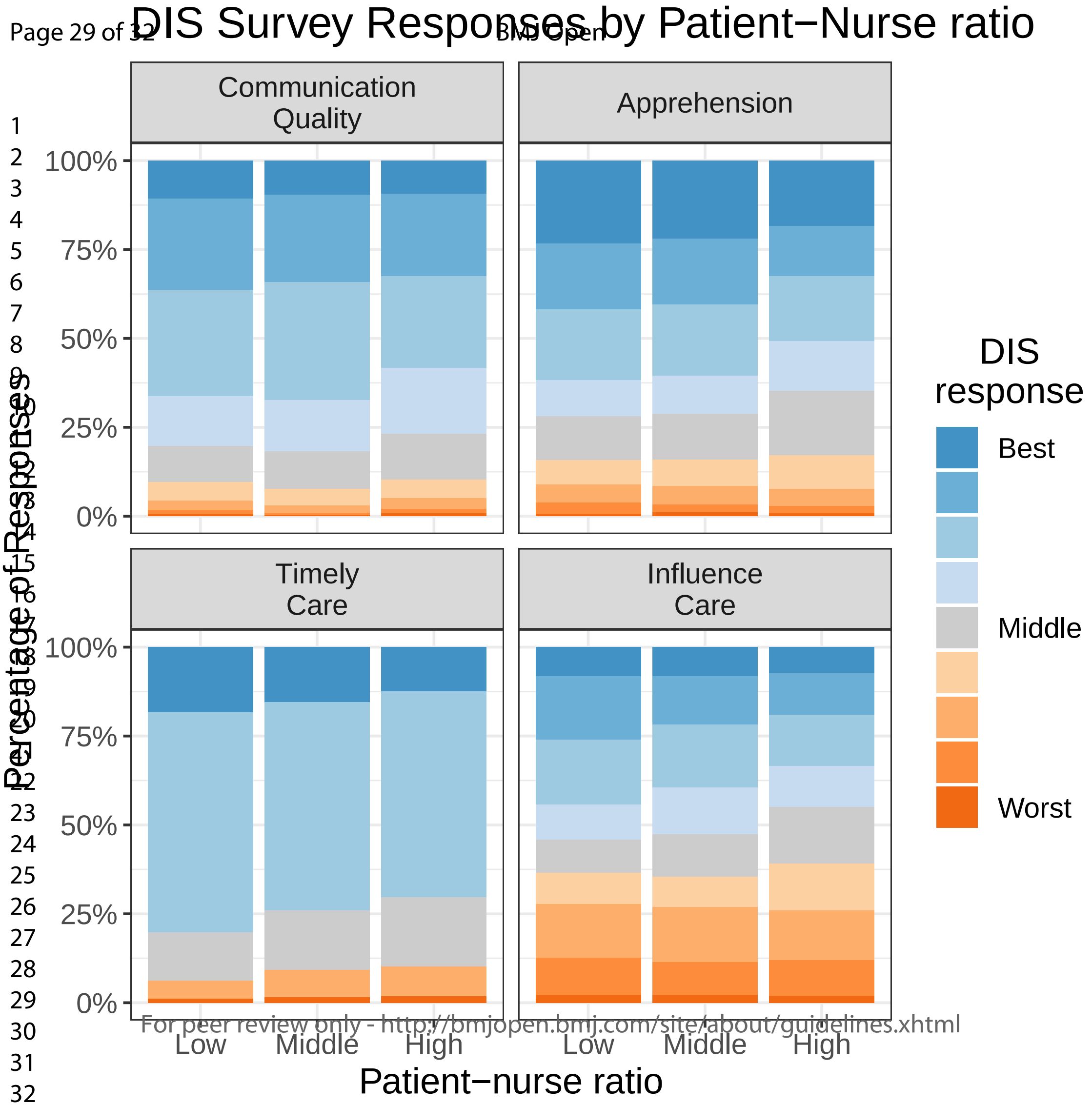
Figure 1A: After excluding the site with outlying patient-nurse ratios in all three period, the association of the mortality and process of care study outcomes and nurse staffing. Each of the 6 panels plots the rate of the outcome in a period at a site against the average patient-nurse ratio in that period at that site, with the areas of the circles being proportional to the number of patient discharges or number of ward days. The fitted values from the univariate random effects models are shown by the solid line (mean) and shaded area (95% CrI).


A
Hospital Mortality
Deaths/1000 Discharges
3.0
1.0
0.3
2.5
3.0
3.5
4.0
4.5
Patient−Nurse Ratio
B
Clinical Deterioration
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
C
Late ICU admission
Events/1000 ward−days
3.0
1.0
0.3
0.1
Patient−Nurse Ratio
D
Stat Call
Events/1000 ward−days
10.0
1.0
0.1
Patient−Nurse Ratio
E
Resuscitation Team
Events/1000 ward−days
1.0
0.3
0.1
Patient−Nurse Ratio
F
PICU Consultation
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
Discharges
1,000
5,000
10,000
Ward−days
5,000
10,000
15,000

Supplementary figure 2A: nurse perceptions of quality of care (sensitivity analysis, excluding site 21)

Figure 2A: Distributions of DIS responses for communication quality (9-point scale), apprehension (9-point scale), timely care (5-point scale) and influence care (9-point scale) from nurses, where higher scores are better perceptions. The responses are grouped according to whether they were collected from a site-period with a nurse -patient ratio in the lowest quartile, middle two quartiles, or highest quartile. The 5 point scale was coded so that 5 was “best”, 3 was “middle” and 1 was “worst” (with 4 mapping onto 7, and 2 mapping onto 3 on the 9-point scale). As the ratio increases, there are proportionally more orange bar segments (worse perceptions) and fewer blues ones (better perceptions).

Legend: DIS=Documentation and Interaction Survey


DIS Survey Responses by Patient−Nurse ratio
Communication Quality
Apprehension
Timely Care
Influence Care
100%
75%
50%
25%
0%
Percentage of Responses
Low
Middle
High
Patient−nurse ratio
DIS response
Best
Middle
Worst

Appendix

Table 1A: Sources of data

Data role	Data	Measurement level	Source within EPOCH	Comment
Outcomes	Clinical outcomes (mortality, clinical deterioration events, late ICU admissions, duration of hospital stay, etc.)	One outcome per patient	Clinical trial outcomes database	All 217,174 patients in the trial had these outcomes documented
	Vital signs documentation	One value per patient	Random selection of 5 patients each week for the 26 weeks of each study period at each site	8,282 patients were assessed for documentation of vital signs
	Documentation and Interaction Survey	One survey per nurse	Nurses at enrolled hospitals	All nurses were approached
Predictors	Patient to nurse ratio	One value per site per time period	Random selection of 5 patients each week for the 26 weeks of each of three study periods at 22 sites	The ratio was based on the average number of patients being cared for by nurses of the selected 8,282 patients.
	Site-specific descriptors (Mean BP,Medical team,PM MD/Fellow,Transplant)	One value per site per time period	Clinical trial site descriptors database	Mean BP could vary by study period. Other descriptors were constant

Table 2A: Vital Signs Monitoring sensitivity analysis (excluding site 21)

Outcome	Univariable		Multivariable	
	RR (95% CrI)	Pr(RR<1)	RR (95% CrI)	Pr(RR<1)
Heart Rate	0.98 [0.86, 1.13]	60.4%	0.96 [0.83, 1.10]	74.0%
Respiratory Rate	1.01 [0.88, 1.17]	43.3%	0.98 [0.83, 1.14]	62.5%
Systolic blood pressure	1.01 [0.79, 1.31]	45.6%	0.89 [0.71, 1.13]	83.4%
Oxygen saturation	1.06 [0.89, 1.27]	25.7%	0.98 [0.81, 1.19]	57.8%
Capillary refill time	0.97 [0.17, 4.77]	52.0%	0.27 [0.06, 1.18]	95.8%
Oxygen therapy	0.92 [0.73, 1.15]	77.8%	0.89 [0.70, 1.14]	81.8%
Respiratory effort	1.04 [0.52, 2.32]	45.6%	0.86 [0.34, 2.01]	63.3%
All of above collected	1.11 [0.76, 1.62]	28.9%	0.78 [0.57, 1.07]	94.1%
Temperature	0.99 [0.89, 1.09]	60.3%	1.00 [0.89, 1.13]	51.3%

Vital signs monitoring -random effects negative binomial models. Estimates are rate ratios (RR) for the relative change in the rate of documentation with one additional patient per nurse, 95% CrIs and P(RR < 1), the probability that the rate of documentation is reduced with an increasing patient-nurse ratio.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5-7*
Bias	9	Describe any efforts to address potential sources of bias	7-8
Study size	10	Explain how the study size was arrived at	In original EPOCH trial
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	N/A
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	7-8

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	/
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*9-12*
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-12
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	N/A

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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Evaluating associations between Patient-to-Nurse ratios and mortality, process of care events, and vital sign documentation on pediatric wards: A secondary analysis of data from the EPOCH cluster randomized trial

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Secondary Subject Heading:	Health services research, Paediatrics, Nursing
Keywords:	PAEDIATRICS, Mortality, Nurses, Hospitals, Human resource management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

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Title: Evaluating associations between patient-to-nurse ratios and mortality, process of care events, and vital sign documentation on pediatric wards: A secondary analysis of data from the EPOCH cluster-randomized trial

ABSTRACT

Objective: to describe the associations between patient-to-nurse staffing ratios and rates of mortality, process of care events, and vital sign documentation.

Design: Secondary analysis of data from the EPOCH cluster-randomized trial.

Setting: 22 Hospitals caring for children in Canada, Europe, and New Zealand.

Participants: Eligible hospitalized patients were aged >37 weeks and <18 years.

Primary and secondary outcome measures: The primary outcome was all cause hospital mortality. Secondary outcomes were five events reflecting process of care also collected on all EPOCH patients; the frequency of documentation for each of eight vital signs on a random sample of patients; four measures describing nursing perceptions of care.

Results: A total of 217,714 patient admissions for 849,798 patient days over the course of the study were analyzed. The overall mortality rate was 1.65/1000 patient discharges. The median (IQR) number of patients cared for by an individual nurse was 3.0 [2.8, 3.6]. Univariate Bayesian models estimating the rate ratio (RR) for the patient-nurse ratio and the probability that the RR was less than one found that a higher patient-nurse ratio was associated with fewer clinical deterioration events (RR=0.88, 95% CrI 0.77, 1.03; P(RR < 1) = 95%) and late ICU admissions (RR=0.76, 95% CrI 0.53, 1.06; P(RR<1)=95%). In adjusted models, a higher patient-to-nurse ratio was associated with lower hospital mortality (odds ratio (OR) =0.77, 95% CrI=0.57, 1.00; P(OR < 1)=98%). Nurses from hospitals with a higher patient-to-nurse ratio had lower ratings for their ability to influence care, and reduced documentation of most individual vital signs and of the complete set of vital signs.

Conclusions: The data from this study challenge the assumption that lower patient-to-nurse ratios will improve the safety of paediatric care in contexts where ratios are low. The mechanism of

these effects warrants further evaluation including factors, such as nursing skill mix, experience, education, work environment and physician staffing ratios.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- This study is based on a multicenter international prospective data dataset of > 210,000 patient-admissions in 22 hospital sites in 7 high-income countries
- The measure of patient-to-nurse staffing was from a randomly selected sample of beds in the inpatient ward areas where studied patients received care.
- Staffing levels and clinical outcomes represent an average over three six month periods.
- Individual patient-level risk adjustment and a wider range of variables to control for case mix and general hospital resources would have increased the precision of our results.
- Unmeasured factors may be confounding the association between patient-to-nurse ratio and the study outcomes.

INTRODUCTION

Nurses are the primary human resource for clinical observation and the delivery of patient care in pediatric hospitals. They are essential components of Rapid Response Systems with roles that include monitoring clinical condition, communicating to others in the primary care team, and escalating the intensity of care as determined by the child's severity of illness (1). Low patient-to-nurse ratios are a well-accepted strategy to mitigate already identified patient risk in intensive care units (ICU) (2–5). In observational studies, lower patient-to-nurse ratios have been associated with lower mortality in adult patients (6,7) and with lower hospital readmission at 15-30 days in children (8). Standards of pediatric nursing care on hospital wards require comprehensive and continuous patient assessments, vital signs measurement, and documentation (9,10) to provide information on early signs of clinical deterioration (11). High patient-to-nurse ratios increase workload for each nurse, which may reduce the frequency of vital signs monitoring, and compromise the effectiveness of interventions and communication (12–15).

While there is evidence on the association of nurse staffing levels and patient mortality in the adult inpatient setting, in pediatric settings this evidence is limited (16,17). A study using nurse staffing administrative data in California from 1996-2001 examining 3.65 million discharges from 286 general and children's hospitals reported no association of patient-to-nurse staffing and mortality in children (18). Another study using the Healthcare Cost and Utilization Project Kids' Inpatient Database (KID) in California showed no association of nurse ratios and Registered Nurses (RN) FTEs with lower risk-adjusted mortality, risk-adjusted complications and risk-adjusted resource utilization for pediatric cardiac surgical services (19). Moreover, a study performed in Korea including over 600,000 children admitted to 46 tertiary care hospitals showed an increased risk of failure to rescue associated with lower patient-to-nurse staffing ratios (Grade 1 (beds/nurse<2), OR 1.39; 95% CI 1.15, 1.70; compared to grade 3 (2.5 ≤ beds/nurse < 3). In the same study, in addition, an association with a better composite outcome of cardiac arrest, shock, or respiratory failure was found with lower patient-to-nurse ratios (grade 1 compared to grade 3 OR 0.48; 95% CI 0.40, 0.58) (20). In the Neonatal ICU setting there is some evidence of an association between patient-to-nurse staffing levels or increased proportions of nurses with neonatal certifications and reduced neonatal mortality (21). In Pediatric ICU (PICU) an association with lower mortality and lower odds of complications was found with increased years of nursing experience and nurses with Bachelor or higher degrees (22–25). Current evidence on safe patient-to-nurse ratios for the pediatric setting is limited and much needed to support future nursing workforce planning (17). Therefore, the objective of this study was to determine the association between patient-to-nurse staffing and rates of clinical deterioration events, and processes and perceptions of care on in-hospital pediatric wards.

METHODS

We performed a secondary analysis of data from 217,714 patient admissions in acute care pediatric wards the 22 hospitals included in the "Evaluating processes of care and outcomes of children in hospital" (EPOCH) cluster randomized trial (26). Outcomes were available for all patients without loss to follow-up. The hospitals were located in Belgium (n=1), Canada (n=11), the United Kingdom (n=5), Ireland (n=2), Italy (n=1), New Zealand (n=1), and the Netherlands (n=1) and had a total of 2085 eligible inpatient unit beds (26). Three hospitals had >200 beds, 10 (45%) had a 24/7 Rapid Response Team and 20 (91%) were University affiliated. Eleven hospitals were randomized to implement the Bedside Pediatric Early Warning System (BedsidePEWS).

Main exposure

The main exposure of interest was patient-to-nurse staffing on inpatient wards of participating hospitals. Within each of three 26-week study periods at each hospital, we recorded the total number of patients cared for by the primary nurse of five randomly selected patients, who were eligible on an inpatient ward for more than 24 hours. For each week in each hospital the study coordinating center provided a randomly generated list of twenty bed spaces generated from a list of the bed spaces in the paediatric wards (not ICU) where eligible patients may receive care. Coordinators sought eligible patients in the indicated bed spaces, beginning at the top of the list and progressing sequentially until five eligible patients were enrolled. The mean value of the (5 patients) $\times$ (26 weeks) = 130 measurements collected in each 26-week period was used to represent typical staffing levels on the inpatient wards of each hospital for that period (26).

Primary and secondary outcomes

The primary outcome was hospital mortality. This was also the primary outcome of the EPOCH trial. Secondary outcomes were (a) five events reflecting process of care, also collected on all EPOCH patients: clinical deterioration events, late ICU admissions, resuscitation team calls, stat calls and PICU consultations; (b) the frequency of documentation for each of eight vital signs on the random sample of patients; and (c) four measures describing nursing perceptions of care.

Clinical deterioration events

Amongst secondary outcomes reflecting process of care, clinical deterioration events were defined as deaths on the ward or urgent admission to a PICU, which itself was defined as an admission with departure from the event location in less than six hours from the time the PICU admission was initiated (26). The timeliness of urgent PICU admissions was classified using the Children Resuscitation Intensity Scale (CRIS), with scores that range from 1 (no major interventions) to 7 (death before or within the first hour after ICU admission); a score >2 was classified as a late ICU admission (26).

Vital signs documentation

Vital signs were documented on the randomly selected patient records. We abstracted the number of documented measurements over a 24-hour period for each patient for each of eight clinical observations: heart rate, respiratory rate, systolic blood pressure, oxygen therapy, oxygen saturation, capillary refill time, respiratory effort, and temperature. We defined vital sign recording as complete when the first seven of these (the clinical indicators in the BedsidePEWS) were documented. We also calculated the BedsidePEWS score (if at least five of the seven measurements were available) from the last available set of vital signs.

Nurses perceptions of quality of patient care

Nurses' perceptions of quality of patient care were recorded once in each study period using a Documentation and Interaction Survey, developed and used extensively in the parent study. This survey had the aim of exploring the perception of the documentation system and quality of care. Questions were judged to have high face validity by the study group, although not formally validated. Responses to the communication quality question "How do you rate communication about patients on your team?" were on a 9-point scale from 1, (extremely poor) to 9 (excellent). Responses to the timely care question "Please indicate your agreement/disagreement with the statement: 'Patients have received the care that they needed when they needed it'" were on a 5-point scale from 1 (strongly disagree) to 5 (strongly agree). Responses to the apprehension question "When calling a physician after-hours to review the patient or their management plan, how apprehensive did you feel?" were on a 9-point scale from 1 (extremely apprehensive) to 9 (not at all apprehensive). Responses to the influence on care question "How confident did you feel that you could influence the plan of care?" were on a 9-point scale from 1 (extremely confident) to 9 (not at all confident), which we reversed, so that a 9 became "extremely confident".

Adjustment variables

In recognition of the modest number of site-by-period observations in the study data set, we carefully considered options for adjustment variables. After consideration of seven options describing the hospital resources – (1) the proportion of full-time (>90% full-time equivalent) registered nurses, (2) number of pediatric beds, (3) presence of a transplant program, (4) overnight in-house consultant pediatrician, (5) overnight in-house senior trainee (fellow), (6) 24/7 medical emergency team, and (7) mean severity of illness – four adjustment variables were used. Two reflected patient risk for deterioration – the presence of a transplant program and the average patient severity of illness (measured as the mean BedsidePEWS score at the site in the period). Two reflected non-nurse staffing resources – the presence of in-house overnight senior trainee (fellow) and having a medical emergency team. We also adjusted by a fifth variable indicating whether the period was assigned to the EPOCH intervention. Table 1A in the supplement summarizes the sources and roles of all variables included in our analyses.

Statistical analysis

Clinical outcomes were aggregated over each 26-week period and represented as rates. Mortality was summarized as deaths per 1000 patient discharges. Five process of care outcomes (clinical deterioration events, late PICU admissions, immediate calls to a physician to attend at the bedside of a patient, resuscitation team calls, and PICU consultations) were summarized as events per 1000 patient days. To assess the dependence of hospital mortality on the patient-to-nurse ratio, we entered aggregate death and admission data for each site in each period into a random effects logistic regression, with site-specific random effects and site-and-time specific predictors (EPOCH intervention, patient-nurse ratio, presence of transplant team, the presence of in-house overnight senior trainee presence of a medical emergency team, and the mean BedsidePEWS). Similar analyses were used for process of care events, except that random effects negative binomial models were used, with event counts as the outcome, and the logarithm of site-period totals of patient ward-days as an offset. Analyses of documentation of vital signs also used a random effects negative binomial models, with aggregated counts of documentation as the outcome and logarithm of the total number of assessments on the randomly selected patients as the offset.

A random effects proportional odds regression model was used to assess the dependence of nurse-reported perceptions of quality of care on the patient to nurse ratio, with site-specific random effects and the same site-and-time specific predictors as above. All models were fitted using Bayesian models in the brms package in R and measures of association are presented with a 95% credible interval (CrI) and the Bayesian posterior probability of a reduction in the outcome with a higher patient-to-nurse ratio. After inspection of the data a post-hoc sensitivity analysis was performed in which we excluded a hospital that was an outlier (site 21) with respect to the patient-nurse ratio.

This study was approved by the Human Research Ethics Board at the Hospital for Sick Children, Toronto, Canada (Approved REB # 1000062622).

Patient and public involvement

Patients and/or the public were not involved in the design, conduct, reporting, or dissemination plans of this research.

RESULTS

Data from 22 hospitals participating in the EPOCH trial (26) included 217,174 patients and 849,798 patient days. Random sampling selected 8282 patients on whom we assessed vital sign documentation and patient-nurse ratios. The median (IQR) number of patients cared for by an individual nurse was 3.0 [2.8, 3.6]. Three hospitals (14%) had a mean patient-to-nurse ratio greater than 4, with one outlier having a patient/nurse ratios of 6.5-7.0 over the three study periods. (Figure 1).

Hospital mortality occurred in 360 patients with an overall rate of 1.65/1000 patient discharges (1.57 in period 1), and other events occurred at rates 0.53 to 5.9/1000 patient days in period 1 (Table 1).

Table 1: Model-based estimates for associations between average patients per nurse and clinical

outcomes. Multivariable models were adjusted for EPOCH intervention, transplant hospital, medical emergency team hospital, overnight In-house fellow trainee, and mean BedsidePEWS score.

Outcome	Period 1 Rate	Univariable		Multivariable			
				All Sites		Excluding Site 21	
		OR (95% CrI)	P(OR <1)	OR (95% CrI)	P(OR <1)	OR (95% CrI)	P(OR <1)
Hospital Mortality (deaths per 1000 discharges)	1.57	0.82 [0.59, 1.08]	92.1%	0.77 [0.57, 1.00]	97.7%	0.6 [0.35, 0.97]	98.2%
Outcomes measured as a rate per 1000 ward-days							
Outcome	Period 1 Rate	RR (95% CrI)	P(RR <1)	RR (95% CrI)	P(RR <1)	RR (95% CrI)	P(RR <1)
Clinical Deterioration	3.49	0.88 [0.77, 1.03]	95.4%	0.90 [0.78, 1.05]	92.0%	1.04 [0.83, 1.3]	37.4%
Late ICU admission (i.e., CRIS ≥ 3)	0.74	0.76 [0.53, 1.06]	94.9%	0.81 [0.56, 1.14]	89.7%	0.63 [0.36, 1.11]	94.6%
Stat Call	5.91	1.16 [0.55, 2.43]	34.6%	1.34 [0.61, 2.95]	77.8%	0.98 [0.32, 2.93]	51.6%
Resuscitation Team	0.53	0.82 [0.60, 1.10]	91.3%	0.82 [0.59, 1.14]	89.0%	0.77 [0.44, 1.33]	82.9%
PICU Consultation	4.79	0.95 [0.71, 1.29]	62.7%	0.92 [0.69, 1.23]	71.4%	0.98 [0.66, 1.44]	55.2%

Legend: CRIS=Children resuscitation intensity scale; ICU=intensive care unit; OR=odds ratio per 1 unit increase in the patient nurse ratio; PICU=pediatric ICU; RR=rate ratio per 1 unit increase in the patient nurse ratio; CrI=credible interval. Multivariable, all sites: The multivariable model including all sites. Multivariable, excluding site 21: Multivariable model excluding site with an outlying patient-nurse ratio.

In univariate analyses we found a higher number of patients per nurse was associated with lower odds of hospital mortality, and lower rates of clinical deterioration events, late ICU admissions, and resuscitation team calls. In multivariable models, point estimates for these four associations were similar to the estimates from univariate analyses; the probability of a reduction in mortality with a higher patient-nurse ratio increased, but other probabilities of associations decreased (Table 1).

Figure 2 plots the association of each of these study outcomes with nurse staffing by 26-week study period, with the estimated univariate association overlaid. In the sensitivity analysis excluding the hospital with a high patient-nurse ratio, the associations with hospital mortality and late ICU admissions were stronger, but the evidence for all other associations with clinical events was weaker (Right-hand columns of Table 1 and supplementary Figure 1).

In multivariable models, nurse perceptions tended to be less favorable in hospitals where nurses were caring for more patients: point estimates of ORs were all < 1, meaning that the odds of more favorable perceptions decreased as the patient-nurse ratio increased. However, it was only for influence on care that there was a high probability (> 95%) that the OR was < 1 in either the univariate or multivariable model. (Table 2).

Table 2: Model-based estimates of the odds ratio for a better score on the Documentation and Interaction Survey (DIS) Outcomes with increasing values of average patients per nurse

DIS Item	Univariable		Multivariable: All Sites		Multivariable: Excluding Site 21	
	OR (95% CI)	P(OR<1)	OR (95% CI)	P(OR<1)	OR (95% CI)	P(OR<1)
Communication Quality	0.97 [0.84, 1.15]	65.9%	0.95 [0.81, 1.19]	68.5%	1.02 [0.78, 1.37]	43.5%
Apprehension	1.10 [0.89, 1.34]	18.1.%	0.94 [0.79, 1.12]	78.6%	1.01 [0.76, 1.33]	47.0%
Care is Timely & Quality	0.95 [0.79, 1.17]	68.2%	0.87 [0.71, 1.11]	87.9%	0.82 [0.59, 1.17]	87.3%
Influence Care	0.87 [0.74, 1.01]	97.0%	0.85 [0.73, 0.98]	98.5%	0.78 [0.58, 1.01]	97.1%

Legend: DIS= Documentation and Interaction Survey. Data were extracted from the Documentation and Interaction Survey (DIS). Multivariable proportional odds models were adjusted for transplant program hospital, medical emergency team hospital, overnight in-house fellow coverage, mean BedsidePEWS score and EPOCH intervention. OR: odds ratio, the relative change in the odds of a better DIS outcome for a one unit increase in the patient-nurse ratio. An OR < 1 means that the DIS score worsens with an increasing patient-nurse ratio.

Findings were largely unchanged in the sensitivity analysis. Supplementary figure 2 shows the nurse perceptions for surveys from site-periods where the patient nurse ratio was in the bottom quartile, middle two quartiles and top quartile.

Documentation of several clinical observations was also related to nurse staffing. Adjusted analyses found, as the patient-nurse ratio increased, greater than 95% probability of reduced documentation for each vital sign, with two exceptions, temperature and respiratory effort. Documentation of the complete set of vital signs was also reduced with increased patient-nurse ratio (Table 3).

Table 3: Model-based estimates of the association between average patients per nurse and vital signs documentation

Outcome	Period 1 Mean Number of Measurements/ Patient/24hrs	Univariable		Multivariable	
		RR (95% CI) (per patient to-nurse)	P(RR<1)	RR (95% CI) (per patient to-nurse)	P(RR<1)
Heart Rate	6.59	0.87 [0.76, 1.00]	97.6%	0.83 [0.72, 0.95]	99.6%
Respiratory Rate	6.14	0.87 [0.73, 1.03]	94.3%	0.81 [0.68, 0.96]	99.2%
Systolic blood pressure	3.8	0.88 [0.73, 1.06]	91.7%	0.80 [0.68, 0.95]	99.4%
Oxygen saturation	5.84	0.93 [0.76, 1.13]	77.8%	0.83 [0.68.1.02]	96.4%
Capillary refill time	1.63	1.1 [0.31, 3.97]	43.8%	0.37 [0.09, 1.19]	95.2%

Oxygen therapy	6.16	0.81 [0.62, 1.08]	92.9%	0.73 [0.55, 0.96]	98.7%
Respiratory effort	2.38	0.98 [0.67, 1.53]	53.9%	0.83 [0.46, 1.45]	75.0%
All of above collected	3.93	0.93 [0.63, 1.34	65.6%	0.72 [0.51, 0.99]	97.8%
Temperature	5.47	0.95 [0.87, 1.05]	83.8%	0.98 [0.88, 1.1]	66.8%

Legend: RR: rate ratio, the relative change in the rate of documentation for a one unit increase in the patient-nurse ratio; P(RR<1) = posterior probability that there is a reduction in the rate of documentation with an increasing patient-nurse ratio. The multivariable model adjusted for transplant program hospital, medical emergency team hospital, overnight in-house fellow coverage, hospital severity of illness (mean BedsidePEWS score) and EPOCH intervention. With the exclusion of the outlying site, only capillary refill [RR 0.27; 95% CrI 0.06, 1.18; Pr(RR<1)=95.8%] and "all of the above" [RR 0.78; 95% CrI 0.57, 1.07; Pr(RR<1)=94.1%] had strong evidence of associations. For all other vital signs, probabilities of reductions with a higher patient-nurse ratio were 83% or lower.

With the exclusion of the outlying hospital, there were reductions in documentation with an increased patient-nurse ratio, but the probabilities of reductions were lower (Supplementary table A2).

DISCUSSION

We evaluated the associations of nurse staffing with mortality, clinical process measures reflecting failure to rescue, documentation of vital signs, and nurse perceptions of care in a secondary analysis of prospective clinical trial data from 217,174 patient-discharges in 22 hospital sites in 7 high-income countries (26). There are 3 main findings and related implications.

First, we found that higher patient-to-nurse ratio was associated with lower mortality and fewer resuscitation team calls, clinical deterioration events, and late ICU admission. The robustness of our findings is suggested by the consistency of observed effects across [i] single variable analyses, [ii] multivariable analyses that include adjustment for severity of illness, and some organizational factors, [iii] a sensitivity analysis where a potential outlier hospital was excluded and [iv] by concordance of the direction of effects for different related process of care outcomes. Our results contrast with observational studies in adult hospital settings (7,27–31) and in the Neonatal Intensive Care Units where more patients per nurse has been associated with worse outcomes – including mortality (21,32–35).

Differences between paediatric wards settings and adult inpatient wards, paediatric and neonatal ICU settings are numerous. Our review of studies found 2 studies evaluating the nurse staffing in paediatric inpatient wards: one in California (3.65 million admissions in 286 hospitals) found no association of staffing with mortality (18) and another from Korea (608,017 admissions in 46 hospitals) found more nurses per patient was associated with increased rates of failure to rescue (36). An additional study evaluating pediatric cardiac surgical services in California showed no association of nurse ratios and RN FTEs with lower risk-adjusted mortality (19). All used coarse methods to calculate nurse-staffing, used administrative data and may not have been able to discern patient location (ICU or ward) at the time of events from the administrative data that was used to identify selected events.

Common practice is for sicker patients – those of higher acuity – to be assigned to nurses who are caring for a smaller number of other patients. This practice may lead to an underestimation of the true effect of nursing staffing in unadjusted analyses (37). Another interpretation of the study results is that they illustrate that (at hospital level) the allocation of nurses to the patients in pediatric wards is matched to the patient's risk of mortality. Thus nurse-staffing is a consequence of expected patient risk of mortality – rather than being its determinant. More studies are needed to understand what other factors related to the work environment, inter-professional collaboration, staffing of other professions, communication, parental advocacy and escalation processes may contribute to failure to rescue and may help identify effective solutions (38–41). Second, adjusted analyses found that documentation of heart rate, respiratory rate, systolic blood pressure, oxygen saturation, capillary refill time, oxygen therapy, and complete sets of vital signs was less frequent with higher patient-to-nurse ratio. While the association or higher level of nurse staffing and the completeness and timeliness of vital signs monitoring is reported in adult settings, the effect of increased nurse staffing on this process is small (15). We note that in unadjusted analyses the observed effect of staffing was less than found in adjusted analyses – suggesting that overall documentation was similar and that once acuity and patient complexity were accounted for then documentation was reduced more if the nurse was looking after a greater number of other patients.

Third, nurses working in hospitals with higher patient-to-nurse ratios reported greater apprehension when calling a physician after hours, and perceived worse communication quality, timeliness of care, and reduced ability to influence care; the finding was strongest for influence of care. This result is consistent with published observational studies suggesting worse patient outcomes and quality of care in hospitals with less staffing in adult inpatient wards (6,28,29,31,42), neonatal ICU (21,32,33,43), and paediatric ICUs (22–25), and of studies linking less favourable perceptions of quality and safety with lower nurse staffing (44–46). Our findings of less favorable nurse perceptions associated with higher patient-to nurse ratio is consistent with our finding of reduced documentation. It also contrasts with our objective data of lower mortality and fewer clinical events with less intensive nurse staffing. We hypothesize that increased workload in hospitals with higher patient-to-nurse ratio may be influencing perceptions of care quality. It is likely that for most respondents their frame of reference is dominated by the hospital in which they work; that is, the local culture may lead to different expectations of quality and safety that is separate from the objectively observed trial data. We hypothesize that greater expectations of frontline staff may be mitigating any adverse consequences of higher patient-to-nurse ratio and contributing to lowered rates of adverse outcomes.

Limitations

There are several limitations of this study. First, our measure of patient-to-nurse staffing was from a randomly selected sample of beds in the inpatient ward areas where studied patients received care. Ideally the nurse staffing would have been recorded for all patients on all days of the 78 weeks of the study. Other approaches, including aggregating nurse staffing each patient day, or sampling a larger sample, may have increased the precision of our description of staffing. This limitation is shared with other studies of inpatient paediatric care (18,36). Our finding of relative stability of estimates from the 130 patients sampled from each 26-week period in the study suggests the approach used was not subject to major random variation. Second, unmeasured factors may be confounding the association between patient-to-nurse ratio and the study outcomes. Possible factors include physician staffing ratios (47) that may be related to a 'teaching hospital' effect; the availability of licensed practice nurses (27) or vocational nurses to moderate the nursing workload; and other patient confounding variables such as case-mix, age and comorbidities. The parent study was performed in relatively well staffed tertiary care hospitals, where the mean patient-to-nurse ratio was relatively low and may have concealed reduced risk from a higher baseline risk in the most acute and complex patients. Possibly, in well staffed settings other solutions need to be found to further reduce patient mortality and failure to rescue.

Third, unaccounted differences in nurse education and skill-mix might have confounded our results. Increased rates of Registered Nurses and nursing support staff (31,42), nurses with Bachelor degrees (7,48,49), nurses with higher levels of education (50), or improved working environments (44) have been found to be essential in reducing safety failures, in-hospital failure-to-rescue and deaths in the adult patient population (29).

Strengths

The multicenter international prospective data collection including 217,174 patient-admissions in 22 hospital sites in 7 high-income countries is a strength of this study. This improves the generalizability of the results of the findings.

CONCLUSIONS

Our 22 -hospital evaluation found that mortality, clinical deterioration, and resuscitation team activation were about 10-20% less frequent with each additional patient per nurse. Our findings were consistent across multiple analyses and in six related measures, and contrast with prior observational data in the adult population showing increased nurse staffing was associated with reduced events. In contrast, these results from paediatric inpatient units suggest that reductions to current patient-to-nurse ratios may not improve the quality and safety of care. Our findings are hypothesis generating and emphasize the value of considering other factors, including skill mix, education requirements, experience, and physician: patient ratios before implementing well-intentioned decisions to increase nurse staffing to improve patient safety and quality of care.

Figure 1: Average patients per nurse and total number of ward-days by hospital.
This figure plots the total number of ward days in a period at a site against the average patient-nurse ratio in that period at that site, with periods at the same site plotted in the same colour. The boxplots in the margin show the 25th and 75th percentiles and medians across site-periods.

Figure 2: The association of the mortality and process of care study outcomes and nurse staffing. Each of the 6 panels plots the rate of the outcome in a period at a site against the average patient-

nurse ratio in that period at that site, with the areas of the circles being proportional to the number of patient discharges or number of ward days. The fitted values from the univariate random effects models are shown by the solid line (mean) and shaded area (95% CrI).

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Competing interests: C Parshuram is a named inventor of the Bedside Paediatric Early Warning System and has shares in a decision support company in part owned by SickKids that was established to commercialize the Bedside Paediatric Early Warning System. All other authors declare no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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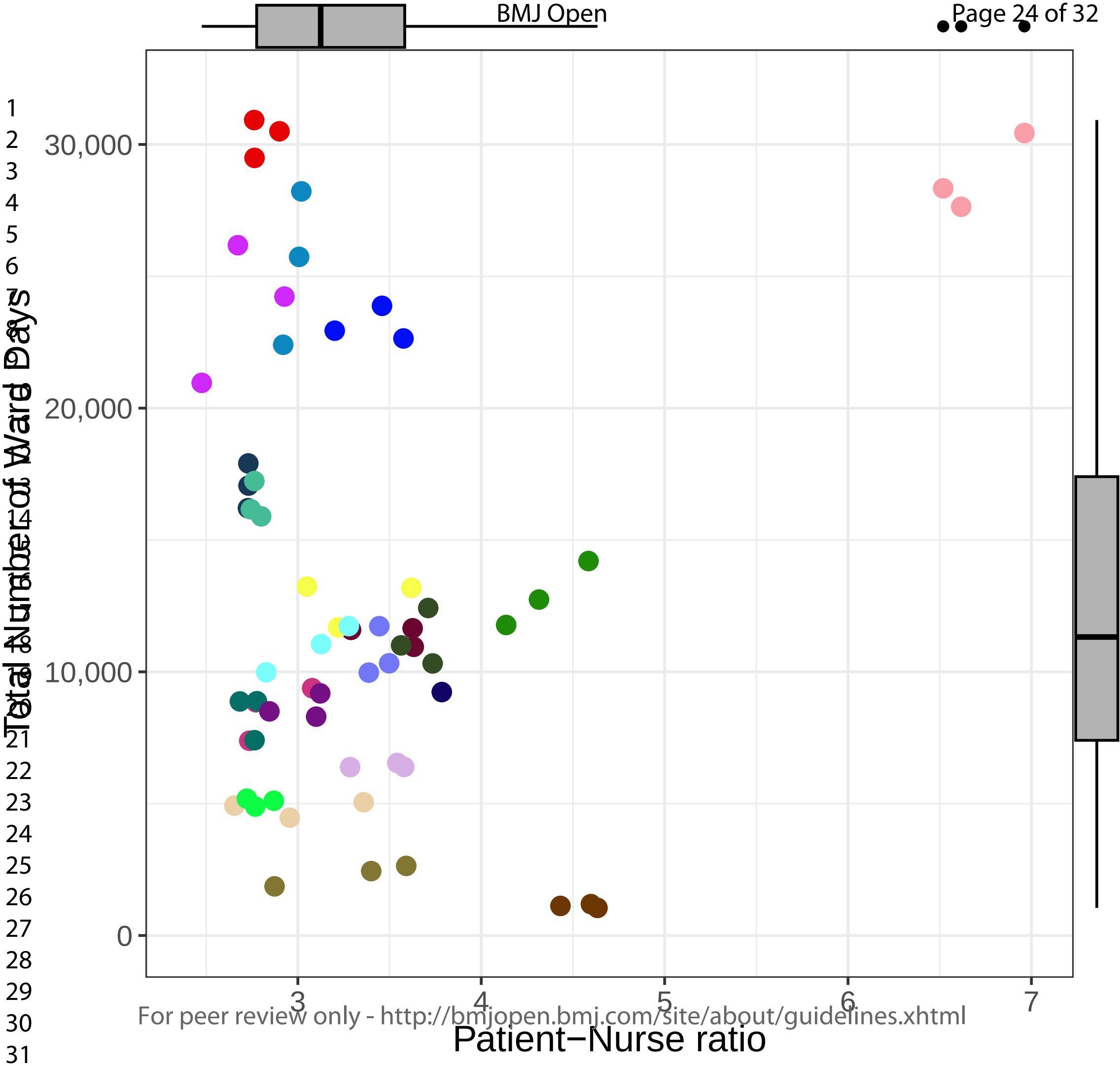
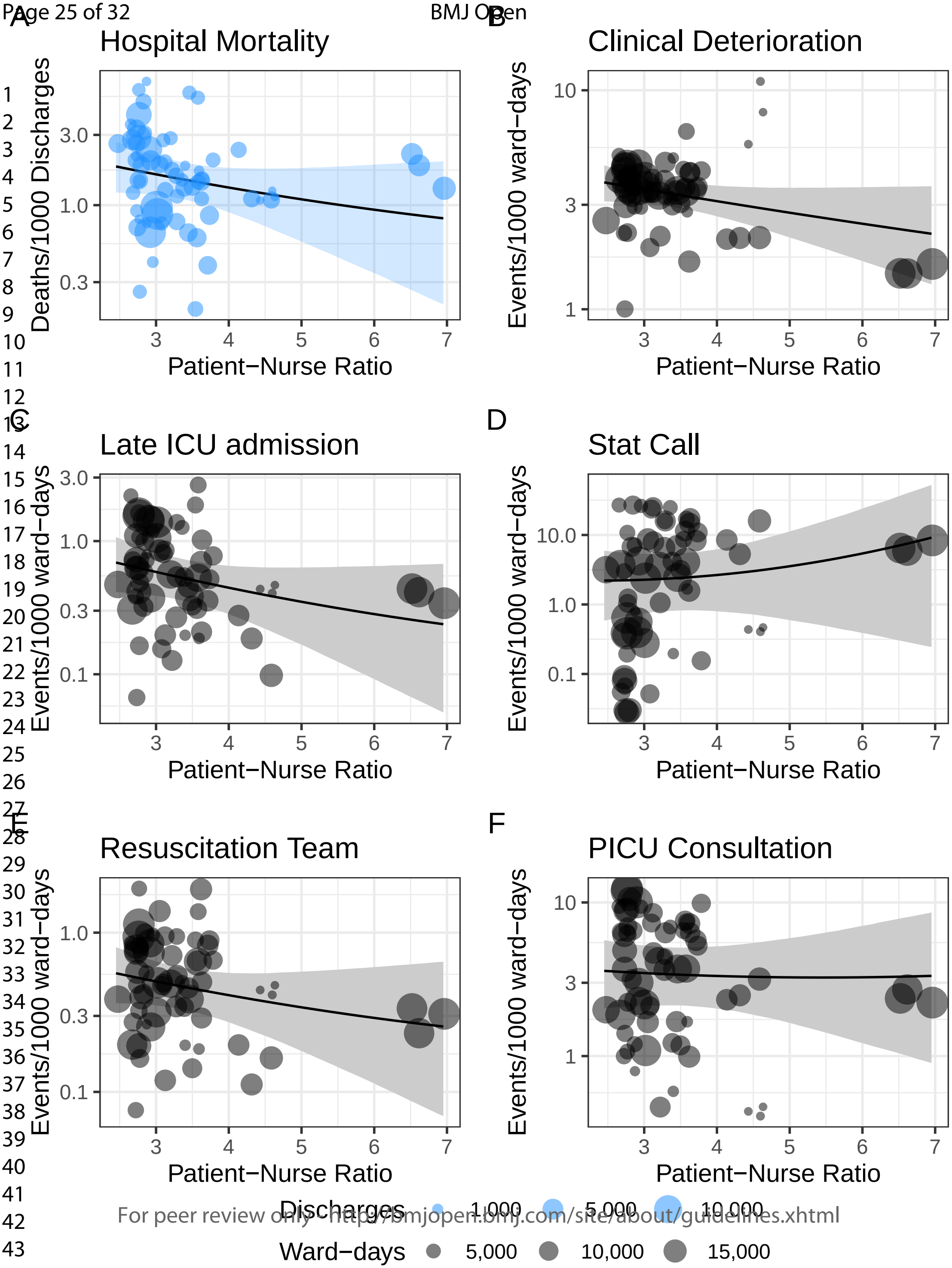
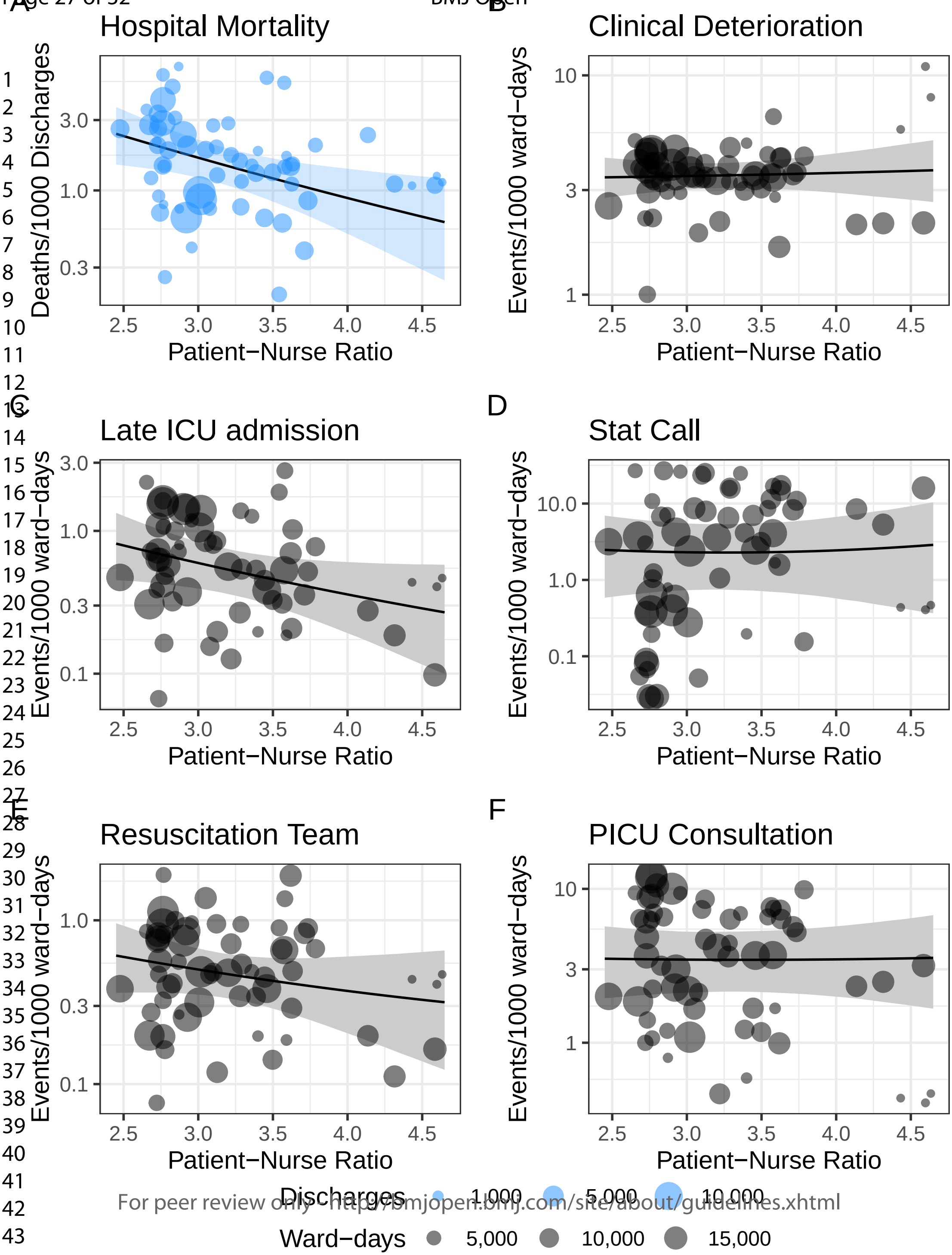

Total Number of Ward Days
30,000
20,000
10,000
0
3
4
5
6
7
Patient−Nurse ratio


A
Hospital Mortality
Deaths/1000 Discharges
3.0
1.0
0.3
3 4 5 6 7
Patient−Nurse Ratio
B
Clinical Deterioration
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
C
Late ICU admission
Events/1000 ward−days
3.0
1.0
0.3
0.1
Patient−Nurse Ratio
D
Stat Call
Events/1000 ward−days
10.0
1.0
0.1
Patient−Nurse Ratio
E
Resuscitation Team
Events/1000 ward−days
1.0
0.3
0.1
Patient−Nurse Ratio
F
PICU Consultation
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
Discharges 1,000 5,000 10,000
Ward−days 5,000 10,000 15,000

Supplementary Figure 1A

The association of the study outcomes and nurse staffing by study period, excluding site 21 (sensitivity analysis)

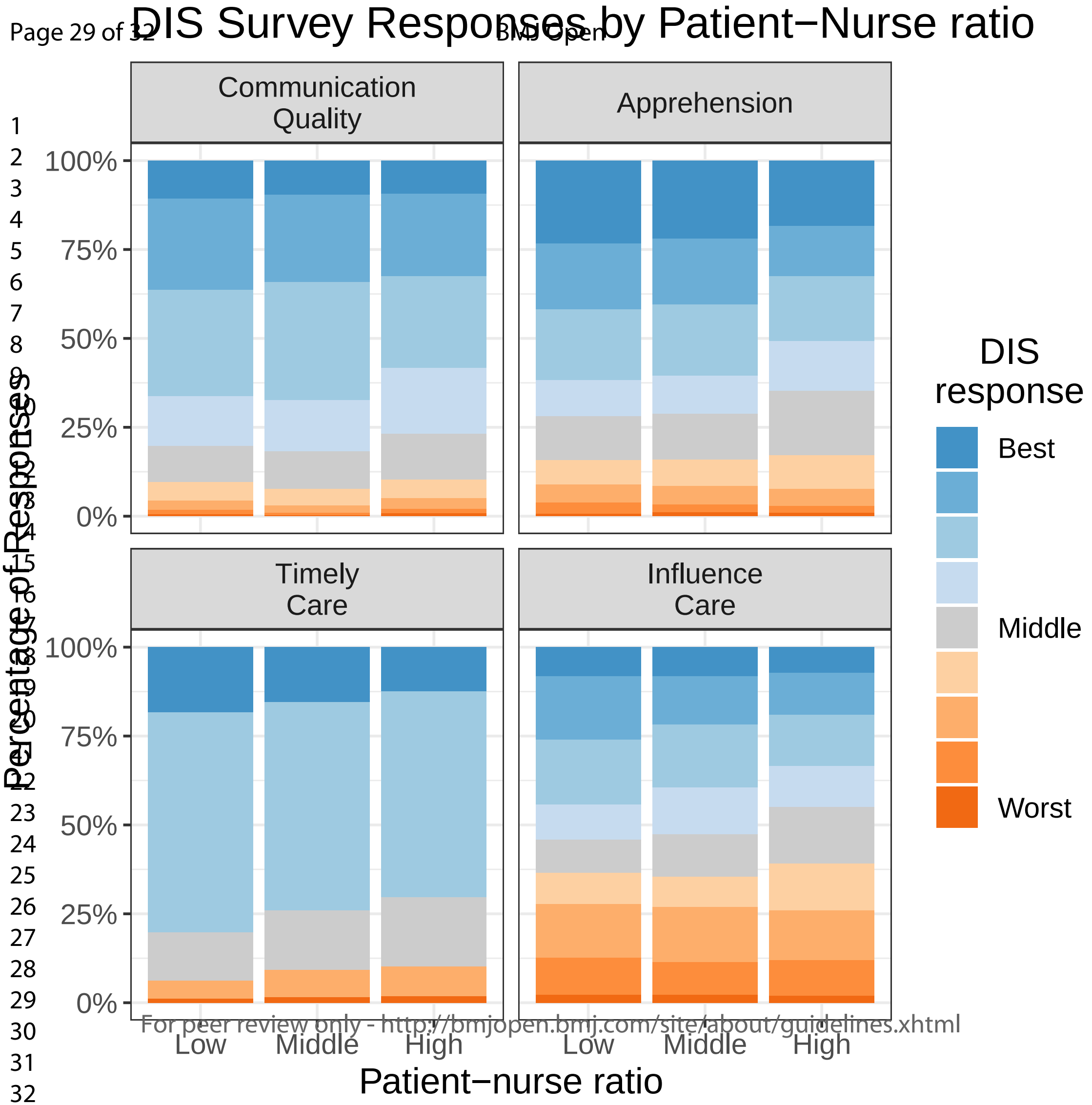
Figure 1A: After excluding the site with outlying patient-nurse ratios in all three period, the association of the mortality and process of care study outcomes and nurse staffing. Each of the 6 panels plots the rate of the outcome in a period at a site against the average patient-nurse ratio in that period at that site, with the areas of the circles being proportional to the number of patient discharges or number of ward days. The fitted values from the univariate random effects models are shown by the solid line (mean) and shaded area (95% CrI).


A
Hospital Mortality
Deaths/1000 Discharges
3.0
1.0
0.3
2.5
3.0
3.5
4.0
4.5
Patient−Nurse Ratio
B
Clinical Deterioration
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
C
Late ICU admission
Events/1000 ward−days
3.0
1.0
0.3
0.1
Patient−Nurse Ratio
D
Stat Call
Events/1000 ward−days
10.0
1.0
0.1
Patient−Nurse Ratio
E
Resuscitation Team
Events/1000 ward−days
1.0
0.3
0.1
Patient−Nurse Ratio
F
PICU Consultation
Events/1000 ward−days
10
3
1
Patient−Nurse Ratio
Discharges
1,000
5,000
10,000
Ward−days
5,000
10,000
15,000

Supplementary figure 2A: nurse perceptions of quality of care (sensitivity analysis, excluding site 21)

Figure 2A: Distributions of DIS responses for communication quality (9-point scale), apprehension (9-point scale), timely care (5-point scale) and influence care (9-point scale) from nurses, where higher scores are better perceptions. The responses are grouped according to whether they were collected from a site-period with a nurse -patient ratio in the lowest quartile, middle two quartiles, or highest quartile. The 5 point scale was coded so that 5 was “best”, 3 was “middle” and 1 was “worst” (with 4 mapping onto 7, and 2 mapping onto 3 on the 9-point scale). As the ratio increases, there are proportionally more orange bar segments (worse perceptions) and fewer blues ones (better perceptions).

Legend: DIS=Documentation and Interaction Survey


DIS Survey Responses by Patient−Nurse ratio
Communication Quality
Apprehension
Timely Care
Influence Care
100%
75%
50%
25%
0%
Percentage of Responses
Low
Middle
High
Patient−nurse ratio
DIS response
Best
Middle
Worst

Appendix

Table 1A: Sources of data

Data role	Data	Measurement level	Source within EPOCH	Comment
Outcomes	Clinical outcomes (mortality, clinical deterioration events, late ICU admissions, duration of hospital stay, etc.)	One outcome per patient	Clinical trial outcomes database	All 217,174 patients in the trial had these outcomes documented
	Vital signs documentation	One value per patient	Random selection of 5 patients each week for the 26 weeks of each study period at each site	8,282 patients were assessed for documentation of vital signs
	Documentation and Interaction Survey	One survey per nurse	Nurses at enrolled hospitals	All nurses were approached
Predictors	Patient to nurse ratio	One value per site per time period	Random selection of 5 patients each week for the 26 weeks of each of three study periods at 22 sites	The ratio was based on the average number of patients being cared for by nurses of the selected 8,282 patients.
	Site-specific descriptors (Mean BP,Medical team,PM MD/Fellow,Transplant)	One value per site per time period	Clinical trial site descriptors database	Mean BP could vary by study period. Other descriptors were constant

Table 2A: Vital Signs Monitoring sensitivity analysis (excluding site 21)

Outcome	Univariable		Multivariable	
	RR (95% CrI)	Pr(RR<1)	RR (95% CrI)	Pr(RR<1)
Heart Rate	0.98 [0.86, 1.13]	60.4%	0.96 [0.83, 1.10]	74.0%
Respiratory Rate	1.01 [0.88, 1.17]	43.3%	0.98 [0.83, 1.14]	62.5%
Systolic blood pressure	1.01 [0.79, 1.31]	45.6%	0.89 [0.71, 1.13]	83.4%
Oxygen saturation	1.06 [0.89, 1.27]	25.7%	0.98 [0.81, 1.19]	57.8%
Capillary refill time	0.97 [0.17, 4.77]	52.0%	0.27 [0.06, 1.18]	95.8%
Oxygen therapy	0.92 [0.73, 1.15]	77.8%	0.89 [0.70, 1.14]	81.8%
Respiratory effort	1.04 [0.52, 2.32]	45.6%	0.86 [0.34, 2.01]	63.3%
All of above collected	1.11 [0.76, 1.62]	28.9%	0.78 [0.57, 1.07]	94.1%
Temperature	0.99 [0.89, 1.09]	60.3%	1.00 [0.89, 1.13]	51.3%

Vital signs monitoring -random effects negative binomial models. Estimates are rate ratios (RR) for the relative change in the rate of documentation with one additional patient per nurse, 95% CrIs and P(RR < 1), the probability that the rate of documentation is reduced with an increasing patient-nurse ratio.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	2
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5-6
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5-6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5-7*
Bias	9	Describe any efforts to address potential sources of bias	7-8
Study size	10	Explain how the study size was arrived at	In original EPOCH trial
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7-8
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7-8
		(*b*) Describe any methods used to examine subgroups and interactions	N/A
		(*c*) Explain how missing data were addressed	N/A
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed	N/A
		(*e*) Describe any sensitivity analyses	7-8

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	8
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	/
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	8
		(b) Indicate number of participants with missing data for each variable of interest	N/A
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*9-12*
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-12
		(*b*) Report category boundaries when continuous variables were categorized	N/A
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-14
Generalisability	21	Discuss the generalisability (external validity) of the study results	16
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	N/A

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.