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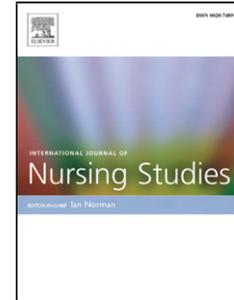
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## Accepted Manuscript

Title: Post-operative mortality, missed care and nurse staffing in nine countries: a cross-sectional study

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## ABSTRACT

**BACKGROUND:** Variation in post-operative mortality rates has been associated with differences in registered nurse staffing levels. When nurse staffing levels are lower there is also a higher incidence of necessary but missed nursing care. Missed nursing care may be a significant predictor of patient mortality following surgery.

**AIM:** Examine if missed nursing care mediates the observed association between nurse staffing levels and mortality.

**METHOD:** Data from the RN4CAST study (2009-2011) combined routinely collected data on 422,730 surgical patients from 300 general acute hospitals in 9 countries, with survey data from 26,516 registered nurses, to examine associations between nurses' staffing, missed care and 30-day in-patient mortality. Staffing and missed care measures were derived from the nurse survey. A generalized estimation approach was used to examine the relationship between first staffing, and then missed care, on mortality. Bayesian methods were used to test for mediation.

**RESULTS:** Nurse staffing and missed nursing care were significantly associated with 30-day case-mix adjusted mortality. An increase in a nurse's workload by one patient and a 10% increase in the percent of missed nursing care were associated with a 7% (OR 1.068, 95% CI 1.031-1.106) and 16% (OR 1.159 95% CI 1.039-1.294) increase in the odds of a patient dying within 30 days of admission respectively. Mediation analysis shows an association between nurse staffing and missed care and a subsequent association between missed care and mortality.

**CONCLUSION:** Missed nursing care, which is highly related to nurse staffing, is associated with increased odds of patients dying in hospital following common surgical procedures. The analyses support the hypothesis that missed nursing care mediates the relationship between registered nurse staffing and risk of patient mortality. Measuring missed care may provide an 'early warning' indicator of higher risk for poor patient outcomes.

**What is already known about the topic?**

- Research spanning decades has reported that lower registered nurse (RN) staffing is associated with higher levels of case-mix adjusted patient mortality
- Lower RN staffing is also associated with a greater risk that necessary nursing care is missed due to lack of time.
- Mediation analysis has shown that missed care explains the association between nurse staffing and patient experiences with care.

**What this paper adds?**

- Building on earlier previously published findings from an observational study of 422,730 patients who underwent common surgeries in 300 European hospitals, this paper provides evidence of an association between missed nursing care and post-surgical mortality.
- Missed nursing care is a mediator in the relationship between nurse staffing and mortality.
- The analysis supports the existence of a causal relationship between nurse staffing and patient outcomes; an interpretation of the relationship that has hitherto been contested.

**Post-operative mortality, missed care and nurse staffing in nine countries: a cross-sectional study****BACKGROUND**

Case-mix adjusted mortality rates have become a common indicator of the effectiveness of health care.<sup>1</sup> Even when restricting analysis to a defined group of patients – for example, those undergoing common surgical procedures – wide variations in case-mix adjusted mortality rates are reported between hospitals.<sup>2</sup> In some healthcare systems complications and mortality rates are used as a performance metric for hospitals or individual surgeons.<sup>3</sup> The premise is that if factors related to the patient are taken into account through case-mix adjustment, any remaining

differences between hospitals in the odds of patients dying during their hospitalization or within a short period following their discharge may reflect differences in the treatment and care provided. However, it is unclear to what extent the variation in patient deaths across hospitals is related to differences in post-surgical care.

Hospitals with high and low mortality rates are reported to have very similar rates of postoperative complications, whereas the risk of death following complications after surgery varies substantially.<sup>2</sup> To lower post-operative mortality it may therefore be as important to ensure effective management of complications as it is to reduce the incidence of complications.

In their review of post-operative care following common surgery, the Royal College of Surgeons<sup>4</sup> in England highlights the importance of adequate ward-based nurse staffing to deliver a “reliable tiered pathway of care” to detect and respond to patients who develop complications. The relevance of adequate nurse staffing to patient outcomes and hospital mortality rates is borne out by research.<sup>5</sup> Studies report an observed association between higher hospital mortality rates and lower levels of registered nurse staffing. Much of this research has come from hospitals in the US but over the past 10 years the same patterns of association have been reported in studies across Europe and other parts of the world.<sup>6 7,8</sup>

More recently researchers have shown that missed care is twice as common in some European hospitals as in others, and examined the relationship between nurse staffing levels and missed care (also termed ‘nursing care that is left undone’, ‘incomplete care’, or ‘rationed care’).<sup>9</sup> When registered nurse staffing levels are low, nursing care is more likely to be reported as missed due to lack of time.<sup>9,10</sup> A higher rate of missed care in turn relates to lower safety grades reported by nurses,<sup>10</sup> patients being less likely to rate their hospital highly,<sup>11</sup> and increased risk of falls and other adverse events.<sup>12</sup> Missed care is thus both an outcome of low nurse staffing as well as a potential predictor of patient experience and outcomes; it may be a key mechanism through which nurse staffing has an effect on patient outcomes.<sup>13</sup> However, this hypothesis that missed care explains the observed relationship between staffing and mortality has remained largely untested,

with few analyses directly assessing it by studying both relationships simultaneously. A recent study has confirmed missed care as a mediator for the association between nurse staffing and patient-reported experience.<sup>11</sup>

Establishing whether missed care increases the risk of patient deaths following surgery will clearly have important patient safety implications. If it is established as a mediator it might be that reports of missed care could provide a leading indicator of nursing related safety. And if missed care not only relates to risk of death following surgery, but partly explains the relationship between staffing and mortality, it would also support the existence of a causal relationship between nurse staffing and outcomes - an interpretation of the relationship that has hitherto been contested.<sup>14</sup>

## **METHODS**

### **Study design and participants**

This is an observational study exploring the relationship between nurse staffing, missed care and mortality. It seeks to explore whether there is an association between missed care and mortality and, through mediation analysis, determine whether this relationship can explain the association between nurse staffing levels and mortality.

The study uses administrative data on hospital patients and hospital characteristics and a survey of nurses in 300 hospitals in nine European countries (Belgium, England, Finland, Ireland, the Netherlands, Norway, Spain, Sweden, and Switzerland). Information about the 300 hospitals (e.g. bed size, available technology, teaching status) was provided by administrators and supplemented with publically available data. The patient data are based on 422,730 patients aged 50 years or older who underwent common general, orthopedic, or vascular surgeries and were discharged from these 300 hospitals between 2007 and 2009 – the year most proximate to the nurse survey in each country for which data were available. The nurse survey data are from 26,516 registered nurses (RNs) in the same 300 hospitals and were collected in 2009-2010. In each country the survey covered a minimum of 30 general acute care hospitals, each with at least 100 beds. The study included most adult acute care hospitals in Norway and Ireland, and geographically

representative samples of hospitals in the other countries. In Sweden, all hospitals were included by surveying medical and surgical nurses nationally. The survey response rates averaged 62%. The study protocol<sup>15</sup> and approach to defining and analyzing patient mortality data<sup>6</sup> are described in detail in earlier publications.

The study protocol was approved by the ethics committee at Katholieke Universiteit Leuven, which was the coordinating centre for the study, and by the relevant ethical committees in all participating countries. Country level approvals to acquire and analyze patient outcomes data were also obtained.

## **Measures**

### *Mortality and related measures*

The primary outcome measure is patient mortality following surgery within 30 days of admission. It was measured using administrative data on discharge status (death or survival), length of stay (less than 30 days) and adjusted for surgical procedure undergone (43 dummy variables for the specific surgery types), patient age, sex and admission type (emergency or elective). Established definitions were used for common surgical procedures and comorbidities.<sup>16</sup> The 17 comorbidities from the Charlson comorbidity index were used to control for differences between patients on admission.<sup>17</sup>

### *Missed care*

The nurses surveyed were asked: “On your most recent shift, which of the following activities were necessary but left undone because you lacked the time to complete them?” and presented nurses with a list of 13 activities, informed by earlier work in USA and Europe.<sup>18,19</sup> The measure included activities related to clinical care as well as planning and communication: adequate patient surveillance, skin care, oral hygiene, pain management, treatments and procedures, administering medication on time, frequently changing the patient’s position, comforting/talking with patients, educating patients and family, preparing patients and families for discharge, developing or updating nursing care plans/care pathways, documenting nursing care, and planning care. The percentage of care activities reported as missed by each nurse (as a

percentage of all possible activities) was averaged across all nurses in each hospital and used as a measure of missed care.

#### *Nurse staffing, nurse education, and the nurse work environment*

Survey respondents were asked for the number of staff providing direct patient care and the number of patients on their ward on the last shift that they worked. From these responses, the mean number of patients per RN providing direct care was calculated, and the mean for each hospital was then derived by averaging across all nurse respondents in each hospital.

In line with previous research examining the relationship between nurse staffing and mortality<sup>6</sup>, data on the educational level of nursing staff and the nurse practice environment were also included in the statistical model. Nurse education levels for each hospital were measured by calculating the percentage of nurses at each hospital that reported holding at least a baccalaureate degree in nursing. The practice environment of each hospital was measured using the 'Practice Environment Scale' which comprises 32 items from the Nursing Work Index<sup>20</sup>. The four items related to perceptions of nurse staffing were excluded to avoid common variance with the nurse staffing measure. The mean score across the remaining 28 items for all nurses surveyed was calculated for each hospital.

#### *Control variables*

The models we used also controlled for hospital bed size, teaching status, and technology. We differentiated non-teaching hospitals (no medical residents or fellows) from teaching hospitals (which had residents or fellows). High technology hospitals were defined as those that had facilities for open-heart surgery, major organ transplants, or both.

#### **Statistical analysis**

The approach taken to testing the mediating effect of missed care is based on Baron and Kenny.<sup>21</sup> A mediator is defined as a variable that accounts, in whole or in part, for the relationship between the independent and dependent variables. To test the mediation hypotheses in this case,

it is necessary to establish that the staffing level (independent variable) is significantly related to 30-day inpatient mortality (dependent variable) and to missed care (proposed mediator). A significant association between the proposed mediator and the dependent variable must also be established. In other words, if missed care does indeed mediate the relationship between staffing and mortality, there will be a significant relationship between missed care and mortality, and the relationship between staffing and mortality will be reduced when the effects of both are examined in the same model.

To examine the association between nurse staffing and 30-day inpatient mortality (Model 1), missed care and 30-day inpatient mortality (Model 2) and nurse staffing, missed care and 30-day inpatient mortality (Model 3), we first used a generalized estimation approach and random intercept models. Thirty-day mortality was analysed at the patient level, whilst missed care and nurse staffing were analysed at the hospital level. Dummy variables to allow for unmeasured differences across countries were included. We used SAS software for this purpose and replicated and expanded on the modeling approach for estimating the association between nurse staffing and case-mix adjusted mortality.

In the first model we specify the association between nurse staffing and 30-day inpatient mortality. These findings, which have been published previously<sup>6</sup>, are presented to place the new analysis in context and include the association between nurse education and 30-day inpatient mortality. No interaction effects between any of the main covariates or control variables were observed.

In the second model we examine the association between missed care and 30-day inpatient mortality.

The third model introduces missed care into the nurse staffing and 30-day inpatient mortality model, as a covariate together with nurse staffing.

In Model 4, a multilevel structural equation model in the form of multilevel mediation analysis is undertaken to test whether missed care directly mediates the relationship between registered nurse staffing levels and 30-day inpatient mortality. Here, we simultaneously examine the association between nurse staffing and missed care on 30-day inpatient mortality, and the association between nurse staffing and missed care. This model also includes the associations between nurse education, practice environment and 30-day inpatient mortality, and between the practice environment and missed care. For Model 4, Mplus Version 7.2 was used as this is specialized software geared towards multilevel structural equation modeling.<sup>22</sup> Estimating the mediation model (appendix A) in this software required several adjustments to be made. Firstly, the risk-adjustment was simplified by summarizing the 17 comorbidities into an index using established procedures.<sup>23</sup> Secondly, the 43 dummy variables for type of surgery were collapsed into three categories: orthopaedic, general or vascular surgery. Sensitivity analyses showed that these simplifications did not impact findings for Models 1 to 3 (appendix B). Country-level random intercepts were used.

The approach used adopts Bayesian methods using probit link. A Bayesian estimator is imposed by the statistical software that was used for constructing this model. In a Bayesian analysis a posterior distribution for parameter estimates is formed by combining prior distributions with the data likelihood. Here, diffuse priors were used. This means that no information from previous studies was used and that the estimate is closer to a maximum-likelihood estimate. Sensitivity analyses again showed that these specifications did not change any of the conclusions for Models 1 to 3 (appendix C). Evidence of convergence was assessed by running longer chains. Parameter values changed very little and for each parameter the Proportional Scale Reduction Factor was below 1.1, suggesting good convergence and model fit.<sup>24</sup>

## RESULTS

The mean hospital mortality rate across all 300 hospitals, before adjusting for case-mix, was 1.3%. Across the nine countries, on average 25.6% of the necessary nursing care activities were reported as missed on the last shift (Table 1).

Table 2 first shows the previously established relationship<sup>6</sup>: nurse staffing levels and the proportion of nurses with a bachelor's degree are associated with 30-day inpatient mortality (Model 1). Each additional patient per nurse is associated with a 7% increase in the odds of a patient dying within 30 days of admission (OR 1.068 95% CI 1.031-1.106). Every 10% increase in bachelor's degree nurses was associated with a decrease in this likelihood by 7% (OR 0.929, 0.886-0.973). In the second model, missed care is significantly associated with 30-day case-mix adjusted inpatient mortality. Each 10% increase in missed care is associated with a 16% (OR 1.159 95% CI 1.039-1.294) increase in the odds of a patient dying within 30 days of admission (Model 2). When nurse staffing and education are included in the model in addition to missed care (Model 3) the relationship between nurse staffing and patient mortality is reduced (from an OR of 1.068 in Model 1, to OR 1.056 in Model 3), signaling a potential mediation effect. The estimate for the association between nurse education (OR 0.928 95% CI 0.885-0.972) and mortality remains almost unchanged.

Model 4 builds on these findings, and shows that missed care mediates the association between nurse staffing and patient mortality (Table 3). This can be seen from the significant indirect effect in the model, which is the product of the path from nurse staffing to missed care, and the path from missed care to mortality. The direct effect of nurse staffing on mortality is no longer significant (the credibility interval includes zero), whilst the effect of nurse education on mortality remains.

## DISCUSSION

Based on data from over 400,000 patients and 25,000 nurses, we found that missed care by registered nurses due to lack of time, is significantly related to mortality following common surgical procedures. More patients die when nurses report that they do not provide complete care, and necessary care is more likely to have been missed when registered nurse staffing levels are low.

The results support a potential explanation for the frequently observed association between nurse staffing and mortality, that nurses who have too many patients to care for do not have time to complete all necessary care, and that this missed nursing care increases the odds of poor patient outcomes, in this case a higher risk of dying in hospital. The findings also confirm that bachelor's level educational qualifications for hospital nurses are associated with lower post-surgical mortality, and the inclusion of missed care in our analysis did not reduce this association.

Errors in hospitals remain a major cause of death.<sup>25</sup> Many patient safety initiatives aimed at reducing post-surgical mortality focus on reducing the risk of potentially fatal errors being made.<sup>26</sup> The findings from our study remind us that errors of omission – in this case missed nursing care – must be considered alongside errors of commission.<sup>27</sup> Reducing deaths following common surgery requires hospitals not just to minimize the risk of mistakes being made, but to maximize the capacity for necessary surveillance to be undertaken and nursing care to be delivered.

Risk control is commonplace in other safety-critical industries; safety systems in nuclear or airline industries make explicit the conditions required for services to be run safely, and to discontinue if these conditions – including staffing levels - are not met.<sup>28</sup> Yet such an approach regarding safe nurse staffing is rare.

These findings have implications for health care systems: for hospital managers responsible for making decisions about workforce size and configuration and deployment patterns, for regulators charged with monitoring patient safety, and for policy makers with responsibility for developing guidance on minimizing risk in hospitals to keep patients safe from avoidable harm. Appropriate workforce policies and practices are needed to minimize the risk of care being missed and of patients dying from factors that are within the health system's control, such as safe nurse staffing.

It is also within the health system's control to educate nurses at the bachelor's level. Our study confirms that after taking into account many other factors including the severity of illness of patients and the adequacy of nurse staffing, the proportion of nurses with bachelor's education is

directly associated with inpatient mortality. It is timely to call attention to this finding in view of continuing debate on the merits of bachelor's education for nurses and proposals to introduce apprentice education for RNs.<sup>29</sup>

There are a number of limitations to the study. Whilst we used patient level analysis of outcomes data, aggregated data were used to construct estimates of nurse measures. Furthermore, the number of nurses from which these measures were constructed varied across countries and hospitals within countries, as previously reported<sup>30</sup>. This may have produced biased estimates.

A limitation of this study is reliance on nurses' reports of missed care. Previous research on nurse reported outcomes such as quality of care shows that nurse reports are a good representation of actual patient mortality derived from independent sources<sup>31,32</sup>. The association between nurses' reports of missed care and mortality from independent data sources as reported here offer confidence that our global measure of missed care is a reasonable proxy measure of what would be found using confirmatory counts of actual missed care which would be difficult if not impossible to collect in a large number of hospitals.

Another limitation of the analysis presented in this paper is that it has examined missed care as a single construct, without exploring differences related to the constituent activities of care. Previously published analysis has explored the prevalence and nature of care left undone by care activity type and found a pattern: clinical activities were less likely to be reported as missed due to lack of time compared with communication and planning activity<sup>10 33</sup>. Future studies could examine the relative effect on patient outcomes of missing different aspects of care, to explore which may be most 'critical' to patient outcomes. Advances in electronic health records will allow for individual nurse-patient matching as well as identification of missed care on a patient level. This would allow researchers to have a more detailed understanding of which care activities are missed, under which circumstances these are missed, and which patient outcomes are affected by which missed care activities.

The cross-sectional study design means that causality cannot be proven. However, having tested a hypothesized causal pathway, we can have more confidence in the inference of causality.

This is the first international health services research study that points to a chain of systemic factors that define quality in terms of in-hospital mortality. The relationships found between nurse staffing, missed nursing care and mortality suggest that measuring missed care could be a useful performance measure for hospitals to monitor, as is being piloted in Ireland.<sup>34</sup> In England, analysis of observed case mix adjusted hospital mortality rates compared against the expected rates revealed that insufficient nurse staffing was a contributing factor with poor patient outcomes at Mid-Staffordshire Trusts.<sup>35</sup> But the analysis and subsequent inquiries came several years after poor care was delivered. Monitoring missed care may offer a more responsive and sensitive early-warning system for hospitals, to detect problems before patients die, rather than using patient deaths themselves as the indicator of poor care.

## **Authorship**

All authors meet the ICMJE recommended criteria for authorship. They have:

- 1a) made a substantial contribution to the conception and design
- 1b) the acquisition, analysis, or interpretation of the data,
- 2a) Contributed to drafting the article or
- 2b) critical revision for important intellectual content
3. They have given (or undertake to give) final approval of the version to be published
4. Have agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.

No further writing assistance other than basic copy-editing has been provided.

## **Ethical approval**

The study protocol was approved by the ethics committee at Katholieke Universiteit Leuven, which was the coordinating centre for the study, and by the relevant ethical committees in all participating countries. Country level approvals to acquire and analyze patient outcomes data were

also obtained and permissions acquired for the research to be undertaken at each hospital. For example in England the National Research Ethics service granted ethical approval. (ref 09/H0808/69).

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## Competing/Conflicting interests

The authors declare that they have no competing interests, or conflict of interests.

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**Table 1. Surgical Patient Discharges and Deaths, and Nursing Characteristics, in the 300 Study**

**Hospitals**

	Mean (SD)	Range (across hospitals)
Discharges	1409	103-6583
30 day in-patient mortality following common surgery	1.3% (0.83)	0.7-2%
Nurse staffing (RN : Patient ratio)	8.3 (2.4)	3.4-17.9
Practice Environment Scale (PES-28) (1-4 scale)	2.68	2.05-3.36
Nurse Education: Percentage with degree	52% (27)	0-100%
Missed care: Percentage	25.6 %	8.3-50.0%

**Table 2. Adjusted models estimating the association between staffing and education and 30-day inpatient mortality (Model 1), the association between missed care and 30-day inpatient mortality (Model 2) and association between missed care, staffing, education and 30-day inpatient mortality (Model 3)**

<b>30-day inpatient mortality</b>				
	<b>Odds ratio</b>	<b>Lower 2.5% CI</b>	<b>Upper 2.5% CI</b>	<b>p-value</b>
<b>Model 1</b>				
Nurse staffing	1.068	1.031	1.106	0.0002
Nurse education	0.929	0.886	0.973	0.0019
<b>Model 2</b>				
Missed care	1.159	1.039	1.294	0.0084
<b>Model 3</b>				
Missed care	1.125	1.006	1.258	0.0392
Nurse staffing	1.056	1.018	1.095	0.0036
Nurse education	0.928	0.885	0.972	0.0018

*All models adjusted for hospital characteristics (bed size, teaching status, and technology) and patient characteristics (age, sex, admission type, type of surgery, and comorbidities present on admission) unless specified otherwise. Models 1 and 3 are also adjusted for practice environment. CI = Confidence Interval.*

**Table 3. Adjusted model estimating the mediating effect of missed care in the association between nurse staffing and 30-day inpatient mortality (Model 4)**

	30-day Inpatient mortality				Missed Care			
	Estimate	Posterior SD	Lower 2.5% CI	Upper 2.5% CI	Estimate	Posterior SD	Lower 2.5% CI	Upper 2.5% CI
<b>Model 4</b>								
Missed care	0.050	0.023	0.005	0.093	--	--	--	--
Nurse staffing	0.013	0.010	-0.006	0.032	0.100	0.016	0.070	0.133
Nurse education	-0.033	0.010	-0.052	-0.011	--	--	--	--
Indirect effect	0.005	0.002	0.000	0.010	--	--	--	--

*The model is adjusted for hospital characteristics (bed size, teaching status, and technology), practice environment, patient characteristics (age, sex, admission type, type of surgery, and comorbidities present on admission). SD = Standard Deviation CI = Credibility Interval (Bayesian estimator).*