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Ward and shift level nurse staffing, vital signs observations and patient outcomes: observational study using routinely collected data

Submission date
03/06/2015

Recruitment status
No longer recruiting

Registration date
11/06/2015

Overall study status
Completed

Last Edited
10/07/2023

Condition category
Other

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims

The NHS in England, like many other healthcare systems, is facing intense pressure to maintain the quality and safety of care provided in hospitals at the same or less cost than in previous years. The quality of nursing care - and the potential for inadequate nursing care to do patients great harm - has emerged as a factor in several reports into failings in NHS hospitals. These reports have often noted that failing to ensure adequate nurse staffing was an important issue that was associated with poor care and preventable deaths. This is consistent with research showing associations between low levels of nurse staffing and increased death rates in hospitals. However, because nurse staffing is only one factor affecting a patient's death, it is difficult to use these studies to directly show the effects of low staffing on nursing care delivery and to help decide the best staffing levels. Recently studies have begun to explore "missed nursing care", defined as nursing care that was needed but not done, as a key factor leading to negative patient outcomes. Missed opportunities to observe and act on deterioration of the patient's condition are thought to be important factors in preventable hospital deaths. Previous studies on missed nursing care have relied on nurses to report the care they missed. This may not be entirely accurate.

This study aims to explore how nurse staffing levels are related to missed or delayed vital signs observation (that is, measurements of blood pressure, pulse and respirations) using direct measures of the timing of observations recorded in a clinical information system. The study will also look at the relationship between staffing levels and possible consequences of missed observations in terms of cardiac arrest calls, unanticipated admission to intensive care and death.

Who can participate?

This is an observational study using information from all adult inpatients in general wards of Portsmouth Hospitals NHS Trust (PHT), from approximately 100,000 nursing shifts.

What does the study involve?

This study will use information about ward and shift level nurse staffing, vital signs observations

and patient outcomes that are routinely recorded in a hospital. Relationships between registered nurse and health care assistant staffing levels and outcomes will be explored using statistical models which can give a picture of relationships showing, for example, how much the risk of missing a set of observations is increased for every additional patient cared for by a nurse. These estimates will be used to estimate staffing required on different wards to achieve satisfactory levels of compliance with vital signs observations. We will look at the costs and consequences of different levels and mix of nursing staff to achieve this consistently. The study will give guidance on the relative importance and costs of different nursing skill mixes and staffing levels in achieving consistent observations and safe care.

What are the possible benefits and risks of participating?
Observational study – not applicable.

Where is the study run from?
Portsmouth Hospitals NHS Trust (PHT), UK

When is the study starting and how long is it expected to run for?
June 2015 to May 2017

Who is funding the study?
NIHR Health Services and Delivery Research (HS&DR) Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 1, 08-04-14

Study information

Scientific Title
Nurse staffing levels, missed vital signs observations and mortality in hospital wards: modelling the consequences and costs of variations in nurse staffing and skill mix. Retrospective observational study using routinely collected data

Study objectives
This study is a retrospective observational study that will use data derived from clinical and workforce databases to explore the relationship between staffing levels on hospital wards and vital signs observations taken by nurses and care assistants. Previous studies on missed nursing care have relied on nurses to report the care they missed. This may not be entirely accurate. This study aims to explore how nurse staffing levels are related to missed or delayed vital signs recording using direct measures of the timing of observations recorded in a clinical information system. The study will also look at the relationship between staffing levels and possible consequences of missed observations in terms of cardiac arrest calls, unanticipated admission to intensive care and death.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East Midlands, 24/02/2015, Northampton REC reference: 15/EM/0099

Study design
Single centre retrospective observational study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Adult inpatient general wards in a large acute care hospital trust

Interventions
This is a retrospective observational study using routinely collected data on ward and shift level nurse staffing, vital signs observation and patient outcomes.

Intervention Type
Other

Primary outcome measure
Missed vital signs observations. A missed observation is defined as an observation that is not performed before the next observation is due. The planned frequency of observations is determined from a national protocol based on NEWS values, which identifies risk of adverse outcome.

Secondary outcome measures
1. Rate of missed observations in high risk sub-groups, defined by elevated NEWS score
2. Absolute delay (time from observation becoming due until an observation is taken)
3. Relative delay (time from observation becoming due until an observation is taken expressed as a proportion of the scheduled observation frequency in minutes)
4. Deaths
5. Cardiac arrests
6. Unanticipated ICU admissions
7. Records of other assessments in electronic vital signs system

Overall study start date
01/06/2015

Completion date
31/05/2017

Eligibility

Key inclusion criteria
All adult inpatients in general wards of a large acute care hospital within a period of 6 months will be included.
Data for the study will be derived from a database of records made using the VitalPAC system, which enables nurses to record clinical data on hand held devices at the bedside. We will also use

data from the Patient Administration System (PAS) and hospital laboratory records to determine rates of mortality and to adjust for patient level variation in risk. E-rostering (available from 2012 onwards) will provide workforce data from approximately 100,000 shifts available for the study.

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Patients: 44,000 estimated patient stays in one year. Wards: estimated 32 wards meeting eligibility criteria (general acute in-patient). NHS Hospital Trusts: 1

Key exclusion criteria
All adult inpatients in general wards will be included. ITU, maternity and paediatric units are not considered.

Date of first enrolment
01/09/2015

Date of final enrolment
31/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Portsmouth Hospital NHS Trust
Trust Headquarters
Queen Alexandra Hospital
Southwick Hill Road
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Government

Funder Name
Health Services and Delivery Research (HS&DR) Programme

Alternative Name(s)
Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The research outputs from this project will be of interest to a wide audience. We anticipate a number of potential papers for academic peer review journals that will contribute to the emerging literature on the mechanisms of the link between nurse staffing and patient outcomes.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/09/2019	01/10/2019	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		01/01/2019	10/07/2023	Yes	No
Other publications		21/11/2018	10/07/2023	Yes	No
Other publications		01/02/2019	10/07/2023	Yes	No
Results article		01/11/2018	10/07/2023	Yes	No