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Authors	Drennan, Jonathan;Duffield, Christine;Scott, Anne Philomena;Ball, Jane;Brady, Noeleen M.;Murphy, Aileen;Dahly, Darren L.;Savage, Eileen;Corcoran, Paul;Hegarty, Josephine;Griffiths, Peter
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University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

PROFESSOR JONATHAN DRENNAN (Orcid ID : 0000-0001-7365-4345)

PROFESSOR CHRISTINE DUFFIELD (Orcid ID : 0000-0001-6534-8743)

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Corresponding author mail id :- jonathan.drennan@ucc.ie

A Protocol to Measure the Impact of Intentional Changes to Nurse Staffing and Skill-Mix in Medical and Surgical Wards

Running Head: A Protocol to Measure the Impact of Intentional Changes to Nurse Staffing

Jonathan DRENNAN* PhD, RN, Professor of Nursing and Health Services Research, School of Nursing and Midwifery, University College Cork

Christine DUFFIELD PhD, RN, Professor of Nursing and Health Services Management, University of Technology, Sydney, Centre for Health Services Management and Edith Cowan University, Nursing and Midwifery

Anne Philomena SCOTT PhD, RN, Professor and Vice-President for Equality and Diversity National University of Ireland Galway

Jane BALL PhD , RN Principal Research Fellow, Health Sciences, University of Southampton

Noeleen M BRADY, PhD BA, Postdoctoral Researcher, School of Nursing and Midwifery, University College Cork

Aileen MURPHY PhD, MEconSc, Lecturer, Cork University Business School, University College Cork

Darren DAHLY PhD, MHS, Principal Statistician and Senior Lecturer, HRB Clinical Research Facility Cork, Department of Epidemiology and Public Health, University College Cork

Eileen SAVAGE PhD, RN, Professor of Nursing, School of Nursing and Midwifery, University College Cork

Paul CORCORAN PhD, MSc (Stats) Senior Lecturer, Department of Epidemiology and Public Health, University College Cork

Josephine HEGARTY PhD, RN Professor of Nursing, School of Nursing and Midwifery, University College Cork

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Peter GRIFFITHS PhD, RN Chair of Health Services Research, Health Sciences, University of Southampton

***Address correspondence to:** Jonathan Drennan, Professor of Nursing and Health Services Research, School of Nursing and Midwifery, Brookfield Health Sciences Complex, University College Cork, College Road, Cork T12 AK54, Ireland. Twitter: jdadrennan

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Conflict of interest

Jonathan Drennan is a member of the Editorial Board of the *Journal of Advanced Nursing*

Abstract

Aim

The aim of this research is to measure the impact planned changes to nurse staffing and skill-mix have on patient, nurse and organisational outcomes.

Background

It has been highlighted that there are several design limitations in studies that explore the relationship between nurse staffing and patient, nurse and organisational outcomes; not least that the vast majority of research in this area emanates from studies that are predominantly

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observational in design. There are limited studies that measure nurse, patient, organisational and economic outcomes using a longitudinal design following a planned change in nurse staffing.

Design

The research will employ a longitudinal, multimethod approach to evaluate the impact that planned changes in nurse staffing and skill-mix have on wards in three pilot hospitals.

Methods

Administrative data collection will take place on a shift-by-shift basis prospectively over a three-year period including the measurement of nursing sensitive outcomes: cross-sectional patient experience data and nurse outcomes (nursing work, job satisfaction, burnout, missed care) will be collected at intervals prior to, during and after the implementation of planned changes in nurse staffing and skill-mix. Data will be analysed using interrupted time series models, adjusted for key hospital, ward and patient-level factors. An economic costing of the changes will further investigate the resources required for the intervention that can then be aggregated to a national level for future roll-out plans.

Discussion

The study aims to provide evidence on the impact of planned changes to nurse staffing and skill-mix based on a systematic approach using a longitudinal design and to determine the extent to which the approach can be implemented at a national level.

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Keywords: nursing; nursing hours per patient day; patient outcomes; nurse staffing; workload; healthcare quality; nursing sensitive outcomes.

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INTRODUCTION

Recent enquiries have identified failings in care that have resulted in adverse patient outcomes in several countries; for example, in Ireland investigations into the safety and governance of two major hospitals (Health Information and Quality Authority (HIQA) 2012, 2013); in the UK, The Mid Staffordshire NHS Foundation Trust Inquiry (The Mid Staffordshire NHS Foundation Trust Inquiry chaired by Robert Francis QC, 2010); and an enquiry into a preventable death at the Royal Darwin Hospital in Australia (Coroner's Court 2008). In several of these reports, the role of safe staffing was highlighted as a factor in ensuring good patient outcomes. Safe nurse staffing requires that there are sufficient nurses available to meet patient needs, that nurses have the required skills and are organised to enable them to deliver the highest care possible. Research over the last 20 years has demonstrated the impact that nurse staffing can have on patient outcomes, with several studies reporting that lower levels of nurse staffing are associated with adverse outcomes (Aiken *et al.* 2002; Kane *et al*., 2007; Needleman 2011; Griffiths *et al.* 2014). In relation to nurse staffing and patient outcomes, it was identified that higher rates of staffing are associated with lower rates of failure to rescue, falls, length of stay and readmission rates. It has also been identified that lower levels of staffing are associated with higher rates of drug administration errors and episodes of care left undone. In particular, there is a growing body of evidence that reports on the association between lower nurse to patient ratios and increased patient mortality (Cho *et al.* 2003; Rafferty *et al.* 2007; Needleman *et al.* 2011; Aiken *et al.* 2014; Griffiths *et al.* 2016a; Ball *et al.* 2017).

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Recently, Griffiths *et al.* (2016b) identified several design limitations in studies that explored the relationship between nurse staffing and patient, nurse and organisational outcomes; not least that the vast majority of research in this area emanates from studies that are predominantly observational in design. This issue has also been highlighted by others who conclude that there are limited studies published that measured outcomes following a planned change in nurse staffing (Shekelle 2013). This may call into question the causal inference of the outcomes associated with nurse staffing, including mortality. The limitations in study designs were also highlighted in safe nurse staffing guidelines developed by the National Institute for Health and Care Excellence (NICE) where they concluded that:

> There is a lack of high-quality studies exploring and quantifying the relationship between registered nurse and healthcare assistant staffing levels and skill mix and any outcomes (NICE, 2014: 27).

In addition, several systematic reviews on the association between nurse staffing and patient outcomes identified few, if any, studies that used interventional designs (Kane *et al.* 2007; Butler *et al.* 2011; Shekelle 2013). To highlight this point, Kane *et al.* (2007: 97) concluded: 'the nature of the study designs precludes any efforts to establish a causal relationship. There are no interventions, let alone controlled trials.' The designs used in studies that measure the economic benefits of safe nurse staffing have also been identified as being variable in quality; the economic models presented were predominantly based on observational data or included several methodological weaknesses (Goryakin *et al.* 2011, Twigg *et al.* 2015; Griffiths *et al.* 2016). This has led to calls for designs that include intervention studies and that cost data is collected in studies with longitudinal designs (Goryakin *et al.* 2011).

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Shekelle (2013) has recommended that the methodological weaknesses outlined should be addressed by time series designs or before and after studies that examine the outcomes associated with intentional changes in staffing. The research design outlined in this protocol attempts to address the shortfalls outlined in previous studies through the use of interventional longitudinal design to measure several outcomes associated with planned changes in nurse staffing in Ireland.

BACKGROUND

Nurses and midwives account for a third of the health workforce in Ireland; by far the largest single group of healthcare professionals in the country (Department of Health 2017). The Central Statistics Office (CSO 2017) quarterly national household survey estimates that there are approximately 52,000 nurses and midwives working in the public and private sectors in Ireland (this figure includes nurses and midwives working in clinical, management and education roles); this approximates to 11.9 nurses per thousand of the population (OECD 2017). Approximately 36,000 whole time equivalent nurses and midwives are employed in the public health sector (Department of Health 2017), with the remainder predominantly in the private hospital and nursing home sector. Between 2008 and 2016 there was a reduction of 4.8% in the public-sector nursing workforce, largely as a consequence of employment control frameworks implemented during the economic recession; there has been some recovery in numbers with a 1.2% increase in the nursing workforce recorded between the years 2016 and 2017 (Department of Health 2017). However, as with other developed countries (Aiken *et al.* 2012), retention of nurses in Ireland remains problematic with a turnover rate of 7.9% amongst staff nurses; this is higher than the overall national health workforce turnover rate of 6.5% (Health Service Executive (HSE) 2016). This has led to demands from nursing and midwifery representative unions that issues with recruitment and

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retention are dealt with as a matter of urgency (Irish Nurses and Midwives Organisation 2016). As well as industrial relations' issues, the Irish arm of the European *RN4CAST* study (Scott *et al.* 2013; Sermeus *et al.* 2011) concluded that there was a lack of data on nurse staffing and on the impact that nursing numbers had on patient outcomes in the healthcare system. Staffing and resource allocation were also highlighted as concerns with wide variations identified in nurse-patient ratios across the system with the determination of the nursing complement in clinical areas predominantly based on historical decisions rather than using a systematic approach to identifying staffing requirements.

To address the issues outlined above, the Department of Health in Ireland published a document entitled a *Framework for Safe Nurse Staffing and Skill Mix in General and Specialist Medical and Surgical Care Settings in Adult Hospitals in Ireland* (henceforth referred to as the *Framework)* (Department of Health 2016). In this report several recommendations were made to ensure that the staffing of hospitals was safe and effective. The recommendations in the *Framework* were based on the best evidence related to determining the nursing resource in medical and surgical settings and drew on evidence reviews undertaken for NICE (Griffiths *et al.* 2015; Simon *et al.* 2015), recommendations and outcomes from the *RN4CAST* programme of research (Sermeus *et al.* 2011) and studies undertaken in the Australian healthcare system (Twigg *et al.* 2011, 2012).

The *Framework* was developed following consultation with key stakeholders in the healthcare system and included national and international experts. The consultation resulted in several recommendations, including that: the Clinical Nurse Manager (CNM) - grade II (equivalent to ward sister/leader) role is fully 100% supervisory (that is, they carry no patient

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caseload) and 'that a systematic … evidence based approach to determine nurse staffing and skill mix requirements is applied' (Department of Health 2016: 9). The skill-mix recommendation outlined in the *Framework* is that 80% of nurse staffing in medical and surgical wards is provided by registered nurses (RNs). The *Framework* also recommended the undertaking of quality research on the association between nurse staffing and patient outcomes as a part of the process of implementing the recommendations.

The *Framework* further recommended that nursing hours per patient day (NHPPD) be introduced on several pilot wards to determine staffing requirements; it proposed that actual and required NHPPD are to be estimated based on patient acuity and dependency levels, bed occupancy and patient turnover rates. Following the introduction of this process, staffing rotas are to be developed based on the required NHPPD. It is envisaged that this will require an alteration in the staffing complement (staffing numbers and skill-mix) on the pilot wards. A relatively similar approach was employed in Western Australia and, following its implementation, resulted in a 3.5% increase in nursing staff, a reduction in agency staff, hospital vacancies declined and there was an increase in staff retention. The additional NHPPD also resulted in an associated decrease in nursing sensitive outcomes (Twigg *et al.* 2011).

The introduction and application of the recommendations in the *Framework* on a ward-by-ward basis, provides a unique opportunity to measure the impact of staff changes on patient, staff and organisational outcomes prospectively rather than through retrospective observational designs, which, as highlighted, are the most frequently used methodological approach in this area of research. In addition, with the economic case for providing care by

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RNs coming under increasing scrutiny and moves to replace nurses with associate or assistant roles (Duffield *et al.* 2016), the introduction of the recommendations in the *Framework* allows for the implementation of a longitudinal design that measures the impact of intentional changes to staffing on economic as well as patient, nurse and organisational outcomes.

THE STUDY

Aim

The aim of this research is to measure the impact planned changes (as outlined in the *Framework*) to nurse staffing and skill-mix have on patient, nurse and organisational outcomes.

Objectives

1. Compare the rates of outcomes in 14 nursing sensitive patient outcomes (NSOs) (mortality, morbidity) before implementing the recommendations in the *Framework* with those achieved after implementation.
2. Examine the extent to which care left undone events (missed care) changed pre and post the introduction of the recommendations in the *Framework*.
3. Examine the extent to which patient satisfaction changed pre and post the introduction of the recommendations in the *Framework*.
4. Examine the extent to which nurse outcomes (job satisfaction, intention to leave, burnout) changed pre and post the introduction of the recommendations in the *Framework.*
5. Examine the extent to which the work environment changed pre and post the introduction of the recommendations in the *Framework*.

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6. Examine the cost effectiveness of introducing the recommendations in the *Framework.*

Design and Methodology

Design

The research will employ a longitudinal, multimethod approach to evaluate the impact that planned changes in nurse staffing and skill-mix have on wards in three pilot hospitals. The recommendations in the *Framework* will be implemented on a step-by-step basis on a ward-by-ward level; initially this will be in 16 out of 35 wards. This will allow us to compare wards that have made a change in staffing with wards that have not. Administrative data collection will take place on a shift-by-shift basis prospectively over a three-year period; cross-sectional patient experience data and nurse outcomes will be collected at intervals associated with changes to staffing. The periods of data collection will allow comparisons to be made pre the implementation of the recommendations in the *Framework*, during transition of the implementation and post-implementation. This approach allows us to measure the impact on changes in patient, staffing and organisational outcomes as they occur. An economic evaluation of the study will further investigate the resources required for the intervention. The research will initially be undertaken on a pilot basis in one large acute hospital (670 beds), one medium-sized acute hospital (235 beds) and, a small acute hospital (109 beds) (see Figure 1). The results from the research will be used to determine the extent to which the recommendations in the *Framework* will be rolled out on a national level.

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Research Plan

Intervention

The interventions in this study will be the implementation of the recommendations in the *Framework*; that is the introduction of required NHPPD to determine staffing levels based on patient acuity and dependency, the alteration in skill-mix (80% RN to 20% HCA) and, ensuring the role of the CNM 2 (ward leader) is 100% supervisory. This will include the measurement of the total nursing hours available pre and post the intervention; this will be further divided into RN hours and HCA hours (skill-mix) and the measurement of supervisory and clinical hours provided by the CNM 2 grade. Actual and required NHPPD will be estimated through *TrendCare*, a commercial workforce planning management system (http://www.trendcare.com.au). The *Trendcare* system provides data on patient acuity and dependency measures, skill-mix and patient allocation and has been identified as a valid approach in predicting the nursing resource for patient care (Plummer 2015). Based on NHPPD measures pre the intervention (actual NHPPD), nurse staffing levels and skill-mix will be adjusted (required NHPPD) in the intervention wards based on patient acuity and dependency needs. As in Needleman et al.'s (2011) study, nursing shifts will be measured in eight-hour blocks.

The following outlines the methods that will be used to measure the objectives of the study:

Objective 1: Compare the rates of outcomes in 14 nursing sensitive patient outcomes (NSOs) (mortality, morbidity) before implementing the recommendations in the *Framework* with those achieved after implementation.

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This will include the analysis of a cohort of all multi-day stay patients admitted to the study wards over the period of the research; analysis will include NSOs and rates of patient turnover. The Hospital Inpatient Enquiry (HIPE) system is Ireland's current method for collecting data on inpatients discharged from acute hospitals and it includes details of mortality, morbidity, length of stay and diagnoses in the hospital setting (O'Loughlin *et al.* 2005); this system will be used to collect data related to NSOs. NSOs measured will follow the format of those identified by Needleman *et al.* (2002) who conducted a review of published and unpublished literature to identify NSOs in hospitals and further refined the outcomes by consulting with experts in the field. Fourteen outcomes sensitive to nurse staffing and coded on hospital discharge database were identified and included: length of stay, urinary tract infection, pressure ulcers, pneumonia, shock, cardiac arrest, upper gastrointestinal bleeding, sepsis, deep venous thrombosis, CNS complications, wound infection, pulmonary failure, metabolic derangement, death and failure to rescue. Needleman *et al.* (2002) developed an algorithm to identify each of these outcomes from the hospital discharge database which used the American ICD-9 coding system. The Republic of Ireland uses the ICD-10 coding system in line with the systems in Australia and New Zealand. McCloskey (2003) mapped the original ICD-9 codes in Needleman's study to the ICD-10 codes that are used in Australia and New Zealand. The ICD-10 Crosswalks have been used in previous research (Duffield *et al.*, 2007, 2009a, b; McCloskey and Diers, 2005; Twigg *et al.* 2011) and permission has been obtained to use the ICD-10 Crosswalks in this research study.

Objective 2: Examine the extent to which care left undone events changed pre and post the introduction of the recommendations in the *Framework*.

The *Framework* highlighted the importance of monitoring care left undone events (referred to as Safety CLUEs) as a means of monitoring the extent to which staffing is safe and

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recommended that six Safety CLUEs are monitored, including: patient surveillance, vital sign monitoring, administration of medications, patients' physical needs, missed staff breaks and, delay in completing care plans. In addition, following on from the work undertaken by Ball *et al.* (2014, 2017), other missed care events measured will include: comforting/talking with patients, updating nursing care plans, educating patients, changing of patient's position, oral hygiene, pain management, preparing patients for discharge, skin care and undertaking procedures. The conceptual definition of missed care in this study is stated as: 'care that nurses regard as necessary but was left undone on their last shift due to lack of time' (Ball *et al*. 2014: 117). Safety CLUEs will be measured by asking nursing staff on each of the wards at six to eight week intervals over the three years of the research programme: 'On your most recent shift, which of the following activities were necessary but left undone because you lacked the time to complete them?' (Ball *et al.* 2013).

Objective 3: Examine the extent to which the patient experience changed pre and post the introduction of the recommendations in the *Framework*

Research has identified that higher nurse-to-patient ratios and a better nurse work environment are associated with higher levels of patient satisfaction (Aiken *et al.* 2012; Aiken *et al.* 2018). Increased patient satisfaction has also been associated with the introduction of clinical nurse leaders into a role, similar to the proposed 100% supervisory status of the CNM II grade highlighted in the *Framework* (Simon *et al.* 2015).

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The *Consumer Assessment of Healthcare Providers and Systems* Survey (CAPHS), developed by the Agency for Healthcare Research and Quality, will be used to measure the patient experience. A shortened version of this instrument, as used in the *RN4CAST* study (Sermeus 2011, Aiken *et al.* 2012), will be used prior to and following the introduction of the recommendations in the *Framework*. The areas of patient experience measured will include: nurse communication, nurse responsiveness, pain management, communication about medication and care transition.

Objective 4 - Examine the extent to which nurse outcomes (job satisfaction, intention to leave, burnout) changed pre and post the introduction of the recommendations in the *Framework*

Registered nurses and HCAs in each of the hospitals participating in the study will be requested to complete a cross-sectional questionnaire at time points both pre and post the implementation of the recommendations in the *Framework*. The questionnaire will first assess demographic, educational and professional details.

Workload of nursing staff has previously been associated with nurses' levels of job satisfaction and intention to leave an organization. In this study, it is proposed that the relationship between changes to staffing and skill-mix and job satisfaction and intention to leave will be measured. Job satisfaction will be measured using a single item; this approach was used in the *RN4CAST* study (Sermeus *et al.* 2011). In addition, the relationship between NHPPD and organisational commitment will be measured through asking staff to indicate their intention to leave the organisation; this will be measured by a single item that will ask respondents to rate the probability of them leaving or intending to leave their current

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employment. This single item measure ranges from 1 ('definitely will not leave') to 4 ('definitely will leave'). A qualitative open question will also ask respondents their proposed reason for intending to leave. The human services version of the Maslach Burnout Inventory (HS-MBI) will be used (Maslach and Jackson 1981, 1996, Maslach *et al.* 1996) to measure three areas associated with burnout over time: emotional exhaustion, depersonalisation and personal accomplishment and was previously used as a cross-sectional measure of burnout in the RN4CAST study (Aiken *et al.* 2012).

Objective 5: Examine the extent to which the work environment changed pre and post the introduction of the recommendations in the *Framework*

As Ball *et al.* (2014) highlight, the organisational climate where nurses work is associated with patient outcomes. The association between NHPPD and several ward/organisational factors will be measured at time points throughout the study using the *Practice Environment Scale of the Nursing Work Index – Revised (NWI-R)* (Lake 2002) as well as staff perceptions of the quality of care and nurse turnover and retention rates. The *NWI-R* is a measure of the work environment and emerged from research on Magnet Hospitals (Kelly *et al.* 2011). The instrument consists of five subscales: nurse autonomy, control over practice, nurse-doctor relations, nursing leadership and resource adequacy (Aiken & Patrician, 2000); items are scored on a four-point Likert scale. Mean scores are calculated for each domain with higher scores indicating a more favourable environment. A single item from the Agency for Healthcare Research and Quality's survey on patient safety culture will measure quality of care on respondents' ward/unit hospital. Nurses will be asked to give their unit an overall grade on patient safety by rating the quality of nursing care on their last shift and changes in

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the quality of nursing care prior to (pre-test), during (transition) and following the introduction of the recommendations (post-test). Rates of nurse retention and turnover will also be measured as high rates of nurse turnover have been reported to be associated with poor working environments (Cho *et al.* 2012).

For both objectives 5 and 6, sample size will be determined on intention to leave as the primary outcome. A minimum sample size of 330 nurses is based on Duffield's previous work (Duffield et al. 2011a,b) which identified that approximately 25% of nurses intend to leave and a hypothesized difference between groups of 15% (prior to and post the implementation of the *Framework* recommendations), a power of 0.8 and significance set at $p < 0.05$. However, it is proposed that all nurses in the wards will be surveyed.

Objective 6 - Investigate the cost effectiveness of introducing the recommendations in the *Framework*

An economic evaluation will be conducted to determine the cost effectiveness of implementing the recommendations in the *Framework*. Economic evaluations provide a means to assess the costs and effects of an intervention and compare this with the next best alternative (Drummond *et al.* 2015). This requires estimating costs and benefits of implementing the recommendations; these are then compared with the *status quo* without the *Framework* to determine cost effectiveness; in effect, comparing before and after. The economic effects of the implementing the recommendations will be measured under two main areas: staffing costs and change in NSOs. If there is a variation in actual and required NHPPD, Department of Health consolidated salary scales (Department of Health 2018) will be used to cost the alterations that occur in nurse staffing (RN and HCA) in line with national

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guidelines on conducting economic evaluations (HIQA 2018). With regards to agency staff costing, both RNs and HCAs will be considered. These changes will be valued in monetary terms, using average hourly cost of agency (RNs and HCAs respectively) per ward; these costs will be collected from the three pilot hospitals.

Economic benefits will be measured by the extent to which nursing sensitive outcomes measures change with implementation of the *Framework*. These will be measured in monetary units, facilitating a cost benefit analysis. In the absence of unit costs, as provided by Personal Social Services Research Unit in the UK (Curtis and Burns 2017), appropriate diagnostic related group (DRGs) from the National Case-mix/National Pricing Office will be employed. Using patient level data collected, the National Ready Reckoner DRGs (Version 8) (National Pricing Office n.d.) will be used to value the relevant inpatient case-mix cost per case (i.e. episode of care) for each patient from the health care provider's perspective. To identify the financial impact of nursing sensitive outcomes on in-patient case-mix cost per case, an ordinary least squares regression will be performed. Estimates from this regression will be used to value the changes in nursing sensitive outcomes from implementing the recommendations in the *Framework.* This is in line with methodology employed in previous international studies (Ehsani *et al.* 2006, Twigg *et al.* 2012). The estimates from the regression will be applied to the change in nursing sensitive outcomes to calculate the benefits in monetary terms. These benefits will be compared with the cost of implementing the recommendations in the *Framework*, to estimate net benefit thereby assessing its cost effectiveness.

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Reliability and Validity

The scales used in this study have previously been tested for both reliability and validity in several settings. The PES-NWI has demonstrated good reliability in previous research (Lake & Friese, 2006; Roche & Duffield, 2010) with reports of good predictive validity (Bruyneel *et al.* 2009). The single item job satisfaction question has been identified as having acceptable levels of reliability (Wanous *et al.* 1997); in addition, the validity of HS-MBI has previously been ascertained through principal components analysis, confirmatory factor analysis and convergent and discriminant validity with reliability scores for the three subscales reported to be greater than the recommended level of .70 (Maslach *et al*. 1996). Further psychometric testing of the scales will be undertaken as part of this research study.

Statistical analysis

All data analysis will be conducted under the quality control system of the Statistics and Data Analysis Unit of the Health Research Board Clinical Research Facility at the university of the principal investigator using the R Project for Statistical Computing (R Core Team 2017). The multimethod data will be thoroughly checked for errors using a variety of techniques (e.g. multivariate outlier detection, extensive plotting of data) prior to being combined into a study dataset that will be used for the subsequent analyses. Data queries will be resolved by returning to the source data. The creation of the study dataset will be clearly documented so that it can be easily reproduced from the source data. The study dataset will be prepared using FAIR principles (Wilkinson *et al.* 2016).

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Following the creation of the study dataset, we will prepare a descriptive code book. Categorical variables will be described using percentages and counts in each category, while continuous variables will be described by the appropriate measures of central tendency and variability. The codebook will also contain plots for each variable. For outcomes that are measured on a daily or weekly basis (e.g. NSOs identified in the HIPE data), we will use interrupted time series models to estimate the impact of the intervention on said outcomes. For outcomes that are available less frequently, we will instead use generalized linear mixed models to estimate the impact of the intervention, while accounting for clustering of observations at the hospital/ward level.

Models will use the appropriate link function (e.g. Poisson for daily counts of NSOs aggregated by hospital; logit for patient-level probability of experiencing an NSO) and be adjusted for key hospital, ward and patient level factors, taking special care to not adjust for possible consequences of the intervention. We will report both unadjusted and adjusted regression coefficients with 95% confidence intervals. Model assumptions will be evaluated as appropriate. Heterogeneity by hospital and ward will also be explored.

With respect to the time-series models, while we expect the influence of the intervention to be apparent in the outcomes shortly after its implementation (if at all), we will test for both step-changes in risk as well as steady changes in the degree of risk over time. Candidate models will be compared using likelihood ratio tests. Residual correlation over time will be further explored and accounted for using standard approaches to time-series data. In addition, a regression analysis will be employed to estimate the impact of nursing sensitive outcomes on in-patient case-mix cost per case. The regression will control for age, gender, admission type, complexity, length of stay and time.

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Ethical considerations

The research ethics committee of the participating hospitals have granted ethical approval for all stages of the study. Anonymised data will be collected from the administrative data systems used in the study. Patient questionnaires will be completed anonymously and will be distributed at ward level. Staff questionnaires will be coded as, due to the study design, it will be necessary to collect data from the same members of staff at different time points. Once data collection and data entry has been completed, staff data will be irrevocably anonymized. All data will be password protected and encrypted and the research team will ensure confidentiality is maintained throughout the study.

DISCUSSION

For many years in Ireland decisions on nurse staffing in healthcare settings were based on historical staff complements or professional judgement; no widespread systematic approach was put in place. However, as a consequence of several factors, including industrial unrest within the profession and changing patient demographics, the Department of Health (2016) published a *Framework* with several recommendations that included the use of a systematic approach to the determination of nurse staffing based on patient acuity and dependency, a setting of the skill-mix and the workload of the ward leader. The introduction of these recommendations on a phased basis in three pilot hospitals provides a unique opportunity for the introduction of a policy initiative on nurse staffing to be aligned with a programme of research. The research outlined here follows several recommendations that have been made on enhancing methodological approaches to measure the association between nurse staffing and outcomes. These approaches include before and after and longitudinal study designs and the addition of an economic evaluation. In addition, the design outlined here follows several

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highly regarded studies in this field including the RN4CAST study (Sermeus *et al.* 2011), research into nurse staffing in Australia (Duffield *et al.* 2011) and Needleman *et al.'s* (2011) study; in particular, Ball (2017: 13) highlighted Needleman's work as a landmark study as it 'allowed temporal precedence to be established.' The strength of the design outlined in this protocol, follows the design in Needleman's work, including the unit of analysis at ward rather than hospital level, repeated measures over time (3 years) and, the collection of staffing levels for each shift (NHPPD) rather than nurse self-reports. The design also lets us explore the variation in nursing hours required and actual hours available on a shift-by-shift basis. This will allow us to measure the temporal precedence of events; that is the outcomes observed followed the intervention (i.e. changes to staffing) (Griffiths *et al.* 2016).

LIMITATIONS

There are several potential limitations to the study. Response rates to surveys can be challenging and this may be more so as respondents will be required to respond to several repeat surveys over time. In addition, administrative data collected is dependent on the quality of data entry and checking of the quality of this data will be essential throughout the process of the study. Several outcomes associated with nurse staffing may not be related to the changes that occur following the implementation of the recommendations; however, the research design outlined here should control for several the limitations highlighted in previous research in this area.

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Author Contributions:

All authors have agreed on the final version and meet at least one of the following criteria (recommended by the ICMJE*):

1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;

2) drafting the article or revising it critically for important intellectual content.

* http://www.icmje.org/recommendations/

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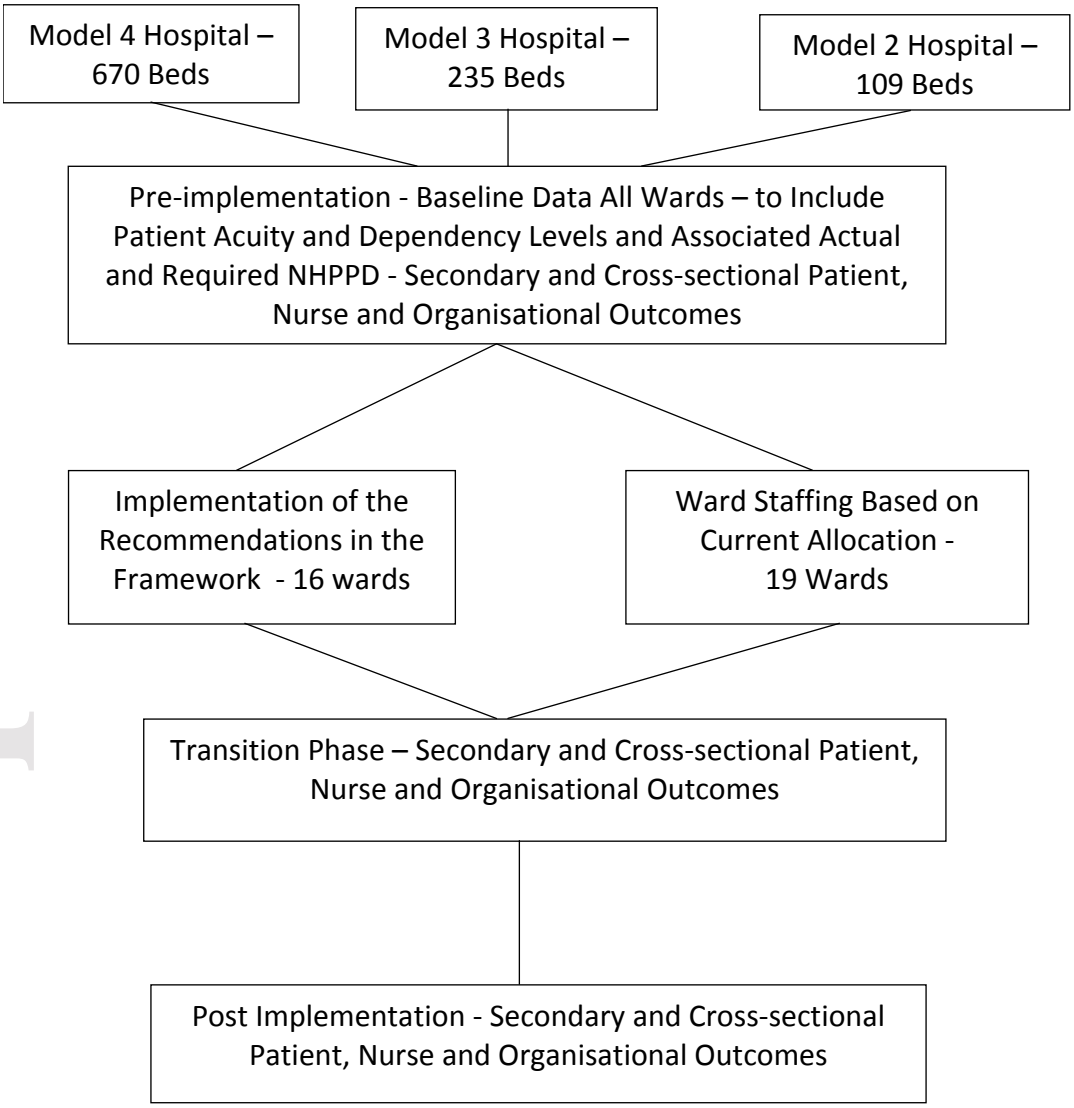


Figure 1 Research Design

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