

NIHR HS&DR Project: 12/128/48
The future of 24/7 care: investigating the links between staffing levels, patient access and inequalities in health outcomes

Research Protocol Version 3
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Background

Overview

There are long-standing concerns that patients admitted to hospital at night and at weekends, when staffing levels are lower and some services are not available, suffer higher complication and mortality rates than patients admitted at times when the hospital is fully operational (Ensminger et al 2004, Kane et al 2007, Freemantle et al 2012, Palmer et al 2012). It is not known, however, what service changes would be required to bring these rates down to levels comparable to daytime and weekday rates, and what the cost implications of such changes would be. The NHS therefore faces difficult decisions in how it should respond to its responsibility to provide health care 24 hours a day, 7 days a week ('24/7'). These decisions include the external margin (for example, when services are open to patients) and the internal margin (for example, when facilities are fully-operational).

Extending availability increases overall costs and, at a time of resource constraint, these investment decisions must recognise the opportunity costs. 24/7 care could be cost-effective if it leads to improved access and better patient outcomes, particularly if these improvements are experienced by population and patient groups that are traditionally under-served and suffer worse health as a consequence. The evidence on equity in service use suggests that more deprived populations make greater use of unplanned services and less use of planned services (Goddard and Smith 2001). It is therefore feasible that extending opening hours differentially benefits the poor and may contribute towards reducing inequalities in health.

However, whilst the literature appears to show that equity of care varies by type of service, it is limited by methodological weaknesses and a lack of explanation for the causes of the inequities that do arise. It is therefore unclear what interventions can ameliorate these inequities. In addition, to date there has been no evaluation of extended hours for general practices, and of changes to community services to provide more support and service to patients in their own homes at all hours.

Importance of the issue for the patients and the NHS

The NHS was founded on, and has continued to aspire to, a fundamental principle of equity, with equality of access and the same high standard of care provided for everyone (Whitehead 1994). Patients therefore have a legitimate expectation that the NHS will provide high quality care on an equitable basis. However, due to the way that the NHS is organized, quality of care for many conditions is dependent on the time at which patients present to services, with higher risks of adverse outcomes at nights and weekends. This ongoing failure of the NHS to meet one of its fundamental obligations has become more widely recognised as evidence on the scale of the problem has accumulated.

The Department of Health and medical professional bodies have now begun to address this issue (Temple 2010). For example, the Academy of Medical Colleges has stated that improving quality and equity of care will require consultants to adopt seven-day working, including supervising junior doctors and reviewing patients at weekends (Academy of Medical Royal Colleges 2012). Our proposed research will help providers and professional bodies to determine whether these aspirations can be met, and the related health care inequalities addressed, within the resources available to the NHS.

In addition to dealing with the issue of equitable urgent care, the NHS is also facing increasing pressure to make routine services available to patients beyond traditional weekday, 9-5, patterns. This is part of a wider drive for greater access and flexibility in public service and efficiency - making better use of scarce resources, such as operating theatre capacity, round the clock. The service has responded to this challenge in different ways, for example through initiatives to extend the hours of radiology and physiotherapy services. As well as these local initiatives, there are wider national trends, including moves towards longer nursing shifts and extended contracts for community pharmacies. Many service providers are working in new ways, but few of these changes have been rigorously evaluated. Well-designed research is therefore urgently needed to address some of the key uncertainties around cost-effective ways of providing 24/7 care.

This study

Exploring issues around 24/7 care is problematic because services with the potential to meet patient demand are inter-related but often offered by different organisations. For example, the hours of operation of local general practices has an impact on the demand for services in A&E. The proposed research will address these important gaps in the evidence-base, and will support related ongoing or planned programmes, including the Royal College of Physicians' Future Hospital Commission (Royal College of Physicians 2012); the development of the Seven Day Working Service Quality Standard by NICE; and the Flow Cost Quality programme of the Health Foundation (Health Foundation 2012).

We propose to use a unique dataset generated by Salford Royal Foundation Trust that links electronic patient records across primary and secondary care to staffing

data. We will exploit the natural variability in staffing composition and levels over time of day, day of week and week of year, to estimate the association between staff inputs and aspects of patient care – including length of stay, in-hospital complications and mortality – across different patient groups. We will identify the effect of extending fully-operational hours on staffing levels and costs, and on patient throughput and quality of care.

Research Plan

Overview

In order to understand how extending fully-operational hours will affect costs and outcomes, research is needed into the relationships between staffing levels, costs, patient outcomes, and quality of care. These relationships are poorly understood because the rich information routinely collected in patient healthcare records is not linked to the data collected by employers on staff inputs and costs. We propose to link these data in an acute Trust – Salford Royal Foundation Trust (SRFT) – that has gradually extended its hours of full operation since 2007, culminating in the implementation of an ‘Emergency Village’ service in 2012, providing consultant-led care from 7am to 11pm, seven days per week.

We will link these data to identify, for each patient care episode, the staff available to provide direct patient care and the availability of direct patient care support services. We will exploit the natural variability in staffing composition and levels over time of day, day of week and week of year, to estimate the association between staff inputs and aspects of patient care, including length of stay, in-hospital complications and mortality. We will also identify the effect on patient care and outcomes of service reconfigurations that extend fully-operational hours.

Research aims and objectives

We aim to answer four key questions:

- What is the impact of changes to fully-operational hours on access to services for different population and patient groups?
- How do service re-configurations affect quality of care and patient outcomes for different population and patient groups?
- How should staff be best deployed to deliver care throughout the week?
- What balance of fully-operational hours represents the most cost-effective use of NHS resources?

In order to address these questions we will follow a 30 month research programme in five overlapping phases:

- Preparatory Phase (6 months): We will conduct a literature review, and hold consultations with local and national stakeholders including patient groups, the Salford Royal Foundation Trust Membership, local Clinical

Commissioning Groups and the Department of Health. We will also conduct a review of national and local policies relating to emergency care and out-of-hours provision in order to provide the necessary context for the difference-in-difference analyses. We will pay particular attention to changes implemented during - or likely to have taken effect at - the same time as the Emergency Village.

- Phase 1 (6 months): We will collate staffing data for Salford Royal, link these to service availability data for local general practices, and perform preliminary analyses of these linked data. For example, we will calculate the additional costs of staffing at anti-social times and days of the week. We will also consult with members of the NHS QUEST network to identify Trust partners for Phase 3.
- Phase 2 (9 months): We will collate data for patient episodes, provider activity and quality for SRFT and for local primary care services, link these datasets, and perform preliminary analyses of these linked data. We will then create a combined dataset from the datasets generated in Phases 1 and 2.
- Phase 3 (15 months): We will use the combined dataset to model health care utilization and patient outcomes for SRFT. For example, we will exploit the natural variability in staffing composition and levels over time of day, day of week and week of year, to estimate the association between staff inputs and aspects of patient care (including length of stay, in-hospital complications and mortality). We will closely examine trends in the outcomes of interest in both the before and after periods for any step/slope changes, and relate these to the relevant service changes. In Phase 3 we will also extend the study to other hospitals, by using data from the Advancing Quality project to model quality of care by time of admission for all 24 Acute Trusts in the North West of England. For one other hospital in the NHS QUEST network we will examine in detail the relationship between quality of care and levels of staffing for patients admitted following a stroke, and compare these relationships to results for SRFT.
- Phase 4 (4 months): We will conduct a series of consultation exercises with stakeholders before producing and disseminating a final report.

Setting

The main study will be based at Salford Royal Foundation Trust, a large acute hospital in Greater Manchester with 790 beds, employing 6,000 staff. Between 2007 and 2012, inpatient mortality rates for weekend emergency admissions to SRFT were 10% higher than for weekday admissions. Over this period, SRFT gradually extended its fully operational hours. In 2007, the pattern of emergency care for acute medical patients was reconfigured from an 'on-request' service to a service led by on-site acute physicians. In 2011, acute and community services were integrated, and in 2012 an 'Emergency Village' service was opened, with consultant-led care provided from 7am to 11pm seven days per week. This move to consultant-led services was supported by internal reconfigurations, in particular with respect to access to point of care testing and diagnostic services.

Following the integration of acute and community services and the establishment of the Emergency Village, SRFT has the potential to provide seven day working across acute, therapy and community services. The Trust is currently aiming to eliminate variations in patient outcomes by time of day and day of week by December 2015 by smoothing activity over time, recognising the need for patients to be seen by senior decision-makers, and understanding the social and cultural barriers to implementing fully-operational hours for patients and staff.

Study population

The target population is patients attending SRFT between 2007 (six years prior to the commencement of the study) and 2015 (two years into the study). SRFT provides general hospital services for the patients of Salford (population 250,000) and tertiary renal, stroke, trauma and neuroscience services for the Greater Manchester area (population 3 million). In 2011/12 the hospital handled 31,415 day cases; 11,829 elective in-patient admissions; and 39,527 non-elective in-patient admissions.

Inclusion/exclusion criteria

Analyses will be retrospective, and will include all patients admitted to SRFT during the study period. Patients transferred from other hospitals (for who there is not likely to be the same level of original admission data) and patients resident outside of Salford (for who there will not be linked primary and care data), will be excluded from the main analysis but will be included in sub-analyses.

Data Sources

SRFT, in partnership with Salford Primary Care Trust, has created the Salford Integrated Record (SIR), with 165 million medical records for over 300,000 patients. SRFT has also been routinely collecting staffing information electronically since 2007. These can be integrated to generate a unique dataset, including information on:

- Patient episodes: admission time, diagnosis, procedures and interventions, length of stay.
- Patient demographics: age, sex, ethnicity, postcode, general practice.
- Quality of care: patient experience, complications, readmissions, mortality.
- Staffing data: number, grade, specialty, skill-mix, remuneration and compensation (hourly pay rates, time in lieu).
- Primary care provision: general practice working hours, quality of care, practice characteristics (list size, staffing, qualifications, disease prevalence), prescribing.

Comparative patient-level data are also available (from the Advancing Quality Initiative) for all 24 Trusts in the North West of England on quality of care for pneumonia, heart failure, acute myocardial infarction, stroke, and for hip or knee replacement surgery.

Analytical Approach

In the first phases of the study, we will examine whether achievement of process measures for quality of care and patient outcomes vary by time and day of admission. For SRFT, we will link these process measures to staffing levels at the relevant times to identify whether staff availability predicts variations in achievement. Staff costs will be decomposed into variations in the volume of staff on duty, and individual-level linked staff information will be used to examine the implications of anti-social working for staff turnover. The estimated models will enable us to compute the additional costs that would be incurred if staffing levels at anti-social times were to be equalised to staffing times in preferred working hours.

The linked data from primary care records will allow us to follow individual patients across sectors and over time in order to examine how patient pathways across care interfaces vary by time of day and day of week. For example, we can examine similar entry and exit points with primary care services on weeknights and weekends and determine whether exacerbations of symptoms first treated in primary care are more likely to lead to A&E presentations if they occur out-of-hours compared with in-hours. We will also examine whether health care needs are met in an integrated health system, including the impact of service reconfigurations in one sector – for example the hospital – on service providers in other sectors. Using data on the adoption of extended opening hours by individual general practices, we will also examine how initiatives to extend opening hours in primary care impact on demands placed on the hospital sector.

In the third phase, we will extend the study to other hospitals. For all 24 Acute Trusts in the North West of England, we will examine - using data from the Advancing Quality initiative - whether achievement of process measures of quality vary by time of admission and day of admission. The Advancing Quality programme has collected patient-level information since October 2008 for process measures relating to acute myocardial infarction (9 measures), heart failure (4 measures) and pneumonia (5 measures). Several of these process measures require timely care on arrival at hospital and, through linkage with data on the hospital episode, we can identify the day and time when patients arrived at hospital. We will model achievement of these quality of care measures by time of admission in each of the 24 Trusts, and outcomes for out-of-hours admissions will be compared with normal hours admissions. This analysis will show whether timely execution of quality processes is compromised at night and at weekends, and whether the developments at SRFT have affected this pattern in a way not also observed in other Trusts in the region. This analysis will enable us to extend the main study in two ways. First, we will be able to check for potential alternative explanatory factors underlying any observed changes in outcomes for SRFT during the implementation of the Emergency Village, by examining contemporaneous changes in the other 23 Trusts. Second, we will be able to apply results from the main study for SRFT to the other 23 Trusts, in order to estimate the potential gains from extending the Emergency Village model to other providers.

For at least one Trust in the NHS QUEST Network we will examine in detail the relationships between processes of care and staffing levels, and compare these relationships to results for SRFT.

Outcome measures

Different outcome measures will be used for the different stages of the study. Examples of outcomes for Phases 2 and 3 - modelling healthcare utilization and patient outcomes in SRFT - are:

Staffing:

- staffing levels
- absence from work
- service delivery costs

Service activity:

- length of stay
- waiting times
- transfers between specialties
- transfers between hospitals

Patient outcomes:

- complications (e.g. infections)
- patient-reported outcomes (e.g. EQ-5D scores, PALS referrals, complaints)
- re-admission
- mortality

Statistical analysis

Several approaches will be used. For example, to model patient outcomes in SRFT:

Stage 1

We will empirically specify SRFT's 24/7 initiatives in terms of times of introduction and the types of patients affected, identifying 'treated' and 'control' groups by stratifying by time/day of admission, and key 'before' and 'after' periods.

We will use difference-in-differences (DiD) approaches to estimate whether changes in service provision had any effects, constructing regression models for each outcome and using patient characteristics as case-mix adjusters (e.g. age, gender, primary diagnosis, co-morbidity, type of admission, place of residence), and dummy variables for time periods. We will include interactions between the 'treatment-control' indicator and the 'before-after' period indicator. Coefficients on interaction terms will provide the DiD estimate of whether there are differential changes in

outcomes for patients admitted at evenings and weekends when 24/7 initiatives are introduced.

The analysis will be extended to a triple-difference (DDD) analysis, with an additional stratification by primary diagnosis so we can test whether differences in outcomes are larger for patients most exposed to the risks of restricted operational hours. This will also control for other local initiatives relating to specific patient groups. National initiatives can be controlled for by extending the analyses to other Trusts. If the comparator Trust(s) have not introduced 24/7 initiatives at the same time, we can test whether differences in outcomes between patient groups that emerge in Salford after the introduction of 24/7 also appear in the other Trusts.

The primary intervention we intend to assess is the introduction of the Emergency Village at SRFT in 2012, and changes to the provision of fully-operational hours of care at SRFT over the study period therefore present two challenges: i) identifying the point at which the Emergency Village became established at the hospital; and ii) accounting for other re-configurations at SRFT that preceded the introduction of the Emergency Village.

With respect to first challenge, in Stage 1 of the study we will examine the changes implemented at SRFT in staffing and service provision in detail, and we will also consult Trust staff, in order to identify appropriate cut-off points for the 'before' and 'after' periods. Because implementation of the emergency village was a process, we will also identify a 'transition' period separating the before and after periods.

The phased extension of fully operational hours over a five-year period at SRFT is an additional analytical challenge, but it also provides the source of variation that we need to measure the impact of service changes. There have been two major points of re-organisation at SRFT:

- In 2007, the pattern of emergency care for acute medical patients was reconfigured from an 'on-request' service to a service led by on-site acute physicians.
- In 2012, an 'Emergency Village' service was opened, with consultant-led care provided from 7am to 11pm seven days per week.

Our analytical plan allows for the possibility that each of these changes had a measurable impact. Working with senior managers and clinicians in SRFT we will identify the exact timings of when these changes took effect and whether they were universally applied. We will then verify that these changes are observable in the data on staffing and rostering.

These developments generate three periods: pre-2007; 2007-2011; and 2012 onwards. We will measure impact through a series of difference-in-difference (DID) and triple-difference (DDD) analyses. These analyses will exploit the fact that we are interested in specific groups of patients that are covered by the successive

developments, e.g. for the 2007 re-organisation, acute medical patients requiring emergency care at night or at weekends can be compared to four potential comparators:

- acute medical patients requiring emergency care at night or at weekends before 2007
- acute medical patients requiring emergency care during a weekday
- other patients requiring emergency care at night or at weekends
- acute medical patients requiring emergency care at night or at weekends in other Trusts

Inventive selection of comparator groups allows us to estimate impact controlling for general changes in context and care that affect similar patients, but which are not attributable to the extension of fully operational hours.

Stage 2

The DiD and DDD coefficients remain 'black-box' estimates of the effects of 24/7 care, and do not provide evidence on the mechanisms by which 24/7 improves outcomes. We will seek to explain any observed 24/7 effect by identifying which measures of staffing and support availability were affected (e.g. numbers and types of staff rostered on-site and on-call, availability of theatres, pharmacy and diagnostics).

Stage 3

We will measure the extent to which staffing and service changes 'explain' the 24/7 effect by introducing staffing and service measures into DiD and DDD models of outcomes. We will compare the results of the simple models (Stage 1) with those from the full models (Stage 3).

Stage 4

To analyse the distributional consequences of 24/7 care, we will consider types of patients classified by age, area deprivation, ethnicity, and long-term conditions and:

- Compare the patient characteristic compositions of the treated and control groups in before and after periods
- Repeat DiD analyses, stratifying by patient type
- Interact the DiD/DDD estimates with patient type identifiers

Assessing cost-effectiveness

Cost-effectiveness will be assessed using a net-benefit framework whereby the average net health benefit is estimated using threshold values for willingness to pay for quality-adjusted life years. The question about the best staff deployment will be assessed by examining: (i) which measures of staffing differ most by time of day and day of week; and (ii) for which measures of staffing do we find an association with outcomes. Staff input measures that differ substantially by time of day and day of week and are more strongly associated with outcomes are priorities for re-

scheduling. Re-scheduling within a fixed complement of staff might lead to deteriorations in outcome for some part of the day/week, which would need to be more than offset by improvements in outcomes in under-served times. Re-rostering to anti-social times also has direct (pay premia) and indirect (time in lieu) cost implications, which we will consider for RQ4.

We will undertake the analysis of cost-effectiveness for the full effect of 24/7 and the estimated effects of the staffing/service deployment components of 24/7 that we identify in the analysis. We will obtain costs for the periods before and after the introduction of 24/7, and separate costs for the different elements of the re-configured staff deployment and support service availability. We will combine these cost estimates with their estimated impacts on outcomes to (a) identify whether 24/7 care is cost-effective compared to pre-24/7 care; and (b) to find re-configurations that might represent a more efficient balance of additional costs and additional outcomes, compared to pre-24/7 care.

The range of outcomes we will consider is:

- Outcome indicators derived from administrative data
- Process indicators from national audits
- Activity and resource use measures
- Patient safety indicators
- Patient experience measures

Focusing on specific conditions

Patients admitted to hospital following a stroke and for trauma are two groups with substantial numbers whose care has been affected by 24/7. We will select appropriate indicators for each condition in consultation with clinical specialists.

For example, for stroke we might consider:

- Mortality within 30 days of admission
- Emergency hospital re-admission within 30 days of discharge
- Return to usual place of residence within 56 days of admission
- Brain scan within one hour or 24 hours of arrival
- Direct admission to and time spent on a dedicated stroke unit
- Length of stay and stay lasting beyond the HRG trimpoint
- National and local HRG costs for the patient's continuous stay
- Number of reported Seriously Untoward Incidents
- Number of complaints via 'Patient Advisory and Liaison Service'
- Number of claims upheld ('Rules 42 and 43')

So, for example, using patient level data for stroke patients in Salford from 2003/4 to 2012/13, we will regress mortality within 30 days on:

- Patient characteristics
- Year and month of admission

- Whether admitted in evening and/or at weekend
- Interaction term between post-24/7 period and evening/weekend admission

Then we will add data on patients admitted for conditions that would not be affected by 24/7 care and extend the model to include interactions between a stroke patient indicator and:

- Year and month of admission
- Whether admitted in evening and/or at weekend
- The interaction term between post-24/7 period and evening/weekend admission

We can also add data for other Trusts that didn't introduce 24/7 care at this time.

Patient and Public Involvement

We will ensure that the aims of the study reflect patient priorities and that outcomes of importance to patients are included in the analyses, and will regularly engage with the public to ensure that findings are communicated to the groups most likely to be affected. Engagement will be achieved through consultation with the Salford Royal Foundation Trust Membership (SRFTM) and the Salford Citizen Scientist Project (SCSP). The SRFTM has 14,545 patient members and 6,179 staff members, and provides feedback to clinicians, managers and researchers via surveys, focus groups, co-design events and public meetings. The SCSP is a forum bringing together researchers and local residents to improve health research and health related services. Focus groups drawn from SRFTM and SCSP will be consulted:

- 3 months prior to commencement, to discuss study aims and objectives;
- At months 9 and 18, to discuss emerging findings and potential changes to analyses;
- At month 27, to disseminate findings and elicit patient and public recommendations for providers.

Patient group representatives will sit on the Advisory Panel and will advise on the design of questionnaires intended to elicit the views of stakeholders and the experiences of patients affected by service changes.

We will work closely with INVOLVE (the NIHR-funded PPI national advisory group) to ensure proper public involvement throughout the study.

Dissemination and Output

We will disseminate our findings through the following channels:

- A final report on study methodology, findings, implications and recommendations and a lay summary, to be made publicly available from the Institute of Population Health (University of Manchester) and NIHR websites. A

project web page will be created at the outset of the project, and updated with interim and final findings. We will collaborate with the press offices of the University of Manchester and NIHR in order to contribute material to local and national media.

- Dissemination events hosted by the Greater Manchester Health Inequalities Network (University of Manchester) and Salford Royal Foundation Trust, with attendees to include patient representatives, clinicians, academics, commissioners, managers and policy makers. We will also consult regularly throughout the project with the Salford Royal Foundation Trust Membership and the Salford Citizen Scientist Project.
- The NHS QUEST network. Founded in 2011, this is the first member-convened network for Foundation Trusts aiming to focus on improving quality and patient safety. Member organisations work together to innovate, share learning, and build capability in order to improve care for patients. The network currently consists of 14 organisations, collectively employing 67,000 people, serving a population of 3.9 million, with an NHS budget of £3.5 billion.
- Scientific papers, to be prepared for submission to relevant international peer reviewed academic journals.
- Academic, policy and clinical meetings, including those held by the Health Economists Study Group, Institute for Healthcare Improvement, International Society for Quality in Health Care, NHS Confederation, and Society for Academic Primary Care.
- We will also establish an independent advisory group with an external chair, comprising external members (from Salford Royal Foundation Trust Membership, the NICE Public Health Excellence Centre, Salford Clinical Commissioning Group, NHS QUEST, the Royal College of General Practitioners, the Royal College of Physicians, and the Health Foundation) and four of the co-applicants. In addition to research design and conduct, the Advisory Group will also advise on dissemination strategy and will facilitate dissemination through their professional networks.

This proposal will provide rigorous and relevant evidence on the relationship of health service re-organisations to quality of and access to health services, including costs and outcomes. The resulting model will support decisions by senior managers and clinicians on the appropriateness, quality and cost-effectiveness of care.

Our original application has been used as the basis for a conversation with the NHS QUEST finance directors and senior leaders, to evaluate their willingness to participate in the latter stages of the project. From preliminary discussions to date, County Durham and Darlington Foundation Trust has requested to be involved in Phase 3 of the study, and we predict that a further 4-6 organisations will come forward. We will then be able to map their service patterns, workforce plans and IT infrastructure to determine whether we can test the models generated in Salford

Royal Foundation Trust in other NHS QUEST organisations and gauge their applicability across the NHS more broadly.

To maximize the impact of the study findings, in Phase 4 we will produce resources to enable end-users, including other NHS QUEST trusts, to apply the study findings in their own organisations. We will tailor these resources to reflect local and national changes in the health care and public health systems, in particular organisational developments such as the creation and maturation of the NHS Commissioning Board, local Clinical Commissioning Groups, Health and Well Being Boards, new local authority roles, and Healthwatch.

We will hold end of project dissemination workshops for a range of UK policy makers, practitioners, managers and academics. We will also use the international contacts and networks of the co-applicants to disseminate the findings beyond the UK, for example through the Institute for Healthcare Improvement and the Commonwealth Fund.

Research Team

The proposed research will combine expertise in public health, health services research, and econometric modelling of health care records from the Universities of Manchester and Bristol; e-Health from the MRC Health e-Research Centre (HeRC); and innovation in delivery of health care from Salford Royal Foundation Trust. The core research team will consist of:

University of Manchester

Tim Doran (0.20 FTE): Doran is a clinical epidemiologist with expertise in health policy and health services research, in particular analysing initiatives to improve quality of care and their impact health inequalities.

Mark Harrison (0.20 FTE): Harrison is a health economist with expertise in evaluating medical technologies, primary and secondary care interventions and policies in the NHS.

Matt Sutton (0.15 FTE): Sutton is a health economist with expertise in econometric methods, analysis of non-experimental interventions, use of large administrative databases, determinants of quality of care and equity in use of health services.

2 Research Associates (each 1.0 FTE) with expertise in biostatistics/economics and working with large health-related datasets will be appointed for 30 months and 24 months and directly supervised by senior co-applicants. The first associate will work primarily on Salford primary and secondary care data. The second associate will work on secondary care data for SRFT and other Trusts in Phases 2-4.

MRC Health e-Research Centre (based at the University of Manchester)

John Ainsworth (0.05 FTE): Ainsworth is an engineer with wide experience of applying computing technology to healthcare problems, specialising in the reuse of routinely captured data for performance and quality analysis.

University of Bristol

Carol Propper (0.025 FTE): Propper is a health economist with expertise in the analysis of the relationships between health service policy changes and outcomes, in particular the effect of competition on management, process and quality in NHS hospitals.

Salford Royal NHS Foundation Trust

Maxine Power (0.025 FTE): Power is a health care manager with expertise in health care improvement. She is currently the National Improvement Advisor for the Quality Innovation, Productivity and Prevention (QIPP) team, and is responsible for leading the design and delivery of a national programme for safety improvement and cost reduction.

The research team will be supported and advised by managers and clinicians from Salford Royal Foundation Trust:

Chris Brookes: Brookes is Executive Medical Director and a consultant in emergency medicine with specialization in the resuscitation of critically ill patients. He was previously the Group Clinical Director for Medicine, Critical Care and Clinical Support Services, including pathology and radiology.

Elaine Burke: Burke is Executive Nurse Director, with expertise in intensive care, general medicine, neurology, neurosurgery, and health service management.

Research Budget

Total costs of £724,142 are associated with the study, for which £600,588.60 is requested from NIHR (university costs are requested at 80%). The major sources of expenditure are research costs (HEI and NHS Trust), advisory input and dissemination. As this is a research-driven project, the majority of the costs have been allocated to research staff and associated consumable, estates and indirect costs.

HEI research costs

The proposed research requires senior academic leadership, research associate support, collaboration with NHS Trusts and associated travel and consumable costs.

HEI research staff allocations are:

- University of Manchester: Doran 20% FTE, Harrison 20% FTE, Sutton 15% FTE, Ainsworth 5% FTE.
- University of Bristol: Propper 2.5% FTE
- Research Associate (to be appointed) 100% FTE for 30 months.
- Research Associate (to be appointed) 100% FTE for 24 months.

Estates and indirect costs are also associated with these staff allocations.

Where possible, research meetings will be conducted by telephone and video conferencing, but regular direct meetings and site visits will also be required. Costs are therefore requested for university-based co-investigators to travel to the NHS Trusts participating in the study. Costs for consumables are requested to support the work of research staff, including two personal computers to support the Research Associate posts, one printer, software licenses, and office consumables.

NHS Trust research costs

SRFT has an international reputation for innovation in health care improvement, and is at the leading-edge of electronic patient record linkage across primary and secondary care. For the purposes of this research project, SRFT will make available relevant clinical, technical and administrative staff, including nationally recognized experts in several clinical fields, for example: Chris Brookes (emergency medicine), Pippa Tyrrell (stroke), Fiona Lecky (trauma/emergency medicine), and Paul Dark (intensive care). The Trust will also support and promote this project through its links with the Greater Manchester Academic Health Science Network, the Manchester Academic Health Science Centre and the NHS QUEST network (leading collaborative organisations on the uptake of innovative applied health research and education into healthcare).

Research costs for SRFT will include: co-investigator and collaborator staff time; financial management overheads; research governance; data collection, extraction and linkage; organisation and hosting of focus groups and consultation exercises; compensation for focus group attendees; and coordination of project related NHS QUEST activities.

Compensation for data extraction costs incurred by other NHS Trusts participating in Phase 3 will be met by SRFT.

Advisory input

We will appoint an independent advisory group with an external chair, to assure the quality of the research, help with interpretation of the findings, and to advise on dissemination. The group will comprise members from key stakeholder groups (including patient representatives, clinical and non-clinical staff representatives, the NICE Public Health Excellence Centre, Salford Clinical Commissioning Group, NHS

QUEST, the Royal College of General Practitioners, the Royal College of Physicians, the Care Quality Commission and the Health Foundation). The group will meet within the first 6 months of the study, at the interim report stage and at the final report stage.

Costs are requested for the production of briefing materials for the Advisory Group and travel of members to and from group meetings.

Dissemination

Costs are requested for attendance of co-investigators and research associates at relevant UK and EU conferences and workshops (for example: the International Forum on Quality and Safety in Healthcare, policy forums hosted by the King's Fund and Healthcare Foundation) and international conferences (for example: the Institute for Healthcare Improvement Annual National Forum, the Academy Health Annual Research Meeting).

Further costs are requested for open access fees for journal publication (we anticipate four open access papers) and dissemination events in Phase 4 of the study.

Research timetable

See separate 'Project Plan'.

Research management arrangements

Tim Doran will be responsible for overall project management, including managing the research elements of the project and liaising between academic and service partners. Rachel Georgiou (Associate Director of Research and Development) will be responsible for project management for SRFT. Tim Doran, John Ainsworth and Matt Sutton will be responsible for mentoring and overseeing the work of the research associates recruited to the study. Maxine Power will be responsible for ensuring the supply of relevant data from SRFT, and the integrated data record will be validated by John Ainsworth and staff at the MRC Health E-Research Centre based at the University of Manchester. Chris Brookes is the Caldicott Guardian for SRFT, and will ensure patient confidentiality and the appropriate use and reporting of patient-related data.

The research team will participate in four public engagement events – to be attended by members of the Salford Citizen Scientist Project and the Salford Royal Foundation Trust Membership – during the course of the study to ensure that outcomes of importance to patients are included in the analyses, and that findings are communicated to the relevant patient groups.

The independent advisory group will include representatives of patient groups, clinical and non-clinical staff, the NICE Public Health Excellence Centre, Salford Clinical Commissioning Group, NHS QUEST, the Royal College of General Practitioners, the Royal College of Physicians, the Care Quality Commission and the Health Foundation. The group will assure the quality of the research, including guidance on ethical issues, local and national perspectives, and maintenance of critical distance by the research team.

Ethical issues

No patient interventions are planned as part of this study, which will involve retrospective analyses of service changes already planned by the participating Trusts, and no ethical approval is required.

However, as the study will involve secondary use of routinely collected patient data, there is a potential risk of breaching patient confidentiality. All the co-investigators are experienced with the appropriate handling with patient-derived data, and are conscious of the need to protect confidentiality. All data will be held on-site, using secure servers located at SRFT and the University of Manchester. In addition, Chris Brookes is the Caldicott Guardian for SRFT, and will ensure patient confidentiality and the appropriate use and reporting of patient-related data.

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