

**A retrospective, observational analysis using Real Time Location Systems (RTLS) technology to explore the effects of clinical staffing on hospital productivity and patient health outcomes**

**SPONSOR: The Royal Wolverhampton NHS Trust**

**Version 8.0, August 30th 2019**

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The Royal Wolverhampton NHS Trust is the research sponsor for this study. For further information regarding the sponsorship conditions, please contact R&D Department, The Royal Wolverhampton Hospitals NHS Trust – Tel: 01902 695065 or email [sarah.glover7@nhs.net](mailto:sarah.glover7@nhs.net) [lorraine.jacques@nhs.net](mailto:lorraine.jacques@nhs.net) or [lucystelfox@nhs.net](mailto:lucystelfox@nhs.net)

## Acknowledgements

To all staff within The Governance, H.R, Information, IT and Library Teams who helped and advised during this project

Every care has been taken throughout the protocol drafting stage to be inclusive and explicit, however amendments may be necessary as the study activities commence and the project evolves. All amendments will follow the appropriate governance notification process and standard operating procedures advocated by the Trusts Research and Development Directorate.

Problems relating to this study should be referred, in the first instance to the Chief Investigator or study co-ordinator. This study will adhere to the principles outlined in the UK Policy Framework for Health and Social Care Research ver. 3.0 (2017).

It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate to the principles of Good Clinical Practice. This is to ensure that the rights, safety and well-being of the study participants are protected and the research data is purposeful and of high quality.

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## GLOSSARY OF ABBREVIATIONS AND TECHNICAL TERMS

[illegible]

## KEYWORDS

Real time location system, quality improvement, contact time, peer effects.

## STUDY SUMMARY

|                            |  |
|----------------------------|--|
| <b>TITLE</b>               | A retrospective, observational analysis using Real Time Location Systems (RTLS) technology to explore the effects of clinical staffing on hospital productivity and patient health outcomes  |
| <b>DESIGN</b>              | Retrospective, observational study   |
| <b>AIMS and OBJECTIVES</b> | <ul style="list-style-type: none"><li>• To measure the amount of time that nurses and other professional groups spend with patients (e.g. at the bedside)</li><li>• To measure the amount of time that nurses and other professional groups spend in co-working spaces (e.g. nurse stations)</li><li>• To explore if the amount of time nurses and other professional groups spend in direct patient care affects patient outcomes</li><li>• To examine if the amount of professional to professional time in ward areas has an impact on patient outcomes</li><li>• To explore if a reduction in rostered nurses impacts patient outcomes</li><li>• To investigate if patient movement from original/speciality base ward has an impact on patient outcomes</li></ul> |
| <b>POPULATION</b>          | All admitted inpatients between 1 April 2016 and 31 March 2019, and all staff members with RTLS badges, at The Royal Wolverhampton NHS Trust (RWT), Wolverhampton, UK.   |
| <b>ELIGIBILITY</b>         | All inpatient and staff covered by the RTLS system   |
| <b>DURATION</b>            | Study duration to last up to 3 years from the date of the protocol approval.<br>Retrospective data to cover the period 1 April 2016 to 31 March 2019.  |

## 1.0 INTRODUCTION

This study will examine the productivity of the hospital workforce utilizing a unique dataset that is stored at the Royal Wolverhampton Trust (RWT). The data is recorded by a Real Time Location System (RTLS) that tracks the second-by-second physical location of patients, staff, and medical equipment. Using this data, we plan to measure the amount of time that clinical staff spend with patients and with other clinical staff, and then explore how these measures of contact time influence patient health outcomes. We will also be able to use the data to measure the location and movement of patients during their hospital stay, and test the impact of moving patients between wards on their health outcomes.

We first describe the RTLS system in more detail, and then provide a review of the relevant literature and a rationale for our study and its contribution. The Royal Wolverhampton NHS Trust partnered with a US company (Tele-Tracking) in 2013 to develop a real-time patient flow and tracking solution to improve patient access, in-patient flow, discharge planning and quality and safety of care oversight (Nash 2014, Stephenson 2015).

Transitioning from an environment of disjointed activity to patient throughput functions which are now Co-ordinated through a centralised command centre, supports staff to deliver efficient, quality driven care by providing real-time location and status visibility to all inpatients, beds, staff and equipment.

The Trust's patient flow solution is enabled by a Real Time Locating System (RTLS) that uses a combination of infra-red and radiofrequency technology to feed data into the patient flow and tracking software. The Trust has to date, badged 1,500 assets (Trust equipment i.e. bladder scanners), 4,000 staff, and all inpatients, making it the world's largest deployment of RTLS technology in a healthcare setting and the first of its kind in the NHS. This technology, coupled with process redesign, has allowed the Trust to:

- automate portering and bed cleaning functions;
- utilize the real-time visibility of bed availability and patient status to allow for precision patient placement from all admission areas;
- automate workflows and provides patient status at a glance information for staff, with the aim to reduce the time spent on administrative tasks;
- improve patient throughput, access, discharge planning, and quality and safety;

- redesign processes and functions of the previous Patient Flow Team for greater efficiency through 24\*7 access to a live bed state;
- provide staff with real-time alerts to patient safety risks, isolation alarms, and patient walk out alarms and a system for escalation of staff safety concerns;
- monitor all staff-patient-asset (hardware/ equipment diagnostic) interactions for incident investigations including infection prevention tracing and root cause analysis of falls and pressure ulcer acquisitions.

## 1.1 LITERATURE REVIEW / BACKGROUND

A wide body of research across the medical and economics literature documents the critical role that hospitals' workforces play in determining patient outcomes. This ranges from the role of management, nurses, doctors, and decisions over patient flow. We review the existing studies from these literatures here.

### Nursing care

The numbers, skill mix and education of nurses to optimally care for patients continues to be debated against a landscape of increased patient demand and a changing demographic of the nursing workforce (Griffiths 2016a). An increasing number of research studies have shown that low nursing levels are associated with poor patient outcomes and an increase in mortality (Griffiths 2016b). Authors have reported that an increase of registered nurses caring for patients, known as a nurse to patient ratio (Kane et al 2007) or nursing hours per patient day (NHPPD) (Twigg 2011) are associated with lower mortality and a decrease in nurse sensitive outcomes, for example urinary tract infections and length of stay (Kane et al 2007, Twigg et al 2011 and Chang et al 2017).

Higher levels of educational preparation of registered nurses and a higher registered nurse skill mix, or ratio, have been associated with lower hospital mortality (Gkantaras et al 2016, Akien et al 2016, Griffiths et al 2016b). The strength of association varies across studies. According to Griffiths et al (2016b) nurses looking after six, or fewer, patients in medical wards in a recent study showed a 20% lower mortality rate compared to nurses on medical wards that cared for ten (10) or more patients. Authors in Australia and USA report policies mandating minimum nurse patient ratios (Twigg et al 2011, Spetz 2005), but with an ageing populations globally, the complexity of care, economic pressures and the shortage of nursing staff, have led many countries to consider the numbers and skill mix of their nursing workforce (Splisbury et al 2009).

Two systematic reviews (Lankshear et al 2005 and Kane et al 2007) were found in a literature review plus two further meta-analysis (Numata et al 2006, Tourangeau et al 2006) and sixteen (16) primary research papers (Needleman et al 2011, Griffiths et al 2016b, Junttila et al 2016, Akien et al 2016, Chang et al 2017, Glance et al 2012, Person et al 2004, Rafferty et al 2007, Sochalski et al 2008, Twigg et al 2011, Cho et al 2009, West et al 2014, Estabrooke et al 2005, Sales et al 2008, Blegen et al 2011, Tourangeau et al 2006), exploring the association between registered nurse numbers, ratios or skill mix and patient mortality. All primary research papers found an association between 'adequate' or an increased level of RN nurses and a reduction in patient mortality, with the exceptions of two research studies one by Sales et al (2008) which found no significant difference in the nursing numbers and patient mortality in ICUs but found significance in non-ICU environments and Sochalski et al (2008), where significant effects were not found in fixed effects analysis. Two studies also explored the multi professional team's (nurse, doctors and healthcare assistants) association with mortality rates, but do not yet present a consistent picture (West et al 2014, Griffiths et al 2016b).

Nursing skill mix and staffing ratios are only a proxy measure of direct or bedside care a patient may receive from registered nurses. There is an underlying assumption that patient outcomes and experience will improve the more time that nurses spend providing care at the bedside (and not engaged in administration). There are of course two main key confounders, firstly patient acuity and dependency need to be measured as the sickest patients are likely to be receiving more nursing care, and secondly the diverse roles of nurses need to be considered, including time for

administration, training, sickness and annual leave, all which may or may not be factored into all staffing calculations. High level nursing numbers provide an indication or an overview of the amount of care that is available to patients, rather than actual care. Keogh, (2013) suggests that nursing workforce data and the number of nurses on the ground may not always correlate, however.

The methodologies for calculating the available care hours that a patient may receive may be expressed as a nurse to patient ratio or Nursing Hours per Patient Day (NHPPD), calculated using direct patient hours or total hours, (a combination of direct and non-direct patient hours). Nurses or managers may collect the NHPPD calculation once or twice a day or on an ongoing basis throughout a 24-hour period. The calculation can be based on average times per activity, or from an acuity and dependency alternative nursing reporting system.

These calculations can assume average care requirements of patients with the same diagnostic related group, presenting in the same ward on the same date as receiving the same amount of care, which may be flawed. Furthermore, when the acuity or dependency of each patient is not considered, the use of NHPPD might be misleading, as this provides an average number of available hours, rather than the actual hours required by an individual patient. These reporting figures again provide a proxy measure for actual care, by calculating the amount of nursing time available for each patient, not the amount of direct or bedside care a patient receives.

Relative to these existing studies, the RTLS data available to this project will allow us to calculate the actual contact time between staff and patients. We will be able to compare contact time calculations across the distribution of patients (e.g. by severity, location) and staff (e.g. nurses and doctors).

### **Other members of the workforce and workforce interactions**

The interaction between staff members and the importance of teams has been shown to influence productivity in numerous settings including hospital care. Economists often prescribe these effects to so-called 'peer effects' or 'free-riding'. Peer effects describe a range of social phenomenon between team members that lead to one individual influencing the productivity or behaviour of another. For example, team members may directly care about the productivity of their peers, communicate well with certain groups, or simply enjoy working with certain team members. As a result of these interactions the group may be more or less productive (Mas and Moretti, 2009; Bandiera, Barankay and Rasul, 2010). Free riding describes a similar concept which has potential negative impacts on productivity. For example, when working with a high productivity team, a health professional may choose to reduce their own productivity when it is difficult for managers to observe this behaviour. Similarly, it may be that the work environment values the social interactions between their peers and do so at the expensive of their productivity (Bandiera, Barankay, and Rasul, 2009).

Recent research has shown that these types of interactions are present in health care settings. Health care teams lose productivity when nurses with significant skill and experience leave, and replacing these staff with a similarly experienced or skilled nurse does not make up the loss in productivity (Bartel, Beaulieu, Phibbs and Stone, 2014). Peer effects also extend to physician interactions. Allowing emergency physicians to monitor one another's workload has been shown to improve productivity and reduce free riding (Chan, 2016). Similarly, the pace of work of emergency doctors has been shown to directly influence the pace of work their peers (Silver, 2016), and the shift pattern assigned to doctors also influences the work-rate of doctors towards the end of their shifts (Chan, 2018). Finally, the role of management has also been demonstrated, where UK hospitals with higher rated managers being associated with improved hospital performance as measured by patient mortality (Bloom, Propper, Seiler and Van Reenen, 2015).

### **Patient flow**

Patient outcomes may not only be affected by the interaction of peer health care providers but also by the flows of patients into or within hospitals. High patient flows can influence the use of resources that might have otherwise been provided to other patients. This is documented in several reviews of associational evidence where 'bed strain' or occupancy (Eriksson et al. 2017) and emergency department crowding (Hoot and Aronsky, 2008) is correlated with increased mortality. Economic studies have shown that these correlations

can arise because hospitals run short of available beds, and as a result must allocate scarce bed resources amongst patients (Freedman, 2016) or new patient arrivals cause hospitals to discharge existing patients early (Hoe, 2018).

These cases suggest that reductions in the physical space and resources devoted to patients, or the management of these resources, can impact patient care and outcomes.

## **1.2 RATIONALE FOR CURRENT STUDY**

The economic and demographic challenges facing the National Health Service are intensely felt by the healthcare workforce delivering services on the front line. Given that approximately 70% of recurring NHS provider costs relates to staffing, and that the NHS is one of the world's largest employers, it is vital that the service invests in making the best use of staff to ensure they can deliver the care required by patients into the future (Addicott et al 2015).

A key feature of the existing research on the workforce is that, to our knowledge, no prior study has been able to precisely measure the physical location of staff and patients. The RTLS system in place at RWT enables us to do this accurately and will be the novel feature of our work. We will be able to study productivity – in terms of staff-to-patient contact time and professional-to-professional interactions – in a detailed and accurate manner that goes far beyond the capability of previous datasets.

## **2.0 STUDY OBJECTIVES**

There are six main objectives of the study, each relying primarily on the unique data recorded by the RTLS at RWT:

- To measure the amount of time that nurses and other professional groups spend with patients (e.g. at the bedside)
- To measure the amount of time that nurses and other professional groups spend in co-working spaces (e.g. nurse stations)
- To explore if the amount of time nurses and other professional groups spend in direct patient care affects patient outcomes.
- To examine if the amount of professional to professional time in ward areas has an impact on patient outcomes
- To explore if a reduction in rostered nurses or other staff, or a change in the skill mix of nursing or other staff, impacts patient outcomes
- To investigate if patient movement from original/speciality base ward, or other aspects of patient flow (e.g. congestion, crowding, capacity strain), have an impact on patient outcomes

## **3.0 STUDY DESIGN**

The protocol relates to a series of studies that will be based on retrospective observation data containing patients admitted to or discharged from RWT over the period 1 April 2016 to 31 March 2019. The most substantial task to produce these studies is to first extract a series of datasets from RWT and link these together such that the RTLS information. This can then be studied alongside information on the characteristics of patients and staff, as well as the health outcomes of patients.

### **Data to be extracted**

Data will be extracted from the following databases held at RWT.

1. The real-time location service part of the TT system ('RTLS data'). The RTLS data contains information on the second-by-second location of each patient and staff member at RWT. The locations cover all areas of the internal hospital buildings at RWT, with each building being classified according to a number of discrete 'zones' (e.g. wards, bed spaces, corridors).
2. The RWT in-patient database ('PAS data'). The PAS data contains detailed information on each inpatient visit to RWT. From the PAS data we will extract information for all patients admitted or discharged at RWT during the sample period. We plan to extract the following

information for each patient-visit: home location (first 3 or 4 digits of postcode), sex, ethnicity, age, administrative category (e.g. overseas vs. regular), admission date, admission method, number of days on waiting list, admission source, discharge date, discharge method, discharge destination, patient classification (e.g. inpatient vs. day case), ward type, specialties treated under, pseudo-anonymised consultant ID, indicators for neonatal or psychiatric care, recorded diagnoses, operation codes and dates, days in critical care, and HRG payment codes.

3. HR records on job roles and absences from work ('HR data'). The HR data contains information on the characteristics of RWT staff (e.g. age, gender, ethnicity, tenure at RWT) and their length of time in role (e.g. position on pay scale), as well as periods of absence from work.
4. The RWT incident reports ('Datix'). The Datix system contains data of untoward / adverse incidents. It is submitted by RWT staff relating to staff, patient and visitors on the trust property or whilst conducting trust business. We will extract the following fields which relate to each incident: date, time, location, patient number, result, harm, type, category, and sub-category. The scope of incidents will only include those relating to patient care.

### **Extraction, pseudo-anonymization and linkage of data**

**Figure 1** (p.11) summarises the four data extracts, how they will be linked together, and the responsible teams at RWT for producing the extracts. The text below gives more specific details of the steps that will need to be taken to complete the process.

The following process has been designed such that Thomas Hoe, the lead analyst, will not be directly involved in producing any of the data extracts which contain identifiable patient or staff information. All data extracted will also be done on site by RWT personnel. A final check / assurances will also be carried out by the Chief Investigator before data (Extracts 1-4) are taken off site for analysis.

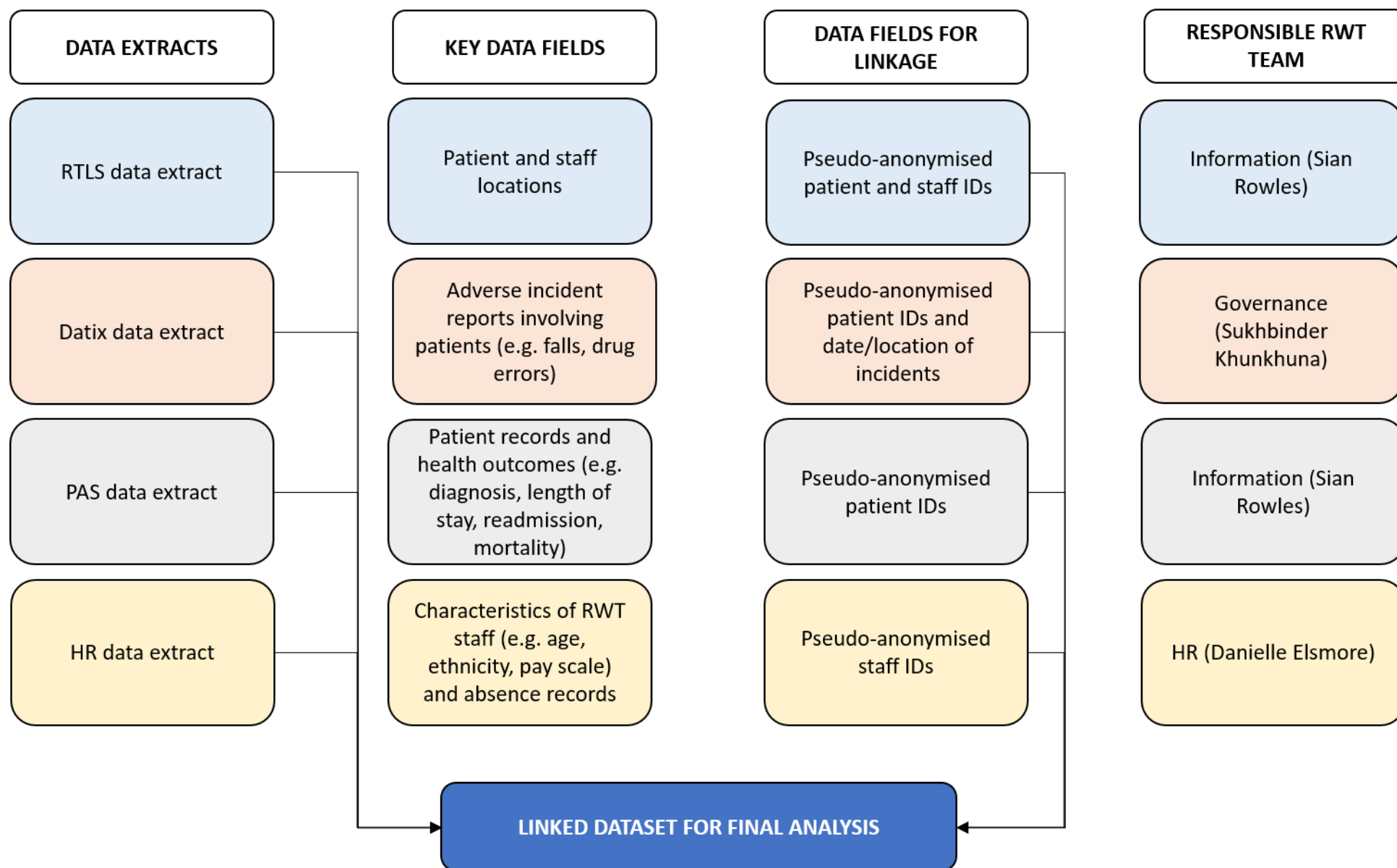
For the PAS data, we will use the datasets created by RWT for submission to NHS England which already remove any patient-identifiable information. We will take the following processing steps:

- S.R (Information Dept.) to replace the medical record numbers in the PAS extracts with pseudo-anonymised patient IDs.
- S.R (Information Dept.) to provide the pseudo-anonymised PAS extracts ("EXTRACT 1") to Thomas Hoe.

For the HR data, we will use the standard reports generated by the HR team. We will take the following processing steps:

- A.R (HR) to provide Thomas Hoe with a list of staff names, job roles, and HR staff IDs from all of the monthly standard reports over the sample period.
- Thomas Hoe to manually match the HR staff IDs, using the name and job role information, to the staff IDs contained in the RTLS dataset, and to create a common, anonymised staff ID across both datasets.
- Thomas Hoe to provide the HR team with the common anonymised staff IDs.
- A.R (HR) to add the common anonymised staff ID to the HR standard reports and then removing all identifiable information from the HR datasets.
- A.R (HR) to provide the anonymised HR standard reports ("EXTRACT 2") to Thomas Hoe.

**Figure1.0 . Summary of data extracts and linkage process**



For the RTLS data, we will take the following processing steps:

- S.R (Information) to produce a lookup file between RTLS tag IDs and pseudo-anonymised patient IDs.
- Thomas Hoe to prepare bespoke data extracts, as these datasets do not contain any identifiable information ("EXTRACT 3"). For the Datix data, we will use custom reports generated by S K We will take the following processing steps:
- S.K (Governance) to produce custom Datix reports as specified above in paragraph (iv).
- S.K (Governance) to provide S. R. (Information) with the custom reports.
- S.R (Information) to replace the medical record numbers in the customer reports with pseudo-anonymised patient IDs.
- S.R (Information) to provide Thomas Hoe with the pseudo-anonymised Datix data ("EXTRACT 4").

Once Thomas Hoe has received EXTRACTS 1 through 4, the extracts will be transported to the Institute for Fiscal Studies as described in Section 8.3.

### **3.1 STUDY OUTCOME MEASURES**

We plan to study the following outcomes:

- 30-day in-hospital mortality (RWT specific)
- 30-day readmission (RWT
- Length of stay
- Nurse sensitive indicators (e.g. Falls, medication errors, pressure ulcers and UTIs,
- Adverse incidents affecting patient care as recorded by the Datix information (e.g. falls, medication errors)

## **4.0 PARTICIPANT ENTRY**

### **4.1 INCLUSION CRITERIA**

Patients are only eligible for inclusion if they satisfy all of the following criteria:

- Patients admitted to inpatient departments at RWT and are present at RWT during the period of 1 April 2016 to 31 March 2019 inclusive.

### **4.2 EXCLUSION CRITERIA**

The exclusion criteria are:

- Patients admitted to outpatient wards at RWT;
- Patients that were not admitted at or discharged from RWT between 1 April 2016 to 31 March 2019 inclusive.

### **4.3 WITHDRAWAL CRITERIA**

No withdrawal criteria, is considered. All information extracted from Trust databases will be pseudo-anonymised by RWT personnel. All care and consideration will be maintained by the researchers involved in the study for the duration of the study. Patients care will not be affected by this study.

## **5.0 ADVERSE EVENTS**

No patient care related adverse events will occur as this is an observational retrospective study.

There are no known or expected risks or specified "Adverse Events" to the patient as this protocol is designed to collect information rather than be designed for any interventional pathway and comparative analysis.

Advice has been sought and consideration has been made with regard to data confidentiality and participant's data protection in the design and the conduct of this study. All data will be anonymised on case report forms/databases and coded appropriately.

The Datix system within RWT will enable the researchers to establish if occurrences such as patient falls or pressure sores are related to staffing or patient flow and will form part of the main dataset.

## **6. ASSESSMENT AND FOLLOW-UP**

Data extraction will not incur any extra visits or patient/staff involvement and therefore no assessments or follow-ups are required for the study.

## **7. STATISTICS AND DATA ANALYSIS**

All processing of the pseudo-anonymised data extracts will be conducted by Thomas Hoe and Stephenson Strobel. The pseudo-anonymised data extracts will remain at the Institute for Fiscal Studies and the processing will be done using a remote access computing environment. No data will move from the secure location during any of the processing. All of the research results that are extracted after the data has been processed will be non-confidential and any results for small groups of individuals (below 30) will be suppressed.

In line with the research topics outlined earlier in this document, the major processing tasks will be:

1. Computing the amount of contact time that staff have with patients (i.e. the number of seconds spent in the same RTLS location);
2. Computing the amount of contact time that staff have with other staff (i.e. the number of seconds spent in the same RTLS location);
3. Computing the amount of time that staff and patients spend in different hospital locations (e.g. the proportion of time that staff or patients spend in the bed spaces).

Each of these measures will be computed using the pseudo-anonymised data extracts with the aid of statistical computer software (Microsoft Excel, Stata, and Microsoft SQL).

These computing tasks will primarily rely on the RTLS data. The other data extracts, such as the HR data and the PAS data which will be linked to the RTLS data using the unique anonymised patient and staff identifiers, will then be used to assess how these measures vary with the type of patient (e.g. severity, age, location) and staff (e.g. seniority, planned and unplanned absences, team composition), and how they correlate with patient outcomes (e.g. readmission, mortality).

The primary statistical methods that will be used are descriptive statistics, correlation and regression analysis, and tests of statistical significance.

To give a more detailed sense of how this analysis will proceed, consider our study of contact time and patient health outcomes. We will first compute the contact time measure. We plan to begin by focusing on a definition of contact time that is time spent with nurses when in a bed space. This will simplify some of the issues that arise when patients move between locations and receive contact time in busy corridors with multiple staff and patients. We will therefore compute, for each patient, the total time in any bed space during their hospital stay using the RTLS data. With the same data, we can make the equivalent computation for the total amount of time spent by nurses with that patient in those bed spaces. From this we can then compute the total amount of contact time in the bed spaces for every patient in our dataset. This can be done for each individual nurse and then aggregated up to types of nurses (e.g. all nurse contact time, all registered nurse contact time, or all HCA contact time).

These measures of contact time, based on the RTLS data, will be themselves a novel contribution to the literature. We will use standard statistical tools to describe and illustrate the extent to which different types of patient (e.g. based on their diagnosis and ward)

receive contact time, and the mix of contact time across different nurse categories (e.g. by qualifications and seniority).

We will then compute the health outcome measures. These will primarily be based on the PAS data, where we will use the discharge information to identify hospital deaths, the pseudo-anonymised patient ID to identify readmission episodes, and the medical record information to identify length of stay and any nurse-sensitive conditions. We will also use the Datix data to identify any adverse medical events associated with that patient's hospital stay (e.g. patient falls).

Finally, we will make comparisons between the contact time and health outcome measures. A potential concern when doing this is that sicker patients may tend to receive more contact time from staff (who are consciously providing more care to those patients with complex medical conditions) and, irrespective of contact time, these patients may tend to have worse health outcomes (as a result of the complex medical conditions). This could generate a negative correlation between contact time and health outcomes.

To deal with this issue, one approach we will take is to risk-adjust the health outcomes using the diagnosis information contained in the PAS data. This will mean we compare the relationship between contact time and health outcomes for patients that have comparable health conditions (i.e. primary diagnosis and comorbidities). The statistical analysis, which will rely on regression models, will therefore implicitly compare similar patients that receive different levels of contact time. We expect this hypothetical type of comparison to be plausible and to exist in our data, which will contain large volume of patients that have received care in different wards, bays, and time periods. As a simple example, some patients may be exposed to time periods when wards are understaffed because of a leave of absence (leading to less contact time) and we can compare these patients to otherwise-similar patients that were not exposed to these leaves of absence (more contact time).

We will use similar methods to analyse the role of professional-to-professional contact time, medical outliers and patient flow.

## **8. REGULATORY ISSUES**

### **8.1 REGULATORY APPROVAL**

The Chief Investigator will obtain the appropriate approvals from an approved Research Ethics Committee and the Health Research Authority (as required). The protocol will be submitted appropriately and will undergo internal governance and scrutiny (peer review), seeking confirmation of RWT Research and Development and appropriate Capacity and Capability approval. The data will not be used outside of the protocol of this study.

### **8.2 CONSENT**

Research data will be collected by the research team who are part of the clinical care team of patients and have access to the data through their day-to-day roles within RWT. They also have access to the staff data as part of their roles. No participants or staff will be affected by the data collection and will not require any intervention; therefore consent is not required in order to collect the data. Patient and staff data will be pseudo-anonymised by the research team who have access to this data as standard practice. Other members of the research team who do not normally have access to the data will only have access to anonymised data and will not be able to link the data to any personal identifiers.

### **8.3 CONFIDENTIALITY**

All data will be kept confidential and protected at all times. Patient and staff data will be pseudo-anonymised so that privacy is protected at all times (see section 3 for details) The preparation of the data extracts, including the pseudo-anonymization process, will be conducted by RWT staff on-site at RWT using the business-as-usual RWT systems. This will ensure that data security and confidentiality provisions are unaffected while preparing the data extracts.

No consent forms will be required for this project.

## Arrangements for securely storing RWT data offsite

The primary analysis for the research will be conducted by Thomas Hoe and his research assistant (Stephenson Strobel). Thomas and Stephenson are employed by Cornell University in the United States. Thomas spends around half of his time at Cornell and the other half working remotely in London at the Institute for Fiscal Studies, while Stephenson is permanently based at Cornell University.

To enable efficient access to the data it is important that it is stored in a location that can be accessed remotely. This will enable Thomas and Stephenson to regularly work on the data, and it will allow Thomas to illustrate the working results to the CI during future visits to RWT.

The pseudo-anonymised data extracts will be stored at the secure data facilities at the Institute for Fiscal Studies in London. These facilities are routinely used by leading economic researchers in the UK to store confidential, sensitive and, in some cases, personally identifiable data. The following security provisions are in place:

- The IFS information security management system is ISO27001 compliant (certificate available on request) and there is an Information Classification and Handling Policy which sets out a comprehensive set of guidelines for handling all types of data and information (including highly confidential information). IFS researchers will follow strict procedures in this policy and adhere to the IFS Information Security Policy when using or collecting data. Any staff involved in the analysis of sensitive data, have been subject to a Baseline Personnel Security Standard check.
- All data are stored on a secure network. Network access is restricted by strong individual passwords for all staff. Network passwords are changed every 91 days unless staffs are accessing specific types of information where there is a requirement for the password to be changed more often. An enforced PC screen lock is in place after a defined period of time. The network is monitored by the IT Manager to check for security breaches. All members of IFS staff also have a responsibility to report security incidents.
- Access to data via the network is only ever given to named individuals who have obtained the correct permission to use them. Permissions are controlled by the IT Department and Data Managers.
- The Local Area Network is protected by a firewall for the web and mail-servers that is Common Criteria EAL4 compliant. This ensures that there can be absolutely no external access to anything on the common network drives. Internet access is through JANET. Security is continually monitored internally using log files.
- The data on the servers are backed up to an off-site machine, stored securely with IDNet in Docklands. Machines are stored in a locked cabinet in a locked room which is physically restricted to named IFS technical support staff and IDnet staff.
- Network access is restricted to named IFS technical support staff. Back-ups are run overnight onto disks and then onto tape. Automated weekly full back-ups to tapes are made, with daily incremental update
- Where data need to be removed from back-ups, long term back up is not carried out. This makes it easier to securely erase data from back-ups.
- Data on the network is not currently encrypted as stand but the systems would allow to do this when required

The IFS offices are not accessible to the general public and are locked when unattended. Access is restricted through the use of door entry codes and there is an out of hours alarm system.

## **Transferring data from RWT to the Institute for Fiscal Studies**

To transfer the data to this location, we take the following steps:

1. Extract the relevant datasets from RWT's systems (as described above, including the process of pseudo-anonymization);
2. Transfer the data to a physical encrypted storage device (e.g. an external hard drive);
3. Courier the physical storage device to the Institute for Fiscal Studies
4. The IT team at the Institute for Fiscal Studies uploads the data to the secure data facility;
5. The physical storage device will then be stored in a secure location either at the Institute for Fiscal Studies or, if required, delivered back to RWT for storage.

Thomas Hoe in conjunction with the IT team at RWT will be responsible for steps 1 to 3. At no point in the transfer process will the data be left unsecured. Once the transfer has taken place, all of the data will remain in a single place which will have restricted access by only Thomas Hoe and Stephenson Strobel.

### **Data use agreement**

Details of the above arrangement will be formalized in a Data Use Agreement (DUA) element of a Collaboration Agreement between the Sponsor and other parties that specifies all the parameters of how the data will be transferred, stored and processed.

## **8.4 INDEMNITY**

Standard NHS Indemnity will apply for the research elements of the study conducted on NHS premises.

The Institute for Fiscal Studies, where the pseudo-anonymised data will be stored, has professional indemnity insurance (£2m limit). The Institute for Fiscal Studies also has insurance coverage for: (i) claims and investigations arising from [...] the misuse of data, including a breach of any data protection legislation (limit of £2m: Corporate legal liability insurance); and (ii) the costs of notifying anyone whose personal data may have been accessed following a data breach or violation of computer system by an employee (limit of £250,000: Crime Insurance).

## **8.5 SPONSOR**

The Royal Wolverhampton NHS Trust will act as Sponsor.

## **8.6 FUNDING**

No funding will be received externally to support this project.

## **8.7 AUDITS AND INSPECTIONS**

The Royal Wolverhampton NHS Trust through the R&D Directorate will support and ensure governance of the project throughout its duration. A monitoring plan for this study will be discussed, agreed and utilized. The level of requirement will be structured on their SOPs for monitoring.

## **9.0 STUDY MANAGEMENT**

The study will be co-ordinated by Mrs Vanda Carter – Trust Practice Education Facilitator for Research alongside the Chief/Principle Investigator, Trust Chief Nurse : Professor Ann-Marie Cannaby.

## **10. PUBLICATION POLICY**

The study and its results will be submitted/ published in a large impact, peer-reviewed journal. All data used for the study belongs to RWT and publications will be subject to review from senior RWT executives. The provider of the RTLS system (Tele-Tracking) will be kept updated regarding any publications.

## 11. ARCHIVING

The study will adhere to RWT Research and Development SOP requirements with regard to archiving S11. for a non c-timp trial. The duration of time study documents will be archived /stored will be documented following standards recommended by the UK Policy Framework for Health and Social Care Research ver. 3.0 (2017).

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