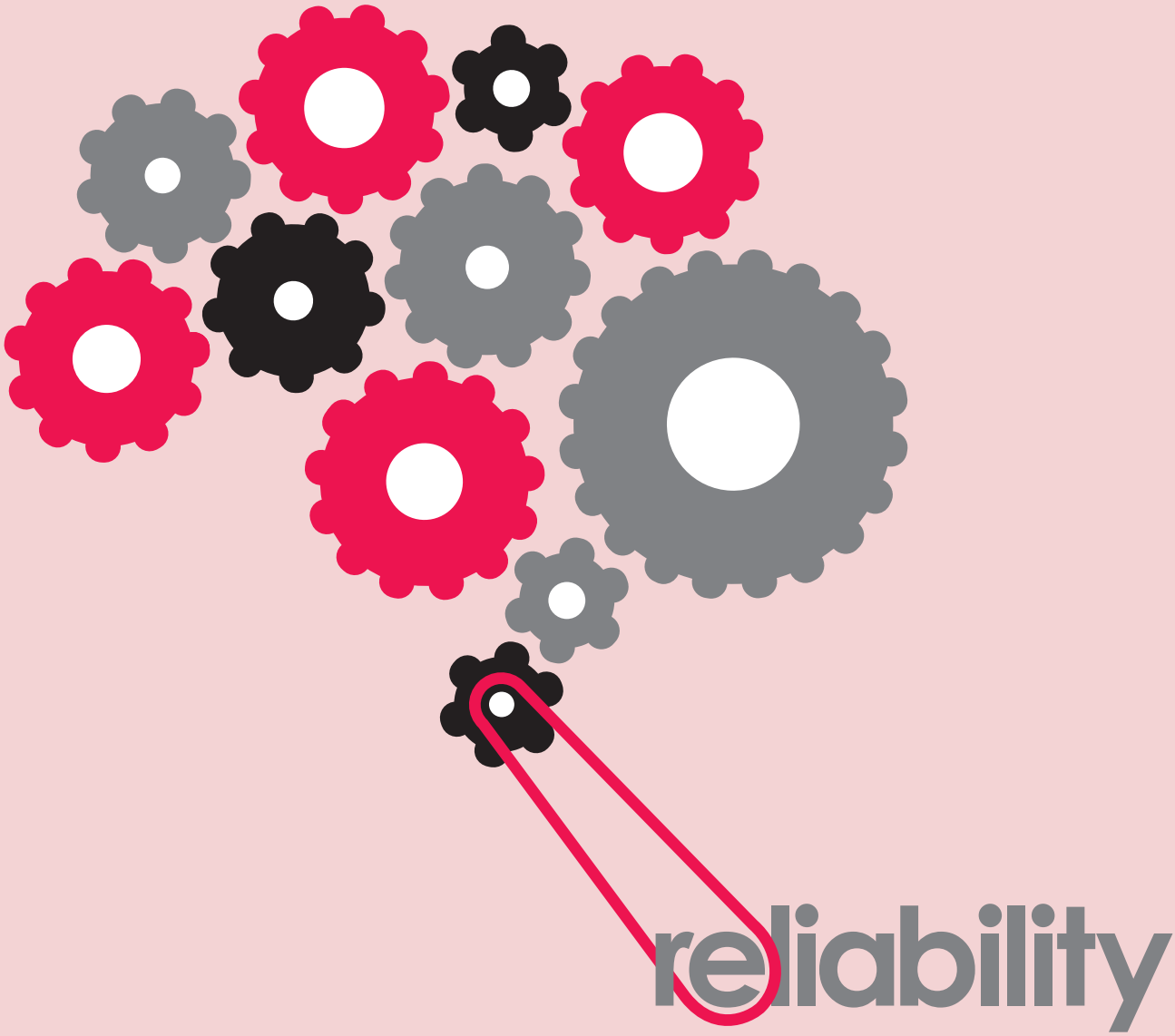
Evidence:

How safe are clinical systems?

Primary research into the reliability of systems within seven NHS organisations

March 2011

The Health Foundation
Inspiring Improvement



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This research was commissioned and funded by the Health Foundation to help identify where and how improvements in healthcare quality can be made. The views expressed in this report do not necessarily represent the views of the Health Foundation.

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Foreword

The knowledge that poor systems can cause harm is not new, but the size of this problem has not been established systematically. This report provides groundbreaking evidence of the extent to which important clinical systems and processes fail, and the potential these failings have to harm patients.

This study forms part of the Health Foundation's work to help healthcare organisations improve the quality of services they offer. Our Safer Patients Initiative has highlighted the need to take a clinical systems approach to improving safety, since it is failings in these systems that often contribute to breakdowns in patient safety.

The work also supports our Safer Clinical Systems programme by providing a much-needed evidence base. It systematically identifies and documents the different defects in specific points of the care pathway, the extent that they vary and their potential for patient harm.

The results of this study identify the variation across healthcare in the reliability of five key systems and processes:

- availability of information when making clinical decision
- prescribing
- handover
- availability of equipment in operating theatres
- availability of equipment for inserting intravenous lines.

We cannot continue to treat the levels of risk identified in this report as acceptable or inevitable. More research is required to investigate the underlying factors affecting the reliability of healthcare systems and processes, and the impact on patient safety.

However, translating this into practice is not simple. The Health Foundation is taking this work forward with our Safer Clinical Systems programme to improve the safety and reliability of healthcare. We would encourage NHS leaders and practitioners to use these findings to consider how to improve reliability in their own organisations.

Introduction, aims and approach

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Chapter 1

Introduction and summary of findings

1.1 Introduction

'Rather than being the instigators of an accident, operators tend to be the inheritors of system defects …their part is usually that of adding the final garnish to a lethal brew whose ingredients have already been long in the cooking' (James Reason, 1990)

This study was commissioned by the Health Foundation as part of its work to examine how systems reliability affects patient safety, and how this can be improved.

The purpose of the research was to describe the nature, type, extent and variation in the reliability of five healthcare systems that have the potential to cause harm to patients in UK hospitals.

These are: the availability of clinical information in outpatient clinics, prescribing for inpatients on hospital wards, clinical handover between doctors, equipment availability in the operating theatre, and systems for inserting intravenous lines.

Seven hospitals from across the UK participated in the research. Each clinical system was studied in three hospital organisations. The research began in January 2009 and, including the time taken to gain ethical approval, was completed within a year.

1.2 This report

The first part of this report sets out the context and background for the research, giving an overview of the Health Foundation's Safer Clinical Systems programme.

We then describe our general approach to the research methods and theoretical framework used. In part 2, each of the five clinical systems is then considered in turn, detailing the specific methods used and discussing the findings in the context of other reported research.

In the final part, the results are drawn together into conclusions and recommendations arising from the study as a whole.

We would like to take this opportunity to thank the participating organisations for their cooperation and support in conducting this research.

We hope that the results and our recommendations will help to drive further improvements in patient safety.

1.3 The research team

The research was led by Professor Bryony Dean Franklin, Director, Centre for Medication Safety and Service Quality, The School of Pharmacy, University of London and Imperial College Healthcare NHS Trust, supported by a team of researchers from the Centre for Patient Safety and Service Quality at Imperial College, in collaboration with the Clinical Systems Improvement Team at Warwick University.

As a research team we have experience in patient

safety research, methods for improving patient safety, reliability in healthcare systems, clinical systems improvement approaches, process and outcome measurement, and knowledge capture and transfer.

The study was generally referred to by the acronym WISeR (the Warwick and Imperial Study of Reliability in healthcare).

1.4 Key findings

Failures in reliability pose a real risk to patient safety

A significant proportion of the reliability failures identified in this research were associated with risks to patient safety.

For example, we found that 15% of outpatient appointments were affected by missing clinical information at our study sites.

In 20% of these cases, the doctors involved judged the patients to be exposed to risk.

Important clinical systems and processes are unreliable

Fully reliable systems would function as intended under expected conditions.

The four clinical systems for which reliability could be measured had an average failure rate of 13% - 19%.

There are wide variations in reliability between organisations

Significant variation was found between organisations, ranging from 63% for equipment availability in organisation D, to 96% for availability of clinical information in organisation A.

Unreliability is the result of common factors

Across the five systems and organisations, unreliability was usually the result of the same factors. These included: a lack of feedback mechanisms for both individuals and systems; poor communication; and a widespread acceptance on the part of clinical staff that systems are going to be unreliable, and that this is not their responsibility.

It is possible to create highly reliable systems

The variation between and within organisations suggests that it is possible to create systems that have higher reliability.

1.5 References

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Chapter 2

Context of the research

by Matthew Cooke and Mark-Alexander Sujan

2.1 Patient safety in the UK and worldwide

The extent to which healthcare can endanger patient safety is now acknowledged worldwide. In the UK, a case note review confirmed that 11.7% of admissions in two UK hospitals led to an adverse event, similar to adverse event rates previously reported in Australia and the US (Vincent et al, 2001). The Chief Medical Officer's review of patient safety in England estimated that 'one in 10 patients admitted to hospitals in developed countries will unintentionally be the victim of an error' and reported that 'the UK was one of the first countries to give priority to tackling patient safety' (Department of Health, 2006).

The need to address patient safety by tackling healthcare systems was made abundantly clear to the NHS in 2001, with the report of an external inquiry into the death of a young man, Wayne Jowett, in the Queen's Medical Centre in Nottingham (Toft, 2001). He died because a chemotherapy drug was mistakenly injected into his spine rather than a vein. The inquiry found over 40 errors in the chain of events leading up to the final mistake. Each part of the medication system was unreliable in some way.

While considerable efforts have been made to improve patient safety in the NHS since Mr Jowett's death, the challenge of how to improve patient safety across an entire system of healthcare on a sustainable basis remains, made more difficult by the fact that there is little quantifiable evidence about the reliability of healthcare systems generally, and on how this affects patient safety.

2.2 This research

The Health Foundation commissioned this research to strengthen the evidence base relating to the impact of healthcare systems reliability on patient safety, and in doing so, create a compelling case that a systems focus in patient safety is required to avoid the negative impact that defects in this area can cause.

This is the first UK study to examine the reliability of healthcare systems and the impact of poor reliability on patient care in a range of organisations. It was commissioned by the Health Foundation against the backdrop of previous work on patient safety, outlined below.

2.3 Patient safety work by the Health Foundation

The Safer Patients Initiative (SPI) was set up by the Health Foundation in 2004, to test the use of an organisation-wide approach to patient safety.

The participants were provided with educational opportunities to develop knowledge and expertise in patient safety, combined with skills in change management and measurement of improvement. SPI introduced a number of initiatives aimed at improving the reliability of certain clinical working practices, together with interventions to improve the safety culture of an organisation.

SPI also focused on gaining executive engagement in patient safety as a key issue on the strategic agenda, to bring about wider organisational change. It addressed issues in diverse areas with

many projects based in critical care, theatres and in detecting deterioration. For example care bundles were used to reduce ventilator-associated pneumonias, central venous catheter infection, and cardiac arrest rates. An evaluation is due to be published shortly. Research is currently underway to evaluate the longer term impact of the changes as well as the sustainability of the SPI programme.

Following the widely recognised short-term impact of the introduction of care bundles in SPI, national campaigns were launched by the Health Departments in England, Wales, Scotland and Northern Ireland aimed at spreading such learning to the wider NHS.

While the SPI approach had success in certain areas of the hospital, tackling specific concerns about patient safety, the issue of how to address system-wide influences on patient safety remained. It became clear that further work was needed in this area.

As a result, the Health Foundation launched the Safer Clinical Systems (SCS) programme in 2008. This programme has a focus on reliability in systems of care. SCS looks at wider systems so that changes should have a much broader impact. The first phase of the programme aimed to develop 'the SCS approach' to enable health organisations to diagnose problems, analyse the system, develop redesign strategies, reduce risk and develop resilience in the system.

The approach is a unique combination of philosophies and uses tools from both improvement science and safety engineering. It focuses on the wider system, defined as 'the arrangement of resources, which can exist on many levels, to achieve objectives that have a single goal'. SCS has a greater emphasis on human factors, safety culture, understanding the concepts of risk and reliability, and the need to develop resilience, when compared with earlier initiatives.

The SCS programme is also aiming to develop an approach that is more risk-based as opposed to the existing harm-based approaches. The aim is to result in improvements that will reduce harm by controlling relevant risks to an acceptable level, by continuously measuring and monitoring performance levels and by creating resilience that allows the system to withstand unforeseen disturbances.

There has also been an appreciation that more complex measurement systems are needed, which combine numeric measures with narrative to explain if and why risk has been reduced.

In June 2009, the Health Foundation set up the Safer Patient's Network (SPN) with membership from the SPI sites to create a 'network as a self-sustaining, member-driven community of practice to catalyse improvements to patient safety' (The Health Foundation, 2009). It currently consists of 18 NHS organisations which are supported by the Health Foundation and the Institute for Healthcare Improvement. The evaluation of the network is being carried out by a consortium between Cardiff University and the York Health Economic Consortium.

The concept of reliability in healthcare has been a major focus of the developing approach to improving patient safety in the SCS programme. Therefore, in the following section, we review the notion of reliability and examine the different meanings that this concept has been given in health, in order to clarify the context in which the present research has been carried out.

2.4 Reliability in healthcare

The aim of WISeR was to contribute towards enhancing the reliability with which care is delivered to patients in the NHS. Owing to the interconnectedness and degree of complexity of many healthcare systems, the notion of reliability needs to be applied carefully and with terminological precision in order to be able to compare findings of different studies. At present, it is very difficult to perform such a comparison due to the different ways in which the concept of reliability has been interpreted and applied. A brief literature review next provides some evidence for a reliability shortfall (in its different meanings) in the delivery of care.

Definition of reliability

In the engineering and safety communities, reliability has received a lot of attention due to the initial unreliability of early electronic components that frequently only had a lifespan of a few hours. With the increasingly pervasive use of computer software, the reliability of software systems has also become an increasing cause for concern. In these

communities, where the study of reliability is an established mathematical science, reliability is commonly defined in the following way (for example, Storey, 1997):

'Reliability is the probability of a component, or system, functioning correctly over a given period of time under a given set of operating conditions.'

In this context, 'functioning correctly' refers to functioning according to a given specification. Reliability is usually expressed in terms of failure rate per hour for systems operating in continuous mode, or probability of failure on demand for demand-based systems. In a healthcare context, the US Institute for Healthcare Improvement (IHI) similarly defines reliability as 'failure-free operation over time'(Resar, 2006).

The above represents an intuitive and seemingly simple definition of the notion of reliability. In healthcare we often intuitively equate reliability to doing the right things for patients, or (as Don Berwick put it) as 'keeping a promise'. However, when transferring the concept of reliability to healthcare, attention needs to be given to some detail 'hidden' in the above definition: electronic and software systems possess a clear specification and the reliability of these systems is assessed against this specification in terms of defined inputs and outputs.

In healthcare systems, as opposed to purely technical systems, it is more complicated to define with precision what 'functioning correctly' means at a specific moment in time and for a particular patient.

Often, the ideal course of treatment emerges only in hindsight when all the facts are known; also, in healthcare there are still many different ways of getting things right, frequently depending on personal preference, style or other local circumstances.

As a result, it is usually not possible to provide the level of exact specification which can be applied in the study of reliability in technical systems, unless the healthcare system under consideration is broken down to components with much lower levels of complexity, allowing the elimination of uncertainty, ambiguity and variation. In this case, the concept of reliability can be applied most meaningfully to those aspects of healthcare systems that are characterised by a higher degree of agreement and standardisation.

Characteristics of 'high reliability organisations' have also been identified in other industries. These include a preoccupation with failure, reluctance to simplify interpretations, sensitivity to operations, commitment to resilience, and deference to expertise (Weick and Sutcliffe, 2001). However, it has been suggested that that such characteristics apply only to industries where core processes are already at least 98% reliable, and that applying such an approach is less applicable to healthcare where these high levels of reliability are rarely achieved (Resar, 2006). In the work which follows, we therefore did consider the 'high reliability organisation' approach. Instead, we focused on measuring the reliability of the processes concerned (Resar, 2006).

Reliability and harm

In high-risk industries such as the nuclear industry or aviation, the distinction between reliability and safety is properly understood and acknowledged. Reliability contributes to safety, but is concerned only with the probability of occurrence of a failure, not with the severity of its consequences.

For healthcare systems this implies that the reliability of care delivery is an important aspect in reducing patient harm, but consideration also needs to be given to the following:

(a) failures may still occur and need to be dealt with

(b) the 'specification' may be inappropriate (for example, because the patient is an exception to a rule) or incomplete. In technical systems a common form of incomplete specification is a situation where the behaviour of the system has been defined only for a subset of inputs (usually, the set of expected inputs) and on encountering an input outside of this subset the system may produce random and potentially harmful outputs (e.g. the random behaviour of some infusion pump interfaces when the user produces unexpected inputs such as two decimal points in succession).

In healthcare, a similar situation may arise when a

protocol only deals with the most common set of patients. For example, a protocol that assumes adult patients and fails to specify what to do in the case of paediatric patients.

Reliability and quality of care

Many aspects contribute to the quality of care that is delivered, e.g. the provision of safe, effective, patient-centred, timely, efficient and equitable care (Institute of Medicine, 2001).

Reliability contributes to these dimensions of quality of care, but the two concepts are not synonymous. For example, the provision of safe and timely care is affected by the reliability of healthcare systems and processes, but it depends also on the means of dealing with failures where they occur (affecting safety) and on the ease with which the system can be restored to normal operation (affecting timeliness). For example, if we are dealing with an x-ray machine that can be replaced easily in case of failure, then we can accept lower levels of reliability and still provide timely care. If, on the other hand, we are dealing with radiation therapy equipment that will suffer severe downtimes for maintenance in case of failure, higher levels of reliability are required.

Reliability and standardisation

The assessment of reliability requires clearly specified processes (i.e. a specification) and is linked to the notion of failure. However, in healthcare many processes are not properly specified and have evolved rather than having been designed explicitly according to a predefined specification.

As a result, there is a lot of variation in the way care is delivered without necessarily any 'failures' in the provision of care. For example, on a ward where patients tend to be well-known to nursing staff and with stable staffing situations, each nurse may follow a different practice to identify patients and the process is supported by their personal acquaintance with the patients. As such, the identification of patients may be extremely reliable (judged by the outcome).

A measure of the adherence to the formal patient identification protocol (the use of multiple patient identifiers), on the other hand, may be low. In such situations, it may be more intuitive and useful to refer to the level of standardisation rather than the reliability of the process. It also illustrates the need to consider measures of the reliability of process as well as outcome.

Reliability shortfall in health

There is increasing evidence in the literature that patients often do not receive high quality care. Studies address different aspects of quality or use reliability in slightly different ways as described above.

Outcome based studies, such as the well-known Harvard Medical Practice study (Brennan et al., 1991), the Utah and Colorado studies (Thomas et al, 2000), and the London study (Vincent et al, 2001) indicate that preventable adverse events affect around 1.5 - 5.4% of patients within a system that creates an overall adverse event rate of 11.7%. This provides an estimate of the failure rate of the 'hospital system'.

Further outcome-based studies focus on specific processes or conditions. A study reviewing 182 deaths in twelve US hospitals estimated that 14% - 27% of these were preventable (Dubois et al, 1988). A study of 44,603 patients undergoing surgery at a large medical centre between 1977 and 1990 estimated that 2.7% of patients had complications due to error (McGuire, 1992). A UK study of complications in surgery estimates that 7% - 10% of major complications are avoidable (Vincent et al, 2004).

In the area of medicines management and prescribing in particular, there are many studies that focus on the incidence or prevalence of errors, rather than on adverse outcomes. Prescribing errors occur in 1.5-9.2% of medication orders written for hospital inpatients in the UK (Vincent et al, 2009); this wide range of figures is partly due to differences in settings, definitions and data collection methods. A median error rate of 7% was reported in a recent international systematic review of prescribing errors in hand-written medication orders for hospital inpatients (Lewis et al, 2009).

In a major study in the USA, the degree to which patients received care consistent with basic quality

standards was assessed by measurement against a number of quality indicators for 30 common conditions (McGlynn et al., 2003). The study found that patients received scientifically recommended care in only 55% of the cases. There was large variability among clinical conditions. For some conditions, patients received 78.7% of recommended care (senile cataract) where as for others only as little as 10.5% (alcohol dependence).

This use of quality indicators has become a popular study design to assess adherence to evidence-based guidelines and practice, albeit as a proxy indicator for patient outcomes. A US study using quality indicators for melanoma care found that adherence to indicators varied from 11.8% to 96.5% at the individual patient level (Bilimoria et al, 2009a). A similar study design was followed in a US study assessing the quality of pancreatic cancer care.

This study found that patient-level adherence with individual indicators ranged from 49.6% to 97.2% (Bilimoria et al, 2009b). A study attempting to assess whether participation in a quality improvement programme for the management of coronary artery disease in women and the elderly would lead to improvement in the quality of care found that adherence to quality indicators rose from 86.5% in 2002 to 97.4% in 2007 (Lewis et al, 2009). All of these studies demonstrate that there is great variability in adherence to evidence-based quality indicators.

2.5 How this research will be used

This research into the reliability of healthcare systems, and its effect on patient safety, was designed to run in parallel with phase one of the SCS project outlined above, which ran from 2008 until 2010, and to support the activities of the four organisations selected for phase one of SCS. The findings from the research will also be used to:

- Inform the design of phase two of SCS, including demonstrating whether phase one SCS organisations are representative of the wider NHS.
- Support the Health Foundation's work to build the will for change using a systems approach.
- Encourage NHS Organisations to apply for phase two of the SCS programme.

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Chapter 3

Aims, objectives and approach

by Bryony Dean Franklin

In this section we set out the study's aims and objectives and present the theoretical framework used. We then give an overview of our methodological approach, followed by a brief account of the choice of study organisations and topics.

The section concludes by summarising the ethical considerations taken into account when designing the study.

The research began in January 2009 and was completed within a year, including the time taken to gain ethical approval.

3.1 Aims and objectives

The overall aims of the research were twofold:

(1) To describe the nature, type, extent and variation of defects in healthcare system reliability that have the potential to cause patient harm.

(2) To provide research support for phase 1 and the design of phase two of the SCS programme. The original brief is given in appendix 1.

The objectives were to:

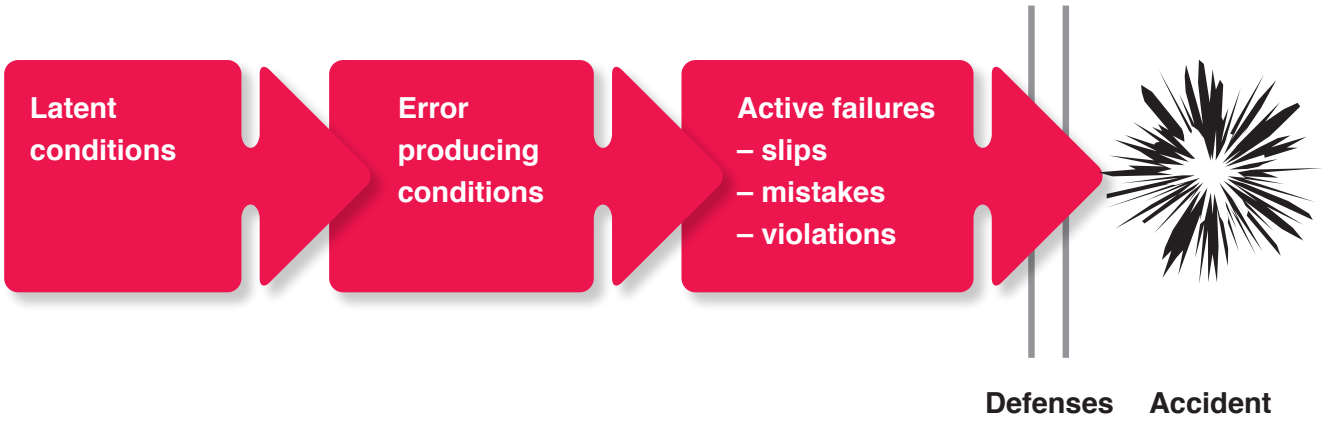
- Apply a systematic research approach to the identification and definition of a number of safety critical care processes and specific points in care delivery, targeted by SCS, in which to explore defects in the reliability of care.
- Explore their nature, extent and variation, both within and between organisations.
- Identify the systems factors involved, in order to make recommendations for improving system reliability.
- Predict the potential for the spread of the good practice developed in phase 1 to the wider NHS in subsequent stages, by understanding the present state of reliability in a sample of NHS organisations.
- Combine the learning of phase 1 and this research to help in developing SCS phase two.
- Support the evidence base in the production of safety briefings being created by the Support Team in SCS phase one.
- Assist the work of the award holders in SCS phase one.

3.2 Theoretical framework

In understanding the causes of poor reliability and systems failure, we used Reason's accident causation model (Reason, 1990). It is now widely recognised that errors and human behaviour cannot be understood in isolation, but must be considered in the context or system in which people are working.

Clinical staff are influenced by a wide range of system factors such as the technology available, the team and staffing levels, their hours of work, the design of their work areas, distractions in the work place, and, of course, patient factors. This is illustrated by the accident causation model (Figure 1) which has more recently been adapted for use in healthcare (Vincent et al, 1998).

Figure1: The accident causation model



Reason's model argues that in modern systems with several lines of defence, an accident is usually the result of numerous failures, both active and latent, rather than being caused by a single human error.

Active failures by frontline staff can be regarded as symptoms of underlying systems defects. These underlying systems defects are the result of practices and decisions that are removed in time and space from the actual accident ('latent conditions'), but create the conditions in which accidents happen.

In the past, the approach to improving safety in healthcare has been to take one type of adverse event and try to reduce its frequency by addressing the immediate active failures. However, as research has shown, it is important that we look at the whole system to reveal the true picture, and create opportunities for preventive actions. Reason (1990) puts this very succinctly:

'Rather than being the instigators of an accident, operators tend to be the inheritors of system defects …their part is usually that of adding the final garnish to a lethal brew whose ingredients have already been long in the cooking'.

A potentially more effective alternative is to address the underlying systems factors, since these can be identified and managed systematically and will have an impact on many paths to failure.

Within the patient safety literature, Vincent et al (1998) identified seven main categories of factors that could affect the safety of the healthcare system.

These factors have been conceptualised in an operational framework and are as follows:

- the institutional context
- organisational and management factors
- work environment
- team factors
- individual (staff) factors
- task factors
- patient characteristics.

The resulting operational framework (Figure 2) was developed based on the accident causation model (Reason, 1990) and the medical literature on errors, adverse outcomes and risk management (Cook and Woods, 1994; Cooper et al, 1984; Eagle et al, 1992; Leape, 1994; Vincent and Bark, 1995).

The framework integrates a number of key contributing factors, in recognition that adverse events or patient safety incidents are generally the result of a whole concatenation of events or failures (active and latent) within the healthcare system, in which human error by frontline staff is only the final element.

In studying the systems factors that contribute to defects in healthcare system reliability, we therefore used the following framework.

Figure 2: Factors that influence clinical practice, from Vincent et al (1998)

1. **Institutional context**
   Economic and regulatory context
2. **Organisational and management factors**
   Financial resources and constraints
   Organisational structure
   Policy standards and goals
   Safety culture and priorities
3. **Work environment**
   Staffing levels and skills mix
   Workload and shift patterns
   Design, availability & maintenance of equipment
   Administrative and managerial support
4. **Team factors**
   Verbal communication
   Written communication
   Supervision and seeking help
   Team structure
5. **Individual (staff) factors**
   Knowledge and skills
   Motivation Physical and mental health
6. **Task factors**
   Task design and clarity of structure
   Availability and use of protocols
   Availability and accuracy of test results
7. **Patient characteristics**
   Condition (complexity and seriousness)
   Language and communication
   Personality and social factors

3.3 Overview of methodology

In this section we describe our general approach to the study; further details specific to each selected topic will be described later in the report.

The study employed a mixed methods approach using both qualitative and quantitative analysis, based around specific topics. For each of our topics, data collection took place in three stages, each of which will next be described.

Analysis of the process and environment

For each of our topics, we began by finding out how the process was intended to operate. This was done by reviewing local or national (or both) guidelines and procedures (as appropriate), as well as observation and discussion with the staff involved.

This resulted in one or more process maps of the systems concerned. The process maps were relatively high level and were intended to describe the key elements of the process concerned at each organisation, rather than details of individual tasks.

Measurement of systems reliability

We identified key areas within each process in which to collect data relating to the reliability issues identified. The data relating to this phase was quantitative, and allowed us to explore the extent of variability between the study organisations. Where applicable we also explored variability between clinical areas within each study organisation.

Specific methods for data collection were determined according to the topic concerned, and through discussion with the study organisations. Some data were collected directly by the research team, and some were collected locally by nominated leads. Members of the research team trained staff in participating organisations in the methods of data collection where needed, and conducted all analysis.

Causes of reliability failures

For each topic, we then explored the causes of the reliability failures identified using qualitative semi-structured interviews with key informants from each study organisation. Potential interviewees were identified by local study co-ordinators, given a participant information sheet and invited to sign a consent form if they were willing to participate in a 20 to 30 minute interview.

These interviews were mainly conducted face-to-face, although some were also conducted by telephone, depending on the availability and

Table 1: The study organisations

Organisation	Country	Teaching / Non-teaching	SPI site	Primary / Secondary care
Phase one SCS organisations				
NHS Lothian	Scotland	Teaching	No	Both
Bolton Hospitals Trust / Bolton PCT	England	Non-teaching	No	Both
Hereford Hospitals NHS Trust	England	Non-teaching	No	Secondary
Plymouth Hospitals NHS Trust	England	Teaching	No	Secondary
Additional organisations				
Cardiff and Vale University Health Board	Wales	Teaching	Yes	Both
Imperial College Healthcare NHS Trust	England	Teaching	No	Secondary
Heart of England NHS Foundation Trust	England	Teaching	No	Secondary
Winchester and Eastleigh Healthcare NHS Trust	England	Non-teaching	No	Secondary

SPI: Safer Patients Initiative

preference of the interviewee. Face-to-face interviews were conducted at a venue of their choice.

We made audio-tapes of interviews if possible, or took detailed notes if interviewees preferred not to be taped.

These interviews were then transcribed and analysed using the accident causation model as the theoretical framework. For each topic, a sample of at least one in four interview transcripts was checked by a second researcher.

3.4 Choice of organisations

The four organisations participating in phase 1 of SCS represented a large teaching hospital integrated with primary care and mental health services within one organisation (NHS Lothian); a large acute organisation and associated primary care organisation (Bolton Hospitals Trust / Bolton PCT), each managed separately; a large teaching hospital taking tertiary referrals from a wide geographical area (Plymouth Hospitals NHS Trust); and a small district general hospital organisation serving a rural area (Hereford Hospitals NHS Trust).

The three features common to each were:

- Acknowledged experience in use of 'lean thinking' approaches.
- An interest and expertise in systems redesign.
- A commitment to improving patient safety.

Four additional organisations were selected to provide a broad match in terms of organisational structure and size, and increase the breadth of the sample in terms of geographical spread and other characteristics. The four additional organisations recruited were:

- Cardiff and Vale University Health Board – comprising one large and eight smaller hospitals, plus associated primary care services.
- Imperial College Healthcare NHS Trust – comprising three large teaching hospitals and two smaller specialist hospitals.

- Heart of England NHS Foundation Trust – a large teaching Trust with one large hospital with some regional services, one medium district general, one small hospital with limited on-site services. One of which is a new addition to the Trust.
- Winchester and Eastleigh Healthcare NHS Trust – a medium sized district general hospital.
- Characteristics of the eight selected organisations are given in Table 1 (page 14). Organisations represent a wide range of types, from around the UK.

3.5 Choice of topics

Six specific topics were initially selected for study. Four of these were selected in conjunction with the four organisations participating in phase one of SCS, to correspond to the broad areas that they had chosen to study. From each of these broad areas, we selected more specific aspects for detailed study, focusing on areas that we felt would be both practical and relevant for multi-centre study. We also chose two additional topic areas, to broaden the range of topics studied, giving a total of six topics (Table 2).

The SCS site associated with communication between healthcare sectors for older people was subsequently unable to participate in the study; this topic and the associated site were therefore excluded. We completed the study for the five remaining topics. For the remainder of this report, organisations will be given codes from A to H to preserve anonymity in relation to the results.

We allocated topics to ensure that data on each one would be collected in three different organisations.

Wherever possible the three organisations were selected to represent a wide range of organisations. We initially planned to select an additional topic for each of the four SCS organisations with the aim of supporting them in their second SCS project. However as the SCS programme progressed, it became apparent that organisations would not start a second project within the timescale of the WISeR study. We therefore reallocated some of these topics to other organisations. Table 3 summarises the final allocation of the five topics to the five organisations participating in the WISeR study.

3.6 Comparison of organisations

Organisations were recruited with the aim of having a sample that was representative of the UK. To explore the extent to which this was achieved, we accessed a range of patient safety measures for the participating organisations (Table 4).

This information is all publicly available from the National Patient Safety Agency, Dr Foster Intelligence, Department of Health, Health Protection Agency or the organisations' internet sites. Some clinical audit data, relating to treatment of myocardial infarction and stroke, are also shown in Table 5. Some of the information was not available for all organisations .

These data demonstrate that the organisations selected for this study and for the SCS programme represent a diverse range of organisations with respect to their safety performance as represented by these measures. It is therefore likely that the results obtained may be applicable to the wider NHS across the UK. It is recognised that there has been debate about several of these measures but they still serve our purpose in demonstrating variation among participating organisations and therefore establishing that we used a reasonably representative sample.

3.7 Ethical considerations

At the start of the research we applied for ethical approval for the entire study (appendix 2). Approval was granted initially only for the quantitative data collection and we were asked to submit separate substantial amendment forms for each of the topics studied, with further details of the interviewees, interviewers, and interview questions. The main ethical issues involved maintaining confidentiality of the participating interviewees, while ensuring that any specific cases of serious breaches of practice were reported via the appropriate channels at the study organisations.

To ensure interviewees' confidentiality, we offered them the opportunity to read their interview transcript or handwritten notes and to identify any sections which they did not wish to be used as direct quotes in any reports and publications.

Table 2: The six topics selected for study

Topics selected by the four SCS organisations	Availability of information at the point of clinical decision making
	Communication between healthcare sectors for older people admitted via urgent care pathway *
	Prescribing errors in hospital inpatients
	Communication and handover within acute medicine
Additional topics selected	Equipment/ technology failures in the operating theatre
	Safe systems for insertion of IV lines

* This topic was subsequently dropped from the study.

Table 3: Allocation of topics to organisations

Organisation	A	B	C	D	E	F	G
Availability of information	◆				◆		◆
Prescribing errors	◆	◆	◆				
Communication and handover			◆	◆		◆	
Equipment in the operating theatre	◆			◆		◆	
IV line insertion	◆			◆		◆	

◆ represents the topic being studied in that organisation.

We also gave our assurance that we would not use the names of any people, departments or organisations in association with any of the interview data.

To address the need to ensure that any serious errors or examples of poor practice were reported, we informed interviewees that if we identified any incidents that had resulted in patient harm or resulted from a serious breach of practice, we would ensure that they were reported on the relevant organisation's incident reporting system as per local procedures.

Sample participant information leaflet and consent forms are given in appendix 3 and appendix 4 respectively. Ethical approval was subsequently gained for each individual topic (appendix 2).

We gained approval from each local research and development office to conduct the study at each organisation, first for the quantitative data collection and then for the interviews relating to each topic once ethical approval was gained.

The next section describes each of the five clinical processes studied in turn.

Table 4: Comparative patient safety data for organisations

Site	A	B	C	D	E	F	G	H
SCS site?	No	Yes	Yes	No	No	No	Yes	Yes
Dr Foster Safety Score[1]	90	10	50	30	NA	70	NA	30
PEAT Environment score	Good	Good	Good	Good		Excellent		NA
HSMR all[1]	80	90	90	100		90		120
HSMR non-elective[1]	80	90	90	100		90		120
HSMR stroke[1]	80	130	120	100		110		110
Low mortality CCS groups	0.0009	0.0024	0.0019	0.0019		0.0013		0.0015
NRLS report	2.81	0.38	1.76	7.53		1.39		5.82
Dr Foster Commit-ment to safety [1]	70	80	90	80		90		100
MRSA rates per 1,000 bed days	8	0	4	6		3		4

1. Scores have been rounded to nearest 10 to maintain anonymity. Scores range from 0 (poor) to 100 (excellent) and represent an overall score based on a number of safety indicators.
NA: not applicable - data not available
PEAT: patient environment action team
HSMR: hospital standardised mortality ratio
CCS: clinical classification system
NRLS: National Patient Safety Agency's national reporting and learning system. Incidents reported per 100 admissions
MRSA: Multi-resistant *Staphylococcus aureus* infection.

Table 5: Comparative clinical audit data for organisations

	Prescription of medication for secondary prevention following myocardial infarction[a]					
	Aspirin (%)	Beta blocker	Statins	ACE inhibitor	Clopidogrel	Overall stroke audit score[b]
National average	98%	93%	97%	92%	94%	Middle half
Organisation A	99%	91%	99%	93%	94%	Upper quartile
Organisation B	92%	88%	93%	89%	83%	Middle half
Organisation C	97%	93%	96%	70%	n/a	Middle half
Organisation D	100%	98%	100%	97%	99%	Upper quartile
Organisation E	Data not Available					Lower quartile
Organisation F	**100%**	**100%**	**99%**	**99%**	**98%**	**Upper quartile**
Organisation G	**Data not available**					
Organisation H	**98%**	**92%**	**97%**	**87%**	**96%**	**Upper quartile**

a. Data are from year 2008-2009 (MINAP, 2009)
b. National sentinel audit of stroke care. Data from 2008 (Royal College of Physicians, 2009)

3.8 References

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Five studies of system processes

2

Chapter 4:

Reliability of clinical information availability in outpatient clinics

by Susan Burnett

4.1 Introduction

Clinicians are often faced with making clinical decisions in the absence of patient records and associated information, and missing clinical information has been found to be a contributory factor in medical errors.

For example in the review of 2,353 adverse events reported in the Quality in Australian Health Care Study (QAHCS), Wilson et al (Ross McL Wilson, 1999) found 1.8% of these were due to 'acting on insufficient information' with 26.4% of these leading to permanent disability.

In 2007, over 36,000 reports were received by the NPSA relating to failures in documentation (NRLS Data Summary Issue 8).

The Health Service Journal (HSJ) analysis of over two million outpatient appointments in 49 hospitals from 2006-08 revealed that 54,000 took place without the patient's full records.

The HSJ suggested that if this rate was replicated across the NHS, approximately 1.2 million outpatients in England would be seen without their medical records every year (Gainsbury, 2008).

Despite these high numbers, the impact of missing records had not previously been reported for outpatients in the UK. We did not know how clinicians proceeded in the absence of key information, or what kind of disruption patient care or risks to patient safety resulted.

This topic was chosen by one of the Safer Clinical Systems organisations to support their work to improve the reliability of core information being available at the point of clinical consultation and was also studied in two additional organisations.

The topic focuses on the prevalence of missing clinical information in surgical outpatient clinics in three hospital organisations, looking at what information is missing, and why and how the doctor proceeded in the absence of this information.

The risks to patient safety are assessed together with the impact on the patient's care pathway.

4.2 Objectives

- To create a process map describing how clinical information is assembled and made available at the time of the patient's appointment.
- To measure the prevalence of missing clinical information for patients attending outpatient clinics in general surgery in each of three organisations.
- To describe the types of clinical information that is missing, the action taken by clinicians in the absence of this information and the associated risk to patients.
- To identify any variation in the type of missing clinical information between organisations.
- To explore the systems factors involved.
- To make recommendations for improving the reliability of the clinical information process in outpatient clinics.

4.3 Methods

Organisation selection and access

This topic was selected by organisation G for investigation as part of the SCS project and was also studied in organisations A and E.

In each organisation we worked with a nominated coordinator and a lead surgeon to develop the core information for the study and to identify suitable clinics for inclusion in the study.

In organisation G no systems changes were made as part of SCS prior to or during our data collection period.

The study was undertaken in one or more of the following clinics at each site: general surgery, gastro-intestinal surgery, colorectal and vascular surgery.

The specific clinics studied at each site varied depending on local practice and clinical specialties.

Process mapping

A process map was drafted based on the processes for gathering information for surgical outpatients in organisation G, and then sent to the lead for the project in organisations A and E for comment and to identify any additional features or differences that needed to be included.

The researcher visited each organisation and consulted with staff in outpatients and medical records to understand the processes and produce individual process maps for each organisation.

The process maps were used to help identify the potential failure points for the data collection and later analysis.

Developing a core data set

We began the work with the surgeons in organisation G to agree a core data set for clinical information that should be available at a surgical outpatient appointment if required by the surgeon.

Following discussion about whether it was relevant to distinguish between new and follow-up patients, or between patients who were long or short-term follow-ups, pre or post-operative and so on, it was agreed that all patients would be included and the core data set should be developed to encompass this.

A list of key clinical information needed during a typical outpatient consultation was drawn up by the surgeons in organisation G and comments were sought from organisations A and E.

The list was then reduced to a core list in consultation with the organisations to ensure that it was sufficient for the purposes of the study but not overly onerous for completion by the surgeons.

It was agreed that information would be considered 'missing' if the surgeon looked for it during the appointment but could not find it either in the written record or on the hospital's computer systems.

In this way the doctors only recorded the information that they considered should have been available, but was not.

The final agreed list of clinical information required for a typical surgical outpatient appointment that might cause a problem if the surgeon looked for it but could not find it, was:

- past medical history
- referral letter/other specialty letter
- discharge summary
- current medication
- allergies
- radiology/imaging results
- diagnostic test results
- procedure notes/anaesthetic record
- electrocardiogram (ECG) report
- blood laboratory results
- outpatient medical records/last clinic letter.

Sampling and sample size

We worked with the organisations to determine the most appropriate sample size, taking into account the practicalities of data collection whilst running busy clinics. We calculated the sample size based on a primary binomial outcome of whether required information was available or not.

A target of 400 patients in each organisation was agreed. This sample size enables the observed proportions across the whole sample to be estimated to the nearest 5% at a 95% confidence level, recognising that the subsets within the sample will have wider confidence intervals.

Data collection and analysis

We worked with the organisations to develop the most practical method for data collection and agreed on a form to be completed by the doctor for each patient where either the whole medical record or the identified information was judged by them to be missing.

The data collection form is included in appendix 5. In brief, doctors were asked to record details of:

- What was required, but missing (test results, images, referral letter etc.).
- Whether or not they relied on the patient for any of the clinical information that was missing.
- Whether they made a clinical decision without the information being present in the medical records or available on a computer.
- Whether or not the patient required another appointment because the information was missing.
- The impact on patient care (delay in management, cancellation of procedure etc) as judged by the doctor using a four point scale (none, minor, moderate, severe).
- The potential risk of harm to the patient as judged by the doctor using a five point scale (no threat, minor, moderate, potential adverse event, potential serious adverse event).

Each record was entered into SPSS for analysis. The total number of patients attending each clinic studied was obtained from the clinic records. Data were collected between July and September 2009.

At organisation A, a researcher briefed the surgeons involved. At organisation E, we explained the requirements for data collection to a local project lead who then recruited auxiliary nurses to prompt the surgeons to complete the forms.

At organisation G, a local project lead co-ordinated the data collection and briefed the clinic nurses who then gave the forms to the surgeons for completion. At organisations E and G, the medical directors also sent an email to surgeons regarding the data collection.

Exploring variability in systems failures

We conducted an exploration of the variation between organisations. In completing the process maps it became clear that there was little, if any variation in the way information was handled in each organisation for each clinic and so we did not explore variation between clinics in the same organisation.

Exploring the systems failures involved

Following data collection in each organisation we identified the number and types of information that was missing and explored the reasons for this, using interviews with key staff involved.

It was important to find out about the causes of the failure – why the information was missing and the reasons for any variability.

Participants were selected to be interviewed if they were involved in the delivery or use of clinical information in the outpatient setting.

Our aim was to interview a sample of staff with an understanding of the issues in clinical records management and the booking and dispatching of clinical investigation results, as well as surgeons using the information in clinics.

The local collaborator in each organisation suggested the appropriate staff and helped to invite them to participate.

A standardised semi-structured research topic guide was used and all interviews conducted by the same interviewer.

Interviews comprised of questions exploring the likely causes of information not being available when needed for clinical decision making in the outpatient setting, and any recommendations for improving the reliability of these systems.

The interview guide is set out in appendix 6.

Figure 3: Process map showing preparation of medical records for outpatient clinics, organisation A

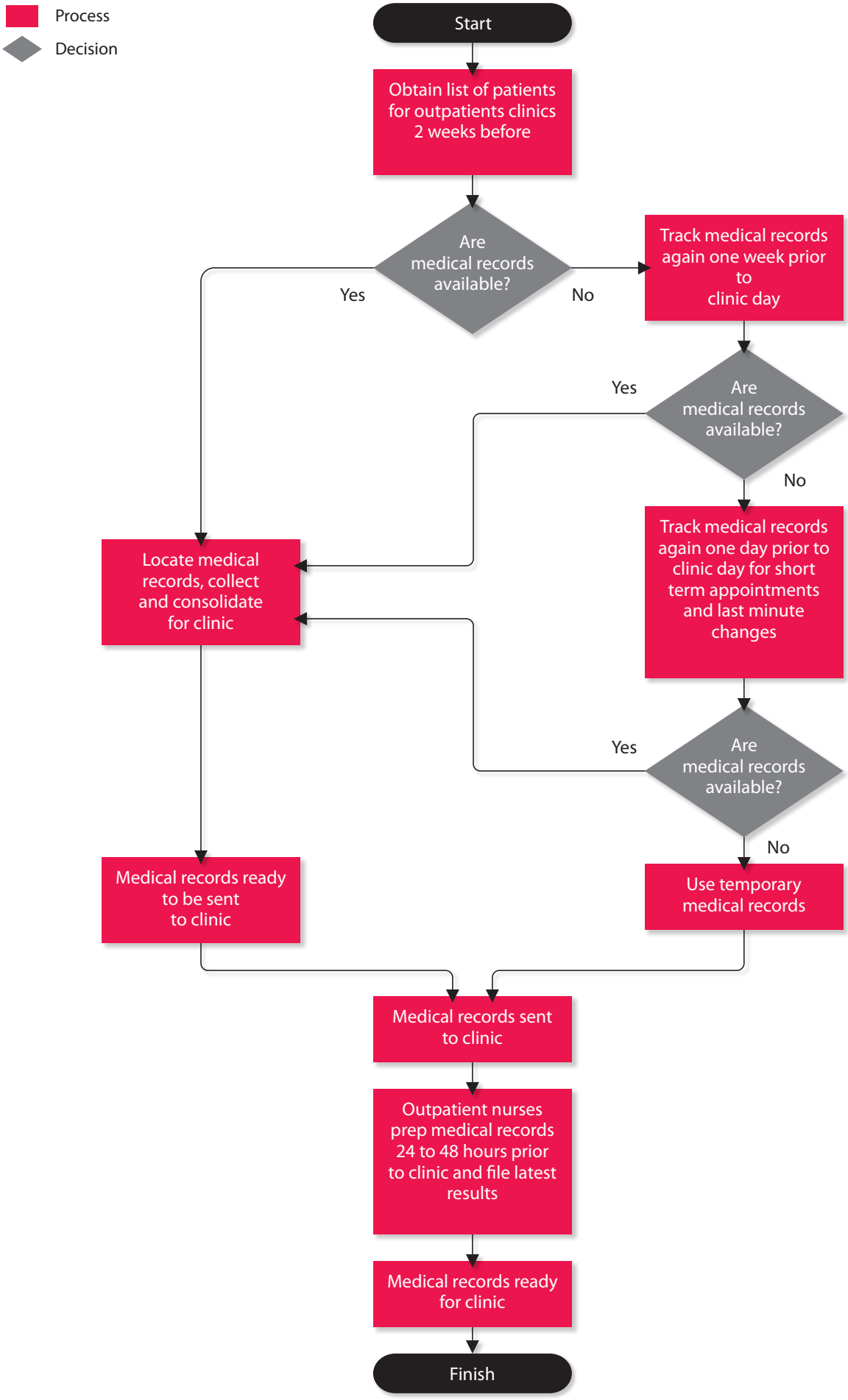


Figure 4: Process map showing preparation of medical records for outpatient clinics, organisation E

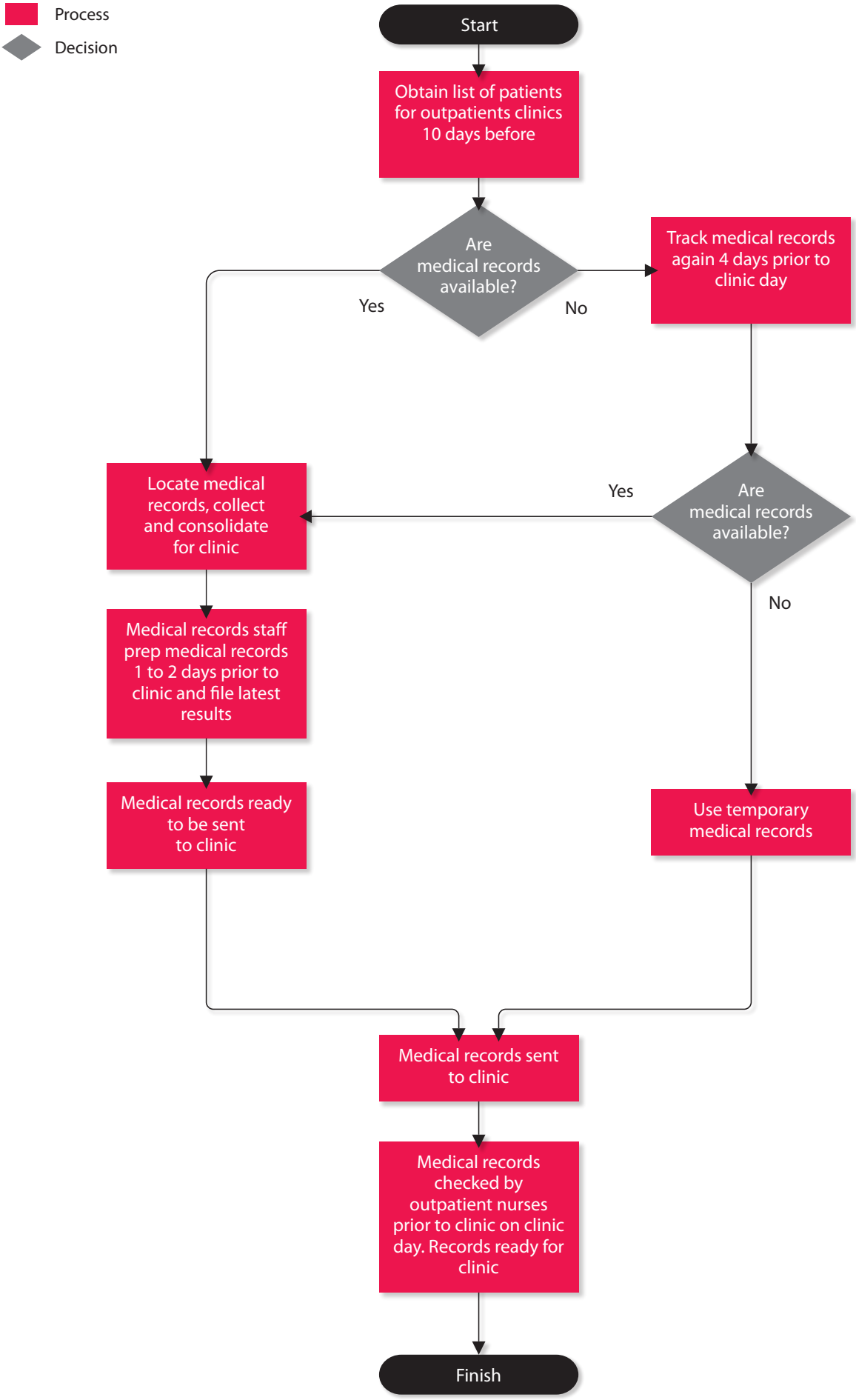
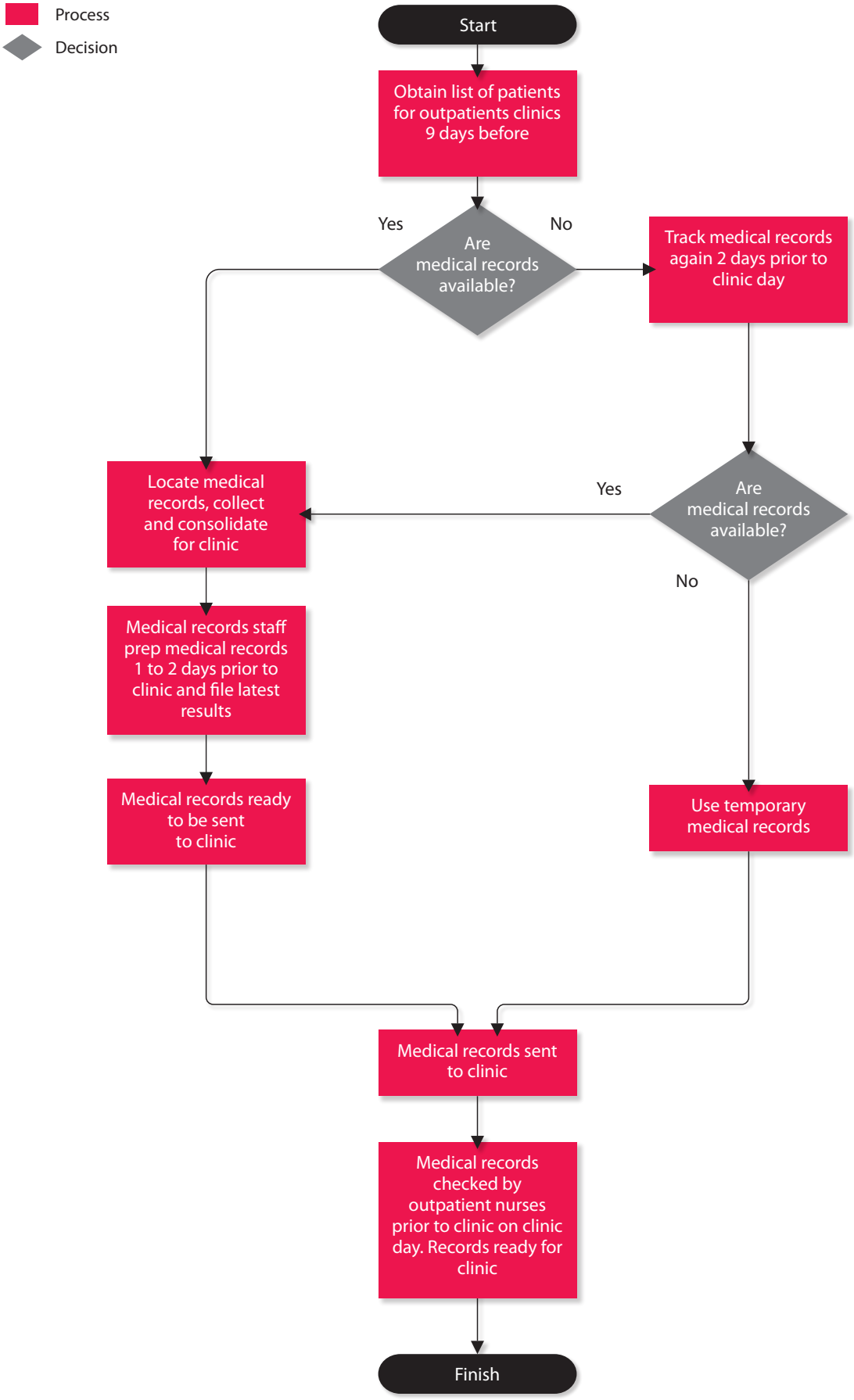


Figure 5: Process map showing preparation of medical records for outpatient clinics, organisation G



Interviews were held between September and November 2009 and lasted between 20 and 30 minutes. All interviewees consented, for their interviews to be recorded and transcribed verbatim.

We performed qualitative analysis of content with the aid of NVIVO (version 8) qualitative analysis software. Thematic analysis was undertaken using the accident causation model.

Associated sub-themes were then drawn from these data. Comparison and refinement was carried out between two researchers.

4.4 Results

Process maps

The process maps for the preparation of medical records for clinics in each of the three sites are shown in Figure 3, Figure 4 and Figure 5.

In each organisation, the process of finding medical records for each clinic began two weeks before the clinic date.

The first part of the process was undertaken by staff in the medical records departments and involved retrieving the records from the library, and, if not available, finding them through the tracking systems in use in each organisation.

A second tracking was undertaken around one week before the clinic to find the records for newly booked appointments, last minute changes and any that had not been found in the first search.

While each organisation had a system in place to track the location of medical records, this was not always followed.

As a result, medical records staff had to spend time visiting the various locations where medical records might be kept and phoning secretaries, doctors and staff in other departments such as clinical audit to search for the missing records.

The process for requesting investigations differed between organisations. In organisation A, most of the requests for investigations were done electronically, with hand written requests used as a backup.

In organisation E, all requests were hand written and sent to the relevant departments for the investigations to be performed.

In organisation G, some were hand written but most were done electronically; this depended on factors such as the type of test, and whether or not the doctor had a computer terminal available.

A new computer system was being introduced at the time of the study and so paper and electronic systems were being run in parallel

At organisation A, most of the investigations were reported electronically. About 24 to 48 hours prior to each clinic, the outpatient nurses prepared or 'prepped' the records, looking at the referral or last clinic letter. Any results required were printed out and filed in the medical records.

The doctors in clinic could therefore review the results either on the computer or in the paper health records. In organisations E and G most of the results were reported electronically.

Hard copies of the results were sent to the relevant consultant's secretary, who filed them (if the medical records were available).

Health records were prepared between six days and one day prior to clinic by coordinators based in the outpatient clinic. Results were printed and filed in the medical records (if not already done by the secretary). As in organisation A, the doctors could review the results either on the computer or in the paper records.

The prevalence of missing information in surgical outpatient clinics

From the total sample of 1,161 patients across three organisations, 175 (15%) had missing information reported by their doctors during the surgical outpatient appointment. This corresponds to a reliability of 85%.

For 122 of these patients the doctor also recorded the type of information that was missing. For the remaining 53 patients, the type of missing information was not recorded, 47 of whom were in organisation E. As a result of this difference the results will be presented, where relevant, both including and excluding these 53 patients. Where the data for organisation E are of interest but conclusions cannot be drawn, this will be noted.

Table 6: Number of patients with missing information in each organisation

Organisation	Total number of patients in the sample	Number of patients with missing information (percentage of all patients in sample)	Number with type of missing information recorded (percentage of those with missing information)
A	**411**	**18 (4%)**	**17 (94%)**
E	**423**	**113 (27%)**	**66 (58%)**
G	**327**	**44 (13%)**	**39 (88%)**
Total	**1161**	**175 (15%)**	**122 (70%)**

Table 7: Availability of entire medical record in each organisation

Organisation	Records unavailable	Percentage unavailable for whole sample
A	1	0.2%
E	3	0.7%
G	14	4.3%
Total	18	1.5%

Figure 6: Frequency of missing information by type, across all organisations

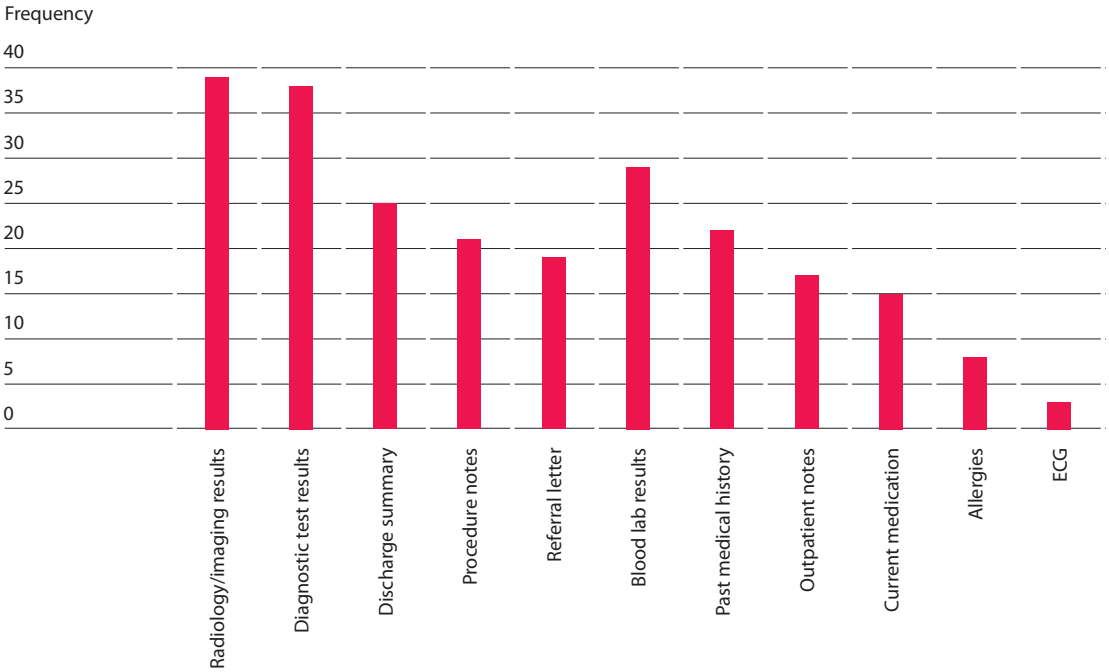


Table 6 shows the number of patients with missing information for the total sample and where the type of missing information was also recorded.

A chi-squared test with a null hypothesis that there is the same proportion of missing data across all organisations, enables us to reject this hypothesis for both the number of patients with missing information (n=175) and the number of patients where the missing information was recorded (n=122). There is a highly significant difference between the organisations (p=0.000) for both sets of data.

A pair-wise comparison of differences in proportions between organisations establishes that the proportion of missing records in organisation A was statistically different from those found in both E and G (p<0.000 in both cases), with less information missing in organisation A than in the other two organisations. TABLE 7

Table 7 displays the availability of the entire medical record for patients in each organisation. The entire medical record was available for 98.5% of patients in the sample.

Conducting a chi-squared test, we can conclude (p=0.000) that the organisations are different in the proportions of missing medical records (in every use of the chi-squared test for this topic the expected values were at least 5). A pair-wise comparison of differences in proportions establishes that the proportion of cases in organisation G was statistically different from that found in both A and E (p<0.001 in both cases), where organisation G had a higher incidence of the entire medical record being missing. Organisations A and E were not significantly different from each other (p=0.330).

Type of missing information

Where information was missing and recorded, the average number of items missing per patient was 1.8 in organisation A; 1.7 in organisation E; and 2.4 in organisation G. The frequency of the information that was missing is set out in Figure 6.

This information is presented by organisation in Figure 7: Frequency of missing information by type, in each organisation.

Figure 7 presents the data from Figure 6 separated for each organisation. Figure 8 presents these data as a proportion of the total sample in each organisation. Figure 9 presents the data as a proportion of the number of patients in each organisation with missing information.

In organisation E a further 47 patients (not included in these figures) had missing information noted, but the type of missing information was not recorded.

From our results, and these tables, it can be seen that in organisation A when information was missing it was most likely to be radiology/imaging and diagnostic test results. Organisation E similarly had these items missing most often with the addition of blood laboratory results. In organisation G written communication was more frequently missing (discharge summary, procedure notes, referral letter and outpatient notes). Organisation A had information missing less frequently than in organisations E and G.

Figure 10 summarises the number of items of missing information per patient for the 122 patients where the type of missing information was recorded. The majority (68) had only one piece of information missing, but three had seven items missing and one had ten items missing.

Impact on patient care

The doctors perceived there to have been an impact on patient care - such as delays in patient management, cancellation of operation etc - in 55 patients (4.7% of the whole sample, or 32% of those patients with missing information). This is summarised in Table 8 (page 33).

The three cases where the impact on patient care was deemed to be severe had the following specific items of information missing: diagnostic test results (n=1); both radiology/imaging results and diagnostic test results (n=1); and procedure notes (n=1).

Figure 7: Frequency of missing information by type, in each organisation

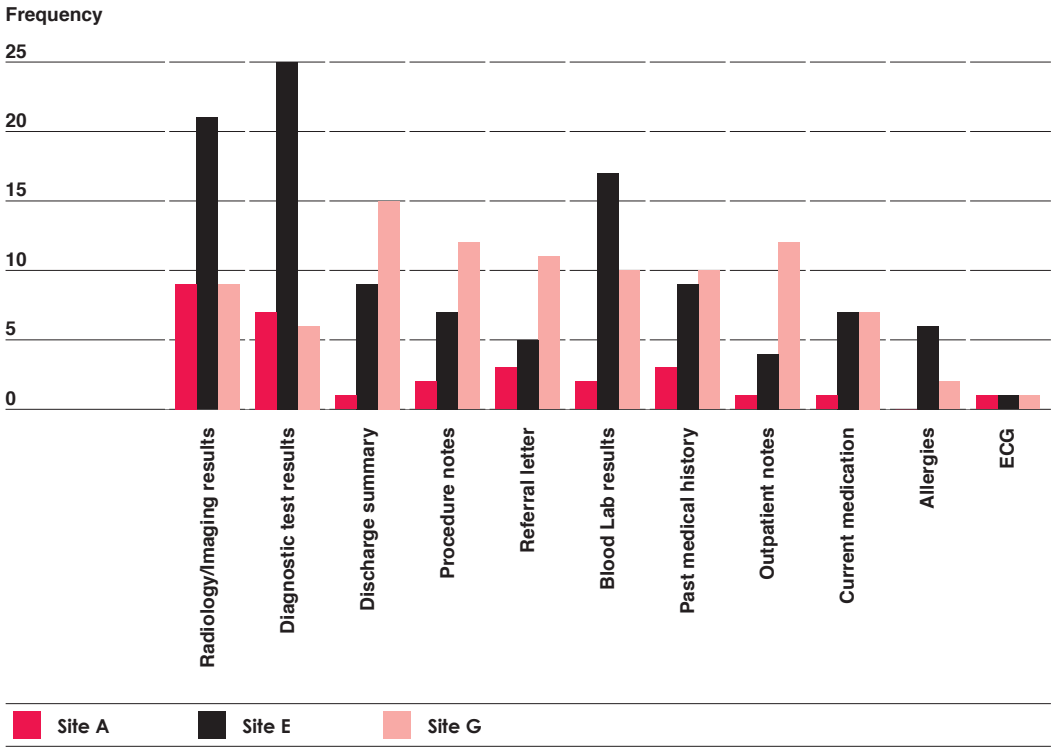


Figure 8: Frequency of missing information by type as a proportion of all attendances in each organisation (A=411, E=423, G=327)

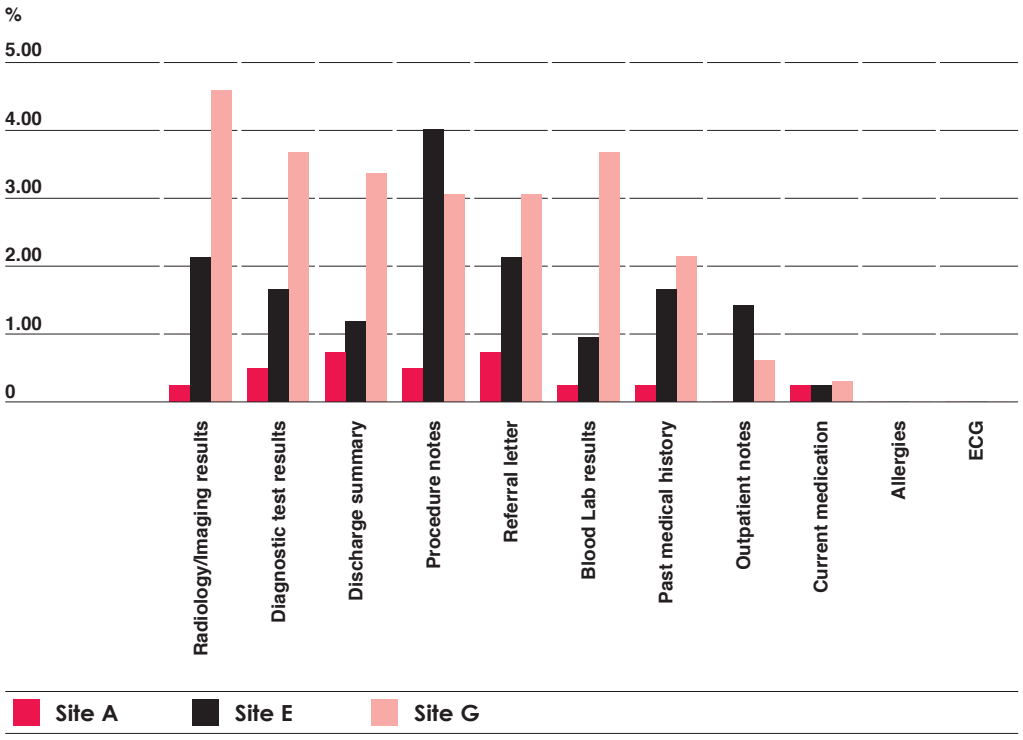


Figure 9: Frequency of missing information by type as a proportion of those patients with missing information in each organisation (A=17, E=66, G=39)

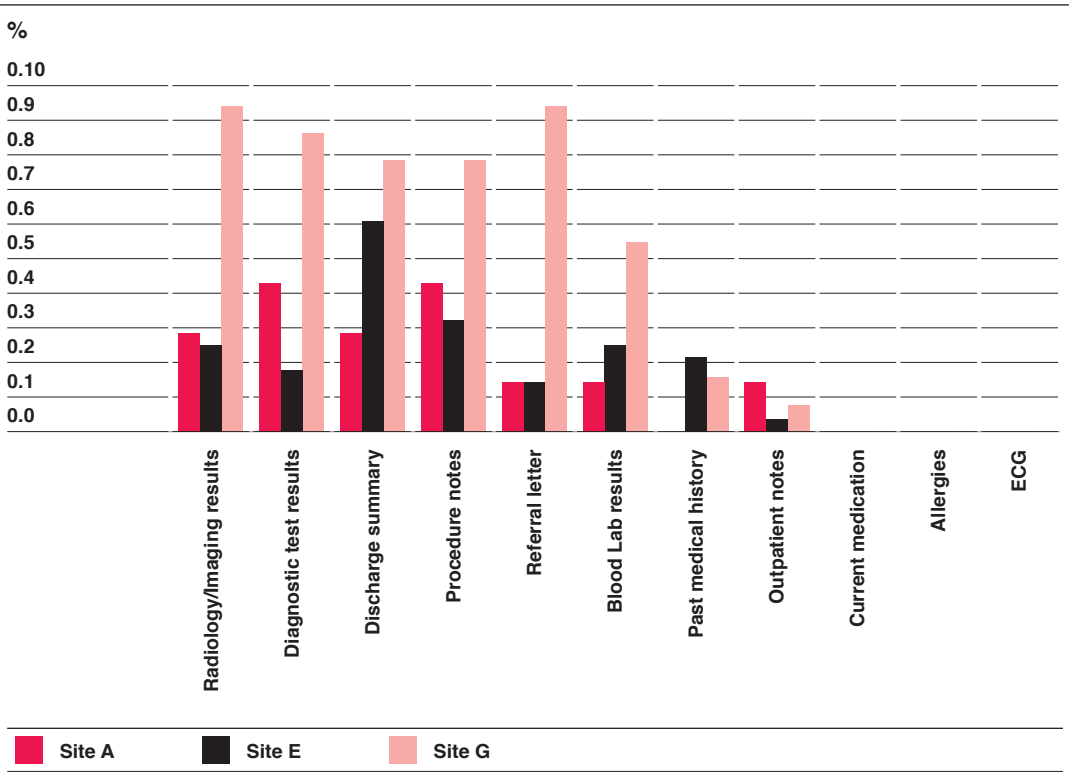


Figure 10: Number of items of missing information per patient

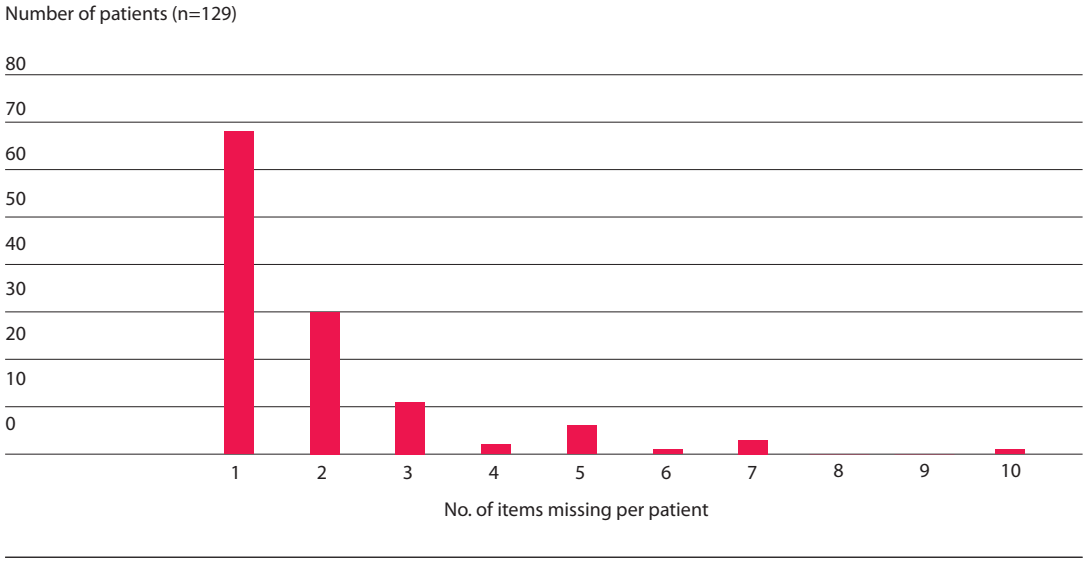


Table 8: Perceived impact on patient care of missing clinical information

Perceived impact on patient care of missing information	Number	Percentage (%) of patients with missing information (n=175)	Percentage (%) of total sample (n=1161)
None	104	59%	
Minor	34	20%	3%
Moderate	18	10%	1.5%
Severe	3	2%	0.2%
Not recorded	16	9%	
Total	175	100%	

Table 9: Risk of harm associated with missing clinical information

Risk of harm associated with missing information	Number of patients	Percentage (%) of patients with missing information	Percentage (%) of total sample (n=1161)
No threat	54	31%	
Minor threat	22	13%	2%
Moderate threat	12	7%	1%
Potential adverse event	0	0	
Potential serious adverse event	1	0.5%	
Not recorded	86	49%	
Total	175	100%	

Extra clinic appointment needed

Twenty patients were given a second appointment because of missing information (1.7% of all patients in the sample). Of these 11 were in organisation A; 7 in organisation E; and 2 in organisation G. The most common types of missing information for these patients were radiology/imaging and diagnostic test results, followed by the referral letter.

Risk of harm

When information was missing, the doctors were asked to rate their perception of the risk of harm to the patient. In 35 patients (3% of the whole sample, and 20.5% of those with missing information), doctors perceived there to be a risk of harm from the missing information ranging from a minor threat to the risk of a serious adverse event (Table 9). The risk of a serious adverse event was recorded for a patient whose diagnostic test results were missing.

Reliance on patients for missing information

Where information was missing, we asked the doctors whether or not they relied on patients for this information. When information was missing, the doctors relied on their patients for help on more than half of all occasions (58%).

Table 10: Reliance on the patient when clinical information is missing

Organisation	Reliance on patient where clinical information was missing	Percentage (%) of patients with missing information (n=175)	Percentage (%) of total sample in each organisation (n=1161)
A	12	67%	3%
E	58	51%	14%
G	32	72%	10%
Total	102	58%	9%

Table 11: Making clinical decisions without key Information

Organisation	**Made a clinical decision where clinical information was missing**	**Percentage (%) of patients with missing information (n=175)**	**Percentage (%) of total sample in each organisation (n=1161)**
A	6	33.3%	1.5%
E	13	11.5%	3.0%
G	18	41.0%	5.5%
Total	37	21.1%	3.2%

Table 12: Participants roles in each organisation

	Profession		
Participant	**Organisation A**	**Organisation E**	**Organisation G**
1	Medical Secretary	Radiology Administration Manager	Radiologist
2	Outpatient Sister	Surgeon	Surgeon
3	Medical Records Manager	Outpatient Sister	Health Records supervisor
4	Radiology Secretary	Pathology Manager	Medical Secretary
5	Surgeon	Medical Records	Outpatient Staff Nurse

Table 10 sets out the number of times doctors relied on their patients to provide missing information.

Conducting a chi-squared test we can conclude (p=0.255) that there were no significant differences between organisations in the proportion of cases where doctors relied on patients to provide missing information.

Making a clinical decision when information is missing

Doctors were asked if they had to make a clinical decision without key information and in 37 cases (21% of those with missing information) the answer was yes (Table 11).

When a doctor made a clinical decision without key information, the most common types of information missing were diagnostic test results and blood laboratory results, with ECGs being the least common.

4.5 Results from system failures analysis

Fifteen people were interviewed, five from each of the three organisations including surgeons, radiologists, administrators and nursing staff, as set out in Table 12. The two surgeons interviewed at organisations E and G had previously assisted with data collection.

The problems associated with missing information relate both to making clinical decisions, and to the effect it can have in the confidence and trust the patient has in the surgeon. This was described by one participant:

'The difficulty is if you see the person without the letter ... the patient's perception of why they're in the clinic may be different to the reasons that the GP stated or there may be pertinent facts which... the patient doesn't describe ... if you see somebody without the episode that pertains to their recent admission, when they're coming back to clinic having been in for the emergency, you're relying on your memory which is obviously not reliable, or you have to ask the patient and that is a very awkward thing to do when you have a patient in front of you who clearly knows you and remembers you but if you have to ask them details of their care they lose a lot of trust in you because you can't remember. Now if I have 150 admissions in a week I can't remember them all but that individual patient is left feeling quite insecure.'

Causes of unreliability

From the analysis, the causes of unreliability could be grouped into those pertaining to paper based systems, issues with computer systems, and the problems of running both paper based and computer systems in parallel. The causes that were common to all three organisations were:

- The difficulties of aligning a patient's complex pathway to ensure all tests are completed and reported before the patient returns for a follow-up outpatient appointment.
- Patients having multiple hospital numbers arising from hospital mergers (each hospital having had its own numbering system prior to the merger).
- Problems associated with running parallel computer and paper based systems, which means staff do not know where to find relevant information.
- Short notice bookings and changes to appointments – making it difficult to find medical records in time and assemble the required information.
- Temporary staff (including locum doctors, nurses and administrative staff) being unfamiliar with the systems.
- Medical records tracking systems not being used or not being used properly in the organisation.
- Records being misfiled or not filed at all.

The following sections describe in more detail the causes of missing clinical information in surgical outpatients appointments, grouped into the accident causation model factors. Where relevant these are subdivided into the findings as they relate to paper based systems, computer systems and running both in parallel.

Organisation and management factors

In all organisations the difficulties of aligning a patient's complex pathway were cited as a particular problem, ensuring that all tests are all completed and reported before patient returns for their follow up appointment:

'Where the patient needs either a biopsy, maybe they need some form of staging scan, may need something else ... you want everything lined up in the right order, and organisationally, that can be logistically very difficult.' Participant 2, organisation E

'Because of the time, it might be, they may have been sent for something that will take longer than their next clinic appointment.' Participant 3, organisation E

Hospital mergers have brought a number of organisational problems to medical records including patients having multiple hospital numbers. Also, patients can have appointments in two different hospitals in the same organisation on the same day, bringing logistical problems in the transfer of the medical records for the appointments.

'It comes full circle back to our staff who are pulling the clinics. Quite often they then have two or three different numbers that they need to look through as well as having two or three different places, whether it's still in the pre file or the file, they might then have the six, number that begins with a six to look at but then if it had been merged into one of the other hospital sites you've got to check that number as well because it could be changed into that one.' Participant 3, organisation G

The lack of accountability or ownership of the medical record was noted as a problem by two organisations, who noted that sometimes no one staff member takes particular care of a patient's records, throughout the process of tracking, filing, storing in offices etc. One example given was of inpatients who are allocated beds on a ward in another specialty (outliers); in a case like this it was felt that the patient's records are not stored carefully and they are given lower priority, and as a result their records go missing more often.

'Some of the doctors do tend to put them [the medical records] in places that we are unaware. But I don't think they do that intentionally. I think they pick them up, off they go, do their thing and they just leave them and walk out, unaware that other people could be looking for their notes.' Participant 5, organisation E

'Who's accountable for looking after the notes upstairs?' Participant 5, organisation G

'If a surgical patient is boarding in a vascular ward or a medical ward, it's [the attitude amongst staff] very much, well, it's not one of our patients, it's not our problem.' Participant 4, organisation G

The ongoing problems with missing information have led to staff lacking confidence in hospital systems and accepting this as normal, so for particularly important cases the doctors kept records locked in drawers or found workarounds rather than using the internal post. Keeping records locked away was reported as a particular problem when patients were admitted as an emergency outside normal working hours.

'And medical records has found quite a lot of notes in the drawers in the doctors' offices. They're not keeping back for the sake of keeping it, they need it because if the patients needs to be discussed at the MDT.' Participant 2, organisation A

Work/Environment factors

Design, availability and maintenance of systems and equipment

Paper systems

Problems with paper systems were wide ranging, including poor storage facilities in offices and clinics meaning medical records were stored on the floor, to problems with tracking medical records, and knowing where the medical records are in the organisation. Poorly fixed folders were cited by two organisations as a problem, with descriptions of thicker folders ('fat folders') for sick patients often falling apart.

'Our case notes lie on the floor, we just do not have enough room to keep our case notes.' Participant 4 organisation G

'What we call 'fat folders'...they're obviously used a lot of the time because the patient is ill. So they become broken ... ripped...' Participant 5, organisation E

The design of the systems to transfer paper records included insufficient fax machines and problems with the multiplicity of forms to fill in which are different for each test or investigation.

'The difficulty with faxes is that often they're relatively inaccessible, so if you're in a clinic and somebody has to fax something through then the clinic staff have to go all the way back along to another clinic to be able to actually get the paper copy..' Participant 2, organisation G

Computer systems

The problems with computer systems included the design of the software, the age and availability of terminals, problems with passwords and logins with multiple systems and universal access to the information.

Poorly designed software led to staff not being able to find out if tests had been requested and not being alerted when results are available. Old technology means that some surgeons cannot view electronic images from scans and X-rays during an appointment because they take too long to load. Some clinics do not have enough terminals for the doctors to access information during the clinic.

'The paper requests should be filed in the notes, if they're not then there's the computers. Computers aren't in every room ... we have a computer in the nurses' station, which is quite a busy area [and so it can be difficult to access results]' Participant 3, organisation E

Passwords and logins to multiple systems were highlighted as a problem in accessing information that staff knew was available – both in terms of the time to login and also forgetting or not being allocated passwords:

'Some of the doctors forget their password or they haven't got a password so they can't always access the system... the x-ray system it's a different password.' Participant 3, organisation E

'The problem with the computer data is it is, it seems to be stored in different systems in different programmes so there's not a unified or united software that brings all the things together. So this does not really help, it makes things even more complicated.' Participant 5, organisation A

In organisation E, there was universal access to the records on the computer system so sensitive results were not entered and showed a nil return, with obvious implications:

'Because it's globally available, we can't put sensitive results on there, because there's no way of controlling access ... You can get them on the clinical portal because when it was designed it had a break glass function built into it, such that you can break that and you can access that particular result. So again, if a result is considered to be sensitive, if somebody tries to view that ... on [the hospital's main computer system], they won't find it. Now whether they know that it's not there or whether they think it should be there and don't know ... it will give them a nil return, and they could conclude from that, the report hasn't come back. It is there, it's just that you can't access it on that particular system.' Participant 4, organisation E

Mixed computer and paper systems

Running both paper and computer systems in parallel was given as a problem in all three organisations, with staff not knowing where to look for information

'One thing is operating notes. Operating notes from previous operations are sometimes very important and I find it hard in this hospital sometimes to find these. And the problem is maybe I don't know where they are but I have the feeling they are handwritten notes' Participant 5, organisation A

Workload and shift patterns

The particular issue here is one of time – time for doctors to review a patient's medical records before a clinic, time during the appointment to log in and review results, time to look for information before the clinic starts. Reviewing the medical records before clinic is often allocated to junior staff who may be inexperienced, not knowing from reading the medical records what tests have been ordered.

'Half the time we don't see the notes at all until the patient arrives at clinic. We don't do anything with the notes, they're all dealt with by the clerical staff

prior to the patient arriving at clinic.' Participant 5 organisation G

The design of work systems in two organisations meant that the patient's medical records may still be on the porter's trolley when the patient arrives for their appointment.

'Sometimes new patients will be arriving...but their case notes have not yet arrived. They've left medical records and they're out on a porter's trolley somewhere round the hospital and if you wait long enough they will arrive.' Participant 2, organisation G

Administrative and management systems

Paper systems

Across all organisations the problems of finding paper based medical records at short notice was described as a problem. The reasons for short notice bookings included urgent appointments, re-bookings and waiting list initiative clinics.

'It's all about the government waiting list times, trying to get the waiting list down, to get the times down you have to see more people obviously quicker, so the clinics that we pull are building up and it's just putting pressure on the folk that are here to pull extra notes without any extra help.' Participant 3, organisation G

The internal post combined with the time taken to type letters was described as a problem in organisation E:

'I think the letter is probably the slowest. Because you've obviously got a secretary waiting to type a letter etc and I think that they hold things up.' Participant 1, organisation E

Mixed computer and paper systems

Delays in returning test results on computer systems were given as a cause of missing information in organisation E, where clinical staff may dictate their reports for a secretary to type and enter on the computer system.

Staffing issues

In two organisations staff shortages have meant that work, such as pulling medical records, may not be completed in time for clinics. In one organisation a shortage of IT staff had led to only junior doctors being trained in how to use the computer system:

'But the doctors...there were not enough staff to train them all to be up to speed in terms of requesting electronic requests from the outpatient department...the junior doctors on the wards ... have been taught how to do it ... but as the older doctors in the hospital are not as au fait with electronic ...they have tended to stick to the old fashioned paper format.' Participant 1, organisation G

In all three organisations problems were experienced with temporary staff or staff covering shifts and being unfamiliar with the local systems. This led to problems with them being unable to find information when required, not having access to certain computer systems, or filling in forms wrongly:

'It could be somebody is asked to sit in at the last minute and wouldn't necessarily know the routine of a clinic or what results were needed.' Participant 3, organisation E

'And [if] it's an inexperienced coordinator on it then possibly something will get missed.' Participant 5, organisation E

Tests can be delayed and results not accessed due to doctors being on call or new into post or locums being unfamiliar with the systems:

'The other week I was working in emergency radiology and a doctor brought some inpatient request down and there was no consultant at the top. So I said, well who's the consultant looking after the patient? I don't know, I'm just on call...and I said, well I'm sorry but I can't process the form without a consultant' Participant 1, organisation E

'And with new doctors that come in they don't always get a password so you're looking on there.' Participant 3, organisation E

Team factors

Communication and team stability were the main factors here. Communication related in particular to doctors being clear about why a patient is coming to the clinic and informing the team about the test

results that should be available:

'Medically we need to be more explicit, say this person's coming for a biopsy result therefore we need to make sure the biopsy result is available.' Participant 2, organisation G

'Sometimes if you read the last doctor's letter it's not always clear what's been requested…' Participant 3, organisation E

'If they don't state in their last clinic letter that, oh I've sent this patient off for whatever, then we really wouldn't have any idea.' Participant 5, organisation E

Poor communication of changes to procedures for ordering tests in one organisation created delays in the test being done and hence delays in the results being available:

'Our big problem at the moment is that they've changed the rules for bowel preparation for barium enema and you have to ... sign another form to say the patient's fit...but they haven't redesigned the form yet because there's going to be a box to tick, so at the moment we're sending them off, we keep forgetting and then we get ... a fax back.' Participant 2, organisation E

Poor writing also created delays in tests being conducted, particularly poor form filling:

'On a daily basis we are contacting GP surgeries and saying, can you fax a form through, no one completed this or, you know, we send quite a few back. The writing is very poor, often you can't read the writing.' Participant 1, organisation E

'It's very much dependent on who fills the form in, and one of the privileges of being a consultant is, an awful lot is done on your behalf, so they write your name at the top and then fill in inadequately. Either they haven't given sufficient information such that the radiologist doesn't feel that the bar is high enough for them to justify an x-ray or whatever it is, or it's illegible or it was the wrong investigation.' Participant 2, organisation E

Finally, team stability was seen as necessary in getting to know what tests a doctor might order so that clinic staff automatically know what to look for:

'A lot of our coordinators only work...for the same consultants all the time so I think they tend to know what happens with their patients. They know if they go for bloods regular, and things like that, so they might just automatically look.' Participant 5, organisation E

Individual staff factors

The individual staff factors mainly related to human error with wrong numbers entered for fax machines, wrong patient numbers entered when booking appointments, tests sent to the wrong department, placed in the wrong envelope or entered on the computer system wrongly and reported in the wrong place so the doctor cannot find the result.

Paper systems

Items being misfiled was described as a problem in all three organisations:

'There's an element of what we call a misfile. They've gone into the library but they've been filed wrong.' Participant 5, organisation E

'I don't doubt that we make mistakes handling the amount of paper that we do. We may well misfile something into an envelope for outpatients. We may end up slipping in something for A&E or something, by mistake.' Participant 4, organisation E

Computer systems

Entering the wrong numbers or not looking in the right place for the results can cause information to go missing or not be available when needed:

'In terms of electronic reporting there really is only two reasons that it wouldn't get back to them. And that is, a) if they didn't even bother to look for it electronically, and second is, if the location at the point of entry was wrong. So if it was sent up to us and it was wrong, or if we entered it wrong, it will go into electronic space, but the wrong electronic space.' Participant 4, organisation E

The GP entering the wrong patient number when booking an appointment for a patient can be a cause of that patient's records not being available in outpatients:

'Because with the Choose and Book system, if you don't get it exactly right [it] will reregister the patient. So we put in place ways to monitor that, but some get through. So, you could go to a clinic with a Choose and Book number and the clinician will then, ... say, but we know you and we will then have to find the old notes.' Participant 3 organisation A

In one organisation attitude was cited as a factor that meant that the medical records tracking system was not used properly:

'I've genuinely had someone say to me on the phone that tracking's beneath me, that's what they said to me on the phone, and we're thinking, it was beneath you? You're not high and mighty, you're not excused from doing the same, and again it comes down to patient care because we phone a certain secretary for a set of notes, this one in particular that I spoke to, she then didn't send, or she did send the notes sorry but didn't track them and she'd sent it somewhere else and I'm phoning her to get the notes back and she started moaning at me and saying, why are you phoning me, I don't have them and stuff, but well because they're tracked to you.' Participant 3 organisation G

Task Factors

Task factors related to protocols and systems being inadequate or not used appropriately - for example, doctors not following protocol for requesting X-rays for their patients. In one organisation some doctors physically hand the radiologist a request card rather than using the formal system. Having different systems running in parallel for requesting tests was also a cause of missing information.

'The requesting side I think is that, I think everybody should use the same method. I think that when you've got consultants writing letters to maybe specific radiologists, ...I think that can cause a problem. I think there should be just one route in. And then that could come in to a central place and then be distributed to the people who need to check the forms.' Participant 1 organisation E

Medical records tracking systems were often described as not being used properly, sometimes deliberately and sometimes through lack of knowledge:

'Where they've gone? Sometimes the notes is not tracked. They take the notes and then they don't track them. Where do you expect us to find them?' Participant 2, organisation A

Patient characteristics

Three factors summarise the patient characteristics that create problems for hospitals in ensuring all information is available to a doctor in a clinic.

Patients who are being seen by many different specialties:

'There are some patients they go to about ten different clinics, so you could imagine this ...' Participant 2, organisation A

'The only time that possibly we couldn't get the notes is if the patient's got an appointment in another hospital ... on the same morning. So it's getting the notes from one site to another ...' Participant 5, organisation E

Patients cancelling the tests that have been ordered:

'Or patients are phoning and cancelling investigations, so when you're looking for results for the consultant we've not actually had the investigations and the department is not telling you that, as the requestor, that it's been cancelled.' Participant 4, organisation G

Patients re-booking appointments to suit their personal circumstances with problems for medical records in finding medical records at short notice:

'Because there are so many short term appointments and that is a problem ... somebody phones up and somebody's just cancelled an appointment, they could make the appointment the day before, and that's where you get the biggest level of information that would be missing, because it's such last minute.' Participant 3, organisation A

Recommendations for improving reliability

With the complexity of the issues causing information to be missing in outpatients, it was not surprising to hear some interviewees saying they could think of no solutions because the problems were too big:

Question: Do you want to add anything, any solutions ...?

'I can't really, no, I really don't know. I think because, sometimes I think it's so big. ' Participant 3, organisation E

Medical records staff proposed solutions such as working night shifts to avoid interruptions when searching for records, together with more training for secretaries and doctors to resolve the problems of medical records tracking not being used, and misfiling:

'Most of it is training, it's training and monitoring, and the more we monitor the more we train, and the more there is, people take responsibility of, Health Records is like the nucleus, we can get the majority right' Participant 3, organisation A

Many of the solutions proposed, such as re-designing forms, having one computer system and one hospital number, or more space to store paper records, or extending the air tube system addressed specific problems in each organisation. Whilst these solutions may address very local problems, the complexity of how each inter-relates and affects other parts of the system is more difficult to envisage. For example many of the computer systems have been installed to improve the reliability of information being available but each has brought other problems such as the need for multiple passwords or too much time required to log in to every department's system to get results, or wrong information being entered. Interviewees said that one solution would be to reduce paper and electronic systems running in parallel:

'In terms of the referrals ... if I was an autocratic dictator I would from right now issue a statement saying that we will accept nothing but electronic referrals.' Participant 1, organisation G

'We should be having GPs emailing in referrals so that, a), it gets to wherever it's going far faster, and b), it has to be typed, because believe it or not, 2009, we still have terrible handwritten referrals, and it's quicker. And then if it's electronic it's less likely to be lost.' Participant 2, organisation E

Using the patient's NHS number as standard across all NHS organisations was supported as a way of reducing problems with patients with common names or who have appointments with different doctors in different hospitals within the same organisation.

'To have a single patient identifier for us would be absolutely marvellous, because when you have a very common name it's not unusual to have multiple files, even within our own database.' Participant 4, organisation E

No solutions were forthcoming about how to improve the systems in the patients' pathway to ensure that after one outpatient appointment all the necessary tests and procedures would be completed and reported before the patient's follow up appointment. This is the challenge for improving systems reliability.

Summary

The reasons that clinicians are faced with making clinical decisions in the absence of either the patient's medical records or key clinical information are many and varied from the complexity of aligning a patient's pathway to inadequate information in a GP letter to misfiling test results. It was apparent from the interviews that solutions introduced to solve one problem in one department had sometimes created new problems for others elsewhere. This could be as simple as introducing a new form for requesting a specific test in one department, meaning there were now multiple forms to be completed by doctors in outpatient clinics, or it could be the introduction of new computer systems in each department – pathology, radiology etc – meaning that staff in clinics have to log in to each different system to find results.

All those interviewed described problems that they dealt with regularly in trying to assemble the relevant information for doctors in outpatient clinics. There is clearly a wealth of knowledge in each organisation about how each part of the system operates and the associated difficulties.

In conclusion, our findings suggest there is no one magic bullet that will solve the problem of missing clinical information in the outpatient setting. What is needed is a process for gathering and considering

the knowledge of key staff, making sense of this for the system as a whole in each organisation and from this designing and implementing plans for an over-arching safer clinical system.

4.6 Discussion

Summary of results

In our study 1.5% of outpatients had their whole medical record missing, despite an enormous effort every day by medical records staff to find missing medical records. Organisation A with only 0.2% missing demonstrates that it is possible to have robust systems for tracking and finding medical records. However we found that across the three organisations, 10 times as many patients had some type of relevant clinical information missing (15% of all patients). The type of information missing varied, with one organisation having written information missing more often, and another having more test and investigation results missing. Of those patients with missing clinical information, 32% experienced a delay or disruption to their care, 20% had a risk of harm and in over half of these patients the doctor relied on the patient for the information. Doctors made a clinical decision anyway in 20% of cases with missing clinical information.

The causes of missing clinical information were many and varied, from simple misfiling of test results to the complexity of making sure a patient had all tests and investigations completed and reported before they returned for their follow up appointment. We found over 60 causes for clinical information being missing when needed in outpatients, covering all aspects of the accident causation model from work and environment factors to those relating to individual patient factors. There were no clear cut solutions but rather the need for each organisation to examine the systems failures at each point and with the knowledge and support of all those involved, design and implement an overarching solution to the system-wide issues.

Comparison with the literature

In studying primary care clinicians reports of missing information in the US Smith et al (1996) found that in one in seven visits (14%), some important piece of data including laboratory results, a radiology report, or a hospital history, was not available. In 60% of these visits clinicians reported that the lack of data was likely to result in either a delay in care or a duplicative medical service (32% in our study) and in 44% physicians believed the patient's well-being was likely to be affected (20% in our study).

Dovey et al (2002) in examining 344 reports of medical errors from family physicians, also in the USA, found that 7.8% were due to the unavailability of information that should have been in the patient's medical records. In this study the majority of error reports were administrative, with 44% of all error reports perceived by the physician to be associated with adverse consequences for the patient or family.

Elder and Hickner (2005) reporting on missing clinical information noted that 'an important part of primary care involves obtaining and explaining clinical information and assisting patient decision making. When information is missing, the ability to communicate with patients about their care is hampered'. Surgeons in our study repeated this, with one describing the feeling of the patients losing trust in their surgeon when information wasn't available.

The frequency and impact of missing imaging data in a Neurology Department of an Australian hospital was studied by Lederman et al (2002). In 24% of cases (10 of 42) they found that some or all of the required information was missing.

The health issues of repeating radiation exposure are noted in the paper and the fact that where it is not possible to delay decision making, there is a possibility of a higher margin for error on decisions taken.

In our study we found that for those patients with missing information, the doctor made a clinical decision in 20% of cases.

In a review of errors and unintended consequences of information technology, Ash et al (2004) note that 'some systems in use in medical work practices today have interfaces that are outdated, with no windows, no intuitive graphic navigation aids, and endless lines of identical-looking text. In such cases, even when the information is there, it could be exceedingly hard to find.' Ash also notes the

difficulty clinicians face in acquiring, maintaining and refining a mental overview of a patient's condition when having to switch between computer screens to gather information whilst also talking to the patient, some also having to read paper records at the same time.

Examples of types of record and filing system errors reported in the 'Threats to Australian Patient Safety' study (Makeham et al., 2008) included:

- Having some parts of a paper based patient record missing (eg. notes falling out of a record in the filing process).
- Having parts of a patient's records stored on both a computer and a paper file, leading to some clinical information missing in the history if only one or the other is used.
- Filing results or correspondence into the file of a different patient with a similar name.
- Spelling errors (particularly surnames) in patient electronic records causing difficulty in importing electronic investigation results into the patient file.
- Losing paper-based patient records in the general practitioners' practice filing system .
- Having multiple records for the same person with different details listed in each, such as two separate medication and allergy lists.
- We found all these factors and more as causes of missing clinical information in our study.

Interpretation

In 2008-09, there were 3.84 million attendances at surgical outpatients in England (The NHS Information Centre), 0.38 million in Scotland (ISD Scotland) and 0.19 million in Wales (2007/08 figures Stats Wales). This gives an approximate total annually of 4.4 million general surgical outpatient appointments in England, Scotland and Wales out of an overall total of 66 million outpatient appointments. Despite the limitations of this study, it is of interest to see how the findings may translate into the wider NHS and Table 13 has been produced on this basis for general interest:.

Strengths and limitations

As far as we are aware, this is the first study to present figures on missing clinical information in outpatient clinics in the UK and the first to look at how clinicians respond, including the associated impact on patient care.

Our data relied on collection by busy doctors in outpatient clinics and may therefore be subject to under-reporting. There were different computer and written record systems in each organisation which we recognise may mean that the forms were not completed in exactly the same way in each organisation.

Table 13: Implications of research findings if applied to outpatients across the NHS

	Estimated annual numbers of patients if study findings are applied to:	
Percentages found in this study	**General surgery outpatients (n=4.4 million)**	**All outpatient attendances (n=66 million)**
1.5% missing medical records	66,300	991,300
15% missing clinical information	663,000	9,913,000
4.7% impact on patient care	207,700	3,106,000
1.7% new appointment booked	75,150	1,124,000
3.2% decision without information	141,500	2,115,000
3% risk of harm	132,600	1,983,000

We relied on doctors to assess their perceptions of risk to patients and the impact of missing information on the patient's care using a simple scoring system and did not give detailed definitions. This type of perception scoring is useful in gaining an assessment of the issue in question but perceptions of similar risks are likely to vary between clinicians and the results should be seen in this light.

Where doctors relied on patients for information, we did not explore the types of missing information concerned. We recognise that patients are more likely to know some information than others, for example they may be more knowledgeable about their allergies than their test results.

The organisations selected were all large teaching hospitals and more research is needed to confirm whether the size of the hospital affects the availability of clinical information in outpatient clinics.

4.7 Recommendations

Whilst the percentage of missing medical records was relatively low in the organisations we studied, we found 10 times more patients being seen in outpatient clinics with one or more pieces of important clinical information being missing. The NHS currently monitors the percentage of missing medical records but to date has not collected information about what is missing from these records.

Each time important clinical information is missing our findings suggest that there is opportunity for the patient's care to be delayed, for disruption to them and their families and also for patient harm. This is clearly an important issue both for patient satisfaction and for patient safety that to date has not been measured across the NHS. We therefore recommend that a method for auditing the prevalence of missing clinical information is developed across the NHS and is measured systematically and regularly to monitor improvements over time alongside that for missing medical records.

It might be argued that measuring the percentage of missing medical records has confined the problem to the medical records department. However we found that the causes of missing clinical information were many and varied and were systems wide and different in each organisation, depending on their systems and their organisational history. We therefore recommend that the causes of missing clinical information are investigated by NHS organisations and systems wide solutions are designed and implemented.

Finally we would emphasise that the problem of missing information may not be quite as intractable as it sometimes seems and that current systems and processes could probably be dramatically improved even in the absence of electronic systems. The most striking finding from our study was that while all three organisations had problems, they were not the same problems.

In each hospital, some systems worked well and others poorly. This suggests that it is possible for all the existing systems to run more effectively if missing information was given higher priority and if sufficient effort was given to applying the standard armament of process improvement tools to the problem. We recommend that those with systems wide management responsibilities receive training in systems theory and practice. This recommendation also arises from the findings in the interviews that local solutions in one department often cause new problems in other departments.

If these latent conditions are to be prevented in future then those with systems wide responsibilities need to be knowledgeable in systems theory. Improving the reliability of clinical records systems would make care safer for patients, less frustrating for clinicians, reduce delay and duplication and save a great deal of money by avoiding extra appointments.

Our recommendations can be summarised as follows:

- The causes of missing clinical information are investigated in every NHS organisation with systems wide solutions designed.
- A common method of auditing the prevalence of missing clinical information in outpatient clinics is developed for the NHS.
- The prevalence of missing clinical information in outpatient clinics is measured systematically in every NHS organisation and repeated at regular intervals in order to track progress of

improvement.

- All members of the extended multidisciplinary team, including administrative staff, should be involved in planning and implementing changes to the process of delivering information at the point of clinical decision making, such as changes to the forms for ordering tests or a new IT system.
- Managers and others with systems wide responsibilities are trained in systems theory in order to consider the wider implications of local solutions, preventing the build up of latent conditions elsewhere in the organisation.

4.8 Conclusion

Clinicians in our study were faced with making clinical decisions without key clinical information in 15% of cases in outpatient clinics. The type of information missing varied, with one organisation having written information missing more often and another having more test and investigation results missing. Of those patients with missing clinical information, 32% experienced a delay or disruption to their care, 20% had a risk of harm and in over half of these cases, the doctor relied on the patient for the information. Doctors made a clinical decision despite the information being missing in 20% of patients.

On the basis of our findings we have made recommendations for the prevalence of missing clinical information to be measured investigated across the NHS and for systems wide solutions to be implemented. Finally we have recommended that all those with systems wide responsibilities be trained in systems theory in order to prevent the build up of latent conditions with the introduction of local solutions to the problems identified.

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Chapter 5

Reliability of prescribing for hospital inpatients

by Bryony Dean Franklin

5.1 Introduction

Prescribing errors are common and have potential for serious patient harm. Errors have been reported in 1.5-9.2% of medication orders written for hospital inpatients in the UK (Vincent et al, 2009); this wide range of figures is mainly due to differences in setting, definitions and data collection methods used. A median error rate of 7% was reported in a recent international systematic review of prescribing errors in hand-written medication orders for hospital inpatients (Lewis et al, 2009).

About 1-2% of UK hospital inpatients are harmed due to medication errors, the majority of which are errors in prescribing (Barber et al, 1998; Neale et al, 2001). This equates to 80,000-160,000 patients per year. Even prescribing errors that do not result in harm create additional work for staff and can adversely affect patients' confidence in their care.

The wide variation in methods and definitions used means that it is virtually impossible to compare results obtained between different studies (Franklin et al, 2005; Franklin et al, 2009a; Franklin et al, 2009b; Ferner, 2009). Although a large multi-centre study of inpatient prescribing errors was recently published in the UK (Dornan et al, 2009), this does not present comparative results between organisations.

The only comparative UK study across more than one organisation was conducted in a paediatric setting (Ghaleb et al, 2009). We therefore have little insight as to whether prescribing error rates are relatively consistent, or whether there are differences between organisations as a result of differences in local systems. Identifying differences between organisations would help us understand best practice and make recommendations for error prevention.

Prescribing errors in hospital inpatients was the topic selected by organisation B for investigation as part of the SCS project with an initial aim of improving the reliability of prescribing, later amended to an aim of creating a demonstrably safe medication system.

We therefore wanted to collect data at organisation B plus two additional NHS organisations, using standard methods and definitions, to explore the differences and similarities between them.

5.2 Objectives

- To measure the incidence of prescribing errors identified by ward pharmacists, for newly written inpatient and discharge medication, in at least two wards in each of three NHS organisations.
- To describe the types of prescribing errors identified and their potential clinical importance.
- To identify any variation in the prescribing errors identified between wards, specialties and organisations.
- To explore the causes of errors and the systems factors involved.
- To make recommendations for improving the reliability of prescribing in hospital inpatients.

5.3 Methods

Methodological considerations

There are several methodological issues that are important in quantitative studies of prescribing errors (Lewis et al, 2009; Franklin et al, 2005; Franklin et al, 2009a; Franklin et al, 2009b; Ferner, 2009). These include whether to focus on process (number of errors) or outcome (patient harm), the definition of error to use, the method of data collection, which types of prescriptions/medication orders to study, and the denominator used to calculate the error rate. We also needed to choose the wards on which to base our study. Each of these considerations will be briefly addressed before we describe the specific methods used for data collection in this study.

Process versus outcome

We chose to focus on the number of prescribing errors (defined later), rather than patient harm. Whilst patient harm is the more important outcome, it is relatively rare and with the short timescale available it was not considered practical for the present study. Furthermore, harm is difficult to measure objectively. This means that studies based on harm can be prohibitively expensive. Collecting data on all prescribing errors, regardless of their outcome, also provides many more opportunities for learning. However we did explore potential for harm by documenting the number of doses given before errors were corrected, and by assessing the potential clinical importance of a sample of the errors identified.

Definitions

The research literature on prescribing errors uses a wide range of definitions. We used a comprehensive practitioner-led definition previously developed using consensus methods (Dean et al, 2000), which has been used extensively by other researchers (Lewis et al, 2009; Ross et al, 2009) and by the Department of Health (2004). It is important to note that prescribing errors are not synonymous with pharmacists' interventions (Donyai et al, 2007). However, we also recorded the proportion of errors that resulted in pharmacists' interventions, and thus had workload implications for pharmacy staff.

Data collection

There are several ways in which quantitative data can be obtained on prescribing errors. These include retrospective review of the medical notes, review of incident reports, and prospective collection of data by ward pharmacists. Retrospective review of the medical notes was considered too time-consuming for the present study. Incident report data has the theoretical advantage of being readily available without any additional data collection, but the level of under-reporting means that these data are not useful for quantitative analyses (Franklin et al 2005, Franklin et al 2007a). Prospective data collection by ward pharmacists is well established, is not overly time consuming when done for short periods, and so was adopted for this study.

Types of medication order studied

The study focused on prescribing errors in newly written 'regular' and 'when required' inpatient and discharge medication. Medication prescribed to be given 'once only', and continuous intravenous infusions, were excluded in order to simplify and standardise data collection.

Denominators

The primary denominator for calculating the prescribing error rate was the number of new medication orders screened by the ward pharmacists; however we also collected data on patient days, so that error rates per 100 patient days could be estimated as a secondary denominator. Previous studies that used medication orders as the denominator have not corrected this denominator to take into account any errors involving the omission of medication. However, for correctness and to facilitate statistical analysis, we added the number of omitted medications (medication that should have been prescribed, but was not) to the denominator (Allan and Barker, 1990).

Wards

We chose to study one or more medical admissions units and one or more surgical wards at each organisation in order to include different kinds of patient and associated prescribing practices. While one UK study suggested no evidence of variation in prescribing error rates between most medical

specialities, wards with a higher patient turnover, such as medical admissions units, had higher error rates due to the volume of prescribing being done immediately following admission, when omission of patients' previous medication is common (Franklin et al, 2007b). It is not known whether error rates on surgical wards are higher or lower than on other wards.

Selection of organisations and wards

As well as organisation B, we also collected data at organisations A and C. We first contacted the chief pharmacist and medical director at each of the three organisations to request their approval and to identify a senior member of pharmacy staff at each organisation who would be responsible for co-ordinating local quantitative data collection by the ward pharmacists. Suitable wards were then identified for study.

At organisation A, we studied a 28-bed surgical ward plus four medical admissions wards across two hospital organisations, comprising a total of 69 medical admissions beds. The surgical ward admitted both elective and emergency patients, under a range of surgical specialties with an emphasis on vascular surgery. Patients typically had a range of medical comorbidities.

At organisation B, we studied two surgical wards and a 24 bed medical admissions ward. The two surgical wards were both single sex and general surgical with an emphasis on urological and gastrointestinal surgery; they had 15 and 18 beds respectively. Each admitted a mixture of acute and elective patients. Although this topic was being studied at organisation B as part of the SCS programme, no SCS-related changes had been made at the time of data collection.

At organisation C, a surgical ward and the 33 bed medical assessment unit were studied. The surgical ward had 26 beds and had a focus on orthopaedic trauma surgery, in particular fractured neck of femur.

All used paper-based prescribing for inpatients, as is the case in most UK hospitals. Discharge prescribing was mainly electronic at organisation A, and part electronic and part paper at organisations B and C, again reflecting typical practice in the UK.

Process mapping

A process map was drafted based on the prescribing processes at organisation B, and then sent to pharmacy staff at organisations A and C for comment and to identify any additional features or differences that needed to be included.

Definitions

We used the following working definition of a prescribing error (Dean et al, 2000):

'A prescribing error occurs when, as a result of a prescribing decision or prescription-writing process, there is an unintentional, significant reduction in the probability of treatment being timely and effective, or increase in the risk of harm when compared to generally accepted practice.'

This definition is accompanied by lists of situations that should be included and excluded as prescribing errors (Dean et al, 2000).

Pharmacists' interventions were defined as any situation where the pharmacist was required to speak with another non-pharmacy member of the healthcare team or write in the patient's medical notes.

The primary denominator used to calculate error rates was the number of newly written regular and 'when required' inpatient and discharge medication orders screened by ward pharmacists, plus any medication orders that should have been written for the patient but were omitted. A medication order is one drug prescribed for a patient; there are usually multiple medication orders on each patient's inpatient drug chart and on each discharge prescription.

Sampling and sample size

We estimated that about 250 new regular, 'when required' and discharge medication orders are written each week on a typical ward, and based our sample size calculations on a 7% rate of erroneous medication orders. Collecting data for two weeks on each ward would therefore allow an erroneous order rate of 7% to be identified with 95% confidence interval of 4.8 to 9.2% for that ward. We therefore collected data for about two weeks at each

organisation with the aim of achieving a sample of 500 medication orders on each ward.

Data collection

Data were collected by ward pharmacists in spring / summer 2009, using established methods (Franklin et al, 2007b). The ward pharmacists were given a verbal briefing, either by the pharmacist member of the WISeR team or by a local pharmacy co-ordinator, supplemented with written guidelines on data collection (appendix 7).

Ward pharmacists were asked to complete a data collection form (appendix 8) with details of the number of newly written regular, 'when required' and discharge items screened each weekday during the study period, together with information on whether or not they had checked each patient's medication history on that particular day. This included any newly written and newly rewritten inpatient charts, but excluded drugs prescribed on anaesthetic charts, once only ('stat') prescriptions, and any drugs or intravenous fluids prescribed on the back of the drug chart or on additional sheets. In addition, the ward pharmacists were asked to record any prescribing errors identified in the medication orders screened. The ward pharmacist was asked to document the details of the prescribing error, the number of doses given (or omitted) before the error was corrected, whether or not the pharmacist made an intervention to correct the error, and the number of occupied beds on the ward on that day.

One medication order could be associated with more than one error. Each individual prescribing error was classified into one of the following categories, which were designed to be exhaustive and mutually exclusive:

- medication omitted when clinically indicated (including unintended omission of patients' usual long-term medication on admission to hospital)
- no indication (prescribing a drug that is not required) / contra-indication for the drug
- duplicate therapy (unintended prescription of the same drug twice, or of two drugs in the same therapeutic class)
- incomplete prescription (includes, for example, missing dose, route, signature or start date)
- prescribing a drug to which the patient has a documented allergy
- incorrect drug (drug A intended, but drug B prescribed)
- incorrect dose
- incorrect frequency or duration (but correct total daily dose)
- incorrect route
- incorrect formulation
- inappropriate abbreviation
- illegible
- missing or incorrect instructions for administration.

The research team checked all completed data collection forms to verify that errors met the study's definition, and that they were classified correctly. If there was any doubt as to which category an individual error fell into, the category highest up the list was selected.

Analysis

We calculated the incidence of erroneous orders for each ward and organisation, defining these as medication orders associated with one or more prescribing errors, and classified the errors identified as set out above, together with accompanying 95% confidence intervals. Where appropriate, we calculated confidence intervals for the difference between two percentage error rates; where the confidence interval for the difference does not span zero, this represents a statistically significant result. We also estimated the error rate per 100 patient days, using the pharmacists' records of the number of patients on each ward each day to estimate the number of patient days. We assumed that prescribing error data collected on a Monday related to three patient days for each patient, since most of the wards studied did not have clinical pharmacy services at weekends.

To explore variation between organisations, specialties, wards, and whether or not the patient's medication history was taken on the day of data collection, we first performed separate analyses for each of these variables. We then conducted multilevel binary logistic regression, aimed at

predicting whether or not each medication order was erroneous.

We used SPPS for analysis. The multilevel models took into account whether or not a medication history was taken for that patient on that day, specialty, and ward (nested within organisation). All were categorical variables and were coded before entry into the model. The output was the odds ratio: the change in odds of a medication order being erroneous resulting from a unit change in a predictor variable.

We assessed the clinical importance of a random sample of one in five sample of the errors identified on each ward, using established validated methods (Dean and Barber, 1999; Kollo and Dean, 2000).

Briefly, five health care professionals (three pharmacists, a doctor and a nurse) assessed each error on a scale of zero to 10, where zero represents an error with no potential effects on the patient, and 10 an error that would result in death. We then calculated the mean score across all five judges for each error, which was used as an index of clinical importance.

Exploring the systems failures involved

For each of the three organisations, we then selected some typical prescribing errors identified on each ward, and explored their likely causes using a series of interviews with prescribers, pharmacists and nurses from that ward, using methods similar to those used previously (Dean et al, 2002; Sanghera et al, 2007).

We aimed to interview between one and three nurses, pharmacists and prescribers of different grades from each organisation. We asked the local collaborator for each organisation to suggest health care professionals from the study wards and invite them to participate. The interview schedule is shown in appendix 9. An initial coding frame was constructed by one researcher based on Figure 2 (page 14) and then revised by a second researcher. Any differences in coding were discussed and agreed between the two researchers.

5.4 Results

Process maps

We developed separate process maps for the prescribing of inpatient and discharge medication, based on the processes in place at organisation B. Pharmacy staff at organisations A and C confirmed that their processes were the same. The process maps for inpatient and discharge medication are shown in Figure 11 and Figure 12 respectively. Inpatient drug charts were very similar at each organisation, with the exception of pre-printed units (g/mg/micrograms) in the 'dose' sections in organisation C and no box for the maximum dose for drugs given 'when required' in organisation B. While the processes for prescribing were the same, there were some differences in the pharmacy services provided across the three organisations. These will be described first for the surgical wards, and then for the medical admissions wards.

The surgical wards at each organisation received a visit from a clinical pharmacist each weekday. However, at organisation A, the types of visits varied across days of the week. On Mondays, Wednesdays and Fridays, the pharmacist conducted 'chart focused' visits during which they screened all drug charts, resolved any urgent problems, and recorded a prioritised list of less urgent issues for follow-up the following weekday. On Tuesdays and Thursdays, the ward pharmacists conducted a 'patient focused' visit during which any newly admitted or pharmaceutically complex patients were seen, and the outstanding issues followed up and resolved. This typically included confirming patients' medication histories, and counselling patients about their medication. These weekday visits were about 120 minutes in duration; the ward also received a short visit on a Saturday from one of the weekend team during which any medications required were ordered.

At organisation B, the two surgical wards received daily visits on weekdays from a pharmacy medicines management technician as well as a pharmacist. The technician examined all drug charts and brought any newly prescribed items to the pharmacist for a clinical check. The pharmacist focused on new patients and discharges. The pharmacist and technician were present on each ward for approximately one hour each weekday.

At organisation C, the surgical ward received a visit from a pharmacist each weekday. The pharmacist screened every drug chart and completed drug histories for all new admissions. At the time of the study, the pharmacist spent about 90 minutes on the ward each day. At organisations B and C, there was no clinical pharmacy service at weekends.

The medical admissions wards at organisation A had a pharmacist present for most of the day. On each of the two hospital sites, a pharmacist was available on the wards from 8am to 7pm on weekdays and from 8am until 1:30pm at weekends. The pharmacists attended the multi-disciplinary post-take ward rounds on most days, including at weekends. During the remainder of the day, the pharmacist completed medication histories and clinical reviews, screened and dispensed discharge medication and counselled patents regarding their medication.

At organisation B, the admissions ward had a pharmacist present from 8.00am to 11.00am each weekday. For the first 1.5 hours, the pharmacist accompanied the doctors on the post-take ward round, and used the remainder of the time to follow up medication histories, facilitate discharge, and resolve any outstanding pharmaceutical issues. At the time of the data collection, pharmacist attendance on the post-take ward round was a new service which had only recently been introduced. There was no weekend clinical service.

At organisation C, the medical assessment unit received a visit from a ward pharmacist each weekday, who clinically screened every drug chart and completed drug histories for all new admissions. The ward pharmacist spent on average 120 minutes on the ward each weekday; there was no clinical pharmacy service at weekends.

The incidence of prescribing errors

A total of 6,237 newly written medication orders were included in the study across 10 wards in the three organisations. A total of 368 omissions were also identified, and these were added to the 6,237 newly written orders to give a denominator of 6,605 which used to calculate the incidence of erroneous orders.

These data relate to 1,289 drug chart screenings (where the same patient's drug chart may be screened more than once on successive days) and an estimated 1,771 patient days. In 493 (38.2%) of 1,289 drug chart screenings, the pharmacist also checked the patient's medication history on the day of data collection.

Overall, 1,025 prescribing errors were identified in 974 of the 6,605 medication orders (14.7%; 95% confidence interval 13.8 to 15.6%). This represents a reliability of 85.3%. In terms of errors per patient day, our data correspond to an estimated 58 prescribing errors per 100 patient days.

Types of error are summarised in Figure 13. The three most common error types were omission of medication that was clinically indicated for the patient, incorrect dose, and incomplete prescription.

Pharmacists recorded the number of doses given before the error was corrected for 904 of 1,025 errors (88.2%). For these 904 errors, a mean of 0.9 doses were given (or omitted) before the error was corrected (range 0-11). Overall, 69.4% of all errors resulted in an intervention being made by the pharmacist.

In the sample there were three types of medication order: regular (n=4,700), 'when required' (n=1,237) and discharge medication (n=668). When expressed by medication order type, the error rate associated with discharge medication was lower than for the other types. Overall, 15.3% of the 4,700 regular medication orders were associated with one or more errors (95% confidence interval: 14.3 to 16.3%), 15.2% of 1237 'when required' medication orders (95% confidence interval: 13.2 to 17.3%), and 9.0% of 668 discharge medication orders (95% confidence interval: 6.8 to 11.2%). The proportions of regular, 'when required' and discharge medication orders were similar across the three organisations.

For those 4035 medication orders that were screened by the pharmacist at the same time as checking the patient's medication history, the error rate was 17.3%; for the 2564 medication orders that were not screened at the same time as checking the patient's medication history, the error rate was 12.1% (95% confidence interval for the difference between the two error rates: 3.5 to 6.9%).

Figure 11: Process map for prescribing inpatient medication at all three organisations

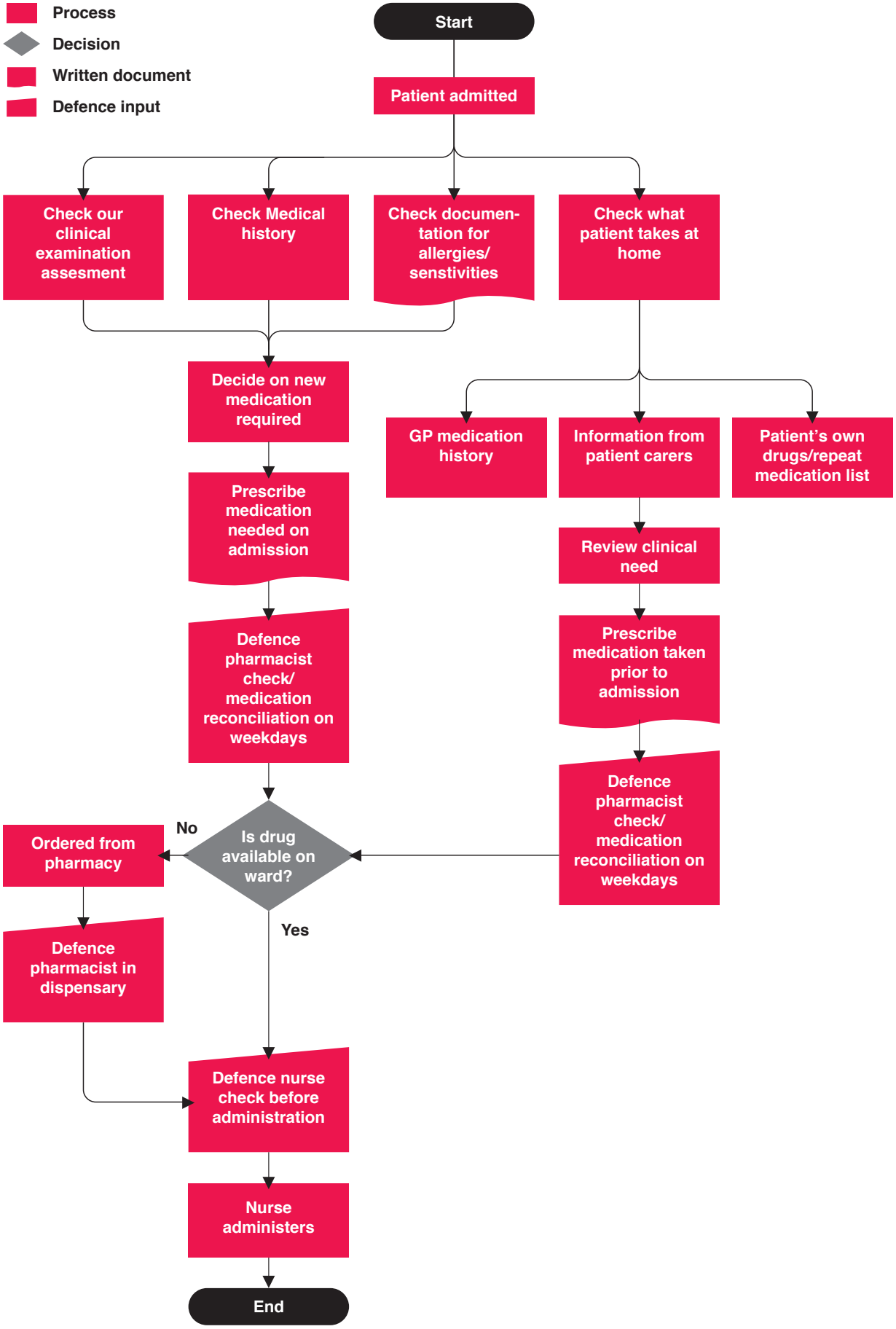
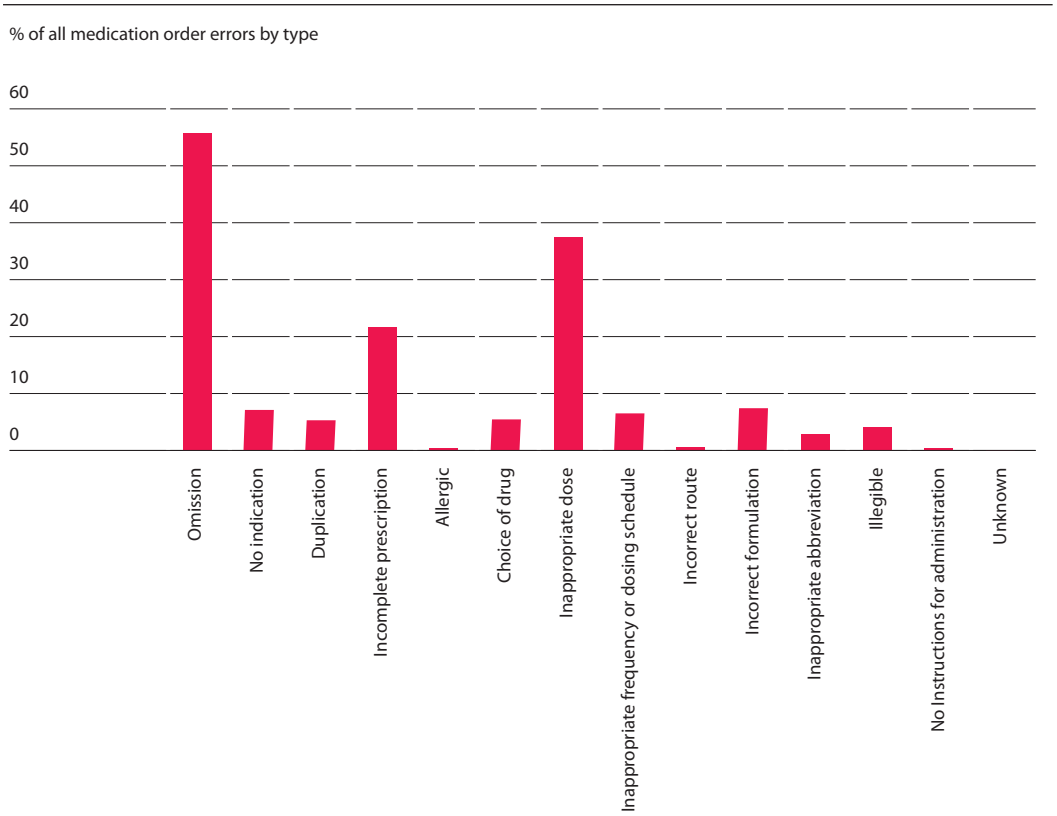


Figure 12: Process map for discharge medication at all three organisations

Figure 13: Types of prescribing error identified, for all three organisations combined



Variability between and within organisations

The error rate for the surgical wards was significantly lower than that identified on the admissions wards (Table 14). However, this may be at least partly accounted for by the dramatic difference between the admissions and surgical wards in the percentage of drug chart screenings for which the patient's medication history was checked on the day of data collection.

For the admissions wards, the pharmacist checked the patient's medication history on the day of data collection in 65.5% of 634 drug chart screenings. On the surgical wards this figure was 11.9% of 655.

Analyses of error rates by organisation are shown in Table 15. The incidence of erroneous orders was significantly higher at organisation C than at organisations A and B. At organisation A, the pharmacist checked the patient's medication history on the day of data collection in 43.2% of 532 drug chart screenings. Corresponding figures for organisations B and C were 31.4% of 389, and 37.9% of 388, respectively. Differences in the prevalence of medication history taking therefore do not explain the variation between organisations.

Table 16 and Table 17 summarise the results relating to pharmacists' interventions and doses given before prescribing errors were corrected, by organisation and by specialty respectively. Errors were generally identified earlier on the admissions wards than on the surgical wards, and were more likely to result in a pharmacist's intervention.

There were smaller differences between organisations than between clinical specialties, although prescribing errors at organisation C were less likely to result in pharmacists' interventions, and more doses were given before they were corrected.

A more detailed breakdown by ward is shown in Table 18. There was considerable variation among the 10 wards. Among the surgical wards, the incidence of erroneous orders was significantly lower at organisation A than at organisations B (surgical ward 1) and C.

Table 14: Incidence of erroneous orders by clinical specialty

Specialty	Number of medication orders screened	Incidence of erroneous medication orders (95% confidence interval)	Errors identified per 100 patient days
Admissions	4059	16.3% (15.2 to 17.4%)	80
Surgical	2546	12.2% (10.9 to 13.5%)	37
Total	6605	14.7% (13.8 to 15.6%)	58

Table 15: Incidence of erroneous orders by organisation

Organisation	Number of medication orders screened	Incidence of erroneous medication orders (95% confidence interval)	Errors identified per 100 patient days
A	2689	13.6% (12.3 to 14.9%)	53
B	1812	12.2% (10.7 to 13.7%)	47
C	2104	18.4% (16.7 to 20.1%)	74
Total	6605	14.7% (13.8 to 15.6%)	58

Table 16: Action taken to remedy errors, presented by organisation

Organisation	Percentage of errors that resulted in an intervention	Number of errors for which the number of doses given was recorded	Mean number of doses given or omitted before error corrected
A	70.1%	333 (86.7%)	0.6
B	74.5%	207 (89.6%)	0.8
C	66.0%	364 (88.8%)	1.1
Total	69.4%	904 (88.2%)	0.9

Table 17: Action taken to remedy errors, presented by clinical specialty

Specialty	Percentage of errors that resulted in an intervention	Number of errors for which the number of doses given was recorded	Mean number of doses given or omitted before error corrected
Admissions	76.4%	601 (87.0%)	0.5
Surgical	54.9%	303 (90.7%)	1.6
Total	69.4%	904 (88.2%)	0.9

Table 18: Incidence of erroneous orders on each of the study wards

Organisation – ward	Medication histories checked*	Number of medication orders screened	Incidence of erroneous medication orders (95% confidence interval)	Errors identified per 100 patient days
A - surgical	13.7%	639	7.0% (5.0 to 9.0%)	19
A - admissions 1	62.7%	963	16.2% (13.5 to 18.9%)	77
A - admissions 2	18.7%	219	12.8% (8.4 to 17.2%)	28
A - admissions 3	84.0%	568	15.8% (12.8 to 18.8%)	94
A - admissions 4	70.7%	300	15.3% (11.2 to 19.4%)	96
B - surgical 1	15.1%	603	12.1% (9.5 to 14.7%)	34
B - surgical 2	8.8%	304	9.9% (6.5 to 13.3%)	37
B – admissions	65.1%	905	13.0% (10.8 to 15.2%)	72
C – surgical	9.1%	1000	16.3% (14.0 to 18.6%)	54
C – admissions	80.8%	1104	20.4% (18.0 to 22.8%)	102
Total	38.2%	6605	14.7% (13.8 to 15.6%)	58

*Percentage of drug chart screenings for which the patient's medication history was checked on the day of data collection

Among the admissions wards, organisation C had a higher rate of erroneous orders than those at organisation B and one of the admissions wards at organisation A.

When expressed as errors per 100 patient days, there was a more than five-fold variation between the highest (admissions ward, organisation C) and the lowest (surgical ward, organisation A).

Types of error

The most common types of prescribing error in all three organisations were omission of medication that was indicated for the patient concerned, and incorrect dose (Figure 14).

There was a lower incidence of omission errors and a higher incidence of dose errors at organisation B in comparison to the other two organisations. There was no clear evidence of any impact of the pre-printing of units on the drug chart at organisation C; there were three errors in organisation A that may have been prevented by such pre-printed units, and one error in organisation C that was likely to have been caused by the pre-printed units.

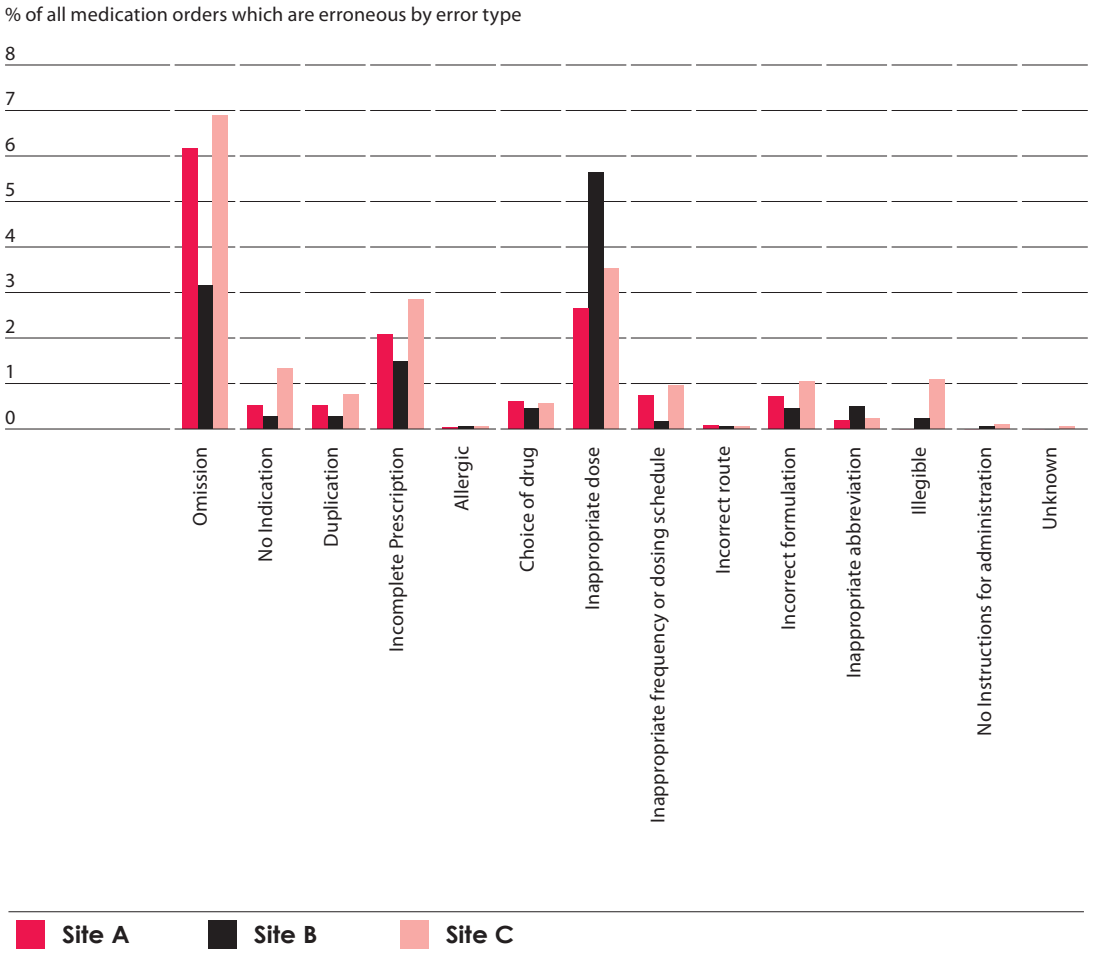
However, the lack of a box for the maximum dose or frequency in the 'when required' section of organisation B's drug chart appears to have affected the incidence of errors involving failure to specify the maximum dose or frequency for 'when required' medication; there was one error of this type at organisation A (2.6% of all 'when required' orders), 35 at organisation B (45.5%) and 10 at organisation C (14.9%). The difference between organisations is statistically significant ($p < 0.001$; chi square test).

When presented by clinical specialty, there was a much higher incidence of omission errors identified on the admissions wards (Figure 15). The incidence of other error types was very similar.

A multilevel logistic analysis showed that, after taking into account the impact of whether or not a medication history had been taken for the patient at the time of pharmacist screening, there was no significant effect for specialty ($p = 0.1$).

We then assessed the relative effects of the remaining two factors. We found that as well as whether or not a medication history had been taken for the patient at the time of pharmacist screening ($p < 0.001$), there was also a significant source of

Figure 14: Incidence of different categories of prescribing error on each study organisation



variation between wards (nested within organisation; $p < 0.001$).

Table 19 shows the odds ratios for each individual parameter category. This shows that medication orders that were screened by the ward pharmacist at the time of medication history taking were significantly more likely to be erroneous.

All three wards at organisation B and the surgical ward at organisation A were less likely to be associated with erroneous orders than the reference ward, the surgical ward at organisation C.

Our panel of judges assessed the clinical importance of a random one in five sample of the prescribing errors indentified on each ward. A total of 183 prescribing errors were assessed in total. The mean clinical importance score was 5.3 on the zero to 10 scale. There was little variation between organisations (mean scores: organisation A 5.2; organisation B 5.5; organisation C 5.4), specialties (admissions 5.4; surgical 5.4) or wards (appendix 10), and statistical analysis thus deemed inappropriate.

A total of 34 (19%) errors in the sample had mean scores of more than 7.0, and were thus classed as serious. These are listed in full in appendix 11; examples are given in Table 20.

Results from system failures analysis

A total of fifteen interviews were conducted. Participants comprised three nurses, five doctors and seven pharmacists. At organisation A, participants were three pharmacists, a nurse and a locum doctor. At organisation B, they were two pharmacists, a consultant and a junior doctor, and at organisation C they were two nurses, two junior doctors and two pharmacists. Some of the pharmacists interviewed had also assisted with the collection of the quantitative data on prescribing errors.

Figure 15: Incidence of different categories of prescribing error by clinical specialty

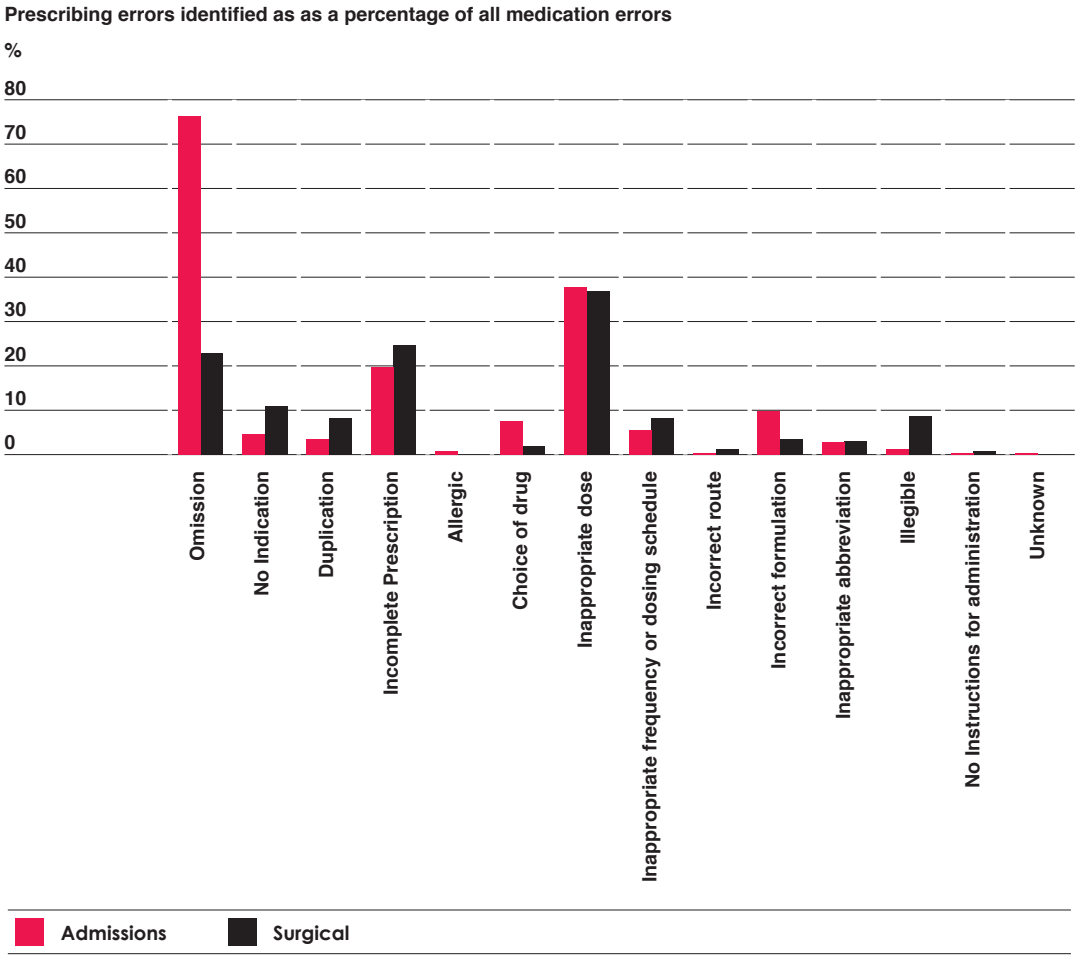


Table 19: Odds ratios for each parameter, following multivariate logistic regression

Parameter	Reference category	Odds ratio (95% confidence interval)
Medication orders screened by pharmacist at time of medication history taking for that patient	Medication orders not screened as time of medication history taking	1.41 (1.17 to 1.70)*
Surgical ward (Organisation A)	Surgical (Organisation C)	0.37 (0.26 to 0.52)*
Admissions 1 (Organisation A)		0.82 (0.63 to 1.06)
Admissions 2 (Organisation A)		0.69 (0.45 to 1.07)
Admissions 3 (Organisation A)		0.76 (0.56 to 1.04)
Admissions 4 (Organisation A)		0.75 (0.51 to 1.09)
Surgical 1 (Organisation B)		0.68 (0.50 to 0.92)*
Surgical 2 (Organisation B)		0.57 (0.38 to 0.87)*
Admissions (Organisation B)		0.63 (0.48 to 0.84)*
Admissions (Organisation C)		1.02 (0.79 to 1.33)

Table 20: Examples of prescribing errors classed as 'serious'

Type of error	Organisation	Ward	Description	Mean score
Omission	B	Admissions	Tinzaparin 3,500 units not prescribed although clinically indicated.	9.4
Omission	A	Admissions 1	Patient uses Insulin Levemir but it was not prescribed in hospital.	8.5
No indication	C	Surgical	Morphine 10-30mg every 6 hours prescribed at discharge. Confused patient and does not require this drug.	8.8
No indication	A	Admissions 1	Patient prescribed amitriptyline 10mg once daily but has possible acute coronary syndrome and myocardial infarction, therefore amitriptyline is contra-indicated.	7.0
Allergic	C	Admissions	Flucloxacillin 1g four times daily prescribed to a patient allergic to penicillin.	9.6
Inappropriate dose	C	Admissions	Prednisolone 1mg once in the morning prescribed but patient's usual dose is 3mg in the morning.	7.5
Inappropriate dose	C	Surgical	Morphine15-20mg orally when required prescribed but no maximum dose or minimum interval stated.	7.4
Inappropriate dose	A	Surgical	Oxycodone (as 'Oxynorm') prescribed twice on 'when required' section of drug chart: 35mg and 40mg, both prescribed for every 4 hours. Correct dose should have been 40mg every 4 hours when required.	8.4
Inappropriate frequency or dosing schedule	A	Admissions 2	Gliclazide 80mg prescribed at 6am, 2pm and 8pm. Should be at 8am, 12pm and 6pm i.e. with meals.	7.3
Incorrect formulation	B	Admissions	Isosorbide mononitrate 120mg once daily prescribed. Should be the modified-release form.	7.6

Perceptions about reliability

The first part of each interview explored participants' views about the reliability of prescribing for hospital inpatients. Some doctors and nurses felt that prescribing was reliable:

'I'd like to think reasonably reliable.' Doctor 3, organisation C

In fact, two doctors completely denied the occurrence of errors:

'Prescribing errors, not in this hospital.' Doctor 5, organisation A

'I'm not sure I've actually seen one [prescribing error] as yet.' Doctor 4, organisation B

Others felt that prescribing was reliable, but noted that this was partly due to pharmacists' interventions in correcting erroneous prescriptions:

'Generally it's very safe, because in our area we have our own pharmacists, and they come, they go through, every day… I think it's pretty safe.' Nurse 2, organisation C

In contrast, pharmacists generally had more negative or conditional perceptions, perhaps because of the number of errors they identify and rectify when screening drug charts:

'Not very reliable. That would probably be the first thing that comes to mind.' Pharmacist 3, organisation A

The majority of interviewees described prescribing as a process that was conditional, depending on a number of factors, in particular the doctors' level of experience:

'That depends on the experience of the person, whether they're used to prescribing that medication and how junior or senior they are. So the more junior you are the less reliable it's going to be, and the more familiar you are and the more senior you are with the drugs, the more reliable it's going to be. ' Doctor 3, organisation B

In the next sections we report in more detail the factors that contribute to prescribing errors, presented according to Vincent's factors that affect clinical practice (Institutional context

The main theme identified here was in relation to medical education policies.

Medical education

Many pharmacist interviewees perceived that one of the main factors affecting prescribing was a lack of specific training about prescribing at medical school:

'They don't pay attention to these things in medical school so I think this goes very deep where awareness and attitude from medical school has to change.' Pharmacist 3, organisation A

'We've learnt it [prescribing] as a subject and they haven't, they've done it as part of what they do and they're not the specialists.' Pharmacist 1, organisation A

In contrast, one doctor reported that he did receive training on prescribing in medical school:

'At medical school within my fifth year I had quite a bit on therapeutics prescribing and within that we addressed prescribing errors and certain areas of prescribing, for example, anticoagulants and antiepileptic medication, some of the slightly more difficult areas which aren't, don't come so straightforward' Doctor 4, organisation C

Organisational and management factors

Themes within this category were organisational priorities within the hospital setting, lack of a common information system between primary and secondary care, and insufficient hospital-based training on prescribing.

Organisational priorities

In relation to organisational priorities, some interviewees felt that prescribing was not one of the doctors' priorities in comparison to diagnosing and stabilising patients, as well as bed pressures and the priority to discharge patients as quickly as possible.

'In terms of the GP and stuff it means a lot of extra work and the thing with doctors is the priorities are different from ours. Their priorities are making sure the patient's stable, making sure the patient's well enough, whereas our priority, as pharmacists, is drugs.' Pharmacist 3, organisation A

'There's also quite a bit of pressure on us with things like discharge summaries, to try and get those done and done quickly.' Doctor 4, organisation C

Lack of common information systems between primary and secondary care

A number of participants highlighted how errors occur due to the lack of a common information system between primary and secondary care:

'It's Chinese whispers, isn't it? I get given a list of drugs from the GP or from the ambulance man who's copied it down from the daughter, he gives it to me and then I copy it down. And then the nurses give it [the medication] and then we change it and I write it down, then I write a letter to the GP and then that letter gets back to the GP …' Doctor 3, organisation C

'Obviously if they're at a loss as to whether somebody takes thyroxine every day, or takes iron tablets …. It might be that hopefully we might be lucky and a patient might come in with their relatives and we can quiz them.' Nurse 4, organisation A

Insufficient hospital-based training

Many participants also felt that hospital-based training on prescribing was lacking or inadequate:

'Typically the junior doctors' training is quite didactic so they sit in a lecture room with consultant lecturers. And, but to get them to move into a more of a workshop scenario where they can, and maybe you can, if you have the pharmacist lead you could talk about some of the prescribing problems that you've encountered and actually get them to talk about and think about what was going on, what were the problems and I think that might be, if you did that regularly through the year that might be a much better way of changing.' Pharmacist 1, organisation B

Work environment

The work environment was the most commonly cited factor in relation to causes of prescribing error. Themes identified included team composition, workload, shift patterns, and distractions while prescribing.

Team composition

Factors related to team composition included insufficient staff, as well as a specific lack of junior medical staff:

'There's always going to be not enough staff.' Pharmacist 2, organisation A

'If we're short staffed, or we're very busy and there's an emergency, I think that's when things, sometimes people make errors.' Nurse 4, organisation A

'We don't have F1s, house officers, we only have F2s, and at that point they're very focused on wanting to get theatre time for their surgical training, which is not unreasonable'. Pharmacist 5, organisation C

Conversely, interviewees also perceived that inexperienced doctors were more likely to make errors:

'If there was responsibility with one doctor who had a good amount of experience, then it [errors] would be less likely to occur.' Pharmacist 2, organisation B

'It just depends on their [doctors'] experience and maybe where they've worked before.' Nurse 4, organisation A

Workload and time pressures

Related factors are workload and time pressures, which were the most frequently reported factors affecting prescribing. Interviewees described how having to see as many patients as possible was a major contributing factor:

'I think on ward rounds a lot they're very rushed, sometimes just generally on the ward when they're just very busy, if I ask them to add something they'll just do it quickly and they'll do it wrong, even if you've given them a list to copy it off it will just be wrong because they're just in a rush, they've just got lots of other things, people asking them to do other things at the same time.' Pharmacist 1, organisation A

'I was in a rush, because I was with a consultant, he was already with the next patient and I was trying to catch him up.' Doctor 3, organisation C

'Just pressure of time is the main one that just makes you potentially make mistakes. Not having time to, if a patient's got polypharmacy and you've been asked, for example, to treat heart failure so potentially you're starting three or four drugs, diuretics, ACE inhibitor, didge [digoxin], a rate control agent, for each of those drugs there are meant to be certain criteria, maybe I haven't always checked the renal function before I start an ACE inhibitor for example, because I'm in a rush.' Doctor 3, organisation C

Shift patterns

In addition to workload, doctors described how during overnight shifts, they were required to prescribe for patients they were not familiar with.

'Sometimes you just don't have enough time or you don't really know the patient, if you're on nights or late and you're covering the whole hospital and you don't know the patient and you don't know that much about them and you're suddenly asked to, can you prescribe this?' Doctor 4, organisation B

Another issue was having 'outlier' patients on distant wards, thus adding stress and time pressures:

'The other thing ... that contributes is having outlying patients, and that happens in all the specialities… If they've got a patient on another ward the other end of the hospital then those patients that are outlying, it puts added stress on the junior doctors to go down there and be back up on the other ward.' Pharmacist 5, organisation C

Distractions

Interviewees often reported distractions that occur while prescribing, leading to errors:

'There's a lot around the fact that they get interrupted when they're working so and they get distracted because they get called to see other patients or a nurse comes about a different patient so I think that doesn't probably help their concentration ... if you looked on any of our wards they can have two or three teams of doctors there at a time, plus physios, plus specialist nurses so you've got perhaps ten people milling round the nurses' station...' Pharmacist 1, organisation B

'I was probably talking to lots of people at the same time, and running the ward round, talking to the patient, talking to the nurse and to the junior doctor, and prescribing at the same time so it's easy to see how you can make a mistake.' Doctor 3, organisation B

Team factors

Themes relating to team factors included incomplete supervision, written communication, perceived professional hierarchy, over-reliance on pharmacists and nurses to identify errors, and lack of feedback to prescribers who make errors.

Incomplete supervision

Often reported was a situation in which junior doctors were under the supervision of their consultants, but consultants would give a prescribing order orally to their juniors without giving any details, assuming the junior doctors would prescribe correctly:

'I think it's certainly true that sometimes the clinicians, the lead clinicians can say, start such and such and they don't give any details about the dose and how long for so if there's quite a lot of detail, start on antibiotic but they don't say which antibiotic, for how long at what dose.' Pharmacist 1, organisation B

'Well, they [consultants] come on the ward rounds, and they do give them [junior doctors] a general, they'll say, stop the tablet or whatever, and change it to this, or we'll give them bisoprolol instead of whatever ... but then once they've gone, they've finished their ward round and they're gone, generally the doc, the junior doctors are left on their own to muddle through.' Nurse 2, organisation C

Some interviewees reported that as a result, junior doctors sometimes had to seek the help of others, usually pharmacists:

'They [doctors] would check with the pharmacist as well. Quite often with the junior doctors they do rely quite heavily on the qualified nurses. And they'd say, oh, what's the normal frequency of this, or the dose?' Nurse 2, organisation C

'The consultant will say, prescribe this, and then they'll come to us and they, what's that, what do I need to do?' Pharmacist 6, organisation C

Communication

Communication between different members of the team, and between primary and secondary care, was perceived to be a major problem contributing to prescribing errors:

'Communication is a big problem in this hospital, I think, and in this department, because it's such a rapid turnover.' Nurse 2, organisation C

Lack of written documentation and poor handwriting were commonly cited as problems by both nurses and pharmacists:

'One of the problems is handwriting, which is always a bugbear, when we find a drug that we can't possibly read across the, because it is manually done. So simply writing... every doctor thinks their handwriting is legible, which often it isn't'. Difficult to do.' Nurse 1, organisation C

'My issue with prescribing communication is that in hospital settings it's not clearly documented in the medical notes … It doesn't get written in the notes, the patient gets transferred, nobody knows, the patient continues on the medicine even if it's not working, ultimately it gives them side effects and makes them fall.' Pharmacist 3, organisation A

'They might have doses from another, an old drug chart, for example, or a drug name from an old drug chart where they, someone's written it and because they're not familiar with the drug they'll write what they think they can see so, and it's not correct, so they write something that looks incorrect or might look like something else or looks like no drug.' Pharmacist 1, organisation A

Perceived professional hierarchy

This relates to reluctance on the part of junior staff to question their seniors, perhaps due to lack of confidence or not wanting to show a lack of knowledge – interestingly, these perceptions were on the part of pharmacists rather than the doctors themselves:

'Sometimes the junior doctor thinks, I think this is right, and actually maybe they're right but their consultant says something different so they're too scared to ask, to argue against the consultant.' Pharmacist 3, organisation A

'I think sometimes junior doctors don't like to question what the consultant says, so if the consultant says, prescribe this drug, or, prescribe this dose, the junior doctor thinks that doesn't sound right but they do it anyway.' Pharmacist 5, organisation C

'At that point they won't ask the consultant, oh how do I spell that drug or what's that drug or what dose is that, because I don't, they probably think that they should know it so they won't ask the consultants.' Pharmacist 1, organisation A

Over-reliance on others to correct errors

There seemed to be evidence of over-reliance on pharmacists and nurses to identify and correct prescribing errors:

'We've got two safety nets, the nurses are the first one and the pharmacists are the second one. And nothing gets prescribed from the pharmacy unless everything is fine with the drug chart. If we send the drug chart down to pharmacy and it's wrong, they'll just send it back, but they check it.' Doctor 3, organisation C

'It's been known where they just leave the dose blank intentionally because they know a pharmacist will come along and check it or question them or write something in or sort it out, which they probably shouldn't be doing.' Pharmacist 1, organisation A

Lack of feedback to prescribers

This was often highlighted. This was partly because if one doctor makes an error and a pharmacist identifies it, another doctor will often rectify it, and partly because pharmacists often correct minor or very obvious errors on the drug chart without informing the prescriber:

'And there's another key issue here as well especially if you're in an area where there's a lot of doctors rotating, sometimes that phenytoin prescription is written by Doctor X, Doctor X has gone home so I have to go to Doctor Y and get them to change it and that's fine, they learn something new, but Doctor X who wrote the prescription doesn't know anything about it.' Pharmacist 3, organisation A

'Also for something like aspirin, I know most pharmacists would just add that on to the drug chart and PNC [prescriber not contacted], so not contact

the prescriber because it's so small you wouldn't contact the doctor just to say, oh it should be enteric coated or, oh it should be dispersible and you didn't write that on … A lot of the time we'll change, we'll add modified release and, without probably telling the doctor.' Pharmacist 1, organisation A

This may at least partly account for some doctors stating that they had never seen a prescribing error.

Individual (staff) factors

Within this category, lack of knowledge was the most commonly cited factor affecting the process of prescribing, in particular in relation to inexperienced junior doctors:

Lack of knowledge

'The other thing is the actual knowledge, some people are aware but they don't know what to do. They don't know how to calculate a creatinine clearance so even if they want to do something about it, they don't have the knowledge to do something about it.' Pharmacist 3, organisation A

'You start picking up drug interactions yourself so if you'd asked me this question when I started I probably wouldn't be able to give you a list of enzyme inducers and enzyme inhibitors whereas I can now and because I've been doing the job for a while now I just know which antibiotics might interact or affect other drugs and I know the side effects of more of the drugs so I can spot interactions quicker.' Doctor 3, organisation C

'Something more important like carbamazepine that should be modified release or not modified release, they tend not to write the enteric coated or the modified release, which is obviously really important because I think once they've got the drug I don't think they always see the importance of the other information that's with it.' Pharmacist 1, organisation A

Task Factors

Task factors are those that affect the actual task of prescribing, such as prescribing guidelines, availability of clinical information, drug chart design issues, lack of standardisation in certain prescribing tasks, and lack of familiarity with certain drugs or tasks.

Prescribing guidelines

When participants were asked about the availability and usefulness of guidelines and protocols, they all answered positively. However, there were some problems where guidelines weren't always accessible.

'Yeah the card, a laminated card, it is in there somewhere. So that's made it really easy for us because that's the one that we prescribe the most I would say, especially on admission to be doing a post treatment drug and you can look it up quite quickly and do it at the time, which is really helpful.' Doctor 4, organisation B

'I think they have trouble getting access to [resources] on the ward sometimes. Like even a BNF, in theory the wards have got BNFs on the ward, but they might not be able to lay their hands on it when they... the formulary, it's mostly online and they haven't always got access to a computer and they don't, it's a hassle to go and look. So I think sometimes the sources are there but they might not refer to them, or they might not be able to lay their hands on them just when they need them.' Pharmacist 5, organisation C

Availability of clinical information

Another factor was a lack of information about the patient, particularly out of hours:

'They don't have that patient's renal function, the weight's not always on the drug charts so they just won't do it.' Pharmacist 1, organisation A

'The overnight environment is quite difficult because we don't have all the information that we would like to prescribe.' Doctor 4, organisation C

Drug chart design

Drug chart design issues were raised several times, including the complexity of the different sections of the drug chart and, in line with our quantitative findings, lack of a box to specify the maximum dose for drugs to be given 'when required' in one of the organisations:

'Why we don't put maximum doses? It's going to sound silly, because there's not a box for it. And if you're writing something like paracetamol or maybe tramadol that you write a lot, you just know it [the

dose] and it's more the routine, but if there's a little box saying maximum dose, because you normally just put ... PRN, this amount and then ... you sign it.' Doctor 4, organisation B

Lack of standardisation

In prescribing certain drugs, lack of standardisation was often a problem. For example this was an issue in indicating drugs that were given less often that once weekly, or those that were to be stopped at a specified future date.

'Everyone's got different ways of writing, give for three days and stop, and some people just write three days and assume that the nurse won't give it on the fourth day, and some people will colour in the days they want it to give and then make crosses and it's obvious that it stops' Doctor 3, organisation C

'The other thing I tend to find is that sometimes when doctors prescribe things and then decide to discontinue, instead of putting, they always put a start date, but instead of putting an actual end date in the box, they tend to just put lines through things.' Nurse 4, organisation A

'I was thinking more that they don't cross off on the boxes when they should that it's once weekly … to write, so they write, in the frequency box they'll write once a week but you know where you have to circle the days, they'll make it look to the nursing staff that it should be every day.' Pharmacist 1, organisation A

Lack of familiarity with specific drugs or tasks

Other task factors related to drugs or tasks that were unfamiliar to the prescriber:

'It's certainly true that some of the mistakes are just because doctors aren't familiar with the drugs and so it's a drug they've not seen before. It's not one they're familiar with, they're not used to the dosage, they don't know or they might put one for one tablet and not know that it comes in three different tablet strengths.' Pharmacist 1 organisation B

'When you're doing calculations, especially when you're not that familiar, that can take a while.' Doctor 4, organisation B

'We're very comfortable with a certain number of drugs, the drugs that frequently get used in primary care and secondary care ...the drugs that we are less familiar with, it's all the sub speciality drugs, which end up on the acute medical unit, we're less familiar with those and as such, not necessarily errors, but omissions may occur because we're not familiar with the drugs and how they should be prescribed.' Doctor 4, organisation C

Patient characteristics

Patients themselves can also play an important role in preventing errors. Relevant factors include patients' knowledge (or lack of knowledge) of their medication, their communication skills, and how ill they are. There was an assumption that patients were the primary source of information about their medication:

'People have incomplete lists of medication, they're unaware of which medications they're currently on and as such, probably we don't get 100% of prescribing right on the first attempt, so drugs will get missed or we won't know doses, so they will be omitted temporarily until we know what those doses and frequency of prescribing is.' Doctor 4, organisation C

'Sometimes this may happen because the patient, on arriving, may be quite unwell or might be not in a position to say what medication he's on and he might be getting discharged the right, second day, even without us knowing the proper medication what he might have been on.' Doctor 5, organisation A

Defences and solutions

The interviewees suggested a number of defences that were already available and in use, as well as other potential solutions.

Pharmacists and nurses

The main current defence identified by most of the interviewees was the presence of a pharmacist on the ward, particularly when pharmacists were also available on ward rounds:

'I know [pharmacist 1] and [pharmacist 2] and I've gone to see them ... they're normally on the ward the same time each day and it's common place to take both the pharmacists with us quite often. I know them quite well to ask them ... "do we normally give this much or?" So that's really helpful, we do ask them.' Doctor 4, organisation B

'When a pharmacist is on the ward round and things we're quite often able to catch things early on when the doctors were there, so there and then you can get things written up and change appropriately.' Pharmacist 6, organisation C

'As a medical doctor prescribing drugs is the corner stone of what we do for patients, isn't it? So it shouldn't need a pharmacist but every day I'm ... the pharmacist comes to me and says, by the way ... I'm sure it's the same with other doctors as well.' Doctor 3, organisation C

Nurses were also referred to as a defence. However, one participant mentioned the effect of recruiting nurses from different countries to work within the NHS, creating a diverse workforce where staff may not challenge their colleagues due to their own cultural values:

'And I think the other problem is that over the years we have recruited lots of nurses from different countries, and I think it's also difficult for those nurses to challenge things as well.' Nurse 4, organisation A

Electronic prescribing

All three participating organisations had electronic prescribing systems available for discharge prescriptions, and these were viewed very positively:

'They're [computer programmes] useful and I think they, it's like every computer program once you know how to use it, it's really great.' Pharmacist 1, Organisation B

'We've now moved to an electronic discharge system, whereby there can't be any ambiguity with the wording...' Doctor 4, organisation C

There was an assumption that inpatient electronic prescribing and an electronic national care record would also reduce prescribing errors:

'But then some of the wards have got obviously electronic systems where the prescribing's probably a lot better.' Pharmacist 2, organisation A

'Well I guess that ultimately you'd have complete electronic systems wouldn't you? The GP, and a national system that you could tap into at any time of day. And anything, any medication that was changed would be entered onto that, but at present I think that's a bit of a dream rather than a reality.' Pharmacist 6, organisation C

Interviewees were also aware of the limitations of such electronic systems:

'The things that the computers wouldn't help with would be things like missing things off drug histories and the computer's not going to know if you've not even attempted to put it in there.' Pharmacist 2, organisation A

'It's not the only solution because you can still make mistakes. You just make a different sort of mistake.' Pharmacist 1, organisation B

'If you've got three or four teams of doctors on the ward and you've got two computers and the ward receptionist needs to use one of them they're not all going to be able to prescribe electronically at the same time with our current infrastructure. So I think that's a solution which is quite a long way off.' Pharmacist 1, organisation B

Better feedback to prescribers about their errors

This was also recommended:

'I don't know whether there's any sort of mentorship programmes because a lot of the prescribing errors are made by more junior doctors and if there's any mentorship because they have their mentor consultants, if there's any way where people who pick up prescribing errors can feed back through their mentor because then it's coming from doctor to doctor, they might be taking it better than some pharmacist.' Pharmacist 3, organisation A

Guidelines presented as summaries or checklists

Other recommendations by the interviewees were to improve the guidelines available:

'It should be simplified maybe on some sort of flowchart, bullet points, maybe even emailed to everybody in a really easy to read format because they are useful. As pharmacists we obviously, being the drug experts, we've read them, most pharmacists have read them, they're very useful, who else is going to sit and read 25 pages? Doctors don't have the time to do that.' Pharmacist 3, organisation A

'I think guidelines need to be made more user friendly I think, in my opinion. Like our example is our antibiotic guidelines, they're a nice card that the doctors carry around, very easy to refer to and actually I don't see that many errors in anti infective prescribing comparatively.' Pharmacist 3, organisation A

Educational interventions

Education and training, with a focus on practicing prescribing skills, was suggested by several of the pharmacists:

'Small group training would be better probably than a lecture, where people probably switch off, that's actually on the ward, physical showing them, this is the drug chart, this is what you write and where and when, would probably improve.' Pharmacist 2, organisation A

Increasing non-medical prescribing

Several interviewees advocated further expanding the numbers of non-medical prescribers:

'So yes that [pharmacist prescribers] can relieve the pressure on the junior doctors and also has the advantage if they're doing those things over and over and over again, they're very familiar with them and they'll probably be the simpler drugs. And the advantage to the patient is that if they need some paracetamol or some lactulose they can get it straightaway without having to wait for the junior doctor.' Doctor 3, organisation B

'I think the other alternative which is something that is becoming a little bit more trendy now- is to have alternative prescribers who can actually reduce the doctors' workload. There's probably more nurse prescribers than there are pharmacists but it's coming.' Pharmacist 2, organisation B

A quiet environment for prescribing

Finally, it was suggested that having a designated quiet area for prescribing would help in relation to reducing interruptions and distractions:

'It would be nice if there was a quiet area where you couldn't be disturbed.' Nurse 2, organisation C

5.5 Discussion

Summary of results

We identified prescribing errors in 14.7% of all newly written medication orders screened by hospital pharmacists on the study wards, corresponding to a reliability of 85.3%. Error rates were significantly higher on admissions units than on surgical wards, but this was accounted for by the high proportion of prescribing on these wards being immediately following admission, when omission of patients' usual medication was common.

There were also variations in the incidence and types of prescribing error among wards and organisations. A mean of 0.9 doses (range 0-11) were given (or omitted) before errors were rectified.

Contributing systems factors included lack of information from primary care about patients' medication, time pressures, lack of feedback to doctors about their prescribing errors, lack of standardisation in how certain drugs are prescribed, poor documentation of prescribing decisions, a focus on the choice of drug at the time of prescribing, with little attention given to other details, lack of practical training on prescribing, and junior doctors not feeling confident to ask consultants, or challenge them, about prescribing.

Comparison with the literature

Our overall erroneous order rate of 14.7% is higher than in most published studies (Lewis et al, 2009). However, there are many subtle methodological differences between studies of prescribing errors (Franklin et al, 2009b). Studies using comparable methodology report a median error rate of 9.9% (range 7.7 to 14.6%) (Franklin et al, 2009b) and a study presenting error rates according to different clinical specialties (Franklin et al, 2007b) presents rates comparable to those in the present study for two specialities with high patient turnover, comparable to the admissions units included in our study.

When presented according to errors per patient day, we identified an estimated 58 prescribing errors per 100 patient days. This is also higher than those reported in the literature. A recent systematic review identified eleven studies which provided an incidence of errors per patient days, the median of

which was 2.4 errors per 100 patient days. However the range was wide (0.01 to 414 errors per 100 patient days), again reflecting wide variation in the methods, denominators, and settings used (Lewis et al, 2009).

Many of these 11 studies collected data over much longer time periods and are more likely to be subject to reporting fatigue, or analysed incident report data, which are known to be subject to significant under-reporting. Our study focused on newly written medication orders that were seen by ward pharmacists in a defined period over about two weeks, rather than all medication orders, and the higher error rate is therefore likely to be at least partly a reflection of the methodology used.

The most common types of error identified in our study were omission, wrong dose, and incomplete prescription. This is in line with the existing literature (Lewis et al, 2009). We also found that 76.4% of errors on the admissions units, and 54.9% on the surgical wards, resulted in an intervention being made by the ward pharmacist.

A previous UK study (Donyai et al, 2007), also on a surgical ward, reported a figure of 40%, suggesting that pharmacists' practice may differ in different clinical specialties, probably due to differences in the availability of medical staff and their working relationships.

The only other UK study of prescribing errors which presents comparative results for more than one organisation was conducted in paediatric wards; this highlighted substantial differences between wards, but wards were not matched across organisations and it is therefore not possible to compare organisations (Ghaleb et al, 2010). Our findings are in line with a previous UK study (Tully and Buchan, 2009) which found that errors were more likely to be identified at admission than at other times, independent of ward type, seniority of pharmacist, and workload.

In relation to the causes of errors, our findings are broadly similar to those identified in previous UK studies of the causes of prescribing error (Dean et al, 2002; Sanghera et al 2007, Tully et al 2009, Dornan et al 2009). Common themes are lack of error awareness, over-reliance on pharmacists and nurses to correct errors, deficiencies in education particularly in relation to linking theory with practice, reluctance to question senior colleagues, poor documentation, and no feedback on performance.

Interpretation

This study has confirmed that there is a high incidence of prescribing error in hospital inpatients. We have also shown this to be the case across three organisations and two clinical specialties. However, there were significant differences between the two specialties, notably a higher incidence of error on the admissions wards. This was accounted for by a higher incidence of omission errors, likely to be due to a higher proportion of the prescribing on these wards being the prescribing of patients' usual medication on their admission to hospital.

It is well known that this is the stage of patient stay most likely to be associated with error (Dornan et al, 2009), resulting in the national recommendation that pharmacists are involved in medication reconciliation as soon as possible after patient admission (NICE/NPSA, 2007). It may also be that admissions pharmacists attending the post take ward rounds are more likely to identify other medication that is clinically indicated for the patient but not yet prescribed.

The lower error rates for discharge medication may be because they are generally transcribed directly from the inpatient medication chart, where most errors will already have been identified and rectified. The errors that do occur are likely to be transcription errors between the two documents.

Some aspects of drug chart design also appear to be important - the lack of a box for maximum dose or frequency for 'when required' medication in one of the organisations appears to have contributed to the increased number of errors involving failures to specify this information at that organisation.

Our study shows that many, but not all, prescribing errors result in pharmacists' clinical interventions. A higher incidence of prescribing errors resulted in interventions on the admissions wards; this may reflect the increased availability of medical staff on the admissions wards in comparison to surgical wards, resulting in pharmacists contacting medical staff to resolve prescribing errors rather than amending directly on the drug chart.

The errors for which no interventions were made were typically those relating to illegible medication orders, missing information about the strength, formulation or maximum dose, incorrect times of administration, and transcription errors between old and new drug charts, Ward pharmacists would typically amend these types of errors on the drug chart without consulting a member of medical staff.

While prescribing errors were common, our study shows that 'defences', usually the ward pharmacists, were generally working – on average, only about one dose was given (or omitted) before the error was rectified. However there were also differences between organisations and specialties in this respect, most likely due to differences in the pharmacy services provided.

The organisation with the lowest mean number of doses given (or omitted), organisation A, had the most comprehensive pharmacy service, with higher levels of pharmacy presence on the admissions wards and at weekends. Our findings therefore suggest that such services do result in erroneous medication orders being identified and rectified more quickly.

We identified some common themes in relation to the causes of prescribing error, the implications of which are addressed later as recommendations.

Strengths and limitations

A key strength of this study is that we used robust methods and definitions, based on our established experience in researching this area. We used these same methods and definitions to study prescribing errors on comparable wards in three NHS organisations. This is therefore the first UK study to present comparable data on error rates across organisations in an adult setting. We used a practitioner-led definition, ensuring that our findings are grounded in practice rather than academic ideals.

As far as we are aware, this is also the first study to present figures on the number of doses administered before errors were corrected. This may be a useful indicator for how good the system's defences are, and we recommend that future studies consider including this as an outcome measure. Future studies could also consider how many days of incorrect medication were received (or omitted) before errors were rectified.

In common with most literature in this area, our data rely on data collection by ward pharmacists. Ward pharmacists' data collection is likely to be subject to under-reporting and possibly some under-identification of errors (Franklin et al, 2009a; Tully and Buchan, 2009). This may be particularly the case when identifying errors that require more in-depth knowledge of the patient's medical history, such as omissions and contra-indications.

However since errors were identified in the context of pharmacists' routine clinical practice, and medical staff contacted to correct errors where necessary, our approach includes an additional validation step in comparison to data collected solely for research purposes. Any medication orders screened and errors identified by dispensary pharmacists were not included; however this is unlikely to affect the error rate calculated.

The binomial proportion confidence interval is appropriate if individual observations are unrelated and the opportunity for success/failure is constant across observations. There may be a number of reasons why this assumption is violated, for example due to variation in error rates between doctors. However, this is not easy to measure or control for and could not be taken into account in the present study.

Recommendations

Our recommendations can be considered as those to reduce errors at the point of prescribing, and those to facilitate defences to stop errors that do occur from causing patient harm.

Reducing errors at the point of prescribing

- Facilitating the development of common electronic information systems between primary and secondary care.
- Allocation of quiet areas for prescribing.
- Increased judicious use of electronic prescribing, for both inpatients and at discharge.
- Provision of better feedback to hospital doctors about their prescribing errors.

- Provision of key prescribing guidelines as pocket guides or other accessible formats.
- Training in practical prescribing skills, both at medical school and in the hospital setting, including better communication of prescribing-related information among the multi-disciplinary team.
- Drug charts in some trusts may benefit from minor changes to design out certain types of error.
- Some clarification of roles and responsibilities may be needed for medication history taking following patient admission. Currently pharmacists provided a key role in this area, potentially leading to medical staff omitting to perform this task.
- More research is needed into the effect on prescribing errors of using non-medical independent prescribers. We need to understand both whether these practitioners make more, less, or different errors to those of medical prescribers, and also whether there is any subsequent knock-on effect on errors made by medical practitioners.

Defences to stop errors from causing patient harm

- Developing pharmacy services to facilitate more proactive use of clinical pharmacists, such as on ward rounds, to provide advice at the point of prescribing rather than retrospectively.
- Further consideration is needed of the roles that patients can play in identifying and challenging medication errors.

One of the NHS's targets in the report 'An Organisation with a Memory' was to reduce serious errors in the use of prescribed medicines by 40% (Department of Health, 2000), but there is no evidence that any progress has been made (Vincent et al, 2008). While numerous studies have described the extent of the problem, to date there have been few UK studies of the impact of interventions to reduce prescribing errors.

Two UK studies of inpatient electronic prescribing demonstrated a modest reduction in errors (Franklin et al 2007a; Shulman et al, 2005), but this is by no means the definitive solution as substantial rates of error still occur.

There is limited evidence that educational interventions can improve prescribing, but studies are mainly in the undergraduate setting (Ross and Loke, 2009). For all of the above recommendations, work is therefore needed to formally evaluate their benefits, as well as their costs.

Conclusion

This is the first UK study to have compared prescribing errors for hospitalised adults across more than one organisation. We identified prescribing errors in 14.7% of all newly written medication orders screened by hospital pharmacists on the study wards, corresponding to a reliability of 85.3%. There were variations in the prevalence and types of prescribing error among the three organisations, but similar contributing factors identified.

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Chapter 6

Reliability of the clinical handover process

by Mark-Alexander Sujan

6.1 Introduction

Communication, coordination and handover of information have been recognised as an important topic in enhancing the quality of care (Institute of Medicine, 2001). Handover has been defined as 'the transfer of professional responsibility and accountability for some or all aspects of care for a patient, or group of patients, to another person or professional group on a temporary or permanent basis' (British Medical Association, 2004). However, a recent systematic literature review conducted on behalf of the Australian Commission on Safety & Quality in Healthcare (ACSQHC) (Wong et al, 2008) suggests that this definition is not universally recognised and that there is still widespread confusion and a lack of common understanding of the term 'clinical handover'. In addition, other terms such as hand-off, shift report and patient transfer are frequently used. There are also many different ways of performing handovers in practice (Roughton & Severs, 1996). Current handover processes are often not standardised and are highly variable (ACSQHC, 2009). A questionnaire survey of Australian doctors in one general metropolitan hospital in New South Wales revealed that 95% of the 74 respondents did not identify a formal or set procedure for handover for on-call junior medical staff (Bomba & Prakash, 2005).

The Australian literature review concludes that 'clinical handover is a high-risk scenario for patient safety with dangers of discontinuity of care, adverse events and legal claims of malpractice' (Wong et al, 2004). This is based on various sources of evidence. For example, respondents to a questionnaire survey in two teaching hospitals in the US believed that around 15% of adverse events, errors and near-misses involved handover (Jagsi et al, 2005). Handover is also among the most common causes of malpractice claims in the USA, accounting for around 20% of cases that involved trainees (Singh et al., 2007). The literature review also found that handovers between ambulance services and emergency care, and handovers within emergency care, were particularly problematic.

There is little evidence as to the actual reliability of clinical handovers. This is exacerbated by the fact that no universally agreed definitions or methods of studying handover exist. A survey in three large metropolitan emergency care departments in Australia (Ye et al., 2007) employed post-handover questionnaires and found that information was perceived to be lacking in 15.4% of handovers. This often concerned details of management (5% of all handovers), investigations (4.7%) and where patients were to be transferred (4.7%).

There is now guidance available on standardising and supporting clinical handovers (British Medical Association, 2004; ACSQHC, 2009). However, there is little empirical evidence as to their effectiveness. A simulation study comparing the reliability of different handover methods (Bhabra et al, 2007) found that information handed over verbally only was retained very poorly (2.5% of information retained after 5 handover cycles), whereas verbal handover with written notes performed more robustly (85.5%). Handover supported by printed electronic documentation suffered almost no information loss (99%). However, many of the influencing factors present in actual practice could not be taken into account in such an experimental setup.

The topic of clinical handover from doctor to doctor was selected for investigation as part of the SCS project by organisation C with the aim of improving the reliability of handover for patients on the stroke pathway. We also explored doctor to doctor handovers at two other NHS organisations, within emergency care, using common definitions and methods.

6.2 Objectives

- To measure the level of standardisation of clinical handovers within a selected medical specialty in each of the three organisations.
- To describe which information is handed over poorly and which is handed over well.
- To identify any variation in the level of standardisation between organisations.
- To explore the systems factors which contribute to poor quality handovers.
- To make recommendations for improving the level of standardisation and quality of the handover process.

6.3 Methods

Methodological considerations

The assessment of reliability requires clearly specified processes and is linked to the notion of failure. However, most clinical handovers are not standardised and take place in informal ways with significant variation in the way they are conducted, their duration and their location, as well as the information that is communicated. In addition, there is no straightforward way of identifying handover failures other than through retrospective reviews of adverse events, an approach that was too resource-intensive for consideration here.

It was therefore decided to assess the level of standardisation of the handover, which can be achieved through observation. We identified an ideal or minimal dataset of clinical information that needs to be communicated at the handovers concerned. This is in accordance with findings that suggest that the presence and use of such a core data set may improve the reliability of clinical handovers (ACSQHC, 2009). The core data set represents information that one would expect to be handed over and was derived through practitioner consensus.

We therefore collected data using observation of actual handovers and described the level of standardisation seen. The level of standardisation reflects the extent to which individual information items, groups of information items or the entire core data set were handed over. This method assesses whether or not information about an item has been provided, but not whether the information communicated was actually correct, or was received correctly by the recipient.

Selection of organisations, departments and handovers

As well as organisation C, we studied this topic in organisations D and F. We established contact through a senior clinician at each organisation with the approval of the medical director or the head of clinical governance. The handovers were selected based on ease of access as well as findings from the literature that suggest that handovers to and within the emergency department are particularly problematic (Wong et al, 2004). A weekly handover from one neurological consultant to another was studied in organisation C, and shift handovers within the emergency care department were studied in organisations D and F. All handovers were from doctor to doctor, however, they were carried out in different ways: telephone handover (organisation C), verbal face-to-face handover (organisation D) and a team-based handover including nursing staff (organisation F). Organisation C had not made any SCS-related changes to the handover process at the time of data collection.

Process mapping

A process map for each of the three handovers was produced to show the location of the handover within the overall care pathway. In addition, more detailed maps were produced to represent the steps involved in each of the handovers.

Core data set

A core data set of information was identified through consensus, to reflect information that clinicians would expect to hand over. The core data set was proposed by the lead clinician involved in organisation C, where it was commented upon and revised by further senior clinicians. It was then

validated and agreed by the lead clinicians involved at the other two organisations.

The resulting core data set was as follows:

- patient identification (name, date of birth, location, and hospital number)
- assessments (presenting condition, diagnosis)
- investigations (tests with results, tests ordered but results not received, tests still needing to be done)
- care plan and management (acute medication, ongoing medication, complications, onward care).

The core data set thus comprised 13 different data items from four broad categories.

Data collection

Quantitative data were collected during summer / autumn 2009 through observations using a data collection sheet (appendix 12). Data were collected by the research team in two of the organisations (D and F) and by the local SCS team at the third (organisation C), following training and mentoring by the SCS support team. We aimed to conduct five observations of handover sessions at each organisation, based on what was practical within the time available. For each patient and for each of the 13 information items of the core data set, we recorded whether or not the information item was explicitly referred to.

Analysis

As a measure of the level of standardisation, we calculated the percentage of patients for whom each item of the core data set was communicated. We also calculated for each of the four broad categories of information (patient identification, assessments, investigations, care plan) the percentage of patients for whom the respective category was communicated. A category was classified as having been communicated if at least one element belonging to the category had been handed over.

Exploring the systems failures involved

We aimed to conduct three interviews in each of the participating organisations. Interviews were all conducted by the same researcher, using the interview schedule in appendix 13. The interviewees were asked about problems with clinical handovers with which they were familiar themselves. They were asked to comment on their likely causes, based on their own experiences, and the consequences for patient care. The interviews were then analysed qualitatively using the framework on page 14, and common themes identified.

6.4 Results

Process maps

We developed separate process maps for the clinical handovers at each of the three organisations, to show where the handovers occurred within the process. We also developed more detailed representations for the handovers within the two emergency care departments. The process maps are shown in Figure 16, Figure 17 and Figure 18. Each study setting will next be described.

Organisation C

The neurology department studied offered a 24-hour on call and inpatient service. The department worked closely with the regional neurosurgical, neuroradiology and neuro-oncology departments and offered a full range of consultant-led inpatient and outpatient general neurology and subspecialty investigations and treatments. The neurology department operated an 'attending consultant' system. This meant that all patients in the department at any one time were under the care of the same consultant. The attending consultant changed each week, requiring a weekly medical handover. The attending system contrasts to the more traditional system of different patients being under a single medical 'firm' for the duration of their stay.

Figure 16: Process map for handover, organisation C

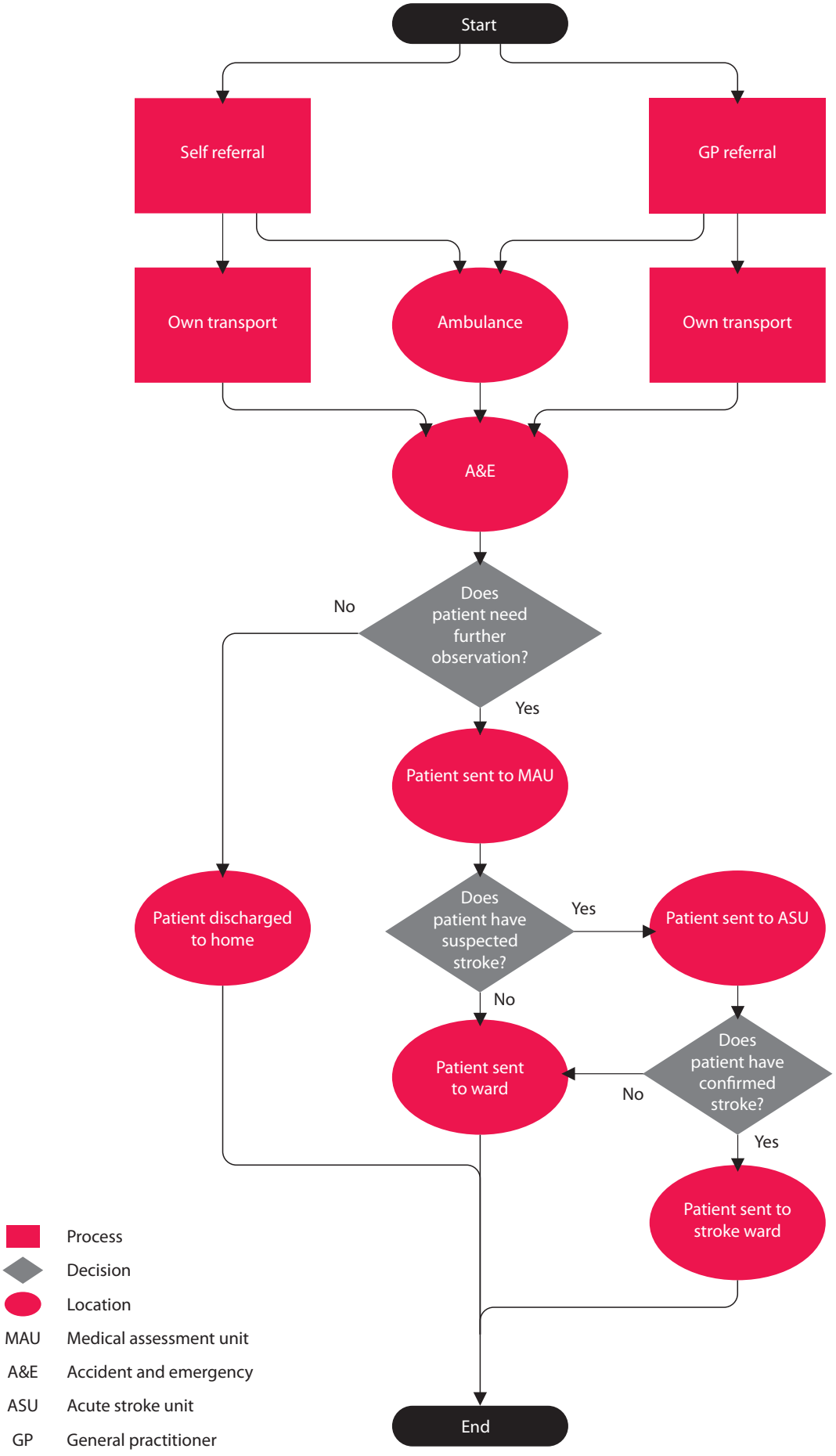


Figure 17: Process map for handover, organisation D

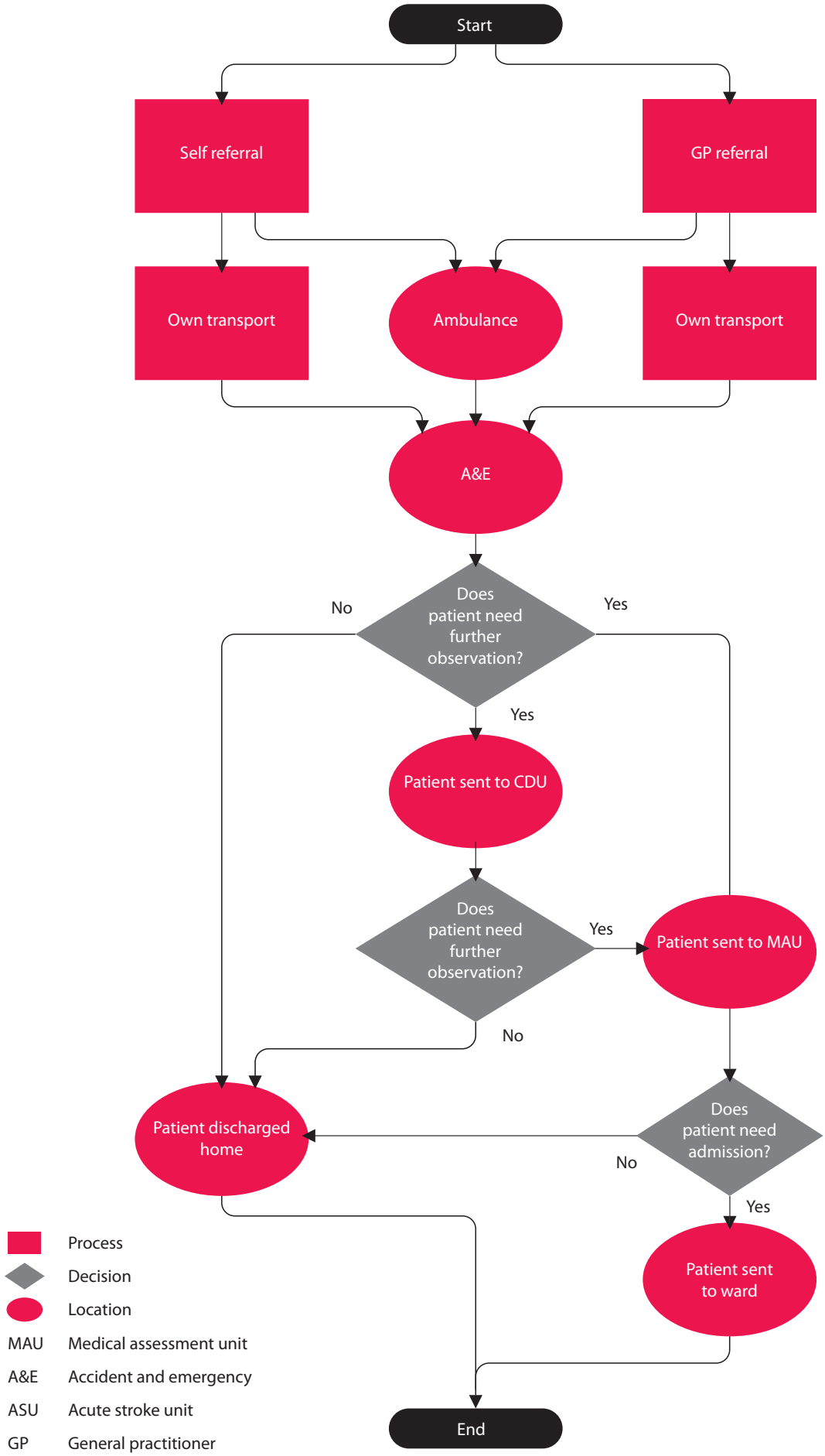
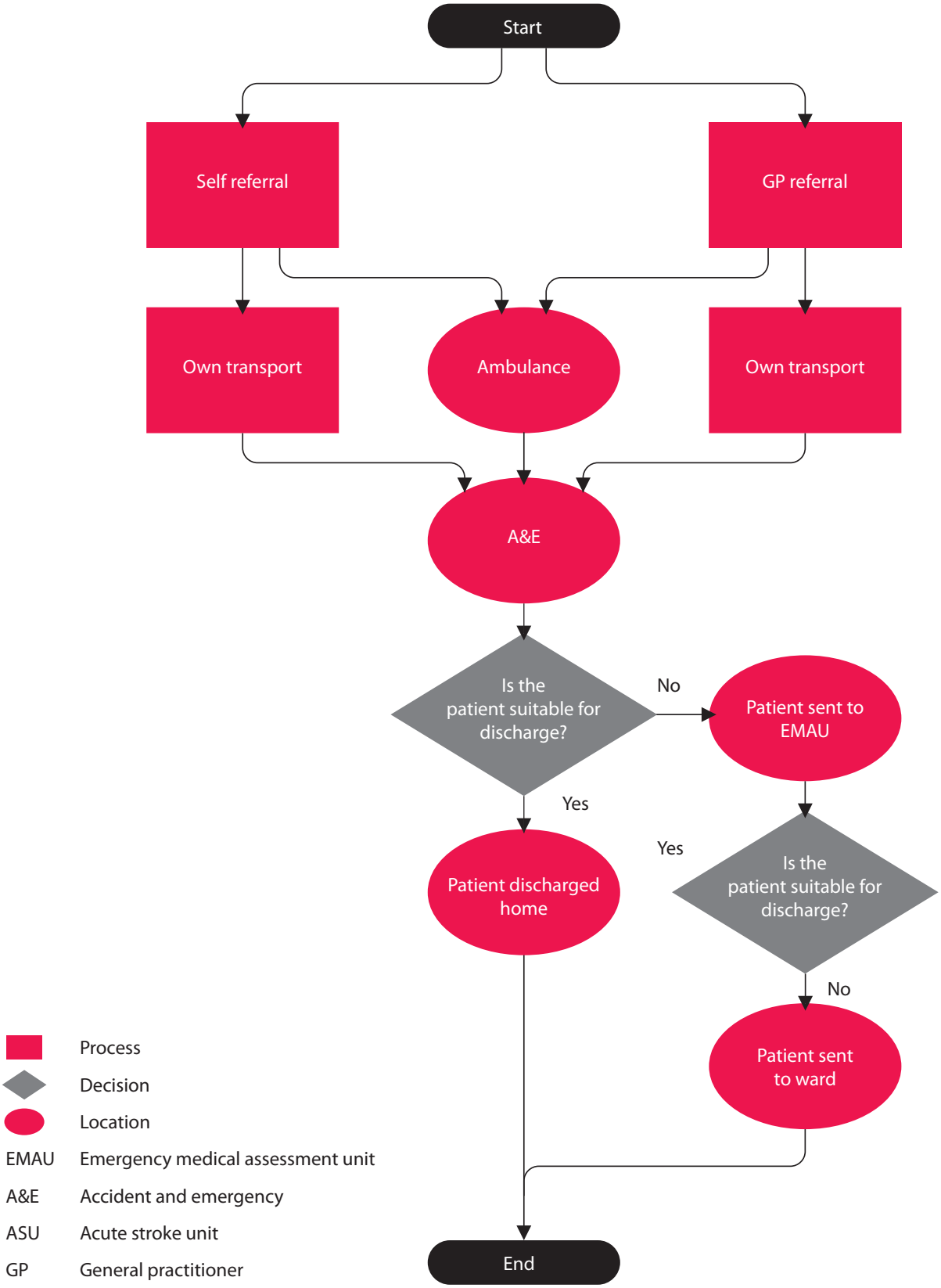


Figure 18: Process map for handover, organisation F



Organisation D

At organisation D we studied the shift handovers on the clinical decision unit (CDU). The CDU was designed to provide rapid investigation and management of specific conditions presenting to the emergency department with an expectation that the majority would be discharged within 12 hours. This included those who needed to follow a specific investigation pathway (e.g. renal stones, chest pain), those who needed a short period of recovery (e.g. minor head injury, resolving anaphylaxis, asthma) and those needing rapid social care arrangements (e.g. frail elderly). The unit was adjacent to the emergency department and had 8 beds and 4 chair spaces. The average turnover was 1.5 patients per bed per day. The patients were managed by the emergency department staff with a senior doctor being responsible for their care. The care of the patients was handed over when these senior doctors changed their shifts in the morning, afternoon and evening. The handover aimed to ensure the accurate transfer of information to ensure timely, safe and specific care.

Organisation F

At organisation F we studied the shift handover on the emergency medical assessment unit (EMAU). EMAU provided a facility for assessing and treating emergency medical patients who attended either following a GP referral or who were referred from the emergency department. The unit had an average of 24 admissions per day.

All patients were seen by a member of each of the nursing and medical teams, and underwent a range of treatments and investigations. Each patient was then reviewed on one of the two daily consultant ward rounds and a plan of care agreed. From the EMAU, patients were discharged home, transferred to another ward or kept on the unit for short stay treatment.

We observed the evening handovers on EMAU. This handover was in a phase of transition at the time of the study; a shift from a doctor-only handover towards a team-based handover was in progress. The handover therefore involved members from the incoming and outgoing medical teams as well as, on occasion, a member of the nursing team.

In addition, this handover incorporated the 'hospital at night' handover, so that not only patients on EMAU, but also those elsewhere in the hospital were potentially being handed over.

Handovers lasted for around 15 to 30 minutes and were scheduled for 9pm. None of the organisations had formal protocols for the handovers studied.

Communication of elements of the core data set

In total, data were collected for 246 patient handovers during 19 handover sessions. These comprised 171 patients during eight handover sessions at organisation C, 43 patients during seven handover sessions at organisation D, and 32 patients during four handover sessions at organisation F.

Figure 19 shows for each information item of the core data set the percentage of patients for whom the information item was communicated.

The information items most commonly communicated were name (77% of patients, 95% confidence interval: 72 to 82%), presenting condition (77%, 95% CI 72 to 82%) and diagnosis (75%, 95% CI 70% to 80%).

The information items least frequently communicated were investigations that had not yet been done (17%, 95% CI 12 to 22%), investigations for which results had not come back (18%, 95% CI 13 to 23%), ongoing treatments (17%, 95% CI 12 to22%]) and complications (17%, 95% CI 12% to 22%).

Each of the higher-level categories was then assessed in terms of whether at least one element from that category had been discussed. For the category 'patient identification' we also specifically looked at whether or not at least two patient identifiers were used.

This reflects the fact that failures in patient identification have been recognised as particular sources of risk (for example, NPSA, 2004), and it is usually recommended that more than one patient identifier is used. Figure 20 presents the percentage of patients for which each of the categories was communicated.

Figure 19: Percentage of patients for whom each information item of the core data set was communicated at handover

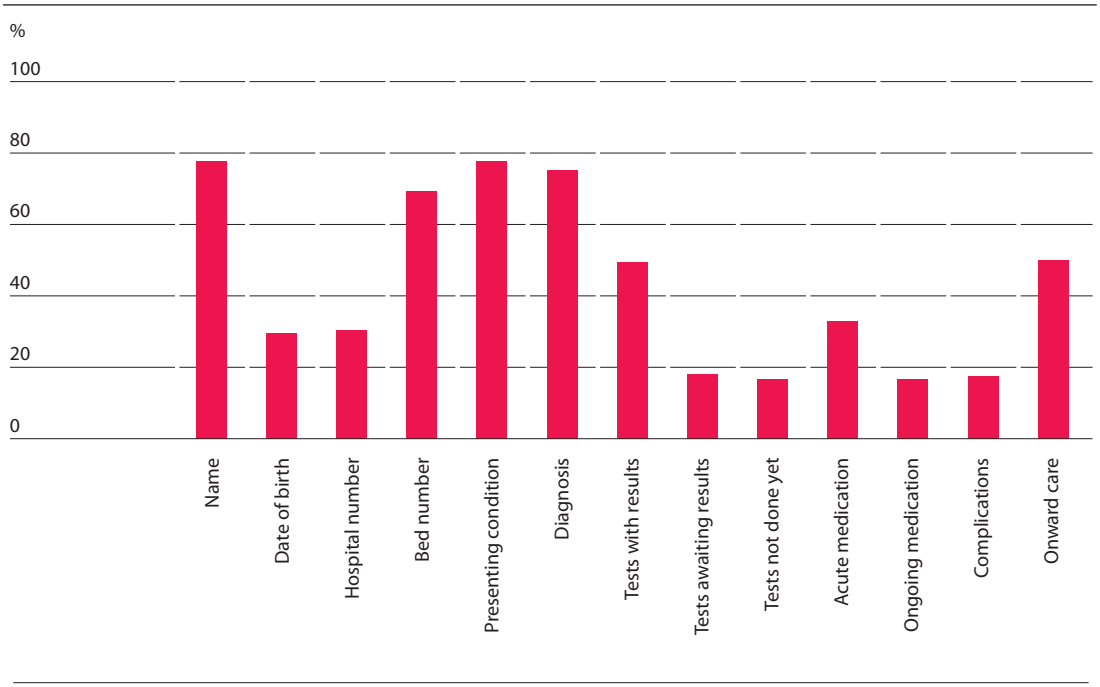
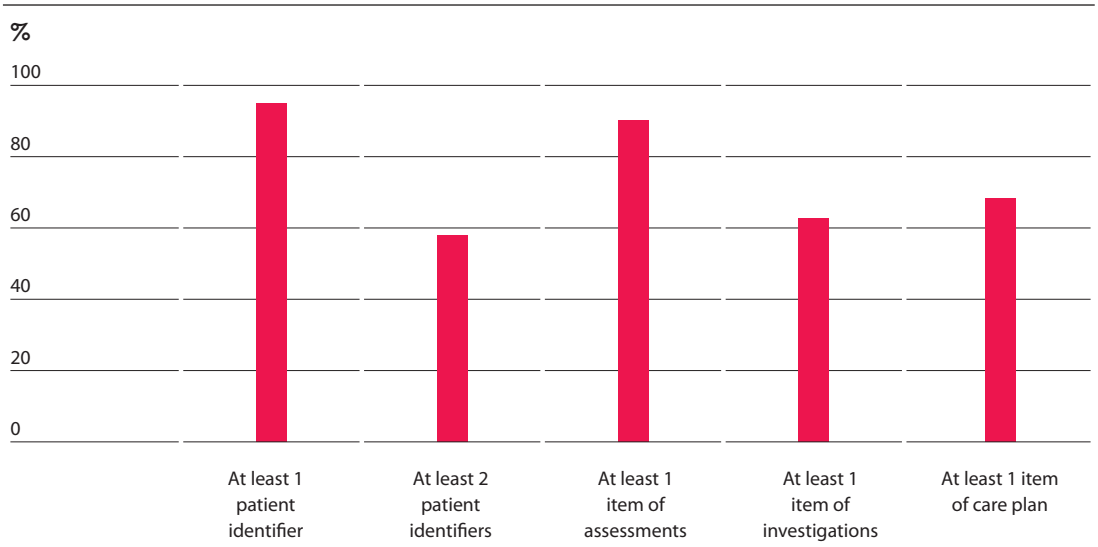


Figure 20: Percentage of patients for whom each broad category of information was communicated at handover



Extent of variability between organisations

Figure 21 and Figure 22 illustrate the percentage of patients for whom individual information elements of the core data set were communicated and the percentage of patients for whom different categories of information were communicated. The greatest variation was for patient identification. Both the date of birth and the hospital number were used in the telephone handover of stroke patients at organisation C.

Staff at the other two organisations, where handover was face to face, relied on either the patient's name, or their location, or both. There was also considerable variation in the number of identifiers that were used.

Figure 21: Comparison between organisations in terms of the percentage of patients for whom each item of the core data set was communicated at handover

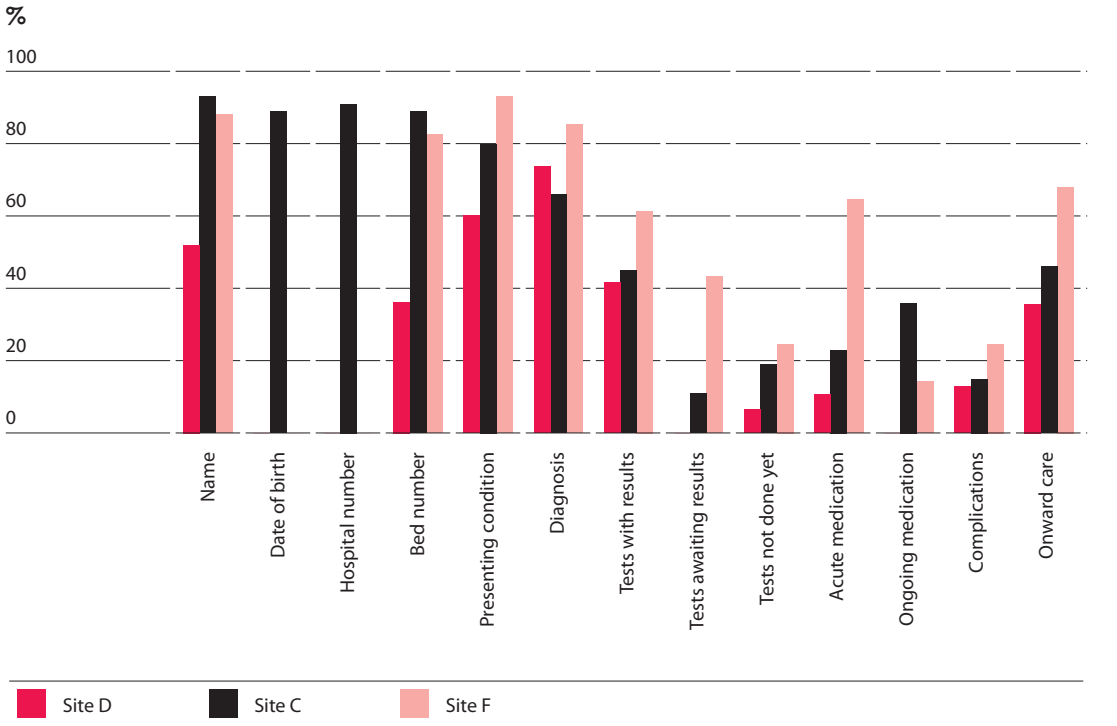
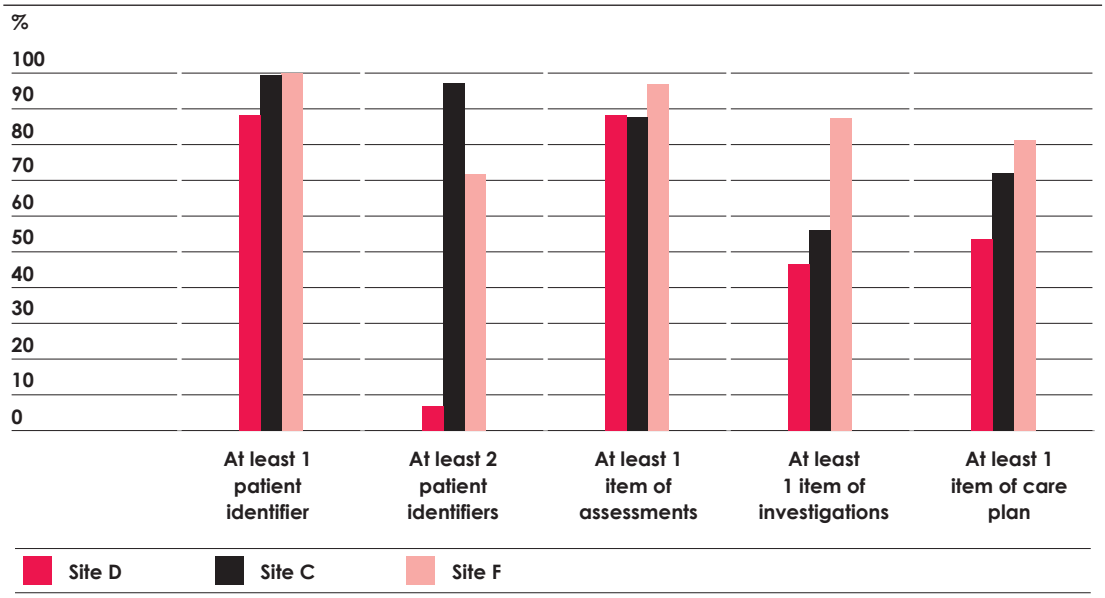


Figure 22: Comparison of organisations in terms of the percentage of patients for whom each broad category of information was communicated at handover



At least two distinct patient identifiers were used in 97% of cases at organisation C (95% CI 94 to 100%), but only 7% at organisation D (95% CI 0 to 15%). Organisation F, with a team based handover, scored consistently higher on the percentage of patients for which the categories of assessments, investigations and care plan were communicated.

Results from system failures analysis

A total of eight interviews were conducted; these were six consultants and two registrars. At organisation C, we interviewed two consultants. At organisation D, we interviewed three consultants and a registrar, and at organisation F we interviewed one consultant and one registrar. Some of the interviewees had also contributed to the development of the core data set; none had assisted with quantitative data collection.

Perceptions about reliability

During the interviews the perceptions of participants about the degree of standardisation and the reliability of the handover were first explored. Most participants felt that the handover was not standardised or reliable, although they varied in their concrete assessment:

'It's, it's... not standardised at all.' Doctor 3, organisation D

'The baseline when we studied it was about 30%.' Doctor 1, organisation C

'I think it's not particularly reliable though, because I think we still miss patients, and we don't hear about all the patients that have been admitted under us, and that's quite a failing.' Doctor 2, organisation C

'I think with again moderate reliability.' Doctor 2, organisation F

One interviewee felt that although handovers were still not very standardised, they were more standardised than they had been:

'I think it's become more standardised because the junior docs use a handover sheet now where they tend to document things, and before they had that it wasn't so standardised, but there's still a fair amount of variability depending on who's doing it, I think, and the other things going on in the department at the same time'. Doctor 4, organisation D

In addition to these explicit responses, the lack of standardisation also became clear from different descriptions about how a handover takes place and the role of the documentation:

'So if I'm looking for,... if I'm being handed over individual patients, then I usually do look through the notes at the same time as hearing it.' Doctor 4, organisation D

'No, it's just a verbal handover...I haven't seen a handover sheet.' Doctor 2, organisation D

In terms of harm, participants agreed that it depends very much on the criticality and the situation of the patient and can therefore range from negligible to serious:

'It could be catastrophic, it could be not, but I can't quantify average number... because if the patient's really ill and we don't know about them that can be catastrophic, if you don't know about them but they're all right it's just inconvenience to the system and the patient and the organisation.' Doctor 2, organisation C

One interviewee felt quite strongly that:

'Oh it's incredible harm. I think it's one of the biggest areas of potential harm for any patient entering our door. It's,... I think the importance and prioritisation we should have on handover is nothing compared to what it should be. Not just within my hospital, within every single hospital I've ever worked in.' Doctor 1, organisation F

In the next sections we report in more detail the factors that affect the quality of handover, presented according to Vincent's factors that affect clinical practice.

Institutional context

Most doctors felt that there was no specific training provided for handover during the medical curriculum:

'No I don't think people have (received training in handover), I think people have a lot of experience in handovers and it might be..., depending on which unit you're working with and which consultants

you're working with, they might all have a different perspective on it.' Doctor 2, organisation D

'I think medics are very bad at handover because it's not part of their education, part of their upbringing, part of their culture.' Doctor 3, organisation D

'We don't formally give training in handover but the middle grade doctors will have worked in this area for some time and so will have been doing handovers for some time and then they [junior doctors] may, they'll just observe how it's done here.' Doctor 4, organisation D

'The second thing would be training sessions in handover. Which we haven't got at the moment but I want to set up.' Doctor 1, organisation F

One doctor also emphasised that training in non-technical skills such as handover is not provided and not recognised as a priority:

'Yeah, they've got virtually no non technical training at all... It's certainly not a priority so they wouldn't be (receptive to training)'. Doctor 1, organisation C

Organisational and management factors

One doctor felt that there is not an effective management structure:

'A functioning operational management structure or a clinical management structure that is able to effect change.' Doctor 1, organisation C

Some doctors commented on incompatible shift schedules and the problems this creates for a team-based handover:

'There isn't always a registrar going home at four that's the other thing, their shifts don't really match up.' Doctor 3, organisation D

'I think everyone hands over individually because all the shifts finish at different times.' Doctor 4, organisation D

'Now the junior doctors' contracts are from nine till five, and the MAU doctors' contract are from eight till four, and noone's found the management time to marry those two together.' Doctor 1, organisation C

Work environment

In terms of the work environment, the main issue related to high levels of workload:

'One of the difficulties that we have is because of the workload. You really need to have a good half an hour before the handover to almost prepare for it, and you can tie up loose ends and you can get sorted in your own mind and on paper, wherever, what needs chasing for overnight. Now, the problem is... when you're on 200% capacity, that time does not exist a lot of the time and you are, ... you try or I try or other people do, to give yourself five, ten minutes but that is just not sufficient. You need sufficient preparation.' Doctor 2, organisation F

'I think people are probably quite hard pressed sometimes and busy and perhaps that bit (documentation) is not done as precipitously as it should be.' Doctor 2, organisation D

'There should be one (handover) at four but not sure it's always happening because that's one of our busiest times.' Doctor 3, organisation D

'Well usually the department is quieter in the morning... Later on in the day, the department is usually much busier and the people...have other responsibilities though there isn't necessarily a fixed time when it (the handover) happens and you're more likely to be interrupted or have conflicting demands on your time.' Doctor 4, organisation D

Team factors

Team factors related predominantly to communication. One doctor felt that junior doctors were not encouraged to challenge or speak up:

'...there's never a huge amount of discussion... unless they are a confident junior they probably wouldn't pipe up.' Doctor 2, organisation F

On the other hand, other doctors felt that among senior doctors communication during handover was essentially a two-way process:

'...from my point of view we usually have an active discussion about people and if I'm not happy about what they're saying then it's questioned and we talk about the management, so it is a two way conversation.' Doctor 2, organisation F

'It should always be a two-way communication.' Doctor 1, organisation F

'If there's a sense that the patient's ill or something needs to be done then it's likely that that will get interrogated and you get much more of a two way dialogue.' Doctor 2, organisation C

This latter issue of the handover being dependent on the perceived criticality of the patient was echoed by other doctors. One doctor expressed quite succinctly the importance of dialogue:

'Sometimes the purpose of the verbal handover is to actually articulate things which may be difficult to write clearly so it may be, you know, when you've written everything down about a patient, it may look very black and white but actually you might think, I'm still not quite sure about this patient or I've still got a bit of a worry and I can't pinpoint what it is. Often it's that kind of thing which you get in a verbal handover which you wouldn't get from reading the notes... What you get from a verbal handover is the subtleties, I think, sometimes as well.' Doctor 4, organisation D

The importance of experience and the responsibility on part of the receiving doctor was also highlighted:

'And you've got to know what those tests are, and you've got to know why they're being done, and if that information is not offered, you've got to go digging for it.' Doctor 1, organisation D

'You know, to not ask that information is negligent. That's why it's there, we do those tests because they will have a bearing on the outcome, so to not ask for those pertinent pieces of information, is negligent.' Doctor 1, organisation D

Another communication factor that was highlighted, was the process of communication that depended on individual initiative and was shaped by individual differences:

'It relies on the individual person taking initiative to do the handover, so I think it, I think it relies on the person who finishes the shift to hand over to the person who's on the next shift and if, you know,... and if that initiative doesn't take place then, then very often the...handover doesn't take place.' Doctor 3, organisation D

Individual (staff) factors

Interviewees pointed out that the quality of a handover is dependent on individual skills and is influenced by different personal styles:

'Then it's really about the quality of the people doing the handover... it's about the where that person is coming from and how wedded they are to the entire process.' Doctor 2, organisation C

'It's often the people. But there will be things documented but some people are much more thorough in their documentation than others.' Doctor 4, organisation D

'Number one, the person handing over. Number two, the, how particular the person receiving the information is, i.e. how accurate they want to have exactly where things are on the plan... Well I can be pretty pedantic so it gets fairly, if I'm the one receiving, I can be pretty pedantic so... it gets fairly reliable, I want to know exactly where we've got, I'm a bit of a veteran T crosser and I dotter.' Doctor 1, organisation D

Task factors

Factors relating to the task included procedures, the time available and other concurrent tasks, and the information that was available.

Procedures

Most participants felt that there was no formal protocol or procedure in place to do handovers:

'No. Well there are guidelines that's being outlayed, aren't there, by The Royal College, but they're not formally followed as far as I'm aware in a hospital level...not that I've been made aware of (a formal procedure).' Doctor 2, organisation F

'The handover in this area is very informal.' Doctor 2, organisation D

'It's not standardised at all and I don't think it's very reliable... I don't think there is a procedure (for handover)... No it's (collation of information) not a formalised process currently.' Doctor 3, organisation D

'There isn't a formal procedure, no. It's an evolved

thing and I suspect there's a bit of variability... I don't think there's any real structure during the evening.' Doctor 4, organisation D

On the other hand, at organisation D all interviewees agreed that certain parts of the relevant patient care are very standardised, which facilitates the handover:

'So there are various pathways to go along, and after a while, particularly as a middle grade, doing it week in, week out, month in, month out, year in, year out, it becomes second nature, it's just the same as writing your own name.' Doctor 1, organisation D

'...the pathways that the patients are actually on, is very standardised and very reliable...They're all on an objective pathway so there isn't any point, if I'm handing over to another, if a doctor's handing over to me, then going into any further detail on those patients at that stage.' Doctor 2, organisation D

However, one doctor at organisation D also pointed out that there was still benefit in standardising the handover even if the patient pathways themselves were already standardised:

'I think there will still be benefits in standardising because we want, we want to come to a point where we do this all the time with everybody in the department.' Doctor 3, organisation D

An exception to the general belief that there are no formal protocols for handover was held by one doctor at organisation F:

'We do (have a formal protocol). We have a policy that defines who should be present. The fact that it's a registered and attended meeting compulsory, the fact that it is sterile and bleep free. And the content.' Doctor 1, organisation F

This particular individual was leading and promoting a lot of improvement work in the area of handover at this organisation, which may explain their different perception.

Time available and concurrent tasks

Interviewees frequently remarked that there was insufficient time to do the handover and that there were other tasks that required their attention:

'On paper if you looked at it in isolation then we have got a time and a place, but actually it conflicts with other things.' Doctor 2, rganisation C

'...for some people it maybe that there's a clash of activities that haven't been properly thought about.' Doctor 1, organisation C

Information availability

Problems were reported in relation to availability of information for patients coming in during out-of-hours periods and in relation to availability of real-time information:

'Yeah, but the patient who has come overnight virtually none of the information.' Doctor 1, organisation C

'Well the data isn't updated, so the patient will have moved wards, you won't know the ward and they may have changed.' Doctor 1, organisation C

'It's a real, the problem is, it's... a real time dynamic list, that is unfortunately chronological in the sense that it's probably updated twice a day. When actually it should be more dynamic.' Doctor 1, organisation F

'Not particularly, the written information is not particularly accurate... I think it gives you a reasonable sense of what's going on...but people generally know and work round it.' Doctor 2, organisation C

One doctor explicitly linked the availability of information to other contributory factors such as individual differences and familiarity with the process:

'It all falls down when, overnight for instance ... when you haven't got a person leading it in there, doing it from their end. So, some nights you can have a very good nurse who's familiar with the processes and knows all about this area, who will update the screen, and update the lists and make sure that all the notes are updated and everything and then it's very easy to get a good picture in the morning. But sometimes you come in and somebody who doesn't really own the process and everything, they might be a bank nurse who never worked there before, so they won't physically know how to update a computer and how to update the lists.' Doctor 3, organisation D

Patient characteristics

In terms of patient characteristics, interviewees agreed that the level of detail and the amount of discussion around a patient was determined to a large extent by the patient's condition, i.e. the sicker a patient, the more thorough the handover would need to be:

'So I mean, my ideal for the handover has always been that it's the patient. It's not for every single patient, because we have hundreds of patients, we don't have time. The people who are either very unwell or people who have interventions that need to be modified based on results that are not available for the first team that asses the patient.' Doctor 1, organisation F

'If the patient who the people are handing over don't think there's anything particularly going on with them, and they're about to go home and everything has been done, then that will be a very passive handover, and the person listening will just receive that information without interrogating it particularly. If there's a sense that the patient's ill or something needs to be done then it's likely that that will get interrogated and you get much more of a two way dialogue.' Doctor 2, organisation C

Defences and solutions

The interviewees identified a number of recommendations for improving the quality of handover.

Standardisation

Standardisation of the handover in terms of participants, time and place, and to a certain extent content was the most frequently discussed recommendation for improvement:

'I would have more structured handover.' Doctor 2, organisation F

'Training sessions in handover ... that when you come into the trust, you immediately get standardised training on what is required of you in handover, what is the trust's standard in handover, what is national standard in handover really.' Doctor 1, organisation F

'I also think somehow, I don't know quite how, greater agreement between the consultant body about how the handover is done would be useful... If there was a standardising when they start on being a bit more rigid about when people start, people tend to drift in and out, and you know what it's like, consultants are all slightly disparate animals and have their own strong views, a lot of them have strong views about the rights and wrongs... but I think you can standardise the place and the time and the process.' Doctor 2, organisation C

'Well I suspect that the,... now having got agreement of what the handover should be and having now got an analysis, a standardisation around where it should be, who should be there, what should be included with the list, I suspect with some targeted energy we'll be able to show a big step change, and once you've got that step change and you can start talking about it, I suspect other teams will want to try.' Doctor 1, organisation C

'I would impose a departmental handover twice a day and I would make it standardised.' Doctor 3, Organisation D

'It would be good if we could get end of the day or middle, you know, interim during the day handovers as clear as they are earlier in the day.' Doctor 4, organisation D

While there was broad agreement about the need for standardisation, there were also cautious remarks about standardising sensibly and appropriately:

'I personally am not a fan of extensive handovers, I think what's important is the sick patients are identified.' Doctor 2, organisation F

'...if someone comes in with a migraine and they're completely fine they can go home, then given that we all have a background of doing our jobs for a number of years, if someone says that to me and says, this patient with migraine there's no problems they came in they were a bit anxious but everything is fine they can go, I wouldn't need to know what the discharge arrangements are because I would trust my colleague having made the referral, having sorted it out, and I think you can only run a system based on trust. Because there are flip sides, you assume that everyone is incompetent unless you can demonstrate they've filled in these fields, and actually the purpose of the handover is to communicate the data effectively, not to generate a paper trail that can be audited to demonstrate that

it's been done properly, and I think if you had a situation where you had 40 patients and each patient you have to say every single line of data whether or not it was actually clinically needed, when it came to an ill patient you'd have, everyone would be bored and you, people wouldn't prick up their ears, and actually that's the important thing.' Doctor 2, organisation C.

Electronic support / prioritisation scheme

Interviewees, particularly those from organisation F, encouraged the adoption of an electronic tool and/or a scheme to indicate the criticality status of patients in order to help doctors prioritise patients:

'I've developed it (electronic handover tool) with some of the people in IT to produce a real time dynamic list of every single patient in the hospital... So it has several sections, presenting complaint, obviously the demographics of the patient, the management plan and the diagnosis, and the awaited tests and how that will influence the outcome. And then finally, a level of intervention, to determine whether patients would be resuscitated should they have a cardiac arrest, or would they be suitable for intensive care. And then free text after that to decide whether the person reviewing the patient during the out of hours time period, have a message for people the next morning who come on to take over the care of the patient. So we have a loop now that's about to start in February that I'm hoping will add the visual and the hard copy and real time dynamic sort of list that I think will improve safety by a lot.' Doctor 1, organisation F

'I would have, I'd probably have a, some kind of recorded database really of the patients that are critically ill, so that everybody is aware at nursing, junior and senior level. So the important things are dealt with overnight. So I would, I think I would have some kind of formalised structured database which has the sick people on it, and what their problem is, so the working diagnosis and the problems that need to be addressed overnight and any outstanding investigations which need chasing...The second thing is outstanding jobs that need doing, so less urgent, so they would be graded, so there'd be a grading system.' Doctor 2, organisation F

'I think there should be a field saying how ill the person is, simply because that's how I believe a lot of medicine works, if someone, if you get phoned up about a patient often the first question is, are they ill? Because if they're not you can relax, and if they are you have to think about it, and do something quickly.' Doctor 2, organisation C

Team-based, multidisciplinary handovers

The adoption of team-based and multi-disciplinary handovers was frequently recommended in order to improve overall situational awareness:

'It's a formal 30 minutes sterile complete handover that involves the incoming and the outgoing medical team who congregate for a 30 minute bleep free period.' Doctor 1, organisation F (reporting on a practice that is being championed in this organisation)

'Handover is not just about one or two people it's about the team, so the team should be there.' Doctor 2, organisation C

'Yeah, but you have to extract it (knowledge about patients), and it won't be known to everybody, but if you have a whole team in the room it will come out... so it's clear that actually at the consultant to consultant handover you do need junior doctors involved to get it accurate.' Doctor 1, organisation C

'They have a sit down handover twice a day about the whole department and so they talk through every cubicle and every...patient and everybody right, and very quickly, but, it only takes about 20 minutes, half an hour but nobody's allowed to actually go on the shop floor unless somebody's dying, until that is done.' Doctor 3, organisation D

Training and Simulation

The absence of training was identified as an issue and the provision of training in handover pointed out as a way forward towards standardisation (see above Standardisation). In addition, the use of simulation and the provision of training in non-technical skills were recommended:

'...so my idea would be to actually video people doing a simulated handover and then you could use it to go to teaching points and training points and learning points so that people improve their practice and then obviously pick them up on things that could be improved.' Doctor 1, Organisation F

'I think the operational management journey is very embryonic, and I think that the, obviously the medical, senior medical journey in terms of non technical skills is very embryonic, but if we're serious about this taking off, two things have got to come together. So I think that the best way for this to be done is, it's going to be so many managers and clinicians off together to get the training, and I did a course at the Royal College of Physicians where I thought that worked really well.' Doctor 1, organisation C

Culture

Several references were made to the need to develop a more open, proactive and pathway-driven culture:

'It's all about getting the right person to do the right job and not having your highly trained doctor doing stuff that another person could be doing when people are waiting. So the purpose of handover is to streamline those out of hours jobs that we have to do into entirely appropriate ones that maximise the time the doctors have to deal with patients who are deteriorating acutely.' Doctor 1, organisation F

'Culture changes from jointly working on the work, we can't change it, it's when you get people work together looking at the system end to end, that that shared understanding emerges which then that blips the culture.' Doctor 1, organisation C

'I can only look at my own practice and know that I don't do it perfectly and it's a question of having the right culture within the environment to allow the inquisition of a senior person by someone of the same grade or someone more junior. And you can only really achieve that if the culture of your working environment supports anyone having a free voice.' Doctor 1, organisation F

'I tend to make it quite clear at the beginning at all the inductions and everything, that one of the things we need to do is be able to challenge each other.' Doctor 3, organisation D

Organisational Issues

The final set of recommendations related to organisational changes in order to ensure that people were actually able to participate in whatever standardised handover format was proposed:

'I mean this applies not only to what you're looking at but to the entire health service is the,... one of the great inefficiencies is that doctors are expected to be the secretaries, and what, if there was more investment and time on, you know vital people to chase results for tests, organise, then our efficiency would go up massively. That is a deficiency all over the health service. And that does again come to down to you know what you're looking at as well, the handovers.' Doctor 2, organisation F

'Oh, you can overcome that (incompatible shifts) because in the morning I think it's only half an hour difference so, would then be a case of letting the, the nursing shift start later or the doctor shift starting earlier or meeting halfway in the middle but I think you do need to reserve that half hour where everybody comes together, either have a walk round as a team or have a sit down as a team.' Doctor 3, organisation D

6.5 Discussion

Summary of results

While there were some differences between organisations in relation to patient identification, there was a clear trend across all three organisations that diagnostic items (presenting condition 77% of patients, diagnosis 75%) were communicated more frequently than items relating to the management of care (outstanding tests 17% of patients, ongoing treatment 17%, complications 18%). This suggests that the focus during handover is on immediate aspects of care rather than on the end-to-end patient pathway.

Systems factors affecting the quality of handover identified during the interviews included:

- Absence of a standard protocol for handover.
- Concurrent activities and competing demands preventing a structured and formal handover.
- Information not being updated in real-time and information flow out of hours being poor.
- The organisational culture being reactive - handover is not seen to be a priority and there is no culture of questioning and challenging.
- Doctors not receiving training in handover or other non-technical skills.

Comparison with the literature

A direct comparison with published studies is difficult due to the differing methods and approaches used across different studies as well as due to the fact that clinical handovers are poorly standardised. To date, there is little systematic evidence as to the actual reliability and potential of harm associated with clinical handovers, and what does exist frequently originates from studies conducted outside the UK. The present study confirms that assessments (presenting condition and diagnosis) were communicated more often during handover than investigations and management, or care plans. This was the case for all three organisations and reflects findings from a study in an Australian emergency care department (Ye at al, 2007). A recent unpublished UK study also found that doctor to doctor handovers were inadequate in acute medicine, general surgery and obstetric-gynaecology wards in a district general hospital (Pezzolesi et al 2009). In Pezzolesi's study, verbal handovers achieved the lowest scores for the patient management plan; scores were higher for current diagnosis and list of current problems.

Other studies (Bomba & Prakash, 2005; Ye et al, 2007; Jagsi et al, 2005) used post-handover feedback to assess whether 'clinically relevant information' was missing, hence it is likely that these studies particularly identified those situations where people felt that they should have been informed about certain issues but were not.

A study conducted in a US hospital employed discourse analysis to assess the type of information discussed during handover between the Emergency Department physician and receiving hospital physician. The study found that the communication was focused primarily on information giving rather than a critical exchange including questions and answers (Apker et al, 2009). This finding was confirmed in part during the qualitative part of our study. However, our interviews also revealed that there was a strong appreciation among doctors of the fact that handover should be a two-way communication with responsibility also on the receiving party to ensure that they get all the information they need.

Recommendations proposed in the literature to improve the reliability and quality of clinical handover frequently include the adoption of a standard protocol (Alvarado et al., 2006; McCann et al., 2007). This is intuitive as many studies (including the present study) provide evidence that there is little standardisation of clinical handover. However, a recent editorial in the Annals of Emergency Medicine also warns of the dangers and frustrations of adopting simple solutions, such as the popular SBAR (Situation-Background-Assessment-Recommendation) method, without having understood and addressed the wider system factors (Patterson & Wears, 2009). The qualitative part of the present study provides some insights into these system factors.

Interpretation

Even though the three handovers that we studied were very different in terms of specialty, number of patients handed over and the specific form in which they were conducted, a number of common threads emerged across all three organisations.

The quantitative analysis of the handovers confirmed prior findings that certain information such as diagnostic information was communicated significantly more frequently than information that was concerned with the management of care. The qualitative analysis suggests that this could be due to the fact that doctors are concerned more with the immediate aspects rather than end-to-end patient care; another explanation is one of practicality, as doctors would like to focus in the limited time available on the most critical patients and their immediate care needs.

The quantitative analysis also established that none of the handovers were standardised and that the way handover was conducted depended on a number of factors, such as the particular individuals involved, the time of day and the demand levels in the department. The qualitative analysis shed some light on the complexity of systems factors that potential solutions need to address. These range from the lack of training in handover and the absence of any training in non-technical skills, to incompatible shift patterns, conflicting concurrent activities and demands, and an overall low organisational priority given to handover. The study suggests that successful interventions will need to address these issues holistically.

It was noted that organisations C and F had one or more clinicians who led and promoted work on handover. At the time of the study, this work was at an early phase and no concrete results were visible. However, the observations and the interviews conducted at the three organisations support a potential hypothesis that at the organisations with a clinical champion in handover there was a greater awareness among staff that handover was an important patient safety issue within their organisation.

Strengths and limitations

The research studied doctors' handover in three very different environments. One environment had few patients to hand over, another environment had moved towards a team-based handover, and the third environment conducted a weekly handover of a large number of patients. The different characteristics of the environment and the patients within the environment make a direct quantitative comparison between the organisations virtually impossible. On the other hand, striking similarities that emerge across such diverse environments reinforce the results of the study with respect to generic deficiencies in the process of handover that are not confined to a single environment or specialty. One could argue that deficient handover is a chronic disease within the NHS.

The design of the quantitative study using a consensus-based core data set allowed a baseline assessment of the percentage of patients for which information items were handed over. This can be a useful tool for a continuing audit of the handover by each of the organisations.

The focus of the quantitative study was on standardisation rather than accuracy as such. During the quantitative study, we only recorded whether or not a particular information item was discussed, not whether this information was correct nor whether it was received and acted upon correctly. Establishing the accuracy of information through an observational study is not possible and requires additional methods, such as post-handover interviews and document review. We also did not consider items that were not in the core data set, but might have been important for individual patients.

The qualitative analysis provided interesting and useful insights into both the systems factors that affect the quality of handover, and ideas for potential improvements. While there was broad agreement among the interviewees around many of the identified issues, the sample of eight participants is too small to provide anything other than an initial set of findings that should be followed up in more detail.

6.6 Recommendations

As pointed out above, a number of systems factors that impact the quality of clinical handover were identified. The recommendations identified by participants to improve handover should therefore be seen as complementary, as it is unlikely that any single intervention will lead to sustainable improvement without addressing the range of factors that were identified (Patterson & Wears, 2009). For example, the introduction of a standard handover protocol may only achieve its full potential when accompanied by appropriate institutional, organisational and specific work place interventions, such as training in non-technical skills, ensuring that there are no competing demands on people's time during handover and the provision of a dedicated location for performing the handover.

Recommendations for improving the quality of clinical handover included:

- Standardisation: agree a standardised handover format including an agreed time and place.
- Organisation: ensure that this standardised format can be enacted in practice. Often departments are busier during the afternoon and handover takes place in an abbreviated or ad-hoc fashion. Interventions, such as streamlining shift patterns for different staff groups, the replacement of multiple specialty-based handovers with a single team-based handover and the introduction of a protected bleep-free time during handover may support staff in following the standard handover protocol.
- Communication: develop team-based handovers; provide an environment for active discussion and (professional) challenge.
- Technology: provide real-time electronic

support systems for handover including a prioritisation scheme for patients (e.g. Red/Amber/Green).

- Training: provide training in handover and non-technical skills, such as through the use of simulation. This could be in medical school or in the hospital setting, or both.
- Culture: progress towards a proactive, pathway-driven culture.

6.7 Conclusion

This study assessed the frequency with which certain information items are communicated during handover and the systems factors that lead to poor handover. Information handed over was concerned more with immediate aspects of patient care and less with end-to-end management of the patient pathway. Clinical handovers in the study organisations were not standardised. There is consensus that standardisation is a first step towards enhancing the reliability of processes (Wong et al, 2008; Australian Commission on Safety & Quality in Healthcare, 2009). However, organisations also need to address other systems factors including training, communication, organisational structures and priorities, and cultural aspects.

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Chapter 7

Reliability of equipment availability in the operating theatre

by Amit Vats, Vashist Deelchand and Krishna Moorthy

7.1 Introduction

According to Vincent et al (2001), one in 10 patients admitted to acute care hospitals suffer adverse events, with 40-50% of these related to surgery (Brennan et al., 1991). Analysis of surgical adverse events reveals that 54% are preventable (Gawande et al., 1999). Considering that over 8 million operations are performed each year in the UK alone, large numbers of patients are coming to preventable harm from surgery. For a few years now, the patient safety agenda has been shifting and risks are now considered to be a product of the underlying factors hidden within the broader socio-organisational context of care delivery (MacReady, 2000, Reason, 2003).

Surgical technology has gone through a rapid and dramatic transformation in the past century and continues to do so. While research into better diagnosis and treatment has been expanding, the need for delivering consistent and reliable surgical care has been largely overlooked.

Under the pressure of a high patient turnover, providing treatment for patients with increasingly complex co-morbidities involves sophisticated technology and is dependent on many individuals from various specialties. Such a system demands a greater degree of inter-professional teamwork and communication. The risks to patient safety associated with high turnover surgery were referred to in many studies e.g. the Harvard and Colorado-Utah studies (Thomas et al., 2000, Brennan et al., 1991).

Half of adverse events in hospitalised patients are related to surgery and almost one third of these occur in the intra-operative period (Gawande et al., 2003, Gawande et al., 1999).

Equipment related problems

Equipment problems are common in operating theatres and not only cause theatre disruption but also, in some cases, inter-professional confrontation and patient harm. Missing and malfunctioning equipment required for a surgical procedure is common in most operating theatres.

Christian et al (2006), in their observation of 10 surgical procedures, found that there were close to 15 additional resources (such as extra surgical equipment) added per procedure after the commencement of an operation. Equipment problems are likely to cause disruptions of workflow, delay case progression and lead to deterioration in the dynamics between team members, as well as compromising patient safety (Christian et al., 2006).

In a survey of UK operating theatre team members, respondents believed that nearly 10% of errors in the operating theatre were related to equipment problems (Flin et al., 2006). The American College of Surgeons' Closed Claims study revealed that in 5% of claims, the errors were equipment-related (Griffen et al., 2007). Equipment failures are also a common cause of stress in the operating theatre (Arora et al., 2010).

Another reason for equipment-related issues to be a potential cause for concern is that surgeons often have to adjust their technique to adapt the

procedure in order to 'work around' equipment problems (Christian et al., 2006). Although this has not been studied in great detail, there is a potential that such an adaptation can result in technical errors. Therefore, in the present study we wanted to explore the reliability of equipment availability in the operating theatres, together with implications for patient safety.

7.2 Objectives

- To create a process map describing how equipment is ordered and supplied to operating theatres.
- To measure the prevalence of surgical equipment failures and non-availability in each of three organisations.
- To identify any variation between organisations.
- To explore the systems factors involved.
- To make recommendations for improving the reliability of ordering and delivery of surgical equipment to theatres.

7.3 Methods

Selection of organisations and theatres

The study was conducted in three hospital organisations across the UK: organisations A, D and F. Theatres were recruited from each organisation to include different specialties: trauma, orthopaedics, general surgery and paediatric surgery. The study was conducted in three theatres at organisation A, and five in each of organisations D and F. The theatre managers at each organisation were initially approached regarding access and initial management approval, together with a discussion of data collection strategies.

Process mapping

The researcher conducted visits to the operating departments at each organisation and engaged operating theatre staff in informal conversations. The information received was used to design a process map showing how surgical equipment was made available for an operation at each organisation.

Definitions

An item of surgical equipment was defined as any resource which is used to perform a surgical procedure. This included the instruments needed for the procedure, any anaesthetic-related equipment, any type of machinery (e.g. suction or diathermy machines), and any other resources needed for the progression of surgery such as sutures, surgical drains or irrigation fluids. It did not include drugs administered systemically to the patient.

An equipment failure was defined as any situation where equipment was not available, was not working, or staff did not know how to use it.

A patient adverse event was defined as an undesired patient outcome that may or may not be the result of errors (Vincent, 2001).

Data collection and analysis

Data were collected over a period of four weeks, including weekends, in the operating theatres selected.

To measure the prevalence of equipment failures in operating theatres, data collection forms were designed for theatre staff to complete after each procedure. In organisation A, the researcher briefed the theatre manager and theatre sisters on how they should be completed. In organisations D and F, the relevant matron and theatre co-ordinator were briefed respectively. These staff were asked to provide onwards briefings to other theatre staff. The forms (appendix 14) were distributed to all the participating theatres; scrub nurses and surgeons were asked to discuss equipment problems and complete a form after each procedure, regardless of whether or not any equipment failures were identified.

In addition, to assess the validity of theatre staff self reporting, we recruited and trained a member of local theatre staff to act as an observer in organisation F for a convenience sample of surgical procedures. We then compared the self-reported data with the observational data, to assess the extent of any under-reporting. Although the observer was normally employed to work in the theatres in organisation F, they did not participate

in the surgical procedure whilst performing the observation.

The form comprised the following sections:

Equipment problem

Under this section, the theatre team was asked to document which item of equipment the problem related to and which surgical procedure was being observed.

Type of equipment problem

There were four categories: not available, faulty equipment, wrong use of equipment (ie when the equipment was not used for its intended purpose), and lack of knowledge on how to use the equipment.

How was the problem dealt with

This section was included to understand how equipment problems are dealt with in operating theatres. There were three options: equipment added (for example, when an item of equipment was missing), equipment replaced/ fixed (for example, when an item of equipment was faulty or broken), and work around the problem.

Did the problem impact on flow of surgery

The impact on the flow of surgery was measured in terms of the time delay the equipment problem had on the procedure. There were five options: no impact, minor (less than five minutes' delay), moderate (delay of five to 30 minutes), severe impact (more than 30 minutes' delay), and surgery cancelled.

Did the problem threaten patient safety

In this section the theatre team discussed and recorded the perceived severity of each failure using a five-point Likert scale in increasing threat to patient safety: no threat, minor threat, moderate threat, potential adverse event, and potential severe adverse event.

Analysis

The denominator was the total number of operations for which forms were completed. We used the Kruskal Wallis test to compare the prevalence of equipment problems between organisations.

Exploring the systems failures

Exploring the systems failures involved semi-structured interviews conducted using a topic guide. The study sample consisted of surgeons, anaesthetists and theatre nurses.

The interviews aimed to explore the factors underlying equipment problems. Healthcare professionals were given a participant information sheet and invited to sign a consent form if they were willing to participate in a 20-30 minute interview. These interviews explored the typical causes of surgical equipment failures in theatres, either face-to-face or by telephone, depending on their availability and which method they preferred. Face-to-face interviews were conducted at a venue of the participant's choice. Interviews were recorded and transcribed verbatim.

The interviewees were asked about any problem with surgical equipment with which they were aware themselves, and were also presented with descriptions of a sample of surgical equipment problems identified in theatres in the quantitative part of the study. They were asked to comment on their likely causes, based on their own experiences. The interview schedule is shown in Appendix 15.

The interviews were then analysed qualitatively, using Vincent's framework as previously described. Thirteen interviews were conducted across the three participating organisations. Coding of a sample of five interviews (39%) was checked by a second researcher to ensure conformity. Furthermore, quotes used for further analysis were agreed upon by the two researchers before they were included in the final report.

7.5 Results

Process map

The process map relating to all three organisations is shown in Figure 23. All theatres had similar processes for the ordering of surgical equipment. Some equipment was 'owned' by the surgical department and some was acquired on loan when

needed. Some equipment was obtained directly from the manufacturers (for example, prostheses). All organisations had an onsite store room where equipment was stored and readily available. Multiple use equipment had to be sterilised before it could be used again. The sterilisation unit at organisation F was in-house while in organisations A and D the sterilisation process was outsourced to off-site commercial sterilisation companies.

The prevalence of equipment problems

A total of 490 operations were included in the study, including 258 at organisation A, 67 at organisation D and 165 at organisation F. The different types of operation studied in each organisation were trauma, orthopaedics, general and paediatric surgery.

A total of 103 cases of equipment failure were reported with 19% (n=94) of operations affected with a minimum of one problem and a maximum of two (average problem rate 1.1, SD±0.3).

Types of equipment failure, and how they were dealt with, are summarised in Figure 24 and Figure 25 respectively.

Figure 26 shows that in about 51% of affected cases, the flow of surgery was affected by the equipment problem, resulting in varying amounts of delay. Most delays were short (less than five minutes). No operation was cancelled due to equipment problems during the course of the study. Figure 27 shows that in 21% of cases where there were equipment problems, the staff involved perceived there to be a potential threat to patient safety of varying degrees.

Table 21 illustrates some of the examples of surgical equipment problems faced by participants.

Variability between organisations

Table 22 shows the extent of variation between the three organisations in terms of the prevalence of equipment failures.

Organisation D had the highest incidence of problems, with 37% of operations having one or more equipment problems, followed by organisation A and organisation F with equipment problems in 19% and 12% of operations respectively. Figure 28 shows the types of equipment failure at each organisation. The Kruskal Wallis test was used to confirm that the differences were statistically significant ($p<0.001$). A post-hoc analysis showed that there were statistically significant differences between organisations A and D, and between D and F ($p < 0.05$; Mann-Whitney test). However there was no difference between organisations A and F ($p = 0.097$).

Figure 29 shows that at organisations A and D, staff were most likely to cope with the equipment problem by working around the problem. At organisation F, the most common response was to replace the equipment or fix the item. Figure 30 shows that at organisations A and F, the majority of equipment problems did not cause any delay to the flow of the surgery. However, at organisation D, the most common response was that the equipment problem caused a minor delay (less than 5 minutes). Site D also had more procedures subject to severe delays (more than 30 minutes).

According to Figure 31, in all organisations staff perceived that the equipment problems did not often cause potential threats to patient safety, although threats to patient safety were more likely to be reported at organisation D than at the other organisations.

Comparison of self-report data with observational data

In organisation F, 43 (26%) of 165 operations were observed and data were collected simultaneously by the observer and the surgical team. Based on the data collected from those 43 operations, only one of the observed operations experienced an equipment problem. The same equipment problem was reported by the observer and the self reporter (100% of 43 operations) suggesting that self reporting was comparable to the observer's reporting. However, for the case in which staff experienced a problem with the equipment, the surgeon reported that the equipment was replaced/fixed and the team had to work around the problem, while the observer reported that an extra item of equipment was added during the operation in order to deal with the problem. Both the observer and the surgeon teams rated the impact on the flow of surgery and patient safety the same.

Figure 23: Flowchart of process for obtaining surgical equipment in all three organisations

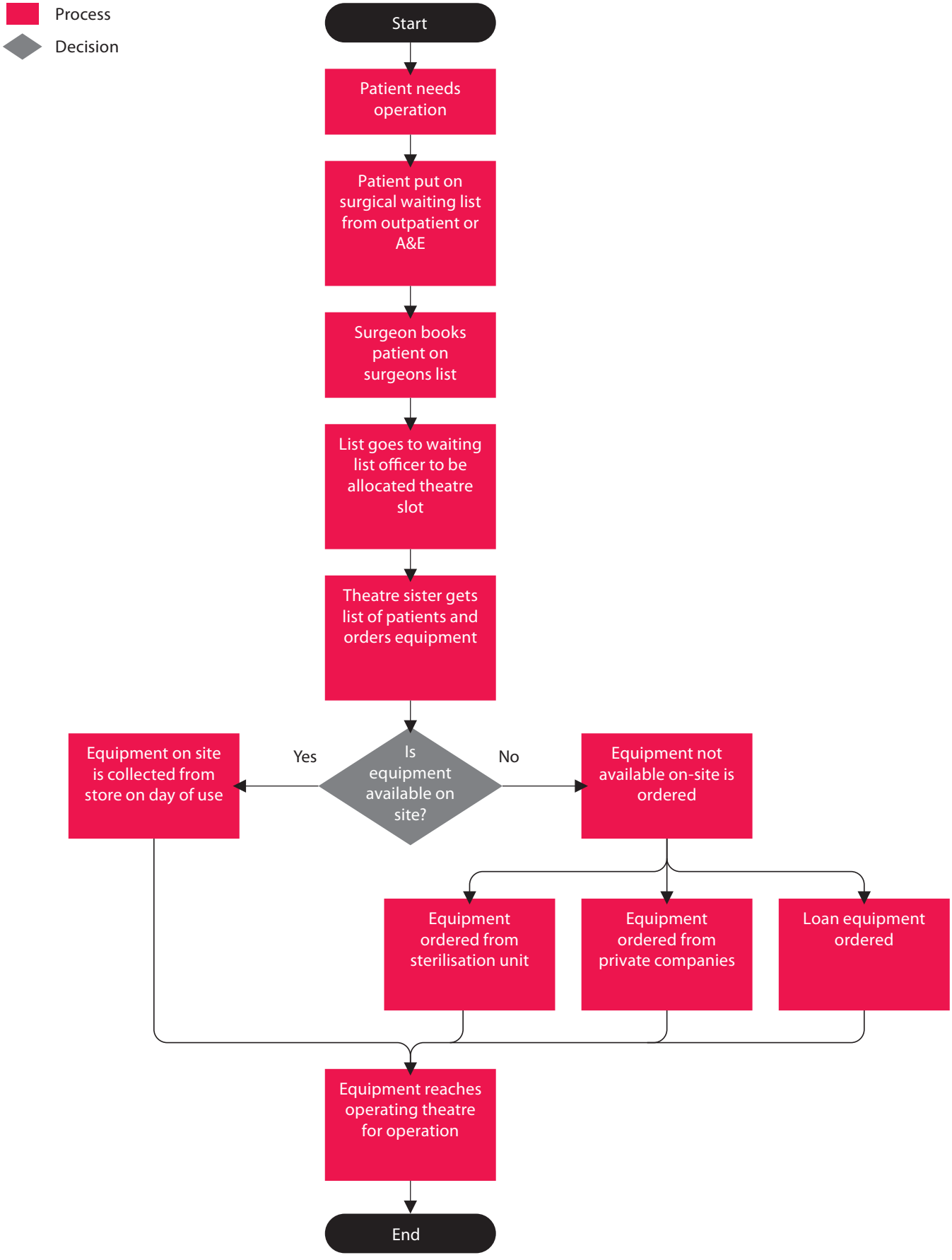


Figure 24: Flowchart of process for obtaining surgical equipment in all three organisations

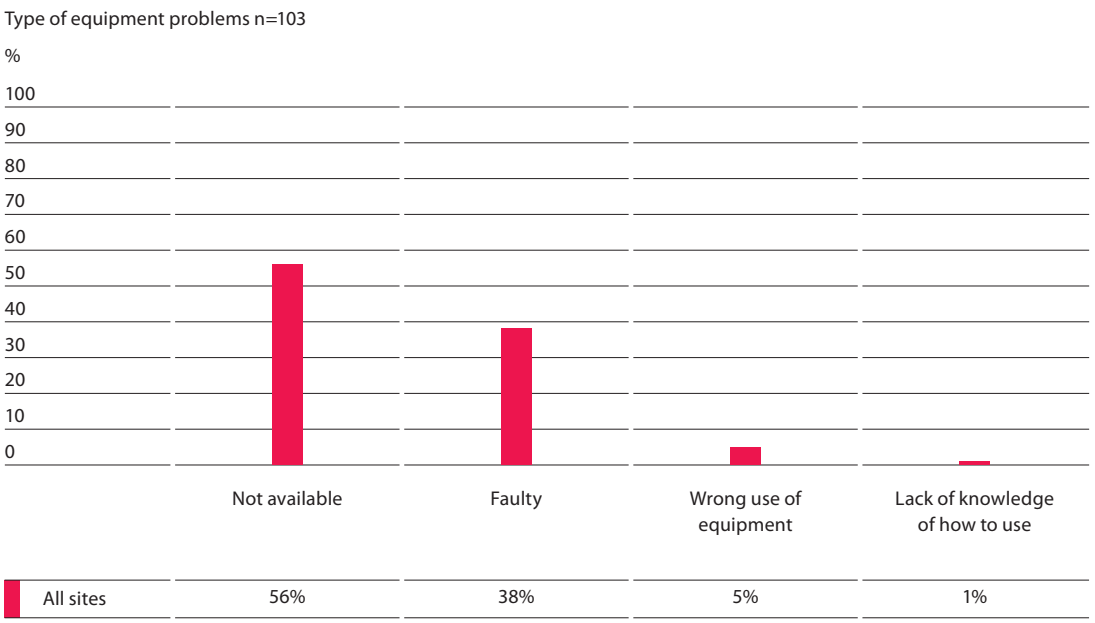


Figure 25: How the equipment problems were dealt with, across all three organisations

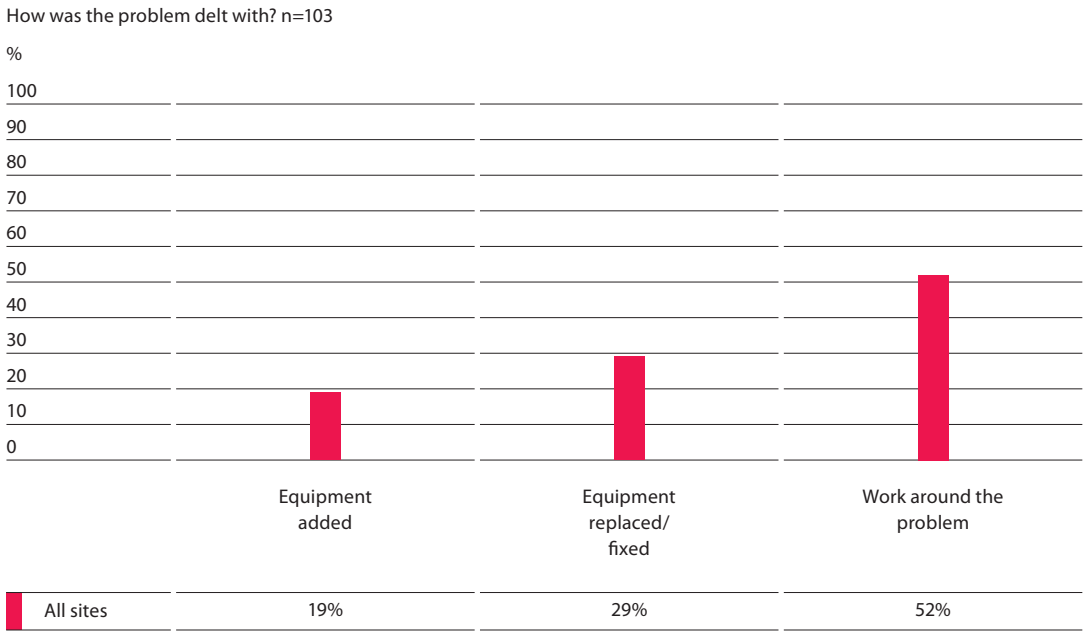


Figure 26: Equipment failures' effect on delays during the procedure, for all organisations combined

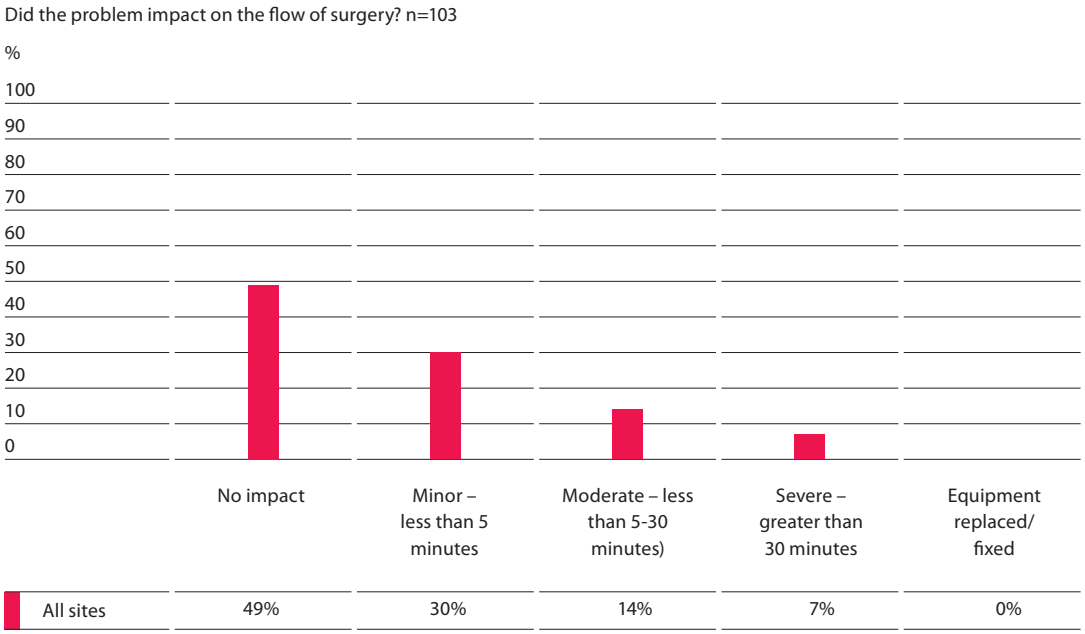


Figure 27: Potential threats to patient safety, for all three organisations combined

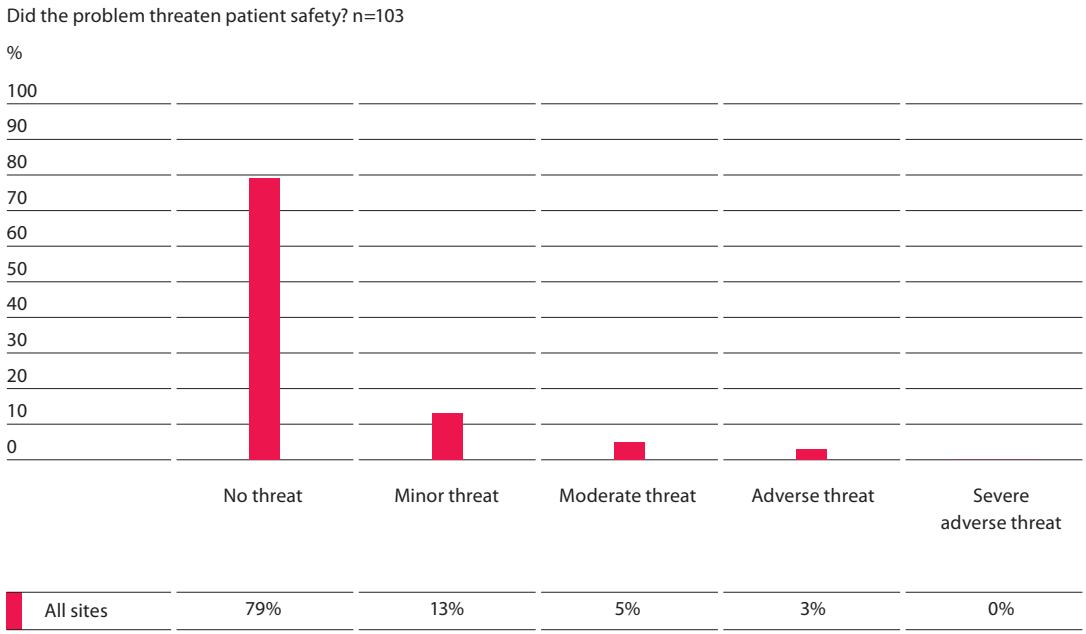


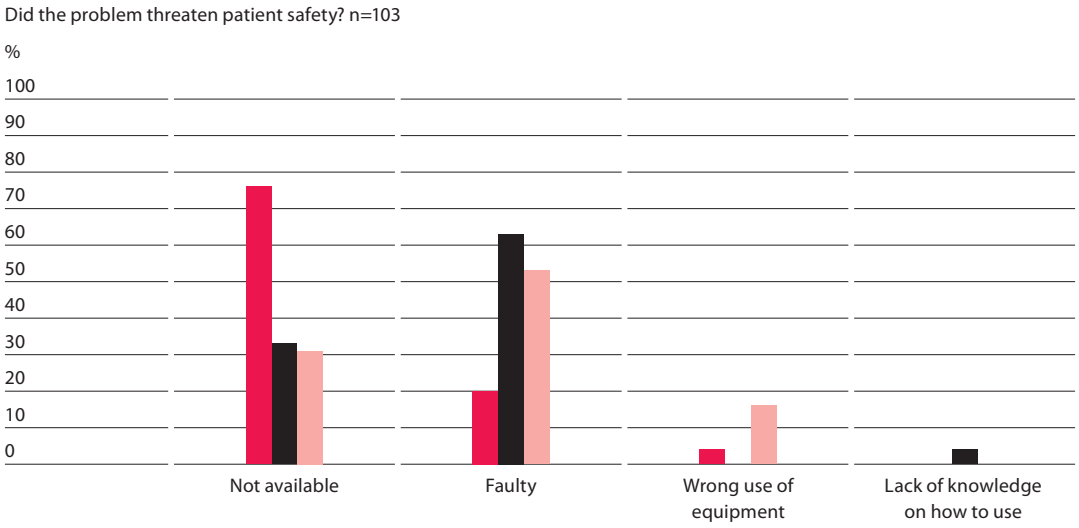
Table 21: Examples of the problems identified

Case Reference	Description of equipment problem	Consequence	Impact on Patient Safety
445 D	During an Orthopaedic knee ligament repair procedure, the special instrument used to harvest tendon for the repair was faulty.	Surgeon had to work without the equipment.	Surgery became technically difficult leading to increased duration of procedure and also the tendon harvested was inappropriate which could impact on patient's quality of life and even failure of repair.
450 D	During a urological procedure (flexible cystoscopy) the cystoscopy machine was found to be faulty.	The surgeon had to work around the problem as despite several attempts the fault could not be corrected.	The procedure had to be performed under suboptimal vision through the cystoscope It posed a moderate threat to patient safety. Moreover it led to severe delay in case progression.
452 D	For an elective list case, the laparoscopic cholecystectomy set was missing.	The surgery was severely delayed due to unavailability of the set. The surgeon had to wait for the set to be made available.	The situation posed a minor threat to safety due to prolonged anaesthetic time.

Table 22: Comparison between the three organisations

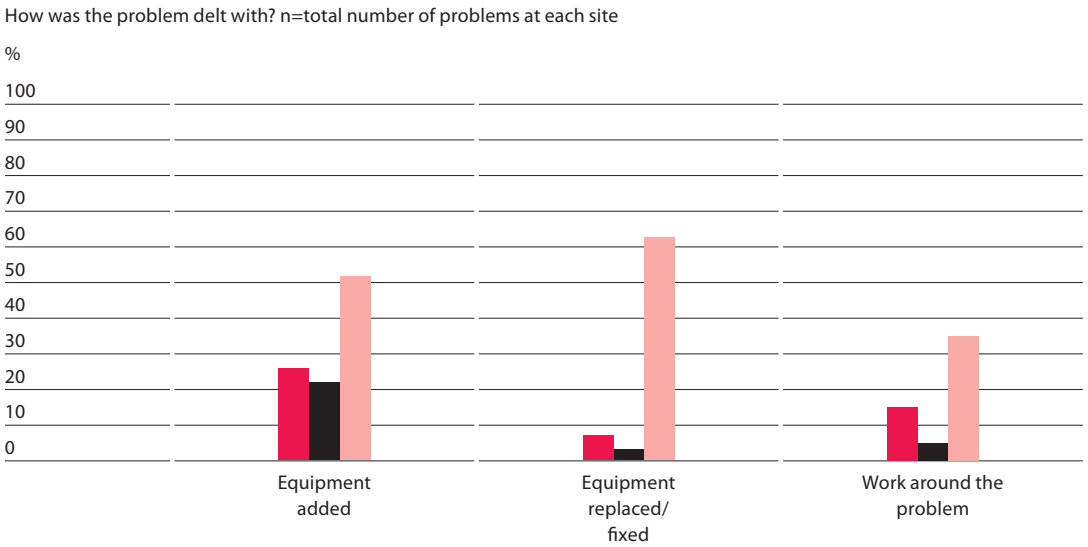
Organisation	Total operations studied	Number of operations with equipment problems	Number of equipment problems	Percentage operations with one or more equipment problems
A	258	50	56	19%
D	67	25	28	37%
F	165	19	19	12%

Figure 28: Types of equipment problem at each organisation



Site A n=56	76%	20%	4%	0%
Site A n=28	33%	63%	0%	4%
Site A n=19	31%	53%	16%	0%

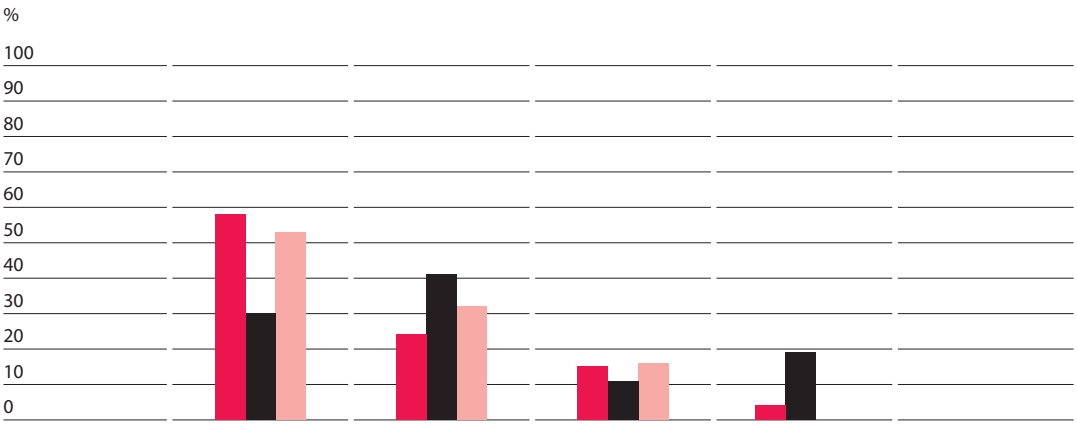
Figure 29: How the problem was dealt with at each organisation



Site A n=56	26%	22%	52%
Site A n=28	7%	30%	63%
Site A n=19	15%	50%	35%

Figure 30: Effect on the flow of surgery, at each organisation

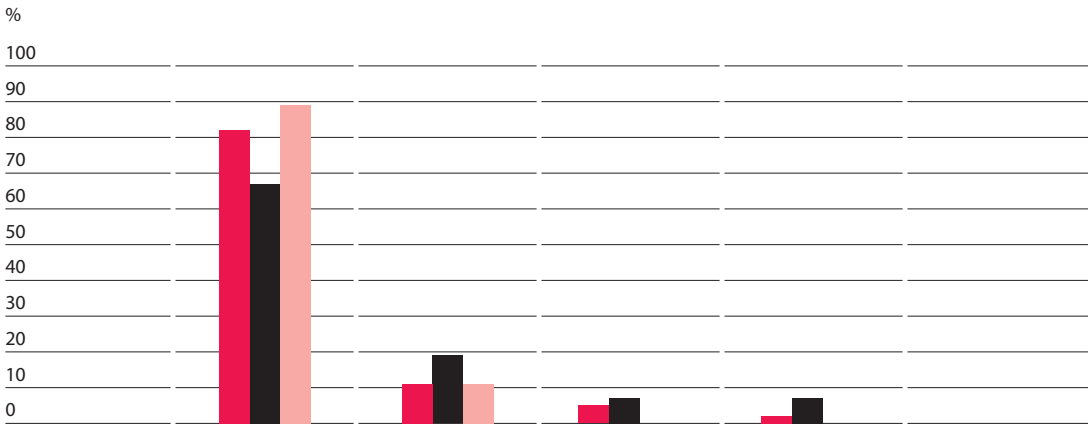
Did the problem impact on the flow of surgery? n=total number of problems at each site



	No impact	Minor – less than 5 minutes	Moderate – 5-30 minutes	Severe – greater than 30 minutes	Cancelled
Site A n=56	58%	24%	15%	4%	0%
Site A n=28	30%	41%	11%	19%	0%
Site A n=19	53%	32%	16%	0%	0%

Figure 31: Threats to patient safety, on each organisation

Did the problem threaten patient safety? n=total number of problems at each site



	No threat	Minor threat	Moderate threat	Adverse threat	Severe adverse threat
Site A n=56	82%	11%	5%	2%	0%
Site A n=28	67%	19%	7%	7%	0%
Site A n=19	89%	11%	0%	0%	0%

7.6 Results from system failures analysis

Thirteen staff members were interviewed in all from the three organisations. Nine staff members were interviewed from organisation A (four surgeons, three anaesthetists and two nurses), two staff members from organisation D (both nurses) and two staff members from organisation F (both nurses). All had also participated in collecting the quantitative data. Coding of the data was based on the pre-established categories adapted from the London protocol for the WISeR study as shown on page 14.

Institutional context

We did not identify any issues relating to the institutional context.

Organisational and management factors

Financial resources and constraints may affect the availability of certain equipment. Interviewees reported that due to financial restrictions, up to date and rarely used equipment could not always be procured.

'No, it's very much up to us. We're still working with some equipment that is very old, 20 years old. You have to keep up to date with the equipment, so that's one thing.' Nurse 1, organisation D

'It could be old equipment, we don't have the most up to date things that are available because of expenditure.' Nurse 1, organisation F

'Occasionally you will find that if you've got somebody who comes in with a trauma injury, and it will be unique stuff that we use maybe two or three times a year that we wouldn't buy to have on the shelf, but that you would hire in. That would be the occasional time whenever you shouldn't have something that's, or you should, it, you'll have something that's not available.' Nurse 2, organisation A

Some expensive equipment gets damaged easily and places more burden on the financial resources available.

'Well we do but it's the cost implication for it. They are expensive and they can get damaged easy.' Nurse 1, organisation D

Organisation A and organisation D have outsourced their sterilisation unit. Although surgical instruments are 'owned' by the theatres, in organisations A and D they are sent off site for sterilisation. In organisation D, the responsibility for replacing equipment when it goes missing between the sterilisation unit and theatres was not always clear.

'And then say to theatres, right we've had to replace them with a new pair of diathermys, then the financial situation, who pays? Where's the money coming from?' Nurse 1, organisation D

Due to recent mergers affecting the organisational structure, sites work slightly differently.

'Because the individual sites do tend to work slightly different, and one of our sites was a merger only two years ago, so they're very used to working on that site, and almost make the expectation when they go to one of the other sites it's going to be exactly the same, and we haven't got that consistency across the board in all specialities yet.' Nurse 2, organisation D

There was sometimes a mismatch between the goals of the outsourced sterilisation unit at organisations A and D; and the needs of the operating theatre. It seemed that the main objective of the sterilisation unit was considered to be to sterilise the equipment, and not necessarily to provide a fully functional and complete equipment tray to the operating theatre.

'Say you open a tray and the diathermy lead's there but with no forceps, you can't use it. You cannot use the diathermy without the forceps, they go together. But on the outside it'll say diathermy forceps missing. What you want is a system in place that if the diathermy forceps are damaged or missing, replace them, set out, it's simple to me.' Nurse1, organisation D

Some problems are recurrent. Learning from mistakes was not always part of staff culture and priorities.

'We always need a colposcope with that list and

time and time again it isn't there or it's broken or it isn't back or nobody knows where it is ' Surgeon 3, Organisation A

Work environment

Equipment items that are shared among several theatre suites may not be available for an operation in specific cases.

'You've got three theatres needing particular equipment. Shall we say you've got three theatres, you've got only two sets of total hip replacement kits, you know, I'm not saying that this was the problem, but I was saying that, for example, we have only two total hip replacement … for instruments. If you've got three theatres who needs that, what would happen with the third theatre if you got only two? So it has to, someone in charge has to check the list first, not only your own list but what's going on to other theatres.' Nurse 2, organisation F

Faulty equipment was sometimes not sent for repair or replaced and was therefore unusable or unavailable for use.

'Maybe it's, I would say it probably isn't maybe checked or sent off to be repaired' Nurse 3, organisation A

'the osteotomes that we cut bone with….they've been around for at least 30 years and they're so over sharpened that they're totally unusable. But they still turn up.' Surgeon 2, organisation A

'Our problems have been the warming blankets, and then various sats [oxygen saturation] probes etc not working, so it's just wear and tear on equipment.' Anaesthetist 2, organisation A

Organisation A uses a system of scanning and automatic delivery for certain store items. However, this system is unreliable and used items are not replenished.

'Some of the things are on top up, which means they automatically get scanned and should get delivered, but for some reason that isn't always you don't always get what you need.' Nurse 3, organisation A

Staff are sometimes rushed between procedures and not enough time is allowed between procedures for pre operative equipment checks.

'I think if people are very rushed for whatever lack of staff, maybe it's not, people have been cleaning from the case before and they've quickly got to set up for the next case. That might be one reason why someone might not, not that it's an excuse or a reason not to, but this might be why people might feel pressure, under pressure and may skip that step.' Nurse 3, organisation A

The sterilisation unit has a high turnover of staff. The work environment for these staff may be a reason for the high turnover of staff.

'they had to then recruit a vast number of staff for night shifts and evening shifts. And people, I don't think, have really enjoyed that work, and there's been quite a big turnover of their staff.' Nurse 1, organisation D

There is a lack of facilities for storing equipment on site.

'The storage that we have on site isn't really very big, and, so storing a lot of the equipment isn't that easy, and it takes up a lot of space.' Nurse 2, organisation A

'It's a nightmare. I shouldn't say that but it's not it's suboptimal. Not very good, we don't have enough space, but perhaps that's always going to be a problem.' Nurse 3, organisation A

'No, none at all, none at all. You have it all in the corridors, as you can see out there, and everything goes on the shelf and instrument trays get ripped where they've been slapped on top of each other and there's no other place to store them so.' Nurse 1, organisation F

Team factors

Prior to the operation, before opening the sterilised equipment tray, theatre staff are not informed of any faulty or missing equipment inside the tray.

'We do know this is a problem so we had some spare telescopes and light leads here ready to use, if that happens. So we have done that, we've tried opening another telescope but then that wasn't good as well. So you can't really know what's in there and how it works in the set.' Nurse 3, organisation A

'There is an intrinsic problem in that you can't actually check they're working before you've opened the set. But there is a step missing there in checking sterile equipment before it's used. Probably the only

way you can do it is to actually open the sets before the patient's asleep and check the equipment's working.' Anaesthetist 1, organisation A

Inadequate labelling of the surgical trays from the sterilisation unit may be the source of some confusion when the tray reaches theatre.

'What we struggle with from sterile supplies, is they don't always label it perhaps quite rightly, and perhaps we need to be more explicit about what we ask them to label it as.' Nurse 2, organisation D

'When, we get the instruments [from the Sterilisation Unit] ... we will check against the checklist for the instruments. And there can be some discrepancy ... Sometimes you should only have six forceps and sometimes it's a hundred forceps but it's only five inside or it could be seven. So you get to be very vigilant, because that can lead to disaster or something can go wrong if you don't count your instruments.' Nurse 2, organisation F

Some information such as that from equipment company representatives on new equipment, delivered during audits or study days, is not passed on to all staff.

'So during the audits, like a rep comes from a company and does not speak to everybody but there, of course, that would come down, the results from that would come down to communication because not everybody will be at the audits…people who were there might get the information but whether or not they pass it on to the next person, that again comes down to word of mouth which is not very reliable.' Nurse 3, organisation A

Communication from surgeons may be lacking. The mode of communication used by surgeons to inform nurses of the equipment they need for a specific procedure is not regularly updated.

'To know what equipment is needed by surgeons, we have kardexes for each surgeon, that our nurses use.... but they need to be updated for new procedures and new surgeons.' Nurse 2, organisation A.

Senior surgeons delegate jobs to junior surgeons who then may not properly communicate information to the team in theatre. In case the patient list changes, sometimes the information is not passed on to the person in charge of the theatre. Sometimes surgeons do not have control of their own list and changes may not be communicated to the surgeons or theatre teams.

'They don't take ownership of it, and they don't take responsibility for it, and what you need is the surgeon to take responsibility and ownership, and then to be communicating out to different people. And one of the things that you have to be very careful about is if they give it, if they give a job to one of their juniors, something gets lost in the translation, and it's like Chinese whispers. So I think it's really important that he communicates, or she communicates with whoever's in charge of that particular area, and then there's a communication to the entire team in theatre, rather than you know.' Nurse 2, organisation A

'I don't think the surgeons are particularly good at communicating, and I think a lot of it revolves around the fact that they're not in control of their own lists, and they have somebody else deciding what's going on their list.' Nurse 2, organisation A

However, according to two surgeons, relying only on a theatre list to determine which equipment may be needed may not be sufficient. The system should allow for enough flexibility in order to provide the surgeon with the specific equipment he/she may require at the point of need.

'I didn't know until I have seen the patient what procedure I'm exactly going to do, because I hadn't seen the patient before and he was on the list for that, for an open procedure and then when I have seen the patient, I decided that it would be better to do it laparoscopically. I discussed it with the patient, the patient wanted to have it done laparoscopically and I told the team that I will do it laparoscopically. What I hadn't told them is what camera I need, because I assumed they will know.' Surgeon 1 organisation A

'I might need that today, I might [need] something else or something specific and that's usually [not mentioned on the theatre list] if it's outside the remit of what you normally do or the other thing is sometimes the theatre list may not exactly have on it what for the operation you're doing so actually ... to come down and say, well actually I'm doing this today and I want this, this, this and this [specific equipment that was not on the theatre list].' Surgeon 3, oganisation A

According to two surgeons, information about

equipment that is likely to be needed but not available or is not working is not highlighted by the nurses prior to the start of the operation.

'It comes to doing the laparoscopy and we're told they don't have any laparoscopes, they haven't come back from the sterilising unit yet,' Surgeon 3, organisation A

Individual Factors

Induction training/ familiarisation with different sites within the same trust is not adequate. Familiarisation for locum staff can also be overlooked.

'Just the way the work plans are, they've just changed things around, and it may be that they predominantly have done a list in one of the sites, and now through various changes, they're doing the list somewhere else. But it's not that frequent, and obviously they may not be as familiar with what they've got on that other site as their normal base site.' Nurse 1, organisation D

'But then this was in the day surgery unit, which is away from the main theatres and they have a, I didn't know that until then, I learned it then actually, they have a reduced amount or a reduced stack of things available there, right there, and if they, if you need a special equipment, although I thought this is not such a special equipment, but for them it was special equipment, you have to announce it in advance, so they will prepare it for the next day or whatever.' Surgeon 1, organisation A

'They have to come in and adapt to our type of equipment which sometimes can be a problem in that because they've not been trained on it and they don't know.' Nurse 1, organisation F

Sterilisation unit staff were perceived to not understand the needs of the operating staff and the surgery. Sterilised trays which are incomplete are therefore sent back to the operating theatre.

'They don't offer a decent salary, and so you get people who are going into TSSU to do a job, where it's absolutely key to get your instruments right. You've got people here working with sets that don't know the first thing about the instruments, don't understand the significance of what happens whenever those instruments aren't available, don't understand the significance of not packing the instrument correctly.' Nurse 2, organisation A

'I'm not saying it was perfect before but there have been lots of issues as in we do get equipment back that obviously the people who are wrapping them don't really have the knowledge or don't really know exactly what's going in the tray.' Nurse 3 , organisation A

'They are there to do a certain job of making sure that it's sterile for us and that tray is like it should be, but they have no interrelation of what the surgical need is.' Nurse 1, organisation D

Theatre nurses may not be trained for specific specialties and cannot find the equipment required.

'Really gynaecology trained theatre nurses, I think that would be the biggest advantage because very often they can't find the equipment we need so we have to compromise and use something which is probably not unsafe but maybe not as good.' Surgeon 3, organisation A

'Whether we make a list of things that we may need for every case, we may not need them but that they should be actually there and available rather than one, two, three people running out of theatre trying to find something and then coming back 20 minutes later and saying they can't find it.' Surgeon 3, organisation A

'And what we're bringing in is, well I've managed to secure funding, so that we have senior sisters for special, by speciality. So that they will be seen as the key person, and then they'll have their deputies, rather than not being too sure who's going to be in that day, or with you at any one time.' Nurse 3, organisation A

Task Factors

It is difficult to check sterile equipment before starting an operation because in order to maintain a sterile field the set will only be opened during an operation.

'Oh yes where it's been rewrapped and said it's fine when actually when you open it the tip is damaged and you cannot use it.' Nurse 1, organisation D

'There is an intrinsic problem in that you can't actually check they're working before you've opened the set. But there is a step missing there in checking sterile equipment before it's used.

Probably the only way you can do it is to actually open the sets before the patient's asleep and check the equipment's working.' Anaesthetist 1, organisation A

Some tasks are not performed, for instance, equipment is not tested or checked before the procedure.

'Eventually it comes down to the surgeon, you're responsible for the equipment but obviously there are situations, so you're supposed to test everything before you start but no-one, including me, is doing that probably all the time, because these are routine things and you just assume that these things are set up properly by the team, but then not.' Surgeon 1, organisation A

'Noone ever checks the diathermy, to make sure it works, before they need it.' Anaesthetist 1, organisation A

Patient characteristics

Prior to an operation, theatre nurses are not informed about the likelihood of the need of any particular instrument specific to the condition of the patient.

'Just before you do the case, maybe saying to the nurse, well actually I might need this today, I might need that today.' Surgeon 3, organisation A

'I don't think that the nursing staff have…the things that they the nursing staff tend not to have the best idea about tend to be the technical, surgical things, what, the positioning of the patient or how long the operation's going to be or what type of specialist equipment you're going to need and ask for.' Surgeon 4 , organisation A

Proposed solutions

Possible solutions were suggested by the participants in areas of communication, training and task allocation.

In order to improve communication, better labelling of items was proposed for sterile supplies and faulty equipment.

'What we struggle with from sterile supplies, is they don't always label it perhaps quite rightly, and perhaps we need to be more explicit about what we ask them to label it as.' Nurse 2, organisation D.

'I have been working in hospitals where they were putting on a tape or something on to the faulty equipment and so when the operation was finished, they sorted it out and they took it to the manufacturer or wherever to fix it' Surgeon 1, organisation A

Visual aids were proposed for sterilisation unit staff in order for them to better understand what is required by the theatre staff.

'One the improvements that I thought of was taking pictures of our sets and bar coding all the instruments,' Nurse 2 , organisation A.

'The companies that you tend to get loans from are very good, because they'll send diagrammatic pictures as well, so it's very clear when you're checking things off, those are the things that you should have on your trays, and they're all the graphic trays, so it's quite easy to see if you've got a gap, what should have been there.' Nurse2,, organisation D.

Better and more specific scanning system may help to counter equipment problem.

'Because you can get bar coders that you can just zap all the way down all the instruments.' Nurse 2, organisation A.

'I think there's probably something around scanning as well, because our trays are scanned to say they leave the site, and they're scanned to say that they're in sterile supplies, and then they're scanned coming back out. But they're not scanned to individual theatres or individual even sites, all we will know is that it's left sterile supplies and it's at Hospital A. Well, Hospital A's got ten theatres, and there's only five that are clustered together, the other five are quite separate. So that's been quite difficult for people, to find out well, where in the ten theatres has it gone back to? And even it may not have gone back to a theatre, it may have gone to an outpatients facility. So I think, and we are currently doing that work around doing almost that secondary scanning so that we can be more precise about where things are.' Nurse 2, organisation D

Better training and exposure for sterilisation unit staff was also proposed.

'But on the back of that people have come and visited from [the Surgical Equipment Sterilisation Unit] and that has helped. And it's a two way

process, they've asked us to visit them as well. And I'm very much the, making sure that that happens.' Nurse 1, organisation D

While training in specific specialty for nursing staff was suggested.

'The main thing that would be good is if we had really gynaecology trained theatre nurses.' Surgeon 3, organisation A

Allocation of tasks to specific people was suggested as a way to maintain the store room.

'In my opinion, a few people will share this, we don't actually have one person allocated to do that, to actually sort out the storeroom, neaten it up, unpack boxes, do this kind of thing, organise it really. I think the expectation is that everyone kind of does it and that doesn't work, doesn't seem to work at the moment anyway. If we actually had, say, one person to do that then it would work. So there may not be lack of space if it was better organised.' Nurse 3, organisation A

Although many of these suggestions would be relatively to implement, none had been implemented in practice, and there seemed to be an acceptance of poor reliability as the norm.

7.7 Discussion

Summary of results

This study shows that equipment problems can affect one fifth of the operations and often surgeons have to work around these problems, which not only leads to delays, but also threatens patient safety. A range of contributing factors were identified.

Implications of the findings

In this study, many factors were identified that could lead to equipment problems. The causative factors behind equipment problems were a complex interplay of communication errors, lack of training and orientation as well as organisational factors such as staffing, space and store management. There is often a lack of communication between surgeons and nurses regarding equipment needs for the procedures on the list. The kardex used by nurses for ordering equipment to be used by a surgeon for a surgery may also be outdated. There is also an element of ambiguity where a surgeon might assume that the nurse would know his or her preferred choice of equipment. Nurses also reported that on a number of occasions, the instruments were missing from the sets. This was largely put down to incomplete sets being sent out from the surgical sterilisation units, suggesting that the staff in the units may not realise the implications of sending incomplete instrument sets. Locum and floating theatre staff members may not be adequately oriented to the specific theatre space and as a result they may not be able to locate the equipment required. This was often a problem when a surgeon needed an instrument during the middle of a procedure.

Analysing the data acquired in this investigation produced a variety of interesting results, some as predicted and some unexpected. We suspected that equipment failure would be common (Flin et al., 2006, Verdaasdonk et al., 2007). The data supported this: 103 of 490 (19%) procedures were associated with one or more equipment problem. The majority of equipment problems related to equipment not being available. This was unexpected as the team had previously suspected that faulty equipment would be the main type of equipment problem (Verdaasdonk et al., 2007). However, the picture was not the same at all organisations. Most equipment problems at organisation A were due to equipment not being available, while at organisations D and F, most equipment problems were due to faulty equipment. Unavailability of equipment may be the result of a bigger problem in theatres e.g. miscommunication between doctors and nurses, especially if scrub nurses were not aware of all the equipment required for the procedure. In order to maintain a sterile field, nurses can only open the equipment pack just before the start of the operation and therefore may not be able to predict if equipment is faulty.

Lack of knowledge on how to use equipment only caused 1% of the problems, allowing one to conclude that most staff were properly trained in using the relevant surgical equipment. Looking deeper into some of the cases, a faulty tourniquet strap used in a knee replacement had to be worked around when it came undone in the middle of surgery. In severe cases, this could have increased

the risk of bleeding and put the patient's life into danger. Wrong sutures and needles were common types of equipment failure and these put patients at risk of having complications after surgery. Scissors and blades not cutting properly delay the flow of the procedure and add unnecessary stress for the staff involved.

Due to the inevitability of equipment failure, it is essential that staff are prepared for these situations. In most cases, staff had to work around the problem, possibly contributing more stress to an already stressful environment.

In most cases, the flow of surgery was affected by less than five minutes and there was no potential threat to patient safety. However in some cases serious concerns were reported. In one such case, the staff perceived there was a potential for an adverse event to the safety of a patient because the stopper on the control knob of an anaesthetic device was not functioning. This equipment defect also caused a delay of more than thirty minutes to the procedure.

It is not clear why one organisation seemed to have a higher incidence of equipment problems; further work would be needed to explore this in more detail.

Comparison with the literature

There is limited knowledge of prevalence of equipment problems in the literature. Our study was novel in many ways in trying to understand these problems, and therefore difficult to compare with the existing literature. In a video observational study of 30 laparoscopic procedures, Verdaasdonk et al (2007), reported that 26 (87%) were associated with at least one incident involving equipment or instruments. They also reported a median time loss of 1.5 minutes per incident. Our study included all types of surgical procedures including open and laparoscopic surgeries and a larger sample size. In our study, 19% of the procedures had equipment problems. There is a marked difference between the two studies. Firstly, our study was dependent on theatre staff reporting equipment problems rather than a trained observer. The staff may have been more likely to report only the major problems that affected their work pattern and may have under reported incidents such as improper set up or connection of equipment. Our study further reports the impact of these problems on safety and contributory causes of these errors.

Strengths and limitations

This is the first study that describes equipment problems in operating theatres in such detail and assesses their impact on flow of surgery and patient safety. The study covered multiple centres across the UK, thereby supporting generalisability of the findings. The study encouraged healthcare staff to assess and report the problems that they considered important, and therefore represents data that are unadulterated with observer bias.

There may potentially have been an under reporting by hospital staff, particularly for those operations where there were no incidents related to surgical equipment. We suspect that data was not completed for all procedures during the study period. Staff may have been more likely to fill in the data sheet when they encountered equipment problems (as they are used to filling in incident forms) and may have forgot to complete the data sheets when they did not encounter any problems. Conversely, it is possible that certain types of equipment problem, such as staff not knowing how to use the relevant equipment, might be less likely to be reported due to staff not wanting to admit that this was the case.

We attempted to quantify any under reporting by observing a sample of procedures in one of the participating organisations. We found good agreement between the two, but this was based only on a sample of 43 procedures during which only one equipment problem was identified. There was also a much lower prevalence of problems in the observed procedures. It is not clear why this was the case; it could reflect under-reporting of problem-free surgical procedures in non-observed cases. Further work is therefore needed to explore the validity of self-reporting in this setting and to assess the extent of any under-reporting.

We initially set out to measure variations between suites of theatres, days of the week and shifts. Unfortunately because these data were not systematically recorded on the data collection sheet by participants, we were unable to analyse these variations.

In relation to the interviews, we were only able to

interview surgeons and anaesthetists at one organisation. Unfortunately at two of the organisations we were only able to interview nurses, and did not interview surgeons or anaesthetists. We were also unable to interview any staff from the sterilisation units. This was mainly due to the limited time frame allocated to complete all interviews at all organisations. Staff tend to be very busy and not available for interviews.

7.8 Recommendations

To resolve the problem of missing equipment there is clearly a need to improve the communication between the surgeons and nurses prior to surgery. Verdaasdonk et al showed that a structured checklist could halve the incidence of laparoscopic equipment problems (Verdaasdonk et al., 2008). Recently the WHO surgical checklist has been mandated in the UK, which provides an opportunity for theatre teams to ensure that the required equipment is available before initiating the surgery (Vats et al., National_Patient_Safety_ Agency(UK), 2009). Online portals may be useful to surgeons in stating the equipment needed for their elective lists. This would not only remove assumptions but also be a learning and audit tool.

To ensure that the equipment sets are not missing any instruments, visual aids can be used to support sterilisation unit staff to better identify equipment that is required by the theatre staff.

There is a need to redesign the procurement system to reduce human error by putting in place checks to ensure that the sets dispatched are complete.

To ensure that the equipment available in the operating theatre suits is easily located and readily traceable, there is a need to redesign the storerooms where equipment is easily identified and located.

Global Positioning System (GPS) technology can be considered for locating expensive equipment that is shared between different theatres.

To reduce human error it is essential that responsibilities are clearly assigned and redundancy added to the system supported by a training and orientation structure that supports new members of staff.

Where the equipment is found to be faulty, a system should be in place to report these errors and ensure that faulty equipment is replaced or repaired.

Also, the staff should be managed more efficiently to ensure that in each theatre there should be senior members who are familiar with the equipment's functioning.

7.9 Conclusion

Equipment problems are common in operating theatres and often surgeons have to work around these problems, which compromises patient safety and cause disruptions in operating theatres. Communications, equipment transit through the sterilisation unit and store management were major contributors to surgical equipment problems. Team training and communication tools such as checklists and team briefings can improve availability of correct equipment at the right time.

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Chapter 8

Safe systems for insertion of intravenous lines

by Matthew Cooke

8.1 Introduction

Intravenous lines (also known as intravascular catheters) are frequently used in hospital, and include both short-term and long-term peripheral and central venous catheters, and arterial catheters. Peripheral venous cannulation is undertaken in a large proportion of patients admitted to hospital. This has the potential to introduce infection into the local tissues at the site of cannulation or directly into the blood stream. A quarter of a million central venous catheters (CVCs) are used annually in the UK, however, the number of peripheral catheters used is not known. In the USA around 300 million catheters are used each year, of which three million are CVCs and 200 million peripheral intravenous catheters (Maki, 2008).

Catheter-related bloodstream infections are associated with significant morbidity, mortality and costs, and are one of the most common types of hospital-acquired infection (Eggimann et al., 2000, Department of Health, 2007a). In 1994, an Australian study (Collignon, 1994) showed a bacteraemia rate of 0.33 per 1,000 cannulae, and a study in 2003 (McClaws et al, 2003) demonstrated an infection rate of 0.2 per 1,000 intravenous cannula days. The organisms most commonly isolated from all types of intravenous cannulae are coagulase-negative staphylococci, usually skin organisms (35% of infections), with Staphylococcus aureus the second most common (25%) (anon, 2004); these organisms are skin commensals, confirming that the intravenous line infections are most likely to have been caused by organisms introduced from the skin. According to a survey of the prevalence of bloodstream infections in England, 42.3% are central-line related (Department of Health, 2007a) while in the USA, 250,000 cases of CVC-related bloodstream infection occur annually in hospitals (Muto C, 2006).

In order to reduce the incidence of harm to patients during intravenous cannulation, improvements in the process of delivery of care have been proposed. The American Center for Disease Control has produced extensive evidence-based guidelines for the prevention of infection associated with peripheral intravenous cannulae and central venous catheters (O'Grady et al, 2002).

In England, the Department of Health has devised the 'Saving Lives' programme consisting of High Impact Interventions (care bundles) to guide specific elements in the process of delivery of care. A care bundle is defined as a protocol put in place to ensure that a set of actions is performed using the latest evidence-based techniques. For instance, High Impact Intervention No 1 relates to the implementation of a Central Venous Catheter care bundle, while High Impact Intervention No 2 focuses on the implementation of a Peripheral Intravenous Cannula care bundle (Department of Health, 2007a, Department of Health, 2007b).

A study published in 2004 found that, in order to comply with the existing guidelines for central line insertion, a physician had to go to eight different places to collect the equipment needed for the procedure and that this could be a barrier to following the established procedures (Berenholtz SM, 2004). Two studies looking at the effectiveness

of implementing a central line care bundle showed that provision of adequate equipment at the point of need was essential in supporting frontline staff in complying with evidence-based care bundle guidelines (Berenholtz SM, 2004, Galpern D et al., 2008). Another study demonstrated the need for a standardised list of equipment for a catheter insertion kit that included all supplies required to adhere to recommended guidelines (Muto C, 2006).

In this study, the availability of equipment for the safe insertion of peripheral intravenous lines was assessed. The measure chosen was the availability of equipment needed to comply with the requirements for the delivery of the care elements from the Dept of Health High Impact Interventions Number 2. This topic was not studied by any of the organisations participating in SCS, but was chosen by the research group as an additional topic.

8.2 Objectives

- To create a process map and description of how equipment is supplied and made available to the relevant clinical areas.
- To measure the reliability of the correct equipment being available for insertion and care of peripheral IV lines.
- To explore the systems factors involved in providing the correct equipment required for safe insertion of IV lines.
- To make recommendations for improving the reliability of processes of ensuring availability of equipment for insertion of IV lines.

8.3 Methods

Methodological considerations

There are national guidelines relating to the insertion of peripheral intravenous cannulae in the form of care bundles, which describe the equipment required. Therefore it is possible to measure the reliability of the system to deliver these pieces of equipment to the clinician at the point of care. Failures can be defined as not having these individual pieces of equipment available. The potential for harm is more difficult to assess as the individual inserting the cannula may not detect the harm from any infection caused, as this could occur several days later and potentially in a different location. Therefore any assessment of the risk and harm has to be based on subjective views of those inserting the cannulae combined with the risks identified in the literature.

We chose to study this topic by asking staff how equipment supply chains work in their unit, asking staff to report on the availability of equipment for each peripheral cannula insertion and the potential impact of any non-availability, and by interviews to explore the causes of such problems.

Selection of organisations and wards

The study was conducted in three hospital organisations: A, D and F. All three organisations were in England, as the Department of Health guidance applies only to England.

At organisation A, the managers of the Accident and Emergency department of the hospital and High Dependency Unit were approached for permission to conduct the study involving their staff.

At organisation D, the matron and the consultant research lead of the Accident and Emergency Department were approached.

At organisation F, the sister in charge of the medical assistants was approached to request participation in the study.

The areas studied and the staff undertaking cannulation in each organisation were as follows:

- Organisation A: Two accident and emergency departments and two acute admissions wards were studied. Cannulation was undertaken by nurses, doctors and medical assistants. At this organisation prepared packs were used which included a single cannula. Disposable tourniquets were used.
- Organisation D: We studied the accident and emergency department, where cannulae were inserted by doctors or advanced clinical practitioners (who may be from a nursing or allied health professional background). In this organisation, cannulation packs were available but did not contain the cannula. These were situated in a trolley containing extra equipment. Disposable tourniquets were routinely used at

this organisation; local policy banned the use of reusable tourniquets.

– Organisation F: We studied medical wards. Intravenous peripheral lines on all wards were inserted by Medical Assistants. No prepacks were available and all equipment was provided separately. Disposable tourniquets were generally available but not mandatory.

None of the three organisations changed relevant procedures during the course of the study nor undertook any intervention for improving the process.

Process mapping

A researcher conducted visits at each organisation and engaged in informal conversations and interviews with staff to identify:

– The process involved in acquiring the equipment identified for the safe insertion of peripheral lines.
– How the equipment was stored.
– Provision of any visual management systems (systems that enable stock levels to be easily seen and monitored).
– How restocking was initiated to detect systems of stock control and feedback.

The information received was used to design process maps showing how the equipment was made available to staff at the point of need.

Definitions

The equipment needed for the safe insertion of a peripheral line was identified using the High Impact Intervention guidelines created by the Department of Health. According to these guidelines, the risk of infection is reduced when all elements within the care bundle are performed every time and for every patient. The availability of sharps disposal bins is also an issue for staff safety. In order to support the frontline staff while they performed intravenous line insertion, we wanted to measure whether the appropriate equipment required was fully available. We studied whether the equipment was available on each occasion it was required or whether staff had to hunt to find the right equipment.

The items in the insertion of a peripheral line care bundle are:

– hand hygiene facilities (hand washing facilities or alcohol gel)
– personal protection (usually gloves alone but when indicated may include apron, goggles etc)
– skin preparation (e.g. 2% chlorhexidine but not restricted to this)
– clean tourniquet (single use or reusable)
– intravenous cannula of appropriate size
– specific intravenous cannula dressing
– sharps disposal bin.

An equipment failure was therefore defined as one of the above items not being present, or not being suitable for use.

Denominator

The denominator was the total number of peripheral IV line insertion procedures that were studied over the data collection period. There could be more than one cannulation procedure per patient if more than one cannula was required, or if more than one cannulation attempt was required for the same cannula.

Quantitative data collection and analysis

Staff at organisation A helped to design a data collection form, which was then used to document details of equipment failures during peripheral IV line insertion. At organisation A and D, the infection control nurses and ward managers were given instructions on how to complete the data forms.

The forms were distributed to all the participating wards, and staff performing peripheral IV line insertions were asked by ward managers or infection control nurses to complete the forms as soon as possible after each procedure.

The infection control nurse or nurse in charge was asked to co-ordinate the data collection in each clinical area. On site F, a vascular nurse was in charge of all the medical assistants who were responsible for line insertion. The vascular nurse, together with two medical assistants, was taught

how to complete the data collection forms. Site D lost the data collection forms and restarted data collection with a locally modified form which did not include details of how the problem was dealt with.

The data collection form (appendix 16) required details of the following:

Equipment used

In this section, the participant had to document the items of equipment from the list that were used.

Type of equipment problem

This was included in order to classify the type of equipment problem involved. The participant had to decide between four options to denote whether each piece of required equipment was available, partially available (for example, staff had access to a sink but the soap dispenser was empty), faulty, or not available.

How was the problem dealt with

This section was included to understand how the participant coped when faced with any equipment problems: Replaced from another area, for example, was any equipment added during the procedure as a consequence of the equipment problem; work-around, for example, the participant found another way of completing the procedure with what he/she had available; postponed procedure, the procedure was not performed.

In your opinion what was the impact on patient safety

Impact of the failure of equipment availability on patient safety was assessed using a Likert scale which recorded the observer's perceived consequences for each failure. The categories were:

- no threat
- minor threat
- moderate threat
- potential adverse event
- potential severe adverse event (as defined by NPSA).

Exploring the systems failures involved

Potential participants were approached by the researchers through our local contacts in each organisation. Participants were first contacted by telephone or email. Our aim was to interview a sample of health care professionals with an understanding of the issues in supplying and inserting IV lines. At each site, we aimed to interview one or two:

- nurses
- doctors
- medical assistants
- ward managers
- service managers.

Interviews were conducted face to face using a semi-structured interview schedule (appendix 17). An initial coding frame was constructed by one researcher based on (page 14) and then revised by a second researcher. Coding of 50% of the interviews was checked by a second researcher; after the initial coding was completed. Discrepancies were reviewed and recoded after discussion and agreement between the two.

8.4 Results

Process maps

We developed a generic process map of the procedure used for restocking those items regularly used for intravenous cannulation at the study organisations. Figure 32 shows the process for ordering cannulae; processes for other items of equipment were the same.

This demonstrated that stock levels of most items were routinely maintained by a system of regular orders of identical amounts of equipment, followed by adjustment of future orders in the case of over-stocking or shortage. There were no specific systems in place to allow ordering to be balanced against demand or utilisation, meaning that there was a potential for overstock or non-availability of items depending on the difference between actual and expected usage.

The level of stock required for each item was determined by previous experience rather than by formal analysis. The map below demonstrates the ordering system for cannulae used in all organisations; the ordering systems for other items was similar. All three organisations used 2% chlorhexidine / 70% isopropyl alcohol with a skin applicator ('Chloraprep') for skin preparation.

Reliability of equipment availability

Across the study organisations a total of 350 peripheral intravenous cannulae were studied during the four week period of observation. A total of 47 incidents of non-availability or non-functional equipment occurred in 46 cannulation operations (one cannulation procedure was associated with 2 equipment problem), representing an incidence of 13.1% of cannulation procedures, hence cannulation without equipment problems had a reliability of 86.9%.

Variability between organisations

At organisation A, we identified 15 equipment problems in 15 (19.7%) of 76 cannula insertions (Table 23). Table 24 shows more detailed information on the type of problem encountered by staff and how it was dealt with. All incidents related to availability of cannulae, tourniquets and sharps bins.

In the two incidents involving IV cannulae, an IV pack with the appropriate cannulae size was not available. In five cases, staff stated that the small sharp bins provided were unsafe to use. Disposable tourniquets were not available in eight cases and staff had to use rubber gloves as tourniquets instead. In thirteen cases the lack of equipment was perceived by staff to have no potential impact while they perceived potential for minor impact in two cases.

At organisation D (Table 25), 62 cannula insertions were studied with seven of these (11.3%) associated with equipment problems. At this organisation the problems were mainly related to availability of skin preparation and correct dressings. In all cases, the problem was resolved by replacing the missing equipment from another area of the department. In four cases the lack of equipment was judged to have had no impact and in three cases a minor impact. Since the data collection form was modified locally, no data were collected on how the equipment problems were dealt with at this organisation.

At organisation F (Table 26), 212 cannula insertions were studied; with 24 cannulation procedures (11.3%) experiencing 25 equipment problems (one cannulation procedure had two equipment problems). In this organisation more detailed information was recorded by participants on the type of problem and how it was dealt with. This organisation also experienced problems with availability of cannulae and sharps bins but also had difficulty with skin preparation and dressings. In 10 of the 25 equipment problems staff replaced a piece of equipment with an alternative, and in 12 cases relating to sharps bins used a workaround using a bin in a distant location. In 19 cases the lack of equipment was perceived by staff to have no potential impact while they perceived the potential for a minor impact in four cases and the potential for moderate impact in two cases.

Types of equipment problem

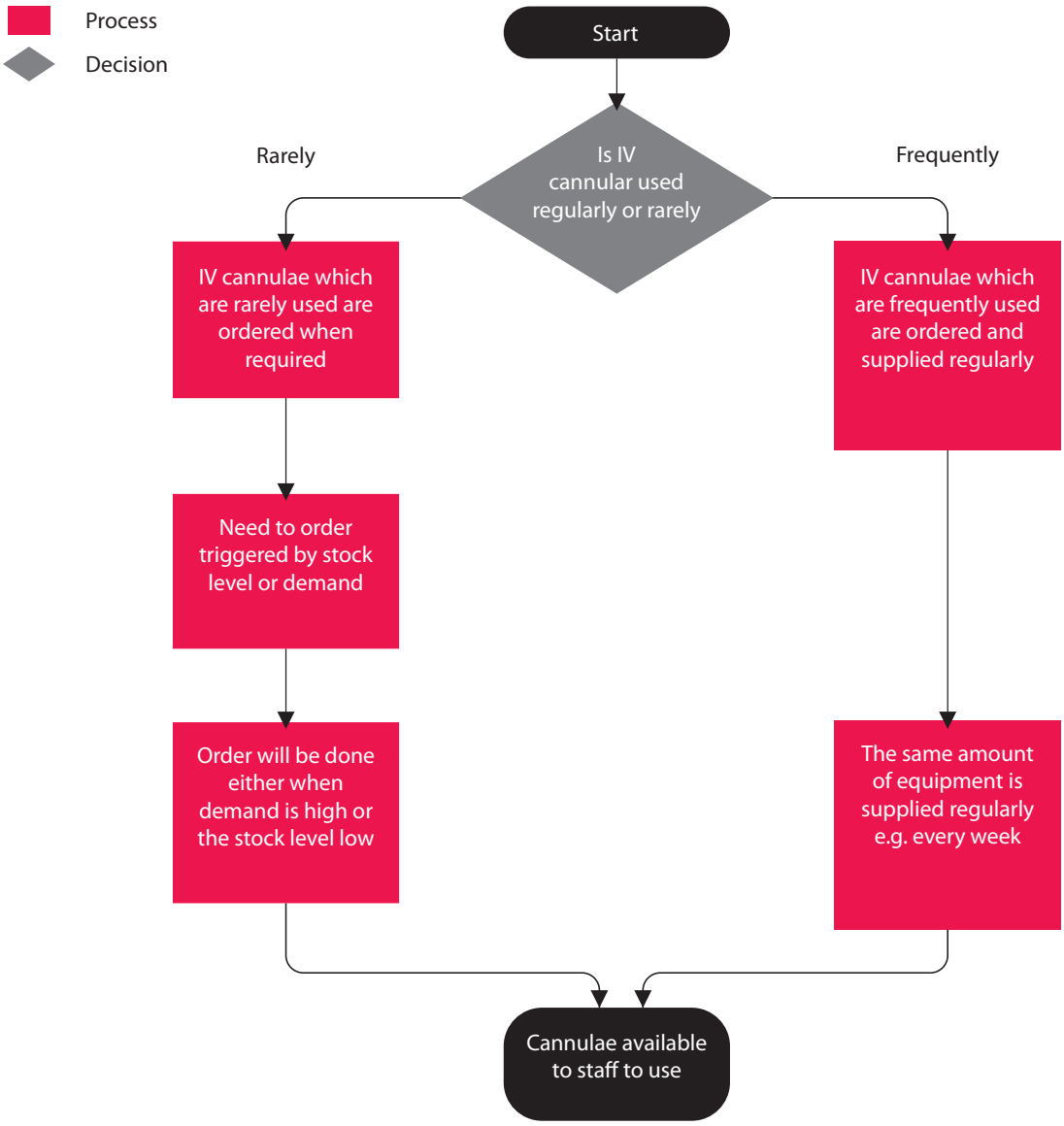
A summary of the incidence of all non-availability incidents is given in Table 27 below. It can be seen that non-availability of an empty sharps bin accounts for a high proportion (51%) of all incidents.

At all organisations the participants also gave their opinion of the possible impact on patient safety of the non-availability or non-functioning incident (Figure 33). Most perceived there to be either no impact or minimal impact on patient safety.

Results from systems failures analysis

A total of eight semi-structured interviews across three organisations were conducted. The participants' professions at each organisation are listed in Table 28. In organisation A, the nurse and ward manager had also been involved in quantitative data collection. In organisation D, the advanced clinical practitioner had been involved in data collection, as had the medical assistant interviewed in organisation F.

Figure 32: Process map for ordering of IV cannulae across the study organisations



Staff were asked similar questions, accepting that some may only know some components of the supply chain and process of cannulation.

The issues identified will next be presented according to each stage of the model of factors that affect clinical practice.

Institutional context

No relevant issues were identified in this category.

Organisation and management factors

The only issue identified here related to purchasing policy. Some organisations use disposable tourniquets but one interviewee commented that:

'They were great but apparently they're really expensive and the trust wouldn't buy them', Participant 1, site F

This meant that reusable tourniquets were used, which have the potential to be less clean.

Table 23: Type of equipment failure and the staff group inserting the cannula at Organisation A

Organisation A: Type of Equipment failure										Staff category		
Department	Total lines inserted	No of equip. failures	IV cannula	Hand hygiene	PPE	Skin preparation	Dressing	Sharps bin	Tourniquet	Nurse	Dr	Medical Assistant
Ward 1	7	0	0	0	0	0	0	0	0	7	0	0
Ward 2	34	3	1	0	0	0	0	0	2	27	7	0
A&E 1	21	8	1	0	0	0	0	2	5	0	21	0
A&E 2	14	4	0	0	0	0	0	3	1	14	0	0
Totals	76	15	2	0	0	0	0	5	8	48	28	0

PPE: personal protective equipment

Table 24: Type of equipment failure in organisation A and how they were dealt with

	Total per item (% of non availability)	Type of problem			How was problem dealt with		
		Part availability	Faulty	Not available	Replaced	Work around	Postponed
IV Cannula	2 (13%)	1	0	1	2	0	0
Hand Hygiene	0	0	0	0	0	0	0
PPE	0	0	0	0	0	0	0
Skin prep	0	0	0	0	0	0	0
Dressing	0	0	0	0	0	0	0
Sharps bin	5 (33%)	5	0	0	1	4	0
Tourniquet	8 (54%)	1	0	7	0	8	0
Totals	15 (100%)	7	0	8	3	12	0

PPE: personal protective equipment

Table 25: Type of equipment failure and the staff group inserting the cannula in organisation D

Organisation D: Type of equipment failure										Staff category
Ward	Total Lines inserted	No of equip. failures	IV cannula	Hand hygiene	PPE	Skin prep	Dressing	Sharps bin	Tourniquet	ACP
A&E	62	7	0	0	0	2	5	0	0	62

PPE: personal protective equipment
ACP: Advanced clinical practitioner

Table 26: Type of equipment failure in organisation F and how they were dealt with

	Total per item (% of non availability)	Type of problem			How was problem dealt with		
		Part availability	Faulty	Not available	Replaced	Work around	Postponed
IV cannula	2 (8%)	0	0	2	2	0	0
Hand hygiene	0	0	0	0	0	0	0
PPE	0	0	0	0	0	0	0
Skin prep	1 (4%)	0	0	1	1	0	0
Dressing	2 (8%)	2	0	0	2	0	0
Sharps bin	20 (80%)	17	0	3	5	12	0
Tourniquet	0	0	0	0	0	0	0
Totals	**25 (11.7%)**	**19**	**0**	**6**	**10**	**12**	**0**

PPE: personal protective equipment
In this organisation we studied medical wards, and all cannulae were inserted by medical assistants

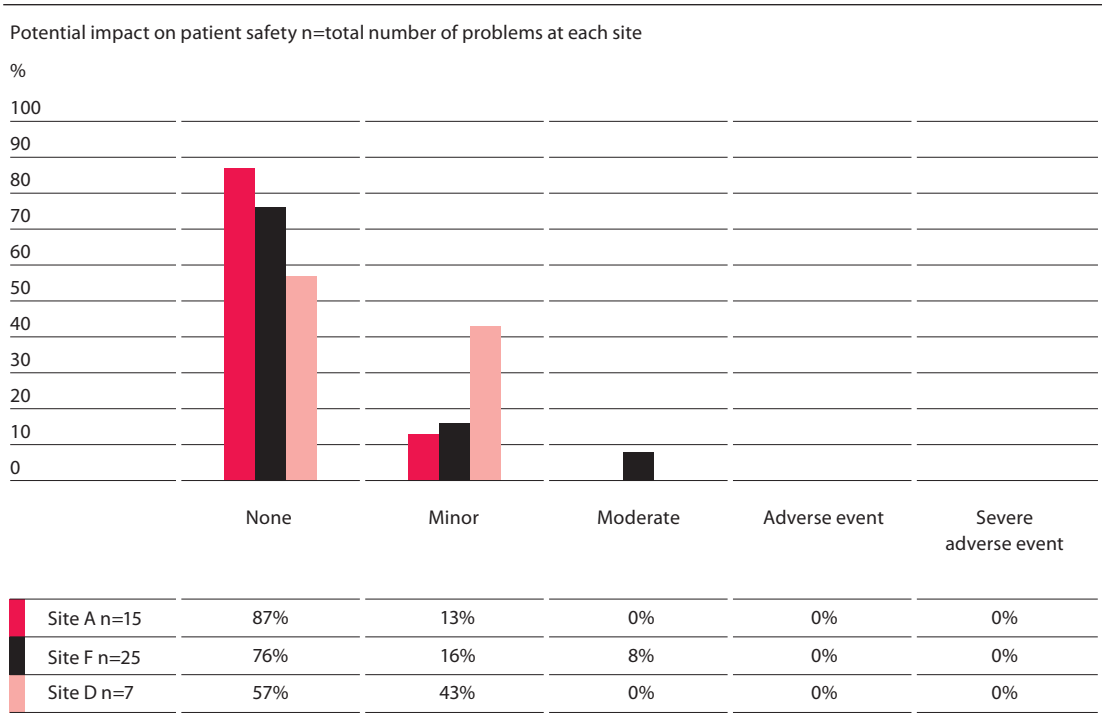
Table 27: Summary of non-availability of equipment across the whole study

Item	Organisation A failures (%)	Organisation D failures (%)	Organisation F failures (%)	All incidents across organisations (%)
Hand hygiene facilities	0	0	0	0
Personal protection e.g. gloves	0	0	0	0
Skin preparation e.g. 2% chlorhexidine	0	2/62 (3.2%)	1/212 (0.5%)	3/47 (6.4%)
Clean tourniquet	8/76 (11%)	0	0	8/47 (17%)
Intravenous cannula	2/76 (3%)	0	2/212 (1.0%)	4/47 (8.5%)
Specific intravenous cannula dressing	0	5/62 8.0%	2/212 (1.0%)	7/47 (14.9%)
Sharps disposal bin	5/76 (7%)	0	20/212 (9.4%)	25/47 (53.2%)
Total failures	15/76 (19.7%)	7/62 (11.3%)	25/212 (11.8%)	0
Reliability	80.3%	88.7%	88.2%	0

Table 28: Professions of participants interviewed

	Profession		
Participant	Organisation A	Organisation D	Organisation F
1	Nurse	Consultant	Medical assistant
2	Ward manager	Junior doctor	Ward manager
3	Doctor	Advanced nurse practitioner (ANP)	

Figure 33: Participant opinion of the impact of equipment failure on patient safety



	None	Minor	Moderate	Adverse event	Severe adverse event
Site A n=15	87%	13%	0%	0%	0%
Site F n=25	76%	16%	8%	0%	0%
Site D n=7	57%	43%	0%	0%	0%

Work environment

The design of the cannulation packs was noted by some to have a potentially negative effect on their use:

'The only thing is, sometimes when you open it up, you know the … it's actually folded, so it's just quite hard ... you can't use it any more, so you have to get a new one, a new ...' Participant 1, site A

Management and design of the storage of equipment was also a concern for many staff and can be considered in three areas:

- Ordering and supply of equipment via the store room.
- Design of the store room.
- Use of satellite storage or mobile storage units.

Ordering and supply of equipment in the store room

Store rooms sometimes ran out of equipment because of delays from suppliers.

'They put itthe order on a Monday and we're expecting it on a Thursday and on Thursday it doesn't come. … then we'll find out that you know it's out of stock or they have given us different stuff.' Participant 2, site A

Design of the store room

Store rooms were perceived not to be user friendly and staff found it difficult to locate equipment.

'They don't seem to be very well grouped together the things, … So it can be very difficult to put your hands on the things you need when you need it most.' Participant 3, site A

'And some store people who stock up rooms will put stuff where they think it needs to go and a nurse may very well put it completely somewhere else…. all the wards have different layouts.' Participant 2, site F

'And things are very,... generally tend to be very badly labelled.' Participant 3, site A

'..have to go up to the other end of the ward to go and get stuff but then that's just a ward base, so that gets used up as well.…, but then night shift it's just anywhere.' Participant 2, site D

'The store cupboard being downstairs is a problem.' Participant 3, site D

'Sometimes people, if they've got to walk up other end, they may very well choose the equipment quicker but not the most ideal for the job.' Participant 2, site F

Use of satellite storage or mobile storage unit:

Satellite and mobile storage units were reported to be very helpful for frontline

staff. However, these storage units have to be constantly replenished to be fully useful.

'You would expect consistency about stocking level.' Participant 1, site D

'It's worse at night time to try and get things. Maybe that's just that they've been used up during the day and not replenished. ' Participant 2, site D

'We've got trolleys set up for peripheral insertion, the cannulae and syringes, everything, we do have a problem with it being stocked,' 'Minors, there's problems with the equipment in minors, I think because there's less insertion of IV lines put down in there, that stock gets depleted and not replenished.' Participant 3, site D

Availability of equipment

When sharp bins are full, they are sometimes not replaced.

'And sharps boxes are a problem, …., we used to have sharps boxes in every cubicle, which is great, then there was a move to take them out because they were harmful to the patient, and you tend to wander around trying to find a sharps box.' Participant 3, site D

Availability of equipment was perceived to be less reliable during bank holidays, weekends and nights, although we did not collect data to support or refute this assertion.

'Mostly Bank Holidays, mostly when the holidays are coming, mostly and sometimes it's Saturdays. It really depends sometimes, like it's mostly Bank Holidays.' Participant 1, site A

'It tends to be based on how busy the department's been…. it is worse over the weekends and bank holidays because those are our busiest times, and the rest of the hospital is on skeleton staff.' Participant 3, site D

Equipment available was often not standard, brands and types may change and this may affect the safe insertion of IV lines.

'In terms of it affecting the patient yes the effect is obviously them having to do this procedure twice or thrice rather than once. So again in terms of familiarity and ease of usage then it's going to be difficult for the staff.' Participant 2, site A

Staffing levels

Activities for replenishing stock and storage units are very dependent on the staffing levels.

'Their staffing levels will be better, they're just more organised. … they don't have that much of a turnover so therefore people know what they're doing all the time, including the people that may well do their sharps bins… you don't get many emergencies on there so hopefully most of the time the day has a routine … it can work quite well.' Participant 1, site F

'Because sometimes somebody's off sick …. then nobody goes round to stock and, which is why I said everybody's trying to do everybody's job ...' Participant 1, site D

'That's down to a staffing issue really, that there's too many areas and too few staff to do the stocking.' Participant 3, site D

Team factors

On the wards, staff work both in teams and with other teams of staff e.g. nurses, doctors and procurement officers. If the team is not functioning properly, then this may influence the availability of equipment

'We don't see if they have placed the order already.' Participant 2, site A.

Staff replenishing the storage units are sometimes not aware that stocking up is required:

'And the doctors, especially at night time, the last thing they're going to go and do is go and get some from somewhere else just so it's stocked up, because their bleeper's going off. ' Participant 2, site D

It was also suggested that the staff who are allocated the task of ordering equipment or replenishing storage units may not comprehend the priority or urgency of the task.

'It might be their job and yet they're not the ones that use it so … that you may not, that wouldn't be your priority because it's not something that's on

your radar.' Participant 1, site F

'The people that do the replenishing don't realise how annoying it is when they're not there, if that makes sense.' Participant 2, site D

Tasks are generally not allocated to a specific member of staff. For example, there is no designated person to perform replenishment of storage and mobile units.

'So you actually find that actually translates to better stocking where some areas it's everybody's job instead of, from my experience anyway, if they have a system where people have designated line manager, designated functions I think it just works better because everybody knows if that happens it's yours.' Participant 1, site D

Individual staff factors

Staff should be knowledgeable about and familiar with the tasks they are meant to perform. Some tasks are performed very rarely and this may affect the staff's skills and knowledge.

'I often end up trying to ask nurses where things are stored, and they often don't know and they vaguely know. There's usually one or two equipment cupboards on each ward, often at different ends of the ward, so it can be impossible.' Participant 3, site A

Task factors

Local protocol and guidelines may vary from hospital to hospital and are not easily available for staff who work in different organisations. The differences between the same task in different hospitals may not be clear.

'But I think what is, what does vary is the, are the local protocols and guidelines for where the lines need to be inserted in terms of location, the ward environment.' Participant 3, site A

Defences and solutions

It was suggested that standardisation of the equipment available for cannulation across the trust can help staff become more familiar with the equipment used and reduce incidents caused by staff not knowing how to use the equipment appropriately.

'Well I think it's one in terms of equipment, I know with us in A&E it's a bit difficult because we've got different users, but if we're going to approach it from a Trust point of view definitely having one equipment in a sense of let's say or getting a Venflon if that Venflon, specific Venflon is being used in the three sites then it would definitely help us.' Participant 2, site A.

Standardising the design of store rooms and making them more user friendly can also help temporary staff who are unfamiliar with the ward to locate the equipment required:

'Certainly from my point of view, going to each treatment room, if each treatment room was pretty similar then that would be great' Participant 1, site F.

Allocating a specific staff member to a particular task in order to ensure that tasks are being performed:

'I think we just need to have a little more structure around who does what. I think it's great in theory, I think it's very … to say everybody does everything. In reality it doesn't work.' Participant 1, site D

'I think a lot of these things would be much better if they were done by a designated person who is, I don't know, a stable member of the team.' Participant 1, site F

Although many of these suggestions were relatively straightforward, it appeared that none had been implemented in practice, suggesting that staff accepted the problems as normal.

8.5 Discussion

Summary of results

The reliability of supply of appropriate equipment for cannulation, as defined by the DH cannulation care bundle, was similar (80.3%; 88.7%; 88.2%) in all organisations. However, the causes of failures were highly variable. In organisation A the main causes were lack of a clean tourniquet and sharps disposal bins, in organisation D it was availability of dressings and in organisation F it was sharps bins. This indicates that the problems are not insurmountable, as at least one organisation had no failures in each category. The failures were not perceived by staff as having serious consequences

and were usually resolved with a workaround. This reliability rate was relatively high compared to some of the other topics studied; this may reflect the attention that infection control has received nationally. This is also one of only a few topics having nationally accepted care bundles so organisations have a benchmark to work to.

This study shows that the supply chain to deliver the correct equipment for peripheral venous cannulation is based on old style routine reordering systems. There are no apparent feedback loops to ensure replenishment of stocks.

In this study, equipment problems may have compromised care in 14% of cases but the harm resulting from this is unknown. The availability of an empty sharps bin and the correct size of cannulae appear common sources of issues.

Comparison with the literature

There is no peer-reviewed literature which assesses the reliability of systems that deliver the appropriate equipment for peripheral cannulation, nor about whether achieving the care bundle does reduce infection rates. This work therefore gives the first evidence of where failures are occurring and potential areas where improvement could be focused. In particular, the work highlights the many human factors related to the supply chain in intravenous cannulation. There are no published results of the results of use of the Department of Health audit tool for the care bundles, so we do not know whether the organisations studied are similar to other NHS organisations.

Interpretation

Development of supply chain systems to ensure adequate stock control and availability and replenishment of full sharps bins would improve the reliability of availability of equipment. The need for extra or different cannulae during a procedure should also be taken into account when designing cannulation packs. The communication along the supply chain was reported as a significant issue. The ability of those responsible for restocking to be aware of the need and the ability to work as a team were continually highlighted in interviews.

Storage and restocking are key issues to ensure that equipment is always accessible and available. Staffing issues can cause problems with restocking, particularly if restocking is seen as a particular person's responsibility (or no-one's) rather than a group function.

The lack of sharps disposal bins often resulted in staff taking their sharps to another location for disposal. Whereas other failures were a potential infection risk to the patient, this problem resulted in a risk to staff, as by transporting sharps there is increased risk of needlestick injuries (Linneman et al, 1991).

It may be that staff familiarity with the type of equipment used has an impact on patient safety, in which case it is important that this be factored into the equipment that is available. The usage of equipment packs will be influenced by their design and way in which they are stored on the ward.

Strengths and limitations

The strengths of our study are that we used the nationally-accepted care bundle and so results represent reliability against standards that should be known by all staff involved and those designing the underlying processes.

In relation to limitations, the availability was measured using self-reporting which may be open to bias, although we believe that this was minimised by anonymity and clear explanation of the purpose of the study. The assessment of the impact on patient safety has significant limitations as this was the subjective opinion of the individual and that such events are likely to be rare and often not traceable to the cannulation, and so this method may underestimate the risk. On site D, due to local modification of the data collection form, following loss of the original data collection forms, staff did not complete the section relating to how the problem was dealt with. We also assessed risks from the patient's perspective and so will not have captured the risks to staff resulting from unavailability of sharps bins. We were unable to interview the numbers of staff that we aimed for. This was mainly due to the limited time frame available to complete all interviews on all sites. Staff were very busy and therefore not available for interviews which often got cancelled at the last minute.

Recommendations

It appears that the majority of issues would be

resolved if:

- Standardised packs were used but with a variety of cannulae available as well as back-up supplies. The design of packs needs to be such that they contain the necessary equipment allowing for individual variation without wastage.
- Availability of disposable tourniquets was increased; this could increase reliability if made mandatory and seen as an affordable option.
- Systems were developed to ensure reliable restocking, including systems to inform those responsible for restocking supplies when supplies are low. These systems could include visual methods so it is apparent when restocking is required with paper based ordering, to complex automated stock level detection systems that automate the reordering.
- Equipment is stored as locally as possible to the procedure, including availability of sharps boxes at the location where cannulation is being undertaken.
- Improved communication and joint working occurs in the team. Over delineation of roles was perceived as a barrier to efficient reliable restocking; staff who are responsible for cannulation may not feel responsibility for either restocking or informing the person responsible.

A basic pack of equipment in a trolley containing more variable equipment, sharps disposal and extras that is taken to the patient and then returned to a restocking point may resolve many of these issues.

More in-depth study is required across multiple organisations to determine whether the failure modes in the study organisations are representative of the NHS.

NHS organisations should already be auditing their compliance against the peripheral venous cannulation care bundle using the Department of Health audit tool. This audit may not detect workarounds which have the potential to increase risk as it looks at whether actions are completed and may be improved by a simple root cause analysis approach to determine whether non-availability was a contributory factor and how the availability could be improved.

It is likely that availability of sharps bins may be a significant problem and organisations should look at how to make these readily available at the point of care.

8.6 Conclusions

Reliability of the supply of correct functional equipment for cannulation is generally high and no single issue was seen across all organisations, suggesting each organisation has resolved some issues. Sharps disposal box supply close to the place of cannulation and availability of clean tourniquets were important issues. It may be possible to improve the reliability of the availability of equipment for peripheral venous cannulation by using supply chain management principles, including the presence of feedback loops when equipment stocks are low, visual management so that low stocks are visible and appropriate design of packs and work areas. There are also some issues that could be resolved by learning from other organisations in the study, e.g. sharps boxes being available with equipment trolleys or in cubicles were used in the two organisations with no problems of non-availability of sharps bins, compared to the organisation that did have problems. Learning from other NHS organisations may therefore be useful when linked to appropriate audits and feedback to staff.

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Analysis and ideas for improvement

3

Chapter 9

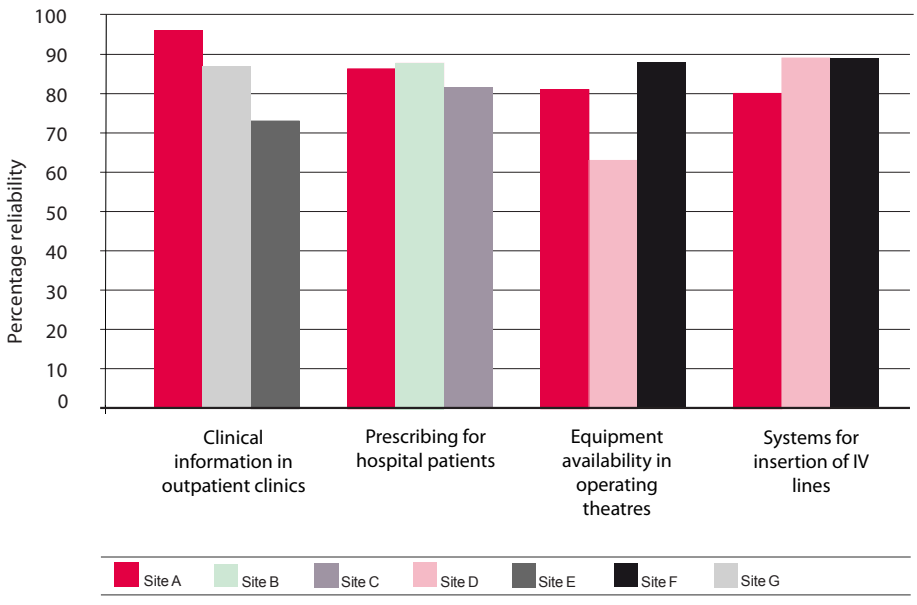
Discussion

9.1 Discussion overview

We studied five common but important processes and measured the reliability (or in one case, standardisation) of each in three NHS organisations. The four clinical systems for which reliability could be measured had an average reliability of 81-87%. However, this apparent similarity hides some significant variation between organisations for some processes. Reliability ranged from 63% for equipment availability in operating theatres in organisation D, to 96% for availability of clinical information in organisation A. No one organisation had consistently higher or lower reliability across multiple topics, although it is difficult to draw concrete conclusions as only one topic was studied at some participating organisations (Figure 34). However, the higher topic-specific levels of reliability identified in some organisations suggest that it is possible to create more reliable systems, although even these can be improved upon.

With the exception of prescribing error, there were no previous studies of the reliability of the systems studied and none studying more than one organisation using the same methods. Our work is therefore the first of its type.

Figure 34: Comparison of reliability across topics and organisations



9.2 Factors contributing to poor reliability

Similar contributory factors were often found between topics and organisations, these included:

- Lack of feedback mechanisms, both for individuals (for example, to doctors regarding prescribing errors) and systems (for example, stock control for cannulation equipment).
- Lack of standardisation, for example in how certain drugs are prescribed, how doctors' handovers are conducted, and how equipment is stored in theatres.
- Poor communication, both written (for example, poor documentation of medication changes in patients' health records) and verbal (for example, handovers interrupted).
- A perception of over complexity of processes (whether or not this was actually the case), for example systems for obtaining health records, off-site preparation of equipment.
- Over time, staff have come to accept poor reliability and accept this as normal, thus not reporting or challenging problems, for example acceptance of handovers of varying standards by the individuals receiving them.
- Lack of ownership of issues, for example blaming others for operating tray content.

We therefore suggest that these are the system-wide areas that need to be addressed in order to improve the reliability of healthcare systems. Many of these areas have been identified previously. For example, Amalberti et al (2005) highlight lack of simplification and excessive worker autonomy (leading to lack of standardisation) as key barriers to achieving safer healthcare. The present work provides further evidence for the existence of these factors across a range of processes in NHS hospitals.

When proposing interventions to improve process reliability, it is important to bear in mind that these system-factors are inter-related and that solutions also need to take into account the local context. For example, a standardised communication protocol may not be effective when critical team members are not attending the meeting due to other work demands or when people have not received training in communication skills (Cleland et al 2009).

Equally, if a standardised communication protocol does not allow for local customisation, it may impose an overly rigid structure that professionals reject (Patterson and Wears, 2009). Patterson (2008) also warns that a focus on standardisation of communication may lead to a situation where frontline staff are increasingly being blamed for communication failures, a strategy that may not be helpful in increasing system reliability.

Some additional organisational factors, while less pervasive than those above, were also identified for two of the processes, namely reliability of prescribing and information availability. These were the additional challenges associated with managing 'outlier' patients on remote wards, issues relating to the obtaining key information out of usual working hours, and handwriting. The similarities between these two topics may relate to them both involving ordering care (whether medication, tests or investigations) and issues involved in communicating these requests in a timely fashion. As would be expected, there were also common issues identified between the systems for obtaining operating theatre equipment and the equipment needed for the insertion of IV cannulae. As well as lack of feedback about supply, these also included lack of communication about requirements, lack of clarity about responsibilities for ordering and checking stock levels, and lack of systems to automatically highlight when stock levels were incorrect. Lack of resources was also raised as an issue in relation to obtaining equipment needed in operating theatres, but to a much lesser extent for the other systems studied.

9.3 Patient safety implications

For four of the five processes studied, we were able to explore the perceived impact on patient safety. When we studied information availability in outpatient clinics, we found that 15% of patients had some type of relevant clinical information missing. Of these patients 20% had a perceived risk of harm. When we studied inpatient prescribing, we found errors in 15% of medication orders, of which an estimated 19% were predicted to have serious consequences to the patient if not corrected. In the study of the reliability of equipment availability in the operating theatre, we found that 19% of operations were affected by equipment problems. Of these, 21% were associated with threats to patient safety. Finally, in

the study of equipment availability for the insertion of peripheral IV cannulae, problems occurred in 13% of cannula insertions, of which 23% were judged to have some impact on patient safety.

In each case, about 20% of reliability failures were therefore associated with a potential risk of harm, although a more formal validated scale was used to assess the clinical consequences of prescribing errors, which is not directly comparable with the approach used for the other topics.

We were not able to study the clinical consequences relating to lack of standardisation in handover, as we observed only the information that was handed over and were unable to follow up or assess any consequences to the patient. However, interviewees in our qualitative study suggested that there can be serious consequences following poor handover.

We also noted that solutions were often adopted through staff developing workarounds, for example by obtaining information from patients rather than their health records, or using disposable gloves as tourniquets, for which the risks could not directly be assessed. In some cases, risks were taken such as making clinical decisions without information, and transferring used sharps to sharps bins in remote locations.

9.4 Economic implications

This section considers some of the implications of this study from an economic perspective, and was commissioned from David Epstein, a health economist from York University.

A direct financial cost to the NHS can be estimated for some of the reliability failures identified in this study, for example, if an outpatient attendance is rescheduled. Here we estimate some of these direct costs from the data presented earlier in this report.

It is beyond the scope of this report to conduct a full economic analysis, however, such an analysis would also identify broader or more intangible opportunity costs or benefits foregone to the NHS organisation concerned, staff and/or patients. These broader opportunity costs may be substantial and might include, among other things, suboptimal care (health foregone), adverse events, loss of confidence and goodwill in the hospital by patients and GPs, and the potential for civil actions and medical negligence claims. Complex, multi-activity organisations such as hospitals may also deal with problems in an inefficient, piecemeal or duplicative way, for example requiring staff in one department to correct problems originating in another, rather than deal with them at their source. It is beyond the scope of this report to quantify these.

In the next sections we discuss some of the economic consequences in more detail for three of the five processes studied.

Clinical information availability in outpatient clinics

Missing information in outpatient clinics might be costly to the NHS and patients in several ways. There may be a direct financial cost of having to book a new appointment. As this research has only sampled from three hospitals, the results cannot reliably be generalised to the whole NHS. However, if 1.7% of 66 million outpatient appointments need to be rebooked because of missing information, this implies a direct annual cost to the NHS of over £110 million, given that an average cost of a outpatient attendance is £97 (Department of Health 2010). This study shows there is variability in missing information between the three hospitals sampled; this variability may indicate that improvements are feasible. Given the variability in reliability rates between Trusts, and the many different causes of poor reliability identified in this report, it is likely that interventions will need to be tailored closely to local circumstances. Improved training in using the existing systems, and ensuring that responsibility for patient records is clearly delineated, appear to be common themes.

Prescribing for hospital inpatients

Among the hospitals sampled, prescribing errors were identified in almost 15% of new medication orders, and 19% of these could be classed as potentially serious. Therefore this study implies that serious errors occur in about 3% of new medication orders in hospital wards. These errors represent an estimate of potential risks to patients, which, if not corrected, may result in inadequate care and/or adverse drug events (ADE). While ADE are rare, they have been found to substantially and significantly increase length of stay. One US study found 60 preventable ADE in 4108

admissions to medical and surgical wards, an incidence of 1.5%. It also found that a preventable ADE increased length of stay (compared with a matched control) by 4.6 days (Bates et al, 1997). In the UK, this would cost about £900 per ADE, apart from any cost of treating longer term complications or malpractice costs.

The current study found that differences in prescribing error rates between wards within hospitals appeared to be greater than variation between hospitals, indicating there may be scope for improvement in most organisations. The study also finds that many, but not all, of errors are detected and corrected, but that there were differences between specialities and organisations in this respect. These factors indicate that interventions to improve prescribing may need to be tailored closely to local circumstances and perhaps even individual departments or staff. The report also highlights that staff perceive an important role for the electronic patient record to improve the system, albeit acknowledging this would not be a panacea.

Equipment availability in the operating theatre

Equipment failures can impose an immediate and direct financial cost in terms of additional time spent in the operating theatre. The study found an equipment failure in 21% of operations, and that 30% of these resulted in a delay of up to five minutes, 14% a delay of five to 30 minutes and 7% a delay of 30 minutes or more. The mean cost of an hour of operating theatre has been estimated to be £1055 in Scotland (ISD Scotland, 2009). On this basis, equipment failure added a cost of between £90 and £527 to 3% of operations in this sample, and at least £527 to 1.5% of operations. This is a considerable cost on aggregate to the NHS. The study found variation in equipment failure rates and the reasons for these between organisations. While this variation could be due to random chance, if valid it might indicate that in principle many of these problems would be preventable in at least some organisations. Similar issues will apply for the reliability of cannulation which demonstrated poor stock control and use of multiple packs if failure occurred. Excessive stock could potentially result in equipment being discarded because it is out of date or because sterile protection has been breached. Repeated understocking could result in more waste and perverse actions (such as 'secret stashes') as well as the costs of any resultant harm.

Wider context

Where reliability failures are in principle reducible by improving processes, managers are likely to want to evaluate and compare the costs and benefits of interventions that aim to achieve this. Many of the solutions proposed in this report will depend on local circumstances. However, it is also relevant to consider the strategic role of the Department of Health (and equivalents in Wales, Scotland and Northern Ireland), the main one in this context probably being the ongoing computerisation of patient records and integration of coding and information systems across the various organisations of the NHS. Several of the respondents in this study in Chapter 4 expected this technology to make a positive improvement to accuracy of prescribing, although Chapter 3 highlights some of the perceived disadvantages of using electronic patient records in outpatient clinics, in particular lack of familiarity and poor access to information systems in the clinic.

Improving reliability fits well with the Department of Health's key QIPP (Quality, Innovation, Productivity and Prevention) agenda. Improving reliability will mean better quality of care with improved outcomes, innovation will help to improve reliability (e.g. manufacturing techniques to improve stock control, electronic records to improve information access and prescribing) productivity is increased (for example by less duplication because of unavailable test results or poor handover) and prevents adverse events and harm. In a time of financial restraint a focus on improving reliability offers an opportunity for saving money whilst also improving the quality of care.

9.5 Strengths and limitations

The strengths of this study are that we studied each process in three organisations, often in more than one clinical area, using standard methods and definitions. While participating organisations were not randomly selected, the use of multiple

organisations increases generalisability compared with most similar studies, which have been based at only one site. We have also been able to synthesise common factors across more than one process, using a published and widely used model of the factors that affect clinical practice.

The main limitation is that data collection for four of the five processes studied was based on self-reporting by hospital staff. This has potential limitations in terms of the reliability and validity of the data collected, especially in relation to potential under-reporting. However, we tried to minimise the extent of any under-reporting by choosing processes where poor reliability is an annoyance for the staff involved, and so staff were likely to be motivated to report problems. We also kept data collection periods relatively short to reduce data collection fatigue, and made data collection forms as simple to complete as possible. For one of the processes studied – the availability of equipment in operating theatres – we attempted to quantify this by comparing self-report data with that reported by a non-participant observer. While agreement was high, an equipment failure was identified (by both the observer and the theatre staff) in only one of the 43 operations observed, and so the true extent of any self-reporting bias is unknown. Ideally we would have collected similar validation data for the other topics, but this was not possible within the time and resources available.

There may also be some response bias in the qualitative data collected in the interviews, in relation to the selection of interviewees and/or their responses. Potential interviewees were identified by local co-ordinators in each site, and it is possible that they may have identified interviewees who were interested in this type of work or likely to be amenable to participate; their views may or may not be representative of other staff. It is also possible that there may have been some social desirability bias in their responses, such as avoiding talking about their own failings. It was noted that there were relatively few references to lack of resource in the interviews; it may be that interviewees did not think that lack of resources was the main issue, it may be that they accepted lack of resources as normal and did not specifically raise this, or it may be that our approach to interviewing and coding did not highlight this area.

Specific issues relating to each process are also presented in the relevant chapters.

9.6 Recommendations for future research

Further research should build on the work presented here by using standardised methods and definitions to study reliability failures across multiple organisations. The identification of differences between organisations was useful here and suggested that processes can be made more reliable. Further studies could also explore the economic consequences of poor reliability in further depth and quantify the link between reliability and harm. Finally, additional research could explore the relationships in reliability of different processes within each organisation, in order to find out whether high reliability in one area predicts high reliability in other areas, and whether unreliability is linked to any particular organisational characteristic. If such 'higher reliability' NHS organisations exist, work would then be needed to identify the factors that support this in terms of organisational maturity or safety climate, for example.

Our findings suggest that improvement may be achieved in many areas. Specific recommendations are given relating to each topic, but some more general recommendations follow. A system-wide approach is likely to be needed rather than viewing individual recommendations in isolation (Carroll and Edmondson, 2002).

9.6 Improving feedback mechanisms

Many systems fail to have effective feedback mechanisms. This was highlighted as an issue in feedback to individuals but also in supply chains. For example, better feedback to doctors about their prescribing errors may help improve prescribing, feedback of low stock levels can prevent non-availability, and feedback of information received in handover could improve quality.

9.7 Standardisation

Standard formats for undertaking procedures are likely to improve the safety of care. Clinical freedom can still exist within standardisation but it

is suggested that some of the present systems allow too much freedom, reducing reliability.

This would also help in measuring quality. For example, a standard format for handover is likely to ensure that all essential items are handed over.

Based on the US IHI's approach, reliability of less than 80-90% (as was the case for most of our topic-organisation pairings; Figure 34) indicates the lack of any articulated common process, whereas reliability of around 95% suggests the presence of a clearly articulated process (Resar, 2006). Only the availability of medical records at organisation

A achieved a reliability of 95%. Standardisation of processes might therefore be expected to have significant benefit in some of the areas studied.

9.8 Improving communication

In several areas there was a failure of communication leading to errors not being identified at an early stage or systems not being corrected. For example, better communication between theatre staff and sterilisation units would help understanding of the requirements of theatre staff.

9.9 Developing a culture of challenge

In many circumstances the interviews revealed a lack of a challenge culture, so that poor reliability and the potential for errors passed without comment.

This is likely to be a complex area. Staff may need to be encouraged to challenge poor reliability, and need to see that suggestions are met positively and without criticism, and result in change.

9.10 Encouraging a sense of ownership

Individuals tend to blame others or the systems rather than seeing themselves as part of the system and therefore someone who can help to improve reliability.

In many cases, these recommendations are complementary. For example, standardisation of handover will only achieve its full potential if accompanied by improved non-technical skills such as communication and questioning, and better feedback about the quality of handover.

The aim of this research was to describe the extent, type and causes of defects in healthcare system reliability in a selection of common but important healthcare processes that have potential to cause patient harm.

A mixed methods approach was used to study five processes in seven acute healthcare organisations selected to represent a range of locations, sizes and types of organisation.

Where possible, reliability was measured against an obvious ideal. However, for one of the topics, reliability could not easily be defined and we focused instead on standardisation.

The four clinical systems for which reliability could be measured had an average reliability of 81-87%. However, this apparent similarity hides significant variation between organisations, suggesting that it is possible to create systems with higher reliability.

A significant proportion of the reliability failures were associated with risks to patient safety. For example, our findings in outpatient clinics imply that almost 10 million British patients are seen each year with clinical information missing, 2 million of whom are exposed to risks as judged by the clinic doctors.

Factors contributing to poor reliability were generally similar across the five systems studied and across organisations. These included lack of feedback mechanisms, both for individuals and systems, lack of standardisation, poor communication, both written and verbal, complexity of healthcare organisation, staff accepting systems with poor reliability as 'normal', and lack of individual ownership of issues. These factors suggest that a systems focus is likely to be required to improve reliability and patient safety.

This is the first study of its kind and gives new insights into healthcare reliability.

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Appendix 1

Original study brief

The original brief from the Health Foundation was as follows:

This study will describe the nature, type, extent and variation of defects in healthcare system reliability that have the potential to cause harm to patients in up to 10 UK hospitals.

We will appoint an organisation or consortium experienced in research into patient safety and reliability in healthcare systems. The team will work with health services across the UK and will have expertise in:

- clinical systems improvement approaches (including but not limited to Lean)
- patient safety
- process and outcome measurement
- knowledge capture and transfer.

The research will last 18 months, beginning in October 2008.

Sample

The sample will include the organisations that have been selected by The Health Foundation for Phase 1of SCS. In selecting the remaining sites for the study the selected organisation will ensure that the total sample is UK wide and looks at different parts of the care pathway, including primary care.

Safety concerns

The research will focus on 5 – 10 common safety concerns that have a systems dimension.

We anticipate that the research will focus on specific points in a care process rather than an entire care process.

A convincing rationale must be provided for selecting the specific points in the care process. In addition, the study itself must describe each entire care process relating to the point of care studied.

The research strategy must provide a clear rationale for the safety concerns that will be explored, the basis on which the sample will be drawn and the recruitment strategy.

The research team will need to work closely with the four organisations selected for phase 1 of SCS as well as the technical team who will have a defined role in capturing what is learned and in developing the full specification (including not just the 'what' but also the 'how') for the interventions that will be taken forward for use in the demonstration programme in phase12 of SCS.

The final selection of 4 - 5 of these topics will be determined by the focus of the organisations. We will require a final protocol by Friday 19 December that reflects the topics chosen by the four organisations to work on during the pilot phase.

Appendix 2

Details of ethics approvals

Participant Information Sheet: Prescribing errors

The Warwick and Imperial Study to Examine Reliability in healthcare (WISeR)

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

What is the purpose of this study?

Healthcare is associated with avoidable harm. Clinical processes and systems, not bad clinicians, often contribute to breakdowns in patient safety. The Safer Clinical Systems project, funded by The Health Foundation, was launched in October 2008 to test and demonstrate ways to improve healthcare systems and processes in order to improve patient safety. The WISeR study is the research arm of the Safer Clinical Systems project. Its aim is to identify the nature, type and variation of defects in specific points of the care pathway and their potential for patient harm. As part of this study, we would like to interview some of the staff involved with specific clinical processes to find out what can go wrong, and why.

Why have I been invited?

Your Trust is one of eight organisations taking part in the WISeR study. We are looking at six specific topics within these organisations to understand the systems involved. We are inviting you to take part as you are working in one of the areas or departments where one of the six topics, in this case prescribing errors, is being studied.

Do I have to take part?

It is up to you to decide whether or not to take part. If you agree to take part, we will ask you to sign a consent form to confirm you have agreed to take part. You are free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part will not affect you, your department or your Trust.

What will happen to me if I take part?

We would like you to take part in a 20-30 minute interview to explore the typical causes of prescribing errors in your clinical area, either face-to-face or by telephone, depending on your availability and which method you would prefer. This will be conducted at a venue of your choice, for example an office or a coffee-shop, or wherever would be most convenient for you. We would like to make an audio-tape of the interview, or we can just take detailed notes if you would prefer. Recordings and notes will be stored on password-protected computers with access only to research personnel. You can ask the researcher to stop the interview at any time if you no longer wish to participate.

We will also offer you the opportunity to check our notes or interview transcript after the interview to identify any errors on our part, and to inform us of any sections that you do not wish to be used as direct quotes in our final report. If you would like to do this, we will need to keep a temporary record of your identity, but this record will be destroyed once you have approved the notes or transcript.

Should the interviewer be made aware of an error that resulted in patient harm, or was potentially the result of a serious breach of practice, they will confirm with the interviewee that the error has been reported on the relevant trust's incident reporting system. If the error has not yet been reported, then the interviewer will liaise with the local study co-ordinator to ensure that the error is reported, according to local incident reporting procedures.

What are the possible disadvantages and risks of taking part?

The interviews will focus on the causes of prescribing errors. We understand that this is a potentially sensitive topic. However, we will take care to conduct the interviews in a sensitive manner. Although we may directly quote your words, you will not be identifiable from those words.

What are the possible benefits of taking part?

The benefit to staff and their organisations will be a better understanding of the systems factors that affect reliability of prescribing. This will hopefully lead to improved quality of care and may also have benefits in improving efficiency and use of resources.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time. A decision to withdraw at any time will not affect you, your department or your Trust.

What if there is a problem?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator Professor Bryony Dean Franklin on 020 8383 0503 / 4308. The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Clinical Research Governance Office.

Will my taking part in this study be kept confidential?

Your taking part in the study may be known by some other members of your Trust, for example if your name was suggested by someone who helped us identify potential participants. However any information which is collected, or any comments or opinions expressed by you during the course of the research, will be strictly confidential, and will not be attributable to you.

What will happen to the results of the research study?

We will present the key findings at meetings of the participating sites, as well as preparing written summaries for dissemination to staff. Our findings will be published on the Imperial College and Warwick Medical School's research centres' websites, published in peer-reviewed journals and presented at relevant conferences, as well as being included in a final report to The Health Foundation.

Who is organising and funding the research?

The research has been organised and funded by The Health Foundation (www.health.org.uk). It is sponsored by Imperial College London, and researchers are employed by the University of Warwick and Imperial College London.

Who has reviewed the study?

This study has been reviewed by the Hammersmith Queen Charlotte's and Chelsea Research Ethics Committee (Ref. 09/H0707/27).

Further information and contact details

If you would like further information please contact the researcher Emmanuelle Savarit on e.savarit@imperial.ac.uk. Alternatively, you can speak to Professor Bryony Dean Franklin who is leading the project, by telephoning 07940 549167 or on bryony.deanfranklin@imperial.nhs.uk

Appendix 3

Example of participant information leaflet for interviews

Participant Information Sheet: Prescribing errors

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Do I have to take part?

It is up to you to decide whether or not to take part. If you agree to take part, we will ask you to sign a consent form to confirm you have agreed to take part. You are free to withdraw at any time, without giving a reason. A decision to withdraw at any time, or a decision not to take part will not affect you, your department or your Trust.

What will happen to me if I take part?

We would like you to take part in a 20-30 minute interview to explore the typical causes of prescribing errors in your clinical area, either face-to-face or by telephone, depending on your availability and which method you would prefer. This will be conducted at a venue of your choice, for example an office or a coffee-shop, or wherever would be most convenient for you. We would like to make an audio-tape of the interview, or we can just take detailed notes if you would prefer. Recordings and notes will be stored on password-protected computers with access only to research personnel. You can ask the researcher to stop the interview at any time if you no longer wish to participate.

We will also offer you the opportunity to check our notes or interview transcript after the interview to identify any errors on our part, and to inform us of any sections that you do not wish to be used as direct quotes in our final report. If you would like to do this, we will need to keep a temporary record of your identity, but this record will be destroyed once you have approved the notes or transcript.

Should the interviewer be made aware of an error that resulted in patient harm, or was potentially the result of a serious breach of practice, they will confirm with the interviewee that the error has been reported on the relevant trust's incident reporting system. If the error has not yet been reported, then the interviewer will liaise with the local study co-ordinator to ensure that the error is reported, according to local incident reporting procedures.

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The interviews will focus on the causes of prescribing errors. We understand that this is a potentially sensitive topic. However, we will take care to conduct the interviews in a sensitive manner. Although we may directly quote your words, you will not be identifiable from those words.

What are the possible benefits of taking part?

The benefit to staff and their organisations will be a better understanding of the systems factors that affect reliability of prescribing. This will hopefully lead to improved quality of care and may also have benefits in improving efficiency and use of resources.

What will happen if I don't want to carry on with the study?

You may withdraw from the study at any time. A decision to withdraw at any time will not affect you, your department or your Trust.

What if there is a problem?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator Professor Bryony Dean Franklin on 020 8383 0503 / 4308. The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College Clinical Research Governance Office.

Will my taking part in this study be kept confidential?

Your taking part in the study may be known by some other members of your Trust, for example if your name was suggested by someone who helped us identify potential participants. However any information which is collected, or any comments or opinions expressed by you during the course of the research, will be strictly confidential, and will not be attributable to you.

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We will present the key findings at meetings of the participating sites, as well as preparing written summaries for dissemination to staff. Our findings will be published on the Imperial College and Warwick Medical School's research centres' websites, published in peer-reviewed journals and presented at relevant conferences, as well as being included in a final report to The Health Foundation.

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Further information and contact details

If you would like further information please contact the researcher Emmanuelle Savarit on e.savarit@imperial.ac.uk. Alternatively, you can speak to Professor Bryony Dean Franklin who is leading the project, by telephoning 07940 549167 or on bryony.deanfranklin@imperial.nhs.uk

Appendix 4

Example of consent form for interviews

Centre Number:

Participant Identification Number:

CONSENT FORM – INTERVIEWS PRESCRIBING

The Warwick and Imperial Study to Examine Reliability in healthcare (WISER)

Please initial box

1	I confirm that I have read and understand the information sheet dated 8 July 2009 (version 1.3) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily	☐
2	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my job or legal rights being affected.	☐
3	I understand that data collected during the study will be looked at by the research team from Imperial College London and the University of Warwick, and may be included in the study's final report and any resulting publications. I give permission for these individuals to have access to this information.	☐
4	The compensation arrangements have been discussed with me	☐
5	I agree to take part in the above study	☐
6	I would like to read the interview transcript or notes at a later stage to approve them for use in the study and to indicate any areas which I do NOT wish to be used as direct quotes.	☐

_____	_____	_____
Name of Participant	Date	Signature
Emmanuelle Savarit	__ _____	_____
Name of researcher taking consent	Date	Signature

When completed: 1 copy for participant; 1 (original) for researcher site file

Appendix 5

Availability of clinical information data collection form

Clinic date:...../...../..... Clinic Code:.....

One form for each patient to be completed by Doctor

Were hospital records available: Yes ☐ No ☐ Not needed ☐ If yes, were they complete (e.g. all volumes available): Yes ☐ No ☐

		Type of information needed during the outpatient appointment (please tick)										
		Past Medical History	Referral Letter/ other specialty letter	Discharge Summary	Current Medication	Allergies	Radiology/ Imaging Results	Diagnostic Test Results	Procedure Notes/ Anaesthetic Record	ECG	Blood and Lab Results	Outpatient notes/ Last Clinic Letter
Was this information needed?	yes											
	no											
Was the information available?	yes											
	no											

Did you have to rely on the patient for any clinical information (e.g. that should normally be in the notes): Yes ☐ No ☐

Did you have to make a clinical decision without key information: Yes ☐ No ☐

How was the problem dealt with: did the patient need an extra clinical appointment: Yes ☐ No ☐

Impact on patient care (e.g. delay in management, cancellation of operation etc):

None ☐ Minor ☐ Moderate ☐ Severe ☐

In your opinion, what was the risk of harm associated with the lack of information for this patient:

No threat ☐ Minor threat ☐ Moderate threat ☐ Adverse event ☐ Serious adverse event ☐

Appendix 6

Interview guide - missing clinical information

Opening questions for non-medical staff

Can you tell me about your job ?

When did you start working in this department?

How are you involved in getting information to the doctors in outpatients?

Opening questions for surgeons

How long have you been a surgeon here?

How many outpatient clinics do you do a week? Are they all in this hospital or do you visit other hospitals?

How often do you think patient information – notes, test results, GP letters and so on, are not available to clinicians when they are conducting outpatient clinics?

[This question will allow us to explore the baseline point of view of the participant regarding the reliability of the system]

Could you give us an example of an event that you have been aware of whereby necessary patient information was unavailable?

[With this question the aim is to obtain a narrative account from the interviewee in terms of remembering their own experience of an event when information was missing at the point of clinical decision, if any]

Why do you think this occurred?

Where do you think the system is going wrong in this specific example?

Is there any source of information which is particularly or frequently unreliable?

(e.g., GP, primary care, hospitals within the trust, hospitals from different trusts)

Why do you think this process is unreliable – where are things going wrong in the system?

What needs to be done to put it right?

Could you suggest any solutions?

Is there any mode of information transfer which is a particular problem?

(e.g. electronic system, fax, telephone message, internal mail or the postal system)

Why do you think this process frequently fails – where are things going wrong in the system?

What needs to be done to put it right?

Could you suggest any solutions?

These are some examples of missing information identified in our earlier study in surgical outpatients here.

[here the researcher will give the interviewee a brief list presenting a selection of the missing information identified in the quantitative part of the study – a range of different failures in terms of source and type of information and the mode of delivery]

Why do you think these types of error occur?

Are there procedures to follow to get this information to outpatients?

How useful are these?

Are they always followed [if 'no' then explore why]

Are there communication problems between departments that contribute to information not being available? [explore where and why]

Are there environmental issues – such as not enough space to keep the notes or records – that contribute to information going missing?

How reliant on staffing levels are the processes to get notes to clinics – do you notice for example that some information isn't available when people are off sick or on holiday? [explore where and why]

Do you know who is responsible for getting all the relevant information together?

ENDING

Thank you very much for your time and for being willing to talk to me. Your comments have been very helpful and will be used together with those of the other participants to gain an understanding of prescribing errors and why they occur.

[confirm plans for getting interviewee's comments on the interview transcript or notes]

Appendix 7

Prescribing error data collection instructions

The WISeR study

Studying the nature and causes of prescribing errors in hospital inpatients - information for ward pharmacists

Data collection: Wednesday 27 May until Tuesday 9 June inclusive

What are we doing?

We are studying the frequency, nature and causes of prescribing errors in hospital inpatients. The study has the approval of Hammersmith, Queen Charlotte's and Chelsea ethics committee, your local research department, and the medical director within your trust.

Why are we doing this?

The data being collected will be used as part of the WISeR study, as well as for local analysis within your pharmacy department. The WISeR study is funded by The Health Foundation and is being carried out in parallel with the Safer Clinical Systems project which your hospital is taking part in, to collect additional data to support the Safer Clinical Systems project. The WISeR study is collecting data on six different topics, across eight NHS Trusts within the UK.

The WISeR study is collecting data using standard methods and definitions to facilitate the comparison of data with other sites.

This data collection is instead of completing a local intervention audit on this occasion.

Which wards?

Prescribing errors will be recorded on XXXX and XXXX surgical wards, and on the Medical Admissions ward. All pharmacists covering these wards during the data collection period will be asked to collect data. Dispensary staff will not be asked to collect data.

Which dates?

Wednesday 27 May until Tuesday 9 June inclusive

Reminders will be put on the ward files before each of these days, and these days annotated on the ward rotas for the wards concerned. Data collection sheets will be put onto ward files, if you run out please ask Sue Vaughan for further supplies.

What do we have to do?

On each of the study days:

Ward pharmacists are asked to record the number of unendorsed 'regular' and 'when required (prn)' medication orders seen, and any discharge items screened, plus any prescribing errors identified in these medication orders. The number of previously unendorsed medication orders is needed for EVERY patient, even if no errors identified for that patient.

Which medication orders should be included?

All 'regular' and 'when required (prn)' inpatient medication orders, and all discharge medication orders (ie those written on a TTO or on EDS) should be included. This includes newly written inpatient charts and newly transcribed inpatient charts.

The following types of medication order should not be included: drugs prescribed on anaesthetic charts; once only ('stat') prescriptions and any drugs or continuous infusions prescribed on the back of the drug chart.

What is a prescribing error?

We are using the following definition:

'A prescribing error occurs when, as a result of a prescribing decision

or prescription-writing process, there is an unintentional, significant:

reduction in the probability of treatment being timely and effective

or

increase in the risk of harm

when compared to generally accepted practice.'

Some notes on this definition:

- All prescribing errors that meet the definition should be included, regardless of their perceived severity. Even 'minor' errors such as not signing the prescription or not specifying the strength of an inhaler should be included. Many errors occur for which pharmacists remedy the error using a chart endorsement (and not contacting the doctor) – these should also be included as prescribing errors.
- Prescribing errors can originate both in the prescribing decision (eg deciding to prescribe a certain dose without taking into account the patient's renal function) and in the prescription writing process (eg accidentally mixing up the doses for two drugs when writing the medication orders onto the drug chart).
- If a prescribing error is detected (ie. the error meets the above criteria) and an intervention is made by the pharmacist but does not result in the doctor changing the erroneous prescription, this should still be counted as a prescribing error.
- Errors that involve the omission of medication on admission should be included as errors
- If in doubt – record it! We can always decide to exclude it afterwards.
- An intervention is not necessarily the same as a prescribing error. For example, consider a prescription for phenytoin 100 mg three times a day. An intervention may be made to change the dose regimen to

300mg once daily if this is more convenient. However, phenytoin 100mg three times daily (if an appropriate dose for the patient) cannot be classed as a prescribing error even though an intervention has been made. Similarly, if a doctor has missed off the strength of an inhaler and you add this to the chart, this is still counted as a prescribing error even if you have not made an intervention.

– Enforcing local policies such as IV to oral switch policies are not prescribing errors.

The appendix contains some more detailed examples of what should and should not be considered prescribing errors.

How do we complete the data collection forms?

Bed

Bed number of patient concerned – so that you can keep track of who you have included.

Have you done a drug history today for this patient?

Answer Yes or No. Only answer Yes if you did the drug history today on the date of data collection.

Number of previously unscreened/unendorsed medication orders

For each patient present on the ward, record the number of unendorsed 'regular' and/or 'when required' prescriptions, regardless of the date on which they were written, plus any discharge (TTO or EDS) items screened. This includes newly rewritten inpatient charts, and initial prescribing on admission. Do not include any unendorsed medication orders that have already been crossed off.

Details of drugs involved in errors

Please provide sufficient detail about the nature of the prescribing error to enable someone else to understand the error. It is essential to record the name of the drug, the dose and frequency, as well as a very brief description of what the error was. For example:

'Vancomycin 1g BD, dose for renal function should be 1g OD'

'Furosemide 1 tablet OD prescribed, strength not specified'

'Ferrous sulphate 200mg BD prescribed, but only one time circled on drug chart – should have been BD'

If a medication order includes more than one error, please record them both but indicate that they were in the same medication order.

We are considering errors per item, rather than per patient.

Error Type

For each error identified, record the error type, using the categories and abbreviations below. These categories and abbreviations are also on the data collection form so you do not have to try and remember them.

– Medication omitted ('Omit')
– No indication for the drug concerned ('No Ind')
– Duplicate therapy ('Dup')
– Incomplete Rx ('IncompRx')
– Prescribing a drug to which the patient is allergic ('Allergy')

– Incorrect drug ('Drug')
– Incorrect dose ('Dose')
– Incorrect frequency/dosage schedule (but correct total daily dose) ('Freq')
– Incorrect route ('Route')
– Incorrect formulation ('Form')
– Inappropriate abbreviation ('Abbrev')
– Illegible ('Illeg')
– Missing/ incorrect instructions for use or administration ('Instruct/Admin')

If in doubt about the category for a given error, don't worry, as the research team will check for consistency of classification at a later stage. As long as you provide a text description of the error, we can classify them later.

Number of doses given before corrected

Record the number of doses given (or omitted) before the error was corrected.

Was an intervention made?

Please indicate here (Yes / No) if you made an intervention (ie contacted to another (non-pharmacy) member of the healthcare team, or wrote in the patient's medical notes), in an attempt to rectify the error. This is to gain an indication of the workload involved in resolving prescribing errors. Clarifying something by writing on the drug chart without contacting another member of the team does not count as an intervention in this context.

Completed data collection forms should be given to XXXXX in the pharmacy department.

Thank you for your participation!

Bryony Dean Franklin, 11 May 2009

Appendix

For the purposes of this study, the following SHOULD be considered as prescribing errors:

- Failure to give essential information correctly
- Writing a medication order for a drug, dose or route that was not the one intended
- Writing 'milligrams' when 'micrograms' was intended - eg writing digoxin 250mg instead of 250mcg
- Prescribing 'one tablet' of a drug that is available in more than one strength.
- Omission of the route of administration for a drug that can be given by more than one route
- Writing illegible or otherwise ambiguous medication orders that would be likely to require clarification before administration (including the use of ambiguous abbreviations)
- Omission of the prescriber's signature
- Omission of duration/review date for anti-infective prescriptions

Errors in transcription

- On admission, writing a medication order that unintentionally deviates from the patient's pre-admission prescription. This includes the unintentional omission of medication on the patient's inpatient drug chart
- Continuing a GP's prescribing error when writing a patient's drug chart on admission
- Transcribing a medication order incorrectly when rewriting a patient's drug chart

Dosing errors

- Prescribing a drug with a narrow therapeutic index in a dose predicted to give serum levels significantly above or significantly below the desired therapeutic range
- Prescription of a drug in a dose above or below that appropriate for the patient's clinical condition (including renal/hepatic function)
- Errors in the calculation of drug doses

Pharmaceutical issues

- Prescribing a drug to be given by intravenous infusion in a diluent that is incompatible with the drug prescribed
- Prescribing two drugs for the same indication when only one of the drugs is necessary
- Not taking into account a potentially serious drug interaction

Errors in choice of drug

- Prescription of a drug to which the patient has a documented clinically significant allergy
- Prescribing a drug for a patient for whom, as a result of a co-existing clinical condition, that drug is contra-indicated
- Prescribing a drug for which there is no indication for that patient
- Prescribing a drug not in the formulary

The following MAY be prescribing errors, if the clinical situation means that they fall within the definition of a prescribing error:

Choice of drug

- Not prescribing a drug for a clinical condition for which medication is indicated
- Dosing
- Prescribing a dose above the maximum dose recommended in the British National Formulary or data sheet
- Prescribing a dose regimen (dose/frequency) that is not that recommended for the formulation prescribed

Administration

- Prescribing a drug to be infused via an intravenous peripheral line, in a concentration greater than that recommended for peripheral administration

Duration

- Continuing a prescription for a longer duration than necessary

For the purpose of this study, the following should NOT in themselves be considered prescribing errors:

Ethical/consent issues

- Not obtaining patient consent for the prescription of a given drug
- Prescribing a drug without informing the patient of its uses and potential side-effects
- Prescribing a drug for which there is no evidence of efficacy, because the patient wishes to receive the drug

Deviation from standard policies and guidelines

- Prescribing contrary to hospital treatment guidelines
- Prescribing contrary to national treatment guidelines
- Prescribing for an indication that is not in a drug's product license
- Prescribing for a child a drug that has no product licence for use in children

Omission of non-essential information

- Prescribing a drug to be given by infusion without specifying the duration over which it is to be infused
- Minor misspelling of a drug name
- Prescribing by brand name
- Prescribing a drug that should be given at specific times in relation to meals without specifying this information on the drug chart

Appendix 8

Prescribing errors data collection form

WISER study: the nature and caused of prescribing errors in hospital inpatients

Pharmacist_____ Ward_____ Number of occupant beds_____ Date_____

Please record details in the bold box for all patients on ward					Details of drugs involved in errors. Include all those identifued in active drugs have not been previously screened							
Bed	Have you done drugs history today for this patient	Number if previously unscreened unendorsed regular items	Number of previously unscreened unendorsed prn items	Number if previously unendorsed TTO/EDS items	Name of drug	Dose	Route	Freq	Details of error (Please start new row for each error and spcify whether regular PRN or TTO/EDS item	Error type	Number of doses received before corrected	Was intervention made?
eg. 1	No	1	2	1	Vancomycin	1g	IV	BD	Regular, Vancomycin 1g BD, dose for renal function shulf be 1g OD	Dose	1	Yes

***Error type: Medication omitted (Omit); no indication for the drug concerned (No ind); duplicate therapy (Dup); incomplete Rx (IncompRX); presecribing a drug to which the patient is allergic (Allergy); Incorrect drug (Drug); incorrect dose (Dose), incorrect frequency/dosage schedule (Freq); incorrect route (Route); incorrect formulation (Form); inapproprate abbreviation (Abbrev); illegible (Illeg); missing/incorrect instructions for use or administration (Instruct/Admin)

Bryony Dean Franklin, 11 May 2009 Please return completed form to XXXX

Appendix 9

Interview guide - prescribing errors

WARWICK & IMPERIAL RESEARCH INTO RELIABILITY IN HEALTHCARE

(The WISeR Study)

EXPLORING THE CAUSES OF PRESCRIBING ERRORS

DATE_____ INTERVIEW REFERENCE NUMBER_____

INTERVIEWER_____ CONSENT FORM SIGNED _____

PROFESSION OF INTERVIEWEE_____

INTRODUCTION

As you know, we are studying the nature, frequency and causes of prescribing errors as part of this study into the reliability of healthcare systems. The overall aim of the study is to identify the systems factors involved so that strategies for preventing errors can be identified. We are studying this in three different hospitals and interviewing a sample of staff in each of these hospitals. I would therefore like to ask you a series of questions about the factors that you feel contribute to prescribing errors. This should take around 20 minutes.

As the participant information leaflet explains, your participation is entirely voluntary and you are free to withdraw. If you do not wish to answer any particular question, then please just say so. There are no right or wrong answers and I am interested in your own personal point of view. The identities of all participants will remain strictly confidential and it will not be possible to identify individual members of staff, clinical teams or hospitals from the final results.

Would you mind if I taped our conversation so that I do not have to write everything down?

Do you have any questions before we begin?

QUESTIONS

Can you tell me a bit about your background - how long have you worked in this hospital?

When did you start working in this speciality?

[add other background questions as needed – the main aim here is to put the interviewee at ease]

How reliable do you think the process of prescribing is?

[This question will allow us to explore the baseline point of view of the participant regarding the reliability of the system]

Could you give us an example of a prescribing error that you have been aware of?

[With this question the aim is to obtain a narrative account from the interviewee in terms of remembering their own experience of a prescribing error, if any]

Why do you think this occurred?

Can you tell me about prescribing this medication?

How familiar do you think the prescriber would have been with this medication?

Are there any guidelines for prescribing this drug?

- how useful are these guidelines?

- is there anything you do not like about these guidelines/instructions?

- do users have training in their use?

Were there any communication problems (either written or verbal)?

Was all the required information available?

Were there any unusual circumstances or stressors?

For each relevant factor, use prompts such as:

- How does this affect prescribers?

- What happens?

- Does this occur in general?

What needs to be done to put it right?

Could you suggest any solutions?

These are some examples of prescribing errors identified in our earlier study identifying prescribing errors on this ward.

[here the researcher will give the interviewee a brief list presenting a selection of the prescribing errors identified in the quantitative part of the study – a range of different errors in terms of error type and the stage of the prescribing process in which they occurred]

Why do you think these types of error occur?

Can you tell me about prescribing on this ward?

How familiar do you think the prescriber would have been with these medications?

Are there any guidelines for prescribing these drugs?

- how useful are these guidelines?

- is there anything you do not like about these guidelines/instructions?

- do users have training in their use?

Are there communication problems (either written or verbal)?

Is all the required information available?

Are there any particular circumstances or stressors on this ward?

For each relevant factor, use prompts such as:

- How does this affect prescribers?

- What happens?

- Does this occur in general?

What needs to be done to put it right?

Could you suggest any solutions?

ENDING

Thank you very much for your time and for being willing to talk to me. Your comments have been very helpful and will be used together with those of the other participants to gain an understanding of prescribing errors and why they occur.

[confirm plans for getting interviewee's comments on the interview transcript or notes]

Bryony Dean Franklin

9 June 2009

Appendix 10

Mean clinical significance scores for prescribing errors identified on each ward

Site	Ward	Mean score (range)
A	Surgical	5.5 (4.2 to 8.4)
A	Admissions 1	5.1 (1.4 to 9.2)
A	Admissions 2	5.8 (4.6 to 7.3)
A	Admissions 3	4.6 (2.0 to 6.8)
A	Admissions 4	5.3 (3.8 to 6.6)
B	Surgical 1	5.8 (3.0 to 8.1)
B	Surgical 2	3.6 (2.8 to 4.4)
B	Surgical 3	5.7 (2.6 to 9.4)
C	Admissions	5.3 (1.4 to 9.6)
C	Surgical	5.4 (0.8 to 8.8)

Appendix 11

The 34 prescribing errors classed as 'serious' in the sample of 183 errors assessed for clinical importance

Site	Ward	Description of error	Mean score
B	Surgical 1	Diclofenac 50mg PR prescribed every 18 hours. Patient already taking diclofenac 50mg orally three times daily	7.0
B	Surgical 1	Morphine 5-10mg IV/IM prescribed when required; no maximum dose or frequency stated, doses not equivalent	8.1
B	Surgical 1	Morphine 5-10mg IV prescribed every 2-4 hourly; dose for this patient should be 5mg	7.9
B	Surgical 1	Morphine 5-10mg IM prescribed when required; maximum dose should have been 5mg	7.2
B	Surgical 1	Fludrocortisone 100mg four times daily prescribed; dose should have been 100 micrograms	7.4
B	Surgical 1	Tramadol 50-100mg PO/IV when required prescribed; no maximum dose or minimum dosing interval stated	7.8
B	Surgical 1	Morphine 5-10mg IV/IM every 2 hours when required prescribed. IV and IM doses are not equivalent	7.5
B	Admissions	Lisinopril 10mg once daily was continued for a patient in acute renal failure	7.3
B	Admissions	Amlodipine 5mg twice daily not prescribed but on drug history	7.8
B	Admissions	Isosorbide mononitrate 120mg once daily prescribed. Should be the modified-release form	7.6
B	Admissions	Tinzaparin 3,500IU not prescribed although clinically indicated	9.4
B	Admissions	8 Half Sinemet CR (controlled-release) tablets prescribed once daily. Should have been 2 tablets four times daily	7.8
A	Surgical	Oxycodone (as 'Oxynorm') prescribed twice on 'when required' section of drug chart: 35mg and 40mg, both prescribed for every 4 hours. Correct dose should have been 40mg every 4 hours when required	8.4
A	Admissions 1	Patient prescribed amitriptyline 10mg once daily but has possible acute coronary syndrome and myocardial infarction, therefore amitriptyline is contra-indicated	7.0
A	Admissions 1	Cefelexin 500mg three times daily prescribed on discharge prescription. GP to continue stated as 'no' but should have been 'yes'	7.2
A	Admissions 1	Phenytoin 400mg three times daily prescribed. Patient usually takes 300mg three times a day	7.8
A	Admissions 1	Patient uses Insulin Levemir but it was not prescribed in hospital	8.5

A	Admissions 1	Patient takes theophylline 500mg twice daily but it was not prescribed in hospital	7.2
A	Admissions 1	Gliclazide 20mg twice daily prescribed; patient usually takes 160mg twice daily	8.2
A	Admissions 1	Paracetamol 1g prescribed regularly but no maximum dose, frequency, or minimum dosing interval stated	7.3
A	Admissions 1	Enoxaparin 40mg DVT prophylaxis omitted although clinically indicated	9.2
A	Admissions 2	Gliclazide 80mg prescribed at 6am, 2pm and 8pm. Should be at 8am, 12pm and 6pm i.e. with meals	7.3
C	Admissions	Carbamazapine 400mg once daily prescribed but two times of day circled for administration on the chart	7.2
C	Admissions	Patient takes levothyroxine 125mcg but not prescribed it in hospital	7.0
C	Admissions	Prednisolone 1mg once in the morning prescribed but patient's usual dose is 3mg in the morning	7.5
C	Admissions	Patient prescribed spironolactone 50mg twice daily but usually takes once daily	7.0
C	Admissions	Paracetamol 1g prescribed when required but with no minimum interval or maximum dose	7.1
C	Admissions	Morphine 10-20mg PO when required prescribed with no minimum interval between doses	7.8
C	Admissions	Flucloxacillin 1g four times daily prescribed to a patient allergic to penicillin	9.6
C	Admissions	Patient takes anastrazole 1mg once a day but not prescribed it in hospital	7.6
C	Surgical	Tramadol 50-100mg four times a day prescribed to a patient already prescribed codeine	7.2
C	Surgical	Morphine 20-30mg when required prescribed with no maximum frequency or dose	8.0
C	Surgical	Morphine 10-30mg every 6 hours prescribed on discharge. Confused patient does not require this drug	8.8
C	Surgical	Patient usually takes atenolol 50mg once daily but was not prescribed it in hospital	7.2
C	Surgical	Digoxin 62.5mcg prescribed to a patient who was taking 187.5mcg once daily before admission. Patient also prescribed a loading dose of digoxin beforehand which was not appropriate	8.0
C	Surgical	Codeine phosphate 30-60mg prescribed when required with no maximum frequency, dose, or minimum interval	7.4
C	Surgical	Morphine15-20mg PO when required prescribed but no maximum dose or minimum interval stated	7.4
C	Surgical	Enoxaparin 80mcg SC prescribed at incorrect treatment dose of 1mg/kg when should have used 1.5mg/kg	8.4
C	Surgical	Tramadol 50-100mg PO four times daily prescribed on discharge to a patient who does not need it	7.0
C	Surgical	Oral morphine prescribed when required but dose was unclear	7.6

The 34 prescribing errors classed as 'serious' in the sample of 183 errors assessed for clinical importance

Appendix 12

Handover of data collection form

Date of observation: Time start: Time finish:

Observer:

	Identification				Assessment		Investigations			Care Plan			
Patient no	Name	DoB	Hospital No	Bed No	Presenting Condition	Diagnosis	Done + results	Done - results	Not done yet	Acute Rx	Ongoing Rx	Complications	Onward Care

Appendix 13

Interview guide - handover

DRAFT INTERVIEW SCHEDULE

NOTE: Italicised comments in square brackets are notes for interviewer only

WARWICK & IMPERIAL RESEARCH INTO RELIABILITY IN HEALTHCARE

(The WISeR Study)

EXPLORING THE FACTORS CONTRIBUTING TO

THE RELIABILITY OF HANDOVER

DATE_____ INTERVIEW REFERENCE NUMBER_____

INTERVIEWER_____ CONSENT FORM SIGNED _____

PROFESSION OF INTERVIEWEE_____

INTRODUCTION

As you know, as part of a study into the reliability of healthcare systems, we are researching the frequency and nature of problems that occur during the handover process, as well as the factors that are likely to affect the reliability of the handover. The overall aim of the study is to identify the systems factors involved so that strategies for improving handover can be identified. We are studying this in three different hospitals and are interviewing a sample of staff in each of these hospitals. I would therefore like to ask you a series of questions about the factors that you feel contribute to the reliability of handover. This should take around 20 minutes.

As the participant information leaflet explains, your participation is entirely voluntary and you are free to withdraw. If you do not wish to answer any particular question, then please just say so. There are no right or wrong answers and I am interested in your own personal point of view. The identities of all participants will remain strictly confidential and it will not be possible to identify individual members of staff, clinical teams or hospitals from the final results.

Would you mind if I taped our conversation so that I do not have to write everything down?

Do you have any questions before we begin?

QUESTIONS

Can you tell me a bit about your background - how long have you worked in this hospital?

When did you start working in this speciality?

[add other background questions as needed – the main aim here is to put the interviewee at ease]

How would you describe the purpose of the handover under consideration?

How reliable or how accurate do you think the handover process is?

[This question will allow us to explore the baseline point of view of the participant regarding the reliability of the system]

What is the impact on patients in terms of patient outcome of a poor handover?

How standardised is the handover and do you have a formal procedure for the handover?

To what extent does it depend on the individual / on personal styles?

In your experience, what are the factors that impact on the quality of the handover, what produces good handovers and what leads to poor handovers?

Do you have a specific time or time slot set aside for doing the handover and a place where you're going to do it?

In your opinion, why are information items such as presenting condition and diagnosis communicated more frequently than aspects of management of care?

If you could change something what would you like to change in your handover to improve it?

ENDING

Thank you very much for your time and for being willing to talk to me. Your comments have been very helpful and will be used together with those of the other participants to gain an understanding of the factors influencing the reliability of handover.

[confirm plans for getting interviewee's comments on the interview transcript or notes]

Appendix 14

Equipment failures data collection

WISER PROJECT: TOPIC 5 Equipment/technology failures in the operating theatre

Equipment problems is perceived as a key issue among surgeons. We would like to capture any equipement problems during a procedure and their effect on the flow of the surgical procedure. Please list the problems encounted furing his procedure. Please fill one box for each problem. The information will be kept anonymous.

Staff position_____Speciality/Theatre _____/_____ Date and time:_____

Equipment problem	Type of equipment problem	How was the problem dealt with	Did the problem impact on flow of surgery	Did the problem threaten patient safety
Item: Procedure:	1 Not available 2 Faulty 3 Wrong useo f equipment 4 Lack of knowledge on how to use	1 Equipment added 2 Equipmen added 3 Equipment replaced/fixed 4 Work around the problem	1 No impact 2 Minor (less than 5 mins) 3 Moderate (between 5 and 30 mins) 4 Severe (more than 30 mins) 5 Surgery cancelled	1 No threat 2 Minor threat 3 Moderate threat 4 Adverse event 5 Severe adverse event

Reason for problem:

Equipment problem	Type of equipment problem	How was the problem dealt with	Did the problem impact on flow of surgery	Did the problem threaten patient safety
Item: Procedure:	1 Not available 2 Faulty 3 Wrong useo f equipment 4 Lack of knowledge on how to use	1 Equipment added 2 Equipmen added 3 Equipment replaced/fixed 4 Work around the problem	1 No impact 2 Minor (less than 5 mins) 3 Moderate (between 5 and 30 mins) 4 Severe (more than 30 mins) 5 Surgery cancelled	1 No threat 2 Minor threat 3 Moderate threat 4 Adverse event 5 Severe adverse event

Reason for problem:

An item of surgical equipment is defined as any resource which is rudes to perform a surgical procedure. It includes the instruments needed for the pvocedure, any type of machinery e.g suction machine or diathermy machine, and any resources needed for the progression of surgery such as suture, surgical drains or irrigration fluidsd etc. It does not include drugs administered systemically to the patient. PLEASE RETURN FORM TO.....

Appendix 15

Interview guide - equipment failures

DRAFT INTERVIEW SCHEDULE

NOTE: Italicised comments in square brackets are notes for the interviewer only

WARWICK & IMPERIAL RESEARCH INTO RELIABILITY IN HEALTHCARE

(The WISER Study)

EXPLORING THE CAUSES OF EQUIPMENT/ TECHNOLOGY FAILURES IN THE OPERATING THEATRE

DATE_____ INTERVIEW REFERENCE NUMBER_____

INTERVIEWER_____ CONSENT FORM SIGNED _____

PROFESSION OF INTERVIEWEE_____

INTRODUCTION

As you know, we are studying the nature, frequency and causes of surgical equipment/ technology failures in theatre during surgical interventions. This is part of our study into the reliability of healthcare systems. The overall aim of the study is to identify the systems factors involved so that these equipment failures can be avoided. We are studying this in three different hospitals and interviewing a sample of staff in each of these hospitals. I would therefore like to ask you a series of questions about the factors due to which you feel equipment and technology failures occur in theatre. The interview should take around 20 minutes.

As the participant information leaflet explains, your participation is entirely voluntary and you are free to withdraw. If you do not wish to answer any particular question, then please just say so. There are no right or wrong answers and I am interested in your own personal point of view. The identities of all participants will remain strictly confidential and it will not be possible to identify individual members of staff, clinical teams or hospitals from the final results.

Would you mind if I taped our conversation so that I do not have to write everything down?

Do you have any questions before we begin?

QUESTIONS

[add other background questions as needed in this section – the main aim here is to put the interviewee at ease]

Opening questions for non-medical staff

Can you tell me about your job in this department?

When did you start working for this department?

Opening questions for surgeons

How long have you been a surgeon here?

When did you start working in this specialty?

[add other background questions as needed – the main aim here is to put the interviewee at ease]

How often do you think surgeons have problems with surgical equipment during a surgical intervention (e.g. missing or broken equipment)?

[This question will allow us to explore the baseline point of view of the participant regarding the reliability of the system]

Could you give us an example of an incident during a surgical procedure that you have been aware of or witnessed whereby surgical equipment was missing or broken?

[With this question the aim is to obtain a narrative account from the interviewee in terms of remembering their own experience of an event when information was missing at the point of clinical decision, if any]

Why do you think this occurred?

Where do you think the system is going wrong in this specific example?

Is there any specific equipment or any specific specialty where this issue is particularly common?

At what stage along the process of ordering to delivery of an equipment to theatre you think there may be a problem? (e.g. TSSU, ordering, booking, storage, loan equipment etc.)

Why do you think this process is unreliable – where are things going wrong in the system?

What needs to be done to put it right?

Could you suggest any solutions?

Do you think there may be processes or systems missing or need improving? (e.g. reporting of missing or broken surgical instruments, better surgical instrument tracking during sterilisation, ordering of loan equipment by locum doctors etc.)

Why do you think this process frequently fails – where are things going wrong in the system?

What needs to be done to put it right?

Could you suggest any solutions?

These are some examples of surgical equipment/ technology failures we have found.

[here the researcher will give the interviewee a brief list presenting a selection of equipment/ technology failures identified in the quantitative part of the study]

Why do you think these types of error occur?

Are there procedures to follow in order to book, order and check surgical equipment?

How useful are these?

Are they always followed [if 'no' then explore why]

Are there communication problems between departments that contribute to surgical equipment/ technology failures? [explore where and why]

Are there environmental issues – such as not enough equipment storage space within the theatre premises?

How reliant on staffing levels are the processes to order, check and maintain surgical equipment?

How do you think these problems can be reduced or prevented?

ENDING

Thank you very much for your time and for being willing to talk to me. Your comments have been very helpful and will be used together with those of the other participants to gain an understanding of surgical equipment failures and why they occur.

[confirm plans for getting interviewee's comments on the interview transcript or notes]

Appendix 16

IV lines data collection form

Date : ...../...../..... Time: ..... Ward: ..... Job title: .....

INSERTION OF PERIPHERAL INTRAVENOUS CANNULAE:

In order to assess system failures during peripheral line insertion, we would like to capture availability of the correct equipments during the cannulation process.

Equipment used	Type of problem				How was the problme dealt with?			In your opinion, what was the impact on patient safety?				
	Available	Partially available	Faulty	Not available	Replace from other area	Work around	Postpone procedure	None	Minor	Moderate	Adverse event	Serious adverse event
IV cannula: correct size and type												
Hand hygiene equipment												
Personal protective equipment (gloves, goggles, aprons)												
Skin preparation equipment												
Dressing												
Shaps bin												
Tourniquet												

Any additional comments: .....

.....

For further information please contact v.deelchand08@imperial.ac.uk (tel 0207 5943149). Completed forms will be collected by Researcher

Appendix 17

Interview guide - equipment failures

WARWICK & IMPERIAL RESEARCH INTO RELIABILITY IN HEALTHCARE

(The WISER Study)

EXPLORING SAFE SYSTEMS FOR INSERTION OF IV LINES

DATE_____ INTERVIEW REFERENCE NUMBER_____

INTERVIEWER_____ CONSENT FORM SIGNED _____

PROFESSION OF INTERVIEWEE_____

INTRODUCTION

As you know, we are studying the nature, frequency and causes of unavailability and failure of equipment needed for the safe insertion of IV lines as part of this study into the reliability of healthcare systems. The overall aim of the study is to identify the systems factors involved so that strategies for safe systems for insertion of IV lines can be identified. We are studying this in three different hospitals and interviewing a sample of staff in each of these hospitals. I would therefore like to ask you a series of questions about the factors that you feel contribute to prescribing errors. This should take around 20 minutes.

As the participant information leaflet explains, your participation is entirely voluntary and you are free to withdraw. If you do not wish to answer any particular question, then please just say so. There are no right or wrong answers and I am interested in your own personal point of view. The identities of all participants will remain strictly confidential and it will not be possible to identify individual members of staff, clinical teams or hospitals from the final results.

Would you mind if I taped our conversation so that I do not have to write everything down?

Do you have any questions before we begin?

QUESTIONS

Can you tell me a bit about your background - how long have you worked in this hospital?
When did you start working in this speciality?

How often do you think healthcare staff encounter equipment problems while inserting a peripheral intravenous line?

Could you give us an example of an incident that you have been aware of or have witnessed while inserting an IV cannula whereby an equipment item was unavailable or not working?

Why do you think this occurred?

Where do you think the system is going wrong in this specific example?

Are there any protocols for inserting peripheral IV lines?

- how useful are these guidelines?

- is there anything you do not like about these guidelines/instructions?

- do users have training in their use?

Is there any specific equipment which more occasionally unavailable or does not work?

Is there any specific wards or specialties whereby equipment problems are more frequent?

Is there any specific activity involved in providing equipment for safe insertion of IV lines which is failing?

What needs to be done to put it right?

Could you suggest any solutions?

These are some examples of equipment problems identified in the first part of our study during safe insertion of IV lines.

Why do you think these types of error occur?

Are there procedures to follow in order to order and check equipment needed for safe insertion of IV lines?

Is there any specific person assigned to perform this activity?

How useful are the procedures?

Are they always followed [if 'no' then explore why]

Are there communication problems between departments that contribute to failure of equipment needed during safe insertion of IV lines?

Are there environmental issues – such as not enough equipment storage space within the wards?

How reliant on staffing levels are the processes to order, check and maintain equipment involved during the safe insertion of IV lines?

ENDING

Thank you very much for your time and for being willing to talk to me. Your comments have been very helpful and will be used together with those of the other participants to gain an understanding of prescribing errors and why they occur.

Appendix 18

Glossary of terms

ACSQHC	Australian Committee on Safety and Quality in Health Care
CCS	Clinical Classification System
CDU	Clinical Decision Unit
DH	Department of Health
ECG	Electrocardiogram
EMAU	Emergency Medical Assessment Unit
HF	Health Foundation
HSJ	Health Service Journal
HSMR	Hospital Standardised Mortality Ratio
IV	Intravenous
MINAP	Myocardial Ischaemia National Audit Project
MRSA	Multi-Resistant Staphlococcus aureus
MTTF	Mean Time To Failure
NA	Not Applicable
NNH	Number Needed to Harm
NHS	National Health Service
NRLS	National Reporting and Learning System
PEAT	Patient Environment Action Team
QAHCS	Quality in Australian Health Care Study
SCS	Safer Clinical Systems
SPI	Safer Patients Initiative
SPN	Safer Patients Network
SPSS	Statistical Package for Social Science
UK	United Kingdom
WISeR	Warwick and Imperial Study to examine Reliability in healthcare

The Health Foundation is an independent charity working to continuously improve the quality of healthcare in the UK.

We want the UK to have a healthcare system of the highest possible quality – safe, effective,person-centred, timely, efficient and equitable.

We believe that in order to achieve this, health services need to continually improve the way they work. We are here to inspire and create the space for people to make lasting improvements to health services.

Working at every level of the system, we aim to develop the technical skills, leadership, capacity and knowledge, and build the will for change, to secure lasting improvements to healthcare.

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