Evidence in brief:
How safe are clinical systems?

Primary research into the reliability of systems within seven NHS organisations and ideas for improvement

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Contents

Foreword from the Health Foundation 04
Key findings 06
Ideas for improvement 08
Introduction 10
Clinical information in outpatient clinics 12
Prescribing for hospital inpatients 14
Clinical handover 17
Operating theatre equipment 20
Systems for inserting intravenous lines 23
Conclusions 25
References 26

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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 to which 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 decisions
- 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.
Reliability in healthcare

Good healthcare is *consistently good* health care. Consistency ensures that people delivering and receiving healthcare can trust that the prescription is right, the different people involved have all the necessary information, the right equipment is available and that all the other factors involved in their care are operating correctly.

The concept of ‘reliability’ in health care has been drawn from other industries – such as the nuclear power and aviation industries – where safety is also paramount. It focuses specifically on the stages where people can make mistakes and sets up systems that should ensure that those mistakes do not happen. If one part does go wrong, the next part of the process should still operate in the right way, so that the potential for damage is minimised.

This is not simply a matter of putting in place proper guidelines and expecting practitioners to follow them. It involves identifying – in advance – the points at which those mistakes can happen, the different elements that contribute to those mistakes, and the systems that practitioners should follow in order to ensure patient safety.
Key findings

This study was commissioned by the Health Foundation to examine the extent, type and causes of failures in reliability in different healthcare systems: failures which have the potential to create risk or cause patient harm. The research shows that:

Failures in reliability pose a real risk to patient safety

A significant proportion of the reliability failures were associated with risks to patient safety. For example, we found 15% of outpatient appointments were affected by missing clinical information at our study sites. In 20% of these cases patients were exposed to risk (as judged by the doctors involved).

Important clinical systems and processes are unreliable

Fully reliable systems would function correctly 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

Different organisations varied significantly in their reliability: problems such as faulty or missing equipment affected 37% of operations at organisation D but only 12% at organisation F.

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 are more reliable.
Ideas for improvement

Our findings suggest that improvement may be achieved in many areas including:

1. Improving feedback mechanisms
Many systems do not have effective feedback mechanisms. This was highlighted as an issue for both individuals and supply chains. For example, better feedback to doctors about their prescribing errors may help improve prescribing.

2. 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, and therefore reduce reliability. For example, a standard format for handover is likely to ensure that all essential items are handed over.

3. Improving communication
In several areas a failure in communication meant that errors were not identified at an early stage or systems were not corrected. For example, better communication between theatre staff and sterilisation units would help the units understand what staff need.
Adverse event – an unintended injury caused by medical management rather than the disease process.

Reliability – the probability that a system will function correctly and, as a result, the chance that evidence based care will be provided.

Failure rate – the inverse of reliability – so a 15% failure rate represents 85% reliability.

Standardisation – establishing a process which always functions in the same way, with no variation.

4. Developing a culture of challenge

Many interviews revealed a culture in which poor reliability and the potential for errors passed without comment or challenge. Healthcare professionals and other members of staff may need to be encouraged to challenge poor reliability, and equally need to see that their suggestions are met positively and result in change.

5. Encouraging a sense of ownership

Individuals tend to blame others or the systems rather than seeing themselves as people who can help to improve reliability.

Study sites and topics

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This research had NHS ethics approval. Seven NHS organisations were studied and we collected data from three different organisations for each topic.
Introduction

The extent to which healthcare can endanger patient safety is now acknowledged worldwide.¹ In the UK, a case note review published in 2001 confirmed that 11.7% of admissions in two hospitals led to an adverse event, which is similar to the adverse event rates previously reported in Australia and the US.²

The need to address patient safety by tackling healthcare systems was made abundantly clear in 2001, with the report of an inquiry into the death of a young man, Wayne Jowett. He died because a chemotherapy drug was mistakenly injected into his spine rather than a vein.³ 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, we still have little quantifiable evidence about the reliability of healthcare systems generally, and on how this affects patient safety.

This is partly because it is difficult to define ideal, fully reliable systems in all aspects of healthcare. For instance, the choice of a drug to treat a particular condition may well depend on many inter-related factors, such as the patient’s other medical conditions and treatment.

In fact, some complex processes cannot be completely standardised without potentially compromising patient safety but when this is the case, it is important to note any reason for deviating from the default procedure (for instance, an allergy to the usual choice of drug).

The Health Foundation commissioned this research to address these issues. We have looked at the extent, type and causes of failures in reliability in different healthcare systems: failures which have the potential to create risk or cause patient harm. Our objectives were to:

- identify and describe a selection of common but important processes within healthcare in which mistakes are commonly made.
- explore the extent to which and the reasons why these mistakes are made, with comparisons between different organisations.
- identify the systems factors involved.
- make recommendations for improving system reliability.
The research was designed to run in parallel with phase 1 of the Health Foundation’s Safer Clinical Systems programme, which started in 2008 and runs until 2010.

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. We examined five important processes within healthcare:

- providing information at the point of clinical decision making
- prescribing for hospital inpatients
- handover within acute medicine
- providing operating theatre equipment
- providing equipment for the insertion of intravenous lines.

Our approach

The study employed a mixed methods approach, using both quantitative and qualitative methods. For each of the topics, data collection took place in three stages during 2009. These were:

- documenting the current processes
- measuring reliability using quantitative data collection methods specific to each topic
- exploring the reasons for failures in reliability through interviews with key staff, using Vincent’s framework of factors that affect clinical practice.
The clinical information needed for a typical surgical outpatient appointment to run properly was agreed to be:

- past medical history
- referral letter and any other specialty letter
- discharge summary
- current medication
- allergies
- radiology and imaging results
- diagnostic test results
- procedure notes and any anaesthetic record
- electrocardiogram report
- blood laboratory results
- outpatient notes and/or the last clinic letter.

CLINICAL INFORMATION IN OUTPATIENT CLINICS

Doctors are often faced with making decisions in the absence of important clinical information. This has been found to be a key contributing factor in medical error\(^5\). We studied this in surgical outpatients to find out how often information is missing, why, and how the doctor proceeded, identifying any risks to patient safety and the impact on the patient’s care pathway.

The process

We measured the frequency with which information was missing in a selection of surgical outpatient clinics in three NHS organisations. They used similar processes for finding medical records, starting two weeks before the relevant clinic. Each organisation used a mixture of electronic and paper systems for requesting and reporting test results, and used faxes to send paper copies of reports at short notice. We assessed a total of 1,161 appointments.

Reliability

We found that overall, 15% of outpatient appointments were affected by missing clinical information (95% confidence interval, 12.9%–17.1%) representing a reliability of 85%. In the worst cases, 1.5% of outpatients had their whole medical record missing (95% confidence interval, 0.8%–2.2%).

Of those patients with information missing, 32% experienced a disruption to their care (such as delays in treatment and cancelled operations) and in 20% of cases there was a perceived risk of harm in the opinion of the doctors involved.

In over half of the cases of missing information, doctors relied on the patient for the information. On one in five occasions, doctors made a clinical decision despite lacking information.

Variation between organisations

There was significant variation between organisations. Reliability in terms of having all the required information present ranged from 73% to 96% between the three organisations. Organisation A had only one of 411 records missing (95% confidence interval, 0–0.6%), which demonstrates that it is possible to have much more robust systems.

The variations between different clinics in the same organisation were not explored, as the type of clinic is not routinely recorded.
**Systems factors**

The doctors we interviewed told us how this lack of information can cause serious problems:

‘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.’

We found over 60 reasons why information might not be available. The main organisational factor was the difficulty in organising a patient’s complex care pathway to ensure all tests results were ready at their next outpatient appointment.

There were particular problems if there were two parallel systems, one paper and one electronic; staff often did not know where they should look for test results.

**Conclusion**

In addition, while paper systems pose their own problems, computers require the need for a password, access to a terminal and the time to log in while an appointment is still going on. Temporary staff were often not trained in computer systems or given passwords.

In 2008–09 there were approximately 66m outpatient appointments in England, Scotland and Wales. If our findings are typical that would suggest that important clinical information is missing from nearly 10m of these and, as a result, patients at 2m appointments may be exposed to the risk of harm.
PRESCRIBING FOR HOSPITAL INPATIENTS

Prescribing errors have the potential for serious patient harm. A median error rate of 7% was reported in a recent systematic review of prescribing for inpatients. However, wide variation in methods and definitions means that it has been virtually impossible to compare the results of different studies and until now there have been no comparative studies in adult populations in more than one UK organisation.

The process

We studied prescribing errors in ten medical admissions and surgical wards in three NHS organisations. All used paper-based inpatient prescribing. Discharge prescribing was mainly electronic at organisation A and part electronic and part paper-based at organisations B and C.

Reliability

Errors in newly written regular, ‘when required’ and discharge prescriptions were recorded by ward pharmacists using established methods and definitions.

Overall, 1,025 prescribing errors were identified in 974 of 6,605 medication orders (14.7%, 95% confidence interval, 13.8%–15.6%) in the three organisations. This represents a reliability of 85.3%. An average of 0.9 doses were given (including cases in which the medication was omitted completely) before each error was corrected (range 0–11). An estimated 19% of prescribing errors were predicted to have serious consequences to the patient if not corrected.

Types of error are summarised in Figure 1. The most common types in all three organisations were incorrect dosing, and omitting recommended medication entirely.

Variation between and inside hospitals

The overall incidence of errors was higher at organisation C at 18.4% (95% confidence interval, 16.7%–20.1%) than at organisation A at 13.6% (95% confidence interval, 12.3%–14.9%) and B at 12.2% (95% confidence interval 10.7%–13.7%). On site B the higher prevalence of dosing errors was partly the result of prescribers failing to specify the maximum dose of ‘when required’ medication, as the drugs chart did not require them to state this.

The error rate for the admissions wards was significantly higher than that for the surgical wards, but this was accounted for by the higher incidence of prescribing for new patients (Figure 2).
Figure 1: Types of prescribing error identified at each organisation

Figure 2: Incidence of different categories of prescribing error by clinical specialty

How safe are clinical systems?
We selected some typical prescribing errors, and explored their likely causes through interviews with prescribers, pharmacists and nurses. There were a variety of systems factors:

- Lack of feedback to doctors about their prescribing errors, as pharmacists either correct many of the more obvious errors without telling the doctor concerned, or consult a different doctor because the prescriber’s shift has finished.

- Variation between doctors in how they prescribe certain drugs, such as those to be given once weekly or those to be stopped at a future date.

- Health records which have not been fully filled out with the details of prescribing decisions.

- A focus on the choice of drug, not on doses and formulations.

- Lack of information from primary care about patients’ medication histories. Junior doctors were reluctant to ask or challenge consultants about prescribing.

Our interviewees suggested a range of solutions:

- Involving pharmacists at the point of prescribing rather than retrospectively.

- Increasing the focus on practical prescribing skills for doctors, both in medical school and in the first few months of practice.

- Increasing the use of electronic prescribing.

- A designated quiet area for prescribing and/or revising drug charts to ensure that prescribers check for certain types of error.

- Encouraging better feedback and learning from errors.

Around one in seven prescriptions contained an error. In one in five cases this would have serious consequences if not corrected.

Systems factors
We identified prescribing errors in 14.7% of all newly written medication orders screened by hospital pharmacists on the study wards, corresponding to a failure in reliability of 14.7%. The prevalence and types of prescribing error varied between organisations, but similar factors contributed to all.

We studied doctors’ shift handovers in two types of clinical area in three NHS organisations. We agreed a core data set of 13 items of information (such as the presenting condition and the diagnosis) which clinicians would expect to be handed over, and observed which of these items were in fact discussed in each patient handover. In this case we focused on standardisation, rather than reliability, since there is currently no definition of an ideal handover.
Reliability

Data was collected for 246 patient handovers during 19 handover sessions across the three organisations (Figure 3). The items of information most commonly communicated were: patient name (77% of patients); presenting condition (77%) and diagnosis (75%). The items least frequently communicated were: which investigations had not yet been carried out (17%); investigations for which results had not yet come back (18%); ongoing treatment (17%) and complications (18%).

Variation between organisations

The handover in each organisation was conducted differently, and a direct comparison is therefore difficult. However, it is clear that although the organisations varied in the degree to which they handed over details of the patients’ identity, there was a distinct trend across all three organisations to communicate diagnostic items such as presenting condition and diagnosis more frequently than the items relating to care management (Figure 4).

We did not explore additional variation within organisations, as only one clinical specialty was studied in each.

Systems factors

We found that the details of patient assessment were communicated more frequently than those of tests and future care. The interviews showed that clinicians focused on the immediate, not the longer-term. One interviewee told us:

‘You’re dealing with clinicians and clinicians are not thinking about the end-to-end clinical journey of their patients. The clinicians are very focused on the presenting complaint and the diagnosis, and to a certain extent the treatment, but in terms of the other bits of the patient pathway such as complications, the discharge planning, even the communication with relatives, that isn’t the primary focus.’
Interviewees indicated system factors affecting the quality of clinical handover included:

– The lack of a standard protocol for handover.
– An atmosphere in which too many things are happening, including demands on clinicians, for a structured and formal handover.
– Information which has not been updated, especially out of hours.
– A reactive organisational culture in which handover is not seen to be a priority and there is no culture of questioning and challenging.
– The lack of training for doctors in handover and other non-technical skills.

There were a number of recommendations for improving the quality of clinical handover:

– A standardised handover format including an agreed time and place.
– Streamlining shift patterns for different staff groups, and insisting on bleep-free time during handover, so that this handover format can be put into practice.
– Developing team-based handovers to improve communication.
– Providing training in non-technical skills.
– Progressing towards a proactive, pathway-driven culture.

There is a general consensus that the first step towards making clinical handovers more reliable is standardisation. In addition, organisations may need to ensure that staff have enough time to concentrate on following formal handover protocols.
OPERATING THEATRE EQUIPMENT

Equipment problems are common in operating theatres, yet few studies have described and evaluated their impact. We aimed to describe the type of equipment problems that clinicians encounter, the way these problems are dealt with, and the effect in terms of delays to surgery and risks to patient safety.

The process

We studied trauma, orthopaedic, general surgical and paediatric theatres in three NHS organisations. All had similar processes for ordering surgical equipment. Some equipment was stored locally, some was taken out on loan when needed, and some was obtained directly from the manufacturer. The sterilisation unit in organisation F was in-house while in organisations A and D, sterilisation was outsourced.

Reliability

Theatre staff were asked to self-report equipment problems, and this was then supplemented with observations by trained staff. Data was collected on 490 procedures. A total of 103 equipment problems were reported, affecting 19% of operations (95% confidence interval, 16%–23%) and representing a reliability of 81%. Types of equipment problems, and the ways they were dealt with, are summarised in Figures 5 and 6. The commonest problem was that equipment was simply not available (56% of equipment problems) followed by faulty equipment (38%). In 52% of cases, surgeons had to work around the problem. It was estimated that 7% of problems led to severe delays in surgery and 3% to potential adverse events.

Variation between organisations

There were significant differences between organisations (Figure 5). Organisation D had the highest incidence of problems, affecting 37% of operations. At organisations A and F, 19% and 12% of operations were affected respectively. Delays were more likely to occur at organisation D. There were also some differences in how equipment problems were dealt with (Figure 6). To simplify data collection, we did not record details of each operation and so did not study variation within organisations.
Systems factors

Interviews with theatre staff showed that many equipment problems were associated with communication and team processes.

Equipment problems in theatre were considered the norm by our interviewees:

‘If you ask staff, any of the staff, they’ll say exactly the same... I’d say in relation to missing instrumentation, every set now has probably got something missing.’

Interviewees highlighted organisational factors, such as storage space, management and sterilisation.

Interviewees also felt that the people preparing the equipment did not understand what was needed for surgical processes highlighted, such as storage space, management and sterilisation processes:

‘All our equipment is sterilised outside the hospital and I think since that has happened... there have been lots of issues... obviously the people who are wrapping [the equipment] don’t really have the knowledge or don’t really know exactly what’s going in the tray.’

Another health professional commented:

‘The people who work in the sterilisation unit have no understanding of what we require. They are there to do a certain job of making sure that it’s sterile for us and that the tray is like it should be, but they have no interrelation of what the surgical need is.’

In addition, locum and floating theatre staff may not be familiar with the particular theatre where they are working, so that they may not know where to find the equipment they need. Finally, equipment was not always stored in its designated place.

Recommendations for resolving equipment problems include:

– Improving communication between theatre staff and sterile services and between surgeons and nurses before surgery.

– Theatre checklists and briefings to improve communication.

– Regular safety checks to pick up unperformed tasks.

– Developing a sense of ownership and responsibility among theatre teams, rather than accepting these problems as inevitable.

– Improving processes for making it clear which equipment is necessary.

– Improving the processes for requisitioning and storing equipment.
Conclusion

Equipment problems were common, occurring in 19% of operations. Often surgeons have to work around these problems, sometimes compromising patient safety and causing disruption.

In nearly one in five operations, the equipment was faulty, missing or used incorrectly – or staff did not know where it was or how to use it.
SYSTEMS FOR INSERTING INTRAVENOUS LINES

A high proportion of patients admitted to hospital require an intravenous line to be inserted. This serves an important purpose but the process is also associated with potential risks to the patient (infection) and staff (needlestick injury). The infections associated with intravenous catheters are in turn associated with significant morbidity and mortality, with bacteraemia rates of 0.3 per 1,000 cannulae. In an attempt to improve this situation, standardised systems known as ‘care bundles’ have been introduced to promote best practice. We studied the availability of the items required by the national care bundle for inserting peripheral cannulae.

The process

Processes varied between organisations. Organisation A had pre-prepared cannulation packs including the cannula, organisation F stored items independently and organisation D had packs excluding the cannula. The organisations restocked in a similar manner.

Reliability

We assessed availability of the following required items using a reporting form completed by the person undertaking the cannulation:

- hand hygiene facilities
- gloves for the person inserting the cannula
- skin preparation equipment
- clean tourniquet
- intravenous cannula of appropriate size
- specific intravenous cannula dressing
- sharps disposal bin.

We studied a total of 350 peripheral cannulations and found 47 problems, covering 46 (13%) cases. This represents a reliability of 87%. Most cases of failure were the result of one missing piece of equipment. Figure 7 summarises the types of failure. In over half the cases, staff worked around the problem (for instance, by using alternative equipment) and in 30% they obtained stock from another area. In 23% of cases the problem was considered to have some impact on patient safety.
Variation between organisations

Reliability rates were similar between organisations: 80% at organisation A; 89% at organisations D and F. However, the specific equipment involved varied between organisations. In one organisation 80% of the failures were the result of a missing sharps bin (or the available sharps bin was full). In another 53% related to missing tourniquets; and at the third 43% involved missing skin cleanser. In the organisation where cannulation packs included cannulae, these were sometimes the wrong size for the clinical situation. The sample size was not big enough to allow us to examine the variability within organisations.

Systems factors

Interviews revealed a variety of causes. The work environment – including problems with storage and supply, and problems with communicating about stock levels – was a major factor. Equipment was less likely to be available out of hours. The supply of sharps bins was a particular issue.

Recommendations included:

- Addressing the availability and design of appropriate sharps bins.
- Making sharps bins readily available at the point of care.
- Ensuring that there are systems to replace full sharps bins.
- Designing cannulation packs which address the need for extra and/or different cannulae.

Conclusion

Equipment for inserting intravenous cannulae was not available in 13% of cases, representing an overall reliability rate of 87%. The reasons for missing equipment appear to vary between the different sites. Interviews suggest that stock control often depends on individuals maintaining the system, rather than on a self-regulating system which ensures that equipment is adequately available.
Conclusions

This is the first study to analyse reliability in healthcare in this manner. With the exception of prescribing error, there were no previous studies of the reliability of these systems, and no studies of more than one organisation using the same methods.

We found significant variation between organisations for each topic. Problems such as faulty or missing equipment affected 37% of operations at organisation D but only 12% at organisation F. This variation, and the fact that some organisations have created more reliable systems, suggests that it is possible for all organisations to create systems that have higher reliability.

We have highlighted some of the underlying causes for failures in reliability. There were many common contributing factors:

– A lack of feedback mechanisms, both for individuals (for example, to doctors about 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, interrupted handovers).

– Overly complex processes (for example systems for obtaining health records and off-site equipment preparation).

– Staff acceptance of poor reliability, which has often built up over time so that they now accept this as normal and do not report problems (for instance, accepting handovers of varying standards).

– A lack of ownership of issues (so that, for example, staff blame other people for the lack of operating equipment).

Staff often found solutions by working around the problem, for example by obtaining information from patients rather than their health records, or using disposable gloves as tourniquets. In some cases, this meant they took risks, for example by making clinical decisions without information, or transferring used sharps to sharps bins in remote locations.

The contributing factors suggest that a systems focus is required to improve the reliability of healthcare processes and patient safety. The higher levels of reliability identified in some organisations suggest that it is possible to create more reliable systems, but even these can be improved upon.
References


This report summarises the results of research into the reliability of five common healthcare systems, examined across seven NHS organisations. The findings show that the reliability of systems has rarely been considered in the healthcare setting and that the variations in reliability identified here increase risk for patients.

The report is relevant for all those working to improve patient safety, from the front line of clinical services to the board room. In particular, senior clinicians and managers will find it useful in highlighting the organisational factors that need to be considered in order to improve system reliability. A full research report is also available.

The Health Foundation wants the UK to have a healthcare system of the highest possible quality – safe, effective, patient-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, teams, organisations and systems to make lasting improvements to health services.

Working at every level of the healthcare system, we aim to develop the technical skills, leadership, capacity, knowledge, and the will for change, that are all essential for real and lasting improvement.