

Prospective Hazard Analysis:

Tailoring Prospective Methods To A Healthcare Context

FINAL REPORT

6 July 2010

V1.1

University of Cambridge

University of Surrey

Greenstreet Berman Ltd.

Research Project PS/035

Patient Safety Research Programme of the Department of Health

Report authors:

Dr. James Ward, University of Cambridge

Prof. John Clarkson, University of Cambridge

Prof. Peter Buckle, University of Surrey

Jon Berman, Greenstreet Berman, Ltd.

Dr. Rosemary Lim, University of Surrey

Dr. Thomas Jun, University of Cambridge



Engineering Design Centre,
Department of Engineering,
University of Cambridge,
Trumpington Street,
Cambridge,
CB2 1PZ,
UK

Tel: +44-1223-748245

Fax: +44-1223-332662

Email: edc-enquiries@eng.cam.ac.uk

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Acknowledgements

We thank the Patient Safety Research Portfolio and the Department of Health for providing funding for this study, the members of the PHA Steering Committee, the Staff Leads of the five Case Studies and the many individuals who took part in this research. Particular gratitude is due to the following people, who have made a special contribution to the research: Alan Card, Cambridge EDC; Sheena Davis, Greenstreet Berman Ltd., Dr. Terry Dickerson, Cambridge EDC; and Paul Leach, Greenstreet Berman Ltd.

We would also like to thank the former members of the PHA project team:

Janet Anderson

Lacey Colligan

Shelly Jeffcott

Melinda Lyons

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1. EXECUTIVE SUMMARY

Prospective Hazard Analysis (PHA) approaches are standard practice in many high hazard industries, including aerospace and nuclear power. However, PHA has had little use in healthcare where it represents a new way to think about risk assessment and safety. In contrast to the current, dominant, reactive approach of learning from past errors, it is both proactive and predictive. The approach demands a different mind-set and organisational culture relating to risk.

PHA is not a single method but rather an approach and a range of tools. PHA methods are systemic, systematic and structured processes that support the identification of hazards, their potential consequences and hence risk. PHA draws upon existing system performance and failure data but also on subjective sources of risk information.

1.1. Project aims and objectives

The aim of this work was to investigate the potential for the use of PHA in the NHS, with a particular focus on patient safety. The objectives of the research project can be summarised as:

- Understand current practice with respect to safety management and how the PHA approach fits in.
- Determine a set of needs (requirements) for a practical set of tools (Toolkit) to support the application of PHA in the NHS.
- Identify a set of appropriate PHA methods for inclusion in a Toolkit.
- Develop and evaluate (Action Oriented Research) a Toolkit for the application of PHA.

1.2. Research approach

Healthcare is complex and there are many PHA tools that could be applied. This has meant that there were many more experimental variables than could be considered in a traditional experimental design. Further, lack of control over the experimental settings ruled out a multi-factorial research design approach. This required a deviation from the original call for proposals which required a direct experimental comparison of PHA methods. A more pragmatic approach was taken, (and endorsed by the expert Steering Committee), and research rigour imposed through control of the research process rather than output validation. The major stages in achieving the project aims were:

- Phase 1 – Definition of healthcare requirements for PHA. This was achieved through literature reviews and research with healthcare and risk experts.
- Phase 2 – Identification, assessment selection and tailoring of PHA methods for the healthcare context. This was achieved through workshops with risk experts.
- Phase 3 – Creation of a Toolkit of PHA methods and a tool selection framework. Achieved through interpretation of the data in Phase 1 and 2 and through evaluations with healthcare domain experts.
- Phase 4 – Refinement of the Toolkit through a series of evaluations. These included case study based PHA workshops in a range of health service settings and with current NHS topics of interest (including risks in surgery; risk assessing mental health patients; and assessing risk in cancer screening services).

1.3. Results and discussion

A PHA Toolkit was developed successfully and is presented along with the main report. It consists of a risk assessment framework and guidance on the selection and use of a multi-level set of tools. The Toolkit was tested in a number of case studies that included settings in mental health, primary care and acute settings.

Problems were identified in the current NHS approach of reactive risk management, such as the subjectivity in using risk matrices. A picture of the NHS emerged which uses PHA techniques rarely, if at all. This lack of awareness of the importance of PHA was evident throughout the research, and presented the research team with significant barriers to the undertaking of case studies. It is thought these will present similar difficulties when the Toolkit is rolled out into the NHS. A number of key guiding principles were made when researching the requirements for the Toolkit development. Chief amongst these was the importance of the process mapping activity that is used to define the process as part of any analysis. This was considered vital and therefore process mapping guidance was specifically included in the Toolkit.

The research has demonstrated that PHA techniques used in other high-hazard industries can be applied within healthcare, and appear to offer real benefits in terms of supporting risk management. Whilst the Toolkit provides a crucial part of risk management, it should not be viewed as a substitute for the entire process: solutions for reducing risk may be presented, but staff in participating organisations will need to implement those actions and to monitor their efficacy.

Despite a number of real and potential challenges of using PHA in the NHS, we believe that the Toolkit provides the following benefits:

- It describes a process that assists the user to be systematic, comprehensive and thorough.
- It enables the user to conduct a systemic analysis.
- It may be used as a screening process to assist risk prioritisation.
- It provides an auditable mechanism for decision making in risk mitigation.
- When implemented, it can lead to attitude and cultural change in risk management, which may in turn lead to improvements in patient safety.
- As it considers only potential future events, it may promote openness amongst staff and the resultant ability to change systems.
- The PHA Toolkit is an adaptable process, in which PHA methods can be added or removed.

Some of the limitations in the application of PHA that the study uncovered were: the availability and reliability of data; the complexity and variability of many healthcare processes; the current understanding of risk management practice and knowledge within the NHS; the need, in many cases, for specialist facilitators to satisfactorily complete a PHA; the availability of resources for PHA and the degree to which current NHS culture is open to such approaches to risk assessment.

1.4. Recommendations

This research has led to four groups of Recommendations; 13 in all: i) Recommendations for introducing the Toolkit into the NHS, ii) for further changes to the Toolkit, iii) for further feedback on the Toolkit and iv) for future research. Each group contains several recommendations; each rated for their importance by the research team. It should be noted that many of these Recommendations are mutually reinforcing, and so the more Recommendations that are implemented, the greater the likelihood that the PHA Toolkit will achieve the original aims.

2. INTRODUCTION

Prospective Hazard Analysis (PHA) approaches are standard practice in many high risk industries such as aerospace and nuclear power. However, PHA has been little used in healthcare and represents a new way of thinking about risk assessment and safety, and their relationship to risk exposure for patients, staff and organisations. In contrast to the current approach of learning from past errors, it is proactive and predictive. PHA not only demands a different mind-set and organisational culture, but also encourages this to be so. There is great potential for the benefits from such an approach to significantly outweigh the challenges that its adoption is likely to encounter.

Currently, NHS staff are likely to rely on risk matrices, or likelihood-consequence grids, to document the perceptions of the most critical risks in a system (as identified largely retrospectively from incident data). Such approaches are most often used to prioritise hazards but, strictly speaking, are not hazard analysis techniques. Rather they are a way of eliciting or summarising perceptions of hazards and do not provide a systematic, prospective, or in many cases, objective means of analysing clinical or operational risks.

The overarching aim of this study was to research the benefits to the NHS in investing in PHA methods and to develop and test a *Toolkit* containing such methods. The Toolkit was developed by reference to existing theory, experience of PHA in other industries and through pragmatic evaluation in a number of healthcare scenarios.

Different scenarios in the NHS vary widely in the range of risks that occur, their root causes and subsequent types of failure. There is also considerable variation across the many different PHA methods that have been developed to suit specific industries and purposes. For example, they may require different levels of preparation before a study can be carried out; may be more suited to technical rather than human systems; or may require different skills to undertake a comprehensive study. All of these issues were considered in the Toolkit development.

This project was initiated through the NPSA and managed throughout the Patient Safety Research Portfolio¹ based at the University of Birmingham. The call for proposals² covers the original technical reasoning behind the commissioning of the research; the work described in this report responds to the original call and develops those ideas further.

2.1. What is Prospective Hazard Analysis (PHA)?

Within high-hazard industries, Probabilistic Safety Assessment comprises the systematic evaluation of conceivable risks. Typically these risks are concerned with harm to workers or the public, but it can also be concerned with disruption to processes, plant and the environment. Within the context of the present study, the term Prospective Hazard Analysis (PHA) has been used to cover such process for proactively considering the potential hazards and their associated risks, whether to people or process.

¹ <http://www.haps.bham.ac.uk/publichealth/psrp/index.shtml>

² http://www.haps.bham.ac.uk/publichealth/psrp/documents/PS035_Call_for_proposals_PHA.pdf

PHA is:

- **systemic** – that is it takes account of the interaction of the part of the system being examined and the wider system within which it sits;
- **systematic** – it has specific aims and scope, and is methodical;
- **structured** – there is a logical approach, which should be followed consistently, and which supports consistency and repeatability,
- **documentable** – the approach allows detailed records to be kept, not only of the hazards and risks that have been identified but also of the reasoning behind their evaluation; and finally,
- **informative** – the output can be used to support improvement and redesign processes.

PHA is a generic term for a set of methods that supports the identification of hazards, assessment of their potential consequences, and consideration of the likelihood of those hazards and consequences being realised. PHA can draw upon existing system performance and failure rate data, but also can draw on more subjective sources of risk information.

Principal characteristics of PHA methods are that they can be applied both to existing systems and to novel systems (i.e. ones where there are no available operating performance data). Although they have certain similarities with methods such as Root Cause Analysis, they differ from them in that they are prospective, i.e. that they systematically consider hazard and risk prospectively, and are therefore of particular value in assessing both existing systems and planned changes to existing systems.

The basic elements, or stages, of PHA are:

- **identification of the need** – the definition of the objectives and scope of the assessment;
- **description of the process** – the development of an agreed description of the socio-technical system and the relevant processes within it;
- **identification of hazards** – the determination of how the system could fail using the process description for systemic and systematic guidance;
- **identification of consequences** – the determination of how those failures could affect vulnerable parts of the system, including patients and processes, and the assessment of the likelihood of those consequences being realised;
- **clarification of the risk** – the assessment of the acceptability of the level of risk and the identification of the manner in which the risk could be reduced, whether by lowering the likelihood of occurrence or the magnitude of the consequence;
- **communication of the results** – the provision of a means to communicate the results of the assessment.

Although the above elements are presented in a linear order, it is highly likely that a real process will be iterative; for instance developing a process description may inform the need or scope. Not every PHA method will encompass every element of the PHA process; some may focus only on one aspect, such as hazard identification, and hence may need to be used in conjunction with others.

It should be noted that PHA supports risk management, but is not synonymous with it. PHA provides the understanding of system vulnerabilities and how they could be reduced.

Whereas, risk management is the over-arching process that ensures that the appropriate measures for controlling risk are implemented and maintained. PHA is therefore an essential element of a wider risk management process.

2.2. Why might PHA help the NHS?

In 2000 the Department of Health published the landmark document “An Organisation with a Memory” (OWAM) which set out government strategy for tackling unacceptable levels of adverse events (medical errors) in the NHS [DH, 2000]. The report quoted some alarming statistics in relation to the scale of unintentional harm in the NHS. Headline figures were that around 10% of admissions were subject to adverse events which were costing the country an estimated £2 billion a year in additional hospital stays alone, without taking any account of human or wider economic costs. Case study reviews indicated that around half of all incidents were judged to be avoidable.

The OWAM report concluded that the NHS must become better at learning from its mistakes. Subsequently, the implementation plan for OWAM, “Building a Safer NHS for Patients” [DH, 2001], resulted in the creation of the National Patient Safety Agency (NPSA) which was given the role of collecting and coordinating adverse event reporting at a national level. More recently the government reaffirmed its commitment to improving safety in the ‘Darzi’ report [Darzi, 2008]:

“Continuously improving patient safety should be at the top of the healthcare agenda for the 21st century. The injunction to ‘do no harm’ is one of the defining principles of the clinical professions, and as my Interim Report made clear, safety must be paramount for the NHS. Public trust in the NHS is conditional on our ability to keep patients safe when they are in our care.”

The NPSA set up the National Reporting and Learning system (NRLS) late in 2003 and since then the number of adverse event reports has been steadily increasing to the current rate of around 300,000 per quarter. This increase is not thought to indicate an increase in adverse events but better compliance in reporting. However, although better reporting rates are correlated with improved safety culture [Hutchinson *et al.*, 2009], there is also no real evidence that the rate of adverse events is decreasing across the world [National Audit Office, 2005] or more specifically in the UK. In England, data from the NRLS for 2008-2009 suggests that 3,735 deaths were the result of adverse incidents and nearly 8,000 patients suffered serious harm [NPSA, 2009]. It should be noted that the concern over high levels of adverse events is not solely a UK issue and a number of other developed countries are in a similar position [National Audit Office, 2005]. In addition, the cost of litigation keeps on rising and was £807M in 2008/09 [NHSLA, 2009].

The above snapshot of data, and there is much more evidence than can be shown here, indicates that although the NHS is a safety critical service [Design Council, 2003] it is actually not very safe [DH, 2000; Kohn *et al.*, 2000].

Although the NRLS has its merits, it should be noted that the approach is one of learning and subsequent improvement – i.e. retrospective acts. An implication of this is that that mistakes ‘have’ to happen and some patients and staff have to suffer to improve things for others. Perhaps, where the consequences of mistakes are minor or recoverable, this could be argued as acceptable. However, where the consequences result in serious injury or death this approach alone should surely be questioned. Also where the likelihood of error is small but the consequences serious and wide-spread it is not sensible to wait for tragedy before examining the risks.

The retrospective approach also imbues a culture of reactive improvement through fixing problems that are highlighted. In crude terms, the organisation is saying that (particularly when reinforced by a 'no-blame culture') that individuals and teams need not think about making mistakes as these will be addressed as part of the corrective processes. This last sentence is of course a parody of reality, nobody likes or wants to make mistakes, but it does illustrate a serious issue, i.e. that of relying on retrospective correction. Also, the approach does not encourage a systems approach to eliminating adverse events, contrary to the views expressed by Professor Lucian Leape, who is quoted [DH, 2001] as saying that:

"Human beings make mistakes because the systems, tasks and processes they work in are poorly designed".

This issue of taking a systems perspective is important and was recognised in the OWAM report [DH, 2000]:

"Human error may sometimes be the factor that immediately precipitates a serious failure, but there are usually deeper, systemic factors at work which if addressed would have prevented the error or acted as a safety-net to mitigate its consequences."

The need to work from a systems perspective is also highlighted in many later reports and is a major defining feature of a safe hospital [Dr Foster, 2009]. Academic publications have also argued for a more embedded systems approach to healthcare [Barach and Small, 2000; Clarkson *et al.*, 2004a; Clarkson *et al.*, 2004b; Shortell and Singer, 2008]. This reflects the view that routine adverse incident reports are unlikely to highlight wider systems issues that may contribute to an incident.

A further disadvantage of reliance on reporting and retrospective analysis is the time delay between a first report and gathering sufficient other reports to recognise a trend in the data. Ongoing research questions the effectiveness of adverse event reporting for individual and organisational learning and effective service improvement through analysis of reporting data [Kodate *et al.*, 2009].

Analysis of NHS policy documents, including and since OWAM, shows that retrospective improvement through analysis of adverse events seems to be the only approach that has been considered as a mode of safety improvement. Whilst other industries use incident reporting as a method of improvement, they also invest extensively in proactive forms of risk assessment and management, as described in Section 4.2 in this report. These structured, proactive approaches are in the form of a range of recognised risk assessment methods, which have been used with great success. The aircraft and rail industries have remarkably low levels of harm to their users, for example.

Whilst it is recognised that a "blind" application of such methods in healthcare is inappropriate, there is a need to gain a deep understanding of the characteristics of healthcare provision before adaptation and delivery of such methods can be considered.

The research behind this report has investigated the issues regarding the use and implementation of PHA in the NHS. There is some evidence that using PHA in healthcare can be effective. For example; the Veterans Administration (VA) in the USA has for a number of years been encouraging its members to use a form of PHA (Healthcare Failure Modes and Effects Analysis); where the VA is considered one of the best healthcare organisations from a safety point of view [Perlin *et al.*, 2005]. A more detailed discussion of research evidence of the use of PHA in healthcare is given in Chapter 4.

In summary, it is thought that healthcare is not as safe as it should be and that, although

great strides in reducing adverse events have taken place since 2000, more needs to be done. This body of research examines alternatives to the current approach of retrospective learning and improvement. The proactive approach proposed not only allows events to be tackled from a systems perspective, but also positively encourages it. The approach also aims to influence at a safety culture level in organisations; empowering staff through encouraging proactive consideration of safety, rather than treating them as passive actors. This all suggests that the NHS should seriously consider using PHA methods to support at least some of its activities. Therefore, this report aims to provide evidence and practical guidance to facilitate the adoption of PHA in the NHS.

2.3. Aims and objectives of the PHA project

The aim of this work was to investigate the potential for the use of PHA to improve the approach to safety management in the NHS and ultimately to improve the safety for patients and staff, and reduce the costs associated with adverse events. The objectives of this research project can be summarised as:

- Understand current practice with respect to safety management and how the PHA approach fits in;
- Determine a set of needs (requirements) for a practical set of tools (Toolkit) to support the application of PHA in the NHS;
- Identify a set of the most appropriate PHA methods for inclusion in the Toolkit;
- Develop and evaluate (Action Oriented Research) a Toolkit for the application of PHA;
- Examine the theoretical and practical perspectives related to the use of the Toolkit in the NHS and draw conclusions about if and how proactive risk assessment should be adopted.

A more detailed list of task-oriented objectives can be found in Table 3 in Chapter 3.

3. METHODOLOGY

3.1. Theoretical background to the research

3.1.1. The systems design approach to risk assessment

The health service is a highly pressured complex system where the potential for error and accidents is ever present [Clarkson *et al.*, 2004b]. The scope for error in all parts of the system is high, although most research studies have tended to focus on only limited components of this complex system.

Design is a structured process for identifying problems and developing, testing and evaluating user focused solutions. Application of the design process to healthcare could generate products, services, processes and environments that are intuitive, simpler, safer to work within, easier to understand and more efficient to use. By contrast, design that does not follow such a structured approach is likely to be confusing, less effective and potentially dangerous to medical staff or patients.

The importance of effective design thinking in healthcare has gained increasing recognition [Bristol Royal Infirmary Inquiry, 2001; DH, 2001]. Recent studies, expert panels and government statements have shown that just as poor design has in the past precipitated accidents, the effective use of design has the potential to deliver a significant reduction in risk of medical error. To achieve an appropriate level of understanding of complex systems is an essential first step if risk is to be reduced.

3.1.2. Systems engineering, ergonomics and error

Ergonomists and systems engineers have long recognised that enhancing performance and reducing risk requires an emphasis on design (or re-design) at a systems level. In typical work systems this includes a consideration of people, equipment, jobs, tasks and the socio-technical context of the work. Those involved with such design have traditionally examined the system goals, the allocation of functions and tasks (e.g. to teams, individuals, equipment, IT) , the equipment design, the interactions between sets of equipment and groups of people, the work organisation and the job design.

One systems model ([Moray, 2000]; see Figure 1) enables the levels of the system to be conceptualised for the purpose of understanding, interpreting, evaluating, information collection, and design purposes. The relevant information [Moray, 1994] needed to reduce error in the design of equipment to be used by humans is readily available. Each level of the system can be considered with respect to risk or error.

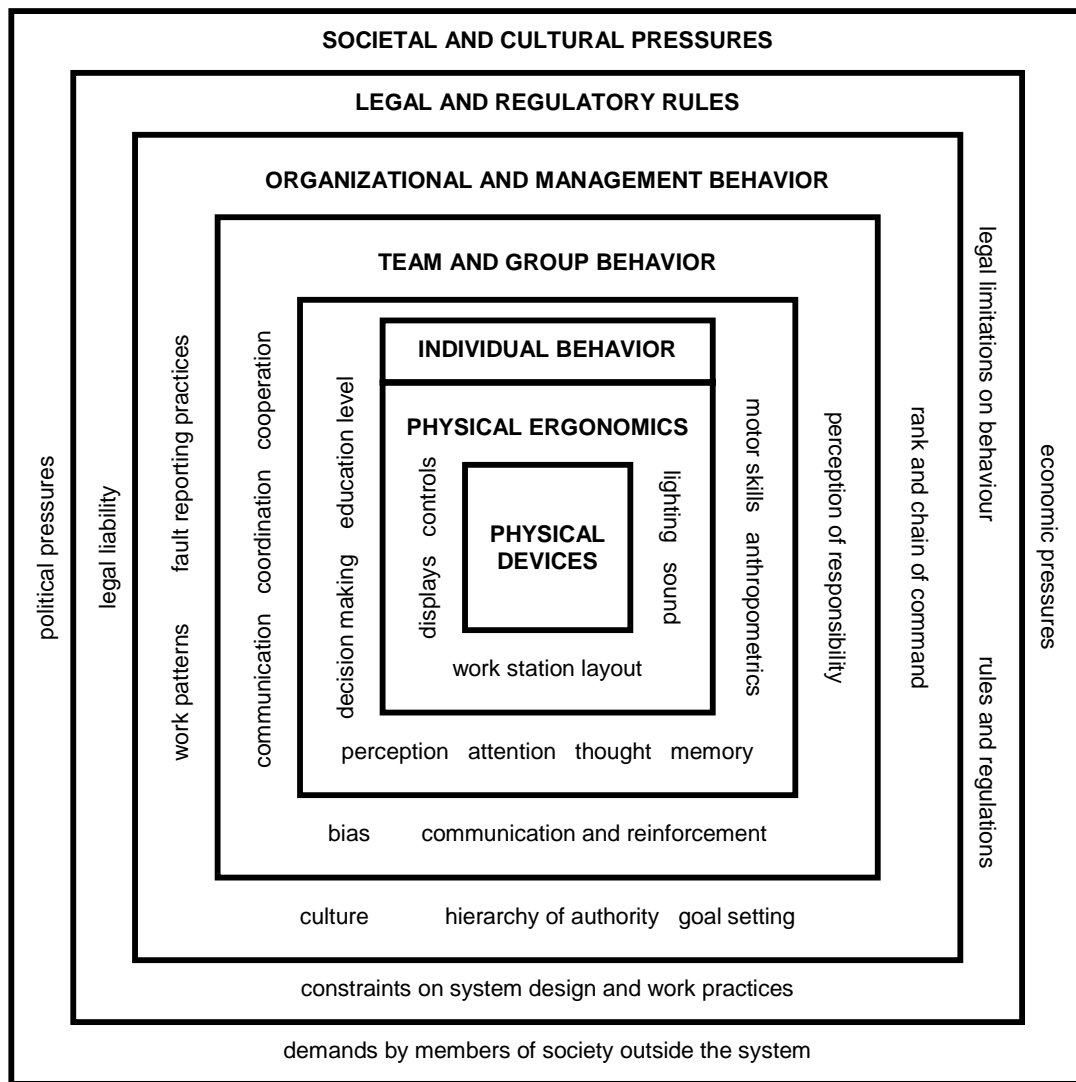


Figure 1 Ergonomics as the study and design of socio-technical systems [Moray, 2000].

Physical devices: At the centre of the system is the physical device or tool being used. There are many illustrations and examples of errors and difficulties associated with the use of equipment (see [Obradovich and Woods, 1996]).

Factors affecting the individual: Omissions (i.e. the failure to carry out some of the actions required to achieve a desired goal [Reason, 1990] were identified as the most common type of error [Poster and Pelletier, 1988]. The role of such errors is evident when considering the giving of drugs to the wrong patient. This is frequently connected with failing to check the patient’s identity bracelet and is often associated with distraction by other patients or interruptions because of the high level of ward activity. Administering the incorrect drug is most often associated with failing to read (or failing to understand) the prescription chart or the drug label and the lack of knowledge of a particular drug [Gladstone, 1995]. Understanding why omissions occur (e.g. what aspects of drug administration require high levels of attention) may lead to improved design of products and work organisation that reduce the probability of such errors occurring.

Physical environment: Noise levels in working environments may cause messages to be misunderstood and can lead to interruptions. For example, Chisholm *et al.* studied the number and type of interruptions occurring in emergency departments [Chisholm *et al.*, 2000]. Emergency physicians were frequently interrupted (about 31 times in 180 minutes).

Team and group behaviour: Most health professionals work within a team, and so a consideration of factors such as communication, supervision and responsibility is required. Absence of, or poor, communication between and within teams is likely to contribute to errors [Dean *et al.*, 2002]. For example, in a hospital setting the most junior medical officer is usually called upon to take a patient's medication history on admission. These doctors are often called upon to prescribe drugs and do so without asking questions under the assumption that this is the correct procedure. In some instances supervision is seen as inadequate and other issues, for example, overlapping responsibilities between teams also contribute to errors [Dean *et al.*, 2002].

Traditionally, information flows vertically through a hierarchy and orders are sent from the top down with the expectation that lower levels will implement them [West, 2000]. Adverse events can occur because individuals of lower status experience difficulties challenging decisions of a person of higher status. Sexton *et al.*, comparing medicine with aviation, suggest that poor communication is the equivalent of poor threat and error management [Sexton *et al.*, 2000].

Organisational and management behaviour: Although factors affecting individuals have been highlighted there is limited value in focusing on individual activity, as this tends to perpetuate a blame culture. The focus needs to widen to include systems issues underlying the problems that are present in any complex work environment [Anderson and Webster, 2001]. System failures are sometimes difficult for "front line" staff to recognise because the decisions underpinning these systems may have been made in the past by those at a higher level of the organisation [Leape *et al.*, 1995]. System changes to reduce errors suggested include adjusted work schedules simplifying work systems and enlisting the help of frontline personnel.

Legal and social pressures: The behavioural options available to those working in a system may be tightly constrained by regulatory rules [Moray, 1994]. For example, only certain drugs may be administered or procedures undertaken. As systems become more complex, the task of regulating becomes ever more difficult. For example, regulators must understand the issues that arise when multiple pieces of equipment are used conjointly (e.g. in intensive care units) or when "intelligent" software is embedded within drug delivery systems. The use of such technologies increasingly blurs the boundaries between equipment design and clinical decision-making.

3.1.3. Summary

The approach required for this research study has to ensure that the 'big systems picture' understanding (that has been so often missing in the health care sector) is central to any PHA methodology and Toolkit. The ergonomics or human factors approach coupled with the discipline of systems engineering provides the necessary mix of systems thinking that has the human in the system as the focus. It also ensures that the process of risk assessment includes the intended user(s) of the system. The approach taken in this research also needs to ensure that appropriate mapping of the system not only takes place but is a central focus, especially for complex and intricate systems. This mapping enables the interfaces between stakeholder groups to become apparent. The potential for error at these interfaces can then be risk assessed. Such mapping exercises have led to the development of a model (Figure 2) to serve as a template for future systems design and are at the core of the design thinking for the PHA Toolkit [Clarkson *et al.*, 2004b].

This "Design for Patient Safety" framework shows that effective design for healthcare depends upon understanding the system into which the product will be introduced.

According to this framework, failure to fully understand the system increases the risk that the artefact will either not be used or will not fulfil the expectations of the designer for delivering safe, high quality care.

This work emphasises building a knowledge base of the system in order to define the requirements for the design. It then proposes both the product and the system into which the product will be introduced will need to be designed. This is seen as a process in which knowledge of the product and the system mutually inform the design of both to ensure that the product is effective. Following the design process, evaluation of the effectiveness of the whole system is conducted to establish the effectiveness of the new product. These stages of the design process correspond to the Requirements Capture, Toolkit Development and Toolkit Evaluation chapters in this report.

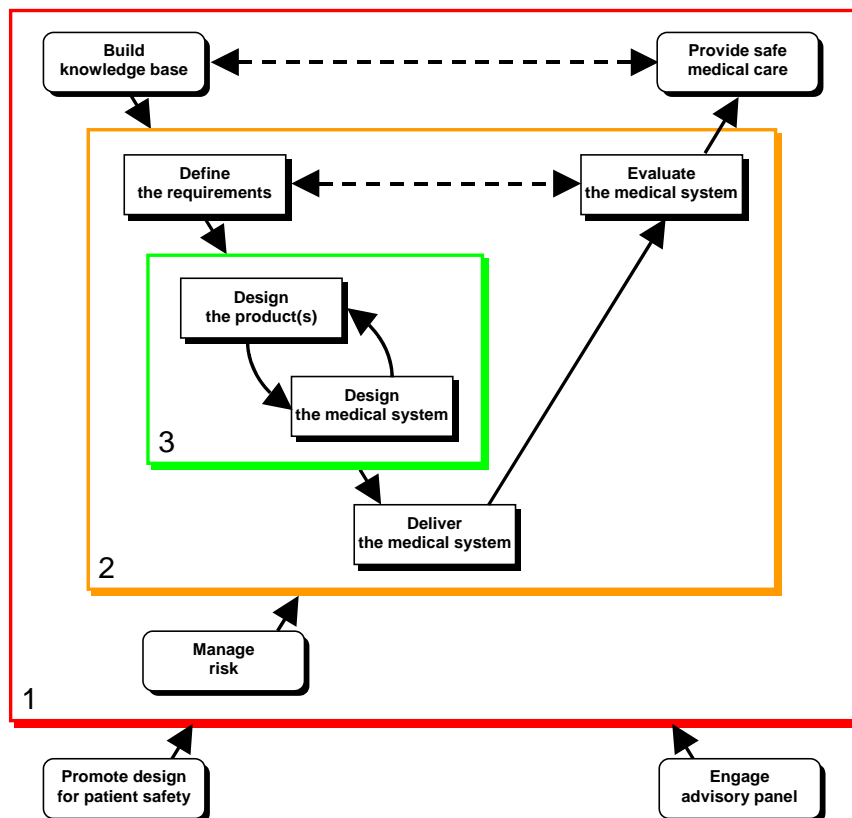


Figure 2 A systems-based user-centred approach to healthcare design (the Design for Patient Safety framework).

3.2. Research framework

3.2.1. Project background

In 2004, the NPSA presented a suggestion for research into PHA methods [Rejman, 2004]. This unpublished report identified a number of the important issues that required addressing and resolving if the health service were to adopt the approaches to risk assessment that had been adopted in other safety critical industries. In particular, Rejman emphasised the need to match the *requirements* of end users with the risk assessment methods in current use across industries. He went further in suggesting that experimental studies were required: *“What is needed therefore, is some measure of efficacy, and some experimental work to show how different methods perform against this, and each other.*

This is unlikely to be a trivial task given a complex dynamic system like healthcare; indeed it may not be possible.”

As a result of this report and discussions within the research team, we proposed to carry out a study, involving four phases:

- Phase 1 – Definition of healthcare requirements. The proposal document presented an initial list of case studies (scenarios across different settings). Along with interviews with healthcare practitioners to understand their needs for PHA (analysis of healthcare practice), the case studies would be investigated to determine a range of “healthcare characteristics” which might ultimately influence the choice of PHA methods in different settings. These characteristics would be linked to each case study, forming a “requirements matrix”. This would be supported by an analysis of healthcare literature, which would help understand current risk assessment practice in healthcare and any gaps in this.
- Phase 2 – Identification, assessment and tailoring of PHA methods. The aim of Phase 2 was to develop two matrices – a PHA methods “characterisation matrix” and, by combining the healthcare requirements matrix from Phase 1 with the characterisation matrix, a “methods matrix”. The methods matrix would be used to determine which PHA methods should be tested in which case studies, and would serve as a prototype “methods selection framework” for the Toolkit. The PHA characterisation matrix would be populated through a literature review, a workshop with risk experts and observations through interviews of PHA practice in healthcare and in other industries, and would contain the characteristics of each PHA method selected (e.g. does it produce a risk rating or just identify hazards / how much resource does the PHA method require). It was anticipated that modifications might be necessary to PHA methods, to make them suitable for healthcare and this would be based on the requirements produced from Phase 1. Phase 1 and Phase 2 would run in parallel and would inform each other.
- Phase 3 – Evaluation of tailored methods. Further refinement of the list of case studies would help identify a final shortlist. Suitable PHA methods (identified by the methods matrix) would then be tested in each case study; as would the methods selection framework. The usability and utility of each PHA method would be tested in each case study.
- Phase 4 – Creation of a Toolkit. The PHA Toolkit would be influenced by the requirements developed from Phase 1, and by the feedback from the case studies.

This process is summarised in Figure 3.

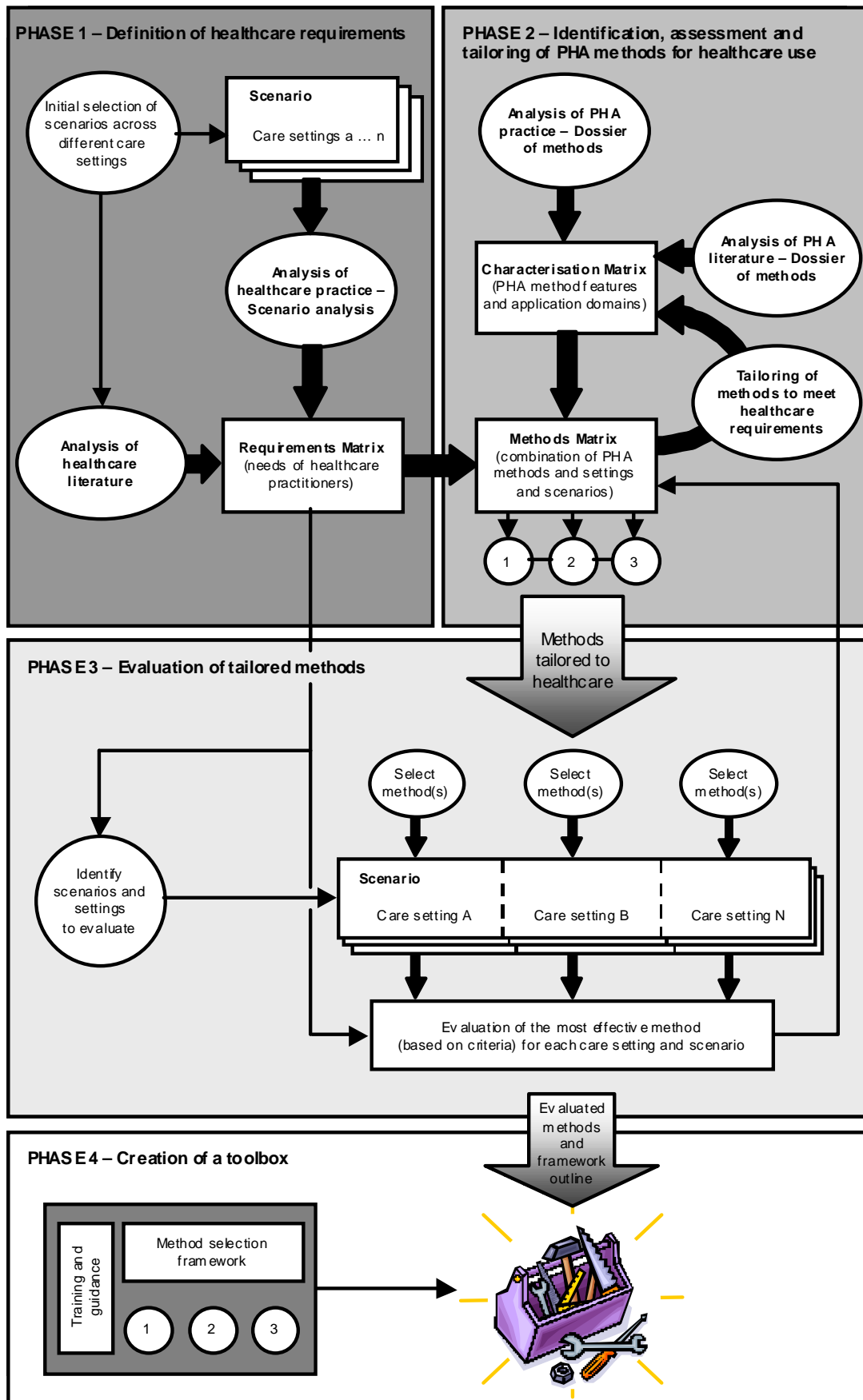


Figure 3 Proposed four-Phase approach for PHA project.

3.2.2. Development and modification of the research plan

Following the award of the research grant a Steering Committee was established that included risk specialists, research academics and risk professionals and other practitioners from the health care industry (see Table 1 for composition of this committee). One of the roles of this Committee was to review the research design and provide inputs regarding feasibility, rigour, and resources as well as pragmatic issues regarding, for example, access to the health service.

Table 1 Composition of Steering Committee.

<p><i>Eleven members in total comprising:</i></p> <ul style="list-style-type: none">• Six NHS representatives (acute pharmacy, acute risk management, acute surgery, community general practice and NHS Arms-length body)• Three independent members (University engineering and risk, University patient safety and risk and rail safety)• Chair• Project sponsor
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This Committee met regularly, as did the research project team. Table 25 in Section 10.2 in the Appendices provides details of these meetings and the significant outcomes. Discussions, presentations and critiques of the plan were a central focus of these meetings and, in particular, the extent to which the phases could be successfully undertaken in the manner described in Figure 3, given study limitations.

After the second steering group meeting, a shift in emphasis was advised. This led the research team to move away from a full experimental model (i.e. of selecting methods for the Toolkit based on health care requirements and expert perspectives and then testing the case studies through carefully selected and characterised case studies) to a more feasible approach characterised by a greater reliance on expert judgement for selection of PHA methods coupled with a detailed consideration of user requirements. The design then led these to be tested in a series of case studies. This can best be summarised as the rephrasing of Phases 3 and 4.

One essential reason for this was that the complexity and number of the variables that would need to be addressed in any traditional 'experimental' design research model. The list of complex variables emerged during the literature review, as well as from the steering group and from other experts during the early stages of the study. A range of these have been summarised in Table 2. Later sections in this report address these issues in more detail.

Table 2 Examples of variables requiring consideration in an experimental design.

<p>PHA Methods (e.g. FMEA, FMECA, FTA, ETA, HACCP, HAZOP, HRA). Which methods to include in the analysis?</p> <p>Content of analysis (e.g. which part of the system should we investigate? What is the nature of what we are to investigate (e.g. human errors / technology unreliability / cultural or organisational problems / specific scenarios, e.g. care at weekends)? To what level of detail? What do we include in any process maps? What sort of description to we choose – e.g. flow chart or textual)?</p> <p>Healthcare setting (e.g. primary care / secondary care / palliative care / within any of these, such as A&E or surgery or GP practice).</p> <p>Participants (e.g. how many people? What backgrounds for each person (e.g. clinical staff / managers / clerical / support staff)? Mix of people (e.g. risk of unwillingness to criticise system in front of line managers / character clashes).</p> <p>Facilitator (e.g. what training do they require).</p> <p>Resources required (e.g. time, funds, training, required experience).</p> <p>Goals for analysis (e.g. quantitative evaluation of risks).</p> <p>Motivation (e.g. may be personally motivated or may not see the value in performing a PHA, which may influence engagement with the process).</p>
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Thus the final research project plan and methods are summarised in the following model (Figure 4). This was presented to, and fully endorsed by, the steering committee in April 2009.

Table 3 shows the originally intended outputs and the actual results from the project. It can be seen that the overall outputs from the project match the original objectives; however the mechanisms by which they were delivered and the order in which these were delivered have changed in some cases.

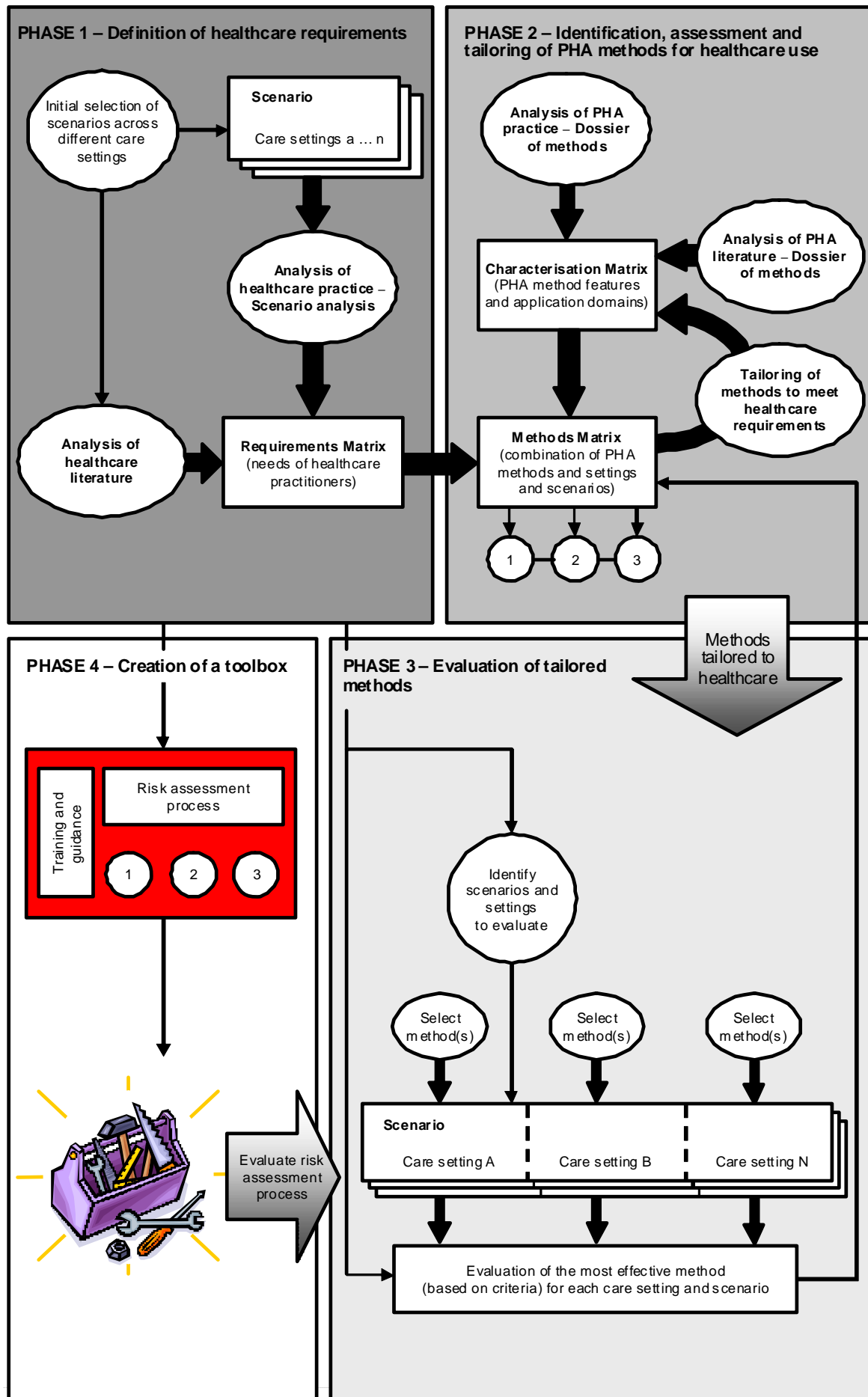


Figure 4 Revised model of methodology.

Table 3 Original project objectives (as per PHA Proposal) and results from PHA Project.

Objective in proposal [Section No.]	Rationale	Result
INTRODUCTION		
A systematic assessment of healthcare practitioners' requirements , and a methodical process for matching specific settings and scenarios to one or more PHA method. [1]	Ensure that the Toolkit meets the needs of its users.	Users' requirements were assessed through a variety of means and heavily influenced the development of the Toolkit. A matching process is included within the Toolkit, which matches objectives with PHA methods.
Involvement of PHA experts. [1]	Experts may be able to provide a far greater insight into PHA use, and its use in healthcare, than literature can.	A "Risk Experts Workshop" took place to understand in particular how Experts select PHA methods. Regular attendance was kept at a regional meeting of Risk Managers, during which feedback was often sought. Interviews were carried out with experts in risk assessment.
A validation of a variety of PHA methods in a range of settings and scenarios, measuring the utility and usability of the methods. [1]	Adequate testing of PHA methods across the NHS.	A range of PHA methods were tested, within the PHA Toolkit, in different settings and scenarios across the NHS. Usability and utility were assessed.
A Toolkit , consisting of guidance for using various PHA methods, an approach for selecting the most appropriate methods for use in different healthcare situations and training protocols. [1]	Providing guidance for the NHS on PHA.	A Toolkit was produced, which contains a risk assessment framework, a range of PHA methods, descriptions of how to use each method and a framework for selecting PHA methods, although it should be noted that there may be several entirely appropriate PHA methods for a given situation in healthcare.
Sample widely across the NHS , testing the PHA methods in a broad range of settings and scenarios. [3.1.3]	Test whether the Toolkit works throughout the NHS.	Requirements sampled and case studies conducted across a broad range of settings and scenarios.
Identify critical features of the medical domain which will impact upon choice of PHA method(s). Provide an overview of the healthcare characteristics which might influence selection of the PHA method. [3.2.1]	It was originally believed that understanding the features of different sectors in the NHS would help select a diverse range of case studies and produce the categories necessary for a PHA methods selection framework.	It was realised that such features were not in general a direct product of the healthcare setting, but were a product of the very specific and individual characteristics of each scenario requiring a risk assessment. These specific characteristics would be individual to each case study, and have been identified in the methods selection framework. An analysis of risk management practice in the NHS has been conducted.

Objective in proposal [Section No.]	Rationale	Result
PHASE 1		
Create initial selection of scenarios and settings (case studies) [4.1.1]	Understanding the characteristics of the case studies will help form a requirements matrix.	List created, but final list produced much later in project. See Section 7.5.
Analyse healthcare literature [4.1.2]	Understand healthcare practice.	Healthcare literature review conducted, including a review of documents which influence current risk assessment practice in the NHS. See Section 4.
Analyse healthcare practice [4.1.3]. Assess current risk assessment practice and characterise case studies through interviews with case study leads and other NHS staff members.	Understand healthcare practice and help form requirements matrix.	Interviews conducted with NHS staff. Case study leads were interviewed later in the project, to characterise each case study. See Sections 5 and 7.5.
Produce healthcare requirements matrix [4.1.4]	Characterise each case study, to determine requirements for selection of PHA methods.	The characterisation of each case study took place, but later in the project. See Section 7.5.
PHASE 2		
Analysis of PHA literature. [4.2.1]	Learn lessons from PHA methods that have already been used in healthcare, and also from outside of healthcare.	Literature review was conducted. See Section 4.
Analysis of PHA practice [4.2.2]. Workshop with PHA experts.	To understand how PHA methods are selected and used in other industries.	Workshop conducted. See Section 6.2.
Development of a characterisation matrix [4.2.3].	This matrix will show the key characteristics of each PHA method, in order to help match PHA methods with case studies.	Characterisation of each PHA method has been described in Sections 4.5.2 and 6.8.
Development of a methods matrix [4.2.4].	The matrix will show which methods are most suitable for use in each scenario/setting. It also aims to help reduce the range of PHA methods to a manageable number for the NHS.	PHA method selection is based predominantly on individual requirements for each case study. It was found that the selection of PHA methods would be more dependent on individual and specific requirements for each case study, and not on <i>general</i> requirements for each setting. The range of PHA methods was reduced with assistance from the literature review, the Risk Experts Workshop and the characterisation process for each PHA method. A methods selection framework is described in Section 6.8. However, we believe that, generally for a given situation in healthcare, more than one PHA method will be suitable.

Objective in proposal [Section No.]	Rationale	Result
Tailoring of methods to meet healthcare requirements [4.2.5].	PHA methods may require a degree of adaptation to be suitable for healthcare.	Whilst the individual PHA methods have not been tailored for use in the NHS, the PHA framework which, sits around them, has been. This framework also includes elements from a range of PHA methods, and can be regarded as an adaptation of PHA for use in the NHS.
PHASE 3		
Identify scenarios and settings to evaluate [4.3.1]	Prior to carrying them out, further refinement of the list of case studies may be required, to ensure that an adequate range of case studies is available.	The development of the list of case studies is described in Section 7.5.
Evaluate PHA method(s) [4.3.2 and 4.3.3]	Testing of the usability and utility of the PHA methods, and also the methods selection framework (methods matrix).	These were tested through five case studies, in each of which, one or more PHA methods were tested. This is described in Section 7.5.7.
Draft PHA Toolkit outline [4.3.4]		This is described in Section 6.
PHASE 4		
Development and evaluation of the utility of a method selection framework [4.4.1 and 4.4.3]	As above.	See Section 6.8 and the case studies in Section 7.5.
Describing PHA methods [4.4.2]	Descriptions of PHA methods will be necessary if staff are to use the Toolkit, since they are unlikely to be familiar with them.	Brief descriptions of each PHA methods were created. See Section 6 and the PHA Toolkit.
Provision of guidance in using the PHA methods [4.4.4]	In addition to the PHA method descriptions, it will also be necessary to describe how they may fit into a risk assessment framework.	Guidance is given to include all elements of a risk assessment process, in addition to specific guidance on the use of a range of PHA methods.
Dissemination plan [4.4.5]]	If the Toolkit is to have a strong impact in the NHS, dissemination needs to be considered.	This is described in Chapter 9.

3.3. Ethics / R&D approvals process

Before funding could be provided, and hence before recruitment of the researchers could begin, it was necessary to obtain ethics approval for the study. The following table describes the timeline for ethics and R&D approval.

Table 4 Ethics / R&D approval timeline

When	What	Notes
Jan-Jul 06	Ethics application preparation	See below for details
26 Jul 06	Ethics application made (v1.0)	
23 Aug 06	“Approvable” letter received (v1.0)	Request for further information from REC.
1 Sep 06	MREC Ethics application made (v1.1)	Further information was provided.
14 Sep 06	MREC ethics approval granted (v1.1)	
Feb-Sep 09	Research Passports applied for / issued to PHA researchers	
1 May 09	Substantial Amendment submitted (v2.0)	Request for additional case studies and minor changes to evaluation method
19 May 09	Substantial Amendment approved (v2.0)	
17 Aug 09	Substantial Amendment submitted (v2.1)	Request to carry out interviews with NHS staff, alongside the case studies, to evaluate the Toolkit
Aug-Oct 09	R&D applications for individual case study sites made / approval granted	Approval was given for five sites (see Section 7.2).

In early-mid 2006, an application for ethics approval for a Multi-Centre study was prepared. Some of the questions raised from the ethics application sheet were:

- *“What will happen to the research participant, how many times and in what order?”*
- *“The justification for including control arms to a trial, if used.”*
- *“Where any interviews will take place.”*
- *“In how many and what type of host organisations (NHS or other) in the UK is it intended the proposed study will take place?”*
- *“How many participants will be recruited?”*
- *“How will potential participants in the study be (i) identified, (ii) approached and (iii) recruited?”*

These questions were particularly challenging since there was little prior art in the literature, which otherwise might have provided details of successful practice. For example, consider a paper that describes a Fault Tree Analysis. Bearing in mind the scope and detail of such analysis, had it explained how many hours the analysis had taken, such observations might have helped predict how long a similar analysis might take during a PHA case study. Secondly, the format of the PHA Toolkit was largely unknown at this point.

Two Substantial Amendments were applied for and approved during the course of the project. The first Amendment reflected the changes to the project, as described in Section 3.2.2). This also enabled further case studies to be conducted, using a broader range of

PHA methods than originally planned. The second Amendment applied for permission to conduct interviews with NHS staff to evaluate the PHA Toolkit on a one to one basis.

4. RISK ASSESSMENT PRACTICE

4.1. Introduction

In order to build a Toolkit, one of the aims stated in Chapter 2 is to review risk related practice from both within healthcare and in other industries, with a view to learning from good practice, and identifying where gaps might lie in NHS practice. This Chapter presents this review, and covers the following topics:

- PHA practice outside of healthcare, which describes different generic stages of risk assessment and discusses good practice principles.
- Healthcare “national” practice, by reviewing a number of significant documents which govern risk management in the NHS at a national level.
- Healthcare “local” practice, which presents a review of risk related documents that are used at an NHS Trust level, such as protocols and risk strategies.
- The use of PHA methods in healthcare, consisting of a review of nine PHA methods and any experiences of their use in healthcare which might be learned from.
- The use of system mapping techniques (an important part of good risk assessment practice) in healthcare.
- Informal interviews with NHS staff, to understand current risk assessment practice.
- A review of guidance documents in healthcare, to identify any generic tips for the development of guidance for use by NHS staff.

4.2. PHA practice outside of healthcare

Since PHA methods are used routinely in the high-hazard industries, a literature review of their practice was conducted with the purpose of learning from their experiences.

4.2.1. Method

Literature was gathered from the following sources:

Internet

Literature was gathered using Google and Google Scholar. Key words were used to help structure the data collection, for example:

- Hazard identification AND high hazard industries;
- Risk assessment AND high hazard industries;
- Prospective hazard analysis AND high hazard industries;
- Hazard analysis AND high hazard industries;
- Risk management AND high hazard industries.

Web libraries

Web libraries for the following organisations were also explored:

- Health and Safety Executive;

- Ministry of Defence;
- Home Office Police;
- Communities and Local Government;
- Rail Safety and Standards Board;
- Internal Atomic Energy Agency;
- Energy Institute.

Reference books and journal articles

The following reference books and articles were reviewed:

- Health and Safety Executive. Five steps to risk assessment [HSE, 2006].
- Health and Safety Executive. Reducing error and influencing behaviour [HSE, 1999].
- Karwowski, W. "International Encyclopaedia of Ergonomics and Human Factors" [Karwowski, 2006].
- Kirwan B, Ainsworth LK. A guide to task analysis [Kirwan and Ainsworth, 1992].
- Kirwan, B (1994) "Practical Guide to Human Reliability Assessment" [Kirwan, 1994].
- Kirwan, B (1998) "Human Error Identification Techniques for Risk Assessment of High Hazard Systems – Part 1: Review and Evaluation of Techniques" [Kirwan, 1998a].
- Kirwan, B (1998) "Human Error Identification Techniques for Risk Assessment of High Hazard Systems – Part 2: Towards a Framework Approach" [Kirwan, 1998b].
- Howard, R., & Matheson, J (2005). "Influence Diagrams" [Howard and Matheson, 2005b]
- Maguire, R (2006) "Safety Cases and Safety Reports: Meaning, Motivation and Management" [Maguire, 2006].
- Nuclear Installations Inspectorate. Safety assessment principles for nuclear power plants [Nuclear Installations Inspectorate, 1992].
- Rail Safety and Standards Board (2008) Understanding Human Factors: A guide for the Rail Industry [Rail Safety and Standards Board, 2008].
- Trost, W. A., & Nertney, R. "Barrier Analysis" [Trost and Nertney, 1985].
- Wilson, J. & Corlett, N. "Evaluation of Human Work". [Wilson and Corlett, 2005].

Standards

The following standards were reviewed:

- IEC61882: "Hazard and Operability Studies (HAZOP Studies – Application Guide)". Geneva: International Electrotechnical Commission [IEC, 2001].
- British Standard BS EN 31010 Draft standard. *Risk management. Risk assessment techniques* [BSI, 2008b]
- IEC 60812 *Procedures for Failures Modes Effect Analysis* [IEC, 1985].
- IEC 61025 *Fault Tree Analysis* [IEC, 2007].
- PD ISO/IEC Guide 73:2002 *Risk Management – Vocabulary – Guidelines for use in Standards* [ISO/IEC].
- ISO/IEC Guide 51:1999 *Safety aspects – Guidelines for their inclusion in standards*

[ISO/IEC, 1999].

- US Nuclear Regulatory Commission (1981) "Fault Tree Handbook". NUREG – 0492 [US Nuclear Regulatory Commission, 1981].
- United States Military (1999). Human engineering design criteria for military systems, equipment and facilities. Document reference: MIL-STD-1472D [DOD, 1999].
- Def Stan 00-25 Human Factors for Designers of Systems, Part 15, Issue 1, Principles and Processes. MOD [MOD, 2004].

4.2.2. Results

4.2.2.1. Overview

As noted in Section 2.1, PHA comprises a number of stages. Dependent on the purpose of the analysis, and the nature of the system or part of it that is being considered, there may be a wish to focus on certain aspects of the PHA process, such as hazard identification, or consequence analysis, and hence different methods may be adopted at different times.

Furthermore, depending on the nature of the system and the potential adverse consequences, different depths of analysis may be undertaken, with varying levels of resource and time commitment. For example, within the UK nuclear industry there is a requirement to undertake an extensive periodic review of the extant safety case and how the system has performed in the intervening period. These periodic reviews of safety tend to be undertaken every 10 years, and consider all aspects of the risks associated with the operation of the facility and the management of those risks. Typically these analyses can take 2 years to undertake, and require many 10's of person-years of effort. At the other extreme, a simple assessment of a proposed change of a minor part of a system might require an assessment that can be concluded within a few hours or days.

The results for the literature review indicated a number of techniques that are commonly used across the high hazard industries. These can be categorised as follows (note that the techniques listed below may not fall exclusively into each category – the purpose is to show at which part of the risk assessment process their predominant contribution lies):

Hazard identification, covering such methods as:

- HAZOP.
- SWIFT.
- Barrier Analysis.

As the name suggests, hazard identification methods focus on identifying relevant hazards and potential failures relating to system operation. These techniques also allow for the development and identification of potential improvement steps to eliminate or mitigate hazards and failures.

These techniques however do not provide an analysis of likelihood or severity and therefore detailed risk assessment techniques are often used after hazard identification to provide further analysis of risk, causes, consequences and probabilities and aid the development of improvement strategies.

Effective hazard identification requires a sufficiently detailed and accurate system description, including both the structure of the system and its method of operation. The preparation of such descriptions can require significant levels of effort.

Risk assessment, covering such methods as:

- FMEA.
- Fault and Event Trees.
- Human Reliability Assessment Methods (e.g. HEART, THERP).
- Absolute Probability Judgement.

Risk assessment approaches build on the information gathered through hazard identification methods and provide a detailed analysis of failures, their causes, consequences, severity and likelihood.

These techniques help to further understand and prioritise risk, error and potential failures that can occur within a system. Moreover, the information can then be used to make risk based decisions on the development and implementation of improvement strategies, i.e. prioritising the development and implementation of improvement strategies based on the severity and likelihood of risk exposure within the system.

Communication, covering such methods as:

- Risk Matrices.

Communication methods are approaches aimed at documenting and summarising perceptions of hazards and risks within a system, as identified through relevant hazard identification and risk assessment techniques. They do not in themselves provide an objective means of analysing clinical risk but can help to communicate and document findings.

These terms, and others, have been defined by the ISO and IEC, as summarised in Table 5.

Table 5 Definitions of components of risk management.

Term	ISO/IEC Guide 73:2002	ISO/IEC Guide 51:1999
Risk assessment	Overall process of risk analysis and risk evaluation	Overall process comprising a risk analysis and risk evaluation
Risk analysis	Systematic use of information to identify [hazards] and to estimate the risk.	Systematic use of available information to identify hazards and to estimate risk
Hazard identification	Process to find, list and characterise [hazards].	
Risk estimation	Process used to assign values to probability and consequences of a risk	
Risk evaluation	Process of comparing the estimated risk against given risk criteria to determine the significance of risk	Procedure based on the risk analysis to determine whether the tolerable risk has been achieved.
Risk treatment	Process of selection and implementation of measures to modify risk	
Risk control	Actions implementing risk management decisions	
Risk acceptance	Decision to accept risk	
Risk communication	Exchange or sharing of information about risk between the decision maker and other stakeholders	

Many of these terms are inter-related in a hierarchical manner, so we add Figure 5. It can be seen that Risk Management is the over-arching term. Based on the aims of the study, the PHA Toolkit will focus on the Risk Assessment process, which includes Risk Analysis.

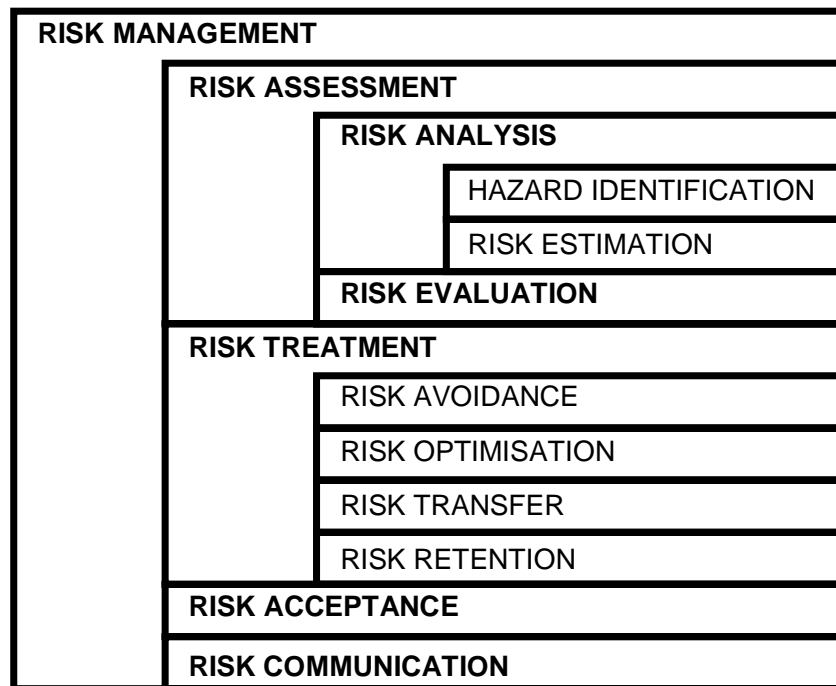


Figure 5 Risk terminology, after ISO / IEC Guides 51 and 73 [ISO/IEC, ; ISO/IEC].

The nuclear industry has been at the forefront of the development of proactive risk assessment methods. These methods need to be appropriate to the assessment of high-consequence low-probability risks. The methods have been developed in conjunction with a sophisticated approach to understand the tolerability and acceptability of risks, and the development of structured approaches to the identification of the risks (such as approaches including Fault and Event Trees, HAZOPs, the use of existing reliability data, and dependency modelling), structured approaches to the assessment of their tolerability (such as the use of ALARP – “As Low As Reasonably Practicable” – approaches), and structured approaches to the reduction in risk (such as the ERICPD concept of risk reduction hierarchies – Eliminate, Reduce, Isolate, Control, Protect, Discipline).

These methods and approaches have been developed in order to support the control of risks that are already very highly defended. Due to the existence of defence in depth, the probability of the adverse event occurring will be low, as will the mitigated consequences if it does occur. Consequently it has become very important within the nuclear industry, and other high-hazard industries, to be able to understand the contribution to risk from a broad range of potential failures, in order to understand the importance and reliability of the multiple defences.

Within healthcare, the probabilities of adverse events are not as low, and hence the visibility of those events and of the performance of the defences and barriers against them is greater. This may permit risk assessment within healthcare to avoid the need for the significant levels of granularity applied within the nuclear industry.

Furthermore, the level of sophistication of risk assessment within the nuclear industry is necessary to support the tolerability of risk decisions. A complex approach to probabilistic

and deterministic analysis is adopted as a means of determining whether the resultant risk is below the 'Basic Safety Limit' (i.e. is tolerable) and is below the 'Basic Safety Objective' (i.e. achieves a level of risk to which the industry is required to work). Additionally, the approach supports the ALARP assessment of small enhancements to safety – in order to demonstrate that the risks have been reduced to levels that are as low as reasonably practicable, and that further risk reduction would incur disproportionate cost.

Within healthcare there is a less sophisticated approach to assessment of the tolerability of risk. Generally, there is no agreed threshold of tolerability (a Basic Safety Limit) and hence the principle objective of risk assessment within healthcare tends to be to ensure that the nature of the risks is understood, and hence that qualitative approaches to risk reduction can be identified and considered.

4.2.2.2. System mapping in PHA practice

A significant element of the risk assessment process within the conventional high-hazard industries is the 'process mapping' phase. The importance of this phase derives from two aspects. One is that for a new system it is essential that there is a complete and agreed description of how the system performs, in order that credible deviations from the intended performance can be identified and assessed. The second is for existing systems, where it is essential that there is a proper description of the 'as-built' system, i.e. the system in its current form, including any modifications and changes that have been implemented since it was originally designed. It is accepted within most high-hazard industries that the 'as-built' system will differ from the original design, even prior to initial commissioning. Those differences may be significant in terms of their impact on risk, and these impacts can be assessed only if the differences are fully and accurately described.

Redmill *et al.*, for example, have highlighted the following important roles that good, visual system representations can play [Redmill *et al.*, 1999]:

- They enable the team to easily and rapidly understand how the system works and then to identify and explore all the critical elements of the system. If the team cannot easily understand the system, time will be wasted in agreeing on how the system works.
- They enable the team to identify and analyse system-wide hazards. Without a good representation, the team can easily become immersed in discussion about a small part of the system, leading to an assessment which is not truly systemic, as it will only examine a subset of the relevant components and interactions.
- They act as an itinerary of systematic analysis for the team. They help the team agree the scope of the analysis and go through the elements the team must study.

Therefore, when selecting the representations it is necessary to check that they are understandable to the team and inclusive of critical items of the system. In particular, diagrammatic representations, which have been considered superior to text-based descriptions [Larkin and Simon, 1987], have been used extensively in other industries. Diagrammatic representations index information by locating it in a plane, which may be shared by many elements. Each element may be adjacent to any number of elements, while text-based representations index information by position in a list [Larkin and Simon, 1987].

Diagrammatic representations can be constructed in many different ways and each type of diagram has its own set of notations and layouts used to portray the features of the system. For example, a flow diagram expresses sequential logic between activities, while a communication diagram expresses information interactions between system

components. The better the description of the original process and the better the match between the properties of the diagram and the properties of interest in the analysis, the more useful the diagrams will be to the risk analysis.

Typical examples are extensive Task Analyses to describe the personnel actions and activities that contribute towards system performance, or the development of suitable descriptions of the hardware system, perhaps in the form of Pipe work and Instrumentation Diagrams. The following examples show a snapshot of different diagram types that have been used with a range of PHA methods. More details of each example are added in the Appendices in Section 10.3.1.

- Hierarchical task analysis and state space diagrams used with SHERPA for human error prediction in vending machine usage [Stanton and Baber, 2005].
- Piping & instrumentation diagrams, process flowcharts, utility flow diagrams and layout drawings used with HAZOP for the risk analysis of chemical processes [Hyatt, 2003].
- Context diagrams and data flow diagrams used with HAZOP for the hazard identification of a semi-automated technical system [Redmill *et al.*, 1999].
- Process flowcharts and block diagrams used with FMEA for the risk analysis of the product's life cycle [DYADEM, 2003a].

4.2.2.3. PHA in the system design process

As noted above, the importance of an adequate process description derives in part from the inevitable variation in the structure and behaviour of the system that arises during the 'construction and commissioning' stages, notwithstanding any further changes that are introduced during operations. This will apply to any system, whether it is a complete hospital (which is likely to undergo design change and modification throughout the construction phase let alone after handover), or an item of equipment.

Various PHA methods have been developed in order to permit their application throughout the design, construction and commissioning lifecycle. Within the nuclear industry there is a structured approach to the production of safety justifications, including the Preliminary Safety Report (developed during the initial design phase), the Pre-Construction Safety Report (developed during detailed design), the Pre-Commissioning Safety Report (developed towards the end of the construction phase to take account of any changes introduced and to ensure that the operational requirements are fully understood), and the Pre-Operational Safety Report (which represents the final assessment of the as-built facility and its methods of operation, including safety management).

Each of these suites of documents is underpinned by a set of risk assessment methods. The underlying methods are similar, but applied at different levels of detail and granularity.

These methods permit a risk assessment to be undertaken at the early design concept phase, and further assessment to be undertaken as the design evolves.

The application of formal risk assessment at the design stage also provides a baseline against which subsequent changes during operations can be assessed. This facilitates the change management processes.

Consequently, the approach to risk assessment adopted at any given stage in the lifecycle of the system will be dependent on the purpose of the risk assessment:

- What question is being answered (assessment of new design, assessment of change,

etc);

- What level of uncertainty can be accepted;
- How significant is the consequence of failure;
- What resources/methods are required in order to provide sufficient confidence in the output from the risk assessment.

4.2.3. Discussion

Lessons learned from the application of risk assessment in other high-hazard industries should be considered for their relevance to healthcare.

Whereas such industries as nuclear and chemical have a long history of the development and application of risk assessment, and hence can provide a set of validated and well-utilised methods to support risk assessment, it should not be assumed that all such methods can or should be imported into healthcare unchanged. There are some exceptions, but four principal differences may exist between healthcare and other high-hazard industries:

- Healthcare does not have the same formality in its development and maintenance of system descriptions. (An exception could be the use of care pathways).
- Healthcare does not have the same level of change control.
- Healthcare does not have the same level of understanding of the tolerability of different risks nor of levels of acceptability. (Such judgements are difficult if realistic baseline data are not available – in terms of the likelihood and consequences of particular outcomes, and also in terms of the number of opportunities for harm to occur. If, for example, one was to consider the risk of a self-medicating patient making a medication error, the likelihood may vary according to the time of day, the mood of the patient, environmental conditions, and so on. The consequences of such an error might depend upon the physical condition of the patient, how quickly the error was spotted, and whether suitable methods for mitigating its effect were readily available. The overall risk of harm to the patient would also depend on the number of times the drug is taken. Whether such a risk is appropriate adds a further layer to the complexity of this issue).
- Healthcare does not have the same potential for high-consequence failures.

In respect of the final bullet, it is recognised that, like any complex system, significant consequences can arise. For example, a closure of a major hospital can affect many thousands of people, although the potential for significant numbers of fatalities may be lower than for, say, the nuclear industry. Similarly, certain medication-related failures such as Thalidomide have had widespread consequences. Systematic inaccuracies in diagnostic tests may also have similar consequences, where an error can be repeated many times, affecting many people, before it is discovered. However, in general the difference between healthcare and certain other high-hazard industries in this respect is that the impact of failure tends to have an immediate effect on a small number of people, and hence those impacts may have less public visibility and impact, at least in the immediate term. This influences the ability to recognise the significance of the risk and to marshal appropriate resources to manage it.

The implications of these differences are that healthcare needs to be selective in the manner in which it selects and adopts risk assessment methods used in other industries. The methods remain appropriate, but the manner in which they are applied may vary in order to take account of the reduced levels of formality and sophistication of risk

understanding. As a consequence, in general it may be appropriate for healthcare to apply a set of risk assessment methods that have been selected for their validity when applied at high levels, to less well-developed system descriptions, and which are oriented towards providing qualitative understanding of risk rather than supporting formal assessment of the quantitative tolerability of risk.

It also implies that any application of risk assessment methods within healthcare is likely to require extensive support in terms of how to apply and interpret the process. There is little guidance concerning the selection and use of methods generally, and the guidance that does exist tends to be aimed at expert users. Lyons clearly reveals the range of methods, the complexity of the selection process, and the lack of guidance to support that process [Lyons, 2009].

4.2.4. Conclusions

Other industries have successfully applied a broad range of PHA methods and techniques to address a range of different risk assessment needs, and use process descriptions as a starting point for risk assessment. A key element of any PHA toolkit to be used within Healthcare will need to be support for the development of appropriate process descriptions. It will also require guidance on how to use the methods within the context of risk assessment, in addition to providing guidance on the use of individual methods.

PHA method selection requires a sophisticated understanding of risk assessment, and hence the development of the PHA Toolkit will need to consider how a surrogate for that understanding can be provided. However, there is little literature available to support the development of such guidance on the risk assessment process. Similarly, there is little literature available to provide guidance on the ease of use of different methods, or the level of resource required.

4.3. Risk-related documents in healthcare (national practice)

4.3.1. Aim

A range of documents were analysed in March 2009 to identify the extent to which formal policy discussed the use of PHA methods and to gauge the climate in healthcare regarding PHA methods. Four research questions were identified:

- 1) Are PHA methods mentioned in the documents?
- 2) If they are mentioned, are they positively, neutrally or negatively presented? Are the benefits of PHA discussed?
- 3) Is there detailed information available about the methods in the documents or in other sources cited?
- 4) Is there direct or indirect pressure on healthcare organisations to conduct PHA?

These questions informed the selection of relevant documents for review, formed the basis of the analysis framework and provided important context to understand the culture of risk management in healthcare.

4.3.2. Selection of documents

The document analysis was not intended to be exhaustive but to provide sufficient depth to answer the research questions. To identify the relevant documents for review, the focus

was on publications produced by the Department of Health (DH) and its Arm’s Length Bodies (ALBs).

Publications from the following organisations were reviewed for their relevance to PHA and wider subject areas of safety, quality, risk assessment and management.

- 1) Department of Health (DH)
- 2) National Patient Safety Agency (NPSA)
- 3) NHS Institute for Innovation and Improvement (referred to hereafter as The NHS Institute)
- 4) NHS Litigation Authority (NHSLA)
- 5) The Healthcare Commission
- 6) Monitor – Independent Regulator of Foundation Trusts

In addition, publications by the Health and Safety Executive (HSE) were reviewed for their relevance to the research aim. The HSE’s role is to “protect people against risks to health or safety arising out of work activities” (HSE 2008) and to has relevance to healthcare organisations.

4.3.3. Analysis method

The official websites of the organisations listed in Section 4.3.2 were searched for relevant documents relating to risk assessment. Every document that was related to risk assessment was reviewed.

4.3.3.1. Framework for analysing documents

Informed by the four research questions presented in Section 4.3.1, the framework in Table 6 was developed to aid the analysis process.

Table 6 Framework used to analyse documents

Title, Year produced	Aim of document	Intended audience	Reference to PHA. If referred to, how are they presented and are benefits mentioned?	Direct or indirect pressure to conduct PHA	Provision of information about the method and/or guidance to perform analysis	References to further guidance/training

- Each document was initially reviewed to identify the aim of the document and the intended audience.
- Further analysis was conducted to identify the following keywords in the documents:
 - Risk assessment
 - Prospective risk assessment
 - Probabilistic risk assessment, failure modes and effects analysis, 5x5 risk matrix,

HAZOP, fault tree analysis, event tree analysis or any PHA method

- In addition to these keywords, phrases such as ‘rating the likelihood’ were also noted in the analysis.
- Whether PHA was positively, neutrally or negatively presented and whether the benefits of PHA were discussed was noted.
- The documents were also analysed to identify whether there was detailed information available about the methods in the documents or in other sources cited.

4.3.4. Findings

A total of 30 documents were reviewed and are listed here. The full analysis is presented in Table 26 in Section 10.3.1 in the Appendices.

1. Department of Health

- a) *The operating framework for the NHS in England 2009/10. High quality care for all (December 2008).*
- b) *Standards for Better Health (2004).*

2. National Patient Safety Agency

- a) *Seven steps to patient safety: An overview guide for NHS staff (April 2004).*
- b) *Seven steps to patient safety. Step 3: Integrate your risk management activity (August 2004).*
- c) *Seven steps to patient safety in mental health. Summary (November 2008).*
- d) *Seven steps to patient safety for primary care. Step 3: Integrate your risk management activity (May 2006).*
- e) *Risk assessment programme: Overview (November 2006).*
- f) *Risk assessment programme: A guide to assist commissioners of out-of-hours services (November 2006).*
- g) *Risk assessment programme. Practice-based commissioning: commissioning for patient safety (November 2006).*
- h) *Hospital at Night. Patient Safety Risk Assessment Guide (March 2005).*
- i) *Hospital at night. Patient safety risk assessment. Quick guide for medical staff. (March 2007).*
- j) *Hospital at night. Patient safety risk assessment. Quick guide for Hospital at Night leads and/or risk managers (March 2007).*
- k) *Healthcare risk assessment made easy (March 2007).*
- l) *A risk matrix for risk managers (January 2008).*
- m) *RCA Toolkit (2008).*

3. The NHS Institute

- a) *Improvement leaders' guide: Process mapping, analysis and redesign (2005).*
- b) *Improvement leaders' guide series (2005).*
- c) *Going lean in the NHS (2007).*

4. NHS Litigation Authority

- a) *NHSLA Risk Management Standards for Acute Trusts, Primary Care Trusts and Independent sector providers of NHS Care 2009/10 (February 2009).*
- b) *NHSLA Risk Management Standards for Mental Health and Learning Disability Trusts 2009/10 (January 2009).*
- c) *NHSLA Risk Management Standards for Ambulance Trusts 2009/10 (January 2009).*

5. Healthcare Commission

- a) *The annual health check 2008/09 (June 2008).*
- b) *Criteria for assessing core standards in 2008/09 Acute Trusts (December 2008).*
- c) *Criteria for assessing core standards in 2008/09: Ambulance Trusts (December 2008).*
- d) *Criteria for assessing core standards in 2008/09: Mental Health and Learning Disability Trusts (December 2008).*
- e) *Criteria for assessing core standards in 2008/09: Primary Care Trusts (as providers and commissioners) (December 2008).*

6. Monitor – Independent Regulator of Foundation Trusts

- a) *Identifying risk, taking action: Monitor's approach to service performance in NHS foundation trusts (April 2008).*
- b) *Compliance Framework (March 2009).*

7. Health and Safety Executive

- a) *Five steps to risk assessment (2006).*
- b) *Management of health and safety at work (1999).*

All the documents produced by the DH and its ALBs stated the need to undertake systematic risk assessment and risk management in NHS organisations. Only documents produced by the NPSA and HSE described specific steps to risk assessment.

Some documents such as those produced by the NPSA and The NHS Institute mentioned the use of prospective risk assessment and listed examples of PHA methods such as FMEA, HFMEA™, HACCP, HAZOP, barrier analysis and PRA. There was very little or no description of these methods and no clear explanation of the purpose of PHA. With the exception of the NPSA that has guidance on using the risk matrix, FMEA (brief guidance) and the RCA Toolkit (a detailed document on barrier analysis was provided), there is minimal guidance on the use of PHA methods in other documents.

The rest of the documents reviewed (the majority) made very little direct reference to PHA.

4.3.5. Conclusions and implications for Toolkit

The awareness of PHA methods is developing slowly and is seen as positive by key stakeholders. However, the knowledge of PHA methods is currently very low. Even where PHA methods were described in the documents, these were generally brief and there was minimal guidance on how to perform the analyses. A PHA Toolkit has the potential to fill this current gap. It is important to involve stakeholders and management in the

development of the Toolkit.

4.4. Risk assessment at the NHS' front line (local practice)

As opposed to national-level guidance, a number of documents influence risk management practice at a local (NHS Trust) level. The purpose of this review was to identify the range of such documents and to assess their content, with a view to identifying good practice, which might be transferred into the Toolkit, and to understand where any gaps in advice might lie.

4.4.1. Method

In July 2007 an email request for information on current risk management practice was sent to NHS Trusts across England, both in the community (n=192) and in acute care (n=152). 52 replies with documents attached were received from the trusts.

The documents were analysed to determine how (if at all) trusts addressed the following issues:

- Risk management process overview
- Hazard identification
- Risk analysis and communication
- Risk control

In order to ensure consistency, the same researcher extracted and analysed the data from all respondents.

4.4.2. Results

Most NHS trusts use a number of policy and guidance documents to govern risk management practice, and this is reflected in the responses we received. Document titles included:

- Risk Strategy
- Risk Assessment Policy
- Risk Assessment Procedure
- Risk Scoring Matrix
- Incident and Reporting Procedures
- Risk Evaluation Table
- Incident Reporting Form
- Risk Register Spreadsheet

Because most trusts responded with only one document, the responses we received probably do not fully reflect the scope of risk management practice at the responding trusts. This is especially true because nearly half (24) of the documents we received pertained only to risk rating (e.g. risk matrix, or risk evaluation table), and 10% (5) of the documents related only to incident reporting and investigation. It is also true that some risks (e.g. patient falls) may be managed primarily through stand-alone committees or in accordance with separate field-specific documents. Nevertheless, the responses we

received provided important insight into current risk management practice in the NHS.

4.4.2.1. *Risk management process overview*

The general approach to risk management among respondents is to initially identify and assess risks at the local level (e.g. ward or department). Risk treatment (control measures) and monitoring are handled at different administrative levels depending on the level of assessed risk. While the details for intermediate-level risks vary from trust to trust, risks in the highest category are generally reported to the trust's board, while risks in the lowest category are normally managed locally (that is, at or near the source of identification).

Risk registers serve as repositories for risk assessments and risk treatment plans. In order to reduce the administrative burden, they are not always used for locally-managed risks, but are otherwise generally maintained at each administrative level with risk management responsibility. They are living documents that are updated regularly and the risk assessments they contain typically undergo periodic review, with the frequency of review based on the assessed risk level.

4.4.2.2. *Hazard identification*

Of the documents intended to cover the comprehensive risk management process, few gave any advice as to how hazards might be identified. Indeed, in many cases the only mention of hazard identification was its inclusion as the first step of the risk management process, with no further elaboration offered. What little hazard identification advice the documents did offer was mostly retrospective in nature (incident investigation) or general health and safety walkthroughs. While the diversity of documents we received limits the utility of any quantitative analysis we might attempt, it is perhaps worth noting that only three documents (two from acute care trusts and one from a primary care trust) made any mention of constructing and using system descriptions as part of the hazard identification process or taking any other steps prior to the hazard identification, itself. This stands in contrast to best practice from other safety critical industries, as is reflected in the fact that the risk management model in the PHA Toolkit includes hazard identification as the fifth step in a seven-part process. No PHA methods for hazard identification were suggested by any of the documents we received.

4.4.2.3. *Risk analysis and communication*

Guidance on risk analysis and communication provided the bulk of the responses we received. Indeed, nearly half the documents were devoted solely to risk rating. Risk matrices, which illustrate the assessed likelihood and severity of a risk, appear to be a universally-used tool for analysing and communicating risks among respondents. Five-by-five matrices were the most dominant, by far, and most of these employed four risk tolerability levels (usually illustrated with the colours red, amber, yellow and green), though matrices with three or five risk tolerability levels were not uncommon. These matrices were usually accompanied by guidance both on rating the severity and likelihood of a risk, and on how risks assessed at different risk tolerability levels must be managed (e.g. by whom, and within what timeframe). Interestingly, though the risk matrix model is based on the risk formula *likelihood x severity = risk*, asymmetrical risk tolerability bands were quite common. That is, numerically equal risks (e.g. $3 \times 2 = 6$ and $2 \times 3 = 6$) might fall into different risk tolerability levels. This presumably reflects the risk appetites of the trusts.

None of the documents addressed the issue of detectability in assessing risk, and very few touched on how to properly account for system-wide or cross-boundary risks, such as those which occur across a number of clinical areas, or which fall under multiple risk

categories (e.g. safety, financial, reputation, etc.).

Guidance on assessing the likelihood of a risk was often problematic. While purely qualitative likelihood ratings (e.g. rare, unlikely, possible, likely, almost certain) were the most common, they were often supplemented by frequency-based and/or probability-based likelihood ratings. Frequency-based categories (e.g. less than once a year, at least once a year, once a month, once a week, once a day) were the more common of the two. The difficulty they present is that they do not take into account the frequency of the process within which the risk occurs. Under such a rating scheme, for instance, a surgical procedure that injures six patients per year would receive the same likelihood score whether the procedure took place once a month (a 50% injury rate) or twenty times a day (a 0.08% injury rate). Somewhat less common were the probability-based likelihood ratings. The difficulty with these is that the most common probability scale in the documents we received used intervals (<0.1%, 0.1-1%, 1-10%, 10-50%, >50%) intended only for assessing "...one-off projects or business objectives..." [NPSA, 2008], and not for use in assessing other types of risk (e.g. patient safety risks). The vast majority of documents that used this probability scale, however, presented it without any accompanying guidance, thus risking its misapplication to other risk categories.

Discussion of formal risk analysis and communication methods beyond risk matrices was limited. Two trusts (both acute care) briefly mentioned the use of barrier analysis, and a number discussed the use of Root Cause Analysis for incident investigation. Some of the risk assessment forms used for trust risk registers also introduced a certain degree of rigour by requiring the barrier analysis-like process of calculating the "residual risk" remaining after taking into account existing and/or planned control features.

4.4.2.4. Risk control

The actual methods for controlling risks were not significantly discussed in the documents we received. Primarily, the documents simply communicated the requirement that risks requiring control measures should have a properly recorded action plan, should be reviewed regularly and that the control measures should be managed at an administrative level and on a timeline appropriate to the assessed level of risk. The documents generally did require that a particular person be designated to take responsibility for controlling each risk, but for the most part did not require that an outcome measure be defined. A noticeable minority of documents called for an assessment of the resource requirements needed to control a given risk. No PHA methods were mentioned in the context of risk control.

4.4.2.5. Conclusion

While the lack of consistency in the documents limited our ability to make definitive statements about many aspects of risk management in the NHS, we can cautiously conclude that the use of PHA methods in the NHS is extremely limited, that little guidance exists to help NHS staff identify or control risks, and that risk analysis and risk communication in the NHS is largely limited to the use of risk matrices. The guidance for assessing likelihood for use in these matrices may also frequently be problematic, and the matrices themselves may be constructed with too many risk tolerability levels to provide accurate information reliably to decision-makers [Cox, 2008].

It does appear that most trusts are not taking a systems-based approach to risk management. This is reflected in a number of areas. For instance, it is common for the first step in the risk management process to be "identify the hazard," with no preceding examination of the process or system within which the hazard occurs. In the risk analysis

and communication domain, there is no discussion of the detectability of hazards, and little guidance on how to assess system-wide or cross-boundary risks. And risk control activities are often conducted without any pre-defined criteria for success.

On the basis of our study, it appears that there is significant scope for the PHA Toolkit to assist NHS staff in using PHA methods to take a systems-based approach to managing risks before they result in harm to patients.

4.5. Use of PHA methods in healthcare

The previous section describes “local” risk management practice, based on a review of official documents across a range of NHS trusts. Through these documents, as little information could be found about the use of PHA methods, a second review was conducted. The primary purpose of this review was to:

1A Identify the degree to which PHA methods have been used in healthcare, for example:

- i. Which methods have been used, in which healthcare settings and investigating what issues?
- ii. How often have they been used?

1B Learn from the experiences of applying the methods in healthcare, for example:

- i. What was the rationale for choosing that particular PHA method?
- ii. How long did it take?
- iii. What conclusions can be drawn about the method’s usability and utility?

4.5.1. Literature review method overview

Informal reviews (internet searches, discussions with subject matter experts, and journal articles) identified 31 PHA methods and related phrases, listed in the Appendices (Table 27 in Section 10.3.3). In February 2008, considering the variations on these methods (for example FMEA, HFMEA™, FMECA) and risk assessment approaches, a range of search terms was used to interrogate four healthcare related databases. The four databases (Embase, DH Data, Kings Fund and Medline) were chosen to give a broad overview of healthcare-related literature. Table 28 in Section 10.3.3 in the Appendices describes the search terms used in this part of the literature review.

The review initially yielded nearly 10,000 hits, prior to parsing for duplicate publications, and applying filtering parameters.

4.5.1.1. Filtering

Papers were first parsed for duplicates, first automatically using reference management software (EndNote®) and then manually. After all duplicates were purged, the number of abstracts identified remained unmanageably large, which forced us to concentrate on evaluating the abstracts related to those methods that were the strongest candidates for inclusion in the PHA Toolkit (see Section 6.7):

- Structured what-if technique (SWIFT)
- Hazard and operability studies (HAZOP)
- Barrier analysis

- Event tree analysis (ETA)
- Fault tree analysis (FTA)
- Failure mode and event analysis (FMEA)
- Human Error Assessment and Reduction Technique (HEART)
- Influence diagrams
- Risk matrices

After all duplicates were removed, the initial 434 hits for this group of methods was reduced to 302. All abstracts were initially reviewed for relevance (e.g. healthcare focus), and those that appeared to meet this criterion (n = 95) were selected for further review. These articles were reviewed against the following exclusion criteria: the PHA method was not used, the PHA method was not used in healthcare, the PHA method was used to assess medical equipment only, the article was not in English, or the full text of the article was not readily available and appeared unlikely to include a description of the experience of using the PHA method. In all, 35 studies qualified for inclusion. Three additional qualifying studies (two related to barrier analysis and one related to SWIFT) were found and included in the final analysis.

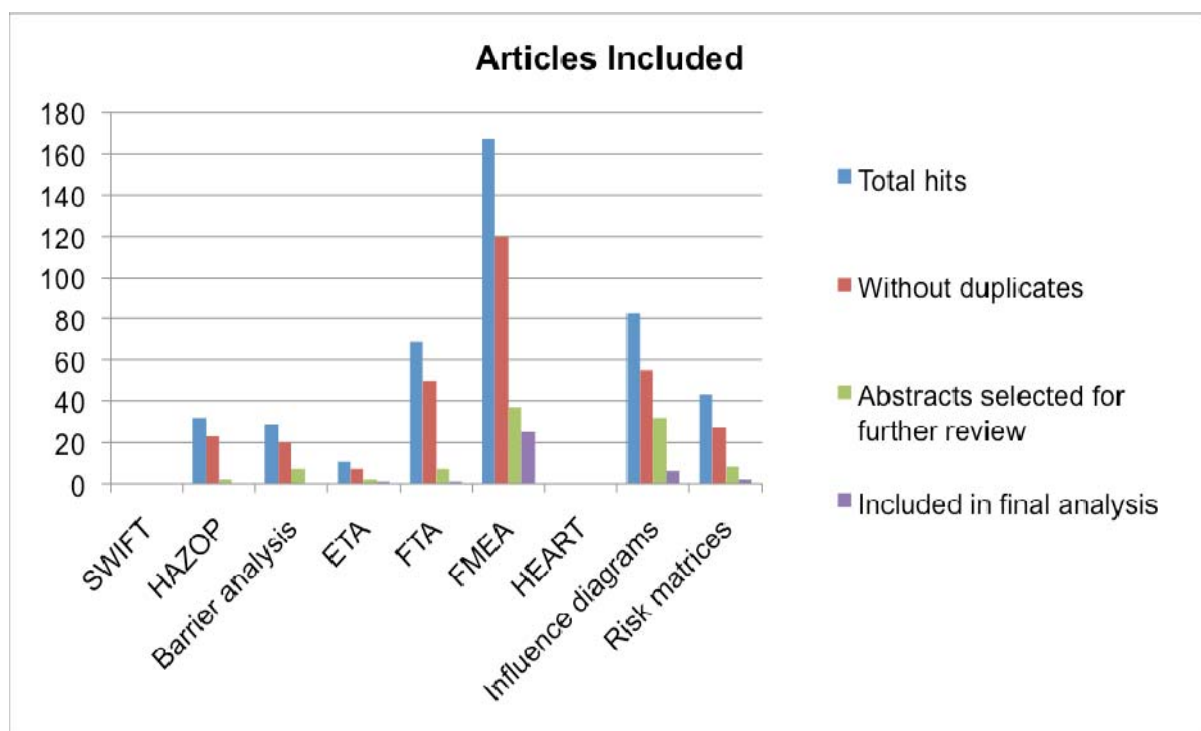


Figure 6 Number of articles included at each stage of analysis..

4.5.2. Results – use of PHA techniques

The primary goals of the literature review were to determine the degree to which PHA had been used in healthcare and to learn from the experiences of applying the methods to healthcare. In general, we found that PHA methods have been little used in healthcare and that, where these techniques *have* been used, the experience of their use is very rarely described. The exception to this rule is that, in the case of influence diagrams and FMEA (and its variants), the time-intensiveness of the methods was mentioned with some frequency. Otherwise, there were few “lessons learned” or examples of good practice to be gleaned from the literature.

In the following sections we briefly describe each of the methods examined in the literature review and discuss the results of the literature review as they apply to each method.

4.5.2.1. Hazard and Operability Study (HAZOP)

Background

Outside of healthcare, the Hazard and Operability Study (HAZOP) is a popular method for hazard identification. Like the Structured What-If Technique (SWIFT), it uses a structured brainstorming method to identify potential hazards in a system. Unlike SWIFT, HAZOP is highly detail oriented and explicitly examines each procedure, piece of equipment, etc. This makes it both more thorough and more time-consuming. HAZOP employs a set of defined *guide words* to elicit ideas on how problems could arise.

Table 7 Example HAZOP Guide Words [Kletz, 2006].

None	Part of
More of	More than
Less of	Other than

Because HAZOP grew out of the chemical process industry, the standard examples used to illustrate the use of these guide words are usually expressed in terms like “flow,” “temperature,” and “contamination,” but they can be applied to nearly any process. For instance, while “other than” might refer to contamination in a chemical process, in the healthcare field it could refer to administering the wrong medication, treating the wrong patient, or divulging protected information about a patient to the wrong party.

Literature Review

Two articles were selected for the final round of review, and both were excluded due to their focus on equipment only.

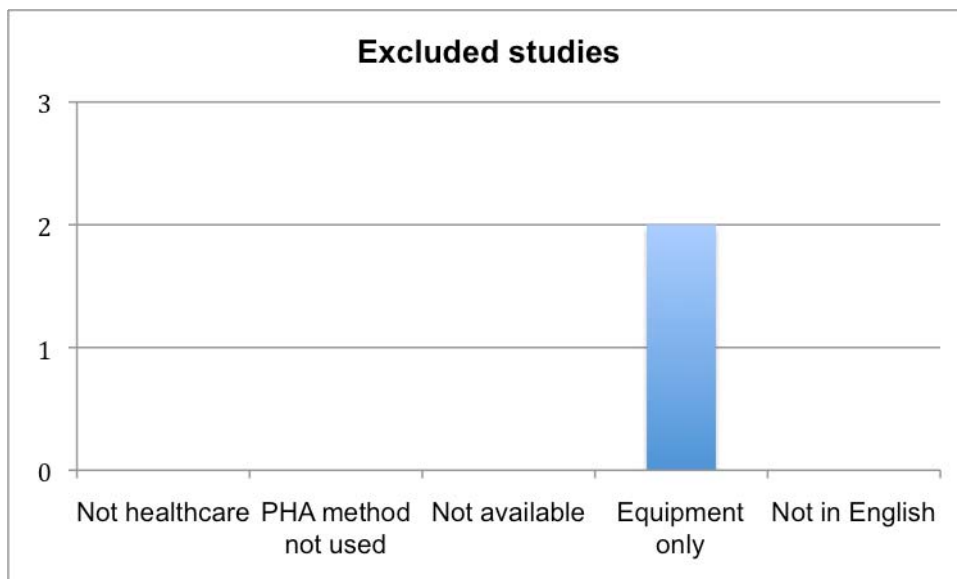


Figure 7 Study exclusion rationales.

Conclusion

HAZOP is a well-known hazard identification method based on structured brainstorming with the use of guide words to ensure the comprehensive review of potential problems. Its main strengths are its thorough, detail-oriented approach and the fact that many qualified

facilitators are likely to be available. Its main weakness is that it can be quite time-consuming. In addition to serving as a stand-alone hazard identification method, it can be used as the second stage of a two-part approach that begins with a faster method, such as SWIFT. The first method can then be used to screen out those components that do not require a detailed HAZOP review.

4.5.2.2. Structured What-If Technique (SWIFT)

Background

The structured what-if technique (SWIFT) is a systems-based hazard identification technique that uses structured brainstorming, supplemented by pre-developed checklists and prompts (which often begin with the phrase “What if...”), to examine hazards at a systems or subsystems level. This differentiates it from its precursor, the hazard operability studies (HAZOP) method, which is similar, but which identifies hazards through a detailed review of low-level processes, pieces of equipment, etc. [Maguire, 2006] Because it focuses on high-level processes, the structured what-if technique can often be conducted more quickly than the HAZOP method. Indeed, one industry source reports that a SWIFT risk assessment can be conducted in as little as one-third the time required for a HAZOP-based approach [Lloyd's Register, 2008], which is a significant advantage. The corresponding disadvantage is that some hazards may be overlooked when using the SWIFT approach that would be identified using the more detail-oriented HAZOP method. This limitation is not irremediable, however. In cases where such an outcome seems likely, SWIFT can be used as the first part of a staged approach to efficiently identify “...subsystems and components that can be subjected to more detailed analysis using other methods such as HAZOP, FTA or FMECA.” [IEC, 2008].

Literature Review

The initial literature review did not yield any potentially qualifying articles; however, one highly relevant abstract was found in the course of our project. Adedokun & Woods described an NHS-based use of SWIFT to identify hazards associated with the anaesthesiologist's role in the perioperative process [Adedokun *et al.*, 2006]. The participants included representatives from primary and secondary care, professional organisations, and the government. The SWIFT was conducted in a series of sessions spread out over the course of five days, lasting more than 30 hours in all. Participants identified, evaluated and made recommendations for the reduction of 103 risks. The importance of taking a systems approach to risk management was illustrated by the fact that only 10 of the 30 recommendations expected to lead to the greatest reduction in risk were found to be primarily within the control of anaesthesiologists. As the researchers concluded:

“A thorough assessment of this type needs a multidisciplinary team, expert facilitation and considerable time. It can, however, enable the production of a robust, ranked set of risks and a prioritised list of risk reduction recommendations. It is clear, too, that the risks to patient safety under anaesthesia may arise from a wide range of sources and hence concentrating our efforts to improve safety within departments of anaesthesiology will not tackle the whole problem.”

Conclusion

SWIFT is a high-level PHA method, mainly designed for hazard identification. As illustrated by the above example [Adedokun *et al.*, 2006], however, “It creates a risk register and risk treatment plan with little more effort.” [IEC, 2008]. SWIFT is less time-consuming than many hazard identification methods, and can be used on a stand-alone basis, or as a screening tool to efficiently identify which aspects of a process require the use of a more detail-oriented method.

4.5.2.3. Barrier Analysis

Background

Barrier analysis is a tool that originated in the nuclear and chemical industries. It involves the assessment of cause-consequence pairings in terms of the barriers that prevent the potential cause from resulting in harm [IEC, 2008]. Barrier analysis is often used in combination with hazard identification techniques such as HAZOP or SWIFT to add rigour to the process of analyzing the hazards revealed. Barrier analysis can be an important part of the PHA process. It makes participants aware of the existing control measures in place for a specific hazard and the degree to which they reduce risk. It also serves as a hazard communication technique by offering insight into the risks involved in the failure of these control measures, and it makes clear the importance of fully independent controls. (e.g. If it is determined that all the barriers for a specific hazard rely on electricity, an additional barrier is required that would continue to function in the case of a power failure).

In addition to these insights, a major strength of barrier analysis is that it is more time-efficient than some other methods, such as fault tree analysis. A major limitation is that it can only look at one cause-consequence pairing at a time, whereas healthcare risks often involve multiple causes and consequences operating at once.

Literature Review

The initial literature review identified seven potentially relevant papers, all of which were excluded in the final round of review. Four did not actually employ barrier analysis, two were not in English, and one was unavailable. Two additional relevant papers were identified in the course of our work, however, and these are described below.

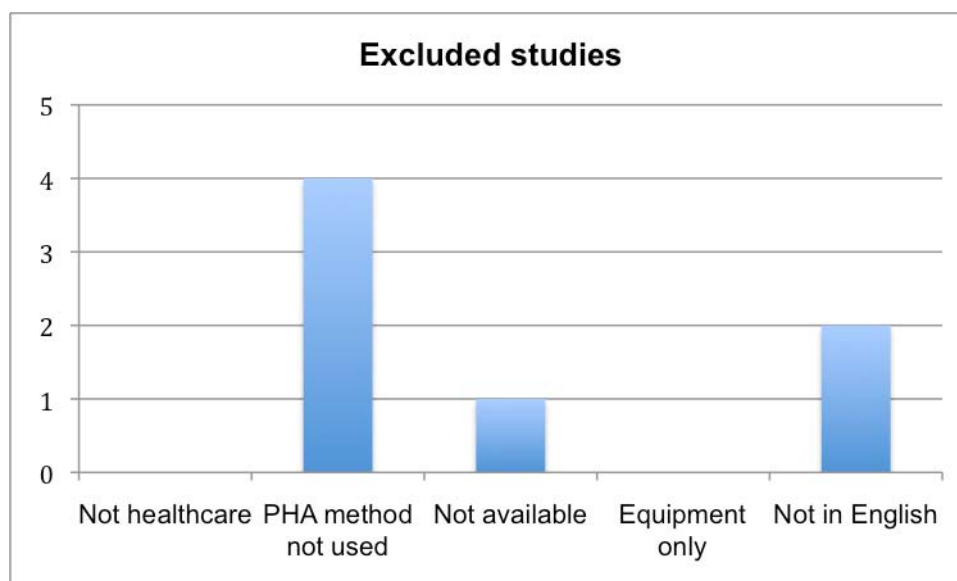


Figure 8 Study exclusion criteria.

Kaplan [Kaplan, 2000] described the use of barrier analysis (in combination with risk matrices) for retrospective analysis of patient safety incidence and near-misses in blood transfusions. There was little discussion of the experience of using the method, but Kaplan indicated that the study resulted in the proposal of additional barriers.

Lyons, *et al.* in their report on error reduction in medicine, describe a case study they conducted on the use of barrier analysis [Lyons *et al.*, 2005]. The researchers used a modified version of the technique that had been adapted "...to look at the factors that

could make the safeguards [barriers] fail – in the shape of a concept called ‘barrier-breakers...’” to examine the hazards related to administering oral medication to majors in a hospital accident and emergency department.

The process began with a hierarchical task analysis followed by the use of guide words to elicit associated hazards for analysis. The implementation of barrier analysis was generally successful:

“Barrier analysis is a relatively quick method of gaining the clinicians’ support and feedback on talking about errors within their environment and practice. It can be seen that the ideas that were evoked were consistent with many of the concepts recognised in human reliability...and the improvements suggested were typical error reduction strategies elicited in industry.”

The researchers highlighted the importance of training, however, especially in assessing the strength of barriers. Participants tended to overestimate the strength of administrative barriers such as rules and regulations and to underutilise physical barriers as suggested safeguards. Additional training would also likely have enabled a more time-efficient assessment of barrier strengths.

Conclusion

Barrier analysis is a relatively simple and time-efficient technique that can also serve as a potent hazard communication tool. Often used in combination with a hazard identification technique such as HAZOP or SWIFT, it examines the barriers that exist to prevent hazards from causing harm. The main limitation of the technique is that it can only examine one cause-consequence pairing at a time. As Lyons *et al.* [Lyons *et al.*, 2005] and Kaplan [Kaplan, 2000] demonstrated, the technique can be further strengthened by combining it with other tools like barrier strength assessment or risk matrices.

4.5.2.4. Event Tree Analysis (ETA)

Background

Event tree analysis (ETA) is a method in which all possible results of a given *precursor event* are graphically represented in a form similar to a decision tree. By illustrating all the outcomes (both good and bad) that could follow from the precursor event, ETAs illustrate not only the chains of events that could lead to failure, but also the importance of control measures that can prevent failure. ETAs can be either qualitative or probabilistic, and are often used along with fault tree analysis to conduct a quantitative risk assessment [Greenberg and Slater, 1991]. Because of their simple, decision tree-like structure, ETAs can be useful in intuitively communicating the potential consequences of a precursor event. However, when used to describe very complex systems, event trees can become extremely large, degrading their explanatory power (although it is acknowledged that some simplification strategies do exist). Another strength of ETA is that “[it] accounts for timing, dependence, and domino effects that are cumbersome to model in fault trees.” [IEC, 2008]. The method’s limitations mostly relate to the difficulty of identifying all possible precursor events and all possible consequences thereof [IEC, 2008].

Literature Review

Two articles were selected for the last round of review, one of which was excluded because it did not describe an application of the PHA method.

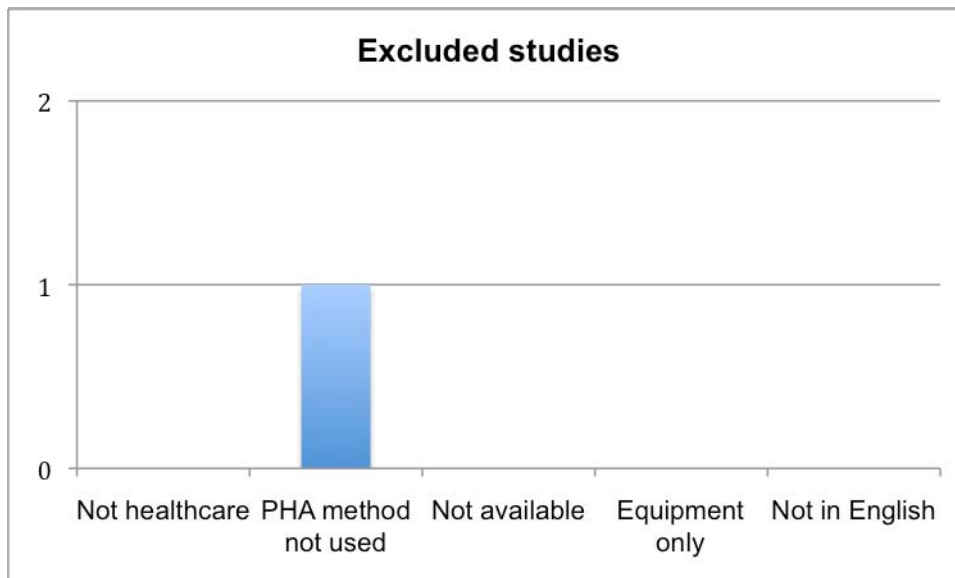


Figure 9 Study exclusion rationales.

The remaining study examined the use of ETAs as a method for auditing out-of-hospital cardiac arrests as part of the assessment process for the emergency medical services (EMS) system in Greater London. The researchers chose to use ETA because the usual audit method was seen as too inflexible, and because ETA was seen as "...suitable for evaluating the impact of management activities on patient outcome, such as the use of defibrillators or EMS response time, because the activities can be represented on a tree in any order and additional factors added later." The ETA was conducted using the London Ambulance Service's (LAS) 1997 database. The authors described ETA as both flexible and useful. They also expressed an appreciation of the method's ability to graphically communicate the way systems components interact, writing: "Event-tree frameworks, although simplistic, are particularly effective in that they provide transparent representation of data, thus, facilitating easy observation and analysis of relationships between variables." [Dowie *et al.*, 2003].

Conclusion

ETA is a flexible method that is used to graphically represent all the outcomes to which a given precursor event could give rise. It can be used both qualitatively and probabilistically, and in the latter case, it is often paired with fault tree analysis. ETA's simple decision tree-like structure makes it a good way to visually assess and communicate the way a series of events can lead to multiple outcomes, but because each unique pathway-outcome pairing is displayed separately, event trees can become very large when used to describe complex systems, making them harder to comprehend. ETA may be especially useful when "timing, dependence, and domino effects" [IEC, 2008] are important, as it is one of few methods that easily takes these into account.

4.5.2.5. Fault Tree Analysis (FTA)

Background

Fault tree analysis (FTA) is "...a technique for identifying and analysing factors that can contribute to a specified undesired event (called the top event). Causal factors are deductively identified, organized in a logical manner and represented pictorially in a tree diagram which depicts causal factors and their logical relationship to the top event." [IEC, 2008].

FTA is somewhat like root cause analysis (RCA), a retrospective fault analysis technique that is used extensively in the NHS [NPSA, 2004], except that where RCA seeks to uncover the *one* underlying causes that *did* lead to a given failure, FTA is used to understand *all* the underlying causes that *could* lead to a given failure. Indeed, as Hyman & Johnson explain "...an RCA could be accomplished using an existing an FTA; that is, the FTA should, if it is thorough and complete, contain the specific situation that led to the incident that is being analysed by the RCA." [Hyman and Johnson, 2008].

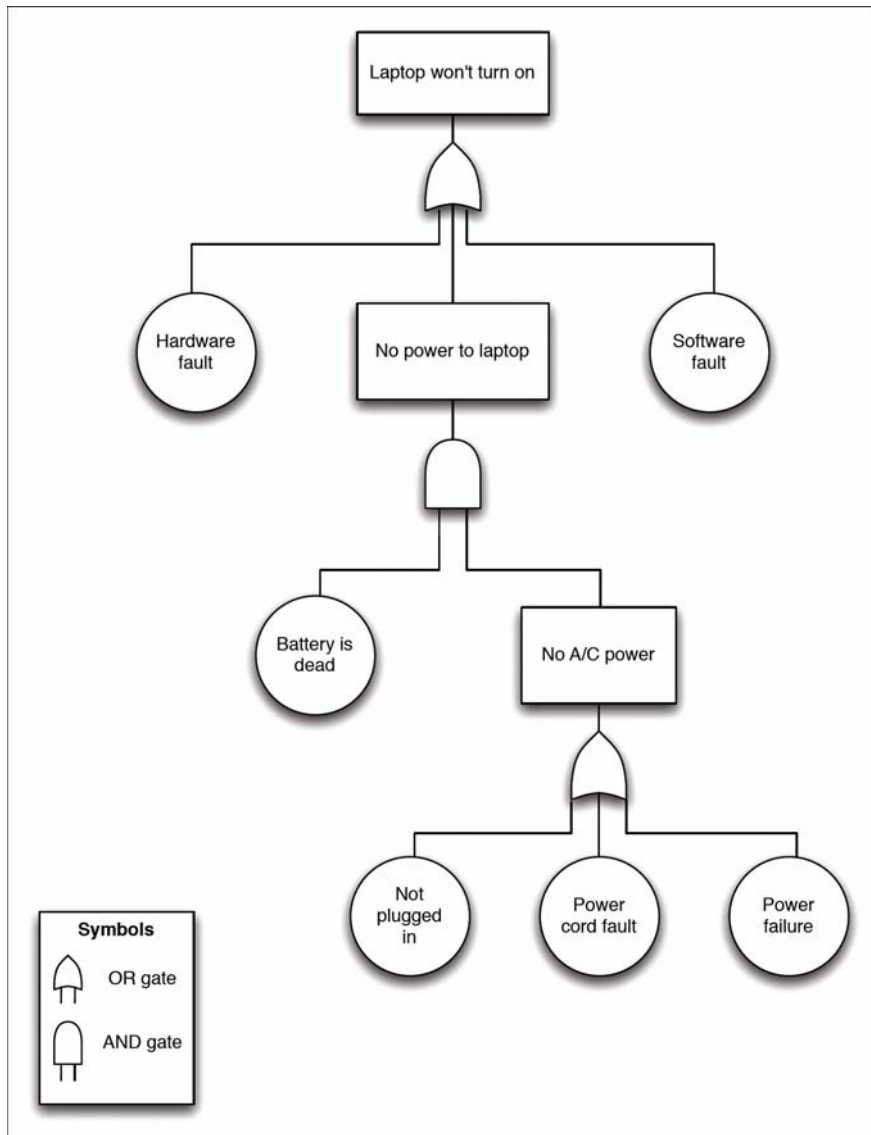


Figure 10 Fault tree example.

FTAs employ a tree diagram with *AND gates* and *OR gates* to illustrate the relationships between contributing factors and the failure they could cause. *AND gates* represent events that must *all* occur together in order to lead to a fault, while *OR gates* represent events *any* of which will lead to a fault. FTAs can be probabilistic, where detailed probability data is known, or qualitative.

Literature Review

Seven articles were selected for the final round of review. Of these, six were excluded. Four described the use of FTA to assess equipment, only. One did not describe a healthcare application, and one did not describe a use of the FTA method.

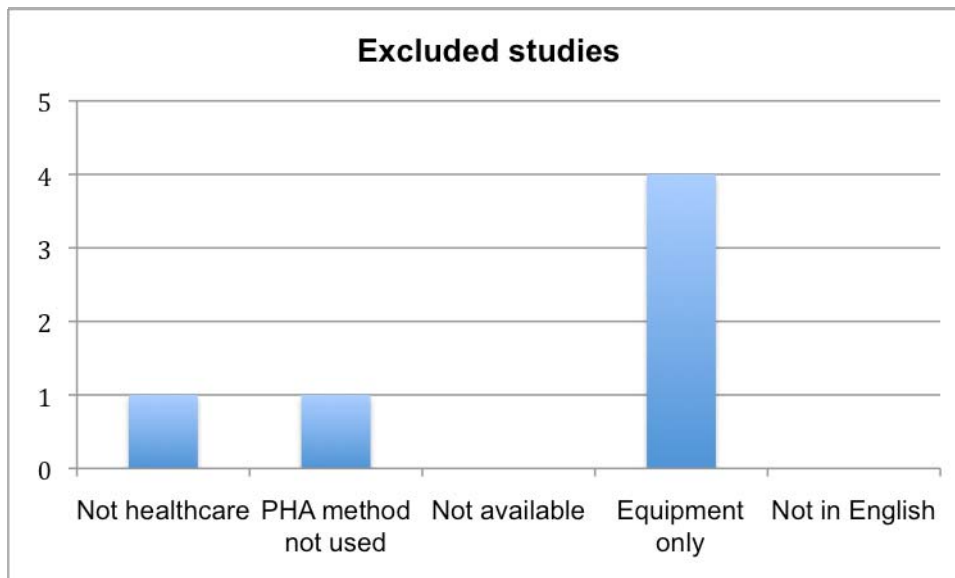


Figure 11 Study exclusion rationales.

The one qualifying study [Ekaette *et al.*, 2007] used probabilistic FTA to assess the chance of inappropriate radiation therapy for cancer patients. The authors also compared the results of the FTA to retrospective data in the form of patient safety incident reports. FTA was chosen because the authors felt that it was likely to lead to a better understanding of the radiation therapy system and the identification of the factors that posed the greatest risk. The FTA was based on a process map drawn up by two radiation oncologists and two medical physicists and a task analysis conducted by one oncologist, three medical physicists, and seven radiation dosimetrists/therapists. A similar group (two oncologists, three medical physicists, and seven radiation dosimetrists/therapists) conducted the FTA, itself. The paper offers a positive evaluation of the method:

“We have demonstrated that the fault tree method is useful in modeling the probability of incidents in complex medical systems. We were able to evaluate the reliability of the fault tree analysis using incident reports. The fault tree analysis helps us to understand the type of incidents that could occur and therefore supports proactive risk analysis. The discussions and analysis of possible incident pathways throughout the process of building the fault tree provided the medical staff better insight of the treatment system as a whole, how their individual areas of expertise and duties interrelate, the vulnerable aspects of the tasks for which they are responsible, and possible systematic interventions for better provision of care.”

While the authors found good agreement, overall, between the expert opinions used to populate the probability values in the FTA and incident reports, there was a portion of the radiation therapy process in which clinicians appeared to have underestimated the probability of incidents. The use of incident reports to test the ground truth of these estimates therefore provided an opportunity to bring this to the attention of the clinical staff. However, some caution is necessary in this conclusion. It should be noted that the use of incident reports to provide baseline data has its own risks: they are ultimately only a measure of the frequency of reports, not necessarily of all events and hence may not provide an accurate absolute measure of probability.

Conclusion

FTA is a tool that can be used to understand how causal factors can contribute to an undesired result (known as a *top event*). Major strengths of fault tree analysis include the fact that it is capable of explicitly modelling combinations of events that could lead to a systems failure (using *AND gates*), its graphical nature, its flexibility, and the fact that it can be used for both qualitative and probabilistic analysis. FTA also allows for a simpler, more

intuitive graphical structure than Event Tree Analysis (a competing analysis method). Fault Trees can also be simplified into “cut sets” and “tie sets”, which provide the minimum requirement for failure or success, respectively. One limitation is that “[FTA] does not enable domino effects or conditional failures to be included easily,” [IEC, 2008] but this is common to many such methods. When used for probabilistic risk analysis, there are also challenges related to the level of uncertainty in the calculated probability of the top event [IEC, 2008]. FTA is widely used in industrial risk management, so it is likely that trained facilitators would be relatively easy to find.

4.5.2.6. Failure Mode and Effect Analysis (FMEA)

Background

Failure mode and effect analysis (FMEA) and its variants, including Healthcare failure mode and effect analysis (HFMEA™) and failure mode, effects and criticality analysis (FMECA) are among the most popular PHA methods used in healthcare. HFMEA™, in particular, has seen wide use within the U.S. Veterans Health Administration, where it is a mandatory part of the patient safety program. The method’s popularity comes despite its relatively high cost. FMEA is designed to be both highly systematic and extremely thorough. It, therefore, involves the examination of *all* potential failures in a system, regardless of their consequences (or lack thereof), [Rausand and Hoyland, 2004] and this necessarily requires a significant time investment.

DeRosier *et al.* propose a five-step process for HFMEA™ [DeRosier *et al.*, 2002]:

1. Define the HFMEA™ topic (the process to be studied)
2. Assemble a multidisciplinary team
3. Graphically describe the process
4. Conduct a hazard analysis
5. [Determine] actions and outcome measures

Step four includes rating the severity and probability of all identified failure modes (ways in which a systems failure could occur) and using a decision tree to determine whether corrective action should be taken. In addition to this rigorous process, one of the major strengths of the FMEA method is that it calls for a graphic representation of the process. Visually mapping the process allows all participants to learn about those parts of the process that are not in their purview, to see how the various sub-processes fit together, and to develop a common understanding of the process as a whole. The main limitations of FMEA include “...the fact that HFMEA™ is very time-consuming and that, particularly, the risk assessment part of HFMEA™ is difficult to carry out. Moreover, a lack of guidance with regard to the identification of failure mode causes and effective actions might influence the quality of the outcomes of an HFMEA™ analysis.” [Habraken *et al.*, 2009].

Literature Review

Thirty-seven articles reached the final stage of review. Of these, twenty-five qualifying articles were identified. Six of the excluded studies did not describe a use of FMEA, four were not available, and three were not in English. Many of the articles excluded in the penultimate round of review were primers on applying the FMEA method to healthcare, but did not include a description of an actual healthcare application.

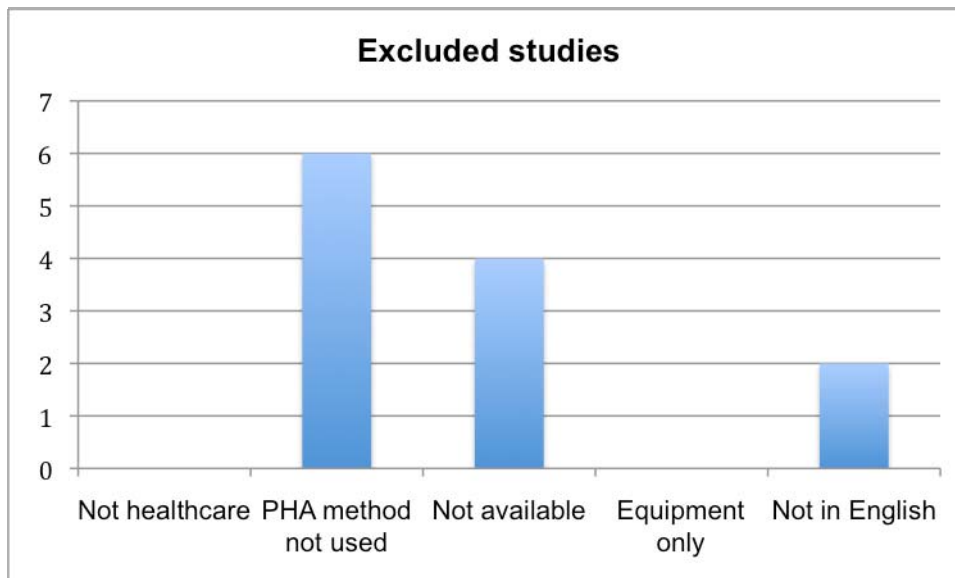


Figure 12 Study exclusion rationales.

Among the studies examined, there was little discussion of the motivations for choosing FMEA, but all of the 17 articles that explicitly discussed the method's utility found it useful. Other than successful outcomes, the only discussion of *why* the method was useful centred on the use of process mapping. Esmail, *et al.* wrote of it that "...[the] team members were unaware of the numerous steps involved in administering this medication and it became obvious that there were many opportunities for errors to occur." [Esmail *et al.*, 2005]. Kimchi-Woods & Shultz found that preparing the flow chart was helpful for defining the problems and generating discussion, though they were forced by the complexity of the process to narrow their scope [Kimchi-Woods and Shultz, 2006]. Kunac & Reith found that some failures were identified simply through the construction of the process map [Kunac and Reith, 2005], while Linkin *et al.* highlighted the potential reusability of the process maps, writing that "We believed that our investigation was worth the effort because of the multiple, correctable system errors that were discovered in this critical process and the creation of a valuable blueprint (i.e., the flow diagram) to use when addressing future surgical instrument issues." [Linkin *et al.*, 2005].

Nine of the articles discussed the usability of FMEA, with the method's time intensiveness as the most common topic. Van Tilburg *et al.* reported that their FMEA examining chemotherapy in a paediatric oncology ward required 140 person-hours [van Tilburg *et al.*, 2006], while Linkin, *et al.* indicate that their FMEA, which focused on surgical instrument sterilisation, required over 250 person-hours to conduct [Linkin *et al.*, 2005]. Esmail *et al.* suggest that in view of the time-intensiveness of the process, it "...would be appropriate to conduct an HFMEA™ on one or two high priority topics per year..." [Esmail *et al.*, 2005], a sentiment echoed by Burgmeier, who also described the process as tedious, and difficult for action-oriented people [Burgmeier, 2002]. Burgmeier noted that, in addition to direct staff time, costs included hiring a consultant, piloting of new procedures, material costs (e.g. meeting room, printing, and refreshments), as well as the cost of replacement staff. Other usability concerns related to the impulse to begin trying to fix identified problems before the solutions had been vetted and difficulty in identifying novel hazards [Day *et al.*, 2006]. Fifteen of the 25 studies (60%) focused specifically on the management of drugs (especially intravenous and drugs with a narrow therapeutic range like heparin, potassium chloride, or chemotherapeutics) or blood products, perhaps because these are viewed as high-risk and therefore high-priority issues worth the investment required of an FMEA.

Just over half of the articles (thirteen, in all) described the multidisciplinary makeup of their FMEA team (a key component of the HFMEA™ approach). One study, which took place in a paediatric oncology ward, included a patient's parent among the participants [van Tilburg *et al.*, 2006]. The researchers wrote of the experience that "...the parent of the patient reported that, by gaining more insight into the hospital procedures, she was more aware of possible risks when her child received chemotherapy. This made her somewhat more anxious, although she is very positive about the attention patient safety gets. Asked what she would remember most, she answered: 'The honesty with which the team members discussed failure modes in the presence of a parent.'"

Conclusion

FMEA is perhaps the most widely used PHA method in the healthcare community today. It provides a structured and rigorous framework for the systematic identification, analysis and prioritisation of potential causes of system failure. Its rigour and its use of process maps are among its main strengths, while its primary limitations are resource intensiveness (especially with regard to staff time), difficulty in carrying out the risk assessment, and a lack of guidance related to hazard identification and risk treatment [Habraken *et al.*, 2009] as well as tediousness [Burgmeier, 2002]. FMEA may be best used for conducting thorough risk assessments of a small number of high-priority hazards.

4.5.2.7. *Human Error Assessment and Reduction Technique (HEART)*

Background

The Human Error Assessment and Reduction Technique (HEART) was developed by Jeremy (Jerry) Williams [Williams, 1988] as a simple, low-cost means of assessing and reducing human error. Originally focused on improving human performance in nuclear power plants, the technique has been widely adopted by industry. A paper by Lyons, *et al* [Lyons *et al.*, 2004] found that it had so far not yet been applied to the healthcare domain, which is supported by the results of our literature review.

HEART is based on the premise that, for any generic task, there is a certain level of *nominal human unreliability* (probability of human error) that can be expected under perfect conditions, and that when perfect conditions do not occur, the degradation of human performance can be predicted as a function of the *error producing conditions* (EPCs) that contribute to poor performance. By extension, it follows that reducing or controlling for these EPCs can improve human performance, and HEART specifies remedial measures to reduce the risk of failure resulting from each category of EPC. The output from a HEART assessment is expressed in terms of the likelihood of human error, and is typically given as a Human Error Probability (HEP). For HEART, this will be the probability of task failure.

HEART's main strengths are that it is fast, simple, and easy to understand, as well as the fact that it suggests relevant strategies to reduce the risk of human error. Its main weaknesses include the fact that the data underlying the model are not complete and have not been validated, that there is significant scope for subjectivity in the assessment stage [Williams, 1988], and that the technique examines only one task at a time.

Literature Review

No relevant articles were found.

Conclusion

HEART is a versatile technique that enables a simple, structured approach to human error

assessment and reduction by focusing on defined error producing conditions (EPCs). While the data underlying HEART have not been extensively verified, Kirwan [Kirwan, 1997] found the method's results to be reasonably valid, and demonstrated that the process was very resource-efficient. While in many ways systems-focused, HEART is capable of assessing only one task at a time, and as Nolan points out, healthcare processes tend to be complex, made up of many tasks with many steps [Nolan, 2000]. However, HEART can be used along with other PHA methods (e.g. it can provide the probability data for a probabilistic fault-tree analysis) to tie together these task-specific assessments into a broader process-focused analysis. Of note, HEART is a very popular method in the UK, which means that trained facilitators are likely to be readily available.

4.5.2.8. *Influence Diagrams*

Background

Influence diagrams graphically and mathematically represent the relationships between variables that influence the outcome of a process. Invented in the early 1970's [Howard and Matheson, 2005a] they have been used extensively as decision modelling tools in the artificial intelligence and management science communities, and have been used for risk management since at least the early 1990's [Yuan and George, 1993]. An influence diagram is commonly defined as an acyclic directed graph, which means that it illustrates the flow of a process (and information in that process) in a specified direction (e.g. from A to B) with no loops (e.g. flow from A to B back to A is not allowed). Modern influence diagrams include three types of nodes:

- Decision nodes (represented by boxes) – These represent decisions
- Chance nodes (represented by ovals, or double ovals if deterministic) – These represent probabilistic or deterministically-derived factors that influence other nodes
- Value nodes (represented by octagons or diamonds) – These represent the end state

These nodes are connected by arrows (also called arcs), that illustrate the direction in which the process flows. Although this flow is clearly and intuitively represented by the influence diagram, it is useful to know the terminology for the different types of arrows, as the terms more clearly describe the relationships between the nodes. Howard and Matheson define them in this way [Howard and Matheson, 2005a]:

“Arrows entering [value nodes or deterministic nodes] are called functional. Arrows going from a decision node into a chance node are termed influences because they imply a causal effect on the probability assessment by the decision undertaken. Arrows going from a chance node into a chance node are relevance arrows; the information from one node simply informs the other. Lastly, arrows going into a decision node are termed informational as the decision maker has this information (and only this information) available when making the decision.”

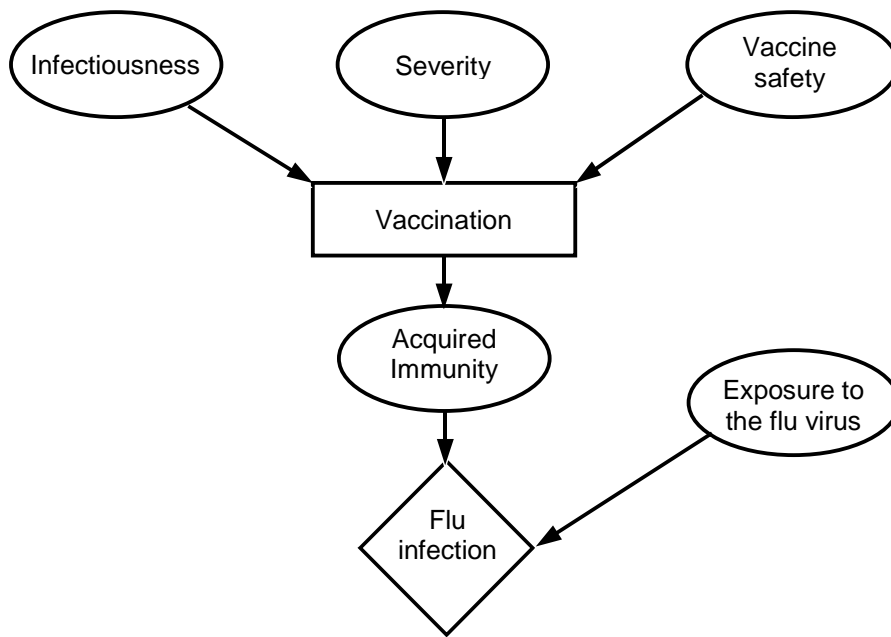


Figure 13 A simplified example illustrating the impact of the vaccination decision on flu infection status.

Literature Review

Of the 32 articles on influence diagrams that reached the final stage of review, six were found to be relevant. Two of the excluded articles did not describe a use of influence diagrams, and one article was not available. The remaining 23 excluded articles did not describe a healthcare application. Most of the articles in this latter group were either primers on influence diagrams or descriptions of software algorithms for analysing influence diagrams with simplified and hypothetical healthcare scenarios worked through as examples.

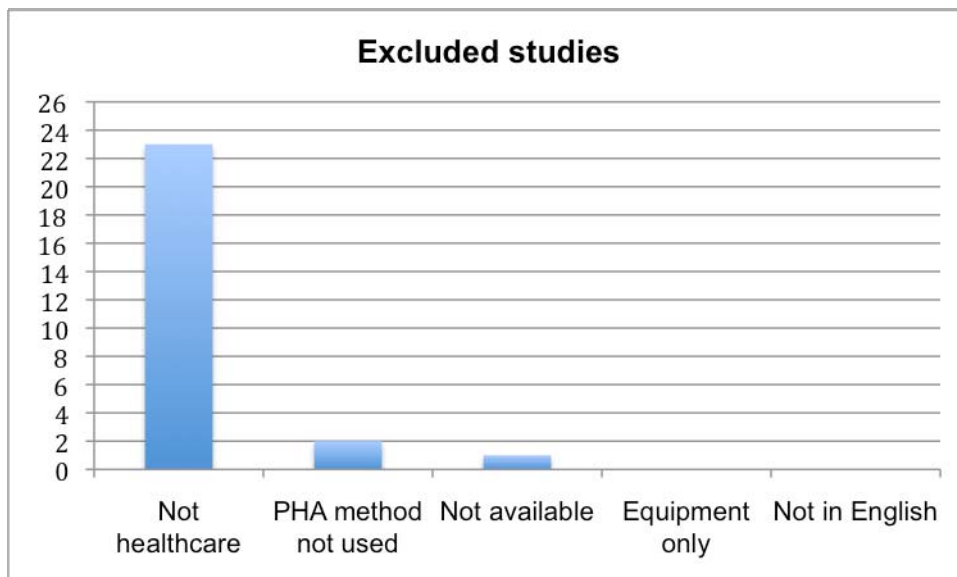


Figure 14 Study exclusion rationales.

One of the six papers [Dy *et al.*, 2005] did not discuss the utility of influence diagrams at all. The other five papers offered positive assessments of the technique. In particular, the importance of the graphical nature of influence diagrams was highlighted by Sonnenberg & Collins [Sonnenberg and Collins, 2006], and by Lee, *et al.* [Lee *et al.*, 2006] who wrote

“Although this is a large number of parameters, the structure of the model helped the team of readers. As 1 reader said, referring to the influence diagram, ‘Because we did the picture together, it was easy to find the parameters.’.” Lee *et al.* further concluded that this technique might prove especially useful in the field of patient safety.

While authors generally found influence diagrams a useful approach for understanding complex problems (especially those related to diagnosis and treatment), only two papers explicitly addressed the issue of usability. Sonnenberg and Collins applied the technique to the management of irritable bowel syndrome, but despite employing a variation on standard influence diagrams which included feedback loops (thus allowing for simpler diagrams than would otherwise have been possible), the authors found that developing a universally-applicable influence diagram was not feasible [Sonnenberg and Collins, 2006]. The set of all possible clinical presentations and treatment histories for this disease was, they felt, unmanageably large. Instead, they recommended using individually-tailored influence diagrams to guide treatment on a patient-by-patient basis.

Gomez *et al.* were successful in applying influence diagrams to the complex issue of managing neonatal jaundice, as evidenced by significant changes in clinical care (including the elimination of one risky treatment), reduced discharge times, and physician opinion [Gomez *et al.*, 2007]. But they also found the creation of a broadly-applicable influence diagram challenging, as the following quotes illustrate:

“...the application of influence diagram methodology in practice can be extremely involved for real large-scale problems. We had to tackle difficulties related to problem structuring (e.g., existence of constraints on the sequence of decisions), knowledge acquisition (probability and utility assignment), and computational limitations.”

“...our custom-built influence diagram contains 5 decision nodes and 68 chance nodes. It took approximately 3 years to build, with 2-h interviews every 3 weeks. The diagram was continuously revised as new and refined knowledge was gained.”

Lee, *et al.* also mentioned that, in the construction of their influence diagram that examined the interplay of staging versus radiation therapy in breast cancer, a lack of pre-existing quantitative evidence presented challenges: “Because probability data was not available for all parameters, the decision model had to be reduced from its original design to one that matched the evidence” [Lee *et al.*, 2006]. Sonnenberg & Collins, on the other hand, pointed out that “Even without calculations, however, such diagrams can prove quite helpful in understanding the underlying disease process and elucidating its complex ramifications. The influence diagrams help to map out the interdependence of various disease parameters and weigh their respective strengths” [Sonnenberg and Collins, 2006].

Motivations for using influence diagrams and inputs for the process were not widely discussed. None of the papers explicitly described the rationale for choosing influence diagrams (or, indeed, any PHA method), nor did any of the studies describe the use of a process map (other than the influence diagram, itself) to help understand the problem space before the influence diagram was constructed. Only two articles ([Gomez *et al.*, 2007], and [Dy *et al.*, 2005]) discussed the users involved in providing input for the influence diagram, and both employed only one type of stakeholder. Finally, as described above, Gomez, *et al.* illustrated the potential for this technique to require very extensive amounts of time when applied to complex problems.

Conclusion

Influence diagrams allow for the probabilistic and graphical representation of processes. One of the method’s major strengths is that its graphical nature allows it to function as a process map. To the extent that they are used for this purpose, however, influence

diagrams are probably not the most time-efficient means of mapping a process. They have been extensively used for the models underlying decision support software because of the existence of algorithms to allow the propagation of probability data through the diagram. When used in software applications, influence diagrams must be formally correct (e.g. no loops) and must generally be populated with probability data (whether on the basis of existing evidence or expert opinion). Finding this probability data is often challenging in the healthcare field. Influence diagrams can become very complex, and their development time-consuming when applied to broad problems with a large number of interrelated variables, such as the treatment of neonatal jaundice. As Sonnenberg & Collins demonstrated, however, influence diagrams can be used to examine more limited problems without the need for formal correctness or complete probability data, and without the same level of time investment [Sonnenberg and Collins, 2006]. This latter, less formal usage is more reflective of how influence diagrams might be used as part of the PHA Toolkit.

4.5.2.9. Risk Matrices

Background

Risk matrices are risk communication tools that graphically represent information about the risk of a given hazard in terms of severity and likelihood, based on the formula *severity (or consequence) x likelihood = risk*. While they are widely used in the NHS for categorising and prioritising risks [NPSA, 2008], there is considerable variation between trusts in how risk matrices are constructed and interpreted. Among the more common formulations is that suggested by the NPSA in *A Risk Matrix for Risk Managers* [NPSA, 2008]:

	Likelihood				
Consequence	1	2	3	4	5
	Rare	Unlikely	Possible	Likely	Almost Certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

Figure 15 A risk matrix based on guidance from the NPSA [NPSA, 2008].

Using the matrix, consequence and likelihood scores are multiplied to arrive at a *risk score*, and these risk scores are grouped into risk tolerability levels (illustrated by different colours on the matrix). Decisions about how quickly and at what administrative level the risks must be managed (and to some extent the budget available for risk treatment) are often based on these risk tolerability levels.

Despite their popularity, Cox suggests that risk matrices should be used cautiously [Cox, 2008]. He points out a number of weaknesses, including the fact that they conceal important amounts of subjectivity in their construction, and that, when assessing risks that combine either low severity and high likelihood or high severity and low likelihood, risk matrices can provide guidance that is so inaccurate as to be worse than nothing. He also advises that, in order to provide accurate guidance, a 5 x 5 matrix must have exactly 3 risk tolerability levels. Any more, he contends, give only spurious resolution, while any fewer would not sufficiently differentiate between the highest and lowest levels of risk. The

primary strength of risk matrices is that they are a simple, easy-to-understand means of communicating risk in a way that makes both the assessed severity and likelihood of a hazard clear to decision makers.

Literature Review

Eight articles were selected for the final round of review, of which six were excluded. Four were excluded because they did not describe a use of risk matrices and two because they were not available.

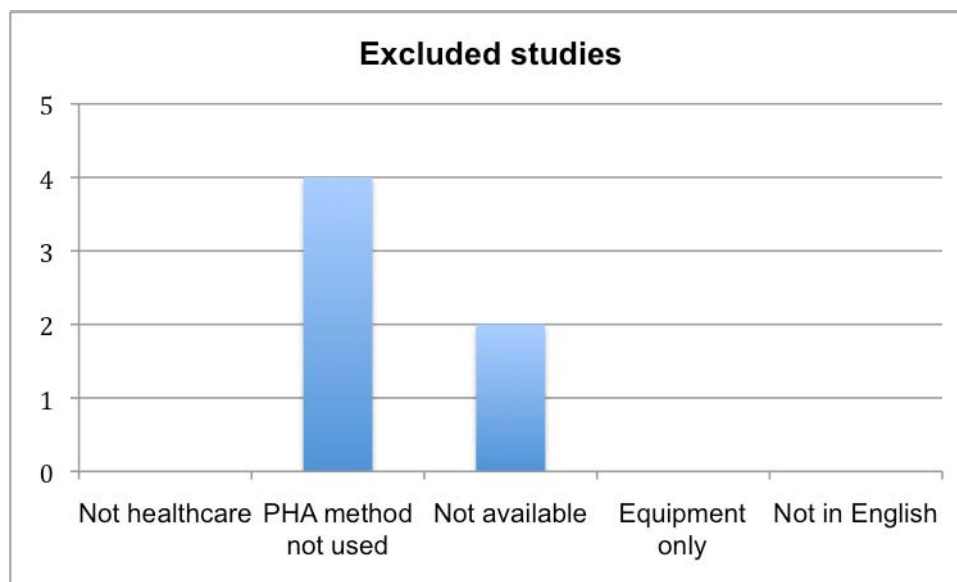


Figure 16 Study exclusion rationales.

One of the two qualifying studies [Kaplan, 2000] is also discussed in Section 4.5.2.3 *Barrier Analysis*. Kaplan used a combination of barrier analysis and a risk matrix to evaluate threats to patient safety in blood transfusion. The paper does not describe the use of the risk matrix, except to say that it was combined with the barrier analysis to develop a *risk assessment index*. The risk assessment index is also not described.

The second paper, by Fertleman, *et al.*, describes an NHS-based study examining the impact on medication management of adding a pharmacist to the team conducting post-admission rounds [Fertleman *et al.*, 2005]. The NPSA risk matrix (see Figure 6) was used to evaluate the pharmacist's patient safety recommendations [NPSA, 2008]. While the results were discussed, the experience of using the method was not. However, to the degree that the risk matrices communicated the success of the pharmacist's risk reduction efforts, the method can be said to have been successful in this case: Despite the cost, a full-time pharmacist was hired to attend the post-admission ward rounds as a result of this work.

Conclusion

Risk matrices are a commonly used risk communication tool in the NHS. Their strengths include simplicity and the explicit representation of assessed likelihood and severity. Risk matrices are most accurate when applied to risks for which likelihood and severity are positively correlated (i.e. high likelihood-high severity or low likelihood-low severity) and can be very inaccurate when applied to risks for which they are negatively correlated. This weakness can be somewhat mitigated by ensuring that an appropriate number of risk tolerability levels are employed. In the case of a 5 x 5 risk matrix (the most commonly-used format in the NHS), three levels should be used to provide the most accurate results ([Cox,

2008]. While risk matrices may provide an illusion of objectivity, it is important to understand that a great deal of unarticulated subjective judgment is involved in their use, as the risk appetite of the assessor can significantly influence the results [Cox, 2008].

4.5.2.10. Discussion and conclusions

This review of the literature has allowed us to characterise the use of selected PHA methods in healthcare. Broadly, we found that the use of PHA methods for healthcare risk management is quite limited and that the existing literature offers little insight into the motivations for, or experience of, their use. The relatively few studies we did uncover were almost exclusively in the form of case reports, with none providing high-quality experimental evidence to guide the use or selection of PHA methods. This probably reflects both the significant difficulty of constructing valid experiments to test PHA methods and the fact that many of the papers described pragmatic studies conducted as part of existing patient safety programs, with the primary goal not of advancing knowledge about PHA methods, but of reducing the risk to patients at a given institution. Overall, we found that the existing literature provides little useful evidence to guide the selection and use of PHA methods in the NHS.

Our literature review examined the published research on nine PHA methods. Two or fewer qualifying studies were located for seven of these methods (all but FMEA and influence diagrams). Indeed, *no* qualifying studies were found for HAZOP or HEART.

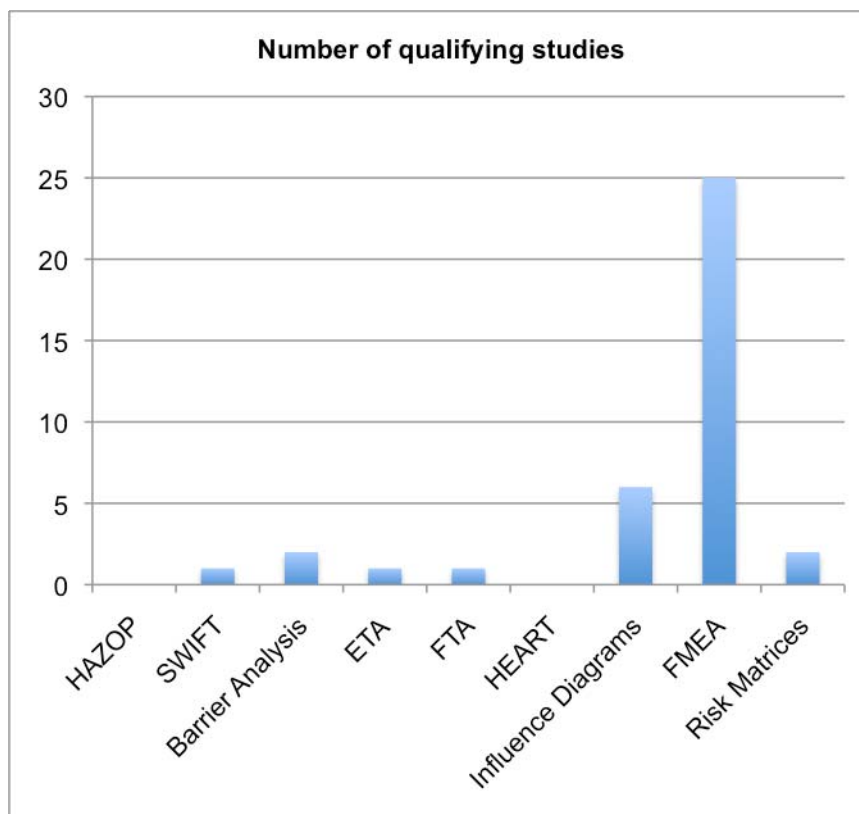


Figure 17 Qualifying studies.

While a small number of studies combined two PHA methods (e.g. barrier analysis and risk matrices), none compared PHA methods, so there is no evidence as to the relative merits of the methods as applied to healthcare. Almost none of the studies explicitly state the reason why the PHA method (or, indeed, any PHA method) was chosen, though a small number do mention that prospective hazard analysis allows one to control or

eliminate hazards before they lead to adverse events. In some cases (as in FMEAs conducted at hospitals run by the U.S. Veterans Health Administration), the method may have been chosen primarily to comply with regulatory requirements.

Other than some comments on the time-intensive nature of FMEAs and influence diagrams, there was little reflection on the usability of the methods. Discussion of the utility of the methods was also rare, and usually consisted of a simple statement to the effect that the method was useful or that its use led to changes that reduced the assessed risk to patients. None of the studies reported that the method used was not helpful.

It appears that the use of PHA methods in healthcare remains in its infancy, with few studies reporting their use and little to be gleaned from those studies that would help NHS leaders to select and efficiently use the most appropriate PHA method for any given scenario. It is this gap in the literature, the lack of useful guidance, that the PHA Toolkit is meant to remedy.

4.6. System mapping in healthcare

It was stated in Section 4.2.2 that developing an appropriate description of the system is an important part of good PHA practice. Since the purpose of this work is to develop a PHA Toolkit, due consideration should be given to mapping systems. As described earlier in this report, a variety of different diagram types have been used in conjunction with a range of PHA methods. This section reviews the diagram types used in healthcare to understand which have been used, in order to gauge the degree of guidance necessary in the PHA Toolkit.

4.6.1. System mapping methods used in healthcare

In healthcare, a very limited range of diagram types – i.e. mostly hierarchical task analysis or flowcharts – have been used to any real extent. A few other types of diagrams, such as sequence diagrams and swim lane activity diagrams, have been tried in healthcare [Beuscart-Zephir *et al.*, 2007; Middleton and Roberts, 2000; Pradhan *et al.*, 2001], but only in isolated situations and without overall consideration of alternative diagram types.

Disregarding the references in the previous paragraph, through a review of the literature, two main sources of information were discovered: a document from the NHS Institute for Innovation and Improvement and also the concept of mapping Care Pathways.

4.6.1.1. Process Mapping, Analysis and Redesign

This Improvement Leader's Guide [NHS III, 2007] published by the NHS Institute provides practical guidance on who to engage with, how to organise a process mapping event and how to map and analyse a patient's journey. Since process mapping is expected to be carried out by a multidisciplinary team when under considerable time pressure, limited diagram types suitable for such an environment are suggested. Diagrammatic representations used for this purpose are shown in Figure 18 and Figure 19. All are comparable to flow diagrams in the PHA Toolkit.

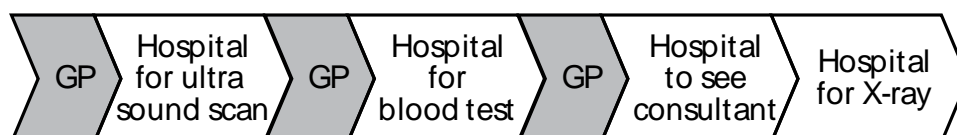


Figure 18 A patient journey for patients with suspected ovarian cancer [NHS III, 2007].

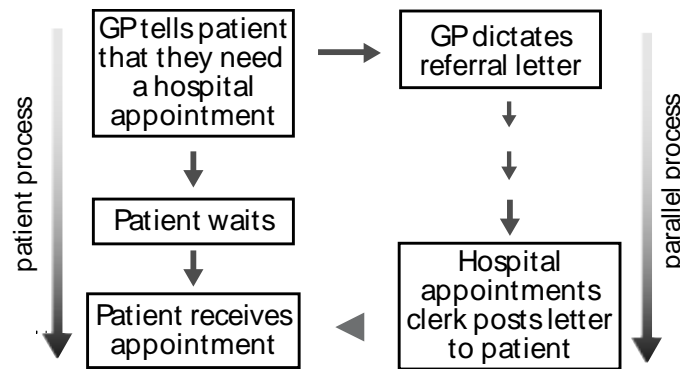


Figure 19 A parallel admission process [NHS III, 2007].

4.6.1.2. Care Pathways

The Integrated Care Pathway (ICP) is a programme which aims to develop a multidisciplinary outline of anticipated care to help a patient with a specific condition or set of symptoms move progressively through clinical procedures, to positive outcomes [Middleton and Roberts, 2000]. Care pathways are diagrammatically described by the representative of a multidisciplinary team in a very similar way to the aforementioned document from the NHS Institute. Figure 20 shows simple flowcharts used for ICP practice for outpatient appointment arrangement.

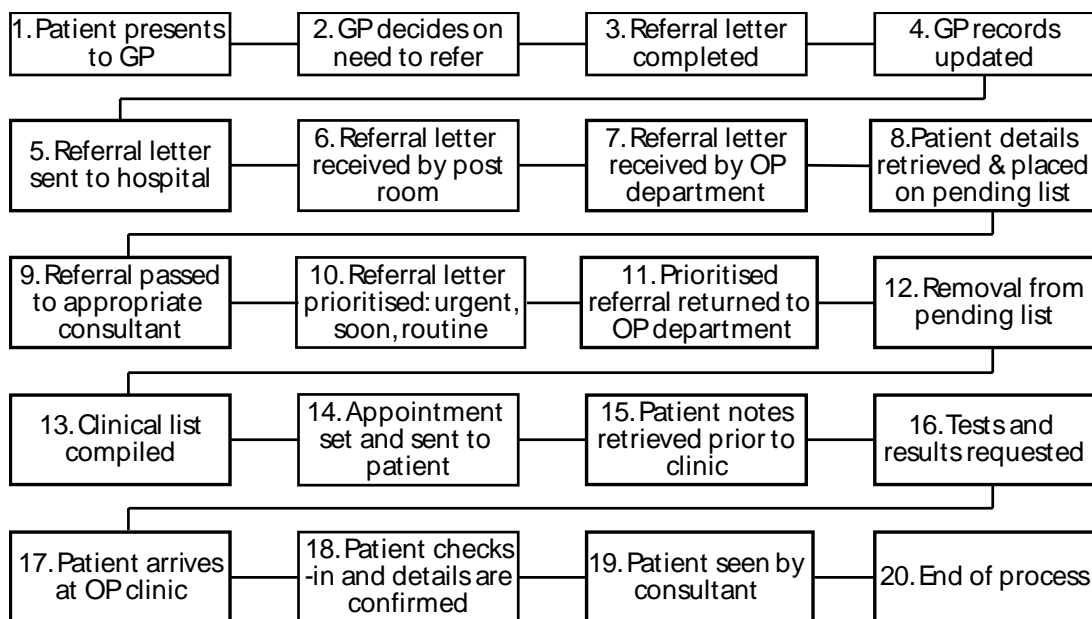


Figure 20 Detailed process map – arranging an outpatient appointment [Middleton and Roberts, 2000].

4.6.1.3. Conclusions

The purpose of this review was to identify examples of any widespread use of system mapping methods in the NHS. By identifying what was already familiar to NHS staff it was hoped that the Toolkit might make use of such prior knowledge, for example by providing shorter descriptions of such methods, and by using familiar language or examples. However, this review revealed only two such methods and underscored the need to develop further descriptions of a range of system mapping methods. This development process is described later in this report, in Chapter 6.

4.7. Informal interviews

Informal semi-structured interviews took place with seven NHS staff members in order to help plan parts of the research project, to understand more about current risk management practice, and to prepare for larger-scale formal interviews (Section 5.4). Notes were made by the researcher during the interviews, and seven were audio recorded. In preparation, an interview topic guide was developed, based on the research questions stated in the PHA Proposal document and through further questions raised during the PHA Team meetings (see Appendices, Section 10.2). Participants were identified through convenience sampling, based upon staff contacts known to members of the research team.

4.7.1. Method

The interview questions (see Section 10.4 in the Appendices) were arranged into three parts:

1. Assessment of current risk management practice
2. Assessment of opinions on PHA
3. Identification of candidate case studies / Staff Leads for future case studies.

At the start of the interview, participants were informed about the aims of the PHA project and were given examples of PHA methods, to help ensure they understood the concept.

4.7.2. Results

Seven NHS staff members were interviewed; details of whom can be found below (Table 8).

Table 8 Demographics of participants taking part in the informal interviews.

No.	Date of interview	Job title	NHS sector
1	22 August 2007	Director of Planning	PCT 1
2	31 August 2007	Chief Pharmacist / Director of Clinical Development	Acute trust 1
3	17 October 2007	Director of Pathology	Acute trust 2
4	02 November 2007	Treatment Centre Manager (until recently a senior nurse)	Acute trust 1
5	06 November 2007	Manager of Radiotherapy Services	Acute trust 2
6	05 December 2007	Service Improvement Manager	Acute trust 1
7	05 December 2007	Risk Manager	Acute trust 1

4.7.2.1. *Assessment of current risk management practice*

Observations were made on current risk management practice. These confirmed earlier findings (e.g. Sections 4.3 and 4.4); for example that local risk assessments are conducted by each department. Initially these may take place through walk-arounds in the department, where a risk form will be completed, which rates the likelihood and severity of potential incidents. These risk assessment forms will be held locally in a folder. The more severe risks will be escalated up through the risk management department to the Board, to consider mitigation strategies. Lower risks will be mitigated locally, where appropriate. Other meetings may occur on a regular basis, for example to consider project risks. Some trusts hold a risk register for each project.

One of the areas of risk management practice which was focused upon by the interviewer were the problems that they experienced with risk management. A considerable number of observations were made, including (figures in square brackets refer to the participant numbers in Table 8):

- A danger from over-reporting: that too much risk assessment creates management difficulties because there are too many risks to monitor.
- A danger from under-reporting: that a failure to report certain incidents left one manager “amazed, really, at some of the types of things that just don’t seem to hit as unacceptable.” [4]
- Difficulties were noted in accurate risk scoring. This can work both ways – inadvertently under-scoring risks, but also deliberately bumping up the numbers in order to raise unwarranted attention to a particular issue. For example: When bidding for equipment: “everybody aims to be as high as possible!” [5]
- Imbalances between reporting rates, where nurses seem to be the main staff members reporting, with only a tiny proportion of reports coming from doctors.
- Risk assessments occurring very locally, in silos, rather than in a systems manner: “It’s kind of ah we’ll do this and off we go and we don’t talk to anybody and we do things in silos and we make autonomous decisions and we don’t have any idea of what the impact’s going to be on anybody else.” [6]
- Major incidents being risk assessed (e.g. pandemic flu, major accidents, continuity planning) and minor local incidents being reported, but “it’s the middle bit that is missing.” [6]
- A lack of thought being given to the risk assessments, compromising their quality.
- A failure to implement actions after risk assessments have taken place.
- No apparent use of process mapping to assist the risk management process.

In addition, a number of observations were made on current proactive risk assessment practice:

- Proactive risk assessments being directed towards particular types of risk (e.g. failure to deliver a project on-time or on-budget), but in some cases with no focus on patient safety. Other cases were more positive, involving a consideration of knock-on effects to services.
- Proactive risk assessments being only in the form of annual walk-arounds.
- A failure to be proactive:
 - “The problem is that we always try and close the stable door once the horse has bolted, and we all sit round doing a root cause analysis once there’s been an incident” [2]
 - “we are not good at it. We don’t really proactively manage risk. But we’re good at identifying when it hits us in the face.” [6]

One of the most common reasons given behind the problems experienced with risk management was simply a lack of time, and the need to deal with other more pressing concerns. This was mentioned by most of the interviewees. An additional reason, which was given by several interviewees, was a complete focus on certain targets, to the neglect of other issues such as patient safety. Such targets could be government service delivery targets or financial targets, and were considered as mandatory.

Interviewees were asked to describe any examples of larger risk assessments that may have taken place within their Trust. Several brief examples are given below:

1. The storage of bulky items was moved from an in-hospital setting to being provided by a private company. There was no time to do a thorough PHA, although what could go wrong and also a worst-case scenario were brainstormed. Risk assessment involved a walk-around the hospital.
2. Movement of a service into a new PFI building. The focus of the risk assessment was on identifying variations from the original plan, being entirely underpinned by financial considerations, to the exclusion of patient safety.
3. Risk assessment of the introduction of new staff members into a particular service. The relevant managers were identified to conduct the review. The review was made against internationally specified performance standards, and hence it was clear what was required.
4. A large piece of medical equipment was purchased for the department. Prior to purchasing, a team was assembled to perform a risk assessment: a clinical lead, the head of medical physics, the service manager and the key people within the service: the research radiographer, the training manager, the lead physicist in charge of the unit and the lead clinician as well as the clinical director.

Whilst these provide examples of elements of good risk assessment practice, it is not clear to what extent this occurs across the NHS. It was also not clear whether there was any structure to the risk assessment, other than the need to identify the right participants and to think about the problem.

4.7.2.2. *Assessment of opinions on PHA*

Having discussed current risk management practice, and having been shown examples of PHA methods, the interviewees were asked for their views on introducing PHA into the NHS. The following observations were made:

- Whilst being aware of the concept of “spend to save”, with the focus on financial savings and meeting government targets, there were concerns over the lack of resources available to conduct a PHA. Further, even if an effective PHA was to be conducted, no action would be taken, for similar reasons. For example:

“And people are just staring at this wall of pain and thinking I'm not going to go through that. Not this week. Go through it next week. No I won't, I'll go through the week after. For 10 years we've been doing that. So I don't think it's going to change.” [6]
- Questions were raised about whether PHA could be applied at a clinical level to predict which patients would require what type of treatment.
- The concept of risk was regarded by one interviewee as “incredibly unpalatable to a lot of people, particularly clinicians.” [6]

However, a belief of its usefulness and importance was expressed:

“looking at your project brief, it just seems such common sense that it's proactive risk assessment... learning after the event has obviously got its place; it is very powerful... [But] what we want to do is try and avoid that, isn't it.” [4]

“risks, I think, are taken on a fairly regular basis. The ideal would be, wouldn't it, to try and be as proactive as possible to avoid the adverse incident.” [4]

“we need to have a different approach and say actually it is valuable for people to take a day out now in order to stop this happening next year. Rather than thinking, I can't afford to take a day out now, we are far too busy. Because we will always be busy.” [6]

4.7.2.3. *Identification of candidate PHA case studies*

The interviews were useful for raising the profile of the PHA work across a number of NHS Trusts, and identified several potential PHA case studies. A list of these is contained in Section 10.9.2.

4.7.3. **Limitations and conclusions**

A number of limitations influenced these interviews, including the small sample size and the fact that all participants were managers (although some had clinical experience). Clearly the participants do not reflect the broad range of healthcare workers in the NHS. Also, given time restrictions, it was possible to ask each participant only a small proportion of all of the questions. Participants were also asked to refer to examples when describing current practice, which also left less time for interview questions. The results should therefore be treated with due caution.

However, they suggest a systematic failure to perform good quality, proactive risk assessments in the NHS. The informal interviews were helpful for understanding how current practice takes place “at the coal face”. In particular, a range of problems were observed with risk management practice, although most of these were centred around practice which might be regarded as reactive (i.e. incident reporting). A limited degree of proactive risk assessment was evident, and even this experienced a range of problems: gaps in proactive risk assessments (a “missing middle” between major risk assessments and local assessments, a lack of structure), a failure to consider safety in the risk assessment, and a failure to consider safety at a systems level, with no apparent use of process mapping to assist any proactive risk management.

The interviewees’ reactions to PHA were mixed: whilst they could see the benefits of PHA and the need to “spend to save”, many were concerned with the lack of resources necessary to carry it out.

4.8. **Review of general guidance documents**

4.8.1. **Background**

A key aspect of the PHA Toolkit is to provide users with detailed guidance to allow them to understand and apply PHA methods effectively to their operations. For guidance to be helpful and effective it needs to contain high quality content, which must be presented in a format that aids understanding and usability.

To further help understand presentational factors and to help inform how guidance for the PHA Toolkit should be presented to meet the needs of healthcare professionals a small scale qualitative evaluation of healthcare guidance was undertaken. The review aimed to help understand:

- The types of guidance that are currently available within healthcare.
- What makes different guidance types effective, i.e. what are the key presentational factors that enhance effectiveness (such as layout, language, style, use of colour, structure of paragraphs, and presentation of key facts and figures).

4.8.2. Method

Literature was gathered using Google and Google Scholar. Key words were used to help structure the data collection, for example:

- Healthcare AND guidance;
- Risk assessment AND healthcare;
- Healthcare AND toolbox;
- Hazard analysis AND healthcare;
- Process driven guidance AND healthcare.

Web libraries for the following organisations were also explored:

- National Patient Safety Agency;
- Department of Health, including DH estates;
- NHS Employer;
- National Institute for Clinical Excellence;
- NHS Confederation;
- Institute for Innovation and Improvement.

This was because these organisations are known to have developed and published a range of healthcare guidance that is regularly used by healthcare professionals and practitioners.

Thematic analysis is a method for identifying, analysing and reporting themes within data and provides a flexible approach that can be applied to the analysis of literature [3]. For this research, thematic analysis was used to group guidance by type and then identify and describe the key factors that underpin guidance types and its effectiveness, particularly factors relating to presentation, comprehension and usability.

4.8.3. Results and discussion

The analysis of literature identified six main types of guidance:

- **Briefs, fact sheets and leaflets** – short one- to two-page high level summary of a topic or intervention;
- **Job aids** – short documents that highlight the key aspects of a process and help individuals understand and apply the process;
- **Process driven guidance** – guidance documents that are underpinned by a process, that is, the guide takes the reader through a process to aid thinking and understanding;
- **Normal guidance** – these documents provide information and guidance on a given topic/area or approach to aid understanding, but are not process driven;
- **Reports** – reports that detail the methodology and findings from research undertaken within healthcare or collate and discuss research undertaken inform the reader;
- **Toolkits** – web and/or excel based tools that are interactive and require users to input information and then provides outputs that can be used to guide activities.

The characteristics of each type of guidance are reviewed in more detail in the Appendices, in Section 10.5.

4.8.4. Conclusions

Although guidance types did differ to some extent in why they were effective, there was significant commonality: a range of generic presentational factors existed that underpinned guidance effectiveness regardless of type. These were:

- **Use of colour** – a range of different colour schemes were used throughout documents to help maintain the readers attention and motivation;
- **Use of pictures** – a range of different pictures were used to break up sections and text, making the information easier to digest and providing a different mechanism to represent information;
- **Columns, small paragraphs and spacing** – text presented in columns, small paragraphs and spacing between words making it easier to digest the text. Moreover, this presentation style meant that large amounts of text appeared smaller and easier to read;
- **Highlighting key points and quotes** - key points and supporting quotes highlighted in different colour and/or different size to the rest of the text, making it easy for the reader to see. This approach allows the reader to easily understand the key points of the section before reading it;
- **Use of graphics** –graphics, diagrams, tables etc. used to either support or represent information. This approach makes it easier to understand information and again breaks up sections of text so it is easier to digest. Moreover, graphics, tables and diagrams used a range of colour schemes to ensure they looked attractive and caught the attention of the reader;
- **Language** – where possible, non technical and non academic language used, supported with concise sentence structure. This approach makes text easier to read and understand and also means information is not marketed or pitched to a certain academic or technical level;
- **Short** – where possible making material short in length to maintain the attention and motivation of the user.

The analysis indicates that these generic factors seem to work on two levels: by, enhancing comprehension and maintaining the motivation and attention of the reader, through using a variety of techniques to break up and by presenting information in a way that makes it easier to understand and digest. Thus it would appear that when developing guidance, enhancing comprehension and reader motivation and attention through a range of presentational methods may be important for guidance effectiveness.

As a consequence of the findings of this brief review of healthcare guidance, the intended structure and format of the planned PHA Toolkit was perceived to need to be consistent with the objectives of *process-driven guidance*, *normal guidance* and *job-aids*. This led to the conclusion that the principal format of the guidance should be consistent with process-driven guidance, i.e. that this was the fundamental aspect of the required guidance. However, the process-driven guidance would need to be supported by normal guidance (i.e. in respect of information concerning specific PHA methods etc), and that the potential complexity and novelty of the process that users were likely to be embarking on means that some form of job-aid also would be of value.

4.9. Summary

A review was conducted of the use of risk assessment in other safety critical industries. This showed that the use of PHA methods is commonplace and demonstrated the benefits of different PHA techniques, each of which may have particular strengths at different stages of the risk assessment process. It stated that the approach to risk assessment will depend upon the aims of the analysis, and highlighted the importance of creating an appropriate representation of the system to be analysed, prior to the risk assessment. However, even when using systems mapping techniques in the NHS, few different types are used, and few examples could be found of wide-ranging guidance on process mapping.

This chapter also pointed towards the need to promote PHA methods which are appropriate for use in healthcare, bearing in mind its particular demands. We also found little evidence of any simple, structured rationale to choosing PHA methods in given situations for analysis.

In the review of risk related documents in healthcare, including both national and local practice, very little guidance was observed on how to use PHA methods, with very little or no description of these methods. Further, very few documents described the stages of risk assessment. A review of documents at a “local” level, led to a description of how risks are managed, across a variety of NHS trusts. This particular review showed that very little advice was given on how to identify risks. There was no mention of using any PHA methods to assist with the risk assessment process, nor was there any mention of using process mapping to consider systems issues. This part of the analysis also suggested that NHS trusts are not taking a systems-based approach to risk management. Additionally, whilst risks might be managed through a matrix based risk process, this itself has a number of problems.

The informal interviews revealed problems with both reactive and proactive risk assessment, although some elements of good practice were observed. Concerns were also raised about potential limitations in applying PHA, for example the lack of necessary resources. It is suggested that the desire for PHA was present, but that this can be overridden by the fear of the extra resources that might be required to put it into practice. Indeed, little evidence was found of systematic, proactive risk assessment.

In combination with the results from the informal interviews, the lack of published evidence also suggests that PHA methods remain little used in the NHS. In conclusion, this review demonstrated the potential for the NHS to use a variety of good practice in risk assessment, including PHA methods.

Many of the research activities described in this chapter helped identify “informal” requirements for the Toolkit. For example, the review of Guidance Documents in the NHS suggested that the Toolkit should be a process-driven type of guidance. The following chapter describes how these were used to influence the development of 54 “formal” requirements for the Toolkit.

5. TOOLKIT REQUIREMENTS CAPTURE

5.1. Introduction and background

5.1.1. Usability and design

The production of the Toolkit was approached as a design problem and the research drew on the work of the systems-based user-centred approach to healthcare design, as described in Section 3.1. This work took a systems approach to design in the healthcare sector, in contrast to the narrow focus on usability that is often used in the design of computer systems and other artefacts. This systems perspective also informs work in other areas of healthcare such as health informatics [Taylor, 2006] and innovation diffusion [Greenhalgh *et al.*, 2005], as will be briefly discussed later in this chapter.

Although the Design for Patient Safety framework [Clarkson *et al.*, 2004b] clearly shows the importance of understanding and designing the system in order to support the effective introduction of the Toolkit, this was not part of the project brief. Yet, an effective Toolkit cannot be designed in isolation from the healthcare system and without considering how it will be introduced and used in healthcare. The project team saw it as important to collect data about the systems features that should be taken into account in the design of the Toolkit, and which would be important in facilitating the introduction of the Toolkit into NHS healthcare organisations.

5.1.2. Research design

As discussed, the framework emphasises the importance of building a knowledge base of the system [Clarkson *et al.*, 2004b]. To do this, an understanding of the current use and attitudes toward PHA methods was important. This information provided the backdrop to identify healthcare users' requirements of the Toolkit – both in terms of “formal” requirements (which were added to a requirements list) and “informal” requirements (which were borne in mind during the Toolkit, but had a lesser influence).

Following this, a draft of the Toolkit was developed by drawing on the requirements of the potential users in the system (see Chapter 6). Finally, this was tested through the activities described in Chapter 7.

5.1.3. Definitions

To aid clear communication and increase the validity of the research, the following definition of PHA was used, as developed by the PHA Research Team:

“PHA is a systematic process for prospectively identifying risks, identifying practical risk reduction measures and the determining the acceptability of levels of risk. It involves the following steps:

1. *Describing the socio-technical system*
2. *Generating a process description*
3. *Identifying hazards prospectively – i.e. where is the potential harm, where might the system fail*
4. *Analysing, prioritising and/or quantifying the risk arising from the hazards*
5. *Recommending mitigation and risk reduction or hazard elimination strategies “*

5.2. Identifying healthcare user requirements

5.2.1. Aims and objectives

The aim of the first stage of the research was to define the requirements for the PHA Toolkit. It was important to first build a knowledge base of the system to provide the context within which the requirements of the Toolkit were derived. Then, information about the requirements of the potential users of the Toolkit and stakeholders who have a vested interest in the use of these tools in the NHS were gathered.

5.2.2. Research design

A knowledge base of the system was developed by understanding the attitudes and use of PHA in healthcare. Chapter 4 describes a variety of activities which bore an influence on the development of the requirements for the Toolkit, such as a documentary analysis of policy documents developed by the Department of Health and its Arm's Length Bodies (ALBs) and a literature review of published studies which describe the application of PHA in healthcare (as described in Section 4.3 and Section 4.5, respectively). The documentary analysis showed the healthcare policy and decision makers' attitudes toward PHA whilst the literature review revealed the extent to which PHA have been used in NHS healthcare settings.

Complementing this work, to identify the requirements for the PHA Toolkit in a more direct manner, semi-structured interviews were conducted with a range of potential users and stakeholders. The conduct of the semi-structured interviews was also informed by another theoretical perspective: the model of diffusion of innovations [Greenhalgh *et al.*, 2005] was used to frame the research questions, identify the sample, define the interview schedule and analyse the results.

5.3. Opportunistic data collection

The main "formal" requirements were generated from semi-structured interviews. However, there were additional opportunities for the research team to collect perspectives and observations from different groups of participants. In addition to the results presented in Chapter 4, these "informal" requirements capture activities are presented in the first part of this section, followed by the formal, planned semi-structured interviews.

5.3.1. Steering Committee and PHA Team Meetings

The PHA Steering Committee met three times during the course of the project, as described in Section 3.2. These meetings were audio recorded, and notes were made on the observations and outcomes from the Steering Committee members. Analysis by the research Team from the transcriptions of the meetings generated a number of "informal" requirements (observations), as listed in Table 9.

Table 9 Requirements generated from Steering Committee meetings.

Observation	Rationale / notes
PHA method should be structured and standardised	Avoid confusion amidst the plethora of different ways the NHS manages risk and saves retraining. Helps benchmarking and communication. May need a degree of flexibility (e.g. to take into account individual preferences).
Might need a lite version at ward level and a more formal method for bigger analysis projects	Pragmatism. Clinical services will have particular pressures on time, so may need to be quick to perform.
PHA should take less than 1 day (Acute)	Staff time pressures.
PHA should take less than 2 hours (GP practice)	
Stress benefits	Benefits could include a Toolkit which minimises fire-fighting on the ward, creates results which can aid comparisons (e.g. before and after) and creates cultural awareness of patient safety. May also reduce insurance premium.
Users include front-line workers, and those with the will and ability to make changes	Those who have time, knowledge, skills and incentive to follow through with action. May be more senior staff involved for larger projects requiring analysis.
The facilitator should be an expert in the method.	
The facilitator should be independent from the system under analysis.	

Additional requirements were generated through the numerous meetings held between the members of the PHA research Team. A summary of these meetings and their outcomes is presented in Table 25 in Section 10.2 of the Appendices. Table 10 lists requirements which were generated from the minutes of PHA Team meetings.

Table 10 Requirements generated from PHA Team meetings.

Observation	Rationale / notes
Engage users in the risk analysis process.	Great benefits may be gained just by encouraging users to think deeply about risks.
Interface with change management activities.	The Toolkit will not “re-invent the wheel” by providing change management advice, but risk assessment must lead into risk management if risks are to be reduced.
Helps users to know what the reliability of the results will be, depending upon the risk analysis route they take.	For example in the nuclear context a “light” analysis version may take place first, but there will be a penalty – a more pessimistic view of safety should be taken and the system built in the light of this. If the pessimistic situation cannot be afforded then more risk assessment is necessary.
May need to encourage users to use more than one risk assessment method on a single problem.	Different PHA methods may have a range of strengths in tackling particular problems
Help users to ask the right questions.	E.g. the importance of correctly framing and phrasing the problem to be addressed.

5.3.2. Risk Forum attendance

Throughout the course of the project, team members attended a three-monthly forum for risk managers from a Strategic Health Authority. Around 70 (clinical) risk managers and health and safety managers from a wide range of sectors of the NHS (primary, acute, ambulance, mental health, etc) were invited to attend each session, with a typical voluntary attendance of around 20 risk managers. A usual agenda would include ten to twenty items, which would vary widely from: compliance with risk management standards, responses to NPSA alerts and guidance, reports on major incidents and sharing of lessons learned, quality inspections, and a multitude of specific items ranging from ensuring staff competencies in dealing with violent patients to the management of patients with no NHS Numbers.

This was a very useful venue for understanding current risk management practice across the SHA. As an illustration, observations in 2007 by two members of staff on the use of Root Cause Analysis showed that they had insufficient time to properly analyse the events (despite typically spending around 50 man-hours on each RCA), and that by the time they had made their best attempt at analysing an incident they had no time left to implement any learning points.

The aims and progress of the PHA project were aired at the majority of these meetings, and feedback obtained from the risk managers on the direction of the project. Later in the project, two specific sessions were arranged to gain feedback on the PHA Toolkit. These are described in Section 7.4. Issues raised during the course of the project included the following:

- Concerns over whether the PHA Toolkit might become another Government target, without the provision of suitable support to enable PHA to take place.
- The scope of the Toolkit (suitability for analysing certain types of scenario and for analysing a range of types of risk).
- Alerts on likely barriers to the implementation of PHA (e.g. finding staff time, obtaining accurate numbers for risk assessment).
- Many risk managers had heard of a few of the PHA methods (HAZOP, FMEA and influence diagrams) but few had used them, either in other professions or within the NHS.
- If the PHA Toolkit guidance is introduced, e.g. by the NPSA, it will likely first be passed very early on to the Trust's Risk Manager, who will be held responsible for managing it. If the Risk Manager does not believe it to be useful, it is likely that this Toolkit will be "shelved".

5.3.3. Health and Safety managers review

In addition to the work with the Risk Forum, one of the members of the PHA Team presented an outline of the PHA project at a gathering of NHS health and safety managers, who were then invited to complete a feedback form on their views on PHA. The feedback form is presented in Section 10.6.1 in the Appendices. The purpose of this form was to understand more about current practice in risk management in the NHS: to identify relevant documents, to learn from any experiences of using the PHA methods (short listed through the Risk Experts' Workshop, and later in the form, any PHA method) and to solicit their views on the usefulness of PHA in the NHS. The form collected both numerical feedback (using a 5-point Likert Scale and corresponding descriptions) and free-text responses.

A further purpose of this meeting was to identify candidates for the formal interviews described in Section 5.4.

5.3.3.1. *Results and discussion*

16 out of 18 participants completed the feedback form. 11 of the 16 were willing to be interviewed. The results are presented in the same order as the questions in the feedback form.

The 5x5 risk matrix was used by all of the Trusts.

Documents identified as influential to risk management were as follows:

- British Standards: BS 18004:2008 *Guide to achieving effective occupational health and safety performance*
- HSE: *5 Steps to Risk Assessment*
- HSE: HSG 65 *Successful health and safety management*
- Standards Australia / Standards New Zealand: AS/NZS 4360:1999 *Risk Management Health and Safety at Work Etc. Act 1974*
- Healthcare Commission: *Standards for Better Health*
- NICE Guidance
- NHSLA Risk Management Standards
- NPSA Risk Assessment guidance
- Institute of Risk Management Standards

This list of documents was used to help identify documents for a review of current NHS risk-related documents (Section 4.2).

The participants were asked whether they had used any of a range of PHA methods. Two responded that they had used both Barrier Analysis and What-If; one who had used HFMEA™/FMEA, and another who had used HAZOP. Perhaps due to the unfamiliarity of use, comments were few, but included the following:

“Have used in group settings as a way of getting people to consider risk.” (What-If)

“Very useful to identify the root cause.” (What-If)

“Not user friendly.” (HFMEA™)

“Very good for planning work. Care pathways etc.” (HFMEA™)

“Use regularly.” (HAZOP)

“Use all the time. Simple and easy for staff to use.” (Risk Matrix)

“Found to be the versatile and easiest for staff to understand.” (Risk Matrix)

“Used currently. My experience is that it is not used extensively in the trust therefore its usefulness is limited.” (Risk Matrix)

Participants were also asked whether they had used any other PHA methods. Three mentioned Fault Tree Analysis. In general, it seems that PHA methods had been little used by the participants, suggesting that – at least for this group – the Toolkit would contain new material. However, it should be noted that a significant proportion of the responses were not numerical responses and had to be discounted from the results. For example, several participants left blank spaces in response to the questions.

The respondents were also asked to comment on three statements:

1) *“It is important for the NHS to use PHA techniques”.*

Not all of the participants answered this question, either numerically or with comments. Of the 14 responses, ten strongly agreed with this statement, one agreed, two neither agreed nor disagreed and one strongly disagreed. Four participants commented further:

“For engineering problems mainly – e.g. border[?] failure, medical devices. The ultimate subject matter of study (medication conditions / patient experience) make it an improbable set of procedures to specify.” (agreed)

“Risk assessment in its own right and as part of risk management is proactive.” (strongly agreed)

“Risk assessment is the simplest and easier system to use”. (No score given)

“Proportionality is the key – better use of available resources targeted at particular high hazard areas and wider use of generic Ras [risk analyses?] for low hazard areas/ activities.” (neither agreed nor disagreed to strongly agreed – 3-5)

2) *“We know what all the problems are and we know how to fix them; we just don't have the resources”.*

Fourteen participants responded numerically to this question, presenting a wide range of scores: 2 strongly agreed, 8 neither agreed nor disagreed and four strongly disagreed. As only two participants responded with comments, it is difficult to explain this broad spread of responses. The comments are as follows:

“The best value improvement will come from incremental improvement of general risk assessment, not “transplant surgery”.” (neither agreed nor disagreed)

“Resources poor.” (No score given)

The first comment might be regarded as highlighting the importance of care in designing and disseminating the Toolkit, and a warning against blind “transplant surgery” of PHA methods into healthcare.

3) *“The NHS will struggle to use PHA techniques”.*

Thirteen numerical responses were received. As with the previous question, a wide range of opinions were collected: Four strongly agreed, five neither agreed nor disagreed and four strongly disagreed. This question, however, prompted more comments than the others; generally involving caution about the update of PHA:

“The ultimate subject matter of study (medical condition / patient experience) make it an improbable set of procedures to specify.”³ (strongly agreed)

“Will depend on methods. District Nurses will not use FMEA, but would use a Matrix linked to a set of questions.” (neither agreed nor disagreed)

“Not of the system – is very clear and simple.” (strongly disagreed))

“Matrix system linked to RA.” (No score given)

“No national incident data for non-clinical events is available to support QRA [Quantitative Risk Assessment]; NRLS data not more sufficiently user-friendly to employ and QRA in clinical setting.” (No score given)

“Unless culture changes PHA techniques may struggle.” (No score given)

³ The participant gave the same response to this question as he/she did to Question 1.

Lastly, participants were asked whether they had ever performed a PHA in the NHS, and if so a) what was the motive, b) what was the aim and c) to describe further details of the assessment. Comments were also collected. Numerical results (questions (a) and (b)) are presented in Table 11.

Table 11 Requirements generated from PHA Team meetings.

	Strongly Agree	Agree	Neither Agree nor Disagree	Disagree	Strongly Disagree
a) MOTIVE					
Response to an incident	13	0	2	0	0
General feeling of unease with provision of care suggested need for further investigation	5	0	2	0	3
Trying to meet a government target	4	0	2	0	5
Following a standard or guidance, e.g. <i>Hospital at Night</i>	4	0	5	0	2
Your manager / Board	3	0	4	0	2
b) AIM					
Trying to identify what could go wrong with the current situation	11	1	1	0	0
Trying to quantify the scale of a known problem	11	0	1	0	0
Trying to identify a solution to a known problem	8	0	4	0	0
Trying to see how good a proposed solution is	9	0	0	0	1
Trying to compare a proposed solution with the current situation to see if it is better	5	0	6	0	0
Trying to see how changes elsewhere might affect the service	6	0	4	0	0

It is intriguing that “response to an incident” was perceived by 13 of the 15 respondents to be a *Proactive* Risk Analysis. This was not intended to be a trick question, as it was believed by the PHA Team that an incident could be used to trigger a wider, proactive, risk assessment. It is not clear whether the participants perceived this question in such a way, and therefore whether the risk assessments were indeed proactive. The following comments do, however, suggest that some participants appreciated the thrust of the question, whereas others, perhaps quite understandably, disagreed:

“Need to move beyond ad hoc judgement to structured process.” (strongly agree)

“Would normally review risk assessments in place first before doing a new RA.” (strongly agree)

“Need to ensure that appropriate determine level of risk.” (neither agree nor disagree)

“Reactively?” (strongly agree)

“Incidents are reactive.” (neither agree nor disagree)

“Always review following incident.” (no score)

Other comments demonstrated a wide variety of motivations for carrying out risk assessments, and a broad spread of opinions for each.

Regarding the aims of risk assessment, opinions varied widely, but perhaps not as widely as for other questions. Across all the possible aims, three appear to be the most common:

identifying what could go wrong; trying to quantify the scale of a known problem; and seeing how good a proposed solution is. Since the aim of a risk assessment may strongly influence the choice of PHA method, these results were noted for the development of the Toolkit.

Considering the different PHA methods used, nine participants went on to describe experiences of using a risk matrix, six regarding FMEA, three with HAZOP, two with What-If, two with Fault Tree Analysis and one with FMECA. These results are somewhat at odds with the results from the earlier question regarding whether they had used such techniques. This may be explained by the fact that several participants did not respond with numerical responses to the questions which requested a numerical response – and hence their responses had to be disregarded. This latter set of results may therefore demonstrate more closely the reality – that the use of a range of PHA techniques was actually not uncommon, although it is not clear whether such techniques were used routinely as opposed to one-off use.

Participants were asked to describe who was involved in the analysis they had chosen to recount. A considerable majority of comments demonstrated the involvement of a wide range of personnel for each case, from the risk management department to nurses, managers, external management consultants, engineers, members of the estates department and ward safety representatives. If PHA should be a multi-disciplinary activity, then the results suggest that it was performed well in this regard.

A wide range of motives were specified for carrying out the risk assessments; from the desire to understand how failures could occur and therefore be mitigated, to legal obligations.

A very broad range of timescales were presented for the assessments: in order of duration: “10 minutes to 2 hours”, “1 hour”, “1-2 hours”, “2 hours”, “3-4 meeting interviews”, “¾ day”, “half a day to 2-3 days”, “a day or so”, “10 days WTE”, “two weeks” and “some can take weeks”. Many responded that the duration can vary considerably. This had useful implications for the design of case studies, as described in Section 7.5.

The participants also highlighted a range of attitudes from the users towards risk assessment and the results, but tended towards the positive. Negative responses were: “disregarded” (FTA), “time consuming” (FMEA), “mixed results” (HAZOP) and “struggled to act on findings to bring out risk reduction”. More positive remarks were: “satisfied with the results and the method” (Risk matrix), “clear, concise, involved” (What-if), “useful” (What-if), “straightforward” (Risk Matrix) and “I find they all have a part to play” (Risk matrix/FTA/FMEA/FMECA/HAZOP, Brain-storming). The positive experiences were explained as those which were comprehensive and delivered the results hoped for (e.g. convincing managers to release funds, deliver action plans and achieve compliance with safety standards). Negative experiences involved: the wrong users being involved in the risk assessment; the assessment being carried out too late; and a failure to implement actions.

5.3.3.2. *General observations*

In addition to the results from the feedback form, observations were made during the meeting, where a number of risk related agenda items were discussed. Further, the group members asked questions about the PHA project and made a number of observations:

- The structured approach provided by these methods may not be necessary in organisations where the problems are so great that common sense is all that is needed.

- Simplicity in the Toolkit was highlighted as essential
- A warning on the challenges in involving clinicians: “We’ve been doing it [proactive risk management] for years, but clinicians don’t want to get involved.”
- The difficult with helping staff to understand that a single risk assessment is not enough – at some level it should be continuous.
- External facilitators can be more convincing and may help achieve results over and above members of staff within the organisation.

Whilst tending to come from individual members, these observations were taken into account when developing the Toolkit.

5.3.3.3. *Summary*

The meeting and feedback form with NHS health and safety managers proved useful for gaining a basic understanding of risk assessment practice in the profession. It identified a range of influential documents in risk assessment, and a number of potential interviewees for the formal interviews (see Section 5.4.).

There were insufficient participant numbers to draw concrete conclusions about the use and usefulness of PHA methods in the NHS; the results demonstrated a very broad range of opinions in response to each of the questions. It is suggested that further work would be necessary to uncover why. However, they provided an indication that PHA methods can be useful: whilst negative experiences were articulated, many were indeed positive. The accounts of using PHA methods provided a useful insight into the use of a range of PHA methods. These insights related to the development of the Toolkit – for example the need for simplicity and clarity. They also assisted the planning and facilitation of the case studies (Section 7.5), for instance suggesting that one day might be a good starting point for planning a risk assessment.

5.3.4. **Informal interviews**

Informal, semi-structured interviews took place with seven NHS staff members, as described in Section 4.7. Many of the observations generated were helpful for understanding current risk management practice, and attitudes towards PHA, and played a minor role generating the formal requirements.

5.4. **Semi-structured interviews**

5.4.1. **Aims**

The aim of the interviews was to gather detailed user requirements for the Toolkit.

There were two stages to this part of the study. The first stage was to conduct scoping interviews with patient safety experts. The aims were to scope out the areas to cover in the interviews by identifying the major themes and issues that would confront users, pilot test the interview schedule and identify potential participants.

The second stage involved gathering detailed information from different groups of participants including potential PHA users and stakeholders.

5.4.2. Scoping interview topics

5.4.2.1. Participants

A total of 3 patient safety experts were interviewed. These were identified through personal contacts and were chosen because of their diverse background and expertise in patient safety. Table 12 presents brief descriptions of the participants.

Table 12 Descriptions of participants

Participant	Work setting	Post
1	Stakeholder organisation	Head of Human Factors
2	Academia	Senior post-doctoral researcher
3	Strategic health authority	Patient Safety Manager

5.4.2.2. Methods

Semi-structured interviews were conducted with each individual participant by two researchers.

Interview schedules were developed for each participant. Each interview informed the development of subsequent interview schedules. Notes were taken during the interviews and these were analysed for common themes and issues relating to the use of PHA.

5.4.2.3. Findings

Although many themes were raised in the interviews, only those related directly to the development of the PHA Toolkit are briefly presented here.

Themes related to the PHA Toolkit

- Definition of PHA – there was a need to define PHA.
- Potential users – the main users were thought to be risk managers and clinical risk managers. These groups of managers are looking for new tools and have an appetite for change.
- Clear benefits, evidence based/used in a similar setting – exemplars to demonstrate what it can do. E.g. of a problem not completely solved where PHA would have helped.
- Identify risks in organisational processes rather than clinical procedures – target more streamlined services initially.
- Support for a tiered approach e.g. light and full PHA :
 - a. Time
 - b. User-support – usability of the Toolkit
 - c. Simple? But there are also dangers. Need to match method to problem.
- Emphasise developing and implementing recommendations.
- Lack of clarity – resources and implementation – gap introducing Toolkit.
- Resources that could be dedicated to PHA.
- Tag onto an existing concept e.g. Lean.

5.4.3. Defining the interview schedules

The interviews with patient safety experts helped informed the interview schedules for

each user group. However, we expected the interview questions to evolve as we conducted the interviews and uncovered issues that we might wish to follow up in subsequent interviews.

5.4.3.1. Diffusion of innovations

There is another body of literature – the “diffusion of innovations” – that could help refine the interview schedules and provide guidance about what information is needed at the design stage of the PHA Toolkit. The diffusion of innovation model provides more detail about the factors that are important in determining how innovations spread in healthcare. This part of the study drew on the systematic review of the diffusion of innovations literature conducted by Greenhalgh *et al.* [Greenhalgh *et al.*, 2005]. They identified many factors that affect the spread of innovations in healthcare organisations and the outcome of this extensive review was a model of the important factors that affect the spread of innovations. A simplified version of the model is shown in Figure 21. Innovations are new services or practices and diffusion refers to the process through which such innovations spread within an organisational setting. This includes both formal planned processes and complex organic processes arising from interactions between people, the system and the planned innovation. Although the systematic review focused on the diffusion of innovation in service delivery, there is no reason to suggest that it would not be relevant to other types of innovations such as the Prospective Hazard Analysis Toolkit (G. Robert, personal communication, August 20th, 2008).

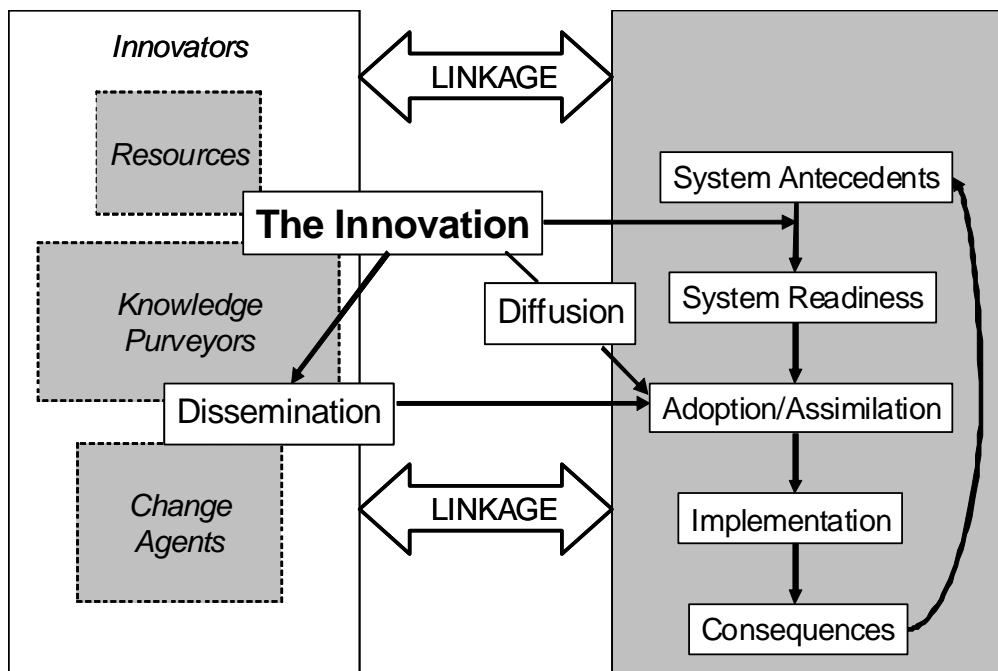


Figure 21 Model of the determinants of diffusion of innovation [Greenhalgh *et al.*, 2005].

In the sections below, each component of the model in Figure 21 is briefly described and the implications on the design of the interview schedules are outlined.

Innovation

The characteristics of an innovation will affect whether it is adopted and determine how it is disseminated. Innovations that have a clear advantage in terms of effectiveness or cost effectiveness, are compatible with the values and needs of the users, are low in

complexity, can be trialled on a limited basis by users, that have a highly observable benefit and can be adapted and modified by users, are likely to be more easily adopted. Additional characteristics of innovations that make them more likely to be adopted are a low degree of risk or uncertainty about the outcome, high relevance to the user's work, easily codified knowledge and the provision of support for users.

Implications for data collection:

- Data collection should include: perceived advantages of PHA, needs and values of current and potential users, perceived complexity of PHA, perceived risks associated with PHA.

Adoption by individuals

Potential users of an innovation will be more likely to adopt it if it meets identified needs and holds a meaning that is shared by top management and stakeholders. The meaning attached to an innovation will be affected by ongoing discussions within and outside the organisation and experience with using the innovation.

Implications for data collection:

- Identifying potential users' needs.
- Identifying potential users' attitudes towards PHA.
- Identifying stakeholder and management attitudes towards PHA.

Diffusion and dissemination

Diffusion refers to the unplanned informal spread of innovations in which social influence and imitation play a large part. Dissemination is an active process that is managed and formal. It is not clear at this stage whether the PHA Toolkit will be disseminated in a formal way. If diffusion will occur informally innovations will be adopted more readily if social network structures are taken into account, there is good similarity between adopters and expert opinion leaders support it. Formal dissemination of the Toolkit will need to include identifying and engaging opinion leaders and key individuals who can champion it.

Implications for data collection:

- Identify social network structures that will help diffusion.
- Identify whether there are expert opinion leaders who can be engaged.

System antecedents for innovation

Large, mature, structurally differentiated organisations with specialised professional knowledge, spare resources to channel into new projects and decentralised decision making, are more likely to adopt innovations. The establishment of semi-autonomous project teams also increases innovativeness. Two other structural characteristics are also important. First, absorptive capacity: if an organisation is able to identify, capture, interpret and link new knowledge to its own existing knowledge base it will be better able to assimilate innovations. This assumes that there is a base of skills and knowledge into which the innovation can be assimilated. Second, cultural factors, such as strong leadership, clear strategic vision, good managerial relations, visionary staff and support for experimentation, create an organisation that is receptive to change.

Implications for data collection:

- Identify existing skills and knowledge in relation to risk management and PHA

methods.

System readiness for innovation

This factor refers to whether the organisation is ready to adopt a specific innovation. The factors that increase the likelihood that the innovation will be adopted are the presence of tension for change, good system-innovation fit, assessment and anticipation of the implications of the innovation, support and advocacy, dedicated time and budget and capacity to monitor and evaluate the intervention.

Implications for data collection:

- Identify whether there is a need for better risk management tools. Are existing tools adequate and are people satisfied with them?
- Does PHA fit with the existing values and goals, skills and technologies of the organisation?
- Are there supporters and opponents of PHA?
- Identify whether there are resources that could be dedicated to PHA.

Inter-organisational networks and collaboration

This factor refers to the wider organisational context. If many similar organisations have adopted an innovation, it is more likely to be adopted by others. The presence of informal networking initiatives that could promote the innovation and external policy pressure, especially if accompanied by a dedicated funding stream, will increase the adoption of innovations.

Implications for data collection:

- What informal inter-organisational networks are relevant?
- Are there external policy pressures that would increase PHA adoption?

Implementation within the system

Successful routinisation is associated with an adaptive and flexible organisational structure, leadership and management support, training and knowledge of staff, funding, effective communication, extra-organisational networks, feedback and adaptation and reinvention of the innovation itself.

Implications for data collection:

- None. This is seen as outside the scope of the current project.

Linkage

In addition to the factors identified above, the model shows that linkage between those responsible for the innovation (the resource system, the knowledge purveyors and the change agency) and the user system is important. If an innovation is centrally developed, as is the case with the PHA Toolkit, the developers should link with potential users early in the development stage to ensure that the user perspective informs the development of the innovation. This is a central aim of this study. Change agencies will also need to link with potential adopter organisations.

Section 10.6.2.1 shows the final version of a generic interview schedule that was developed. Due to variations in the groups of participants, as shown in the next section, slight modifications in the interview schedule were necessary to reflect their experiences.

5.4.4. Interview participants

Although the intended target audience of the PHA Toolkit was not finalised at the time of the interviews, the diffusion of innovation framework showed that it is important to engage different groups of people who could potentially show similar or conflicting values and needs. The scoping interviews identified a gap in understanding the needs of different groups of potential PHA users. Two of the three patient safety experts did not have hands-on experience using PHA methods. To gain rich information about the user requirements of PHA, four groups of participants were identified:

1. PHA experts.

These participants have published reports in the scientific literature of the application of PHA to healthcare settings and so can be regarded as expert users. They were identified from the published literature.

2. Novice PHA users.

These participants have used a PHA method in the past to a limited extent but have not published the results in the scientific literature. They could be clinicians with an interest in this area or risk managers. Participants were identified from personal contacts and from attendance lists of seminars about PHA methods.

3. Potential users.

These are people who were perceived to have an interest in PHA but have not yet used any of the methods. Of interest were the perceived barriers to using PHA and factors that could aid the facilitation or adoption of the PHA Toolkit. These could be clinicians or risk managers.

4. Stakeholders and NHS management.

This group belongs to organisations that have a vested interest in safety in the NHS. These organisations could include the NPSA, NHS Institute and NHS trusts and could play a key role in raising the profile of PHA in the NHS and are likely to have key insights into the factors affecting the use of PHA.

A total of 18 participants across the four participant groups were interviewed. They were sampled across different hospitals and academic institutions across England. Their job titles are listed below. Purposive sampling was used to identify participants who could provide rich information about the user requirements for PHA.

Participants ranged from (may appear twice due to their background):

- Heads of department (n=2)
- Assistant director (n=1)
- Health and safety manager or advisor (n=4)
- Healthcare professionals (n=8)
- Patient safety manager (n=1)
- Researchers (n=2)
- Risk managers (n=4)
- Safety risk manager (n=1)

5.4.5. Method

Semi-structured interviews were conducted with each individual participant by one or two researchers. The venue of the interviews varied but was mostly held in a quiet area at the

participants' workplace. For others, it was more convenient for them to meet at a public space.

The interview schedule was used according to the type of participant group. In some cases, the researcher(s) realised that the participant did not fall into the perceived group of participant but this did not pose many problems as the nature of the interviews were semi-structured and the topic areas for interviews were clear.

All the interviews were audio-taped with consent from the participants and then transcribed verbatim.

5.4.6. Analysis of interviews

Qualitative analyses of the interviews were guided by the themes in the interview schedule. A qualitative analysis computer software programme, NVivo7 (QSR International Pty Ltd. 2006) was used to aid analysis. The analysis comprised four iterative stages:

Stage 1: A single researcher conducted the initial analysis by coding interview transcripts into high level themes e.g. factors affecting use of Toolkit

Stage 2: Three members of the research team conducted a second level analysis by further developing the high level themes and organising them into sub-themes. This process also served to validate the initial coding. Excerpts of the findings are shown in Sections 10.6.2.2 to 10.6.2.5.

Stage 3: A single researcher revisited data sources to identify further themes or irrelevant information that may have been initially coded. These were changed accordingly. Interview themes were further categorised and descriptions were provided for each theme. Sections 10.6.2.2 to 10.6.2.5 for the full documents.

Stage 4: The interview themes were evaluated against expert knowledge of the literature and research team, leading to design requirements. A human factors approach was used.

5.4.7. Requirements for the Toolkit

A total of 54 requirements were generated from the interview analysis. These are presented below.

Setting the scene:

1. **Description of PHA.** The Toolkit should contain a clear description of the aims of prospective hazard analysis and how it should be approached by the Toolkit user. This should include information about a systems approach to improving safety, and it should emphasise that the techniques in the Toolkit provided a structured and systematic way to make decisions to improve the system.
2. **Mature approach to risk management.** The Toolkit should contain information about how the use of prospective techniques indicates a mature approach to risk management, compared to approaches that are mainly retrospective and that rely on benchmarking of quantitative data.
3. **Benefits.** The benefits of prospectively assessing risk should be emphasised but these need to be realistic and should include the following:
 - a. Prospective methods provide a systematic and documented way to examine risk in a system
 - b. Prospective methods can improve safety and reduce harm if used appropriately

- c. The results of the analyses may be able to be re-used to monitor changes in processes and risk over time
 - d. Prospective methods provide evidence that the organisation has a systematic approach to safety and is using the full range of methods to improve safety.
4. **Benefits for managers.** The Toolkit should contain information about the benefits of these methods for managers. Higher level management support will be crucial in ensuring that these methods are adopted and resourced appropriately
5. **Address assumptions.** The Toolkit should contain information to dispel some common assumptions about the benefits of these methods, including beliefs that a prospective analysis will reduce litigation, improve efficiency, save time, be cost effective and will allow healthcare personnel to work quicker, easier and smarter.
6. **Limitations.** The limitations of the techniques should be clearly defined. These should include the following: (1) the lack of quantitative data in healthcare and the implications of this particularly regarding its limitations for comparing the safety of different organisations and industries, (2) the subjectivity inherent in many judgements about risk and how this should be approached.
7. **Integration with other risk management activities.** The Toolkit should contain information about the need to integrate prospective techniques with other organisational risk management activities, including the risk matrix and the risk register and how this should be approached.
8. **Fit with retrospective methods.** The Toolkit should explain how the methods link to retrospective methods such as incident reporting and root cause analysis. For example, recommendations derived from RCA should be prospectively analysed for risk.
9. **Relationship with clinical risk management.** The Toolkit should contain information about the similarities of prospective techniques and the clinical risk management activities that are already carried out by clinicians. This should assist with engaging clinician support for the Toolkit.
10. **Importance of organisational support.** The Toolkit should emphasise that the benefits of using the methods will be determined by how effectively the results are used and acted upon in the organisation. Thought needs to be given to how the results of prospective analyses will be processed within the organisation to ensure the benefits are realised.
11. **Weighing costs and benefits.** The Toolkit should address the issue of how to weigh up the costs and benefits of conducting an analysis. This is likely to be difficult because the benefits are unknown until the analysis is conducted whereas the costs are known. Users will however grapple with this issue.
12. **Misconceptions.** The Toolkit should address potential users' assumptions about the methods, including that the methods are extremely complex and difficult, that they can make an a priori judgement about the impact of a change in the organisation without the need to conduct an analysis, and that these methods will not fit with other tools and approaches currently in use. Examples should be used to demonstrate these points.

Purpose of the Toolkit and its uses:

13. **All NHS organisations.** The Toolkit should be able to be used in all NHS organisations, including primary care, secondary care, ambulance, and allied health

areas such as pharmacy, radiography, pathology laboratory etc. The range of areas it can be used in should be specified.

14. **Clinical and non clinical.** The Toolkit should be designed to allow analyses of both clinical and non clinical processes.
15. **Different front ends.** The Toolkit should be designed to allow use by users with different aims. It should accommodate four triggers for the analysis (1) the introduction of something new to the system – this could be a piece of equipment, service, solution or any change to the current work system, or development of a new process (2) a serious safety incident (3) the need for an organisational analysis – this includes both high level analysis of the organisation as a whole to diagnose problem areas, and the analysis of specific processes, pathways or areas with specified QA requirements (4) need for an organisational governance or risk management tool to provide assurance that the organisation is managing risk effectively. To meet these needs the Toolkit should have four different front ends that engage with the needs of users with these different aims.

Potential Users:

16. **Clinicians are crucial.** Every consideration should be given to engaging clinicians' support for the Toolkit at every stage of its development, dissemination and use. Even if clinicians do not undertake analyses they are crucial to the success of introducing prospective methods to healthcare. If they are supportive they will be advocates for the use of the methods, will support analyses that others undertake and will be more likely to be receptive to changes that result from these analyses.
17. **Range of users.** A wide range of healthcare staff are potential users of the Toolkit, including risk and safety staff, clinical staff from a wide range of backgrounds, management staff and designers of care pathways and service redesign leaders.
18. **Analysis owner.** The analysis should be owned by a person who is responsible for overseeing it and ensuring that it is carried out to a high standard. The owner of the analysis should have access to different parts of the organisation, the resources required to conduct the analysis, autonomy to engage team members, knowledge about the ethical aspects of conducting the analysis, have an understanding of system approaches to error and be able to ensure that the results of the analysis are acted upon.
19. **User training.** The Toolkit should contain a description of the different users involved in an analysis and specify the level of training and experience that is required.
20. **Facilitator.** The Toolkit should state that the facilitator should have training in and experience of facilitating workshops and process mapping.
21. **Analysis team.** The Toolkit should explain that a multi disciplinary team should conduct the analysis led by a facilitator. The team could include managers, administrative staff, nurses, patients, clinicians and other healthcare staff.
22. **Team composition.** The Toolkit should contain guidance about who to include in the analysis team. It should include a range of stakeholders and people with different levels of expertise and experience and explain why these different perspectives are important. Newcomers will have a different perspective to experts who have learned the system well.

23. **Stable team.** The Toolkit should recommend that the team should remain stable throughout the analysis to ensure that the analysis is of high quality and is not biased. This requires commitment from all team members and from managers.

Content of the Toolkit:

24. **Title.** The title should be acceptable to all users, including clinicians. The use of words such as risk, error and hazard are off putting for potential users and should be avoided. Alternative words include learning, safety and understanding.
25. **Examples.** Examples should be used extensively throughout the Toolkit to illustrate (1) how prospective techniques constitute a systems approach to safety (2) how the techniques can be used in different NHS organisations and (3) the appropriate use and benefits of the techniques. Examples should be specific and tailored to different user groups, organisations and different reasons for undertaking the analysis. Examples of the use of these techniques in the NHS could also be provided, such as the use of SWIFT by the NPSA and the use of FMEA by LIPS.
26. **Methods.** The Toolkit should contain a small selection of methods to a maximum of 5. Ideally, these methods will vary in complexity and the resources required, allowing users to match the method to different kinds of problems.
27. **Matching criteria.** The Toolkit should contain criteria for matching the method with an analysis problem.
28. **Avoid shortcuts.** The Toolkit should contain guidance on the need for the analysis to be systematic and carried out fully. Shortcuts should be avoided.
29. **Method outcome.** The Toolkit should contain a description of the outcome of each method and in which situation the outcome would be appropriate.
30. **Process and outcome benefits.** The Toolkit should contain information about the benefits of both the process of conducting the analysis and the outcome of the analysis.
31. **Boundaries.** The Toolkit should contain information about how to define the boundary of the analysis. This could be done by flagging areas on the process map for further analysis. Further data may be available to support this choice of the area for analysis.
32. **Process variability.** The Toolkit should discuss variability in processes in healthcare, the implications for process mapping and the need for analyses to be repeated to increase method validity if there is a great deal of variation in the process.
33. **Organisational processes.** The Toolkit should recommend that the results of the analysis should be fed into organisational processes for implementing change, reviewing effectiveness and feeding back information to the analysis team.
34. **Guidance.** The Toolkit should contain guidance for all steps in the analysis.
35. **Checklist and criteria.** The Toolkit should provide a checklist for each stage of the analysis and criteria for achieving a satisfactory standard at each stage
36. **Crib sheet.** The Toolkit should provide a summarised set of instructions for the analysis that provide guidance for each critical decision point – a crib sheet.
37. **Language.** The language throughout the Toolkit should avoid aversive terms such as risk, hazard and error as much as possible. These terms are not clinician friendly.

38. **Definitions.** All key terms in the Toolkit should be clearly defined and explained. A glossary would be useful. Key terms include risk, hazard, safety, prospective and error and the names of the PHA techniques included in the Toolkit.
39. **Fit with other approaches.** The Toolkit should contain information about how the prospective methods complement and could fit with other approaches to healthcare performance improvement such as Lean, care bundles and PDSA cycles.
40. **Engaging.** The Toolkit must be interesting and engaging. This can be achieved by ensuring that it is relevant to the needs of healthcare and that it is easy to use and understand.
41. **Resources required.** The Toolkit should specify what resources are required for an analysis. This should include an estimate of the time required for the steps, the expertise required, and the costs.
42. **Training.** The Toolkit should specify the training required for the analysis. This should be hands on training rather than simply reading written material. Ideally there should be an assessed level of competency required for the owner of the analysis before embarking on the analysis.

Form of the Toolkit:

43. The Toolkit should be available online in order to provide the ability to document and share results electronically, the ability to link the process map and the stages of analysis.

Development of the Toolkit:

44. **User testing.** The form and content of the Toolkit should be reviewed and tested by potential users, including clinicians. This should be an iterative process.

Introduction, dissemination and ongoing use of the Toolkit:

45. **Pilot sites.** The Toolkit should be introduced at pilot sites and refined as appropriate following user feedback before further dissemination.
46. **Champions.** Leads or champions within the NHS should be identified who can positively influence the adoption of the Toolkit.
47. **Ease of access.** The Toolkit should be easy to access.
48. **Cost.** The Toolkit should be free.
49. **Co-ordinating organisation.** The Toolkit should be introduced in a co-ordinated and structured way by an organisation that has responsibility for it, such as the NPSA, or the Royal Colleges.
50. **User forum.** An online moderated forum for users of the Toolkit should be set up. It will need to be moderated to ensure that prospective users are not discouraged by negative experiences.
51. **Repository.** Consideration should be given to forming a central repository of analyses conducted in the NHS, with appropriate guidance about how these could be used and the dangers of applying the results of one analysis across organisations.
52. **Expert resource.** There should be an external expert resource that users can draw on when required. For example, an expert who can answer questions and advise a course of action could be available to assist teams.

53. **Curricula.** Consideration should be given to including prospective risk analysis in CPD programmes and in the curriculum of healthcare professionals.

54. **Organisational learning.** Outputs of application of PHA should be shared across or within organisations to enhance learning of safe systems.

5.5. Summary

In common with the design approach advocated in Section 3.1, a range of requirements were developed for the PHA Toolkit: some informal and implicit, and others formal and listed explicitly (see Section 5.4.7). A variety of research activities were used to develop these requirements: interviews, a literature review, team meetings, membership of a Forum of risk managers and a review of health and safety managers' practice. Informal requirements included the need for simplicity and the need to develop a toolkit which engages with its users (including Risk Managers, who may be responsible for its successful introduction into their NHS Trust and also general staff, who may be reluctant to take part in such assessments). 54 "formal" requirements were developed for the Toolkit, including those regarding its content, its intended audience and pointers towards successful dissemination.

The Diffusion of Innovations literature described in this chapter was instrumental in forming requirements for the PHA Toolkit. One of the most critical requirements was the need to engage with the potential users of the Toolkit and to ensure that their perspective would inform its development; a philosophy which was adopted throughout this research project. This literature also identified various conditions which were anticipated to encourage favourable adoption of the Toolkit through dissemination. These were also reflected in the list of formal requirements. Whilst actual dissemination of the Toolkit was outside the scope of this research project, this issue is discussed further in Chapter 9, which presents a number of Recommendations based on the findings from this chapter:

- Build up an evidence base of Toolkit use (Recommendation 1). Importance: High.
- Disseminate the Toolkit through a UK Agency (Recommendation 2). Importance: High.
- Use the Toolkit initially in specific areas (Recommendation 4). Importance: Medium.
- Set up a PHA Web site (Recommendation 5). Importance: Medium.

6. TOOLKIT DEVELOPMENT

This chapter describes the process followed to develop the PHA Toolkit. A copy of the Toolkit can be found in Section 10.10. This was a multi-stage process, which at times involved the entire PHA Team and which was supported throughout by a range of other NHS Staff. The earliest stages of Toolkit development began whilst the PHA Project was being planned by the research Team, with steady input into the Toolkit throughout the course of the project. Efforts to develop the Toolkit ramped up considerably in the final 12 months of the project; towards the end of which a number of evaluations took place, including reviews by the PHA Team, two evaluations with a group of risk managers and five case studies across a range of settings in the NHS. An iterative cycle between development and evaluation activities took place throughout this process.

6.1. Development process

The development of the Toolkit followed a “design-led” approach, using the Design for Patient Safety (DPS) model described in Section 3.1. The research Team had extensive experience in the fields of risk assessment, systems engineering and the development of process-based guidance on a range of issues for a variety of industries. Crucially, the development and evaluation process was supported by regular input from NHS staff members, through informal interviews, discussions and the case studies. It drew heavily on the information from the requirements capture phase of the research, together with an understanding of how risk assessment is undertaken both currently within healthcare and within other high-hazard industries.

The requirements capture phase identified the user needs, and provided an indication of the target audience description – the potential users of the Toolkit, their knowledge and understanding risk issues, the contexts within which the Toolkit might be used and the outputs that they require. Extensive discussion with risk experts both within healthcare and in other industries was used to clarify the risk assessment process that was to be represented within the Toolkit. Clarification of the risk assessment process formed a key and significant element of the Toolkit development in order that the described process was recognisable, relevant, usable and informative.

An expert user group was convened to identify a shortlist of potential risk assessment methods. This shortlist could then be further refined and would form the basis for the method set within the Toolkit. The method set would be supported by the elements of the Toolkit that explained the overall risk assessment process.

The conclusions from the requirements capture phase drove the project towards using the model that had been successfully applied within the Inclusive Design Toolkit [Clarkson *et al.*, 2007] as the similarities in intent were sufficient to underpin its use. The project Team had extensive experience from the Inclusive Design Toolkit development to inform the PHA Toolkit. The PHA Team met frequently throughout the project, with the major focus of development efforts taking place in the final 12 months of the project, largely through face to face Team meetings. The broad content of these is listed in Table 25 in Section 10.2 in the Appendices. In addition to these larger Team meetings, many one-to one meetings took place. This table also shows the details of the Steering Committee meetings, through which the structure and high-level content of the Toolkit was reviewed throughout the project.

Many other activities during the course of the project had a more minor but often very specific role in the development of the Toolkit. For example, the literature review revealed a need for proactive risk assessment in the NHS. It identified standard descriptions of the main components of risk assessment, and a number of tips and common pitfalls. Similarly, a number of PHA methods include specific components, which have been incorporated into parts of the Toolkit, including, for example, the identification of the likelihood and impact of harm and the existence and efficacy of barriers. This review also pointed towards the need for a process-based Toolkit.

The requirements developed in Chapter 5 were of critical importance in the development of the Toolkit. In particular, many of the requirements influenced collectively the appearance and format, structure and content of the Toolkit. The following requirements were of acute significance:

Setting the Scene:

1. Description of PHA – the Toolkit needs to provide sufficient explanation of how its content supports the overall aims of PHA.
3. Benefits – provide sufficient explanation of benefits such that users can make informed selection decisions.
6. Limitations – the PHA method descriptions should clarify the limitations.
7. Integration with risk management – the Toolkit must indicate how risk assessment outputs are used within a broader risk management context.
11. Weighing costs and benefits – the Toolkit must support selection of methods and allocation of appropriate levels of resource to the assessment.

Purpose and Use of Toolkit:

8. All NHS organisations – the Toolkit should be of generic relevance.
9. Clinical and non-clinical – as for 8, the approach and methods should be generic.
10. Different front-ends – the Toolkit should cater for different ‘risk issue’ triggers that prompt its use.

Potential Users:

- 16 – 23. The Toolkit should address the range of different users who may wish to make use of it, and should clarify the necessary skills required for its use. It should not restrict itself solely to expert users.

Content:

26. Methods – a small selection of methods varying in complexity and required resources should be included.
31. Boundaries – the Toolkit should include sufficient focus on the importance of establishing the boundaries of the analysis.
36. Crib-sheet – the Toolkit needs to support the user during the course of the analysis.
37. Language – the Toolkit needs to comprise a language that is unambiguous and informative for the intended NHS user groups.
41. Resources – the Toolkit must provide guidance on the required resources for undertaking a successful analysis.

The Toolkit was evaluated throughout the development process. Whilst the evaluation activities are described in Chapter 7, the two processes were closely intertwined. Furthermore, the development process itself was highly iterative, and included input from a range of risk experts and user-group representatives.

As stated earlier, a copy of the Toolkit can be found in Section 10.10.

6.1.1. Challenges in Toolkit development

A number of significant challenges presented themselves during the development of the Toolkit, as noted below:

- Risk assessment is inherently iterative, with a need to develop a suitable process map and description before appropriate assessment methods can be identified, but also a need to understand the risks at a high level and the method of assessing them before an appropriate method of process representation can be selected. The Toolkit therefore represents not merely a set of methods, but an overall risk assessment process within which those methods are applied. Developing a Toolkit that captures and clarifies this iterative process required extensive consideration.
- The iterative process requires a number of passes through the risk assessment process, at increasing levels of detail, both with respect to the process description and to the levels of analysis applied. Conventional risk assessment draws significantly on the expertise of the risk assessors to determine how best to manage this iteration (initial screening processes, use of “cut-sets” and “bounding cases”, etc). The Toolkit needed to support iteration by non-expert users and also to be cognisant of the need to establish useful outputs at each stage in the process.
- The levels of risk assessment applied in other high-hazard industries may be excessive for many of the risk issues to be addressed within healthcare. Furthermore, the level of understanding of risk assessment within healthcare is lower than in certain other industries. It is therefore important that the risk assessment methods represented in the Toolkit are ‘fit-for-purpose’ in terms of their level of complexity and usability – they must be sufficiently practical that users are not deterred from applying them, whilst at the same time providing sufficient rigour and validity to ensure that the results are of value.
- Early in the development process it became apparent that two versions of the Toolkit were likely to be required – a Preliminary Risk Review that could be undertaken by less skilled users in order to understand the risk assessment needs of the particular issue, and a more Comprehensive Risk Assessment that could be undertaken if the need were identified from the Preliminary Assessment. It was important that the development of the two elements was sufficiently synchronised that the methods are consistent and synergistic.
- Both the user requirements capture and the early development of the Toolkit identified the need for ‘worked examples’ and “vignettes” to illustrate risk issues and the application of the Toolkit. These examples needed to be drawn from healthcare applications and relevant ‘real’ situations, but this presented a difficulty as the case studies represented the best source of such material, but were to be undertaken after the Toolkit had been drafted.

6.2. Risk Experts Workshop

6.2.1. Introduction

The literature review of the use of PHA methods in healthcare indicated that only FMEA (or closely allied methods) appears to have been used frequently, yet the high-hazard industries outside of healthcare use a much wider range of PHA techniques on a routine basis. We therefore wished to understand this further. In addition, although there are many risk analysis techniques available there is no clear guidance about how to select the appropriate method for the range of risks in healthcare. It was felt that expert knowledge should be captured to help understand better how this selection was achieved and to then use this knowledge to help construct the tool box and its use.

Our earlier work had suggested that the diversity of processes and problems in healthcare and the variety of assessment techniques available makes choosing the appropriate method difficult. It was considered important that we understood why this situation existed and how experts in the area made decisions about which methods to use. This is particularly so as the overall design and resources for this study did not enable a full set of PHA methods to be evaluated against each other using real case studies. This would have proved far too expensive in time and have posed immense difficulties to arrange or set up within the constraints that exist in the current health service. The following study was therefore designed to inform our knowledge regarding methods and method selection.

6.2.2. Aims

The following aims were addressed:

- To understand the decision making process that experts use when selecting methods to prospectively analyse risk.
- To understand what characteristics of both the healthcare process and the risk assessment methods are important for this decision making.
- To establish how such knowledge might be used to develop the risk assessment Toolkit and select appropriate methods for inclusion.

6.2.3. Method

Five experts in risk assessment and human factors in the UK were invited to participate in a consensus workshop addressing two components of the user-centric design framework: healthcare characteristics and methodology characteristics. Three experts had extensive experience with healthcare and the other two experts had extensive experience with safety management in other industries. Being called away to an unexpected and urgent appointment, one risk expert left before the workshop was completed, so his responses were eliminated. The experts were reimbursed for their time and travel expenses. They met in October 2007 in London.

The Nominal Group Technique was used to guide the group discussion and ensure participation by every member of the expert panel. Although the researchers were unsure if consensus would be achieved given the complexity of the issues, the Nominal Group Technique was applied to enable rating or prioritisation of themes. Figure 22 graphically summarises the workshop.

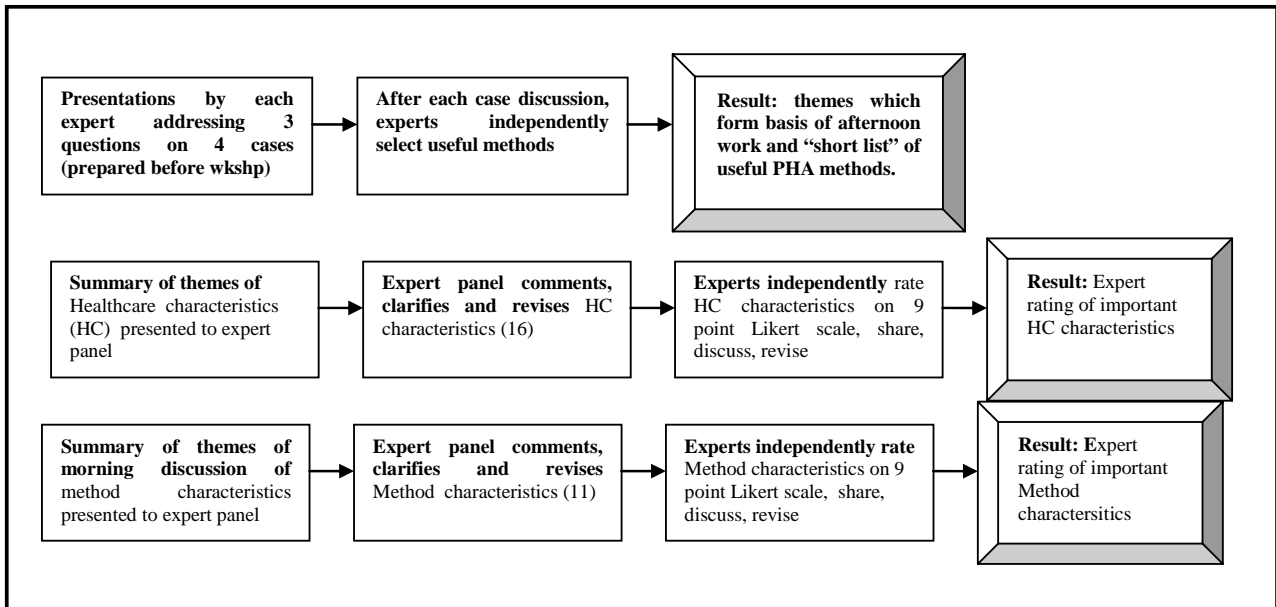


Figure 22 Summary of Nominal Group Technique.

The Research Team consisted of two design engineers, two human factors experts and a paediatrician. The Team developed four healthcare scenarios presenting a range of processes and risk assessment objectives to the risk experts. Paediatric cases were drawn from a direct clinical and safety improvement experience. Primary care prescribing drew from Team expertise in medication safety and previous risk assessment experience in general practice. Preliminary lists of healthcare characteristics and method characteristics were developed based on literature review and experience. The cases and preliminary lists of characteristics were piloted with an independent risk expert and this led to adjustments to the format. The cases are listed in Section 10.7 in the Appendices.

Table 13 PHA methods considered for inclusion in the study.

Title of Case	Scenario	Objective
Paediatric Fracture Case	Patient flow/ redesign problem	the redesign of the existing system for assessing suspected fractures in children to optimise efficiency and patient safety.(see case 1, below)
ICU lines	Technical/ tool problem	to prevent adverse events arising from improperly connected devices and lines during patient transport. (see case 2, below)
GP repeat prescribing	Routine process with established protocols	to identify where the risks are in the repeat prescribing process. (see case 3, below)
Handover case	Cognitive and communication task	To improve future training and improve continuity of care over shifts. (see case 4, below)

The experts were provided with a brief description of the case (see below) and asked to put themselves in the role of a consultant called in to facilitate a risk assessment.

They were asked to address three questions:

1. What would you ask the team leader in order to better understand the case?
2. What characteristics of the case affect your selection of PHA method(s)?
3. What characteristics of the PHA methods affect their choice for this case?

They were also presented with a list of nineteen methodologies that could be considered in relation to the cases. The list was purposively developed to capture PHA methods that are best known and more likely to be accepted by expert and novice risk assessors. Other authors have previously presented more exhaustive lists of error identification and risk assessment methods [Lyons *et al.*, 2005]. This list was compiled by polling experts independently regarding methods they would start with. During the case preparation and discussion, the experts were encouraged to introduce a method of their own if appropriate. This list (see Table 14) is not a comprehensive list of all such methods but does reflect the views of experts that have extensive experience of risk assessment across a range of industries, including the health sector.

Table 14 PHA methods considered for inclusion in the Risk Experts Workshop.

Method	Full Name
APJ	Absolute Probability Judgment
Barrier Analysis	
ETA	Event Tree Analysis
FMEA	Failure Mode And Effects Analysis
FMECA	Failure Mode And Effects Criticality Analysis
FTA	Fault Tree Analysis
HACCP	Hazard Analysis And Critical Control Points
HAZOP	Hazard And Operability Study
HAZOP	Human Error Hazard And Operability Study
HEART	Human Error Assessment And Reduction Technique
HFMEA	Healthcare Failure Mode And Effects Analysis
Influence Diagrams	
Risk Matrix of Likelihood Impact Grid	
PHECA	Potential Human Error Cause Analysis
SHERPA	Systematic Human Error Reduction and Prediction Approach
SWIFT	Structured What If Technique (DNV)
WHAT IF ANALYSIS	

The aim of the scenario cases was to make elicit the experts' diagnostic/ strategic approach to the specific cases and the basis of their choice of methodology. The case-based work introduced risk experts without healthcare experience to the domain and served to clarify terms amongst the participants. Each expert was given five minutes (timed) to present their answers to questions 1-3. After all experts presented, case specific questions were addressed by the research Team followed by group discussion. Written documentation of the presentations and discussion formed the background from which healthcare and method characteristics were drawn.

After the case-based group discussion, the experts were asked to independently select the methodologies they deemed useful to the case. Possible responses to “is this method useful to this case?” were “yes”, “maybe” and “no”. Again, they were given the option of adding additional methods to the list. Thus, four cases were completed in order resulting in four expert listings of useful methods.

While the experts were given a break, the research Team surveyed the documentation to identify important themes. Because there was significant overlap between experts' questions to the team leader and about the healthcare process (questions 1 and 2), it was decided to merge the results. The process was repeated for method characteristics. Review of the expert's decision as to whether they considered a method useful (yes, maybe, no) identified the most useful methods based on consensus.

The afternoon session shifted group focus from the specific cases to healthcare in general. The experts were first presented with the healthcare characteristics based on documentation from the discussion. They were asked, “what characteristics of healthcare processes are important to your selection of PHA methodology?” Guided discussion allowed clarification of terms and revision of characteristics. The research Team presented several characteristics from their preliminary list to the experts for consideration, but they were not added to the list.

After adjustment and agreement to the listings of healthcare characteristics, the experts were asked to rank them on a 9-point Likert scale with 1 being “not at all important” and 9 being “very important”. After independently ranking the characteristics, the experts shared rankings and discussed. Experts could revise their ranking after the discussion.

A similar process was undertaken for the list of method characteristics developed from presentation and discussion documentation. The experts were asked, “what characteristics of PHA methodologies are important in your matching of method to process/setting?”

Lastly, a “short list” of most useful methods (developed from case-based data) was presented to the expert panel for their review. It was emphasised that this list represented the methods that reached greatest agreement amongst the panel and was not intended to be an exhaustive listing of techniques. The list was discussed and accepted without further alteration.

6.2.3.1. *Workshop process*

The workshop was designed around 4 key activities:

1. Discussion of cases and pre-prepared presentations.
2. Listing of all the salient characteristics of both the cases and the methods that were discussed by the experts.
3. Expert rating of the importance of the healthcare characteristics and the method characteristics (using a 9 point Likert scale)
4. Experts rating of each method (using a scale comprising ‘useful’, ‘maybe useful’ and ‘not useful’) for each case scenario.

Each stage was facilitated and recorded by members of the research Team (Figure 23).



Figure 23 Recording of workshop outcomes.

Limitations: Only five risk experts were available within funding and availability constraints. Design of the cases may have been biased by one researcher’s personal experiences, however, the three experts in healthcare agreed they were reasonable representations of possible scenarios for risk assessment in the NHS. Previous relationships may have influenced the discussion and agreement between experts but the Nominal Group Technique was used to minimise this bias.

6.2.4. Results

The results section has been organised to reflect the workshop activities and aims.

The findings of the listing of salient characteristics of both the cases and the methods have been shown in Table 15. This provides a useful and concise template of those factors that needed to be prioritised in understanding both the process being risk assessed and in assisting the choice of method(s). These results were incorporated into the Toolkit.

Table 15 Findings of salient characteristics of healthcare processes and risk analysis methods.

Most important characteristics of healthcare process	Most important characteristic of PHA method
Resources available- time, money, people	The resources required to apply the method
Requirement for a quantitative or qualitative analysis	Whether the method required a task analysis
Whether the process involves patient flow	The identification of new or existing hazards
Whether the people involved were empowered and committed to developing mitigations	Ability to engage stakeholders’ interest in the study
The scope of process boundary of the problem	The level of complexity the method can address
	The ease with which the results can be communicated to stakeholders

The four cases were designed to cover a range of potential healthcare settings and scenarios. Experts responded to how useful each PHA method would be (specific to the case in question). If 3 out of 4 experts responded yes, the method was considered useful for inclusion to the Toolkit, thus creating an expert-generated “short list” of methods. Table 16 shows that the methods thought to be most useful, most often, were ‘Barrier analysis’, ‘The structured what if approach’ and the ‘what if’ approach. However, depending on the characteristics of the scenario, methods such as FMEA, HFMEA, FMECA were also considered for inclusion. Influence Diagrams and HAZOP were also deemed to be appropriate by the experts.

Table 16 Methods cited by the experts (n=4) as “definitely” useful for each of the four case scenarios.

Risk assessment method	Fracture	ICU lines	GP repeat prescribing	Handover	Total
Barrier analysis	3	4	3	1	13
What if	3	3	4	2	12
Structured what if (SWIFT)	3	3	3	2	11
Influence diagram	0	3	2	3	8
FMEA/HFMEA	3	3	1	0	7
HAZOP	3	2	1	2	5
FMECA	2	2	0	0	4
Risk Matrix	3	0	0	0	3

The experts discussed their approach to each case. The discussion was focussed around the characteristics of the healthcare process in each case. This led to the compilation of a list of characteristics deemed to be important (see ‘Comment’ column in Table 17).

The experts then completed Likert ratings (9 point scale) individually (the first time; time 1). After completing this they were then asked to discuss the results. The Likert scores after discussion (the second time; time 2) are shown in Table 17. Only one expert changed their response from time 1 to time 2. Results are presented in order of highest number of expert consensus.

Table 17 Experts' (E1 to E4) consensus of importance of characteristics of the healthcare process being risk assessed

Comment	E1	E2	E3	E4	Range	Median
Qualitative/quantitative	8	7	8	6	2	7.5
Resources: time/money/people	8	8	7	7	1	7.5
Process flow incident	7	7	7	3	4	7
Ability to make change	7	7	6	8	2	7
Boundaries/scope	9	7	7	3	6	7
Information available	7	6	6	7	1	6.5
Human error type	7	5	9	6	4	6.5
Level of risk	6	6	9	5	4	6
Technology v human	6	6	7	5	2	6
Communication/information flow	6	5	7	6	2	6
Skill level of staff delivering care	5	8	7	3	4	6
Users of risk assessment	4	8	4	9	5	6
Robustness of method	5	5	6	7	2	5.5
Standard operating procedure	3	6	6	4	3	5
Ease of mitigation	1	7	8	3	7	5
Need for training	1	5	7	4	6	4.5

After discussion of the health care characteristics that would influence their choice of PHA method, the experts ranked the method characteristics that would be likely to determine their choice of method (Table 18). Results are ordered as above.

Table 18 Experts' ratings of characteristics of the healthcare process determining choice of method

Comments re Characteristics	E1	E2	E3	E4	Range	Median
Resources/staff/time/money/commitment	7	8	8	8	1	8
Task analysis pre RA or level of process map	7	7	9	9	2	8
Identification of new and existing hazards	7	6	8	8	2	7.5
Communication of results to audience	4	7	7	7	3	7
Complexity: can the method handle complex systems	4	7	7	7	3	7
Engagement with the process	6	8	6	8	2	7
Completeness of method	4	7	6	7	3	6.5
Reliability of method	5	7	7	6	3	6.5
Prior accurate or appropriate use of method by self or others in similar scenario	7	5	8	6	3	6.5
Depth	6	6	6	5	1	6
Qualitative/quantitative	7	8	5	5	3	6

6.2.5. Discussion

The main aims of this stage of the research project were, firstly, to understand the decision making process that experts use when selecting methods to prospectively analyse risk and, secondly, a deeper understanding of both of these issues as these would be essential to the subsequent development and testing of the PHA Toolkit.

The findings reported here were based on written scenarios with a small group of expert risk analysis experts. These experts were drawn from a range of backgrounds but all had experience of risk assessment in both health care and other sectors. One general comment around this has been the relatively small number of experts with such experience, and the difficulty that this research Team had in identifying those who met the necessary criteria. This has implications for the subsequent roll-out of the PHA Toolkit approach, as the current expertise base in the UK is evidently very limited.

The experts demonstrated an acceptable degree of agreement when asked to identify issues that were important for risk assessment in healthcare (this was judged by the researchers, from the range of ratings and their spread around the median). This was true both for those characteristics most important within the *healthcare process* and those characteristics of each *risk analysis method* that required matching.

One issue that emerged with a high degree of consensus was that of resourcing. The introduction of Prospective Hazard Analysis methods to healthcare will need to be properly resourced if it is to be effective. The best risk assessment methods seem resource intensive and the experts felt this would limit the adoption of methods in healthcare. Hence some of the factors in their decision making were the availability of resources and the commitment of organisations to implement the risk assessments and to effect change.

As mentioned above, the *available resources* were deemed critical. Many of the additional qualitative comments provided by experts gave greater insights into the paucity of resources available within health care for such assessments and the importance of confronting these issues at the outset of the exercise and in gaining true commitment from stakeholders.

“You need to understand how much it is worth to the client. The danger is that you put in a proposal and then they try to decrease it to a single day of work. This actually happens.” [E1]

“How do you identify up-front how long it is going to take? This is very difficult. This is affected by their understanding, their resources and who gets involved.” [E2]

“It depends on what resources [are] available: Time/money/commitment/people” [E4]

“What are their motives? They looking for a quick fix? You need commitment from the Trust.” [E5]

E= Expert

It should be emphasised, however, that the issue of resources was noted as being one that would influence the experts' choice of method, rather than being advocated as a method selection criterion. The implication is that there is a range of methods available to address risk, and these have varying resource demands (whether in terms of expertise, time or other factors). Whilst the experts would shortlist methods on the basis of their match to the risk issue requirements, there was agreement amongst the experts that selection would then be made on the basis of resources. The experts all recognised a tendency amongst clients, for understandable reasons, to prefer the least resource intensive approach, and hence the experts also perceived that it was their responsibility to ensure that the client understood the strengths and limitations of the different methods

when making their decisions.

The implication of this is that any guidance on the use of methods needs to take account of the tendency to prefer the least resource-intensive methods, and to ensure that users of the guidance are supported in considering the benefits of the methods with greater resource demands.

Qualitative or quantitative assessment also appears to be an important characteristic and may be, in part, driven by the key stakeholders who are driving the need for a specific risk assessment.

“Clinicians are sceptical, they want to see the evidence. They feel that numerical risk assessment may be plucking numbers out of the air.” [E2]

“If you want to make a change then you need a target and numbers can create an incentive.” [E3]

A further area that emerges a priority is that relating to mapping processes and scoping the process boundary.

Importance of Boundaries: type of problems and breadth of problems. [E3]

Recommended process mapping. [E3]

“Process mapping helps produce a systematic assessment, and helps the facilitator to understand the process. As does task analysis.” [E2]

“Process mapping takes you a long way towards the answer. The risk analysis methods require an “appropriate level” of mapping. To get an agreed picture is very important in helping safety.” [E1]

“Process mapping helps because people normally see things from their own isolated perspective. Process mapping helps foster teamwork.” [E5]

“Process mapping is brilliant in opening up people’s minds to help them to see where the important parts are?” [E5]

The strong views of the experts on this issue were taken forward in the Toolkit design, where process mapping and setting of boundaries for any given risk assessment was prioritised.

Selection of appropriate PHA methods for assessment of a given problem should result in a high quality analysis that improves safety and mitigates risks. The experts provided great insights into the suitability of current methods in the context of healthcare scenarios. These were deliberately designed to reflect a wide range of healthcare applications. The results showed that a short list of methods (i.e. Barrier analysis, What if, SWIFT, Influence diagrams, FMEA/HFMEA, HAZOP, FMECA and the Risk matrix, although the latter is acknowledged not to be a risk assessment tool in its own right) can be derived and these were taken forward to the next stage of Toolkit development. The matching process has also demonstrated that guidance, if not rules, can be provided that will enhance the effectiveness of the Toolkit by assisting users to reach an appropriate decision on PHA method selection more rapidly and with the understanding that expert knowledge and experience lies behind the decision making methodology provided.

This process showed that whilst no one method is appropriate for all scenarios, there are a number of ‘better’ options, depending on key characteristics of the issue to be assessed, and that often there is more than one method that can be chosen and is likely to produce equally useful and robust outcomes. Experts also appear to accept that there will not necessarily be, or need to be, consensus. They are also prepared to adapt to the circumstances they encounter.

You need to be able to adapt the technique depending on situation. The Expert gave an example of an interview with a GP. He was going to ask about hazards and then run a risk matrix. However, the GP dominated the session so he removed the risk matrix part: They just did the first two parts and then looked at the solutions. The risk matrix would not have worked with such a dominant GP. [E4]

“Bear in mind that you have to expand the scope too much then you may be accused of milking the situation.” [E4]

“I’d be very surprised if we ended up with the same approach!” [E1]

“40% or 50% variability in our choice of method.” [E5]

“You may get a similar outcome, but you might get there using a dissimilar route.” [E4]

One important limitation of the study has been the nature of the ‘case scenarios’ presented to the risk experts prior to the workshop. Experts were asked to prepare a list of PHA methods that might have been appropriate for use to investigate these case scenarios. It is probable that, despite their careful construction and choice, different scenarios would have prompted different PHA methods to be advanced by the experts. Thus the shortlist, whilst extremely helpful, might not be exhaustive. The list of methods were therefore subject to further review and modification later in this study.

6.2.6. Conclusions

In conclusion, the workshop provided important insights into:

- how a Toolkit should be developed,
- what PHA methods are appropriate (based on a limited set of case studies) and
- how an understanding of the characteristics of each health care issue to be risk assessed can be used to help choose the risk method.

The design of the workshop and the methods chosen to collect data at the workshop enabled an acceptable level of confidence to be placed on the results. The findings were therefore used as evidence to support the next stage of development of the PHA Toolkit.

6.3. Toolkit Principles

In accordance with the information obtained from the requirements capture, the underlying philosophy of the Toolkit was that it should support healthcare sector staff in undertaking risk assessment. Consequently, the focus was not solely on the use of specific PHA methods, although their selection and correct application is an integral part of the Toolkit. Instead, the focus included support for understanding the risk assessment requirements of a particular issue, and the manner in which risk assessment methods can support an integrated risk management process.

This approach is underpinned by a systems approach to risk assessment, and to PHA in particular. The Toolkit supports the user in developing a proper understanding of the overall system within which the element under analysis exists, and hence the boundaries and cross-boundary interactions that need to be considered. It also encourages a socio-technical perspective, taking account of the organisation, the individuals and the equipment and processes.

The requirements capture, together with the Risk Experts Workshop and other inputs, indicated that a challenge for the Toolkit was the wide variation in understanding of risk within healthcare, and the organisational challenges associated with resourcing effective

risk assessment. Consequently the Toolkit, as noted below, has focused on a limited set of risk assessment methods, spanning all aspects of risk assessment: scoping, screening, hazard identification, risk assessment, and reporting.

The emerging Toolkit structure and content, as discussed below, has therefore presented guidance on the risk assessment process and its integration, rather than solely on aspects of risk assessment.

6.4. Toolkit appearance and format

The General Guidance Review (Section 4.8) identified a broad range of different guidance documents, both within healthcare and externally. These documents adopted different structures and formats, depending on the nature of the guidance and the intended users. As noted, there are different characteristics of guidance documents for process guidance (where the guidance is aimed at supporting the application of an agreed process) and for guidance where the information needs to be readily available at the point of use (job-aid guidance). Both of these characteristics were considered necessary in order to address the identified user requirements, and hence the adopted workbook format comprising guidance, pro-formae and examples was deemed appropriate.

Iterations of the Toolkit during its development led to a multi-part structure as a means of making navigation through the Toolkit as straightforward as possible. This was supported by a number of existing guidance documents.

An Inclusive Design (ID) Toolkit (www.inclusivedesigntoolkit.com) [Clarkson *et al.*, 2007] has been developed and evaluated by one of the researchers. Extensive positive feedback on this (a large number of "hits" on the Internet, high regard by the peer-review process and substantial feedback from others) led to the ID Toolkit becoming a significant influence on the design of the PHA Toolkit.

The ID Toolkit enables people to apply a complex process in a way that that is effective and robust. We believe that the complexity of the ID process is similar to the risk assessment process, at the highest level (i.e. independent of the specific risk assessment methods). This is prima facie evidence that the ID Toolkit may be a suitable approach to conveying this form of complexity. At a more detailed level, it was recognised that the risk assessment process was inherently different from the ID process, but shared sufficient characteristics to justify its use. In particular, the two processes shared a requirement for clarity of purpose and objectives, for ensuring a proper and sufficient process description, for representing an iterative process, and for enabling user judgement to be applied, recorded and tracked. The format was deliberately chosen to restrict the number of words per page – a two-column format was adopted, using both words on one side and pictures on the other. This restriction served two purposes. It forced the development Team to consider carefully the value of every item of information put into the Toolkit, thereby ensuring that it was succinct. It also thereby ensured that the Toolkit presented a navigable document that would not overwhelm the user. By restricting each page in terms of content, the task of scrolling through the document is reduced, and, importantly, the information required for each step in the process is contained on a single page or spread of pages. The importance of not breaking information across pages is a constant theme within guidance on the production of such tools.

A further attribute of the ID Toolkit is that it is able to be presented in identical form both in

hard-copy and electronically. The user requirements capture for the PHA Toolkit identified a wish for the PHA Toolkit to be presented electronically. This has a number of benefits in terms of usability, including the use of hyperlinks and electronic form-filling. However, it was also recognised from the requirements capture that there was a need for the guidance also to be available in hard-copy format in order not to unnecessarily constrain the use of the document (even if electronic delivery such as via a website was adopted, the ability to print a hard-copy was seen as important).

Consequently, the decision was taken by the project Team to adopt the ID Toolkit approach and to ensure that the format was consistent with both printed and electronic presentation.

The ID Toolkit used a 'waterfall' model of the process it was representing. This approach was explored by the project Team and found to be entirely consistent with the risk assessment approach being represented in the PHA Toolkit. The waterfall model represents states, and the transitions between them. It was identified that the risk assessment process also comprises states and transitions between them, and hence the waterfall model underpins the structure of the Toolkit. It also facilitated the development of the overall approach by providing a means of structuring the logic of each step: each element of the risk assessment process comprised a transition from one state to the next, with the new state providing a representation of the system that could be captured as part of an audit trail.

6.5. Toolkit structure

The Toolkit structure was developed iteratively from the basis of the requirements capture, the ID Toolkit structure, the outputs from the Risk Experts Workshop on selected methods, and an understanding of risk assessment within the PHA Team.

The overall structure of the Toolkit can be represented in Figure 24.

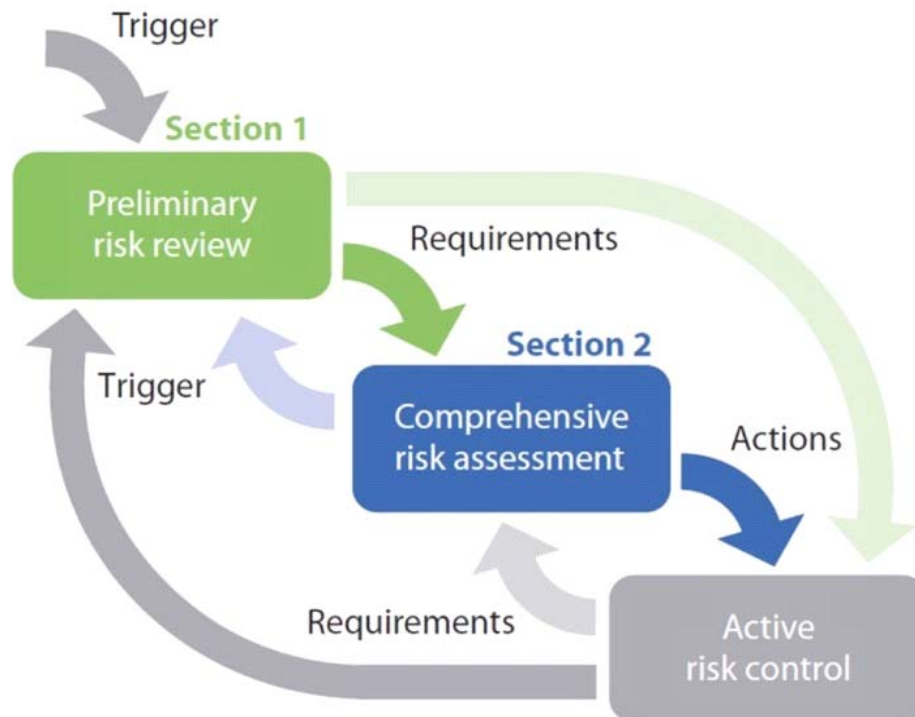


Figure 24 Toolkit Structure.

This represents the staged approach – with a Preliminary Risk Review followed by a Comprehensive Risk Assessment. The risk review clarifies the requirements for the risk assessment (and may identify that no further assessment is required), and how it should be undertaken. The comprehensive assessment may prompt a revision to the requirements, and also should identify actions to be fed into the risk management process. Those actions, in support of active risk control, may prompt further risk review.

The iterative nature of the development process enabled the team to adapt the Toolkit as it developed, to take account of the emerging clarity in respect of the target audience, the manner in which it could be used, the limitations of current use of risk assessment within healthcare and the feedback from discussions with potential user groups throughout the development process.

This iterative element of the development provided the mechanism by which it was identified that a two-part process would be valuable, comprising a “Preliminary Risk Review” process that ‘triages’ the risk assessment, followed by a more detailed “Comprehensive Risk Assessment” process that could be applied as required.

6.5.1. Generic risk assessment framework

An important starting point for the development of the Toolkit was a clear and agreed understanding of the risk assessment process. This was derived from a number of sources:

- The material gathered during the Risk Experts Workshop provided insight into how risk assessment is approached for different scenarios.
- The draft British Standard on risk assessment [BSI, 2008a] provided a basic structure that was also consistent with the Risk Experts’ views.

By developing a sound understanding of the risk assessment process, the emerging structure of the Toolkit would be better able both to reflect this process, and to present a comprehensive set of guidance that enables users to understand how the various methods complement each other, and how they should be used as part of an overall risk management process.

As a result, the following basic structure emerged:

- **Step 1 Identify the problem.** Risk assessment is not undertaken without a purpose, and the purpose for a given assessment will influence both the manner in which it is undertaken, the methods used and the manner in which the outputs should be represented and communicated. Risk assessment is undertaken within an organisational context, and it is important to gain clarity of that context at the outset. For example, the need for a risk assessment might be triggered by a planned change either to a process or to equipment. It might therefore need to focus on the impact of the change, or on the identification of potential impacts. Alternatively, it might be triggered by a series of adverse events that identify the need for further risk reduction measures, and the value of different measure may need to be assessed and compared. A further reason for risk assessment might be as a means of undertaking a routine assessment of the performance of the system. A benefit of risk assessment is that it provides a structured process that supports challenge to the existing or proposed approach, thereby ensuring that it is optimised.
- **Step 2 Create a high level description of the process.** It is essential to produce an agreed and sufficient description of the system, to underpin the risk assessment. There are many ways in which the system description can be produced, and a suitable description may already be available. It is important that the description is produced in terms of the system process – how it operates and the inputs and outputs. It is also important that the description is accurate. A further key element of the production of a system description is the identification of the system boundaries within which the analysis will be undertaken. This also enables identification of interactions across those boundaries which, whilst potentially outside the scope of the analysis, nevertheless need to be identified as assumptions as they may fundamentally affect the analysis. It is important that the risk ‘owner’ (i.e. the person who has the authority to address the identified risk) agrees and accepts the system description and boundaries.
- **Step 3 Screening.** Conduct Preliminary Hazard Identification. Early in the process of Toolkit development it was identified that a preliminary screening process would be required. Consideration of how risk assessment is undertaken in practice highlighted the need for a high-level assessment process that would support scoping the risk assessment activities. Initially this preliminary process was considered as ‘PHA-Lite’ – a process that could be applied quickly by less skilled users as an alternative to a full risk assessment. As the Toolkit development progressed it became apparent that the preliminary risk assessment process needed to be seen as an integral part of the overall approach. The subsequent development of this “Preliminary Risk Review” therefore was undertaken alongside the development of the detailed process, and intentionally mirrored the approach adopted for the Comprehensive Risk Assessment. It was recognised that the preliminary risk assessment needed to include an appropriate level of system description, a suitable rapid assessment approach identifying hazards and risks, and a means of understanding the implications of the identified risks in terms of actions, or a requirement for further analysis. The preliminary assessment process should provide guidance on the planning and completion of that further analysis, or an auditable justification for screening out risks that do not require further analysis.

- **Step 4 Planning.** The success of any risk assessment is dependent on the availability of appropriate resources, including time, skilled analysts, subject-matter experts, etc. Assembling these resources requires planning and the risk assessment method should support the planning process. The assessment may require further iterations of the system description process, or even of the risk assessment itself if the outcome of the assessment is insufficient in terms of precision or coverage.
- **Step 5 Analysis.** Once the preliminary screening, the system description development and the planning process are complete, the analysis itself can be undertaken. This may comprise the application of a number of methods in combination, depending on the purpose of the assessment and the nature of the risk.
- **Step 6 Output.** It was recognised that there is a need to emphasise that the risk assessment itself does not reduce or manage the risk – it merely clarifies the nature and magnitude of the risk and the options for risk reduction. It is therefore important that the output from the risk assessment is presented in a manner that is consistent with the risk management arrangements within the organisation, and that those outputs support risk management (whether through reduction in likelihood and/or mitigation of consequences).

An emerging aspect of this structure is the sequence of activities, and hence the importance of the early steps. The aspect of assessment that is most often considered when identifying methods – the analysis stage – is preceded by a number of critical steps. The importance of these early steps was therefore made explicit within the emerging guidance.

6.5.2. PHA “Lite” and PHA “Pro”

As noted in the previous sub-section, the development of two ‘variants’ of the risk assessment process – PHA-Lite and PHA-Pro – was recognised as a requirement early in the Toolkit development and all subsequent development was aimed at producing these two synchronised versions.

Various elements of the project influenced this:

- Team meetings discussions (see Table 25 in Section 10.2 in the Appendices).
- Steering Committee (see Table 25 in Section 10.2 in the Appendices).
- Requirements Capture (see Chapter 5).
- User reviews e.g. Risk Management Forum (see Section 7.4.1).
- Personal communication with risk assessment / patient safety expert on 18 September 2007:

“In practical terms the PHA Lite approach would have tremendous appeal to large numbers of people in the Health Service.” “Given our knowledge of how overburdened people are and how little time they have to devote to a complex methodology... if there’s a simple methodology they could follow... that would I’m sure would get tremendous support.”

Initially the intention was to develop two stand-alone processes, one aimed at less experienced users with fewer resources or time, and the other aimed at more competent users with the resources to address complex risk issues. The challenges of development of two parallel processes included the need to have coupling between Lite and Pro. It was recognised that the existence of the ‘Lite’ version would inevitably encourage users to apply only the Lite, quick, version even when the risk issue merited a more comprehensive analysis.

As a consequence, during the development process, it became apparent that the 'Lite' version would represent the necessary screening process that needed to be encouraged. Consequently the emerging Toolkit comprised a Preliminary (rather than 'Lite') tool which was intended to be used by less experience people and to be applied quickly with limited resources. The Preliminary tool would provide the justified basis for further analysis (and thereby provide the justification for securing the necessary resources) or the justification for undertaking no further analysis.

It was therefore decided that the two processes should be very similar in structure, both because they were applying the same underlying process (albeit at different levels of detail) and because it would familiarise the participants in the basic assessment process.

A recurring issue within the development discussions was the appropriate balance of information between the Preliminary and Comprehensive versions. The agreed approach that emerged was to limit the information in the preliminary version only to the minimum needed to understand the purpose and application of the process, together with a simple explanation of the role of risk assessment. The comprehensive version contains more detail of the application of risk assessment in general, the mapping methods and the assessment methods.

There are several reasons for conducting a preliminary analysis:

- This can provide an indication of the likely consequences and therefore the level of detail and accuracy necessary during the comprehensive assessment.
- Scope and prioritisation of the area of the system and intentions for a more detailed analysis.
- Identifying suitable participants for the main analysis.

The meeting with Risk Managers on 9 April 2009 (see Table 25 in Section 10.2 in the Appendices) provided confirmation that they recognised the importance of this two-stage approach.

As a consequence, the preliminary analysis comprised a simplified version of the comprehensive approach, but followed the same underlying model. The comprehensive approach was developed into a number of elements (as illustrated in Figure 25), including the explanatory framework and guidance on the application of the process, supported by additional sections that provide further guidance on relevant methods and activities, such as process mapping, and specific PHA method selection and application. Similar to the Preliminary Review, it also includes a set of blank templates to support the use of this part of the Toolkit.



Figure 25 Comprehensive Risk Assessment Process.

6.5.3. Waterfall model

As noted in Section 6.5.1, the use of the generic risk assessment framework provided a basic structure for the Toolkit guidance. This structure comprised the six elements of the framework. The waterfall model was taken from the Inclusive Design Toolkit as it provided an effective representation of a series of related 'states' and the method of transition between them. The diagram was developed to represent the risk assessment method as described above. The development process was highly iterative, and was tested out against example risk assessment scenarios. The six elements of the generic framework were elaborated:

- Identify problem – this comprises a trigger for the assessment which is then articulated as a better-described purpose and a defined set of requirements
- High-level description – this provides an agreed understanding of the system, its performance and its interactions with other systems
- Screening – this considers the hazards associated with the system and permits certain elements to be removed from the proposed detailed analysis
- Planning – this is an essential element of the process whereby the specific requirements of the assessment are set out, together with the manner in which they will be considered. It also provides greater clarity of the limitations of the proposed approach.
- Analysis – the specific analyses, including hazard and consequence identification, risk assessment, and identification of remedial measures and risk treatments
- Output – provision of the output of the analyses in a manner that can be utilised by the existing risk management processes.

Figure 26 presents the Toolkit waterfall model. Additional feedback loops have not been represented, but exist from later states to earlier ones. This model is highly iterative in two

respects. The first is in terms of the overall 'journey' through the steps, such that a high-level analysis can be undertaken before repeating the process at greater levels of detail to re-consider risks whose significance has been identified by the high-level analysis. The second is in terms of the individual steps, where later steps might prompt a review of earlier ones. For example, as the system description develops, it may become apparent that the purpose of the risk assessment warrants re-definition.

The overall approach within the Toolkit was developed to support and actively encourage such iteration as necessary.

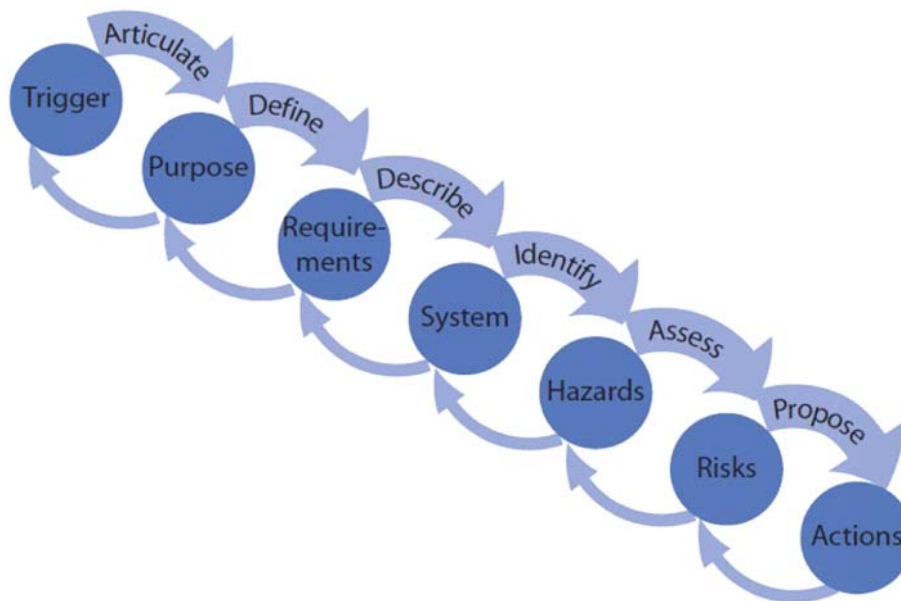


Figure 26 Waterfall model of risk assessment process.

An early task in the development of the Toolkit was to identify the set of questions that underpin a risk assessment when undertaken by an expert, and which would need to be captured within a risk assessment Toolkit. The Toolkit needs to ensure that the questions are asked, and are answered in an appropriate manner.

Typically, these questions are likely to include:

- 1) Purpose:
 - a) System 'healthcheck'?
 - b) Assessment of new system/process or planned change?
 - c) Procurement?
 - d) Incident investigation/resolution?
- 2) What is the scope of the analysis?
 - a) Hazard identification (what could go wrong)?
 - b) Understanding consequences (what could arise from those failures)?
 - c) Understanding likelihood?
 - d) Prioritising solutions?
 - e) Addressing existing expectations or preconceptions?

- f) Considering process, equipment, people, training, culture, communication, etc?
- g) What is the expectation that the results will be used for?
- h) Could there be difficulty resourcing the required solutions?

3) Resources:

- a) What are the limits (time, availability, expertise, etc)?
- b) Is the assessment multi-disciplinary?
- c) Are there time constraints (calendar, duration)?
- d) What domain knowledge is required?
- e) Are there useful pre-existing resources available?

4) Boundary:

- a) One complete system?
- b) Interactions between systems?
- c) Are there significant stakeholders outside the boundary?
- d) What are the relevant inputs and outputs? Are there potential 'upstream' or 'downstream' effects? How would you know?
- e) Where is there complexity within the system?
- f) Are there key decisions contingent upon the risk assessment?
- g) What are the boundaries in respect of people, systems, equipment, duration, etc?
- h) Are there cross-Trust implications?

5) Arrangements:

- a) Who 'owns' the assessment?
- b) Who 'owns' the risk and the potential actions?
- c) Are there resource issues for implementing actions?
- d) Are there political, organisational or implementation issues to be considered?
- e) What are the enablers and barriers for the assessment?
- f) Is there any information about risk 'appetite' and risk criteria that can be used?

It was recognised that the Toolkit needed to encourage the users to consider these questions at an appropriate level during their assessments, and hence that the guidance on the application of specific risk assessment methods was only one part of the overall purpose of the Toolkit if the Toolkit was to support the effective deployment of risk assessment within the healthcare context.

6.5.4. Iteration

As noted above, a key element of the Toolkit is the iterative nature of the process. When commencing a risk assessment it is unlikely that a complete understanding of the risks and their implications will exist (as such an understanding could negate the need for the assessment). Consequently, it is expected that the process of undertaking a risk assessment would itself shed further light on the nature and extent of the required assessment, and hence require iteration and further analysis of particular elements, as

illustrated in Figure 27.

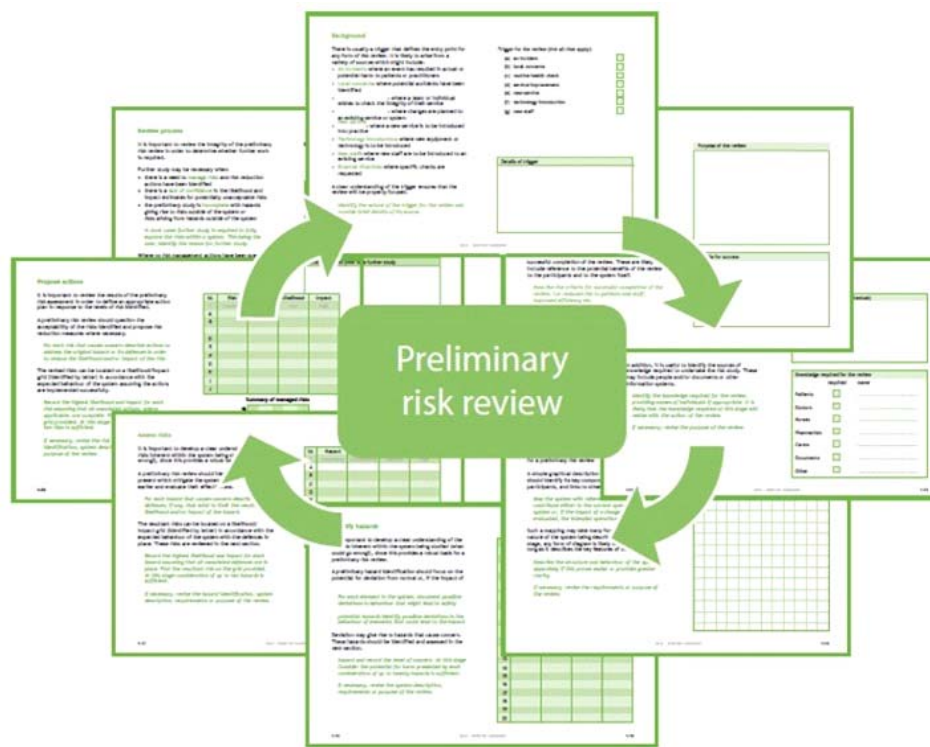


Figure 27 Iterative nature of the process.

The underpinning process represented within the Toolkit accommodates iteration in two ways. Within each part of the process (the Preliminary and the Comprehensive Assessments) there is a constant emphasis on the importance of reviewing and revisiting the emerging assessment as it progresses, and hence, potentially, the need to modify earlier elements and repeat the subsequent steps (such as if a particular boundary is shown to be significant and the process map needs to be redrawn).

At the same time, the underpinning philosophy of the Toolkit is that the comprehensive risk assessment process is a more detailed version of the preliminary process, and hence will act as a form of iteration of the emerging assessment derived from the preliminary assessment. There is further emphasis that one of the potential outcomes of the assessment, at any stage, is the identified need for further more detailed analysis of a part of the system.

Thus, the entire process is structured as an iterative one, but the Toolkit supports the identification of a stopping rule once a sufficient understanding of the risks has been developed.

6.5.5. Developing the Toolkit’s initial questions

The Toolkit contains a set of questions at the start that encourage the user to establish the purpose of the assessment, its trigger and its objectives. These questions are important both because the purpose will influence the choice of methods and approach, and also because by establishing these points it becomes possible to ensure agreement between the participants. The process of answering these questions may lead to a revision to the scope, or an agreement to exclude certain elements. In doing so, an auditable record of the decision can be maintained.

The purpose of the risk assessment is considered to have a greater influence on the choice of method(s) than the specific scenario under consideration (an issue which shall be discussed further in Section 7.5.1).

Lyons notes the very broad range of risk assessment methods available, together with the very significant range of requirements associated with their use (e.g. levels of expertise, speed of use, types of output, etc) [Lyons, 2009]. The PHA team considered at length the manner in which one might select methods, and how a toolkit could capture and represent this process in order to support users when making method selections. Given the complexity of the issue, the challenges that were raised during the Experts Workshop, and the consistency between these issues and those noted by Lyons, it was recognised that the underlying method selection issue would need to be simplified. The approach adopted by the PHA Team is to limit the choice of methods, whether for hazard identification or for risk assessment. Hazard identification in particular is a phase of risk assessment that can be undertaken by a broad range of methods (see Section 4.2.2). One of the important attributes of the Toolkit therefore is to provide clarity in respect of the phase of the process being addressed and its purpose, in order that users can choose to apply other methods with which they may be familiar. For example, some trusts (although this may be a very small number, bearing in mind the results from the "local" risk practice review) may already use a range of hazard identification methods, such as tailored checklists, and this use should not be unnecessarily discouraged or obstructed.

6.5.6. Consideration of “trigger” questions

Early in the development of the Toolkit, consideration was given to the context within which the risk assessment is being undertaken. The reason why risk assessment is being considered is important for guiding the subsequent approach. Four potential ‘triggers’ were identified:

1. Health check: there is a requirement to undertake a routine risk assessment to determine whether all relevant risks have been adequately identified and are being adequately managed. This may be prompted by an internal process within the organisation, or an external requirement placed upon them. Such a trigger might typically demand a high-level comprehensive review with more detailed assessments if the outcome demands it.
2. Planned change: some aspect of the existing system is being changed, such as the introduction of a different process or item of equipment. The assessment needs to consider not only the risks associated with the new element of the system, but also any potential interactions with other existing parts of the system which might remain unchanged, but which could be influenced by the change.
3. Novel system or equipment: a new process may be being introduced, or new technology. The risks associated with it may need to be considered.
4. Failure: an incident may have occurred, from which Root Cause Analysis may have identified a shortfall, or a trend may have been identified in a series of minor incidents. Risk assessment may be required in order to understand and evaluate alternative approaches to risk reduction.

As the Toolkit was developed, it was identified that Trigger 4 was subsumed in 2 or 3 – where the RCA identifies a set of potential solutions to an identified incident, risk assessment would be used to evaluate the planned change. These three generic triggers were elaborated slightly within the Toolkit to guide the user, and hence not only would incidents (and the response to them) be considered a trigger, but also local concerns such

as could arise from a trend in near misses or minor incidents. Similarly, Novel System or Equipment was elaborated to indicate that this could comprise new technology, new processes, or new staff, and that new processes could include changes to existing arrangements as well as completely new approaches.

The clarification of triggers early in the assessment process enables the team to focus their efforts appropriately.

6.5.7. Designing the Toolkit for different user groups

An early distinction was drawn between the risk owner, the process facilitator and the users (analysis team) of the Toolkit.

It is important that the owner of the risk is involved in the risk assessment process. They have a role in determining the scope of the assessment, and in securing the resources necessary both to assess the risk and to address actions that may be the outcome of the assessment. The Toolkit assumes that the risk owner will be closely involved in the assessment.

Separately, it was identified that the majority of the formal risk assessment methods need to be applied by a facilitator with experience in the use of the method (although the other participants may not require that same level of experience, being reliant on the skill of the facilitator). The Preliminary Risk Assessment tool was designed such that it does not require an experienced facilitator, although one would add value. Instead, it was structured with the assumption that the risk owner will undertake the preliminary assessment in order to be confident that the risk assessment is appropriate, and to understand the necessary resources.

The comprehensive risk assessment tool assumes that a trained facilitator will lead the assessment. It was considered inappropriate to attempt to capture the subtleties of complex risk assessment within a short document. It is possible that the risk owner also could be the facilitator, if they have the necessary training and experience, but it is not necessary. Other members of the risk assessment team were deemed “users” of the Toolkit.

6.5.8. Incorporating a screening process

Risk assessment approaches in other industries apply a screening process to identify the elements of the system on which the risk assessment should focus. Typically this screening process will be based on consequence – with only high-consequence risks being sentenced for further assessment. It is noted that this approach potentially could screen out low-consequence high-probability risks, which may merit further assessment, and this is a further reason why it is important both for the screening process to be explicit, and for the risk owner to participate.

The preliminary risk assessment process supports this screening process, and enables the team to make explicit their decisions whether to include something for further analysis or to screen it out. By providing an audit trail for the risk decisions, it is possible subsequently to revisit the assessment if the need arises.

The screening process also provides a mechanism for engaging with other stakeholders, such as those who control required resources for the assessment.

Such screening processes are integral to a number of risk assessment methods already

used within healthcare, such as the decision tree within HFMEA™.

HFMEA™ uses a “decision tree” to prioritise failures which warrant further investigation. The decision tree uses the following criteria:

1. A risk analysis of each hazard to determine its risk (i.e. consideration of the likelihood and severity of failure).
2. Whether the hazard presents a “single point weakness” (i.e. if a failure occurs, will it result in actual harm or is there a barrier to prevent this? This represents a barrier which works *after* failure has occurred).
3. Whether an “effective control measure” exists to prevent failure (i.e. is there a mechanism for preventing the failure in the first place? This represents a barrier which works *before* failure has occurred).
4. Whether a failure is highly detectable (i.e. if a failure occurs, will it be so obvious that it will be discovered before harm can occur?).

The approach adopted within the Toolkit is to guide the user during the preliminary risk assessment to consider the significance of identified failure modes. Rather than prescribe a decision-tree, the Toolkit supports a broader consideration of the same issues. Use of the Toolkit will identify whether further explicit support is required.

6.5.9. Recognising the ‘reality’ of risk assessment

Risk assessment is a socio-technical system itself. It comprises formal methods together with facilitated team-based activities. It is also a process that, despite the formality of a number of well-validated methods, is also reliant on the manner in which the team-based assessment is managed, and hence is sensitive to team dynamics, individual knowledge and competence, and engagement with the process.

Consequently it is important that the risk assessment process is properly and actively managed. The Toolkit includes guidance on how to determine who should be involved in the process, and the guidance on the individual methods provides a structure for how the information is elicited and assessed. A judgement was required in respect of the level of guidance within the Toolkit, and hence generic guidance on facilitation was excluded from the Toolkit as it is not specific to risk assessment.

6.6. System mapping

Given the diversity and complexity of the healthcare system, earlier sections in this report have described the need for better application of diagrammatic representation approaches to healthcare ([Clarkson *et al.*, 2004a; Edwards, 2005]), and in particular in the context of risk assessment. Earlier sections also described how the NHS currently uses such process mapping techniques, and indicates a need for a broader range to be included to assist risk assessment. In order to take full advantage of diagrammatic representations for the Toolkit, the following questions need to be explored first:

- What types of diagrammatic representations are available and how are they different?
- Which of these should be included in the Toolkit?

6.6.1. System mapping methods in general

In the field of management science, many diagram types have been used to represent

various business processes. These methods include process maps, activity cycle diagrams, stock flow diagrams, just to name a few [Bozarth and Handfield, 2005; Pidd, 2003].

On the other hand, the systems engineering community has recently made collective efforts to unify such diverse mapping methods and produced the Systems Modeling Language (SysML) – i.e. a comprehensive set of diagram types – for broader domains including hardware, software, information, processes, personnel and facilities [OMG, 2008]. Figure 28 shows nine different diagram types defined in the SysML.

6.6.2. System mapping methods shortlist and selection

Jun made an attempt to apply various diagram types to healthcare and identified ten distinct diagram types potentially applicable to healthcare [Jun *et al.*, 2010]. Their perceived usefulness was evaluated by healthcare managers and clinicians, and researchers in healthcare. These perceptions were measured in terms such as ease of understanding the diagrams, and the degree to which they were perceived to help identify various types of hazard in healthcare. Some of the diagram types defined in the SysML were not included on Jun's list since they are only suitable to hardware and software systems: internal block diagrams, package diagrams and parametric diagrams. Conversely, some of the diagram types broadly defined in the SysML were separately included in the list, e.g. block definition diagrams and activity diagrams. Table 19 shows how the ten different diagrams were defined in terms of node types and link types along with comparable SysML diagrams.

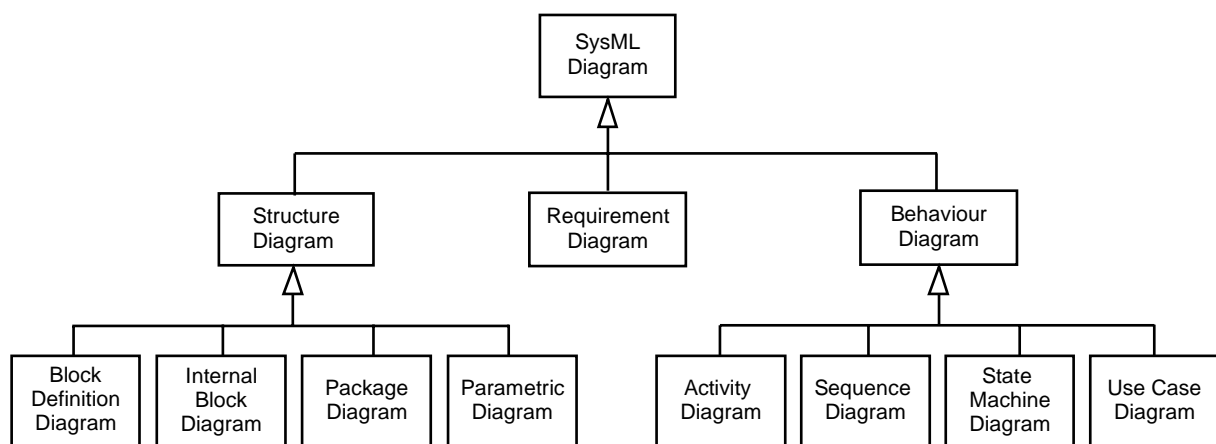


Figure 28 SysML diagram taxonomy [Friedenthal *et al.*, 2008].

Based on Table 19, and the results from Jun's evaluations in healthcare, this study suggests six different diagram types as a basic set of diagrammatic representations for the healthcare PHA application. This number was arrived at firstly by considering pragmatic concerns regarding the sheer number of different techniques, secondly, process mapping techniques that are associated typically with particular PHA methods and thirdly, other practical concerns regarding the inherent need to describe a range of situations in healthcare.

Regarding the first two concerns, this research team believed that one or two diagram types, as have been used in healthcare so far, were too limiting to describe a full range of characteristics in healthcare, and to support the use of a range of PHA methods. 10 diagram types would be too many to be readily usable. Therefore, some of the similar

diagram types were grouped together: ④, ⑤ and ⑥; ⑦ and ⑧; ⑨ and ⑩.

Section 10.3.1 in the Appendices presents a range of diagram types which are associated with a variety of PHA methods. Such associations also influenced the shortlist of six diagram types in the Toolkit.

We now address the third point. Figure 29 shows the six different diagram types and what each of them represents in terms of process, information and people. A detailed definition of each diagram type follows afterward.

Table 19 Diagram type categorisation – adapted from [Jun *et al.*, 2010].

Diagram types	Nodes	Links	Comparable SysML diagrams
① Stakeholder diagram	People	Hierarchy	Block definition diagram
② Information diagram	Information	Hierarchy	Block definition diagram
③ Process content diagram	Process	Hierarchy	Block definition diagram Use case diagram
④ Flowchart	Process	Sequence (control flow)	Activity diagram
⑤ Swim lane activity diagram	Process People	Sequence (control flow)	Activity diagram (partitioned) Use case diagram
⑥ State transition diagram	System state	Sequence (transition action)	State machine diagram
⑦ Communication diagram	People	Information (object flow)	Block definition diagram
⑧ Sequence diagram	People	Information (object flow)	Sequence diagram
⑨ Data flow diagram	Process	Information (object flow)	Activity diagram
⑩ IDEF0	Process	Information (object/control flow)	Activity diagram

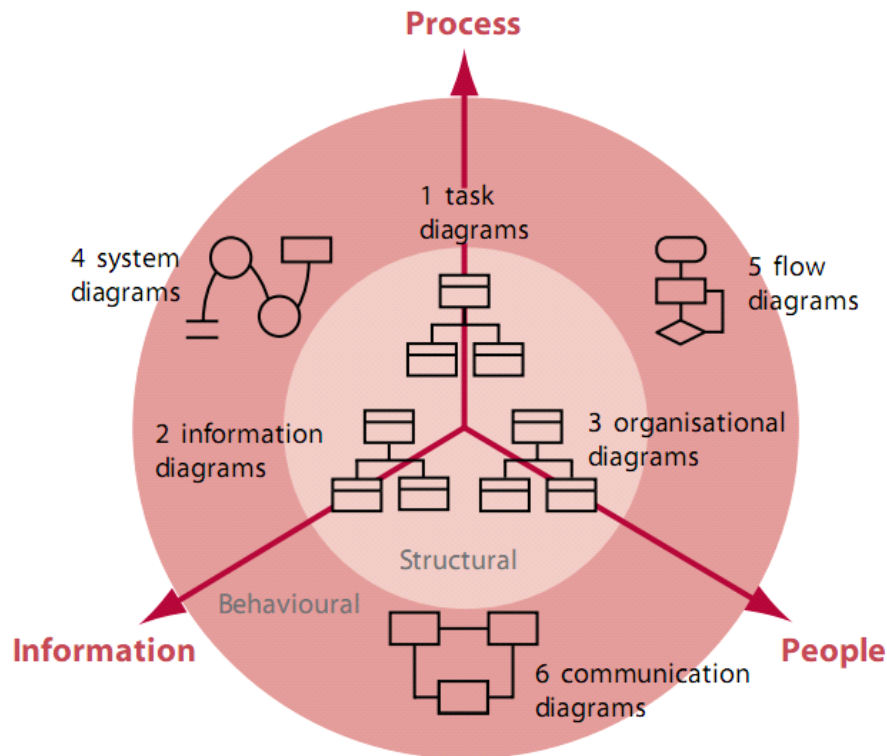


Figure 29 Six different diagram types for healthcare PHA application.

- 1) **Task diagrams:** describe a hierarchy of operations (tasks) and plans (necessary conditions to undertake these operations).
- 2) **Information diagrams:** describe a hierarchy of information and/or materiel (things) used or needed in physical or electronic form.
- 3) **Organisational diagrams:** describe a hierarchy of people and/or roles within single or multiple organisations.
- 4) **System diagrams:** represent how data (or objects) are transformed through activities, where such data are stored, and how such activities are sequenced.
- 5) **Flow diagrams:** represent activities occurring in sequence or in parallel, e.g. traditional flow charts and swim-lane diagrams.
- 6) **Communication diagrams:** represent information and materiel flows between people (stakeholders) linked by some common process.

Based on healthcare workers' feedback on the utility of each diagram type in Jun *et al's* research [Jun *et al.*, 2010] and some suggestions from other literature, the applicability of each of the diagram types in describing certain aspects of the system is suggested in Figure 30. This highlights the relative suitability of different diagram types for capturing specific attributes of a system. A large tick indicates a significant match between the diagram type and characteristic, a small tick a partial match and no tick indicates there is no match. In practice, more than one characteristic may need to be investigated to describe the operation of a given system and to inform a PHA method.

System mapping approach Characteristics of interest	1.Task	2.Information	3.Organisational	4.System	5.Flow	6.Communication
Process and procedure <i>e.g. patient pathways</i>	✓	✓		✓	✓	
Human behaviour <i>e.g. performance measures</i>	✓			✓	✓	
Role and responsibilities <i>e.g. team working</i>			✓		✓	
Communication <i>e.g. referral</i>		✓		✓		✓
Human-technology interface <i>e.g. medication devices</i>	✓			✓		✓
Procurement and supply <i>e.g. medication flows</i>			✓	✓	✓	✓

Figure 30 Suitability of different diagram types for representing a range of system attributes in healthcare.

6.7. Developing a shortlist of PHA Methods

We aimed to identify a minimal set of PHA methods. This set would be flexible enough to analyse a suitable range of situations in healthcare. By narrowing down the range of PHA methods, this would help avoid the Toolkit being overly complex, and contribute to the validity of the results from the case studies by minimising the range of variables to be tested.

Many of the existing risk assessment methods have significant overlaps. It was therefore recognised that those methods selected for inclusion in the Toolkit would be a subset of the totality of methods, and may not include certain methods that users of the Toolkit are already familiar with.

Consequently a structure for the Toolkit has been determined that permits other methods to be adopted. It is not a prescriptive Toolkit. Instead, the Toolkit identifies the purpose of a set of methods, and ensures that the users are aware of the purpose with respect to their specific assessment. For example, if it is determined that hazard identification is an important element of a specific assessment, the Toolkit advocates such methods as SWIFT for a rapid high-level assessment and HAZOP for a more detailed examination. However, it does not exclude the use of other methods, such as checklists, if those are familiar to the users. The focus of the Toolkit is on the structured risk assessment process.

6.7.1. Rationale for selection of shortlist

The Risk Experts Workshop identified an initial set of methods for inclusion in the Toolkit.

The workshop considered a range of scenarios, and identified those methods that the experts would consider for application. The shortlist of methods comprised both complex and detailed methods for use in complex risk contexts, and more high-level methods that could be used where time or resources were limited, or the risk issue did not justify extensive analysis.

The shortlist of methods that emerged from the workshop were:

- Barrier Analysis – identifies the barriers that prevent hazards from being realised, and their efficacy.
- What If Analysis – a structured approach to the identification of hazards and consequences. Does not identify likelihood.
- SWIFT – a rapid approach to what-if analysis.
- Influence Diagrams – indicates interactions and hence potential cause and consequences of failures.
- FMEA/HFMEA – a structured approach to hazard identification and the assessment of likelihood. Does not provide robust consideration of complex failures.
- HAZOP – a hazard identification method which provides a systematic and structured analysis of a system, focusing not only on hazards, but also on operability issues.
- FMECA – Similar to FMEA with greater focus on consequence.
- Risk Matrix – represents derived risks in terms of likelihood and consequence.

These emerged as the methods most likely to be used by the experts at the workshop. It was noted that the scenarios used in the workshop did not include the full spectrum of risk issues that the Toolkit may need to address. The majority of the scenarios called for hazard identification rather than full risk assessment, and hence at subsequent team meetings additional methods were introduced:

- HRA methods (including HEART and THERP) – provides an assessment of the likelihood of identified human errors, and indicates methods for error reduction.
- Fault and Event Trees – represents complex fault sequences that lead to a failure (fault tree) and the nature of the consequences of the failure if certain barriers fail or other events occur. Supports detailed quantification of risk and understanding of complex failures.
- APJ – Absolute probability judgement. A structured approach to allow an expert group to establish numerical probabilities.

Subsequent team meeting considered the underlying purpose of the methods, and three categories of method were identified, being hazard identification, risk assessment, and risk communication, in line with the categories described in Section 4.2.2.

The shortlisted methods were then grouped accordingly:

Hazard identification:

- HAZOP
- SWIFT
- What If Analysis
- Influence Diagrams

- FMEA/HFMEA

Risk Assessment:

- FMEA/HFMEA
- FMECA
- Fault and Event Trees
- HRA Methods
- APJ

Risk Communication:

- Risk Matrix

There was recognised to be overlap between methods: certain methods occupied more than one category, and certain methods were more familiar within healthcare than others.

On this basis it was determined that certain methods would not be taken forward within the Toolkit.

For hazard identification it was considered that What If did not add significantly to what could be achieved with SWIFT. HAZOP was retained for instances where complex hazards needed to be considered in a more structured manner. Barrier Analysis and Influence Diagrams were retained as they provided alternative means of considering hazards. HFMEA was discarded as it is a Trade-Marked method.

For risk assessment, FMEA was retained, together with Fault and Event Tree Analysis for complex systems. FMECA was discarded as adding little benefit beyond that achieved with FMEA. An HRA method was deemed appropriate, and HEART was selected because of its ease of use, availability and validation by use in other industries. APJ was also retained as a means of quantifying likelihood where few data were available.

For risk communication, only one method was included in the shortlist, being risk matrices. It was considered important to include risk matrices due to their ubiquity within healthcare, although the Toolkit emphasises that they are a means of communicating risk and may not provide sufficient rigour if used for risk assessment.

6.8. PHA Methods Selection Strategy

An element of the Toolkit is the process by which the user selects the PHA method or methods for use in their risk assessment.

Initially the intent was to provide an algorithm for selection, which would take account of the purpose of the assessment, the knowledge and experience of the team, the demands of the methods, the available resources, and the significance of the risk issue and hence the required level of confidence in the output.

The set of questions that typically underpin the development of an assessment, as noted in Section 6.5.3, was considered as a basis for selection, together with the characteristics of the methods. This process was applied to the shortlisted set of methods noted in Section 6.7.1. Additionally, the selection criteria identified by Lyons [Lyons, 2009] were

reviewed. These criteria comprised:

- Resources and constraints (personnel and training, time, information, special tools)
- Requirements of the assessment (interim requirements, output requirements)

These criteria were already included in the question set under consideration and hence provided some validation of their selection.

The following criteria informed the development of the method selection approach. Predominantly these are criteria that relate to the assessment process and the characteristics of the methods, and not to the scenario being assessed. These criteria included issues concerning the granularity of the system description and how the different methods deal with this, the balance between ease of use and rigour, the extent to which the method can address changes in scope as the assessment progresses, previous use within healthcare, the utility of the outputs, the extent to which they support quantification. The emerging consensus from the team meetings was that adoption of a robust and rigorous risk assessment process was potentially as important as the selection of the right method, given that there were overlaps between the different methods.

- 1) Risk Management Stage (the aspect of risk assessment for which the method is required):
 - a) Hazard Identification
 - b) Risk Estimation
 - c) Risk Evaluation
 - d) Risk Treatment
- 2) Method Characteristics (the characteristics of the method and its suitability to the risk issue):
 - a) Handles system complexity
 - b) Resolves uncertainty
 - c) Systematic
 - d) Considers deviations
 - e) Identifies failure modes
 - f) Identifies causes of failure
 - g) Analyses functions
 - h) Analyses technical components
 - i) Considers human error
- 3) Input requirements (the demands that the method makes in terms of resources, expertise, etc):
 - a) Required resources
 - b) Necessary facilitator skills/experience
 - c) Level of preparation needed by facilitator
 - d) Level of preparation needed by team
 - e) Level of detail needed in system description

- f) Extent to which is team-based
 - g) Requirement for specific tools
- 4) Outputs (the nature of the outputs from the method and how they might be used):
- a) Quantitative
 - b) Used in conjunction with other methods
 - c) Similarities with other methods

Based on a review of the literature from both within and outside the healthcare sector, Lyons (2009) describes a number of factors to consider when choosing a PHA method and how these factors relate to a broad framework for selecting PHA methods [Lyons, 2009]. The paper identifies that "...there is a lack of practical experiences described in the literature to conclusively define a technique for selection and a need for a dedicated research in this area to make it accessible for healthcare and other novice users". Lyons goes on to develop a framework that identifies the factors that could be considered when selecting a method.

However, Lyons also acknowledges that the complexity of the range of potential methods means that it is currently not possible to do more than provide "an initial framework to support selection of predictive safety techniques. A number of challenges for constructing the framework are also noted, such as inconsistencies or a lack of specificity within the literature for supporting method selection. Consequently, the selection criteria identified by Lyons were considered alongside those noted above, given their consistency. Lyons' findings support the decision by the PHA Team to pre-select a limited set of methods and then to provide guidance for selection between them.

This approach is broadly consistent with that advocated within the Draft BS EN 31010 [BSI, 2008b].

The standard recommends that the choice of a PHA method should be justifiable, that the results should fit the intentions of the analysis and that the analysis should be traceable, repeatable and verifiable. The *objectives* for the analysis will influence the choice of method. It is important to consider the *risks* involved, the *resources* available, the *availability of information and data*, the need for *repeating* the analysis and also any *regulatory or contractual arrangements* (although in the case of the NHS, we are not aware of any such arrangements with regard to PHA). For example, the level of detail and the accuracy of the results should fit the intentions of the study, which themselves should be based on the potential consequences of failure of the system's elements. The standard states that method selection should consider the experience and time available from the participants, as this may produce better results than an overly sophisticated and time-consuming method which is applied poorly.

Risk assessment approach	1. SWIFT	2. HAZOP	3. Influence diagram	4. Barrier analysis	5. FMEA	6. HEART	7. APJ	8. Event tree	9. Fault tree	10. Risk matrix
Characteristics of interest										
Hazard identification	✓	✓	✓		✓					
Risk identification		✓	✓	✓	✓	✓	✓			
Existing barrier identification		✓	✓	✓	✓	✓		✓	✓	
Required barrier identification			✓	✓	✓	✓		✓	✓	
Risk prioritisation					✓	✓	✓	✓	✓	
Risk communication					✓	✓	✓	✓	✓	✓

Figure 31 Toolkit Method Selection Strategy.

Figure 31 illustrates the simplified approach to method selection that therefore emerged. It provides simple guidance in respect of the suitability of the methods, and then directs the user to a more detailed description of the method’s strengths and limitations, to allow the user to make an informed selection. It is important to re-iterate the approach to considering resource demands that underpins the method selection process within the Toolkit. Whereas Lyons notes the importance of resource demands as a major selection criterion, and that this appears to be consistent with the outcome of the Risk Experts workshop, resource demands has not been highlighted as a key determinant within the Toolkit.

The importance of resource demands is fully recognised, and guidance is provided on the differing demands of different methods. However, as noted by the Risk Experts, it is important to counter the tendency by naïve users to select the least resource-intensive approach. Consequently, the Toolkit approach is to encourage the user to consider the nature of the risk issue being examined – its complexity, the potential significance, the options for risk treatment, and to use these factors initially to identify suitable methods. Having done so, the process encourages the user to consider what are the resource demands and how these can be met in order to undertake the analysis. In this way, defensible decisions can be taken, and the process can be used either to justify the need to allocate additional resources to the analysis process, or to understand the limitations that will be imposed if fewer resources are available. This is considered to be an important attribute of the Toolkit approach, in contrast to one that merely allows the naïve user to veer towards the use of low-resource methods.

6.9. PHA Methods descriptions

A set of PHA methods is presented within the Toolkit. These are standard methods, selected according to their relevance within healthcare and for the identified non-expert user group. The purpose of the Toolkit is to enable this group to undertake effective risk assessment. In recognising that the process requires a trained and knowledgeable facilitator, there is then a requirement to determine the level of detail for each method to be provided within the Toolkit.

It was concluded that it was not appropriate for the Toolkit to provide a sufficiently detailed description of the method and its application such that a novice user could apply it unaided. Instead, it was recognised that the purpose of the Toolkit was to identify relevant methods, to assist the user to select the relevant method, and to guide the user in the application of the output from the method.

Consequently, the Toolkit does not attempt to provide a detailed description of each method. Instead, it provides sufficient information concerning each method to allow the user of the guide to understand the strengths and limitations, and in what context it is best to apply the methods.

For this reason, the methods descriptions within the Toolkit are deliberately brief. Further information is provided within the cited references in these descriptions.

The methods description is intended to be accessible to healthcare professionals rather than risk experts, and the focus is on identification of the background to the method, its use, its strengths and limitations, what knowledge and experience is required, other resource demands, and the nature and use of the output.

The overall format of the Methods Section (the Purple Section) is consistent with the format and structure philosophy adopted for the Comprehensive Risk Assessment section (the Blue Section).

6.10. Actions from Toolkit

One of the key elements of the Toolkit is to place risk assessment within the broader context of risk management. There is always potential for inexperienced users of a guide to risk assessment to consider that the assessment process reduces risk. Consequently the Toolkit emphasises that risk assessment only provides a better understanding and description of the risks – including their causes and consequences, and opportunities for risk reduction.

It is essential that the output from the risk assessment is used within an established risk management framework, to ensure that the outcomes of the assessments are properly evaluated. This requires that there is an effective risk management process that is able to consider the nature of the identified risk, the extent of risk reduction that is required, and to evaluate alternative risk reduction measures. As noted previously, the comparative evaluation of risk reduction measures may itself demand further risk assessment (to understand alternative outcomes).

The Toolkit provides an initial discussion of the importance of considering options for reducing likelihood or consequence. Within other high-hazard industries a hierarchy of risk reduction measures tends to be made explicit, sometimes referred to as 'ERICPD' (as

noted in Section 4.2). This refers to the recommended approach which is to:

- Eliminate the activity – stop the activity that presents the risk.
- Remove the risk – change the activity.
- Isolate the hazard – prevent the risk from occurring.
- Contain the hazard – ensure that the risk cannot cause harm.
- Protect the exposed population – provide barriers and other means.
- Discipline – require administrative controls, PPE, etc to mitigate the consequences.

The importance of this hierarchy is that it drives towards the most effective means of risk reduction in the first instance, and only considers less effective strategies if the better ones are impracticable.

It also provides clarity in respect of the balance of benefit from addressing likelihood or consequence.

The Toolkit refers to the importance of action planning and evaluation, and supports this process with appropriate proforma. However, the Toolkit addresses risk assessment and is not intended to present a complete risk management process. It is important that the organisation has in place an effective risk management process, and understands the role of risk assessment within it. It is not the purpose of the Toolkit in its current form to consider enhancements to risk management within healthcare, although the data gathered during this project suggest that there are opportunities for such enhancements.

6.11. Summary

The development of the Toolkit relied heavily on the information from the requirements capture phase of the research, together with an understanding of how risk assessment is undertaken both currently within healthcare and within other high-hazard industries. A workshop with risk experts from a range of industries also helped gain understanding of factors which might influence the selection of PHA methods, and help generate a shortlist of PHA methods. This shortlist was developed further by members of the PHA team afterwards.

Other significant influences were a previously developed Toolkit [Clarkson *et al.*, 2007], many PHA team meetings and particularly NHS staff, through the five case studies which will be described in the following chapter. These influences were also combined with the understanding of risk methods and their application, both within healthcare and in other industries, to provide a clear process for risk assessment that needed to be represented within the Toolkit.

The principal characteristics of the Toolkit comprise:

- A systems-based approach, both in terms of understanding the importance of the socio-technical systems within which it will be applied, and the understanding of how risk assessment is itself a system;
- A 'triage'-based approach, whereby the user is assisted in undertaking a preliminary risk review to ensure that there is a sufficient understanding of the risk issues and what is needed to assess them that appropriate resources can be deployed effectively, to address the significant risks;

- An iterative approach, such that as the understanding of risk emerges from the assessment process so the process itself can be modified. In this way the risk assessment can remain suitably focused and appropriate, and can be sensitive to the organisational requirements that will become apparent as the assessment progresses;
- User-focused, such that it supports a range of different users, including risk specialists and healthcare professionals with less experience of risk assessment. It provides a degree of tutorial, and encourages an enhanced understanding of how risk assessment supports an integrated risk management approach;
- Modular, so that the Toolkit itself can be expanded and developed as experience in its use is gained;
- Output-focused, such that the results of the assessment can be communicated to end-users of the information in a manner that is of practical benefit to them. It also provides an audit-trail for the assessment process, thereby providing appropriate justification for any risk-based decisions that are subsequently taken.

The PHA research has identified the need to include examples of PHAs in the Toolkit. However, the best way to create these was from the case studies themselves, but none of which created sufficient information to populate a full example. This led to the need for Recommendation 6 in Chapter 9:

- Add worked examples to the Toolkit (Recommendation 6). Importance: High.

Additionally, whilst the Toolkit does not present advice explicitly on the development of actions, further enhancements to the Toolkit could take place, including providing advice on generating actions, enhancing the descriptions of the PHA methods and strengthening the connection between the Toolkit and current local risk management activities such as reporting. This led to the following Recommendations:

- Add advice on generating actions to the Toolkit (Recommendation 7). Importance: Medium.
- Generate more comprehensive descriptions of PHA methods (Recommendation 8). Importance: Medium.
- Integrate further into current risk management procedures (Recommendation 9). Importance: Low.

7. TOOLKIT EVALUATION

7.1. Method

Following the design approach advocated in Section 3, the PHA Toolkit was evaluated regularly throughout the development process. Evaluations took place on two broad levels:

1. Evaluations within the PHA Team (for logical consistency and formatting, and against the PHA Requirements).
2. Evaluations with NHS Staff (for a more objective measure of usability and utility – usefulness). These occurred through an evaluation with a forum of risk managers, one-to-one evaluations with NHS staff members and through five case studies.

The results from the evaluations were regularly fed back into the development of the Toolkit; hence many Toolkit iterations were made, as described in Section 6.

Table 29 in Section 10.6 in the Appendices summarises the Toolkit evaluation activities which took place during the course of the PHA project. This also includes illustrative examples of the outcomes from the meetings, but is not intended to be a fully comprehensive list. The outcomes were weighed up by the PHA Team, with many but not all incorporated into later versions of the Toolkit.

During the project a decision was made to evaluate the Toolkit through a number of case studies. However, there were many unanswered questions as to how such case studies should be run. Therefore, an initial case study was conducted, as described in the following section.

7.2. Initial case study

From early in the project there had been concerns over the length of time that the evaluation of PHA methods might take. The literature shows that risk assessments, even in healthcare (which may be less thorough than in other industries), can take dozens of man-hours. For example, van Tilburg *et al.* reports on a HFMEA™ which took place over 7 meetings, constituting 140 man-hours [van Tilburg *et al.*, 2006].

The purpose of this case study was to conduct an initial test of a range of PHA methods to gain an understanding of what results could be achieved in a set period of time, and to obtain feedback on the usability and utility of these methods. The study was based at a GP practice and focussed on the process behind the repeat prescribing of medicines at the practice. It should be noted that this study took place before the PHA Toolkit was developed, and so did not test the Toolkit – only some of the PHA methods therein.

7.2.1. Method

Based on the PHA Team's understanding of a range of PHA methods, three dissimilar PHA methods were chosen to be tested in this study:

1. FMEA – chosen because it is a “bottom up” method, where specific failure modes are identified and where the effects of single failure modes are investigated, but not combinations of these.

2. FTA – chosen because it is a “top down” method, and can deal with combinations of failure modes.
3. SHERPA – chosen because it involves the analysis of human tasks.

Participants were invited into the study through a letter of invitation. The study was arranged on a practice training day, but due to other agenda items from the practice, was limited to two hours.

The participants were divided into three multidisciplinary groups, with five members of staff in two groups and six in one group, as shown in Table 20. Care was taken to ensure an even as possible a distribution of professions, across the groups. Each group ran simultaneously and was facilitated by a member of the research team, with another researcher in each group who was responsible for taking notes and audio recording the session. Two additional “roaming” observers were free to move between the parallel sessions, and also took notes.

Table 20 Composition of the three Groups

	GP (n)	Receptionist / secretary (n)	Nurse (n)	Other
Group A – FMEA	2	2	1	
Group B – FTA	1	2	2	1 (Practice Manager)
Group C – SHERPA	2	2	1	

Prior to the main analysis, a model of the practice's repeat prescribing procedures was developed in the form of a flowchart, though three meetings with members of the GP practice. The flowchart was used in Groups A and B. Since a SHERPA requires a Hierarchical Task Analysis as its basis, an HTA was also developed and used in Group C. Samples of both models can both be found in the Appendices, in Section 10.9.1.1.

At the start of each analysis, the participants were given the opportunity to familiarise themselves with the process map. The facilitator answered any questions. Since the maps had been developed with only a single member of staff, the now broader group of participants was offered the opportunity to modify the map.

Next, the PHA method was explained to each group, using straightforward illustrations. In the FTA group, for example, participants were encouraged to build their own fault tree, with the “top event” being a puncture on bicycle tyre. Some of the events necessary to cause the puncture included the presence of glass on the road and the bicycle riding over it.

After amending the process maps, the participants were each given five adhesive stars and were invited to stick them to the steps in the process which they believed to be most risky, being given freedom to distribute the stars as they saw fit (more than one star on a process step, if appropriate). This “triaging” process helped identify most risky step/steps, and this/these formed the basis for the PHA.

The participants were each given a sheet of paper and, during the PHA, were invited to make notes to record their opinions on their chosen PHA method.

To measure the utility and usability of each PHA method, the participants were asked the

following questions:

- 1) *How easy was the method to learn how to use?*
- 2) *Process map. How easy was it to understand?*
- 3) *Process map. How accurate was it?*
- 4) *Process map. How comprehensive was it?*
- 5) *Were the hazards identified realistic?*
- 6) *Did the analysis reveal any significant risks of which you were previously unaware?*
- 7) *Was there anything crucial missed by this method?*
- 8) *Did you find any limitations with the method?*
- 9) *Do you think the same results could be achieved without the formal structure of the method? (E.g. Holding a meeting to discuss problems).*
- 10) *Is there anything that should be changed about the way the evaluation was carried out?*

Participants were invited to respond with comments to the majority of the questions (marked above in italics). For the first five questions, a five-point Likert scale was used: Very x, Moderately x, Unsure, Moderately y, Very y, where x signifies the words “easy, easy, accurate, comprehensive, realistic” and y signifies the words “difficult, difficult, inaccurate, incomprehensive, unrealistic” for the first five questions, respectively.

7.2.2. Results – FMEA

Compared with the other Groups, more time was spent digesting and amending the process map at the start of the study. This left just 35 minutes to conduct the FMEA.

Three areas of the process map were regarded as particularly risky. One of these was chosen to focus on in particular for the analysis, due to a similar previous incident having occurred in the practice. There were different opinions over the usefulness of the process map. A senior and very experienced GP felt that he could easily have identified the main problems without it. However, a GP who had recently joined the practice felt that this was very useful for her to see the whole process mapped out; an observation which was repeated by the two receptionists. The receptionists indicated that they would want to continue discussions within the practice about how to address some of the problems.

The FMEA was useful in raising awareness of hazards and identifying hazards, but it was time consuming. There was insufficient time to analyse all the failure modes or to discuss actions to eliminate or control hazards. All five participants completed the feed back form. Results are shown in Section 10.9.1.1 in the Appendices.

7.2.3. Results – FTA

After completing the earlier steps (i.e. reviewing the process map, outlining the method and prioritising the process), 65 minutes were available to conduct the FTA.

Whilst the process map was useful for framing the problem, the participants did not appear to refer to it during the construction of the Fault Tree. This may have been because the events within the Tree were easily recalled by the participants and the process map did not display this information at such a specific level. It was noted that the process map did not capture any variations in normal practice, for example if a receptionist accepts a telephone request for a repeat prescription as a favour to a patient.

The facilitator (inexperienced in leading FTA) found it difficult to construct the Tree, since it was modified many times, with different events being deleted, combined or moved to different levels. At the end of the 65 minutes the fault tree represented only a part of the practice’s prescribing procedures, since there was insufficient time to analyse their procedures comprehensively. Towards the end of the session a brief attempt was made to add probabilities to some of the events. The participants seemed to have no difficulty in identifying probabilities which they were content with – little disagreement was observed by the research team.

The participants believed the fault tree to be an accurate representation of how the top event could occur, and the analysis process led to two key conclusions. Firstly, participants felt they left the session with a better overall picture of the practice’s procedures. Secondly, several practice members had made assumptions about the robustness of the practice’s procedures, which were incorrect.

All six participants completed the feed back form. Results are shown in Section 10.9.1.1 in the Appendices. The results indicate that Fault Tree Analysis can be used effectively and can provide a perceived benefit to clinicians, but time and patience is required in order to construct a logical and comprehensive fault tree.

7.2.4. Results – SHERPA

Although three tasks were identified through the triaging process, there was sufficient time to analyse one task only. After reviewing the process descriptions (including the HTA), 60 minutes were available for the SHERPA. This seemed to run smoothly, although some participants initially found it difficult to understand the process.

7.2.5. Numerical results and summary

The numerical results from the feedback from each of the three Groups are summarised in Figure 32. It is notable that despite there being no feedback between the groups, remarkably similar results emerged. Commenting on the PHA methods in particular, the participants “agreed” that all three methods were easy to use, and, on the whole, “strongly agreed” that the hazards identified were realistic, on average. The numerical results do not seem to demonstrate any significant differences between the usability and utility of each of the PHA methods.

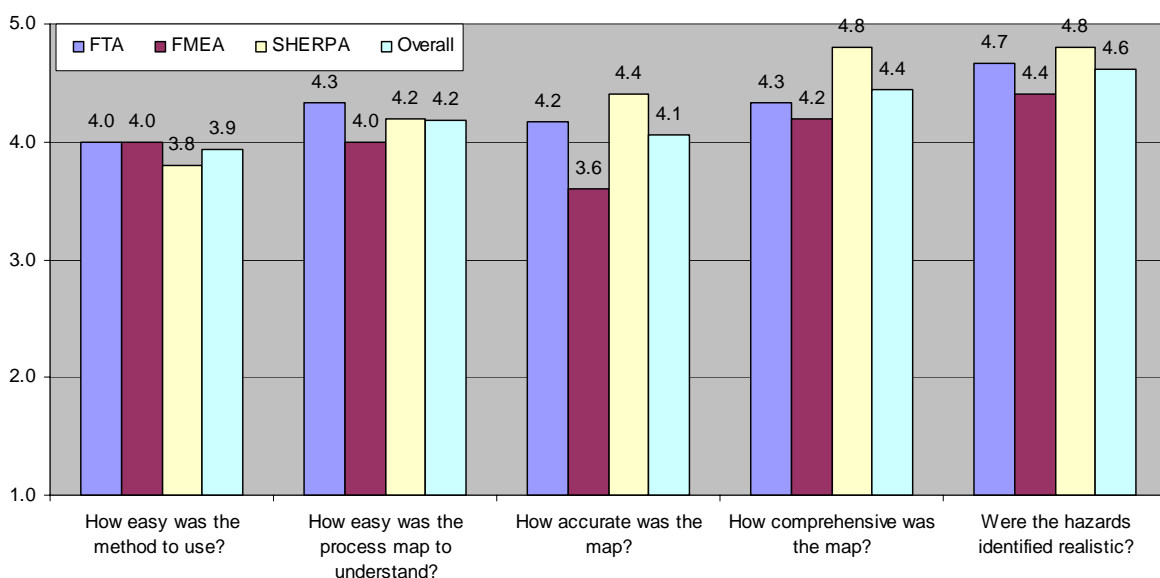


Figure 32 Averaged numerical results from the three case study Groups.

Comments from each of the Groups can be found in the Appendices in Table 30 in Section 10.9.1.1. In terms of the usability and utility of each of the methods, a variety of opinions were voiced. A number of staff said that the sessions had highlighted new risks (Q6), although it is possible that such risks could have been identified by a less structured method (Q9) – opinions were divided over the usefulness of the structure that the PHA methods provided, with some participants being adamant that this was helpful. The participants agreed that the methods were comprehensive (Q7). Other limitations (Q8) were highlighted with the difficulty in providing numbers for severity ratings due to the number of variables, and also the narrow scope of analysis possible in the time allotted. Indeed, the case studies investigated a small part of the practices procedures – i.e. the repeat prescribing process. Through a triaging process, each of the groups identified a shortlist of several process steps. However, for each of the three groups the time available allowed only a tiny part of this process to be investigated – a single process step.

The researchers believe the process map was helpful for prioritisation, but suffers from a limitation in that it can fail to capture variations in practice (clinically appropriate but different versions), as this could make it too complex. In a short analysis session with a very focused scope, such a process map may not be so useful for the risk analysis, depending upon whether the map contains information at a level that is pertinent to the scope of the analysis.

Insufficient time meant that it was not possible to conduct a full analysis of each of the PHA methods. However, across the groups, the processes seemed to run smoothly, with most of the participants being engaged with process.

7.2.6. Conclusions

This initial case study suggested that each of the PHA methods were usable in a primary care setting, although only a very small part of their procedures could be analysed in the space of an hour or so.

The case study was also extremely helpful to the research Team for learning about using the PHA methods in practice, and helped direct the planning of the main case studies, as described in Section 7.5.

7.3. Evaluations within the PHA Team

It was stated earlier that the PHA Team conducted a number of evaluations of the Toolkit in its various levels of development. PHA Team evaluations consisted of face to face meetings within the research Team, telephone discussions, a review by the project's Steering Committee, and two reviews against the requirements developed in Section 5. In addition, three "virtual case studies" took place, where members of the Team each worked through a fictional example. The italicised rows in Table 29 in Section 10.6 in the Appendices describe these activities, and are presented in date order, corresponding to the order of development of the PHA Toolkit. The reader is reminded that the table presents illustrative examples of the outcomes from the evaluations, but not a complete list.

7.4. Evaluations with NHS staff

7.4.1. Review by Risk Management Forum

7.4.1.1. Introduction

An evaluation workshop was conducted with risk managers on an early draft of the Toolkit (Version 4d). An open invitation to participate in the workshop was given to the members of a risk manager's forum in one part of the country. A total of eleven participants took part. They comprised of those who worked in the acute (n=6), mental health and learning disability (n=1), primary care providers (n=3) and ambulance (n=1) sectors. Participants had been in their current job role ranging between three months and fourteen years.

Participants were asked to discuss and comment on the concept and usefulness of the Toolkit. This section is organised around the themes that emerged from the discussion rather than the exact progress of the workshop. Firstly, the initial impressions of the framework are discussed. These included positive views of the framework and organisational issues that may affect the use of the PHA Toolkit. Several issues relating to the framework in its current form were raised and these are discussed. Finally, a list is presented of suggestions made by the participants to improve the Toolkit.

7.4.1.2. Impressions of the Toolkit

Participants were asked to describe their initial impressions of the Toolkit: whether it was familiar to them, had the potential to address some of the challenges of risk management that they faced and whether it would be of value to them or other groups.

One of the areas on which the participants focused their feedback was the process mapping element of the Toolkit. Process mapping was familiar to the participants but is used in a different way to that presented in the Toolkit, such as for process improvement rather than risk assessment. When asked about the form in which the process maps are presented, participants revealed that it is not usually in a pictorial form as their in-house risk assessment forms may not require them to do so. Although the participants did not use process mapping in the same way, this did not mean that they thought this was unhelpful:

"I am speaking probably for most if not all of the risk managers, we do not approach risk assessment or hazard analysis in this way. But this is not to say that this is not what we need."

The risk management framework itself was new to the participants. Currently, risk managers use their own judgement to assess whether risk analyses are conducted systematically and whether all the risks are identified. Despite the unfamiliarity with the proposed framework, the 'waterfall' model resonated with some participants as shown by the reference to the model in the discussion.

7.4.1.3. Usefulness of the tool

An issue raised by a participant was a lack of understanding of the risk assessment process amongst managers. There was a poor understanding of what risk is and how to conduct risk assessments. Hence, a risk management framework that can help managers understand the risk assessment process and help them prioritise risk would be helpful. This point was echoed by another participant who was encouraged by the development of the framework and saw the potential for it to be a good educational tool for managers on corporate strategic risk management to enable them to allocate appropriate risks in the risk register.

7.4.1.4. *Organisational issues*

Although the framework of risk management presented was generally accepted conceptually, participants were vocal about the perceived large amount of resources that was needed to conduct risk assessments using the proposed framework. Practical constraints specifically the time and human resources available in the current NHS were the main barriers. To work within these constraints, it is not unusual for risk managers to conduct risk assessment in a “quick and dirty” way or as described by one participant, using the acronym SWAG that stands for “scientific wild-arse guess”.

When the idea of a “PHA lite” version was suggested that requires less resource whilst still maintaining the same framework as presented, there was strong support from the participants.

Besides the constraints of resources, there were indications that the ‘blame culture’ is still prevalent in some NHS organisations and this prevents some people from undertaking risk assessments.

“The biggest reason that people don’t undertake it is a fear of the process.....fear of ‘if it’s all going to go wrong, it is all going to come back to me’.”

7.4.1.5. *Issues with the current Toolkit*

There was discussion about the need to quantify risks. Currently, risk managers use their own judgement based on their skills and expertise to quantify and prioritise risks. There was also difficulty in quantifying ‘soft issues’ such as the potential impact to patient safety. The framework did not seem to have addressed this issue of risk quantification. Perhaps, as suggested by one participant, quantification need not necessarily be numbers but the assessment of risks requires a systematic process so as to enable replication.

Touching on the same point, another participant was not confident that managers in his organisation would be able to use the Toolkit in its current form on their own. The PHA methods in the Toolkit were not perceived as supporting managers to quantify risk objectively. However, it was recognised throughout by the participants that the presented framework was still “work in progress”.

7.4.1.6. *Suggestions to improve the Toolkit*

Participants raised several issues that could improve the concept and usefulness of the Toolkit. These are presented in point form as follows and are not in order or importance:

- **Prioritise and communicate risks to CEO.** The output of the Toolkit should be the prioritisation of risks and communication of this information in a form that engages the CEO of the organisation.
- **Prompts and aids.** Users should be able to identify hazards and go through the process of risk assessment without spending too much time. The use of appropriate prompts and aids, such as placing prompts throughout the guidance to direct users to the relevant parts of the process, were thought to be helpful.
- **Describe risk.** The Toolkit should be able to help users describe risk properly.
- **Generic tool.** There was a suggestion for a generic PHA method to simplify the process. However, it was recognised that one size doesn’t always fit all. Two participants related their experience of reviewing risk assessment reports and noticed that the type of risk assessments conducted depended on organisational changes, staffing issues or the person who was conducting the risk assessment.

- **Use in procurement.** The applicability of the Toolkit in the process of medical equipment procurement was raised. Currently, procurement decisions are made based on subjective judgement.
- **Training of users.** Potential facilitators/users need to be trained to use the Toolkit.
- **Electronic tool.** It would be easier to use the Toolkit in an electronic form.
- **Compatible with HSE and NPSA risk assessment guidance.** Organisations currently refer to this guidance (this was reviewed in Section 4.3). Designing the framework to be compatible to the guidance makes it easier for potential users to understand and utilise the Toolkit.
- **Accessible language.** Use language that is accessible or familiar to users.
- **Simple.** The Toolkit should be simple to understand and use.

7.4.1.7. *Concluding comments*

There were indications that the risk management framework that was presented was accepted conceptually. To apply the framework practically, several organisational barriers might first be needed overcome: that of resource constraints and a change in organisational culture that does not blame the individual when things go wrong. The participants seemed engaged in the discussion and provided their suggestions to improve the framework despite the short time that was available for the workshop. These suggestions were also reflected in our earlier study that aimed to identify the requirements for the PHA Toolkit. The consistent findings of this workshop and the earlier study support and validate the list of requirements for the Toolkit that was previously developed. It was also very encouraging that when asked, some participants were willing to continue their involvement in providing feedback to subsequent versions of the PHA Toolkit.

7.4.2. **Informal reviews with Risk Manager**

During the Toolkit development process, two brief reviews of the PHA Toolkit took place face to face with a risk manager. These were conducted by the risk manager by reading, at speed, through the Preliminary Risk Review section of the Toolkit. One of the main features of the Toolkit is to split the risk assessment into two parts, with the front-end being a brief "Preliminary Risk Review". The risk manager was particularly keen on this, and stressed again the importance of simplicity. The importance of answering the right question was also emphasised, and the approach in the Preliminary Risk Review which follows this was also favoured by the risk manager.

7.4.3. **Review with Patient Champion**

Whilst the case studies did not involve patients directly, the patient's view of the Toolkit was sought through conducting an interview with the "Patient Champion" for a Strategic Health Authority. This occurred in between the Group 1 and Group 2 case studies (Section 7.5). An interview question topic guide was used to direct the interview. In particular, the question was addressed of patient involvement in using the Toolkit. The interview was audio recorded.

A member of the PHA project Team walked the interviewee through a brief (10 minute) review of the Toolkit, using an example of a forced ward closure due to the outbreak of Norovirus. The interview focused on the Preliminary Risk Review, but it was also explained how the Comprehensive Risk Assessment could be followed using the same example.

The interviewee was enthusiastic about the Toolkit and thought that using it would benefit

staff, patients and carers and would “help immensely”. Regarding the benefits to patients, many positive comments were recorded. For example:

“I would like one of these for every main situation [any big changes planned].”

“We need to design these problems away and this (PHA tool) is one way of tackling these problems.”

“It would benefit patients a lot if this process is being done and actions are not being done in desperation. Knowing that some one has planned what must be done and looked at the peripheral things... will make a big difference to patients.”

“This (PHA tool) is a good way of looking at the changes. This is what we are missing. It is a simple thing to do, whether they will do it is another matter.”

“This would and should be used. It will be piloted won't it?”

The interviewee was less positive towards patients actually being involved in the risk assessments, and felt that “if this [risk assessment] is done properly, all this [could be] done on the patients' behalf... [with] patients not necessarily directly being involved in this exercise.” However, the interviewee believed that patients should be informed that such assessment were being carried out on their behalf as this would be encouraging for patients, being a direct demonstration of the organisation taking their needs into account. The interviewee advised that it would be necessary to run a training programme as part of a roll-out of the Toolkit.

7.5. Case Studies

Five case studies were conducted with five sets of NHS staff to assess the usability and utility of the PHA Toolkit. These were split into two Groups – Group 1, consisting of three case studies, and the remaining two case studies under Group 2. The purpose of the split was to allow for changes to the case studies' facilitation and for additional changes to the Toolkit, in between the first Group and the second. Each case study followed a specific scenario and took place in a specific NHS setting, ranging from a risk assessment of an Acute Trust's patient discharge process (at the interface between Acute and Community care), to a risk assessment of a Mental Health Trust's patient risk assessment procedures at patient admission to a secure unit. NHS staff were selected who had a knowledge of each scenario in their NHS Trust. Over a few minutes, each staff set was first made familiar with the Toolkit's structure and then, over several sessions of 1.5-4 hours, was asked to work through the Toolkit, with the assistance of a facilitator. Feedback on the Toolkit's usability and utility (usefulness) was collected through a range of media, from audio recorded comments during each session to written comments on an evaluation sheet at the end of the final case study session.

7.5.1. Case study selection criteria

The PHA Proposal document stated that sampling for case studies would occur across a range of settings and scenarios. A setting was defined in the Proposal as a particular care environment, such as a GP surgery, an ambulance Trust or an intensive care unit, but can also be defined more broadly to include a sector of health care such as community pharmacy, acute hospital care or general practice. A scenario describes a particular task or activity that is performed within that setting.

The Proposal identified a range of characteristics of healthcare settings that might impact upon the choice of PHA methods, and – crucially – it was suggested that case study selection should be based upon sampling in different settings. These characteristics are

shown in Table 33 in Section 10.9.3 in the Appendices.

However, during the course of the research project, more was learned about the different characteristics of the PHA methods, and most of the criteria in this table were believed not to bear direct relevance to choosing particular case studies. For example, many of the criteria relate to practical aspects of setting up or running the case studies. The “assessment approach”, “knowledge”, “supervision”, “staff mix”, “use of protocols” and “system issues” may all influence who should be invited to take part in the study, for instance. However, these criteria may vary hugely from one setting to another, and it is not possible to say that a particular criterion will always have the same characteristics in every setting.

Through the Risk Experts Workshop (Section 6.2) and the initial case study (Section 7.2), it was realised that some of the most important influencing factors on the choice of PHA method are the scope and objectives of the study. These can be hugely individualistic, and cannot easily be predicted until the case study has started, and are relatively independent of the choice of each setting.

There are exceptions to the above. The “patient condition”, if critical, may mean that assessing the presence and robustness of any barriers to preventing harm may be particularly important. Technology demands *could* also influence the choice of PHA method, but not always as technology will have a human interface, and therefore this does not rule out the need for HRA methods. In addition, some cultural aspects may mean more free time to allow for analysis – for example through the case studies it was found that surgeons appeared more willing to devote time to the PHA than GPs; one reason for this may be the differences in payment mechanisms between GP practices and those who work in acute care. In addition the tasks that are performed typically in different settings may be substantially different – GPs, for example, may be concerned principally with diagnosis and medication treatment tasks, rather than carrying out other forms of health care. However, in the main, we believe it is the specific characteristics of each case study which would likely override the generic characteristics of different settings.

In his book on case study research, Stake has written the following on selecting case studies [Stake, 1995]:

“Case study research is not sampling research. We do not study a case primarily to understand other cases. Our first obligation is to understand this one case.”

“The first criterion should be to maximise what we can learn... If we can we need to pick cases which are easy to get to and hospitable to our inquiry.”

“Even for collective case studies, selection by sampling of attributes should not be the highest priority. Balance and variety are important; opportunity to learn is of primary importance.”

In response to this, and the considerations highlighted in discussion above (in particular in reference to the findings from the Risk Experts Workshop), it was believed that a number of practical aspects should heavily influence case study selection. To test the Toolkit carefully, it was considered necessary to take into account a range of additional characteristics when choosing suitable case studies. Table 34 in Section 10.9.3 in the Appendices presents a history of how various parameters for selecting case studies developed over the course of the project. A section of this table is reproduced below (Table 21), showing the final criteria, which bear this more pragmatic hallmark in selecting case studies.

Table 21 Categories considered for the selection of case studies

	Parameter	Significance
23	Resource avail. – how much time is available?	xx
27	Stakeholders* – does the case study contain exclusively clinical or managerial staff?	x
28	NHS setting** – which is the predominant setting in which the case study takes place?	xx
29	UK Location – how geographically close is it to the researchers?	xx
30	Complexity – what is the level of interconnectedness between the elements to be studied?	x
31	Key questions / problem type – what is the scenario we are trying study? E.g. introducing a change / service improvement.	x
32	Ease of access to staff – will staff be available to take part?	xx
33	Anticipated level of staff engagement with process – are they likely to want to be involved?	xx
34	Leadership (i.e. level of senior support for case study) – are we likely to obtain the necessary management permissions?	xx
35	Anticipated PHA methods – is the nature of the study likely to lean towards one PHA method, or a set of PHA methods?	x
36	General nature of study – is the study dealing with e.g. a technical, managerial or organisational problem?	x
37	Size of problem – how long is a thorough investigation likely to take?	x
38	Level of desired detail – what level of investigation are the staff likely to require?	x

Criteria marked with “xx” denote those which were of predominant influence in the choice of case study (over and above those marked with “x”). This was a subjective judgement based on the strength of judgements made during team meetings. A single x does not necessarily indicate that the category was of minor importance; rather that no specific level of importance could be identified from the content.

* **Stakeholders.** Different groups of individuals may have different objectives for a PHA. For example, front-line workers may have interests in investigating very specific risks, which only they come into contact with, whereas managers may consider broader-range analyses or analyses regarding meeting NHS targets to be a higher priority.

** **NHS Setting.** The following were considered as a list of NHS settings: Acute hospital, Ambulance service, Community hospital, Community nursing (medical and therapy service), Community pharmacy, Dental service, General practice, Hospital pharmacy, Learning disabilities, Mental health service (from <http://www.nrls.npsa.nhs.uk/resources/healthcare-setting/>, accessed 31 December 2009).

In addition to the above, some case studies were omitted due to significant unstable organisationally political situations, which may have resulted in the cessation of the case study part way through. A further significant consideration was any benefit that could be provided to the participants. It was suggested that high-risk areas might provide a suitable starting point for conducting a PHA, since they might prove more beneficial to owner of the case study.

7.5.2. Case studies considered

During the course of the project, research activities such as the interviews and attendance at the risk forum led to a wide range of case studies being identified. One of the main delays in beginning the case studies was the decision to use the case studies to test the Toolkit, rather than PHA methods directly. This required the Toolkit to be developed first. A list of case studies considered is presented in Table 31 in Section 10.9.2 in the Appendices. This list was gradually refined, according to the parameters set out in the previous section (Section 7.5.1).

A number of case studies were short listed, and discussions were held with each Staff Lead responsible for locally setting up the case study. However, these case studies did not take place for a variety of reasons. Details of these case studies, and the reasons for them being unselected, are presented in Table 32 in Section 10.9.2 in the Appendices.

7.5.3. Case studies selected

7.5.3.1. *Main case studies – Group 1*

Apart from the unselected case studies (Table 32 in Section 10.9.2 in the Appendices), five case studies were chosen and divided into two Groups. The following three case studies formed Group 1. These involved the following risk assessments:

- **CS1 – Patient discharge process**, in an Acute Trust setting. This case study focused in particular on the management of medicines information and its influence on the discharge process, and involved staff from both primary and acute care. Particular challenges are timely patient discharge and issuing an accurate discharge record, including ensuring the patient leaves the hospital with the correct medicines.
- **CS2 – Patient risk assessment procedures**, in a Mental Health setting. During admission into a secure unit, patients are assessed for their risk of harm to themselves and to others. This case study involved a risk assessment of the information used to assess patients. Particular risks are associated with difficulties in predicting patient behaviour, and knowing how best to deal with it.
- **CS3 – Surgeons’ journey through the operating theatre**, in an Acute Trust surgical setting. This case study focused on the processes (including the use of equipment and space, and communication between healthcare professionals) involved in the surgeons’ journey through a defined physical boundary. The aim was to conduct a ‘health-check’ of the system to identify potential risks to the process. Specific risks identified included the use of the WHO checklist and writing of the operative notes.

Further details of the case studies and the demographics of the case studies and the participants can be found in Table 35 and Table 36, respectively, in Section 10.9.5 in the Appendices.

7.5.3.2. *Main case studies – Group 2*

The following two case studies were executed under a slightly amended facilitation protocol and with a newer version of the Toolkit:

- **CS4 – Opening a “Contingency Ward”**, in an Acute Trust operations management setting. This involved consideration of risks on preparing for and opening a ward which aims to relieve the hospital of winter pressures; particularly for patients with respiratory difficulties. Particular risks are associated with staff continuity, unfamiliarity of staff in working together, and other “unexpected” happenings such as late changes to the planned opening date to the ward.

- **CS5 – Introducing a new screening test**, in a Bowel Cancer Screening centre setting. The case assessed the risks of introducing a new immunochemical test used to screen for bowel cancer in England. There were many issues that had yet to be finalised before pre-piloting the system such as determining the appropriate test analyser, running two systems (old and new) concurrently, relevant skills required and the processes from sending tests, collecting samples, analysing them and disseminating test results to the appropriate people.

7.5.4. Preparation for the case studies

Before selecting a case study, at least one discussion (usually a face to face meeting) took place between the PHA Team researchers and the Staff Leads for each study. These pre-meetings took place to explain the purpose of the study to the Staff Leads, to consider issues such as scope and objectives and to answer any questions on the research process. Issues considered were based largely on the case study selection criteria specified in Table 21 in the Section 7.5.1. In particular these meetings considered the following:

- Explaining the details of the study – that approximately one day was requested for each study participant.
- Highlighting the aims of the study and the risks and benefits, including explaining that the study was experimental, and as a result the outputs would need to be treated with caution.
- Briefly explaining the PHA process: that it would begin with a “Preliminary Risk Review”, consisting of a range of questions about the scope and aims of the study, process mapping and a brief risk analysis. Potentially, there would then follow a “Comprehensive Risk Assessment” which would ask similar questions but require more detail, and would utilise one or more PHA methods.
- Discussing the Staff’s (Staff Lead and members of their team) availability to take part, their level of enthusiasm and engagement with the project, and authority of the Staff Lead to request other Staff to join the study.
- Arranging suitable composition of teams up front (where possible) and booking meeting dates.
- Highlighting the ethical permissions for the study, showing the participants the information sheets and answering questions.

Other preparation activities included the need to gain R&D permissions, and in some cases arranging senior support such as from divisional managers or the Chief Executive of the Trust.

7.5.5. Measurement of usefulness

7.5.5.1. Definitions and criteria of usefulness

Usefulness

Nielsen describes usefulness as ‘whether the system can be used to achieve some desired goal’ [Nielsen, 1993]. To evaluate the usefulness of a ‘product’, the usability and utility of the product are determined. As such, these two concepts were used to evaluate the PHA toolkit, based on a set of criteria. In conducting the case study, various other evaluation tools were used, as discussed in the following section. The evaluation performed was primarily user-based rather than an expert evaluation. This section focuses on the development of an evaluation questionnaire that was administered to every

study participant at the completion of each case study.

Usability

The concept of usability, as defined by the ISO, was used in the development of the evaluation form. ISO 9241-11: 1998, definition 3.1 states:

Usability: the “extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.”

Several factors should be considered when measuring usability, as described by Nielsen [Nielsen, 1994] and these are briefly described below:

- **Learnability:** How easy is it for users to accomplish basic tasks the first time they encounter the guidance? These could include the amount of training that users require, whether there are substantial differences between the cognitive approaches of various users that will affect the design or can a one size fits all approach be used, what documentation or other supporting materials are available to help the user and can users find the solutions they seek in these materials such as links to other more specialised guidance.
- **Efficiency:** Once users have learned the guidance, how quickly can they use it?
- **Memorability:** When users return to the guidance after a period of not using it, how easily can they re-establish proficiency?
- **Errors:** How many errors do users make, how severe are these errors, (and how easily can they recover from the errors)? What do users have to do to recover from errors? Does the product help users recover from errors?
- **Satisfaction:** How pleasant is it to use the guidance? *Utility*

In terms of utility, criteria such as whether the guidance enabled a risk assessment to be conducted, whether the findings were realistic and its potential impact of the assessment such as safety and cost that reflected what was important to the users.

7.5.5.2. Development of evaluation form

Several information sources were used to develop the evaluation form. These included the criteria listed in the published literature (as described above), published papers on the subject and the evaluation form used in the initial case study. From these sources, a draft version of the evaluation form was developed. The initial draft was reviewed by another member of the PHA team and revisions were made to incorporate the comments. Further development of evaluation form was iterative and involved evaluation of the form with the rest of the PHA team members.

The final version of the evaluation form consisted of three sections; the first two consisted of questions where participants were required to tick their responses on a five point Likert-scale. The last section were open-ended questions ranging from questions on usefulness of the PHA toolkit to participant demographics and prior experience (if any) of using PHA methods or similar toolkits. The final version of the evaluation form is presented in the Appendices in Section 10.9.4.1.

7.5.6. Running the case studies

7.5.6.1. Facilitation

Case study facilitators were issued with an agenda to describe how to run each case study. In addition to highlighting the responsibilities of different facilitators / researchers in

the study and any equipment necessary, this document outlined the following procedure:

1. Introduce participants, observers and facilitators.
2. Present timetable for the meeting (and highlight any later meetings).
3. Introduce the research study: background, purpose, potential risks and benefits to participants, aims for the study, and highlight the importance of feedback on the usability and utility of the Toolkit.
4. Conduct Research Governance activities: checking information sheets have been read, answering questions on study, and inviting participants to sign consent forms. Checking that consent forms have been signed in their entirety.
5. Start case study by introducing the Toolkit.
6. Towards end of final case study session, hand out evaluation sheets and collect feedback.

Case studies were generally attended by a main facilitator, a second facilitator (tasked with recording the results on flip charts) and a researcher/observer (tasked with running the agenda for the case study and making notes on the findings). Given the significance of the task and the resulting danger of major bias upon using different facilitators, the same member of the project team was the main facilitator throughout all five case studies.

7.5.6.2. *Data collection*

Feedback on the usability and utility of the Toolkit was collected through a variety of means during the case studies:

- Audio recordings of the complete case study.
- Written notes made by a researcher/observer – in particular noting the timings for each section of the Toolkit and any general issues arising such as requests by the participants for clarification, observations stated by the participants on the Toolkit's structure, language or content and any disagreements or controversies with using the Toolkit.
- Marked up copies of the Toolkit, with annotations from each of the participants – participants were each given a copy of the Toolkit.
- A notepad for each of the participants, for them to record any thoughts on the Toolkit, to give them the opportunity to make comments anonymously as well as verbally.
- An evaluation sheet, as described in Section 7.5.5.

Each of the participants was allocated a unique number, which was used by the researcher to record any comments. In addition, for the case studies involving a larger number of people, a facilitator made notes on enlarged print-outs of the templates, to record progress on each of the pages on the template in the Toolkit. Photographs were taken of each of the pages and any process maps which were produced. Examples of these are given in the figures below.

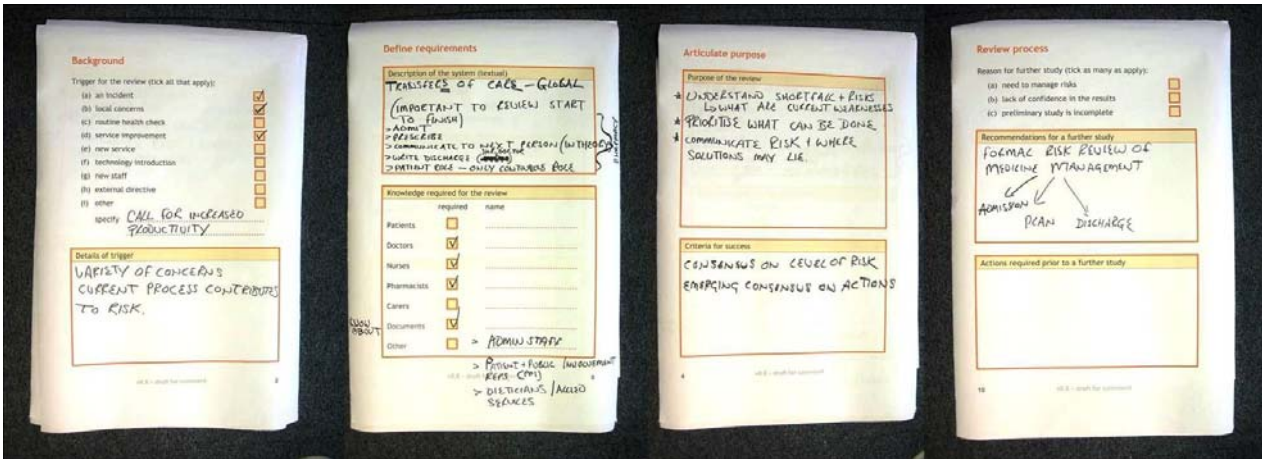


Figure 33 Completed templates from a Preliminary Risk Review.



Figure 34 A process map from a Comprehensive Risk Assessment.

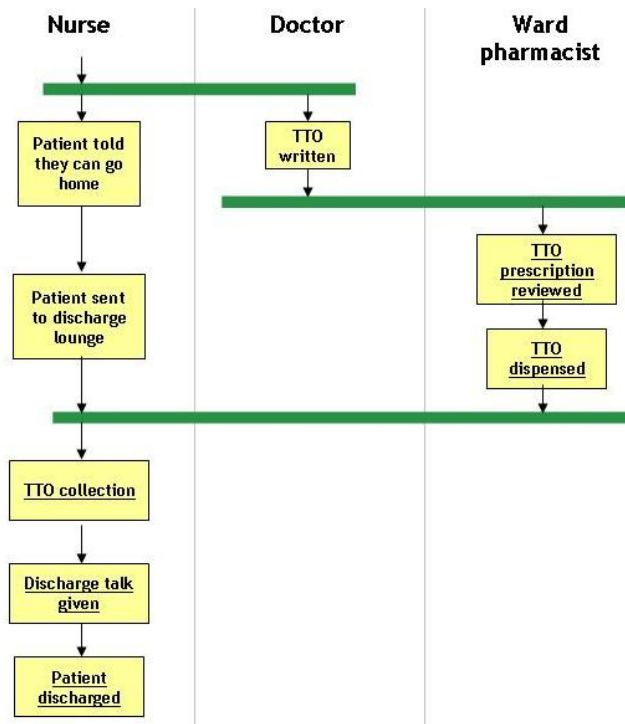


Figure 35 Part of another process map from a Comprehensive Risk Assessment.

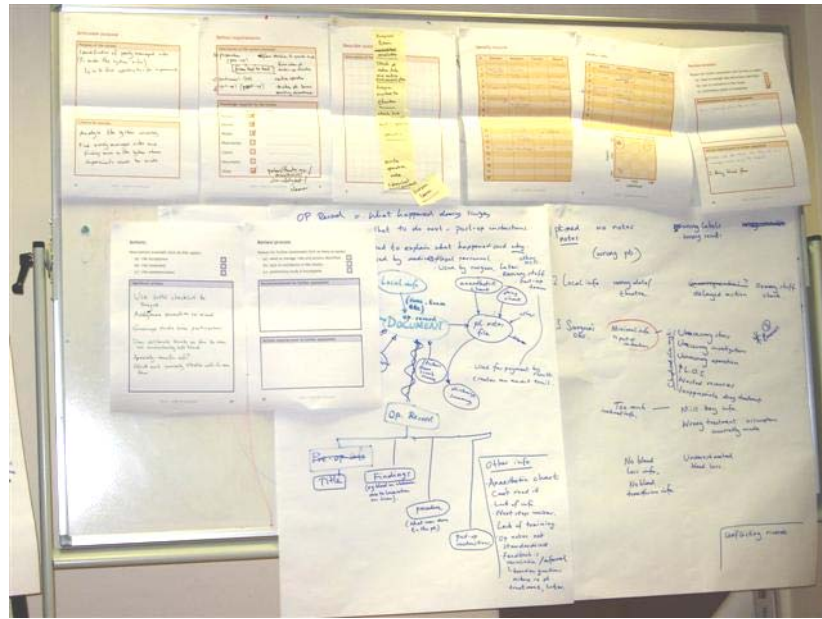


Figure 36 Example of records made during one of the case studies, including templates from the Preliminary Risk Review and the Comprehensive Risk Assessment, and a process map.

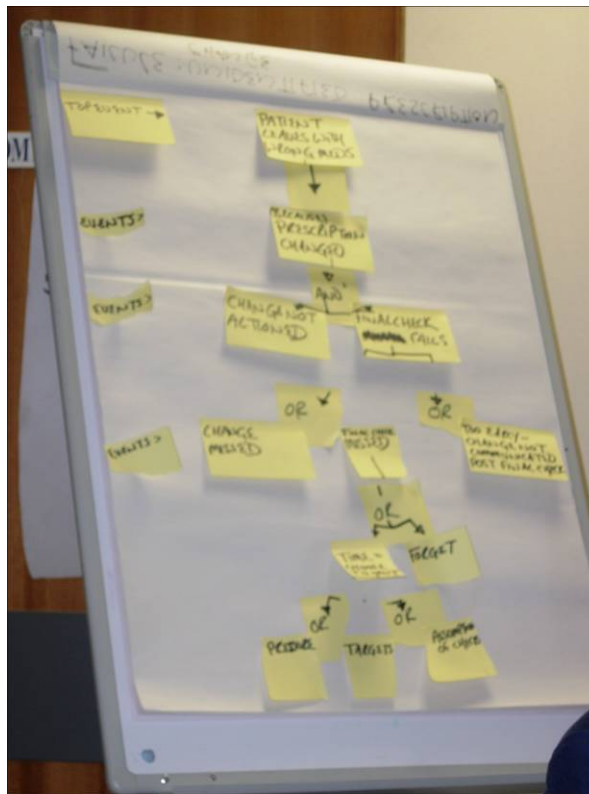


Figure 37 A fault tree from one of the case studies.

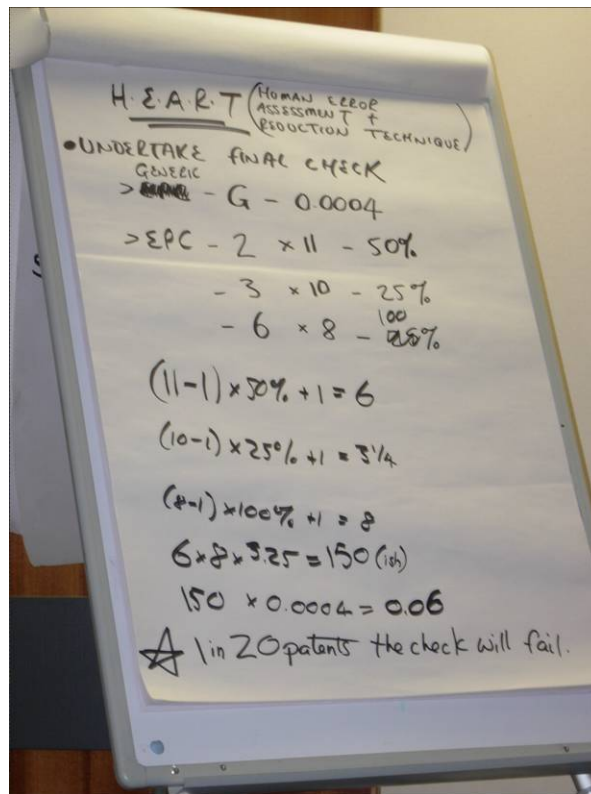


Figure 38 A HEART from one of the case studies.

7.5.6.3. Data analysis

In addition to analysing the researchers' notes, comments relating to the usability or utility of the Toolkit were analysed from the audio recordings for feedback on:

1. Observations on NHS practice (focusing on patient safety).
2. Observations on risk management practice in the NHS / at the Trust.
3. Observations on Toolkit / suggestions for modifications.
4. Observations on facilitation / suggestions for modifications.

Comments falling into the above categories, and of particular pertinence to the research project were transcribed verbatim. An example of a researcher's notes is given in Figure 39. An example of a transcript is shown in Figure 40, and an extract from a researcher's notes, transcribed from the participants' annotations on their Toolkits, is given in Figure 41 (this also includes a researcher's own observations).

[28:40] [b] highlighted the point that we were now in danger in doing a risk assessment on NHS improvement processes.

[29:20] 1.17 [b] asked the question about what might constitute the criteria for success. The participants were then directed to the example at the back of the Orange section. It was suggested by [b] that in this case the criteria for success might be that we simply agree to go on to analyse the system further and the level of effort we're ready to commit to the analysis, and also to work out what steps we'd need to take next. You may look for consensus on the priorities, also. [1] stated that the criteria for success might be: agreement that there is a major problem and that a multi-disciplinary and multi-agency approach is needed. This was summarised by [b] as the significance of the risks and consensus on the solutions, and that the right people appreciate this – convincing other people.

[36:10] 1.19. Description of the system. [1] handed round a diagram produced by members of the Trust: *"A safer medicines management pathway for [Trust location]: Improving efficiency,*

Figure 39 An extract from a researcher's written notes from one of the case studies.

1	[7] said that there's a tendency to skew things to avoid reporting upwards when you use the 5x5 matrix . "Certainly in the trust the 5x5 matrix I'm sure the scoring is influenced by the fact that above a certain level you have to report upwards, and come up with action plans, and below a certain level you don't. So I think there's a tendency to skew things and say I really can't be arsed to do this at this point. I'll score it at 12, because that's below the threshold." [4:05-4:27]	Current practice problems: Inadequacy in 5x5 process.
2	[6] – what if you can't change the problem? "...if colleagues have identified a problem that they're given permission or are empowered to actually make the changes... if you make the effort to identify the problem but actually can't change the problem then you're in a worse place than if you'd never made	Toolkit changes: Include advice in guidance – how effect change? Or do we suggest you get a change

Figure 40 An extract from a transcript from one of the case studies.

Under Participant No., numbers indicate a Staff participant's annotation and letters indicate a researcher's annotation.

Guidance version and Participant No.	Section and Page	Annotation	Researcher's comment
V0.8, 1	-	-	-
V0.8, a	1.7	<i>Prospective risk management, an ongoing process to...</i> Say more about "risk control actions" – jargon	Need to explain this more.
V0.8, a	1.10	<i>Section 1.1</i> is in light orange, not dark	Formatting
V0.8, a	1.12	<i>Section 1.1</i> is in light orange, not dark	Formatting
V0.8, a	1.13	<i>The review should take no more than a few hours.</i> About an hour!?	Change?
V0.8, 2	1.17	<i>Describe the criteria for successful completion of the review, i.e. reduced risk to patients and staff, improved efficiency, etc.</i> "Question doesn't make sense"	Include some more examples to help the reader make sense of this?
V0.8, 7	1.18	<i>Criteria for success</i> "understand risk? Make changes?"	Providing some examples of the criteria for success.
V0.8, 5	1.20	<i>Knowledge required fro the review.</i> "Represented / actually present" – trying to draw a distinction between those who actually need to be in the meeting and those whose knowledge you simply require.	
V0.8, 6	1.22	<i>Element explicit what an element is</i>	Explicit

Figure 41 An extract from a summary of participants' annotations on their own copy of the Toolkit.

7.5.7. Results

Results from all five case studies are presented in this section and have been collated from the various mechanisms for feedback.

7.5.7.1. General observations on each case study

This section begins with descriptions of the nature and specific outcomes pertaining to each case study. More general observations will be described in the sections which follow.

CS1 was described by three of the participations as a highly complex process – as “vast” by one, and “the most complex process in the NHS” by another. As a result a great deal of time was spent in prioritising on which part of the system the case study would focus. With seven participants, most of whom were very vocal, it was noticed that many minutes were spent in filling in each template (e.g. 10 minutes for the Triggers section), where it was intended that each would take only perhaps 2-3 minutes. Much of the group’s time was spent in discussion on the types of issues and barriers that may be faced in implementing the results from the analysis, versus conducting the actual analysis. Whilst all of the participants made very valid and helpful points for the research project, progress through the Toolkit was slow. It was hoped that each template could be timed to see how long it would take to fill in. However, with so much discussion around a range of issues (usually perfectly valid but peripheral to the template) the timings made by the researcher were misleading and treated with due caution.

The group was unusual because several of the participants had spent years analysing the robustness of their system, whereas others (namely front-line staff members) had not considered such broader “systems” issues before. It took the first session (three hours in duration) for the less experienced participants to be brought up to speed with the others. With participants from very different backgrounds (nursing, GP, consultant, pharmacy) there was some confusion over medical language, although this did not delay the study very significantly.

Perhaps because of the complexity in this study, one of the greatest challenges was in choosing a suitably sized area of the system to analyse – one which would be of interest to the participants, but one that the facilitators felt would have a hope of being analysed by the end of the time allotted. This underscored the importance of the “triaging” nature of the Preliminary Risk Review. Sources of variability included treatment at different times of the day or week, different staff sometimes performing similar duties (and therefore it not being entirely predictable who would do what), or simply whether a patient’s medication had changed or not.

Several issues were noticed with process mapping. Participants were keen to “jump the gun” to describing failure modes before the process map was complete, which required frequent intervention from the facilitator. The process maps were helpful for ensuring that all staff had an understanding of the system. This led to the inadequacy of some of the barriers to failure being revealed. Several different process maps were drawn under the Comprehensive Risk Assessment. One participant noted that she was particularly keen on swim-lane diagrams, stating that: “I can immediately, really in ten seconds, relate to what you’re on about.” [6]

Three PHA methods were chosen. The first was FMEA. Due to the difficulties in combining different types of risk – e.g. Trust reputation vs. patient safety (and different individual severity scores) – difficulties were observed in making severity ratings. At least 15 minutes were lost in trying to locate the Trust’s risk ratings.

After 25 minutes and a request by one of the researchers to try a method that had not been used so frequently in healthcare, the session moved on to FTA. The FTA described explicitly the causes behind errors, and revealed that a particular staff member would have been unable to perform a certain task reliably, and that no other safety nets existed in the system: the system was guaranteed to fail. There was insufficient time to investigate other branches, which might have contributed to the error; this was seen as unfortunate by some of the participants who appeared strongly engaged and interested in the process. Some disagreement was noticed about what the “top event” should be – this appeared to be due

to different personal interests from different individuals. Despite the limitations stated, most comments received towards FTA were positive.

In order to arrive at probability data for a human task which influenced the top event in the FTA, a HEART was chosen. This worked quickly and smoothly, giving an estimate of 1 in 16 particular types of check failing. The figure was appreciated as valuable by the participants. However, despite there being 9 hours available for the study, all three PHAs were cursory.

Another major finding was a disadvantage in the effectiveness of the case study. A number of significant problems were identified, but concerns were raised on how staff would be supported now these problems were aired.

Overall, in particular regarding obtaining feedback on the Toolkit, the case study appeared to be a great success, although even when analysing a small scenario in only one part of the medicines management system, it was possible to only conduct very brief risk analyses, with no time remaining for investigating solutions.

CS2, in contrast to CS1, created far less discussion on the Toolkit and more discussion on the system to be analysed. It was noticed that there were a number of “systems” issues which required attention, and so the analysis was seen as a novelty and as useful: “the people we are involving in are not looking at the whole system. So if you are ever going to do that preventative work, that service development work, that’s where the focus needs to be”.

Overall, there appeared to be a mixture of known problems but a lack of resources to deal with them (e.g. insufficiently trained staff) and unknowns such as the unpredictability of patients’ behaviour, specific triggers to violent behaviour and the best strategy for defusing a situation quickly.

Similar to CS1, long discussions were held over various deviations from the norm (e.g. admissions of patients from the Police and admissions late at night when suitably qualified staff aren’t necessarily available) and which scenario(s) to analyse further. Prioritisation took considerable time (45 minutes in CS2), with the focus lying on the admissions process, since it led to a range of common downstream problems. One of the key issues was the need for reliable and timely communications between staff.

Whilst a variety of systems issues were noted in nearly a dozen different process maps, difficulties were experienced in ensuring the right people attended the risk analysis session – it was stated that many of the up-stream risks came from areas which were outside of their control, for example IT systems not talking to each other. This limited the risk assessment.

A SWIFT was conducted in CS2. This again seemed to work smoothly with the participants. As part of the SWIFT, various guide words were used (too soon / too late / doesn’t happen / wrong order, etc), which were systematically gauged against a process map with six steps, centred around the admissions stage. As with CS1, time ran out before the PHA could be completed (e.g. ranking risks and investigating actions).

CS3 was attended by three surgeon participants with different surgical background and length of qualification. A distinct difference to the other case study was that the staff lead was not present in both sessions of the case study that lasted only two hours each. The participants were very enthusiastic and focused on analysing the system with fewer

comments on the Toolkit.

Due to the absence of the Staff Lead and the broad remit of the aim of the risk assessment the entire case study depended heavily on the direction given by the facilitator. The limited time meant that the facilitator focused on a high level process of the surgeons' journey through the operating suite. There were lengthy discussions on the boundaries of the process being analysed such as whether to start the process as the patient is being admitted to the hospital to when they leave, when the surgeon enters and leaves the operating theatre or when the surgeon assesses the patient right until post-operative care. Different dimensions of the process were assessed but there was a deliberate decision to exclude the operating process in the operating theatre. The process map developed consisted of only seven broad steps, hence was at a very high level. Hazards were identified from this process map and the risk of only some of these was determined due to time constraints. From the preliminary risk review, the highest risk lay in the use of the WHO checklist and actions were proposed to reduce the risk.

The comprehensive risk review focused on the writing of the operative notes, as agreed at the end of the preliminary risk review. Two hours were allocated for this session with the same three participants minus the Staff Lead. There were lengthy discussions surrounding the boundaries of the analysis, as to whether to include both the downstream effects and details of the process of writing the operative notes, and the downstream details were disregarded from the analysis. A SWIFT analysis was conducted, albeit incomplete. Many issues regarding the current operative notes were raised and the risks were assessed. Proposed actions included writing the operative notes as a team rather than an individual effort, and incorporating this process in the WHO checklist since it is widely used now in surgery.

Overall, there was increased insight to the processes being risk assessed. The limited time available for the case study restricted the depth of the risk assessment. However, in a typical NHS setting, four hours per person was probably a realistic time that most healthcare professionals can spend on a risk assessment. Both sessions were heavily facilitated and the implications for this was that the facilitator will need to have a reasonable level of knowledge of the toolkit, risk assessment, methods and experience in facilitating group discussions. Training of facilitators will be an important requirement for using the toolkit. Due to the lack of time, the participants did not have time to read through the workbook. They said that it would have been better if they had more time to read through the workbook either during the session or prior to that.

In **CS4**, only two participants attended the first session. With little guidance from the researchers / facilitators, 58 minutes were taken to complete the Preliminary Risk Review. Few points of clarification were requested and the process seemed to run very smoothly, suggesting that the Preliminary Risk Review was written at a suitable level for the participants. It was clear that a Comprehensive Risk Assessment would be necessary as it was not practical to review the risks properly in the Preliminary Review – the process was too complex, with too many elements.

The focus was on the staffing of the ward, and the challenges that affect the ability to provide the right number of staff and to understand how this would link with the ward's operation. However, due to a major operational issue which emerged unexpectedly at the Trust, at the request of the Trust, the second case study was delayed until after the PHA project was concluded, and hence sadly had to be cancelled.

CS5 concerned introducing a new technology into the community. As the details for this

introduction had not yet been decided and it was in the early stages of planning, some time was spent deciding on the boundaries of the analysis. Issues that were raised included instructions for using the new kit (a medical device), logistics of sending the new kit, processing issues when the kit arrives back at the laboratory such as the skills and competencies required to process the kit, quality assurance and labelling, and transferring data, and liaising with Connecting for Health regarding IT needs so that relevant healthcare professionals receive and/or can access the results.

The decision was made to focus on the processing issues within the laboratory as that matched the skills of the participants most closely. There were a lot of uncertainties in the process as there has yet to be discussions surrounding the introduction of the new kit. As such, most of the discussions focused around completing the risk assessment rather than on the Toolkit. The participants worked through the toolkit relatively smoothly with few problems, except when there was a temptation to veer from the focus of the risk assessment due to the many uncertainties in the potential introduction of the new kit.

Two PHA methods were chosen: SWIFT and barrier analysis. However, due to time constraints (2 hours allocated for each of the two sessions), it was not possible to finish the analysis using both methods. In general, there were few problems using the Toolkit to analyse a small and defined part of the system. It was also important to have the Staff Lead present at the risk assessments as there were many unknowns with both the technology and the process of introducing in the community.

The participants of CS1 were the most vocal of all of the groups, not just with many observations made regarding the Toolkit, but also a considerable number on the healthcare system. The following sections describe observations from all of the groups, but a natural bias occurs towards CS1, due to the sheer volume and insightfulness of comments.

7.5.7.2. Observations on NHS practice (focusing on patient safety)

Across the case studies, undesirable and preventable situations regarding patient safety were presented as the norm. Whilst many of the problems were known, “nothing’s happening about getting a grip on it”, as one participant put it. Another stated that, “There’s not a day goes by when someone doesn’t describe a problem in the system.” Still another stated that as there are so many problems, it is difficult to know where to start. Since the Toolkit offers a prioritisation process in the Preliminary Risk Review, this may help answer this issue. Other problems were pointed out with the “freneticism” of care and the insufficient time to consider the risks and implications of practice.

According to one participant, much time was spent in “reactive governance. Most people just spend their time dealing with things that have gone wrong.” Staff in another case study pointed out that the system of care was “ad-hoc. [If] you pick it up, well and good, if not...”.

The problems may be known but it is less clear whether the root causes are really known – as one of the participants said: “It’s not a malicious attitude, it’s a complete lack of awareness actually.” Although there were indications that the barriers to improvement were known, and it was just a case of overcoming them. One of the barriers may have been the level of pressure that staff seem to be under. As one participant stated: “the pressure on us is so great... The amount of patient flow we have is incredible.” Another stated that the frequency of changes to the system (e.g. new Government targets) meant that “the systems have never got time to self improve and settle down.”

7.5.7.3. *Observations on risk management practice*

A number of observations were made regarding current risk management practice, including a variety of problems with risk matrices, supporting the conclusions made in the literature review in this research study. For example, risk matrices were perceived to “create an illusion of risk control”, by one participant, and were seen as “subjective” by another. Another stated that there is a tendency to use them as a political tool, by skewing the results upwards or downwards, depending upon the point that is trying to be made. The difficulty with making sense of high scores on one axis and low scores on the other was also raised.

7.5.7.4. *Observations on usability of the Toolkit*

Table 22 presents the findings from the evaluation forms, aggregated per case study. CS4's results were discounted from the study as, for reasons described earlier, the case study was cancelled before the Comprehensive risk assessment could begin. The reader is reminded that 5 = Strongly Agree, 4 = Agree, 3 = Don't Know, 2 = Disagree and 1 = Strongly Disagree.

Participants generally agreed that the Toolkit was easy to use (Q1). The significantly lower score for CS1 may have been due to the style of facilitation which was unique to the first study (see Section 7.5.8), involving extensive explanation of every section of the Toolkit. This, with hindsight after the first case study, was not repeated in the others as it was clear that this was both unnecessary and undesirable.

Table 22 Participants' responses to questions on the usability of the Toolkit.

Q.	USABILITY	CS1	CS2	CS3	CS5	Ave.
1	I thought the Toolkit was easy to use	2.40	3.75	3.67	4.00	3.45
2	I found the Toolkit unnecessarily complex	3.60	2.75	2.33	2.00	2.67
3	I think that I would like to use this Toolkit every time I perform a risk assessment	2.50	3.00	2.33	3.00	2.71
4	I would need the support of an expert to be able to use this Toolkit	4.67	3.00	3.67	2.50	3.46
5	The Toolkit covered all the relevant information to help me undertake risk assessments	3.50	3.75	4.00	3.00	3.56
6	The Toolkit goes into an appropriate level of detail to help me undertake risk assessments	3.33	3.00	4.33	3.50	3.54
7	The language used in the Toolkit is clear	3.17	4.00	4.33	4.00	3.88
8	The sections in this Toolkit were well integrated	3.50	3.50	4.00	3.50	3.63
9	There was too much inconsistency in this Toolkit	2.33	2.25	2.00	2.50	2.27
10	I found the Toolkit easy to work through	2.83	3.75	3.67	4.00	3.56
11	I found the language easy to understand	3.50	4.25	4.00	4.00	3.94
12	I found the examples helpful	3.83	3.75	3.67	4.00	3.81
13	Most people would learn to use this Toolkit quickly	2.17	2.75	3.33	4.00	3.06
14	I found the Toolkit cumbersome to use	3.50	2.50	2.33	2.00	2.58
15	I think that other people in the NHS would use this Toolkit frequently to aid performing Risk Assessments	3.00	3.50	4.00	3.00	3.38
16	I felt confident using the Toolkit	2.20	3.00	4.00	3.50	3.18
17	I needed to learn a lot of things before I could get going with the Toolkit	4.17	3.00	3.00	3.00	3.29

Similar results were observed for the second question (Q2). Regarding whether they would always like to use the Toolkit (Q3) the responses were neutral to slightly disagreeing. Since the participants were asked to respond to the questions regarding their view of both the Preliminary and Comprehensive assessments, the researchers agree that the Comprehensive assessment may not be appropriate or necessary for *all* risk assessments – indeed this was never the intention. One of the reasons for not wishing to use the Toolkit is likely to be the time pressures that staff are under. For example:

“I had quite a fair bit of flak this morning, and pressure from my colleagues to say, you know, I'm jeopardising clinical service delivery by leaving the ward.” [Consultant]

“We're too busy fighting the crocodiles to drain the swamp.” [GP]

Markedly different results for CS1 can be seen in the response to Q4, compared with the other case studies. This may also be explained by the analysis in response to Q1; as one participant put it: “I could not have used the Toolkit without support.” The researchers agree that, at least for the Comprehensive version of the Toolkit, the support would be required of an expert facilitator, and this was a significant finding for the study. With the exception of CS1, participants thought the language of the Toolkit was clear (Q7). There was a particularly strong focus on language issues in CS1, which may have led to this finding. For example, the phrase “Fault Tree Analysis” was criticised as it was feared the word “fault” might mean the method might be construed as blaming individuals.

The responses to the remaining questions tend to be positive, suggesting that the Toolkit was reasonably easily usable. Again, a similar pattern can be observed across most of the responses of a significant difference between the results from CS1 and the others.

7.5.7.5. Observations on utility of the Toolkit

Table 23 presents the findings from the evaluation forms, aggregated per case study. The reader is reminded that 5 = Strongly Agree, 4 = Agree, 3 = Don't Know, 2 = Disagree and 1 = Strongly Disagree.

Table 23 Participants' responses to questions on the utility of the Toolkit.

Q.	UTILITY	CS1	CS2	CS3	CS5	Ave.
1	The team was able to perform a PHA	4.00	4.00	4.67	3.50	4.04
2	I had a better understanding of the work process that was risk assessed	3.83	4.00	4.33	4.00	4.04
3	I became more aware of system-wide safety issues	4.00	3.50	3.67	3.50	3.67
4	I found a change in my perception of safety	3.50	2.50	3.33	2.00	2.83
5	I thought that it took too long to perform the risk analysis	3.80	3.00	3.00	3.00	3.20
6	Using the Toolkit would improve work practices	3.50	3.50	4.00	4.00	3.75
7	Using the Toolkit would improve safety in the NHS	3.50	3.25	3.67	4.00	3.60
8	Using the Toolkit would benefit the work of other people in the organisation	3.67	3.25	4.33	4.00	3.81
9	The PHA Toolkit would be useful in my work	3.67	3.50	3.33	4.00	3.63
10	I think that the team would have identified the same hazards and risks without using the PHA Toolkit	2.50	3.25	3.33	2.50	2.90
11	I think that the team would have identified the same hazards and risk in less time using other methods	2.67	2.75	3.00	3.00	2.85

It can be seen from Table 23 that the results are generally positive towards the utility of the Toolkit. Across the case studies, the Toolkit was viewed as being of benefit, being particularly helpful in assisting participants to better understand their work processes and system-wide safety issues. A selection of verbal and written responses to the Toolkit from a range of participants are presented below:

"Very realistic." [CS1, 4]

"These sessions are hugely beneficial; I've learned so much." [CS1, 6]

"Raised awareness of risks of [triaging?] and prescriptions late. Risks of having two different medicine stocks..." [CS1, 7]

"The need for a structured consistent approach is clearly helpful to enable contact and comparison with other risks and other trusts." [CS1, 1]

"It's evidence that you have weighed things up and you haven't just made a gung-ho decision... Not that you'd ever do that...!" [CS4, 1]

"If that [PHA] was something we did routinely we'd be sort of a four, automatically [moving up from a 3 on the safety culture assessment tool – note there are five levels, the highest being the most positive towards patient safety]." [CS1, 7]

"And I suppose for me, this is starting to raise a few things... So I [now] might be slower on the ward... You talk about attitudes and I think that's the main thing that I've suddenly had a change in! Actually this is quite important, and not because somebody's asked me to do it." [CS1, 2]

Despite this, it is intriguing that little change could be observed in the participants' perception of safety (Q4). Given the positive response towards the Toolkit, this might be explained by a pessimistic view of safety across the participants, which was only confirmed by using the Toolkit.

Participants, on average, only slightly disagreed that similar results could have been achieved without using the Toolkit, although opinions were somewhat evenly divided across the case studies. As one participant put it:

“Was it that we had multi-disciplinary people standing and thinking and was it nothing to do with risk assessment but more about multidisciplinary conversation...? Clearly there was a new conversation there.” [CS1, 6]

One of the frustrations of the case studies was that there was insufficient time for any of the PHA techniques to have been used comprehensively. It is perhaps no wonder that similar results might have been achieved, therefore. Another explanation, particularly in the case of CS3, is that the Toolkit may be of less use for more simple cases (in this case study, whilst initially complex, the scope was narrowed down sufficiently for it to be considered relatively simple), where the risks and possibly the solutions are obvious. In contrast, CS1 is relatively complex. As one of the participants stated:

“what you don't want is the local area that happens to have spotted it to sit round the table and sort it for themselves and improve it in their area. Because that will just add to the risk. Because they'll create new procedures and policies just in their patch and when the next person comes along they'll still be applying the generic one that applies everywhere else and it'll create havoc.” Until you do that [create an overview] you can't really understand how your role fits.” [CS1, 3]

Participants also only mildly disagreed with the statement that similar results could have been achieved in less time with other methods. This is perhaps a sign that there is no “magic bullet” to such healthcare problems – that such problems are difficult to investigate and solve, no matter what methods are used.

7.5.7.6. *Toolkit evaluation form – written feedback*

The following section describes the participants' responses to the remaining questions on the evaluation form, which also include further comments on the Toolkit's usability and utility. The responses are summarised from a review of all 15 evaluation forms. It should be noted that whilst the numerical feedback was completed for most of the case studies, the majority of the written feedback from was from the participants in CS1.

- **Do you think that the hazards and risks identified were realistic? If not, could you describe why you think so?** Almost without exception, the participants thought that the hazards were realistic. However, a few comments in different case studies were made regarding whether the system boundaries were placed in the right location, and the difficulties with assessing a system with so many variables.
- **Did the use of the PHA Toolkit reveal any significant risks of which you were previously unaware? If so, could you describe them?** There were mixed responses to this in CS1, probably because many of the group had been assessing risks in the same area for some time; some for several years. Those who had not been involved in such assessments did mention the novelty of some of the risks; including the downstream implications of their actions. A similar range of responses was observed in the other case studies, where feedback was available. For example, a participant noted that the process flagged up a particular issue to be more important than originally thought.

- **Have you conducted risk assessments before? If so, could you please describe your experiences specifying the name of any method(s) used and any problems encountered?** There were few responses to this question, with the majority of these mentioning using the Trust's risk matrix or taking part in a Root Cause Analysis. One participant mentioned FMEA and another had conducted simple risk assessments in a laboratory setting. Further examples were mentioned of clinical risk assessments on a patient by patient basis (e.g. using specific clinical tools such as falls management).
- **Have you used a Toolkit of a similar kind to this one (PHA Toolkit) before? If so, could you please describe it?** Across the case studies, it was clear that the Toolkit was a new concept although one commented that the overall steps in the risk assessment process were familiar to them. In some cases this was because they had not performed risk assessments before. Comments from two of the participants are reproduced below:

“because I’m almost 100% clinically based I don’t get to hear or experience any of this...”

“we never are taught to think about risk. You think about risk maybe at the end of the day, and you think, oh that’s happened. But every step you take, you don’t really have the time to think about OK I’m doing this, what are going to be the consequences.”
- **In the context of your job, what is familiar and what is new about the PHA Toolkit?** The concept of drawing a process map was familiar to a few of the participants, as was rating risks in terms of likelihood of severity. A participant commented that the logical stepwise methodology was familiar. Several participants mentioned that a structured, systematic and systems-wide assessment was a new concept, which was popular amongst the participants who mentioned this:

“I’d love to learn how to do some of this [PHA]. I’d love to learn to look at systems.” [CS1, 4]

“Coming back to where we have to look at it as a whole, if you’re the person writing the TTO discharge drugs, what you’re doing has a bearing on the work of somebody that you never see, out in the community, and unless you begin to have an appreciation of the how a whole thing links together, you can’t really make any progress.” [CS1]

“that’s what would be novel about this approach, because every other effort that has been made has focused on one aspect of it. That’s the whole point.” [CS1, 3]

“I guess the other thing is that because we’re all sort of finding it slightly difficult... it is completely new vocabulary and a different way of thinking, is that it just shows that we’ve never done this. Lots of people at lots of levels and why don’t we know about this? We should know about this!” [CS1, 7]
- **In your view, is any of the information presented inaccurate or incorrect? If so, could you describe it and specify the section where this was identified?** Four participants noted that there were no inaccuracies, with another stating that he/she was unsure, possibly due to the lack of other sources of information for comparison. A minimal number of comments were received on language issues, from participants in CS1, as discussed earlier.
- **Is any of the information open to misinterpretation? If so, could you describe it and specify the section where this was identified?** The importance was highlighted of using a facilitator, to help set the boundaries of the problem. There were also comments on the possibilities of misinterpreting the terminologies used. Others said that there was no information that they considered were open to misinterpretation. Other than this, no comments were received.
- **Are there any notable omissions from the PHA Toolkit? If so, could you describe what they are?** Four participants thought that there were no notable omissions from

the PHA Toolkit. Two more lengthy comments were received; one on how to manage any changes arising from using the Toolkit, and another on how to take into account specific clinical issues. However, both of these were judged by the researchers to be outside of the remit of the research project.

- **Do you think there is one type of analysis that the PHA Toolkit is better suited for (e.g. routine analysis of clinical risks)? Could you describe it?** One participant commented that a combination of risk analysis techniques is useful. Another two commented that the Toolkit was better suited for assessing ‘bigger risks’ whilst another stated that risks with fewer variables were more suitable given the short amount of time available for the analysis. Another stated that:

“I think it may be best applied to "systems" type risks. I.e. a care process or task function”
Similar observation from another participant in this case study.

- **What changes would you recommend to improve the PHA Toolkit?** Many participants wanted the Toolkit to include more examples, which was duly noted by the researchers. Another participant was keen to be educated further on risk assessment issues. Still others commented that more time should be dedicated for participants to read through the Toolkit.
- **Is there any other information or support you would need to be able to effectively use the Toolkit? If so, can you describe what these are?** It was suggested that the Toolkit would need to be “owned” by managers at the coal face before it would be used effectively. The participant had commented earlier that for the Toolkit to be introduced into the NHS effectively it would need to be marketed in such a way as to avoid it appearing like “yet another initiative”. Another participant noted the need to train users.

7.5.7.7. *Roll out of Toolkit*

The participants made a range of comments on how the Toolkit might be disseminated to the NHS, including whether it would be free, how staff might be made aware of it, and whether or not they would have a choice in using it. Concerns were raised in particular about the resources available to use the Toolkit, not just in terms of users but also who would facilitate such sessions. Warnings were given about trying to prevent it from being seen as “another directive, rule from above” by ensuring that staff understand *why* it is necessary. One suggestion to enable this understanding is to introduce mandatory training, although this received a mixed response from the participants in CS1 – some felt that mandatory training could be counter-productive.

“I never had a lecture on risk assessment or risk or anything like that. I doubt if anybody does. But actually that’s another potential outcome. We have all these spurious mandatory training sessions we have to go on about whatever it is, but not a mandatory one on risk. Well, why not?... Why are we not taking that seriously?”

Another participant thought it important that any potential users would be fascinated with the process first. There were elements of such fascination in some of the participants, who were particularly interested in the way in which the PHA Toolkit could assist people to think in a systems way:

“I think your documents are really excellent. But I just think that if they’re presented to people without being fascinated then that’s quite challenging...”

7.5.7.8. *Other issues*

Another issue raised in one of the case studies was the importance of supporting staff, once the PHA process had led them to an understanding of the true level of risk in their system:

“This [risk assessment] is not in itself without implications, because if you raise awareness of what you’re doing, but have nothing to support the awareness that is raised [e.g. in providing more time for staff to complete tasks more thoroughly than they had done in the past] then that’s actually quite a tricky place to be, and has ramifications. In the report to the Department of Health, it’s not about saying more money... it’s just about if you move people from place A to place B but there’s nothing else that has changed, the practitioners are quite vulnerable... And they will stop doing what they were happy to do the day before because they’re now concerned.”

Change management: importance of ensuring the right people (i.e. those who many need to change practice) are in the room for the analysis, so they can see the problems first hand, and therefore be more convinced of the need for change.

7.5.7.9. *Limitations in evaluation method*

A number of limitations were noted with the case studies:

- An enormous volume of data was collected: opinions, past experiences, verbal exchanges, observations on current practice, difficult decisions, etc. Due to the size and nature of this, these data were difficult to analyse.
- The process was confounded by a wide range of variables, which made it difficult to form firm conclusions and to make comparisons between the case studies. These variables included the following: specific characteristics of the system (e.g. contribution of human error and general complexity in terms of the number of elements and links between them), the staff attending (including the number of staff, their skills, their knowledge of the system and the nature of any professional relationships between them which may have inhibited making comments), differing personal agendas giving rise to conflict in which part of the system to assess, the amount of time available (both for each complete case study and for different elements of the assessments), the amount of time spent on the different sections of the Toolkit, whether particular sections of the Toolkit were used (e.g. particular PHA methods), the degree of iteration between one element of the Toolkit and another and the amount of time spent on giving feedback on the Toolkit, and the quality of this.
- Despite the scope of each case study having to be narrowed further and further during the meetings due to a lack of time, none of the case studies were “completed” – every case study ran out of time before a risk assessment could be finished; let alone any solutions to problems being identified. Even the Preliminary Risk Assessments suffered from a lack of time available. It is suggested that efficiency could be vastly improved with experienced facilitators and participants, but it is still likely that a PHA would take more than a day’s time. Whilst this lack of coverage across the system might have been frustrating for both the facilitators and the participants, this is a usual occurrence in risk assessment. In this way, small parts of the system can be analysed comprehensively and the total system can be analysed piece by piece, ensuring appropriate coverage.
- It was unclear whether the triaging process in the Preliminary Risk Review performed its function as intended – there may be cases when the focus for a Comprehensive Assessment is known before conducting a Preliminary Risk Review, and there may be cases where a Preliminary Risk Review changes the users’ minds on what should be investigated further.

- It was not possible to test the PHA method selection strategy reliably, since it was finalised after the case studies were complete and the methods (and diagram types) were selected based on the experience of the main facilitator, not using the strategies directly.
- An experienced facilitator is absolutely essential. Experience is necessary both in matching the technical demands of the different process mapping and PHA methods, but also in all the usual general facilitation skills.

7.5.8. Significant changes to Toolkit / facilitation process between Group 1 and Group 2 case studies

All of the case studies were intended to be conducted over two or three sessions (details of timings can be found in Table 35 in Section 10.9.5 in the Appendices). Whilst both Groups followed these timings, subtle differences were intended to take place between the two, as shown below:

- Group 1: All participants invited to all sessions. Group 2: Case Study Lead and minimal number of staff invited to first session; remaining staff invited to remaining session(s).
- Group 1: Facilitator explains the Toolkit by outlining each page and its intentions and guides the Participants through each page. Group 2: Participants work through the Preliminary Risk Review with minimal input from the Facilitator (only to answer questions and to steer if progress becomes significantly awry). Facilitator guides participants throughout the Comprehensive Risk Review.

Thus, the intention was that both CS4 and CS5 would follow this modified process. In actual practice, due to risks specific to CS5, the participants and researchers preferred to divert from the original plan, and for the facilitator to take a more leading role than originally intended. As was described earlier, in CS4, two participants attended the first session and received minimal input from the facilitator and researcher.

Further details of suggested changes to the facilitation made during the case studies are given in Table 38 in Section 10.9.7 in the Appendices. As a result, a review within the PHA Research Team resulted in a number of conclusions based on the observations, and changes to facilitation (see Table 24). It should be noted that changes marked with a * were effected immediately after the CS1.

Table 24 Changes to facilitation practice.

Conclusion from Group 1 case studies	Suggested change
In particular for the Preliminary Review, too much time was taken to fill in each of the pages on the templates due to extensive discussions between the participants over the nature of the problem, discussions over office politics, sometimes lengthy anecdotes, the provision of feedback on the usefulness of the Toolkit, and detailed explanations of the process by the lead facilitator.	<p><i>Facilitation:</i> Explain less about the specific details of the PHA process and allow more time for discussing the actual problem.*</p> <p>Run the Preliminary Review with fewer participants, and the Comprehensive Assessment with the full team.</p> <p>Avoid explaining the Process Mapping and PHA Method Selection Toolkit chapters and select the PHA methods ourselves, based on asking questions from the selection processes from each of these chapters.*</p> <p>Try to discourage the participants from speaking for too long if what they are saying does not relate directly to the case study.*</p>
It was only possible to assess a very small part of the healthcare system suggested for analysis, due to reasons stated above.	<i>Facilitation:</i> Spending less time on the Preliminary Review should allow more time to cover a greater part of the system in the Comprehensive Assessment.*
The increased awareness of risk, particularly during CS1, led to the need for staff support being highlighted.	-
The mechanisms for feedback (audio recording, participants' note taking, participants' annotations on their individual copies of the Toolkits, and evaluation sheet) were effective in eliciting results. However in one case study, little feedback was obtained.	<i>Facilitation:</i> Continue to remind participants to give feedback.

7.6. Summary

The PHA Toolkit was evaluated in many different ways, both internally within the PHA team and externally with NHS staff. The evaluations with NHS staff took the form of a review with a forum of risk managers and two separate informal reviews with a risk manager and a Patient Champion.

In addition, five case studies took place with NHS staff, across a range of NHS settings and scenarios. The observations point towards an unsafe healthcare system with little systematic and system-wide investigation of risk related issues. None of the participants had seen anything similar to the Toolkit before; a similar finding to that observed during the evaluation of the Toolkit with the forum of risk managers.

The case studies were invaluable in providing feedback on both the usability and utility of the Toolkit. The responses were positive, with some of the strengths of the Toolkit perceived to be its ability to tackle systems-related issues, that it was easy to understand, that it improved the participants' understanding of the system and that using it would lead to improvements in safety. By following a structured process it also provides a mechanism to help document and prioritise problem solving, and to identify who is needed to assist with this.

One of the most common findings was a need to constantly narrow down the scope of each study by considering an ever more specific scenario. Despite this, and the allotted time of around 8 hours per case study, it was not possible to analyse thoroughly any of the systems under investigation – considerably longer than a day would have been necessary. Whilst assessments were perceived to be systematic but time-consuming, it was unclear as to whether alternative methods to the Toolkit would have been more helpful or more efficient. PHA is not a magic bullet – it still relies on the knowledge and skills of the participants and the facilitator. Indeed, both the case studies and the review with risk managers underscored the need to train expert facilitators if the Toolkit is to be rolled out into the NHS. The need for a trained facilitator led to the following Recommendation in Chapter 9:

- Train a limited number of facilitators initially (Recommendation 3). Importance: High.

Further Recommendations in Chapter 9 have been based on the limitations in conducting the case studies, and the desire to create further evidence of the efficacy and ease of use of the Toolkit, as follows:

- Conduct further verification of the Toolkit (Recommendation 10). Importance: Medium.
- Link the Toolkit into a reporting system (Recommendation 11). Importance: Low.
- Conduct a review of SUI Reports (Recommendation 12). Importance: Low.
- Investigate the suitability of the Toolkit in different scenarios (Recommendation 13). Importance: Low.

The case studies raise major questions as to whether the NHS is ready to devote the resources necessary to performing comprehensive risk assessments. As one participant put it, "we are too busy fighting the crocodiles to drain the swamp." However, others believed the cost of a PHA to be paid for by the savings that might be brought about by doing it. The NHS must ask itself whether it is ready to "spend to save":

"The idea of PHA within the NHS is clearly laudable. Anything that moves our view of medicines risks from reactive – "why things went wrong" – to proactive – "how we can ensure a safe proactive environment" – is to be applauded, but requires a major cultural change!"

8. SUMMARY AND CONCLUSIONS

8.1. Overview of the PHA project

This project aimed to assess the suitability of Prospective Hazard Analysis for use in the NHS. It aimed to develop a Toolkit which would contain a range of PHA methods and to test this Toolkit across a range of settings and in different scenarios in the NHS.

In order to develop this Toolkit many healthcare professionals and a number of risk experts were consulted through interviews and workshops to understand their requirements and to seek advice on what form such a Toolkit might take. A literature review was also conducted to assess the usability and utility of a range of PHA methods, and to learn lessons from their application in healthcare. These activities formed the earlier stages of a “design approach” to developing this Toolkit. Later stages of the design approach involved a variety of evaluation activities which took place in parallel with the development of the Toolkit, including interviews, workshops and case studies with NHS staff.

8.2. Current practice and requirements capture

To gauge the potential benefit of PHA, the research began by gaining an understanding of the level of safety in the NHS. Despite the efforts of many highly professional staff, many “systems” problems exist, which contribute to a significant level of error. Since many other high-hazard industries use PHA techniques routinely, early research activities also investigated the nature of such practice, including why they use particular techniques and what constitutes “good practice” in these areas.

In order to identify the potential for the introduction of PHA methods into healthcare by understanding current practice, interviews, workshops and a literature review were conducted. Relevant documents describing risk management practice were identified, both at a national and local level, and were perused for advice on using PHA in healthcare. Interviews with a range of NHS staff and workshops specifically with risk managers also helped to understand how risks are managed in the NHS at present.

A clear picture emerged, which showed that the NHS – and indeed healthcare outside of the NHS – appears to use PHA techniques rarely, if at all. This lack of awareness of the importance of PHA was evident throughout the research, and at times presented barriers for undertaking case studies, and may present similar difficulties when the Toolkit is rolled out. Furthermore, little evidence was found of risk assessment practice which is proactive, systematic and systemic in nature – characteristics of risk assessment that would be expected to be seen in other high hazard industries. Thus, this part of the research identified a significant gap in the use of PHA.

Additional problems were identified as part of the typically reactive nature to risk management, such as the subjectivity in using risk matrices and anecdotal evidence of inappropriate manipulation of the numbers, and the length of time taken to perform Root Cause Analysis.

This assessment of current practice also aimed to identify NHS staff's attitudes toward PHA, and the existence of barriers to its uptake. Staff appeared to be cautiously positive towards the concept of PHA, but were wary about its adoption into healthcare practice, particularly given the time pressures that they tended to operate under.

These research activities helped produce a list of 54 "formal" requirements and numerous "informal" requirements for the development and dissemination of the Toolkit. The formal requirements were influenced heavily by the Diffusion of Innovation literature, and formed a number of recommendations for the dissemination of the Toolkit into the NHS.

8.3. Toolkit development and evaluation

Continuing the user involvement, and based heavily upon the requirements that were generated throughout the research project, a Toolkit was developed and tested in an iterative fashion through a number of research team reviews and assessments with NHS staff, including five case studies.

The development process addressed questions such as which PHA methods should be included in the Toolkit (10 methods were selected), and how might they be selected for particular use in the NHS. A number of significant findings were made.

- 1) It was realised that it was critical to consider a range of questions, prior to the selection and use of any PHA methods. Whilst there is a danger that risk assessments in the NHS may begin with "hazard identification", in the case of the Toolkit several steps were introduced prior to hazard identification, to ensure the consideration of these questions. These questions address issues such as the aims and scope for the assessment, and require the consideration of risk assessment at a "systems" level, with the intention of helping the user to address systems problems.
- 2) In ensuring that the Toolkit was capable of addressing such systems problems, a significant part of the PHA process is devoted to process mapping. On these lines, it was realised that several process mapping techniques should be presented as options, since different techniques specialise in representing different types of information – a one size fits all process mapping technique cannot address sufficiently the range of problems experienced in healthcare.
- 3) The Toolkit was split into two parts. Both parts of the Toolkit introduced these questions, but the front part of the Toolkit (called a Preliminary Risk Review), was intended to be a relatively brief analysis to determine whether the second part of the Toolkit (called a Comprehensive Risk Assessment) was warranted. By splitting the Toolkit into two parts, this also allows users to use time efficiently by stopping the process where necessary, after the Preliminary Risk Review, answering one of the most important requirements of providing a balance between rigour and simplicity.
- 4) It was noted that it is quite possible – and may be quite appropriate – to use one or more different PHA methods, for the situation which is to be risk assessed. Different PHA methods have different strengths. However, it was believed by the research team that no single PHA method should always be used for a given situation warranting an analysis. We believe that answering the right question is considerably more important than choosing broadly the right PHA method, and that a variety of PHA methods may be suitable for solving any one problem.

- 5) In recognition of this point, whilst 10 PHA methods were selected for inclusion in the Toolkit, the Toolkit was developed in such a form to allow methods to be added to or removed from this list.

The Toolkit provides a crucial part of risk management, but should not be viewed as a substitute for the entire process: solutions for reducing risk may be presented, but it is up to the staff in the participating organisations to implement those actions and to monitor their efficacy.

At the start of the project we asked who might be the user of the Toolkit, and postulated that the main user might be Trust Risk Managers. However, we believe that the Preliminary Risk Review could be used by a wide range of NHS staff: from medics to managers. In contrast, we believe that the Comprehensive Risk Assessment requires an experienced facilitator to run the risk assessment. Such facilitators would require excellent general facilitation skills and also strong technical knowledge of a range of process mapping techniques (as described in the Toolkit) and PHA methods.

Five case studies were conducted across a range of settings in the NHS, involving over 20 NHS staff. We found that none of these participants were familiar with anything similar to the PHA Toolkit, but the majority rated its usability and utility positively. Some of the strengths of the Toolkit were perceived to be its ability to tackle systems-related issues and that it was easy to understand. By populating the “templates” that are part of the Toolkit with the results from the analysis, a documented summary is provided of the process, the risks in the system and any necessary actions to be taken to reduce risk to an acceptable level. Whilst the results were positive, a number of limitations were noticed. Perhaps the most significant of these is the need to narrow down the scope of the analysis in order to perform a thorough risk assessment in a timely fashion. Indeed, rigorous and comprehensive risk assessment requires a significant time commitment from NHS staff. It also requires suitable knowledge of the system, and hence it is essential that the right staff attend the risk assessment sessions – an issue which the Toolkit requires the user to give due consideration to.

8.4. A challenging process

Developing and evaluating the Toolkit was extremely challenging, both methodologically and practically. Whilst every intention was made to involve users at all stages of the process, gaining access to NHS staff was particularly difficult. Even when access had been granted, the amount of staff time available was extremely limited, despite in some cases the provision of clinical support fees. Given the necessary commitment of staff time to perform suitable risk assessments, this does raise the question as to whether the NHS is ready for PHA – an issue which we return to later in this Chapter.

In addition, it was felt by the research team that often the bureaucracy of gaining the permissions necessary to gain access to NHS staff were in some cases deeply disproportionate to the level of risk involved in conducting this study. Ethical, research and development, management and finally personal permissions were necessary. Given the lengthy nature of gaining such permissions, it was found that these somewhat stifled the flexibility necessary to conduct this research, particularly since the precise way forward was often difficult to predict. For example, developing and testing the Toolkit iteratively, whilst involving extensive user feedback, meant that there were inevitable unknowns in this process.

Finally, perhaps the greatest challenge of this research was the sheer number of variables to consider when planning it. These variables involved, for example, a multitude of PHA methods, a potentially infinite range of case studies and the skills and backgrounds of the participants. Given this, and the time limitations in each case study (in general, one day), a wider range and larger number of case studies would have been preferred. However, the difficulties of arranging these would have been prohibitive, both in terms of the time required and the subsequent cost, largely due to the bureaucratic burden. Given these variables, the multiple routes through the Toolkit, and the potential for iteration whilst using it, significantly meaningful comparative evaluation between the case studies was not possible. Since the Toolkit contained 10 different PHA techniques and six different diagramming types, with five case studies it was not possible to test all of these and even any of the PHA methods fully. Indeed, because there was insufficient time to generate actions through the case studies, and for these actions to be implemented into NHS practice, it was not possible to fully test the utility of the Toolkit. In some cases, even providing further funding to enable full clinical support would not have been enough given the pressures that staff were experiencing on the front line. In one situation, a case study had to be cancelled after extensive planning due to such time pressures. Another case study was terminated half way through, again due to front-line pressures on the participants. The lack of time available meant that it was necessary to test the Toolkit largely on its face validity.

8.5. The suitability of the PHA Toolkit for the NHS

We believe that there is no magic bullet for high-quality risk assessment – this is driven inevitably by gaining an excellent understanding of the system and the questions the assessors are asking, and this takes time.

8.5.1. Limitations of PHA in the NHS

We believe that there are number of limitations in applying PHA to the NHS. These involve the following:

- **Availability and accuracy of data and information.** During the assessment of current practice, a number of participants highlighted the difficulty of conducting accurate risk assessments without reliable data. This may, for example, mean that it is difficult to make comparisons between one risk and another, and to make decisions based on this. Several participants commented that the Trust risk matrices could be used as a political tool by “massaging” or “inventing” the numbers. Okoroh *et al.* in a review of business risks faced by purchasers of support services in the NHS states that the diagnosis of risk suffers “severe limitations” due to the scepticism towards the reliability and accuracy of the judgements [Okoroh *et al.*, 2002]. On the positive side, however, the fact that at least some discussion takes place over the numbers means that the nature of the problems is at least being considered. This problem may be overcome, at least partially, through additional clinical audit and more robust and detailed reporting and analysis of incidents.

Data aside, a similar problem may occur regarding information, in that the NHS does not have the same formality in its development and maintenance of system descriptions as compared with other high hazard industries. However, other activities such as care pathway mapping, may help relieve this problem.

- **Complexity.** Each of the five case studies demonstrates the complexity of the healthcare system. To manage this, in each case study it was necessary to reduce the scope of analysis considerably. If these are indicative of the situation in general in healthcare, this will mean that proper risk assessments will either take a great deal of time or can only cover a very small part of the system in one attempt. However, it should be noted that, by taking systems approach and then narrowing down the scope, the area of analysis can be identified precisely, meaning that later analyses can “fill in the gaps”. There is no reason to believe that healthcare is fundamentally different from other similarly complex systems that include human behaviour. These other systems are successfully assessed. It should also be noted that whilst at present analyses may take a considerable length of time, as the body of risk assessment increases, so the level of further analysis required to undertake additional assessments may reduce. Thus, a key obstacle to the uptake of methods may be the lack of previous use of the methods.
- **Process variability.** One of the great challenges for evaluating the Toolkit was in coping with process variability. This seems to be prevalent in healthcare and may be undesirable from a risk perspective. For example, risks might be at one level during the day and at an entirely different level at night or at the weekend. Variability occurs both at a micro level (different staff, different patients, etc.) and also at a macro level (new services, targets, procedures, etc). Compounding this problem, such changes may not be recorded to the extent that they might be in other high-hazard industries through a change-control process. Risk assessments need to take this variability into account. In the case studies, this was again tackled by analysing a particular situation at a time. Risk assessment of all process variants is likely to be too costly, as would be the assessment of a base-line example and comparison to variant processes. Nonetheless the reduction of variability is important and a risk-based evaluation built upon a mapping of the processes is a useful approach to facilitating the level of discussion that might lead to a unified, or at least less variable, process.
- **Current risk management practice.** The level of understanding of risk and risk management within healthcare is varied. The use of risk matrices has the potential to hamper the uptake of risk assessment methods as it is frequently seen as a means of risk assessment rather than its real contribution, which is simply a means of representing and communicating the results of a risk assessment. In particular, it is essential that there is recognition that risk assessment (the focus of this project and the Toolkit) is not equivalent to risk management. Instead it is a necessary element of risk management, but must be supported by an effective risk management process that can identify, prioritise, resource, track, assess and review risk treatments. It is not appropriate for this project to consider risk management within healthcare, but the indications from the case studies and other elements of the present research are that healthcare is significantly behind most other high-hazard industries in terms of risk management. Without effective risk management, the benefits of PHA will not be fully realised. However, this is not a reason to abandon PHA. Instead, it is a reason to adopt PHA at the relatively simple level represented in the Toolkit, as a means both of delivering short-term benefit in respect of better understanding of individual risk, and long-term benefit in respect of enhanced understanding of risk management.
- **The need to train specialist facilitators.** The Comprehensive Risk Assessment in the PHA Toolkit cannot be run without a trained facilitator, who is familiar with the application of a variety of process mapping techniques and risk assessment methods. In setting up the Risk Experts Workshop, the research team noted the scarcity of such

experts in the UK, and this raises the issue of exactly who would run such assessments if the Toolkit were to be rolled out into the NHS.

- **Availability of resources.** It is likely that considerable resources would need to be made available to perform PHA. The quality of the process is dependent upon the collective knowledge of those performing the PHA, and may suffer greatly if an insufficient range of participants is chosen, especially if the assessment is conducted on a system-wide basis. A potential barrier to the uptake of PHA is the impossibility of predicting precisely how long it will take. This means that convincing an analysis team to perform a PHA may be an uphill battle – saying “as long as it takes” (which may be entirely acceptable in some other domains outside of healthcare) is unlikely to wash in the time-starved NHS. Indeed, a greater (and entirely understandable) priority is the minute by minute delivery of care.

On a positive note, documents such as *A first class service: Quality in the new NHS* highlight the possibility “spend to save” [DH, 1998]:

“There is a view that high quality care costs more money. But this fails to recognise that poor quality is itself costly. Operations that need to be re-done, patients who need to be re-admitted within weeks or months, infections picked up on wards, unnecessary or inappropriate treatments, complaints and litigation, might all be reduced with higher quality care.”

Less positively, despite the recognition of the spend to save concept, the Diffusion of Innovations review in Chapter 5 stated that “spare resources to channel into new projects” would be needed for successful introduction of innovations such as the Toolkit. Convincing senior managers to release such spare resources, particularly given the anticipated spending cuts in the NHS over the coming years, will be a challenge for all but the most forward-thinking NHS Trusts. Yet, Sir Bruce Keogh, Medical Director of the NHS in England, has stated that: “Financial considerations are only one input into quality. Others include technical innovation, service redesign, and customer satisfaction and clinical outcomes... With imagination these inputs can extract a bigger bang for the taxpayer’s buck, elevating the quality bar higher than when pure finance is the dominant driver.” [West, 2009]. On similar lines, top of the recent Dr Foster assessments of NHS Trusts was University College London Hospitals Foundation Trust, whose CE has said that he had “made patient safety, outcomes and experience its top three priorities.” [West, 2009]. Again, with sufficient foresight, it may be possible to release the resources necessary to make service improvements.

- **Culture.** It was stated in Chapter 5 that successful innovations are those which are compatible with the values and needs of the users. Whilst it is suspected by the researchers that most NHS staff perceive a need to improve services, it is not clear to how easy it would be to persuade them that the answer lies in performing PHA. Additionally, it is suspected that the “blame culture” is still rife across the NHS, and this may discourage NHS staff from looking under the carpet for fear of personal repercussions. For example, in a review of the Toolkit by risk managers, a comment was made that:

“The biggest reason that people don’t undertake it [risk assessment] is a fear of the process.....fear of ‘If it’s all going to go wrong, it is all going to come back to me’.”

8.5.2. Benefits of PHA in the NHS

Despite these potential limitations of using PHA in the NHS, we believe that the Toolkit provides the following benefits:

- Since it describes a step-by-step process, it assists the user to be systematic (and

therefore comprehensive and thorough).

- In addition to being systematic, the PHA Toolkit enables the user to conduct a systemic analysis, meaning that a “systems” understanding can be gained. The process mapping step, although difficult, helps direct analysis effort onto the right part of the system, and to tackle the right questions in a time-efficient way. This also helps the user of the Preliminary Risk Review to identify who might need to take part in any Comprehensive Assessment, meaning that there is the potential to tackle issues which are outside of the initial user’s control. The “professional / organisational silos” problem was stated many times during the research team’s contacts with NHS staff.
- The screening process and the fact that the Toolkit has a simple “front end” addresses the obvious need for simplicity and assists prioritisation to minimise wasted time.
- As the outputs from this process are recorded in templates, this provides an auditable mechanism for convincing managers, or the Trust Board, of a business case.
- There was some evidence of a change of attitude observed in some of the participants during the case studies, because they were beginning to consider the system in a different light; perhaps realising the common ownership of the system across NHS staff.
- Unlike when conducting a root cause analysis, which may take place when events are particularly raw, PHA has the advantage of considering events which may not yet have happened, and hence may promote openness amongst staff and the resultant ability to change systems.
- The PHA Toolkit is an adaptable process, in which PHA methods can be added or removed. This adaptability, according to the Diffusion of Innovation Literature, can allow the complexity of the toolkit to be somewhat adjusted, to suit the needs of individuals or organisations.

8.6. Should the NHS use the PHA Toolkit?

We believe that the answer to this question is yes, but *whether it will* lies in whether the right people in the NHS can be convinced of the potential benefits of the Toolkit versus the costs of not using it.

Many medical errors are caused by systems problems, and the Toolkit has been designed to tackle these. However, it is suspected that the concept of “spend to save” is rarely popular; even less so at present with the anticipated cost savings necessary in the NHS over the coming years. Without further financial support to release staff from front-line duties, the Toolkit may not be adopted as much as it perhaps should be.

However, we believe that the Toolkit may be just as applicable to enabling efficiency savings, and for prioritising spending in the NHS, as it can be for creating improvements in patient safety, without unduly compromising the quality of care. If this can be demonstrated, this may be just what is required.

At this stage of the PHA research and given the limited number of evaluation case studies, these are necessarily value judgements. Further evidence must be collected of the Toolkit’s effectiveness to maximise its chance of success for integration into the NHS and to strengthen the robustness of these findings. The following Chapter considers a number of Recommendations to develop and evaluate the Toolkit further.

9. RECOMMENDATIONS

This research has led to four groups of recommendations: for introducing the Toolkit into the NHS; for further changes to the Toolkit; for further feedback on the Toolkit; and for future research. Each group contains several recommendations, and each is given a rating of the importance of following it, according to the PHA team. Recommendations have been derived from the observations made during the research, the Diffusion of Innovations literature, the "formal" Requirements listed in Section 5.4.7 and other less formal recommendations for the development of the Toolkit, which have been left unresolved. It should be noted that many of these requirements are mutually reinforcing, and so the more requirements that are implemented, the greater the likelihood of the PHA Toolkit being a success.

9.1. Recommendations for introducing the Toolkit into the NHS

Whilst actual dissemination of the Toolkit was outside the scope of the project, one of the aims of the research was to give due consideration to how such dissemination might take place into the NHS. The following recommendations are based largely on the Diffusion of Innovations literature described in Chapter 5.

Build up an evidence base of Toolkit use (Recommendation 1)

Importance: High

Source: Chapter 5

One of the needs identified by the Diffusion of Innovations literature was that the Toolkit should have a "highly observable benefit". The feedback on the Toolkit, which forms part of this observable benefit, was generally neutral to positive, but there remains a need to strengthen the evidence base of its effectiveness in healthcare. For example, it is clear that using the Toolkit takes a considerable amount of staff time. Further evaluation is needed to see whether any recommendations from using the Toolkit are able to, for example, recoup the cost of evaluation. Collecting this evidence will take time and require investment from NHS staff, which leads to Recommendation 2.

Disseminate the Toolkit through a UK Agency (Recommendation 2)

Importance: High

Source: Chapter 5

At a meeting on 30 June 2007 with a senior employee of the NPSA, it was strongly recommended to members of the PHA team that the introduction of the Toolkit be tied into a programme within the NPSA or NHS Institute.

Several of the formal Requirements (Section 5.4.7) regarding dissemination may be satisfied by this. Utilising the high profile of such an agency should assist ease of access to the Toolkit (Requirement 47). An agency with good connections to a range of NHS staff may also help "champions" to be identified who may positively influence the adoption of the Toolkit (Requirement 46).

Requirement 49 stated that the Toolkit should be introduced in a coordinated and structured way; a process which may well also require the support of an organisation of sufficient size.

Requirement 48 specified that the Toolkit should be free; this may be easier with the backing of an agency, which may also be able to run training courses for any facilitators, which leads to Recommendation 3.

Train a limited number facilitators initially (Recommendation 3)

Importance: High

Source: Chapter 7

Earlier chapters have specified the need for trained facilitators to run the risk assessment sessions. This finding was confirmed in particular through the case studies (Chapter 7). These individuals would constitute an expert resource to be called upon when required (Requirement 52). We anticipate that the facilitators will require excellent general facilitation skills, as well as the obvious technical skills necessary to utilise different PHA methods. Given the difficulties experienced by the PHA team in identifying risk experts for the Risk Experts Workshop (Section 6.2) it is likely that a considerable amount of training will be required. Work during this project with health and safety and risk managers suggests that these individuals may have some experience of using these methods, but it is unlikely that they will be familiar with several PHA methods.

In order to enable the Toolkit to be rolled out on a larger scale across the NHS, it may become necessary to provide more widespread training, albeit of a general risk assessment nature (Requirement 53). This may assist the training of further facilitators in the future.

Use the Toolkit initially in specific areas (Recommendation 4)

Importance: Medium

Source: Chapter 5

This Recommendation links closely with Recommendation 1. Requirement 45 stated that the Toolkit should be introduced initially at pilot sites. These sites may be helpful for establishing this evidence base. Given the need for “highly observable benefit”, case studies with significant potential benefits should be chosen. In the previous chapter, it was stated that the NHS will need to introduce significant cost savings in the near future. A risk assessment of such initiatives might constitute one such pilot case study area. Another area which might warrant initial attention is the Commissioning process of care pathways, which may have the advantage of a ready-made process maps. The process of case study selection (Chapter 7) also highlighted a variety of pragmatic needs such as finding participants with sufficient resources and a desire to engage with the process.

Set up a PHA Web site (Recommendation 5)

Importance: Medium

Source: Chapter 5

Requirements 51 and 54 stated that outputs from PHAs should be shared (albeit with due caution) across and within organisations to enhance learning of safety lessons. The IHI maintains a web site which provides complete instructions for conducting an FMEA and enables the user to create an electronic log of demographic and study data, which can be shared with others⁴. We recommend setting up a similar Web Site for the PHA Toolkit.

⁴ <http://www.ihl.org/ihl/workspace/tools/fmea/> (Accessed 27 January 2010)

This also would provide the opportunity to satisfy Requirement 50, which suggested that an online moderated Forum be set up for users of the Toolkit. This would allow experiences of using the Toolkit to be shared, including feedback on its usability and effectiveness (which may assist further Toolkit development) as well as the results from using it. By providing the Toolkit in electronic form, this might also enable it to be free of charge (Requirement 48).

9.2. Recommendations for changes to the Toolkit

Add worked examples to the Toolkit (Recommendation 6)

Importance: High

Source: Chapter 6

The PHA Toolkit presents an example of a completed template in the Preliminary Risk Review. However, it was found from the case studies (and research earlier in this project) that participants would have preferred "worked" examples, both for the Preliminary Risk Review and the Comprehensive Risk Assessment. A worked example could include extensive annotations on the entries in the templates, for example explaining a rationale for the content and describing potential pitfalls for each section. Gadd *et al.* have published advice on such pitfalls [Gadd *et al.*, 2004], and evidence such as this could be used to populate these examples.

Add advice on generating actions to the Toolkit (Recommendation 7)

Importance: Medium

Source: Chapter 6

The Toolkit did not include advice on generating actions, such as the ERICPD concept, described in Section 4.2.2. Alternatively, the need for this might be lessened by providing suitable training to the facilitators (Recommendation 3).

Generate more comprehensive descriptions of PHA methods (Recommendation 8)

Importance: Medium

Source: Chapter 6

In the interests of simplicity, the PHA methods descriptions were limited to a single page in the Toolkit. Whilst these descriptions may give users a flavour of the different methods, considerably more comprehensive descriptions are necessary in order to trained facilitators in the technical requirements of each of the methods.

Integrate further into current risk management procedures (Recommendation 9)

Importance: Low

Source: Chapter 7

During the evaluation of the Toolkit by the PHA team members, it was noticed that hazards in the screening process could be identified both from the process maps and from any previous failures that had been recorded. Specifying this in the Toolkit may help risk assessments to be more comprehensive and may speed the identification of hazards.

9.3. Recommendations for further feedback on the Toolkit

Conduct further verification of the Toolkit (Recommendation 10)

Importance: Medium

Source: Chapter 7

Complementing the case study results by testing the Toolkit in a very different way, independent risk assessment experts could be consulted to assess its usability and utility. Validation of the suitability of any recommendations from using the Toolkit could be gained by careful implementation of the results, followed by monitoring of the effects. Such work might also complement Recommendation 1. For example, in CS1 the HEART analysis indicated that a particular check would fail 1 in 14 times. This could be monitored by clinical audit to see whether such a result is accurate. As described in Recommendation 1, further tests could be conducted to compare the costs versus the benefits of the risk assessments.

The research team at Cambridge are involved in a large NHS-based research project over several years, which provides an excellent opportunity for such testing to be conducted.

We also think an independent evaluation should be conducted of the risks and benefits of introducing the Toolkit into the NHS. During the case studies one of the most striking comments from the participants was that should future risk assessments reveal unacceptable risks, who would provide the staff support necessary to bring about the changes to practice? Other similar risks (and benefits) might be revealed from such an assessment.

9.4. Recommendations for other further research

Link the Toolkit into a reporting system (Recommendation 11)

Importance: Low

Source: Chapter 7

Recommendation 9 indicated that adverse incident reports and hazard identification can be linked. Further links could be explored between the recommendations made from a risk analysis and the observations made through incident reports in actual practice. Indeed, Kessels-Habraken *et al.* have conducted similar research between prospective and retrospective methods for risk analysis in The Netherlands, which showed different but complimentary benefits of the two approaches [Kessels-Habraken *et al.*, 2009].

Other industries use prospective risk assessments to assist in accident investigation, since such analyses may have already predicted how such an error might occur. It is postulated that any PHA results from the Toolkit could be used to assist Root Cause Analysis investigations, which were observed in Chapter 4 to be lengthy and costly.

Conduct a review of SUI Reports (Recommendation 12)

Importance: Low

Source: Chapter 7

Similar to the previous Recommendation, an additional method for evaluating the effectiveness of the Toolkit would be to assess any accident investigation reports with

sufficient detail (for example reports of Serious Untoward Incidents or national enquiries) to investigate whether using the Toolkit could have predicted such incidents in advance. This would add weight to the evidence base of its effectiveness.

Investigate the suitability of the Toolkit in different scenarios (Recommendation 13)

Importance: Low

Source: Chapter 7

The Toolkit was designed to be highly flexible, and its successful testing across a range of case studies supports this. However, without conducting further case studies it is difficult to know whether the Toolkit is more suited towards one type of analysis than another. For example, complexity theory says that the interactions between different elements of the system generate new properties called " emergent behaviours" which cannot be predicted, no matter how much detail is known [Burton, 2002]. It is not known to what extent this is uniformly the case in health care, and whether the Toolkit can genuinely assist in predicting errors in a comprehensive fashion in all cases.

10. APPENDICES

(Please note that, with the exception of the References and the Toolkit, the order in which the Appendices appear is related to their relevant sections in the main body of the report).

10.1. References

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10.2. PHA Team meetings / Steering Committee meetings

The following table presents the dates of PHA Team meetings where the majority/all of the Team were present, and includes the dates of the Steering Committee meetings. This outlines the main discussion points and significant outcomes of each of these meetings.

Table 25 PHA Team meetings during the project

When	What	Notes / significant outcomes
17 Jan 06	Ethics application preparation. Review NPSA work on PHA. Set up Steering Committee.	Representative from NPSA in attendance.
21 Feb 06	Ethics application preparation. Review NPSA work on PHA.	Representative from NPSA in attendance. Consideration of measurement of utility of PHA methods.
6 Mar 06	Ethics application preparation.	Consideration of multitude of variables and details of study design.
14 Mar 06	Ethics application preparation.	-
5 Oct 06	Recruitment, Steering Committee planning, planning of initial case study.	-
24 Nov 06	R&D approval and planning for first case study. Consideration of a PHA methods workshop with risk experts. Suggestions for expanding network of contacts.	-
21 Feb 07	Review of initial case study. Steering Committee preparation	-
27 Feb 07	Steering committee meeting 1	Many observations on current practice in NHS, recommendations for next steps in project, including setting up Risk Experts' Workshop, and suggestions for requirements for PHA Toolkit. Realisation of the importance of process mapping to successful PHA. Discussion re different levels of PHA – from "lite" to "pro".
3 May 07	Review of research questions and results to date.	-

When	What	Notes / significant outcomes
4 Jun 07	Continuing development of requirements for Toolkit	<p>Realisation of the importance of distinguishing between the needs of users of the Toolkit and stakeholders (those who have some motivation for it being used). Consideration of “process description” (e.g. process map) and its influence on PHA method selection.</p> <p>Difficulty with providing justification for case study selection as specific details of each case study unknown, until each case study has been selected.</p> <p>Suggested requirements for Toolkit:</p> <p>PHA “lite” – engagement and usability.</p> <p>PHA “pro” – rigour, comprehensiveness of analysis, accuracy of results.</p> <p>Consideration of different types of case studies (PHA in planning a change / new service, PHA in primary care / acute care).</p> <p>Suggestion to start interviews with NHS staff to collect more requirements</p>
18 Jul 07	<p>Consideration of more case studies</p> <p>Plans for literature review of experiences of using PHA methods in healthcare</p> <p>Set up of project Web site.</p> <p>Planning for Risk Experts Workshop.</p> <p>Consideration of more interviews with NHS staff</p>	<p>Discussion re case study on transfer of anticoagulation services from acute care to the community.</p> <p>Literature review had been conducted by member of PHA Team, which focused on help in matching PHA methods to the situation to be analysed. No useful prior art had been found.</p> <p>Planning for a two-day Risk Experts workshop to learn how they select PHA methods, also considering selection of process mapping methods for PHA use.</p> <p>Initial shortlist of PHA techniques was made (FMEA, FTA, HAZOP, Likelihood-impact grid, SHERPA)</p> <p>Development of interview questions for formal interviews with NHS staff.</p>
20 Sep 07	Risk Experts Workshop preparation, including selection of broad range of scenarios.	
9 Oct 07	<p>Final preparation for Risk Experts Workshop.</p> <p>Preparation for Steering Committee 2</p>	<p>Due to there being too many PHA methods, and not having a tested approach for narrowing them down, we decided to assemble a shortlist of PHA methods.</p> <p>Reiteration of the importance of process mapping and its link to PHA. Need to consider more than just task analysis as a process mapping technique.</p>
1 Dec 07	6-month project freeze starts	
13 Dec 07	<p>Discussion on suitability of NHS’ risk matrices</p> <p>Consideration of what makes a good guidance document for the NHS</p> <p>Discussion regarding balance between rigour and pragmatism for running the PHA project, and also regarding the NHS’ use of the Toolkit – do we produce</p>	<p>Investigate what makes a good guidance document for the NHS.</p> <p>Consider PHA “Lite” as well as “pro” in the Toolkit.</p> <p>Need to gather more evidence of:</p> <ol style="list-style-type: none"> 1. Current PHA practice in healthcare, 2. PHA practice in other industries, 3. Requirements for Toolkit, based on needs of stakeholders,

When	What	Notes / significant outcomes
	PHA "lite"?	<p>4. Effectiveness of PHA in healthcare (including relative effectiveness of different stages of PHA, including process mapping, and the different PHA methods).</p> <p>5. Usability of the different PHA methods</p>
17 Jan 08	Project management issues and recruiting	-
31 Jan 08	Review of PHA literature review Project management issues	-
20 Feb 08	<p>Considering structure of PHA Toolkit</p> <p>Discussed possibility of second Risk Experts Workshop / Interviews to validate results from first.</p>	<p>PHA Lite front-end / Pro back-end. Or Perhaps use a what-if analysis first, and then qualitative approaches.</p> <p>Suggestions on selection of PHA methods.</p>
30 Apr 08	<p>Literature review (use of PHA methods in healthcare) results discussed</p> <p>Results from FMEA conference attendance discussed.</p> <p>Review of use of process mapping in healthcare.</p>	<p>Discussion on some links between different process mapping methods and PHA methods (e.g. Task Analysis and FMEA).</p> <p>It was suggested that it doesn't matter which PHA method is used in the NHS. We don't need a methods selection process.</p> <p>Risk matrix is a communication tool, not for risk assessment.</p> <p>PHA seen as an essential prerequisite / component of change management.</p> <p>Concerns expressed over lack of time in the NHS to perform PHA, and the need for further funding to enable it to happen.</p> <p>Importance of process mapping prior to PHA was emphasised.</p> <p>In the nuclear industry, they may consider avoiding analysing in detail areas that have low consequence should failure occur. They therefore operate a preliminary review process to weed out the areas which don't require further analysis.</p> <p>Importance re-emphasised of asking the right questions at the start of the risk assessment.</p> <p>Need to have more rigour in our choice of case studies (but we can't establish meaningful metrics to choose them).</p> <p>Conclusion to go ahead and start developing PHA Toolkit, and perhaps to test this prototype with risk experts.</p>
1 Jun 08	6-month project freeze ends	<p>Concluded the following features would be important in the Toolkit:</p> <ol style="list-style-type: none"> 1. Gaining engagement from the users. 2. Mapping the process 3. Hazard ID and screening of risks 4. Choosing the right PHA method and then doing it.
3 Jun 08	<p>Review of literature</p> <p>Recruitment of summer vacation students</p> <p>Plan presented for next steps in project</p>	<p>Normally in a risk assessment there will be some sort of preliminary analysis based on a description of the system and the purpose of the exercise.</p> <p>An out line of the PHA process was constructed, consisting of five steps: ID the problem, describe the process, screen using a preliminary hazard identification, select a PHA</p>

When	What	Notes / significant outcomes
		<p>method and plan the assessment (may need to describe the process again), conduct the analysis and then determine the action.</p> <p>We need to identify hazard identification approaches.</p> <p>Next steps in project include literature review on current practice in healthcare, continuation of interviews, development of PHA method descriptions, expansion of the PHA guidance.</p>
28 Jul 08	<p>Summary of results from meeting with health and safety managers</p> <p>Findings so far from student work.</p> <p>Further consideration of list of case studies.</p>	<p>Results from workshop with health and safety managers. Many documents influence risk management practice. The PHA concept produced widely varying responses, from very much in favour to those who saw little point in doing it.</p>
24 Sep 08	<p>Preparation for next Steering Committee</p> <p>Review of literature review results</p> <p>Preliminary results delivered from work (interviews and literature review) characterising current risk management practice.</p>	<p>Results show minimal guidance on use of PHA techniques in healthcare. Interviewees positive towards PHA, but seen as time-consuming.</p> <p>A “tiered approach” is necessary in the Toolkit, to take into account different users' needs.</p>
16 Oct 08	<p>Review of literature review results</p> <p>Review of shortlist of PHA methods</p> <p>Review list of possible case studies</p> <p>Forming front end of Toolkit</p>	<p>Shortlists of PHA methods were presented, historically throughout the project. Risk Experts Workshop shortlist of PHA methods had too many hazard ID methods and not enough risk assessment methods. Not enough HRA assessment methods. Scenarios chosen did not require quantification of results.</p> <p>The front end of the Toolkit needs to help the user to understand what they are trying to achieve, so that they try to answer the right question.</p> <p>Long list of 19 case studies reviewed.</p>
4 Nov 08	Steering committee meeting 2	<p>It was accepted that there will no longer be a complex matching process between PHA technique and healthcare setting, but a process that exists within the context of tiered guidance.</p>
13 Nov 08	<p>Categorisation of PHA methods to help modify PHA method shortlist.</p> <p>Interviews with stakeholders continuing.</p> <p>Consideration of other methods, in addition to case studies, for evaluating Toolkit.</p> <p>Consideration of evaluating guidance through interviews as well as case studies.</p>	<p>Categorisation of PHA methods into hazard identification, risk assessment and risk communication methods.</p> <p>Shortlist of 9 case studies.</p>
21 Nov 08	Development of PHA Toolkit case study evaluation strategy	<p>Consideration of whether to evaluate PHA Toolkit through case studies which involve testing the overall PHA process, the PHA methods, or both. Consideration of methods for</p>

When	What	Notes / significant outcomes
		evaluating usability and utility.
2 Dec 08	PHA Toolkit development meeting.	Consideration of three “trigger” situations: investigation as a response to failure, investigation prior to a planned change, a general “health check” on the system.
8 Jan 09	Review of PHA requirements, developed from interviews with stakeholders More work on case study selection strategy	The PHA Toolkit has become more than a collection of PHA methods, but a process by which the users can follow risk assessment, with the PHA methods in support.
5 Mar 09	Review of PHA requirements Development of Guidance Document review process Review of Toolkit development process Review of Toolkit evaluation strategy through case studies.	Toolkit development: Will include blank “Templates” for the users to fill in. Metrics considered for measurement of usability and utility of the Toolkit through the case studies, including: understanding of each specific step in the process, was the part of the system investigated, did use of the Toolkit give rise to changed perceptions of risk, etc.
9 Apr 09	Review of PHA Toolkit feedback from evaluation at Risk Managers Forum meeting	Evaluation with Risk Managers confirmed usefulness of two-stage review process for the Toolkit. It was agreed that a simple approach to the front-end of the Toolkit would require a template. There would then be a more rigorous assessment, to form the main part of the Toolkit.
21 Apr 09	Steering committee meeting 3	Minutes available.
14 May 09	Review of feedback from Risk Managers Forum Review of Substantial Amendment submission for ethics approval to allow for more case studies. Planning for case studies, and review of shortlist. Discussion on assessing usability of Toolkit. Review of process mapping section of Toolkit.	Review of HFMEA decision tree, and considering adding some elements to PHA Development process. The Toolkit will need to at a minimum dovetail into solution-finding strategies.
19 May 09	Consideration of PHA methods shortlist Further consideration of assessment method for usability/utility of the Toolkit Development of PHA Toolkit	PHA Toolkit will use templates, so users can make notes on their responses to each of the sections.
28 May 09	Development of PHA Toolkit Preparation for Risk Managers Forum review Number 2.	
11 Jun 09	Review of case studies list Review of current NHS risk management practice documents	Various comments on version 4h of Toolkit.

When	What	Notes / significant outcomes
	Review of PHA Toolkit	
16 Jun 09	<p>Meeting with Risk Manager and PHA project review afterwards.</p> <p>Review of case study planning progress.</p> <p>Review of PHA Toolkit.</p> <p>Review of current NHS risk management practice documents</p> <p>Further review of case study list</p>	
1 Jul 09	<p>Review of Toolkit development progress.</p> <p>Review of Toolkit against PHA Requirements.</p>	<p>Consideration of seven case studies: surgeon's journey (acute), communication of medicines information (primary/acute boundary), moving and handling of obese patients (ambulance), bowel cancer screening (primary / acute), patient admissions (mental health), commissioning of Out of Hours services (primary).</p> <p>Consideration of format of PHA Toolkit (number of volumes), PHA method selection framework.</p> <p>Decisions to split case studies into two groups – three case studies first, then a second group of three second, with time in between for modifications to the guidance to take place.</p> <p>Consideration of case study running and evaluation – e.g. how much intervention from the facilitator, when to ask for feedback, expected preparation by participants before first case study session.</p> <p>Planning for up to 20 1-1 interviews to evaluate Toolkit</p> <p>Many minor Toolkit changes suggested. More significantly, it was suggested that the Toolkit needed to encourage the users to “think in systems terms” more.</p>
20 Aug 09	<p>Update on case study progress, timing, running. Review of R&D permissions progress.</p> <p>Review of PHA Toolkit.</p>	<p>Need for two further case studies.</p> <p>Decision to run Group 1: Patient Discharge (acute), Risk Assessment of patients (mental health),</p> <p>Review of PHA method descriptions in Toolkit.</p> <p>Further planning for 1-1 interviews.</p> <p>Toolkit development: need for more introduction, decision to highlight areas that provide advice on filling in the templates.</p> <p>Review of diagram in Toolkit which shows how it fits together.</p> <p>Review of PHA Team-based evaluations of the Toolkit and feedback resulting.</p>
13 Oct 09	Review of case study findings so far.	Ongoing findings from Group 1 case studies and input into next version of the Toolkit, prior to conducting Group 2 case studies.
19 Oct 09	<p>Review of PHA Toolkit – conversion to book format.</p> <p>Discussion on patient involvement.</p>	Patient involvement was not possible due to the restrictions imposed by the ethical permissions for the study. However, it was agreed that a Team member would arrange to interview a patient representative about using the PHA Toolkit.
22 Oct 09	Review of case study progress and planning for Group 2 case	One of the main challenges in producing a table for selecting PHA methods is the flexibility with which PHA methods can

When	What	Notes / significant outcomes
	studies. Further development of PHA Method Selection process.	be used – each technique can be used in different ways, with different emphases on the components within. Also, there are not necessarily single agreed definitions of how to conduct each method. Furthermore, some methods may produce a very definite benefit, whereas others may indirectly produce such a benefit. This can be difficult to articulate in the table.
3 Nov 09	Review of PHA Toolkit, prior to Group 2 case studies.	Include more worked examples, in particular of how different types of process map can contribute to an understanding of the problem and the setting of scope. Move examples section at rear or Preliminary Assessment to front, by replacing existing blank templates on the right hand side of each page – users can use the separate handouts for templates. These, and other changes, are included in Section 6.10.

10.3. Literature review

10.3.1. Types of system map used in association with PHA methods

10.3.1.1. System representations for human error identification methods

Human Error Identification (HEI) methods are risk assessment methods which focus on human error and were originally used to identify potential errors that may arise as a result of man-machine interactions in complex systems. The majority of HEI methods, e.g. SHERPA, TRACER, HEART, etc, adopt Hierarchical Task Analysis (HTA) for their system description. Figure 42 shows a hierarchical task analysis for operating an overhead projector ([Kirwan and Ainsworth, 1992]). Hierarchical task analysis produces a hierarchy of operations – things which people do to attain goals – and statements of conditions. It focuses on steps required by humans to complete the given task. Hierarchical descriptions can be developed in as much detail as is necessary to deal with a particular task.

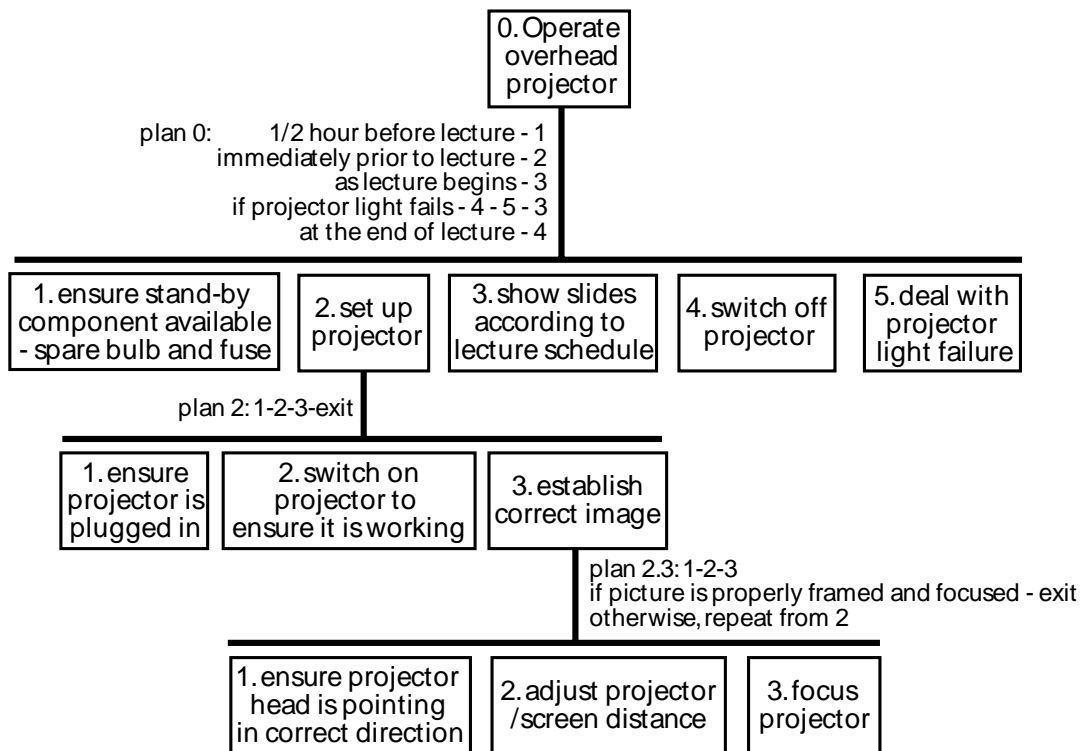


Figure 42 HTA for operating an overhead projector (comparable to task diagrams in the PHA Toolkit)

10.3.1.2. System representations for HAZOP

HAZOP is an acronym for Hazards and Operability Analysis and originated from the chemical industries. Although originally applied to chemical plants, its application has been extended. It is a highly structured hazards identification tool and simulates abnormal situations by using guidewords applied to parameters and operations to create deviations. [Kletz, 2006]. The guidewords are applied to any variables of interest such as flow, temperature, pressure, and time.

HAZOP collects applicable documents and drawings to better understand a process from different perspectives such as piping and instrument diagrams, process flow diagrams, utility flow diagrams, layout drawings, etc. As illustrated in Figure 43, Piping and Instrument Diagrams (P&IDs) are the schematic illustration of the functional relationship of piping, instrumentation and system equipment components, without showing detailed flow parameters [Hyatt, 2003]. Base on the P&ID, the guidewords can be applied to those functional relationships.

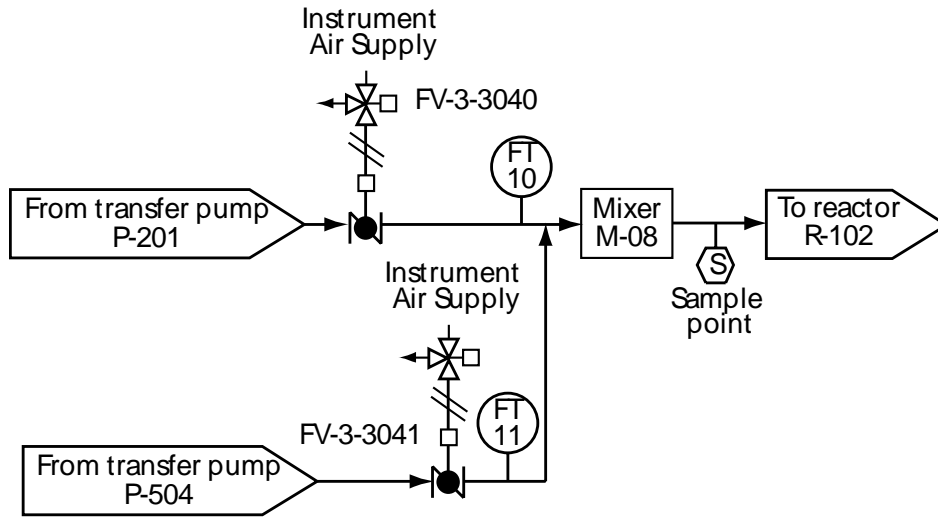


Figure 43 Piping & Instrumentation diagram (simplified) [Hyatt, 2003] (comparable to flow diagrams in the PHA Toolkit).

On the other hand, Process Flow Diagrams (PFD), illustrated in Figure 44, show the relationships between the major components in the system and include a table of process design values, e.g. flow pressure, temperature and rate, in different operating modes, typically minimum, normal and maximum [Hyatt, 2003]. In this case, the guide words can be applied to the flow-related attributes.

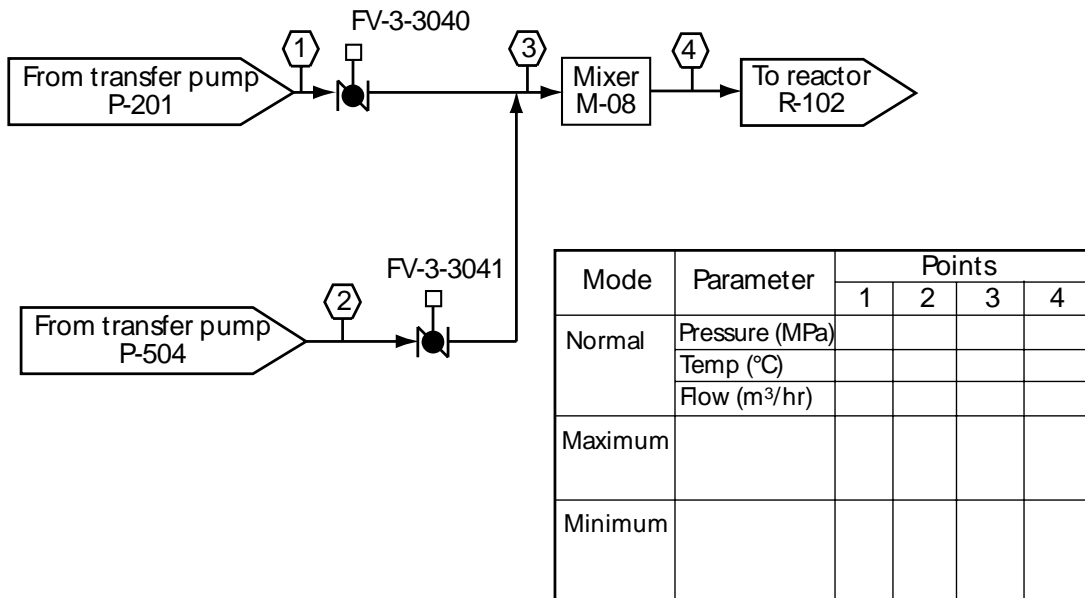


Figure 44 Process flow diagram (simplified) [Hyatt, 2003] (comparable to communication diagrams in the PHA Toolkit).

HAZOP was also applied on the basis of context diagrams, data flow diagrams and state transition diagrams to describe a human-machine system [Redmill *et al.*, 1999]. Figure 45 shows a context diagram for a vehicle collision warning system. The guidewords, in this case, can be applied to data or control flows of the system.

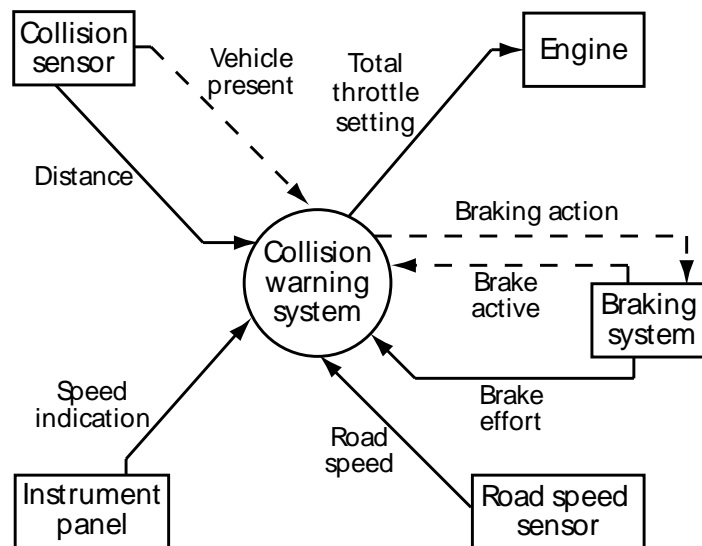


Figure 45 Context diagram for a collision warning system [Redmill et al., 1999] (comparable to communication diagrams in the PHA Toolkit).

10.3.1.3. System representations for FMEA

Another analysis method called Failure Mode and Effects Analysis (FMEA) was developed by reliability engineers to permit them to predict equipment reliability and was widely used in the aerospace and automobile industries. The first step in an FMEA is to identify and list all components and their failure modes. For each failure mode, the effects on all other system components are determined along with the effect on the overall system. Then the probabilities and seriousness of the results of each failure mode are calculated.

The following three diagrams are commonly used with FMEA to produce a system description: process flowcharts, functional block diagrams and reliability block diagrams [DYADEM, 2003b]. These diagrams are normally used to identify the failure modes of different elements of the system and the effects of the failure modes.

First, process flowcharts (Figure 46) provide a clear picture of the process and allow users to identify the main sequence of activities easily.

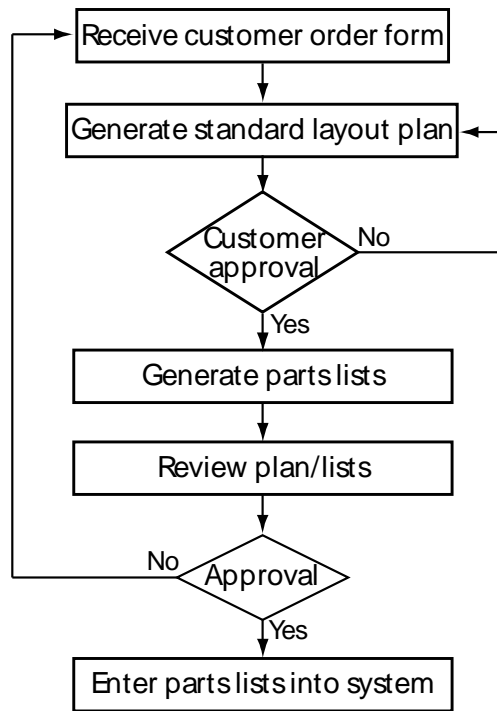


Figure 46 Process flowcharts for order entry [DYADEM, 2003b] (comparable to flow diagrams in the PHA Toolkit).

Functional block diagrams (Figure 47) illustrate the operation and interrelationships between functional entities of a system.

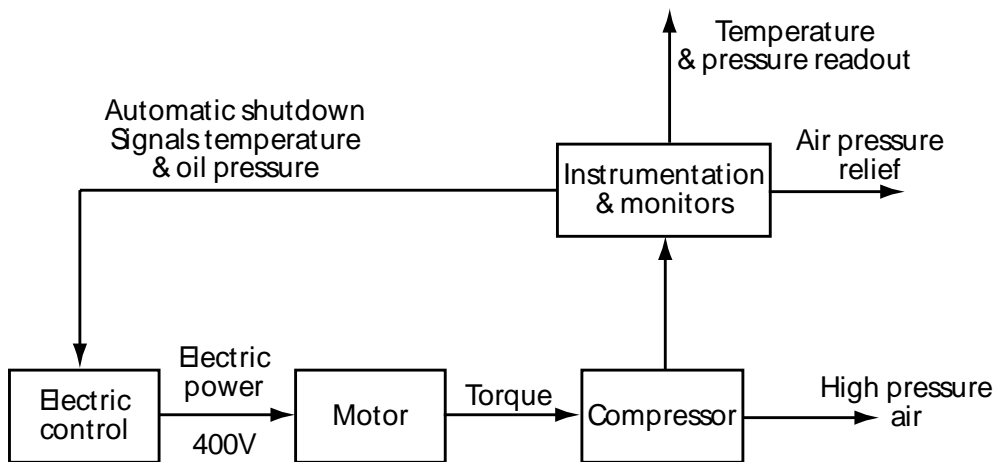


Figure 47 Functional block diagram of high pressure air compressor [DYADEM, 2003b] (comparable to communication diagrams in the PHA Toolkit).

Reliability block diagrams (Figure 48) are useful for identifying the series dependence or independence of major components, subsystems or detail part in achieving the required functions.

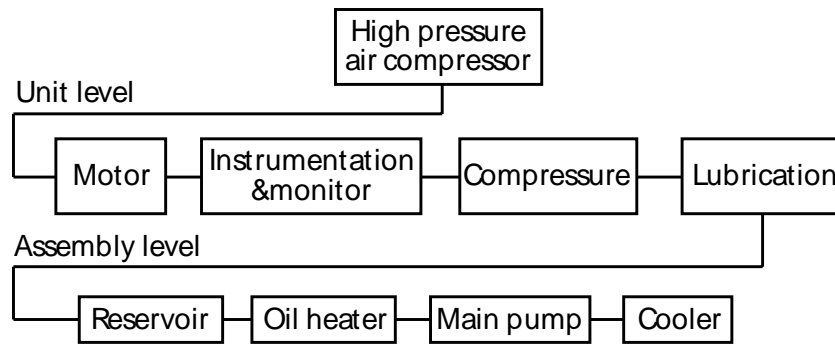


Figure 48 Reliability block diagram of high pressure air compressor [DYADEM, 2003b] (comparable to task diagrams in the PHA Toolkit).

10.3.2. Review of risk-related documents in healthcare (National practice)

Table 26 presents the findings of the review of risk-related documents in healthcare.

Table 26 Findings of document analysis

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
Organisation: Department of Health					
<p>The operating framework for the NHS in England 2009/10. High quality care for all. December 2008.</p>	<p>“This document sets out the specific business and financial arrangements for the NHS during 2009/10. The Operating Framework for 2009/10 describes the national priorities for the year and how the visions set out in <i>High Quality Care for All</i> can be delivered with the development of Payment by Results, tariff details and the standard contract. It sets out how we expect services to be transformed so that quality is our organising principle and patients are the arbiter of success.”</p>	<p>Higher management in NHS organisations e.g. PCTs, NHS Trusts, SHAs, Foundation Trusts</p>	<p>No specific references to PHA. There was mention of the use of root-cause analyses in the analysis of Never Events.</p> <p><i>Pg. 43: “SHAs will support PCTs and providers by providing advice on root-cause analyses of never events, should they occur. The NPSA will provide web resources and publish an annual report on never events, disseminating the lessons learned.”</i></p> <p>Other comments:</p> <p>Emphasised clinical ownership and leadership in making changes.</p> <p><i>Pg 24: “Clinical ownership and leadership was crucial to the success of the Next Stage Review process, and this must be maintained during implementation. If we get it right, the quality agenda has great potential to mobilise and empower clinicians across the system. And, conversely, we will get nowhere without clinicians on board. So clinical leadership needs to be part of everything we do.”</i></p>	<p>None provided</p>	<p>None provided</p>

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
Standards for Better Health, 2004	<p>Sets out the core and developmental standards that reflects the level of quality that all organisations providing NHS care in England are expected to meet.</p> <p>Note: The standards in the document are organised within seven domains. Within each domain, there are two types of standards: core and developmental. Core standards must be met by healthcare organisations but</p>	Organisations providing NHS care in England	<p>The first domain of the standards is 'Safety' and is described as follow:</p> <p><i>"Patient safety is enhanced by the use of health care processes, working practices and systemic activities that prevent or reduce the risk of harm to patients."</i></p> <p>The core standards for this domain state the need to identify and learn from all patient safety incidents and other reportable incidents, implying a retrospective analysis of events. Applying best practice in assessing and managing risks formed the developmental standard. However, there was no explicit mention of any risk assessment method.</p>	None provided	None provided

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
	<p>developmental standards are not yet compulsory. Nevertheless, the Healthcare Commission uses its own criteria to assess the progress of healthcare organisations towards achieving developmental standards.</p>		<p>The third domain is 'Governance' and is described as follows:</p> <p><i>"Managerial and clinical leadership and accountability, as well as the organisation's culture, systems and working practices ensure that probity, quality assurance, quality improvement and patient safety are central components of all the activities of the health care organisation."</i></p> <p>Core standard C7c states the need to undertake systematic risk assessment and risk management in NHS organisations. The document provided definition of the following terms:</p> <ul style="list-style-type: none"> ▪ Risk management: <i>Covers all the processes involved in identifying, assessing and judging risks, assigning ownership, taking actions to mitigate or anticipate them, and monitoring and reviewing progress.</i> ▪ Systematic risk assessment: <i>a systematic approach to the identification and assessment of risks using explicit risk management techniques.</i> <p>There was no explicit mention of the need to proactively identify risk or the use of PHA methods.</p>		

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
Organisation: National Patient Safety Agency (NPSA)					
Seven steps to patient safety: An overview guide for NHS staff, April 2004	Overview of patient safety and the tools that NPSA has developed to support NHS organisations	NHS organisations	<p>Step 3 of 7 referred to a programme of proactive risk assessment and to “use the information generated by your incident reporting system and organisation-wide risk assessment to proactively improve patient care.”</p> <p>Step 4 of 7 referred to reporting incidents that might happen. The notion of prospectively anticipating events/risks.</p>	None	None that was specific to PHA methods
Seven steps to patient safety. Step 3: Integrate your risk management activity, August 2004	Details Step 3 of the document Seven Steps to Patient Safety that details the need and approach for integrated risk management.	NHS organisations	<p>Part of an integrated risk management approach included:</p> <p>Pg 65. integrating both reactive and proactive data sources related to risk and safety. Example of ‘proactive data’ include the results of risk assessments;</p> <p>Suggested structure for effective risk management included a board-level risk management committee and local risk management groups.</p> <p>At the local level, teams are to forecast problems and plan for contingency by reviewing findings from RCAs, risk assessments and FMEAs.</p> <p>Mention the need for a central team of risk experts and as part of their role, among others, is to</p> <p><i>“identifying and handling risks that cut across departments; managing potential risks or risks that have already become a major crisis for the organisation; and</i></p>	<p>PRA: a concise introduction, an example of its application, how it can improve patient safety. Did not state how to perform an analysis.</p> <p>Risk matrix: an introduction, considerations for choosing among different risk matrices including the balances of analysis and resources. Did not have any guidance on how to use it.</p> <p>FMEA: an introduction,</p>	<p>References to FMEA provided.</p> <p>NPSA outlined plans to develop risk assessment tools such as the risk matrices and FMEA by end of 2004. (In 2009, only risk matrix documents are available).</p>

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
			<p><i>coordinating risk communication and learning</i></p> <p>A section on risk assessment tools that included the following:</p> <ul style="list-style-type: none"> - probabilistic risk assessment - risk matrix - failure mode and effects analysis - risk assessment checklist 	<p>stages of analysis explained, how it can improve safety and its benefits.</p> <p>Risk assessment checklist: Checklist provided.</p>	
<p>Seven steps to patient safety in mental health. Summary. November 2008</p>	<p>Framework to improving safety of service users in mental health</p>	<p>Mental health organisations, staff and teams.</p>	<p>Step 3: Integrate your risk management activity.</p> <p>Develop systems and processes to manage your risks, and identify and assess things that could go wrong</p> <p>Pg 10. Step 3: Integrate risk your risk management activity.</p> <p>Described this step to include <i>“an organisational risk management strategy (involving a consistent approach to training, management, analysis and investigation of all risks), a programme of proactive risk assessments and the compilation of an organisation-wide risk register.”</i></p> <p>Pg 10. Document states the goal to be a ‘high reliability organisation’ and one of the characteristics stated is a “Commitment to resilience, proactively seeing out potential hazards and containing them before they cause harm.”</p>	<p>None provided</p>	<p>NPSA can help. Resources listed include “Risk assessment made easy”, “Foresight training resource pack” and “RCA investigation report tools”. However these do not cover PHA methods per se.</p>
<p>Seven steps to</p>	<p>Define an integrated</p>	<p>Primary care</p>	<p>Part of an integrated risk management</p>	<p>PRA: a concise</p>	<p>References to</p>

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
<p>patient safety for primary care. Step 3: Integrate your risk management activity May 2006.</p>	<p>governance approach and develop and integrate risk management systems, how this can improve patient safety, and how the NPSA can support organisations achieve this.</p>	<p>organisations, including practices.</p>	<p>approach included: Pg 6. integrating both reactive and proactive data sources related to risk and safety. Example of 'proactive data' include the results of risk assessments. Pg 9. Organisations to forecast possible problems and plan for contingency by reviewing aggregated risk management data, risk assessments and FMEAs. A section on risk assessment tools that included the following: - probabilistic risk assessment - risk matrix - failure mode and effects analysis - risk assessment checklist</p>	<p>introduction, an example of its application, how it can improve patient safety. Did not state how to perform an analysis. Risk matrix: an introduction, considerations for choosing among different risk matrices including the balances of analysis and resources. Did not have any guidance on how to use it. FMEA: an introduction, stages of analysis explained, how it can improve safety and its benefits. Risk assessment checklist: Checklist provided</p>	<p>FMEA provided at the end of the document.</p>
<p>Risk assessment programme: Overview,</p>	<p>Describe the NPSA's programme of work in risk assessment</p>	<p>NHS organisations</p>	<p>Described a range of prospective risk analysis methods such as FMEA, HFMEA™, HACCP, HAZOP, barrier</p>	<p>Brief description of conducting FMEA</p>	<p>List of references provided for background</p>

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
Nov 2006			analysis, PRA.		reading
Risk assessment programme: A guide to assist commissioners of out-of-hours services, Nov 2006	Guide to help commissioners ensure that new and existing OOH service providers consider patient safety during service development, service reviews and during quality review and monitoring	Commissioners of out-of-hours services	Case studies presented in the appendices made reference to proactive risk assessments. The use of 'what if?' questions were used to proactively identify what could go wrong.	Three case studies were described showing worked examples of a method for proactively assessing risk. There was no formal name to the process or tool described.	Audience referred to local NPSA patient safety manager
Risk assessment programme. Practice-based commissioning: commissioning for patient safety, Nov 2006	A patient safety risk assessment process to support general practices, clinicians and local (integrated) commissioning groups when undertaking practice-based commissioning	NHS organisations involved in practice-based commissioning	'What if' questions in step 3 of 4 in the risk assessment process described implied the intention of identifying risk prospectively.	Description of risk assessment process developed. No formal name to the process or tool described.	Audience referred to local NPSA patient safety manager.
Hospital at Night. Patient Safety Risk Assessment Guide March 2005	Guide to risk assessing Hospital at Night (HaN) solutions.	Higher management such as Medical Directors, Directors of Nursing, Directors of HR, Hospital at Night project managers/teams and SHA WTD Leads.	Pg 2." Your hospital is responsible for the safety of patients at night. Be proactive, risk assess now. Avoid accidents!" Annex 1 listed "What if..." questions.	Detailed guidance on conducting a risk assessment including templates, checklists and examples.	Questions and issues with risk assessment can be directed to the NPSA.
Hospital at night. Patient safety risk	Short guide to hospital at night risk assessment.	Medical staff	No direct reference to PHA but the document provided a concise overview of a	A summary of the process was	Website links to the NPSA website

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
assessment. Quick guide for medical staff March 2007	Format of document is an invitation to attend a risk assessment session.		risk assessment.	provided.	provided for more information.
Hospital at night. Patient safety risk assessment. Quick guide for Hospital at Night leads and/or risk managers March 2007	Short guide to hospital at night risk assessment.	Hospital at night leads and/or risk managers	No direct reference to PHA. Document gives an overview of the need for risk assessment, when to conduct a risk assessment, pointers on starting the process, the assessment team composition and a summary of the risk assessment process.	A summary of the process was provided.	Website links regarding Hospital at Night and risk assessment provided. However, some links are now obsolete.
Healthcare risk assessment made easy, Mar 2007	Provide a risk assessment tool and guidance for use	NHS frontline staff, specifically acute care. May be adapted for use in primary care	Steps 1 and 2 of 5 mentioned identifying potential hazard and how it could go wrong suggesting proactively assessing risk .	Brief description of the five steps to risk assessment.	None
A risk matrix for risk managers, Jan 2008	Guidance for assisting NHS risk managers in implementing an integrated system of risk assessment through the use of the risk matrix as a risk assessment matrix.	NHS risk managers	Guidance and method for using the 5x5 risk matrix was described.	Detailed method for using the 5x5 matrix	Users referred to Patient Safety Manager/ Project Lead. List of references provided.
Root cause analysis Toolkit and e-learning programme (RCA Toolkit) 2008	Web-based training Toolkit to use root cause analysis	NHS staff	Described the use of barrier analysis both as a retrospective and prospective method .	Method provided including a worked example in the Barrier Analysis document in the Resources section.	References provided at the end of the Barrier Analysis document.
Organisation:					
Improvement	Part of the learning modules	NHS organisations	No specific mention of PHA	None	None

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
leaders' guide: Process mapping, analysis and redesign, 2005	in the "Leading in Patient Safety Programme"	specifically those signed up on the programme			
Improvement leaders' guide 2005	Learning modules in the "Leading in Patient Safety Programme"	NHS organisations specifically those signed up on the programme	(In speaking to a trainer, FMEA is being taught in one the modules. However, reference to this in the learning modules was not found.)	N/A	N/A
Going lean in the NHS, 2007	Introduce the concept of lean to the NHS	NHS organisations	No specific mention of PHA	None	None
Organisation: NHS Litigation Authority					
NHSLA Risk Management Standards for Acute Trusts, Primary Care Trusts and Independent sector providers of NHS Care 2009/10, February 2009	Manual detailing risk management standards designed to address organisational, clinical and non-clinical/health and safety risks. These should be referred to when organisations prepare for an NHSLA assessment	NHS Acute Trusts, Primary Care Trusts and Independent sector organisations providing NHS care under 'specifically designated centrally negotiated contracts' engaged by PCT members that are members of NHSLA schemes such as CNST, ELS, LTPS, PES and RPST.	<p><i>"Criterion 1.5 - Risk management process: Organisation has approved documentation which describes the organisation-wide systematic risk management processes."</i></p> <p>There are minimum requirements for a systematic risk management process with reference to the need to perform risk assessments on a variety of areas. However there are no specific guidance on the method and no explicit reference to prospectively analysing risk.</p>	None	None
NHSLA Risk Management Standards for	Manual detailing risk management standards designed to address	NHS mental health and learning disability trusts that are	<i>"Criterion 1.5 - Risk management process: Organisation has approved documentation which describes the organisation-wide</i>	None	None

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
Mental Health and Learning Disability Trusts 2009/10, January 2009	organisational, clinical and non-clinical/health and safety risks. These should be referred to when organisations prepare for an NHSLA assessment	members of NHSLA schemes such as CNST, ELS, LTPS, PES and RPST.	<i>systematic risk management processes.</i> " The criterion applies to Foundation Trusts. There are minimum requirements to perform risk assessments on a variety of areas. However there are no specific guidance on the method and no explicit reference to prospectively analysing risk.		
NHSLA Risk Management Standards for Ambulance Trusts 2009/10, January 2009	Manual detailing risk management standards designed to address organisational, clinical and non-clinical/health and safety risks. These should be referred to when organisations prepare for an NHSLA assessment	NHS ambulance trusts that are members of NHSLA schemes such as CNST, ELS, LTPS, PES and RPST.	<i>"Criterion 1.5 - Risk management process: Organisation has approved documentation which describes the organisation-wide systematic risk management processes."</i> There are minimum requirements to perform risk assessments on a variety of areas. However there are no specific guidance on the method and no explicit reference to prospectively analysing risk.	None	None
<p>Organisation: Healthcare Commission</p> <p>Set up in April 2004 as an independent watchdog for healthcare in England. Main roles include assessing and reporting on the quality and safety of services provided by the NHS and the independent healthcare sector. They also work to improve services for patients and the public.</p> <p>In 1 April 2009, a new organisation called Care Quality Commission (CQC) will be responsible for regulating healthcare and social care services in England. CQC will bring together the work of the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission in England.</p>					
The annual health check 2008/09, June 2008	Describes the components and design of the yearly assessment framework	Acute Trusts (including Foundation Trusts), Ambulance Trusts, Mental Health Trusts (including Foundation Trusts), Learning Disability Trusts, Primary Care Trusts (both as providers and	No reference to PHA.	None	None

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
		<p>commissioners of care), Care Trusts, the Health Protection Agency, NHS Direct and, NHS Blood and Transplant.</p> <p>The focus here excludes the HPA, NHS Direct, NHS Blood and Transplant.</p>			
<p>Criteria for assessing core standards in 2008/09 Acute Trusts, December 2008</p>	<p>Outlines the criteria for assessing core standards in acute trusts</p>	<p>Acute Trusts</p>	<p>Contained within the domain "Safety": Core standard C1(a): Element 2 <i>"Individual incidents are analysed rapidly after they occur to identify actions required to reduce further immediate risks, and where appropriate individual incidents are analysed to seek to identify root causes, likelihood of repetition and actions required to prevent the reoccurrence of incidents in the future."</i></p>	<p>None</p>	<p>None</p>
<p>Criteria for assessing core standards in 2008/09: Ambulance Trusts, December 2008</p>	<p>Outlines the criteria for assessing core standards in ambulance trusts</p>	<p>Ambulance Trusts</p>	<p>Core standard C1(a): Element 3 <i>"Reported incidents are aggregated and analysed to seek to identify common patterns, relevant trends, likelihood of</i></p>		

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
Criteria for assessing core standards in 2008/09: Mental Health and Learning Disability Trusts, December 2008	Outlines the criteria for assessing core standards in mental health and learning disability trusts	Mental Health and Learning Disability Trusts	<p><i>repetition and actions required to prevent the reoccurrence of similar incidents in the future, for the benefit of patients/service users as a whole.”</i></p> <p>The retrospective analysis of incidents was emphasised with the need to analyse the likelihood of reoccurrence or evaluate the risks. There was no specific mention of prospectively identifying hazards or mention of specific analysis methods.</p>		
Criteria for assessing core standards in 2008/09: Primary Care Trusts (as providers and commissioners), December 2008	Outlines the criteria for assessing core standards in primary trusts as providers and commissioners	Primary Care Trusts (as providers and commissioners)	<p>Contained within the domain “Governance”</p> <p>Core standard C7(a) & (c): Element 3</p> <p><i>“The healthcare organisation systematically assesses and manages its risks, both corporate/clinical risks in order to ensure probity, clinical quality and patient safety.”</i></p> <p>No specific mention of prospectively identifying hazards or specific analysis methods.</p>		
Organisation: Monitor – Independent Regulator of Foundation Trusts					
Identifying risk, taking action: Monitor’s approach to service performance in NHS foundation trusts April 2008	Describes Monitor’s approach to risk	NHS Foundation Trust	<p>The document stated that</p> <p><i>“boards must address and resolve any risks that have been identified, including those relating to complying with the trust’s terms of authorisation. They must also address and resolve any issues raised by external audit or other external bodies.”</i></p> <p>There was no mention of PHA.</p>	None	None

Title, year produced	Aim of document	Intended audience	Reference to PHA	Provision of guidance to perform analysis*	References to further guidance/training
Compliance Framework March 2009	Describes Monitor's approach for monitoring compliance by NHS foundation trusts with the terms of their authorisation.	NHS Foundation Trusts	Reference made to risk assessment but there was no reference to PHA	None	None
Organisation: Health and Safety Executive					
Five steps to risk assessment, 2006	Guide to assessing health and safety risks in the workplace	Any organisation	Step 1 of the risk assessment process – identify hazard. Do not mention conventional PHA methods but point to ways that hazards can be identified that include both prospectively and retrospectively identifying hazards. For example: walk around, ask employees, check manufacturers' instructions and to seek information from organisations such as the HSE, Workplace Health Connect or trade associations.	Little guidance. A sentence pointing to possible ways of identifying hazards. Provided a risk assessment template that could be printed and used readily.	Provided website addresses and telephone numbers should the organisation wishes to contact the HSE or Workplace Health Connect.
Management of health and safety at work, 1999	Outlines guidance on issues related to health and safety at work	Any organisation	A section on risk assessment. No specific reference to PHA.	None	None

10.3.3. Use of PHA methods in Healthcare – literature search strategy

Informal reviews (Internet, discussions, journal articles) identified the following 31 PHA methods and related phrases (Table 27).

Table 27 PHA methods and risk assessment related phrases identified prior to the literature review.

- Barrier Analysis
- CREAM Cognitive Reliability and Error Analysis Method
- ETA Event Tree Analysis
- Fault Tree Analysis
- HACCP Hazard Analysis and Critical Control Points
- (H)HAZOP / Healthcare HAZOP
- HEA Human Error Analysis/Assessment
- HEART Human Error Assessment and Reduction Technique
- HERA Human Error in Air Traffic Control project
- (H)FMEA (Healthcare) Failure Mode(s) (and) Effect(s) Analysis (various variations of this!)
- HRA Human Reliability Assessment / Analysis
- HTA Hierarchical Task Analysis
- Influence Diagrams
- JHEDI Justification of Human Error Data Information
- Likelihood Impact Grid
- PHEA Predictive Human Error Analysis technique
- PHECA Potential Human Error (and) Cause Analysis
- PRA (Proactive) risk assessment/analysis
- PHA (Proactive) hazard assessment/analysis
- Prospective risk assessment/analysis
- Prospective hazard assessment/analysis
- PRA Probabilistic Risk Assessment
- Risk Matrix
- SCHEMA Systematic Critical Human Error Management Approach
- SHERPA Systematic Human Error Reduction and Prediction Approach
- SWIFT Structured What-If Technique
- TAFEI Task Analysis for Error Identification
- TALENT Task Analysis-Linked Evaluation Technique
- THERP Technique for Human Error Rate Prediction
- TRACER Technique for the Retrospective and predictive Analysis of Cognitive Errors
- What-if

From the above, Table 28 describes the search terms used in this part of the literature review, conducted in February 2008.

Table 28 Search terms used in the review of the use of PHA Methods in healthcare

	Search term	Database				Sum
		EMBASE	DH DATA	Kings Fund	Medline	
1	BARRIER ADJ ANALYSIS	15	0	1	13	29
2	COGNITIVE ADJ RELIABILITY NEAR ERROR ADJ ANALYS\$2 ADJ METHOD\$2	2	0	0	2	4
3	EVENT ADJ TREE ADJ ANALYS\$3	7	0	1	3	11
4	FAULT ADJ TREE ADJ ANALYS\$3	39	3	1	26	69
5	HAZARD ADJ ANALYS\$3 NEAR CRITICAL ADJ CONTROL ADJ POINT\$2	171	8	0	349	528
6	HAZOP OR HAZOP	13	0	0	11	24
7	HAZARD NEXT OPERABILITY	12	1	0	7	20
8	(HEALTHCARE OR HEALTH ADJ CARE) NEAR (HAZOP OR HAZARD ADJ OPERABILITY)	0	0	0	0	0
9	6 OR 7	19	1	0	12	32
10	HUMAN ADJ ERROR ADJ ANALYS\$3 OR HUMAN ADJ ERROR ADJ ASSESS\$5	14	1	0	8	23
11	HUMAN ADJ ERRORR ADJ ASSESSMENT NEAR REDUCTION ADJ TECHNIQUE\$2	0	0	0	0	0
12	HUMAN ADJ ERROR ADJ IN ADJ AIR ADJ TRAFFIC ADJ CONTROL ADJ PROJECT	0	0	0	0	0
13	HFMEA OR FMEA	44	5	1	69	119
14	FAILURE ADJ MODE\$2 NEAR EFFECT\$1 ADJ ANALYS\$2	56	9	2	78	145
15	13 OR 14	65	9	2	92	168
16	HUMAN ADJ RELIABILITY ADJ ASSESS\$5 OR HUMAN ADJ RELIABILITY ADJ ANALYS\$2	47	0	1	29	77
17	HIERARCHICAL ADJ TASK ADJ ANALYS\$2	19	1	0	20	40
18	INFLUENCE ADJ DIAGRAM\$2	35	2	0	46	83
19	JHEDI OR JUSTIFICATION NEAR HUMAN ADJ ERROR ADJ DATA ADJ INFORMATION	3	0	0	3	6
20	LIKELIHOOD ADJ IMPACT ADJ GRID\$2	0	0	0	0	0
21	PHEA OR PREDICTIVE ADJ HUMAN ADJ ERROR ADJ ANALYS\$2 ADJ TECHNIQUE\$2	209	0	0	206	415
22	PHECA OR POTENTIAL ADJ HUMAN ADJ ERROR NEAR CAUSE ADJ ANALYS\$2	1	0	0	1	2

23	PROBABILISTIC ADJ RISK ADJ ASSESS\$5	151	1	1	96	249
24	RISK ADJ MATRIX	22	1	1	19	43
25	SCHEMA OR SYSTEMATIC ADJ CRITICAL ADJ HUMAN ADJ ERROR ADJ MANAGEMENT ADJ APPROACH	3161	23	13	3824	7021
26	SYSTEMATIC ADJ CRITICAL ADJ HUMAN ADJ ERROR ADJ MANAGEMENT ADJ APPROACH	0	0	0	0	0
27	SHERPA OR SYSTEMATIC ADJ HUMAN ADJ ERROR ADJ REDUCTION NEAR PREDICTION ADJ APPROACH	105	2	0	118	225
28	SYSTEMATIC ADJ HUMAN ADJ ERROR ADJ REDUCTION NEAR PREDICTION ADJ APPROACH	1	0	0	2	3
29	SHERPA	104	2	0	117	223
30	SHERPA NOT (TIBET OR NEPAL)	60	2	0	48	110
31	STRUCTURED ADJ WHAT ADJ IF ADJ TECHNIQUE\$2 OR STRUCTURED ADJ WHAT-IF ADJ TECHNIQUE\$2	0	0	0	0	0
32	TAFEI OR TASK ADJ ANALYS\$2 NEAR ERROR ADJ IDENTIFICATION	3	0	0	2	5
33	TASK ADJ ANALYSIS ADJ LINKED ADJ EVALUATION ADJ TECHNIQUE\$2	0	0	0	0	0
34	TECHNIQUE NEAR HUMAN ADJ ERROR ADJ RATE ADJ PREDICTION\$2	1	0	0	0	1
35	TECHNIQUE ADJ FOR ADJ RETROSPECTIVE NEAR PREDICTIVE ADJ ANALYS\$2 NEAR COGNITIVE ADJ ERROR\$1	0	0	0	0	0
36	WHAT-IF	5	0	0	8	13
37	PROACTIVE ADJ RISK ADJ ANALYS\$2 OR PROACTIVE ADJ RISK ADJ ASSESS\$5	5	0	0	9	14
38	PROACTIVE ADJ HAZARD ADJ ANALYS\$2 OR PROACTIVE ADJ HAZARD ADJ ASSESS\$5	0	0	0	0	0
39	PROSPECTIVE ADJ RISK ADJ ASSESS\$5 OR PROSPECTIVE ADJ RISK ADJ ANALYS\$2	26	0	0	27	53
40	PROSPECTIVE ADJ HAZARD ADJ ANALYS\$2 OR PROSPECTIVE ADJ HAZARD ADJ ASSESS\$5	1	0	0	2	3
					Total:	9758

10.4. Informal interviews – question topic guide

1) Current practice:

- a) What is the culture like towards patient safety at your Trust?
- b) What are your top 10 challenges / risks you experience at the Trust?
- c) What are the current key documents in your area which deal with risk management?
- d) How do you record and act on risks?
- e) Are there any problems with the risk management system?
- f) How does your work interface with other risk management areas at your Trust?
- g) Do any of these discuss proactive risk management?
- h) What would describe as proactive risk management that is performed now at your Trust?
- i) Which PHA methods are used?
- j) When, where and why might they be used. By whom? Why?
- k) Are people keen to use it?
- l) What resources are available for this?
- m) Are these resources sufficient?
- n) What do you think the limitations of PHA might be?
- o) Process mapping – is this something that is done in your organisation?
- p) When would process mapping take place – which processes?
- q) How does process mapping take place?

3 Future use of PHA:

- a) What resources are available for this?
- b) Where might PHA help most in the NHS?
- c) When should it be used?
- d) What might trigger it?
- e) Who should take part?
- f) What is a realistic amount of time that you could spend on this? What about for other colleagues?
- g) What might prevent the uptake of PHA in the NHS?
- h) What features should a PHA Toolkit have?
- i) What outputs should it produce?

4 Identify potential case studies:

- a) Try to produce a list of a range of case studies

10.5. Results of review of general guidance documents

The analysis of literature identified 6 main types of guidance:

- Briefs, fact sheets and leaflets;
- Job aids;
- Process driven guidance;
- General guidance;
- Reports, and;
- Toolkits.

10.5.1.1. Briefs, fact sheets and leaflets

Description

These guidance types provide short, succinct summaries of a chosen topic, study or area of concern/interest within healthcare. Their key purpose is to help the reader understand key points and where further information can be obtained. The information provided within the brief, fact sheet and/or leaflet is of enough detail to educate the reader, in terms of making them aware of an issue/study or topic, but is not sufficient to allow them to understand the topic/study in great detail.

What attributes make this guidance effective?

A key reason why briefs, fact sheets and leaflets are effective is because they are short and succinct. Typically they are around 3 to 8 pages and as already mentioned focus on key points, thus helping to maintain the motivation of the reader. That is, the reader is not put off by the length of the document and complex information.

Moreover the briefs, fact sheets and leaflets present information in a variety of ways that help to maintain the attention of the reader. Rather than providing a couple of pages of text, the following presentational techniques are used:

- **Coloured bullets and coloured text boxes**– certain key points or key figures are presented using coloured bullets and coloured text boxes to draw the readers attention and break up text;
- **Text in columns** – text is presented in columns, meaning text is not presented in long sentences, rather paragraphs are presented in smaller looking “chunks”;
- **Diagrams** – where possible small coloured diagrams are used to represent information, thus removing the need for text and providing a more colourful representation of information;
- **Language** – language is succinct and not overly complex as the focus is on providing key points or learning. References are provided to allow the reader to gather more detailed information.

When is the guidance most effective?

Briefs, fact sheets and leaflets seem to be most effective when they are used to either introduce an audience to a topic and/or provide the audience with essential action information, for example leaflets for swine flu.

Therefore on one level this guidance type can act as a marketing/advertising tool,

providing readers with enough information to stimulate interest and motivate them to read further resources and learn about the topic/study in more detail.

For example NHS employer briefing:

“The opportunity to engage” provides key information on a program implemented by the NHS to enhance engagement. This brief provides key reasons for the program, evidence of success and a list of further resources, and who to contact to become involved, thus providing promotion and key information for the reader to stimulate interest.

On the other hand, when needed, the guidance type can act as a key educational document to help readers understand a topic and key steps to take.

For example Department of Health (2007) “How much is too much?” provides key figures to highlight the effects of alcohol and then provides key action steps to help reduce the amount of alcohol a person should drink.

What needs to be included and avoided to make the guidance as effective as possible?

Use of key figures and case studies need to be included to ensure this guidance type is effective. Using figures and case studies helps to deliver a strong argument and message to the reader, without using too many words, thus keeping the document short but maximising impact. Moreover a list of resources also needs to be included so that the reader can find further information. This is because the guidance type can only provide a certain amount and level of information and therefore resources are needed to help guide the reader to further information to carry on the learning process.

Consideration should however be given to the type of topic/study/area to be presented within a brief/leaflet/fact sheet. It may be the case that the topic is overly complex and hence not best suited to a short brief, fact sheet and/or leaflet. Using a leaflet to provide key elements of a complex topic will be less effective and often confuse the reader. Moreover providing leaflets that contain mainly text will again reduce motivation. Using figures and case studies helps to break up page layout, while providing important information.

10.5.1.2. Job aids

Description

Job aids are short documents that help individuals undertake a process, whether physical or mental. These are support tools such as checklists or instructions that act as an aide memoir. The information provided is short and concise and details the key process steps and information to be considered, thus supporting the reader.

What attributes make this guidance effective?

Job aids appear to be effective firstly because the way information is presented and secondly because they are often process driven.

Information is presented in a concise manner, using short sentences, representing key points. Coloured diagrams are often used to represent the information, helping the reader to easily understand the information and see how information links together.

This representation of information aims to stimulate thought rather than instruct, thus engaging the reader and the readers attention and cognitive function.

Moreover, job aids are often very short. This again helps maintain the motivation of the reader and ensures they are not put off by document length. Indeed as job aids are often designed to be used while the reader undertakes a task, they need to be short in length and concise to ensure usability.

Job aids are also process driven, that is, they represent a process and require the reader to follow that process, as they work through the job aid. This requires the reader to engage with the document and stimulates thought and cognitive function. The requirement for engagement and thought helps hold and increase the reader's level of attention, particularly as job aids require the reader to apply the process to a task further enhancing cognitive function and engagement.

In essence job aids are effective because they require or "force" the reader to be active and actively use information, as opposed to other forms of guidance such as reports or leaflets which require the reader to take a somewhat more passive role of absorbing and taking in information, rather than directly applying it.

When is the guidance most effective?

Job aids are not instruction manuals and are most effective when supported by detailed guidance or procedures. For example, if established procedures or guidance already exists, then job aids can help condense the information down to a useable level and act as an aide memoir to the guidance/procedure.

However, if no such guidance exists, then the audience will firstly need detailed guidance to be produced, followed by a set of supporting job aids.

Moreover, job aids require and assume a certain level of understanding. Therefore job aids are most effective when they support guidance or procedures and the intended audience already has an underpinning understanding of the process or topic represented in the job aid. Without the underpinning knowledge job aids may be misinterpreted and used incorrectly. Indeed job aids are more focused around guiding readers, rather than educating them on a topic or process, like leaflets, briefs and fact sheets.

Finally consideration should also be given to the complexity of the process to be presented within a job aid, for example:

1. Can the process realistically be condensed down into a number of job aids that will effectively support the reader?
2. If not, what other guidance types may be needed?
3. If job aids can be used are any other support mechanisms needed, for example training in the job aids?

What needs to be included and avoided to make the guidance as effective as possible?

To be effective this form of guidance needs to present a step by step process that can be easily followed by the reader. To do that the job aid firstly needs to use a flow diagram or chart to represent the process, this should be a simple step flow diagram illustrated in colour. Secondly the job aid should list out each numbered step and under each step provide several key bullets that detail each sub task. The bullets should be around 1 to 2 sentences long. Thirdly at the end of the job aid, resources should be provided that can help the reader gather any further information if needed, these should reference relevant guidance and procedures and organisations to contact. Finally some job aids provide a

relevant checklist at the end to help the reader ensure they have covered all relevant steps, thus acting as a further aid memoir during the activity.

The guidance type should avoid overly complex diagrams and representation of complex procedures that require a large number of steps and therefore would require a large number of bullets or text to describe each step. Indeed the job aid needs to remain short and useable, long job aids with complex diagrams will not help to support the user.

10.5.1.3. *Process driven guides*

Description

Process driven guidance is guidance that is structured around a process and requires the user to work through that process. Flow diagrams are used to represent the process and each section of the guide is a section of the process. Moreover, self reflective questions and tasks are used as the reader goes through the process to aid self-reflection and thought generation. Process driven guidance is not prescriptive, rather the focus is on allowing the user to work through a flexible process and reflect on their environment and operations and consider how the process can be applied and improvement steps. The focus of the guidance is therefore very much application and the user is seen as active and responsible for interpreting information and applying the process to their given context.

What attributes make this guidance effective?

Process driven guidance is effective for two main reasons – interaction and presentation. The underpinning purpose of process driven guidance is to stimulate thought, self reflection and encourage the user to apply a process. This therefore requires the user to engage with the material and take an active role in reflection and application. This emphasis on participation and interaction stimulates thought and attention, engaging the user with the material. Indeed as process driven guidance often encourages collaborative reflection, this further enhances participation, interaction and stimulation. Moreover, processes that are presented are not prescriptive; meaning that the process can be applied to meet the user's needs and also reinforces the principles of user control and responsibility.

Process driven guidance also uses a number of key presentational factors to help enhance user attention, motivation and ensure the process can be easily followed and understood:

- **Flow diagrams** – diagrams are coloured to attract attention and used to represent the process in a simple format for the reader to understand;
- **Length** – the documents are relatively short (30 pages) so that user motivation and attention is maintained. Moreover shorter length means more time can be spent on reflection and application that reading the actual guidance;
- **Job aids** – linked to the flow diagrams, job aids are used to help the reader follow the process and undertake the self-reflective activities;
- **Language** – non-technical language is used to aid usability and help maintain user motivation and attention. Complex technical language may discourage readers;
- **Colour and pictures** – different colours and pictures are used throughout the document to provide an aesthetically pleasing presentation of information. This maintains attention and can stimulate cognitive functioning that can enhance motivation.

When is the guidance most effective?

Process driven guidance is most effective when the application of a topic is significantly effected by a range of contextual and organisational factors and hence a prescriptive approach to application will not meet the needs of the audience. In this case process driven guidance provides a flexible approach for self-reflection and application, that allows the reader to consider their operational and organisational context and consider how they can apply the topic and learning to their specific environment.

Indeed consideration needs to be given regarding the extent to which the topic can and should be represented within a flexible process. The topic may be too complex or may cover mandatory requirements that must be implemented and therefore a prescriptive approach is needed.

Finally process driven guidance often requires collaboration with different personnel, to aid self-reflection and remove bias in responses to self-reflective activities and tasks. This has the advantage of encouraging individuals to work together and reflect on their context, but assumes that such collaboration can be undertaken. It may not always be possible within high demanding contexts to undertake such collaborative reflection and hence if collaboration is not feasible the guidance is likely to be less effective.

What needs to be included and avoided to make the guidance as effective as possible?

Process driven guidance needs clear instructions detailing the purpose of the process driven guidance explicitly stating that it provides a flexible approach and that the reader is responsible for interpreting and applying the guidance to their context and that the guidance is not providing a prescriptive approach. Without this explicit instruction, readers can become confused as to the purpose of the guidance and how it should be used. Indeed information should be clearly provided detailing how the guide should be used collaboratively, for example a paragraph on using self-reflective questions to structure a workshop or interview.

Process driven guidance should include upfront a flow diagram that clearly details the process that the guidance is structured around, so it is clear to the reader how the guidance is structured and the process to follow.

The guide should also contain self reflective question sets or checklists to help the reader consider their operational and organisational context and a range of case studies that demonstrate the application of learning. This helps the reader think about their context and then see how others have implemented the learning.

A set of references and resources should also be provided to ensure the reader is provided with further information and support for application.

10.5.1.4. Normal guides

Description

Normal guides provide guidance on a specific topic or activity but are not process driven. These guides are support aids that help the reader understand a topic/activity more clearly and understand how it applies to their context.

What attributes make this guidance effective?

Normal guides are effective when they utilise a range of presentational factors:

- **Language** – non technical and unbiased language is used, making the information easy to understand and also read, which helps maintain attention and motivation;
- **Pictures** – use of pictures to break up sections, providing the reader with time away from the reading text and creates an aesthetically pleasing document. Moreover pictures can be used to represent the “essence” of a section or page of text. This enhances user understanding and provides an alternative method of representing information. Changes in methods can aid cognitive function and subsequent attention and motivation;
- **Layout of text** – Presenting text in columns, making the text easier to digest and also making substantial junks of text seem smaller, thus enhancing motivation;
- **Colour** – using different colour through the document i.e. different colours for headings, texts and key points. This makes the document more attractive and helps to break up text, thus having a positive impact on attention and the extent to which the user will engage with the document;
- **Highlighting key points** – key points provided in text boxes and often in different colours. This technique again highlights the key messages and essence of paragraphs and arguments, again providing a different way of presenting information to maintain attention;
- **Diagrams and tables** – use of coloured diagrams and tables to represent arguments. This aids understanding and provides another mechanism for representing information. This form can appeal to different users who may learn better through diagrams etc as oppose to text;
- **Length of document** – where possible guidance is shorter to help maintain motivation and attention.

When is the guidance most effective?

This type of guidance is effective on most occasions. It can be prescriptive or more general and can in some cases be quite high level and other times can be very detailed. Indeed the format for normal guides’ means that in reason any type of topic or activity can be detailed within a guide, and be effective, as oppose to process driven guidance and job aids which are less amenable to complex topics and mandatory requirements.

What needs to be included and avoided to make the guidance as effective as possible?

These guides can lack a level of interaction as they are not process driven, meaning the user is essentially passive - the guide only requires the user to read the information rather than carry out any activity and follow a process. Therefore for the guidance to be effective the reader needs to be stimulated through the use of pictures to break up and represent sections, quotes and cases studies and figures to highlight the importance and value of the topic and demonstrate application.

Moreover with this in mind, the guidance needs to avoid the use of long paragraphs and continuous pages of text; otherwise this type of presentation will decrease the reader’s motivation and attention.

10.5.1.5. Reports

Description

Reports are documents that either detail the findings and methodology of a research project or collate research findings and present them in an informative way for the reader. These documents do not provide guidance per se, but rather provide detailed information to help inform the reader. Indeed the emphasis is on the reader to consider how the information presented in these reports can be applied to their work context.

Moreover, reports explicitly detail the evidence base on which arguments and recommendations are based thus providing the academic rigour, which can appeal to many audiences within healthcare.

What attributes make this guidance effective?

The key reason why reports are effective is presentation. There appears to be a move away from presenting reports as an academic document. Rather attention is focused on presenting the information in an engaging and exciting way that attracts the reader to the document and maintains their attention. Moreover, this presentation style means that documents which can be significantly long and detailed appear shorter and easier to read. This again maintains reader attention and motivation, but also opens up the report to a wider audience, i.e. not just those individuals interested in reading academic based reports or lengthy research reports.

Reports utilise the following presentational elements to enhance reader motivation and attention:

- **Colour** – different colours are used for headings, sub headings and text, attracting and stimulating the reader's attention and making the text seem more appealing;
- **Use of pictures** – sections of the report are broken up by pictures and/or pictures used to emphasise key points, providing an aesthetically appealing and engaging way to break up text into more manageable segments and represent key points;
- **Language** – language used is not pitched at an academic audience, this means that the writing is more appealing to a wider range of audiences. Use of colour and pictures further helps to enhance this appeal;
- **Text in columns** – text is represented in columns breaking up large bodies of text into more manageable chunks. Moreover, the use of columns helps large bodies of text appear shorter in length;
- **Headline figures in larger font and different colour** – headline figures and quotes are provided in larger text, different colour to the main text and within coloured text boxes. Use of different colour and font sizes stimulates reader's attention and encourages them to read the headline figures and more than likely the rest of the page. This type of presentation also helps to reinforce the key points of a paragraph, page or section.

When is the guidance most effective?

This guidance is most effective when a study or research project has been completed and the results have significant implications and importance across the NHS and require wide audience uptake. However the level of information provided within these reports may not be suitable for everyone. Some audiences may not require or want this level of information. Indeed in this case it may be necessary to provide a leaflet or fact sheet to

certain audiences highlighting the key points of the report, rather than providing the whole report, hence enhancing effectiveness.

What needs to be included and avoided to make the guidance as effective as possible?

The reports are not process driven and are essentially tools to inform the reader. This means the reader is much more passive, and the focus is on information presentation, rather than application. This can have a negative effect on attention and the successful application of information within the workplace. Like normal guidance, to be effective reports need to include the use of pictures to break up and represent sections, quotes and figures to highlight the importance and value of the research all to stimulate the reader and maintain attention.

Moreover these reports often have an explicit section that clearly details why the research was needed and the benefits this will bring. This is often emphasised through a case study of an incident or accident and/or figures detailing the current problem and its impact. This brings to the fore the need for the research and what the research can bring.

Also to ensure effectiveness the reports detail results of the research but also clearly states potential application of results and what the results mean for NHS employees. This helps the reader to consider the results within their operational context and enhances effectiveness.

10.5.1.6. Toolkits

Description

Toolkits guide the user through a process and provide a discernable output that the user can then use to help guide the undertaking of an activity. Toolkits come in two forms excel based toolkits and web based toolkits.

Excel based toolkits focus on providing an output for the user. The user is required to input relevant data and the excel toolkit provides a basic representation and/or analysis of the data, providing an output for use.

Web based toolkits combine guidance with providing an output. Web based tools tend to firstly provide guidance for the user to help them understand the topic and the process that is being presented to them. This is then followed by an evaluation or analysis section, where the user is required to input relevant data or provide relevant answers to questions. This information is then used to provide output(s) that can be used to help guide activity.

What attributes make this guidance effective?

Toolkits are effective mainly because they are process driven and require interaction by the user. Toolkits guide users through a process that requires them to reflect on their environment and operation, and require users to input information which again “forces” the user to interact with the tool. Moreover web-enabled toolkits are developed as a roaming resource which allows individuals to click on different tabs and access different information. This encourages exploration of information and interaction with the tool. Moreover, the user is in control of their learning and information exploration.

Tools also are effective because they provide a discernable output, they give the user something concrete that can help guide an activity. Finally tools (mainly web-based tools) use a number of presentational factors to maintain attention and aid usability:

- **Colour** – different colours are used for pages, tabs and text attracting and stimulating the reader's attention and making the text seem more appealing;
- **Use of pictures** – toolkit pages are broken up by pictures providing an aesthetically appealing and engaging way to break up text;
- **Language** – language is not complex making it easier to understand and read;
- **Short pages** – web pages are not long and therefore the user is not put off;
- **Logical structure** – the tool is structured in way that is logical, making navigation easier and hence enhancing usability.

When is the guidance most effective?

This guidance type seems to be most effective when the audience requires a diagnostic tool to help enhance decision making.

Excel and web-based tools however rely on the user being able to access a computer and be computer literate, in terms of being able to effectively use excel and computer based applications. Moreover users may prefer paper based support tools which can, if desired, be used while undertaking a task, as with job aids.

What needs to be included and avoided to make the guidance as effective as possible?

To be effective tools should clearly detail how they should be used, particularly the use of evaluation results. That is that they are for reflection purposes to aid decision making. Moreover guidance should be provided on how to carry out any type of evaluation with the tool, especially around collaboration and how to use tools in workshops or using evaluation questions for a survey.

Web-based tools that provide guidance followed by an evaluation seem to provide an effective structure, helping the reader to understand a topic and then providing them with a method for evaluation that allows them to consider their context and identify improvement steps. Indeed the guidance can be referred to after the evaluation has taken place thus aiding decision making.

Moreover web-based tools tend to provide cases studies and good practice examples to help the user understand application of results and develop improvement steps. Microsoft Excel based tools on the other hand do not provide guidance and therefore are based on the assumption that the user already understands the process they are about to undertake using the excel tool. Prior training and knowledge development is needed before excel tools can be used to ensure that the user understands how to use the application, understands the topic and what should be done with the results.

10.6. PHA Requirements development

10.6.1. Health and Safety Managers feedback form

(Please see overleaf)



1

Name and job title:

NHS Trust:

RATINGS: 5 = Strongly Agree; 3 = Neither Agree nor Disagree; 1 = Strongly Disagree; 0 = Not applicable

1 Current practice at your institution

Does it use a risk matrix and if so what dimensions (e.g. 5x5)?

Please mention any standards or documents which influence risk management which might be useful for our research:

2 Experience of PHA methods

Have you used any of the following PHA methods? (Please use the ratings scale above). Please add any comments on their usefulness / usability / strengths / weaknesses in the NHS.

<i>PHA method</i>	<i>Your rating + any comments</i>
Barrier Analysis	
Influence Diagrams	
What-if	
HFMEA / FMEA	
HHAZOP / HAZOP	
Likelihood Impact Grid (Risk Matrix)	

SWIFT	
FMECA	
Others (please list):	

Using the scale on page one, please rate your degree of agreement / disagreement with the following statements, and *please add comments*:

It is important for the NHS to use Proactive Hazard Analysis techniques:

We know what all the problems are and we know how to fix them; we just don't have the resources:

The NHS will struggle to use PHA techniques:

PLEASE ONLY USE THE FOLLOWING SHEET IF YOU HAVE DONE A PHA IN THE NHS BEFORE

If you have done a PHA before in the NHS, what caused you to do it? Please use the ratings scale again:

<i>Motive for PHA</i>	<i>Your rating + any comments</i>
Response to an incident	
General feeling of unease with provision of care suggested need for further investigation	
Trying to meet a government target	
Following a standard or guidance, e.g. <i>Hospital at Night</i>	
Your manager / Board	
Other	

If you have performed a PHA in the past, what were you trying to achieve?

<i>Aim of PHA</i>	<i>Your rating + any comments</i>
Trying to identify what could go wrong with the current situation	
Trying to quantify the scale of a known problem	
Trying to identify a solution to a known problem	
Trying to see how good a proposed solution is	
Trying to compare a proposed solution with the current situation to see if it is better	
Trying to see how changes elsewhere might affect the service	
Other	

4

What PHA method(s) did you use?

Who was involved, and how many people of each type? (e.g. nurse / professional facilitator, consultant, practice manager, GP, etc)

What were the motives and aims?

How long did it take?

What did the users think of the method and the results?

What was successful about the analysis?

How could it have been done better?

Please put your email address here if we can get in touch with you to ask you some more questions:

Thank you!

Please use the rest of this sheet if you'd like to add other comments

10.6.2. Interviews

10.6.2.1. User requirements: Interview schedule

Introduction

- Introduce ourselves
- describe the aim of the PHA project
- describe the aim of the interview
- how long it will take
- confidentiality issues

Questions

- Can you describe your role as a patient safety manager?

Probe: Can you briefly describe your background and expertise in patient safety research?

- What do you understand by prospective hazard analysis?

Probe: definition?

Probe: describe stages of analysis?

- What is your opinion on PHA methods? (more from a theoretical point of view)

Probe: useful/needed?

Probe: feasible in healthcare – characteristics of different healthcare settings

- Do you have experience using PHA methods? If so, can you describe your experience? Can you describe the usability of PHA methods?

Probe: process mapping

Probe: boundary issues

Probe: problem identification

Probe: motivation

Probe: Was it easy/difficult?

Probe: Time-consuming?

Probe: Analysis performed alone/multi-disciplinary team?

Probe: In the context that it was conducted, did it result in an implementation of a recommendation? Was it sustained? If not, why not?

Probe: what were the obstacles?

- Can you describe the types of PHA methods used currently by NHS organisations?

Probe: the use of the risk matrix

Probe: FMEA, HFMEA, HAZOP mentioned in NPSA documents?

Probe: are there plans for the NHS to advocate the use of PHA methods? Which ones? Why have they been chosen?

- What is your opinion on 'lean thinking', 'six sigma', 'lean sigma' promoted by the NHS institute of innovation and improvement?

Probe: do you think it is a viable tool for use in the NHS in general? Would it be applicable to particular types of healthcare setting?

- In your opinion, who may be the potential users of PHA?

Probe: risk managers – in what type of trusts?

Probe: frontline staff like healthcare professionals?

Probe: service development leads?

- What might be the factors that may promote the use of the PHA Toolkit?

Probe: content of the Toolkit itself? Need such a Toolkit?

Probe: state of the system?

Probe: characteristics of the users?

Probe: how it may be implemented? Easy or difficult to introduce the concept?

Probe: influence from what other NHS organisations are doing?

Probe: governmental pressure or autonomy to choose what is best for their organisation?

- What factors may hinder the adoption of the PHA Toolkit?

Probes similar to question 5 above.

End questions

- Is there anything else that you would like to add?

Close and thank you. Assure confidentiality.

10.6.2.2. Interview findings and interpretations: Factors affecting use of the Toolkit

Participants commented and highlighted various factors that could affect the use of the PHA Toolkit. These are discussed under the following headings:

1. Potential users
2. Advocates
3. Prioritisation from without
4. Commitment from within
5. Benefits of the Toolkit
6. Resources required
7. Support provided
8. Readiness of NHS organisations
9. Accessibility of the Toolkit

Potential users

A wide range of healthcare staff were mentioned in interviews as potential users of the Toolkit. The potential users cited in interviews were:

- 1) Risk and safety staff:
 - a) Governance and risk people
 - b) Risk managers
 - c) Patient safety officers
- 2) Clinical staff:
 - a) Consultants
 - b) Clinicians
 - c) Pharmacists
 - d) Nursing and care staff
- 3) Management staff:
 - a) Managers
 - b) Ward managers
 - c) Directors
 - d) Commissioners
 - e) Project managers
- 4) Designers:
 - a) Care pathway designers
 - b) Service redesign leaders

People who should be involved in the risk analysis process, but not leading it, were managers, administrative staff, patients, clinicians. There were a number of mentions of the need to involve a multi disciplinary team in the analysis.

There are a number of issues that emerged from the responses to this question that should be highlighted.

1. The importance of assessing hazards in the clinical setting was emphasised by a number of people. Clinical staff already risk assess patients and carry out other informal risk assessments and the Toolkit was seen as building on this process.
2. Several respondents highlighted the distinction between PHA being used at an organizational level and in the care environment (at the sharp end). At the organizational level PHA could be used to assess risks to business objectives and other risks that span the organization. At the clinical level it would assess problems within a care plan or within a planned care pathway. These respondents specifically stated that the Toolkit should address both needs and that it should be structured in order to fulfil both functions.
3. A number of respondents emphasised that even if clinicians are not the primary users of the Toolkit they need have a positive attitude to PHA or it will not work. Only some clinicians are highly motivated by risk and safety issues to use these methods. However, if any clinicians are not supportive and don't perceive PHA as beneficial they won't contribute to the process or listen to the results. Doctor champions are needed. Nurses were seen as more receptive because they are willing to adopt new things, willing to change, follow protocols better and work predominantly in teams.
4. The issue of training was highlighted A number of respondents highlighted the problems of applying a technique without understanding it, so several suggested that expert facilitators be used. These would be healthcare professionals who have been

trained to a high level in using PHA. But they also thought that as many people as possible, including all clinicians, should have some knowledge of PHA. Retaining skills in PHA if the clinician is only involved in conducting an analysis occasionally was seen as a problem, hence the need for an expert facilitator.

Advocates

There were opinions about a gap within NHS organisations to introduce new methods or guide organisations in its use because Patient Safety Managers who previously had that role have now cease to exist. Although Patient Safety Action Teams have now been formed and are widespread, they have different priorities and targets to meet. Hence, they may not use the Toolkit or advocate its use.

Clinicians as advocates

Based on the assumption that clinicians are the potential users of the Toolkit, clinicians were viewed to be potential advocates of the Toolkit because they are viewed to be credible and have relevant or common experiences.

“You have a trainer, external, someone who has come to train, but you need clinicians to sell it to clinicians. I think that’s, you can use other ways but one reason I’m in my job is because I’m a clinician, OK so, I have facilitators who are not clinicians and if they have a problem they roll me out...I can talk the language, I can counter argue the opposition, you know, so a surgeon who says, I’m not going to mark sides because I’ve never, ever made a mistake. OK, so I can argue the case, whereas someone who is not a doctor may find it difficult to meet that kind of resistance.” (16)

A recent encounter by a participant suggests the support for clinicians to be advocates of the Toolkit and stresses the need for sensitivity when approaching and training clinicians.

“I mean I went to one and I’m sort of relatively keen on this sort of stuff, but I went to one of the briefings and it was just awful. You know there were about thirty clinicians there and the person talking to us obviously thought we sort of kindergarten kids, and you know that sort of thing doesn’t go down well...Yeh, yeh. Talking down, ehm, and it was a whole load of pre-prepared slides and one of my colleagues put his hand to me and said, that’s factually incorrect. You know, it’s just not true. And, you know, you just have to be very, very careful how it’s done.” (15)

“And, you know, you just have to be very, very careful how it’s done, but you know there are so many initiatives and any smack of the whole things being politically correct or sort of department of health dry, and that rather counteracts what I said before, you know, if you give it a bit DOH label, you know that immediately puts everybody off. So, the whole thing I think has to be done very sensitively if you want it to work.” (15)

Credibility of the person/institution

Participants talked about engaging a credible person to introduce the Toolkit, one who has earned the respect of staff members and able to communicate effectively with staff members within a particular organisation. Across organisations, there were suggestions of engaging credible institutions to introduce the Toolkit such as the NPSA or the Royal Colleges.

Support networks

The introduction of the Toolkit to clinicians via support networks may be useful. Within these networks, organisations that have had first hand experience applying the Toolkit or those that have heard about it from a different source may share any relevant experiences, whether positive or negative. Hence, there is a risk that support networks could present the Toolkit in a negative light and discourage its adoption. Peer groups sharing within these support networks could also be effective to bridge the gap between clinicians and

management because of the existing gulf and resistance to do be part of a seemingly bureaucratic exercise.

“I think from a clinical perspective probably networks would be a stronger encouragement than management because I don't know if you know about the NHS, but management and clinicians don't necessarily get on particularly well. So I think it's about peer groups and some sort of demonstrable process...that through sort of osmosis our representative in that network comes back here and says this is a really good tool...and that sort of peer encouragement is actually probably stronger than, this is what we are going to do guys not let's get on with it, because there is a resistance to that sort of thinking and behaviour.” (I9)

Prioritisation of PHA

In order to facilitate buy-in of the Toolkit, some participants commented on the role of politics in prioritising PHA. Participants talked about their daily competing tasks and that it is routine to only deal with those that are at a crisis or have been given a certain level of priority. Hence, unless there is a higher level requirement to use PHA, it may not be easily adopted and used.

“The second is that there is some sort of political priority attached to it. You know, from something like the strategic health authority level, ehm, but it's got, realistically it's got to have those sorts of badges on it I think.” (I5)

PHA methods have been used by the NPSA in several projects and in the Leading in Patient Safety programme developed by the NHS Institute of Innovation and Improvement. These could be used as examples of use in current practice.

Commitment

Commitment and support from high level

Participants discussed the need for commitment from both the higher level and those at the sharp end of the organisation. However, there is a greater need for the higher management to be convinced of the need of the Toolkit first.

“You need both but if you've got the will and the passion lower down in the organisation they struggle if it's not also at the top...Whereas if it's at the top you can usually engender it below because most clinicians want to improve.” (I11)

Senior management would need to be sold on the benefits of the Toolkit: to be convinced that it is relevant and have been trialled successfully in similar settings. They may then be able to provide the necessary support to staff working at the sharp end of the organisation.

Benefits

Participants discussed the need for the benefits of the Toolkit to be clearly presented. Generally, participants were concerned with the potential benefits for individual staff members, the organisation and patients. These are discussed under indices of benefits. More importantly, participants commented on the need to provide evidence for the mentioned benefits.

Indices of benefits

Individual gain without pain

Participants referred to the potential benefits for individual clinicians that are trying to deliver a world class service or care for complex patients. The Toolkit would ideally provide information that is unknown to them in an easy way.

“...people are naturally reluctant to change, they have to be sold on the idea, they have to see the benefit, and that benefit has got to come at not too great a price in terms of change or routine, inconvenience, all those negative things that people willingly put up as a reason why

they can't do something." (I12)

Multiple use of the Toolkit

The Toolkit would ideally have multiple uses such as the use of the process map that is developed to conduct hazard analysis. This comment was probably made because participants were not provided with information about the Toolkit.

Cost benefits

Benefits of cost in terms of cost savings or cost effectiveness were likely to influence those at the higher management of the organisation.

Efficiency/Time savings

Staff members in NHS organisations are concerned with the lack of time to perform even daily routine tasks. The potential for their job to be made "easier, quicker and smarter" or more efficient could encourage the use of the PHA Toolkit.

Safety

The potential to increase the safety of staff, patients and other people in the hospital was considered to be an important benefit.

Improve patient care

Improved patient care was an index of benefit that was important to clinicians.

Time vs perceived benefit

Due to the limited time resource within NHS organisations, participants commented on the need to weigh up the potential benefits of conducting the analysis against the amount of time that is spent. It would be less likely for potential users to invest the time to use the Toolkit if the perceived benefits were not convincing or important for them.

Reduce harm

The potential for PHA analysis to identify and provide recommendations to reduce harm was mentioned. Participants did not state whether this was harm to the patient, staff or the organisation.

Reduce litigation

NHS organisations are weary of litigation. The reduction of the likelihood of organisations being sued may help the adoption of the Toolkit.

Improve quality of work

Some participants mentioned the benefit of improved quality of work. It was not clear whether this referred to clinical and/or non-clinical work.

Measurable outcome

Participants commented on the benefit of the Toolkit providing definable, demonstrable results to measure change, risk reduction or to benchmark the organisation that may motivate potential users to adopt the Toolkit.

Robust methodology for generating recommendations

The generation of recommendations using PHA methods follows a robust methodology and this benefit could motivate the use of the Toolkit.

Centralised database of risk assessment

There is currently no centralised database of risk assessment in the NHS. NHS organisations have different systems or databases such as Ulysses, Datix that have risk assessment modules attached to them, excel databases and different forms of paperwork.

Providing a centralised database of risk assessments or generic risk assessments using the PHA Toolkit is seen to be a benefit because organisations do not have to re-invent the wheel. This is based on the assumption that work in the NHS does not vary greatly to enable the utilisation of generic risk assessments.

“People, they don’t make a lot of use of generic risk assessment either, which you could quite easily do, all the wards do roughly the same work, so why can’t they get together and do generic risk assessments.” (I18)

Evidence of action

Some participants mentioned the benefit of the PHA Toolkit in providing evidence that a particular action had been taken against a risk that had been identified or a decision not to take any action for litigious purposes.

“And the risk of not doing them of course is infinite because it’s evidence that you’ve identified what you think and you have a problem and you’ve done something about it and you are aware of the risks that you face, and we know when we get claims in, unless we prove, provide the risk assessment prior to the incident and the review after the incident, we’ll lose that claim every time. So they are important *and do need to be done...*” (I18)

Evidence of benefits

Participants emphasised the need to show evidence of these benefits. Evidence of how PHA methods had been applied in specific or relevant settings to that of potential users and shown to result in these benefits was important.

Resources

There is recognition amongst the participants of the potential resources that are needed within NHS organisations to be able to use the Toolkit. The resources referred to include finances, manpower, skills and knowledge, and time. These are discussed here under the following headings:

1. Time
2. Cost vs. perceived benefit
3. Skills and knowledge or competence to apply the Toolkit
4. Implementing recommendations
5. Analysis team
6. Follow up

Time

The issue of time was raised by all the participants. Time is a limited commodity in NHS organisations and some participants mentioned that some staff members do find it difficult to even perform their routine tasks. There is always a need for prioritisation of work.

“But the tools may be useful but I think very often the barrier we come up against is the time to be able to use those...And it’s the time bit that’s the six million dollar question, how do you get round that because we know for example, that in certain, if not all, the vast majority of secondary care hospitals people don’t have enough time to do all of their activities in a normal working day anyway and so people will shortcut and do things the quickest possible way which is not necessarily the safest....” (I9)

A few participants mentioned that constraint of time lead people to work in the most efficient but not necessarily the most effective or safe way in order to reach a reasonable outcome.

“So that again goes back to what I was saying about, we do things in the most efficient way, not necessarily the most effective way, so we are looking at time management rather than actually perhaps spending time on it and getting the best possible outcome we can get. We get a reasonable outcome.” (I9)

Participants highlighted the areas where time was needed to enable the use of the Toolkit.

Forming the analysis team and required commitment

Participants repeatedly mentioned the difficulty in forming the analysis team due to the varying work commitments. External pressures such as the need to meet multiple targets set by the Department of Health and the pressures of having to also treat patients.

“Only that I think that the only barrier to it really is the time that it takes in getting the group together and getting the commitment from the proper group of people, if you are going to get all these stakeholders rather than just the keen ones.” (I1)

There is a need for clear commitment from the analysis group. This can sometimes be difficult for clinicians who are often called away to perform other tasks.

Conducting the analysis

Unlike other industries such as aviation and military, there is no dedicated time within NHS organisations to conduct risk analysis because of other pressures such as DH targets and the inability to find time away from routine work.

The time that is taken by the entire analysis team away from their routine work to conduct the analysis equates to a lot of time resource. A participant commented that the analysis that he had conducted identified more than two hundred failures and it would take a lot of time to analyse these and the NHS currently do not have the availability of resource.

“I mean with ours we came out with two hundred and something failures and literally to go through all those two hundred and fifty failures and rank them before we even went any further was a lot of work and I, the thing I kept on thinking with this is that, I think I put this in, I can't remember was that practicalities of bringing this in to the NHS would be very difficult.” (I4)

The ability or willingness to spend the necessary time on the analysis corresponded to the size or nature of the issue.

“...but again it depends on what you are trying to do, if you're implementing a new service then you've got to spend a lot of time on doing it, if it's just sort of something small then I suppose it would take less time to get there.” (I1)

Training users

A new set of Toolkit or methods would require training and this would invariably require time.

Time vs perceived benefit

Participants raised the point of the need to consider the potential benefits versus the time that is spent on the analysis. A few participants had the perception that there would be no extra benefit using PHA methods to a method that is simpler and required less analysis time. There was a need to know that time is spent well.

Cost vs. perceived benefit

Cost is an issue that was raised and some participants mention the ideal scenario where no or little cost needs to be met to gain the potential benefits of applying the Toolkit.

“There has to be cost benefits, they want to know exactly how its, what the safety benefits are

and how it's going to benefit their trust, and ehm, you've got to be able to do it at no cost..." (I1)

Skills and knowledge

It is important for potential users to have the knowledge and skill to be able to apply the Toolkit competently.

"Well you need some people who have the skill set to do it and the patience and the interest and I'm not, if it's reduced to a very simplistic tool just because that means that your lowest common denominator risk manager can use it, it probably loses it's value." (I11)

Analysis team

Time constraints

The issue of time constraints was mentioned in the previous section. This leads to the difficulty forming the analysis team that is comprised of the relevant stakeholders not just those who are keen to be part of the analysis team.

Who to be involved

Facilitators would need to know the appropriate people with different but relevant expertise to be involved in the analysis team because the choice may possibly influence or affect the findings.

"...is the fact that to do it successfully YOU need a multi-disciplinary team who know the task that you are undertaking a review of to be able to describe that either verbally or in writing, and then for somebody like us as risk management experts to actually be questioning the process, where are the triggers, where are the bottle necks, where are the hitch points in that process, so what hazards can we spot, what risk can we see of it not being successful and why." (I9)

Implementing recommendations

The organisation should also ideally have the capacity or intention to implement the recommendations that result from the analysis. Otherwise, users in the organisation may find that their efforts have gone to waste.

Follow up

There was also mention of the need to have follow up within the organisation so that there is meaning or reason for conducting the analysis.

Support

Support here refers to the support that NHS organisations may require to facilitate the use of the PHA Toolkit.

Identify champions

Champions across NHS organisations or within the organisation can help encourage potential users to use the Toolkit.

Level of external support

There seems to be an expectation for further support besides training such as being a point of contact for NHS organisations if they encounter problems.

However, there was a clear resistance to the use of external consultants due to the lack of resources, the potential that the external consultants lack understanding of the healthcare system and the possible issues with ownership and continuity of the project. There could also be a possible conflict with the role of risk managers as they could be seen to be less involved in risk assessments.

“... as long as you do a good job, they’ll come back to you and that’s how it will grow, so if you have that external that will just lose a bit of that as well.” (I16)

“I think it does need some expert facilitation. But I think that is something that people within the service can be trained on, I don’t think it needs, you know, it doesn’t need an expert patient safety, you know, these sort of train the trainers methodology where somebody locally it trained to, you know, who is already perhaps involved in risk management or facilitation or education could be trained to facilitate.” (I2)

Pre-existing expertise

Potential users may run into difficulties if they do not have a background or certain level of knowledge or skill in applying the methods. Hence, there may be a need for someone else with a particular level of expertise to guide the process.

Training

Content of training package

Some participants mentioned a need for potential users to understand the concept of risk assessment and the meaning of terms such as hazard and risk, in addition to the application of the Toolkit. Participants also suggested a need for basic training on what risk management is and knowing how to recognise or mitigate risk.

“...but yes there’s a definite need for people to be trained in what risk assessment is about, in conjunction with how this tool kit will help you and how it works.” (I18)

There is also a training need for the facilitators to know who and when to appoint or select the most appropriate people to be part of the analysis team.

“I think people who are using it facilitating it need some degree of training in terms of even getting the right people involved and being systematic.” (I2)

Standardised

A few participants highlighted the importance for standardised training across different organisations so that there is consistency or uniformity.

Training model

The training model suggested by some participants was for appropriate staff such as risk managers or clinicians to be trained initially by those outside the organisation. They can then act as trainers to the users in their own organisation. There was specific mention to train clinicians so that they can train other clinicians in turn.

Hands-on

Training may be more effective if users were shown how to use the Toolkit, not just be trained verbally or read a written document.

“from the experience I have had as a patient safety manager and now...I think the strength of it was that we were told, right this tool kit is coming out you’ve got to go out and do it, but we actually worked with the trust to work through it. If you just put something on the website for people to access, however much guidance you put with it I don’t think they stick with it, or they are really not going to go in a look at it in any depth if they’ve got to sit and read reams of paper, they want someone to go out there and show them how to do it, if it’s more successful.” (I1)

Sensitivity

One participant recounted his experience in a training session where the trainees felt that they were being talked down to as clinicians and they were presented with incorrect information. This highlights the need for careful preparation of the training materials and to

conduct the training at an appropriate level with a certain level of sensitivity.

Competence

Users should have reached a certain level of competency so that they are competent to not just apply the tool to the right issue but also knowing how not to use the Toolkit and when it has been applied correctly.

Pilot projects

Many participants highlighted the need to conduct small tests of change within the organisation and not introduce the Toolkit en masse. Different NHS organisations present different characteristics and it would be unwise to assume that it can work equally well across different parts of the organisation. There were suggestions of appointing specific NHS organisations to adopt the Toolkit as a pilot project. This could help resolve the potential problems that may arise before introducing it to other NHS organisations.

Readiness of NHS organisations

Patient safety not prominent

A few participants had the view that patient safety is not currently seen to be as important or prominent in NHS organisations compared to clinical targets or other organisational targets.

There were questions raised about whether the Toolkit would be viewed from a risk or safety standpoint. However, one participant had the view that the Toolkit should not be tied in too closely to the safety agenda but to be viewed from a positive standpoint of prevention rather than cure.

Fire-fighting mentality

Participants commented that it may be easier to get a group of people to spend time investigating a serious untoward incident (SUI) but to analyse a particular issue prospectively is more difficult.

Attitude or ability of the organisation to respond or react to hazards

It would de-motivate potential users if there was no clear indication that the organisation have a positive attitude, react appropriately and is willing to action some of the findings of the analysis. The engagement of the implementers of recommendations in the process may be useful.

“Secondly, that the system doesn’t respond appropriately to react to the hazard, so if you identify hazard there’s no way of responding to it, so what, why bother to identify something you can’t do anything about. And we often do those kind of things.” (I6)

Motivation for conducting risk analysis

There are also potential mismatch of goals between NHS organisations and the clinicians who work within them in terms of risk. A problem within an organisation may have serious implications to the clinician and clinicians may resort to disregard some of the actions recommended by the organisation if they perceive that those actions may increase the exposure of risk to clinicians.

“And it’s a very nasty atmosphere out there, if you get something wrong, you know the ultimate sanction the patients have it to phone up the GMC, and even if your practice is good, you know, you make a mistake you can be in for a very, very rough nine months and most people will do anything that they perceive reduces that risk to them personally. To the extent that it doesn’t matter if you tell me that organisationally this would be much better, if I perceive that

organisational flow chart as increasing my risk of some sort of complaint then I am likely not to follow it...Whereas I would think almost in every other organisation the risk is to the organisation not to the individual within that organisation, and that's the big difference between the NHS and any other organisation, that there are risks to the individuals working within that organisation." (15)

A fire-fighting culture within NHS organisations is still evident as some participants talked about dealing with political hot potatoes and not necessarily the issues that pose greater risk to the organisation, staff or patient.

Perception of complexity, assessment of need and confidence in existing methods/tools

There is a perception that PHA methods are very complicated and NHS organisations would not have the capacity nor the ability to grasp or use them. Complex methods were viewed to be suitable for other complex organisations such as NASA and aviation.

"Won't work in the NHS, too complicated. I went to a seminar with a lot of NHS people on risk assessment, an OIOSH (???) set up, the professional body for health and safety and there was some guy there with fault tree analysis, fault mode and all that, and people's eyes just glazed over. Now that's the people who are meant to be experts, goodness knows what people out there will do, that's what I meant by simple. We do use root cause analysis, but that's normally for incident reporting, but anything other than very straightforward will not work in the NHS, if you complicate issues it won't be done, even I won't use those tools because to me they are far too complicated, great for the aeronautical world, for NASA, for the airlines and all that, great for them, not for the NHS." (118)

The perceived complexity of the PHA methods led participants to view the need of the Toolkit in their own organisation. There is a certain level of confidence that the current tools or methods and/or the expertise that exists within the organisation can provide the relevant answers to a given problem.

"I mean, I don't need to, I mean, a lot of the stuff I do being non-clinical, in general I've got an understanding of what goes on, what happens, you know, I'm from an engineering background, actually even down to the basics of diagnosing a fault of a gearbox or an engine, it is cause and effect so fundamental to my training that's built within it anyway, you know what I mean ...unclear.... There's very few.....unclear.... in relation to patient. If we are not dealing with clinical, immediate and underlying causes are fair or apparent, I mean I can't say, you know what I mean, I've not needed to use that sophisticated a tool in relation to what I do." (114)

"Now whether they are searching for answers in different places, but I'd say that any problems they talked about there [FMEA workshop] you could have got them to do the simplest form of risk assessment and come up with a sufficient number of answers." (117)

Not a bureaucratic tool

If there was a perception that the Toolkit was a management tool, it would be less likely for the clinicians to use the Toolkit because they do not see that it is their responsibility to solve a management problem. There may also be a perceived conflict with clinicians' control if the Toolkit was seen as a bureaucratic tool.

"You do get people who really don't want their autonomy taken away from them and if it's just another piece of paper for managers to use against them." (11)

Accessibility of the Toolkit

Name of the Toolkit

Some participants commented that the word 'hazard' in 'Prospective Hazard Analysis' does not sound 'clinician-friendly'. It has a negative connotation and may put clinicians off. Suggestions include using terms such as reliability, safety?

There was also comment on the perspective of the Toolkit – whether it was concerned with

risk or safety.

Access

The Toolkit should ideally be easily accessible by potential users. They should be able to find and obtain the Toolkit without much difficulty.

Cost

There is mention of the cost of the Toolkit to be free so that it would be easier for potential users to obtain and use it without having to apply for financial approval from the relevant departments that could potentially be problematic due to resource constraints.

Interview findings and interpretations: Content of Toolkit

An important finding of the semi-structured interviews was the participants' view of the Toolkit. This category could be divided into:

1. Purpose or aim of the Toolkit
2. Development of the Toolkit
3. Elements, characteristics of the Toolkit and usability issues
4. Guidance provided with the Toolkit
5. Form or presentation of the Toolkit

Purpose or aim of the Toolkit

The focus of the Toolkit should be made clear as to whether it is meant for analysing clinical issues only and/or non-clinical issues such as those under the banner of health and safety issues.

"I tend to find out when it goes national, the national bit tends to take, because health and safety is already there with health and safety law, so they say well, it's already there, but surely you are trying to integrate...." (I18)

There is also a potential danger that the focus would be on the conduct of the analysis rather than the outcomes of the analysis and there is a need to address this balance.

Some participants suggested that the purpose of the PHA Toolkit should not just be about performing the analysis but also be about changing the culture of the organisation to one that values and understands the need for risk analysis.

Transparent about limitations of the Toolkit

Any tool will have its limitations. A description of the opportunities afforded by the Toolkit and its limitations should be discussed explicitly in the Toolkit. The difficulties of applying the Toolkit can provide realistic expectations of the benefits of the Toolkit and prevent users from attempting to apply it to every problem.

"Otherwise you get into an IHI like stage where you know everything in the garden is rosey but when you start using things you find it's not as easy as everybody said. And that really puts people off, if they don't understand the difficulties as well as the opportunities." (I8)

Development of the Toolkit

A user-centric approach to designing and developing the Toolkit was advocated. Participants who had previous experience developing or introducing new tools or methods discussed that a collaborative approach with different user groups increases user engagement and can help to increase buy-in.

Elements, characteristics of the Toolkit and usability issues

Versions of the Toolkit

The current understanding is that the Toolkit is designed for use by different NHS organisations. Some participants commented on the need to have different versions of the Toolkit for different NHS organisations. The nature of the problems or processes in NHS organisations varies and it is difficult to breakdown some processes into individual steps because they are usually performed automatically. A participant had the opinion that the Toolkit should be process-focussed.

Cascade of methods

There was acknowledgment that there was a need for a cascade of methods within the Toolkit. Methods that have different levels of complexity and suited for analysing problems of varying nature or size such as an analysis of the organisation or a particular process was needed in the Toolkit. For example, several participants mentioned the use of prompts or a checklist of triggers or potential hazards initially to identify serious problems. These more serious cases can then be analysed in more detail.

“I think that the idea of having a range of tools if going to be important because you certainly don't want to be suggesting to people that they use a large and complex system for something which might need just a check list of questions.” (I8)

There was also suggestion to not include a large range of methods that users can choose from as it can cause confusion.

Context-specific

Some participants expressed the need to provide context to the use of PHA methods in NHS organisations such as examples of success in specific UK settings. Proof of success in other service settings or countries can be seen to be irrelevant or foreign to NHS staff and it is not uncommon for them to dismiss a particular method or initiative on that basis.

“And if it's been used in the type of service that they are running or something that's very ehm something that they know rather than some obscure, something in America, Oh yes it's been used in America, OK, not the same really.” (I1)

Simple tool

Relevance, easy to use and easy to understand

Underlying the need for the Toolkit to be simple are several assumptions about the Toolkit and the potential users. The first is that PHA methods are very complex and some are sophisticated. Some participants do not view their work to be so complex hence these methods are viewed to be not relevant.

“I probably wouldn't put it into mine because I am trying to keep it as simple as possible and in getting people to start looking at Fault Tree analysis of inventory even if you go down to the basic sort of doing root cause and you come back with fish bones and so on and so forth.” (I14)

There was also the opinion that there is no need to use methods that are perceived to be complicated because the basic risk analysis processes are the same.

“I don't believe there's anything in the health service that needs complicated or different levels of calculation because you look at what risk assessment is or risk analysis is, you're always asking the same question, what is it, what could go wrong, who does it affect, and how we are going to control it, the four whys.” (I18)

The complexity of the tool could potentially discourage buy-in from potential users.

“... I think it leads to difficulties of its own because it makes it too complicated so you switch off participants and you lose their engagement so its making something that’s relatively simple and understandable but measurable as opposed to something that’s very very complex, that you need to be a hazard analysis expert to be able to understand and it just turns off clinicians.” (I2)

A participant who trains risk assessors within the organisation commented on the challenges faced during training sessions due to the different levels of cognitive abilities of trainees. Hence, there was a need to simplify the Toolkit.

“And very often we’re, this is going to sound awful, but we tend to be teaching some people in the organisation who are doing risk assessment but are not that intelligent, and so some of the more junior members of staff who are the risk assessors for the ward or the department where they work, they have to do it under supervision of the manager but their IQ levels are probably not that great, and so it needs to be a simplistic process.” (I9)

The Toolkit should ideally be simple to use and intuitive without the need for participants to spend considerable time being trained to use it.

Crib sheets/concise concept, instructions or information

Participants discussed a need for a concise summary of the concepts, analysis process and where to obtain more information if required, or a crib sheet to accompany the Toolkit. This would aid to reduce the level of detail or complexity or information overload so that the focus could be placed on the essential aspects of the analysis. It could potentially increase awareness of the Toolkit as potential users are more likely to read a concise document that would take less time and effort.

“...but I mean, flow diagrams, or something like that, this is how it works, with references to the pages you then go to when you get stuck. But not something that starts off with, you know, a four page dialogue on the history of ehm,...Because it would be sent round the hospital and people will delete it. Because that’s what they do with protocols and guidelines, they are forty pages long, delete.” (I5)

Clear instructions and terminology

The language and terms used in the Toolkit need to be clearly explained to avoid confusion when users are faced with a list of new methods. When providing instructions, they should be clear and any potential questions should be relevant to the analysis.

Integrate Toolkit with existing methods or initiatives

The majority of participants had the view that integrating rather than competing with existing methods, tools or initiatives would facilitate buy-in of the Toolkit.

“I think one of the barriers to this project being successful if not thought through it competing with people like the NPSA. So, and the difficulty is there are so many things, so many projects going on at any one time that you can’t be aware of what the NPSA are doing...” (I9)

“If you can get something fitting with the existing systems that will be easy to use, if you don’t do this you have to do something new, but you need to make sure that if you get something that can be easily integrated.” (I7)

Some participants talked about modifying or formalising current practices of clinicians or to design the Toolkit such that it is seamless with the performing of current tasks. The Toolkit should be used as part of routine tasks and should not intrude, impede or inhibit current tasks. Clinicians as a potential user group are currently performing some form of risk analysis albeit not in a formalised way. A Toolkit that could help put structure to current practices would be helpful.

It was also important that the Toolkit was not seen to be a tool that was imposed by the

management on staff.

“..and also the other problem is that it's seen as a management tool, then it's going to fail. It's got to be tied in to what people do.” (I6)

There were also opposing views of integrating the Toolkit with existing practice as it could be very difficult to ensure compatibility with current methods.

“I'd bring it out as a new tool which could work with other tools because if you try to do that because there are so many different systems that people have you'll find it very difficult to make it compatible.” (I18)

Another participant had the view that a new Toolkit with new concepts was a breath of fresh air and may be better received compared to the traditional retrospective analysis of problems.

Measuring risk or change and its meaning

Many participants discussed the need for some form of quantification or risk or measurement of change. This was seen to be important to understand how serious the identified problem is and can help prioritise areas for improvement due to the limited resources that are available in the organisation. There was also a need to show any relevant improvement and provide justification for the use of resources that had been allocated for the analysis. Doctors were also viewed to be more convinced of the value of a particular method or intervention if there was a form of measurement.

Some participants expressed the view that these measurements or quantification may not necessarily be numerical but it should bear clear meaning for example, how does the organisation interpret and react to a problem that has been colour-coded orange or red. If the measurements are numerical, they should have clear meaning for example, what does a hazard or risk of 6 mean to the organisation?

Some participants discussed the use of these measurements to compare the performance of their organisation to other organisations.

Speed of analysis and interpretation of findings

The methods included in the Toolkit to enable a quick analysis of the problem and be able to interpret the findings to reach an outcome or decision of change within a short period of time.

Standard tool

A standard tool with a structured and systematic process of conducting an analysis was advocated by some participants. The rationale is that NHS trusts have the same standards and similar targets to meet and there is no need to reinvent the wheel in every trust or organisation if there was a standard process. Findings that were derived from a standard tool can also be useful to benchmark the organisation.

However, there were comments that the Toolkit should not be prescriptive, allowing the utilisation of existing experience in the organisation to inform the analysis.

Validity and reliability of the range of methods

The Toolkit should be fit for purpose and provide the type of information that was expected from using the Toolkit.

In a Toolkit with a range of methods, there is an expectation that these methods would derive the same findings.

“I think the difficulty comes because you need to end up at the same result, which is a degree of risk, then whatever system you use has to use the same formula to get to your answer.” (I18)

There is hence a need for the guidance of the Toolkit to make clear the form or types of results that may be expected.

Interesting

Two participants suggested making the Toolkit interesting to increase buy-in.

Guidance provided with the Toolkit

The need for specific guidance to accompany the Toolkit was raised. Participants commented on several aspects that were relevant to the development of the suggested guidance.

Error theories

It was unclear whether the understanding of error theories was embedded within the majority of NHS organisations. There could still be theoretical and cultural barriers where persons at the sharp end are still blamed for incidents or errors that happen within the organisation. This suggests a need to address this potential issue.

Glossary of terms

Terms such as hazard and risk may not be clearly understood by clinicians. The researcher also made an observation that some participants were not clear themselves. Hence, an explanation of these terms with clear examples or a glossary of terms would be useful.

Selection of methods

Potential users' level of understanding of PHA methods is unclear and there was comment of providing appropriate level of information or descriptions of these methods. The range of issues or problems that could be analysed in NHS organisations make selecting the most appropriate method challenging. Some areas for analysis are more straightforward than others.

“If you are talking about someone tripping over a bit of carpet it's fairly obvious and apparent, you know what I mean, and doesn't need detailed analysis.” (I14)

Others may be more complicated and a dilemma presents as to the scope of the analysis and the most appropriate method to use.

“you don't want to get it too narrow to silos because [sic] you don't want it too broad so that it doesn't mean anything.” (I6)

“Well, it depends what you want it for. I am thinking of redesigning systems so I need something grander, whereas, if I was a clinician in an area, or working in one small area, I would need something more quick and dirty, you know, that gets me there.” (I6)

There was also a view that there was a need to understand the whole process. Clear guidance showing the suitability of different methods to different problems was suggested.

“...so some simple way of presenting which methods are best for which contexts would be a really useful starting point...” (I15)

Presenting a short list of methods, possibly around 5 instead of 10-15 methods would probably make it easier for potential users to make appropriate choices without feeling that they are drowned with a lot of new information.

Further guidance or information

Links to further reading or information should ideally be provided in the guidance.

Form or presentation of the Toolkit

There was general agreement that the Toolkit should ideally be on a CD or online. An advantage of an online tool could be the development of a central repository of completed risk assessments that allow organisations to access and adapt these to their own organisation. The design of the Toolkit should be compatible with current technology and if it was to be introduced by the Department of Health (DH), to be downloadable from the DH central website. A few participants envisaged the Toolkit to be able to analyse some data such as perform calculations.

10.6.2.3. Interview findings and interpretations: Understanding of PHA

There were varying levels of understanding of what PHA meant. Most participants were able to provide some description of their understanding. Some however found it more challenging.

The following categories describe the understanding of the participants:

1. Reference to names of methods
2. Similar or synonymous with existing risk assessment
3. Identification or analysis of hazards and/or risks
4. Mitigating hazards and/or risks
5. Quantification of risk and its likelihood

Reference to names of methods

A few participants found it difficult to explain their understanding of PHA and referred to the names of PHA methods or other methods. For example fault tree analysis, FMEA, HAZOP and even root cause analysis and the 5x5 risk matrix were used as descriptors.

Similar or synonymous with existing risk assessment

Some participants had the opinion that PHA was similar or synonymous to routine risk assessment or management. PHA is viewed as a risk assessment tool and not different to health and safety risk assessments. There was also suggestion that current risk assessment methods could be considered part of PHA methods.

“In other words, which is what risk management is about is trying to be proactive, is trying to identify what could go wrong before it actually does and then either getting shot of it or minimising exposure to it and putting in the appropriate control measures. I mean that’s basically how I see it.” (118)

Identification and analysis of hazards and/or risk

Most participants recognised the element of identifying hazards and/or further analysis of these hazards and/or risk. A participant highlighted the importance of not being influenced by past experiences when conducting the analysis. Another talked about the importance of analysing the systems of work, the working environment and the tasks that are performed by staff members.

Proactively

Participants commented on the proactive nature of the analysis of hazards and/or risk. There is recognition by some participants that humans are fallible and inevitably can make mistakes and PHA could help to predict what could go wrong before hand and in time before implementing a new service, process, procedure or activity. They talked about identifying what could go wrong before it actually does happen in real life and the need to try and resolve these problems at an early stage. Some participants talked about a systematic way to identify hazards.

“So I guess I see it as, rather than responding to errors that have taken place, so rather than noticing a problem as it occurs and then trying to address that problem, it’s a case of looking at the systems of work and the working environment and the tasks that people do and trying to identify before they happen any potential errors.” (I15)

Retrospectively

There was also comment that these hazards and/or risk could also be identified after the occurrence of an event.

“I guess they are more or less the same thing aren’t they in terms of you are looking proactively at things rather than you are looking at things once they have happened. Although obviously you can use risk assessment when something has happened to risk assess, to stop something happening in the future.” (I1)

Quantification of likelihood

Some participants placed importance in the ability of the tool to predict the likelihood and quantify the risk of a particular procedure or intervention. The quantification may not necessarily be numerical such as the use of colour but these should be clearly explained.

Mitigate risk

Participants talked about mitigating or engineering out the risks or hazards that have been identified at an early stage to prevent incidents from happening.

There was also comment about the PHA analysis providing evidence to justify the need to apply particular findings in the work place.

Summary

There was general understanding that PHA involved the identification and analysis of hazards proactively. The importance of quantifying the risks was an important factor to some and most recognised a need to mitigate these risks at an early stage to prevent it from occurring. There was some mention of the need to understand the wider work system in order to identify and analyse potential hazards.

10.6.2.4. Interview findings and interpretations: Existing methods (non-PHA), tools of interventions in NHS organisations

Participants were asked to discuss their experience using PHA methods. However, many of them had not used any before. So they were asked to name the methods that are currently used in their organisation or those that they know were used in NHS organisations. A few participants gave brief descriptions of the methods whilst others commented on specific projects or interventions that their organisation are currently undertaking.

List of methods, tools or interventions

A variety of methods was mentioned by the participants and listed below. The majority of

participants conducted risk assessments in their organisation and used the 5x5 risk matrix. The rest of the methods mentioned were not used widely and were mainly used in the participants' own organisations:

1. Action After Review (AAR)
2. Audits
3. Brainstorming
4. Briefing and de-briefing for surgeons
5. Care bundles
6. Check-lists
7. Decision tree analysis
8. Run charts/fiscal process control
9. Fishbone
10. Foresight
11. Global trigger tool
12. Incident reporting
13. In-house risk assessment Toolkit – covers general risk assessment, COSHH assessment
14. In-house transformation programme
15. Inventory
16. Lean, lean and six sigma
17. Leading Improvement in Patient Safety (LIPS)
18. Managing Variability
19. Observational Clinical Human Reliability Assessment (OCHRA)
20. Plan-do-study act (PDSA) cycle
21. Process mapping
22. Risk assessments
23. Risk matrix particularly the 5x5 matrix
24. Root cause analysis
25. Situation-background-assessment-recommendation (SBAR)
26. Strengths, weaknesses, opportunities, threats (SWOT)
27. Timeline

Users

There were two main groups of users: clinical and non-clinical staff. Hospital consultants and ward sisters were the main clinical staff users. Within each department in a hospital, managers have overall responsibility for ensuring that risks are managed but they could appoint or nominate representatives. Staff workers who have health and safety or risk as part of their job were also users of these methods. It was usual to involve a team of staff when performing the analysis.

Support provided with existing tools

A few participants discussed the support that was provided with the use of existing methods. The NHS Institute of Improvement and Innovation leads the LIPS program and train organisations to use the tools but they do provide consultation work. With the AAR, there was in-house training that involved role play with the use of real actors.

Benefits of existing tools

The benefits of process mapping were discussed by some participants. For them, process mapping helped to define the problem area and provided evidence that risks were considered.

“I think it helps you to define exactly which bits you are looking at...” (I2)

"I mean I thought it was worth the effort because we didn't know what the risks were and we needed to be confident that we weren't exposing the organisation, the patients and staff to unnecessary risks." (I10)

Another participant gave an example of how conducting a simple risk assessment provided useful information that helped to affect change in the organisation.

"...it shows the effectiveness of the process that a small one page document, two page document, could have that much effect." (I17)

Problems or issues faced

Although there are numerous methods that are currently used in NHS organisations, some participants found several issues with the methods that they were using. The 5x5 risk matrix is widely used across NHS organisation probably due to the encouragement by the NPSA. However, there is no standardisation of the way that the 5x5 risk matrix is used across different organisations. For methods that require some form of scoring (may not be numerical), there were issues of subjectivity in scoring risks and deriving consensus on scoring was not straightforward. Participants commented on the difficulties of attaching and translating the meaning of the scores and their significance into practice and highlighted that they could sometimes give a false sense of security.

(The participant was discussing the difficulties in understanding the magnitude of a given problem using the 5x5 risk matrix)

"...but they sit there and think, oh it's only twenty, at least it's not twenty five, but it's only one off being a twenty five. It gives a false sense of security, if they're sort of wandering about in this sort of like, in the middle area, oh yeh its not such a problem. But you will find that twelve is not many steps on from give, there's more steps between one and twelve than there is between twelve and twenty five but everyone thinks it's in the middle." (I17)

Scores sometimes required moderation for example in the use of the 5x5 matrix to reflect the magnitude of the problem.

"We tend to be arbiters of this [risk rating in the 5x5 risk matrix] as well because I manage the risk register and so when risk assessments come to me I think, hang on a minute, that's twenty five risk which is the highest we can possibly have but comparing to a lot of other things I know that are on the risk register, there's no way that's a twenty five risk, so then we would challenge that and say, are you really sure, where's your evidence to support that it's going to be a catastrophic outcome and it's almost certain that it's going to happen, and then they need to rationalise that to us, and if they can't then we actually say, well I think you need to review it and downgrade the risk." (I9)

Despite the difficulties in scoring, some participants still emphasised the need to assign weightings to understand the significance of the problems being analysed. One participant strongly opposed the recommendations that were derived from an investigation of an incident because they were counter-intuitive and illogical. This led the participant to search for other methods of analysis to provide an alternative view to the incident.

Summary

NHS organisations are currently using a variety of methods, tools or interventions. However, besides the ubiquitous use of 5x5 risk matrix and general risk assessments, there was no clear structure or strategy for risk management across NHS organisations as a whole. NHS organisations can adopt any method, tool or intervention that they see appropriate. The dissatisfaction with current methods suggests that there is a gap for methods that can provide information about the magnitude of any problem facing the organisation.

10.6.2.5. *Interview findings and interpretations: Potential uses of PHA*

Participants were asked to comment about the potential use of PHA methods in their own organisation or in the wider healthcare system. A range of applications were discussed and these are presented as four main categories.

- 1) Introduction of an artefact to the system and post-incident
- 2) Potential impact of change to the organisation
- 3) Organisational and process analysis
- 4) Governance and risk management tool

Introduction of an artefact to the system and post-incident

In this category, participants discussed the potential use of PHA methods prospectively and retrospectively. To illustrate, participants discussed the potential use of PHA methods when introducing an artefact in the system. Examples of an artefact mentioned included the introduction of a new service, a piece of equipment, implementing a new solution for service improvement, any change to the current work system or the development of a new business.

“I think people are introducing new systems or pieces of equipment things like that then risk assessment is vital. Just so that you are not introducing another risk and creating complications. That’s so often the case isn’t it, you introduce one thing and it just triggers off something else you haven’t thought of that might be a knock on effect.” (I1)

Participants also suggested the use of PHA methods post an incident for example following a serious untoward incident (SUI) that had occurred in their organisation.

“Yeh, I mean if you look at executive teams and boards and things I think sometime sits quite a reactive thing.....SUI, ehm, they might use it to try and prevent another one.” (I2)

Potential impact of change to the organisation

The magnitude of the impact of any proposed change was a consideration for potential use of PHA methods. Opposing views were presented with some participants suggesting the use of PHA methods in areas where the potential impact of any change was great whilst others considered changes with small impact to be more appropriate. A participant discussed the potential time that was required to conduct a detailed analysis hence the opinion that the use of PHA methods in areas where the impact of change was small was suggested. An important point was raised regarding the inter-relationship between any proposed change and the impact that it could have on other parts of the system suggesting that the assessment of the potential impact of any change was not straightforward.

“Yeh, I mean you’d use it on big things, yeh, when something’s hit the fan really.” (I11)

“I think it would have to be small areas of, like a small area of concern or, ehm, and not a big service thing.” (I4)

Organisational and process analyses

Participants discussed two levels of analysis of the work system using PHA methods. One was a high-level analysis of the organisation as a whole, potentially as a diagnostic tool of problem areas in the organisation whilst the second was the analysis of specific processes with clear pathways or areas where there are specified quality assurance requirements such as manufacturing units in hospital, radiotherapy, chemotherapy and pharmacy.

“...you may want to have an organisational based one, which managers will do, for the whole organisation, which is a totally different part of the Toolkit.” (I6)

“I mean, or the use of devices or interventions,...if people had been doing a PHA on infusion pumps ten years ago and done them properly, they would have seen that the user computer interface was problematic, that teaching nurses how to use the on the day shift is not the same as trying to find where the night shift starts and ends and how many bank nurses you’ve got in the system and how you are going to teach them.” (I8)

Governance and risk management tool

PHA was also seen to be a potential tool for organisational governance or as a risk management tool by some participants. To illustrate, the process of performing PHA could be used to provide assurances that the organisation is managing its risk effectively or used to manage the process of risk assessment within the wider organisation and be part of a reporting structure.

“...not too clear about how well we are managing our risks, and we are not too clear whether we have got the assurance we are managing the risks as effectively as we might be, so how can you prove it to us. And one of the questions I might throw back to them is, well instead of picking up risks as problems when the problems occurred, if we pick, identify the hazards before hand and make a decision based on our knowledge of those hazards, then you might have better assurance that you are managing the risks.” (I10)

“It’s a management tool at the end of the day which allows you to identify and action plan and control risk but at the same time manage the whole process and where it’s a lot easier to do than what we have at the moment.” (I18)

Some participants discussed the potential use of PHA findings to inform further analysis.

10.7. Risk Experts workshop case study details

For case studies were presented to the Risk Experts during the workshop, as described below.

10.7.1. Case One: Fracture Care

Setting: District general hospital. Paediatrics, Radiology and Orthopaedics clinics

Scenario: Children with reduced range of movement often present to general paediatric clinic. If there is a suspicion of a fracture, the paediatric registrar refers the patient to radiology for appropriate x-rays. If radiology suspects a fracture, they call the orthopaedic registrar to review the films. If the registrar concurs, he refers the patient for treatment (casting) by the covering registrar. Follow-up arranged by the orthopaedic clinic secretary. The hospital has received many complaints about the stressful process for parents and their children.

Objective of Analysis: Redesign the existing system to optimise efficiency and patient safety.

Please prepare a 5 minute oral presentation of your thoughts and how you would approach this case. Written presentations are not necessary, although you may want to make some notes for yourself. We anticipate the presentations will guide further discussion about the issues raised. Please address the following questions:

1. *In order to better understand the case, what questions would you ask the stakeholders? (framework 1a,b).*
2. *What characteristics of the case affect your selection of PRA methodology? (framework 1a,b).*
3. *What characteristics of the PRA methodologies affect their choice for this case? (framework*

2a,b,c,d).

10.7.2. Case Two: ICU Lines Case

Setting: Adult Intensive Care unit

Scenario: During bed to gurney transfer for transport to MRI, equipment lines for patient support were confused by multiple team members. This patient's enteral nutrition (NG-tube feed) was almost connected to his iv port which would have had a serious outcome, probably death. Although the Respiratory Therapist was not responsible for reconnecting the lines, he noticed the problem and averted the catastrophe.

Objective of Analysis: Prevent adverse events risk from improperly connected devices and lines.

Please prepare a 5 minute oral presentation of your thoughts and how you would approach this case. Written presentations are not necessary, although you may want to make some notes for yourself. We anticipate the presentations will guide further discussion about the issues raised.

Please address the following questions:

1. In order to better understand the case, what questions would you ask the stakeholders? (framework 1a,b).
2. What characteristics of the case affect your selection of PRA methodology? (framework 1a,b).
3. What characteristics of the PRA methodologies affect their choice for this case? (framework 2a,b,c,d).

10.7.3. Case Three: GP Repeat Prescribing

Setting: GP practice

Scenario: A patient of this small GP practice was seriously harmed when he was mis-prescribed a repeat medicine with the wrong dose. Since then, the practice has been concerned about the robustness of their prescribing procedures. The Head Partner at the practice has asked a risk expert to work with the practice to review their procedures and see where the safety risks are.

Objective of Analysis: Identify where the risks are in the repeat prescribing process.

Please prepare a 5 minute oral presentation of your thoughts and how you would approach this case. Written presentations are not necessary, although you may want to make some notes for yourself. We anticipate the presentations will guide further discussion about the issues raised. Please address the following questions:

1. In order to better understand the case, what questions would you ask the stakeholders? (framework 1a, b).
2. What characteristics of the case affect your selection of PRA methodology? (framework 1a,b)
3. What characteristics of the PRA methodologies affect their choice for this case? (framework 2a,b,c,d).

10.7.4. Case Four: Handover Case

Setting: Accident and Emergency at foundation trust.

Scenario: Registrars change shift every 8 hours to meet work directives. They discuss

each patient and what needs to be done next. There have been protocols set but no one follows them. The registrars have a variable level of English fluency. It is not possible for the consultant to attend these handovers due to clinical responsibilities.

Objective of Analysis: Address requirements for future training and improve continuity of care over shifts.

Please prepare a 5 minute oral presentation of your thoughts and how you would approach this case. Written presentations are not necessary, although you may want to make some notes for yourself. We anticipate the presentations will guide further discussion about the issues raised. Please address the following questions:

1. *In order to better understand the case, what questions would you ask the stakeholders? (framework 1a,b).*
2. *What characteristics of the case affect your selection of PRA methodology? (framework 1a,b).*
3. *What characteristics of the PRA methodologies affect their choice for this case? (framework 2a,b,c,d).*

10.8. Toolkit evaluation activities – general

The following table (Table 29) summarises the Toolkit evaluation activities. Activities which occurred within the PHA Team are indicated in italics.

Table 29 Toolkit evaluation activities

No.	Activity	Date (y, m, d)	Toolkit Version	Examples of findings
1	Telephone evaluation of PHA Toolkit concept with a Risk Manager – description given verbally	09-01-12	n/a	Risk Manager stated that it would be helpful to have a section early in the Toolkit that helps the user answer the right question.
2	<i>PHA Team evaluation of early draft of “Green” Toolkit</i>	<i>09-02-10</i>	<i>“Green” version</i>	<i>Very early draft. Includes early development of process mapping selection strategy. Comments provided on how to structure the Toolkit around diagramming. Suggests drawing two sets of diagrams – one to provide context and the others to provide detail.</i>
3	Evaluation 1 with risk managers (Risk Forum)	09-03-17	4d	Idea of PHA “lite” version was supported. A more in-depth version may be needed in addition to this. It was helpful to create an overview of the risk assessment process (Waterfall diagram). Different versions for different stakeholders could be considered. There is a need for balance between pragmatism and rigour in terms of how much detail is included in the Toolkit.
4	<i>Steering Committee meeting</i>	<i>09-04-21</i>	<i>4d</i>	<i>Verbal description of the Toolkit was delivered to the Committee. Suggestions included avoiding the term “risk assessment” and to mention that decommissioning of services is another potential application area for the Toolkit.</i>
5	<i>Evaluation discussion (conducted on telephone)</i>	<i>09-05-13</i>	<i>4d</i>	<i>There is a need for more of a lead-in to the risk assessment in the introduction. Try to educate the user in systems thinking, to move away from person-centred model of error.</i>
6	<i>Meeting for development / evaluation</i>	<i>09-05-19</i>	<i>4d</i>	<i>Preliminary risk review: Explain why the Preliminary risk review complements the Comprehensive risk assessment, and why it is necessary. Use proformas for the recording of results. Balance needed between simplicity of the Toolkit and usefulness. Comprehensive risk assessment: Repetition of philosophy of Preliminary risk review, but in more detail. Comprehensive risk assessment may contain simple descriptions of each of the PHA methods, and a separate section may need to contain more comprehensive descriptions of the methods.</i>
7	<i>Meeting for development / evaluation</i>	<i>09-05-26</i>	<i>4d</i>	<i>Toolkit should allow appropriate level of analysis – i.e. there are advantages to having two sections to the Toolkit. Need to include question on who needs to take part in the analysis.</i>

No.	Activity	Date (y, m, d)	Toolkit Version	Examples of findings
8	Brief test	09-05-28	4e	Brief test to create an example to be used in the Preliminary Risk Review section.
9	Research issues	09-06-09	4e-4j	Unclear what is the range of risks that we are considering (e.g. risk to Trust reputation or safety of patients). Not clear why the guidance looks at deviations but not failure modes – Explain the importance of deviations vs. failure modes. Section 1.17 in V 4j – not clear how the decision to proceed to a full assessment takes the “actions” into account.
10	Meeting with Risk Manager	09-06-15	4j	Preliminary risk review and Comprehensive risk assessment split (triaging process) was popular. May need to design Toolkit to deal with the difference between what is expected (e.g. procedure) (as-should-be) and what is (as-is) practice.
11	Evaluation against PHA requirements	09-06-30	4j	Many of the requirements will be answered in the introduction to the Toolkit, which has not yet been written comprehensively. A number of other requirements have yet to be implemented.
12	Virtual case study 1a	09-07-02	4m	Approximately 20 suggestions were made for changes to Preliminary risk review section. Case study focused on the scenario of closing a geriatric ward due to the outbreak of Norovirus.
13	Virtual case study 2	09-07-09	4m	Virtual case study investigating medication use in care homes. Preliminary risk review section only. Approximately 1 dozen suggestions were made for changes in this section of the Toolkit.
14	Virtual case study 1b (parts i-iii)	09-08-11 09-08-13 09-08-18	4r	Case study focused on the scenario of closing a geriatric ward due to the outbreak of Norovirus. Need to introduce concept of Systems thinking into introduction. Approximately 45 additional comments on Comprehensive risk assessment section, process mapping and PHA methods sections.
15	Evaluation	09-09-25	4t, V0.8	Approximately 10 further suggestions made. Various suggestions over language issues, and need for more explanation over the transitions in the stages in the Waterfall diagram.
16	Telephone evaluation	09-11-03	4u	Advise users that the analysis in the Preliminary risk review section should be at a high level – that if they are starting to have to deal with many variations in standard practice, the analysis may be too detailed. Changes to the risk assessment tables in Preliminary Risk Review section: Consideration whether to split up the tables into two or even one table. We could have an example that has a single table, and another with the table split into three, as it is currently. We should remove the “concerns” column and explain in the text that if the deviation presents a concern, then write down what the hazard is. Otherwise, leave the hazard row blank.

No.	Activity	Date (y, m, d)	Toolkit Version	Examples of findings
17	Evaluation with PHA risk expert	09-11-16	4v	Over 30 suggestions made. For example, suggestion to explain rationale behind the staged approach to risk assessment. Consider developing the Toolkit into electronic form. A training video may be helpful for the facilitators. Add examples of process deviations in Preliminary risk review section.
18	Evaluation with patient champion for an SHA	09-12-14	4w	Patients do not necessarily need to be involved in the risk assessments, but these assessments should be done on the patients' behalf. The Toolkit should be used, but it may be a challenge to get the NHS to adopt it.

10.9. Toolkit evaluation activities – case studies

10.9.1. Initial case study

10.9.1.1. Results

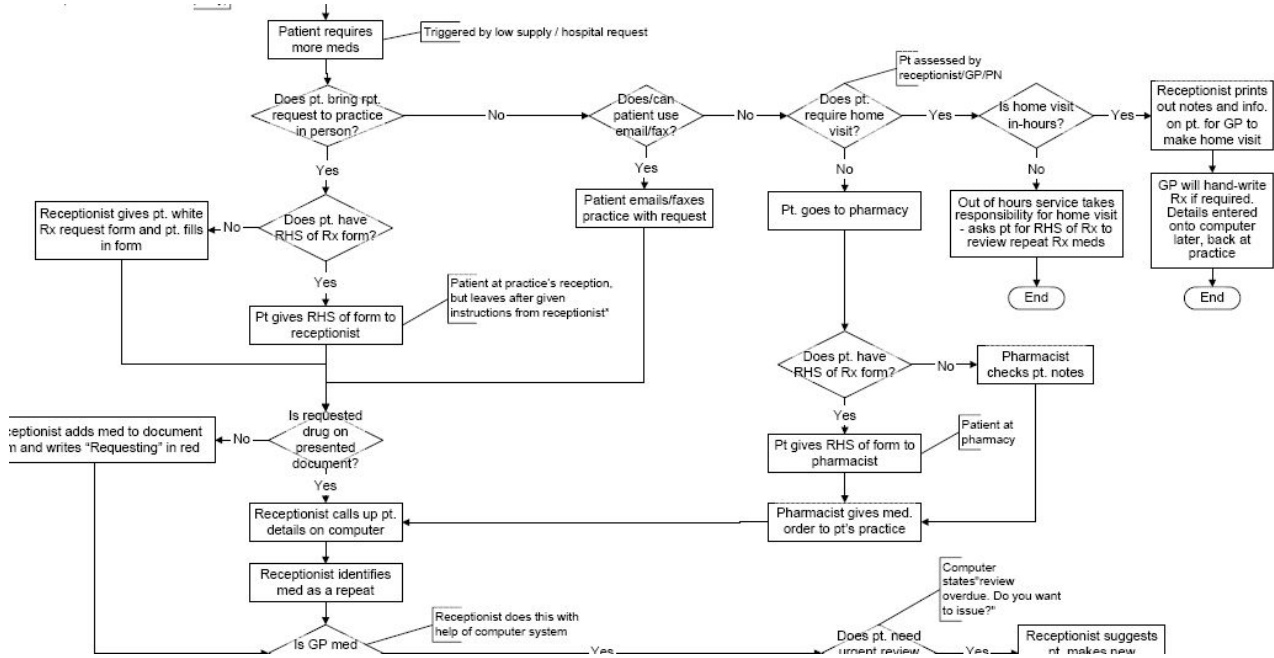


Figure 49 An extract from a flowchart of the practice's repeat prescribing procedures.

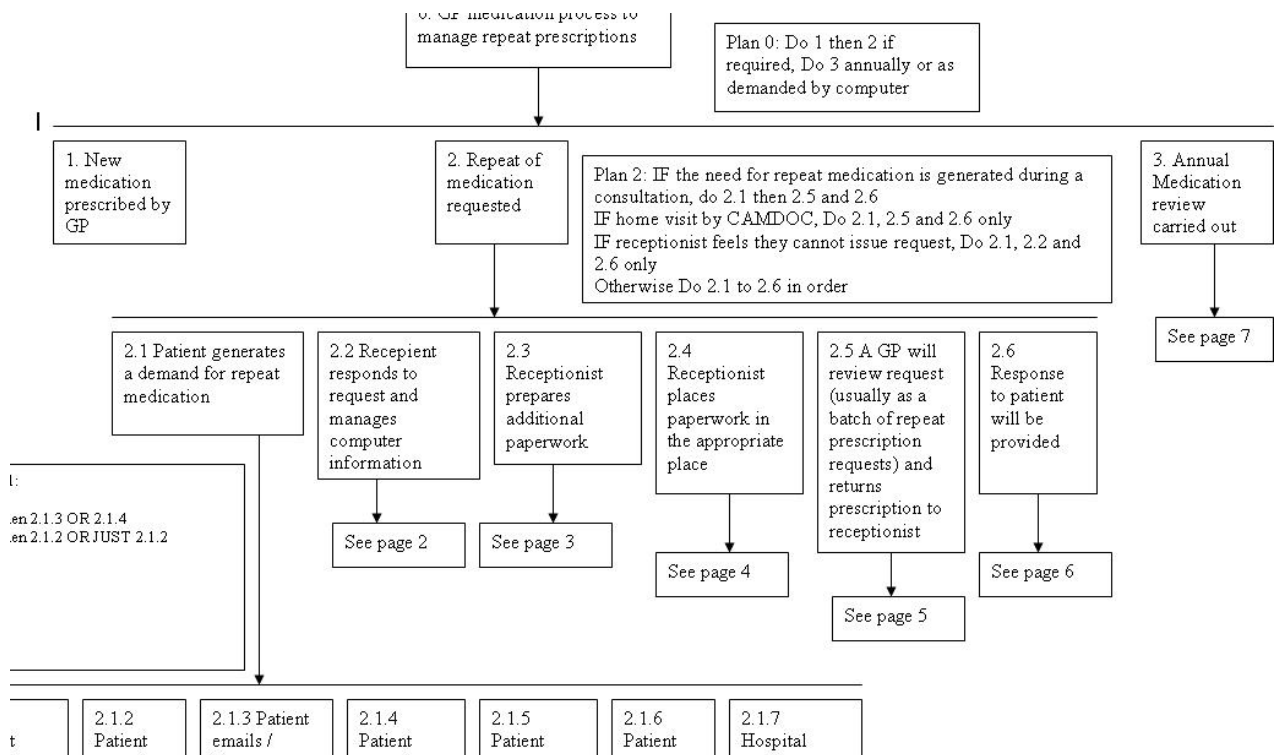


Figure 50 An extract from a HTA of the practice's repeat prescribing procedures.

At the end of each session, participants were asked the following questions. Responses are in Table 30. Blanks to questions indicate no responses.

Table 30 Feedback from initial case study

Question and responses	FMEA	FTA	SHERPA
1) How easy was the method to learn how to use?			
<i>Good to have some illustrative cases first</i>		x	
<i>Clarify better divisions (e.g. 1,2,3) and subdivision (e.g. 2.1, 2.1.1) etc</i>			x
<i>Very difficult to begin with but improved</i>			x
<i>Unsure at first about what was being discussed. Made more clear as afternoon went on</i>			x
2) Process map. How easy was it to understand?			
3) Process map. How accurate was it?			
4) Process map. How comprehensive was it?			
<i>Well constructed and thorough</i>			
5) Were the hazards identified realistic?			
6) Did the analysis reveal any significant risks of which you were previously unaware?			
<i>Was aware but brought them to my attention</i>	x		
<i>Made me more aware of process used by receptionists and how things could go wrong</i>	x		
Yes	x		
No	x		
<i>Yes as I have nothing to do with repeat prescribing therefore many risks became aware</i>		x	
No		x	
<i>Yes (2 participants)</i>		x	
<i>Probably not</i>		x	
<i>Yes – importance/danger of inexperience</i>		x	
<i>Interesting to hear about risks from GP/Nurses perspective</i>			x
<i>Yes, I thought NHS hospital and PCT issued the same drugs therefore made me more aware of the problem we face</i>			x
<i>No (2 participants)</i>			x
7) Was there anything crucial missed by this method?			
<i>No (3 participants)</i>	x		
<i>No (4 participants)</i>		x	
<i>Not as far as I am aware</i>		x	
<i>No (3 participants)</i>			x
<i>I don't think so</i>			x
<i>I thought the stage where changes could be made was the next stage beyond what we were discussing. We were discussing issues outside our control</i>			x
8) Did you find any limitations with the method?			
No	x		

<i>Different drug errors have very different effects from huge to insignificant.</i>	x		
<i>Variable causes and events so may not fit</i>	x		
<i>Impossibility of scoring the severity as there are so many pt and drug variables</i>	x		
<i>No (2 participants)</i>		x	
<i>Maybe time could be a limitation, but it does need to be limited.</i>		x	
<i>Everything had to be put into a certain structure and so this possibly limits discussion, which may not be a bad thing. The method forces the team to focus.</i>		x	
<i>Needed to limit to part only – ambiguous white sheet. Time consuming to look at all of repeat prescribing – and that is only a small part of practice activity.</i>		x	
<i>Some</i>			x
<i>The process we looked at didn't find changes we could implement</i>			x
<i>No I can think of [any]</i>			x
<i>No</i>			x
9) Do you think the same results could be achieved without the formal structure of the method? (E.g. Holding a meeting to discuss problems).			
<i>Not really</i>	x		
<i>Yes</i>	x		
<i>Yes, and I think we would do it quicker</i>	x		
<i>Yes (3 participants)</i>		x	
<i>I think this might depend upon the topic although I know that it an illogical statement</i>		x	
<i>“NO” We could clearly have missed some key issues.</i>		x	
<i>I believe it would help with meeting but not too many it should be resolved ASAP</i>			X
<i>Yes</i>			x
<i>No, the structure allows to bring up the complete picture and not to focus on just one aspect like during an open discussion</i>			x
<i>Maybe discussion with other service users but would be time consuming</i>			x
10) Is there anything that should be changed about the way the evaluation was carried out?			
<i>I feel it would be somewhat easier to start at the top and work down</i>		x	
<i>No</i>		x	
<i>Not particularly</i>		x	
<i>Really productive session from point of view of practice</i>		x	
<i>A meeting/group discussion evaluating the session and method would also be a good way of highlighting the advantages / disadvantages</i>		x	
<i>The beginning</i>			x
<i>No</i>			x

10.9.2. Potential case studies

The following table shows some of the case studies which were considered throughout the project.

Table 31 Potential case studies

- | | | |
|---------------------------------------|-----------------------------------|---|
| • Repeat prescribing | • Tele-monitoring | • Syringe driver use |
| • DVT management | • Paediatric medication error | • Gastro-oesophageal surgery |
| • Pharmacy automation | • Patient discharge process | • Handover in Resuscitation Room |
| • Surgical site infections | • NG tube placement | • Non-luer spinal connectors |
| • Obstetrics and gynaecology | • Respiratory med. | • Purchasing procedures |
| • Mental Health | • Design of operating theatres | • Communication of medication information |
| • Surgeons' journey | • Staff safety / patient handling | • Cancer screening |
| • Introduction of new medical devices | • Commissioning | • Out of Hours services |

A short list of case studies is presented in Table 32. The actual (completed) case studies are excluded from this list.

Table 32 Case studies which were short listed, but were not executed.

Case study setting	Planned risk assessment details	Background	Outcome
Ambulance Trust	Procedures for the manual handling of obese patients	[Details omitted for reasons pertaining to the Trust]	Lack of staff available to take part in research.
Ambulance Trust	Procedures for responding to potentially violent patients	[Details omitted for reasons pertaining to the Trust]	Lack of staff available to take part in research.
Primary Care Trust	Commissioning procedures	General assessment of procedures for commissioning – e.g. to what extent is patient safety considered.	Staff Lead too busy.
Primary / Acute care	Movement of service from Acute to primary care	At the planning stage.	Politically volatile situation.
Acute Trust	Specific care pathway	Care pathway under development.	Alternative case study chosen.
Acute Trust	Introduction of new venous thromboembolism procedures	Concerns were raised over the suitability of the procedures and the potential failures that might result.	Alternative case study chosen.
Acute Trust	Staff alert procedures for awareness of patients with particular medical conditions	Medical conditions including poor eyesight, or being hard of hearing, or being previously MRSA positive or being at risk of CJD. How to make these visible to staff.	Alternative case study chosen.
Acute Trust	Movement of pathology services to alternative provider, outside the Trust.	For various reasons pathology services were no longer to be provided by the Trust. Assessment of alternative options.	Case study moved on too quickly before Toolkit was ready.

10.9.3. Case study selection criteria

Table 33 presents a range of criteria considered early in the research project for selecting case studies.

Table 34 presents the full range of criteria considered for selecting case studies and the stages through which these criteria changed during the course of the research project. Due to the nature of data collection (largely from PHA Team meeting minutes) this is not a completely comprehensive record of all categories. It should also be noted that many of the categories partially overlap with other categories, requiring a degree of subjective judgement in order to place the “x” (e.g. 20 and 31 – presence of change and key questions (including change), respectively). x = considered. xx = strongly considered (this was a subjective judgement based on the strength of judgements made during team meetings. A single x does not necessarily indicate that the category was of minor importance; rather that no specific level of importance could be identified from the content).

Table 33 Healthcare criteria identified in the PHA Proposal, and arranged by healthcare setting.

Criterion	Explanation	Primary	Palliative	Ambulatory /Acute Care	A&E/Intensive Care
Speed of delivery	What is the clinical urgency of the task?	Variable	Variable	Low	High
Type of patient care	Is this scheduled or unscheduled?	Both	Scheduled	Scheduled	Unscheduled
Patient condition	Is this critical or non-critical?	Both	Critical	Non-Critical	Critical
Assessment approach	Individual or team-based patient assessments?	Individual	Individual	Team	Team
Technology demands	How reliant is treatment on the use of technology?	Variable	Variable	Medium	High
Quality of documentation	To what extent are records complete at the time of diagnosis?	Complete	Variable	Complete	Often incomplete
Knowledge	Are caregivers typified as specialists or generalists?	Both	Specialist	Specialist	Both
Supervision	What is supervision / managerial support like?	High	Low	Medium	Low
Use of protocols	How reliant are caregivers on defined care protocols?	Low	High	Variable	High
Timescales	Is the typical treatment time long or short?	Both	Variable	Short	Both
Staff mix	Multiple or single disciplines?	Mostly single	Single	Multiple	Multiple
Shift patterns	Regular or irregular?	Mostly regular	Irregular	Regular	Irregular
System issues	Cross-setting interaction?	High	Medium	Medium	High

Table 34 Categories considered for the selection of case studies.

		Mar 06	Nov 08	Jan 09	Jun 09	Jul 09
1	Speed of delivery	x				
2	Type of patient care	x				
3	Patient condition	x				
4	Assessment approach	x				
5	Technology demands	x				
6	Quality of documentation	x				
7	Knowledge	x				
8	Supervision	x				
9	Use of protocols	x				
10	Timescales	x				
11	Staff mix	x				
12	Shift patterns	x				
13	System issues	x				
14	Consequences of error	x				
15	Human contribution to risk	x		x		
16	Tech contribution to risk	x		x		
17	Immediacy of risk impact	x				
18	Predictability of risk/error	x				
19	Individual/Team assessment	x				
20	Presence of change	x				
21	Qual. outputs/investigation	x				
22	Quant. outputs/investigation	x				
23	Resource avail (time/people)	x	xx	x	xx	xx
24	Availability of risk data	x				
25	Availability of process data	x		x		
26	Scope issues	x				
27	Stakeholders (clinical / manager)				x	x
28	NHS setting		xx	x	xx	xx
29	UK Location				xx	xx
30	Complexity		xx	x	x	x
31	Key questions / problem type (e.g. introducing a change / service improvement)		xx	x	x	x
32	Ease of access to staff			x	xx	xx
33	Anticipated level of staff engagement with process			x	xx	xx
34	Leadership (i.e. level of senior support for case study)		xx		xx	xx

		Mar 06	Nov 08	Jan 09	Jun 09	Jul 09
35	Anticipated PHA methods			x	x	x
36	General nature of study					x
37	Size of problem		xx	x		x
38	Level of desired detail		x	x		x
39	Target – safety or operability		x			
40	Type of flow (e.g. people / information, etc)		x			

10.9.4. Main case studies

10.9.4.1. Data collection forms – main case studies



|

Dear Participant,

Thank you very much for participating in the evaluation of the prospective hazard analyses (PHA) toolkit.

Your individual opinions and experiences in using the PHA toolkit will be valuable in helping us improve the toolkit. We hope that you will be willing to take a little time to answer some questions that we have. There are three sets of questions that should take you around 20 minutes to complete in total.

The information given will be analysed and used to inform the development of further improved versions of the toolkit. All the information collected will be kept in strict confidence by the research team. No individuals will be identified in written reports.

For more information about the project, please visit our website at <http://www-edc.eng.cam.ac.uk/pha/>

Thank you very much for your time and valuable feedback.

Addresses for contact:

Dr. James Ward,
PHA Project Manager
Engineering Design Centre, University of Cambridge
Trumpington Street, Cambridge, CB2 1PZ, UK
Tel: 01223 765107
Email: jrw38@cam.ac.uk

Dr. Rosemary Lim
Robens Centre for Public Health
Postgraduate Medical School
Faculty of Health and Medical Sciences
University of Surrey
Daphne Jackson Road, Guildford, GU2 7WG
Tel: 01483 68 3375
Email: r.lim@surrey.ac.uk

Section 1: Ease of use of the prospective hazard analyses (PHA) toolkit

Please read through the list. For each item, please tick the column that most closely matches your experience of using the PHA toolkit. Please feel free to comment using the space provided at the end of the section.

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
1. I thought the toolkit was easy to use					
2. I found the toolkit unnecessarily complex					
3. I think that I would like to use this toolkit every time I perform a risk assessment					
4. I would need the support of an expert to be able to use this toolkit					
5. The toolkit covered all the relevant information to help me undertake risk assessments					
6. The toolkit goes into an appropriate level of detail to help me undertake risk assessments					
7. The language used in the toolkit is clear					
8. The sections in this toolkit were well integrated					
9. There was too much inconsistency in this toolkit					
10. I found the toolkit easy to work through					
11. I found the language easy to understand					
12. I found the examples helpful					
13. Most people would learn to use this toolkit quickly					
14. I found the toolkit cumbersome to use					

Section 2: Usefulness of the prospective hazard analyses (PHA) toolkit

Please read through the list. For each item, please tick the column that most closely matches your experience of using the PHA toolkit. Please feel free to comment using the space provided.

	Strongly agree	Agree	Don't know	Disagree	Strongly disagree
1. The team was able to perform a PHA					
2. I had a better understanding of the work process that was risk assessed					
3. I became more aware of system-wide safety issues					
4. I found a change in my perception of safety					
5. I thought that it took too long to perform the risk analysis					
6. Using the toolkit would improve work practices					
7. Using the toolkit would improve safety in the NHS					
8. Using the toolkit would benefit the work of other people in the organisation					
9. The PHA toolkit would be useful in my work					
10. I think that the team would have identified the same hazards and risks without using the PHA toolkit					
11. I think that the team would have identified the same hazards and risk in less time using other methods					

Section 3: General comments about the prospective hazard analyses (PHA) toolkit

Please complete the following questions by writing in the space provided.

1. Do you think that the hazards and risks identified were realistic? If not, could you describe why you think so?

2. Did the use of the PHA toolkit reveal any significant risks of which you were previously unaware? If so, could you describe them?

3. Have you conducted risk assessments before? If so, could you please describe your experiences specifying the name of any method(s) used and any problems encountered?

- 4. Have you used a toolkit of a similar kind to this one (PHA toolkit) before? If so, could you please describe it?

- 5. In the context of your job, what is familiar and what is new about the PHA toolkit?

- 6. In your view, is any of the information presented inaccurate or incorrect? If so, could you describe it and specify the section where this was identified?

- 7. Is any of the information open to misinterpretation? If so, could you describe it and specify the section where this was identified?

8. Are there any notable omissions from the PHA toolkit? If so, could you describe what they are?

9. Do you think there is one type of analysis that the PHA toolkit is better suited for (e.g. routine analysis of clinical risks)? Could you describe it?

10. What changes would you recommend to improve the PHA toolkit?

11. Is there any other information or support you would need to be able to effectively use the toolkit? If so, can you describe what these are?

Finally, here are a few questions to help us understand your work.

What is your job title?

Please describe briefly the work that you do, particularly in relation to safety, risk or quality.

Thank you for your time and valuable feedback.

10.9.5. Demographics

Table 35 Case study details.

Case study No.	Case study setting	No. of participants (session 1, session 2, etc.)	Total no. of hours (session 1, session 2, etc.) [total participant-hours]	Toolkit Version number evaluated
0*	Primary care, GP practice	18 (split into three equal groups of 6, with GPs, clerical staff and nurses)	2 = 2 [36]	n/a (evaluated PHA methods of FMEA, FTA and SHERPA)
1	Acute Trust, primary / secondary care boundary	7, 7, 6	3, 3, 3 = 9 [60]	<i>Process 4u</i>
2	Mental Health Trust, Learning Disabilities service	6, 4	4, 4 = 8 [40]	<i>Process 4u</i>
3	Acute Trust, surgery	3, 3	2, 2 = 4 [12]	<i>Process 4u</i>
4	Acute Trust, general	2	1.5 = 1.5 [3]	<i>Process 4w</i>
5	Acute Trust, bowel cancer screening centre	3, 3	2, 2 = 4 [12]	<i>Process 4w</i>

* = Initial case study (did not test Toolkit), see Section 7.2.

Table 36 Case study demographics

Case study No.	Participant No. * = Staff Lead	Profession
1	1	Head of Medicines Management
1	2	Junior hospital doctor
1	3	Clinical governance pharmacist
1	4	Junior Sister
1	5	GP
1	6	GP
1	7*	Consultant
2	1*	Senior manager
2	2	Project management
2	3	Occ. Therapist / researcher
2	4	Deputy unit manager
2	5	Clinical Director
2	6	Consultant Psychiatrist
2	7	Unit Manager
3	1	Surgical registrar and clinical research fellow
3	2	Surgical registrar (cardiac)
3	3	Clinical research fellow (surgical background)
4	1	Senior clinical nurse
4	2	Senior clinical nurse
5	1	Director, senior lecturer, consultant biochemist, senior research fellow
5	2	Laboratory/quality lead
5	3	Administration manager

10.9.6. Feedback on Toolkit from case studies

Table 37 lists a range of outcomes from each of the case studies. This is intended to be an illustrative list, but is not exhaustive.

Table 37 Illustrations of feedback given on Toolkit content – Group 1 and Group 2 case studies.

Case study	Examples of findings on Toolkit, including suggestions
1	<p>Include level of doctors in the list of “knowledge required for the review” section. Many other suggestions provided of types of people who could be involved in the assessment (e.g. OTs, dieticians, service improvement staff).</p> <p>Consider changing word “deviation” to “variation (from intent)” or “process deviation”.</p> <p>Include more guidance on how to narrow down the process map, e.g. whether to consider a very specific scenario.</p> <p>Consider adding comment on whether to fit descriptions of low-medium-high into Trust’s own definitions for the 5x5 matrix.</p> <p>“A worked example from NHS practice would give it NHS... "ownership".”</p> <p>“...the way that you would submit something to one of the higher committees in the Trust is a sort of front cover sheet that says how this fits in with the strategic objectives.” E.g. It needs to engage the Board – how. “The politics of all this is absolutely critical – how to engage the Board isn’t to focus on risk and methods of risk. It’s to go to them with a proposal for service improvement and productivity” there was a suggestion by this participant to submit proposals to the Board on a single sheet, and to explain how it would fit in with the Trust’s strategic objectives. “if the project is successful in articulating what the high level risks are, then we’ll get their engagement.”</p>
2	<p>Include HAZOP-style words in the guidance. E.g. what would happen if you had too much or too little of xyz?</p> <p>Consider adding a column on ease of proposed risk revision action, which may help prioritisation?</p> <p>Provide guidance on situations where you could bypass part of the process map and start the analysis at a particularly risky area – e.g. in this case we could have ignored the admissions process and have started with the discharge process – when would such a decision be appropriate?</p>
3	<p>Explain the term ‘element’, ‘likelihood’</p> <p>Include ‘near miss’ in the list of triggers</p> <p>Title - be nice to have ‘safety’ in the title and then perhaps ‘toolkit’ or ‘how to do’. If the purpose is for people to take it, not like a textbook, it’s like a manual.</p> <p>Difficult for people who have no expertise to know what the title means. People are more likely to pick it up by reading the book by its cover if it said safety and how to do safety analysis or a toolkit for safety analysis.</p> <p>Unclear about the terms impact and hazard – these have to be made explicit. Potential for harm given the defences – impact</p> <p>Suggest that the ‘hazard’ column in identify hazards can be deleted.</p> <p>Commented on whether ‘concern’ column is needed.</p> <p>Seemed like we’re building on what has happened before, does not quite match the initial perception of prospectively identifying hazards. Process reliant on people’s imagination.</p> <p>Even the simplest thing, there are exceptions – model would look different</p>

Case study	Examples of findings on Toolkit, including suggestions
	Incident – could mention the word ‘near miss’ because people understand the word.
4	We could consider adding in a column on why the defence is so weak? Note that the grey text in the diagram is too light to read
5	Debate took place over whether to add scales on the likelihood / impact grids in the triaging section of the Toolkit.

10.9.7. Feedback on Toolkit facilitation from case studies

Table 38 lists a range of outcomes from each of the case studies. This is intended to be an illustrative list, but is not exhaustive.

Table 38 Suggestions for changes to facilitation of the case studies.

Case study	Examples of findings on facilitation
1	<p>Discussion over how much the facilitator should simply tell them what to do, given the danger that this may decrease rapport and feedback. We agreed that we would need to play it by ear to some extent, to ensure the case studies run smoothly.</p> <p>Conclusion that the Preliminary section should be designed to be stand-alone, i.e. would require minimal or no input from a facilitator. We would need a facilitator for the Comprehensive section.</p> <p>A facilitator will need an understanding of the risk assessment process, facilitation skills and an understanding of systems issues, and an understanding of the implications of what they're doing – there may be systems repercussions if changes are made. Training of the facilitator will be necessary.</p> <p>A facilitator to use the Comprehensive section of the PHA Toolkit</p> <p>One of the challenges in running the case studies was in getting the right people together and all up to the same level of understanding about the scenario. This took time during the session.</p>
2	<p>May need to encourage the participants to stay at a top level, and not consider specific scenarios in the preliminary risk assessment. Very easy to get bogged down in the complexity of the process to be analysed – causes and effects, links, variations, etc.</p> <p>We need to work very carefully through the table, in a disciplined manner.</p> <p>It may alternatively become necessary to re-draw the process map, if it is felt the deviations are becoming too involved.</p> <p>Could invite <i>many</i> different people to the risk analysis. Should we consider this issue of crowd management?</p>
3	<p>Require more than 4 hours to have a good go at using the entire Toolkit</p> <p>Heavily facilitated – would this be the case for cases where the Staff Lead is not present and the participants have no seniority to implement any changes?</p> <p>Allow more time for participants to read through the workbook to enable reflection of the process and workbook.</p>
4	<p>No feedback provided.</p>
5	<p>Staff Lead needs to take ownership of the risk assessment to enable it to be successful – ensuring this would make it easier to define the boundaries of the process and to propose actions for further action.</p> <p>Assessments such as this will require more than 4 hours to complete.</p> <p>Allow more time for participants to read through the Toolkit to enable reflection of the process and workbook. Participants would have appreciated it if they were given the Toolkit before hand to read through it before the actual session so that they could give informed comments.</p> <p>Add an “issues” flip chart, to park other issues not directly relevant to the analysis at the time.</p>

10.10. Toolkit

Please see overleaf.

Prospective Hazard Analysis Toolkit

Edited by:

John Clarkson

James Ward

Peter Buckle

Jon Berman

Draft v0.9

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Printed and bound by Kall Kwik Cambridge

E-mail: info@kkcambs.co.uk

Web: kallkwik.co.uk/cambridge

First published in 2010 by
Engineering Design Centre
Department of Engineering
University of Cambridge
Trumpington street
Cambridge, UK
CB2 1PZ
E-mail: edc-enquiries@eng.cam.ac.uk
Web: www-edc.eng.cam.ac.uk

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ISBN 978-0-9545243-4-0

Prospective Hazard Analysis Toolkit

If you would like to obtain a large print
version of this book, please contact
edc-enquiries@eng.cam.ac.uk

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Engineering
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Centre



The Engineering Design
Centre, University of
Cambridge
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Preface

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Part 2:
Comprehensive Risk Assessment

Part 3:
System Mapping Approaches

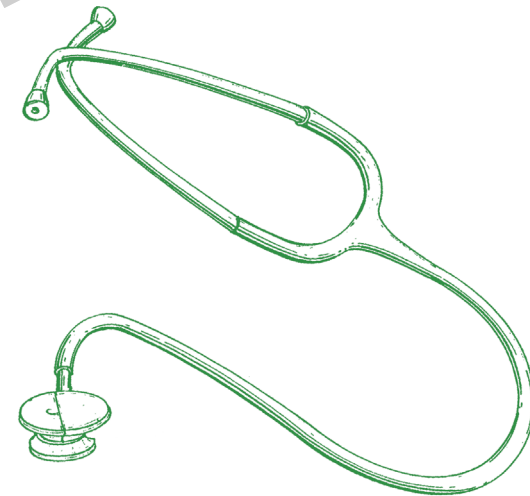
Part 4:
Risk Assessment Approaches

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Part 1: Preliminary Risk Review

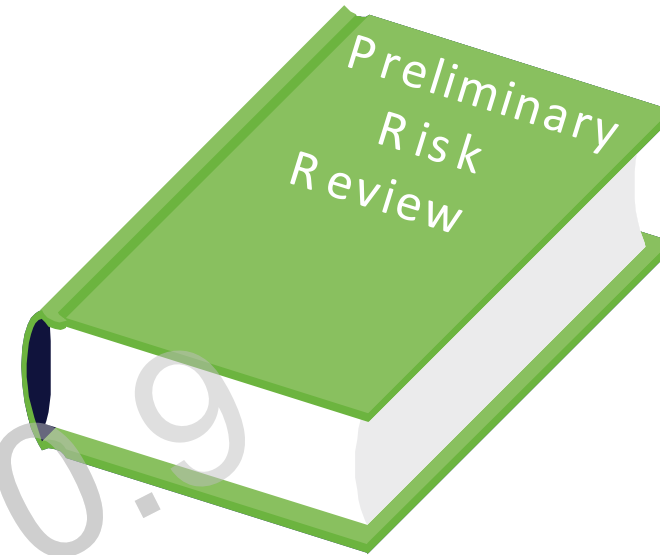
John Clarkson, James Ward,
Thomas Jun, Jon Berman

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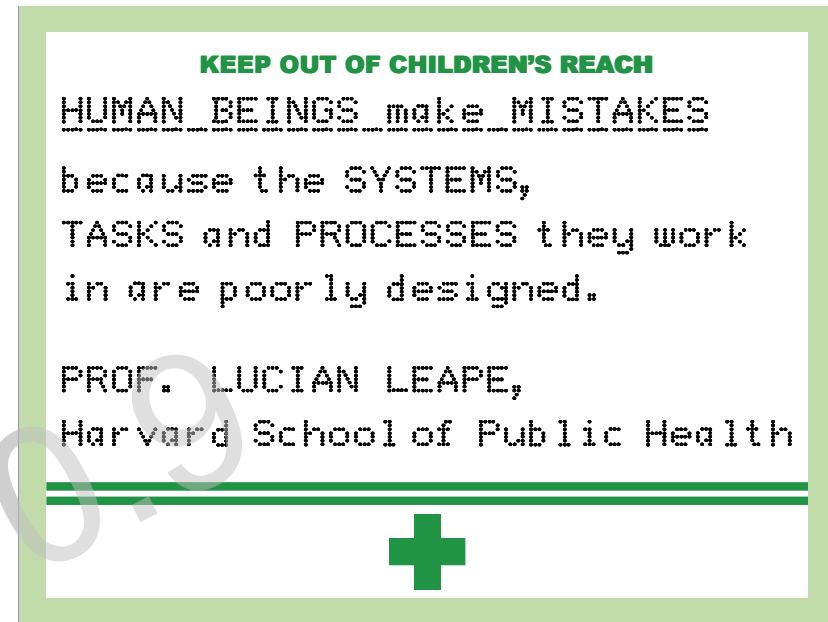
Introduction

In his Foreword to the Design for Patient Safety report, Sir Liam Donaldson, is quoted as saying:

- Properly addressed, improvements in patient safety will contribute significantly to **improving the quality of care** for NHS patients;
- Reduction in errors will also **free up resources** at present used to cope with the consequences of those errors;
- The NHS would gain greatly if it were to adopt modern thinking and practice with regard to **designing for safety**.

The aim of this guide is to provide practical advice on steps that can be taken to reduce medical errors, building on the broad systems approach introduced in the Design for Patient Safety Report.

It is written for healthcare service providers, patients, carers, risk managers, commissioners, managers and designers.



Design for Patient Safety
(www-edc.eng.cam.ac.uk/medical/downloads/report.pdf)

Introduction

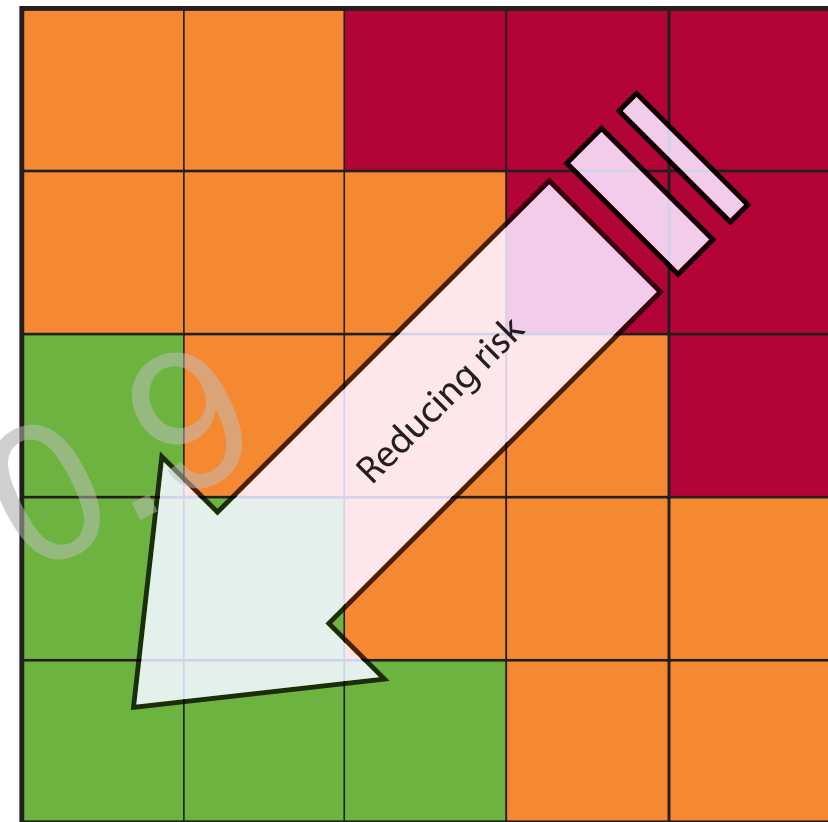
All systems are designed with a particular purpose in mind. For example, a car is designed to meet a variety of performance, comfort, safety and cost requirements.

Equally, with all systems there is a possibility that they will not perform as expected, leading to some undesirable behaviour. Risk in this context is defined as the product of the likelihood of an undesirable event and its impact, measured in some appropriate unit of cost.

$$\text{risk} = \text{likelihood} \times \text{impact}$$

Healthcare systems often exhibit unavoidable risk, such as is related to the outcome of a clinical procedure performed on a critically ill patient. However, much risk is avoidable by design.

Undesirable behaviour may be predicted though the application of prospective risk management, i.e. the search for, and elimination of, likely failures before they occur. This has particular value during the design and implementation of new systems. Conversely, reactive risk management approaches, such as Root Cause Analysis, seek to understand the nature of events after they happen.



Design for Patient Safety – reducing risk by design

Prospective risk management

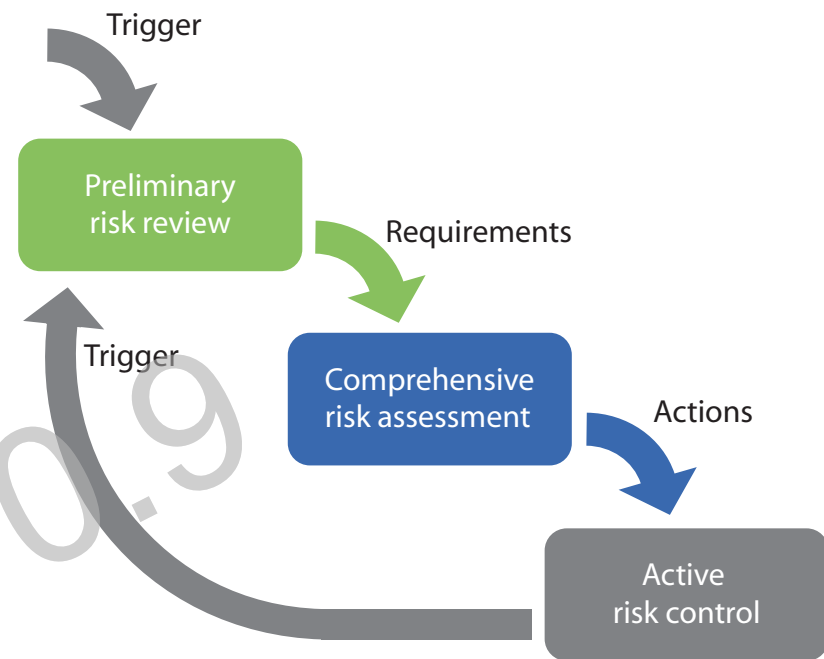
The objective of this guide is to provide the knowledge and tools required to deliver a preliminary risk review as part of a staged approach to support prospective risk management.

Three stages are proposed, in the following order, to manage the risk within a particular system:

- **Preliminary risk review**, a quick review to explore the need for analysis and develop requirements for an in-depth study;
- **Comprehensive risk assessment**, a rigorous risk assessment leading to a set of risk control actions.
- **Active risk control**, an ongoing process to implement risk control actions and identify needs (triggers) for risk analysis.

The preliminary risk review assumes knowledge of the system under review, but no prior experience of risk assessment.

Actions arising from the subsequent risk assessment may be targeted to address patient and staff safety, effectiveness of care and/or the patient experience.



A staged approach to risk management

Structure of the guide

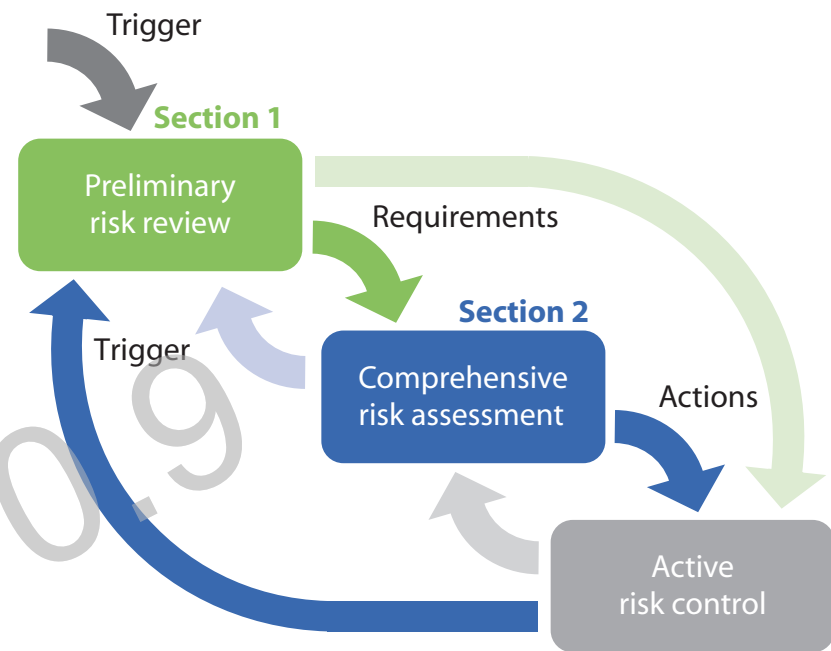
The objective of this guide is to provide the knowledge and tools required to deliver an effective risk assessment process.

The structure of the guide is based on the three-stage approach to risk assessment:

- Section 1 describes the **preliminary risk review**, which explores the need and requirements for a more in-depth study;
- Section 2 describes a **comprehensive risk assessment**, a more complete approach based on the same principles as the preliminary review and including tools and guidance for conducting a risk assessment.

All risk assessments should begin with a preliminary risk review and, for the large majority of cases where a comprehensive risk assessment is required, the preliminary review then serves as the planning phase for the assessment.

Formal guidance on active risk management is not included here since it is already the topic of numerous texts on business management.



A staged approach to risk management

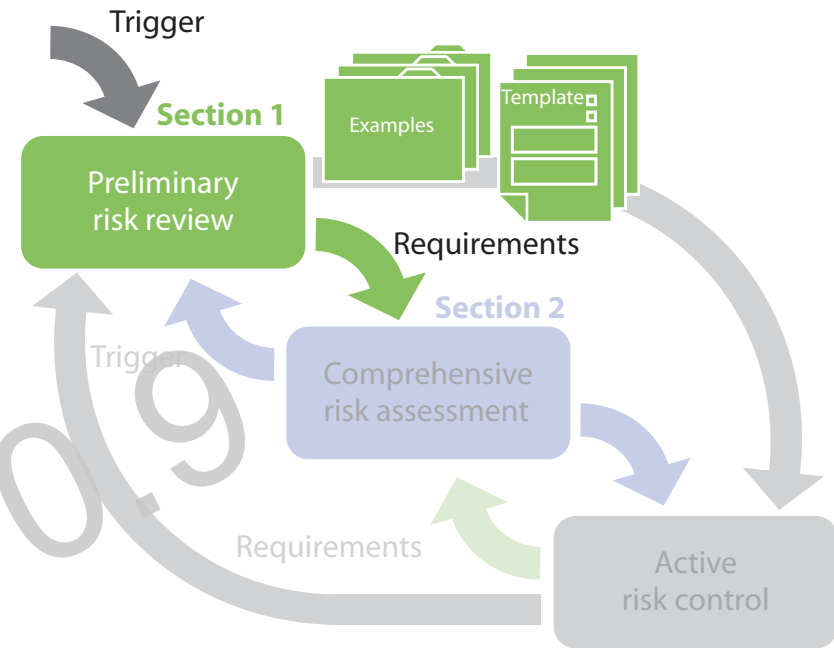
Preliminary risk review

The preliminary risk review affords a rapid assessment of the nature and extent of the potential risks within a system, and hence the scope and nature of further risk assessment that may be required, and the resources needed to do it.

The following sheets seek initial responses to a set of simple questions:

- **Background:** why undertake a review?
- **Articulate purpose:** what is the purpose of the review?
- **Define requirements:** who, what, when, where?
- **Describe system:** what is to be assessed?
- **Identify hazards:** what could go wrong?
- **Assess risks:** what is likely to go wrong?
- **Propose actions:** what actions are required?
- **Review process:** what next?

The results recorded for each question provide not only the audit trail for any decisions concerning further risk assessment, but also the basis for guiding such an assessment.



A staged approach to risk management

Preliminary risk review

The preliminary risk review may be undertaken by completing the sheets that follow. A separate set of templates is available, which can be reproduced in a larger size to aid completion.

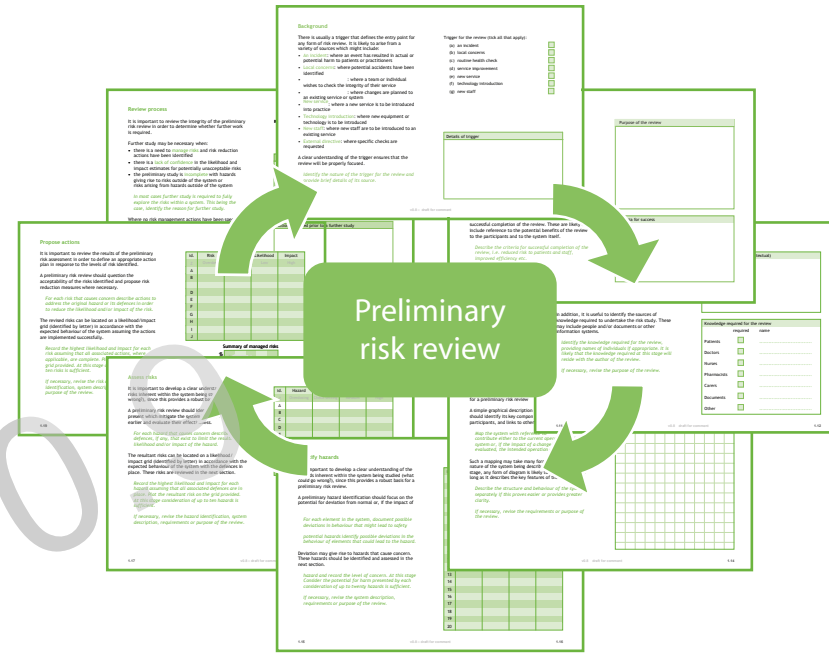
All stages of the review should be completed.

Stages should be completed in the order presented, but earlier sheets can be revisited as often as required. It is quite normal to follow such an iterative process.

The review should take no more than about an hour for an experienced user. If it is taking longer, it is likely that too much detail is being considered.

The review can be undertaken as an individual or team activity, depending on the range of knowledge required to complete the task.

Case examples at the end of this section provide further insight as to how each sheet should be used.



A staged approach to risk management

Background

There is usually a trigger that defines the entry point for any form of risk review. It is likely to arise from a variety of sources which might include:

- **An incident:** where an event has resulted in actual or potential harm to patients or practitioners;
- **Local concerns:** where potential accidents have been identified;
- **Routine health check:** where a team or individual wishes to check the integrity of their service;
- **Service improvement:** where changes are planned to an existing service or system;
- **New service:** where a new service is to be introduced into practice or an existing one decommissioned;
- **Technology introduction:** where new equipment or technology is to be introduced;
- **New staff:** where new staff are to be introduced to an existing service;
- **External directive:** where specific strategic changes or checks are requested

A clear understanding of the trigger ensures that the review will be properly focused.

Identify the nature of the trigger for the review and provide brief details of its source.

Trigger for the review (tick all that apply):

- (a) an incident
- (b) local concerns
- (c) routine health check
- (d) service improvement
- (e) new service
- (f) technology introduction
- (g) new staff
- (h) external directive
- (i) other

specify

.....

Details of trigger
<p>We have reached a certain threshold in the number of patients with D&V on our ward (D9) and are considering its isolation.</p> <p>Isolating the ward would have a significant impact on service delivery across the Trust.</p>

Articulate purpose

It is important to record the purpose for any risk review since the nature of this motivation can influence decisions regarding its scope and the methods used.

The purpose of the review is likely to be based in the need:

- to assess the likelihood of occurrence of a particular undesirable event;
- to identify potential sources of risk within a given system;
- to assess the impact of a spontaneous or planned change to a system.

Describe the purpose of the review with reference to the system to be reviewed and any particular events, sources of risk, or changes that are of interest.

In addition, it is important to identify criteria for the successful completion of the review. These are likely to include reference to the potential benefits of the review to the participants and to the system itself.

Describe the criteria for successful completion of the review, i.e. reduced risk to patients and staff, improved efficiency etc.

Purpose of the review

Thinking through all the main risks of isolating a ward (D9) and minimising their impact on bed pressure on other wards in the hospital through an appropriate action plan.

Criteria for success

Action plan, including dates and responsibilities for completion of tasks.

Define requirements

It is important to develop a clear understanding of the scope of the system to be studied and the knowledge required for the preliminary review.

A brief textual description of the system should identify its purpose and key elements. It is also helpful to document links to other systems.

Describe the system with reference to its purpose, key elements and links to other systems.

In addition, it is useful to identify the sources of knowledge required to undertake the risk review. These may include people and/or documents or other information systems.

Identify the knowledge required for the review, providing names and rank/role of individuals if appropriate. It is likely that the knowledge required at this stage will reside with the author of the review.

If necessary, revise the purpose of the review.

Description of the system (textual)
Ward D9 — a mixed sex ward with 24 elderly patient beds. Some patients with neurological conditions including dementia and confusion.

Knowledge required for the review		
	Required	Name
Patients	<input type="checkbox"/>
Doctors	<input checked="" type="checkbox"/>	Dr Smith, microbiologist; Dr Jones, geriatrician
Nurses	<input checked="" type="checkbox"/>	Sr Brown, ward manager
Pharmacists	<input type="checkbox"/>
Technicians	<input type="checkbox"/>
Documents	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>	Mrs White, trust bed manager

Describe system

It is important to provide a clear description of the system to be studied, since this provides a robust basis for a preliminary risk review.

A simple graphical description of the system (mapping) should identify its key components, processes and participants, and links to other systems.

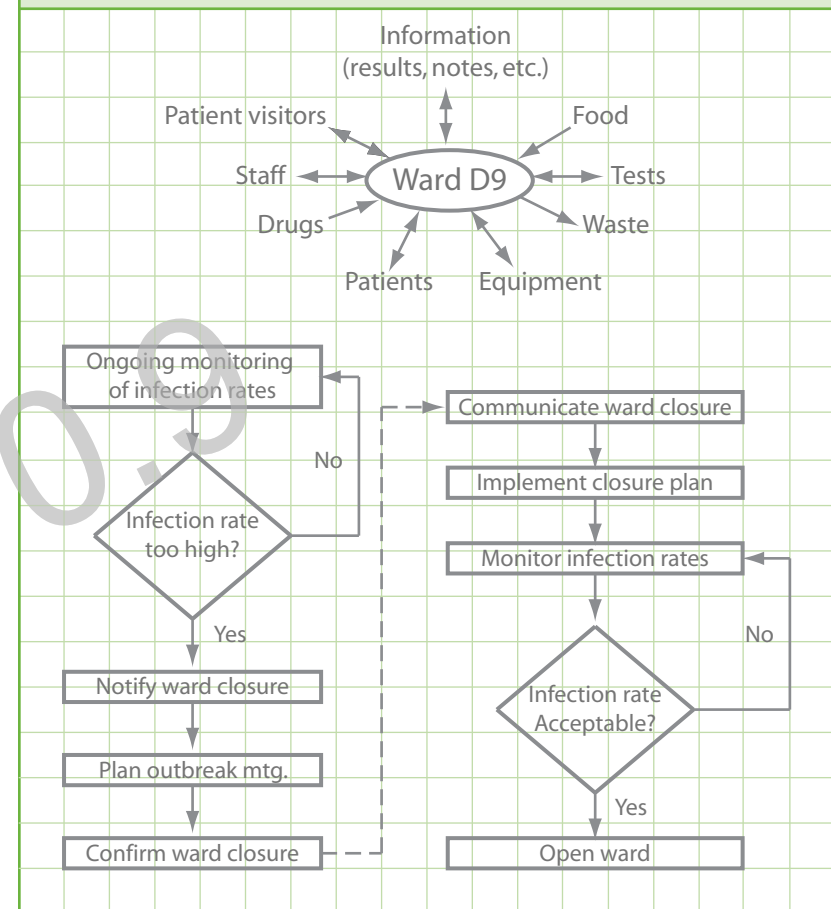
Map the system with reference to all elements that contribute either to the current operation of the system or, if the impact of a change is to be evaluated, the intended operation of the system.

Such a mapping may take many forms, dependent on the nature of the system being described. However, at this stage, any form of diagram is likely to be appropriate as long as it describes the key features of the system.

Describe the structure and behaviour of the system separately if this proves easier or provides greater clarity.

If necessary, revise the requirements or purpose of the review.

Description of the system (graphical)



Identify hazards

It is important to develop a clear understanding of the hazards inherent within the system being reviewed (what *could* go wrong?), since this provides a robust basis for a preliminary risk review.

A preliminary hazard identification should focus on the potential for deviation from normal or, if the impact of a change is to be evaluated, intended system behaviour.

For each component in the system, document possible deviations (i.e. more than, less than, none etc.) in system behaviour that might lead to safety concerns and specific hazards. Conversely for potential hazards identify possible deviations in the behaviour of elements that could lead to the hazard.

Deviation may give rise to hazards that cause concern. These hazards should be identified and assessed in the next section.

Consider the potential for harm presented by each hazard and record whether this is of concern. At this stage try to avoid excessive detail ; consideration of up to twenty hazards is usually sufficient.

If necessary, revise the system description, requirements or purpose of the review.

Id	Element	Deviation	Concern	Hazard
0	Infusion pump	Elevated flow	Yes	Overdose
1	Patient visitors	No visitors	Patients	Harm to patient's mental health
2	"	"	Depressed Visitors frustrated	Complaints
3	Patients	Patients wandering off ward	Patients violating ward closure	Infection spreads to another ward
4				
5				
6				
7				
8				
9				
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20				

Assess risks

It is important to develop a clear understanding of the risks inherent within the system being studied (*will it go wrong?*), since this provides a robust basis for action.

A preliminary risk review should identify the defences present which mitigate the system hazards identified earlier and evaluate their effectiveness.

For each hazard that is of concern describe the defences, if any, that exist to limit the resultant likelihood and/or impact of the hazard.

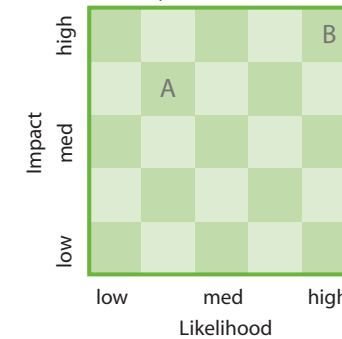
The resultant risks can be located on a likelihood/ impact grid (identified by letter) in accordance with the expected behaviour of the system with the defences in place. These risks are reviewed in the next section.

Record the highest likelihood and impact for each hazard assuming that all associated defences are in place. Plot the resultant risk on the grid provided. At this stage consideration of up to ten hazards is sufficient.

If necessary, revise the hazard identification, system description, requirements or purpose of the review.

Id	Hazard	Defence	Likelihood	Impact
Z	Overdose	Check setting	Medium	High
A	Infection spreads to another ward	Lock ward doors	Low-med	High
B	"	Tell patients to remain on ward	High	High
C				
D				
E				
F				
G				
H				
I				
J				

Summary of current hazards



Propose actions

It is important to review the results of the preliminary risk review in order to define an appropriate action plan in response to the levels of risk identified.

A preliminary risk review should question the acceptability of the risks identified and propose risk reduction measures where necessary.

For each risk that causes concern describe possible actions to address the original hazard or its defences in order to reduce its likelihood and/or impact.

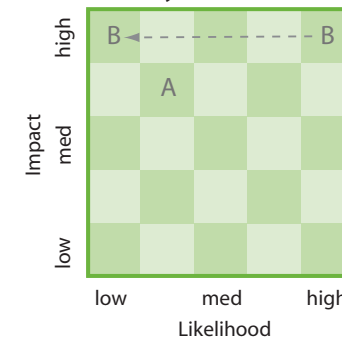
The residual risks can be located on a likelihood/impact grid (identified by letter) in accordance with the expected behaviour of the system assuming the actions are implemented successfully.

Record the highest likelihood and impact for each risk assuming that all associated actions, where applicable, are complete. Plot the residual risk on the grid provided. At this stage consideration of up to ten risks is sufficient.

If necessary, revise the risk assessment, hazard identification, system description, requirements or purpose of the review.

Id	Hazard	Defence	Likelihood	Impact
Z	Overdose	Check setting	Medium	High
A	Infection spreads to another ward	None	Low-med	High
B	"	Repeat message to stay in bed	Low	High
C				
D				
E				
F				
G				
H				
I				
J				

Summary of residual risks



Review process

It is important to review the integrity of the preliminary risk review in order to determine whether further work is required.

Further assessment may be necessary when:

- **risk reduction actions** have been identified in order to manage risks;
- there is a **lack of confidence** in the likelihood and impact estimates for potentially unacceptable risks;
- the preliminary review is **incomplete** with hazards giving rise to risks outside of the system or risks arising from hazards outside of the system

In most cases further assessment is required to fully explore the risks within a system. This being the case, identify the reason for further assessment.

Where no risk management actions have been specified in the presence of adequate data and a well defined system there may be no need for further assessment.

Note any specific actions required immediately to control risks or necessary for further assessment.

Reason for further assessment (tick as many as apply):

- (a) need to manage risks and actions identified
- (b) lack of confidence in the results
- (c) preliminary review is incomplete

Recommendations for further assessment

The assessment did not give us sufficient confidence that the results were accurate or comprehensive. We might start by looking more systematically at the current barriers and their adequacy.

Actions required prior to further assessment

Get a patient/representative for the next assessment, to present patient perspective on barriers. This may also help us understand the risks more clearly.

Overview

Review name, location, owner, date
Infection control, Ward D9. Morrison and Ward, September 2009.
Details of trigger
We have reached a certain threshold in the number of patients with D&V on our ward (D9) and are considering its isolation. Isolating the ward would have a significant impact on service delivery across the Trust.
Purpose of the review
Thinking through all the main risks of isolating a ward (D9) and minimising their impact on bed pressure on other wards in the hospital through an appropriate action plan.
Description of the system
Ward D9 — a mixed sex ward with 24 elderly patient beds. Some patients with neurological conditions including dementia and confusion.

Significant hazards
Infection on ward.
Significant risks
Infection spreads to another ward
Significant actions
Repeat message to patients to stay in bed.
Recommendations for further assessment
The assessment did not give us sufficient confidence that the results were accurate or comprehensive. We might start by looking more systematically at the current barriers and their adequacy.

Comprehensive risk assessment

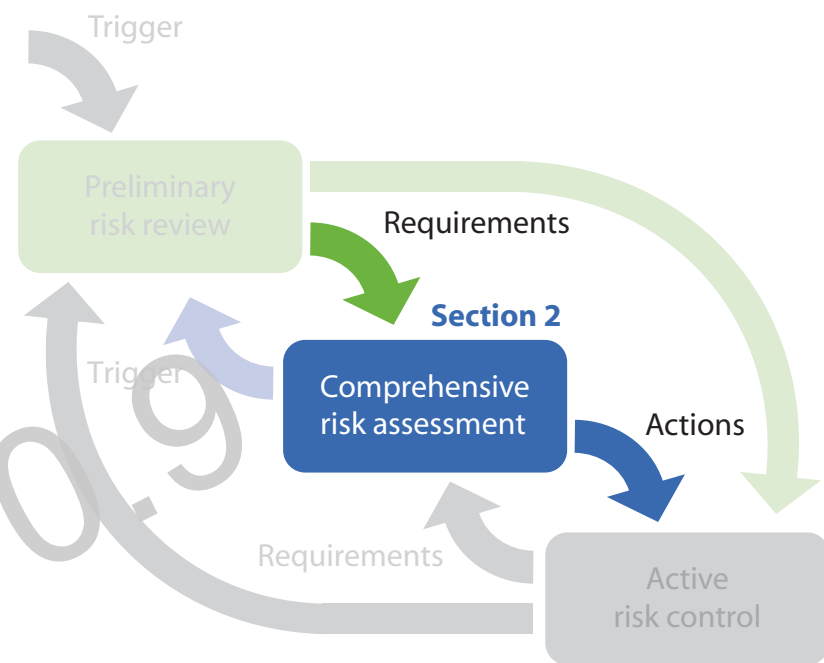
The comprehensive risk assessment affords an in-depth assessment of the nature and extent of the potential risks within a system, and hence the scope and nature of risk control actions that may be required.

It is based on the same structure as the preliminary risk review and draws on the initial understanding developed from that work. Information on system mapping and risk assessment techniques is also provided.

Section 2 seeks to further develop previous responses to the set of simple questions:

- **Background:** why undertake a review?
- **Articulate purpose:** what is the purpose of the review?
- **Define requirements:** who, what, when, where?
- **Describe system:** what is to be assessed?
- **Identify hazards:** what could go wrong?
- **Assess risks:** what is likely to go wrong?
- **Propose actions:** what actions are required?
- **Review process:** what next?

The results recorded for each question provide not only the audit trail for decisions concerning subsequent risk control, but also the basis for guiding management actions.



A staged approach to risk management

Part 2: Comprehensive Risk Assessment

John Clarkson, James Ward,
Jon Berman, Peter Buckle, Rosemary Lim

Draft v0.9

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Describe system	
Identify hazards	
Assess risks	
Propose actions	
Review process	



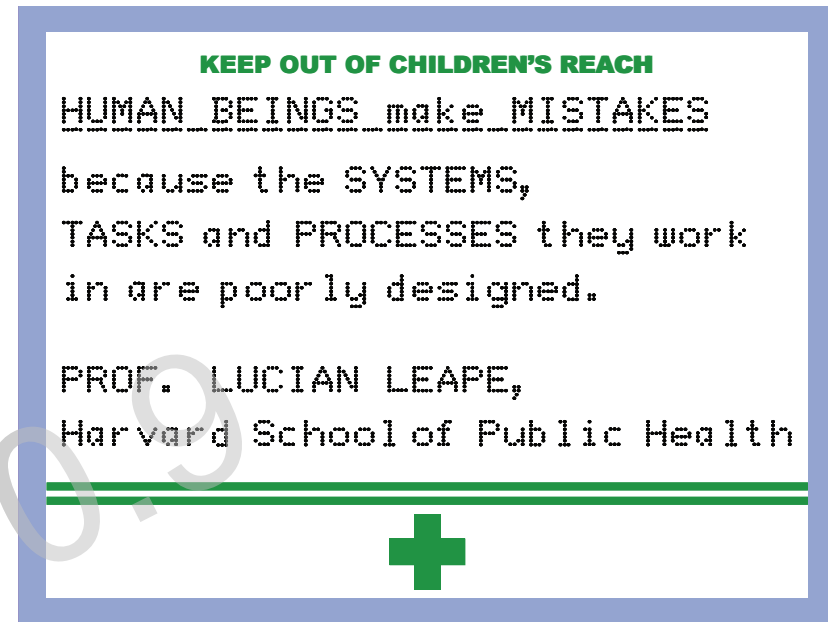
Introduction

In his Foreword to the Design for Patient Safety report, Sir Liam Donaldson, is quoted as saying:

- Properly addressed, improvements in patient safety will contribute significantly to **improving the quality of care** for NHS patients.
- Reduction in errors will also **free up resources** at present used to cope with the consequences of those errors.
- The NHS would gain greatly if it were to adopt modern thinking and practice with regard to **designing for safety**.

The aim of this guide is to provide practical advice on steps that can be taken to reduce medical errors, building on the broad systems approach introduced in the Design for Patient Safety report.

It is written for healthcare service providers, patients, carers, risk managers, commissioners, managers and designers.



Design for Patient Safety
(www-edc.eng.cam.ac.uk/medical/downloads/report.pdf)

Introduction

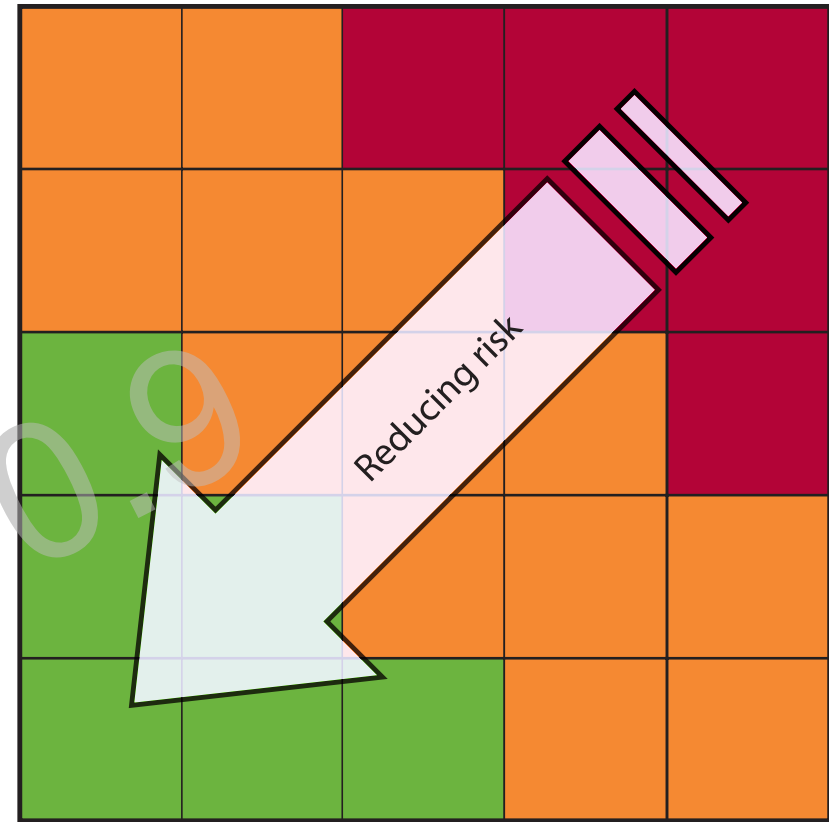
All systems are designed with a particular purpose in mind. For example, a car is designed to meet a variety of performance, comfort, safety and cost requirements.

Equally, with all systems there is a possibility that they will not perform as expected, leading to some undesirable behaviour. Risk in this context is defined as the product of the likelihood of an undesirable event and its impact, measured in some appropriate unit of cost.

$$\text{risk} = \text{likelihood} \times \text{impact}$$

Healthcare systems often exhibit unavoidable risk, such as is related to the outcome of a clinical procedure performed on a critically ill patient. However, much risk is avoidable by design.

Undesirable behaviour may be predicted though the application of prospective risk management, i.e. the search for, and elimination of, likely failures before they occur. This has particular value during the design and implementation of new systems. Conversely, reactive risk management approaches, such as Root Cause Analysis, seek to understand the nature of events after they happen.



Design for Patient Safety – reducing risk by design

Prospective risk management

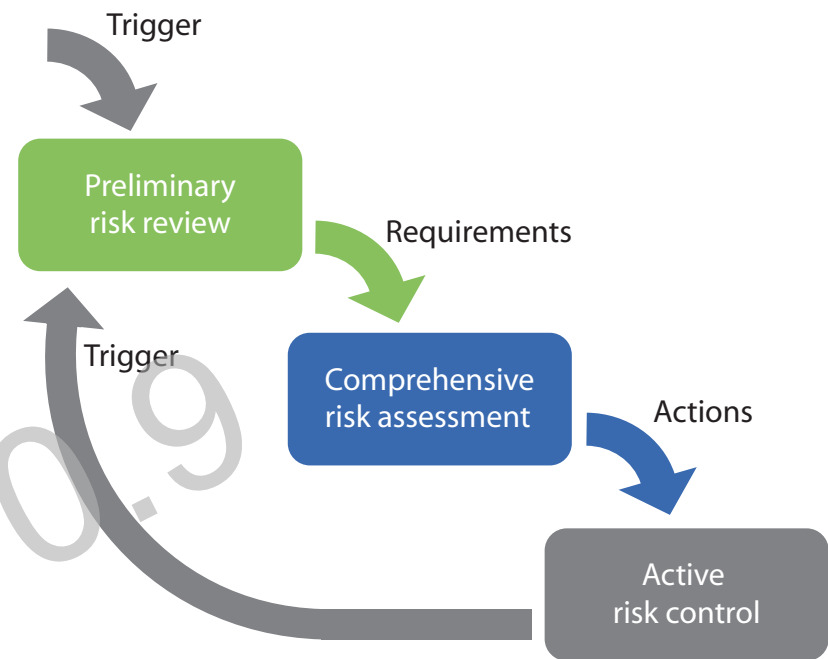
The objective of this guide is to provide the knowledge and tools required to deliver a comprehensive risk assessment as part of a staged approach to support prospective risk management.

Three stages are proposed, in the following order, to manage the risk within a particular system:

- **Preliminary risk review**, a quick review to explore the need for analysis and develop requirements for an in-depth study;
- **Comprehensive risk assessment**, a rigorous risk assessment leading to a set of risk control actions;
- **Active risk control**, an ongoing process to implement risk control actions and identify needs (triggers) for risk analysis.

The preliminary risk review assumes knowledge of the system under review, but no prior experience of risk assessment.

Actions arising from the subsequent risk assessment may be targeted to address patient and staff safety, effectiveness of care and/or the patient experience.



A staged approach to risk management

Structure of the guide

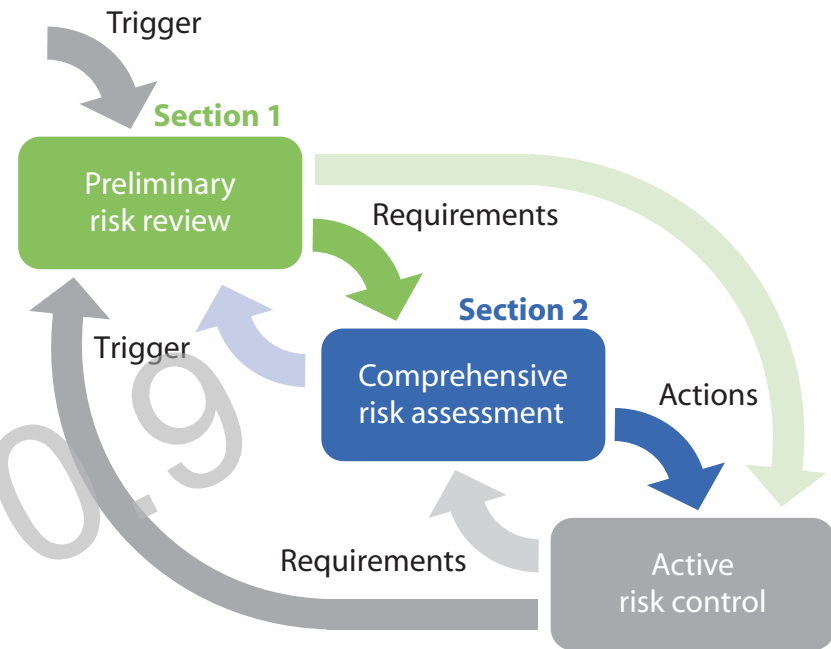
The objective of this guide is to provide the knowledge and tools required to deliver an effective risk assessment process.

The structure of the guide is based on the three-stage approach to risk assessment:

- Section 1 describes the **preliminary risk review**, which explores the need and requirements for a more in-depth study;
- Section 2 describes a **comprehensive risk assessment**, a more complete approach based on the same principles as the preliminary review and including tools and guidance for conducting a risk assessment.

All risk assessments should begin with a preliminary risk review and, for the large majority of cases where a comprehensive risk assessment is required, the preliminary review then serves as the planning phase for the assessment.

Formal guidance on active risk management is not included here since it is already the topic of numerous texts on business management.



A staged approach to risk management

Comprehensive risk assessment

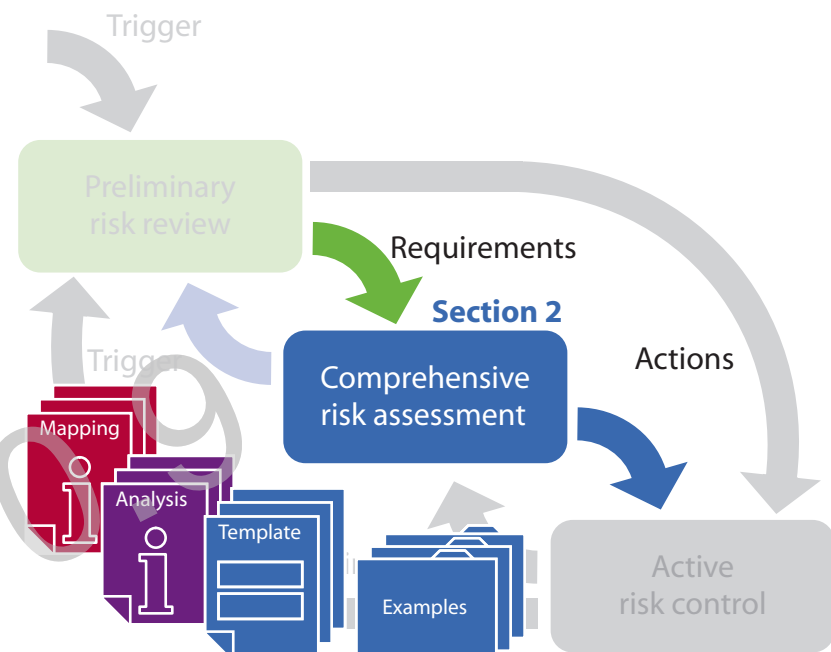
The comprehensive risk assessment affords an in-depth assessment of the nature and extent of the potential risks within a system, and hence the scope and nature of risk control actions that may be required.

It is based on the same structure as the preliminary risk review and draws on the initial understanding developed from that work. Information on system mapping and risk assessment techniques is also provided.

The following pages seek to further develop previous responses to the set of questions:

- **Background:** why undertake a review?
- **Articulate purpose:** what is the purpose of the review?
- **Define requirements:** who, what, when, where?
- **Describe system:** what is to be assessed?
- **Identify hazards:** what could go wrong?
- **Assess risks:** what is likely to go wrong?
- **Propose actions:** what actions are required?
- **Review process:** what next?

The results recorded for each question provide not only the audit trail for decisions concerning subsequent risk control, but also the basis for guiding management actions.



A staged approach to risk management

Comprehensive risk assessment

The comprehensive risk assessment may be undertaken by completing the sheets that follow. A separate set of templates is available, which can be reproduced in a larger size to aid completion.

All stages of the assessment should be completed.

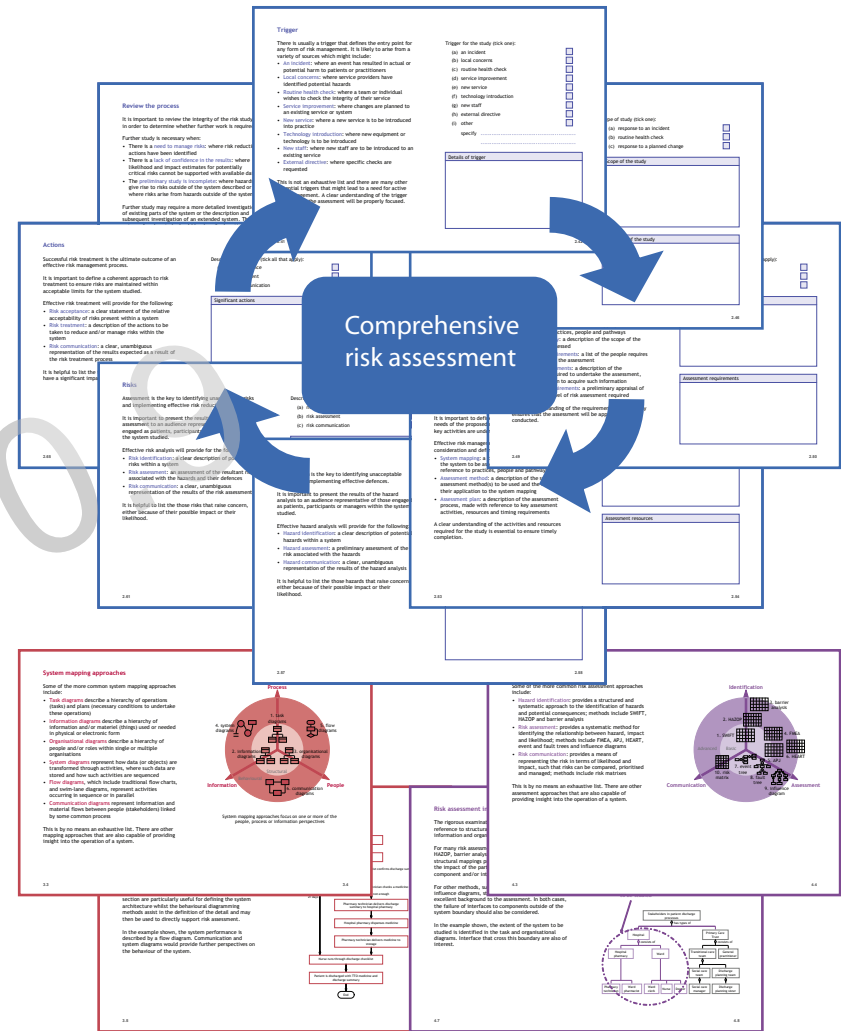
Stages should be completed in the order presented, but earlier sheets can be revisited as often as required. It is quite normal to follow such an iterative process.

The assessment may take from a few hours to a number of weeks depending on the scale and complexity of the system being assessed.

The assessment can be undertaken as an individual or team activity, depending on the range of knowledge required to complete the task.

Case examples at the end of this section provide further insight as to how each sheet should be used.

Later sections also describe in more detail the selection of system mapping methods (burgundy) and risk assessment methods (purple).



A staged approach to risk management

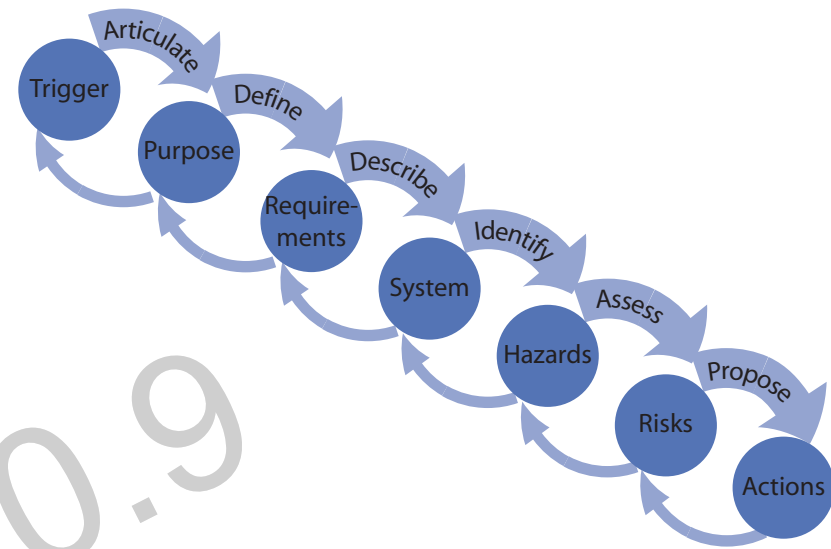
Comprehensive risk assessment

Successful risk assessment, which forms a part of the wider risk management process, must be driven by a robust process. This process must aid identification of appropriate risk assessment tools which can be used in conjunction with appropriate system mapping tools.

The 'waterfall' model is one of the more useful ways to describe the risk management process:

- **Articulate:** the recording of the **trigger**; leading to a description of the **purpose** of the assessment;
- **Define:** the consideration of the purpose; leading to a description of **requirements** for the assessment;
- **Describe:** the early response to these requirements; leading to a description of the **system** to be assessed;
- **Identify:** the undertaking of a systematic search to identify system hazards; leading to a list of **hazards**;
- **Assess:** the undertaking of a structured review to evaluate system risks; leading to a set of **risks**;
- **Propose:** the detailed evaluation of the risks; leading to a list of proposed **actions**.

The objective of this toolkit is to provide the knowledge and tools necessary to deliver an effective risk assessment process.



A 'waterfall' model of a risk management process

Background

There is usually a trigger that defines the entry point for any form of risk management. It is likely to arise from a variety of sources which might include:

- **An incident:** where an event has resulted in actual or potential harm to patients or practitioners;
- **Local concerns:** where potential accidents have been identified;
- **Routine health check:** where a team or individual wishes to check the integrity of their service;
- **Service improvement:** where changes are planned to an existing service or system;
- **New service:** where a new service is to be introduced into practice or an existing one decommissioned;
- **Technology introduction:** where new equipment or technology is to be introduced;
- **New staff:** where new staff are to be introduced to an existing service;
- **External directive:** where specific checks are requested.

A clear understanding of the trigger ensures that the review will be properly focused.

Identify the nature of the trigger for the review and provide brief details of its source.

Trigger for the assessment (tick all that apply):

- (a) an incident
- (b) local concerns
- (c) routine health check
- (d) service improvement
- (e) new service
- (f) technology introduction
- (g) new staff
- (h) external directive
- (i) other

specify
.....

Details of trigger

Articulate purpose

It is important to record the purpose for the risk assessment since the nature of this motivation can influence decisions regarding its scope and the methods used.

The purpose of the assessment is likely to be based in the need:

- to assess the likelihood of occurrence of a particular undesirable event;
- to identify potential sources of risk within a given system;
- to assess the impact of a spontaneous or planned change to a system.

Describe the purpose of the assessment with reference to the system to be reviewed and any particular events, sources of risk, or changes that are of interest.

In addition, it is important to identify criteria for the successful completion of the assessment. These are likely to include reference to the potential benefits of the review to the participants and to the system itself.

Describe the criteria for successful completion of the assessment, i.e. reduced risk to patients and staff, improved efficiency etc.

Purpose of the assessment
Criteria for success

Purpose

The purpose defines the motivation for the risk assessment. Whether a response to an incident, a routine health check or a response to a planned change, the purpose defines the broad objectives of the assessment.

The objectives identify the:

- **Type of assessment:** a response to an incident, routine health check or response to a planned change;
- **Scope of the assessment:** broad scope of system to be assessed and level of detail to which it will be assessed;
- **Execution of the assessment:** outline of time and resources available for assessment.

Identify the type of assessment to be undertaken.

Describe the scope of the assessment with reference to the system to be assessed and the level of detail required for the assessment.

Describe the outline plan for the execution of the risk assessment, with particular reference to the resources required and the timescale expected.

The objectives may need to be approved prior to defining requirements.

Type of study (tick one):

- (a) response to an incident
- (b) routine health check
- (c) response to a planned change

Scope of the assessment
Execution of the assessment

Define requirements

It is important to develop a clear understanding of the scope of the system to be assessed and the knowledge required of the comprehensive assessment.

In general, understanding arises from the following:

- **System mapping:** the development of a high-level description the system to be assessed;
- **Boundary setting:** the definition of the extent of the system to be assessed along with details of interfaces to other systems;
- **Mapping planning:** the identification of people and actions required to further map the system to the extent appropriate to achieve the proposed level of risk assessment.

Describe the system with reference to its purpose, key components and links to other systems.

System mapping and boundary setting may take many forms. There are a number of graphical techniques (see section 3) that have particular merit and are extensible to include further detail as required.

Identify the knowledge required for the assessment, providing names of individuals if appropriate. It is likely that the knowledge required at this stage will reside with a number of people.

Description of the system (textual)		
Knowledge required for the assessment		
	Required	Name
Patients	<input type="checkbox"/>
Doctors	<input type="checkbox"/>
Nurses	<input type="checkbox"/>
Pharmacists	<input type="checkbox"/>
Technicians	<input type="checkbox"/>
Documents	<input type="checkbox"/>
Other	<input type="checkbox"/>

Requirements

Understanding is the key to specifying a successful risk assessment. It is important to understand the particular needs for the proposed risk assessment to ensure that appropriate requirements and plans are defined.

Effective understanding arises from careful consideration of the:

- **System description:** a high-level description of the system to be assessed, made with appropriate reference to practices, people and pathways;
- **System boundary:** a description of the scope of the system to be assessed;
- **Knowledge requirements:** a list of the people required to contribute to the assessment;
- **Mapping requirements:** a description of the information required, along with a plan to acquire it;
- **Assessment requirements:** a preliminary appraisal of the type and level of risk assessment required.

Identify the understanding achieved.

Identify the mapping to be undertaken (see section 3) along with the resources required, the timescale expected and the risk assessment requirements.

The requirements may need to be approved prior to describing the system.

Understanding achieved (tick all that apply):

- (a) system description
- (b) system boundary
- (c) knowledge requirements

Mapping requirements

Assessment requirements

System

A clear, unambiguous system description is essential when undertaking a successful risk assessment. It is also important to define and communicate the particular needs of the proposed risk assessment to ensure that key activities are undertaken in a timely manner.

Effective risk management is dependent upon careful consideration and definition of the:

- **System detailed description:** a clear and complete description of the system to be assessed, made with reference to practices, people and pathways;
- **Assessment method:** a description of the specific risk assessment method(s) to be used and the means of its application to the system mapping;
- **Assessment plan:** a description of the assessment process, made with reference to key assessment activities, resources and timing requirements;

Identify the system and assessment descriptions available.

Identify the assessment activities to be undertaken (see section 4) along with the resources required and the timescale expected.

The assessment plan may need to be approved prior to identifying hazards.

Descriptions available (tick all that apply):

- (a) system detailed description
- (b) assessment method
- (c) assessment plan

Assessment activities
Assessment resources

Identify hazards

It is important to develop a clear understanding of the hazards inherent within the system being assessed (*what could go wrong?*), since this provides a robust basis for a comprehensive risk assessment.

In general, identification involves the following stages:

- **System familiarisation:** the development of a common understanding of the system to be assessed and the identification method to be used;
- **Identification of hazards:** the formal application of a hazard analysis method to identify and assess hazards within the system;
- **Communication of results:** the presentation of the results of the analysis in a clear manner.

Select a hazard identification approach, dependent on the system being assessed. There are a number of techniques available (see section 4) that have particular merit and are compatible with a range of system mapping approaches.

Identification methods are typically used individually, but there can be some advantage in using more than one to gain different perspectives on the system behaviour.

Consider the potential for harm presented by each hazard and record whether this is of concern.

Id	Element	Deviation	Concern	Hazard
0	Infusion pump	Elevated flow	Yes	Overdose
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				

Hazards

Identification is the key to identifying unacceptable hazards and implementing effective defences.

It is important to present the results of the hazard analysis to an audience representative of those engaged as patients, participants or managers within the system studied.

Effective hazard analysis will provide for the following:

- **Hazard identification:** a clear description of potential hazards within a system;
- **Hazard assessment:** a preliminary assessment of the risk associated with the hazards;
- **Hazard communication:** a clear, unambiguous representation of the results of the hazard analysis.

Identify the hazard descriptions available.

List any significant hazards identified as a focus for risk assessment activities.

The hazard analysis results may need to be approved prior to assessing risks.

Descriptions available (tick all that apply):

- (a) hazard identification
- (b) hazard assessment
- (c) hazard communication

Significant hazards
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Assess risks

It is important to develop a clear understanding of the risks inherent within the system being studied (*will it go wrong?*), since this provides a robust basis for action.

In general, assessment involves the following stages:

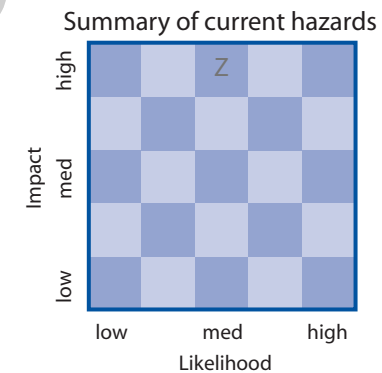
- **System familiarisation:** the development of a common understanding of the system to be assessed and the assessment method to be used;
- **Identification of defences:** the application of a risk assessment method to identify the defences within the system and evaluate their effectiveness;
- **Identification of current risk:** the application of a risk assessment method to identify how likely it is that the event will occur given the defences;
- **Communication of results:** the presentation of the results of the assessment in a clear manner.

Select a risk assessment approach, dependent on the system being assessed. There are a number of techniques available (see section 4) that have particular merit and are compatible with a range of system mapping and hazard identification approaches.

Assessment methods are typically used individually, but there can be some advantage in using more than one to gain different perspectives on the system behaviour.

It can be useful to locate each hazard on the grid, according to their likelihood of occurrence and impact.

Id	Hazard	Defence(s)	Likelihood	Impact
Z	Overdosing	Check setting	Medium	High
A				
B				
C				
D				
E				
F				
G				
H				
I				
J				



Risks

Assessment is the key to identifying unacceptable risks and implementing effective risk reduction.

It is important to present the results of the risk assessment to an audience representative of those engaged as patients, participants or managers within the system studied.

Effective risk analysis will provide for the following:

- **Risk identification:** a clear description of potential risks within a system;
- **Risk assessment:** an assessment of the resultant risk associated with the hazards and their defences;
- **Risk communication:** a clear, unambiguous representation of the results of the risk assessment.

Identify the risk descriptions available.

List any significant risks identified as a focus for developing risk control actions.

The risk assessment results may need to be approved prior to proposing actions.

Descriptions available (tick all that apply):

- (a) risk identification
- (b) risk assessment
- (c) risk communication

Significant risks
<p style="font-size: 48px; opacity: 0.3; text-align: center;">Draft v0.9</p>

Propose actions

It is important to review the results of an assessment in order to define an appropriate action plan in response to the levels of risk identified.

In general, review involves the following stages:

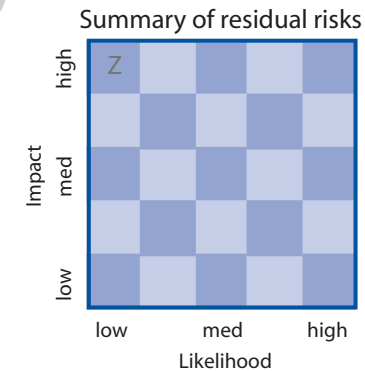
- **System familiarisation:** the development of a common understanding of the system to be assessed and the review method to be used;
- **System review:** the formal review of the risk assessment results to evaluate risks within the system and identify needs for treatment;
- **Identification of managed risk:** the application of a risk assessment method to identify how likely it is that the event will still occur given the actions;
- **Communication of results:** the presentation of the results of the review in a clear manner.

Review the risks and determine whether action is required. There may be benefit in involving additional patients, participants or managers to assist in the definition of an action plan.

Further risk assessment may be required if the initial results do not provide a satisfactory response to the original risk assessment proposition and requirements.

It can be useful to locate each risk on the grid, according to their likelihood of occurrence and impact.

Id	Risk	Action(s)	Likelihood	Impact
Z	Overdose	Check bloods	Low	High
A				
B				
C				
D				
E				
F				
G				
H				
I				
J				



Actions

Successful risk treatment is the ultimate outcome of an effective risk management process.

It is important to define a coherent approach to risk treatment to ensure risks are maintained within acceptable limits for the system studied.

Effective risk treatment will provide for the following:

- **Risk acceptance:** a clear statement of the relative acceptability of risks present within a system;
- **Risk treatment:** a description of the actions to be taken to reduce and/or manage risks within the system;
- **Risk communication:** a clear, unambiguous representation of the results expected as a result of the risk treatment process.

It is helpful to list those actions that are likely to have a significant impact on the current levels of risk.

Identify the risk descriptions available.

List any significant actions identified as a trigger for managing risk.

The risk treatment plan may need to be approved before actions are undertaken.

Descriptions available (tick all that apply):

- (a) risk acceptance
- (b) risk treatment
- (c) risk communication

Significant actions
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Review process

It is important to review the integrity of the risk study in order to determine whether further work is required.

Further assessment is necessary when:

- Risk reduction actions have been identified in order to manage risks;
- There is a lack of confidence in the risk data for potentially critical risks;
- The assessment is incomplete with hazards giving rise to risks outside of the system described or where risks arise from hazards outside of the system

Further study may require a more detailed investigation of existing parts of the system or the description and subsequent investigation of an extended system. The nature of such a study should be described, noting any prior actions required.

Determine whether further assessment is required to fully explore the risks within the system. This being the case, identify the reason for further assessment.

Where no risk management actions have been specified in the presence of adequate data and a well defined system there may be no need for further assessment.

Provide clear recommendations for further assessment, noting any specific actions required prior to undertaking the assessment.

Reason for further assessment (tick as many as apply):

- (a) need to manage risks and actions identified
- (b) lack of confidence in the results
- (c) preliminary study is incomplete

Recommendations for further assessment
Actions required prior to further assessment

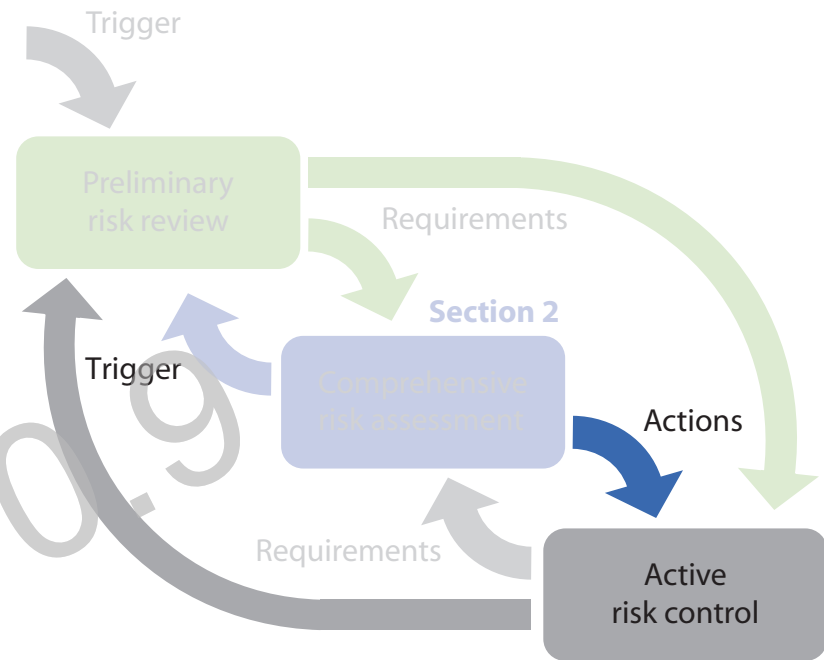
Active risk management

The objective of this guide is to provide the knowledge and tools required to deliver an effective risk assessment process.

Formal guidance on active risk management is not included here since it is already the topic of numerous texts on business management.

However, there are a few points worth noting:

- **Actions:** all actions identified from risk reviews or assessments should be assigned to an 'owner' and given a clear timetable for implementation
- **Trigger:** active risk management should regularly give rise to triggers for preliminary risk reviews
- **Requirements:** on occasion it may be appropriate for a comprehensive risk assessment to be actioned without first conducting a preliminary risk review



A staged approach to risk management

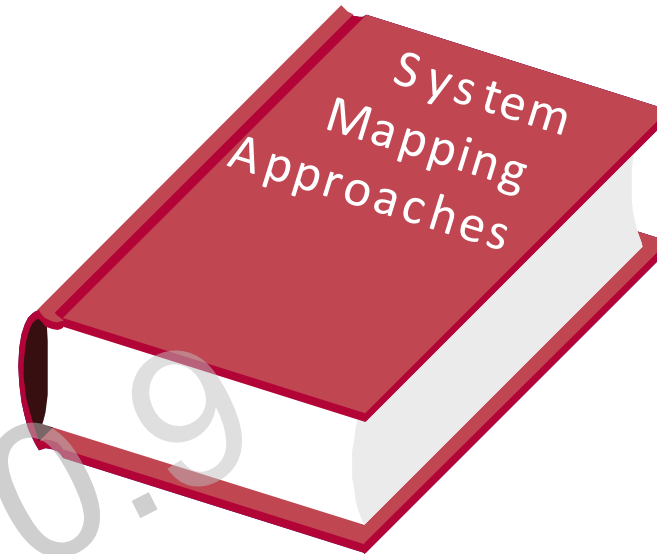
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Part 3:
System Mapping Approaches

John Clarkson, James Ward,
Thomas Jun, Jon Berman

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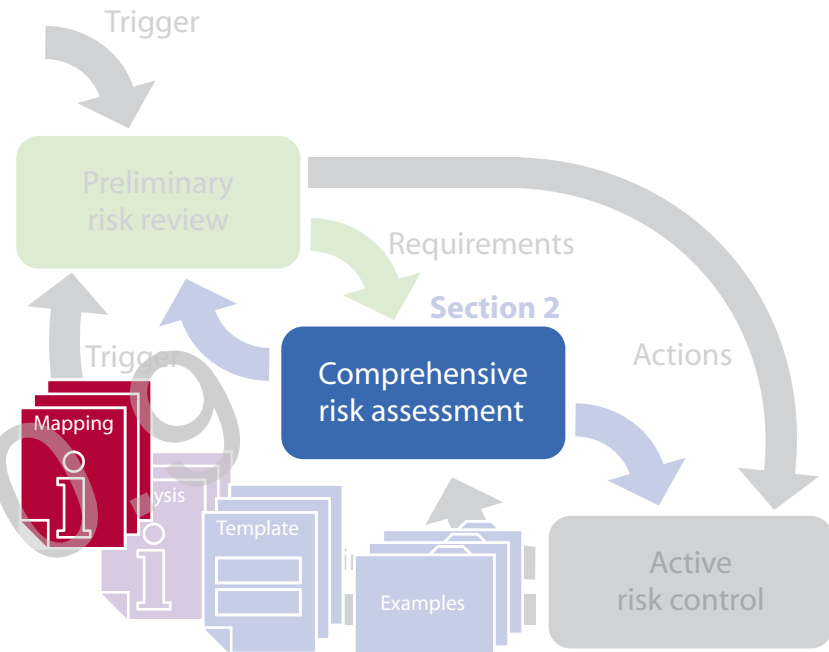
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Introduction

The objective of this part of the guide is to provide insight concerning the selection and application of system mapping approaches.

These following pages provide information concerning a variety of system modelling methods. Guidance is also provided concerning the selection of the methods and their application.



A staged approach to risk management

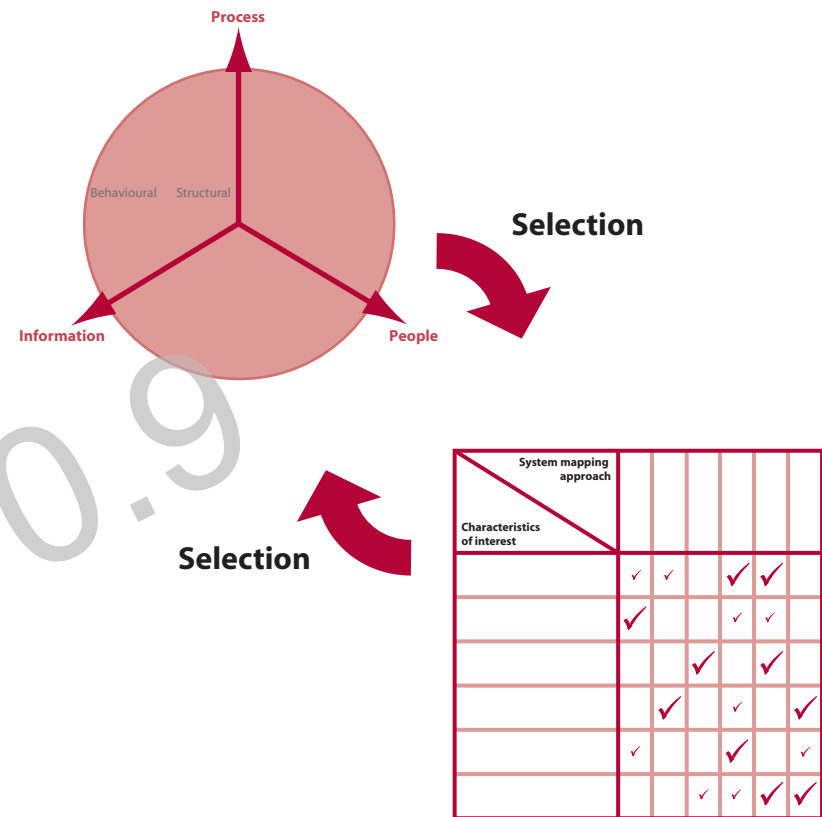
System mapping approaches

The selection of a system mapping approach, and its associated diagrams, will determine the value and integrity of the emerging risk assessment.

The most suitable mapping will be that which explicitly and unambiguously describes the system, capturing not only the key characteristics of the system, but also communicating such information to the participants in the risk assessment process.

The pages that follow enable the selection of an appropriate system mapping approach(es) by reference to the primary purpose of each approach and attributes describing its use.

Iterative reference to both the diagram and the table will be necessary to identify and select appropriate approaches.



An iterative approach to method selection

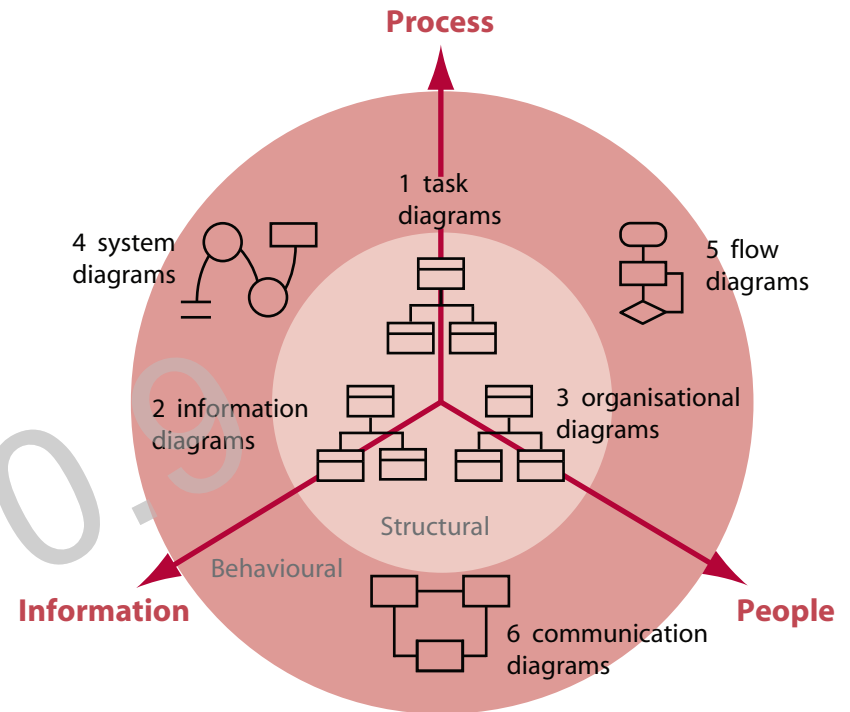
System mapping approaches

Some of the common system mapping approaches include:

- **Task diagrams** describe a hierarchy of operations (tasks) and plans (necessary conditions to undertake these operations);
- **Information diagrams** describe a hierarchy of information and/or material (things) used or needed in physical or electronic form;
- **Organisational diagrams** describe a hierarchy of people and/or roles within single or multiple organisations;
- **System diagrams** represent how data (or objects) are transformed through activities, where such data are stored, and how such activities are sequenced;
- **Flow diagrams**, which include traditional flow charts, and swim-lane diagrams, represent activities occurring in sequence or in parallel;
- **Communication diagrams** represent information and material flows between people (stakeholders) linked by some common process.

This is by no means an exhaustive list. There are other mapping approaches that also are capable of providing insight into the operation of a system.

Identify the broad type of mapping required, noting the methods most closely associated with this objective. Use of more than one method may be necessary to complete the system description.



System mapping approaches focus on one or more of the people, process or information perspectives

System mapping approaches

Whilst it is important to take account of people's prior experience in reading such diagrams, it would be inappropriate to choose an approach solely on this basis if it were not suited to the system being studied. Training or expert facilitation may be necessary to enable use of some approaches.

The table opposite highlights the relative suitability of different mapping approaches for capturing specific attributes of a system. In practice, more than one characteristic may need to be investigated to describe the operation of a given system.

Identify those characteristics that may influence the choice of method. A large tick indicates a significant match between the method and characteristic, a small tick a partial match, and no tick indicates there is no match. More than one method may be required to complete the system mapping.

The table presents the primary focus for each of the methods; particular strengths and weaknesses are discussed in the following pages. In practice, more than one approach may be required to undertake a complete risk management process.

System mapping approach \ Characteristics of interest	1. Task	2. Information	3. Organisational	4. System	5. Flow	6. Communication
Process and procedure <i>e.g. patient pathways</i>	✓	✓		✓	✓	
Human behaviour <i>e.g. performance measures</i>	✓			✓	✓	
Role and responsibilities <i>e.g. team working</i>			✓		✓	
Communication <i>e.g. referral</i>		✓		✓		✓
Human-technology interface <i>e.g. medication devices</i>	✓			✓		✓
Procurement and supply <i>e.g. medication flows</i>			✓	✓	✓	✓

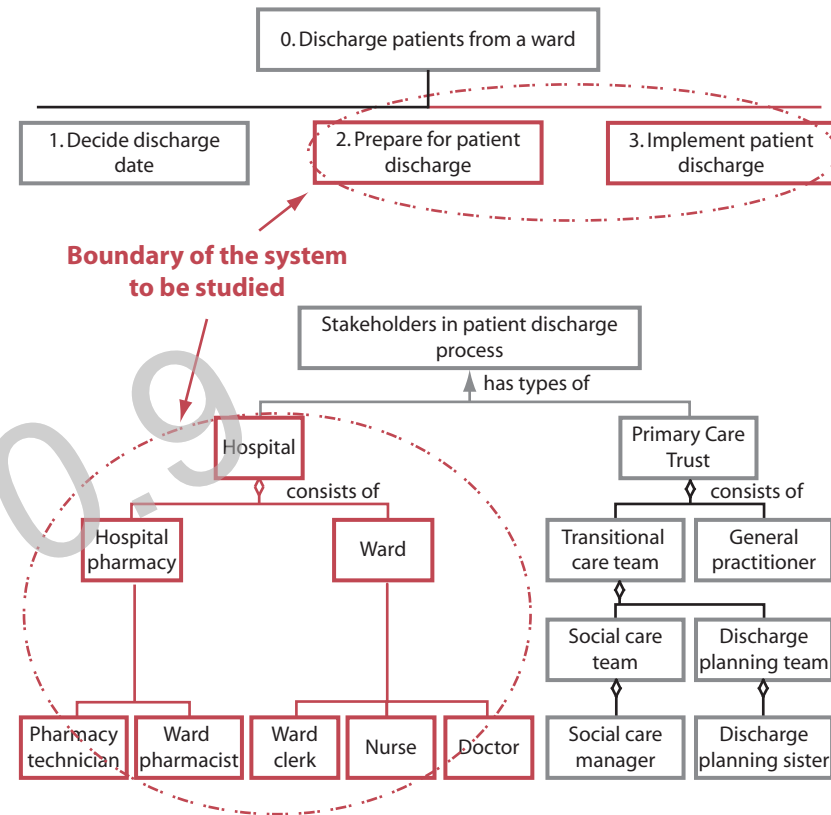
Mapping the System

It is important to develop a clear understanding of the scope and depth of the proposed risk study. Defining the boundary of the system to be studied assists such focus.

Boundary setting may best be achieved by describing a system that is more extensive than the one which is to be studied and then explicitly defining the boundary within that description. This has the advantage of highlighting those parts of the larger system that interface to the system under study.

The structural diagramming methods described in this section are particularly useful for defining the system boundary. Behavioural descriptions may then be used to further expand the system description within the system boundary.

In the example shown, the extent of the system to be studied is identified in the task and organisational diagrams.



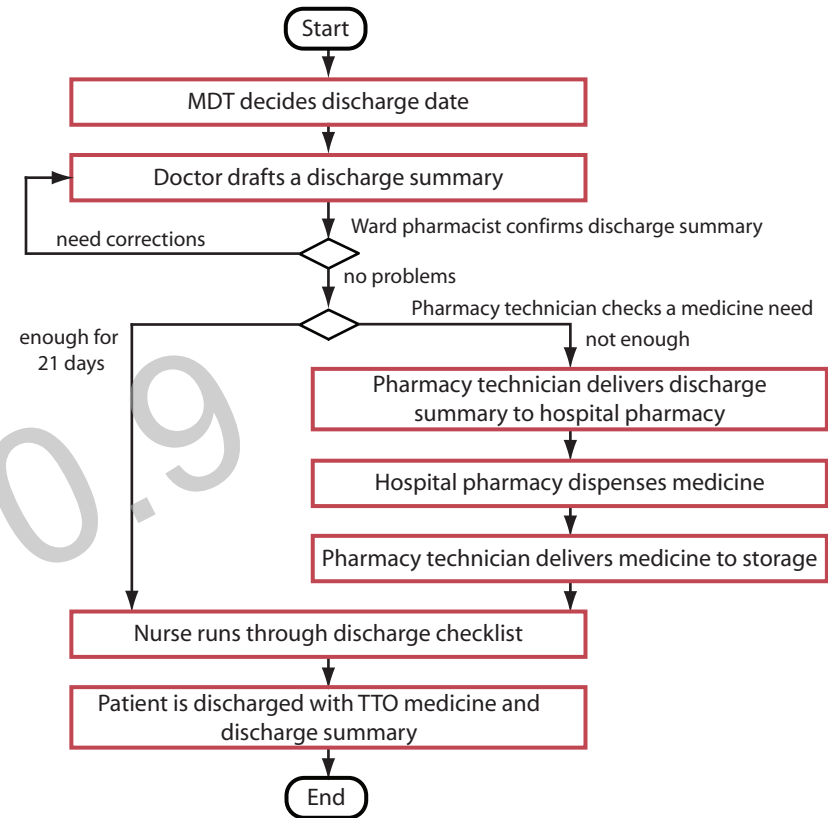
Mapping the System

It is important to develop a clear understanding of the structure and behaviour of the system to be assessed by the proposed risk study. Mapping the system to be studied assists such focus.

Mapping may take a variety of diagrammatic and textual forms, each focusing on a particular, but limited, perspective of the system. It is important to select the mapping method(s) that best capture the essence of the system to be studied.

The structural diagramming methods described in this section are particularly useful for defining the system architecture whilst the behavioural diagramming methods assist in the definition of the detail and may then be used to directly support risk assessment.

In the example shown, the system performance is described by a flow diagram. Communication and system diagrams would provide further perspectives on the behaviour of the system.



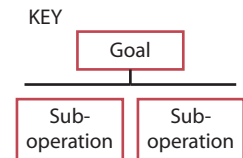
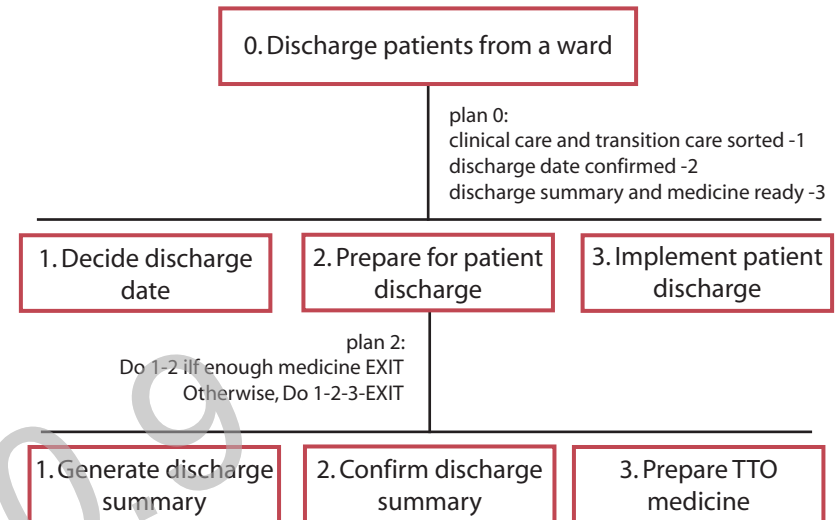
1. Task diagrams

Task diagrams describe a hierarchy of operations (tasks) and plans (necessary conditions to undertake these operations). They are a diagrammatic representation of the structure of **activities** (nodes) and their **relationships** (links).

The hierarchical nature of this representation allows the description of a particular task with as much or as little detail as necessary; making it appropriate for describing whole processes as well as specific issues, such as interface design and work organisation.

The possible deviation or failure of each task (or plan) can be considered as a basis for risk assessment.

Kirwan, B. & Ainsworth, L.K. (Eds.) (1992) A guide to task analysis, Taylor and Francis.



TTO: To Take Out

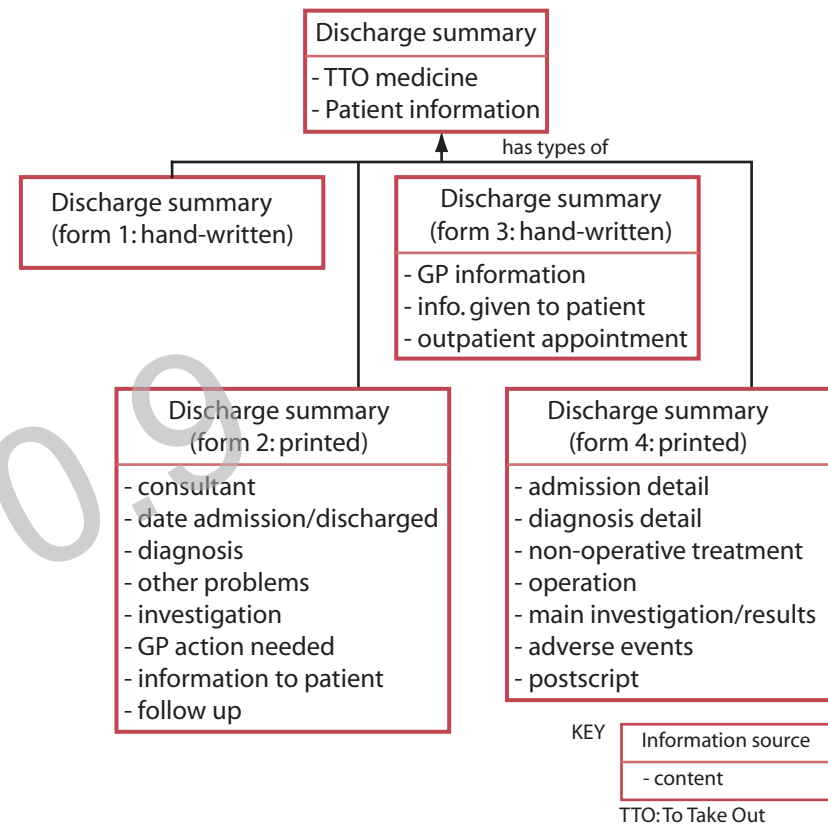
2. Information diagrams

Information diagrams describe a hierarchy of information and/or material (things) used or needed in physical or electronic form. They are a diagrammatic representation of the structure of **information** or **documents** (nodes) and their **relationships** (links).

They are suitable for understanding documentation issues; such as the degree of standardisation of documents, level of usage of electronic documents and links between electronic and paper-based documents.

Information diagrams alone are not sufficient for supporting risk assessment, but they are often used as a base for building other types of diagrams, for example, communication diagrams or data-flow diagrams.

Shlaer, S. & Mellor, S.J. (1988) Object-oriented Systems Analysis: Modelling the World in Data, Prentice Hall.



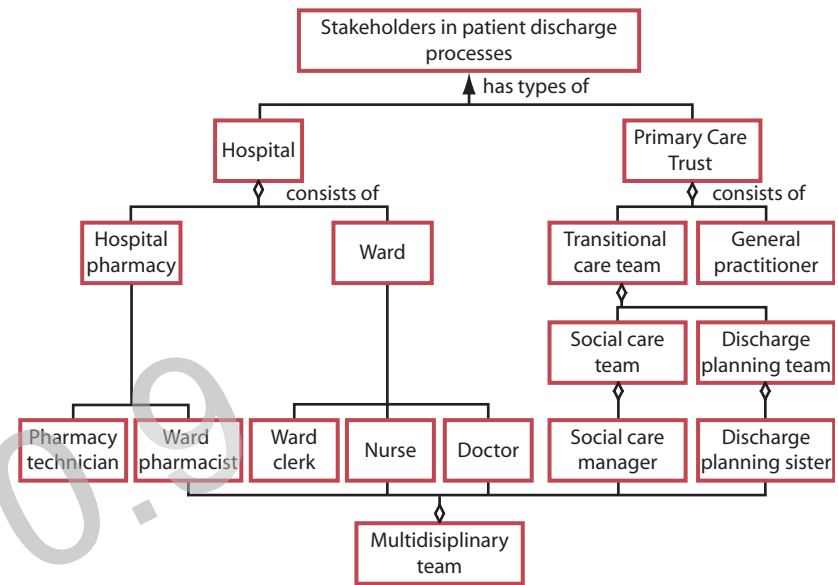
3. Organisational diagrams

Organisational diagrams describe a hierarchy of people and/or roles within single or multiple organisations. They are a diagrammatic representation of **departments**, **teams** and **individuals** (nodes) and their **relationships** (links).

They are suitable for identifying key stakeholders in a system; enabling subsequent data collection to support risk assessment and refinement of the scope and boundary of any such study.

Organisational diagrams alone are not sufficient for risk supporting risk assessment, but they are often used as a base for building other types of diagrams, for example, flow diagrams or communication diagrams.

Paul, D. & Yeates, D. (Eds.) (2006) Business Analysis, British Computer Society.



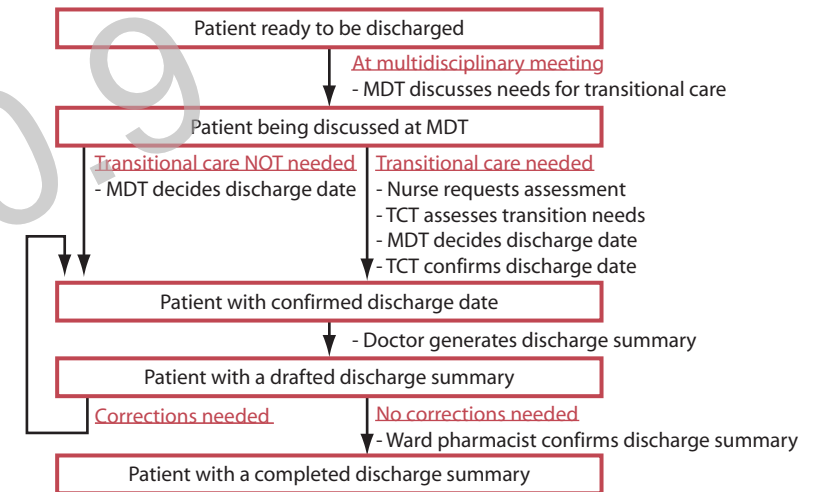
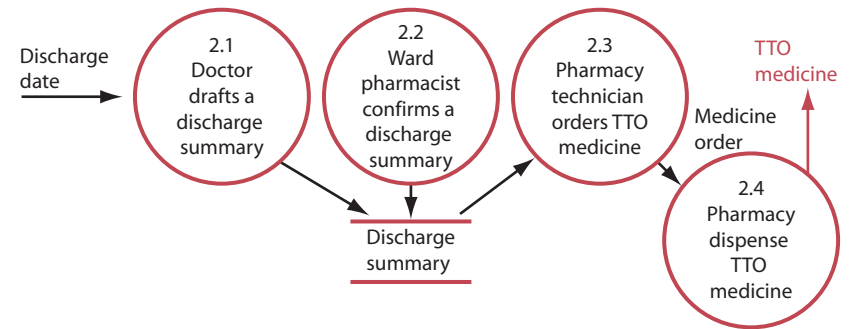
4. System diagrams

System diagrams represent how data (or objects) are transformed through activities, where such data are stored and how such activities are sequenced. They are a diagrammatic representation of the **data-flows/ functions** and **events/state-transitions** within a dynamic system.

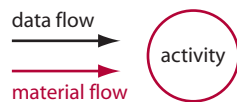
They are particularly helpful in describing real-time data-driven processes, e.g. human-technology interactions. These diagrams are particularly suitable for creating understanding of an overall process.

The possible deviation or failure of each data-flow, function or state-transition can be considered as a basis for risk assessment.

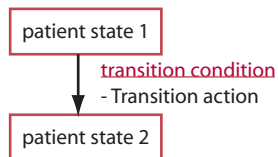
Yourdon, E. (1989) Modern Structured Analysis, Prentice Hall. Also at: <http://yourdon.com/strucanalysis/wiki/>



KEY



data/material storage



MDT: Multidisciplinary team
TCT: Transitional care team

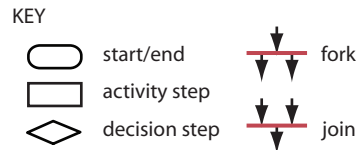
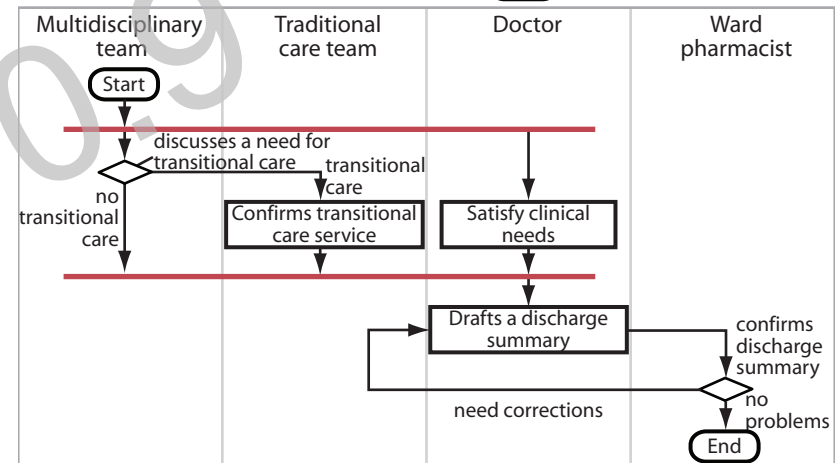
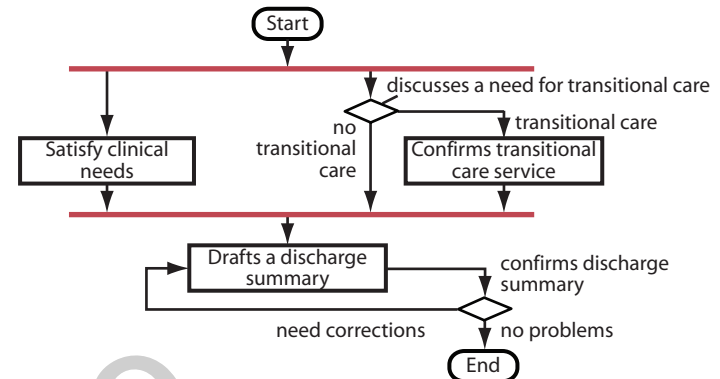
5. Flow diagrams

Flow diagrams, which include traditional flow charts, and swim-lane diagrams, represent activities occurring in sequence or in parallel. They are a diagrammatic representation of the ordering of activities, showing key **steps** (nodes) and the **conditions** for moving between them (links).

In their simplest form they are similar to traditional flow charts, while further annotation may be used to identify the key stakeholders responsible for each activity. These diagrams are particularly suitable for creating understanding of an overall process.

The possible deviation or failure of each step or link can be considered as a basis for risk assessment.

Hunt, V.D. (1996) *Process Mapping: How to Reengineer your Business Process*, John Wiley & Sons Ltd.



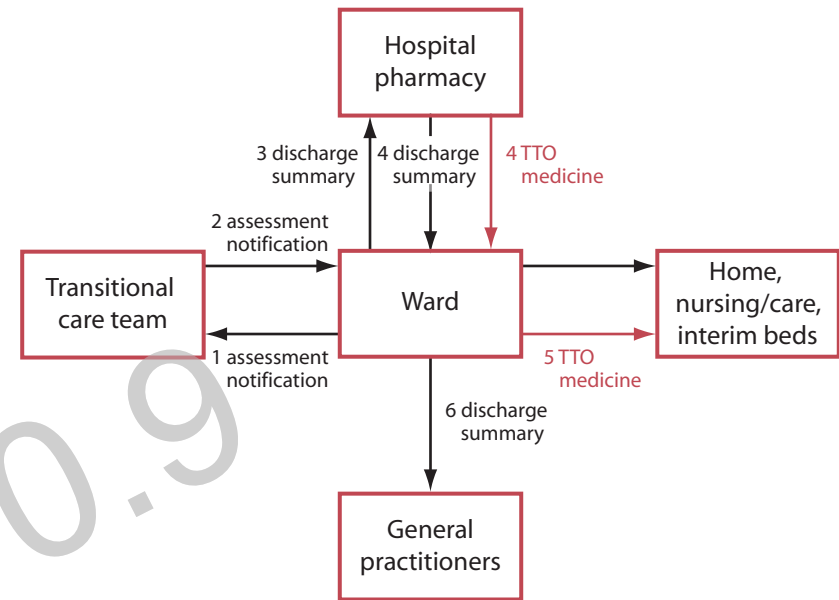
5. Communication diagrams

Communication diagrams represent information and material flows between people (stakeholders) linked by some common process. They are a diagrammatic representation of the **information** and **material flows** (links) between **stakeholders** (nodes).

They are particularly suitable for describing interactions between trusts, departments, teams and individuals, where the 'flow' indicated by the diagram allows an effective description of a supply chain.

The possible deviation or failure of the flows and/or absence of the stakeholders can be considered as a basis for risk assessment.

Holt, J. (2007) UML for Systems Engineering: Watching the Wheels, London, Institution of Engineering and Technology.



KEY

Stakeholder

→ Information flow

→ Medicine flow

Draft v0.9

Part 4: Risk Assessment Approaches

John Clarkson, James Ward,
Jon Berman, Sheena Davis, Paul Leach

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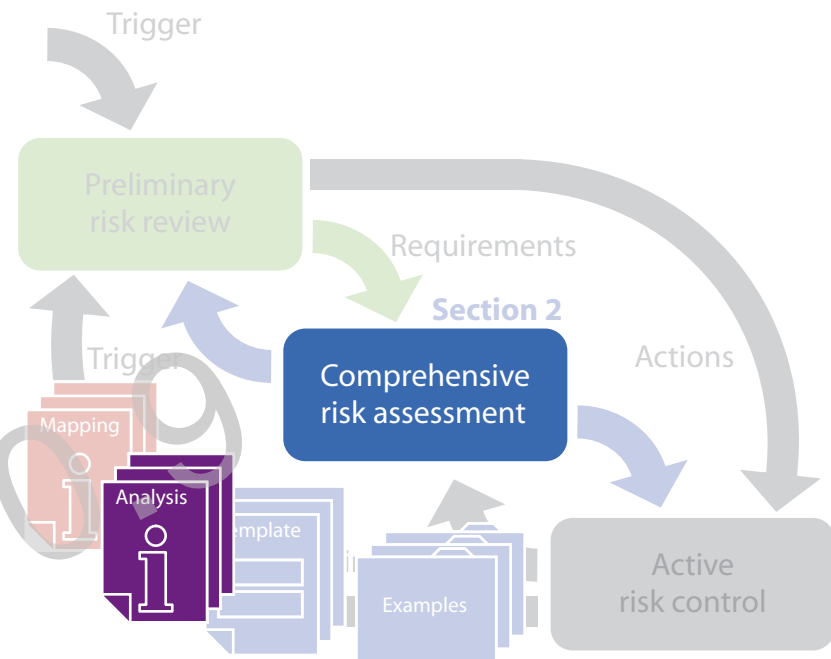


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Introduction

The objective of this part of the guide is to provide insight concerning the selection and application of risk assessment approaches.

The following pages provide information concerning a variety of risk assessment methods. Guidance is also provided concerning the selection of the methods and their application.



A staged approach to risk management

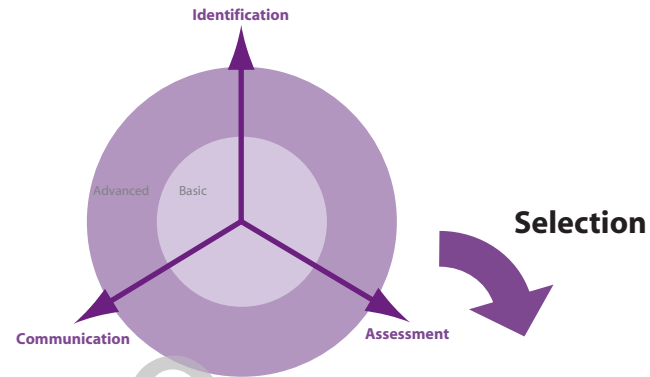
Risk assessment approaches

The selection of a risk assessment approach, and its associated method, will determine the value and integrity of the emerging risk assessment.

The most suitable assessment will be that which systematically and correctly assesses the system, identifying not only the key risks and barriers, but also communicating such information to the participants in the risk assessment process.

The pages that follow enable the selection of an appropriate risk assessment approach(es) by reference to the primary purpose of each approach and attributes describing its use.

Iterative reference to both the diagram and the table will be necessary to identify and select appropriate approaches.



Risk assessment approach					
Characteristics of interest					
	✓	✓		✓	✓
	✓			✓	✓
			✓		✓
		✓		✓	✓
	✓			✓	✓
			✓	✓	✓

An iterative approach to method selection

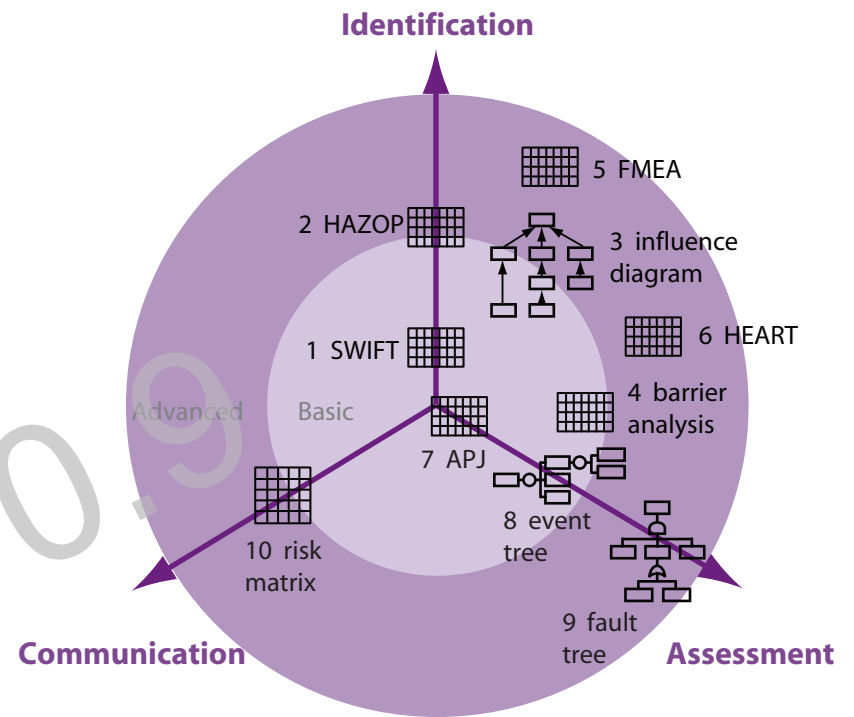
Risk assessment approaches

Some of the common risk assessment approaches include:

- **Hazard identification:** provides a structured and systematic approach to the identification of hazards and potential consequences; methods include SWIFT, HAZOP, FMEA and influence diagram
- **Risk assessment:** provides a systematic method for identifying the relationship between hazard, impact and likelihood; methods include HEART, barrier analysis, APJ and event and fault trees
- **Risk communication:** provides a means of representing the risk in terms of likelihood and impact, such that risks can be compared, prioritised and managed; methods include risk matrixes

This is by no means an exhaustive list. There are other assessment approaches that also are capable of providing insight into the operation of a system.

Identify the broad area of assessment required, noting the methods most closely associated with this objective. Use of more than one method may be necessary to complete the risk assessment.



Risk assessment approaches focus on one or more of the identification, assessment or communication perspectives

Risk assessment approaches

Whilst it is important to take account of people’s prior experience in using such methods, it would be inappropriate to choose an approach solely on this basis if it were not suited to the system being studied. Training or expert facilitation may be necessary to enable use of some approaches.

The table opposite highlights the relative suitability of different risk assessment approaches to match to the purpose of the assessment.

Identify those characteristics that may influence the choice of method. A large tick indicates a significant match between the method and characteristic, a small tick a partial match, and no tick indicates there is no match. More than one method may be required to complete the risk assessment.

The table presents the primary focus for each of the methods; particular strengths and weaknesses are discussed in the following pages. In practice, more than one approach may be required to undertake a complete risk management process.

Risk assessment approach Characteristics of interest	1. SWIFT	2. HAZOP	3. Influence diagram	4. Barrier analysis	5. FMEA	6. HEART	7. APJ	8. Event tree	9. Fault tree	10. Risk matrix
Hazard identification	✓	✓	✓		✓					
Risk identification		✓	✓	✓	✓	✓	✓			
Existing barrier identification		✓	✓	✓	✓	✓		✓	✓	
Required barrier identification			✓	✓	✓	✓		✓	✓	
Risk prioritisation					✓	✓	✓	✓	✓	
Risk communication					✓	✓	✓	✓	✓	✓

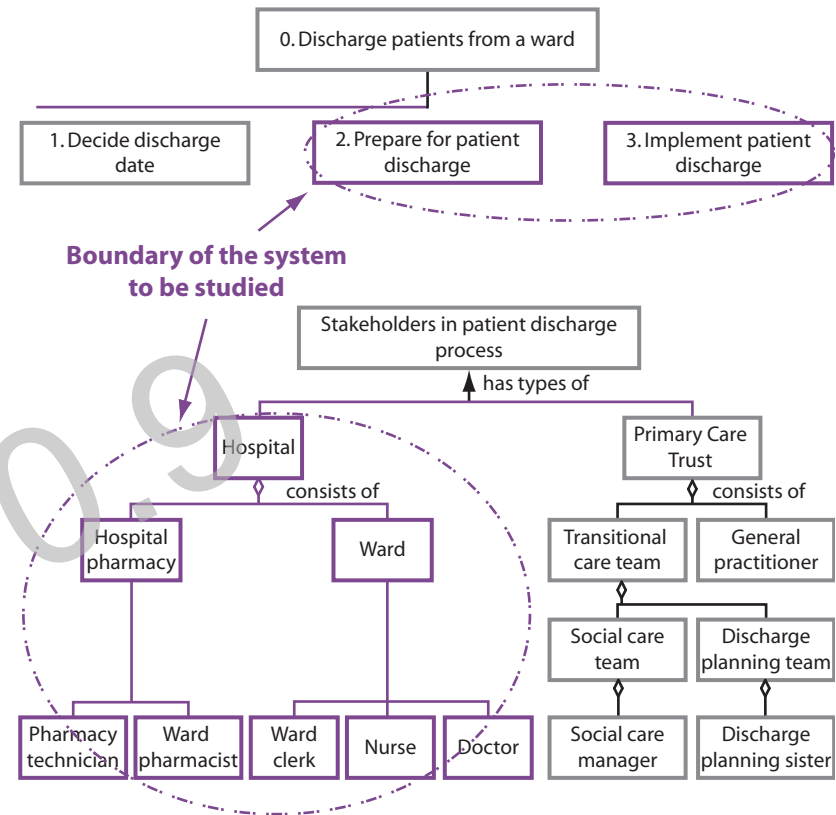
Risk assessment in practice

The rigorous examination of a system can be assisted by reference to structural systems mappings such as task, information and organisational diagrams.

For many risk assessment methods, such as SWIFT, HAZOP, barrier analysis, FMEA, APJ and HEART, structural mappings provide the basis for investigating the impact of the partial or complete failure of each component and/or interface in the system.

For other methods, such as event and fault trees and influence diagrams, structural mappings provide an excellent background to the assessment. In both cases, the failure of interfaces to components outside of the system boundary should also be considered.

In the example shown, the extent of the system to be studied is identified in the task and organisational diagrams. Interface that cross this boundary are also of interest.



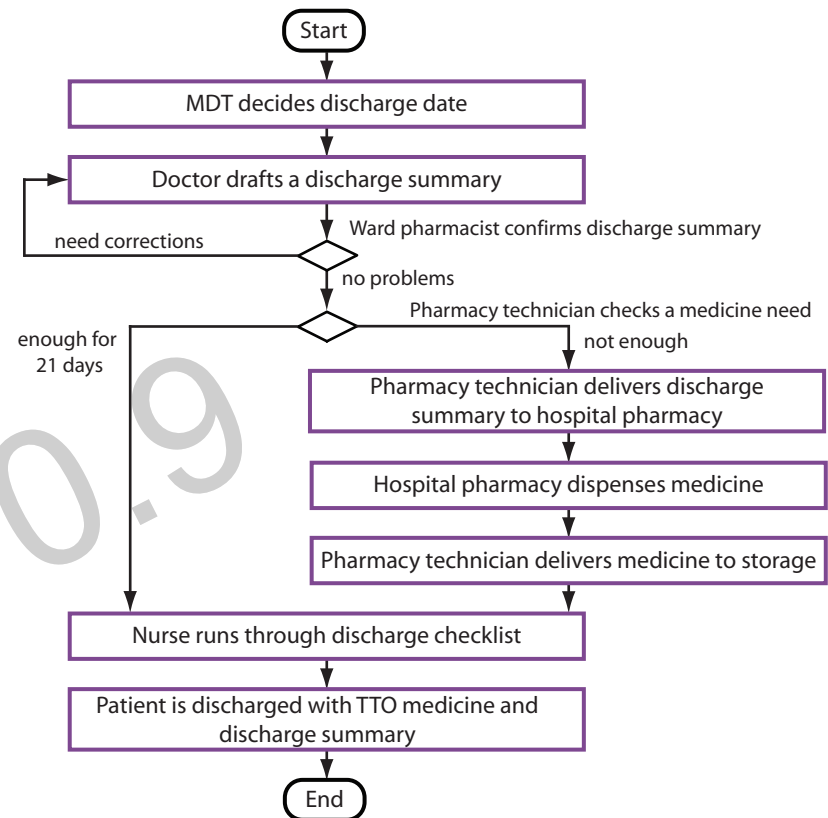
Risk assessment in practice

The rigorous examination of a system can be assisted by reference to behavioural systems mappings such as system, flow and communication diagrams.

For many risk assessment methods, such as SWIFT, HAZOP, barrier analysis, FMEA, APJ and HEART, behavioural mappings provide the fundamental basis for investigating the impact of the partial or complete failure of each component and/or interface in the system. Such investigation should be systematic and exhaustive, considering all aspects of system behaviour.

For other methods, such as event and fault trees and influence diagrams, behavioural mappings provide an excellent background to the assessment.

In the example shown, the system performance is described by a flow diagram. Communication and system diagrams would provide further perspectives on the behaviour of the system.



1. Structured what-if technique

SWIFT is a structured team-based study that uses “what-if” questions to help a team think about and identify relevant hazards and risks. It focuses on deviations from normal operations and the impact they may have on a system, procedure or organisation.

SWIFT facilitates discussions to help the team explore differing scenarios, their consequences, causes and impacts. It provides a quick approach to brainstorm, consider and identify major hazards, provides a high level exploration of improvement actions; and is widely applicable and flexible to most processes.

SWIFT relies heavily on advanced facilitation skills; mainly focuses on major hazards, complex hazards can be missed or over-simplified; and does not consider risk.

SWIFT provides an effective platform for risk identification and prioritisation.

Maguire, R. (2006) Safety Cases and Safety Reports: Meaning, Motivation and Management, Ashgate Publishing.

Id	What-if questions	Hazards and risks	Relevant controls	Risk ranking	Action notes
X	how much?				
A					
B					
C					
D					
E					
F					
G					
H					
I					
J					

2. Hazard and operability

HAZOP is particularly suited to hazard identification.

HAZOP is a **hazard identification** method which provides a systematic and structured analysis of a system, focusing not only on hazards, but also on **operability issues**. It provides a qualitative assessment of the presence of hazards, their potential consequence and appropriate actions.

HAZOP is a team-based activity; that draws on the expertise and understanding of a group of people who are experienced either in the specific or similar systems; and should be used where there is a good description of the system available.

HAZOP focuses on deviation from the intended performance of the system. It can reveal shortcomings in the overall activity, the design of its component parts, proposed methods of operation, or interactions between these.

HAZOP can be time consuming; does not address risk (likelihood and impact); and may lose sight of whether there are better approaches to undertaking tasks.

HAZOP provides an effective platform for risk identification and prioritisation.

IEC 61882 (2001) Hazard and Operability Studies (HAZOP Studies) — Application Guide, American National Standards Institute (ANSI).

Id	Prompt words	Deviation	Causes	Consequences	Existing barriers	Actions
X	less than					
A						
B						
C						
D						
E						
F						
G						
H						
I						
J						

3. Influence diagram

Influence diagrams are particularly suited to existing barrier identification

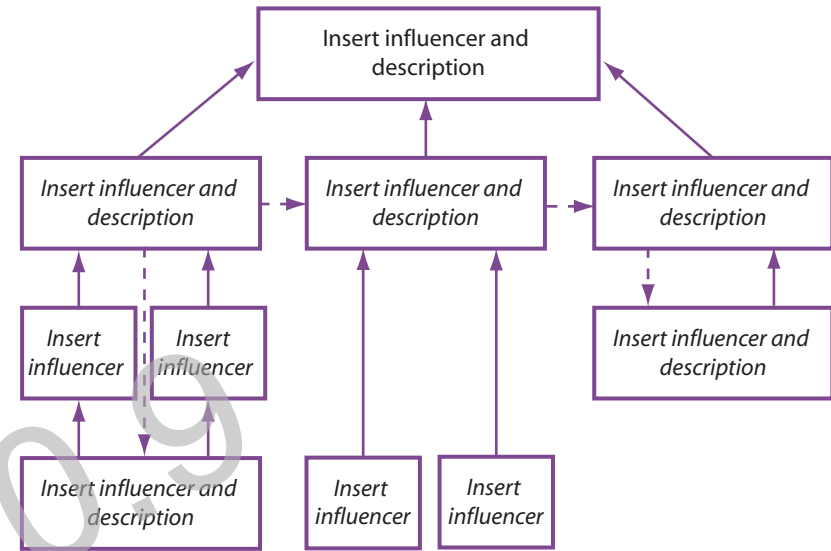
Influence diagrams use a graphical technique to represent all relevant factors that can **influence** the occurrence of an **event**. They are developed through defining and describing the conditions, setting and high-level actions that lead up to events.

Influence diagrams are used when there is a demand to understand the physical, environmental, managerial and organisational factors that can influence system behaviour; and enable consideration of influencers to identify hazards and safeguards.

Influence diagrams require a variety of experts; can become extremely complex; need to be used in conjunction with a hazard identification technique; and focus on influencers as opposed to hazards.

Influence diagrams provide an effective platform for risk prioritisation

Oliver, R. & Smith, J. (1990) Influence Diagrams, Belief Nets and Decision Analysis, John Wiley & Sons.



4. Barrier analysis

Barrier analysis is particularly suited to existing barrier identification.

Barrier analysis is a technique that focuses on how harmful **energy** is passed to vulnerable **people** (objects) and provides qualitative and functional analysis of the barriers that are in place, or need to be in place, to prevent such transfer and enhance safety. It relies on the use methods such as observations and structured interviews to gather system and event information.

Barrier analysis examines safeguards in terms of both physical and administrative safeguards; and can be used to understand and describe the effectiveness of current safeguards within a process,

Barrier analysis focuses only on safeguards as opposed to hazards or risk; and can provide limited information when used for very complex events and multiple interactions and inter-dependencies.

Barrier analysis provides an effective platform for risk prioritisation.

Davis, Jr. & Thomas, P. (2004) Barrier Analysis Facilitator's Guide, Washington, DC: Food for the Hungry.

Id	Activity	Energy/ people	Barrier function	Barrier failures	Barrier actions
X	Prescribing				
A					
B					
C					
D					
E					
F					
G					
H					
I					
J					

5. Failure mode and effects analysis

FMEA is particularly suited to hazard identification, risk identification and risk prioritisation.

FMEA is a flexible approach that can be used to consider and identify the effects of **human error on systems**; including both individual operator failures and/or team failures. It identifies the likelihood of the failure and its impact for each failure mode identified by the team, enabling the rank ordering of failure modes and prioritisation of corrective actions.

FMEA is a team-based activity; that draws on the expertise and understanding of a group of people who are experienced either in the specific or similar systems; and should be used where there is a good description of the system available.

FMEA only identifies single failures, rather than combined failures, and can become complex when assessing multilayered systems.

FMEA may be used in conjunction with other barrier identification methods.

IEC 60812 (2006) Analysis Techniques for System Reliability — Procedure for Failure Mode and Effects Analysis (FMEA), American National Standards Institute (ANSI).

Id	Task steps	Failure modes	Causes	Likelihood /severity	Recovery steps	Actions
X	Infusion					
A						
B						
C						
D						
E						
F						
G						
H						
I						
J						

6. Human error assessment and reduction technique

HEART is particularly suited to risk identification and risk prioritisation.

HEART is a human reliability method that is used to evaluate the probability of a **human error** occurring during the execution of a specific **task**. It is based on the principle that every time a task is undertaken there is a possibility of failure and the probability of failure is affected by error producing conditions, for example distraction, experience, tiredness.

HEART should be used when there is a requirement to understand and determine a quantified probability of task failure. It is highly flexible and quick to use and provides information on error reduction strategies.

HEART focuses only on human error/task failure; uses generic tasks for the analysis that are not domain specific; and does not consider the interdependence of error producing conditions.

HEART may be used following hazard identification and in conjunction with other barrier identification methods.

Wilson, J. & Corlett, N. (2005) Evaluation of Human Work, Taylor & Francis.

Id	Task class	Error condition	Total effect	Assess affect	Assessed affect	Prob of failure
X	Complex					
A						
B						
C						
D						
E						
F						
G						
H						
I						
J						

7. Absolute probability judgement

APJ is particularly suited to risk prioritisation.

APJ is a human reliability method that is used to evaluate the probability of a **human error** occurring during the execution of a specific **task**. It involves a group of experts (front line staff, engineers, managers etc) using their knowledge and experience to estimate and determine human error probabilities.

APJ can be used to provide detailed qualitative probabilities when limited data exists to calculate quantified human error probabilities. It is also able to provide insights into the types of strategies that are likely to reduce the probability of error and task failure.

APJ relies on subjective judgements which are susceptible to bias; and validating judgements can be difficult as the process often is used when there is limited data available.

APJ may be used following hazard or risk identification and in conjunction with other barrier identification methods.

Kirwan, B. (1994) Practical Guide to Human Reliability Assessment, Taylor & Francis.

Id	Potential errors	Maximum probability	Minimum probability	Range	Geometric mean
X	Overdose				
A					
B					
C					
D					
E					
F					
G					
H					
I					
J					

8. Event tree

Event trees are particularly suited to existing barrier identification and required barrier identification.

Event trees are graphical devices used to logically investigate the sequence of **operator actions** leading to an **event** and identify the possible consequences of these sequences. They use nodes to depict each task within an event sequence and paths leading from the nodes to indicate possible outcomes of the task.

Event trees can be used throughout the lifecycle of a system or procedure to identify potential scenarios for testing; help identify operator behaviour and ways to improve system reliability; and help represent adverse events that have occurred and the impact of operator behaviour on that event.

Event trees can over simplify the complexity of human behaviour and the sequence of events,

Event trees may be used following hazard or risk identification and provide an effective platform for risk prioritisation.

Rausand, M. & Høyland, A. (2004) System Reliability Theory: Models, Statistical Methods and Applications, John Wiley & Sons.

Id	Initiating event	1 st defence active?	2 nd defence active?	3 rd defence active?	Resultant event
X	Overdose				
A			Y	Y	
B		Y		N	
C			N	Y	
D		N		N	
E					
F					
G					
H					
I					
J					

9. Fault tree

Fault trees are particularly suited to existing barrier identification and required barrier identification.

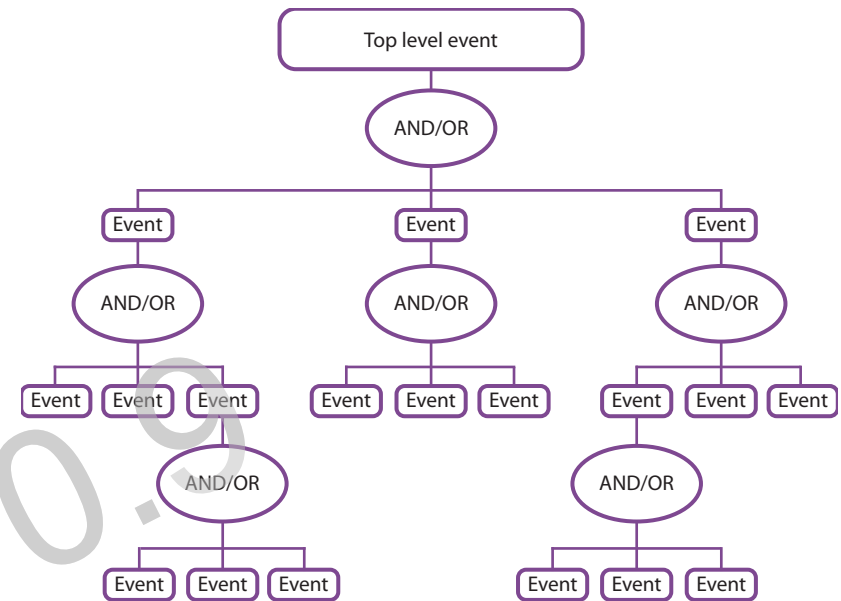
Fault trees are graphical devices for identifying and analysing factors that contribute to the occurrence of an adverse or undesired event. They provide insight into the relevant causes of failure and can be used either to quantitatively or qualitatively assess the likelihood of an undesirable event occurring.

Fault trees use a pictorial tree structure representation that is easy to understand; and help the analyst understand the causes of failures and events, and assess the likelihood of an undesirable event occurring .

Fault trees can be hard to construct due to the complexity of human behaviour; can be vulnerable to high levels of uncertainty when used to calculate the likelihood of an event occurring.

Fault trees may be used following hazard or risk identification and provide an effective platform for risk prioritisation.

IEC 61025 (1990) Fault Tree Analysis, American National Standards Institute (ANSI).



10. Risk matrices

Risk matrices are particularly suited to risk communication.

Risk matrices allow individuals to visualise and rank the risks associated with the undesired events, acts or activities. They are made up of two axes, **likelihood** and **impact**, and may be partitioned into regions of acceptable and unacceptable risk. In general entries in the upper right of the matrix are not desirable, while those in the lower left are likely to be acceptable.

Risk matrices can use a qualitative scoring system from 1 (low) to 5 (high) for likelihood and impact, or a quantitative one; and be used to show impact of many forms including injury to persons, property and/or profit.

Risk matrices do not on their own enable hazard or risk identification, but can easily be used in conjunction with other methods that do fulfil these needs.

Risk matrices may be used following risk identification.

Adams, J. (1995) Risk, London, UCL press.

