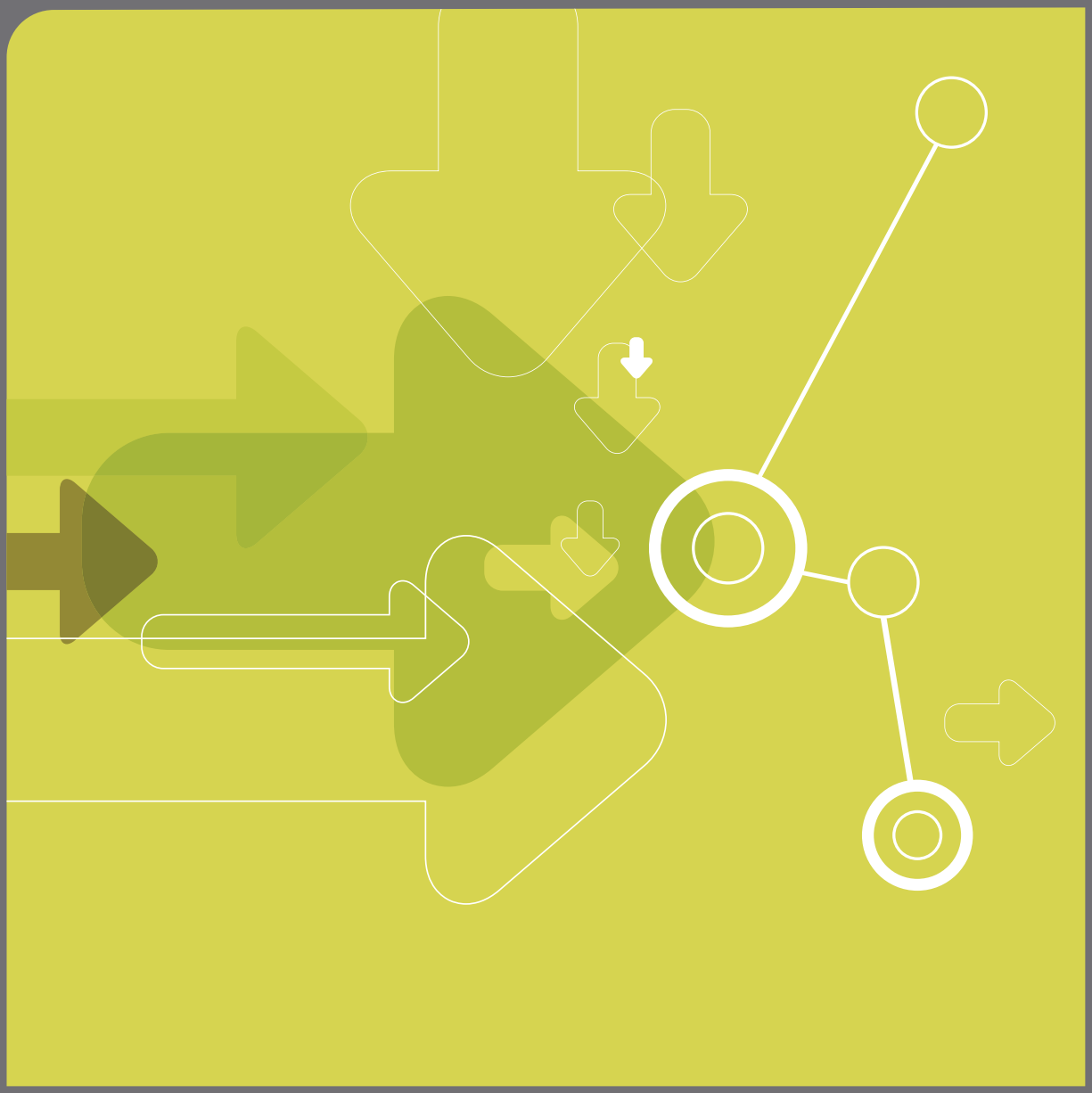
NHS
National Patient Safety Agency

Risk assessment programme
Overview

November 2006



Contents

Summary

The following document describes the NPSA's programme of work in risk assessment. This will be continually updated and expanded to include links to examples of good practice and expertise. The resources will be developed from research, practical experience of using the tools, and local practice and experience from NHS organisations. The approaches described here are suggested tools and techniques that NHS local organisations can use.

Section 1 explains what risk assessment is, why it is important, when to do it, who should do it, and provides a practical approach on how to do it.

Section 2 explains the relevance risk assessment has for patient safety.

Section 3 details some of the key models used in industry and healthcare.

Section 4 describes what healthcare providers can do.

Section 5 outlines the NPSA's programme of work and what the NPSA is doing to help the NHS, with links to detailed case studies and practical examples.

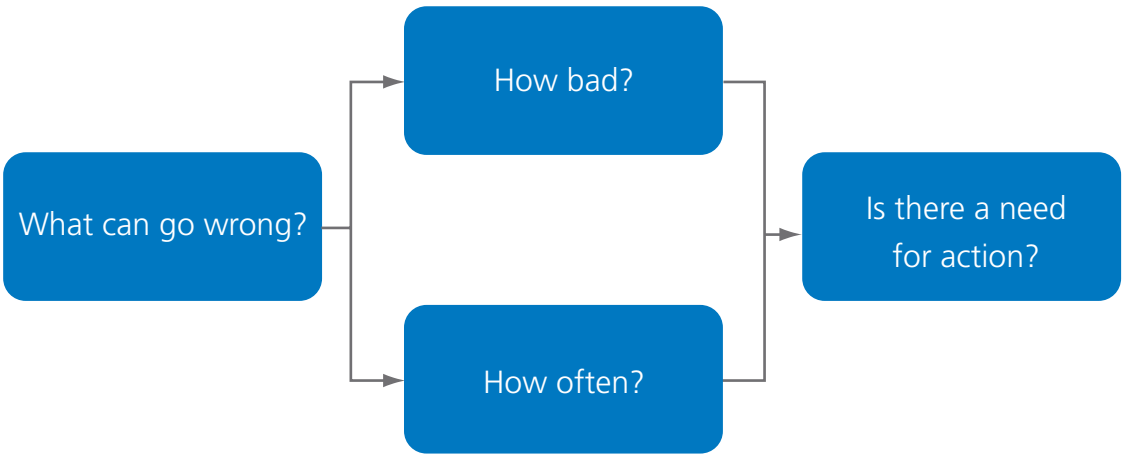
1 The risk assessment process

1.1 What is risk assessment?

Step three in *Seven Steps to Patient Safety* (NPSA 2004) describes the importance of an integrated approach to risk management and how it can be used as an improvement tool. Risk management is the process of identifying, assessing, analysing and managing all potential risks. Decisions made within an organisation, and within practice, should take into account potential risks that could directly or indirectly affect patient care. If risks are properly assessed, the process can help all NHS organisations, teams and individuals set their priorities and improve decision-making to reach an optimal balance of risk, benefit and cost. Risks can be clinical, environmental, financial, economic, political, and those affecting public perceptions and reputation. Risk is inherent in all aspects of healthcare, including:

- organisational strategy and business planning;
- financial planning;
- projects and service developments;
- purchasing;
- design of services;
- treatment and care delivery.

The process of risk assessment seeks to answer four simple, related questions:



For each **hazard** identified, it is important to decide whether it is significant and whether appropriate and sufficient controls or contingencies are in place to ensure that the **risk** is effectively minimised.

Hazard: a situation with the potential to cause harm.

Risk: the combination of likelihood and consequence of hazards being realised.

1.2 Why risk assessment is important

Risk assessment is a valuable tool that can help managers and clinical staff improve their work and the care delivered. The NHS is continuously changing and this can cause the risk profile to change. If NHS organisations systematically identify, assess, learn from and manage all risks and incidents, they will be able to reduce potential and actual risks, and identify opportunities to improve healthcare across the NHS.

The benefits of risk assessment:

- strives for the optimal balance of risk by focusing on the reduction or mitigation of risk while supporting and fostering innovation so the greatest returns can be achieved with acceptable results, costs and risks;
- helps NHS organisations comply with the Standards for Better Health for England and the Healthcare Standards for Wales;
- supports better decision-making through a solid understanding of all risks and their likely impact;
- helps NHS organisation plan for uncertainty, cope with the impact of unexpected events and increase staff, patient and public confidence in care that is delivered with well-considered contingency plans;
- highlights the weakness and vulnerability in procedures, practices and policy changes.

1.3 When to do a risk assessment

A risk assessment should be conducted at various stages of a change, development or project:

- **early on** – to help ensure the basic design provides appropriately safe care;
- **during detailed design** – to help ensure the risks are considered throughout;
- **modification** – post implementation or modification; risk assessment helps ensure that new risks are not unintentionally introduced.

How long does it take?

Time will be required for preparation and follow-up of the recommendations. Meeting time can be minimised with effective preparation. The total time required for the risk assessment meetings will vary according to the magnitude and complexity of the changes or service provision. For example:

- if a new ENT service was being set up then it is likely that half a day would need to be put aside to assess the risks associated with delivering a new service;
- if an existing service is partially modified, for example the transfer of part of a service from the acute setting to primary care, only the provision of service in the new environment would need to be risk assessed.

1.4 Who should do the risk assessment?

Risk assessments should be conducted with staff for which the risks are relevant. For example, board and management teams will need to advise on strategic risks, while clinical teams will need to be involved when assessing an individual patient's care or a procedural risk in their department. All parties affected by risks, including patients and the public, can also be involved in the decision process where possible. It is advised that each service takes ownership of their own risks and feed these into a risk register for the organisation, department or practice. The risk assessment process is then used to develop local plans and used as evidence for service development. A nominated person should be responsible for ensuring the actions are followed up.

The table below describes the different roles in risk assessment.

Roles in risk assessment

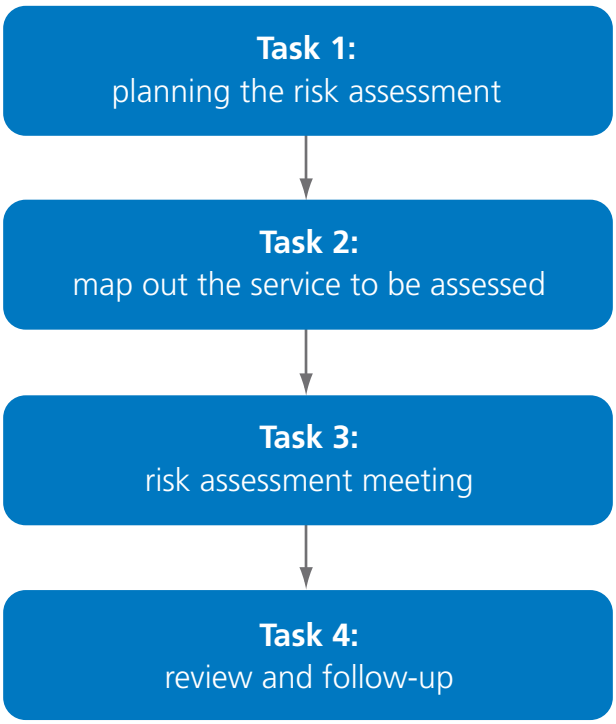
Role	Responsibilities	Required skills, knowledge and experience
The risk assessor	Responsible for preparation, facilitating the assessment meeting and ensuring the recommendations are picked-up. When facilitating the assessment meeting they should ensure that a structured approach is followed, encourage open discussion, and summarise the discussion and recommendations.	This is a lead role and the risk assessor needs to be fully conversant with the risk assessment process, and have an understanding of the service being assessed. They need to be a good facilitator and not be too closely involved in the development or refinement of the new service. They could be the person in charge of or responsible for a service, or the risk manager of the department or organisation.
Multi- disciplinary team (MDT) clinical and non-clinical participants	Participants are responsible for contributing during the assessment meeting in terms of identifying the hazards, causes, consequences and controls, ranking risks and developing recommendations.	Should consist of staff with complementary skills and experience. The team be drawn from those who are designing the service and who will work within it.
The recorder	Supporting the risk assessor and recording the discussion and recommendations during the assessment meeting.	Needs to be conversant with the risk assessment process and have an understanding of the activities. They need to be able to record discussion and hence an understanding of 'the language' and common acronyms used in the hospital is advantageous.

1.5 How to conduct the risk assessment

This section provides a step-by-step description of the risk assessment process. Participants do not need to have past risk assessment experience to contribute. The approach does, however, require a multi-disciplinary team knowledgeable about the practice(s) populations, the 'locality', the current service and the proposed service, or treatment. The team should include someone skilled in using the method and also someone with group facilitation skills.

Essentially, the process is composed of four main tasks as depicted below.

Figure 1: The four tasks of risk assessment



Task 1: plan the risk assessment

Start by defining the risk assessment's objective and scope. Key considerations should be:

- **estimating probability**. Assessing the chances of a risk happening can be highly subjective. When estimating probability the assessor needs to take into account the fact that memorable events seem more common and constant feedback is necessary to ensure accuracy of predictions. The use of incident data, literature and other sources of intelligence will help with this.
- **effectiveness of estimated potential impact for prevented incidents**. There is the potential to over- or under-estimate the possible impact of an incident, which can then bias the organisation's risk register and future actions.
- **balance of analysis**. The chosen system should not concentrate exclusively on the most serious incidents or risks while ignoring the low to moderate incidents or risks, which occur much more frequently. If these are reported, the lessons learned could prevent the serious incidents from occurring. There is something to learn from all levels of risk and patient safety incidents, including those that have been prevented (near misses).
- **resources**. Each organisation should ensure their policies and approach match the capacity to act. For example, if an organisation states that all incidents that led to harm should be investigated using root cause analysis or significant event audit, the organisation should ensure there are enough staff with the expertise and resources to do this.

Task 2: map the services to be assessed

The service or treatment to be assessed needs to be fully mapped which means breaking the task down into its component parts. It is recommended that this is done by:

- listing or mapping out the activities, for example patient booking or treatment;
- identifying interactions with all component parts;
- identifying other changes resulting from your proposed service or treatment;
- changes in the activities of others should be included in the activities' map and be risk assessed;
- collecting relevant documents including protocols, care escalation policies and patient information leaflets.

Task 3: risk assessment meeting

Preparation is an essential component that assures a robust assessment and an efficient and effective meeting. Preparation should include:

Sub-task	Components
Develop initial prompts: 'what if' questions	This is the development of a set of 'what if' questions to help identify hazards and their causes. This is key to delivering an effective and robust assessment. The following 'what if' questions could be developed: • What if an appointment letter is not produced for the patient? • What if the patient does not attend? • What if the patient does not receive appointment letter? • What if blood and urine tests are not completed? • What if the electronic patient record is not updated? • What if the nurse does not know when to refer to the GP?
Develop record sheet	It is important to record the findings of the risk assessment as they are developed. In particular, it is necessary to show the link between causes identified, the consequences and controls, the risk ranking and the recommendations. In this way the basis of the recommendations will be clear.
Obtain risk matrix	This should be available from the governance or risk department.

It is recommended that the risk assessor starts the meeting by taking the MDT through all the prepared materials, including the process map. The risk assessment process and roles of the delegates should also be explained. To help identify hazards, it is useful to have a list of 'what if' questions that can be used by the MDT team during the risk assessment meeting.

Task 4: review and follow-up

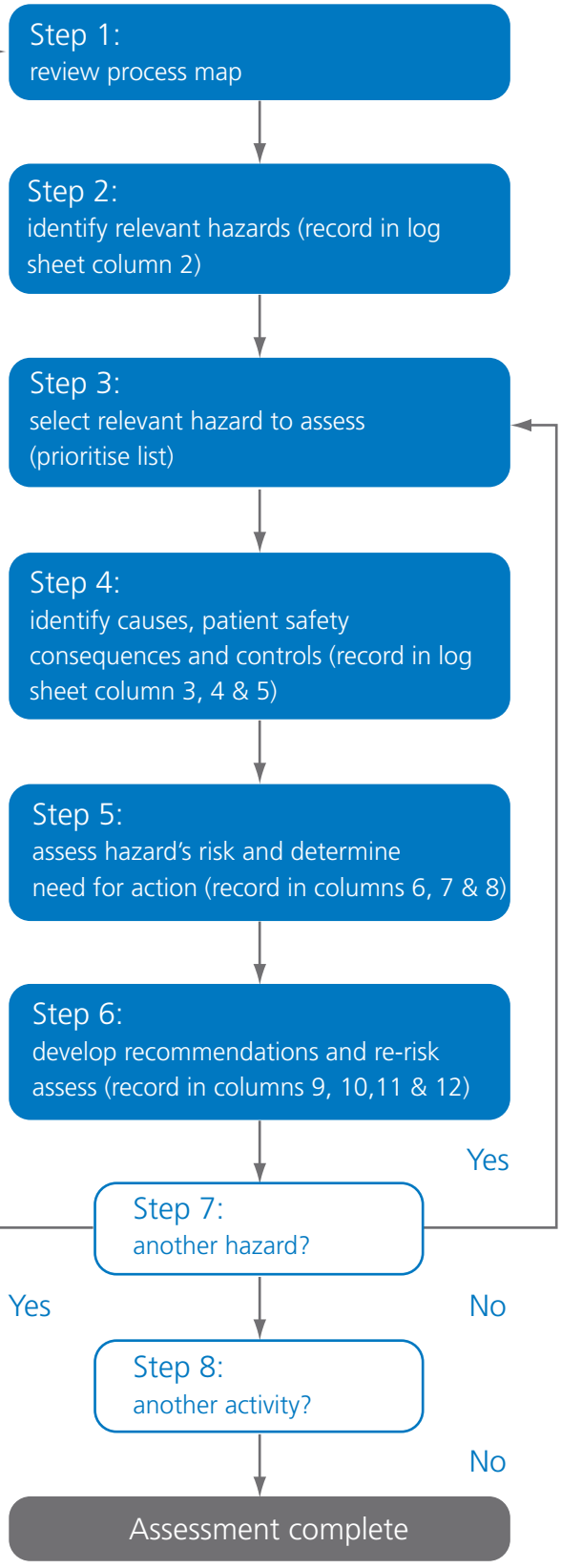
The outcome of the risk assessment should be addressed according to the organisation's risk management policy and procedures. Subsequent to the risk assessment meeting, the team should review the recommendations from the assessment meeting, and agree whether to implement them as they stand or to modify them. The team will also need to agree how they should be implemented. The identified hazards and the agreed actions need to be placed either on the organisation's, or practice's, local risk register. This should include the name of those responsible for carrying out any actions.

If the actions will have an impact on other parts of the organisation's operations, for example community nursing services or allied health professionals, or on other organisations' operations, for example the ambulance service, they will need to be agreed with all relevant parties.

The total risk assessment process is described further on the next page.

Figure 2: risk assessment process

Step 1	The risk assessor and MDT review the process map. The person who knows most about the activity or activities describes them and includes: • inputs (e.g. clinical information on patient); • outputs (e.g. GP knows which patients need treatment or investigations); • resources used (e.g. treatment centre and nursing staff); • controls (e.g. protocol and patient assessment tools).
Step 2	Team review the prompts, the 'what if' questions, and further develop the relevant hazards and risks.
Step 3	The risk assessor and MDT select a hazard to assess.
Step 4	The team identify potential causes, consequences and controls for the selected hazard. (Following the '80:20 rule', the leader should guide the team to focus on significant causes and consequences to be efficient and effective).
Step 5	The team assess the hazard's risk using their risk matrix, and determine if further mitigation is required. Further mitigation (see step 6) should be considered wherever the risk is assessed as medium or high.
Step 6	The team develop relevant recommendations to control the high/medium risk hazards, and re-assess the risk with these recommendations in place. If the risk is still high, further recommendations should be developed. If the team cannot identify any practical means of mitigating the risk, the risk should be escalated for acceptance in accordance with the organisation's risk management
Step 7	Repeat steps four to seven until all the hazards relevant to the activity(ies) have been assessed.
Step 8	Repeat steps one to eight until all the activities have been assessed.



2 Risk assessment and patient safety

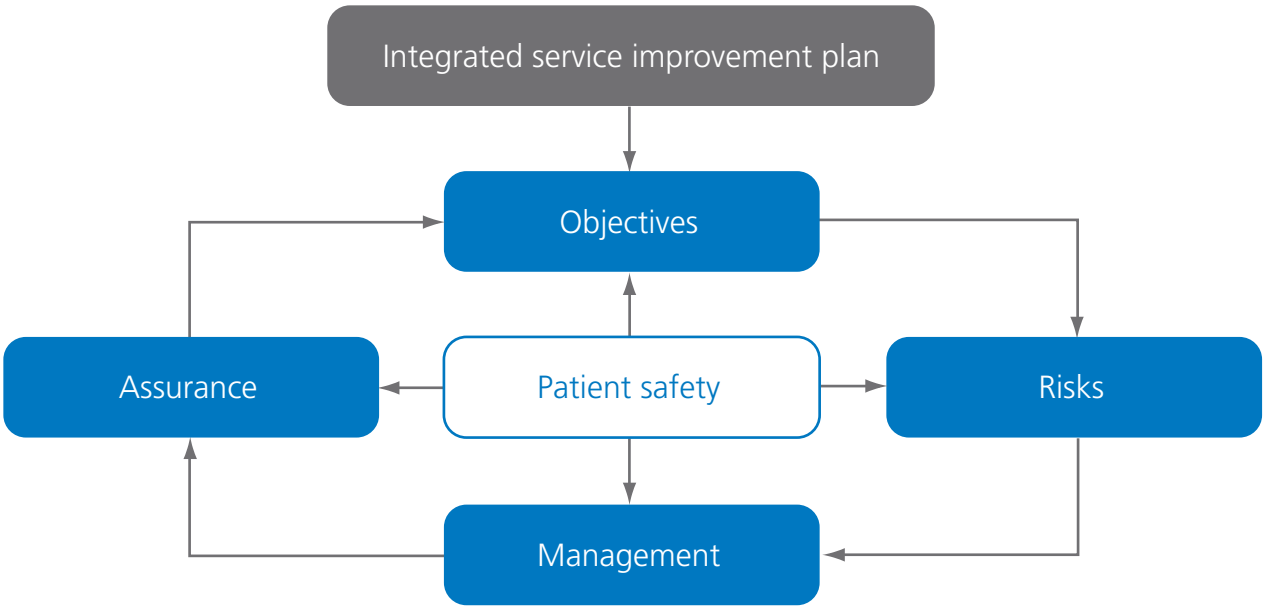
Patient safety should be considered throughout the development and implementation of a service or treatment. It is now well recognised that healthcare involves a wide range of risks and that any development, change or innovation brings new risks as well as rewards (National Patient Safety Agency 2004). Many people regard incidents as random occurrences or unpredictable events beyond effective control. But although chance does play a part, and human error can never be eliminated entirely, the majority of incidents fall into systematic and recurrent patterns.

Patient safety risk assessments are careful examinations of systems to identify factors that could potentially cause or contribute to patient harm. They facilitate decisions about whether adequate precautions are being taken to ensure timely and safer provision of care, or if further measures are needed to prevent harm. They aim to make sure, as far as possible, that patients are not harmed by the actions of healthcare staff or unsafe conditions. The following information should be reviewed as part of the process:

- patient safety incident data for relevant incident types;
- audit and patient satisfaction questionnaires for patient safety issues.

The steps that should be taken to assure an organisation is controlling its risks are outlined below.

Figure 3: patient safety risk management assurance framework (HCSU)



Objective: the assessor identifies the key purposes and achievements for the organisation, service or treatment.

Risks: the systematic identification and assessment of risks affecting the organisation, service or treatment.

Management: controls for assuring that the identified risks are mitigated through targeted recommendations and/or solutions.

Assurance: evidence of assurance, for example audit, patient safety incident (PSI) reporting, investigation and analysis via significant event auditing or other systematic methods, monitoring and review of contract.

3 Risk assessment models

There is a growing awareness that interventions, knowledge and expertise used to improve safety in other industries can help the healthcare sector improve patient safety by dealing with comparable incidents and risks. There are over 40 tools currently used in industry, both prospective and reactive, and some of these are now being used in healthcare to identify potential failures or reasons for failures.

They include:

- failure modes and effects analysis (FMEA);
- healthcare failure modes and effects analysis (HFMEA);
- hazard analysis and critical control points;
- hazard and operability;
- barrier analysis and the development of risk controls;
- probabilistic risk assessment.

The models chosen here are those mostly likely to be used in healthcare but this does not mean that there are not other applicable tools. The United States, Canada, the Netherlands and Denmark are all conducting proactive risk assessments using FMEA or HFMEA. The United States has now had several years' experience of teaching and carrying out HFMEAs, influenced in part by the Joint Commission on Accreditation of Healthcare Organisations' (JCAHO) instruction to conduct at least one FMEA per year.

The following sections describe the models listed in more detail. Some commentators may feel that these are consuming and unnecessarily complex. The NPSA is addressing this by developing simpler proactive risk assessment tools specifically for the NHS.

3.1 Failure modes and effects analysis (FMEA)

FMEA was developed by the US military and it has been used in engineering, manufacturing and by NASA. FMEA can identify potential process failures before they happen. It is a proactive qualitative tool for evaluating a process, a new product or service design. The aim is to identify potential points of failures and the effects these failures could have on individuals and/or the organisation. The actions that need to be taken to prevent an incident can then be prioritised. The emphasis is on preventing risk, and it is, therefore, relevant in healthcare where the aim is to prevent risk to both patients and staff. It is particularly useful in evaluating a new process before it is implemented, and in assessing the impact of a proposed change to an existing process. FMEA can also be used to evaluate the potential impact of changes over time.

FMEA is applied to the processes that make up a system. A medication delivery system, for example, is made up of a number of different clinical professions, processes and services: initial diagnosis (GP practice), prescribing (GP practice), preparation (pharmacy), dispensing (pharmacy), administering (pharmacy or home care) and follow-up (nurses, general practice or home care). Each step in these processes has the potential to result in failure.

FMEA identifies the following factors:

- **process:** how is care expected to be delivered?
- **failure mode:** what could go wrong?
- **contributory factors:** why would the failure happen?
- **effect:** what are the consequences of the failure?

Seven stages of an FMEA

1 Identify a high-risk system from the organisation's risk register and incident reporting system. Break it down into various processes for analysis. This can be conducted on a system but the most effective way is to perform a separate analysis on each process within the system and then integrate the results.

2 Recruit a multi-disciplinary team to chart the process in the form of a flow chart to identify all the steps that are taken.

3 As a team, identify where that process can go wrong or fail and what could stop those failures from happening (controls and barriers).

4 Identify what the effects could be if the failures occurred. Existing evidence of incidents and departmental risk assessments can be used to inform the process.

5 Assign priority scoring or rating to each failure and effect. This is normally done by using a risk matrix asking the following:

- How likely is it that this failure mode will occur?
- If the failure mode occurs, how likely is it that the failure will be detected?
- If the failure mode occurs, how likely is it that harm will occur?

6 Evaluate the results and either reduce the probability of the failure to an acceptable level or add controls and safety mechanisms to mitigate or minimise the effects of the failure.

7 Complete an action plan for improvements.

The benefits of FMEA are:

- improved design of care processes;
- a multi-disciplinary approach that promotes teamwork and group discussions about errors;
- a system-based approach to thinking about the possible causes of each error;
- it provides a systematic, thorough and consistent tool to identify potential root causes and enables corrective actions before an incident happens;
- the outcome and changes made to the steps of the process are made on the evaluations and suggestions of the frontline staff themselves;
- it ensures that care is fit for purpose and delivered according to expected outcomes.

Examples of FMEA used in healthcare

Adachi and Lodolce (2005) used FMEA to identify dosing and administration errors associated with intravenous medications, and to develop interventions to change the process. One year later medication errors relating to intravenous fusion pumps were reduced. Burgmeier (2002) found FMEA a valuable tool for reducing the risks and problems inherent in the blood transfusion process. Gowdy and Godfrey (2003) used FMEA to assess and prevent inpatient falls within a geriatric psychiatric unit. Once the FMEA action plan was implemented, the inpatient fall rate steadily decreased.

3.1.1 Healthcare failure modes and effects analysis (HFMEA)

HFMEA is an adapted FMEA tool for risk assessments in healthcare. It was developed by the American organisation Veterans Affairs National Centre for Patient Safety (VA NCPS). HFMEA is a hybrid prospective analysis model that combines the concepts found in FMEA and hazard analysis and critical control points (HACCP) described below, with tools from the VA's root cause analysis process (Derosier et al. 2002).

Constraints for both FMEA and HFMEA:

Time consuming: One solution may be to hold group meetings only when the combined opinion of the team was necessary, for example, when the process mapping exercise is being carried out. Agendas for the meetings can also be circulated beforehand to keep them focused and brief.

It can be frustrating when little or no benefit is seen until the process of FMEA is complete (Duwe, Fuchs, & Hansen-Flaschen 2005). This might also result in staff losing interest or rushing to complete, thereby compromising the quality of the FMEA. All staff involved need to be willing and committed to address the issues as the process relies on consistency and completeness (Hardell 2005).

3.2 Hazard analysis and critical control points (HACCP)

Hazard analysis and critical control points is a systematic methodology evolved from team work by Pillsbury, NASA, Natick Laboratories of the United States Army, and the US Air Force Space Laboratory Project Group. It was originally designed to ensure that the food provided for astronauts was not contaminated. HACCP has since become the standard risk assessment approach within the food industries in both the UK and the United States.

The key steps in HACCP are:

- identify hazards and assess their severity and risk;
- determine the critical points – a 'critical control point' is where control can be exercised to prevent, eliminate or minimise a hazard;
- specify criteria to ensure control;
- monitor critical control points;
- take corrective action whenever monitoring indicates criteria are not met;
- verify that the system is functioning as planned.
(Baird, Henry, Liddell, Mitchell and Sneddon, 2001)

HACCP has been used to review healthcare associated infections (Richards 2002) and to review the antenatal serum screening programme for Down's syndrome (Derrington et al 2003). It is currently being used by the NPSA to develop an approach to reviewing hospital-acquired infections referred to in this document.

3.3 Hazard and operability (HAZOP)

Hazard and operability (HAZOP) is a methodology originally designed for use in the chemical industry in Great Britain (Kletz 1974), although it has since been applied successfully and widely to other industries. It is a team-based, systematic and qualitative method that employs brainstorming to identify hazards in process industries. Typically the team will consider a process and, for each component in the process, consider it against a set of around eight to ten hazard-identification key words in a checklist. For example, in a medication example, prompts such as dose too high, dose too low, wrong drug, would direct the team's efforts. Potential causes for these deviations are then sought and addressed. When all the hazards have been identified, the team develops an action plan to take the process forward.

Very few risk assessment studies within healthcare appear to have adopted HAZOP analysis; therefore it is difficult to identify applicability. However, it is currently being used by the NPSA to develop the keyword checklist for its Hospital at Night work **(www.npsa.nhs.uk/web/display?contentId=5222)**.

3.4 Barrier analysis and the development of risk controls

Barrier analysis is a risk assessment model which identifies:

- which barriers should have been in place to prevent the incident;
- why the barriers failed;

- which barriers could be used to prevent the incident happening again.

  A barrier is a defence or control measure for preventing harm to vulnerable or valuable objects such as people, buildings, organisational reputation and the wider community. A barrier in healthcare is either an obstruction, such as a locked controlled drug cupboards, or preventative action such as using a checklist. The fact that a patient safety incident has taken place means that one or more of the barriers failed. It offers a structured way to visualise the events related to system failure and can be used reactively to solve problems or proactively to evaluate existing barriers.

  There are four types of barriers. Examples of each type are listed below.

  1 Physical barriers: an actual physical hindrance

- keypad-controlled doors;
- computer programmes that prevent a reporter from continuing if a field is not completed;
- controlled drugs kept in double-locked cabinets that require two keys, usually kept separately.

  2 Natural barriers: barriers of distance, time or placement

- a procedure which ensures that two similar drugs required in two different routes are given by different people, at different times and in different places. Thereby ensuring that the drug routes are not mixed up, for example, chemotherapy.

  3 Human action barriers

- checking the temperature of a bath before immersing an elderly patient;
- checking patient's identify with another staff member;
- checking patient's identify with the patient, carer or relative.

  4 Administrative barriers

- protocols and procedures;
- checklists;
- alert notices;
- professional registers.

  Physical barriers are the most reliable in terms of providing failsafe solutions to safety problems. Natural barriers, while less effective, generally provide a more robust solution than human action and administrative barriers. Barriers 3 and 4 are considered the least reliable because they rely on human action and behaviour, and mistakes can be made.

  More detail on barrier analysis can be found in the NPSA's root cause analysis toolkit at **www.npsa.nhs.uk/rcatoolkit**

3.5 Probabilistic risk assessment

Probabilistic risk assessment uses a top-down approach that identifies the undesirable outcome first, and then investigates all combinations of process failures that may lead up to this event, (Marx & Slonim 2003). Probabilistic risk assessment uses two complementary graphical tools: event tree analysis[1] and fault tree analysis[2]. These identify the potential causes of the event and how they are related. It examines incidents and their contributory factors and determines the likelihood of the event happening and involves a mixture of quantifying risks and using expert judgement.

The assessment defines the nature and size of the risks and weighs these up against the benefits of reducing or eliminating them and the costs of achieving this. A judgement is then made on how best to manage the risk. For example the probabilistic risk assessment process could be used to try to understand the potential ways the wrong drug could be dispensed. There could be a number of different ways this could happen:

- the drug was prescribed wrongly in the general practice and not picked up by the pharmacy;
- the drug was prescribed correctly, but the pharmacy selected the wrong drug to be given to the patient;
- the drug prescription was unclear, and the pharmacy selected the drug thought to be written, but this was the wrong one.

The probabilistic risk assessment approach works out the likelihood of each outcome and what could be done to reduce that likelihood. It also attempts to quantify the potential risks by scoring the likelihood of a particular risk or incident actually happening, including considering the frequency with which it may arise. To help quantify this, incident data can be assessed along with expert estimation of how often a process could fail, or by undertaking clinical audit of the process to demonstrate actual failure rates. Fundamentally a probabilistic risk assessment will mean fewer surprises. It will provide evidence of the key risk areas and therefore steer prioritisation for improvement and risk management activity. In turn, this can help ensure lessons are learned without having to suffer a crisis or a major incident. It will also enable NHS organisations to target their limited resources more efficiently.

1 **Eventtree analysis:** this is an approach which like the branches of a tree, maps out the different paths and factors that can lead to an event occurring.

2 **Fault tree analysis:** this is an extension of the event tree which shows the cumulative effects of the faults within a system.

4 What do healthcare providers need to do?

To be most effective, integrated risk management should be woven into the normal working processes and into existing decision-making structures and processes.

Each NHS organisation, including practices, are advised to:

- have a risk management strategy and associated policies;
- where possible, create a single point of coordination for the overall policy and strategy;
- review the effectiveness of the organisation's ability to minimise risk, that risk is actively managed and appropriately communicated throughout the organisation or practice;
- demonstrate that there is an appropriate reporting process when things go wrong to ensure lessons are learned;
- use the information gained through risk assessments to develop future business and strategic plans balancing innovation with risks and benefits.

Each NHS organisation should train relevant individuals who could be part of the risk assessment team:

- ensure that relevant staff have an awareness of risk management and risk assessment;
- help the organisation achieve compliance with external accreditation;
- help establish an effective risk register;
- learn how to review aggregated risk management data and risk assessments and other tools to help forecast possible problems and contingency planning.

NHS organisations' boards should:

- establish principal strategic and directorate objectives;
- identify the principal risks that may threaten the achievement of these objectives. The Department of Health suggests a range of 75–200 depending upon the complexity of the organisation;
- identify and evaluate the design of key controls intended to manage the principal risk;
- set out the arrangements for obtaining assurance on the effectiveness of key controls across all areas of principal risk;
- evaluate and identify areas where the controls are working well and areas where there are gaps in controls;
- put plans in place to take corrective action where gaps have been identified;
- establish sound, dynamic risk management arrangements including, crucially, a well founded risk register.

5 What the NPSA is doing to help

5.1 Information and research

Key resources:

- Seven Steps to Patient Safety;
- Root cause analysis e-learning toolkit;
- Patient safety managers;
- Reference list in this document provides a key resource for the reader.

5.2 Case studies and practical risk assessment tools:

The NPSA has created a number of tools which NHS organisations can use to help develop their approach to risk management and risk assessment.

5.2.1 Practice-based commissioning (PbC)

Practice-based commissioning is a key change in the way the NHS will be working. It is a risk assessment process that enables general practices and local commissioning groups to undertake practice-based commissioning and commission 'safely'. The aim of such an assessment is to help ensure services commissioned through primary care are designed, implemented and sustained to provide safer patient care. The tool is designed for those responsible for commissioning new services, or reviewing current services, to ensure that patient safety has been considered throughout the development. It can also be used to brief others on the risk assessment process.

www.npsa.nhs.uk/riskassessment

5.2.2 The Hospital at Night (HaN) solution

The Hospital at Night (HaN) solution will change the way care is provided. It consists of a multi-disciplinary team with the competencies to cover a wide range of interventions and the capacity to call in specialist expertise when necessary. This is in contrast to the traditional model of doctors-in-training working in relative isolation, and in speciality-based silos.

The HaN model advocates taking a multi-professional approach and using other professionals in the team such as advanced nurse practitioners and operating department practitioners who have the competency base to attend and offer urgent and emergency care to patients with the ability to call in specialist expertise when necessary.

As with any change of this type it is important to ensure and demonstrate the new way of working provides safe care, so far as is reasonably practical. Delivering a safer solution requires not only identifying its risks and appropriate control measures, but also assuring that the risk management controls are implemented, maintained and effective.

The tool is designed for those responsible for the HaN solution to ensure that patient safety has been considered throughout the development of this change process. It can also be used to brief others on the risk assessment process. NHS trusts are encouraged to use the NPSA's risk assessment guidance when implementing the HaN solution.

www.npsa.nhs.uk/web/display?contentId=3658

5.2.3 Hospital-acquired infections (HAI)

In 2003, the Chief Medical Officer stated in *Winning Ways* that the NPSA and the Inspector of Microbiology will work jointly to ensure that the techniques of root cause analysis are developed for healthcare-acquired infections (HAI) and applied in every NHS organisation. The NPSA has developed and implemented a programme of systematic incident investigation using the risk assessment and root cause analysis methodology for hospital-acquired infections. The tool is aimed at all grades of infection control (IC) staff, especially those who are new to IC or have been recently appointed as IC staff-in-training. It can be used by those training undergraduates (medical and nurses) and IC link nurses. It can also be used by a variety of healthcare staff who are undertaking IC investigations such as modern matrons, clinical governance staff and risk management staff. The tool is not intended to replace current robust structured outbreak investigation methods and techniques, more to enhance attempts to investigate, find the root causes and learn lessons for future improvement.

www.npsa.nhs.uk/web/display?contentId=5222

Conclusion

Risk assessment is a valuable tool that can help managers and clinical staff improve their work and care delivered. The NHS is continuously changing and this can cause the risk profile to change. If NHS organisations systematically identify, assess, learn from and manage all risks and incidents at every level, they will be able to reduce potential and actual risks, and identify opportunities to improve healthcare across the NHS.

In the UK, most healthcare organisations address risks by employing risk registers and risk matrices, both of which tend to be retrospective. Although a few organisations have employed other techniques, very few have used more advanced methods of prospective risk assessment. The NPSA has a number of examples of its work that demonstrates the use of different risk assessment methods in hospitals at night, for practice-based commissioning and reducing hospital-acquired infections.

Background reading

Adachi, W and Lodolce AE. Use of failure mode and effects analysis in improving the safety of i.v. drug administration. *American Journal of Health-System Pharmacy,* 2005; 62(9): 917-920

Adams S. The Development of a Human Error Database based on Current Models of Human Performance. Unpublished PhD Manuscript. Birmingham University. (1996).

An introduction to FMEA. Using failure mode and effects analysis to meet JCAHO's proactive risk assessment requirement. *Health Devices.* 2002; 31(6): 223-6.

American Society for Healthcare Risk Management. Strategies and tips for maximizing failure mode and effect analysis in your organization. Chicago: One North Franklin. (2002)

Apkon M et al. Design of a safer approach to intravenous drug infusions: Failure mode effects analysis. *Quality & Safety in Health Care*. 2004; 13(4): 265-271

Baird DR et al. Post-operative endophthalmitis: The application of hazard analysis critical control points (HACCP) to an infection control problem. *Journal of Hospital Infection*. 2001; 49(1): 14-22

Benjamin DM. Reducing medication errors and increasing patient safety: case studies in clinical pharmacology. *Journal of Clinical Pharmacology*. 2003; 43(7): 768-83

Bramstedt KA. Failure mode and effects analysis as an informed consent tool for investigational cardiothoracic devices. *ASAIO Journal*. 2002; 48(3): 293-5

Burgmeier J. Failure mode and effect analysis: an application in reducing risk in blood transfusion. *Joint Commission Journal on Quality Improvement*. 2002; 28(6): 331-9

Capunzo M et al. A FMEA clinical laboratory case study: how to make problems and improvements measurable.' *Clinical Leadership & Management Review*. 2004; 18(1): 37-41

Chudleigh MF. Hazard analysis of a computer based medical diagnostic system. *Computer Methods & Programs in Biomedicine*. 1994; 44(1): 45-54

Cohen MR, Senders J, and Davis NM. Failure mode and effects analysis: A novel approach to avoiding dangerous medication errors and accidents. *Hospital Pharmacy.* 1994; 29(4): 319-324, 326-328, 330

DeRosier J et al. Using health care Failure Modes and Effects Analysis: the VA National Center for Patient Safety's prospective risk analysis system. *Joint Commission Journal on Quality Improvement*. 2002; 28(5): 248-267

Derrington MC. Can safety assurance procedures in the food industry be used to evaluate a medical screening programme? The application of the Hazard Analysis and Critical Control Point system to an antenatal serum screening programme for Down's syndrome. Stage 2: Overcoming the hazards in programme delivery. *Journal of Evaluation in Clinical Practice*. 2003; 9(1): 49-57

Derrington M. Can safety assurance procedures in the food industry be used to evaluate a medical screening programme? The application of the Hazard Analysis and Critical Control Point system to an antenatal serum screening programme for Down's syndrome. Stage 1: Identifying significant hazards. *Journal of Evaluation in Clinical Practice*. 2003; 9(1): 39-47

Department of Health. *Winning Ways: Working together to reduce healthcare associated infections in England*. CMO report. (2003)

Duwe B, Fuchs BD and Hansen-Flaschen J. Failure mode and effects analysis application to critical care medicine. *Critical Care Clinics*. 2005; 21(1): 21-30, vii

Failure mode and effects analysis. A hands-on guide for healthcare facilities. *Health Devices*. 2004; 33(7): 233-43

Joint Commission on Accreditation of Healthcare Organisations. *Failure mode and effects analysis in health care: Proactive risk reduction* (2005) 2nd Edition.

FMEA (failure mode analysis): a new QI tool to help improve case management processes. *Hospital Case Management*. 2003; 11(3): 33-6

Fijan S, Sostar-Turk S and Cencic A. Implementing hygiene monitoring systems in hospital laundries in order to reduce microbial contamination of hospital textiles. *Journal of Hospital Infection.* 2005; 61(1): 30-38

Fletcher CE. Failure mode and effects analysis: An interdisciplinary way to analyze and reduce medication errors. *Journal of Nursing Administration*. 1997; 27(12):19-26

Gering J et al. Taking a patient safety approach to an integration of two hospitals. *Joint Commission Journal on Quality & Patient Safety*. 2005; 31(5): 258-66

Gowdy M and Godfrey S. Using tools to assess and prevent inpatient falls. *Joint Commission Journal on Quality & Safety*. 2003; 29(7): 363-8

Grissinger M and Rich D. JCAHO: meeting the standards for patient safety. *Journal of the American Pharmaceutical Association*. 2002; 42(5 Suppl 1): S54-5

Grissinger M. Failure Mode and Effects Analysis Can Help Guide Error-Prevention Efforts. *P & T*. 2003; 28(1)

National Patient Safety Agency. *Hospital at Night: Guide to Risk Assessment.* (2005).

Hardell T. Using failure mode effects analysis to solve clinical system problems... It's easier than you think! *Director*. 2005; 13(2): 66-8

HCSU 2002. Making it Happen - A Guide for Risk Managers on How to Populate a Risk Register. Risk Management Working Group ISBN: 1-904276-02-4.

Israelski EW and Muto WH. Human factors risk management as a way to improve medical device safety: a case study of the therac 25 radiation therapy system. *Joint Commission Journal on Quality & Safety*. 2004; 30(12): 689-95

Krouwer JS. An improved failure mode effects analysis for hospitals. *Archives of Pathology & Laboratory Medicine*. 2004; 128(6): 663-7

Kunac DL and Reith DM. Identification of priorities for medication safety in neonatal intensive care. *Drug Safety*. 2005; 28(3): 251-261

Lenz R et al. Demand-driven evolution of IT systems in healthcare: A case study for improving interdisciplinary processes. *Methods of Information in Medicine*. 2005; 44(1): 4-10

Linkin DR et al. Applicability of healthcare failure mode and effects analysis to healthcare epidemiology: Evaluation of the sterilization and use of surgical instruments. *Clinical Infectious Diseases*. 2005; 41(7): 1014-1019

Marx DA and Slonim AD. Assessing patient safety risk before the injury occurs: An introduction to sociotechnical probabilistic risk modelling in health care. *Quality & Safety in Health Care*. 2003; 12(suppl 2): ii33-ii38

McNally KM, Page MA and Sunderland VB. Failure-mode and effects analysis in improving a drug distribution system. *American Journal of Health-System Pharmacy*.1997; 54(2): 171-177

McNally KM and Sunderland VB. No-blame medication administration error reporting by nursing staff at a teaching hospital in Australia. *International Journal of Pharmacy Practice*. 1998; 6(2): 67-71

National Patient Safety Agency. *Seven steps to patient safety: The full reference guide.* 2nd Edition. (2004). Available at: www.npsa.nhs.uk

National Patient Safety Agency. *Exploring Incidents –improving Safety: a guide to Root Cause Analysis* (NPSA V1.0). 2002. Available at: www.npsa.nhs.uk/rcatoolkit

Nichols JH. Reducing medical errors through barcoding at the point of care. *Clinical Leadership & Management Review*. 2004; 18(6): 328-34

Pate-Cornell ME et al. Anesthesia patient risk: A quantitative approach to organizational factors and risk management options. *Risk Analysis*. 1997; 17(4): 511-523

Richards J. Risk management in infection control - HACCP, a useful tool? *Cpd Infection*. 2002; 3(2): 59-62

Rischitelli G, Lasarev M and McCauley L. Career risk of hepatitis C virus infection among U.S. emergency medical and public safety workers. *Journal of Occupational & Environmental Medicine*. 2005; 47(11): 1174-1181

Shiu KK and Rosen MJ. Probabilistic risk assessment and performance index applications for the ICU.' *Chest*. 2005; 128(5): 3773-3774

Singh R et al (2004) Estimating impacts on safety caused by the introduction of electronic medical records in primary care. *Informatics in Primary Care*. 2004; 12(4): 235-241

Spath PL. Using failure mode and effects analysis to improve patient safety. *AORN Journal*. 2003; 78(1):16-37 quiz 41-4

Stalhandske E, DeRosier J, Patail B and Gosbee J. How to make the most of failure mode and effect analysis. *Biomedical Instrumentation & Technology*. 2003; 37(2): 96-102

Uslan MM at al. Accessibility of insulin pumps for blind and visually impaired people. *Diabetes Technology & Therapeutics*. 2004; 6(5): 621-634

Wehrli-Veit M, Riley JB and Austin JW. A failure mode effect analysis on extracorporeal circuits for cardiopulmonary bypass. *Journal of Extra-Corporeal Technology*. 2004; 36(4): 351-357

Weir VL. Best-practice protocols: preventing adverse drug events. *Nursing Management*. 2005; 36(9): 24-30

Willis G. Failure modes and effects analysis in clinical engineering. *Journal of Clinical Engineering*. 1992; 17(1): 59-63

Woodhouse S. Engineering for safety: Use of failure mode and effects analysis in the laboratory - A well-known engineering tool now being used to assure patient safety. *Laboratory Medicine*. 2005; 36(1): 16-18

Wreathall J and Nemeth C. Assessing risk: The role of probabilistic risk assessment (PRA) in patient safety improvement. *Quality & Safety in Health Care*. 2004; 13(3): 206-21

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