

**THE RISK MANAGEMENT OF HAI:  
A METHODOLOGY FOR NHSSCOTLAND**

**HEALTHCARE ASSOCIATED INFECTION TASK FORCE**

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## 1. Background

Healthcare Associated Infection (HAI) is a priority issue for NHSScotland. The profile of prevention and control of HAIs has been transformed within the past few years. Significant milestones include:

- A revised framework for national surveillance of healthcare associated infection in Scotland, HDL(2006)38, *Scottish Executive Health Department*<sup>1</sup>
- Preventing infections acquired while receiving healthcare : The Scottish Executive's action plan to reduce the risk to patients, staff and visitors 2002-2005 (2002) *Scottish Executive Health Department*<sup>3</sup>
- Healthcare Associated Infection Standards (Revised 2008), *NHS Quality Improvement Scotland*<sup>4</sup>
- Scottish Management of Antimicrobial Resistance Action Plan (ScotMARAP) (2008) *Scottish Government Health Directorate*<sup>5</sup>
- National Cleaning Services Specification (2004) *Health Facilities Scotland*<sup>7</sup>
- A Framework for Mandatory Training in HAI (2004) *NHS Education for Scotland*<sup>8</sup>

A major programme of work to improve the prevention and control of HAI across the NHS in Scotland was initiated by the Scottish Executive Health Department in 2002 with the production of the Ministerial Action Plan on HAI which concentrated on ensuring structures were in place to reduce infections. A second programme of work (focusing on implementation and delivery) building on the success of the first was developed and delivered between 2005 and 2008. The prevention and control of healthcare associated infection continues to be a top priority with a third three year programme of work being undertaken from April 2008.

An HAI Task Force working group was formed to develop the risk-based methodology to set priorities for targeting measures to reduce the risk of HAI and to facilitate action to ensure strict compliance with standards. This multidisciplinary working group included representation from NHS clinical and support services, members of the public, the non-NHS care sector including independent hospital representation and staff partners (full membership at Annex 4).

The draft document was consulted on and the risk based methodology was piloted in NHSScotland under the direction of Health Protection Scotland (HPS). This pilot tested the methodology for applicability, utility and ease of use. This final document was amended by the Working Group to take account of the outcome of the pilot and consultation.

## 2. Introduction

Since the introduction of the first ministerial action plan in 2002 considerable progress has been made across NHSScotland organisations to establish co-ordinated risk management structures and processes as recommended by the Carey Group Report<sup>9</sup>. This is evidenced by NHS Boards having a Board approved risk management strategy, key people responsible for the co-ordination of risk and have monitored their progress against NHSScotland risk management standards to identify how well these controls are working. The increasing focus on patient safety as a priority area, supported by the implementation of the Scottish Patient Safety Programme<sup>18</sup>, for clinical and corporate governance reinforces the need to assess and control risks to health as an integrated part of everyday working for staff at all levels within the organisation.

NHSScotland organisations are dynamic and operate in dynamic environments: therefore the identification, treatment and monitoring of risk must be a continuous and developing process that runs throughout the organisation's strategy and the implementation of that strategy. The organisation's Risk Register provides a framework in which identified risks can be recorded and actions detailed and instigated to reduce the probability and the impact of that particular risk. Different levels within an organisation need different information from the risk management process and good governance requires each organisation to adopt a methodological approach that ensures appropriate internal and external reporting with a clear audit trail of decision-making and escalation/de-escalation processes.

The required compliance with the Statement of Internal Control ensures that, as risk management frameworks develop, they enable organisations to apply a whole systems approach to corporate, clinical and staff governance, demonstrating that risk management is an integral component of everyday activity. **The management of HAI must be viewed within the context of a whole systems approach.**

### 2.1 Risk Management and HAI

Effective action to control HAI involves systems, culture and management. It is a problem for which there is no quick or easy solution. Systems include structures and processes, policies and procedures, education and training, audit and surveillance. Much of this is already addressed through compliance with NHS Quality Improvement Scotland (NHS QIS) Standards 'Healthcare Associated Infection: Infection Control'<sup>4</sup> which focuses on compliance, patient focus and public involvement, prevention and control of infection, environment and equipment and education. The key role of structural elements within the organisation was further developed in a Health Department Letter "Management and accountability structures"<sup>10</sup> in 2005 which laid out the importance of clearly delineated relationships and communications between the Chief Executive and the Infection Control Manager, the Infection Control Committee, the Risk Management Committee or structure, and the Clinical Governance Committee or structure.

Effective action to reduce HAI requires improving the quality of individual behaviour, clinical care, the clinical environment and equipment, underpinned by risk management and prioritisation. Risk assessment in the context of HAI entails identifying, evaluating, prioritising and treating risks, with ongoing monitoring and review. Extensive and clear communication and consultation when carrying out this process of risk assessment is essential. Values must include openness, partnership, learning and development, within a 'just' culture. Successful identification of risks can result in the prevention of adverse events.

Further development in risk management systems for infection prevention and control must be consistent with those already in use for risk management and incident reporting in NHSScotland. In response to work undertaken with NHSScotland risk managers, NHS Quality Improvement Scotland purchased the licence for the Australian/New Zealand (AS/NZS) 4360: 2004 Risk Management Standard<sup>11</sup> in January 2005. This provides NHS Boards with a tool to drive forward this need for consistency in terminology and methodology. Implementation of risk management structures, processes and outcomes are also supported by the NHS QIS Clinical Governance and Risk Management Standards<sup>4</sup>.

If risk management terms are to be adopted for infection prevention and control, they must be in a format that is consistent with methods in use by staff that are actively assessing risk and operating the organisational adverse incident management system.

*“Learning from Experience”*: *How to improve safety for patients in Scotland*<sup>12</sup> (2003) endorsed the principles and recommendations of the Department of Health (England) reports *An Organisation with a Memory*<sup>13</sup> (2000) and *Building a Safer NHS for Patients*<sup>14</sup> (2001). This established the NHSScotland commitment to applying AS/NZS 4360:1999 Risk Management<sup>11</sup>. This standard provides a generic framework for establishing the context, identification, analysis, evaluation, treatment, monitoring and communication of risk. The emphasis however, must be on local systems and application, as organisations' risk management will be influenced by varying needs, objectives, products, services, processes and specific practices employed. Effective establishment of proactive organisational risk management systems, evidenced by reporting and learning systems that collect and analyse information on adverse events and near misses is key to success.

## **2.2 The Human Factor**

Success in reducing the risk of HAI depends upon the commitment given to hygiene and the prevention and control of infection by staff in healthcare settings and the general public. Key to this are the attitudes and culture, local management responsibilities and sharing and learning from good and bad experiences.

The term “human factors” refers to the role played by human beings in “complex socio-technical systems” (Davies J et al<sup>15</sup>, 2003), a set of circumstances in which people and machines interact with each other. NHSScotland is a complex socio-technical system. Human error is said to occur in situations that arise where a particular human action has, or could have, an unwanted consequence; and where the action in question is deemed with hindsight to have been incorrect. The term is frequently used incorrectly to describe a mistake made by a front-line operator. However, human error can occur at any point in a complex socio-technical system, from the front-line workers through middle-management and supervisory staff, and ultimately to senior management.

In recent times systems have been devised which look at human error at three distinct levels. These are:

- *proximal* level where the errors made are defined by the jobs that front-line staff are required to do 'at the coal face' (e.g. staff member refuses or forgets to wash hands)
- *intermediate* level which encompasses issues such as staff training, supervision and local procedures (e.g. poor estates planning – lack of hand basins in clinical areas)
- *distal* level which includes the kinds of errors that management may make concerning decisions such as resource allocation, staffing levels, recruitment of contract labour etc.

There is evidence to suggest that proximal errors are relatively more common, more likely to be self-detecting (i.e. at this level, the fact that an error has been made is usually obvious) and less likely to have catastrophic consequences for the organisation than errors at the distal level. By contrast, errors at the distal level are more likely to remain dormant for long periods of time, more likely not to reveal their presence until too late, and more likely to be involved as root causes in major incidents/catastrophes. It is also the case that errors at the front line can sometimes occur because decisions made higher up in the organisation have inadvertently created the conditions under which certain types of front-line error are more likely to occur.

### **2.3 Training and Education**

Enabling staff within NHSScotland to understand risk management and how it applies to their everyday practice is crucial to the success of any organisational risk management system. The requirement for a nationally co-ordinated approach that also enables local delivery of education according to each NHS Board training needs analysis has been acknowledged in previous work<sup>8</sup> and reinforced by the consultation and pilot processes for this document.

NHS QIS and NHS Education for Scotland (NES) have collaborated to commission accredited education in Clinical Governance and Risk Management and develop an on-line knowledge resource. In September 2006 Glasgow Caledonian University commenced delivery of the suite of three modules and the on-line resource ([www.clinicalgovernance.scot.nhs.uk](http://www.clinicalgovernance.scot.nhs.uk)) went live in March 2007.

### **3. NHSScotland model for organisational risk management**

#### **Introduction to the process**

In January 2005 NHS Quality Improvement Scotland (NHS QIS) purchased the licence on behalf of NHSScotland for the Australian/New Zealand (AS/NZS) 4360: 2004 Risk Management Standard<sup>11</sup>, in order to provide NHS Boards with a consistent tool to implement risk management systems, providing consistency of terminology and methods. Within the context of a national framework for risk management, NHS QIS also commissioned work that enabled development of a national approach to incident and near miss reporting (Safe Today - Safer Tomorrow<sup>16</sup>, 2006). This work was undertaken in partnership with NHSScotland.

**It is essential that management of risks related to Healthcare Associated Infection (HAI) is set within the context of an organisation's system of governance and risk management.** An example of an HAI risk management tool already available is the 'Watt Group Risk Management Matrix'<sup>17</sup> (2002). This was developed for use by infection control teams in the practical management of infection incidents or outbreaks.

Risk management requires the development of a method to identify, measure and manage the risks thereby reducing the potential for unexpected loss or harm. Such a method involves the consistent use of suitable techniques throughout the organisation. The risk management process should involve the following stages (see also Figure 1 on page 15):

- 3.1 Communicate and consult**
- 3.2 Establish the context**
- 3.3 Identify the infection risks**
- 3.4 Assess the infection control risks (likelihood and impact)**
- 3.5 Evaluate**
- 3.6 Treat risks (plan and control)**
- 3.7 Monitor & review**

**Adapted from AS/NZS 4360:2004<sup>11</sup>**

Risks cover all aspects of healthcare activity. However, key triggers of particular importance to each organisation may be developed from key plans and operational policies. No single category or trigger should be analysed in isolation.

#### **3.1 Communicate and consult**

It is essential to communicate and consult with internal and external stakeholders as appropriate at each stage of the risk management process. This is an important consideration at each step of the way and should be an opportunity for all to contribute rather than a one way flow of information. Effective communication will ensure that those responsible for managing risk understand how to escalate risks, why decisions are made and feedback on any actions taken.

#### **3.2 Establish the context**

Establish the external, internal and risk management context in which the rest of the process will take place. The criteria against which risks will be evaluated should be established and the structure of the analysis defined.

### 3.3 Identify the infection risks

Comprehensive identification of ‘what, where, when, why and how’ in relation to risks and potential risks to the organisation at all levels is crucial. Some of these risks will be immediately identifiable; others may be less recognisable.

An important feature of this stage is to focus on the full range of risks across the organisation’s objectives. This exercise will also identify current controls. Not every risk will be controlled at an acceptable level. The risks should be stated explicitly and must be communicated to the organisation, patients and public; and others. **Healthcare Associated Infection is a significant risk for all NHS organisations.**

### 3.4 Assess the infection control risks (likelihood, impact)

This stage is concerned with developing an understanding of the risks. The consequences, likelihood and hence the level of risk need to be determined at this stage. (see Tables 1, 2 and 3)

It is useful to consider and develop an understanding of the following of when analysing infection risks:

- What are the risks associated with the work of the team (for staff, patients and others)?
- Assess the potential consequence of each risk (for staff, patients and others).
- Assess the likelihood of the risks occurring.
- What is the team’s capacity/ability to reduce the impact of the risks identified (to staff, patients and others)?
- Cost/benefit of controls in relation to the identified risks

When this is translated to the organisational level, the following should be considered:

- Nature and extent of the risks and their existing control measures
- Degree and category of risk, including what is regarded as acceptable
- Likelihood of the risks materialising
- Organisation’s ability to reduce the likelihood and the potential impact on business

All identified risks then need to be assessed and prioritised. The risk assessments will identify significant risks arising from the activities of the organisation (or infection control team), and these can then be assessed for potential impact on, for example:

- Patient outcome and experience
- Failure to meet objectives
- Cost – resulting from civil action /claims /litigation /enforcement actions e.g. Health & Safety Executive
- Activity – result of operational delays, increased waiting times, reduction of service or service failure
- Loss of reputation.

Once the risks of an HAI incident or outbreak have been identified, the next step is to consider the likelihood of the risk actually happening and then relate this to the potential consequences or impacts that this event would have on the organisation, patients and staff.

## Likelihood

This is based on the likelihood of the event occurring. Identifying the likelihood of most events occurring in health can be subjective and based upon the knowledge and expertise of those involved in the risk analysis. However, evidence and statistics may be available regarding the recurrence of certain events and this information can help you to assess the likelihood level. Within the management of HAI available evidence includes the wealth of surveillance data collected locally and nationally. Only one level to describe likelihood may be selected for each risk from Table 1.

**Table 1: Likelihood descriptions**

Descriptor	Frequency of event occurring	Timescales
Rare	Can't believe this event would happen – will only happen in exceptional circumstances	These should be defined locally by each NHS Board at corporate level and by teams at Unit / Directorate level. May be in terms of days, weeks, months or years.
Unlikely	Not expected to happen but definite potential exists – unlikely to occur.	
Possible	May occur occasionally, has happened before on occasions – reasonable chance of occurring.	
Likely	Strong possibility that this could occur - could occur several times.	
Almost certain	This is expected to happen frequently / in most circumstances – more likely to occur than not.	

(Adapted from AS/NZS 4360:2004)

## Consequences

Once the likelihood is determined, the consequences or impact of the risk on the organisation must be agreed. In identifying the consequence level, the **worst case** scenario has priority. Executive teams and infection control teams should agree the tolerance of consequences for the organisation.

A consequence matrix based on AS/NZS 4360:2004<sup>11</sup> is provided for guidance as Table 2. This table has been developed in collaboration with NHSScotland risk managers and is designed to be used as guidance when NHS Boards are developing or reviewing their own risk assessment matrices. An example of what an adapted, specific matrix for HAI might look like (based on existing practice within NHSScotland) is presented as Table 3. Several consequence descriptors may apply to a single risk. The most serious/significant of these should be used to determine the risk exposure rating.

The **likelihood** and **consequence** levels are then cross tabulated to give a **risk exposure rating**. This determines whether a risk is categorised as red, amber, yellow or green (Table 4). Use of colour coding facilitates rapid communication and understanding of risks. Prioritising of risks that are assigned the same risk exposure rating is achieved by examining the strength of the control measures in place for these risks. For example, a 'high' rated risk could have effective control measures in place that cannot be improved upon, whereas a 'medium' rated risk may not have any control measures in place, and this is the risk that should be prioritised for action by the team.

**Table 2: NHS QIS Core risk assessment matrix: Consequence descriptors (February 2008)**

Descriptor	Negligible [WHITE]	Minor [GREEN]	Moderate [YELLOW]	Major [AMBER]	Extreme [RED]
Patient Experience	Reduced quality of patient experience/clinical outcome not directly related to delivery of clinical care.	Unsatisfactory patient experience/ clinical outcome directly related to care provision – readily resolvable.	Unsatisfactory patient experience/ clinical outcome; short term effects – expect recovery <1wk.	Unsatisfactory patient experience/ clinical outcome; long term effects – expect recovery >1wk.	Unsatisfactory patient experience/ clinical outcome; continued ongoing long term effects
Objectives / Project	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over-run.	Inability to meet project objectives; reputation of the organisation seriously damaged.
Injury (physical and psychological) to patient/visitor/ staff.	Adverse event leading to minor injury not requiring first aid.	Minor injury or illness, first aid treatment required.	Agency reportable, e.g. Police (violent and aggressive acts). Significant injury requiring medical treatment and/or counselling.	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling.	Incident leading to death or major permanent incapacity.
Complaints / Claims	Locally resolved verbal complaint.	Justified written complaint peripheral to clinical care.	Below excess claim. Justified complaint involving lack of appropriate care.	Claim above excess level. Multiple justified complaints.	Multiple claims or single major claim. Complex justified complaint
Service / Business Interruption	Interruption in a service which does not impact on the delivery of patient care or the ability to continue to provide service.	Short term disruption to service with minor impact on patient care.	Some disruption in service with unacceptable impact on patient care. Temporary loss of ability to provide service.	Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked.	Permanent loss of core service or facility. Disruption to facility leading to significant “knock on” effect
Staffing and Competence	Short term low staffing level temporarily reduces service quality (< 1 day). Short term low staffing level (>1 day), where there is no disruption to patient care.	Ongoing low staffing level reduces service quality.. Minor error due to ineffective training/implementation of training.	Late delivery of key objective / service due to lack of staff. Moderate error due to ineffective training/implementation of training. Ongoing problems with staffing levels.	Uncertain delivery of key objective/ service due to lack of staff. Major error due to ineffective training/ implementation of training.	Non-delivery of key objective/service due to lack of staff. Loss of key staff. Critical error due to ineffective training/ implementation of training.
Financial (including damage / loss / fraud)	Negligible organisational/ personal financial loss. (£<1k). (NB. Please adjust for context)	Minor organisational/personal financial loss (£1-10k).	Significant organisational/personal financial loss (£10-100k).	Major organisational/personal financial loss (£100k-1m).	Severe organisational/personal financial loss (£>1m).
Inspection / Audit	Small number of recommendations which focus on minor quality improvement issues.	Recommendations made which can be addressed by low level of management action.	Challenging recommendations that can be addressed with appropriate action plan.	Enforcement action. Low rating. Critical report.	Prosecution. Zero rating. Severely critical report.
Adverse Publicity / Reputation	Rumours, no media coverage. Little effect on staff morale.	Local media coverage – short term. Some public embarrassment. Minor effect on staff morale/public attitudes.	Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation.	National media/adverse publicity, less than 3 days. Public confidence in the organisation undermined. Use of services affected.	National/international media/adverse publicity, more than 3 days. MSP/MP concern (Questions in Parliament). Court Enforcement. Public Inquiry/ FAI.

**Table 3: Example HAI Infection Control Consequence Matrix**

Descriptor	Negligible [WHITE]	Minor [GREEN]	Moderate [YELLOW]	Major [AMBER]	Extreme [RED]
Impact on Individual	Minimal problems with HAI	Short term problem <1 month e.g. delayed discharge, short term treatment	Injury/treatment up to 1 year e.g. re-admission, further surgery, prolonged IV treatment. Deferred non-urgent procedure due to HAI	Permanent injury ITU admission Deferred urgent procedure(s)	Death due to HAI
Impact on Service	Minimal impact due to HAI	Ward(s) under enhanced surveillance, not restricted or closed, minimal need for agency staff.	Ward(s) closed/ restricted, inappropriate boarding of patients but no cancellation of services. Increased need for agency staff.	Ward(s) closed or restricted causing cancellation of elective cases / procedures. Staff shortages due to sickness.	Ward(s) closed / restricted leading to cancellation / transfer of emergency cases to other hospitals / Closure of hospital.
Impact on organisation	Minimal	Some internal public relations	Needs local public relations / Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) report	Major public relations exercise beyond local area	External investigation e.g. FAI
Non-compliance – Infection Control standards/advice	Minimal	Minimal exposure to infection risk due to non-compliance with Infection Control Policy / advice	Possible exposure to infection risk due to non-compliance with IC Policy / advice	Definite exposure to infection risk due to non-compliance with Infection Control Policy / advice. e.g. MRSA, VRE, Norovirus	Exposure to serious infection risk due to non-compliance with IC Policy / advice. e.g. SARS, BBV, TB
Surveillance data (national/local)	Minimal rise in infections	>1SD <2SD rise compared with average*	>2SD rise in infections compared with average	>3SD rise in infection compared with average	Single case of ‘major alert’ organism or very large outbreak
Public Health implications	Minimal	Cross infection with minimal public health impact	Outbreaks, cross infection affecting hospital service. 1-20 cases e.g. Norovirus, MRSA, VRE	Outbreaks, cross infection with public health considerations 1-60 cases depending on organism e.g. 1-2 Salmonella 20-60 Norovirus	Major public health considerations 1- 60 cases depending on organism e.g. one SARS, BBV, MDRTB >60 Norovirus

\*SD = standard deviation

**Table 4: Risk Exposure Rating**

Likelihood	Potential Consequence				
	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	Medium	High	High	Very high	Very high
Likely	Medium	Medium	High	High	Very high
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High
Rare	Low	Low	Low	Medium	Medium

Key for black & white print:

Green	Low
Yellow	Medium
Amber	High
Red	Very high

### 3.5 Evaluate

The purpose of evaluation is to make decisions, based on the outcomes of risk analysis above, about the controls and the level of priority required for each risk as laid out in the section below. Communication, consultation and consideration of the wider context are key to the success of this stage in the process.

### 3.6 Treat risks (plan and control)

Develop and implement a plan for the control of these risks. This can include many actions such as eliminating a particular activity because it is too dangerous, the use of protective measures, special training, or new policies and procedures to improve the current arrangements. NHS activity is inherently risky. All staff throughout the organisation currently manage aspects of risk within their existing practice to give some level of control.

There are three distinct types of control level:


- **Risk control level:** this represents the current position and the **existing** control mechanisms at the time any risk is identified and assessed.
- **Target risk control level:** the target will represent the **highest** control level considered realistically achievable for any risk.
- **Tolerance control level:** following detailed analysis of the identified risks, the organisation must indicate an acceptable tolerance level for the risk. This should reflect the **minimum** steps considered necessary in a short timescale to improve control of any risk to a tolerable level. This will highlight areas for immediate further action or demonstrate a milestone in the achievement of the target control level.

#### Control Groups and Control Level

The systems and processes that are in place to control risk can be categorised into five groups of control. This helps to ensure that controls are recorded consistently and accurately throughout the organisation.

- **Management:** the management systems/structures required to control risk
- **Policies and procedures:** policies and procedures in place to control the risk
- **Contingencies:** emergency plans/alternative arrangements that intervene should the risk become apparent
- **Active controls:** implementation of immediate actions required
- **Passive controls:** activity/information/legislation, outside your direct control, which may have an effect of reducing the risk

The controls within each group are explored using brief bullet point information. This information will help to determine how much control there is against each group across the following scale:

	1	No control
	2	Controls under review
	3	Controls planned
	4	Controls partially operational
	5	Controls fully operational.

Descriptors for each of these levels are detailed in the risk control matrix (Table 5). Within each of the five groups choose the one level of control that applies to the risk. This must be done for all five control groups. When completed this allows a gauge of the total level of current control to be made and a decision on what actions (if any) are required to increase the level of control.

An organisation (or infection control team) may identify several 'red' risks that require to be prioritised for action. Examining the current level of control enables this prioritisation to take place. For example, if several 'red' risks are identified some of these will have acceptable control measures in place that cannot be improved upon. These risks do not decrease, but are being actively managed to keep them under control. The remaining 'red' risks can be prioritised for action according to the level of control measures in place and whether or not these are acceptable to the organisation. Risk control plans or action plans can then be developed.

### **The risk control plan or action plan**

After considering the risk control level, you are now able to decide whether a target control level is required, and if any improvements are necessary. If so, then decide the level of control that you need to achieve to reach the target control level.

Specific actions can be assigned to any or all of the five control groups and will aim to increase the control level (Table 5). The summarised list of actions becomes the risk control plan or action plan. The plan must also detail the timescale for the improvement to be achieved and any cost benefit in relation to the risk. Additional information required to complete the risk control plan includes:

- The named risk owner – the person ultimately accountable for the risk
- The named risk manager – the person actually responsible for managing the risk
- The reporting arrangements for review – the review timescale and the person responsible for that if different from the risk owner. The risk control plans may also be reviewed by a group or committee
- Details of the person recording the information and the date.

### **Resources**

The risk control planning process should also compare the risk exposure costs (should the risk materialise) with the cost of planned improvements to current controls. Capital and revenue, recurring and non-recurring costs must be considered. Any increase in other resource requirements must also be considered and identified. It is possible that the impact in cost or resources required might outweigh the actual impact of the risk materialising on the organisation. The prioritisation of risks allows the organisation to further characterise the risks that require early attention on a cost and benefits basis and address them in the most effective way.

**Table 5: Risk control matrix**

<b>Control Group (Priority)</b>	<b>None (1)</b>	<b>Under Review (2)</b>	<b>Planned (3)</b>	<b>Partially Operational (4)</b>	<b>Fully Operational (5)</b>
<b>Management</b>	No systems at present	Recognise change is necessary	Objectives set Action plan Evidence of problem areas	Measured outcomes so some improvement Not applicable over the whole dept/organisation	Evidence that controls are reducing risk. Audit of system can demonstrate reduction in likelihood or severity
<b>Policies Procedures</b>	Not available No evidence that a procedure exists	Recognition that current policy requires review /amendment	Action plan to review policy identifiable Implementation plan for policy in operation	Evidence of staff awareness of policy and associated practices within some areas of the organisation /department	Evidence of audit of policy, which has reduced the likelihood or severity of the risk identified
<b>Contingencies</b>	If something goes wrong with current controls no plans available	Awareness that plans are required. Evidence of investigation	Contingency plan under development	Evidence of the implementation of contingency plan Tested and reviewed as a result	Contingency plans have been tested and proved to be operational if required
<b>Active Controls</b>	No action taken	Plans to be reviewed	Action plan for this risk under development with clear deadlines	Partially achieved	In full operation Immediate action of plans
<b>Passive Controls</b>	No evidence available	Currently have some knowledge of passive control	Plan to identify information and other systems which may have an impact on risk exposure	Emerging evidence that changes introduced elsewhere are having an unexpected effect on outcome and reducing risk.	Demonstrable reduction in risk from passive risk awareness activity

### 3.7 Monitor & Review

Establish a system where all risks have a review process and defined reassessment timetable. This will ensure that the risk management process is dynamic and continuous. The review process must include the addition of new risks as they are identified.

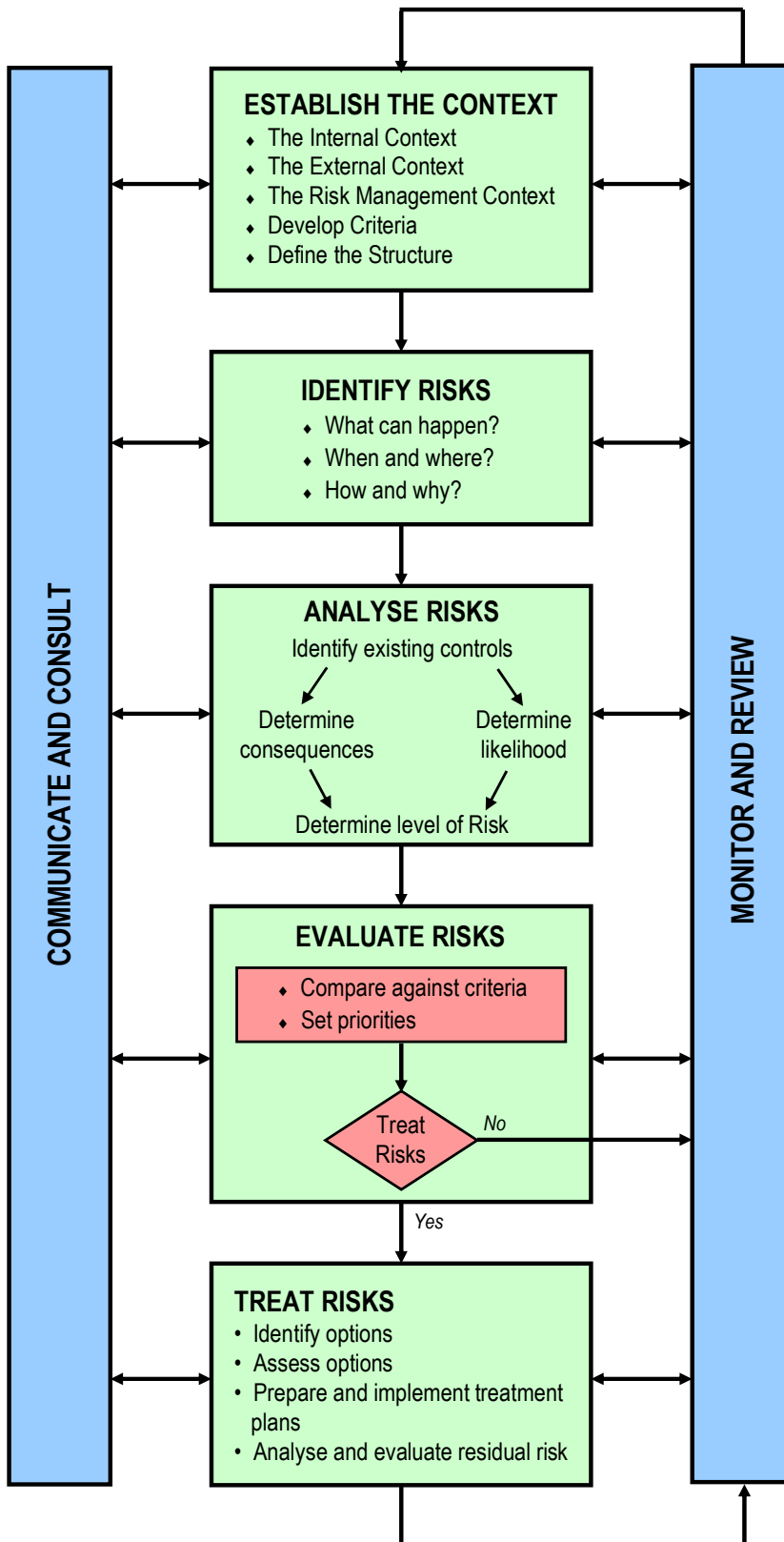
All identified risks and associated actions must be monitored and reviewed on a continuous basis by named individuals and/or groups, for example, the Infection Control Committee. A risk control plan that does not change very often may indicate that risk is being identified, but not managed or controlled.

A monitoring process which is able to provide assurance to the NHS Board that appropriate control measures are in place and being followed for all significant risks, is key to ensuring effective risk management. In addition, there should be formal procedures in place for reporting weaknesses and for ensuring corrective action. Additional support for the review process will come from effective internal audit and clinical governance systems.

#### Summary of this section

*To summarise the process laid out here, **risk identification** leads to decisions on the **likelihood of the event** and the **severity of consequences** if the event happens: cross tabulating these two values give a red/amber/green colour coded **risk exposure rating**. The risk controls already in place under five categories give a **risk control level**, and 'red' or 'amber' risks in particular can be prioritised for action by assessing their existing risk control level. The risk can then be placed on the risk register for the team and the organisation, and action taken to increase risk controls to a level the organisation can tolerate.*

**Figure 1: Risk Assessment Process (AS/NZS 4360:2004)**



## 4. Critical Success Factors

Success in reducing the impact of HAI depends on:

- Creating a managed environment that minimises the risk of infection to patients, staff and the public
- Compliance with relevant national Scottish standards (e.g. NHS QIS standards on HAI control<sup>4</sup>, National Cleaning Services Specification<sup>7</sup>) and HAI Task Force documents
- Implementation of national best practice and infection control guidance

This will be achieved by:

- Development of a patient safety focused, partnership culture that secures the involvement and participation of all staff in risk assessment and adverse incident/near miss reporting in relation to HAI
- Ensuring that routine and systematic identification, assessment and control of infection risk is an integral component of all work activities
- Ensuring that an effective reporting process is in place to facilitate the systematic identification of HAI adverse events and near misses
- Acknowledgement that even though staff are accountable for their own actions and decisions, the greatest risk of loss is most likely due to failure in the system rather than individual error alone. (This principle will determine how NHSScotland organisations respond to adverse events)
- Securing the commitment of management at all levels to promote HAI risk management and provide the necessary leadership and direction
- Adoption of agreed standards of risk management throughout the organisation which are audited and monitored at corporate and operational level ensuring that corrective action on infection control is taken where necessary
- Having in place effective communication systems to make sure everyone in the organisation is sufficiently informed about risk management and incident reporting in relation to HAI and infection control
- Providing resources, facilities, information, training, instruction and supervision to meet these objectives

8. **ANNEX 1: Healthcare associated infection (HAI) incident/outbreak risk matrix [adapted from the Watt Report 2002<sup>2</sup>]**

The Infection Control Team will quantify the infection control risk criteria and ascertain the associated risk, which will determine the appropriate action to be taken. Four infection risk categories can be identified: Red -High Risk, Orange -Moderate Risk, Yellow -Low Risk, Green -Very Low Risk.

Criteria	Quantification Criteria	Risk Category	Action Required	Communications
3 or more met	Death and/or serious illness Major implications for public health Exceptional or unusual infection episode Major disruption of health and/or public services Major public anxiety and concern	<b>Red</b> – High Risk	Implement Area Major Incident/Outbreak Plan	Full (eg NHS Board, HPS, SGHD) and others as appropriate (eg FSA, Local Authority, Scottish Water, SEPA, HSE etc)
1 or 2 met	Death and/or serious illness Major implications for public health Exceptional infection episode Major disruption of health and/or public services Major public anxiety and concern	<b>Orange</b> – Moderate Risk	Implement Hospital Incident/Outbreak Plan – Full Incident Management/Outbreak Control Team	Full (eg NHS Board, HPS, SGHD) and others as appropriate (eg FSA, Local Authority, Scottish Water, SEPA, HSE etc)
3 or more met	Serious illness and/or infection episode and/or cases Moderate impact on public health Short-term disruption of health and/or public services Moderate public anxiety and concern	<b>Yellow</b> – Low Risk	Implement Hospital Incident/Outbreak Plan – Infection Control Team	Hospital and NHS Board communications. SGHD if likely press interest or ward closures
All 4 met	Minimal infection episode and/or case Minimal impact on public health Minimal disruption of health and/or public services Minimal public anxiety and concern	<b>Green</b> – Very Low Risk	Implementation – Infection Control Team Investigation	Hospital communications

NB Infection risk category coding may vary slightly from Hospital to Hospital. No more than four risk categories should apply to this infection control risk matrix.

## ANNEX 2: Glossary

<b>Adverse incident</b>	Any event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage to patients/public/staff or organisation
<b>Assurance statement</b>	A written declaration of confidence in an organisation
<b>Clinical Governance</b>	The purpose of clinical governance is to make sure that patients receive the highest quality of care possible, putting each patient at the centre of their care. This is achieved by ensuring that those providing services work in an environment that supports them and which places safety and quality of care at the top of the organisation's agenda. (NHS Quality Improvement Scotland 2005)
<b>Compliance</b>	The degree to which organisations adhere to standards
<b>Cost</b>	Cost of activities, direct and indirect, involving any negative impact, including money, time, labour, disruption, goodwill, political and intangible loss.
<b>Exposure rating</b>	This determines whether a risk is red, amber, yellow or green.
<b>Harm</b>	Injury (physical or psychological) suffering, disability or death which was unexpected
<b>Hazard</b>	A source of potential harm or a situation with a potential to cause loss
<b>Healthcare Associated Infection</b>	Infection acquired in a hospital or other healthcare setting
<b>Incidence (of infection)</b>	Rate at which new cases occur
<b>Infection control incident</b>	<a href="#">A single case of a serious illness with major public health implications where action is necessary to investigate and prevent ongoing exposure to the infectious agent.</a>
<b>Infection control outbreak</b>	<a href="#">Either as two or more linked cases of the same illness (i.e. associated in person, place or time) or as a situation when the observed number of cases of an illness unaccountably exceeds the expected number.</a>
<b>Likelihood</b>	Used as a description of probability or frequency
<b>Near miss</b>	Where no harm loss or damage is caused but could have resulted in other circumstances
<b>Performance Assessment Framework</b>	The method used within NHSScotland to measure performance of NHS Boards against agreed indicators
<b>Probability</b>	A measure of the chance of occurrence expressed as a number between 0 and 1. It is the extent to which an event is likely to occur.
<b>Risk</b>	The chance of something happening that will have an impact upon objectives. It is measured in terms of the severity of the consequence and likelihood of it occurring.
<b>Risk assessment</b>	The overall process of risk identification, risk analysis and risk evaluation.
<b>Risk control</b>	The policies, procedures or processes in place that play a part in managing the risk.

<b>Risk management</b>	The culture, processes and structure that are directed towards the effective management of potential opportunities and adverse effects
<b>Risk management process</b>	The systematic application of management policies, procedures and practices to the tasks of communicating, establishing the context, identifying, analysing, evaluating, treating, monitoring and reviewing risk
<b>Risk reduction</b>	Actions taken to lessen the likelihood, negative consequences, or both, associated with a risk.
<b>Risk register</b>	A register of an organisation's risks, providing detail on level of risk, control, exposure and responsibility.
<b>Stakeholders</b>	Those people and organisations who may affect, be affected by or perceive themselves to be affected by a decision, activity or risk.

### ANNEX 3: References & Bibliography

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## ANNEX 4: Membership of HAI Task Force Working Group 12

Name	Membership Representation	Title	Organisation
Eunice E. Muir	Chair	Nurse Director	NHS 24
Dr Alison Bramley	Learning from Experience	Project Manager	NHS Lothian
Richard Carey	Chief Executive	Chief Executive	NHS Highland
Professor John Davies	Academic	Director	Centre for Applied Social Psychology
Sean Doherty	NHS Quality Improvement Scotland	Review Team Manager	NHS Quality Improvement Scotland
Dr Anne Eastaway	Microbiology/Risk Assessment	Consultant Microbiologist	NHS Argyll & Clyde
Maureen O'Neill	Public Involvement Representative		
Donna O'Boyle	CNORIS	Risk Management National Assessor	NHS/Willis
Pat O'Connor	Risk Manager	Head of Risk Management	NHS Tayside
Roy Pettigrew	Public Involvement Representative		
Joan Sneddon	Risk Assessment/Infection Control	Nurse Consultant Infection Control	Health Protection Scotland
Dr Eric Walker	Scottish Joint Consultants Committee	Consultant Physician Epidemiologist	Health Protection Scotland
Dr Brian Watt	Watt Group Report/Risk Management	Retired Consultant Microbiologist	

### SEHD Secretariat:

Mrs Margaret Tannahill, Project Leader, HAI Task Force  
 Dr Peter Christie, Senior Medical Officer

Supported by Hazel Borland, Head of Clinical Governance and Patient Safety, NHS Quality Improvement Scotland.