Royal College of Obstetricians and Gynaecologists

Setting standards to improve women's health

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IMPROVING PATIENT SAFETY: RISK MANAGEMENT FOR MATERNITY AND GYNAECOLOGY

This is the third edition of this guidance. The original edition, entitled *Clinical Risk Management for Obstetricians and Gynaecologists*, was published in January 2001 and revised in 2005 under the title *Improving Patient Safety: Risk Management for Maternity and Gynaecology*.

1. Background

Across the world, healthcare providers are increasingly obliged to adopt a systematic approach towards reducing the risk of harm to patients. In the UK, impetus for such an approach was provided by the report, *An Organisation with a Memory*, which emphasised the need to learn from clinical error.[1] A major step was taken with the establishment of the National Patient Safety Agency (NPSA)[2] in 2001. In the USA, Australia and other countries, various governmental and nongovernmental agencies have led the way in the setting of standards, training and research on issues of patient safety.[3–6] Maternity care is particularly susceptible to risk and, in England, the safety of maternity services has been the subject of recent inquiries and reviews. The National Health Service Litigation Authority (NHSLA) has developed a separate assessment scheme for maternity units, encompassing a wide range of standards.[7] The equivalent schemes in Wales and Scotland are the Welsh Risk Pool[8] and the Clinical Negligence and Other Risks Indemnity Scheme (CNORIS),[9] respectively. While maternity care is widely recognised as a high-risk specialty, risk management is also pertinent to gynaecological practice.

2. Patient safety, risk management and quality of care

The document, *Standards for Better Health*, published by the UK Department of Health, outlined seven domains of health care (Box 1), the first of which is safety.[10] These domains constitute the framework by which the quality of care will be provided and assessed. Safety is one dimension of the quality of care but initiatives to enhance patient safety usually drive other dimensions as well. Some patients suffer harm from the care that is intended to help them. Patient safety initiatives aim to reduce the chance of this happening

Box 1: The domains of health care

- Safety
- Clinical and cost effectiveness
- Governance
- Patient focus
- Accessible and responsive care
- Care environment and facilities
- Public health

and a variety of resources and strategies can be employed for this purpose. One approach is risk management. This brief guide describes the basic principles of risk management, structures for managing risk at local and national levels, and processes for implementing risk management.

3. Managing risk

3.1 Definition of risk management

A comprehensive definition of risk management is provided by the joint Australia/New Zealand Standard: 'the culture, processes and structures that are directed towards realizing potential opportunities whilst managing adverse effects'.[11] When applied to the healthcare setting, this definition helps to dispel some misconceptions regarding risk management:

I. Risk management is not primarily about avoiding or mitigating claims; rather, it is a tool for improving the quality of care. Poor-quality care may lead to litigation, so risk management should reduce outcomes that induce claims but this is not its sole or primary purpose. Risk management is also as much about learning from claims as it is about mitigating claims.

II. Risk management is not simply the reporting of patient safety incidents. Incident reporting is only one aspect of the identification of risk. There are other ways of identifying risk and identified risks have to be analysed, treated and monitored. In one sense, incident reporting is on the reactive side of risk management. More emphasis needs to be placed on the proactive side, as risk management is more effective when resources are used to minimise the occurrence of patient safety incidents instead of 'fire fighting' after things have gone wrong. Scenario training ('fire drill') is one example of proactive risk management.

III. The misconception is that risk management is the business of service managers and of little concern to working clinicians. Risk management is actually the business of all stakeholders in the organisation, clinicians and non-clinicians. It sits well with the clinicians' exhortation, *primum non nocere* (firstly, do no harm) and will be a critical element in the recertification of specialists.

3.2 Basic questions addressed by risk management

The basic questions addressed by risk management can be summarised as shown in Table 1.

Table 1. Basic questions addressed by risk management

What could go wrong?	Risk identification
What are the chances of it going wrong and what would be the impact?	Risk analysis and evaluation
What can we do to minimise the chance of this happening or to mitigate damage when it has gone wrong?	Risk treatment The cost of prevention is compared with the cost of getting it wrong
What can we learn from things that have gone wrong?	Risk control; sharing and learning

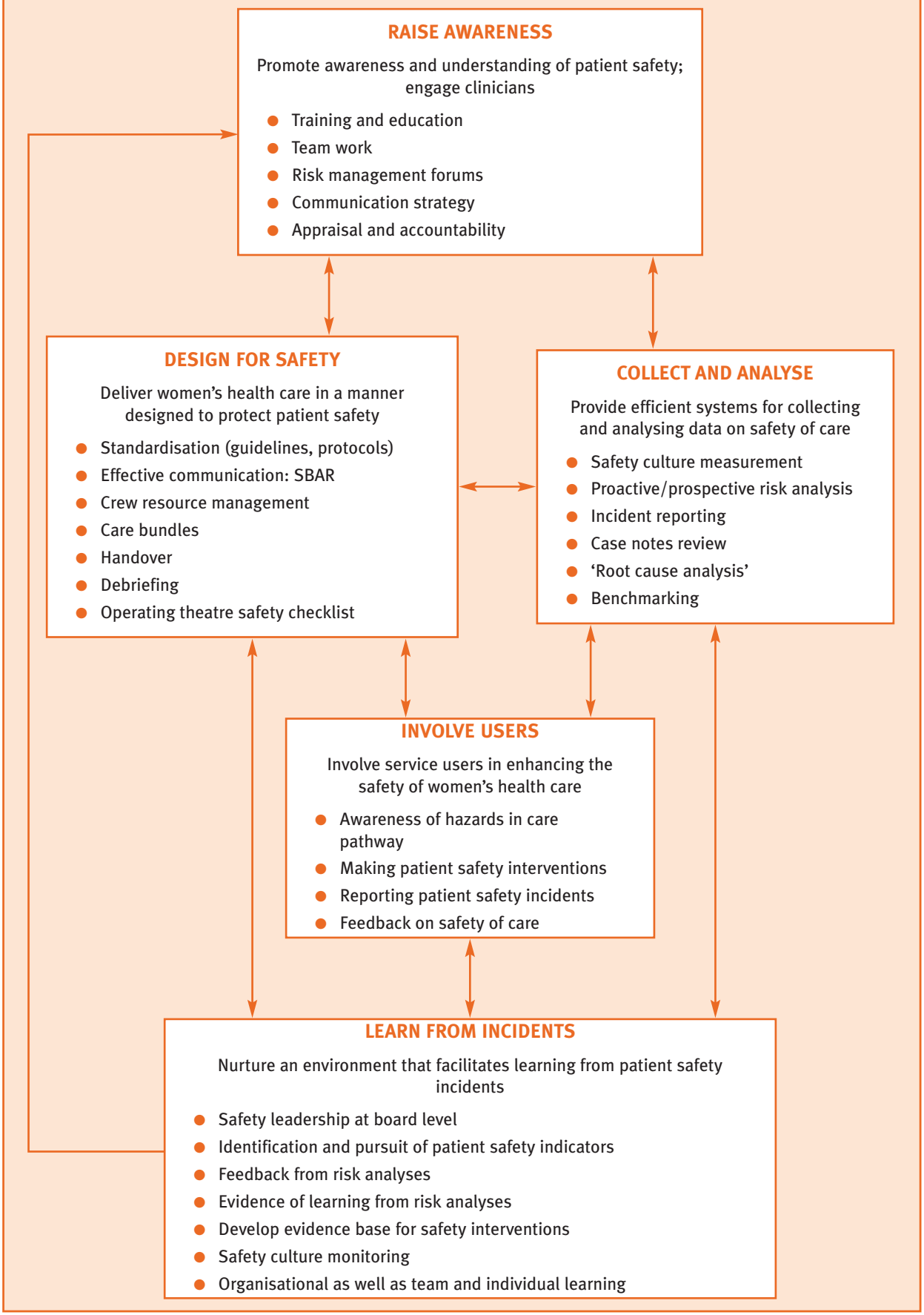
3.3 A holistic view of patient safety

The term 'clinical risk management' is sometimes used to refer to the application of risk management in the clinical setting but it is more helpful to take a holistic view of patient safety. The demarcation between clinical and non-clinical risk is not always clear-cut and sometimes an adverse event is the culmination of clinical as well as non-clinical failures. Whether the patient suffers harm as a result of a medication error (clinical risk) or as a result of falling from a trolley (non-clinical risk), the factors, such as organisational culture or poor staffing levels that allowed this incident to happen may be the same.

3.4 Application of risk management

Risk management may be applied at any level of an organisation or process. Senior management may be concerned with the local strategy for infection control in the directorate; for example, what are the chances

Figure 1: The RADICAL framework for management of risk in health care (**R**aise **A**wareness, **D**esign for safety, **I**nvolve users, **C**ollect and **A**nalyse safety data, and **L**earn from patient safety incidents)



of an epidemic resulting in closure of the neonatology unit and how can this event be mitigated? A multidisciplinary team may trace the journey of a couple undergoing fertility treatment, assessing and treating the risks flagged up in this process. An individual clinician could identify changes that he or she could make to enhance patient safety and quality of care; for example, planning joint procedures with a bowel surgeon in cases where difficulty is anticipated.

4. Organisational requirements for risk management

4.1 Integrated framework

Risk is best managed not in isolation but within a framework that integrates all aspects of clinical governance including clinical audit, education and training, complaints and claims handling, health and safety, research and service development. The RADICAL framework (Figure 1)[14] serves this purpose. The organisation should nurture a safety culture and provide the necessary resources. A safety culture is more likely to flourish where there is strong leadership, teamwork, communication, user involvement and training.[12] These themes are addressed in the joint Royal Colleges document, *Towards Safer Childbirth*.[13] Approaches employing these themes to establish organisational standards of quality and safety in maternity and gynaecology are described in various texts.[14–18]

Communication within and between teams is a key safety issue. Particular care should be taken when a patient is transferred from one health professional to another. At all times, emphasis should be on learning rather than blame. System analysis often reveals inadequate training as a key contributor to adverse outcomes and training is central to patient safety initiatives.[19,20] Also, measures to reduce risk are more likely to be successful if there is involvement of those most likely to be harmed by the risk; that is, the users of the service.

4.2 Linked with hospital-wide strategies and initiatives

Risk management at the specialty or subspecialty level should be linked with hospital-wide strategies and initiatives. Locally, risk management should be integrated with general management and business planning. Each department (maternity, gynaecology or obstetrics and gynaecology) should have a written risk management strategy and a designated risk lead. Strategic direction and leadership should be provided by a multidisciplinary risk management or clinical governance committee. For a maternity unit, membership would typically include a senior obstetrician as well as a training-grade doctor, a midwife, an anaesthetist, a neonatologist and the unit manager. For a gynaecology unit, membership may include a gynaecologist, a nurse, an ultrasonographer, a service manager, a theatre practitioner, an anaesthetist and a manager. Whatever the local arrangement, the message to emphasise is that these committees are not there as sole managers of everyone's risk; they are there to facilitate the efforts of everybody in managing risks in their own clinical practice.

5. The risk management process

5.1 Risk identification

All clinical areas should have formal processes for identifying anything that might interfere with the delivery of a safe, good quality service. To find out 'what could go wrong', we could either prospectively check our systems to flag up possible sources of patient safety incidents before the event has actually happened or we could look back at things that did go wrong. Risks could also be identified through a variety of other sources (Table 2).

Incident reporting

Each unit should have a list of reporting incidents (trigger list) for maternity and gynaecology (Tables 3 and 4). To optimise the reporting of incidents, staff should be aware and motivated. Feedback drives motivation. Feedback does not stop at periodic summaries of reported incidents. It is more important to report what changes have been implemented and what demonstrable benefits have resulted from reported incidents.

Table 2. Identifying risk

Internal sources	External sources
Risk assessment conducted in all clinical areas (wards, clinics, theatre, delivery suite, day assessment unit, etc.)	National Confidential Enquiries
	CNST standards
Incident reporting	RCOG guidelines, protocols and visitation
Complaints and claims	National Patient Safety Agency alerts
Staff consultation – workshops, surveys, interviews	Postgraduate dean's specialty site visits
Clinical audit	Care Quality Commission

Table 3. Suggested trigger list for incident reporting in maternity

Maternal incident	Fetal/neonatal incident	Organisational incidents
Maternal death	Stillbirth > 500 g	Unavailability of health record
Undiagnosed breech	Neonatal death	Delay in responding to call for assistance
Shoulder dystocia	Apgar score < 7 at 5 minutes	Unplanned home birth
Blood loss > 1500 ml	Birth trauma	Faulty equipment
Return to theatre	Fetal laceration at caesarean section	Conflict over case management
Eclampsia	Cord pH < 7.05 arterial or < 7.1 venous	Potential service user complaint
Hysterectomy/laparotomy	Neonatal seizures	Medication error
Anaesthetic complications	Term baby admitted to neonatal unit	Retained swab or instrument
Intensive care admission	Undiagnosed fetal anomaly	Hospital-acquired infection
Venous thromboembolism	European Congenital Anomalies and Twins (Eurocat)[21]	Violation of local protocol
Pulmonary embolism		
Third-/fourth-degree tears		
Unsuccessful forceps or ventouse		
Uterine rupture		
Readmission of mother		

Table 4. Suggested trigger list for incident reporting in gynaecology

Clinical incident	Organisational incidents
Damage to structures (e.g. ureter, bowel, vessel)	Delay following call for assistance
Delayed or missed diagnosis (e.g. ectopic pregnancy)	Faulty equipment
Anaesthetic complications	Conflict over case management
Venous thromboembolism	Potential service user complaint
Failed procedures (e.g. termination of pregnancy, sterilisation)	Medication error
Unplanned intensive care admission	Retained swab or instrument
Omission of planned procedures (failure to insert planned intrauterine contraceptive device after a hysteroscopy)	Violation of local protocol
Unexpected operative blood loss > 500 ml	
Moderate/severe ovarian hyperstimulation (assisted conception)	
Procedure performed without consent (e.g. removal of ovaries at hysterectomy)	
Unplanned return to theatre	
Unplanned return to hospital within 30 days	

Incident reporting in the unit should be linked to the hospital or trust-wide reporting system, which is, in turn, linked to the NPSA's National Reporting and Learning System (see section 6 below).

Identifying prospective risk

One way of identifying what potentially could go wrong is to use a tool called Failure Mode and Effects Analysis (FMEA).[21] In FMEA, a **process** is examined to identify what could go wrong and analyse the possible consequences of such failures (Box 2). This tool has been more extensively used in aviation, aerospace and automobile industries but is applicable to health care.[21,22]

Box 2: Steps in failure mode and effects analysis

1. Examine a process in detail and outline every step.
2. Identify ways in which any of the steps might go wrong; that is, the 'failure modes'.
3. Establish the consequences (effects) of each failure mode.
4. Identify what could be the underlying causes (contributory factors).
5. Rate each contributory factor and/or failure mode in terms of its frequency or likelihood of occurrence and each effect in terms of the severity of its consequences.
6. Identify any existing 'controls' (factors acting to prevent, detect, monitor or mitigate this risk).
7. Use the ratings to prioritise risks; decide which risks to accept and which ones to treat.
8. Devise an action plan

Looking at what went wrong

An after-the-fact approach to identifying what could go wrong entails analysis of patient safety incidents, including near misses, that have occurred (system analysis or 'root cause analysis'). The London Protocol is a useful tool for achieving this.[23] This protocol offers a structured and systematic approach to the investigation of clinical incidents. The key steps are:

1. Identify incident and take decision to investigate.
2. Select members of the investigation team.
3. Gather data (such as records, interviews, protocols) and relevant physical items.
4. Determine the chronology of the incident.
5. Identify care delivery problems (unsafe acts; for example, failure to act or incorrect decision).
6. Identify contributory factors (such as inadequate training, lack of supervision).
7. Devise an action plan.

In analysing incidents, it is necessary to look not just at the individual at the 'sharp end' of the incident but at the entire system. It is also necessary to avoid two fallacies: professionals who try hard enough will not make any errors (the perfection fallacy) and people will make fewer errors if they get punished for any error (the punishment fallacy).

Investigators must be familiar with mechanisms underlying error, particularly the role of the human factor.[24] It is important to distinguish between 'active' and 'latent' failures and also between error and violation. These distinctions are important because the aim is not to apportion blame for the index incident but to reduce the risk of similar incidents happening again. An active failure is the immediate cause of a patient safety incident; for example, misidentification of a patient or sample; while a latent failure is a more remote but important cause, such as the absence of protocols for checking and confirming identification. A patient safety incident may occur when, as a result of fatigue, a doctor loses concentration and uses an addressograph from the wrong case notes (error), or where the doctor hurrying to finish a busy session decides to use an addressograph, where existing protocols had stipulated that the patient's details should be handwritten (violation).

In-depth analysis of a small number of incidents is more useful than cursory examination of a large number but this should not be an excuse for not reporting all patient safety incidents. From the large number of incidents reported, trends can be identified and risk control interventions can be monitored.

In the evolution of risk management, a unit is more likely to start by looking back at incidents that have happened ('root cause analysis') rather than prophylactically examining processes (FMEA) but either or both approaches can be used, provided that staff undertaking the exercise have been appropriately trained. Generally, FMEA is more time consuming and should be reserved for high-priority processes.

5.2 Risk analysis and evaluation

To manage risks efficiently, we should assign a risk score. This helps, for example, to identify risks or incidents that require in-depth investigation or those that require immediate action. The risk score is commonly derived by multiplying the **severity** of the incident by the **likelihood** of its occurrence. Levels of severity will be locally defined, taking into account the extent of harm caused to the patient and the organisation. The likelihood rating considers how frequently an incident is expected to occur or the probability of its occurrence (for example, an 'unlikely' event could occur sometime but a 'likely' event will probably occur at some time). An example of a risk score matrix is given in Table 5. With this matrix, a risk with a score of 20 or higher is deemed an unacceptable risk.

Table 5. Risk score matrix

Likelihood/severity		1	2	3	4	5
1	Low	Low	Low	Low	Low	Low
2	Slight	Low	Low	Significant	Significant	High
3	Moderate	Low	Significant	High	Very high	Very high
4	Major	Low	Significant	Very high	Very high	Unacceptable
5	Catastrophic	Low	High	Very high	Unacceptable	Unacceptable

5.3 Risk treatment

Options for dealing with the risk(s) are weighed up and the appropriate course, which may be elimination, substitution, reduction or acceptance of the risk, is selected. This informs the action plans referred to in FMEA and the London Protocol. Selection of the appropriate treatment will be influenced by the risk rating and there may be significant resource implications. Alternatively, the action plan may require more of a change of culture than a huge capital outlay. An example of this would be measures to improve communication within a team (such as a theatre or ward/clinic) or between teams (such as medical staff and physiotherapists or sonographers).

Lessons learned from the identification and treatment of risk should be shared with other parts of the hospital/trust and with the wider community as may be appropriate, through channels such as multidisciplinary team meetings, ward meetings, safety alerts, newsletters, intranet and educational meetings. Both the NPSA and the RCOG have communication channels that can be employed for this purpose.

5.4 Risk registers

Each clinical area, such as the antenatal clinic, the gynaecology ward or the *in vitro* fertilisation (IVF) unit, should have a risk register. Risks identified through the processes described above should be entered in the register, with columns showing risk evaluation, controls and residual risk. Residual risks exceeding a preset threshold are escalated to a departmental or directorate register and significant risks from that register are in turn escalated to a hospital/trust-wide risk register. A risk register is not a static document. It is modified as

risks are treated or new ones emerge. Ideally, a risk register should be in electronic format.

A gynaecology risk register could include, for example, risks identified in the care pathways for emergency gynaecology, local difficulties with ensuring patient safety when emergency operations are carried out at night or other risks flagged in the reports of the National Confidential Enquiry into Patient Outcome and Death (NCEPOD).[25] The register for an IVF unit could include local controls for the risk of misidentifying patients and embryos and controls for the care of patients admitted out of hours with ovarian hyperstimulation.

The register is not populated exclusively by strictly 'clinical' issues. Is your unit at risk of stumbling at the next Deanery or Clinical Negligence Scheme for Trusts visit? Does implementation of the Working Time Directive pose significant risks? Does the directorate's budget deficit threaten the continued provision of certain services? Are there difficulties in implementing research governance? These and similar risks should be on the register, together with the unit's control measures and/or action plan.

6. The national context

The NPSA was established to develop a national approach towards reporting incidents and learning from them. One of its key objectives is to transform the prevailing culture of blame into a culture of safety and openness. Its remit is to look at systems rather than individuals. It disseminates safety alerts and facilitates development of solutions to identified risks. One of its major achievements to date is the National Reporting and Learning System (NRLS), a facility which enables NHS staff in England and Wales to report patient safety incidents and prevented patient safety incidents ('near misses') to an anonymised database. A useful tool produced by the NPSA is the Incident Decision Tree,[27] which helps managers decide the best course of action when dealing with a member of staff involved in a patient safety incident. A punitive approach is not conducive to incident reporting, although there are situations where individuals have to be held accountable. The decision tree helps distinguish between cases requiring disciplinary action and those attributable to system failure. It takes the user through a series of structured questions about the individual's action, motive and behaviour at the time of the incident. These questions consider whether deliberate harm was intended, whether illness or substance misuse was contributory, whether local guidelines were in place and followed and how a peer would have handled the situation.

In addition to the NRLS, there are other ways in which local patient safety initiatives can link with and be supported by the NPSA. The agency has a network of regional patient safety managers whose remit is to assist local organisations. It also provides training in root cause analysis and other aspects of patient safety.

7. Conclusion

Patient safety has always been a prime concern of the clinician. What has changed in the last decade is the way in which this important aspect of health care has been managed. Our current approach to patient safety has been informed by risk management principles developed in the spheres of psychology, aviation and high reliability organisations. These principles must be applied at strategic and operational levels, by the clinical unit as a whole and by individual practitioners; they should be at the core of undergraduate, postgraduate and lifelong learning.

8. Related issues

Clinical governance advice related to sexual health services is addressed in a separate guidance document *Service Standards for Sexual Health Services*, produced by the Faculty of Sexual and Reproductive Health Care.[27]

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