

# Service Standards for Risk Management in Sexual and Reproductive Health



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## Glossary of terms

**Hazard** - an event or situation that has the potential to cause injury, loss, damage or harm to:

- ▶ people (staff, patients, contractors, public)
- ▶ the organisation (finance, operations, objectives)
- ▶ the environment (pollution, inefficient use of resources)

**Event** - a hazard which materialises.

**Risk** - the likelihood of occurrence and severity of consequence of an event occurring. Other words, such as probability or impact, are sometimes used instead.

**Risk Assessment** - the systematic process for prioritising risks on the basis of a combination of the severity of consequence and likelihood of occurrence.

**Risk Management** - the systematic process for identifying, assessing, mitigating and reviewing risk.

**Controls** - those documents, systems, processes, devices and equipment intended to mitigate the likelihood and/or severity of a risk.

**Near Miss** - a hazard which fails to turn into an event by chance or by timely intervention, for example, medicines discovered to be out of date and removed. If the medicine were administered to the patient and they suffered no ill effects, this would be a “no harm” incident.

**Incident** - any event which results, or might have resulted, in injury or abuse to any staff, patients, visitors, external contractors, students, volunteers or other person or in loss of or damage to property or equipment.

**MHRA** - The MHRA is a government agency that is responsible for the regulation of medicines and medical devices and equipment used in healthcare and for the investigation of harmful incidents.

**NHSLA**- The National Health Service Litigation Authority (UK) manages negligence and other claims against the NHS in England on behalf of its member organisations.

**RIDDOR**- The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013. These Regulations require employers, the self-employed and those in control of premises to report specified workplace incidents.

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## SERVICE STANDARDS FOR RISK MANAGEMENT IN SEXUAL & REPRODUCTIVE HEALTH

### Changes introduced since review

- ▶ Updated introduction in accordance with new national governance structures, devolved nations and regulatory bodies
- ▶ Inclusion of a risk matrix
- ▶ Inclusion of statement on risk management relevant to online provision of care and use of health technology
- ▶ Updated references

### Introduction

Risk Management is an approach to improving the quality and safety of health care by identifying circumstances that put patients and staff at risk and acting to prevent or control those risks. The overall aim of any risk management strategy is to make the effective management of risk part of everyday practice. This can only be achieved if there is a comprehensive and cohesive framework in place, underpinned by clear accountability arrangements across the organisation.

Risk is defined as *an uncertain event or set of events that, should they occur, will have an effect on the achievement of objectives of a programme area also known as critical success factors.*

It is measured in terms of impact and likelihood. It consists of a combination of the probability of a perceived threat or opportunity occurring, and the magnitude of its impact on the objectives, where:

- ▶ threat is an uncertain event that could have a negative impact on objectives.
- ▶ opportunity is an uncertain event that could have a favourable impact on objectives.

Risk management can be defined as the systematic application of management policies, procedures and practices, which in turn identify, analyse, assess, treat and monitor risk.

Risk assessment is the process used to evaluate the risk and to determine whether precautions are adequate or more should be done. The risk is compared against predetermined acceptable levels of risk.

[The Health and Safety Executive \(HSE\)](#) is the national independent regulator for health and safety in the workplace. It works in partnership with co-regulators within the devolved nations to inspect, investigate and where appropriate take enforcement action. Within England the main co-regulator is the [Care Quality Commission](#) which was established in 2009 to regulate and inspect health and social care services in England. Within Scotland regulation of health and social care is shared between [Healthcare Improvement Scotland \(HIS\)](#) and the [Care Inspectorate](#). Within Wales these responsibilities are shared with the [Healthcare Inspectorate Wales \(HIW\)](#) and the [Care and Social Services Inspectorate Wales \(CSSIW\)](#). In Northern Ireland, these regulation responsibilities are overseen by the [Regulation and Quality Improvement Authority](#).

There are many other bodies responsible for regulating different aspects of these sectors, many of which have more specific powers and legislation than HSE and may therefore be in a better position to respond to patient or service user incidents or complaints. They include

professional bodies such as the [General Medical Council \(GMC\)](#) and [Nursing and Midwifery Council \(NMC\)](#) and the [Medicines and Healthcare Products Regulatory Agency \(MHRA\)](#). Together these regulating bodies can help to inform local policy on risk management and prevention.

Good risk management is central to clinical governance. Every organisation should have an ongoing risk management process of identifying, assessing and prioritising risks with the objective of preventing avoidable risks and managing and controlling those risks that remain.

Clinical risk is interdependent with other types of risk, e.g. operational and financial risk, and should not be viewed in isolation. There may be resource implications to minimising or eliminating risk.

A risk management strategy should be read in conjunction with all other key documents, policies and procedures that are relevant to the management of risk and that have been set in place to support the organisation in the management and control of risk. Such policies would include those on:

- ▶ Health and Safety
- ▶ Fire
- ▶ Infection Control
- ▶ Incident Reporting
- ▶ Complaints Procedure
- ▶ Claims and Legal Advice
- ▶ Manual Handling
- ▶ Information Governance
- ▶ Record Keeping
- ▶ Lone Working
- ▶ Confidentiality.

The management of clinical risk is the responsibility of all staff and should be part of a quality improvement programme. All staff must accept the management of risk as one of their fundamental duties. Individual roles and responsibilities should be clearly understood. Ongoing training in quality improvement and risk management is important for all professionals working in sexual and reproductive healthcare services and support should be available to staff.

Risk will always be a factor present in the provision of health care. The key to successful risk management is to strike a balance between overprotection that inhibits progress and innovation, and insufficient protection which can lead to unnecessary injury, loss or damage.

This document outlines the basic principles of risk management and the process for implementing risk management in Sexual and Reproductive Healthcare Services.

## 1. Standard Statement on Risk Management Strategy

**Sexual and Reproductive Healthcare services should have a Risk Management Strategy which is linked with the organisation's own Risk Management Strategy.**

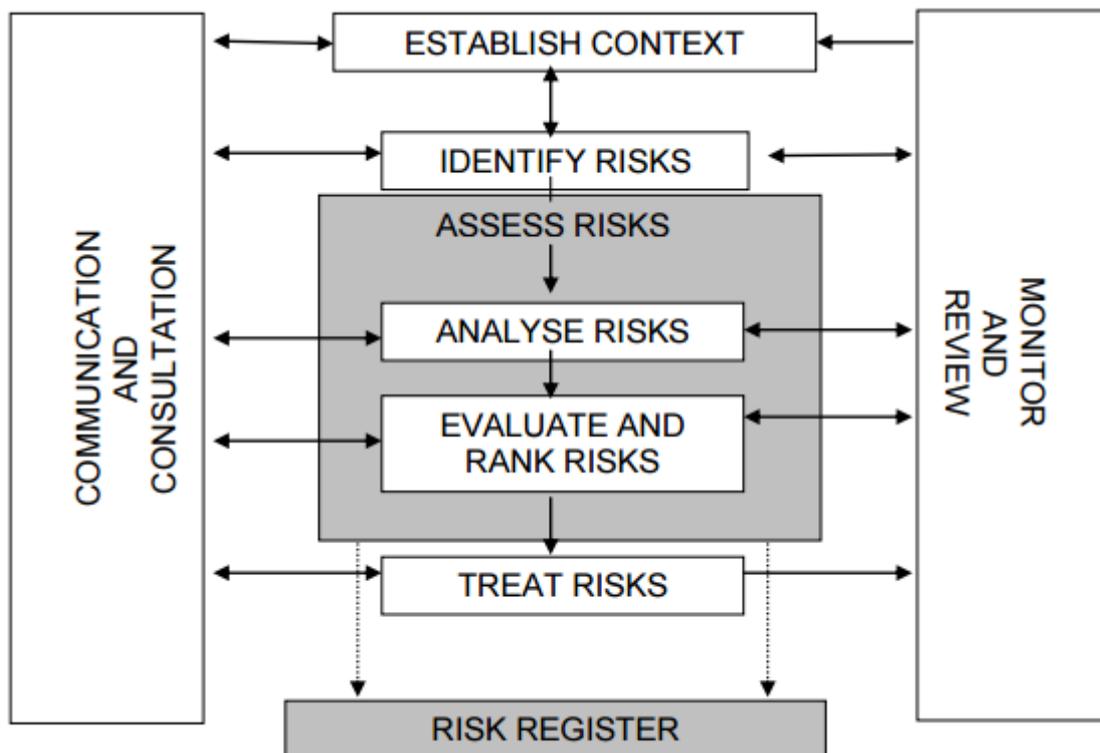
- 1.1 Clinical risk management should follow a structured approach within a clinical governance framework, to meet the needs of the patient, clinician and organisation.
- 1.2 Strategic direction should be provided by a risk management group with a senior member of staff as the designated lead.
- 1.3 Membership of this group should be multi-disciplinary e.g. nurses, administrative staff and a link person from the organisation's clinical governance team.
- 1.4 A risk register which includes clinical and non-clinical risks should be established. There should be an action plan relating to the risks contained in the register. Stratification processes should be in place to determine levels of risk (Standard 4).
- 1.5 Systems should be in place to communicate effectively with all staff. Staff involvement will increase awareness of potential risks and make it easier to implement changes in practice.
- 1.6 It should be the responsibility of every member of staff to recognise, respond to, report, record, be accountable for and reduce risks whilst they are undertaking work for the organisation.
- 1.7 Training and updating programmes for risk management should be available to all staff. There should also be central access to relevant policies for all staff e.g. through intra-web or shared-drive.
- 1.8 Although avoidance of complaints / litigation is important, the care and safety of patients, carers and staff should be the primary concern.

## 2. Standard Statement on Risk Management Process

**A register should be established with a process in place to monitor and review risk regularly.**

- 2.1 An effective Risk Management System should be able to apply policies, procedures and practices systematically in order to identify, analyse, evaluate, treat, and communicate risk in an effective way.
- 2.2 The risk register should be reviewed regularly and in line with trust / organisation policy.

### Typical risk management process:



### 3. Standard Statement on Risk Identification

**Sexual and Reproductive Healthcare services should have a system which enables a comprehensive approach to risk identification and should include both prospective and retrospective indicators.**

- 3.1 All services should have formal processes for identifying anything which may interfere with the delivery of safe, good quality care. These should apply to all modes of service delivery including outreach.
- 3.2 Risk identification should address factors relating to service providers as well as service users.
- 3.3 All staff should be able to complete an incident report.
- 3.4 Local tools used to identify risk include:
- ▶ Incident and near-miss reporting systems. (A suggested trigger list for incident reporting in sexual and reproductive health care services is contained in the Appendix.)
  - ▶ Complaints and claims
  - ▶ Freedom of Information (FOI) request
  - ▶ Patient satisfaction surveys
  - ▶ Staff consultation – surveys, workshops, interviews
  - ▶ Clinical Audit
  - ▶ Structured assessment when reviewing services or planning changes in services
  - ▶ New or changing legislation
  - ▶ Performance monitoring
  - ▶ Actions following an inspection by infection prevention, fire or safety experts etc.
  - ▶ Actions following inspection by independent healthcare regulators e.g. [Care Quality Commission \(England\)](#), [Healthcare Improvement Scotland \(HIS\)](#), [Healthcare Inspectorate \(Wales\)](#) and the [Regulation and Quality Improvement Authority \(Northern Ireland\)](#)
  - ▶ Information from manufacturer's/suppliers e.g. safety data sheets and hazard warning labels
  - ▶ Safeguarding protocols, reports and case reviews
- 3.5 National data useful in identifying risk includes:
- ▶ [Care Quality Commission \(CQC\)](#) reports
  - ▶ Medical Defence Society data
  - ▶ [MHRA](#) reports

- ▶ National Guidance - e.g. [FSRH](#), [British Association for Sexual Health and HIV \(BASHH\)](#), [Scottish Intercollegiate Guidelines Network \(SIGN\)](#), [National Institute for Health and Care Excellence \(NICE\)](#), [Public Health England \(PHE\)](#), [Cochrane](#)
- ▶ [National Service Frameworks \(Wales\)](#)
- ▶ [NHSLA](#)
- ▶ Professional bodies e.g. [General Medical Council \(GMC\)](#), [Nursing and Midwifery Council \(NMC\)](#), and [General Pharmaceutical Council \(GPC\)](#).

3.6 Online provision of sexual health services and digital health is a growing field of expertise. Use of online service provision should follow the general principles as detailed in this document and [Service Standards for Sexual and Reproductive Healthcare](#). There is further supporting guidance from the [CQC](#).

## 4. Standard Statement on Risk Assessment and Evaluation

**Risk assessment should be carried out routinely to establish the level of risk associated with a particular activity.**

- 4.1 Risk is regarded as being composed of two factors: the likelihood of an event occurring or re-occurring and the consequences that may result.
- 4.2 Likelihood and consequences are combined to produce a level of risk. A risk might have a low likelihood of occurring or re-occurring, but if it did, would have significant consequences for the user, staff and/or the organisation. Alternatively, a risk may occur every day, but have little or no consequence.
- 4.3 Every organisation has its own risk assessment matrix, where a severity ranking is applied to give an indication of how serious an event would be. (Example 1)
- 4.4 Staff should be familiar with their local Risk Assessment matrix.

Example 1. Risk Matrix ([National Patient Safety Agency, 2007](#))

	Catastrophic	Yellow	Orange	Red	Red	Red
	Major	Yellow	Orange	Orange	Red	Red
Consequence	Moderate	Green	Yellow	Orange	Orange	Red
	Minor	Green	Yellow	Yellow	Orange	Orange
	Negligible	Green	Green	Green	Yellow	Yellow
		Rare	Unlikely	Possible	Likely	Almost certain
		Likelihood				

## 5. Standard Statement on Response to Risk

**The cause of any incident should have a clear process for analysis.**

- 5.1 This process of analysis should include:
- i) Identifying the range of responses for dealing with the risk highlighted
  - ii) Preparing a risk reduction action plan and
  - iii) Implementing the plan in a specified time-frame.
- 5.2 One of the following Risk responses should be considered:
- ▶ **Avoid:** making changes or alterations so that the risk can no longer happen or have an impact
  - ▶ **Reduce:** proactive actions are taken to reduce the probability of the risk happening or to reduce the impact should it occur by putting in measures to minimise the consequences
  - ▶ **Accept:** a conscious decision is taken to retain the risk as benefit outweighs harm. This decision should be continuously monitored to ensure the risk remains tolerable
  - ▶ **Share:** arrange for a third party to share some part of the risk through joint ventures, contracts or partnerships, etc.
- 5.3 The response made to a specific risk will be influenced by the risk severity ranking (see 4.3).
- 5.4 An action plan should be developed by the risk management group to implement the appropriate response identified.
- 5.5 Consideration should be made within the action plan for a “risk budget”. Funds may be necessary to enable the risk response to be actioned e.g. to pay for retraining of staff or procurement of equipment.
- 5.6 There should be a realistic timeframe set for the implementation of each element of the action plan.
- 5.7 Strategies for measuring how effective the risk response has been and methods for communicating the outcomes should be embedded within the action plan (Section 6).

## 6. Standard Statement on Monitoring, Review and Feedback

**Risk and response to risk should be monitored by a designated team within a department and a risk register should be maintained.**

- 6.1 The risk management group should meet regularly to monitor and review incidents and their action plans within the service.
- 6.2 All identified risks, responses, action plans and consequent outcomes should be entered into a risk register.
- 6.3 The risk management group should liaise, as appropriate, with staff to inform changes in protocols and patient referral pathways.
- 6.4 Feedback within the service should be provided in ways appropriate to the service, e.g newsletters, face-to-face meetings, email, departmental training days.
- 6.5 Feedback should:
  - ▶ Acknowledge the contribution of staff
  - ▶ Include the incidents or risks identified
  - ▶ Demonstrate learning using the data collected e.g. a Root Cause Analysis (RCA) and reflection exercise
  - ▶ Identify actions taken or seek assistance to address these e.g. through further training
  - ▶ Aim to develop trust in the reporting system
  - ▶ Emphasise the importance of risk management and the value of reporting.
- 6.6 Communication to external sources as relevant e.g. [RIDDOR](#), [NHS Improvement](#), [NHSLA](#), [MHRA](#) should take place through the organisation's risk management team or other appropriate pathways.
- 6.7 Support should be provided, including emotional support, for those involved in reporting and a culture of 'no blame' should be promoted.

## Appendix to Standard Statement 3 on Risk Identification

***These are areas of potential risk in sexual and reproductive health care settings. Please note that the lists below are not exhaustive. They are a guide and should be added to as and when further information becomes available.***

### **1. Procedures**

#### 1.1 Invasive procedures:

- ▶ Intrauterine e.g. IUD insertion, removal; surgical abortion
- ▶ Cervical Screening
- ▶ Genital swabs
- ▶ Contraceptive implant insertion and removal
- ▶ Vasectomy
- ▶ Venepuncture.

#### 1.2 Intramuscular injection e.g. progestogen-only contraceptive injection.

#### 1.3 Improper handling of sharps and clinical waste.

#### 1.4 Use of Latex.

#### 1.5 Resuscitation: training, equipment and drugs.

### **2. Organisation and/or Environmental hazards**

#### 2.1 Lack of communication to staff regarding change in organisation of clinics/services.

#### 2.2 Poor standards of cleanliness.

#### 2.3 Poor physical environment.

#### 2.4 Lack of prompt access to appropriate health care for staff exposed to blood borne viruses.

#### 2.5 Interruptions causing distraction and potential mistakes.

#### 2.6 Non-availability or poor quality of equipment necessary for the procedure e.g. non-adjustable couch could cause a back injury to clinician.

#### 2.7 Lack of security for staff.

- 2.8 Aggression of clients.
- 2.9 Lack of team working.
- 2.10 Lone working.
- 2.11 Inadequacy of relevant information sharing between agencies.

### **3. Capacity versus Workload (see also [FSRH Workload Standards](#))**

- 3.1 Too many patients for capacity.
- 3.2 Too few doctors/nurses in individual settings.
- 3.3 General staff shortages and difficulty covering sickness and annual leave, leading to services not meeting needs of patients (e.g. in walk-in clinics).
- 3.4 Shortage of time to counsel patients properly.
- 3.5 Excessive number of trainee/junior staff needing additional time for consultations or for supervision and feedback from mentors and trainers.
- 3.6 Clinics running over time.
- 3.7 Staff doing too many clinics in one day (tiredness of staff).
- 3.8 Poor communication resulting from working under pressure of time.
- 3.9 Vulnerable clients needing staff time and expertise (e.g. under 16s, those with language difficulties and/or learning disabilities).

### **4. Staff Management (see also [FSRH Service Standards for Sexual and Reproductive Healthcare](#), [Record Keeping and Workload Standards](#))**

- 4.1 Lack of training, competencies and accreditation.
- 4.2 Lack of clinical supervision and regular appraisals.
- 4.3 Poor morale, communication skills and team working.
- 4.4 Inadequate/no time for continuing professional development.
- 4.5 Limited or no access to up to date departmental and national guidelines, in paper and electronic format.
- 4.6 Lack of clarity about individual roles and responsibilities.

- 4.7 Lack of awareness of risk and importance of risk management and reporting procedures.
- 4.8 Inadequate knowledge of particular service (new staff/locums).
- 4.9 Poor record keeping i.e. illegible, inaccurate, incomplete or non-contemporaneous records.
- 4.10 User identification not clearly established.
- 4.11 Patient consent not obtained.
- 4.12 Inadequate labelling of diagnostic samples.
- 4.13 Lack of adequate chaperone provision.
- 4.14 Lack of support around communication e.g. interpreters.
- 4.15 Lack of safeguarding supervision (through, for example, lack of policies, guidelines or clinical support) with regard to the management of children and vulnerable adults.

## **5. Medicines Management (see also [FSRH Record Keeping and Medicines Management Standards](#))**

- 5.1 Labelling is not clear and does not meet legal requirements.
- 5.2 Inappropriate storage, handling and administration of medication.
- 5.3 No patient information leaflets provided with supply of medicine.
- 5.4 Inadequate medical history, hence inability to prevent drug interaction and anaphylaxis.
- 5.5 Lack of security to prevent theft of drugs and prescription pads.
- 5.6 Usage of similar containers for different drugs.
- 5.7 Lack of processes in place for checking expiry date and stock rotation.
- 5.8 Lack of clear prescribing - i.e. details of prescription and indication not clearly recorded.

- 5.9 Provision of treatment outside clinician's competence - e.g. supply beyond PGD parameters.
  
- 5.10 Inadequate knowledge and use of reporting systems for errors or adverse reactions - both organisational internal incident reporting procedure and external reporting to MHRA – Yellow card.
  
- 5.11 Lack of system, where appropriate, for explanation to user and recording of supply/administration off-licence.

## **6. Confidentiality (see also [FSRH Confidentiality and Record Keeping Standards](#))**

- 6.1 Absence of Confidentiality Statements in all clinics.
- 6.2 Lack of staff training in confidentiality.
- 6.3 Lack of awareness/avoidance of conversations (including those on the telephone) being overheard.
- 6.4 Contact restrictions and permissions not discussed and recorded and not checked prior to contacting patient or other parties - e.g. GPs.
- 6.5 Records/forms left where other patients can read them.
- 6.6 Lack of sound-proofing of rooms.
- 6.7 Lack of access to confidential electronic network e.g. - nhs.net.

## **7. Patient Involvement (see also [FSRH Service Standards for Sexual and Reproductive Healthcare](#))**

- 7.1 Lack of patient involvement in service design.
  
- 7.2 Patients' needs not catered for in service design.

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