Faculty of Sexual and Reproductive Health Care
of the Royal College of Obstetricians and Gynaecologists

SERVICE STANDARDS FOR RISK MANAGEMENT IN SEXUAL AND REPRODUCTIVE HEALTHCARE SERVICES

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GLOSSARY OF TERMS associated with risk management

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, reputation); or • 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a hazard which fails to turn into an event by chance or by timely intervention, for example, medicines discovered to be out of date and removed.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 suffered no ill effects, that 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 loss of or damage to property or equipment
NHSLA	NHS Litigation Authority
MHRA	Medicines and Healthcare products Regulatory Authority
NPSA	National Patient Safety Agency
DFSRH	Diploma of the Faculty of Sexual and Reproductive Healthcare
LOC	Letters of Competence of the Faculty of Sexual and Reproductive Healthcare
IUD	Intrauterine Device
PGD	Patient Group Direction

SERVICE STANDARDS FOR RISK MANAGEMENT

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.

Definitions for risk management may vary. The NHS Commissioning Board (NHS CB) [1] defines a risk as an uncertain event or set of events that, should it occur, will have an effect on the achievement of objectives of a programme area (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.

The NHS Commissioning Board goes on to define:

Risk management as the systematic application of management policies, procedures and practices to the tasks of identifying, analysing, assessing, treating and monitoring risk.

Risk assessment as 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 process of risk management was integrated into the Department of Health's "Standards for Better Health" document (2004)[2]. This document describes 24 essential or "core" standards that all healthcare organisations should be achieving. These standards are the main driver for continuous improvement in quality. They provide the framework for the provision and assessment of health care in terms of safety, clinical and cost effectiveness, governance, patient focus, accessible and responsive care, environment and amenities and public health. The "Standards for Better Health" were then replaced in 2009/10 by registration criteria[3] established by the Department of Health and Care Quality Commission.

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 on other types of risk, i.e. operational and financial 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. Risk should not be ignored. Ongoing training in quality improvement and risk management is important for all professionals working in sexual and reproductive healthcare services.

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.

The NHS Litigation Authority has produced Risk Management Standards[4] for the following areas:

1. Governance
2. Learning from Experience
3. Competent and Capable Workforce
4. Safe Environment
5. Acute, Community and Non-NHS Providers
6. Mental Health and Learning Disability.

The NHS LA standards are designed to:

- improve the safety of patients, staff and others;
- provide a framework within which to focus risk management activities in order to support the delivery of quality improvements in patient care, organisational governance, and the safety of patients;
- assist in the identification of risk;
- contribute to embedding risk management into the organisation's culture;
- focus organisations on increasing incident reporting whilst decreasing the overall severity of incidents;
- encourage awareness of and learning from claims;
- reflect risk exposure and enable organisations to determine how to manage their own risks;
- encourage and support organisations in taking a proactive approach to improvement;
- provide information to the organisation, other inspecting bodies and stakeholders on how areas of risk covered by the standards are being managed at the time of the assessment.

The progression of organisations through the standards is logical and follows the development, implementation, monitoring and review of policies and procedures.

Level 1 – Documenting (Policy)

This demonstrates that the process for managing risks has been described and documented.

Level 2 – Implementing (Practice)

This demonstrates that the process for managing risks, as described in the approved documentation, is in use. Evidence should be provided for a number of departments and/or staff groups and/or patient types, etc. The evidence may include risk assessments, records, e.g. training, medical device inventories, incident reports, completed proformas, evaluations, etc.

Level 3 – Monitoring (Performance)

This demonstrates whether or not the process for managing risk, as described in the approved documentation, is working across the entire organisation. Where failings have been identified, action plans must have been drawn up and changes made to reduce the risks. Monitoring is normally proactive - designed to highlight issues before an incident occurs - and should consider both positive and negative aspects of a process.

The existence of a risk management system, even one complying with the NHS LA standards, does not of itself mean that an organisation is safe. There are lots of other factors that are relevant when considering safety. Although effective risk management processes are important, they are only one of the many things which should be considered when assessing whether practices are safe for staff and patients. Because of this the NHS LA has decided that it will no longer update the standards and there will be no further assessments from March 2014. In their place the NHS LA is developing a Safety and Learning Service.

The Safety and Learning Service will provide:

- Information: Real time data related to claims on a secure extranet.
- Knowledge: Best practice guidance including those developed by new Safety and Learning Advisory Groups to be shared with NHS LA members on the Safety and Learning Library in the extranet.
- Targeted activity: The NHS LA will work in partnership with clinicians, risk managers, claims managers, Royal Colleges and other key stakeholders to support the NHS to initially target a reduction in harm in maternity and surgery.
- Mechanisms for Sharing: The NHS LA will get people together to share knowledge, ideas and local activity via webinars, local events and targeted collaborative networks.

This document outlines the basic principles of risk management and the process for implementing risk management in the context of contraceptive and sexual and reproductive healthcare services.

1. Standard Statement on Risk Management Strategy

Sexual and Reproductive Health Care services should have a Risk Management Strategy which is linked with the Organisations 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 clinician as the designated lead.

1.3 Membership of this group should be multi-disciplinary e.g. nurses, administrative staff and link person from the Organisation's clinical governance team. Consultation and involvement of staff and service users is essential.

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.

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. It should be the responsibility of every member of staff to recognise, respond to, report, record, be accountable and reduce risks whilst they are undertaking work for the Organisation.

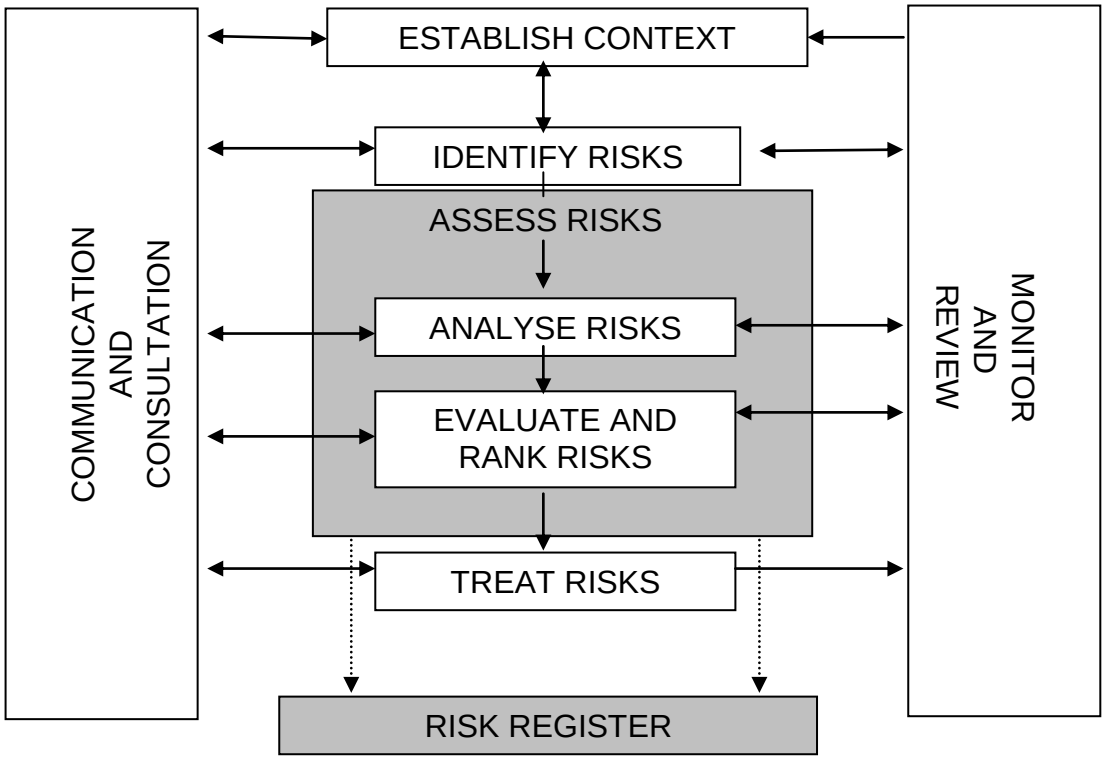
1.6 Training and updating programme for risk management should be available to all staff.

2. Standard Statement on Risk Management Process

The Risk Management Process should identify, assess and treat risk. A risk register should be established with a process for monitoring and review of risk.

An effective Risk Management System is the systematic application of management policies, procedures and practices to the tasks of establishing the context of, identifying, analysing, evaluating, treating, monitoring and communicating risk.

A Typical Risk Management Process[10]



3. Standard Statement on Risk Identification

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

3.1 All areas where services are provided should have formal processes for identifying anything which may interfere with the delivery of a safe, good quality service. This includes outreach settings.

3.2 All staff should be able to complete an incident report.

3.3 Local tools used to identify risk include:

- Incident and near-miss reporting systems
- (Suggested trigger list for incident reporting in sexual and reproductive health care services are 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 service or planning changes in service
- New or changing legislation
- Performance monitoring
- Following an inspection by infection prevention, fire or safety experts etc.

3.4 National data useful in identifying risk:

- National Patient Safety Agency (NPSA) Alerts
- Healthcare Commission reports
- Medical Defence society's data
- Training, accreditation and competencies e.g. DFSRH and LoC
- MHRA reports
- NICE guidance's
- National Service Frameworks
- NHSLA
- SIGN

3.5 Although avoidance of complaints/litigation is important, the care and safety of patients, carers and staff should be the primary concern.

4. Standard Statement on Risk Assessment and Evaluation

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

4.1 Risk is regarded as being composed of two factors: the likelihood of an event occurring and the consequences that take place as a result.

4.2 Likelihood and Consequences are combined to produce a level of risk. A risk might have a low likelihood of occurring, but if it did, would have severe 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.

4.4 Relevant staff should be familiar with their local Risk Assessment matrix.

5. Standard Statement on Treatment of Risk (Action Plan)

The cause of any incident should be managed by identifying the range of options for dealing with the risk associated, assessing the options, preparing a risk reduction action plan and implementing the plan.

5.1 Risk Treatment Options: One of the following options should be considered:

Risk Avoidance:	do not proceed with activity or enter that situation
Risk Reduction:	put in measures to minimise the consequences
Risk Acceptance:	risk will never be completely eliminated
Risk Transfer:	arrange for another party to share some part of the risk through joint ventures, contracts or partnerships, etc.

5.2 Risk treatment will be influenced by the risk rating.

5.3 An action plan should be developed by the risk management group to define the strategies to be implemented to reduce the risk of similar events occurring again.

5.4 There should be identification of significant resource implications required to reduce risk and where a change in the culture of the service is needed.

5.5 The action plan should address responsibility for implementation of each action item identified including a timeframe.

5.6 The action plan should also have strategies for measuring the effectiveness of the action items.

6. Standard Statement on Monitoring, Review and Feedback

Risk should be monitored by establishing and maintaining a risk register.

6.1 All identified risks, action plans and consequent outcomes should be entered into a risk register.

6.2 The risk management group should meet regularly to monitor and review incidents within the service.

6.3 This group should liaise with the protocol group to inform changes in protocols and patient referral pathways.

6.4 Feedback within the service should be provided via newsletter, meetings or e-mail where available. Feedback should:

- Acknowledge the contribution of staff,
- Include the issues identified,
- Demonstrate learning using the data,
- Identify the actions taken or seek assistance to address these

6.5 Feedback should also be given to individual staff; the objective of this is to:

- Reassure them that they make a valuable contribution to the enhancement of safety,
- Develop trust in the system,
- Make them understand the importance of risk management and the value of reporting

6.6 Communication to external sources as relevant e.g. NPSA, NHSLA, MHRA should take place through the organisations risk management team.

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 instrumentation e.g. IUD insertion, surgical abortion
- Cervical Screening
- Genital swabs
- Contraceptive implant insertion and removal
- Vasectomy
- Venepuncture
- Immunisation

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 bourne 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 Faculty website for Workload Standards[5])

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 process 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 time

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, language difficulties, learning disabilities)

4. Staff Management (see also Faculty website for Service Standards for Sexual and Reproductive Healthcare [8], Record Keeping[7] and Workload Standards[5])

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

4.8 Inadequate knowledge of particular service (new staff/locums)

4.9 Patchy record keeping

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 regards to the management of children and vulnerable adults.

5. Medicines Management (see also Faculty website for Record Keeping[7] and Medicines Management Standards[9])

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

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 externally 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 Faculty website for Confidentiality[6] and Record Keeping standards[7])

6.2 Absence of Confidentiality Statements in all clinics

6.3 Lack of staff training in confidentiality

6.3 Lack of awareness/avoidance of conversations (including those on the telephone) being overheard

6.4 Communication status not discussed with patients and documented before any contact from the clinic

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 Faculty website for Service Standards for Sexual and Reproductive Healthcare [8])

7.1 Lack of patient involvement in service design

7.2 Patients needs not catered for in service design

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