FSRH The Faculty of Sexual & Reproductive Healthcare

Service Standards for Clinical Risk Management in Sexual and Reproductive Healthcare

2022 | FSRH

The Faculty of Sexual and Reproductive Healthcare (FSRH) is the largest UK professional membership organisation working in the field of sexual and reproductive health (SRH). We support healthcare professionals to deliver high quality healthcare, including access to contraception. We provide our 15,000 doctor and nurse members with National Institute for Clinical Effectiveness (NICE) accredited evidence-based clinical guidance, including the UK Medical Eligibility Criteria (UKMEC), the gold standard in safe contraceptive prescription, as well as clinical and service standards.

The FSRH provides a range of qualifications and training courses in SRH, and we oversee the Community Sexual and Reproductive Healthcare (CSRH) Specialty Training Programme to train consultant leaders in this field. We deliver SRH focused conferences and events, provide members with clinical advice and publish *BMJ Sexual & Reproductive Health* – a leading international journal. As a Faculty of the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK, we work in close partnership with the College but are independently governed.

The FSRH provides an important voice for UK SRH professionals. We believe it is a human right for all individuals to have access to the full range of contraceptive methods and SRH services throughout their lives. To help to achieve this we also work to influence policy and public opinion, working with national and local governments, politicians, commissioners, policy makers, the media and patient groups. Our goal is to promote and maintain high standards of professional practice in SRH to realise our vision of holistic SRH care for all.

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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)

Risk - the likelihood of the hazard occurring multiplied by the severity of the consequences. Other words, such as probability or impact, are sometimes used instead.

Risk Assessment - a systematic process for identifying and prioritising the need to plan for likely risk.

Risk Management - a systematic process for assessing the likely impacts and planning mitigation strategies to be implemented. This is supplemented by testing and reviewing plans.

Controls - documents, systems, processes, devices, and equipment intended to mitigate thelikelihood 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 Medicines and Healthcare products Regulatory Agency (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.

NHS Resolution- NHS Resolution 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 reportspecified workplace incidents.

Contents

SERVICE STANDARDS FOR CLINICAL RISK MANAGEMENT IN SEXUAL AND REPRODUCTIVE HEALTHCARE

Changes Introduced since Review

- Updated introduction in accordance with the new national governance structures, devolved nations and regulatory bodies
- References are added as footnotes

Introduction

Clinical Risk Management is an approach to improving the quality and safety of health care by identifying circumstances that put patients at risk and acting to prevent or mitigate against those risks. The overall aim of any clinical 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 measured in terms of impact and likelihood. Every action taken could have either a positive, negative, or neutral impact, and the likelihood of these impacts occurring can range from very high to very low.

Risk assessment and management, therefore, can be defined as: the systematic application of policy, procedure, and practice to identify the possible impacts and likelihoods in certain situations, having actions in place to minimise those that are not acceptable at their current level and monitoring the ongoing effectiveness of these actions, changing and reassessing where necessary.

This document does not explicitly consider all types of risk independently. It does acknowledge that there are significant interdependencies between clinical risk and other types of risk, and that reducing risk in one area may increase it in others. Information on where to explore some of these other risk categories is contained in Appendix 1.

A clinical 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

Clinical risk management is the responsibility of all staff, regardless of individual roles and responsibilities, and should be part of an ongoing focus on quality improvement. Ongoing training in quality improvement and risk management is important for all professionals working in sexual and reproductive healthcare services and support should beavailable to staff.

Risk will always be a factor present in the provision of health care. The key to successful clinical 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 clinical risk management and the process for implementing clinical risk management in Sexual and Reproductive Healthcare Services.

1 Standard Statement on Clinical Risk Management Strategy

Sexual and Reproductive Healthcare services must have an up-to-date Clinical Risk Management Strategy, linked to any parent organisational strategy where appropriate

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 parent organisation's clinical governance team.

1.4 A risk register, including clinical risks, must be established.

1.5 There must be an action plan relating to the risks contained in the register.

1.6 Stratification processes should be in place to determine levels of risk (Standard 4).

1.7 Systems must 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.

1.8 It is 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.

1.9 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.

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

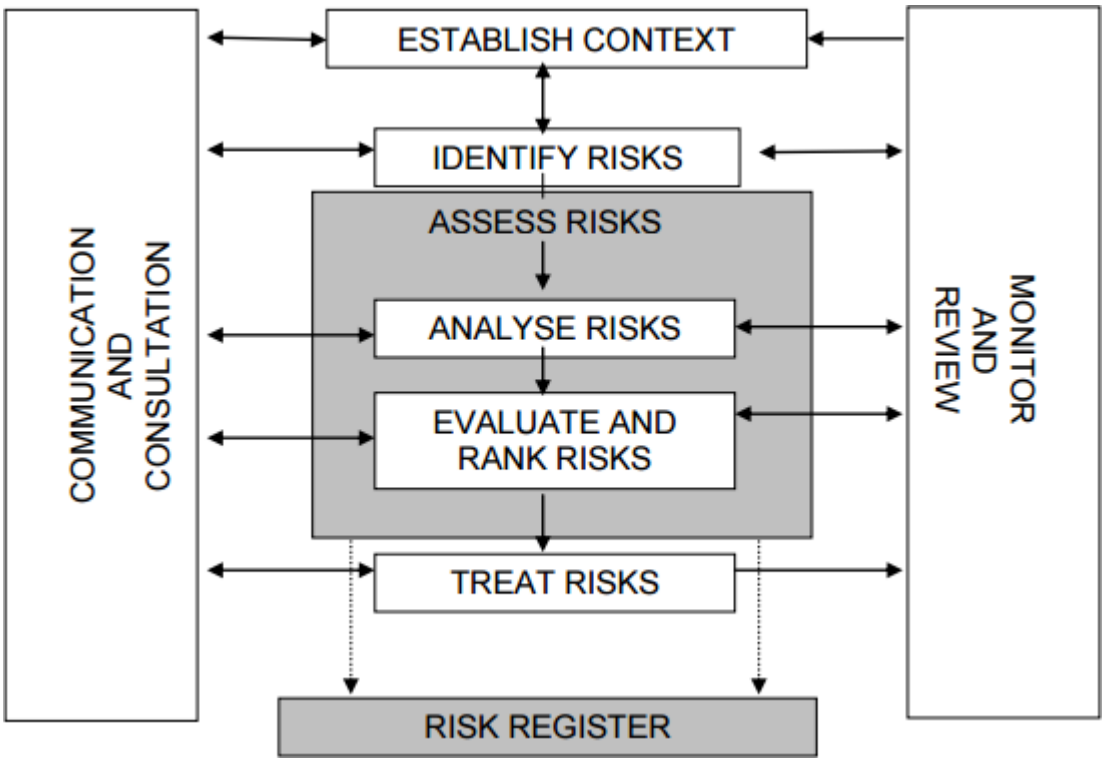
2 Standard Statement on Clinical Risk Management Process

A detailed risk register must be established, alongside a process to monitor and review the risks regularly

2.1 An effective Risk Management System should be able to apply policies, procedures, and practices systematically in order to identify, analyse, evaluate, manage, and communicate risk in an effective way.

2.2 The risk register must be reviewed regularly and in line with trust / organisation policy.

Typical risk management process



3 Standard Statement on Clinical Risk Identification

All sexual and reproductive healthcare services should offer the opportunity for staff and patients to provide feedback on their clinical risk management strategy

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 must 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 Appendix 2)
- 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),**Error! Bookmark not defined.** Healthcare Improvement Scotland (HIS),**Error! Bookmark not defined.** Healthcare Inspectorate (Wales)**Error! Bookmark not defined.** and the Regulation and Quality Improvement Authority (Northern Ireland)**Error! Bookmark not defined.**
- 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)**Error! Bookmark not defined.**
- Medical Defence Society data[1]
- National Guidance - e.g. FSRH[2], British Association for Sexual Health and HIV (BASHH),[3] Scottish Intercollegiate Guidelines Network (SIGN),[4] National Institute for Health and Care Excellence (NICE),[5] Cochrane Library[6]
- National Service Frameworks (Wales)[7]
- NHS Resolution
- Professional bodies e.g., General Medical Council (GMC),[8] Nursing and Midwifery Council (NMC),[9] and General Pharmaceutical Council (GPC)[10]

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 FSRH Service Standards for Sexual and Reproductive Healthcare.[11] There is further supporting guidance from the Care Quality Commission.

[1] Medical Defense Society, 2021. *Medical Defense Society*
[2] FSRH, 2021. *Faculty of Sexual and Reproductive Healthcare*
[3] BASHH, 2021. *British Association for Sexual Health and HIV*
[4] Sign, 2021. *Scottish Intercollegiate Guidelines Network*
[5] NICE, 2021. *National Institute for Health and Care Excellence*
[6] Cochrane Library, 2021. *Cochrane Library*
[7] NHS Wales, 2021. *National Service Frameworks*
[8] GMC, 2021. *General Medical Council*
[9] NMC, 2021. *Nursing and Midwifery Council*
[10] GPC, 2021. *General Pharmaceutical Council*
[11] Faculty of Sexual and Reproductive Healthcare, 2016. *FSRH Service Standards for Sexual and Reproductive Healthcare*

4 Standard Statement on Clinical Risk Assessment and Evaluation

Risk assessment must be carried out every time a new service change/activity is introduced

4.1 Risk is regarded as being composed of two factors: the likelihood of an event occurring or re-occurring and the severity of the consequences that may result.

4.2 Likelihood and consequence 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 must be familiar with their local Risk Assessment matrix.

Example 1. Risk Matrix[12]

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

Likelihood

[12] Health and Safety Executive, 2021. *Complaints – Step 6: Risk Matrix and Local factors.*

5 Standard Statement on Response to Clinical Risk

1. All Serious Unexpected Incidents must be subject to root cause analysis

2. Opportunities should be sought wherever possible to share learning around clinical risk management e.g., audit presentations, peer review publications, local or regional staff meeting feedback

5.1 Allocated time within training clinics should be used for feedback and assessment with a focus on clinical risk assessment. This process of analysis should include:

- Identifying the range of responses for dealing with the risk highlighted
- Preparing a risk reduction action plan and
- 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 clinical risk management group to implement the appropriate response identified; consider using SMART goals to structure this

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 clinical risk response has been and methods for communicating the outcomes should be embedded within the action plan (see Standard 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 an up-to-date risk register must be maintained

6.1 The risk management group must 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 must be entered into a risk register.

6.3 The risk management group must liaise, as appropriate, with staff to inform changes in protocols and patient referral pathways.

6.4 Feedback within the service will 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, NHS Resolution, MHRA should take place through the organisation's risk management team or other appropriate pathways.

6.7 Organisations must strive to develop a 'no blame' culture around risk and risk management

6.8 Support must be provided, including emotional support, for those involved in reporting of risks and incidents

Appendix 1

The Health and Safety Executive (HSE)[13] 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[14] 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)[15] and the Care Inspectorate[16]. Within Wales these responsibilities are shared with the Healthcare Inspectorate Wales (HIW)[17] and the Care Inspectorate Wales (CIW)[18]. In Northern Ireland, these regulation responsibilities are overseen by the Regulation and Quality Improvement Authority.[19]

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 ina better position to respond to patient or service user incidents or complaints. They include professional bodies such as the General Medical Council (GMC)[20], Nursing and Midwifery Council (NMC)[21], and the Medicines and Healthcare Products Regulatory Agency (MHRA)[22] .

Appendix 2

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 beadded to as and when further information becomes available.

1. Procedures

1.1 Invasive procedures:

- Intrauterine e.g., IUD insertion, removal; surgical abortion
- Cervical Screening

[13] Health and Safety Executive (HSE), 2021. *Health and Safety Executive*.
[14] Care Quality Commission, 2021. *Care Quality Commission.*
[15] Healthcare Improvement Scotland (HIS), 2021. *Healthcare Improvement Scotland.*
[16] Care Inspectorate, 2021. *Care Inspectorate.*
[17] Healthcare Inspectorate Wales (HIW), 2021. *Healthcare Inspectorate Wales.*
[18] Care Inspectorate Wales (CIW), 2021. *Care Inspectorate Wales.*
[19] Regulation and Quality Improvement Authority, 2021. *Regulation and Quality Improvement Authority*.
[20] General Medical Council (GMC), 2021. *General Medical Council.*
[21] Nursing and Midwifery Council (NMC), 2021. *Nursing and Midwifery Council.*
[22] Medicines and Healthcare Products Regulatory Agency (MHRA), 2021. Medicines and Healthcare Products Regulatory Agency.

- Genital swabs
- Contraceptive implant insertion and removal
- Vasectomy
- Venepuncture

1.2 Intramuscular injection e.g., progestogen-only contraceptive injection, vaccinations

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 Unsafe physical environment

2.4 Lack of prompt access to appropriate health care for staff exposed to blood borne viruses, including occupational follow up if required

2.5 Physical or virtual 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 effective team working

2.10 Lone working

2.11 Inadequacy of relevant information sharing between agencies[23]

3. Capacity versus Workload (see also FSRH Workload Standards)[24]

3.1 Too many patients for clinic capacity

3.2 Too few staff members of required skill mix in individual settings

3.3 General staff shortages and difficulty covering sickness and annual leave, leading to

[23] FSRH, 2020. *FSRH Service Standards for Confidentiality in Sexual and Reproductive Health Services*.

[24] FSRH, 2020. *FSRH Service Standards for Workload in Sexual and Reproductive Health Services*

services not meeting needs of patients (e.g., in walk-in clinics)

3.4 Shortage of time to counsel patients properly

3.5 Reduced capacity for educational supervision

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)[24, 25, 26]

4.1 Wrong mix of training, competencies, and accreditation amongst employed staff

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 and appraisal

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 as requested by staff/patients

4.14 Lack of support around communication e.g., interpreters

4.15 Lack of safeguarding supervision (through, for example, lack of policies, guidelines, or

[25] FSRH, 2016. *FSRH Service Standards for Sexual and Reproductive Healthcare*
[26] FSRH, 2019. *FSRH Service Standards for Record Keeping in Sexual and Reproductive Healthcare*

clinical support) with regard to the management of children and vulnerable adults

5. Medicines Management (see also FSRH Record Keeping and Medicines Management Standards)[26, 27]

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 leading to inability to prevent drug interaction and anaphylaxis

5.5 Lack of security to prevent theft of drugs and prescription pads/access to online prescription systems

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)[23, 26]

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 and online remote consultations) 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

[27] FSRH, 2018. *FSRH Service Standards for Medicines Management in Sexual and Reproductive Health Services*

6.6 Lack of soundproofing of rooms

6.7 Lack of access to confidential electronic network

7. **Patient Involvement** (see also FSRH Service Standards for Sexual and Reproductive Healthcare)25

7.1 Lack of patient involvement in service design

7.2 Patients' needs not catered for in service design