Communitas Clinics

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Incident and Near Miss Events Policy

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SUMMARY

The DOH paper 'A First Class Service' (1998) and the DOH report 'An Organisation with a Memory' (2000) places risk management programmes and incident reporting as some of the main components of clinical governance.

Extensive study has shown that with most unintentional failures, there is usually no single explanatory cause for the event. Rather there is a complex interaction between a varied set of elements, including human behaviour, technological aspects of the system, socio-cultural factors and a range of organisational and procedural weaknesses.

This policy and procedure for identifying, reporting, processing and evaluating incidents draws on identified best practice and recommendation from DOH guidance. It incorporates and encourages:

- A unified mechanism for reporting and analysis when things go wrong and emphasising the requirement for all staff to report all untoward events, including near misses.
- A more open culture, in which errors or service failures can be reported and discussed with assurance of no disciplinary action except in cases of gross misconduct, criminal or malicious acts, clinical negligence and repeated errors or violations.
- Mechanisms for ensuring that, where lessons are identified, the necessary changes are put into practice.
- A wider appreciation by all staff of a systematic approach in preventing, analysing and learning from errors and near misses.
- A system for ensuring Communitas is prepared to report to the necessary agencies such as the National Patient Safety Agency (NPSA) and complying with the Reporting of Injuries, Diseases, Dangerous Occurrence Regulations 1995 (RIDDOR).

CONTENTS

1 ASSOCIATED DOCUMENTS

This document should be read in conjunction with the following documents:

- All Information Governance Policies
- Health and Safety Policy
- Risk Management Policy
- Safeguarding Policies
- Serious Untoward Incident Policy
- Incident reporting procedure
- Incident reporting form
- Root Cause Analysis procedure
- Root Cause Analysis template

2 INTRODUCTION

2.1 Background

In a service as large and complex as the NHS or as a provider of services e.g. Communitas Clinics Ltd (Communitas), things will sometimes go wrong. When they do, the response should not be one of blame and retribution, but of learning, a drive to reduce risk for future patients, and concern for staff who may suffer as a consequence. In relation to doctors and patients, this is a fundamental pledge made by the Government, the medical profession, and the NHS in 'A Commitment to Quality, A Quest for Excellence', published on 27 June 2001.

The Department of Health publications 'An Organisation with a Memory' and 'Building a Safer NHS for Patients' identified the significant opportunities that exist to reduce unintended harm to patients arising during NHS care. This is supported by the recent work of Neale et al, who have established from retrospective medical record reviews that at least one in twenty NHS patients suffers preventable harm. The report of the public inquiry into children's heart surgery at the Bristol Royal Infirmary adds further impetus to the drive to improve the safety and quality of care.

2.2 Principles

The management of risk is a fundamental cornerstone of the delivery of healthcare. Whether there is the chance of something detrimental happening that impacts on the public's health, patient and staff safety or the organisation's ability to provide and commission care, or whether something actually happens, there

needs to be a framework that ensures proactive and appropriate management of those occurrences.

This policy describes Communitas' approach to recognising and reporting those incidents, and more importantly learning from them so that they do not occur again. The policy is intended to address both clinical and non clinical incidents – patient and staff harm, and organisational concerns.

The principles of the policy are that:

- Communitas recognises patient safety as paramount to the organisation;
- A clear process is needed for reporting, internally and where necessary externally;
- Learning from all events must take place;
- Learning must be translated into improved practice;
- An open and just culture is promoted that encourages reporting and supports learning from practice.

2.3 Purpose

This document sets out the key requirements for the organisation to manage, report, analyse and learn from incidents. The aim is to:

- Reduce the risk of harm to future patients through improving patient safety and quality of care;
- Reduce the risk of harm to staff whilst carrying out their duties;
- Ensure organisational fit for purpose.

It is not sufficient for organisations and individuals involved in provision of NHS care to learn and improve only from things that go wrong. Engaging in proactive risk management activity, in addition to the reactive process of incident management, will enable the identification of many things that could go wrong as part of a systematic approach to risk assessment. This is a fundamental requirement set out in the Department of Health Risk Management System standard (6). The need for sound ‘clinical’ risk management is further reinforced through the clinical governance agenda.

The cornerstone of the requirements set out in this policy is the need to establish the underlying cause(s) of serious incidents through root cause analysis. Unless the causes of adverse incidents are properly understood, lessons will not be learned and suitable improvements will not be made to secure a reduction in the risk of harm to future patients, or the organisation.

In many instances, the root causes of adverse incidents lie in the management and organisational systems that support the delivery of service, and blame cannot, and should not, be attributed to individual health care workers. Identifying and addressing dysfunctional systems is, therefore, the key to reducing future risk of harm.

The organisation will collect and analyse incident and other patient safety information and provide timely and relevant feedback to healthcare organisations, health care professionals, and patients/carers in a way that promotes learning and risk reduction through:

- Environmental and/or systems changes and/or
- Changes in organisational, management or clinical practice.

This policy should be read in conjunction with the following Communitas policies:

- Risk Management Policy
- Disciplinary Policy
- Health and Safety Policies
- Serious Untoward Incidents Policy

2.4 Definitions

Patient safety incident: any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving NHS-funded healthcare.

Serious incident requiring investigation (SIRI) one where serious actual harm has resulted (commonly classified as a 'red' incident). Reported via IGTK SIRI reporting tool

Serious Untoward Incidents (SUIs) involve the occurrence of the most serious incidents. There is no single definition but in general terms it is any event which involves the process of treatment, care or consultation on Communitas premises and results in, or could have resulted in:

- Significant harm;
- Unexpected death;
- Death directly related to an adverse event;
- Substantial damage or loss to Communitas' assets
- Adverse media interest;
- Risk to the Communitas' reputation and Infection outbreaks

Never Event: a serious, largely preventable patient safety incident that should not occur if the available preventative measures have been implemented

Near miss: a situation in which an event or omission, or a sequence of events or omissions, arising during clinical care fails to develop further, whether or not as a result of compensating action, thus preventing injury to a patient

Harm: an injury (physical or psychological), disease, suffering, disability or death. In most instances, harm can be considered to be *unexpected* if it is not related to the natural course of the patient's illness, treatment or underlying condition, or the natural course of events if harm occurs to other than a patient

Root cause analysis: A well recognised way of investigating incidents, claims and complaints, which offers a framework identifying what, how and why the event happened. Analysis can then be used to identify areas of change, develop recommendations and look for new solutions.

Accident:

- Anything that happens without apparent cause

Breach of confidentiality which includes:

- Finding a computer printout with a header and a person's information on it at a location outside of any Communitas premises/building;
- Finding any paper records about a patient/member of staff or business of the organisation in any location outside of the Communitas premises/buildings;
- Being able to view patient records in the back (or front) of an employee's car (e.g. Doctors and Nurses);
- Discussing, in person or on the phone, patient or staff personal information with someone else in an open area where the conversation can be overheard;
- A fax, email or letter being received by the incorrect recipient.

Breach of Security:

- Loss of computer equipment due to crime or an individual's carelessness;
- Loss of computer media e.g. floppy disc, CD due to an individual's carelessness;
- Accessing any part of a database using someone else's authorisation either fraudulently or by accident;

- Trying to access a secure part of the organisation using someone else's PIN number, swipe card;
- Finding the doors and/or windows have been broken and forced entry gained to a secure room/building.

Information Security Incident: any event that has resulted or could result in:

- The disclosure of confidential information to any unauthorised person;
- The integrity of the system or data being put at risk;
- The availability of the system or information being put at risk;
- An adverse impact e.g.:
    - Embarrassment to the NHS;
    - Threat to personal safety or privacy;
    - Legal obligation or penalty;
    - Financial loss;
    - Disruption of activities.

Hazard: 'a situation or risk with the potential to cause harm or damage':

- Hazards are situations with the potential to cause harm or damage. They could include faulty equipment, worn or loose floor coverings, irritant chemicals etc.
- Incident Report Forms must be completed for all hazards;
- Staff are responsible for not only completing the Incident Report Form but also taking reasonable steps at the time to minimise the risk of injury from the identified action.

Other incidents: Some incidents may impact on other parts of Communitas e.g. a computer virus and if this is the case the incident should be reported to the IT(NELCSU) Helpdesk. All Information Security Incidents will be reported to the Information Governance Lead by the IGSG.

Other Incident Categories:

- Accidental injuries
- Work related ill-health
- Unusual or dangerous occurrences
- Medication errors
- Adverse drug reactions
- Patient safety incidents
- Missing health records
- Violence or damage to property
- Equipment failures
- Fraud etc.

This list is not exhaustive but gives some examples of the wide range of adverse events that are categorised as reportable incidents.

Reportable Incidents: any event which contains one or more of the following components:

- Standards of patient care fall below those expected to deliver good patient care;
- An incident that places patients, staff or visitors at unnecessary risk;
- An incident that may adverse legal or media attention;
- There is risk or damage to property.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR 95) A number of incidents and accidents must be reported to the Health and Safety Executive under the RIDDOR regulations as defined below:

- **Dangerous Occurrences**: A 'dangerous occurrence' is a term used in RIDDOR 95, which specifically denotes types of incidents that are reportable under these regulations;
- **Major Injury**: RIDDOR regulations do not define a major injury; the list in Appendix A of the Incident Reporting Procedure identifies the types of injuries that are reportable. Further details can be obtained from the Communitas RIDDOR Policy and web site: http://www.riddor.gov.uk/.

Staff: 'Staff, volunteers, students and sub-contractors working for Communitas and independent contractors commissioned by the company.

2.5 Scope

A 'traffic light' system, where red denotes serious reportable incidents, and green acceptable risk, has been developed and this approach is supported by national agencies. The organisation has adopted the same principles within this policy for ease of compliance with national reporting guidelines.

The requirements presented in this policy with respect to red adverse patient and organisational incidents are applicable to all of primary care, including independent contractors. Complying with the requirements of this policy will enable the organisation and meet Department of Health incident management and reporting standards.

To maximise learning the policy not only relates to adverse incidents that could have or did lead to harm, but also relates to non-clinical incidents and those not

directly involving people. The policy describes a holistic and integrated system covering management, reporting, analysis and learning from practice.

The policy is congruent with the Medical Devices Agency mandatory 'vigilance' reporting scheme for medical device and equipment manufacturers and the voluntary system for reporting adverse incidents involving medical devices.

This policy is congruent with the Medicines Control Agency (MCA), which operates a national voluntary system for reporting suspected patient adverse drug reactions.

2.6 Roles and Responsibilities

It is the roles and responsibilities of the SIRO to ensure implementation of this policy. Managers will be responsible for implementing this policy and keeping the detailed implementation plan. The Board is responsible for setting the strategic context in which organisational policies and procedures are developed and for the formal review and approval.

2.7 Duties

This covers both strategic and operational roles, and can be an individual e.g. Finance Director or a committee, e.g. Information Governance Steering Group.

3 PROCEDURE/COURSE OF ACTION REQUIRED

3.1 Reportable Incidents

A reportable incident in this policy is any event that compromises patient, staff or visitor care or safety or causes damage to Communitas property, its assets or reputation event which contains one or more of the following components:

- Standards of patient care fell below those expected to deliver good patient care;
- An incident that places patients, staff or visitors at unnecessary risk;
- An incident that may adverse legal or media attention;
- There is risk or damage to property.

3.2 Serious Untoward Incidents (SUIs)

SUIs are reported to ICO/commissioner through IGTK SIRI reporting tool and also National Patient Safety Agency NPSA and Care Quality Commission CQC where appropriate.
All SUIs must be notified to the SIRO (or nominated deputy) immediately.
Full details of SUI definitions, notification and investigation arrangements are provided in the Communitas Serious Untoward Incident Policy.

3.3 Equality Impact Assessment

Communitas aims to design and implement incident reporting processes and procedures that meet the diverse needs of their service, population and workforce, ensuring that none are placed at a disadvantage over others. The Equality Assessment tool is designed to help staff consider the needs and assess the impact of the policy. See the AH Equality Impact Assessment tool.

3.4 Key requirements

All individuals involved directly or indirectly in patient care, including the organisational delivery of healthcare services, are aware of what constitutes an incident.

Incident reporting, grading and root cause analysis is part of the induction training for new staff. Training is also provided for those conducting investigations. Updates will be available.

Lessons will be learned from individual adverse patient incidents, from local aggregate reviews and from wider experiences, including feedback from the NPSA, Care Quality Commission Agency and other agencies or benchmarking processes.

Improvement strategies aimed at reducing risk will be implemented and monitored by the Commissioner. Where appropriate, local staff will learn lessons and change practice in order to improve the quality of care for patients and the safety for patients, staff and organisation.

3.5 Reporting Arrangements

Internal Reporting Arrangements

Flow charts directing the handling and reporting of adverse incidents occurring within Communitas are detailed in Incident Reporting Procedure. These charts should be laminated for display in all service delivery areas so they are available for immediate reference.

An Incident Reporting Form must be completed for all incidents relating to clinical services and organisational business . All identified risks will be added to the Risk Register and subsequently removed when all necessary action has been taken to eliminate or minimise to prevent future recurrence.

All reported incidents are graded either Red, Amber, yellow or green, according to the actual impact on the patient(s), potential future risk to patients and to the organisation, and reviewed to establish stakeholder reporting requirements e.g. MDA. The individual reporting the incident will carry out the grading.

		Consequence			
Likelihood	Insignificant	Minor	Moderate	Major	Catastrophic
Certain	High	High	Extreme	Extreme	Extreme
Likely	Moderate	High	High	Extreme	Extreme
Possible	Low	Moderate	High	Extreme	Extreme
Unlikely	Low	Low	Moderate	High	Extreme
Rare	Low	Low	Moderate	High	High

Incidents graded Green/yellow

The reporter must:

- Ensure the immediate safety of those directly affected by the incident
- Complete an adverse incident reporting (AIR) form
- Inform the appropriate senior member of staff / line manager

The senior member of staff must:

- Review and confirm the grading
- Complete details of any long-term actions necessary
- Copy form to the Adverse Incident Folder - to ensure a comprehensive history of incidents and actions taken
- Ensure feedback is provided to the reporter

Incidents graded Amber

The reporter must:

- Ensure the immediate safety of those directly affected by the incident
- Complete an AIR form
- Inform the appropriate senior member of staff/line manager
- Send copy of form to the Risk Management Department within 24 hours

The senior member of staff must:

- Review and confirm the grading;
- Ensure an amber investigation is instigated, in conjunction with the CSC Governance Lead;
- Consider the appropriateness and process for discussion of the incident with the patient, family or carer;
- Ensure feedback on decision to investigate is given to reporter;
- Ensure a copy of the investigation report is provided to the Risk Management Team, for inclusion on the incident database.

Incidents graded red

Incidents graded red should be managed in accordance with Communitas's SUI Policy.

The SIRO will inform the CCG as necessary, depending on the type / severity / scale of the Incident

Patient(s) and/or relatives must be informed of any incident which directly affects their care or well-being. This should be carried out by the most senior or experienced member of the team who is caring for the individual. In cases where there are many involved this may be delegated to a number of experienced individuals.

Investigation

All incidents will be subject to an appropriate level of investigation and causal analysis and, an action plan will be prepared and implemented. With the exception of red incidents and some amber incidents, this process will take place at first line.

Where an incident is thought to be a Serious Untoward Incident it should be handled through the Serious Untoward Incident policy and immediately reported to a senior manager.

Adverse incidents and near misses are subject to an appropriate level of investigation and root cause analysis and where relevant an improvement strategy prepared. Not all events need to be investigated to the same extent or depth and the investigation and analysis should be relative to the seriousness, complexity of the event and/or whether it resulted in actual harm and the potential for learning, such as those which are high frequency but may be of low severity.

Red Incidents

Any red or potential red incident will be subject to investigation as set out in the SUI Policy.

Amber Incidents

Investigation of amber incidents will be carried out by one or two key staff e.g. local manager or clinician with advice from the SIRO or Clinical Director, if required. Whilst these investigations may require less input than investigations into red incidents it is essential to establish the root cause(s) and lessons to be learned. All incidents in this category will be subject to review and monitoring by the IGSG, to ensure learning and the implementation of any required changes in practice.

Yellow/Green/Near Miss Incidents:

It is the responsibility of the CMT to ensure that all incidents in this category are investigated with the appropriate thoroughness and subject to aggregated review and monitoring by the IGSG, to ensure learning and the implementation of any required

changes in practice. They are unlikely to warrant individual investigation, but root cause analysis of trends should be undertaken, perhaps as part of a working group, and a preventative risk management strategy established to prevent recurrence.

Internal Reporting

All adverse incidents and near misses and the outcome of any investigations are inputted onto the service Risk Register. Reported incidents will be reviewed at service Clinical Governance Meetings. The Risk Register and action plans are reviewed by IGSG to analyse and feed back key themes and organisational learning to local services and the Board.

Incidents are communicated to the patient when applicable in accordance with the organisation's policy and all communication including additional support offered is documented, in line with the NPSA Being Open Framework

No adverse event policy will be effective unless there is organisational learning and feedback on the lessons learned and any required changes in practice implemented.

External Reporting

Incidents that are deemed Serious in nature (SUI's) will be reported in accordance of the SUI Policy

3.6 Root Cause Analysis

Root cause analysis (RCA) is a structured investigation that aims to identify the true cause of a problem and the actions necessary to eliminate it. RCA is required for all significant incidents. A description of how to undertake RCA is detailed in Root Cause Analysis procedure.

If there is evidence of criminal intent or a gross breach of professional conduct a report must be made to the appropriate professional body. However the ethos behind this policy remains that “Improvement strategies which punish individual clinicians (people) are misguided and do not work. Fixing dysfunctional systems on the other hand is work that needs to be done”. A no blame culture should prevail wherever necessary.

3.7 Monitoring

Reporting of incidents is a standing item on the IGSG meeting agendas.

The Board Annual Report will contain a list of all category red adverse event root cause analysis carried out over the year, together with information on improvement strategies.

4 IMPLEMENTATION PLAN

4.1 Consultation

Stakeholders and sub-contractors will be made aware of this policy and offered the opportunity to comment or advise on content. Patient forum will asked for comments.

4.2 Ratification

Board ratification has been sought for this policy

4.3 Dissemination

The policy will be made available on the Intranet

All policies will be held on the Hub system and made available to all staff.

4.4 Training/Awareness

The policy will be introduced to all staff at induction and reviewed at annual appraisal or supervisory session.

4.5 Audit and/or Monitoring

This policy will be monitored, assessed and reviewed through incident reporting and supervisory sessions. The IGSG is responsible for review and the frequency that this review will be carried out.

Compliance with this policy will be monitored through the annual audit process and overseen by the IGSG.

It will be the day to day responsibility of all managers to monitor that the requirements of this procedure are being adhered too, and that appropriate risk control measures are in place.

Managers are responsible for ensuring effected staff have followed the reporting and management procedures highlighted in this policy.

An annual audit will be completed using the audit tool in to monitor overall compliance with the processes and requirements of this policy. Results will be reported by the Lead on the IGSG. Adverse event reporting will also be used to ensure compliance with procedures.

4.6 Breach of this Policy

This policy is mandatory and all staff must implement this policy and follow the procedures associated with it. Conformance with this policy and its procedures is a contractual requirement and failure may result in termination of employment. Non-compliance with the policy and procedures will be dealt with in accordance with agreed disciplinary procedures

5 VERSION HISTORY TABLE

VERSION	DATE UPDATED	UPDATED BY	REASONS

APPENDIX A – KEY STAKEHOLDERS REQUIRING NOTIFICATION

Key stakeholders requiring, or potentially requiring, information on selected adverse patient incidents.

1. Care Quality Commission
2. Centre for Communicable Disease Control
3. Confidential Inquiries
4. Coroner
5. Department of Health
    - Regional offices –serious untoward incidents, including category red adverse patient incidents.
    - Ionising Radiation (medical exposure) Regulations 2000
    - Other policy branches as appropriate e.g. CCDC
6. Environmental Health
7. Food Standards Agency
8. Strategic Health Authority
9. Health and Safety Executive
    - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995
    - Ionising Radiation Regulations 2000
10. Home Office
    - Mental Health Act notification scheme
11. Medical Devices Agency htpp://www.medicaldevices.gov.uk
    - Voluntary user reporting of all adverse incidents involving medical devices and equipment
    - Mandatory "vigilance" reporting scheme for medical advice and equipment manufacturers
12. .Medicines Control Agency
    - Adverse Drug Reaction (yellow Card) scheme
    - Defective medicines reporting
13. National Patient Safety Agency
14. NHS Estates
    - Fire code-reporting of incidents
    - Buildings and non medical equipment defect and failure report
15. NHS litigation Authority
    - CNST
    - Losses to third parties (LTPS) and property expenses (PES) schemes
16. Police
17. CCG-other CCG's
18. Professional regulatory bodies (e.g., GMC, CFN etc)
19. Public Health Laboratory Service
20. RIDDOR
21. Serious Hazards of transfusion (SHOT)

APPENDIX B – INCIDENT REPORTING

Incident Risk Assessment Form

Assessor ☐ **Job Title** ☐

Location ☐ **Service** ☐

Date ☐

Reference Number ☐

Category

Description of incident
☐

Description of controls in place
☐

Assessment of existing controls **Adequate** ☐
Inadequate ☐

Risk rating

Likelihood

Consequence

Rating **1**

Rating Category

Action plan

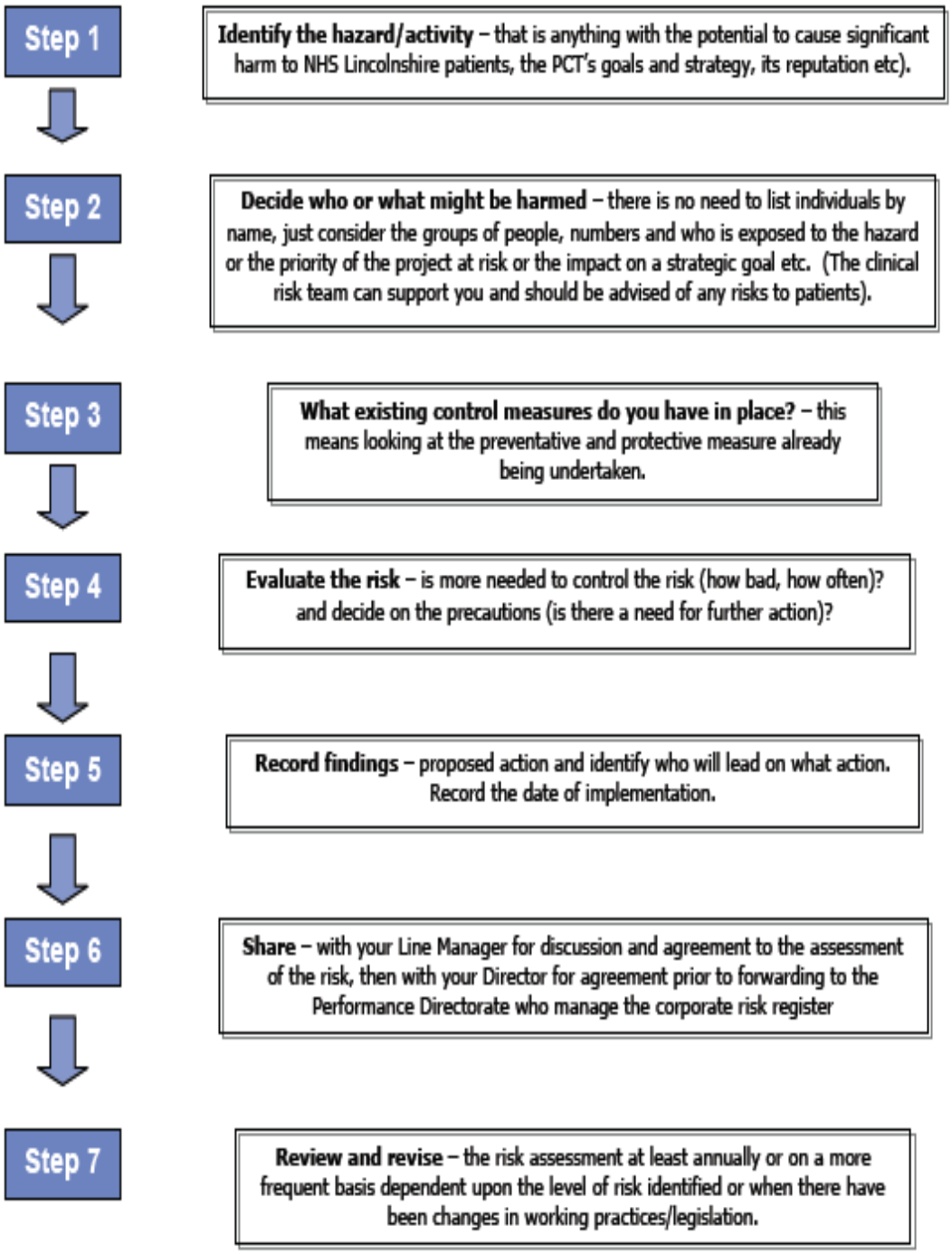
Follow up date

Service Manager

SIRO

On completion of form inform SIRO

Risk management is assessment, analysis and management of risks. It is simply recognising which events (hazards) may lead to harm in the future and minimising their likelihood (how often?) and consequence (how bad?). This flowchart summarises the process for risk management.



Guidance on completing the risk assessment

Consequence

When undertaking a risk assessment, the consequences of "how bad" the risk being assessed must be measured. In this context, consequence is defined as: the outcome of the potential outcome of an event. Clearly, there may be more than one consequence of a single event. For example catastrophic means death or debilitating permanent injury and minor means requiring first aid.

Likelihood

Once a specific risk has been assessed and its consequence score agreed, the likelihood of that consequence occurring can be identified, when assessing the likelihood it is important to take into consideration the controls already in place. The likelihood score is a reflection of how likely it is that the adverse consequence described will occur. This must be estimated over a stated period or related to a given activity.

Matrix

Table 1 - Consequence score (severity levels)

Consequence/ score	Descriptor	Risk to patients	Organisational impact	Personal injury
5	Catastrophic	Death Multiple fatalities or permanent injuries or irreversible health effects.	Permanent loss of service/ facility. Loss of several key staff. Total loss of public confidence. Significant financial loss.	Death An event which impacts on a large number of patients.
4	Major	Major injury leading to long-term incapacity/disability.	Key objectives not met. Major financial loss.	HSE defined major injury including amputation/fracture.
3	Moderate	An event which impacts on a small number of patients.	Suspension of some operational activity for sustained period. Schedule slippage. High financial loss.	Serious injury to one or more persons.
2	Minor	Minor injury or illness requiring minor intervention.	Low staffing level that reduces service quality. Medium financial loss.	Minor injury or illness requiring minor intervention.
1	Rare	Minimal/no injury.	Minimal/no impact. Low financial loss.	Minimal/no injury.

Table 2 – Likelihood score (risk occurring during the next year)

Likelihood score	Probability	Description/Frequency
5	Almost certain	Will undoubtedly happen/recur, expected to occur in most circumstances.
4	Likely	Will probably happen/recur, but is not a persisting issue.
3	Possible	Might happen or recur occasionally.
2	Unlikely	Do not expect it to happen/recur but is possible it may do so.
1	Rare	Probably never happen/recur only in very exceptional circumstances.

Risk (5 x 5) Matrix

			Likelihood				
			Rare 1	Unlikely 2	Possible 3	Likely 4	Almost Certain 5
Consequence	5	Catastrophic	5	10	15	20	25
	4	Major	4	8	12	16	20
	3	Moderate	3	6	9	12	15
	2	Minor	2	4	6	8	10
	1	Rare	1	2	3	4	5

	1-3	Very low risk
	4-6	Low risk
	8-12	Moderate risk
	15-25	High risk

Instructions

1. Define the risk(s) explicitly in terms of the adverse consequence(s) that might arise from the risk.
2. Use table 1 to determine the consequence(s) score for the potential adverse outcome(s) relevant to the risk being evaluated.
3. Use table 2 to determine the likelihood score(s) for those adverse outcomes.
4. Calculate the risk score by multiplying the consequence by the likelihood: **C: consequence x L: likelihood = R: risk score.**