University Hospitals of Leicester NHS
NHS Trust

Management of Reported Medication Errors Policy

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Trust Lead:	Elizabeth McKechnie, Medication Safety Lead Pharmacist
Board Director Lead:	Dr Andrew Furlong, Medical Director
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REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

2018 - Changed into new Policy format.

Addition of Medicines Operational Group

2021 – minor changes to wording. Removal of reference to a policy which no longer exists.

KEY WORDS

Medication Errors. Incidents, Prescribing errors, Dispensing errors, Administration errors

1 INTRODUCTION AND OVERVIEW

1.1 This document sets out the Trust's policy on the management of reported medication errors. It aims to:

- Strengthen the Trust's just and fair accountability culture in response to adverse healthcare events
- Facilitate organisational learning through the findings of thorough and careful investigation at local level
- Provide a framework for practitioners to improve practice
- Ensure appropriate actions are taken by managers and applied consistently across the Trust

1.2 The Trust encourages a sensitive response to medication errors through a comprehensive assessment taking full account of the context and circumstances surrounding the incident

1.3 This policy is to be used in conjunction with the UHL Incident and Accident Reporting Policy (Including the investigation of Serious and RIDDOR Incidents) A10/2002.

1.4 It is acknowledged nationally that under reporting of medication errors occurs with only approximately 10% of medication errors being reported, many having no harm or are near misses. The Trust may be no different from national figures but encourages staff to report under a just and fair culture as learning may lead to improved patient safety. This policy outlines the management and learning from the medication errors which are reported.

2 POLICY SCOPE

2.1 This policy applies to all healthcare staff, including bank and agency involved in any medication processes including (not a definitive list)

- Nursing and Midwifery staff
- Medical staff
- Pharmacy staff
- Allied Health Care Professionals and Health Care Scientists involved in medication administration

2.2 This policy also applies to Pre-registration Healthcare Professional Students (e.g Medical, Nursing, Pharmacy) who may be involved in any medication process under direct supervision. If a student is involved in / makes an error their University / place of study must also be involved

3 DEFINITIONS AND ABBREVIATIONS

3.1 A patient safety incident may be defined as 'any unintended or unexpected incident which could have or did lead to harm for one or more patients'.

3.2 Medication errors are incidents in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring medicines or providing advice, regardless of whether any harm has occurred. These incidents can be divided

into two categories; errors of commission or errors of omission. In the majority of cases errors do not result in harm.

3.3 The following list gives examples of scenarios where medication errors can occur. Near Misses in any of the sections below should also be considered. The definitions have been divided into sections according to the National Patient Safety Agency (NPSA) Safety in doses: medication safety incidences in the NHS (2007), now part of NHS Improvement.

3.4 This is not a definitive list and as such clinicians and managers must exercise professional judgment prior to progressing the issue.

3.5 Prescribing Errors

- Patient prescribed the wrong medication / dose / route / rate
- Medication prescribed to the wrong patient
- Failure to prescribe
- Transcription errors
- Prescribing without taking into account the patients clinical condition
- Prescribing without taking into account patients clinical parameters e.g. weight
- Prescription not signed
- Deviation from UHL Policy and Guidelines relating to Medicines Management; (Leicestershire Medicines Code)

3.6 Dispensing / Supply Errors

- Patient dispensed the wrong medication / dose / route
- Medication dispensed / supplied to the wrong patient
- Patient dispensed an out of date medicine
- Medication is labelled incorrectly
- Incidents relating to discharge for example medicines given to a patient which have been stopped on the discharge letter or unlabelled medicines.
- Deviation from UHL Policy and Guidelines relating to Medicines Management (Leicestershire Medicines Code) and the pre-pack policy

3.7 Preparation and Administration Errors

- Patient administered the wrong medication / dose / route
- Patient administered an out of date medicine
- Medication administered to the wrong patient
- Medication omitted without a clinical rationale
- Medication incorrectly prepared

- Incorrect infusion rate
- Medication administered late / early*****

  *****(UHL recognises this is a complex issue and the full context of late/early administration should be taken into account, however where it would have a significantly detrimental effect on patient care, this would constitute an error)

- Deviation from UHL Policy and Guidelines relating to Medicines Management (Leicestershire Medicines Code)

3.8 Monitoring Errors

- Patient allergic to medication but the medication was prescribed and/or dispensed and/or administered
- Failure to provide the patient with correct information regarding their medication e.g. when to take, what it is for, side effects
- Failure to monitor therapeutic concentrations
- Failure to monitor patient / carer who is undertaking self medication (for further information about self administration see Self Administration Policy B13/2004)
- Deviation from UHL Policy and Guidelines relating to Medicines Management (Leicestershire Medicines Code)

4 ROLES & RESPONSIBILITIES

4.1 The roles and responsibilities are outlined in the Incident and Accident Reporting Policy (Including the investigation of Serious, RIDDOR and security Incidents.) A10/2002

4.2 The **Executive Lead** for Patient Safety and responsible for this policy and that of the policy above is the Medical Director.

4.3 **Staff Individual** responsibilities:

All registered professionals for example medical staff, nursing & midwifery, pharmacists and pharmacy technicians, radiographers etc (the list is not exhaustive) have a responsibility according to their codes of practice to report patient safety incidents including medication errors when they have been identified.

This will include Medication incidents they have made themselves or those that they identify have occurred.

Often prescribing incidents which lead to no harm or are identified before a patient receives medication are not reported. These are still errors and valuable learning can often be gained from them. Staff are encouraged to report these medication errors using the Datix incident reporting system .

4.4 Additional responsibilities not mentioned in the above policy and relate to the specific

management of medication incidents are outlined in the table on the next page:

Responsibility	Action
Medication Safety Lead Pharmacist	1. Is the nominated Medication Safety Officer for the Trust 2. Provide support and guidance to pharmacy staff involved in the investigation of medication incidents 3. Involvement with investigation of medication SI (Serious Incident) as required working closely with the Corporate Patient Safety Team. 4. Overview of all medication incidents within the Trust, identifying themes and trends, monitoring particularly those medicines identified through alerting reports from NHS England and the Never Events Framework. 5. Provide bi-monthly reports to the Medicines Optimisation Committee : • Medication incidents figures (including level of harm) • Incidents relating to high risk medicines / never events • 10 fold under or over dosing of medicines • Ad hoc reporting of specific concerns 6. Assist in the implementation of actions arising from medication safety concerns resulting from the medication incident reports 7. Provide alerts, learning to staff resulting from incidents 8. Communicate with the Senior Pharmacist Patient Safety, NHS Improvement re specific incidents : providing further information or highlighting issues for national consideration.
Chief Pharmacist	1. Receives and provides comment for all SI medication incidents 2. Provides support with learning and action in relation to findings from the investigation, changing and reviewing medication practice and policy as required. 3. Reports to the Assistant Medical Director and Medicines Optimisation Committee concerns relating to medication incidents. 4. Escalate serious concerns to the Chief Executive
Senior Medicines Management Nurse	1. Provide support and guidance to nursing staff involved in the investigation of medication incidents

	2. Involvement with investigation of medication SI as required working closely with the Corporate Patient Safety Team. 3. Assist in the implementation of actions and learning arising from medication safety concerns resulting from medication reports
Medicines Optimisation Committee (MEDOC)	1. Receive regular reports on trends and key issues arising from medications incidents 2. To be responsible for the medication error reduction plan, ensuring actions are completed. 3. Escalate concerns to the Executive Quality Board where felt appropriate by the committee.
Medicines Operational Group (subgroup of Medicines Optimisation Committee)	1. Review medication incidents and share learning from investigations between CMGs. 2. Disseminate learning from medications incidents to staff within the CMGs

5. POLICY IMPLEMENTATION AND ASSOCIATED DOCUMENTS

5.1 All staff involved in the prescribing, dispensing or administration of medicines must be able to demonstrate understanding and compliance with relevant professional guidance and UHL Policies and procedures

Staff who promptly report in relation to a medication error will not be subject to disciplinary action except under the following circumstances:

- Where the member of staff acted in a criminal, deliberate or malicious manner
- Where the member of staff concerned is guilty of gross carelessness with the potential for serious consequences and where they can be reasonably be expected to appreciate the direct consequences of his / her behaviour
- Where a member of staff has been involved in an adverse event follows other similar incidents of a similar nature and where the Trust has provided all necessary training, counselling and supervision to prevent a recurrence.

In the above cases following the use of the incident decision tree (found in the Incident policy) the UHL Improving Performance (Capability) Policy (B12/2014) or UHL Conduct, Capability, Ill Health & Appeals Policies for Medical Practitioners will apply (A2/2005) to staff. Following this staff may go through the disciplinary process outlined in the Disciplinary Policy & Procedure (A6/2004).

Actions to be taken following the discovery of a Medication Error

5.2 Immediate Actions

5.2.1 Assess the patient's condition and take necessary actions to maintain patient stability

5.2.2 The error must be reported immediately to the Nurse in charge / Line Manager / person in charge and the Consultant team in charge of care for the patient

5.2.3 Seek advice from Pharmacy staff regarding the possible outcomes of medication error where appropriate.

5.2.4 In the instance of a dispensing error, inform the local pharmacy department manager and return the incorrect medication to pharmacy for re-dispensing

5.2.5 Complete a Datix web incident form (following UHL Policy for Incident and Accident Reporting) photocopying any relevant charts and obtain statements. Ensure the incident is documented in the patient's case notes

5.2.6 The line manager will ensure the incident report form is completed and escalated as appropriate e.g to the Matron / Medical Lead/ Head of Service, Corporate Patient Safety Team who will take further action as required. It is essential this is carried out expediently to allow for a timely investigation in the event of the more serious events. Out of hours the Duty Manager should be informed.

5.2.7 Inform the patient as appropriate (see section 5.5 for more details). There is a Duty of Candour requirement for all incidents graded as moderate harm and above which require patients to be informed within 10 days of the incident or knowledge of the incident.

5.3 Medium Term Actions (to be completed with 7 days)

5.3.1 A systematic review of the root causes for the error must take place with the staff involved using the most appropriate Root Cause Analysis checklists (Appendix One). For serious incidents the Corporate Patient Safety team will lead the investigation involving a member of the Senior pharmacy team (Lead Clinical Management Group (CMG) pharmacist or Medication Safety Pharmacist) as appropriate.

5.3.2 Following initial Root Cause Analysis and using the incident decision tree (as per the UHL incident and Accident Reporting Policy) the line manager may feel it is appropriate to stop the member of staff from undertaking medication prescribing, dispensing or administration until a critical incident reflective exercise has been undertaken. In these cases the line manager must consult with the Human Resources department, Clinical Management Group (CMG)

Head of Nursing / Clinical Director / Head of Service and Patient Safety team before any decisions are made. (See Section 5.6 on Suspension in Practice and Addressing Concerns of Competency)

5.3.3 There may be occasions where staff wish to stop themselves from prescribing, dispensing or administration. This should be respected and addressed within the critical incident reflective exercise. (See Section 5.6 on Suspension in Practice and Addressing Concerns of Competency)

5.3.4 The line manager or delegated deputy, in conjunction with the Matron, Clinical Tutors and Educators etc will undertake a critical incident reflective exercise with the member of staff (see appendix Two). This will be undertaken within no more than 7 days of reporting the error.

5.3.5 If following this reflective exercise it is felt appropriate to stop the member of staff from undertaking medication prescribing, dispensing or administration then Human Resources must be contacted to discuss the various options available.

5.3.6 A copy of the agreed actions as identified within critical incident reflective exercise is kept on the member of staff's personal record and reviewed in line with the appraisal process confirming positive change.

5.3.7 Any training needs identified for individuals should be discussed with CMG Education Teams / Clinical Tutor.

5.4 Long Term Actions

5.4.1 The Clinical Management Group Senior Management team (Medical Lead, and Head of Nursing) must have clear processes in place to review information on medication errors from Datix to identify any themes and trends. Concerns regarding medication errors must be highlighted and escalated as appropriate to the Medical Director, Chief Pharmacist and Chief Nurse.

5.4.2 Medication incidents which are involved in harm or potential harm and meet the definitions for a morbidity / mortality review will be reviewed by CMGs within their Morbidity & Mortality meetings. Please refer to the Mortality and Morbidity Review Process Policy (B48/2017).

5.4.3 A Copy of the Root Cause Analysis Checklists must be sent to the Medication Safety Lead Pharmacist c/o Pharmacy Department, Glenfield. The results will be entered into a database and analysed and reviewed to identify any themes and trends. These results will be reported to the Medicines Optimisation Committee on a bi-monthly basis

5.5 Informing the Patient

5.5.1 The trust acknowledges that when things go wrong, open and honest communication with the patient and / or relatives is fundamental to the ongoing partnership between them, those providing their care and the Trust (see Being Open (Duty of Candour) Policy B42/2010)

5.5.2 The Patient should be informed by nurse in charge / department manager and /or the Consultant team in charge of the patients care. An apology should be given, acknowledging that an apology is not an admission of liability (in line with UHL Incident and Accident Reporting Policy)

5.5.3 The patient's consent must be sought prior to informing other family members; if the patient is unable to provide this consent (e.g. they are unconscious or an infant, child, etc) then the most appropriate family member may be informed. For any issues relating to consent, please contact the Assistant Director - Head of Legal Services. In an emergency contact can be made out of hours via the Duty Manager.

5.5.4 There is a Duty of Candour requirement for all incidents which are graded as moderate harm or above which requires patients to be informed as practicably possible and a follow up letter within 10 days of the incident or knowledge of the incident.

5.5.5 Where the Consultant and Senior Nursing staff considers there are compelling clinical reasons not to discuss the event with the patient / relative(s) a clear record should be made of this in the patient's case notes. In such circumstances further advice may be sought from the CMG Medical Lead or Lead nurse but the final decision is that of the Medical Director or Chief Nurse.

5.5.6 If appropriate, following the investigation, a meeting should be offered to the patient and/or relatives with the relevant clinician(s) / personnel. The purpose of such a meeting would be to discuss the findings of the investigation, share the lessons learned and outline the recommendations put into place to reduce the risk of a similar incident re-occurring in the future

5.6 Suspensions in Practice and Addressing Concerns of Competency

5.6.1 The Line manager may feel it is in the patients and staff's best interests to stop them from undertaking medication prescribing, dispensing or administration until a critical incident reflective exercise has been undertaken (within 7 days of the error). In these cases the line manager must consult with the Medical Lead /Lead nurse/ Head of Service as appropriate in consultation with the Human Resources department before any decisions are made / actions taken.

5.6.2 The member of staff themselves may decide to stop their practice due to concerns regarding their own practice being out of date or a loss of confidence. This should be discussed and agreed with their line manager as it may have implications for staffing levels / allocation. They must also undertake a critical incident reflective exercise with their line manager within 7 days of the error.

5.6.3 If, after the period of education, training and re-assessment the member of staff's competence is still in doubt they should be managed in accordance with the UHL Improving Performance and Capability Policy or UHL Conduct, Capability, Ill Health & Appeals Policy for Medical Practitioners and the

Disciplinary Policy and Procedures if deemed appropriate.

5.6.4 Where an individual member of staff has made subsequent errors, the process as above will be undertaken by their line manager and comprehensive assessment made of the practitioners competence level, timescale and context

5.7 Support for Staff

5.7.1 Support for staff throughout the medication error process is available from (not a definitive list):

- Line Manager
- Education and Practice Development Staff
- Senior Nurse Medicines Management
- Staff Side
- AMICA
- Occupational Health
- Human Resources department
- Professional Bodies

5.7.2 Line Managers can gain advice and support in managing staff that have made a medication error from:

- Corporate Patient Safety Team
- CMG Head of Nursing / Clinical Director/ Head of Service
- Education Teams
- Matrons
- Senior Pharmacy Team
- Corporate Nursing Team
- Medical Directors Team
- Occupational Health
- Human Resources

5.8 Learning from Medication errors:

5.8.1 Medication Incidents will be dealt with through the CMGs as for other patient safety incidents, (UHL Incident and Accident Reporting Policy) and through the Mortality and Morbidity review process. Learning from these reviews will be communicated to staff in a variety of methods for example bulletins, face to face meetings etc .

5.8.2 Additional analysis and review of trends for medication incidents will be undertaken by the Medication Safety Pharmacist reported to the Medicines Optimisation

Committee on a bi-monthly basis.

5.8.3 Trust wide communication on specific issues resulting from this analysis and the outcomes from investigations will be issued via a variety of communication routes; medication alerts, Pharmacy newsletters, messages on INsite.

5.8.4 Changes in practice leading from medication error incidents will be monitored by the review of Datix incident reporting and specific audits as required.

6 EDUCATION AND TRAINING REQUIREMENTS

6.1 There are no specific training requirements for this policy.

7 PROCESS FOR MONITORING COMPLIANCE

7.1 This policy has been developed by a sub group of the Medicines Optimisation Committee

7.2 Compliance with this policy will be monitored through the Datix incident reporting system using medication error as a search term.

7.3 The Medicine Optimisation Committee will receive a bi-monthly incident report and for Medication errors from Medication Safety Lead Pharmacist.

7.4 Lessons learnt and best practice identified in this report will be shared across the Trust by the CMG representatives and the Medication Safety Pharmacist.

7.5 Concerns raised within the reports will be flagged to UHL Executive Team by the Deputy Medical Director as chair of the Medicines Optimisation Committee.

See table.

Element to be monitored	**Lead**	**Tool**	**Frequency**	**Reporting arrangements Who or what committee will the completed report go to.**
Breakdown of incidents – numbers & themes	Medication safety pharmacist	Datix reporting	Bi-monthly	Medicines Optimisation committee – Never events framework Learning & reports to go to CMGs. Escalation to EQB
Development of a medication safety indicator for harm – national indicator	Medication safety pharmacist	Datix reporting	Bi-monthly	Medicines Optimisation committee Escalation to EQB when increase in harm reported.

8 EQUALITY IMPACT ASSESSMENT

8.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

8.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

9 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

GMC Medical Practice Guidelines
Leicestershire Medicine Code Chapters available via INsite
National Patient Safety Agency (NPSA) Safety in doses: medication safety incidences in the NHS (2007).
NMC Standards for Medicines Management
NMC The Code, Standards of Conduct, Performance and Ethics for Nurses and Midwives
Royal Pharmaceutical Society Medicines, Ethics and Practice
UHL Incident and Accident Reporting Policy (Including the investigation of Serious and RIDDOR Incidents). A10/2002
UHL Duty of Candour (Being Open) Policy B42/2010
UHL Improving Performance (Capability) Policy and Procedure – non medical staff B12/2014
UHL Conduct, Capability, Ill Health & Appeals Policy for Medical Practitioners (A2/2005)
UHL Intravenous Drugs Policy B25/2010
UHL Disciplinary Policy & Procedures A6/2004
UHL Assessment of Administration of medicines by nurses and Midwives Policy and procedures (B13/2009)
UHL Morbidity & Mortality Review Process Policy (B48/2017)

10 PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

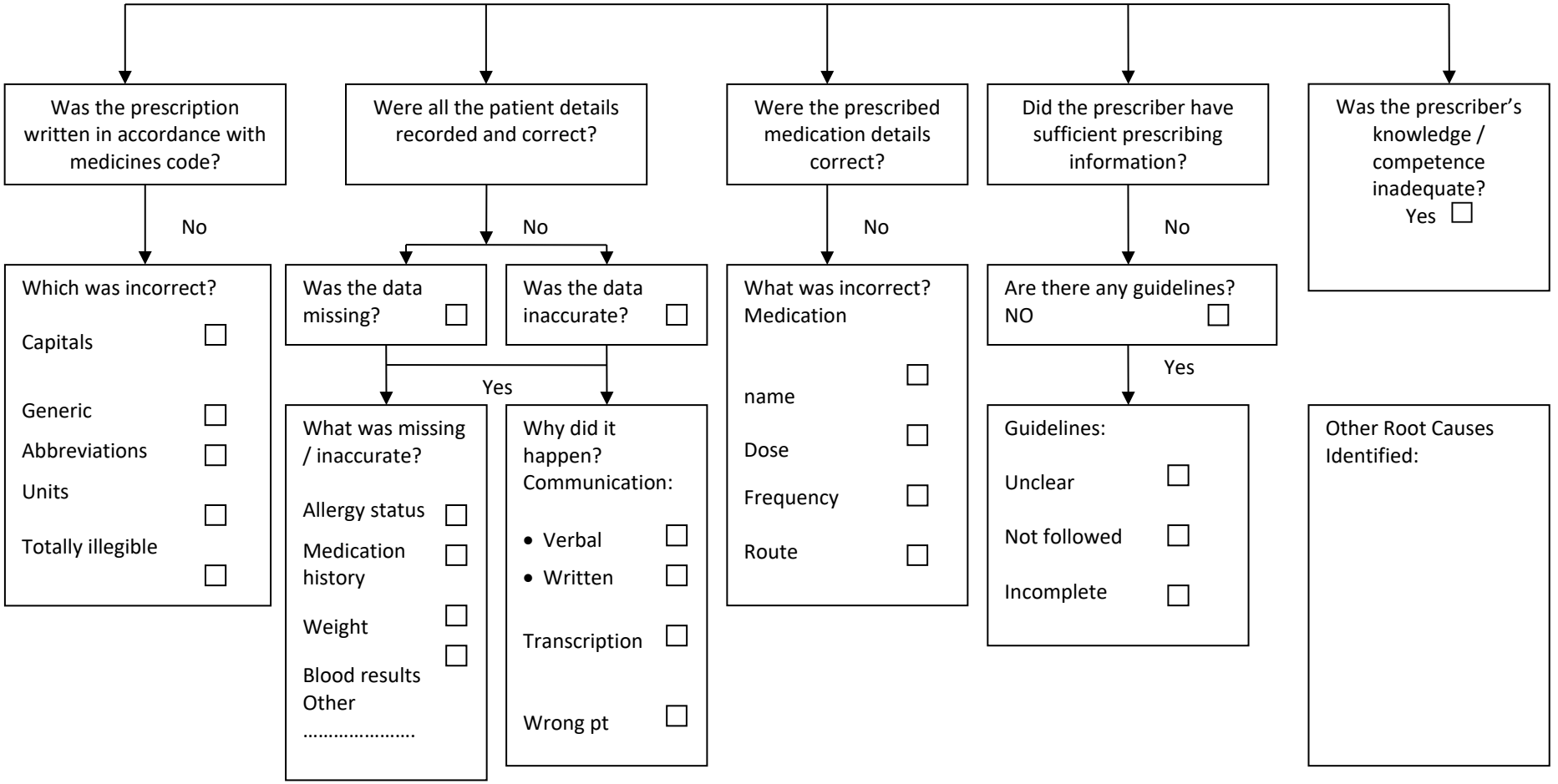
10.1 The policy will be reviewed every three years unless there is reason for earlier review. Document review will be the responsibility of the document author.

10.2 The updated version of the Policy will then be uploaded and available through INsite Documents and the Trust's externally-accessible Freedom of Information publication scheme. It will be archived through the Trusts PAGL system.

Appendix One

Root Cause Analysis Checklist for Prescribing Errors

Use this checklist to undertake a systematic review of the error. It will help pinpoint where things went wrong and identify areas for action / improvement

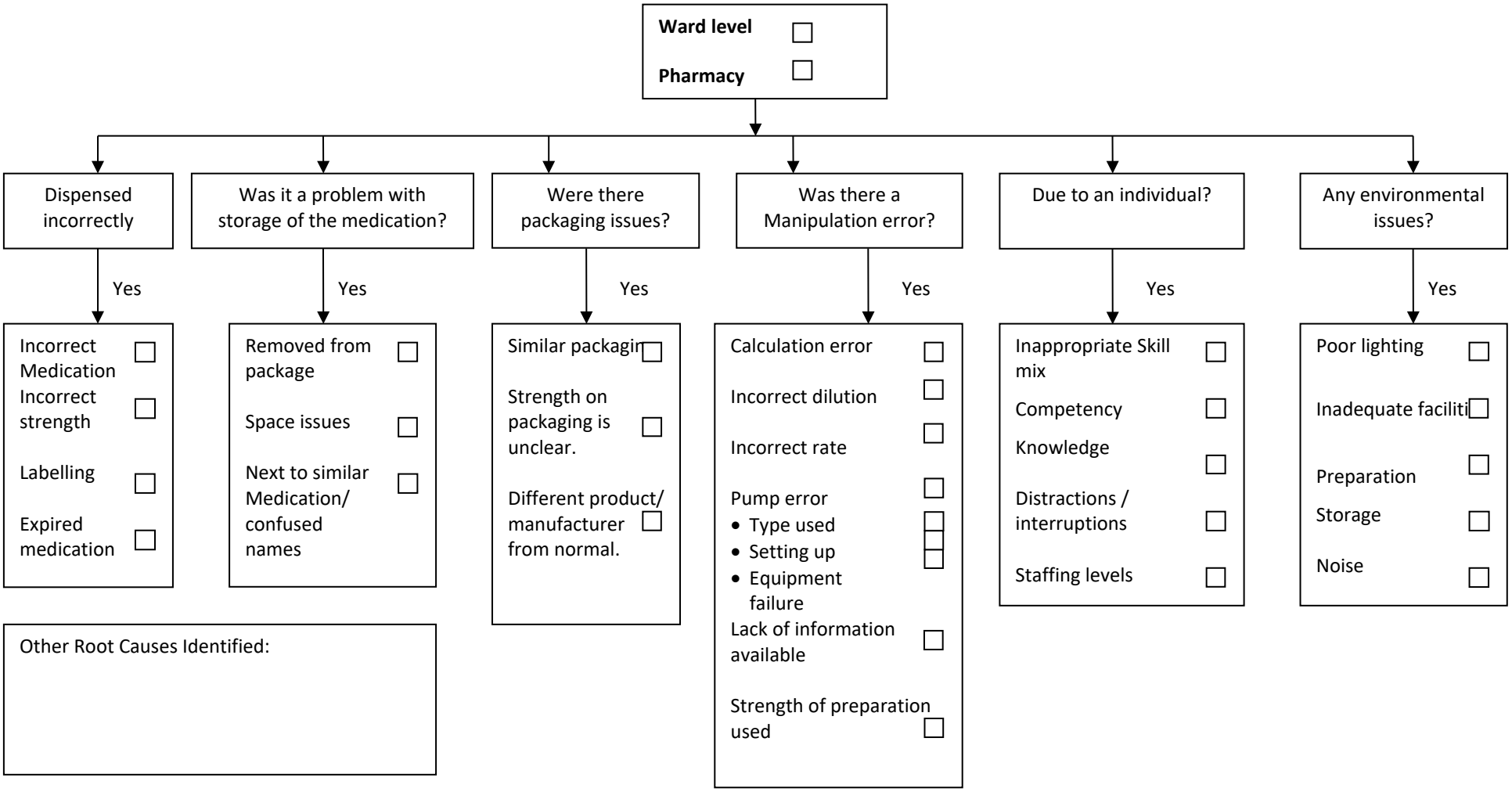


Completed by: (Print Name & Job Title)		**CMG:**	**Date:**	**Datix Ref No:**

A copy of this form must be kept by the lead investigator and a copy sent to: Medication Safety Pharmacist, c/o Pharmacy Dept, Glenfield

Root Cause Analysis Checklist for Preparation / Dispensing Errors

Use this checklist to undertake a systematic review of the error. It will help pinpoint where things went wrong and identify areas for action / improvement

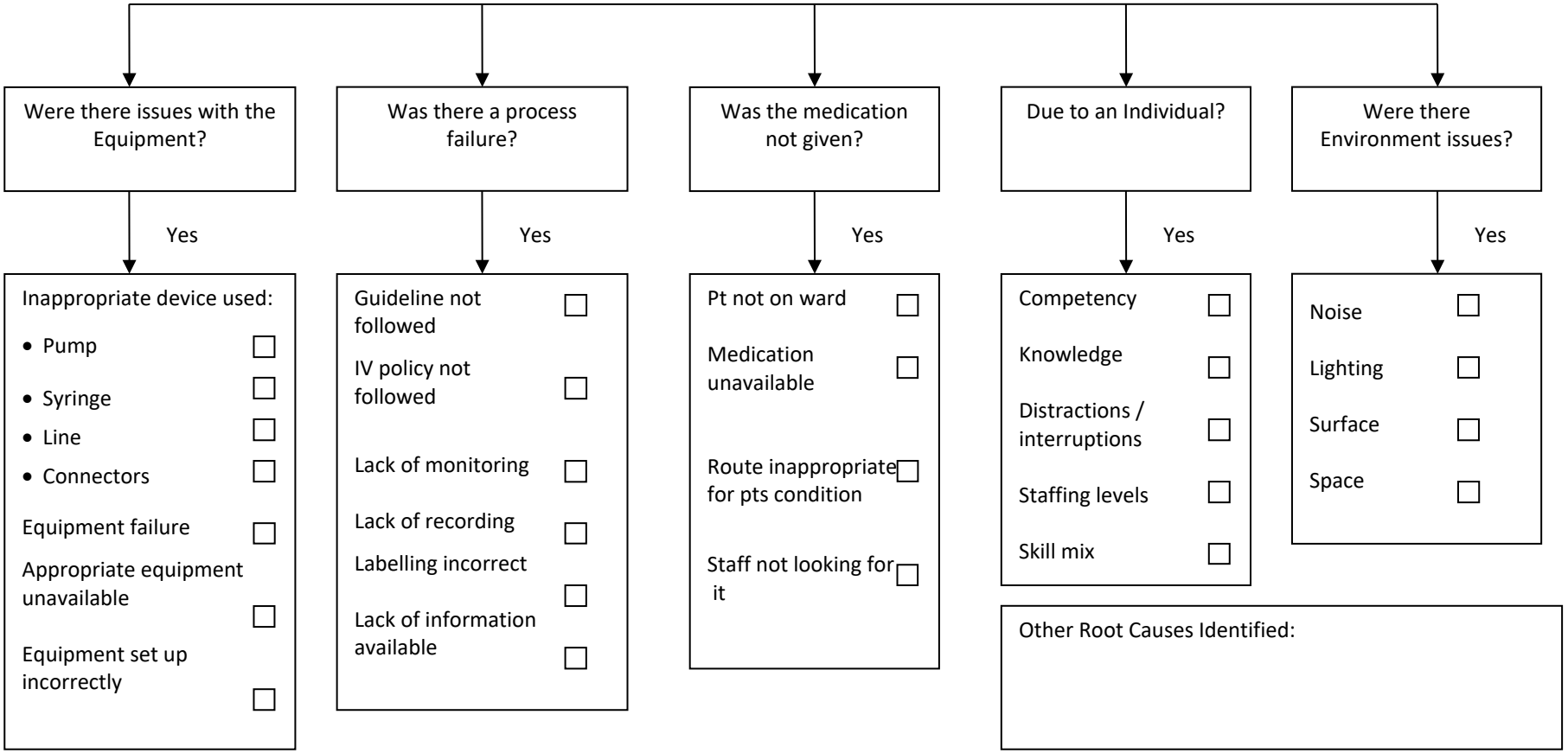


Completed by: (Print Name & Job Title)		CMG:	Date:	Datix Ref No:

A copy of this form must be kept by the lead investigator and a copy sent to: Medication Safety Pharmacist, c/o Pharmacy Dept, Glenfield

Root Cause Analysis Checklist for Administration Errors

Please use this checklist to undertake a systematic review of the error. It will help pinpoint where things went wrong and enable you to identify areas for action / improvement

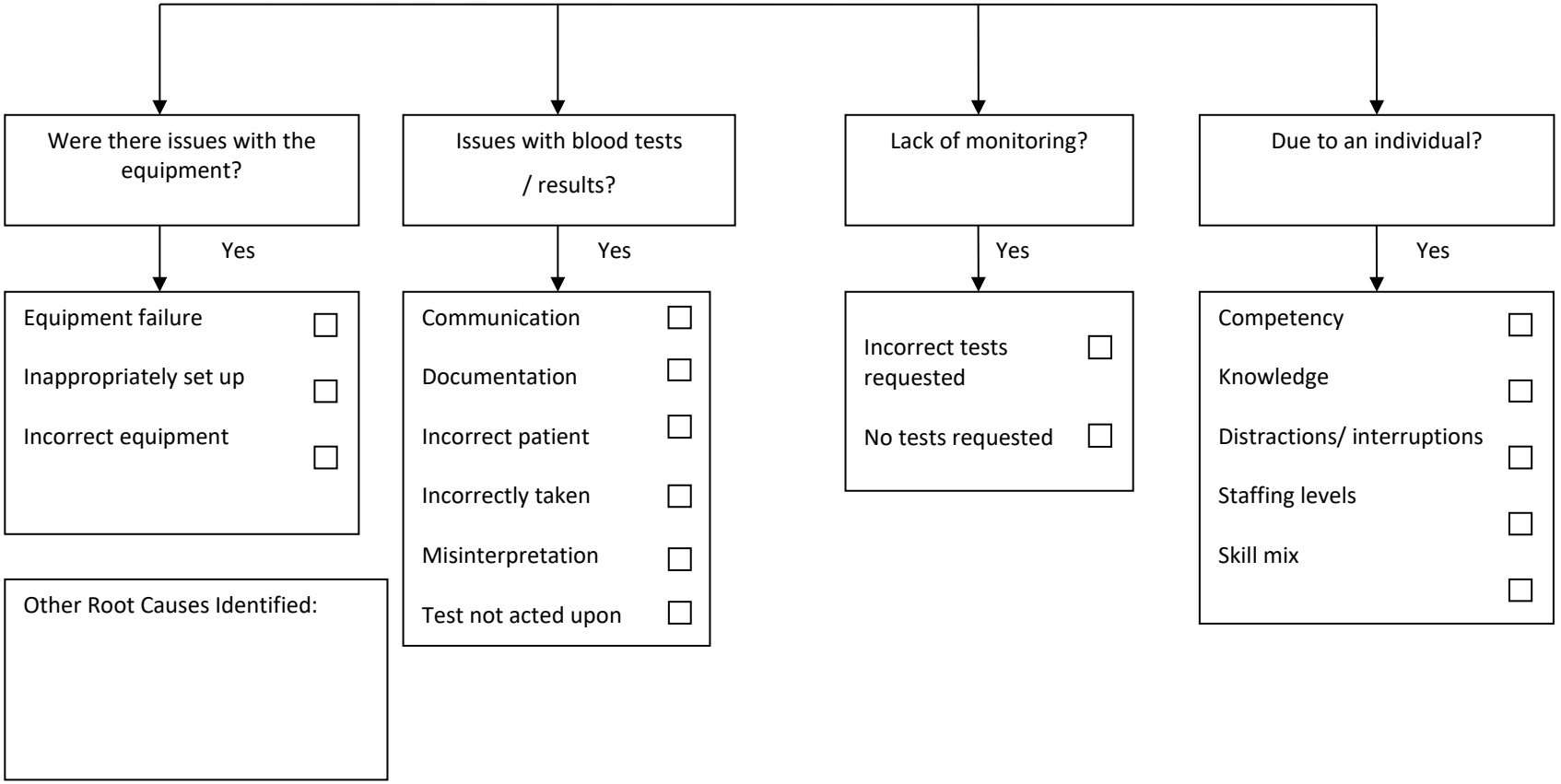


Completed by: (Print Name & Job Title)		**CMG:**	**Date:**	**Datix Ref No:**

A copy of this form must be kept by the lead investigator and a copy sent to: Medication Safety Pharmacist, c/o Pharmacy Dept, Glenfield

Root Cause Analysis Checklist for Monitoring Errors

Please use this checklist to undertake a systematic review of the error. It will help pinpoint where things went wrong and enable you to identify areas for action / improvement



Completed by: (Print Name & Job Title)		**CMG:**	**Date:**	**Datix Ref No:**

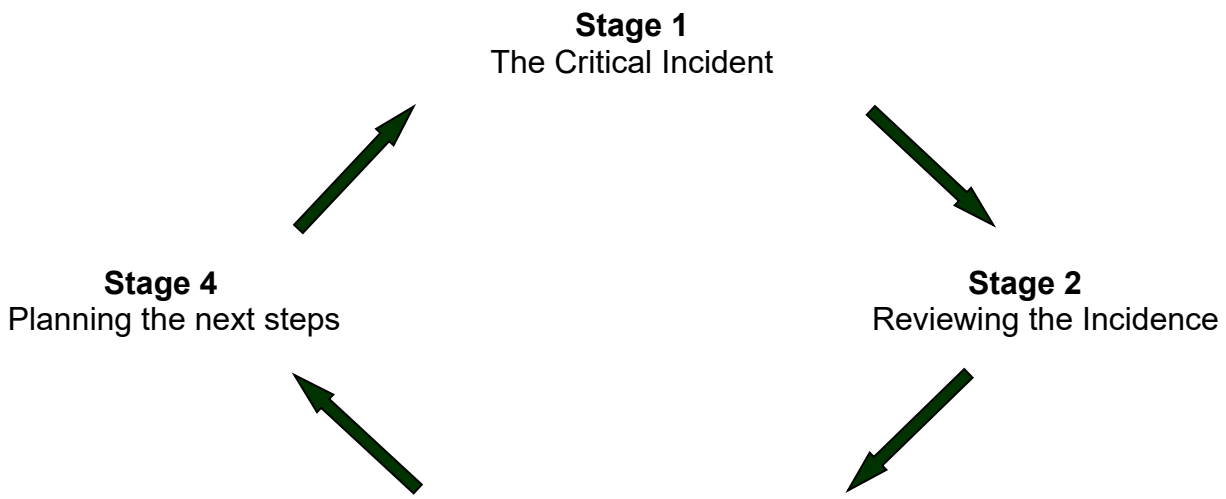
A copy of this form must be kept by the lead investigator and a copy sent to: Medication Safety Pharmacist, c/o Pharmacy Dept, Glenfield

University Hospitals of Leicester NHS
NHS Trust

Critical Incident Reflective Exercise for Medication Errors

This document has been developed to enable practitioners to have a formal process of learning from incidences that they have been involved in. You must complete this form in conjunction with your manager. You will keep the original form; your manager will keep a copy.

THE LEARNING CYCLE



The Critical Incident Reflective Exercise is in three parts:

Part A: You write a factual statement about the incident. This will be kept by your manager with the relevant incident form and not on Datix.

Part B: Is an informal learning exercise for you to reflect on the incident and to discuss any issues with your manager – this is for you to keep

Part C: Is an action plan that arises from the incident and will be kept as part of your appraisal documentation to be reviewed as appropriate.

There are several hints and suggestions in each part of the document to assist you in completing it; these do not have to be followed exactly as set out

Part A: Formal Statement of the Incident

Write a detailed account of what happened before, during and after the incident.
(For assistance please refer to the UHL Stating the Facts Leaflet - INsite Document No 41799)

Returning to the situation:

- What exactly occurred in your words?
- What did you see?
- What did you do?
- What were the consequence of your actions for yourself, the patient, visitors, your colleagues?
- What did other people do? (e.g. colleagues, patient, visitors)

(Write your statement here)

(Continue on another sheet if necessary)

Name of person completing the form:		**Signature:**		**Date:**
Name of person reviewing the form:		**Signature:**		**Date:**

Part B: Reflection on the Incident (To be completed within **one week** of the incident, to be kept by the individual practitioner and discussed with their manager)

Write a reflective account of the events leading up to, during and after the incident Reflecting on the incident: • What was I trying to achieve? Why did I act as I did? • What internal / external factors influenced my decision making or actions? • What sources of knowledge did or should have influenced my decision making actions? • What were my feelings at the time? • What are my feelings now? Are there differences? Why? • What were the effects of what I did or did not do? • What 'good' emerged from the situation e.g. self / others? • What troubles me know (if anything)? • What would I have done differently / better?
(Write your reflection here) Date you completed the reflection:……. (Continue on another sheet if necessary)

Part C: Action Plan arising out of the Incident (to be kept by the manager with appraisal documentation)

List your learning points from the incident, with an action plan of what you need to concentrate on or do differently as a result Looking to the future: • What needs to happen to alter the situation? • What are you going to do about the situation? • What happens if you decide not to alter anything? • What information do you need to face a similar situation again? • What are your best ways of getting further information about the situation should it arise again? • Have I taken effective action to support myself and others as a result of this experience? • Identify anything that may hinder your action plan and how you can tackle these
(write your learning points here)

Learning Need	**Actions to address learning Needs**	**Progress review**

Name of person completing the form:		**Signature:**		**Date:**
Name of person reviewing the form:		**Signature:**		**Date:**