journey to change

NHS
Tees, Esk and Wear Valleys
NHS Foundation Trust

Public – To be published on the Trust external website

Title: Supporting Staff and Learning from Medication Incidents

Ref: PHARM-0045-v3

Status: Approved
Document type: Procedure
Overarching policy: Medicines Overarching Framework

Contents

1 Introduction

Medicines management is part of the NHS performance ratings. Incidents reported into the National Reporting and Learning System (NRLS) (which will be replaced by PSIMS in 2021) provide valuable learning to make the NHS safer for patients. To improve safety, we must recognise that to make progress, we must significantly improve the way we learn, treat staff and involve patients. (The NHS Patient Safety Strategy). As a Trust, we need to ensure we operate in a fair and just way, so that staff feel able to be open and honest about when incidents occur without fear of blame. It is recognised that staff may experience emotional distress or wellbeing issues as a result of patient safety incidents. (HSIB 2021) This needs to be considered when supporting staff following such incidents.

Patient Safety incidents are 'unintended or unexpected events which could have, or did lead to harm to patients' (NHS, 2017). Medication errors are the single most preventable cause of patient harm; these can be broadly defined as any error in the prescribing, ordering, transcribing, dispensing, administration, transporting, storage, security or disposal of a drug, irrespective of whether such errors lead to adverse consequences or not. The majority of medication incidents have actual clinical outcomes of no harm or low harm, but all medicine incidents need to be reviewed to ensure the reduction of risk and improvement in patient safety. The most common incidents tend to be caused by errors in medicine administration and, to a lesser extent, prescribing. This may be because for every individual drug prescribed once there will be multiple drug administrations, which present with opportunities for error.

'A Just Culture Guide' (Appendix 1) is a support tool to aid discussions to help determine whether a staff member involved in an incident requires support /interventions to safely work. The guide should not be used routinely. It is to be used when there is already suspicion that a member of staff requires some support or management to work safely, or as part of an individual practitioner performance/case investigation. In a just culture, the aim is to understand the root cause of the incident and why this led to the error. It holds people to account when gross negligence/deliberate act is evidenced.

This procedure has links to the following goal in Our Journey To Change:

To co-create a great experience for our patients, carers and families, so you will experience:

- **Outstanding** and compassionate care, all of the time.
- **Access** to the care that is right for you.
- **Support** to achieve your goals.
- **Choice** and control.

2 Purpose

This document has been developed to provide guidance and a defined pathway for all staff involved in medication incidents. The aim is to increase consistency in supporting staff involved in medicine incidents or errors, The Trust should have a no-blame culture embedded. The aim of incident reporting is not to assign blame, but to learn from incidents, with the purpose of reducing the risk of future errors.

There may be rare occasions where a reported incident requires further in-depth exploration. If required, this policy should be used in conjunction with the Trust's Incident Reporting and Investigating Policy, Disciplinary Procedure and Capability Procedure which set out the appropriate processes and procedures to formally deal with issues raised.

Following a reported incident, regardless of severity level it is essential that the staff are appropriately supported by line managers, involved in any subsequent investigation and advised of the investigation outcomes and recommended changes to practice.

Following this procedure will help the Trust to:-

- implement a systematic response to medication errors and incidents to enable the identification of individual and organisational failures and
- reduce adverse patient outcomes.
- identify themes, trends and learning from incidents.

3 Who this procedure applies to

This procedure applies to all staff involved in the medicines journey

This document covers all staff involved with medicine management, irrespective of setting, designation or profession. It covers all stages of medicine management. It has been developed to provide a standardised approach to supporting staff involved in medication incidents. It offers a structure to encourage staff to report all medication incidents within a framework that promotes professional development and patient safety without fear of retribution. It enables identification of operational and systemic failures that may have resulted in, or contributed to, medication incidents.

The organisation's response to incident reporting and investigation will be open and inclusive, will value learning from staff, patients and carers and will react to problems positively, encourage questioning and learning from mistakes. It is recognised that staff may respond to incidents differently, and this should be considered when offering support after an incident has occurred. Support may be needed as emotional and psychological assistance through talking, listening and practical engagement. (HSIB 2021)

In regards to Duty of Candor, the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 ensures that providers are open and transparent with people who use services and other 'relevant persons' (people acting lawfully on their behalf) in general in

relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, including informing people about the incident, providing reasonable support, providing truthful information and an apology when things go wrong.

There will be an open and supportive approach with an emphasis on discovering and addressing the root causes of an incident through a thorough analysis of all the contributory factors. There may however be instances where recourse to the disciplinary process is required if there is evidence that the incident was due to an action deemed reckless, deliberate or as a result of gross negligence.

When action is necessary, as a result of a disciplinary investigation, it will be seen to be fair and reasonable and will not be influenced by the outcome of the incident or the position or profession of the individual.

3.1 Roles and responsibilities

Role	Responsibility
Operational directors, Heads of Service and other Managers	Are responsible for ensuring this guidance is accessible to staff and implemented across the services for which they are responsible. This involves supporting individuals in dealing with incidents and signposting them to other sources of advice and support as necessary.
Pharmacy Medication Safety Team- consisting of Medication Safety Officer (MSO) and Lead Pharmacy Technician- Medication Safety	Improve medication incident reporting and learning, manage medication incident reporting within the organization, authorise the release of medication error reports to the NRLS and improve the quality of medication incident reporting. To identify and implement local and national medication safety initiatives. To reduce medicines related risks by working within the Trust framework for medication error reporting and implementing risk reduction strategies. Work towards ensuring safe medication practice in the Trust and across the primary and secondary interface of quality, safety and governance issues related to the use of medicines. The development and implementation of policies, procedures and guidance for medicines safety, as driven by national or regional guidance and/or patient safety alerts, or through analysis of internal processes.
Medicines Management Nurses	To ensure competency based training and assessment packages are developed and available to nursing staff and adherence to training is monitored via the Trust Training information system. To offer advice, assistance and support in relation to medication incidents and any subsequent investigations, action plans or training needs identified.

All staff involved with the use of medicines	Are responsible for ensuring they work in accordance with all guidance around the safe and secure handling, storage, prescribing, ordering, administration and disposal of medications and bring to the attention of their manager any issues that prevent this. The Trust expects that every member of staff will understand their own personal accountability and responsibility for patient safety and staff will be required to review their own practice in relation to the incident.
Students	Whilst on placement in a clinical area must have a named registered practitioner responsible for their actions; all incidents involving students must be reported to the relevant training coordinator and training establishment involved where appropriate. For student nurses the Practice Placement Facilitator (PPF) and Heads of Nursing must always be informed and involved in any subsequent investigation.

4 Related documents

This procedure describes what you need to do to implement section 4.1.10 of the Medicines Overarching Framework (MOF).

The MOF states that medication errors are identified, recorded, and monitored appropriately reported and investigated according to Incident reporting and serious incident review policy.

This procedure also refers to:-

- ✓ Medicines – Prescribing and Initiation of Treatment
- ✓ Incident Reporting and Serious Incident Review Policy
- ✓ Disciplinary Procedure
- ✓ Capability Procedure
- ✓ Safeguarding Adults Protocol
- ✓ Safeguarding Children Policy

5 Guidance

The Trust's approach to risk management recognises that both human and systemic factors can influence incidents. Lessons should be learnt from any incident or error and where appropriate both behavioural and system changes should be implemented to improve patient safety. The Trust acknowledges incidents resulting from human factors may occur for many reasons, may not be intentional and can be caused by human error, lack of knowledge or lack of competence. However, practitioners should be professionally responsible for reporting and learning from incidents.

All medication related incidents, at any stage in the medication process, must be reported in accordance with Trust policy and a Datix incident report form must be completed. There is a guide to the categories to use in reporting medicine incidents on Datix. This can be found in the pharmacy, medication safety pages on the Trust intranet here.

In 2005 the NPSA developed an incident decision tree to help managers deal fairly and consistently with those involved in any patient safety incident. It takes into consideration both individual factors and organisational issues and has been adapted for use within these guidelines.

Following are a list of examples of types of medication related incidents; this list is not exhaustive:

- Omission of signature or appropriate administration code on patient administration record
- Inappropriate/wrong drug, dose or formulation prescribed, dispensed or administered
- Inappropriate route, frequency or time of administration
- Out of date medicine dispensed and/or administered
- Medication administered to a wrong patient
- Omission of a prescribed drug
- Malicious intent
- Administration of unauthorised medication
- Administration by inappropriate personnel
- Incorrect medications dispensed by pharmacy
- Security of medicine
- Missing medication, controlled stationery or medication keys
- Working outside the parameters of role (e.g. non prescribers giving advice around medicines to prescribers external to the Trust or AHPs giving advice directly to patients)
- Omitted monitoring of medication effects e.g. post rapid tranquilisation/ clozapine titration/ detox monitoring

Following any medicines incident please refer to the process flowchart for supporting staff involved in medicine related incidents (Appendix 2). It is important to understand the root cause of the incident, whilst keeping an emphasis on support and not blaming. Confidentiality should be maintained where appropriate, whilst considering the best way to share learning. The flowchart should be used to guide decision making, to identify a consistent process utilising the supervision and appraisal process to ensure staff have reviewed their practice and that any action is taken to

address any development requirements through Personal Development Plans. The process should take into account any mitigating circumstances and previous involvement in medicine incidents within a set timeframe.

If unclear Line managers should seek involvement from the pharmacy medication safety team – which comprises, medication safety officer, lead pharmacy technician for medication safety and medicines management nurses.

Practitioners should be held professionally responsible accountable for their actions and the management of such incidents should be dependent upon the nature of the incident.

Practitioners should reflect on the incident, complete the reflection form (appendix 4) and use the reflection to discuss the incident with the line manager.

Medicine incidents should be dealt with in a timely way and monitored to ensure issues around capability are dealt with accordingly. Investigation Tool for Medication Incidents and Near Misses can be used to when investigating a medication incident (appendix 5)

If at any time during the medicine incident investigation safeguarding concerns arise, they must be managed in accordance with current Safeguarding Adults Protocol and the Safeguarding Children Policy.

If in the course of an investigation procedural matters relating to professional standards, conduct and performance are identified, the investigating team must refer these matters to the relevant head of service and/or professional lead.

If there are concerns that a criminal act has taken place then the scene of the incident must be secured and preserved, all investigations will cease and the relevant head of service and, if agreed appropriate, police notified immediately.

6 Definitions

Term	Definition
Clinical incident	An adverse health care event or omission arising during clinical care and causing physical or psychological harm to a patient.
Medicine incident	Any incident where there has been an error in the process of prescribing, transcribing, ordering, dispensing, preparing, administering, monitoring or providing medicines advice, regardless of whether any harm occurred or was possible. **NB:** It is not well recognised that serious consequences can arise when medicines are omitted, or assumed to be omitted due to missing signatures, therefore **all** omitted signatures should be reported as medicine incidents. This is particularly important when 'critical medicines' are omitted- see MSS 17.
Near miss	A medication incident that will not have caused harm but will be judged to have the potential to cause harm; an event or situation that could have resulted in an incident but through timely intervention or good fortune did not reach the patient. Reporting near misses provides valuable insight into where systems need to be improved to prevent death or serious harm. They are important as patients with different susceptibilities may suffer harm from the same incident.

7 How this procedure will be implemented

- This procedure will be published on the Trust's intranet site.
- Line managers will disseminate this procedure to all Trust employees through a line management briefing.

8 How the implementation of this procedure will be monitored

Auditable Standard/Key Performance Indicators		Frequency/Method/Person Responsible	Where results and any Associate Action Plan will be reported to, implemented and monitored; (this will usually be via the relevant Governance Group).
1	Analysis of medication incidents	Medication Safety Team	Pharmacy medication safety and governance group
2			
3			

9 References

- Ipswich Hospital NHS Trust (2010) Medication Incidents – guidance for the management of qualified nurses/midwives involved in medication incidents v1
- Larsen De et al (2007) Implementing a systematic response to medication errors Nursing Standard 21, 48, 35-40 2007
- NPSA (2009) Safety in Doses
- A Just Culture Guide – NHS Improvement.nhs.ukhttps://improvement.nhs.uk/resources/just-culture-guide/
- GPhC Standards for pharmacy professionals
- Northumbria Healthcare NHS Foundation Trust Procedure for reducing and learning from internal pharmacy dispensing process deviations v1 OP13
- TEWV Disciplinary Procedure
- TEWV Incident reporting and serious incident review
- RPS Professional guidance on the safe and secure handling of medicines
- RPS and RCN Professional guidance on the administration of medicines in healthcare settings January 2019
- HEE Advisory guidance administration of medicine by nursing associates
- NHS England and NHS Improvement. The NHS Patient Safety Strategy. Safer culture, safer systems, safer patients. July 2019
- Health and Social Care Act 2008 (Regulated Activities) regulations 2014: Regulation 20. Duty of Candour
- NHS England and NHS Improvement. The NHS Patient Safety Strategy, July 2019
- HSIB National Learning Report. Support for staff following patient safety incidents. January

10 Document control (external)

To be recorded on the policy register by Policy Coordinator

Date of approval:	25th March 2021	
Next review date:	1st April 2024	
This document replaces:	Version 2 [titled: Guidance for managing staff involved in medicine incidents or errors (excluding prescribing errors)]	
This document was approved by:	Name of committee/group	Date
	Drug & Therapeutics Committee	25th March 2021
This document was ratified by:	Name of committee/group	Date
	Drug & Therapeutics Committee	25th March 2021
An equality analysis was completed on this document on:	12th October 2021	
Document type	Public	
FOI Clause (Private documents only)	n/a	

Change record

Version	Date	Amendment details	Status
2	26 Jan 2017	Full revision	Withdrawn
	09 Jan 2020	Review date extended to 01 Apr 2020	Withdrawn
3	25 Mar 2021	Full review. Just culture guide added. Junior Dr flowchart added. Pharmacy error section added. Appendix 3 removed. Appendix 2 reviewed. Document title amended. Transferred to new template.	Published

Appendix 1A - Equality Analysis Screening Form

Please note: The Equality Analysis Policy and Equality Analysis Guidance can be found on the policy pages of the intranet

Name of Service area, Directorate/Department i.e. substance misuse, corporate, finance etc.	Pharmacy					
Policy (document/service) name	Supporting Staff and Learning from Medication Incidents					
Is the area being assessed a…	Policy/Strategy		Service/Business plan		Project	
	Procedure/Guidance			√	Code of practice	
	Other – Please state					
Geographical area covered	Trust wide					
Aims and objectives	Following this procedure will help the Trust to:- • implement a systematic response to medication errors and incidents to enable the identification of individual and organisational failures and • reduce adverse patient outcomes. • identify themes, trends and learning from incidents.					
Start date of Equality Analysis Screening (This is the date you are asked to write or review the document/service etc.)	25th March 2021					
End date of Equality Analysis Screening (This is when you have completed the equality analysis and it is ready to go to EMT to be approved)	12th October 2021					

You must contact the EDHR team if you identify a negative impact - email tewv.eandd@nhs.net

1. Who does the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan benefit?

Patients
All Trust staff involved in medication incidents

2. Will the Policy, Service, Function, Strategy, Code of practice, Guidance, Project or Business plan impact negatively on any of the protected characteristic groups below?

Race (including Gypsy and Traveller)	No	**Disability** (includes physical, learning, mental health, sensory and medical disabilities)	No	**Sex** (Men, women and gender neutral etc.)	No
Gender reassignment (Transgender and gender identity)	No	**Sexual Orientation** (Lesbian, Gay, Bisexual and Heterosexual etc.)	No	**Age** (includes, young people, older people – people of all ages)	No
Religion or Belief (includes faith groups, atheism and philosophical belief's)	No	**Pregnancy and Maternity** (includes pregnancy, women who are breastfeeding and women on maternity leave)	No	**Marriage and Civil Partnership** (includes opposite and same sex couples who are married or civil partners)	No

Yes – Please describe anticipated negative impact/s
No – Please describe any positive impacts/s

All staff will be supported when involved with a medication incident.

3. Have you considered other sources of information such as; legislation, codes of practice, best practice, nice guidelines, CQC reports or feedback etc.? **If 'No', why not?**	**Yes**	√	**No**	

Sources of Information may include: • Feedback from equality bodies, Care Quality Commission, Equality and Human Rights Commission, etc. • Investigation findings • Trust Strategic Direction • Data collection/analysis • National Guidance/Reports		• Staff grievances • Media • Community Consultation/Consultation Groups • Internal Consultation • Research • Other (Please state below)

4. Have you engaged or consulted with service users, carers, staff and other stakeholders including people from the following protected groups?: Race, Disability, Sex, Gender reassignment (Trans), Sexual Orientation (LGB), Religion or Belief, Age, Pregnancy and Maternity or Marriage and Civil Partnership

Yes – Please describe the engagement and involvement that has taken place

Medicines Management Nurse's, members of Trust Pharmacy and medical staff were consulted for the review of the procedure

No – Please describe future plans that you may have to engage and involve people from different groups

All staff will be invited to comment on the revised procedure when it is due for review.

5. As part of this equality analysis have any training needs/service needs been identified?	
Yes	Please describe the identified training needs/service needs below Trust staff to be made aware of the changes to the procedure at locality medicines management meetings. Briefing session to be arranged for pharmacy staff in relation to the changes in the process. Procedure will be highlighted during medicines management training.

A training need has been identified for;					
Trust staff	**Yes**	Service users	No	Contractors or other outside agencies	No
Make sure that you have checked the information and that you are comfortable that additional evidence can be provided if you are required to do so					

Appendix 1B – Approval checklist

To be completed by lead and attached to any document which guides practice when submitted to the appropriate committee/group for consideration and approval.

	Title of document being reviewed:	Yes/No/ Not applicable	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	procedure
2.	**Rationale**		
	Are reasons for development of the document stated?	yes	
3.	**Development Process**		
	Are people involved in the development identified?	yes	
	Has relevant expertise has been sought/used?	yes	Pharmacy, medic, nurses
	Is there evidence of consultation with stakeholders and users?	yes	
	Have any related documents or documents that are impacted by this change been identified and updated?	N/A	
4.	**Content**		
	Is the objective of the document clear?	yes	
	Is the target population clear and unambiguous?	yes	All Trust staff involved in medication incidents
	Are the intended outcomes described?	yes	
	Are the statements clear and unambiguous?	yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	yes	
	Are key references cited?	yes	
	Are supporting documents referenced?	yes	
6.	**Training**		
	Have training needs been considered?	yes	
	Are training needs included in the document?	yes	
7.	**Implementation and monitoring**		

	Title of document being reviewed:	Yes/No/ Not applicable	Comments
	Does the document identify how it will be implemented and monitored?	yes	
8.	**Equality analysis**		
	Has an equality analysis been completed for the document?	yes	
	Have Equality and Diversity reviewed and approved the equality analysis?	no	
9.	**Approval**		
	Does the document identify which committee/group will approve it?	yes	
10.	**Publication**		
	Has the document been reviewed for harm?	yes	Procedure does not guide patient care
	Does the document identify whether it is private or public?	yes	
	If private, does the document identify which clause of the Freedom of Information Act 2000 applies?	N/A	

Appendix 2 – A Just Culture Guide

NHS

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. Was there any intention to cause harm?

→ Yes

Recommendation: Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual.

→ END HERE

No go to next question - Q2. health test

2a. Are there indications of substance abuse?

→ Yes

Recommendation: Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier.

→ END HERE

2b. Are there indications of physical ill health?

2c. Are there indications of mental ill health?

→ Yes

Recommendation: Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier.

→ END HERE

if No to all go to next question - Q3. foresight test

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

→ If No to any

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

→ END HERE

if Yes to all go to next question - Q4. substitution test

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

→ If Yes to any

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

→ END HERE

if No to all go to next question - Q5. mitigating circumstances

5a. Were there any significant mitigating circumstances?

→ Yes

Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

→ END HERE

if No

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

→ END HERE

improvement.nhs.uk

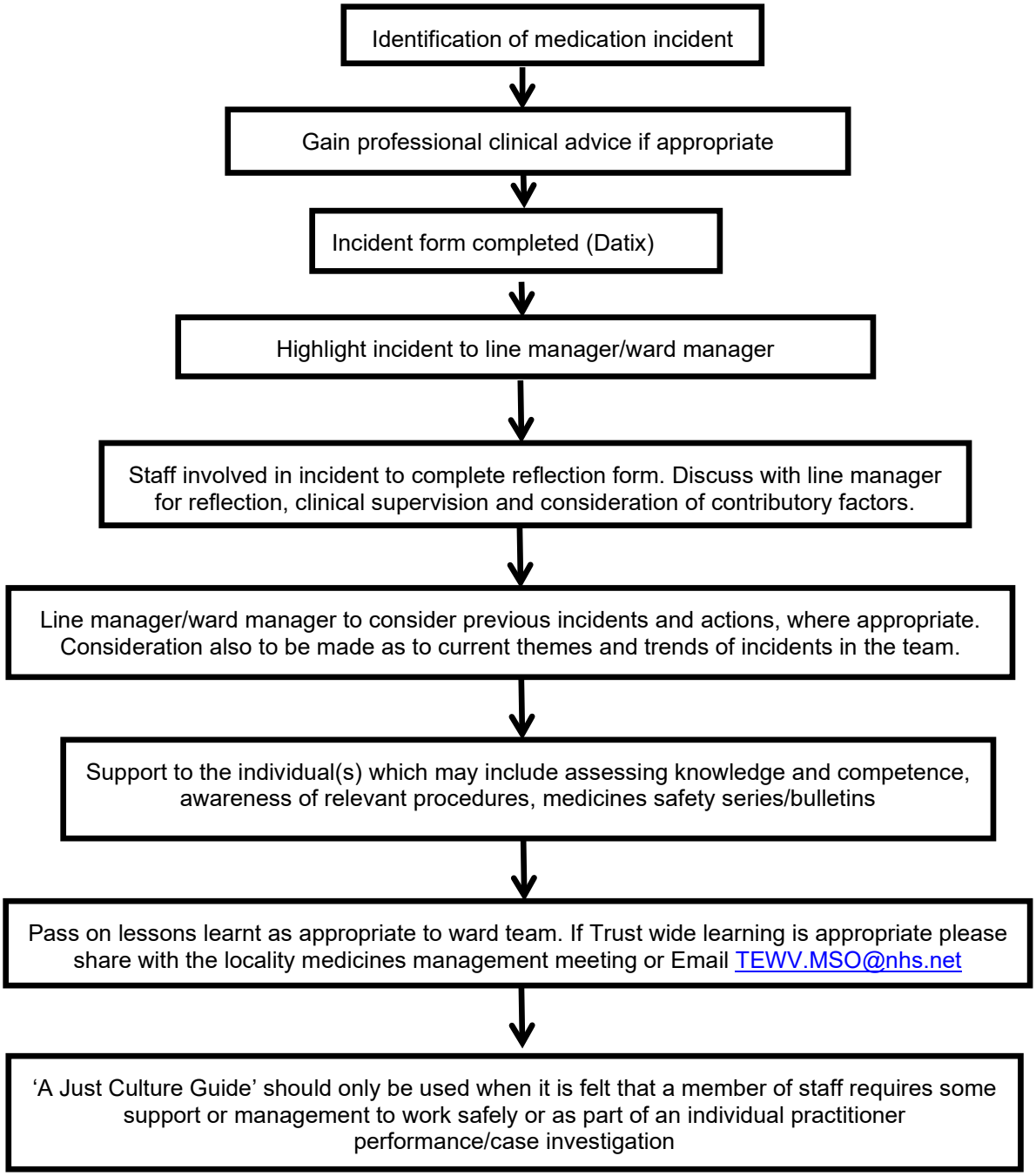
Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by:

Academy of Medical Royal Colleges · avma · BMA · Care Quality Commission · GMB · General Medical Council · National Guardian Freedom to Speak Up · NMC Nursing & Midwifery Council · Royal College of Nursing · Royal Pharmaceutical Society · UNISON Health Care · Unite the Union

NHS England and NHS Improvement

Appendix 3 - Process Flowchart for supporting staff involved in medicine related incidents



Further information and support should be obtained from the Lead Medicines Management Nurse or Medication Safety Officer: linda.johnstone4@nhs.net or TEWV.MSO@nhs.net

Appendix 4 - Medication Incident Reflective Form

Incident ID DATIX WEB:……..

It is important to reflect and review an incident so that everyone involved and the wider Trust can learn from what has occurred and improve patient safety in the future. Please reflect on the incident as soon as possible, ideally within seven days of the incident occurring.

This document will be used to reflect on the incident with your line manager. It should be retained in a portfolio or CPD record and presented at annual appraisal or submitted as part of the revalidation or portfolio review process. Note: As a professional you may wish to reflect on this incident for part of your revalidation using the professional bodies paperwork.

Please describe the incident (time of occurrence, venue, medication/s involved, presentation of the patient, the nature of the error, any other staff involved etc.)
Please reflect on your actual practice when the medication incident occurred (try to recall what you actually did on that day. Why did I act as I did? How does this differ from my normal practice? What internal/external factors may have influenced my actions?)
Please reflect on the environment on the ward or in the department at the time the incident occurred (were you required to respond to interruptions, how many staff were on duty, what was their skill mix, how many shifts since your last day off, were any other patient safety incidents occurring at the same time, did any patients require a high degree of attention or observation, was it busy / chaotic?)
Did you have all the information you required to hand in order to complete the task (specific drug information, all relevant patient information, a clear legible prescription etc?)

Do you experience any difficulties in accessing and implementing Trust policies, procedures and protocols in relation to medicines management? Did this play a part in the incident?
What would you have done differently, what have you learnt from this incident for yourself and for your team?
Evaluation
Agreed action plan
Completed by: **Date:**
This space is completely optional and can be used by you if you wish, to consider anything occurring in your personal life which may have had an impact on your ability to practice

Acknowledgement The Newcastle upon Tyne Hospitals NHS Foundation Trust

Appendix 5 - Optional Investigation Tool for Medication Incidents and Near Misses

Note the Trust HoS paperwork provided by the Central Approvals Team must be completed and submitted when requested.

Datix ID _____

1.Brief details of the incident

2.Chronology of events

Date	Time	Fact *e.g. recorded in patient medical notes at the time of or immediately after the incident*	Comment *e.g. opinion or verbal recollection*

3.

Medication factors		If Yes:		Comments, further information & detail
Did the incident involve an omitted medication?	Y / N	**Was the drug?** • Unavailable • Ward stock • A critical medicine . Patients Own Drug **Was a community nurse visit?** • Missed • Not booked	 Y / N Y / N Y / N Y / N Y / N Y / N	

Did the patient receive incorrect medication?	Y / N	**Was the drug?** • Patients Own Drug • Ward stock • Labelled for patient by pharmacy • Clearly labelled • Out of date • Wrong formulation • Sound alike	 Y / N Y / N Y / N Y / N Y / N Y / N Y / N	
Did the patient receive an incorrect dose?	Y / N	**Was the dose** • An under dose • An overdose • Due to wrong frequency	 Y / N Y / N Y / N	
Did the patient receive the medication via an incorrect route?	Y / N	**Was the drug** • Oral/enteral medication or feed/flush administered by parenteral route • Clearly labelled • Ward stock • Prepared/labelled by pharmacy • Prepared by nurse/medical staff • Prepared by a student	 Y / N Y / N Y / N Y / N Y / N Y / N	
Was the medication an injectable?	Y / N	**Was the injectable medicine** • Pre prepared commercial product • Prepared on the ward/unit • Prepared in patients home • Second checked	 Y / N Y / N Y / N Y / N	
Were the prescription details missing or unclear?	Y / N	**Was the following missing or unclear** • Patient details • Medication details • Allergies • Similar name alert • Frequency/dose to be held or reviewed before administration	 Y / N Y / N Y / N Y / N Y / N	

Equipment factors				
Was there a problem with the medicine delivery device?	Y / N	**Was the device** • Maintained • Trust approved • Appropriate for the purpose	 Y / N Y / N Y / N	
Was the correct equipment available?	Y / N	**What was not available – please state**		
Is there a suspected fault with the device?	Y / N	**Please state name of item, batch number and expiry date**		

Policy, procedure and protocol factors				
Were local procedures and policies followed?	Y / N	**Is the policy/procedure** • Approved and on the Trust intranet • Up to date • Complicated/difficult to follow • One of several for the same process • Unclear • Included in staff training	 Y / N Y / N Y / N Y / N Y / N Y / N	
Physical environment				
Did the working environment contribute to the incident?	Y / N	**In the area where the incident occurred is there** • Lack of space/clutter • Poor temperature control • Poor lighting • Difficulty in observation of patients due to poor layout • Noisy or interruptions	 Y / N Y / N Y / N Y / N Y / N	
Time, workload and staffing				
Did any time delays or ward/unit/team pressure issues play a part in this incident?	Y / N	**Was there** • Delay in provision of care • Inappropriate patient transfer • No available bed • Difficulties in contacting responsible staff • Lack of support out of normal hours • High unit workload • Insufficient staff despite being fully staffed • Staff sickness/vacancies	 Y / N Y / N Y / N Y / N Y / N Y / N Y / N Y / N	
Patient factors				
Was there a reason why this incident was more likely to occur with this patient?	Y / N	**Did the individual or their carer** • Have language difficulties • Act in an uncooperative manner • Have a complex medical history or unusual physiology • Appear intoxicated • Act in an aggressive manner	 Y / N Y / N Y / N Y / N Y / N	

Communication				
Did poor/difficult communication contribute to the incident?	Y / N	**Was there** • Poor communication between staff • Poor communication with patient • Absence of /incomplete handover • Incomplete discharge process • Unclear / incomplete / unavailable notes • Difficulty contacting individuals	 Y / N Y / N Y / N Y / N Y / N Y / N	
Team and individual factors				
Were the individuals involved in the incident carrying out their usual role?	Y / N	**Was the task** • Straightforward • Unfamiliar • Difficult/complex • Monotonous • Delegated inappropriately • Unclear • Poorly supervised by someone more senior	 Y / N Y / N Y / N Y / N Y / N Y / N Y / N	
Did anything impact on the ability of staff to function as a team at the time of the incident?	Y / N	**Within the team was there** • Conflicting team goal • Lack of respect • Poor delegation • Lack of monitoring and feedback • Tiredness /fatigue • Stress • A feeling of being rushed • Distraction • Inexperience • Staff felt unable to raise concerns	 Y / N Y / N Y / N Y / N Y / N Y / N Y /N Y / N Y / N Y / N Y / N	

Education and training				
Did issues with staff knowledge and skills contribute to the incident?	Y / N	**Within the team or on an individual basis was there** • Inadequate induction • Inadequate training • Lack of protected teaching time • Non standardised training • Lack of regular updates	 Y / N Y / N Y / N Y / N Y / N	
Has a similar incident occurred within this area before?	Y / N	**Datix number**	Y / N	

Staff members involved in the incident

Staff name	Job role	Reflective form/ statement completed received	Reflective form / statement returned

Duty of candour				Additional information/comments
Was the patient affected by the incident?	Y / N	Has a verbal apology been given and documented?	Y / N	
Is the patient harm graded moderate or above?	Y / N	The formal Duty of candour applies. A letter of apology must be sent with an offer to share the findings of the investigation. All letters must be saved to DATIX		

Final report

4. Key findings / root cause from investigation
5.Outcome from NHS improvement "A Just Culture Guide"
6. What support has been provided to staff involved in the incident?
7.Lessons learned
8.Recommendations

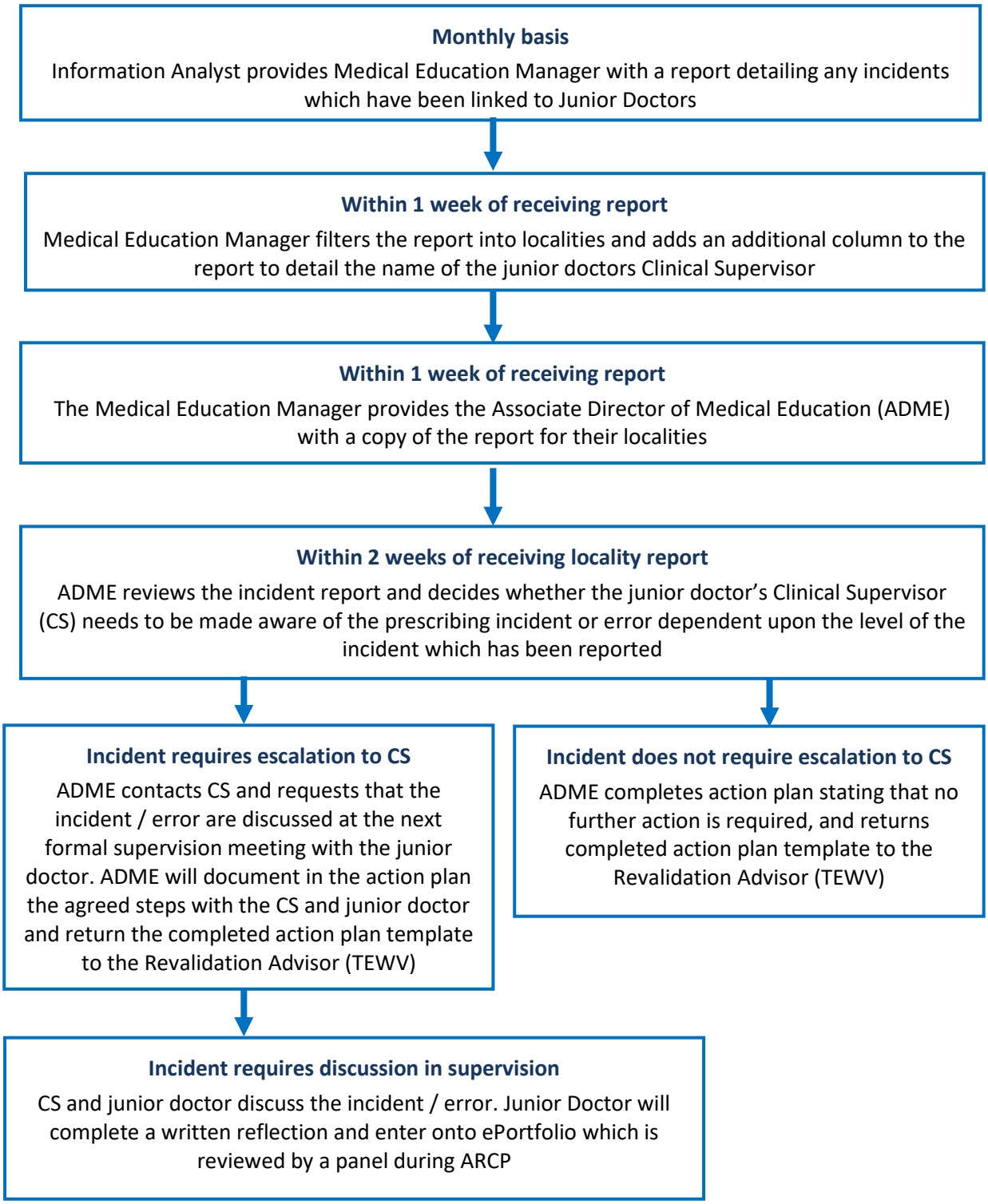
Members of staff completing the incident review

Name (print)	Designation	Date

Acknowledgments The Newcastle Upon Tyne Hospitals NHS Foundation Trust

The following appendices include guidance for Pharmacy staff and Junior Doctors

Appendix 6 - Junior Doctors Involved with Medication Incidents or Errors Flowchart



Appendix 7 - Pharmacy staff involved in medication incidents

What is an error?

- Any dispensing error that leaves the dispensary
- A dispensing error that is picked up before it leaves the department (known as a near miss error)
- A clinical error on the ward for example: - incorrect medicine reconciliation, transcribing error
- An operational error for example: - wrong medication ordered for a patient

Definitions

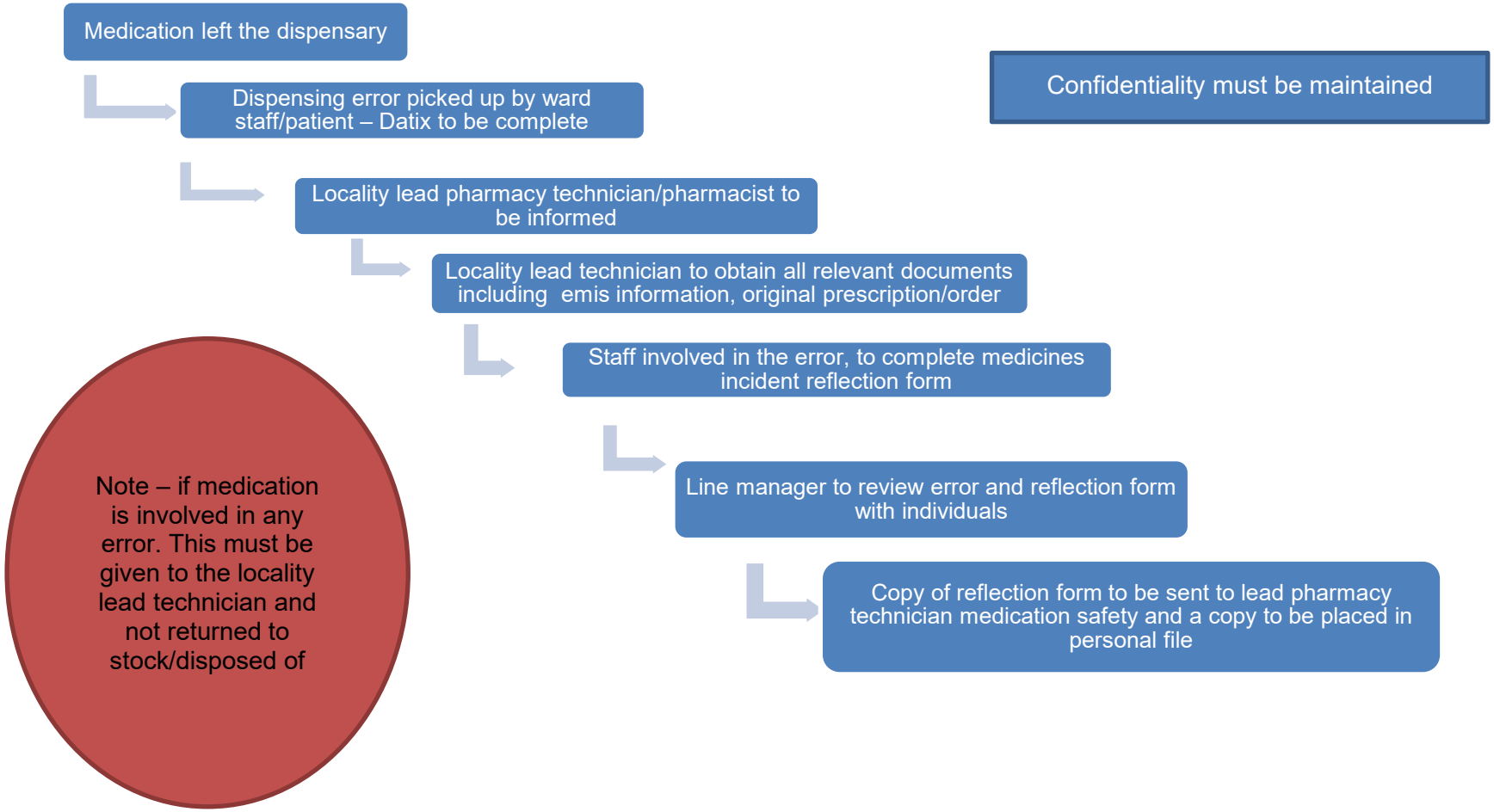
Role	Definition
Dispenser	Pharmacy assistant, pharmacy technician, pharmacist who dispense medication in a pharmacy dispensary/ward
Clinical pre screen	Pharmacist who pre-screens prescriptions/orders for clinical and legal accuracy
Final accuracy checking	Accredited accuracy checking pharmacy technician or pharmacist who checks dispensed items before they leave the dispensary

Process to be followed immediately after the error or when notified of an error

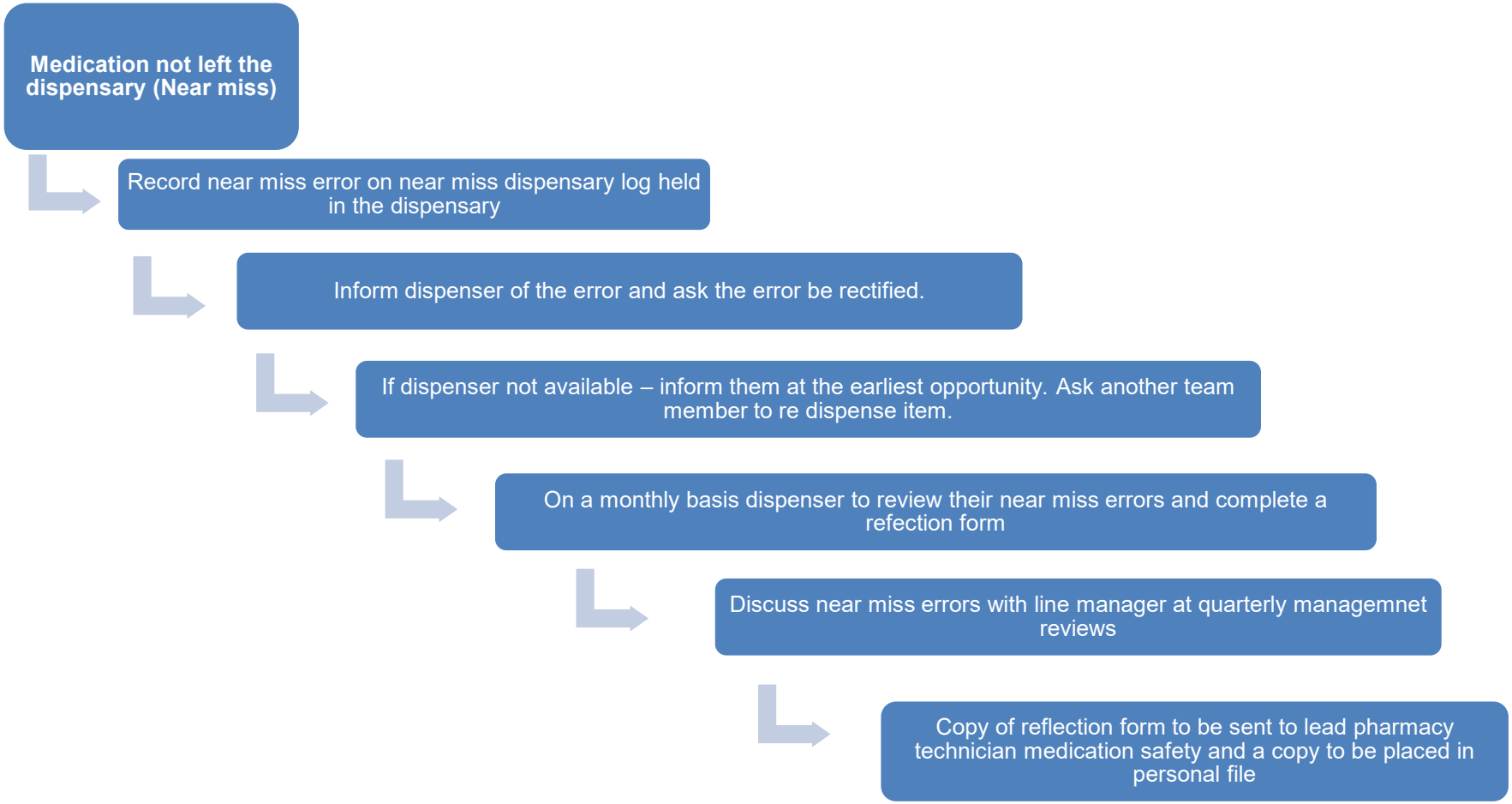
- For dispensary errors that have left the department or clinical/operational errors that have occurred on a ward, staff MUST report the error within 24 hours of being notified of the incident using Datix.
- For dispensary near miss errors complete the pharmacy error log held within the dispensary, appendix 11
- Reflection form is to be completed as soon as possible after the incident, no later than one week after the incident appendix 4.
- Line manager to meet with the individual to review the incident and reflection form.

Appendix 8 - Management of Dispensing Errors

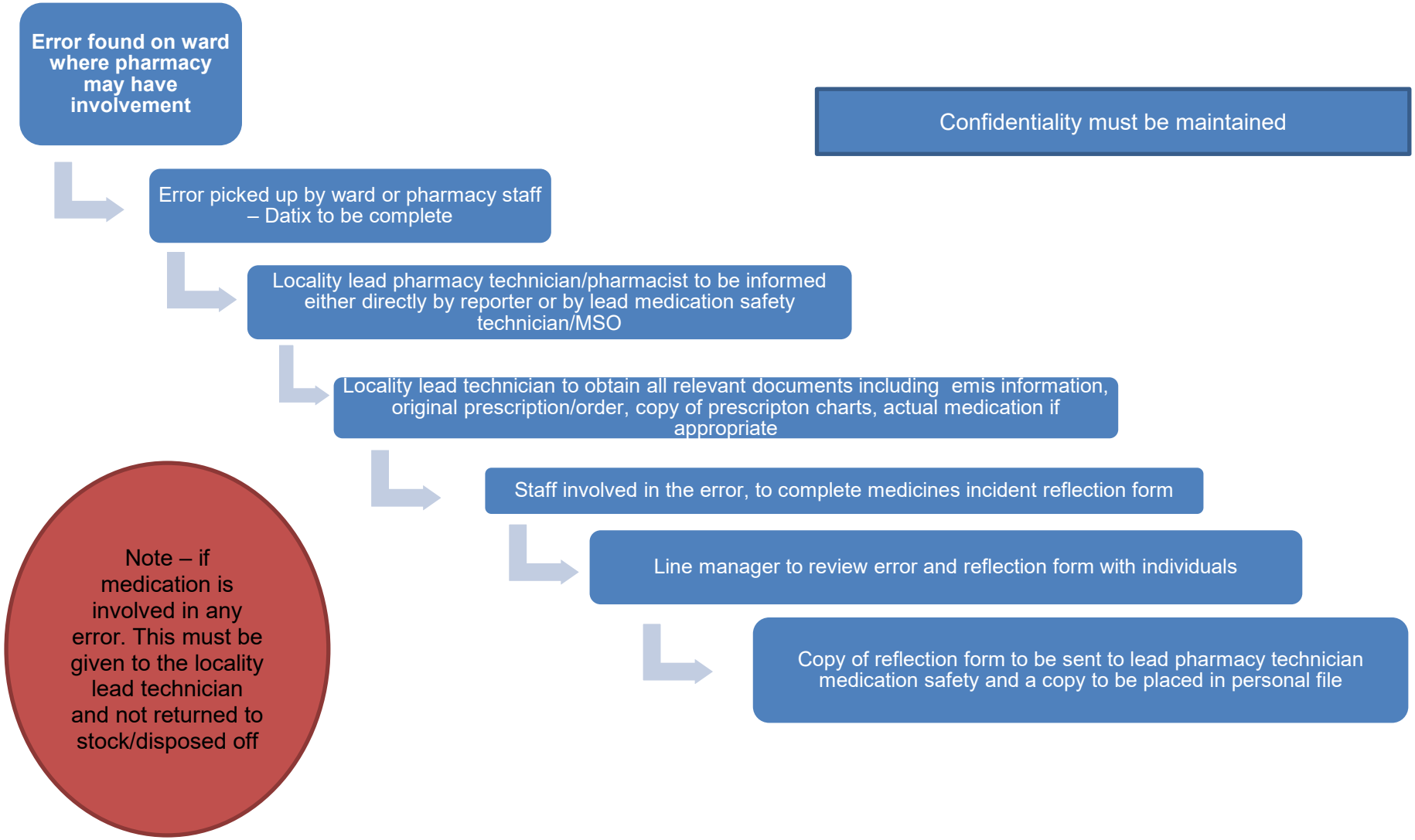
8a Medication has left the dispensary



8b Medication has not left the dispensary (near miss)



Appendix 9 – Pharmacy Clinical or Operational Errors



Appendix 10 - Pharmacy error stage process

Stage 1

- If a staff member exceeds the error rate:

Role	Error rate
Dispenser Ward clinical / operational	No more than 4 major errors per month
Clinical pre screener	No more than 3 minor errors or 1 major error in 1 month
Final accuracy checker	No more than 3 errors within 3 months

- Final Accuracy checkers will enter into a 2 month monitoring period in which no further errors should leave the department

Stage 2

- A staff member will enter into Stage 2 of the process if either, they have triggered in two consecutive months, or they have not had a period of two months trigger free since being in stage 1.
- Final accuracy checkers will enter into stage 2 if they do not pick up an error that leaves the department within the 2 month monitoring period mentioned above.

Stage 3

- A staff member will enter into Stage 3 of the process if either; they have failed to meet the standard in three consecutive months, or they have not had a period of two months trigger free since being in stage 2.
- Final accuracy checkers will move into stage 3, if they did not successfully complete the checking simulation identified in stage 2 at the first attempt, but did so on the second or third attempt.

A discussion between the individual and the line manager will occur. The discussion will involve reviewing all errors made to identify any themes/trends, discuss any internal/external factors which may have contributed and how these can be managed/supported and identify any knowledge gaps and address them. They will reinforce the steps in the dispensing or clinical pre-screening.e.g. The importance of self-checking, and ensure that any knowledge gaps are identified and addressed, any support which the department could give should be discussed. Any support that can be given by the department must be discussed and where necessary the E&T or medication safety lead technician can be involved in the discussion. A written record of the discussion is completed and added to the staff member's personal file.

- Monitoring period only

- In addition to this discussion;
  - Dispensers must complete and pass the self-check and dispensing simulations. Once complete the staff member may continue with dispensing duties.
  - Clinical pre screeners will have an action plan created. The action plan may utilise clinical pre-screening simulations, but must be signed off as complete by the E&T lead pharmacist.
  - Final accuracy checkers must complete and pass a final check simulation and a 100 item competency log. If the staff member completes both successfully, they will return to the standard 3 month monitoring period, however if they trigger within that period, a discussion with the line manager, a member of the Trust's Human Resource department and the staff member must take place. The outcome of this discussion could be that the staff member may be entered into the trust Capability procedure. If the staff member fails to complete either the simulation or the log successfully they will move into stage 3.

- At stage 3, in addition to the previously described stages, the dispenser will be asked to complete a competency log of 500 items, see appendix 4. To complete this log successfully no more than 4 errors - will be accepted.
- Once the log has been successfully completed the staff member must not trigger for 3 months to demonstrate continued improvement.
- If a member of staff fails to meet the standards described in the error rate table within this set time frame they will re-enter the process at stage three.
- If the staff member completes the competency log and does not trigger within the subsequent 3 months, the staff member will re-enter the process at stage 1 if they were to trigger again.
- If the log is not successfully completed i.e. if they trigger whilst completing the competency log, a discussion with the line manager, a member of the Trust's Human Resource department and the staff member must take place. The outcome of this discussion could be that the Dispenser will be entered into the trust capability procedure.
- Final accuracy checkers reaching stage 3 will undertake a discussion with their line manager, and a member of the Trust's Human Resource department. The outcome of this discussion could be that the staff member will be entered into the trust capability procedure.
- Validating Pharmacists who reach stage 3 should undergo a further review with their Line Manager as per Trust capability procedure accompanied by a member of the Trust's Human Resource department.

Near miss errors

Dispensary near miss errors will be reviewed at quarterly management reviews with the staff member and line manager. Further advice can be obtained from the Lead Medication safety technician and E&T lead technician. Near miss errors will be monitored for themes and trends and medication safety huddles will be held with dispensary teams to discuss.

Monitoring

Dispensary near miss errors will be logged on the log sheet held in each of the dispensaries at Rosebery Park, Foss Park and Westpark.

On the 1st working day the following month, the error logs are to be scanned to the medication safety lead technician

The medication safety officer, medication safety lead technician, education & training lead technician and clinical services lead pharmacist will meet on a quarterly basis to review pharmacy errors and identify any learning to share with the wider pharmacy team through bulletins and supervision. The data will be reported to PLT patient safety huddle on a quarterly basis.

Medication safety team will review all reported incidents and near miss errors and identify trends/themes. E.g. number of errors per individual, number of errors as a percentage of total items handled and reports to locality

Learning bulletins will be produced and themes discussed in supervision sessions.

Acknowledgment Adapted from Northumbria Healthcare NHS Foundation Trust Pharmacy Procedure for reducing and learning from internal pharmacy dispensing process errors

Clinical Pharmacy Errors on in-patient areas/community – all need reflections completing by staff

Type	Minor	Major
Meds rec error	Anything that had no significant impact on the patient (judged by line manager)	Anything that has led to missed doses of medication, is detrimental to the patient's care or lead to negligent consequences (judged by line manager)
Kardex screening error		
Kardex endorsement error		
Allergy error		
Professional check error		
Kardex rewrite error		
PODs error		
Ordering error		
HDAT % error		
Leave/Discharge Rx Checking error		
Transcribing Leave/Discharge Error		
Expired stock not removed		
Stock list review error		
Audit completion error		
CD ordering error		
Error recording on PARIS		
Medication reminder chart error		
Inappropriate advice given		
NMP prescribing error		

Incidents will be classed as minor or major incidents dependent upon the scenario and the outcome of the investigation. Some examples of the severity could be as follows:

Examples of Major

- PODs error –eg item expired, wrong patient name
- Meds rec – eg medication missed off by staff
- Professional Check error – eg interaction missed
- Ordering error – eg code 1 not actioned – so medication not ordered for patient in timely manner
- Accuracy check of leave/discharge prescriptions – eg prn medication missed off – and staff didn't check if patient was using routinely and was needed
- HDAT % error – eg staff error in calculating % led to patient not being identified as HDAT (monitoring not per TEWV procedure)
- Kardex rewrite error –eg item missed off new kardex – not spotted on rewrite check – led to missed doses of medication
- Missed off allergy eg in medicines reconciliation process.

Examples of Minor

- Endorsement of drug chart – medication endorsed against wrong drug
- Meds rec error – not all recently stopped medication listed on PARIS
- Audit completion error
- Stock list review error – item removed from stock list in error

Appendix 11 – Dispensary Near Miss Log

Dispensary Near Miss log				**Site** :-			
Date & time error picked up	**Staffing levels (P, T, A)**	**Order type**	**Description of error found** **Please state what should have been supplied and what was actually dispensed**	**Error code**	**Dispensed by**	**Checked by (print & sign name)**	**Date feedback given**

ERROR CODES				
1. Incorrect drug	2. .Incorrect strength	3. Incorrect form	4. Incorrect patient name	5. Incorrect directions
6. Correct drug, incorrect label	7. Incorrect drug, correct label	8. Missing additional warnings	9. Expired medication	10. Incorrect quantity
11. Incorrect cost code	12. Missing item	13. No clinical check	14. Wrong expiry or no expiry	15. . Compliance aid error – please add detail

t the end of each month please scan the error logs to amandametcalf@nhs.net

Appendix 12 – Dispensary accuracy log

Name…… Hospital……

Consecutive Item Number	Date	Type of Prescription (see below)	Drug name, form and strength	Dispensing error detected Yes/No	Error Found (see code)	Checkers Signature

Type of Prescription Codes:
Ip=In-patient, Lv=Leave Rx, Dis=DischargeRx, St=Stock, SM=Self-Medication, CD=Controlled Drug,PGD, MP=Medipack, DP=Depot Rx, M=Miscellaneous – please specify

Total of checked items on sheet

Error codes (* = major error)

1. Incorrect label
a) drug name*
b) drug form*
c) drug strength*
d) directions*
e) quantity*
f) incorrect patient's name*
g) missing/incorrect additional BNF warnings*
h) Missing or inappropriate additional warnings
i) directions not in accordance with local SOPs*
j) Illegible label (due to set up in printer)*
k) Ward/consultant/cost centre
l) incorrect expiry date*
m) incorrect batch number
n) misspelt patient's name
o) other – please specify

2. Incorrect Contents
a) drug*
b) drug form*
c) drug strength*
d) expired stock*
e) containers with transposed labels*
p) quantity*
f) other – please specify

3. Other
a) prescription not pre-checked by pharmacist*
b) bag contains extra or missing items*
c) failure to meet legal requirements*
d) outside range of items agreed may check in local SOP*
e) incorrect container/closure
f) incorrect or missing oral measuring device
g) missing signature/endorsing
h) missing sundry item - no PIL, warning card
i) missing/inappropriate bag
j) missing owing information
k) bag not labelled / labelled incorrectly
l) other – please specify