Shropshire Community Health
NHS Trust

Document Details	
Title	**Medicines Policy Part 8: The management of medicines incidents**
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Main points the document covers	Process following identification of a medicines related incident
Who is the document aimed at?	All clinical staff
Author	Medicines Management
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Approved by (Committee/Director)	Patient Safety Committee
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Subcategory	Medicine
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Method	Electronically to senior staff and available to all staff via the Trust website
Document Links	
Required by CQC	Yes
Required by NHLSA	Yes
Other	None

Amendments History		
No	Date	Amendment
1	June 2017	Re-write of the policy including flow chart and template documentation
2	April 2021	Scheduled review Inclusion of dispensing and prescribing incidents and how to manage. New definitions with broader content for high-risk medicines Addition of RCA template Reference to Patient Safety Strategy
3	May 2024	Major changes to support implementation of new Patient Safety Incident Response Framework

Contents

1.0 Introduction

1.1 What is a Medication Error?

The National Patient Safety Agency's (NPSA) definition of medication errors is: "Patient safety incidents involving medicines in which there has been an error in the process of prescribing, dispensing, preparing, administering, monitoring, or providing medicine advice, regardless of whether any harm occurred".

Examples of medication errors are given below: (this is not an exhaustive list)

- Omissions – any prescribed dose not given
- Wrong dose administered, too much or too little
- Extra dose given
- Un-prescribed medicine – the administration of medication which has not been prescribed
- Wrong dose interval
- Wrong administration route
- Wrong time for administration
- Not following 'warning' advice when administering e.g. Take with or after food
- Administration of a drug to which the patient has a known allergy
- Administration of a drug past its expiry date or which has been stored incorrectly

All medicines have inherent hazards. Most medicines are toxic in overdose or have the potential to cause harm if used inappropriately or incorrectly. Usually, medication errors happen because the safeguards and defences intended to prevent medication errors from happening are inadequate or fail.

Medication is the most common medical intervention within the NHS. Whilst every care is taken by individuals and the organisation when managing medication, errors involving medicines are sometimes inevitable due to human components.

A medication error can pose a threat to the patient as well as the organisation. Members of staff making errors may be greatly affected and require support.

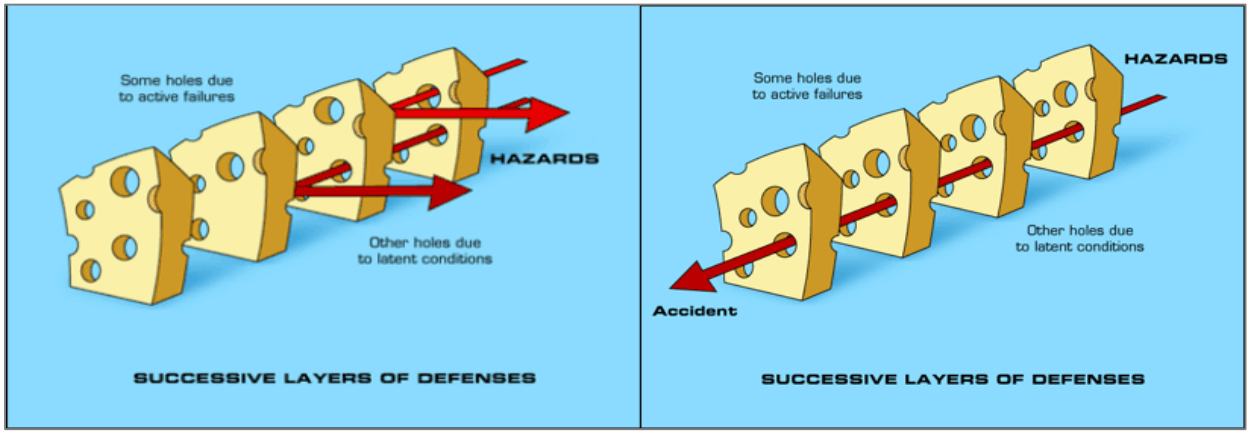
The Safe and Secure Handling of Medicines report (Royal Pharmaceutical Society of Great Britain, 2005) stated that there are key factors in the safe management of medicines. They describe these as:

- An increased emphasis on the need for governance
- A growing awareness of medication errors
- Changing public expectations
- Changing models of patient care
- Technological advances
- Developing roles of staff

CQC Fundamental Standards (2023) Regulation 12: Safe Care and Treatment intends to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm. The regulation states that medicines must be supplied in sufficient quantities, managed safely and administered appropriately to make sure service users are safe.

1.2 Why do Medication Errors Occur?

The administration of a medicine to a patient is the result of several activities by different practitioners and may also be underpinned by organisational policy. Every step in the medicines management process has the potential for failure, to varying degrees. The ideal system is analogous to a stack of slices of Swiss cheese. Consider the holes to be opportunities for a process to fail, and each of the slices as “defensive layers” in the process. An error may allow a problem to pass through a hole in one layer, but in the next layer the holes are in different places, and the problem should be caught, e.g. an unsafe prescription being challenged by a nurse or pharmacist or a clinician challenging unsafe organisational policy. Each layer is a potential defence against potential error impacting on a patient.



For an error to impact on a patient, the holes need to align for each step in the process allowing all defences to be defeated and resulting in an error. If the layers are set up with all the holes lined up, this is an inherently flawed system that will allow a problem at the beginning to progress all the way through to adversely affect the outcome. Each ‘slice of cheese’ is an opportunity to stop an error. The more defences you put up, the better. Also, the fewer the holes and the smaller the holes, the more likely you are to catch/stop errors that may occur.

1.3 Why Reduce Medication Errors?

- Reduces the risk of a patient being harmed.
- Can prevent unnecessary hospital admissions or re-admissions.
- Can prevent prolonged hospital stays.
- Reduce unnecessary costs to the NHS.
- Increase staff confidence and morale.
- Reduces risk of litigation for clinical negligence
- Reduce risks of harm to Trust reputation
- Provide reassurance to regulatory bodies and commissioners.

1.4 What are the Statutory Requirements around Reporting Medication Errors?

There is no requirement to notify CQC about medicines errors, but a notification would be required if the cause or effect of a medicine error met the criteria for one of the following to be notified. The flow chart identified in Appendix 1 produced by the CQC (Duty of candour: notifiable safety incidents - Care Quality Commission (cqc.org.uk)) should be followed in relation to notifiable events.

All incidents should be investigated in line with the Patient Safety Incident Response Framework (2022) (NHS England » Patient Safety Incident Response Framework and supporting guidance). As well as, the local patient safety incident response policy (Patient Safety Incident Response Policy (PSIRF)) and the local patient safety incident response plan (Patient Safety Incident Response Plan) which highlights 'Medication Events' as one of the identified 'local focus's' for the Trust.

The Patient Safety Incident Response Framework (PSIRF) sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety.

Patient safety incidents are unintended or unexpected events (including omissions) in healthcare that could have or did harm to one or more patients.

The PSIRF replaces the Serious Incident Framework (SIF) (2015) and makes no distinction between 'patient safety incidents' and 'Serious Incidents'. As such it removes the 'Serious Incidents' classification and the threshold for it. Instead, the PSIRF promotes a proportionate approach to responding to patient safety incidents by ensuring resources allocated to learning are balanced with those needed to deliver improvement.

The PSIRF is not a different way of describing what came before – it fundamentally shifts how the NHS responds to patient safety incidents for learning and improvement. Unlike the SIF, the PSIRF is not an investigation framework that prescribes what to investigate. Instead, it:

- advocates a co-ordinated and data-driven approach to patient safety incident response that prioritises compassionate engagement with those affected by patient safety incidents,
- embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management.

The Royal Pharmaceutical Society (2024) produced the following document in response to patient safety professional standards: Patient safety professional standards responding to patient safety incidents 2024-270324-B.pdf (rpharms.com)

2.0 Purpose

This policy describes the procedures that should be followed when a medication error occurs. The procedure describes immediate action to ensure patient safety, grading of errors (where appropriate) and longer-term actions to ensure that individuals, team, group and organisation can learn from errors.
This policy is specifically written for all clinical staff involved in the prescribing, dispensing, administering or monitoring of medication. The policy is also relevant for managers of such staff and gives instruction for managing staff who have been involved in a medication error.

Nurses and Nursing Associates are registered and regulated by the Nursing & Midwifery Council (NMC).

Pharmacists and Pharmacy Technicians are registered and regulated by the General Pharmaceutical Council (GPhC).

Doctors are registered and regulated by the General Medical Council (GMC).

Other Health Care Professionals with a responsibility to administer medicines will be accountable to their relevant professional body / council.

Administration of specified medication(s) which have been agreed by the Trust can be delegated by a registered professional to an unregistered professional who has been deemed competent in that task, e.g., administration of insulin in a patient's home. It is the responsibility of the delegating registered professional to ensure the unregistered professional is competent to undertake the task and the overall accountability remains with the delegating registered individual. Any errors resulting from an "unregistered" staff member (e.g. healthcare assistants) administering medication should be handled by the staff member's line manager. Support is available via the Medicines Safety Officer to agree an appropriate investigation method for these types of incidents.

3.0 Objectives

The principal objectives of this policy are to:

- Ensure the immediate and long-term safety of the patient.
- Support the member of staff who made the error in an individualised manner so that risk of such errors are minimised where possible and in-line with the "just culture" guide (NHS England » A just culture guide)
- Support and provide guidance for managers when dealing with staff who have made an error.
- Provide a framework for grading errors so that staff are managed fairly and consistently in-line with the Patient Safety Incident Response Framework (2022)
- Ensure the organisation embeds a culture of learning from the error in order to minimise such occurrence in the future and adopt a pro-active quality improvement approach to patient safety.

4.0 Process

Human error is inevitable. Identifying incidents, recognising the needs of those affected, undertaking meaningful analysis and responding to reduce the risk of recurrence remain essential to improving safety. This policy aims to support staff and managers to operate systems, underpinned by behaviours, decisions and actions, that assist learning and improvement, and allow the Trust to examine incidents openly without fear of inappropriate sanction, support those affected and improve services.

All medication errors should be reported via the Trusts incident reporting system Datix and all staff involved in the incident should also be recorded to support the review process and ongoing learning and improvement.

In order to assign the appropriate level for a given medication error, the incident should be assessed, and the consequence of the error determined by the degree of harm or potential degree of harm to the patient (e.g., near misses).

Tools in place to support the decision making around this process include the Patient Safety Incident Response Framework (2022) and NHS Improvement (NHSI), A just culture guide. In addition, the Trust's Incident Levels guidance and Risks Categorisation Matrix which are all available on the Trust intranet and should also be referred to prior to making a decision.

It is not possible for this policy to be prescriptive in its guidance relating to the determination of the level of seriousness of any given medication error due to the multi-factorial nature of errors. The tools described above, and the discretion of the management teams should determine the level. The Medicine's Safety Officer (MSO) can support with this decision making where required (please contact Shropcom.MSO@nhs.net).

4.1 Recognition of Errors and Incident Themes

Medication related incidents should always be formally reported as soon as possible via the Datix Incident Reporting System: Datix: DATIX Incident Form (DIF1) . This should automatically notify the line manager involved in the incident.

Errors can be further escalated or highlighted to managers via one of the following routes:

- Self-reporting by staff member
- Patient/representative reporting
- Complaints / PALS by patient/representative
- Reporting by colleagues
- Routine audits (retrospective reporting)
- Audits (routine planned or spot audits)
- Regulatory bodies
- Themes highlighted via the MSO's Medicines Incident Thematic Review

4.2 Informing Patient / Parent / Carer Regarding Medication Errors

The importance of the role of patients, their families and carers, and other lay people in improving the quality of NHS care is increasingly recognised. 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 and to support the review and learning process.

Where a medication error at any stage has been detected and has affected a patient, the patient should be informed as soon as possible by the healthcare professional involved / nurse in charge / line manager or doctor in charge of the patient's care (select most appropriate dependant on the error that has occurred).

Immediate actions to support patient and / or family engagement following the incident should include:

- Informing the patient (and / or family) that an error has occurred.
- Counselling the patient (and / or family) with regards to the likely risk and outcome of the incident as appropriate
- Ensuring the above discussion is recorded in the patient's clinical record.
- Reassuring the patient (and / or family) that the error will be reviewed, and an appropriate level of investigation will occur with an aim to avoid re-occurrence.
- Emphasising to the patient (and / or family) that their care is a priority.

- Giving the patient (and / or family) the opportunity to be involved in the review process in line with the Patient Safety Incident Response Framework (2022).

Where an apology is given, it is acknowledged that an apology is not necessarily an admission of any liability. Saying sorry meaningfully when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them. NHS Resolution (2023) acknowledges that saying sorry is:

- always the right thing to do,
- not an admission of liability,
- a way to acknowledge something could have gone better,
- the first step to learning from what happened and preventing it recurring.

The 'Duty of Candour' is a general duty for any staff providing care to be open and transparent with service users. More information regarding duty of candour can be found here: 'Regulation 20: Duty of Candour (cqc.org.uk)'. There is also a short animation available via NHS Resolution: 'Duty of candour animation - NHS Resolution'. For more information regarding the specific trust Duty of Candour Process, please follow the trust 'Duty of Candour and Being Open Policy (shropcom.nhs.uk)'.

Duty of candour should be applied within the Trust for any medication events reported that are rated as moderate or above (level of harm definitions can be found in Appendix 2). The below scoring tool should also be used identify the consequence and harm rating to the patient.

4.2.1 Scoring the Consequence and Harm Rating to patient

				Consequence Score	Will undoubtedly occur, possibly frequently	Will occur but not persistently	May occur occasionally	Do not expect to happen but is possible	Cannot believe this will ever happen
Injury/Harm	**Finance**	**Service**	**Reputation**		**Almost certain**	**Likely**	**Possible**	**Unlikely**	**Rare**
Likelihood Score					**5**	**4**	**3**	**2**	**1**
Very minor or no harm	Less than £10,000	No or very little impact on services	Some negative publicity	**None 1**	**LOW 5**	**LOW 4**	**VERY LOW 3**	**VERY LOW 2**	**VERY LOW 1**
Minor injury/ illness (e.g. cuts and bruises) will resolve within a month	£10,000 to £50,000	Disruption of services causing inconvenience. May cause efficiency/ effectiveness problems	Regular negative publicity	**Minor 2**	**MODERATE 10**	**MODERATE 8**	**LOW 6**	**LOW 4**	**VERY LOW 2**
Injuries of illness which requires extra treatment or protracted period of recovery. Should resolve within a year.	£50,000 to £500,000	Loss of service for a significant period of time (less than a month)	Loss of public confidence, protest action	**Moderate 3**	**HIGH 15**	**MODERATE 12**	**MODERATE 9**	**LOW 6**	**VERY LOW 3**
Single serious (life threatening) injuries/ illness	£500,000 to £3.5m	Loss of services to such an extent that effects on public health will be measurable	Punitive action, e.g. HSE, Healthcare Commission, significant organisational change results	**Major 4**	**HIGH 20**	**HIGH 16**	**MODERATE 12**	**MODERATE 8**	**LOW 4**
Multiple serious (life threatening) injuries/ illness	£3.5m plus	Permanent loss of a significant service. Threatens the viability of the organisation	Damage to such an extent that the organisation must cease to exist as is	**Catastrophic 5**	**HIGH 25**	**HIGH 20**	**HIGH 15**	**MODERATE 10**	**LOW 5**

The incident must be scored appropriately using the above matrix within the Datix proforma to capture the seriousness of the incident or near miss.

For any incidents categorised as moderate harm or above. The incident should be discussed at the trust Patient Safety Investigation Panel where the most appropriate investigation response will be decided as per the Patient Safety Investigation Response Framework (2022).

Where the incident is a near miss, ensure it is still scored as if it happened. Following investigation, once it is confirmed that there is no patient harm, the harm level can be downgraded following discussion at Patient Safety Incident Response Panel.

In these instances, this information will be used as a positive learning point as no harm came to the patient but, may still require some investigating to ensure the process which captured the incident is failsafe and unlikely to allow an incident to take place unnoticed.

4.3 Management of Medication Administration Errors

Preparation and Administration Errors may include:

- Administration without a valid prescription.
- Administered of the wrong medication / dose / route / formulation.
- Patient administered an out-of-date medicine.
- Medication administered to the wrong patient.
- Medication omitted without a clinical rationale.
- Medication incorrectly prepared / reconstituted.
- Incorrect infusion rate.
- Inappropriate administration of “prn” medicines.
- Medication administered late / early*.

*(The Trust 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).

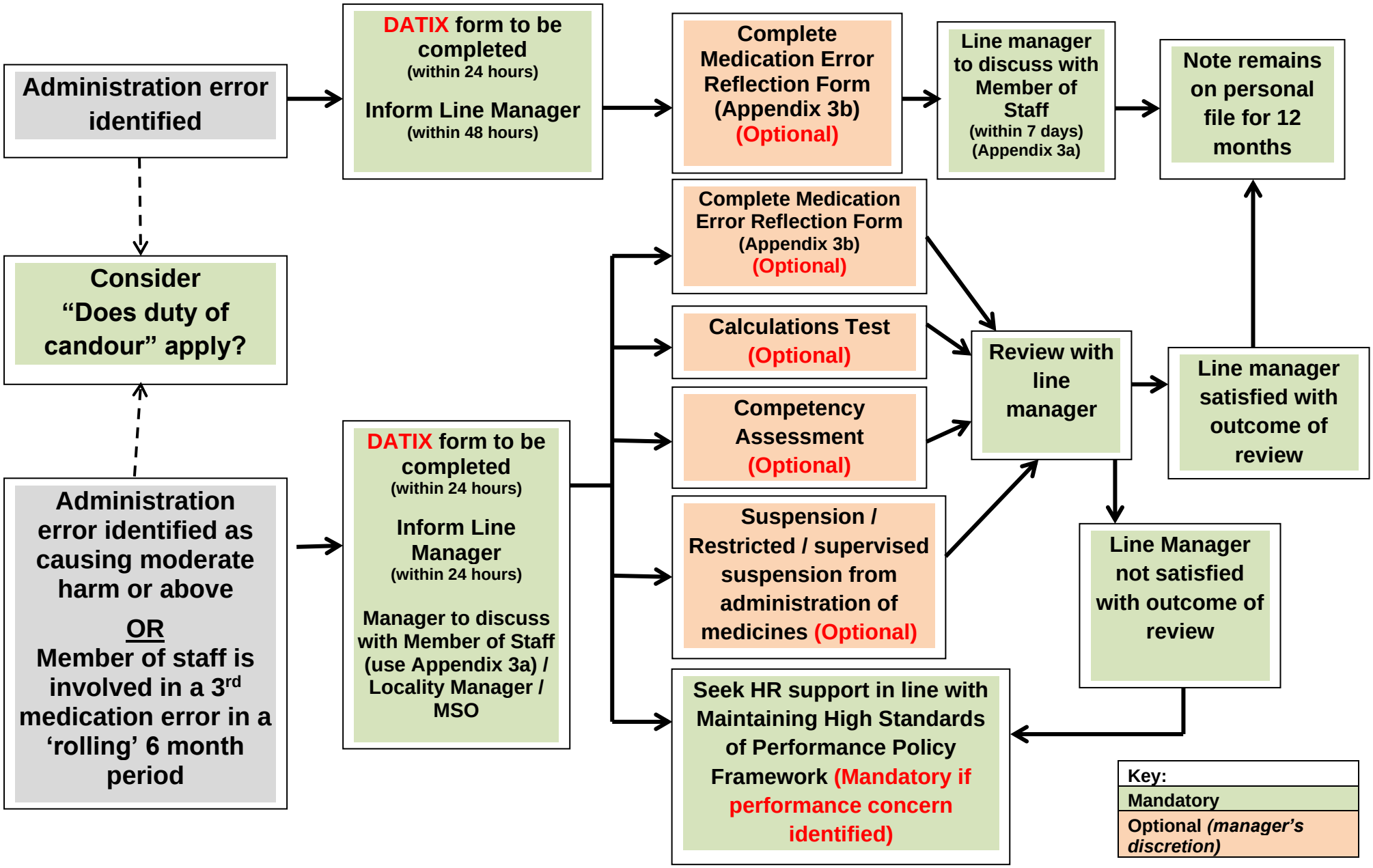
The below section outlines suggested methods that can be used to manage medication errors within the Trust. Please note this is not an exhaustive list – see flow chart 4.3.1 for further guidance regarding appropriate management of medication errors or liaise with the trust Medicines Safety Officer (Shropcom.MSO@nhs.net) for further support.

Please note: It is the responsibility of the individual line managers to monitor the number of incidents a staff member has been involved in. Where it is identified that they are involved in multiple incidents, support should be provided in line with the just culture guide and HR process (see 4.3.2).

Suggested Management Method	Explanation
Discussion (Mandatory)	The member of staff will should always be given the opportunity to discuss the incident with their line manager or a designated senior colleague.
Reflection of the Incident	A piece of written reflection can be useful before agreeing supportive actions using the just culture guide **(Appendix 3a & 3b)**
Drug Calculation Tests	In some cases, a drug calculation test may be deemed an appropriate supportive action. The expectation for a pass mark for the drug calculations will be 100%. It is vital that staff involved with medicines are able to calculate drug dosages and volumes accurately. A ‘sample’ calculation assessment is provided in **Appendix 4** Whenever a pass is not achieved first time, staff will be supported to undertake further training prior to retaking the test. A total of three attempts are permitted, before consulting HR processes in line with the Maintaining High Standards of Performance Policy.
Assessment of Competency	The competency assessment relevant to the professional group can be completed with the member of staff. The assessor, ideally, should be of the same profession as the individual completing the competency assessment. For example, Nursing will be assessed by the Ward / Team Manager /

	Clinical Practice Teacher or a Band 6 registered nurse or a subject matter expert. The assessment may consist of questions and observations relating to the medicines management related activities which may be developed by each clinical speciality. The scope of the assessment will be determined by the individual's area of work and will include all key areas of administration with a specific emphasis on the area for improvement following the error made. Assessments should be conducted across a variety of shifts or days as necessary. For clinical care staff, the staff member must carry out drug administration under supervision of the assessor a minimum of 3 times using the competency assessment tool provided by the line manager the number of times this is carried out can be extended either at the outset or at the discretion of the assessor. Following each medication administration assessment, the assessor will provide verbal feedback including their level of competence and any further areas of development. This should be fed back to the line manager.
Medication Activities to Continue Under Supervision Only	It may be deemed appropriate for the member of staff to continue with medication activities under supervision. If implemented, a time frame should be agreed (usually a maximum of 2 weeks) for the member of staff to resume activities following competency re-assessment or satisfactory feedback from supervisor(s).
Temporary Pause from Medication Activities	In certain circumstances, it may be deemed appropriate for the member of staff to pause from all medicine related activities. This should be identified as a supportive action for the staff member to give them a period of reflection and avoid a pattern of continuous mistakes. The member of staff may be withdrawn from prescribing, administration or dispensing some or all medication if the reported error requires further review / investigation and or further training and assessment. This would be in line with the just culture guide and HR processes. It is not expected, for example, that a staff member with issues relating to administering a depot injection safely should necessarily be removed from giving oral medications (unless the concerns are wider than a specific route of administration).
Performance Improvement Process	The member of staff may be managed under the Trust processes if all the supportive mechanisms have failed to enable an improvement. This is more likely if an error resulted in serious harm to a patient. This should be supported by a human resources advisor.
Errors involving Temporary Workers (Agency, Bank and Locum Staff)	Where agency workers are involved in medication errors or incidents, the Trust must also inform the agency for whom the healthcare professional was working and the centralised bank team. If a substantive member of staff normally employed by the Trust, is involved in an error whilst working extra shifts on the 'bank', their substantive line manager must also be informed of the incident.

4.3.1 Management Flowchart of Actions Following a Medication Administration Error



4.3.2 Supporting and Maintaining High Standards of Performance

If the member of staff who has made the medication error:

- Is unsuccessful at assessment of competency on the 2nd attempt
- Is unsuccessful at a drug calculation assessment on the 3rd attempt
- Is involved in a 3rd medication error* in a 'rolling' 6-month period

(*) = Consideration will be given to the severity of the incident e.g. level of harm and the medication involved.

They may be withdrawn from specified medication management activities as appropriate and supported using the Just Culture guide and relevant Trust policies. Human Resource colleagues should support managers and individual staff in this process.

If repeated errors continue to occur by the same member of staff despite all efforts from the Trust to provide additional training and other supportive measures deemed necessary, the line manager should escalate the matter and seek advice from Human Resources. Together they will consider the options open to them to preserve patient safety. This may include, but is not limited to, the recourse to manage the member of staff using the Trust's policies and processes.

4.4 Management of Prescribing and Monitoring Errors

Any prescribing error must be discussed with the prescriber as soon as it is discovered, and / or Medical Advisor. A Datix report must be completed within 24 hours.

Prescribing Errors may include:

- Incorrect or incomplete patient or medicine details on the prescription including
- Incomplete "prn" details
- Inappropriate medicine / dose / route / preparation / rate
- Poor or illegible prescribing
- Inappropriate indication
- Prescribing without taking into account the patient's clinical condition, including
- past medical history, past drug history
- Incorrect length of course for the patient
- Medication prescribed to the wrong patient
- Transcription errors
- Inappropriate monitoring/follow up
- Medicine prescribed that the patient is allergic to
- Allergy status not recorded or incorrect
- Prescription not signed
- Prescribing guidance not followed

Monitoring Errors may include:

- Inappropriate monitoring / follow up
- Failure to monitor therapeutic levels

Skill based errors – Memory lapses are generally picked up by pharmacists and senior staff and are therefore rectifiable with practice and learning.

Rule based errors e.g. antimicrobial stewardship will require supportive actions to ensure learning is firmly established, these can usually be avoided by checking interactions, allergies and ensuring full documentation of indications and course lengths.

Prescribing errors (such as poor legibility or failure to use capital letters) can be pointed out to the member of staff and corrections made as part of a peer/pharmacist review using discretion.

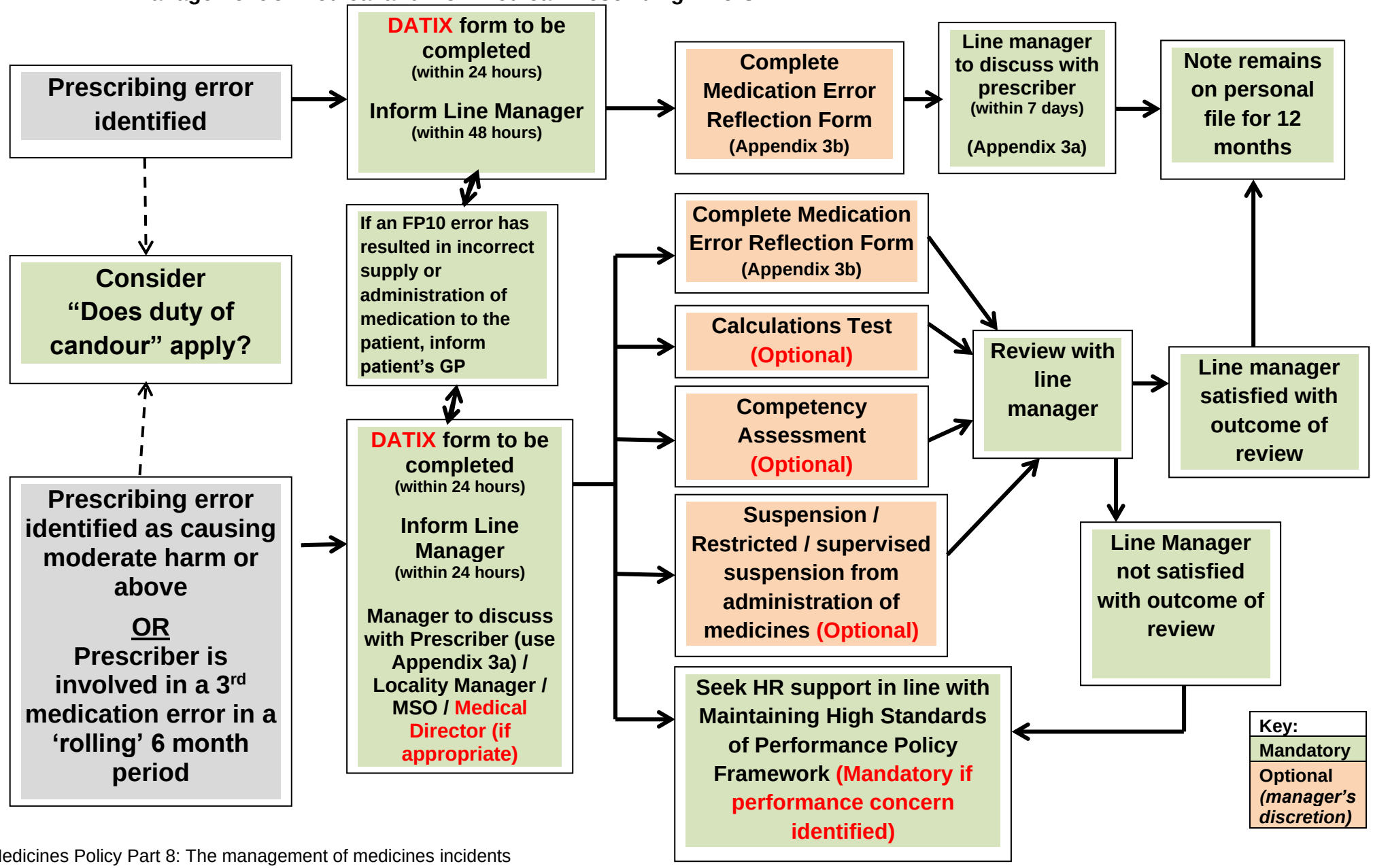
In the case of the below, the framework on the next page should be used:

- Repetitive errors of this kind
- More serious errors
- Errors which have resulted in patient harm or increased monitoring

The appropriate clinical supervisor* will meet with the prescriber to discuss the error. This discussion should explore any factors that could have contributed to the error (e.g. stress, health, organisational and environmental factors).

Actions will be recorded on the medication error reflection form, a copy of which will be given to the prescriber; a further copy will be placed on their personal file for 12 months.

4.4.1 Management of Medical and Non-Medical Prescribing Errors



4.5 Management of Supply or Dispensing Errors

This type of error can be undertaken by any member of clinical staff, particularly where the selection of a medicine is required. Some examples of selection / dispensing errors are:

- Patient supplied / dispensed the wrong medication / dose / formulation /strength / quantity (on a ward, MIU, clinic, dental service or their own home)
- Medication supplied / dispensed to the wrong patient e.g., medicines placed into wrong medicine locker.
- Patient supplied / dispensed an out-of-date medicine.
- Medication is labelled incorrectly or not at all.
- Medication supplied contains incorrect quantity.

4.5.1 What to do in the Event of a Supply / Dispensing Error

Once an error has been discovered, it is important to establish if the patient has taken any of the incorrect medicine, as this may change how the incident is dealt with.
For external dispensing error's relating to community pharmacies, please follow: Medicines Management Team - SOP 08.03 - How to report a Community Pharmacy Dispensing Error V1.pdf - All Documents (sharepoint.com)

4.5.1.1 Establish if the patient has taken any of the incorrect medicine

Where the individual discovering the error is a prescriber, nurse or pharmacist, they should determine if the patient has taken any of the incorrect medicine and establish whether the patient has been harmed. This may require medical examination or diagnostic testing. Where the person discovering the error is not a registered doctor, nurse or pharmacist, this should be escalated to facilitate this.

If there has been evidence of harm, a pharmacist should provide the patient and the prescriber responsible for the patient with the medicines advice they may need with the appropriate urgency. The Out of Hours Doctor service may need to be contacted outside work hours.

Where no harm appears to have been caused, the prescriber responsible for the patient (e.g. their usual GP) should still be informed and this should be documented in the patient's notes.

Refer to various pathways **4.5.2** and **4.5.3** on dealing with the incidents.

4.5.1.2 Inspect the incorrect medicine where possible

Inspecting the medicine can give valuable clues about what went wrong.

When reviewing dispensing errors which have resulted in a serious patient safety incident, the Incident Framework helps to identify why individuals acted in a certain way, and this may be a very useful tool for pharmacists, managers and organisations to consider using prior to action being taken.

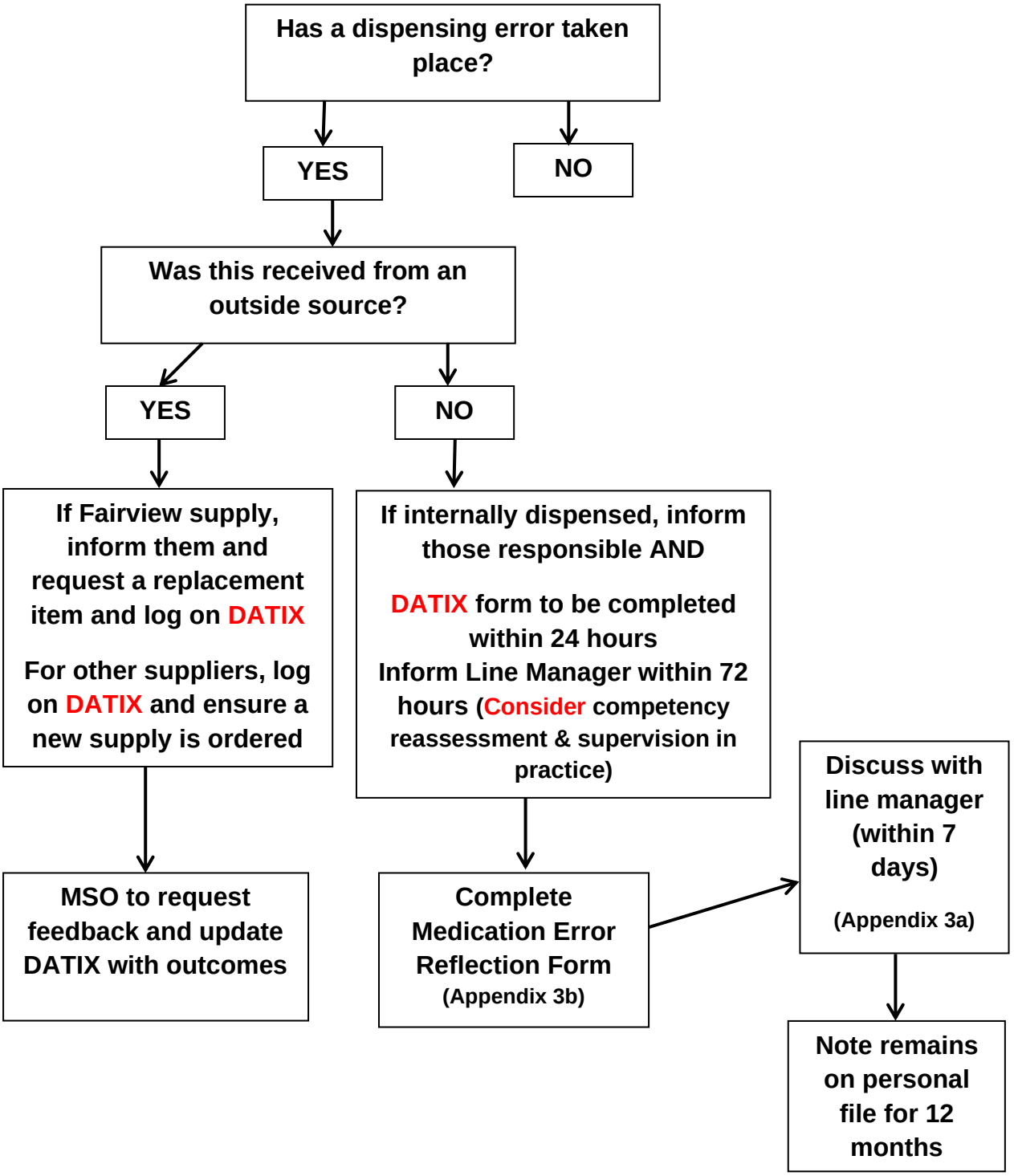
From a pharmacy point of view, a dispensing error may be seen as wrong label, drug, strength or quantity. However, for the purposes of this policy, dispensing relates to

selection of a drug by a member of staff that may not be labelled. Therefore, any member of clinical staff could be involved with a “dispensing” incident.

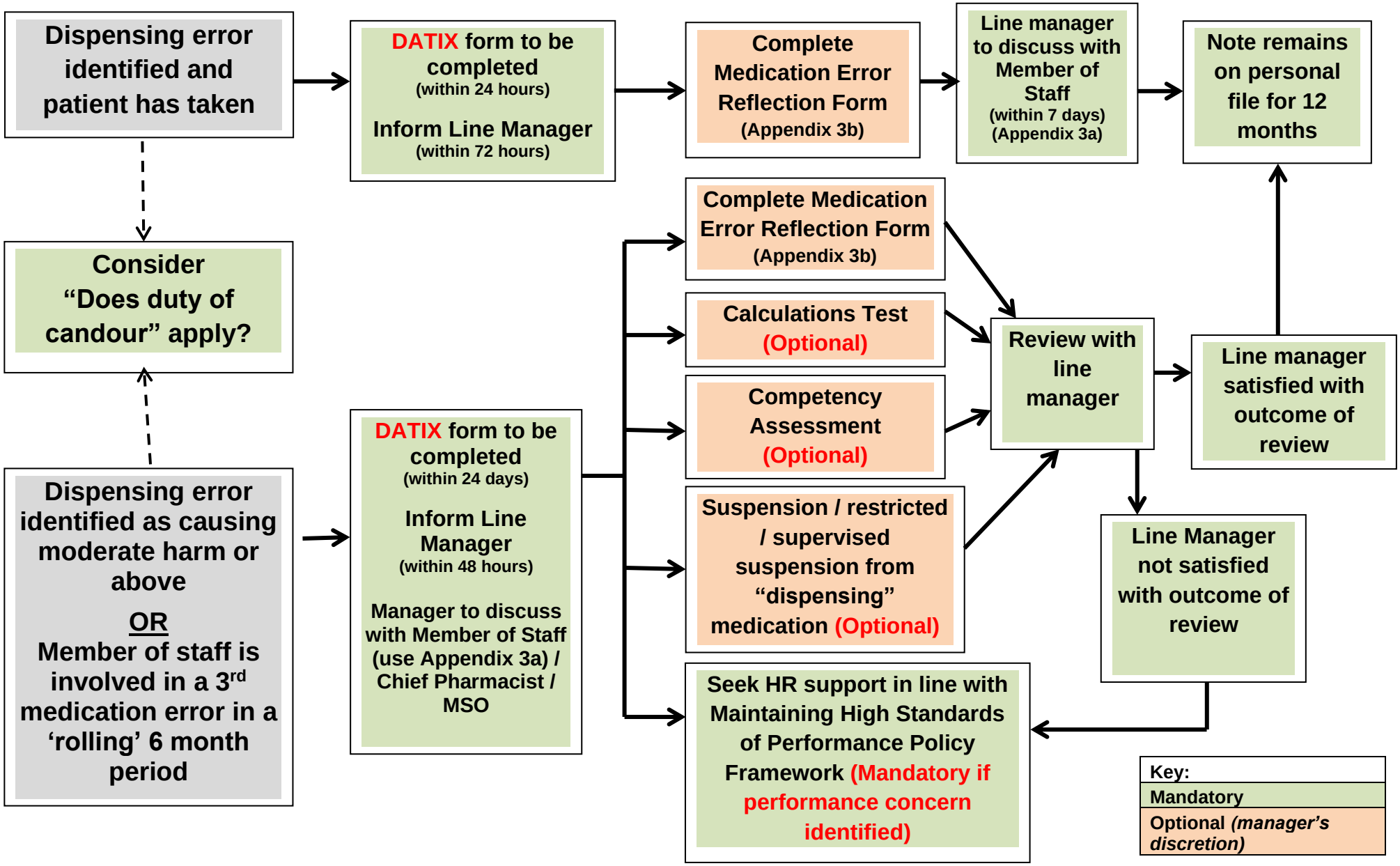
Once an error has been detected, a medication error reflection form **must** be completed (**Appendix 3a + 3b**). The line manager will meet with the staff member to discuss the error. This discussion should explore any factors that could have contributed to the error.

Actions will be recorded on the medication error reflection form, a copy of which will be given to the staff member; a copy will also be placed on their personal file for 12 months.

4.5.2 Management of Dispensing Errors where the Patient hasn’t taken the supplied medication



4.5.3 Management of Internal Dispensing Errors Where the Patient has taken the medicine



5.0 Policies and Procedures Connected to this Policy

Patient Safety Incident Response Policy
This policy supports the requirements of the and sets out the approach taken by Shropshire Community Health NHS Trust (SCHT) to developing and maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

Controlled Drugs policy
The purpose of this policy is to ensure that all controlled drugs are used in a safe, secure and effective way and that all processes involving controlled drugs adhere to current regulations across Shropshire Community Health NHS Trust.

Disciplinary Policy
This policy is designed to underpin the commitment of the Trust to create a working environment where the highest possible standards may operate. It will ensure employees maintain high standards of conduct and professionalism, and the Trust applies a consistent fair approach to dealing with inappropriate conduct.

Maintaining High Standards of Performance
The purpose of this policy is to support and encourage staff to achieve and maintain the high standards of performance expected by the Trust and to provide a consistent framework for handling performance issues in a fair and consistent manner.

Medicines Policy and associated SOPs
The purpose of this policy is to ensure that all staff dealing with medicines follow safe practice in the prescribing, requisition, storage, administration and control of Medicines. It applies to all individuals employed or contracted by Shropshire Community Health NHS Trust including all locum and agency staff and to all activities relating to medicines use within in-patient, out-patient, community and any residential facilities.

Risk Management policy
This policy describes how risk is managed within the Trust and the responsibilities of managers and committees that review these risks. It also describes how to assess risks and record new risks onto a risk register.

6.0 References

- Advisory Guidance on Administration of Medicines by Nursing Associates, HEE, 2017
- Professional guidance on the safe and secure handling of medicines, RPS, January 2024
- Professional Guidance on the Administration of Medicines in Healthcare
- Settings, RCN & RPS January 2019
- The Safe and Secure Handling of Medicines (a Team Approach). Royal Pharmaceutical Society of Great Britain March (2005). A revision of the Duthie Report (1988)
- CQC: Guidance for Providers on Meeting the Fundamental Standards

- CQC's Enforcement Powers (July 2014)
- NHS Improvement; A Just Culture Guide 2018 A Just Culture Poster & Appendix 8
- Professional Guidance on the Administration of Medicines in Healthcare settings, January 2019 (Royal Pharmaceutical Society)
- Driscoll, J. (2007). Practising Clinical Supervision: A Reflective Approach for
- Healthcare Professionals. Blackwell: Philadelphia
- GMC Good Practice in Prescribing and Managing Medicines and Devices
- (2013)
- British National Formulary (BNF) Edition 80 – (September 2020 - March 2021)
- https://www.radcliffehealth.com/sites/radcliffehealth.com/files/samplechapter/mandalia_chapt_01.pdf
- http://www.gmcuk.org/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf_28935150.pdf
- http://spars.rcpe.ac.uk/sites/spars/files/uploads/hospital-medication-errors-the-junior-doctors-perspective.pdf
- The Royal Pharmaceutical Society (2024): Patient safety professional standards responding to patient safety incidents 2024-270324-B.pdf (rpharms.com)
- "Swiss Cheese" Model – James Reason, 1991. Found in: Reason, J. (1990) Human Error. Cambridge: University Press, Cambridge
- Health Care Commission (2007). The Best Medicine. The management of medicines in acute and Specialist Trusts. London: Health Care Commission
- Statutory Instruments. Medicines Act 1968 and 1971. London: HMSO
- National Prescribing Centre. (2004). Patient Group Directions. A practical guide and framework of competencies for all professionals using PGDs. London: National Prescribing Centre
- Department of Health (2004). Building a safer NHS. Improving Medical Safety.
- London: HMSO
- Patient Safety Incident Response Framework (2022) NHS England » Patient Safety Incident Response Framework and supporting guidance
- Parts of the Black Country Policy for Management of Medicines Incidents has been adopted into this policy with thanks.
- Patient Safety Strategy 2019 Patient Safety Strategy Version 4
- Quick reference guide to regulated activities by service type (cqc.org.uk)

7.0 Roles and Responsibilities for this Policy

7.1 The roles and responsibilities for this policy can be seen in the following tables, this demonstrates that all staff working within the Trust that also handle medicines will contribute to the execution of this policy.

Title	Role	Responsibilities
Directors for Nursing, Operations and Governance	Executive Lead	• Has lead responsibility for the implementation of this policy and ensuring this policy is discharged appropriately • Ensure a systematic and consistent approach to medication errors in all service areas
Trust Board	Strategic	• Strategic overview and final responsibility for overseeing the implementation of managing medication errors in the Trust • Legal responsibility for Trust policies and for ensuring that they are carried out effective
Quality and Safety Committee	Responsible	• Ensure that assurance is provided to this committee in regarding to medication errors being managed efficiently and effectively in accordance with the Board's Assurance Framework and strategic priorities
Medicines Safety Group and Medicines Governance Group	Monitor	• Monitors medicine related incidents across the organisation • Receives all medicine related audit reports and considers their recommendations and action plans to improve current practice • Ensure that there is opportunity for learning across organisation that this information is then disseminated to all those who may benefit from it
Medicines Management Team	Monitor	• Detect trends and clusters of activity • Make recommendations to Medicines Governance Group and Medicines Safety Group for actions to improve and change current practice • Responsible for acting on and investigation of dispensing errors and concerns occurring under the service level agreement with the provider of medicines to the Trust
Service Delivery Groups	Monitor	• Responsible for monitoring medication errors in their group • Receive the results and recommendations of all completed clinical audits
Chief Pharmacist	Strategic	• Advise on the relevant guidance and regulations related to this policy • Ensure that policies and procedures are up to date

Medicines Safety Officer	Implementation Lead	• Responsible for identifying trends and data • Responsible for identifying and escalation patient safety incidents • Responsible for supporting service leads to investigate incidents appropriately

Title	Role	Responsibilities
Service Managers and Team Leaders	Implementation	• Ensure systems are in place to enable this policy to be implemented within their service area and that they are familiar with the policy • Support their teams in ensuring that medication errors are managed consistently • Report any concerns around medication errors to the group lead nurse • Ensure this policy is implemented in their area of responsibility • Manage medication errors in line with this policy • Ensure their staff are appropriately trained in line with the requirements of this policy
Ward Managers and Locality Managers	Operational	• Ensure that staff within their areas of responsibility adhere to this policy • Lead on the initial management of an error, meeting with the staff member, liaising with the locality manager / MSO / Chief Pharmacist as appropriate • Lead on medication errors and some serious medication errors investigations • Management of medication errors may, where appropriate, maybe delegated to the charge nurse (or equivalent clinical lead – band 6) • Ensure that staff attend training applicable to their role • Report concerns to their service manager
Risk Managers	Governance	• Support the clinical team in relation to the use of the Datix system • Support the Lessons Learned Group by contributing to analysis of incidents and advising on duty of candour where required
Human Resource Advisor	Advise	• Support clinical managers in situations where management of a medication error involves the use of the Managing High Standards of Performance policy
Trade Union Representative	Represent	• Provide trade union representation at all points of the process and can be consulted as required by members relating to the application of this policy
Staff	Adherence	• Ensure that they are familiar with this policy, particularly the immediate actions to take when a medication error is identified • Ensure they undertake medicines management training specific to their role as provided by the Trust as part of their mandatory and ongoing training

8.0 Training

8.1 Medicines Management training will be provided on induction as supported by the Medicines Management Team

8.2 Medicines competency and training will be provided / assessed by Teams Leaders / Ward Managers / Service leads during an induction period

8.3 The reporting of medicines incidents using Datix will be introduced at induction by the Risk Management Team.

8.3.1 Datix training in greater depth can be requested from the Governance Team

8.3.2 PSIRF training can also be requested from the Governance Team

9.0 Quality Equality Impact Assessment (QEIA)

Shropshire Community Health NHS Trust is committed to ensuring that the way we provide services and the way we recruit and treat staff reflects individual needs, promotes equality and does not discriminate unfairly against any particular individual or group.

10.0 Data Protection and Freedom of Information

Data Protection Act provides controls for the way information is handled and to gives legal rights to individuals in relation to the use of their data. It sets out strict rules for people who use or store data about individuals and gives rights to those people whose data has been collected. The law applies to all personal data held including electronic and manual records. The Information Commissioner's Office has powers to enforce the Data Protection Act and can do this through the use of compulsory audits, warrants, notices and monetary penalties which can be up to €20million or 4% of the Trusts annual turnover for serious breaches of the Data Protection Act. In addition to this the Information Commissioner can limit or stop data processing activities where there has been a serious breach of the Act and there remains a risk to the data.

The Freedom of Information Act provides public access to information held by public authorities. The main principle behind freedom of information legislation is that people have a right to know about the activities of public authorities; unless there is a good reason for them not to. The Freedom of Information Act applies to corporate data and personal data generally cannot be released under this Act.

All staffs have a responsibility to ensure that they do not disclose information about the Trust's activities; this includes information about service users in its care, staff members and corporate documentation to unauthorised individuals. This responsibility applies whether you are currently employed or after your employment ends and in certain aspects of your personal life e.g. use of social networking sites etc. The Trust seeks to ensure a high level of transparency in all its business activities but reserves the right not to disclose information where relevant legislation applies. The Information Governance Team provides a central point for release of information under Data Protection and

Freedom of Information following formal requests for information; any queries about the disclosure of information can be forwarded to the Information Governance Team.

11.0 Monitoring

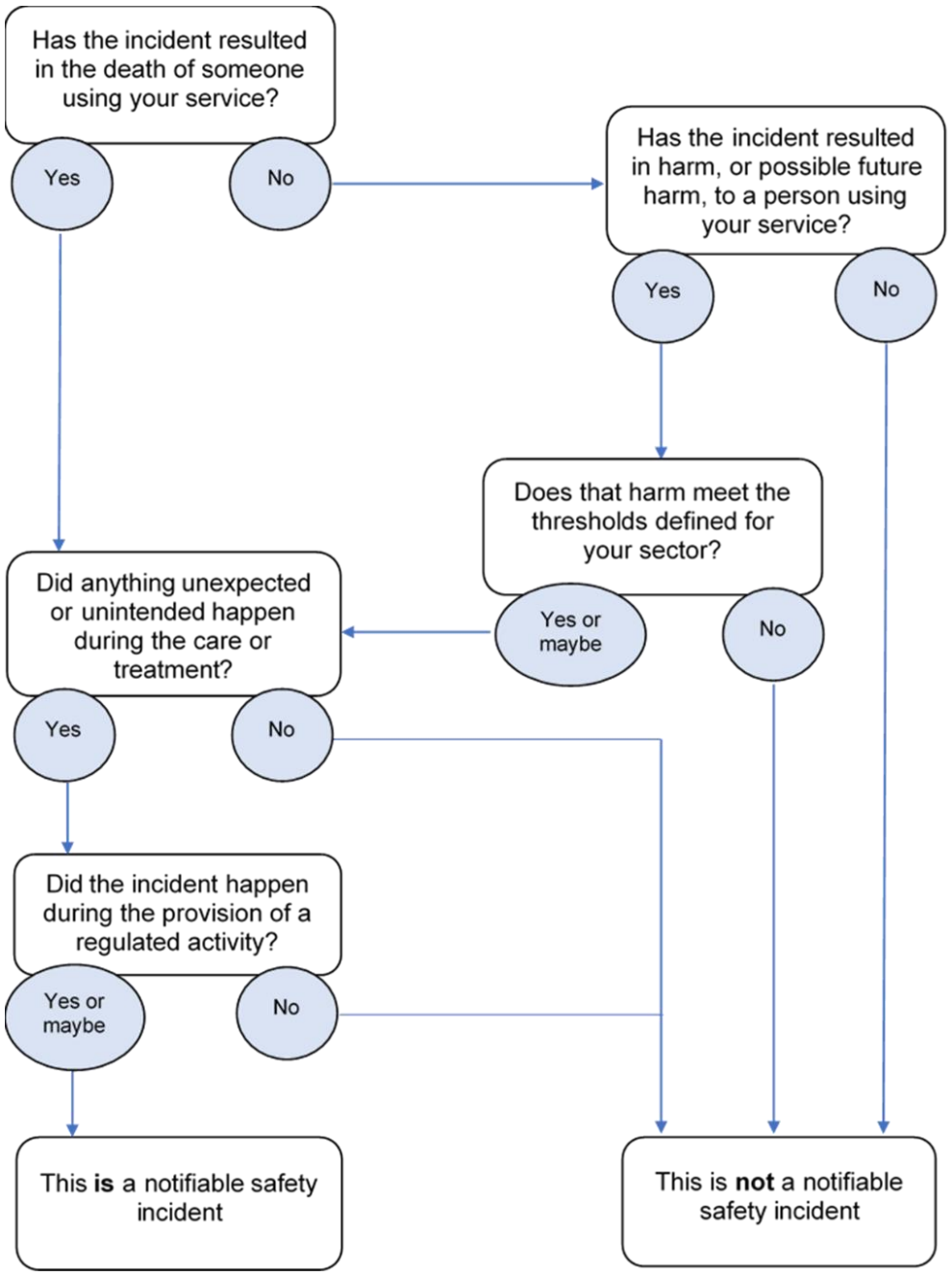
11.1 Routine monitoring and provision of reports will demonstrate that this policy is working. The table below will identify relevant reports.

Monitored Activity	Method	Who will undertake?	Frequency	Group / Committee that will review results?	Group / Committee that ensure actions completed	Evidence this has happened?
Medicines incidents are routinely assessed and shared	Report is created following analysis	Medicines Safety Officer	Monthly	PSC	PSC	Minutes of meetings / Action Log
Identification of medicine related themes and trends	Quarterly thematic review	Medicines Safety Officer	Quarterly	Medicines Safety Group PSC Q+SC	Medicines Safety Group PSC Q+SC	Minutes of meetings / Action Log

12.0 Consultation

This policy was shared via the Medicines Management Policy Consultation Group and Medicines Governance Group where it received approval ahead of its presentation at Patient Safety Committee for final ratification.

Appendix 1: Duty of Candour – Notifiable Safety Events



Please use below link for definitions of 'regulated activities':
Quick reference guide to regulated activities by service type (cqc.org.uk)

Appendix 2: Level of Harm Definitions (as per Duty of Candour Being Open Policy)

Physical Harm

No Physical Harm / Near-miss
Incident prevented – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care. Incident not prevented - any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.

Low Physical Harm
Any incident that did not or is unlikely to:

- Affect a patient's independence.
- Need further healthcare beyond a single GP, community healthcare professional, emergency department or clinic visit.
- Need further treatment beyond simple dressing changes or short courses of oral medication.
- Affect the success of treatment for existing health conditions.

Moderate Physical Harm
Any incident when at least one of the following apply:

- Has, or is likely to limit the patient's independence, but for less than 6 months.
- Has, or likely to need treatment beyond a single GP, community healthcare professional, emergency department or clinic visit and beyond simple dressing changes or short course of medication, but less than 2 weeks additional in-patient care and/or less than 6 months of further treatment and did not need immediate life-saving intervention.
- Has affected, or likely to affect the success of treatment, but without meeting the criteria for reduced life expectancy or accelerated disability described under severe harm.

Severe Physical Harm
Any incident when at least one of the following apply:

- Needed, or likely to need additional inpatient care of more than 2 weeks and/or more than 6 months of further treatment.
- Likely to have reduced patient's life expectancy.
- Needed immediate life-saving intervention.
- Has, or is likely to have, reduced the chances of preventing or delaying disability from their existing healthcare conditions.
- Has limited or is likely to limit the patient's independence for 6 months or more.

Fatal / Death
You should select this option if the patient has died and there is at least a slight possibility the incident that you are recording may have contributed to the death, including stillbirth or pregnancy loss. You will have the option later to estimate to what extent a patient safety incident contributed to this fatal outcome.

Psychological Harm
No Psychological Harm / Near-miss
As detailed above in physical harm definition

Low Psychological Harm
Any incident when at least one of the following apply:

- Distress that did not or is unlikely to affect the patient's normal activities for more than a few days.
- Distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit.
- Distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition

Moderate Psychological Harm
Any incident when at least one of the following apply:

- Distress that did not or is unlikely to affect the patient's normal activities for more than a few days.
- Distress that did not or is unlikely to need extra treatment beyond a single GP, community healthcare professional, emergency department or clinic visit.
- Distress that did not or is unlikely to result in a new mental health diagnosis or a significant deterioration in an existing mental health condition.

Severe Psychological Harm
Any incident when at least one of the following apply:

- Distress that did or is likely to affect the patient's normal activities or ability to live independently for more than six months.
- Distress that did or is likely to need a course of treatment or therapy sessions that continues for more than six months.
- Distress that did or is likely to result in a new mental health diagnosis, or a significant deterioration in an existing mental health condition, and recovery is not expected within six months.

Appendix 3a: Record of Informal Interview - Medication

Datix reference number	
Date of incident	
Date of interview	
Practitioner	
Line Manager conducting interview	
Level of Medicines Incident	
Discussion of the event (brief summary) **Action -** (should include personal reflection (Appendix 3b) any restrictions to practice, support and supervision and any service or /and process issues identified that may have contributed to the incident)	
Line Manager signature and date	
Practitioner signature and date	

Action Plan Following Staff / Manager Discussion:

N.B: Not all sections will be relevant – only complete those required.

Learning need	Actions required to address learning need	Is this relevant?	Completion date	Signature of completion
Refresh / update medicines administration in accordance with Trust policy	Re-assessment of medicines administration competency. This will be conducted by <insert name>	Yes ☐ No ☐		
Update on XX required e.g. Diabetes	Undertake additional training <state which>	Yes ☐ No ☐		
Refresh Numeracy Skills	Undertake medicines calculation test – contact MSO for numeracy test documents	Yes ☐ No ☐		
Identify any additional learning needs	Complete reflective practice (Appendix 3b) a copy to be held in personal file and retained by yourself as part of professional revalidation process	Yes ☐ No ☐		
Any Other				

Staff member signature		**Date**	
Line Manager signature		**Date**	

Copy to be retained in personal file and copy to staff member

Appendix 3b: Reflective Practice Record + Identification of Learning Needs

Reflective Practice Record (based on Gibbs reflective cycle 1998)

Shropshire Community Health NHS Trust

Name:
Work base:
Datix reference number:
Description: what happened?
Feelings: what were you thinking and feeling at the time of the incident.
Evaluation: what was good and bad about the experience?

What else was going on at the time of the incident? (e.g., Carers or family interruptions)
Analysis: what sense can you make of the situation? (Why did it happen?)
Conclusion: what else could you have done to prevent the incident?
What measures did you take to ensure patient safety following the incident?
Action plan: if the situation arose again, what would you do?
Signature of practitioner:
Date:

Appendix 4: Medicines Competency Example Calculations Assessment

Shropshire Community Health NHS Trust

ADMINISTRATION OF MEDICINES ASSESSMENT OF COMPETENCY

Staff Name		**Date of assessment**	
Designation		**Assessor Name**	
Department / Site		**Result**	
No calculator should be used for this test			
30 minutes is permitted for this assessment			
100% is the required pass mark			

1. Express 100milligrams in grams

2. Express 5000micrograms in milligrams

3. Express 2.2L in millilitres

4. If a dose for a given drug is 10mg/kg and a patient weighs 70kg and is 180cm tall, what is the dose to be administered?

5. If a dose is 1mg/kg and the patient weighs 120kg, what is the dose to be given?

6. You need to give 7.5mg of drug to a patient but the liquid medicine you have says it is a 15mg/5ml suspension. How much liquid do you need to give?

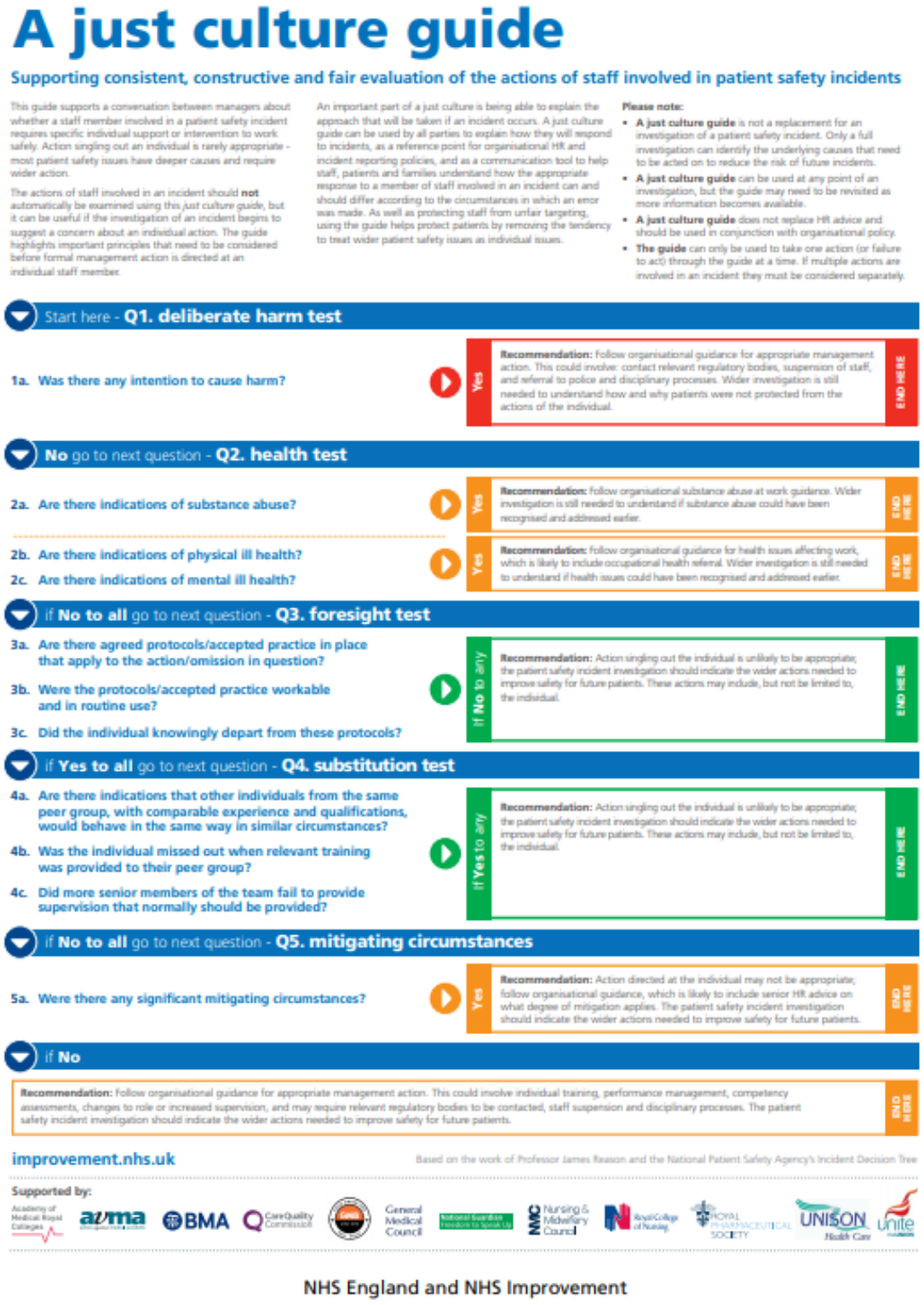
7. A patient has been prescribed 300mg Zuclopenthixol Decanoate IM as a depot. The preparation is only available as a 500mg/1ml dose. What volume would you administer?

8. If a 38 year old female patient weighs 50kg and is 150cm tall and is prescribed a drug with a dose of 100mg/kg, what is the dose to be administered?

9. A patient is prescribed a course of a drug at 100mg TDS for 7 days. You have 25mg tablets in stock. How many tablets will be required to complete the course?

10. A drug has been prescribed at 100mg/kg. The total dose of the infusion is 1600ml and is to be given over 8 hours. What is the flow rate (in millilitres per hour) to be administered?

Appendix 5: A Just Culture (link can be found in references for a clearer copy)



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:

NHS England and NHS Improvement