Standard Operating Procedure - Medication Incidents and Near Misses Management and Sharing the Learning

1. Overview

Background

University Hospitals of Derby and Burton (UHDB) NHS Foundation Trust encourages a sensitive, timely, constructive, and supportive response to medication incidents and near misses.

As an organisation, we are **good** reporters of medication incidents - at the time of writing, medication incident reports account for approximately 11% of all patient safety incidents reported at UHDB. This positive statistic places UHDB in the top 25% for medication incident reporting, with comparable organisations reporting an average of 9.3% of patient safety incidents as medication incidents.

Learning from incidents and near misses is essential to the delivery of high standards of care and to maintain patient safety. The management of incidents and near misses must therefore facilitate and support learning, as well as providing support and guidance for any staff who may be affected or involved.

A key part of the learning process is ensuring that a comprehensive assessment of incidents and near misses occurs, taking full consideration of the context and circumstances surrounding the incident. The next stage of the learning process is to facilitate Trust-wide learning by sharing the recommendations from these assessments.

This SOP provides guidance on how to go about this.

Objective

- Ensure investigations and actions following a medication safety incident or near miss.
    - Promote or enhance patient safety **and**
    - Consider <u>all</u> patients and staff who may have been affected e.g. if medications prescribed for patient A are given to patient B, what are the possible consequences for both patients? Does this have any impact on the staff members who may also be affected or involved?
- Facilitate organisational learning by providing guidance on how to share the findings of local level investigation.
- Ensure consistent, fair, and equitable management of <u>all</u> staff in response to a medication incident or near miss.
- Outline the support available to staff and how they may access this.
- Ensure that evidence of individual learning is documented and that repeated incidents or near misses, or repeated non-compliance with expected policies / standards are managed appropriately and in a timely manner.

Describe here the purpose of the procedure/ routine covered by the SOP.

2. SOP Governance

Department: Trustwide Medication Safety Group (Tier 4 Governance)	**No of pages**: 16	**Version & Date**: V1 March 2024
Author: Julie Vanes, Medication Safety Pharmacist	**Authorised by**: Medicines Safety Group	**Review date**: February 2025

Frequency and Time frame: Review every 3 years in line with UHDB Medicines Policy. Interim changes to either UHDB Medicines Policy or UHDB Incident Management Policy will require review of this SOP.

3. Definitions

Patient safety incident (PSI) - something unexpected or unintended has happened, or failed to happen, that could have or did lead to patient harm for one or more patients receiving NHS care (1).

Patient harm - an incident that results in harm to a patient such as impairment of structure or function of the body and/or any deleterious effect arising from or associated with actions taken during the provision of healthcare rather than an underlying disease or injury (2).

Near miss – where no harm occurred but there was potential for harm (3).

Medication error – any patient safety incident (PSI) where there has been an error in the process of prescribing, preparing, dispensing, administering, monitoring, or providing advice on medicines (3).

Medication incident – widely used as an alternative term to medication error. Some examples of medication errors are listed in Appendix 1.

ePMA - Electronic Prescribing and Medicines Administration systems. These clinical systems are used to document the prescribing and administration of medications.

4. Scope

This SOP applies to **all** health care professionals, including bank and agency staff, temporary and locum staff, all grades and all disciplines involved in medication processes. This includes prescribing, endorsement of prescriptions, dispensing, checking, supplying, preparation, administration of medication and the transport or receipt of medicines.

This SOP also applies to any student or trainee Healthcare Professionals e.g. Nursing, Midwifery, pharmacy, Drs who may be involved in medication processes under direct supervision. If a student (of any professional healthcare discipline) is involved in a medication incident, their supervisor (and University if appropriate) should also be made aware, so they are able to provide support and guidance.

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

4.2 Staff who report medication incidents <u>will not</u> be subject to performance and competence review <u>unless</u> incident investigation raises possible concerns <u>and</u> any subsequent discussions using the NHS tool “A Just Culture Guide” indicates that this may be appropriate (4).

A Just Culture Guide aims to support managers investigating patient safety events, including medication incidents, to ensure consistent, constructive, and fair evaluation of the actions of staff involved. See Appendix 2 (4).

An example of when UHDB Trust Policy for Managing Performance and Supporting Staff (Capability) would be applied would be where there is evidence of intent to cause harm.

5. PROCESS - Actions to be taken following the INDENTIFACTION OF A MEDICATION INCIDENT

5.1 Immediate Actions

5.1.1 Identify any immediate risks to the patient because of the medication incident.

5.1.2 Report the incident to an appropriate person in charge e.g. Department Manager / Nurse in Charge / Consultant Team caring for the patient / Line Manager.

5.1.3 If appropriate, seek advice from pharmacy or medical colleagues regarding potential outcome of the incident and for advice on how to manage it.

5.1.4 For dispensing incidents, inform pharmacy and return any incorrect medication to pharmacy for re-dispensing.

5.1.5 For prescribing errors, inform the Consultant team staff looking after the patient and, if possible, inform the prescriber.

5.1.6 If the incident involves a Controlled Drug (CD), consider whether any additional escalation is required e.g. to pharmacy or the CD Accountable Officer (5).

5.1.7 Complete an incident form (6).

5.1.8 For incidents associated with evidence of moderate or severe harm to the patient*, the appropriate person in charge must ensure immediate and appropriate escalation e.g. to the Matron, Consultant, Midwifery Lead, Service Lead. Out of hours, escalate to the appropriate on call team or service lead e.g. hospital out of hours and/or clinical site practitioner. An initial review of the incident should be carried out promptly to allow for clinical intervention and a timely investigation.

**harm definitions are linked via Datix (DCIQ) and included in the UHDB Incident Management Policy*

5.1.9 Inform the patient/carer/family as appropriate of the medication incident, and any actions being taken as a result, according to the UHDB Policy for Being Open and Duty of Candour (7).

5.2 Incident review, reflection, and systems-based analysis

5.2.1 A holistic approach should be taken when reviewing a medication incident to understand how and why it may have happened.

5.2.2 A **systems-based analysis** should be undertaken as part of the review process to help identify any areas of practice, process or the environment which may benefit from review or change.

The SEIPS (System Engineering Initiative for Patient Safety) template (8) is a useful tool to use when reviewing incidents. It considers both human and technological aspects of situation to help identify processes, actions, or environmental issues which may benefit from a review or need to be addressed to help prevent things happening in this way again.

5.2.3 A **reflective exercise** should be undertaken by staff involved in or affected by the incident. This can help identify reasons why or how the incident happened, as well as help ensure anything additional which may be needed e.g. training or wellbeing support is identified and scoped or sourced.

Reflective exercises should be carried out in a timely fashion, ideally within a few days of the incident occurring or of being made aware of it. Line managers or other appropriate colleagues should support staff with this exercise as needed and make themselves available to discuss it with them (9)(10)(11).

The above resources are all widely used in Nursing and Midwifery training, practice, and revalidation. However, the area in which you work or the professional body to whom you are accountable may also have reflective tools available. You may also find that reflections you complete, or provide support for, are useful for professional revalidation submissions.

Appendix 3 provides more detail around reflective exercises and includes a copy of the Gibbs Reflective Cycle.

It is recommended that copies of reflections, and associated actions, be kept in staff members' personal record. This is because reflections can be useful as part of the appraisal process to demonstrate learning and development as well as help identify any training needs or other support that may be beneficial.

5.2.4 The Datix incident report should be updated with investigation findings, including actual and intended service / process changes and any recommendations from reflections or SEIPS review. Personal reflections do not need to be uploaded to Datix unless it is felt to be essential to the investigation and the author of the reflection consents to this.

Patient safety actions such as new or reviewed guidelines, SOPs or teaching resources, improved access to medications or resources, additional training, targeted education sessions, updates to electronic prescribing system, sharing of the incident and learning at other forums can arise from any investigation, regardless of the actual or perceived level of harm. Here are some examples:

- *Group or individual pump training organised following issues with pump setting which had led to delays in medication administration.*
- *Parkinsons medicines added to pharmacy stock lists in admission areas following delayed and missed administrations.*
- *Electronic prescribing system dose sentences/order strings updated after repeated selection of wrong dose.*
- *New dose sentence/order string added to electronic prescribing system following reports of difficulty prescribing a particular dose regimen.*
- *Targeted education sessions in clinical areas led by specialist nurses following identification of knowledge gaps in the team.*
- *Supervised medication practice following breaches of medicines policy and/or identified lack of confidence with medicines.*
- *Guidelines updated following realisation that they are out of date.*
- *Guidelines updated following realisation that local, regional, or national pathways or clinical recommendations have since changed.*

5.2.5 If competency concerns are raised by a line manager or by the colleague(s) themselves, follow guidance in section 6 - Addressing Concerns of Competency.

5.3 Themes and Lessons from Medication Incidents

5.3.1 The Medicines Safety Group and Divisional Clinical Governance teams can support Business Units (BU) to identify themes or trends for reported medication incidents, undertake thematic or incident-specific reviews and to develop action plans as part of the review process. BU are encouraged to apply quality improvement (QI) principles where possible to demonstrate ongoing improvements made to patient safety and patient care.

5.3.2 Medication Safety Group (MSG) will escalate any significant medication incident themes to the appropriate meeting as per UHDB Quality & Governance structure.

5.3.3 Communication and sharing of learning should form part of any actions plans developed following incident review or as part of any quality improvement work relating to medication. This may be very localised e.g. within a department or extend to a wider audience such as across a BU, Division or Trust-wide. Examples of shared learning include ePMA updates, SOPs, guideline, or training updates. Communication can be achieved using posters, newsletters, screen savers, formal and informal training sessions, for example. Organisational memory is supported by incorporating important messages and process updates into induction programs, in-house learning portals or platforms and regular refresher training.

6. Addressing Concerns of Competency

6.1 If it is felt that patient safety and /or staff well-being would be best served by temporarily suspending medication related activities, such as prescribing, dispensing, preparation or administration, this should be discussed with Service Lead before implementing any changes.

6.2 If any staff member involved in a medication incident identifies concerns with their own practice and wishes to step-back from medication-related tasks, their concerns should be listened to, options for support explored and a plan discussed and agreed with their line manager. A suitable time limit for this period should be applied, taking into consideration the potential support required for the individual and to assist with implications for staffing levels in the clinical area.

6.3 If a period of re-training and re-assessment is deemed appropriate, this should be planned in collaboration with Line Manager or clinical supervisor. For nursing and midwifery colleagues, including students, the Professional and Practice Development Clinical Educator Team are available to provide additional support. For pharmacy staff, the pharmacy Education and Training team can provide support. Medical colleagues can access support via the Postgraduate Education Team, Clinical Supervisors, and pharmacy colleagues.

6.4 If, after the period of education, training, and re-assessment the member of staff's competence is still in doubt they should be managed in accordance with the UHDB Trust Policy for Managing Performance and Supporting Staff (capability).

6.6 In all cases, it is important that the member of staff is supported by their manager during this process and kept informed of any actions that may have to be taken. Managers must ensure that support is offered / sign posted and encourage staff members to access support services as needed. See section 7 for help with this.

7. Support for Staff

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

- Line Managers
- Matrons, Senior Nursing/Midwifery team
- Professional and Practice Development Team *(*Clinical educators)
- Practice Learning Support Unit (search PLSU on Trust Intranet)

- Clinical and education supervisors
- Clinical Governance teams
- Well-being services and resources (search Well-Being, or Health, Safety and Well-Being on Trust Intranet)
- Occupational Health
- Professional Bodies
- Higher Education Institute
- Internal and External Educational Resources
- Out of hours - Clinical Site Practitioner (QHB) or Hospital out of Hours team (RDH)

7.2 Line Managers can gain advice and support for managing and supporting staff involved in a medication incident from:

- Associate advanced practitioners.
- Medicine Safety Team (MSO and colleagues)
- Patient Safety Team
- Divisional Clinical Governance Facilitator (CGF) or advisors (CGA)
- Divisional Nurse Director
- Divisional Medical Director
- Non-medical Prescribing lead
- Director of Allied Health Professionals
- Professional and Practice Development Team (Clinical educator team)
- Senior Pharmacy Team
- Occupational Health
- Human Resources
- Matrons
- Advanced Clinical Practitioners
- Learning and Education
- Union Representative(s)
- Professional Bodies

8. Legal Liability

8.1 The Trust will generally assume vicarious liability for the acts of its staff, including those on honorary contract. However, it is incumbent on staff to ensure that they: -

- Have undergone any suitable training and assessment of competence identified as necessary under the terms of this procedure or otherwise.
- Have been fully authorised by their line manager and their division to undertake the activity.
- Fully comply with the terms of any relevant Trust policies and/or procedures at all times.
- Only depart from any relevant Trust guidelines providing always that such departure is confined to the specific needs of individual circumstances. In healthcare delivery such departure shall only be undertaken where, in the judgement of the responsible clinician it is fully appropriate and justifiable – such decision to be fully recorded in the patient's notes.
- Work within the defined roles and responsibilities of their job description
- Follow up on any actions identified during discussions with their manager or during the investigation.

8.2 Staff are recommended to have Professional Indemnity Insurance cover in place for their own protection in respect of those circumstances where the Trust does not automatically assume vicarious liability and where Trust support is not generally available.

Suitable Professional Indemnity Insurance cover is generally available from the various Royal Colleges and Professional Institutions and Bodies.

9. Sign off (separation, supervision, authorisation)

Stage/ purpose	Name and role	Date (how/ where evidenced)
Peer review:	Medicines Safety group including MDT input from P&PD team, digital team, adult and paediatric Nursing & Midwifery representatives. PSIRF launch group and liaison with Jo Ralph, Head of Governance & Lisa Lamb, Patient Safety lead. Kathryn Fearn, Trust solicitor in respect of section 8 only.	
Supervisor/ Lead review:	Julie Vanes, Medicines Safety Pharmacist	March 2024
Information Asset Owner/ Trust Lead:	James Hooley, Medication Safety Officer and Chair of Medicines Safety Group	March 2024

10. References, Related National Documents, and UDHB Policies

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11. Appendices

Appendix 1 - Examples of medication errors / incidents

Appendix 2 - NHS England Just Culture Guide

Appendix 3 - Reflective Exercises

Appendix 4 - SEIPS Framework - Systems Engineering Initiative for Patient Safety (Framework + blank template)

Appendix 5 - Pharmacy Department - Medication incident Reflection Form

Appendix One

Examples of medication errors / incidents *(this list is not exhaustive)*

Prescribing Errors

- Patient prescribed the wrong medication / dose / route / rate.
- Medication prescribed to the wrong patient.
- Prescribing without considering the patient's clinical condition
- Prescribing without considering patients' clinical parameters e.g. weight
- Prescription not signed.
- Transcription errors
- Allergy status not taken into consideration; allergy status not updated in timely manner.
- Critical medicine not prescribed in a timely manner.
- Critical medicine prescribed but prescribed route not available.
- Need for critical medicine administration not escalated to appropriate staff.

Dispensing Errors

- Patient dispensed the wrong medication / dose / route.
- Medication dispensed to the wrong patient.
- Patient dispensed an out-of-date medicine.
- Medication is labelled incorrectly.

Preparation and Administration Errors

- Administration of wrong medication / dose / route to patient
- Out of date medicine administered to patient.
- Medication administered to the wrong patient.
- Medication omitted without a clinical rationale.
- Significant delay in administration of medication
- Medication administered too early.
- Medication incorrectly prepared
- Incorrect infusion rate
- 2nd check not completed as per UHDB Trust Policy for Medicines Management
- Critical medicine not given / delayed administration with no documented reason or escalation to prescriber.

Monitoring Errors

- Failure to carry out required patient monitoring / blood tests for the drug being given.
- Failure to monitor therapeutic levels at appropriate time
- Patient allergic to medication but the medication was prescribed / dispensed for them or administered to them.
- Failure to provide the patient / carer with correct information regarding medication e.g., when to take, what it is for, side effects etc.

Any deviation from UHDB Trust Policy for Medicines Management would also be an example of a medication incident.

Appendix Two

NHS
University Hospitals of Derby and Burton
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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**

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

Supported by:

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Reflective Exercises

Reflective Exercises can be considered in 3 parts. The Gibbs Reflective Cycle can be a useful tool to support this. Alternatively, consider the 3 parts as below:

Part 1: A factual statement about the incident. This statement should be used to ensure the relevant incident form (Datix) is accurately updated. In some circumstances it may also be useful to upload this to the Datix – this should not be done without the author's consent.

Part 2: The reflective aspect of the exercise. Whilst practitioners may wish to start the reflective process by themselves, it is important to review it and work through it in conjunction with a manager or mentor as well. This helps to ensure all learning that can be taken from the incident is, provides an opportunity for well-being support, and helps ensure that any follow up actions (such as process changes, guideline updates, system change etc) are passed to the appropriate personnel to action or manage.

The following are useful prompts to consider as part of the reflective aspect of this exercise:

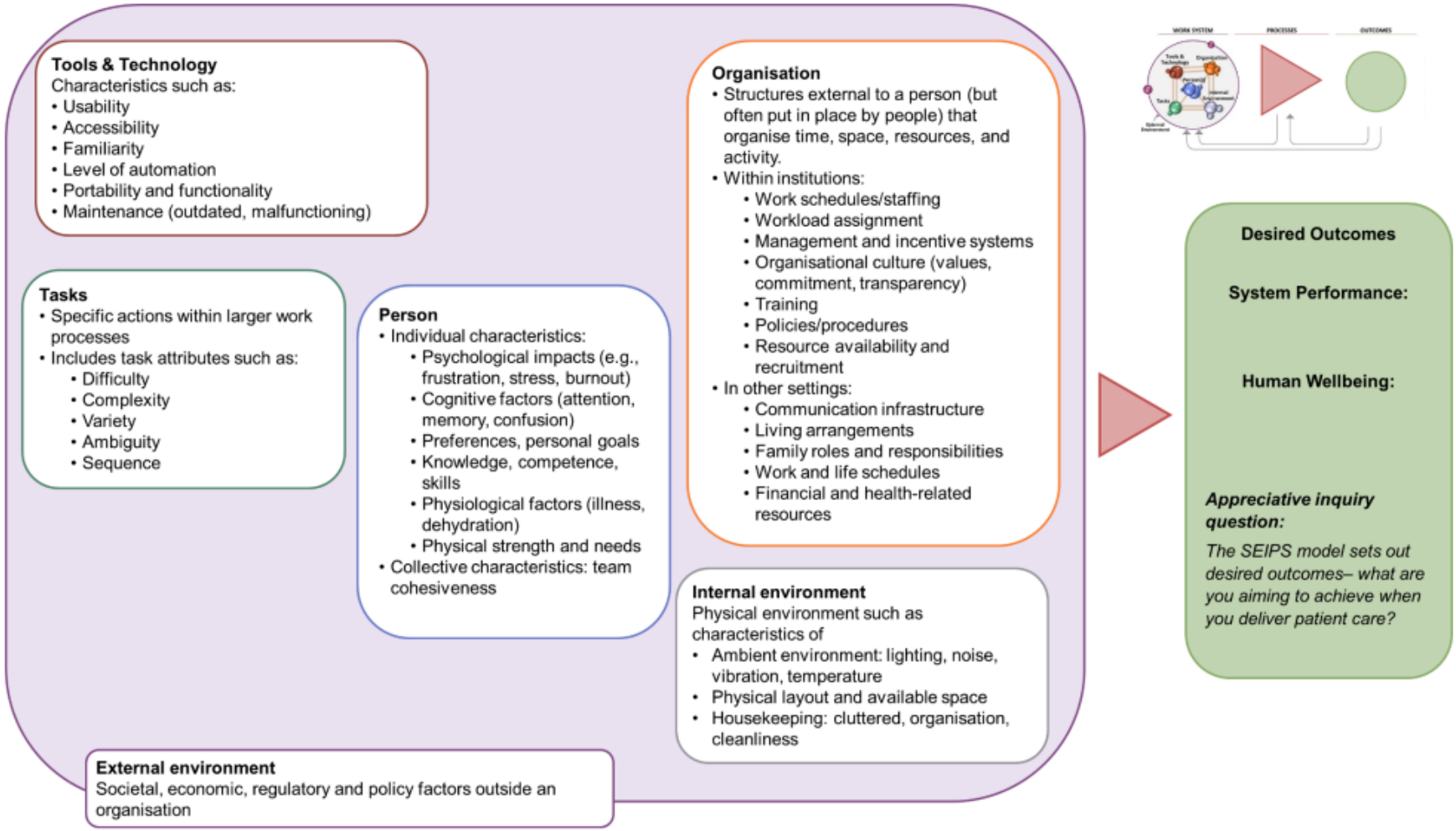
- What happened because of the incident?
- The seriousness of the incident
- What may have caused or contributed to the incident? *Consider the environment, what else was happening at the time etc.*
- What would help to prevent it happening again?
- How did you react when the incident was realised?
- How do you feel about the incident and your reaction / response?
- How did others react?
- How do you feel about the reaction / response from colleagues or others?
- Do you feel competent and confident when managing medicines?
- Is there any support or training which you feel could be helpful, for yourself or anyone involved or affected? *Think beyond process and training support e.g. Occupational Health or other support services*.
- Have medication incidents happened before (think about the situation and environment, not just personnel)? Is there a pattern or trend occurring? Or is there potential for this?

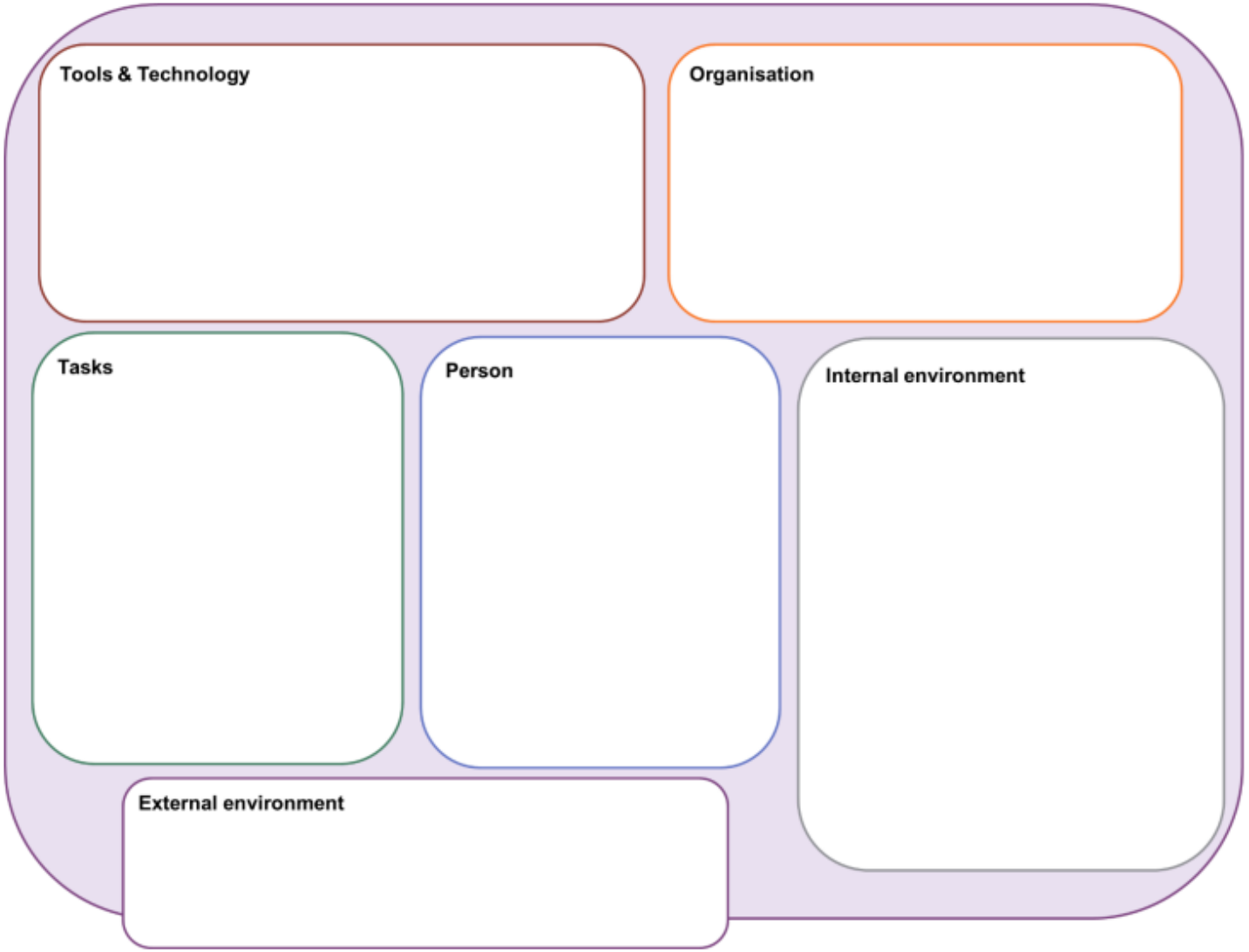
Managers should also consider:

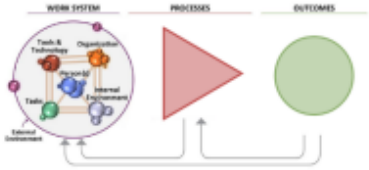
- How other colleagues felt or reacted when the incident was realised and afterwards
- Have similar incidents happened before - consider the situation, environment, colleagues involved? Is there a pattern or trend occurring? Or is there potential for this?

Part 3: An action plan that arises from the incident – this can be kept as part of your appraisal documentation to be reviewed as appropriate and may be uploaded in whole or in part to the relevant incident form.

Appendix Four (next Page): SEIPS Framework - Systems Engineering Initiative for Patient Safety







Desired Outcomes

System Performance:

Human Wellbeing:

Appreciative inquiry question:

The SEIPS model sets out desired outcomes– what are you aiming to achieve when you deliver patient care?

Appendix Five

Pharmacy Department Example of a Medication Incident Reflection form

DISPENSING ERROR ☐		CHECKING ERROR ☐		CLINICAL ERROR ☐ (Please tick)	
Staff Name		Date Of Error		Datix reference (external errors to be on Datix)	

Consider the following:

- The seriousness of your error
- What happened (actual consequences) or might have happened (potential consequences) because of your error?
- What caused and/or contributed to the error?
- What errors have you made prior to this and is there a pattern or trend occurring?
- How will you prevent this error happening again?
- How will you re-establish your confidence in checking/dispensing/clinical review?
- Does your dispensing/checking process need reviewing?
- Do you have any ideas or suggestions for a change in practice that will prevent the same error happening again?

1. Briefly describe the error AND state the potential and actual consequences of your actions.

2. Were there any contributing factors?
1. 2. 3. 4.

3. How could you have prevented this error from occurring?
4. How will you prevent this error from happening again in the future?
5. Is there any support or training needed to help you prevent this error reoccurring?

Error database updated:	Yes / No	Retraining requirement identified:	Yes / No
Signature of staff member	Date	Signature of line manager	Date