Trust Standard Operating Procedure	Plymouth Hospitals NHS

Management of Drug Errors

Date	Version
February 2016	**3.2**

Purpose

Plymouth Hospitals NHS Trust recognises the importance of supporting staff when they have been involved in a medication error. It is essential that a sensitive response is demonstrated through a comprehensive assessment, taking full account of the context and circumstances surrounding the incident, prior to any action being taken in a clear and consistent way.

The Standard Operating Procedure (SOP) has been written to:

Strengthen the Trust's open and fair blame culture in response to adverse healthcare events.

Facilitate organisational learning through the findings of thorough and careful investigation at local level.

Provide a framework for practitioners to improve practice.

Ensure appropriate actions are taken by managers and applied consistently across the trust.

Who should read this document?

All clinical staff

Key messages

To give staff direction in order to manage the process when staff have been involved in a medication error.
To ensure consistency across the Trust
This applies to all staff who prescribe, dispense, prepare and administer drugs.

Accountabilities

Production	Sharron Barclay, Sue Timmins Matron
Review and approval	Medicines Utilisation and Assurance committee, Nursing and Midwifery Board.
Ratification	Sue Johnson, Head of Nursing
Dissemination	All Matrons, Service leads across PHNT
Compliance	Senior nurses and managers

Links to other policies and procedures		
Management of medicines Policy		
Performance and Conduct Policy		
Supporting Staff Policy		
Management of Adverse Events Policy		
Risk Management Framework		

Version History		
1	May 2014 Draft	Initial version for consultation
2	October 2014 Draft	Medicines Governance committee
3	February 2016	Medicines Utilisation and Assurance Committee
3.1	March 2019	Extended to September 2019
3.2	September 2020	Extended to March 2020

Last Approval	Due for Review
March 2016	Extended to March 2020

The Trust is committed to creating a fully inclusive and accessible service. By making equality and diversity an integral part of the business, it will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Standard Operating Procedures are designed to promote consistency in delivery, to the required quality standards, across the Trust. They should be regarded as a key element of the training provision for staff to help them to deliver their roles and responsibilities.

Standard Operating Procedure (SOP)

MEDICATION ERRORS

1	Purpose and Scope

Introduction

Plymouth Hospitals NHS Trust recognises the importance of supporting staff when they have been involved in a medication error. It is essential that a sensitive response is demonstrated through a comprehensive assessment, taking full account of the context and circumstances surrounding the incident, prior to any action being taken in a clear and consistent way.

The Standard Operating Procedure (SOP) has been written to:

Strengthen the Trust's open and fair blame culture in response to adverse healthcare events.

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Definitions

The following list gives examples of scenarios where medication errors can occur (National Patient Safety Agency, 2007). It should not be considered a definitive list and professional judgement must be used. Near misses in any of the sections below should also be considered.

Prescribing Errors

Patient prescribed the wrong medication/dose/route/rate.

Medication prescribed to the wrong patient.

Transcription errors.

Prescribing without taking into account the patients clinical condition.

Prescribing without taking into account patients clinical parameters e.g. weight.

Prescription not signed.

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

Patient administered the wrong medication/dose/route.

Patient administered an out of date medicine.

Medication administered to the wrong patient.

Medication omitted without a clinical rationale.

Medication incorrectly prepared.

Incorrect infusion rate.

Medication administered late or early (where it would have a significantly detrimental effect on patient care).

Documentation error in controlled drug book or drug chart

Monitoring Errors

Patient allergic to medication but the medication was prescribed and/or dispensed and/or administered.

Failure to provide the patient with correct information regarding their medication e.g. when to take, what it is for, side effects.

Failure to monitor therapeutic levels.

Regulatory background

Nursing and Midwifery council (2007) standards for Medicines Management : NMC

Medicines and Healthcare Products Regulatory Authority (MRRA)

Medicines Act 1968 – sections 64 and 68

General Pharmaceutical's Council Code of Conduct – "Standards of Conduct, Ethics and Performance" – July 2012

Key Duties

This Standard Operating Procedure (SOP) applies to all staff involved in any medication process, including prescribing, dispensing, preparation, administration and monitoring, within Plymouth Hospitals NHS Trust provided services.

Monitoring and assurance

- Monitor the performance and outcome following the performance of a drug error

- Pharmacy has a key responsibility for the monitoring of drug errors within their governance framework.

- Yearly monitoring of the performance management framework

- if any shortfalls are identified the policy will need to be looked at

- the results of any monitoring will be discussed at the monthly Drugs and therapeutics committee.

2	Procedure to Follow

Actions to be taken following the discovery of a medication error

Immediate Actions

Assess the patient's condition and take necessary action to maintain patient stability.

Ensure appropriate medical assessment and treatment is provided as necessary.

The error must be reported immediately to the line manager/senior nurse/Matron, and the senior medical doctor in change of care for the patient (e.g. consultant). The on-call manager and senior nurse should be informed out of hours.

All controlled drug errors to include missing drugs must be reported the Director of Pharmacy as the accountable officer for the Plymouth Hospitals NHS Trust.

If unsure, seek advice from the Pharmacy department or Medicines Management team regarding the possible outcomes of medication error.

Record details of the incident in the medical/nursing notes.

Report the incident, following the Trust's Management of Adverse Events Policy using the datix reporting tool. The report must include:

- patient name and area where incident occurred
- time the incident occurred
- a factual account
- medicines involved and doses
- route of administration
- actions taken to ensure patient safety
- any mitigation and key factors present at the time which impacted on the incident

Inform the patient and their carer or relatives of the incident as soon as possible, following the Trust's Being Open Policy. With any moderate or serious incident consider Duty of candour with an apology to the patient and family member.

Medium Term Actions (within a week of the incident) – see Appendix A

The consequence incident score (appendix A) should be used by the line manager to grade the incident.

If the incident is of low/moderate severity (green or yellow risk), clinicians involved should reflect on the incident with the investigating manager and any comments/learning from this discussion should be included within the incident report review. A written reflective account should be made by the practitioner following the first error.

If the incident is of high or extreme severity (orange or red risk), or if this is this is the 2nd medication error to the individual staff member within a 2 month period, the individual involved should complete the critical incident reflective exercise (see Appendix B). This should be completed within a week of the incident, at most and should include a plan to share the outcome and learning with the wider team. This should include an assessment in practice for registered nurses.

A copy of the agreed actions as identified within the critical incident reflective exercise must be kept on the member of staff's personal record and reviewed in line with the appraisal approach, confirming positive change. This will be agreed in line with the Performance and Conduct policy.

The Decision Tree should be used to determine the type of action that is required and this should be detailed within the reflective exercise and actions.
Line managers must also consult with their HR partner, if there are concerns about the performance of a member of staff and discuss the consequences if the actions are not successful.

Guidance on the management of incidents and the criteria for escalation are included within the Trust's Management of Adverse Events Policy and the Risk Management Framework policy. Where a Significant Event investigation is indicated, this must be completed within 5 working days.

If the incident has resulted in harm to the patient it may be nominated, following a review by the Safety and Quality Committee who report to the Executive Directors, as a potential SIRI (Serious Incident Requiring Investigation) by the organisation and would then follow the SIRI formal process with a round table review and report to the Serious Complaints and Incident Review Group (SCIRG), in line with the Trust's Management of Adverse Events Policy.

There may be occasions where staff wish to stand themselves down from prescribing, dispensing or administration following a medication error, even if this is not identified as an action from the Safety Decision Tree. This should be respected and addressed within the critical incident reflective exercise. If this impacts significantly upon the role they hold this would need to be discussed with their line manager so arrangements could be made to support this decision with minimal impact on service continuity.
Alternatively the line manager, with advice from the professional leads may consider restriction of practice for an individual whilst an investigation takes place. This would be appropriate to reduce risk, whilst competence is confirmed and skills are attained which have not been demonstrated by errors relating to the incident.

The line manager is responsible for supporting the member of staff during this process, in line with the Trust's Supporting staff with an incident, complaint or claim policy. The member of staff must be kept informed of the progress of any investigation, and should also be informed of the support and counselling service available from the Occupational Health Department.

Long Term Actions (within 3 months of the incident)

If the critical incident reflective exercise highlights an issue with competency relating to medication prescribing, dispensing or administration, the individual must undertake a period of education, training and re-assessment planned in collaboration with their line manager, with support from the workforce development department and clinical educator. Specific timescales must be set and regularly reviewed.
During this time their practice may be restricted and this should be clearly described to them with assistance from the HR team and followed up in writing. This will enable all concerned to understand how these restrictions are being supported and in what time frame improvement is anticipated.

If, after the period of education, training and re-assessment, the member of staff is still not competent, they should be managed in accordance with the Trust's Capability Procedure.

All medication incidents will be reviewed within the Service Line governance Group on a monthly basis. This group comprises representatives from Medical and Nursing and any actions or learning agreed within the group will be disseminated throughout

the trust. Any concerns that are identified will be shared with the Trust Executive Board.

Themes from Serious Incidents Requiring Investigation and Significant Event Audits will be reported through the normal processes to the Safety and Quality Committee and Healthcare Governance.

3	Document Ratification Process

The design and process of review and revision of this procedural document will comply with The Development and Management of Trust Wide Documents.

The review period for this document is set as default of three years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the Medicines Utilisation and Assurance committee and ratified by the Head of Nursing.

Non-significant amendments to this document may be made, under delegated authority from the Head of Nursing, by the nominated author. These must be ratified by the Head of Nursing and should be reported, retrospectively, to the Medicines Utilisation and Assurance committee

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes

Dissemination and Implementation

Following approval and ratification, this procedural document will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process, currently the 'Vital Signs' electronic newsletter.

Document control arrangements will be in accordance with The Development and Management of Trust Wide Documents.

The document author(s) will be responsible for agreeing the training requirements associated with the newly ratified document with the Head of Nursing and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

4	Reference Material

General Medical Council (2009) EQUIP Study. An in-depth investigation into causes of prescribing errors by foundation trainees in relation to their medical education [online] Available from http://www.gmc-uk.org/FINAL_Report_prevalence_and_causes_of_prescribing_errors.pdf_28935150.pdf (Accessed 28/02/2013)

General Medical Council (2009) Good Medical Practice. London: GMC.

Gibbs, G. (1998) Learning by Doing: A Guide to Teaching and Learning. London: FEU.

Meadows, S., Baker, K. and Butler, J. (2005) The Incident Decision Tree: Guidelines for Action Following Patient Safety Incidents [online] Available from http://www.ncbi.nlm.nih.gov/books/NBK20586/ (Accessed on 28/02/2013).

National Patient Safety Agency *(2004)* Incident Decision For Secondary/Tertiary Care, Ambulance and Mental Health Studies*. London: NPSA*

National Patient Safety Agency (2007) Safety in Doses: Medication safety incidences in the NHS. London: NPSA

National Patient Safety Agency (2008) A Risk Matrix for Risk Managers. London: NPSA

National Patient Safety Agency (2010) Medical Error: What to do if things go wrong, a guide for junior doctors. London: NPSA

Nursing and Midwifery Council (2007) Standards for Medicines Management. London: NMC

Royal Pharmaceutical Society (2012) Medicines, Ethics and Practice. London: RPS.

Appendix   Appendix A

Table 1 Consequence scores

	Consequence score (severity levels)				
Domains	**None**	**Minor**	**Moderate**	**Severe**	**Catastrophic**

Impact on the safety of patients, staff or public (physical/psychological harm)	Minimal injury requiring no/minimal intervention or treatment.	Minor injury or illness, requiring minor intervention Increase in length of hospital stay by 1-3 days	Moderate injury requiring professional intervention Increase in length of hospital stay by 4-15 days An event which impacts on a small number of patients	Major injury leading to long-term incapacity/disability Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients

Table 2 Likelihood score (L)

What is the likelihood of the consequence occurring?

Likelihood score					
Descriptor	**Highly unlikely**	**Not expected**	**May occur at sometime**	**Strong possibility**	**Very Likely**
Frequency How often might it/does it happen	This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting issue	Will undoubtedly happen/recur,possibly frequently

Table 3 Risk scoring = consequence x likelihood (C x L)

Likelihood score					
	Highly unlikely	**Not expected**	**May occur at sometime**	**Strong possibility**	**Very likely**
Catastrophic					
Severe					
Moderate					
Minor					
None					

For grading risk, the scores obtained from the risk matrix are assigned grades as follows

Low risk
Moderate risk
High risk
Extreme risk

Appendix B – Critical Incident Reflective Exercise

This document is designed to enable practitioners to have a formal process of learning from incidents that they have been involved in. You must complete this form in conjunction with your line manager. You will keep the original form and your manager will keep a copy.

The exercise is modelled around Gibbs reflective cycle (1998), shown below:

Action Plan

If the situation

arose again what

would you do?

Description

What happened?

Analysis

What sense can

you make of the

situation? What

else could you

have done?

Feelings

What were you

thinking and

feeling?

Evaluation

What was good

and bad about

the experience?
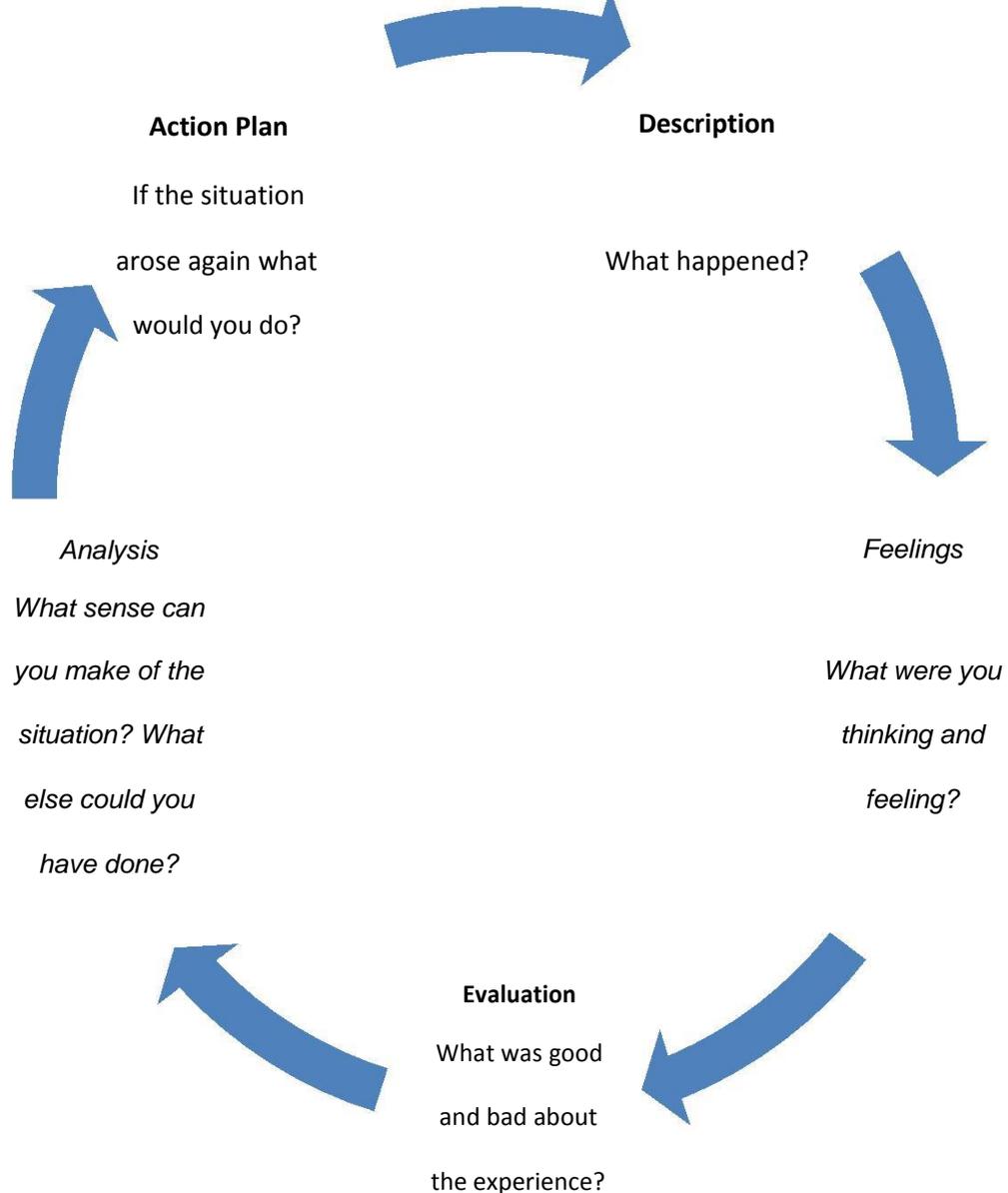
The critical incident reflective exercise is in three parts:

Part A   You write a factual statement about the incident. This will be kept by your manager and   included within the incident report.

Part B   This is an informal learning exercise, for you to reflect on the incident and to discuss any   issues with your manager.

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

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

Part A – Formal Statement of the Incident

Write a detailed account of what happened before, during and after the incident.
- What exactly occurred?
- What did you see?
- What did you do?
- What were the consequences of your actions to yourself, the patient, visitors, your colleagues?
- What did other people do? (e.g. colleagues, patient, visitors)
- Write your statement here, and continue on another sheet if necessary

Name of person completing form		Date
signature		
Name of person reviewing form		

Part B – Reflection on the incident

Write a reflective account of the events leading up to, during and after the incident.

- What was I trying to achieve? Why did I act as I did?
- What internal/external factors influenced my decision-making or actions?
- What sources of knowledge did or should have influenced my decision-making or actions?
- What were my feelings at the time?
- What are my feelings now? Are there differences? Why?
- What were the effects of what I did or did not do?
- What "good" emerged from the situation for myself and for others?
- What would I have done differently/better?
- What troubles me now (if anything)?
- Write your reflection here, and continue on another sheet if necessary

Date reflection completed

Part C – Action Plan arising Out of Incident

List your learning points from the incident, with an action plan of what you need to focus on or do differently as a result.

- What needs to happen to alter the situation?
- What are you going to do about the situation?
- What happens if you decide not to alter anything?
- What information do you need to face a similar situation again?
- What are the best ways of getting further information about the situation should it arise again?
- Identify anything that may hinder your action plan and how you can tackle these
- Have you taken effective action to support yourself and others as a result of this experience?

Write your learning points here

Learning Need	Actions to address need	Progress Review

Name of person completing form		Signature Date	
Name of person reviewing form		Signature Date	

PART D

1. How the Incident Decision Tree works

The Incident Decision Tree is based on a flowchart, and it takes you through a series of structured questions about an individual's actions, motives and behaviour at the time of the incident. In the majority of cases system failure turns out to be the cause of the incident.

2. The Deliberate Harm Test

In the vast majority of incidents the individual had the service objectives at heart. There may be extremely rare occasions when the intent was to cause harm physical, emotional, fraud etc. The Deliberate Harm Test asks questions to help identify or eliminate this possibility at the earliest possible stage and determine if it is appropriate to refer the case to the Police and/or the relevant regulatory/professional body.

3. The Physical/Mental Health Test

If intent to harm has been discounted, the Physical/Mental Health Test helps to identify whether the employee's ill health or substance abuse caused or contributed to the incident.

4. The Foresight Test

If physical and mental health issues have been discounted the Foresight Test examines whether protocols and safe working practices were adhered to by the staff member.

5. The Substitution Test

Finally, if protocols were not in place or proved to be ineffective the Substitution Test helps to determine if another individual coming from the same professional group, possessing comparable qualifications and experience, would have been likely to deal with the situation in the same manner.

6. After you have worked through the questions

The individual's employee group may affect the processes you need to follow and although some processes vary from employee group to employee group, we promote comparable treatment for individuals of all professional backgrounds. Once you have made your selection, you will be led to the appropriate outcome box.

7. Outcome box

The outcome box will suggest a range of actions to consider taking in the circumstances

Start Here

Deliberate Harm Test	**Incapacity Test**	**Foresight Test**	**Substitution Test**

Were the action as intended?	Does there appear to be evidence of ill health or substance abuse?	Did the individual depart from agreed protocols or safe procedures?	Would another individual coming from the same professional group, possessing comparable qualifications and experience behave in the same way in similar circumstances?

No → (between Deliberate Harm and Incapacity)
No → (between Incapacity and Foresight)
No → (between Foresight and Substitution)
Yes → (from Substitution Test, to System Failure)

↓ Yes	↓ Yes	↓ Yes	↓ No
Were adverse events as intended?	Does the individual have a known condition?	Were the protocols and safe procedures available, workable, intelligible, correct and in routine use?	Were there any deficiencies in training experience or supervision?

No (from "Were adverse events as intended?")
Yes (from "Does the individual have a known condition?" to next)
No (from Foresight middle box)
Yes (from "Were there any deficiencies in training experience or supervision?")
No (from "Were there any deficiencies in training experience or supervision?")

		↓ Yes	↓ No
		Is there evidence that the individual took an unacceptable risk?	Were there significant mitigating circumstances?

Yes (from "Is there evidence that the individual took an unacceptable risk?" to "Were there significant mitigating circumstances?")
Yes (from "Were there significant mitigating circumstances?")

↓ Yes	↓ No	↓ No	↓ No	

Consult relevant body
 	
Advise individual to consult trade union
 	
Consider
  Suspension
  Police
  Occupational Health
	Consult relevant body
	
	Advise individual to consult trade union
	
	Consider
	  Occupational Health
	  Adjustment to duties
	  Sick leave
		Advise individual to consult trade union
		
		Consider
		  Corrective training
		  Improved supervision
		  Occupational Health
		  Adjustment to duties
			Consult relevant body
			
			Advise individual to consult trade union
			
			Consider
			  Disciplinary body
			  Adjustment to duties
			  Occupational Health
			  Suspension
				System Failure
				Review system

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Ward level	☐
Pharmacy	☐

Dispensed incorrectly → Yes

- Incorrect Medication ☐
- Incorrect strength ☐
- Labelling ☐
- Expired medication ☐

Other Root Causes Identified:

Was it a problem with storage of the medication? → Yes

- Removed from package ☐
- Space issues ☐
- Next to similar Medication/ confused names ☐

Were there packaging issues? → Yes

- Similar packaging ☐
- Strength on packaging is unclear. ☐
- Different product/ manufacturer from normal. ☐

Was there a Manipulation error? → Yes

- Calculation error ☐
- Incorrect dilution ☐
- Incorrect rate ☐
- Pump error ☐
  - Type used ☐
  - Setting up ☐
  - Equipment failure ☐
- Lack of information available ☐
- Strength of preparation ☐

Due to an individual? → Yes

- Inappropriate Skill mix ☐
- Competency ☐
- Knowledge ☐
- Distractions / interruptions ☐
- Staffing levels ☐
- Environment ☐

Any environmental issues? → Yes

- Poor lighting ☐
- Inadequate facilities ☐
- Preparation ☐
- Storage ☐
- Noise ☐

Were there issues with the Equipment?	Was there a process failure?	Was the medication not given?	Due to an Individual?	Were there Environment issues?
Yes	Yes	Yes	Yes	Yes

Were there issues with the Equipment?

Inappropriate device used:
- Pump ☐
- Syringe ☐
- Line ☐
- Connectors ☐

Equipment failure ☐

Appropriate equipment unavailable ☐

Equipment set up incorrectly ☐

Was there a process failure?

Guideline not followed ☐

IV policy not followed ☐

Lack of monitoring ☐

Lack of recording ☐

Labelling incorrect ☐

Lack of information available ☐

Was the medication not given?

Pt not on ward ☐

Medication unavailable ☐

Route inappropriate for pts condition ☐

Due to an Individual?

Competency ☐

Knowledge ☐

Distractions / interruptions ☐

Staffing levels ☐

Skill mix ☐

Environment ☐

Were there Environment issues?

Noise ☐

Lighting ☐

Surface ☐

Space ☐

Other Root Causes Identified:

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┌─────────────────────┐   ┌─────────────────────┐   ┌─────────────────────┐   ┌─────────────────────┐
│ Were there issues   │   │ Issues with blood   │   │ Lack of monitoring? │   │ Due to an individual?│
│ with the equipment? │   │ tests / results?    │   │                     │   │                     │
└─────────────────────┘   └─────────────────────┘   └─────────────────────┘   └─────────────────────┘
         │ Yes                      │ Yes                      │ Yes                      │ Yes
         ▼                          ▼                          ▼                          ▼
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Were there issues with the equipment?	Issues with blood tests / results?	Lack of monitoring?	Due to an individual?
Yes	Yes	Yes	Yes

Were there issues with the equipment? — Yes

- Equipment failure ☐
- Inappropriately set up ☐
- Incorrect equipment ☐

Issues with blood tests / results? — Yes

- Communication ☐
- Documentation ☐
- Incorrect patient ☐
- Incorrectly taken ☐
- Misinterpretation ☐

Lack of monitoring? — Yes

- Incorrect tests requested ☐
- No tests requested ☐

Due to an individual? — Yes

- Competency ☐
- Knowledge ☐
- Distractions/ interruptions ☐
- Staffing levels ☐
- Skill mix ☐
- Environment ☐

Other Root Causes Identified: