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| Department/Location/Project: POCT/EPAC | SOP Document Reference Number: **SOP/POCT/63** |
| Risk Assessor(s): Francesca Mills | Highest Risk Rating Identified\*: |
| Date of assessment:14/10/2021 | Informed QM of any Risk Score >9 (initial when done or NA): |

**\* Any identified risk which has a rating >9 must be communicated with the Quality Manager**

| **Description of risk** | **Existing control/ safe****System of work** | **Initial Risk** **Rating****(S X L= RR)** | **What further action is required** | **Responsible person** **and target date for completion** | **Final Risk** **Rating****(S X L= RR)** |
| --- | --- | --- | --- | --- | --- |
| Example wording:*There is a risk that …**As a result of …**Which may result in …**Who is exposed to the risk?** *Staff (including contractors)*
* *Patients’*
* *Organisation*
 | What prevents the risk occurring, if anything? |  |  |  | What needs to take place to prevent the risk occurring. Consider - elimination, substitution, physical controls/safeguards, safe systems of work, other methods i.e. personal protective equipment etc.Include cost. **[If None state N/A]** | Required information**[If None state N/A]** |  |  |  |
| Risk to staff and patient surrounding puncturing patient skin when collecting the blood sample* Needle stick injuries
* Infection
* Blood spillages due to wound
 | * Training for use of iSTAT
* Needle stick injury policy
* Immunizations
* PPE
* Sharps Disposal policy
* Procedure for spillages of body fluids
* Pathology Health and safety policy
* Training for treatment of wounds.
 | 2 | 2 | 4 | N/A | N/A | 2 | 2 | 4 |
| Risk to staff when analysing patient or EQA samples* Exposure to potential biohazard
 | * Training for use of iSTAT
* EQA screened for HIV and Hepatitis
* PPE
* Disposal of samples and cartridge into contaminated waste bin
 | 1 | 1 | 1 | N/A | N/A | 1 | 1 | 1 |
| Risk to staff and patient of misinterpretation of results that fall above or below the action limit set by EPAC that could result in patient mismanagement. | * Only trained staff should use the meters
* Interpretation of results is included in departmental training and in the clinical guideline
* Concurrent sample is always sent to the lab for hCG (and other tests) and this result will be reviewed when available on Millennium
 | 2 | 2 | 4 | N/A | N/A | 2 | 2 | 4 |
| Risk to staff and patient of misinterpretation of results that fall above or below the technical limits of the meter that could result in patient mismanagement. | * Concurrent sample is always sent to the lab for hCG (and other tests) and this result will be reviewed when available on Millennium. The lab assay has a wider analytical range than the meter.
* Only trained staff should use the meter
* The meter displays > or < when the result is above or below the technical limit
 | 2 | 2 | 4 | N/A | N/A | 2 | 2 | 4 |
| There is a risk that the patient ID is not entered into the meter before the blood is analysed which results in an incomplete audit trail for that patient and previous results cannot be checked.  | * Only trained staff should use the meter and they are trained to input patient ID with each test
* The meter will be audited to check compliance and use of emergency numbers
 | 1 | 4 | 4 | N/A | N/A | 1 | 4 | 4 |
| There is a risk of manual transcription of results into patient notes could be incorrect. This is a risk to the patient and could lead to mismanagement.  | * During training the importance of careful manual transcription is highlighted
* Concurrent sample is sent to the lab for hCG measurement so there will be an electronic record of this hCG result.
 | 1 | 2 | 2 | N/A | N/A | 1 | 2 | 2 |
| There is a risk that if the meter or cartridge is damaged incorrect results could be reported which could lead to mismanagement of the patient. | * A optical check should be run on the meter weekly
* EQA sample is run monthly
* iQC samples should be run weekly
* Each test is an individual cartridge system with internal checks – if any of these fail the cartridge will fall. A new cartridge will need to be used.
 | 2 | 1 | 2 | N/A | N/A | 2 | 1 | 2 |

**Risk assessment matrix**

**Acceptable Risk**

Risk is tolerable as long as it is well managed and controlled. In addition to identified hazards, all incidents claims and complaints will be risk assessed according to the following process and investigated according to the severity or the consequence and likelihood of (re)occurrence.

**All Risk Assessments within the Trust will identify:**

1. The hazards within the Task/ area being assessed inherent in the work undertaken
2. who and how many people would be affected
3. how often specific events are likely to happen (may be based on frequency of previous occurrence):
4. how severe the effect or consequence would be
5. how controllable the hazards are.

Acceptable risk will be determined using the following traffic light system:

**Severity/consequence**

Given the (in) adequacy of the control measures, how serious the consequences are likely to be for the group, patient or Trust if the risk does occur (using the matrix).

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| --- | --- |
|  | **Consequence score (severity levels) and examples of descriptors**  |
|  | **1** | **2** | **3** | **4** | **5** |
| **Domains** | **Negligible** | **Minor** | **Moderate** | **Major** | **Catastrophic** |
| **Impact on the safety of patients, staff or public (physical/****psychological harm)**  | Minimal injury requiring no/minimal intervention or treatment. No time off work | Minor injury or illness, requiring minor intervention Requiring time off work for ≤3 days Increase in length of hospital stay by 1-3 days  | Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days RIDDOR/agency reportable incident An event which impacts on a small number of patients | Major injury leading to long-term incapacity/ disability Requiring time off work for >14 days 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 effectsAn event which impacts on a large number of patients  |
| **Quality/complaints/****audit**  | Peripheral element of treatment or service suboptimal Informal complaint/inquiry  | Overall treatment or service suboptimal Formal complaint (stage 1) Local resolution Single failure to meet internal standards Minor implications for patient safety if unresolved Reduced performance rating if unresolved  | Treatment or service has significantly reduced effectiveness Formal complaint (stage 2) complaint Local resolution (with potential to go to independent review) Repeated failure to meet internal standards Major patient safety implications if findings are not acted on  | Non-compliance with national standards with significant risk to patients if unresolved Multiple complaints/ independent review Low performance rating Critical report  | Totally unacceptable level or quality of treatment/service Gross failure of patient safety if findings not acted on Inquest/ombudsman inquiry Gross failure to meet national standards  |
| **Human resources/ organisational development/ staffing/ competence**  | Short-term low staffing level that temporarily reduces service quality (< 1 day)  | Low staffing level that reduces the service quality  | Late delivery of key objective/ service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance for mandatory/key training  | Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff Very low staff morale No staff attending mandatory/ key training  | Non-delivery of key objective/service due to lack of staff Ongoing unsafe staffing levels or competence Loss of several key staff No staff attending mandatory training /key training on an ongoing basis  |
| **Statutory duty/ inspections**  | No or minimal impact or breech of guidance/ statutory duty  | Breach of statutory legislation Reduced performance rating if unresolved  | Single breech in statutory duty Challenging external recommendations/ improvement notice  | Enforcement action Multiple breeches in statutory duty Improvement notices Low performance rating Critical report  | Multiple breeches in statutory duty Prosecution Complete systems change required Zero performance rating Severely critical report  |
| **Adverse publicity/ reputation**  | Rumours Potential for public concern  | Local media coverage – short-term reduction in public confidence Elements of public expectation not being met  | Local media coverage –long-term reduction in public confidence  | National media coverage with <3 days service well below reasonable public expectation  | National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the House) Total loss of public confidence  |
| **Business objectives/ projects**  | Insignificant cost increase/ schedule slippage  | <5 per cent over project budget Schedule slippage  | 5–10 per cent over project budget Schedule slippage  | 10–25 per cent over project budget Schedule slippage Key objectives not met  | Incident leading >25 per cent over project budget Schedule slippage Key objectives not met  |
| **Finance including claims**  | Small loss Risk of claim remote  | Loss of 0.1–0.25 per cent of budget Claim less than £10,000  | Loss of 0.25–0.5 per cent of budget Claim(s) between £10,000 and £100,000  | Uncertain delivery of key objective/Loss of 0.5–1.0 per cent of budget Claim(s) between £100,000 and £1 millionPurchasers failing to pay on time  | Non-delivery of key objective/ Loss of >1 per cent of budget Failure to meet specification/ slippage Loss of contract / payment by results Claim(s) >£1 million  |
| **Service/business interruption Environmental impact**  | Loss/interruption of >1 hour Minimal or no impact on the environment  | Loss/interruption of >8 hours Minor impact on environment  | Loss/interruption of >1 day Moderate impact on environment  | Loss/interruption of >1 week Major impact on environment  | Permanent loss of service or facility Catastrophic impact on environment  |

**Likelihood**

Given the (in) adequacy of the control measures for each risk, decide how likely the risk is to happen according to the following guide. Scores range from 1 for rare to 5 for very likely.

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| **Score** | **Descriptor** | **Description** |
| **1** | **Rare** | Extremely unlikely to happen/recur – may occur only in exceptional circumstances – has never happened before and don’t think it will happen (again) |
| **2** | **Unlikely** | Unlikely to occur/reoccur but possible. Rarely occurred before, less than once per year. Could happen at some time |
| **3** | **Possible** | May occur/reoccur. But not definitely. Happened before but only occasionally - once or twice a year |
| **4** | **Likely** | Will probably occur/reoccur. Has happened before but not regularly – several times a month. Will occur at some time. |
| **5** | **Very Likely** | Continuous exposure to risk. Has happened before regularly and frequently – is expected to happen in most circumstances. Occurs on a daily basis |

**Risk Score is determined by Severity x Likelihood**

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|  | **Consequence** |
| **Likelihood** | **1****Insignificant** | **2****Minor** | **3****Moderate** | **4****Major** | **5****Catastrophic** |
| **5 – Almost certain** | **5** | **10** | **15** | **20** | **25** |
| **4 - Likely** | **4** | **8** | **12** | **16** | **20** |
| **3 – Possible** | **3** | **6** | **9** | **12** | **15** |
| **2 – Unlikely** | **2** | **4** | **6** | **8** | **10** |
| **1 - Rare** | **1** | **2** | **3** | **4** | **5** |

