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| Department/Location/Project: Children’s OP Paediatric diabetes team | SOP Document Reference Number: **SOP/POCT/57** |
| Risk Assessor(s): Nicola Hodges | Highest Risk Rating Identified\*: |
| Date of assessment:09/11/2022 | Informed QM of any Risk Score >9 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)** | | |
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| Puncturing patient skin, therefore risk of needle stick injury, injection, blood spillage due to puncture wound.  Risk to Patient, parent, staff | * Patients perform regular finger pricks (>5 per day) experienced in doing so. * Patients perform puncture on themselves. * Staff go through correct procedure of lancing patients during training from Abbott. * Needle stick injury policy * Sharps disposal policy Procedure for spillages of body fluids | 2 | 2 | 4 | * It is rare that staff are required to do finger prick, patients or parents routinely do this. * Safety lancets are used, the sharp needle is not accessible after use. |  |  |  |  |
| Use of external quality control, therefore biohazard risk to staff | * External quality control is screened for HIV and Hepatitis * Personal Protective equipment is worn (ie. Gloves) when handling EQA sample * Samples are stored in the lab until analysis can take place, thus reducing time ward staff come into contact with EQA. | 1 | 1 | 1 |  |  |  |  |  |
| Risk to staff of coming into contact with cartridge components. | * Reagent is contained within plastic cartridge. Contact with reagent will not occur providing cartridges are handled as stated in the Standard Operating Procedure * In case of leakage, avoid contact with eyes and skin. Wash with plenty of water. * Dispose of as contaminated waste after use. | 1 | 1 | 1 |  |  |  |  |  |
| Transportation of equipment from office base to various community hospital sites, therefore risk to staff of carrying awkward equipment | * Staff to use Afinion carrying bag to transport equipment from base to base. * Manual handling mandatory training | 2 | 2 | 4 | * Ensure staff are covered by business insurance for vehicle transporting equipment * Staff must complete their mandatory training and this is reviewed at appraisal. | Individual staff who need to transport the analyser must only do so once correct insurance is in place. | 1 | 2 | 2 |
| Transportation of cassettes, therefore risk of them not being at correct temperature – Possible erroneous results produced causing alterations to patient’s treatment. | * Cassettes to be stored as per Standard Operating Procedure * Cassettes to be transported in bag supplied by manufacturer * Afinion not to be stored in PDSN car overnight | 2 | 3 | 6 | Temperature monitoring of cassettes whilst in fridge, at room temperature, and during transportation. |  | 1 | 3 | 3 |
| Risk to patient care if Afinion has a fault and is out of use. Unable to provide results during appointment increasing the time taken to adjust treatment if necessary. | * A service contract is in place – offers a temporary or permanent replacement analyser whilst the faulty analyser is being repaired/checked.   EXP: May 2025 | 2 | 2 | 4 | * Clinics can continue without the Afinion - staff can take whole blood EDTA samples into paediatric purple top tubes and process them through the laboratory. * Department will have to review continuation of service contract after 3 yrs. | * This is a contingency and would only require action if the Afinion was abruptly out of use. * Children’s OP will need to get a new contract in place by May 2025. | 1 | 1 | 1 |
| A risk to patients if results are transcribed incorrectly into patient notes. | * Results are recorded onto electronic patient record (Diamond) immediately by the person performing the test. Whilst out in the community results are written in the diary and transcribed once back in clinic. * Results can be looked up on the Afinion if required to confirm. * Clinic appointments are written up on a letter which contains the results, these letters are accessible through millennium. | 2 | 2 | 4 | Connectivity. Connection of the Afinion into the electronic patient record would remove any transcription errors and would reduce the time spent doing so. | POCT coordinator & Children’s OP manager 2023 – Paperless project would not fund the connection of POCTdevices to the EPR. An individual business case would need to be put in to connect the Afinion to the EPR. | 1 | 1 | 1 |
| Incorrect storage of cartridges/iQC/analyser has a risk of unreliable results being produced that could affect patient care. | * Training & Competency assessment required before staff can use the analyser. * Weekly QC testing compared to mean and 2 SD stated by manufacturer. * Results of QC recorded and sent to lab * Correct storage of QC and time out of fridge before using is stated in SOP. * Ensure date opened and expiry are recorded on box/stock sheet. * EQA performed monthly to confirm user and equipment producing correct results. * Comparison of Afinion results against laboratory result performed monthly/bi monthly. * Fridges are monitored with a thermometer and are checked daily. * Ambient temperature where analyser and small number of cartridges are stored not checked. | 2 | 3 | 6 | * Review of appropriateness of EQA sample type and range of concentrations. Is there a more appropriate scheme on the market now * Introduction of a calibrated thermometer linked to the laboratory comark system for the refrigerated cartridges and reagents. * Room temperature and transportation temperature to be monitored. | * No immediate plans before the MES tender is complete July 2023 | 1 | 1 | 1 |
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**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 effects  An 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 million  Purchasers 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** |

