

Blood Glucose and Ketone meter Quality Assurance Policy

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1 Introduction

This document sets out Northern Devon Healthcare NHS Trust's system for the Quality Assurance (QA) of Blood Glucose and Ketone Meters. It provides a robust framework to ensure a consistent approach across the whole organisation.

2 Purpose

The purpose of this document is to ensure adherence to UKAS Accreditation, Department of Health and International Standards. (See section 12).

The policy applies to all Trust staff involved in blood glucose and ketone monitoring.

Implementation of this policy will ensure that:

- Point of Care Testing (PoCT) devices used are regularly Quality Controlled (QC).
- The Quality Control process is demonstrable and auditable.
- There is a Quality Assurance (QA) process by which poor system performance can be identified and improved.

3 Definitions

3.1 Point of Care Testing (PoCT)

Pathology tests performed outside the conventional laboratory setting by healthcare professionals or patients.

3.2 Quality Control (QC)

The process or material used to test a device.

3.3 Internal Quality Control (IQC)

Performing routine quality control with material where the user knows the desired result.

3.4 External Quality Control/Assurance (EQA)

Performing a periodic quality control check with a material where the user does not know the desired result.

3.5 Quality Assurance (QA)

The overall assessment of the quality of an entire process.

4 Responsibilities

4.1 Role of the Director of Facilities

The Director of Facilities is responsible for medical devices and is chair of the Medical Devices Group, reporting to the Director of Operations and Trust board.

4.2 Role of the Point of Care Testing Manager

The Point of Care Testing Manager is responsible for:

- Monitoring the implementation of this policy
- Maintaining and updating the inventory of reusable Point of Care Testing devices owned by the Trust.

4.3 Role of the Medical Device Manager

The Medical Device Manager is responsible for:

- Ensure compliance with all policies and procedures relating to medical devices.
- Provide advice on medical device management issues as required.

4.4 Role of Directorates, Departmental Managers/Clinicians

Directorates, Departmental Managers/Clinicians are responsible for:

- Controlling the risks of all medical devices used within their area of authority. This will include ensuring their staff are aware of access methods to data, statistics and information related to medical devices operated within their area of responsibility. Competency assessed training on medical devices will be identified, provided and fully established for professional and end users.
- Formal acknowledgement of responsibility and accountability for the active implementation of the medical device management process.
- Ensuring that appropriate directorate or departmental medical devices management policies, procedures and systems are actively in place to ensure continual improvement.
- Seek advice on medical device management issues, as required.
- Ensure training matrices are continually updated.
- Suitably delegate responsibility for key device and equipment management and use matters.

- Ensure that devices designated for 'single use only' are not re-used under any circumstances.

4.5 Role of all staff involved in blood glucose/ketone monitoring

All staff involved in blood glucose and ketone monitoring are responsible for:

- Maintaining general risk awareness at all times.
- Maintaining awareness of the Point of Care Testing Department procedures to report defects appropriately, and to contact any member of the Team to ascertain specific device related information.
- Complying with approved policies and procedures.
- Participating in medical device education and training, and ensure individual training records and Personal Development Portfolios are updated.
- Accepting individual or team responsibility and accountability for maintaining a safe environment and only operate devices for which the user is competent and this competence can be demonstrated.
- Adhering to incident reporting procedures.

5 Policy for performing Blood Glucose and Ketone Meter Quality Control checks

To minimise the risk of producing erroneous results the meters must:

- Only be operated by staff who have received training (evidenced by having completed and recorded the relevant competency)
- Be maintained
- Be used according to the manufacturers' instructions

Quality control must be performed to establish that the meter is functioning correctly. This is not a definitive process and the operator should use a second meter or send a sample for laboratory analysis if they are suspicious of the results obtained.

The meters are supplied with two levels of quality control solutions in dropper bottles. These must be used to check the performance of the meters:

1. at **least** once a week (preferably twice for glucose meters);
2. when a new "pot" of glucose or lot of ketone test strips is started;
3. when the battery is changed;
4. if the meter is dropped (even if it appears undamaged);
5. when the result of a patient test does not fit with their clinical state;
6. whenever the operator has any concerns about the meter/test strips in use.

These two solutions have a shelf-life expiry printed on them which should be crossed out and replaced with a three month expiry when they are first opened.

Periodically an E.Q.A. sample, in a dropper bottle, will be sent from the Laboratory this must be tested and the result recorded on the accompanying letter. Return the

completed letter to the laboratory as soon as possible and no later than the return date on the letter. A report will then be sent back to you on the meters performance.

Where a meter is faulty or gives QC failures that do not respond to basic corrective actions it must not be used and the Point of Care Testing team must be informed. All IQC, instrument failures and corrective actions must be recorded in the QC log book provided. When recording data in the log books use the operator's full name, not initials.

6 The Development of the Policy

6.1 Prioritisation of Work

This policy has been revised and updated to align with the Medical Devices Policy, accreditation standards and Trust's standard format.

6.2 Document Development Process

As the author, the Point of Care Testing Manager is responsible for developing the policy and for ensuring stakeholders were consulted with.

Draft copies were circulated for comment before approval was sought from the relevant committees.

6.3 Equality Impact Assessment

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are placed at a disadvantage over others. An Equality Impact Assessment Screening has been undertaken and there are no adverse or positive impacts ([Appendix A](#)).

7 Consultation, Approval and Ratification Process

7.1 Consultation Process

The author consulted widely with stakeholders, including:

- Clinical staff, in particular the Diabetes Specialist Nurses.
- The Medical Devices group and its training/governance sub-group.
- The Pathology Quality Manager.
- The Peninsular PoCT network.

Consultation took the form of a request for comments and feedback via email and at Devices Group meetings. Hard copies were available on request.

7.2 Policy Approval Process

Approval of the policy was sought from the Medical Devices Group on 08/03/09 having completed the consultation process.

7.3 Ratification Process

The policy will not need to be ratified by the Trust Board.

8 Review and Revision Arrangements including Document Control

8.1 Process for Reviewing the Policy

The policy will be reviewed every three years. The author will be sent a reminder by the Pathology Q-Pulse document control system before the due review date. A reminder will be sent by the Corporate Affairs Manager four months before the due review date. The author will be responsible for ensuring the policy is reviewed in a timely manner and that the reviewed policy is approved by the Medical Devices Group and given final approval.

All reviews will be recorded by the author in the Document Control Report and Q-Pulse.

8.2 Process for Revising the Policy

In order to ensure the policy is up-to-date, the author may be required to make a number of revisions, e.g. committee changes or amendments to individuals' responsibilities. Where the revisions are minor and do not change the overall policy, the author will present the revised version to the Pathology Quality Management Group for approval.

Significant revisions will require final approval by the Medical Devices Group.

All revisions will be recorded by the author in the Document Control Report and Q-Pulse.

8.3 Document Control

The author will comply with the Trust's agreed version control process, as described in the organisation-wide Guidance for Document Control facilitated by the Pathology Q-Pulse system.

9 Dissemination and Implementation

9.1 Dissemination of the Policy

After approval by the Medical Devices Committee, the author will provide a copy of the policy to the Corporate Affairs Manager to have it placed on the

Trust's intranet. The policy will be referenced on the home page as a latest news release.

Information will also be included in the weekly Chief Executive's Bulletin which is circulated electronically to all staff.

An email will be sent to senior management to make them aware of the policy and they will be responsible for cascading the information to their staff.

In addition, staff will be informed that this policy replaces any previous versions.

9.2 Implementation of the Policy

Line managers are responsible for ensuring this policy is implemented across their area of work.

Support for the implementation of this policy will be provided by Pathology Point of care Team.

10 Document Control including Archiving Arrangements

10.1 Library of Procedural Documents

The author is responsible for recording, storing and controlling this policy facilitated by the Pathology Q-Pulse system.

Once the final version has been ratified, the author will provide a copy of the current policy to the Corporate Affairs Manager so that it can be placed on the Trust's intranet. Any future revised copies will be provided to ensure the most up-to-date version is available on the web pages.

10.2 Archiving Arrangements

All versions of this policy will be archived in electronic format within the Pathology Q-Pulse system. Archiving will take place by the Point of Care Team Manager once the final version of the policy has been issued.

Revisions to the final document will be recorded on the Document Control Report and Q-Pulse system. Revised versions will be added to the policy archive held by Pathology Point of Care Team.

10.3 Process for Retrieving Archived Policy

To obtain a copy of the archived policy, contact should be made with the Pathology Point of Care Team.

11 Monitoring Compliance With and the Effectiveness of the Policy

11.1 Process for Monitoring Compliance and Effectiveness

Monitoring compliance with this policy will be the responsibility of the Pathology Point of Care Team. This will be undertaken by regular audit by the Pathology Point of Care Team and/or equipment manufacturer.

Where non-compliance is identified, support and advice will be provided to improve practice. Non-compliance will be recorded via the Trust's incident reporting system. Repeated non-compliance will necessitate the withdrawal of the meter/s.

11.2 Standards/ Key Performance Indicators

Key performance indicators comprise:

- Compliance with IQC requirements
- Compliance with EQA requirements
- Compliance with Infection Control Policy

12 References

- Management and Use of IVD Point of care Test Devices, MDA DB2002(03): MHRA March 2002.
- Point-of-Care testing (POCT)—Requirements for quality and competence, BS EN ISO 22870:2006.
- Medical laboratories—Particular requirements for quality and competence BS EN ISO 15189:2003

13 Associated Documentation

- Northern Devon Healthcare NHS Trust, Pathology Quality Policy
- Northern Devon Healthcare NHS Trust, Medical Devices Policy
- Northern Devon Healthcare NHS Trust, Point of Care Testing Department procedures

Appendix A - Equality Impact Assessment Screening Form

Equality Impact Assessment Screening Form			
Title	Quality Assurance Policy for Point of Care Blood Glucose Monitoring		
Author	David O'Neill, Point of Care Testing Manager		
Directorate	Clinical and Support Services		
Team/ Dept.	Point of Care Testing, Pathology		
Document Class Policy	Document Status Current	Issue Date Sep 2017	Review Date Sep 2020
1	What are the aims of the document? This document sets out Northern Devon Healthcare NHS Trust's system for the Quality Assurance (QA) of Blood Glucose and Ketone Meters. It provides a robust framework to ensure a consistent approach across the whole organisation.		
2	What are the objectives of the document? The purpose of this document is to ensure adherence to Clinical Pathology Accreditation, Department of Health and International Standards.		
3	How will the document be implemented? Line managers are responsible for ensuring this policy is implemented across their area of work. Support for the implementation of this policy will be provided by PoCT team.		
4	How will the effectiveness of the document be monitored? Monitoring compliance with this policy will be the responsibility of the PoCT team. This will be undertaken by regular audit by the PoCT team and equipment manufacturer.		
5	Who is the target audience of the document? All staff involved in blood glucose and ketone monitoring.		
6	Is consultation required with stakeholders, e.g. Trust committees and equality groups? Yes		
7	Which stakeholders have been consulted with? <ul style="list-style-type: none"> • Clinical staff, in particular the Diabetes Specialist Nurses. • The Medical Devices group and its training/governance sub-group. • The Pathology Quality Manager. • The Peninsular PoCT network 		
8	Equality Impact Assessment Please complete the following table using a cross, i.e. X . Please refer to the document "A Practical Guide to Equality Impact Assessment", Appendix 3, on Intranet for areas of possible impact.		

<ul style="list-style-type: none"> Where you think that the policy could have a positive impact on any of the equality group(s) like promoting equality and equal opportunities or improving relations within equality groups, cross the 'Positive impact' box. Where you think that the policy could have a negative impact on any of the equality group(s) i.e. it could disadvantage them, cross the 'Negative impact' box. Where you think that the policy has no impact on any of the equality group(s) listed below i.e. it has no effect currently on equality groups, cross the 'No impact' box. 				
Equality Group	Positive Impact	Negative Impact	No Impact	Comments
Age			X	
Disability			X	
Gender			X	
Race / Ethnic Origins			X	
Religion or Belief			X	
Sexual Orientation			X	
<p>If you have identified a negative discriminatory impact of this procedural document, ensure you detail the action taken to avoid/reduce this impact in the Comments column. If you have identified a high negative impact, you will need to do a Full Equality Impact Assessment, please refer to the document "A Practical Guide to Equality Impact Assessments", Appendix 3, on Intranet.</p> <p>For advice in respect of answering the above questions, please contact the Equality and Diversity Lead.</p>				
9	<p>If there is no evidence that the document promotes equality, equal opportunities or improved relations, could it be adapted so that it does? If so, how?</p> <p>No means currently apparent</p>			

Completed by:

Name	David O'Neill
Designation	Point of Care Testing Manager
Trust	Northern Devon Healthcare NHS Trust
Date	01/08/2012 and subsequent reviews