Quality Requirements of a Point of Care Testing Service

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Objectives

- Know what is meant by Point of Care Testing
- Know what is involved in setting up a Point of Care Testing Program
- Understand the issues associated with Point of Care Testing
What is Point of Care Testing?

Point of Care Testing is the testing of patient samples outside the confines of the clinical laboratory.

Usually performed by nurses:
- Hospital areas near to the patient (wards, physician offices)
Point of Care Testing

- Satellite Testing
- Near patient Testing
- Ancillary Testing
- Peripheral Testing
- Bedside Testing
- Decentralized Testing
- Patient focused Testing
Some POCT instruments.....
Main Function of POC tests

- To provide rapid results

- Results should improve immediate patient management
Examples of Point of Care Tests

- pH
- Blood gases: pCO2, pO2
- Lactate
- Glucose
- HbA1c
- Urea, creatinine
- Cholesterol, TGs
- BNP, Troponin, CK-MB,
- Myoglobin
- Bilirubin
- PTH

- Drugs of abuse
- Occult blood (fecal or gastric)
- Urinalysis
- hCG, ketones, glucose,
- Leukocytes, pH, nitrite,
- Bacterial/viral Infections
- Coagulation
- Hemoglobin/ hematocrit
Physician performed tests (microscopy)

HIV-1/2 testing

Blood in feces (fecal-occult blood testing)

Pregnancy testing for hCG

pH testing

Urinalysis using the dipstick

Blood glucose by glucose meter
Blood gases
Activated clotting time
Blood oximetry
H. pylori testing by HpOne
POCT: Challenges

- Staff training and competency maintenance
- Testing without institutional review or approval
- Noncompliance with procedures (specimen labeling, QC, proficiency testing etc.)
So what does a POC Testing Service need?

- Good Management Team
- Good Training Program
Management Team

The first requirement for maintaining quality in a POC testing service is to have a good management team.

- Establishes
- Monitors
- Enforces

Quality Standards
Management Team

At the bare minimum this team needs:

- **DIRECTOR** or equivalent that has the authority to cause institutional change

- **POINT-OF-CARE COORDINATOR** who is the instrument for implementing that change
Management Team

Point-of-Care Coordinator

- Meets the users daily
- Regularly performs audits to assess the quality of the service

Director

Together: advises and resolves problems as they occur
Compliance Review

- Weekly review of POCT test stations
- Compliance with written protocol?
- Corrective action for outlier results?
- Annual review of user competency (test)
A Good Training Program

In a hospital environment healthcare workers that will use point-of-care tests include:

- Physicians
- Registered Nurses
- Students
- Nurse aids
- Licensed practical nurses
- Respiratory care practitioners
- Anesthesia technicians
- Perfusionists
- Emergency technicians
- Paramedics
The Procedure Manual

- It is important that POCT users receive the same information regarding the test to ensure consistency of practice:

- This is the function of the:
  - PROCEDURE MANUAL
The Procedure Manual

- Written procedures reduce variability, and its variability in test procedures between operators that leads to errors and discrepant results.

- The manual should not only mention the procedure but should be more comprehensive.
The Procedure Manual

- Scope (who can perform the test)
- Principles of the test
- Specimen requirements
- Reagent/Kit storage conditions
- Procedure for performing Quality Control
- Instrument maintenance (if needed)

- Procedure for performing the test
- Safety precautions
- Test result interpretation
- Test limitations / interferences
- Documentation of the test result
The 3 Stages of a Diagnostic Test

A diagnostic test can be divided into three stages:

- the pre-analytical stage
- analytical stage
- post analytical stage

Each step is susceptible to errors that can significantly affect the result.

This should be mentioned in the Procedure Manual
Training Users in POC Testing

Once the procedure manual has been created it is necessary that all users have read it and this process should be documented.

The salient features for each test need to be understood and demonstrated during training.

This would be followed by a competency assessment which would be the exit examination before the healthcare worker can test patients.
Challenges in Training...

Management of Training:

- Number of staff requiring training be in the thousands
- A high turnover rate
- Nursing staff can be transferred between different departments
- Poor communication between nursing administration and POC coordinator.
Nurse trainer may not be aware of all the pre-analytical, analytical and post-analytical errors that could occur when using the POC test.

They may also be performing the test in a different way that could be prone to a higher error rate.

Furthermore, from a regulatory standpoint, the trainer would need to have passed their competencies as well.
The Designated Trainer

- Better way to train new hires
- This designated trainer would be aware of all the issues that could occur with the test and would be up-to-date in their competencies.
Training Methods

- Direct classroom demonstrations and observations
- Supplemented with self-learning, e-learning, lectures via webcam, power point, and a training kit containing manual, laminated posters/aids and CD-ROM.
Competency Assessment

The aim:
To ensure healthcare workers can not only generate quality results consistently from the instrument but can correctly manage them in the decision making process.
Assessment in two parts:

PRACTICAL

WRITTEN
Practical Assessment

Direct observations of patient testing:

- Using a specimen (previously analyzed specimen, external proficiency testing material, quality control material or calibrator)
- if applicable include any patient preparation
- if applicable include any specimen handling and processing
Practical Assessment

- Recording and reporting test results.
- If applicable, direct observation of instrument maintenance and function checks.
- Assessment of problem solving skills (reviewing temperature and QC logs; knowledge of common error messages; knowing who to contact for help).
Written Assessment

- Multiple Choice type questions
- True / False
- Determine what is the “pass” grade
- Users must reach this satisfactory level in the written examination.
Acquaintance with procedure

User

Procedure Manual

• Health care workers
• Aid agencies
• Military
• Civilian volunteers

Training

• Acquaintance with procedure

• Hands-on
• Self-directed learning

Test

• Direct observations
• Reporting critical
• Documentation
POCT – Quest for Quality

- Results from POCT dictate the next step in a diagnostic algorithm.

- Errors in laboratory testing occur in preanalytical and postanalytical stages. → also true for POCT.

- The **same** rigorous quality assurance procedures apply as if testing were performed in the main laboratory.
Sources of Error - Preanalytical

- Test ordering
- Patient identification
- Specimen collection
  - Arterial vs venous vs capillary
- Specimen identification
- Fasting vs non-fasting
- Wrong anticoagulant
- Contamination with IV fluid
- Hemolysis
- Inadequate sample
Sources of Error - Analytical

- Inadequate mixing of sample
- Air bubbles
- Environmental conditions
- Outdated reagents (deterioration)
- Instrument failure
- QC out of limits
- Inadequate maintenance/calibration
Sources of Error - Postanalytical

- Incorrect reading of results
- Result outside the linear limit
- Non-recognition of interferences
- No result recorded
- Result recorded on wrong patient chart
Quality Assurance Program

POC instrument

Correlation studies

Laboratory Instrument
External Quality Assessment Schemes

- EQA schemes are very useful in helping to:
- Identify if healthcare workers are adequately trained.
- Identify if there are procedural deficiencies mentioned in the product insert but omitted in the final procedure.
- Identify procedural deficiencies not mentioned in the product insert.
More on EQA Program

- Sample provided by e.g. College of American Pathologists (CAP)
- Sample is treated like a patient sample
- Results are sent to CAP
- Your result is compared to others using the same instrument
When External Samples are Not Available

- Patient samples can be split and either sent to another instrument or be used by another operator.
- The advantage of using patient samples is that matrix effects are eliminated as real patient samples are being used.
Criteria for Split Sample Studies

It is important to define criteria for acceptability of the sample correlation. This can be obtained from published guidelines or using ± 2 or 3 standard deviations from the mean from quality control data for quantitative assays.
Summary of External Quality Assessment Scheme

CORRECTIVE ACTION

Sample of known result

Point-of-Care Test

Correct Result

Incorrect Result

Testing process in place produces reliable results

Root Cause Analysis

Root Cause Analysis

• Not following procedures
• Preanalytical errors
• Analytical errors
• Postanalytical errors

• QC material
• Calibrator
• Patient Specimen
• Reference standards
• Manufactured patient-like sample
Quality Control

- Running quality controls (QC) is a mandatory requirement for any point-of-care test because they are designed to detect problems in the test system.
- They are tested before or alongside a patient test and should always be run according to the manufacturer’s instructions in the product insert.
- Their use monitors test kit and reagent integrity.
Quality Control

- For example a QC failure could arise:
  - from incorrect storage of kits and/or also
  - be due to poor techniques or procedures.

- Thus QC gives assurance that the device is working and the testing is being performed correctly.
Quality Control

- Non-instrumented qualitative point-of-care tests such as pregnancy tests, HIV tests, rapid strep A or flu tests typically have two types of controls:

  - Internal controls - built into the test system and are run whenever a patient sample is tested.

  - Confirm that the test system is working, and for lateral flow methods, sufficient specimen has been added to the well to allow the sample to migrate correctly through the strip.
Quality Control

- External controls are run just like a patient sample
- They test the entire testing process including:
  - Specimen collection
  - Specimen application
  - Result documentation
ASSESS REGULATORY REQUIREMENTS THAT NEED TO BE SATISFIED

GATHER INFORMATION ON POINT-OF-CARE TEST AND THE TESTING PROCESS

RISK ASSESSMENT

DEVELOP A QUALITY CONTROL PLAN TO MITIGATE ERRORS

IMPLEMENTATION AND MONITORING OF PLAN

- Pre-analytical steps
- Analytical steps
- Post-analytical steps

Sampling Errors
Operator Errors
Errors arising from Environment
Errors due to poor reagents/QC/Calibrators
Measuring system errors
Developing an IQC Plan

- Assessing any regulatory or accreditation requirements that need to be satisfied.
- Gathering information about the instrument and the testing process for the analyte(s) from the manufacturer.
- Risk Assessment - mapping the process to identifying procedural weaknesses.
- Developing a Quality Control Plan to mitigate errors identified in the risk assessment.
- Implementation and monitoring the Quality Control Plan to ensure that it is always appropriate, making adjustments as necessary.
<table>
<thead>
<tr>
<th>Stage in which Failure Occurs</th>
<th>Problem</th>
<th>Effect</th>
<th>Remedy</th>
<th>Prevention</th>
<th>Monitor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre analytical</strong></td>
<td>Wrong reagent lot used</td>
<td>Incorrect result</td>
<td>Repeat using the correct lot</td>
<td>Operator training</td>
<td>Audit frequency to target operator for training</td>
</tr>
<tr>
<td><strong>Analytical</strong></td>
<td>Reagents expired</td>
<td>Incorrect result or no reaction</td>
<td>Verify expiration date/storage conditions; rerun with non-expired reagents</td>
<td>Train operator to check dates and label any new expiration date as required by manufacturer</td>
<td>Audit reagents to ensure not being used beyond expiration date. Audit operators training</td>
</tr>
<tr>
<td><strong>Post analytical</strong></td>
<td>No indication on patient chart that physician was notified of critical or abnormal result</td>
<td>Delayed treatment</td>
<td>Give treatment or retest</td>
<td>Operator training on handling critical and abnormal results</td>
<td>Audit frequency of critical and corresponding notification</td>
</tr>
</tbody>
</table>
Final thoughts......

“Garbage in” (Preanalytical Errors) → World’s best POC Instrument → “Garbage out”

“0” Preanalytical Errors → World’s best POC Instrument → Transcription error
→ Result meaningless

“Effective monitoring and education – essential!”
Thank You for your Attention!

Questions?