Quality Control of POCT instruments

What is important and what is different to the Laboratory

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- University hospital of eastern Paris
- Hospital beds capacity: 700
- Medical staff: 900
- ISO 15189 accredited laboratory
ISO 22870 5.6
The quality manager is responsible for the design, implementation, and operation of quality control that ensures POCT conforms to the quality standards of the central laboratory (...)

IQC

EQA
Challenges of POCT
Unique vulnerability to error

• Underestimation of risk by the user
  – False perception of infallibility
  – Pressures of a busy clinical environment

• Training and competency verification
  – Large number of users
  – Diverse educational backgrounds

• Technical aspects
  – Many locations to control (metrology, documents...)
  – Adequate storage space to store specimens to repeat the tests between the last successful QC and a failed QC
  – Clinical management on receipt of results does not allow the system to be out of control

Lapses or violations in the performance of POCT
Bad understanding of the purpose of proceedings
But values discrepant with the patient’s clinical condition are more likely to be detected
Which POCT Quality Control? (1)

• Internal quality control (IQC) and external quality assurance (EQA) are integral components of the laboratory quality system.

• These tools ensure that the quality of results will not compromise the clinical care of the patient.

• QC samples should be treated just like a patient sample by the user.

• Principle of quality assessment should be the same when:
  – Testing environment → POC
  – Analyzer → POCT device

ISO 22870 5.1.2
The Laboratory Director shall be responsible for:
- a) procuring, evaluating, and selecting all POCT quality control material (...)
- b) establishing documented quality policy and protocols for the performance of all POCT and associated quality control and quality assurance.
Which POCT Quality Control? (2)

• The key question:

  Are IQC and EQA relevant, transferable, practical and cost effective for monitoring analytical quality on POCT devices?

• Methods by which IQC and EQA are applied will be affected by:
  – Complexity of the devices
  – Inbuilt checks
  – Frequency of testing
  – Non-laboratory operators
  – Cost
POCT devices
The role of manufacturers

• Development of POCT devices that are simple, easy to use, and designed to prevent user and analytic errors

• Instrument design to overcome reliance on the user for performing and interpreting IQC

• Development of built-in IQC features
  – auto-QC
  – positive/negative controls
  – electronic QC

• Devices with QC rules built into the software to ensure controlled patient testing
IQC plan according to the device complexity

- **Laboratory type instruments**
  - IQC plan should follow the procedures of the laboratory
  - Multi-level QC
  - auto-QC

- **Cartridge-based instruments**
  - Built-in QC check
  - designed to perform QC automatically without the need for operator intervention

- **Strip-based instruments**
  - designed such that the device will not permit testing unless QC has been performed and the results are in range
  - Built-in positive/negative control
Electronic QC

- Electronic QC checks the electronics of the system using surrogate material
- It does not check the analytical process including issues related to specimen type or application.
- **Electronic QC cannot be a substitute for regular QC**
- It is a supplement to traditional liquid QC requirements
- It has do be performed according the manufacturer’s instruction
“Extreme” built-in IQC: the IQM system (IL)

- Fully automated system in an all-in-one cartridge (blood gas, electrolytes)
- Multi-level solutions that contain the actual analytes assessed
- Monitoring of the whole analytical process in a traditional QC format
- Free from user intervention
- No patient test result is released unless the system is within specifications
- Deactivation of test channels which fail to meet specifications
- All patients results are preceded and followed by a successful QC
Challenges in POCT ICQ

• Especially, when no enhanced QC design features on the POCT device
• User-dependent +++
  – Users neglect to perform QC
  – Users fail to take corrective action for out of-range results.
  – Users fail to document or record QC results
• Expensive costs, especially in low volume settings (QC/patient ratio).
Training in IQC POCT

• Collaborative approach POCT manager/suppliers

• Should cover theory and practice:
  – Storage of QC material
  – Preparation of QC material
  – Appropriate QC frequency for each test
  – Principles and practice of QC testing
  – Remedial actions for failures
  – Recording and documentation of actions

• Proof of assessment (theory and practice):
  – written short questions, multiple choice test
  – Situational to test skills : how to run QC

ISO 22870 5.1.15
A person with appropriate training and experience, should manage the training and competency assessment (…)
The knowledge/skill requirements include (…)
quality control and quality assurance
Figure 1: Point-of-Care Site Inspection Checklist

Date: __________ Location: _______________ Staff involved: ____________________________

Approved test menu: ________________________________________________________________

☐ Test materials found that are not on menu? Items found: __________________________________________

Tracer performed? Y or N * Patient MRN: _______________ Patient name: ____________________________

<table>
<thead>
<tr>
<th>Indicator:</th>
<th>Compliance Yes, No, or N/A</th>
<th>Findings:</th>
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<tbody>
<tr>
<td>Quality Controls/Proficiency Testing -</td>
<td></td>
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<tr>
<td>- Appropriate QC frequency for each test</td>
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<tr>
<td>- Appropriate QC documentation for each test</td>
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<tr>
<td>- Remedial action documented for failures</td>
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<tr>
<td>- Monthly review of QC for nonwaived tests</td>
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<tr>
<td>- QC reagents properly dated and stored</td>
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<tr>
<td>- Proficiency testing available/appropriately reviewed</td>
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<tr>
<td>- Remedial action noted for proficiency failures</td>
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<td>- 6-month correlations performed if required</td>
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Which characteristics for a QC for use in POCT?

- QC sample included with the test kit may be used
- controls from a third party supplier recommended where possible.

• Convenient and easy-to-use
• No need for dilution or reconstitution
• No need to thaw before use
• Wide range of storage temperature (ambient ++) 
• In the clinically relevant range

ISO 22870 5.4
Instrument-generated quality control shall be acceptable provided that regulatory authorities have accepted it.
Which frequency of QC testing?

• Any POC site should consider its own situation

• In addition to the regular QC program, when:
  – New delivery of consumables/reagents
  – New lot number of consumables
  – An operator lacks confidence in a patient result
  – The POCT result does not fit the patient’s clinical picture
  – Substantial maintenance procedures have been carried out
  – The device has suffered a physical insult

• Electronic QC as defined by the manufacturer

• Low complexity devices using strip technology
  – One QC sample per month as a minimum requirement (in pathological range ++)
  – If 2 levels available: one normal, one abnormal

ISO 22870 5.5.3
Manufacturer's recommendations regarding minimum quality control of a specific instrument system may be accepted, following review.
IQC recording and interpretation

- This step has to be simple and reliable +++
- Systematic and immediate interpretation
- Plotting of result on a control chart with date, values, operator’s name
- Comparison with limits of acceptability
- Protocol of actions If QC fails

ISO 22870 5.6
(...)
The relationship between values (of QC) obtained in the laboratory and POCT shall be established, and published, or available upon request.
ISO 22870 5.6.5
Where available, participation in an external quality assessment (EQA) shall be required.

ISO 22870 5.6.5
In the absence of an EQA scheme, the Laboratory Director, or designated person, should establish an internal quality control assessment scheme involving the circulation of samples or replication of the test within the laboratory.
Challenges in POCT EQA

• Limited period of time to perform testing and to return results on each POCT site
• Low frequency of testing
• Packaging: sealed glass vials...
  – How to safely break open the vial
  – How to reconstitute the material
  – How pipetting the material if necessary
• In case of unsuccessful result:
  – identifying the cause
  – developing an action plan
• Recording of results
Split sample testing

• When EQA is not available
• At a regular predetermined frequency
• POCT sample is also tested in the laboratory

• Advantage:
  – Use of patient samples
  – Test also the preanalytical procedure

• Limitation:
  – Level of uncertainty of the 2 methods
  – You cannot assume that the laboratory results is the true
  – No peer comparison
  – Limited range of concentration level
  – Sample deterioration during transport

ISO 22870 6.8
Split patient samples, or other acceptable QC materials, shall be used to verify performance of POCT systems used in multiple sites.
Conclusion

• Quality control management of POCT instruments is challenging

• The principles of IQC and EQA should apply but there is no universal strategy

• A pragmatic approach taking into account the manufacturer’s recommendations, the device technology and the capability of the users should aim to increase the benefit/risk ratio for the patient