The challenges of quality assessment for point-of-care testing

Anne Stavelin

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General challenges

• Easy to use - “everybody can do it”
• Often used by people with little or no lab experience
• “The instrument will give an error message if something is wrong”
• “No mistakes can be done”
• “Expensive to perform controls”
• “What is the advantage of performing controls – can you prove it?”
Different analytical control systems

- **Built-in-controls/on-board QC systems**
  - Integrated control systems, both in the instrument (electronic controls) and in each test strip/cuvette

- **Internal quality control (IQC)**
  - Commercial control materials

- **External quality assessment (EQA)**
  - Schemes provided by an EQA organizer

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On-board QC systems

**Two principles:**

1. **Electronic controls**
   - In instrument (and test strips/cuvette)

2. **Control of the chemical test process**
   - In test strip/cuvette
   - Every test is controlled!

**Is this type of control sufficient?**
- No: Collective opinion paper (CCLM 2011;49:793-802)
IQC of POCT

• Everything is different
  - Copy the routines from central laboratories?
• No agreement on how to do it
  - Frequency?
  - Control rules?
  - Control materials? Patient split samples?
• How to handle the alarms?
• No evidence that IQC for POCT is useful!

Different types of POC instruments

1. «Laboratory type» used in POC environment
   - IQC and maintenance: As for central lab instruments

2. «Cartridge based» instruments
   - Electronic control: Daily
   - IQC: Monthly + change of reagent lot
   - Maintenance: Rarely, because the sample never touches the reader

3. «Strip based» instruments
   - IQC: Change of reagent lot + daily (if no electronic controls) or monthly (if multiple electronic controls)

IQC for POCT

• It is important to know which part of the POCT system that is controlled

• One size does not always fit all!

EQA of POCT - challenges

• Large number of participants
• Little or no lab experience
• Direct communication with the users (clinicians, nurses, patients)
• Different control materials to different POCT devices → cannot compare results between instruments
• Lack of control material to some instruments
Example – EQA for POCT INR

Study within the EQALM working group of hemostasis

• Number of participants (2011)
  - NEQAS (UK): 2662
  - MQ (Switzerland): 2264
  - CSCQ (Switzerland): 2232

• Control materials
  - Instrument-specific materials
  - Lyophilized plasma, lyophilized whole blood, fresh frozen plasma, artificial liquid material, capillary whole blood (patient slit sample)
  - No material available for one instr. → special EQA approaches

• Performance specifications
  - Varied from 12% to 30%
  - Not a POCT specific challenge only
Is participation in EQA useful?

Urine albumin POCT scheme from 1998 to 2012


The total testing process

Examples
- correct identification of the patient
- appropriate test selection
- obtaining a satisfactory specimen
- analyze and record the results promptly and correctly
- interpret the result accurately
- taking appropriate action
- documenting all procedures and maintaining accurate records
Summary

• Many challenges in performing IQC and EQA
• Little evidence that IQC for POCT is useful
  - However, it has been shown that EQA for POCT can be useful
• It is impossible to give universal recommendations of how QC of POCT should be done
• One size does not fit all