



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

Anne Stavelin

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Norwegian quality improvement of primary care laboratories

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

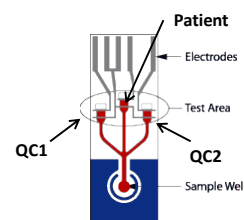
- Built-in-controls/on-board QC systems
 - Integrated control systems, both in the instrument (electronic controls) and in each test strip/cuvette
- Internal quality control (IQC)
 - Commercial control materials
- External quality assessment (EQA)
 - Schemes provided by an EQA organizer



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!

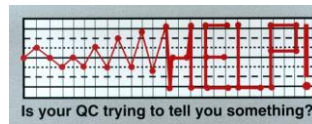


- Is this type of control sufficient?
 - No: Collective opinion paper (CCLM 2011;49:793-802)



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!



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Different types of POC instruments

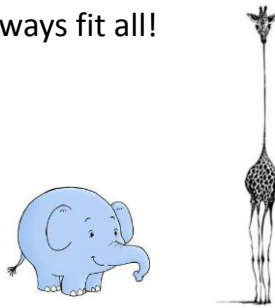
1. «Laboratory type» used in POC environment
 - IQC and maintenance: As for central lab instruments
2. «Cartridge based» instruments
 - Electronic control: Daily
 - IQC: Monthly + change of reagent lot
 - Maintenance: Rarely, because the sample never touches the reader
3. «Strip based» instruments
 - IQC: Change of reagent lot + daily (if no electronic controls) or monthly (if multiple electronic controls)

Martin CL. Clin Biochem Rev 2008; 29 Suppl 1: S79-82

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IQC for POCT

- It is important to know which part of the POCT system that is controlled
- One size does not always fit all!



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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

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Example – EQA for POCT INR

Clin Chem Lab Med 2012;50(1):81-88 © 2011 by Walter de Gruyter • Berlin • Boston. DOI 10.1515/CCLM.2011.719

External quality assessment of point-of-care International Normalized Ratio (INR) testing in Europe

Anne Stavelin^{1,4,*}, Piet Meijer², Dianne Kitchen³ and Sverre Sandberg^{4,5}

¹ Norwegian Quality Improvement of Primary Care Laboratories (NOKLUS), Haraldsplass Diaconal Hospital, Bergen, Norway

Keywords: anticoagulation treatment; external quality assessment; international normalized ratio; point-of-care testing.

Study within the EQALM working group of hemostasis



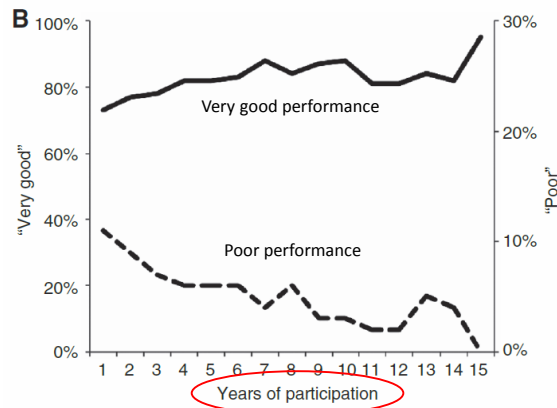
Example – EQA for POCT INR

- 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



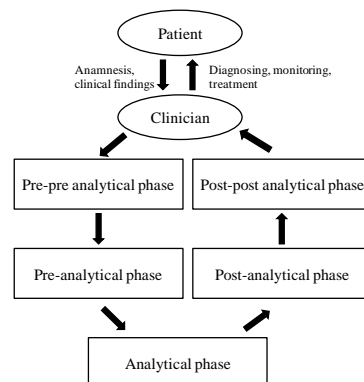
Bukve T et al. Clin Chem Lab Med 2015; 53(1): 45-51

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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



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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