Principles of Quality Control

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IFCC PoCT Symposium
16 - 17 November 2015 Cancun, Mexico
Quality control

Far too many laboratories consider quality control just a necessary evil, little more than periodic pass/fail exercises we perform solely to meet regulatory requirements. In addition, too many of us belittle point-of-care (POC) testing as a passing fad, a technology so inferior to what we use in our own laboratories that it hardly warrants our attention.
Clearly, a report that combines these 2 topics runs the risk of commanding little attention. That would be a very unfortunate mistake, because it has important lessons for all of us who practice laboratory medicine in our efforts to improve patient care.

Modified from
Horowitz G. Proficiency testing matters. Clin Chem 3013; 59: 335-7 (Editorial)
Quality control and POC

• Everything is different
• Should we use internal quality control, for which analytes, what rules 2\(_3\)s, ?? / split sample?
• Can we show that this is of importance?
• What do we do with the alarms?
• How to perform EQAS, how often?
• How to perform quality assurance of self-measurement?
Analytical quality assurance of POCT - challenges

- “Easy to use”
- “Everybody can do it”
- “No mistakes can be done”
- “The instrument will give an error message if something is wrong”
- “Expensive to perform controls”
- “What is the advantage of using quality control – can you prove it?”
What I will talk about

✓ Performance Specifications
✓ Internal QC
✓ External QC
✓ Examples of how it can be done
Performance specifications

The importance of Performance specifications

Perf spec. modifier

Precision  Bias

Quality control rules / total error / prec/trueness

EQAS
Model 1. Based on the effect of analytical performance on clinical outcomes

1a. Direct outcome studies

1b. Indirect outcome studies

Model 2. Based on components of biological variation of the measurand

Model 3. Based on state of the art

Some measurands could have different performance specifications defined when the test has multiple intended clinical applications. For example,

- for blood glucose in a critical care setting by simulation of the impact of the test on probable patient outcomes (model 1b),

- for self-monitoring of blood glucose in type 1 diabetes by clinical outcome studies (model 1a) or

- by a more general approach based on biological variation (model 2).”

Internal quality control - POC

It is easy to replicate what is done in the hospital, but it is difficult to convince the users that this is important.

Recommendations varies – from daily to every second month. What limits to use? What reactions to take when the control is outside the limits.

- The evidence for the usefulness of this is very limited
IQC protocols used at POCT should be defined based on risk management. The protocol will therefore be dependent on analyser complexity and availability of inbuilt system checks, and the risk associated with release of an incorrect patient result.
Different types of POC instruments

1. “Laboratory” instruments used at POC
   - Test chemicals in the instrument

2. Cartridge / Strip based instruments
   - Test chemicals in the cartridge/strip and calibrators could be in the same cartridge/strip or the instrument
   - Instrument is a detector, e.g. Photometer

Adapted from Martin CL. Clin Biochem Rev 2008; vol 29 Suppl (i): I S81
Detector – ”inbuilt control”

– Technical functions of the instrument
– Technical aspects of the strips, enough blood, position of strip, temperature, light humidity. There can be reagents in the strips that are sensitive to these factors and that can be detected by the ”instrument”.

– Calculation of the results
What is not detected

Pre-analytical factors
Quality of reagents in the strips / cartridge

The use of IQC is recommended
- weekly?
- with a new batch of reagents?
- with an unexpected result?
For some strips there are inbuilt controls that also examines the quality of the reagents

Containing a negative and positive control that give a result if reagents are OK

It is difficult to justify use of internal quality control in these circumstances
External quality control

- is a monitoring process in which control samples are received from an independent external organization and the expected values are not known by the laboratory. The results for the EQA/PT samples are compared to results from other laboratories or a true value to verify that a laboratory’s measurement procedures conform to expected performance.

Adapted from Miller G and Sandberg S Quality Control and the Analytical Examination Process in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, 6th Edition 2016, in press
Differences in EQAS for POC testing and hospital laboratories

EQAS for Primary Health Care

General practitioner
Nursing homes
Nurses
Patients

EQA hospitals

Specialists in lab medicine
Laboratory technologists
Statisticians

Clinicians
Nurses

?
EQA and POC - what is the difference from usual EQA?

Often many participants / users
Situated in remote areas
Users with little knowledge about the laboratory
Direct communication with patients, nurses, clinicians, GP-offices
Selfmeasurement
Guidelines Recommendation to participate in EQA schemes


- CLSI POCT 07-A 2010. Quality Management: Approaches to Reducing Errors at the Point of Care; Approved Guideline.

New EQA model for POCT

✔ Method bias is established by split sample analyses of patients samples e.g. 100 samples for each method.

✔ Participant performance is estimated by deviation from method specific target value using non-commutable control material.

Example 1

The POCT method: Too high values

The participant: OK
EQAS for self-monitoring glucose
Norwegian quality improvement of primary care laboratories - Noklus –

How so we do it?
Population per sqkm in Mexico (61) Norway (15) and Australia (3.2)
Noklus: What are the physicians and the patients interested in?

- Which constituents that shall be analysed in what places.
- That the results are correct.
- To have someone to consult with when something goes wrong.
- Advices about what instruments to buy.
- Correct interpretations of the results.
Noklus: What are the physicians and the patients interested in?

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NOKLUS – 2015*

– 2855 participants in NOKLUS
  • 1725 GPs offices (99.8%)
  • 848 (96 %) nursing homes
  • 31 military installations
  • 48 oil platforms
  • 120 others
  • 88 Norwegian Hospitals

• 60 % of the participants have been visited
• 350 courses with 5254 participants
• 34 surveys (20 schemes) for EQAS
EQA surveys

- Urinstrimmel
- CRP
- Glukose
- Hb
- Preanalytisk
- PT-INR
- Blod i fæces
- Graviditetstest
- HbA1c
- Streptokokker
- Urin-albumin
- Mononukleose
- Hematologi allmennpraksis
- Postanalytisk hematologi
- Urin Dyppekultur
- Helicobacter Pylori
- Hematologi SH
- D-Dimer
- Kolesterol
- Koagulasjon SH
- Troponin T
- Klinisk kjemi
- ProBNP
Is it useful to participate in EQA?

Tone Bukve*, Thomas Røraas, Berit Oddny Riksheim, Nina Gade Christensen and Sverre Sandberg

**Point-of-care urine albumin in general practice offices: effect of participation in an external quality assurance scheme**
Still: there is not much evidence for the use of internal QC

We have a research project to see

- How GP offices are running internal quality control (we recommend once a week)
- What limits they are using to accept results
- What they do when the control results does not meet the criteria
- How often do they think that this has consequences for patients
So – let us discuss
What can/ should we do concerning Internal and external quality control?

1. Control material, target values, replicates.
2. Frequency
3. Follow up
4. (Pre- and post-analytical aspects).
Thank you