كفاءة المختبرات
LABORATORIES PROFICIENCY

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FIRST GCC CONFERENCE FOR LABORATORIES PROFICIENCY

Workshop on Proficiency Testing for Medical Laboratories

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Workshop Schedule

- It's a Workshop! …not a lecture
  - Discussion expected
- My background in PT for medical laboratories
- Your interests and motivations in attendance
- Models for PT/EQA
- Review of sample reports
- Recommendations for Gulf Region

My background in Medical PT

- M.S. Biostatistics, Public Health
- 1981-1995, College of American Pathologists (CAP)
  - Surveys, external QC, accreditation
  - CLIA regulations development, 1988-1992
  - Member, WG for ISO/IEC Guide 43 (1994-1996)
- 1996 – current: US CDC, Laboratory Services
- CLSI (NCCLS) Standards development
  - Evaluation Protocols (EP5, EP6, EP17, EP15)
  - GP27: Using PT to improve laboratories (ver. 1, 2, 3)

What is EQA?

- **E**xternal **Q**uality **A**ssessment
- Definition, ILAC G13: Interlaboratory comparisons and other external performance evaluations that may extend throughout all phases of the testing cycle, including interpretation of results.
- *Note: The primary objectives of EQA are educational, and may be supported by additional elements.*

What is EQA?

- Note2 definition of **proficiency testing** in ISO 17043:

"Some providers of proficiency testing in the medical area use the term 'External Quality Assessment (EQA)' for their proficiency testing schemes, or for their broader programmes, or both. The requirements of this International Standard cover only those EQA activities that meet the definition of proficiency testing."

- Discussed further in Annex A, section A.4
  - Could be same as PT (CAP, Bio-Rad, Oneworld Accuracy)
  - Could be more (Australia RCPA, Ontario QMP-LS)
    - Interpretive samples
    - Corrective action review

Does ISO/IEC 17043 Apply?

- YES!
- ISO/IEC Guide 43-1 and ISO/IEC 17043 were written by experts from medical PT/EQA programmes
- Several major programmes are accredited
  - RCPA, Australia
  - Bio Rad, USA
  - QMP-LS, Ontario, Canada
  - Randox WEQAS, UK NEQAS, UK
  - Others?

Advantages of ISO/IEC 17043

- Competence of PT Provider staff
- Homogeneity and Stability of Samples
  - Including shipping
- Impartiality of PT Provider
  - Cannot be also an accreditation body (ISO/IEC 17011)
- Customer Service

Basic Models for Medical PT

- Periodic mass shipments
  - 2 to 5 samples every 3-4 months
  - US CLIA, Ontario QMP-LS, Oneworld Accuracy
- Cycles of 6 months or annual
  - Many samples from several lots or material
  - Every 2-4 weeks, test a sample from storage
  - RCPA, WEQAS, NEQAS, BioRad

Advantages of design

- Cost to manufacture
  - Advantage… none
- Cost to ship
  - Advantage… once per 6 month cycle (2/year)
- Risk control
  - Advantage… more frequent testing (shorter look-back)
- Blind samples
  - Advantage… new lots every shipment

Basic Models for Medical PT

- Many large medical laboratories outside US are accredited by CAP, also by their national accreditation body (ISO 15189)
  - Take CAP Surveys (required by CAP)
  - Take BioRad, RCPA, WEQAS, or NEQAS – for risk control
- Risk assessment – look-back in case of undetected error.

Models for Grading

- Most PT, each result graded separately
  - D or D% statistic (Total Error)
  - Standard Deviation Interval
  - Z statistic
  - Proportion of allowed error (PAD, PAE)
- Some grade multiple samples (e.g., 80% acceptable)
  - By analyte, multiple samples
  - By specialty, in shipment
- Some PT graded across shipments (e.g., 2 out of 3 rounds)

Models for Grading

- Some PT grade other aspects of performance
  - Short term precision
  - Long term precision
  - Linearity
  - Percentile
  - Compare methods

Penalty or Reward Grading

- Some PT grade severity of errors
  - Correct response: 0 points
  - Incorrect response, no patient impact: 1 point
  - Incorrect response, possible patient impact: 3 points
  - (Low scores for best performance)
- Some PT assign points as reward (high scores for best performance)

Penalty or Reward Grading

- Transform scores to Percentage of possible points
- Sum for all samples
- Calculate z statistics and evaluate with conventional $|z| < 3.0$

- Can be confusing, especially whether high scores are for good or poor performance

Recommendations for GCC

- Require accredited PT schemes?
- Same PT schemes for all GCC medical laboratories?
- Different scoring for different levels of laboratories?
- Scores:
  - Penalty/award points?
  - D or D%
  - Z score?
- Other?

Thank you for participation!