Possible Solutions to Lack of External Quality Assurance

Mark de Hóra

BMS Training Group

Metbionet Quality Day 2011

CPA Standard H 5.4

When a formal inter-laboratory comparison programme is not available, the laboratory shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated.
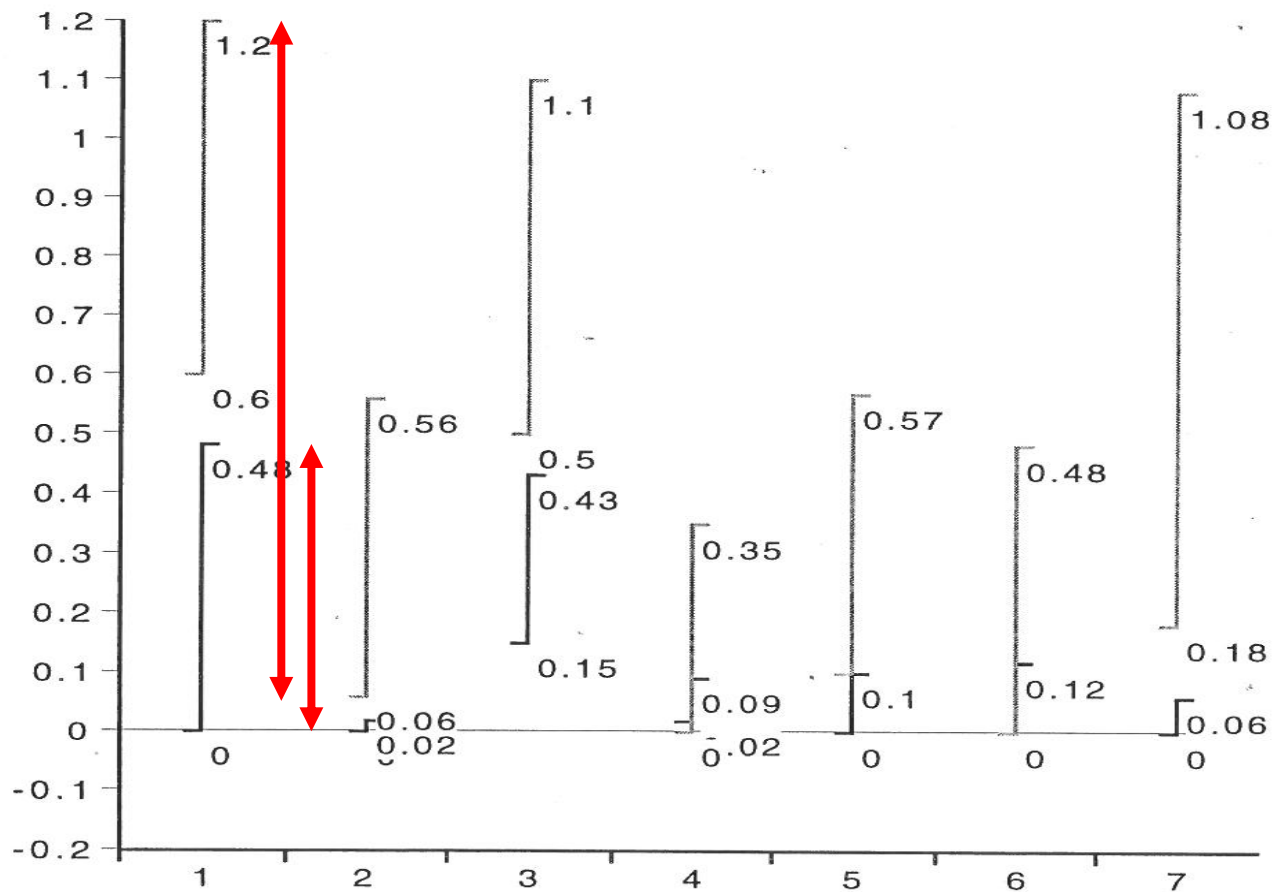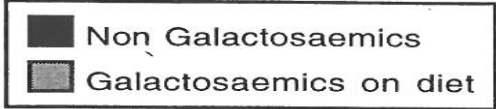
Mechanisms may include exchange of samples and preparations such as slides and digital images between laboratories

Sample Exchange
Previous Work 1997

- Jean Kirk for the Galactosaemia Steering Group

- One of the aims was to audit dietary management and biochemical measurements

- Numerous differences between labs with respect to units, sample prep, method and reference ranges.

Galactose 1 Phosphate Reference Ranges corrected to umol/gHb

Results from labs with all 4 returns

Gal-1-P results for samples sent by 1st Class Post
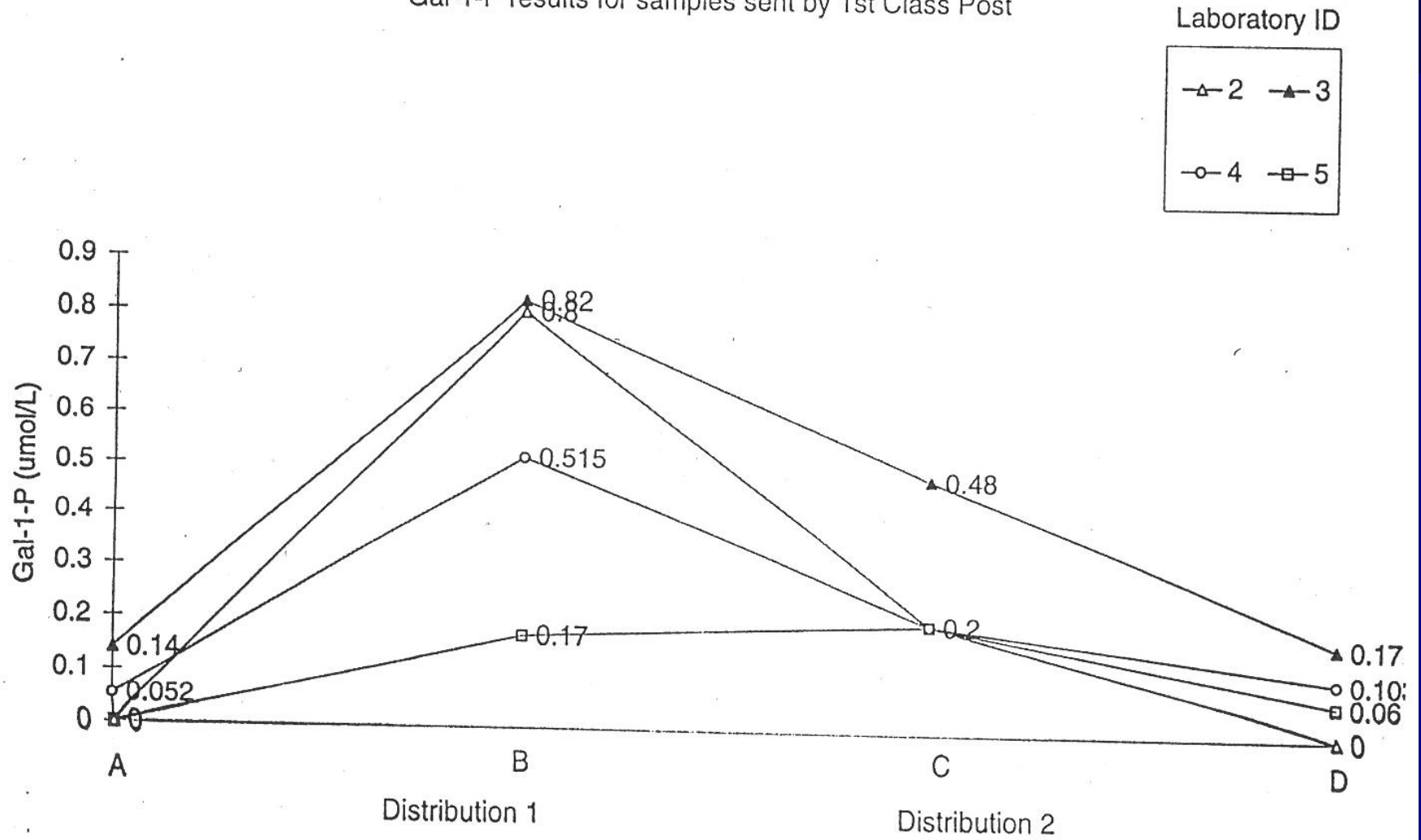
Sample Exchange
Previous Work 1997

- Jean Kirk for the Galactosaemia Steering Group

- One of the aims was to audit dietary management and biochemical measurements

- Numerous differences between labs with respect to units, sample prep, method and reference ranges.

- 2 centres stopped offering service as a result of the exercise.

Metbionet Quality Day Wish List 2004
Results of Questionaire presented by Jacqui Calvin

- VLCFA
- GAL-1-P
- Pristanate
- Free fatty acids
- Chitotriosidase

- Biotinidase
- Total Carnitine
- Bloodspot carnitines
- CSF amino acids
- Interpretive amino acids
- Clinical data interpretation

Candidate Tests
Figures from website

Assay	No. Labs (metbionet)
Biotinidase	13
Quant G1P uridyl transferase	12
Chitotriosidase	6
Urine Oligosaccharides	7
Urine Sugar Chromatography	?
Galactose-1-Phosphate	6
Sialic Acid	5
Urine Cystine	8
Galactokinase	5
Glycogen	4

What are the Options?

- Set up Pilot Schemes?

- Patient sample exchange?

- Provide recommendations via the website on ensuring quality where EQA is absent?

- Maybe things are fine as they are and labs can organise themselves?

Pilot Schemes

- Huge amount of work!!!

- Would require funding although bursuries are available (e.g CPA)

- Would have been done for any of the candidate analytes if appropriate.

- Not an appropriate function for the BMS Training group.

Sample Exchange

- Is already in place for some analytes

- May be extended to include a number of laboratories who each in turn distribute samples.

- Can express results as a percentage of the reference range

- Or use as a proficiency scheme and compare interpretive results

- Could be organised via the BMS group

Suggestions for Sample Exchange

- Host laboratory for each analyte chosen to organise and perform data analysis

- Each lab in sample exchange take turns in provision of samples.

- Suggest 1 to 2 distributions per year

- Host laboratory to write a report for each analyte for distribution.

What Considerations?

- Sample stability (at least at -20C)
- Can we do initial sample preparation if needed
- Sample type
- Can we distribute our IQC or share IQC data.
- How often?
- Quantitative data with reference ranges plus interpretation?
- Do we have adequate sample at appropriate levels?

Where do we Start ?

- Examination of Assay finder on website.

- There may be schemes in development. ?ERNDIM

- Questionnaire or make some decisions at the workshop today ?

My Questions

- Which assays are amenable to sample exchange?

- Are there exchanges going on already? Can others join?

- Do we really need to organise this?

- What do labs do to ensure quality if they do not have any form of external quality assessment of their assays?