

Meeting Report – Empower IVD • Globe

Note: all presentations of the 10 December 2014 meeting can be found at <http://www.stt-consulting.com/>

VENUE

Holiday Inn, Akkerhage 2, 9000 Gent

ORGANISATORS

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SPEAKERS

- Linda Thienpont (LT)
- Dietmar Stöckl (DS)
- Kenneth Goossens (KG)
- Timothy Ghys (TG)

PARTICIPANTS

The meeting was attended by approximately 80 participants. Most of them were clinical chemists (and coworkers), but also representatives of the IVD manufacturers and LIS providers were present. Most participants were from Belgium, but there were also some attendees from France, Germany, Ireland, Turkey, and the UK.

OPENING OF THE MEETING

The chair (LT) welcomed the meeting attendees and presented the agenda. The goal was not only to present the content and results of the Empower project (Master Comparisons & Patient Percentile Monitoring/Percentiler), but also to hear the opinion of the participants about the project, and/or comments for improvement. Therefore, much time was allotted for discussion.

1. Master Comparisons and future (KG)**Content of the presentation:**

Assay comparability results of the 2014 Master Comparison (MC) survey were summarized and compared with results from the Percentiler. Although the Percentiler can be used to study the relative bias at the median concentration, only the MC survey data can give additional information about i) bias at high and low concentration ends, ii) within-run imprecision and sample-related effects, and iii) assay total error.

In addition, the statistical concept and the hierarchy of targets and limits were explained by use of the Excel files supplied to the participants.

The financial aspects for conducting the MC survey were presented with the conclusion that the costs are quite high for a merely descriptive exercise. Therefore, the next survey might be postponed in order to give the respective manufacturers sufficient time to address issues that were observed in the 2012 and 2014 surveys.

Discussion:

The attendees deem the MCs in general of great value and clearly expressed the wish to continue with the surveys, even though the financial burden for its organization is high. They deemed their own measurement costs reasonable, also for potential immunochemistry surveys. Therefore, the organizers will look for funding, possibly by industry or EQA partners.

Potential analytes for future surveys might be acid phosphatase, ammonia, amylase, bicarbonate, total bilirubin, iron, lipase and urea. However, it was mentioned that acid phosphatase is no longer measured in Belgium and measuring total bilirubin and bicarbonate might prove difficult due to stability issues.

Participants asked for an explanation about the use of the regression Sy/x value as measure for imprecision. In short, the Sy/x is a measure for the distance of the residuals to the regression line parallel to the y-axis. When the "x-method" is error-free (in our case this can reasonably be assumed because of the use of the AMTM), the Sy/x reflects the imprecision of the laboratory assay because 20 samples have been measured. Naturally, it has to be interpreted with caution in case of a wider concentration range (imprecision may depend on the concentration).

The target used in the survey is the All Manufacturer Trimmed Mean (AMTM), which is the mean of the peer group means. Calculation of the AMTM in this way prevents that the target is dominated by the largest peer groups of the study. Trimming is done by applying a Grubbs test to identify outlying laboratories and/or assays.

2. Relevance of Patient Percentile Monitoring/Percentiler for medium sized labs (TG)

Content of the presentation:

In the introduction, the Hospital AZ St Lucas Gent was shortly presented in terms of bed-size, laboratory services, and quality management efforts to situate the use of the Percentiler in a mid-sized hospital laboratory. Indeed, the Percentiler proved valuable in observing assay variability. It is an added value in the overall quality control strategy, in particular, for mid- to long-term quality management. Nevertheless, data analysis needs to consider population effects and test volumes ("size matters"). In addition, there is a need for solid peer groups.

3. ALT case study – Relevance of mild transaminase elevations (LT)

Content of the presentation:

Literature indicates the relevance of mild elevations of transaminases (ALT and AST) in nonalcoholic fatty liver disease (metabolic syndrome), which becomes more and more prevalent as obesity rates increase. A case study (female developing metabolic syndrome) was presented with the following ALT values (U/L): 17, start; 44, development; 28, six months of treatment; 18, long-term treatment. Correct monitoring would need stable and comparable assays. However, in the Percentiler application, significant lot-to-lot changes are

sometimes observed (for example: ALT 35 to 22 U/L, in several steps), which can confound monitoring of the above case. The significant between-manufacturer differences observed in the 2014 MC survey can similarly be confounding if a patient moves.

4. Patient Percentile Monitoring/Percentiler and future (DS)

Content of the presentation:

The current status of the Percentiler (i.e. participants, peer groups, IT-connectivity, and user interface) and the theoretical concept of the project were presented. Results were shown indicating that the quality specifications selected by the project organizers can be achieved. These specifications are based on biological variation, but take into account what is currently achievable (state-of-the-art).

In addition, the existence of the Flagger was emphasized. This online application has the potential to translate analytical quality into quality of medical decision making using locally important cut-offs, but it requires that the IT-connectivity enables participants to send their hypo- and hyper-flagging rate automatically.

The presentation was concluded with a summary of the project benefits, such as real-time monitoring of (in)stability, strengthening the communication between the laboratory and manufacturer or clinician, establishing realistic quality specification goals, and providing a basis for cross-manufacturer comparison.

Discussion:

Attendees expressed the wish for additional information on peer group sizes and potential benefits of making the distinction between instrument types and method principles. Although the 1st request (providing updates on peer group size) can be met, the 2nd one proves more difficult as the survey is too small to split up the analytes according to measurement principle or the peer groups according to instrument types.

Attendees wondered about the possibility to expand the number of observed analytes (e.g. hematology). Although this is not excluded in the future, current time management and available work forces do not yet allow to expand the Percentiler. However, in the context of the thyroid standardization project, FT4 and TSH will be added in the not too distant future, but only for medium to large sized laboratories on invitation.

Although some peer groups are not yet available, it was stressed that some analytes don't require a peer target, as manufacturers use the same reference intervals. This is, for example, the case for sodium, calcium, potassium, magnesium, and inorganic phosphate.

5. Conclusion

Participants deemed both the Percentiler and MC surveys useful tools for their quality management and incentives for manufacturers to improve assay comparability and stability. The current intention is to keep the Percentiler free of costs as long as possible. The MC surveys will continue if sufficient funding can be found.

Note: if any participants still need to register their RIZIV number, please do so before the end of the year.

Meeting report made by Kenneth Goossens, on behalf of the Empower Team.