

ICHCLR Joint Council/Harmonization Oversight Group (HOG) Conference Call

DATE: September 3, 2015 7:00AM-8:00AM EST

In attendance:

Dr. Gary Myers (Council Chair)

Dr. Greg Miller (HOG Chair)

Dr. Stephen Master

Mr. Joseph Passarelli

Dr. Ian Young

Dr. Naotaka Hamasaki

Mr. Hirofumi Koide

Dr. Katsuyuki Nakajima

Dr. Hideo Kato

Ms. Stefanie Kleinman (AACC Staff)

Meeting Minutes:

I. Welcome and Introductions

Dr. Miller welcomed everyone to the Joint Council/HOG Conference Call. The purpose of the call was to review the draft spreadsheets of lists of frequently ordered tests and determine if this approach is worth pursuing as a method to develop a list of prioritized analytes for harmonization.

II. Discussion of PT Results for Most Frequently Ordered Tests

Dr. Miller has reviewed the spreadsheets that have been submitted and indicated that data from EQAS and PT programs, such as CAP may have limited value due to lack of commutability with the survey materials. When agreement is good, despite unknown commutability or likely non-commutable samples, the analyte is less likely to be a candidate for harmonization prioritization. When agreement is poor, other patient based information is needed. Dr. Master proposed several steps for further CAP PT data collection and evaluation.

1) Dr. Master is developing a R Script for automated extraction of CAP PT data. Unit conversion module has been completed, next is parsing of files after conversion with pdf2txt. His goal is to have an extracted set of data for all analytes that is suitable for export to a spreadsheet and/or statistical processing within R. His expectation is that he can get this running in a 2-3 week time frame.

2) Dr. Master proposed to develop a structured format to collect patient data results from method crossover studies. Dr. Lee had submitted several examples from method comparisons between analyzers from her lab. Both Dr. Miller and Master have recently conducted fairly large methods comparisons for installation of new equipment. Dr. Master will pull his recent

method comparison data and he and Dr. Miller will develop a draft format for review by the group. This spreadsheet format will form the basis for aggregating patient sample method comparison data within the Council/HOG group for analytes of interest for harmonization as well as public calls for crossover data sets (on Artery, e.g.).

Dr. Master volunteered to spearhead the process of data collection. He will start to put together a straw format for the data and will gather the CAP data.

Dr. Young asked about identifying analytes with high percentage differences between method means in the UK NEQAS program that uses a large number of commutable samples. It was agreed that he will request data for commutable samples from the UK proficiency schemes for any analytes with between method means greater than 20%. There was agreement that variations greater than 20% have the potential to be clinically meaningful and represent analytes for consideration for harmonization. Dr. Young also mentioned that Dr. Ichihara, Chair of the IFCC Committee on Reference Intervals and Decision Limits, has patient data from his reference interval study across different method platforms. Dr. Young will see if Dr. Ichihara will share his data.

Dr. Myers suggested getting data from PT schemes in Japan as well. Dr. Hamasaki agreed to look into it. Dr. Miller says that pursuing these patient-based strategies to get some real comparisons will be quite helpful.

III. Action items

1. Dr. Masters will gather CAP PT data as described above.
2. Dr. Masters and Dr. Miller will develop a format for collecting patient-comparison data and circulate it to the group. All participants with access to such data will then contribute to the data set.
3. Dr. Young will pursue commutable analytes in UK data with greater than 20% difference
4. Dr. Young will check on obtaining patient sample comparison data from Dr. Ichihara.
5. Dr. Hamasaki will also look into obtaining PT data from Japan.

Dr. Myers inquired about posting a request for method comparison data on the AACC Artery. The group decided to wait until they review the data they are gathering now before requesting more.

IV. Conference call dates

October 28, 7:00AM ET USA (daylight savings time; GMT-4)