

International Consortium for Harmonization of Clinical Laboratory Results
Harmonization Oversight Group / Council Conference Call Meeting

DATE: 15 January 2015

TIME: 7:00 a.m. to 8:00 a.m. EST

HOG Members:

Dr. Greg Miller (Chair)

Dr. Eunice Lee (Vice-Chair)

Mr. Joseph Passarelli

Dr. Ian Young

ICHCLR Council Liaisons:

Dr. Gary Myers - AACC

Dr. Gye Cheol Kwon - KSCC

Dr. Naotaka Hamasaki - JCCLS

Guests:

Katsuyuki Nakajima, JCCLS

Hirofumi Koide, JCCLS

AACC Staff:

Ms. Ashlie Doran (Scientific and Practice Affairs Coordinator)

Minutes:

1. Welcome

Dr. Miller thanked everyone for joining the conference call.

2. Review Council changes and goals for 2015

Dr. Myers shared that Dr. Wenxiang Chen informed him that the Chinese Association for Clinical Laboratory Management would not be able to continue – despite interest – their participation in the ICHCLR Council. The Chinese government indicated they would not financially support them participating in the Council.

The College of American Pathologists (CAP) has also withdrawn from the Council but expressed interest to participate at a different level.

The ICHCLR Council will continue in 2015 with its three committed Council members; AACC, JCCLS, and KSCC. AACC continues to be supportive as the secretariat. Council will review the dues structure and possibly revise it for 2016.

3. Systematic approach to identify analytes for harmonization

It was agreed to contact EQA providers and professional clinical and lab organizations, as well as to review test offerings from larger laboratories.

Analytes offered in EQA programs are more likely to be widely used. Last year, AACC staff contacted a number of EQA providers and professional clinical and lab organizations but got very little response. The renewed initiative would have

all correspondence come directly from Dr. Myers and other HOG/Council members. Perhaps a more personal approach may yield better responses. Dr. Myers will investigate having an email account that will identify ICHCLR rather than AACC as the sender to build recognition and acceptance for the Consortium. Dr. Myers suggested that AACC staff would review EQA and professional clinical and lab organizations websites with directives to identify an analyte list for consideration.

The scope of the analyte list to be developed was discussed and the group felt that all areas of lab medicine should be included but the initial prioritization should be limited to clinical chemistry, immunology and molecular diagnostics to keep the initial effort more manageable.

The current template for submitting analytes that is on the web site was reviewed to simplify the information needed for proposing an analyte. The suggestions are shown on a revised template attached to the minutes.

4. Systematic approach to prioritize analytes

The group agreed that a scoring process for prioritization was needed that was simple to apply. Dr. Young suggested focusing on three main elements: the extent of differences in results among current measurement procedures; how widely an analyte is used in clinical care; and the impact of harmonization on improving clinical care decisions based on an analyte.

Drs. Lee and Hamasaki volunteered to develop a draft scoring mechanism to prioritize the analyte list. Their draft proposal will be discussed on the next conference call.

5. Progress on identifying what other organizations are working on in the areas of standardization and harmonization

Other than IFCC activities, past responses to requests to organizations involved in harmonization have yet to be fruitful. A new strategy involves Dr. Myers and other HOG/Council members personally requesting information on the standardization/harmonization efforts of other organizations via networking. Dr. Myers has found that some organizations have stated that this information is proprietary and cannot be shared.

6. SPG update needed (last one 10 July 14)

Dr. Miller volunteered to draft a SPG update. Once completed, he will distribute it for review by the HOG/Council.

7. Other business

Dr. Hamasaki inquired about the minutes from AACC's meeting with the FDA in October 2014. Dr. Myers commented that FDA's Dr. Alberto Gutierrez has yet to approve the draft minutes. Nevertheless, Dr. Myers agreed to share the draft minutes with the HOG/Council.

Mr. Passarelli inquired about the status of harmonization of human growth hormone that was initiated last year but never led to formation of a HIG due to budget concerns. Dr. Miller had contacted Dr. Eef Lentjes who had volunteered to be the HIG Chair to transition the effort to the IFCC Scientific Division. Dr. Young indicated that the Scientific Division has not had an inquiry. Dr. Miller will send a follow-up email to Dr. Lentjes encouraging him to propose that IFCC continue the harmonization activity.

8. Next Call

Dr. Miller thanked everyone for their participation.
The next HOG conference call is February 25 at 7-8 AM EST.