

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

DATE: 7 Aug 2019

TIME: 12:00-2:00 p.m. USA WDT

HOG Member	Present	Council Member	Present
Greg Miller (chair)	x	Gary Myers (chair, AACC)	x
Eunice Lee (Vice-Chair)	x	Gye Chol Kwon (KSLM)	
Joseph Passarelli	x	Akira Seki (JCCLS)	x
Steve Master		Sverre Sandberg (IFCC)	
Ian Young	x	Tony Killeen (CAP)	x
Masato Maekawa	x		
Philippe Gillery (IFCC SD)			
Anja Kessler			
Melissa Snyder	x	Observer	
Yeo-Min Yun		Loretta Doan (AACC)	x
Andy Hoofnagle		Katsuyuki Nakajima (JCCLS)	x
Amrom Obstfeld			
Ross Molanaro			
Jeanne Rhea-McManus (for Ross Molanaro)	x		

Minutes:

Council activity:

1. Revision of operating procedures. Draft operating procedures had been circulated for comment. Key points agreed were to retain term limits for Council and HOG chairs with an option for Council to extend terms for special circumstances. HOG members appointed by Council members will have no stated term limits and will follow the practice of the Council member making the appointment. Similarly, liaisons representing Council organizations will follow the term policies of those organizations. Gary will prepare a draft with all agreed language for review and approval by the Council.
2. Gary reviewed the most recent financial statement for the period to August 1, 2019 received just before the meeting. The fund balance is \$242,298.72. We have committed to fund one-half of the cost for the workshop on reference materials and regulations to be

held following IFCC World Lab in Seoul May 2019. All agreed to increase efforts to reach out to organizations to request applications for startup funding for new harmonization projects for which the money is intended.

HOG activity:

3. The application form on our web site to request startup funding for harmonization projects will be reviewed to ensure proposals address high priority measurands from our web site.
4. The announcement for the IFCC/ICHCLR workshop on reference materials and regulations May 29-30, 2019 following the IFCC WorldLab meeting is on our web site and is included among the ancillary meetings on the preliminary program for the WorldLab meeting.
5. Subsequent to this meeting, the ICHCLR signed a memorandum of understanding with EQALM on August 15 to jointly develop an EQA data aggregation project to provide feedback to the IVD manufacturers and clinical laboratories. Data supporting feasibility from a pilot project using creatinine results from four EQA providers will be presented at the EQALM meeting in October.
6. The links to commutable EQA on the measurand table were discussed. We decided to keep the links and to review the criteria used to determine that an EQA program has commutable materials since most programs have not done a formal commutability assessment. The disclaimer language on the web site will also be reviewed to ensure we are not endorsing the EQA programs.
7. We agreed to review the disclaimer on the web site for links to certified reference materials (CRMs) and reference measurement procedures (RMPs) for analytes to ensure we are providing useful information but not endorsing the CRMs or RMPs as suitable for use.
8. We discussed the focus of HOG activity going forward. We have developed priority recommendations for approximately 100 measurands but are having difficulty evaluating the more esoteric measurands and those outside traditional clinical chemistry and toxicology. Possibilities for reaching out to expand expertise were discussed.
 - a. Eunice informed us that KSLM has established a committee for harmonization that we can ask for advice; Eunice is a member of that committee.
 - b. Ian will pursue a similar resource within ACB.

- c. Fellowship training programs might be interested to assign review of a measurand to trainees to expose them to harmonization issues and develop interest in this area of lab medicine.
 - d. AACC's SYCL program can be asked to contribute; Laura Parnas is the chair of SYCL.
 - e. AACC's Evidence Based committee offered to assist but has not followed up. Greg will contact the co-chairs.
 - f. EFLM has a harmonization group that may be interested to assist with review of measurands.
 - g. The measurand list can be reviewed at IFCC SD meetings to stimulate interest and identify priority status reviewers.
9. New HOG member recruitment was discussed. We agreed to develop a list of expertise needed to assist with identifying potential new members.
10. The JCCLS members presented the commutable multiple analyte conventional reference material developed for EQA in Japan. This work was published in Clinical Chemistry 2016;62:392-406 and included commutability assessment data. JCCLS will send participant results for a creatinine normal concentration EQA sample to be included in the pilot program for aggregation of EQA data in item 5 above.
11. Gary agreed to prepare a draft Stakeholders Update report.

Follow-up pending from our previous calls.

12. The assessment for Anti-myeloperoxidase (MPO) antibody IgG was reviewed regarding the recent work of the IFCC WG and reluctance of IVD to adopt the newly released reference material. We agreed the priority was high. Melissa will send a final version to post to the measurand table.
13. A proposal to the IFCC SD for standardization of phosphatidylethanol was referred to the HOG for a priority recommendation. Greg discussed the topic with Loralie Langman who suggested the biomarker was not commonly used outside a research setting. Following the call, Ian sent a recent review for consideration with a comment that this measurand is not a high priority based on limited clinical use at present. Yeo-Min will follow up with additional review.

14. A review of Theophylline from Yeo-Min was reviewed. We agreed the priority was medium and harmonization status was adequate/maintain. Anja provided data for the German EQA program showing good agreement among participants. Although the commutability of the samples is not clear, as we have done in the past, when EQA data shows good performance we accept it as evidence of harmonization. Anja will send Yeo-Min a sentence describing the EQA data to add to the Theophylline summary report for the measurand table.
15. A preliminary review of BCR-ABL from Tony was reviewed. Tony will contact the chair of a CAP committee with expertise in this measurand for additional information to review on the next call.
16. The commutable sample preparation from Biologie Prospective needs additional information to assess likely commutable status. Greg will follow up.
17. The Table below shows measurand assignments for prioritization recommendations for review by HOG and posting to the measurands table.

Next conference call meeting: to be scheduled

Measurand	Assigned to
Hemoglobin and CBC parameters, blood – POCT to do	Amrom
Hematocrit	Amrom
Iron saturation	Amrom and Greg
Iron binding total	Amrom and Greg
Apolipoprotein A1 and B	Amy
Pseudocholinesterase	Amy
Calcium urine	Amy
Chloride urine	Amy
Compliment CH-50	Amy & Melissa
Glucose, urine	Anja

Measurand	Assigned to
Calcium, ionized	Anja will provide additional EQA data to support the recommendation draft from Greg
Pregnancy associated plasma protein A (taken down)	Eunice?
Chlamydia; for STD	Eunice
Folate (taken down)	Greg
Vitamin B12	Greg
Iron	Greg
Protein urine	Greg
Creatinine, urine	Greg
Hemoglobin, plasma free	Greg was not able to find suitable information of harmonization status
Methemoglobin	Greg was not able to find suitable information on harmonization status
Lactate dehydrogenase	Ian
Lipoprotein(a)	Ian
anti-nuclear antibody (taken down)	Melissa
Anti SS-A	Melissa
cytokeratin fragment 19 (CK19F)	Melissa
Elastase 1	Melissa
Elastase 2	Melissa
IgA	Melissa
IgG	Melissa

Measurand	Assigned to
IgM	Melissa
HIV-1 genotype	Steve
Beta-2 microalbumin	Steve; difficult to find information
Albumin, CSF	Steve; Likely dependent on urine and serum albumin harmonization
BCR/ABL	Tony
Hepatitis A Ab IgM	Tony and Melissa
Hepatitis A Ab IgG	Tony and Melissa
Hepatitis A Ab (Total)	Tony and Melissa
Hepatitis B core IgG and IgM	Tony and Melissa
Hepatitis B core Ab	Tony and Melissa
Hepatitis B DNA quant	Tony and Melissa
Hepatitis C Ab	Tony and Melissa
Phosphatidylethanol (from SD)	Yeo-Min
Drugs: acetaminophen, salicylate, tobramycin, gentamycin, benzodiazepine, amphetamines, tacrolimus, serolimus, lidocaine, methotrexate, N-acetylprocainamide, procainamide, primidone, quinidine, valproic acid, amikacin, barbiturates, cyclosporine, cocaine urine, methadone	Yeo-Min