

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

DATE: 20 December 2018

TIME: 8:00-9:00 a.m. USA EDT

HOG Member	Present	Council Member	Present
Greg Miller (chair)	x	Gary Myers (chair, AACCC)	x
Eunice Lee (Vice-Chair)	x	Junghan Song (KSLM)	
Joseph Passarelli	x	Akira Seki (JCCLS)	x
Steve Master	x	Howard Morris (IFCC)	
Amy Saenger		Tony Killeen (CAP)	x
Ian Young			
Masato Maekawa			
Philippe Gillery (IFCC SD)			
Anja Kessler		Observer	
Melissa Snyder		Loretta Doan (AACCC)	x
Yeo-Min Yun		Katsuyuki Nakajima (JCCLS)	x
Andy Hoofnagle			
Amrom Obstfeld	x		

Minutes:

Council activity:

1. EQALM joined as a Stakeholder Member.

HOG activities:

2. A Stakeholder's report was sent to all members and posted to the web site.
3. Solicitation for measurands in guidelines was sent to Nader Rifai who sent it to Tietz Textbook clinical chapter authors; and was sent to Paola Bramati at IFCC who sent it to IFCC member national representatives. Feedback will be brought to future meetings for review.
4. Solicitation for EQA programs that use commutable samples was sent to EQALM and to CAP. Links to these programs will be posted to the web site as they become available and are approved by the HOG.

5. Solicitation for links to active harmonization projects/materials were sent to Vincent Delatour (LNE), Chris Burns (NIBSC), Karen Phinney (NIST), Wenxiang Chen (NCCL). Links will be posted to the web site as they become available.
6. ICHCLR and IFCC SD are developing a conference proposal for a satellite meeting following the IFCC WorldLab 2020 Seoul (WorldLab is 24-28 May, satellite meeting planned for 29-30 May 2020). The planning group consists of Greg Miller, Gary Myers, Jim Pierson Perry, Christa Cobbaert, Philippe Gillery. HOG reviewed the initial proposal on a previous call and will review the revised proposal when ready.
7. Greg was invited to attend the BIPM Consultative Committee for Amount of Substance: Metrology in Chemistry and Biology (CCQM) meeting in Paris France 10-12 April 2019 to discuss harmonization approaches, prioritization and synergies between ICHCLR/IFCC SD and metrology institutes. Council approved attending.
8. Summary explanations for adequate harmonization status for measurands on the web site that did not have explanations were reviewed and approved for: bilirubin total, blood gasses, calcium, chloride, cholesterol total, creatinine, ethyl alcohol, glucose, hemoglobin A1c, iron binding capacity (unsaturated), lactate, magnesium, phosphate, potassium, protein total, sodium, triglycerides, urea N, uric acid.
9. CK-MB, HBV Ag and anti-HBs AB (to be developed by Eunice), HIV-1 Ag with HIV-1 and HIV-2 Abs (qualitative), IgG antibodies to myeloperoxidase, and Treponema pallidum (syphilis) will be removed from the web site until suitable summary explanations are prepared.
10. The term "Adequate" on the web site was discussed from the perspective it could convey the impression that funding for reference systems such as the CDC lipid standardization program and similar are no longer needed. A different term will be identified.
11. Our practice has been not to include on the web site an entry for medical impact (priority) of harmonization when the status is "Adequate." This omission could have an impression that sustained harmonization and standardization reference systems are not needed which is not correct. The group agreed to add back a medical impact for all measurands. Greg will investigate having the default measurand table sort by "Harmonization Status" to focus on those in need of harmonization effort.
12. A measurand summary for hemoglobin was reviewed and approved. Amrom will add reference to a CLSI guideline before posting to the web site.

13. HOG and Council were encouraged to suggest new HOG members for 2019.

Expertise in molecular diagnostics, infectious disease and representation from IVD industry are needed.

14. The Table below shows measurand assignments for prioritization recommendations for review by HOG.

Next conference call meetings: all 8 AM USA Eastern time: 2019; Jan 22, Feb 25, Mar tbd, Apr 29

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
Calcium, ionized	Anja will provide additional EQA data to support the recommendation draft from Greg
Chlamydia	Eunice
HBV Ag and anti-HBs AB	Eunice
Vitamin B12	Greg
Iron	Greg
Protein urine	Greg

Measurand	Assigned to
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 SS-A	Melissa
cytokeratin fragment 19 (CK19F)	Melissa
Elastase 1	Melissa
Elastase 2	Melissa
IgA	Melissa
IgG	Melissa
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

Measurand	Assigned to
Hepatitis B DNA quant	Tony and Melissa
Hepatitis C Ab	Tony and Melissa
Drugs: acetaminophen, salicylate, theophylline, tobramycin, gentamycin, benzodiazepine, amphetamines, tacrolimus, serolimus, lidocaine, methotrexate, N-acetylprocainamide, procainamide, primidone, quinidine, valproic acid, amikacin, barbiturates, cyclosporine, cocaine urine, methadone	Yeo-Min