

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

DATE: 25 October 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) | |
| Steve Master | | Howard Morris (IFCC) | |
| Amy Saenger | | Tony Killeen (CAP) | |
| Ian Young | x | | |
| Masato Maekawa | | | |
| Philippe Gillery (IFCC SD) | | | |
| Anja Kessler | x | Observer | |
| Melissa Snyder | | Loretta Doan (AACCC) | |
| Yeo-Min Yun | x | Katsuyuki Nakajima (JCCLS) | |
| Andy Hoofnagle | | | |
| Amrom Obstfeld | | | |
| | | | |

Minutes:

Council activity:

1. Gary reviewed that the Australasian Society was interested to join as a Stakeholder member; some current Stakeholder contacts were no longer valid and new contacts were being solicited. He will continue to solicit other potential Council and Stakeholder members.
2. Council and HOG were asked to identify potential new HOG members for 2019 including representatives from the IVD industry.

HOG activities:

3. Members were asked to send Greg suggestions of recent activities for inclusion in the next Stakeholders Report
4. Final text was reviewed for solicitation of information on tests used in guidelines to be sent by Greg to Nader Rifai who agreed to pass our request to the Tietz Textbook chapter authors to identify key guidelines in their areas of expertise.

Greg will request Paola at IFCC to send the request to IFCC National Society and Affiliate Members representatives.

5. Final text was reviewed for solicitation of organizations with active harmonization work to link to from our web site. The following organizations will be contacted: JRC (Howard); NIST (Gary); LGC (Ian); NIBSC (Greg); LNE (Greg). Gary will ask Wenxiang Chen for a contact in China. Contacts are needed in Korea (KRIS) and Japan.
6. Questions were reviewed to be asked of organizations that offer EQA/PT with commutable samples that can be linked to from our web site. The HOG will need to review suitability of EQA programs before links are added to the web site. The following organizations will be contacted: CAP (Tony); RCPA (Greg to contact Tony Badrick); DEQAS UK (Greg to contact Finlay MacKenzie); DEQAS vitamin D (Greg to contact Graham Carter). At a recent meeting, EQALM was receptive to receiving solicitations and requested clarification regarding qualifications for listing. We agreed to inquire of the IFCC Committee on PT, EQALM (Piet Mier), Graham Jones, others for comments on the qualifying questions. Gary will add to the agenda for discussion at the December JCTLM meeting.
7. A draft proposal for development of a conference on reference materials and regulations for global standardization of clinical laboratory testing in collaboration with the IFCC SD was reviewed. The ICHCLR supports a joint conference and will collaborate on content development.
8. The HOG and Council endorsed the concept to be part of an effort to develop procedures to aggregate EQA data from commutable materials as a surveillance mechanism for harmonization status and feedback to IVD manufacturers. Anja pointed out that some multi-country activities are underway in Europe (e.g. HbA1c and others) and a key issue is lack of standardized coding among EQA schemes for IVD measurement procedures. Greg to contact IFCC Committee on PT and IFCC WG HbA1c for current activities in this area.
9. Greg will update the web site measurands that do not have an explanation for priority or status based on EQA data.
10. Measurand summary for ammonia was approved for posting to the web site.
11. The Table below shows measurand assignments for proposed prioritization recommendations for review by HOG.

Next conference call meeting: to be scheduled

| Measurand | Assigned to |
|--------------------------------------|---|
| Hemoglobin and CBC parameters, blood | 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 |
| 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 |

| Measurand | Assigned to |
|------------------------------------|--|
| 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 |
| Hepatitis B DNA quant | Tony and Melissa |
| Hepatitis C Ab | Tony and Melissa |

| Measurand | Assigned to |
|---|--------------------|
| 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 |