

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

**DATE:** 14 June 2016

**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 Members:**

Dr. Gary Myers (chair)  
Mr. Hirofumi Koide  
Dr. Junghan Song

**Members Absent:**

Dr. Steve Master  
Dr. Tony Killeen  
Dr. Hamasaki

**AACC Staff:**

Ms. Stefanie Kleinman (Scientific and Practice Affairs Coordinator)

**Minutes:**

1. Website update status

Gary Myers and Greg Miller have determined three areas of the harmonization.net that need updating: adding Organizational members, reformatting the measurand table and changing some text and documents.

Gary and Greg met with Stefanie Kleinman, Loretta Doan and the AACC web team via conference call to discuss the proposed web updates. The web team is evaluating the request and will submit an itemized statement of work explaining how long the requested work will take and whether or not they will be able to complete it. The HOG and Council will be updated at the next meeting, August 3, in Philadelphia.

2. Continue review of measurand prioritization spreadsheet

- a. CO<sub>2</sub>; correlation for two sets of instruments indicated some disagreement; additional crossover data between instruments is needed.
- b. Tacrolimus; Ian reported that he contacted LGC and Loralie Langman and concluded that harmonization was needed. IFCC is considering a WG to

address tacrolimus and other immunosuppressant drugs. Ian will update at the next meeting.

- c. HIV 1,2 Ab; the group agreed to make low priority based on good performance in qualitative PT surveys. Greg to write justification summary.
- d. HbSAg; the group agreed to make low priority based on good performance in qualitative PT surveys. Eunice to write justification summary.
- e. Anti-HBs Ab; the group agreed to make low priority based on good performance in qualitative PT surveys. Eunice to write justification summary.
- f. HCG; the group agreed was high priority but additional data is need for the justification summary. Greg will inquire from colleagues if any EQA programs with commutable samples are available.
- g. B12; the group agreed that harmonization was adequate.
- h. Folate; information from CDC and NEQAS suggests that harmonization is needed; the group agreed a high priority because of importance in particular for maternal/fetal development. Gary will write justification summary.
- i. Urine sodium; the group agreed harmonization is adequate based on PT data; in addition PT data supports that harmonization is adequate for urine calcium, glucose, urea, uric acid. Additional information is needed for urine magnesium, osmolality, phosphorous, potassium, chloride, creatinine, amylase, total protein because PT data showed less good agreement but may still be adequate for medical use requirements.
- j. Ethanol in serum; agreement for PT data was good except Vitros that may be a non-commutability issue. Greg will do a literature search for additional information.

### 3. Assignments for the next meeting

- a. Greg: request additional commutable sample EQA data for HCG; review literature for ethanol harmonization status; contact colleagues regarding harmonization status for CMV DNA; write justification summaries for HIV 1,2 Ab and urine sodium, calcium, glucose, urea, uric acid.
- b. Eunice: investigate harmonization status for HCV Ab, HIV-1 RNA, HIV-1 Ag with HIV-1 and HIV-2 Abs; and write justification summaries for HbSAg and Anti-HBs Ab
- c. Steve: follow up on harmonization status for D-Dimer and vancomycin
- d. Ian: follow up on tacrolimus and other immunosuppressant drugs
- e. Gary: write justification summary for B12 and folate

### 4. Updates to web site measurand table

Measurand	Matrix	Medical Importance	Harmonization Status	JCTLM Listed	Organization
HIV 1,2 Ab	Serum	L			
Hbs Ag	Serum	L			
Anti-HBs Ab	Serum	L			
HCG	Serum	H			
Vitamin B12	Serum		Adequate		
Folic acid	Serum	H			CDC
Sodium	Urine		Adequate		
Calcium	Urine		Adequate		
Glucose	Urine		Adequate		
Urea	Urine		Adequate		
Uric Acid	Urine		Adequate		

5. Meeting in Philadelphia

The next meeting will take place at AACC's Annual Meeting in Philadelphia.

Proposed agenda items:

- Review status justification summaries
- Plan how to address remaining measurands on the list
- Process to acquire instrument cross-over data
- Review additional measurands

**Wednesday, August 3, 2016, 12:30-2:00 pm (lunch provided)**

**Marriott Philadelphia Downtown, Room 303**