AIUM/QIBA
Ultrasound Volume Blood Flow Biomarker

Summary 03-August-2020

Attendees: Brian Fowlkes, Oliver Kripfgans, Jim Jago, Todd Erpelding, CY Lee, Shriram, Michelle Robbin, Stephen Pinter, Rimon, Jing Gao, Jon Rubin, Mark Lockhart, Jim Zagzebski, Paul Carson. AIUM Staff – Therese Cooper

1. Review of previous call summary and approved
   1.1. Review of Action Items
   Effect on Bias and Reproducibility
   1.1.1. Important factors carrying into the profile. Constant flow bias and coefficient variation between labs. Results: Adjusted for site differences. The systems could be compared to each other. System 3 (underestimating the true value) was significantly different from the bias of systems 1 and 2. The bias of systems 1 and 2 did not differ significantly.

   Bias: Statistically significant interaction between the system and true value ($P < .001$): Model suggests that
   - Bias of systems 1 and 2 decreased as the true value increased (moving closer to zero bias).
   - Bias of system 3 'increased' (smaller negative numbers!!) (moving closer to zero bias, just from the opposite direction).

   Between-site reproducibility: Statistically significant effect of system ($P = .003$) on the between-site reproducibility.
   - System 3 having greater variance (less precision) than system 2 ($P = .002$).
   - System 1 having greater variance (less precision) than system 2 ($P = .004$).

   Based on these results we would choose 10% for bias and 5% for reproducibility, as 2 out of 3 systems would fulfill this requirement. 2D spectral Doppler has higher variability when used in challenging locations. There is also a high likelihood of it being biased. In the end, a survey of the literature needs to set the thresholds for a reasonable claim, based on the target applications we have listed (umbilical venous flow and dialysis graph flows). Currently, it is anticipated to choose 15% for bias and 20% for reproducibility.

2. The group discusses the necessity for in vivo estimation of bias and variability as well as confounding factors. The latter may depend on the target application, such as within day variations of digestion.

3. Request made for vendors to complete the survey. Todd Erpelding is still trying to get Canon to complete the survey. It is felt that there is nothing proprietary.

4. Update on VBF Profile Discussions
    4.1. The leadership of 3 subgroups
        4.1.1. Clinical Rationale and Performance (Mark L and Jon Rubin)
        4.1.2. QA and Phantom (Jim J. and Cristel B.)
        4.1.3. Image Acquisition and Analysis (Oliver L. and Stephen P.)
            4.1.3.1. Subgroup assignments - Most got their first choice
                4.1.3.1.1. Slide shows who was placed in which group
        4.1.4. Writing activities - Timeline

5. Draft for BC by September 9

Next meeting for Profile task groups is 8/12 8/26 and 9/9. Considering using breakouts for subgroups

The next full VBF BC September 14