QIBA Ultrasound Shear Wave Speed (SWS) Biomarker Committee (BC) Call

Friday, February 7, 2020; 11 AM CT Call Summary

In attendance

Brian Garra, MD (Co-Chair) Karen Alton, BS, RDMS, RVT Michael André, PhD Paul Barbone, PhD Jun Chen, PhD Todd Erpelding, PhD, MSE Reinhard Kubale, MD Viksit Kumar, PhD Stephen McAleavey, PhD Arinc Ozturk, MD Jacques Souquet, PhD Theresa Tuthill, PhD Michael Wang, PhD, MASc Keith Wear, PhD Jim Zagzebski, PhD RSNA

Joe Koudelik Julie Lisiecki

Moderator: Dr. Garra

Public Comment Resolution:

- The comment period closed on December 18, 2019
- Dr. Garra is working on public comment resolution and a conformance checklist for the Profile
- Once comments have been addressed, Dr. Garra will submit them for posting on the QIBA wiki <u>Comment</u> <u>Resolutions Page</u>, and the
- BC and CC voting will follow in efforts to publish the Profile as "Consensus" (Stage 2)

Profile v2.0:

- Dr. Garra proposed pursuing a second Profile that builds on the first Profile
- Profile v1.0 has data only for elastic phantoms; v2.0 would include a reconciliation of FibroScan data with viscoelastic phantom data
- The inclusion of FibroScan is important because it is the most commonly used technique in the field
- It will be necessary to consider how to compare QIBA results with FibroScan results to address value differences
- BC members agreed that a literature search would be a logical next step
 - Drs. Andre, Ozturk, and Souquet have agreed to organize a small task force to lead a literature search and provide data back to the BC
- Data in a study that Dr. Andre is currently working on are being collected from GE, Siemens, and FibroScan, with comparable trends thus far
- Creating a correction factor (with validation) for the data may be difficult, as a mechanism that would allow for substitution of one vendor for another may impinge on proprietary details
- Other studies that are exploring the correction factor topic include:
 - The <u>Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE)</u>, funded by the Foundation for the National Institutes of Health (fNIH)
 - NIMBLE will utilize multiple modalities (MR, FibroScan, SWS) and include several vendors and will
 measure repeatability and reproducibility
 - o Review of recent study data needed to modify the Profile's statement of clinical applicability
 - $\circ~$ A study in Japan which includes regression equations for FibroScan
 - The study that Dr. André is working on at UCSD, which includes patient context with hepatologist input, and comparisons of Shear Wave, MR, and FibroScan
 - A study at Massachusetts General Hospital
 - Mendeley may be used to compile the literature search, though unfortunately, Dr. Garra cannot access this system; so, he will need a Word document or spreadsheet of the compiled references
- The claims in v1.0 of the Profile primarily deal with variance, though bias in implied
- According to Dr. Obuchowski, 5% is negligible in terms of variability
 - Providing data that shows variance is only 5%, would be of great benefit
- If a more obvious claim for bias is needed, bias would be measured against a reference system

Profile Approval Process: See voting and balloting process links: <u>http://qibawiki.rsna.org/index.php/Process</u>

QIBA US Schedule:

02/28	US Coordinating Committee at 11 am CT
03/06	SWS BC
03/13	CEUS BC