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

Friday, February 1, 2019; 11 AM CT

Call Summary

In attendance			**RSNA**
Brian Garra, MD (Co-Chair)	Rik Hansen, PhD	Anthony Samir, MD, MPH	Joe Koudelik
Tim Hall, PhD (Co-Chair)	Ted Lynch, PhD	Leah Schafer, MD	Julie Lisiecki
S. Kaisar Alam, PhD	Stephen McAleavey, PhD	Jacques Souquet, PhD	
Paul Carson, PhD	Nancy Obuchowski, PhD	Theresa Tuthill, PhD	
Jun Chen, PhD	Arinc Ozturk, MD	Keith Wear, PhD	
Todd Erpelding, PhD, MSE	Mark Palmeri, MD, PhD		

Moderator: Dr. Garra

Approval of 11.02.2018 call summary

- The summary was approved as written

Manuscript update:

- Dr. Palmeri has submitted a comprehensive paper to *Radiology* for publication consideration
    - The paper summarizes conclusions from the ultrasound shear wave speed (US SWS) phantom phase I & II experiments, which informs the Profile regarding acoustic attenuation in the liver
    - He is awaiting feedback from the reviewers

Proposed letter to accompany manuscript:

- Dr. Carson proposed sending a letter to the editor to accompany the manuscript (if accepted) to promote efforts of the SWS BC and request collaboration on obtaining data from clinical sites comparing ultrasound shear wave speed measurements with those from other clinically available elasticity measurement tools, including both FibroScan and Magnetic Resonance Elastography (MRE) systems, in subjects across a range of disease etiologies and fibrosis stages
- The letter refers to the manuscript and provides additional details for collaboration efforts
    - Dr. Samir has volunteered the services of his lab to collect and manage statistical analysis of the data
    - Although desirable, use of retrospective data may be hindered by lack of institutional review board (IRB) approval or prior patient consent
    - Efforts to use European data may be further hindered by General Data Protection Regulation (GDPR)
        - It may be necessary to use a waiver or to retrospectively obtain patient consent
        - Dr. Samir suggested consulting with respective IRBs to ask for advice; he and Dr. Ozturk will investigate further
        - Drs. Samir and Ozturk to review the letter prior to distributing it beyond BC membership
        - Dr. Samir assured the group that data can be centralized in a manner that is compliant with IRB and local regulations

- It was suggested that the letter be addressed to Dr. Linda Bresolin, as she would know the correct channels for distribution at RSNA
    - It was also proposed that the letter be drafted on QIBA letterhead or include the QIBA logo
    - Institutional contact information for the BC chairs (Drs. Garra, Hall, and Mr. Milkowski) must be included on the letter for any follow up/comments

- Organizations/institutions to ask for help in distributing the letter were suggested:
    - American Institute of Ultrasound in Medicine (AIUM) – Technical Standards Committee
    - AIUM – the editor of the Journal of Ultrasound in Medicine (JUM)
    - American College of Radiology (ACR) Bulletin
    - Aunt Minnie
    - Other appropriate news outlets

- Colleagues within QIBA
- QIBA Japan
- The European Imaging Biomarkers Alliance (EIBALL)
- The European Federation of Societies for Ultrasound in Medicine and Biology (EFSUMB)
- The World Federation for Ultrasound in Medicine and Biology (WFUMB)
    - All are asked to provide any additional contacts to Dr. Garra (Brian.Garra@fda.hhs.gov; bgarra@gmail.com) and RSNA Staff (jlisiecki@rsna.org)

Data Needed:

- Patients having both FibroScan and SWS data needed for platform output comparison
- These data are needed because there is a difficulty in relating ultrasonic shear wave speed measurements from the human liver to those reported by other commercially available liver elasticity measurement devices, including the Fibroscan system (Echosens, Paris) and Magnetic Resonance Elastography (MRE) systems, due to differences in the frequency of the shear waves generated by external vibration and focused ultrasound.
- What is missing is quantification of the way in which shear wave speed varies with the wave frequency for liver in various pathological conditions.
- At a minimum, numerical data is needed to begin statistical analysis
- If possible, quantitative data and imaging data will be aggregated
    - It is uncertain whether data can be aggregated and analyzed as it is collected or if permission is needed to aggregate the data prior to analysis
- If data is shared, it is anticipated that only broad parameters will be provided
- Dr. Samir and his team will aggregate all available data based on "informal consent".
    - Pursuing a research waiver was also suggested
- Some wordsmithing of the letter and appropriate permissions/procedures to be IRB compliant are needed

Profile update:

- Dr. Garra is incorporating latest edits to the Profile and will soon redistribute for additional BC review
- Concepts that require further discussion include the following:
    - Frequency range issue remains unsolved; only recommendations can be made
    - Profile tolerances are set for the elastic phantom, not the viscoelastic phantom
- Industry-specific contact email addresses for public comment should be provided to RSNA staff: jlisiecki@rsna.org
- Comments are welcome to Drs. Garra and Hall: Brian.Garra@fda.hhs.gov; bgarra@gmail.com; tjhall@wisc.edu

Discussion from RSNA 2018 QIBA Breakout Session:

- Equipment manufacturers have indicated some resistance to conformance testing their machines as outlined in the SWS Profile
- What is a practical level of manufacturer testing?
    - Is it necessary to test each machine/unit as it comes off the line, or is this too stringent?
    - Is product line spot-checking acceptable?
    - Would this type of testing be for quality assurance or for testing Profile conformance?
        - To be QIBA conformant, testing machine specifications is necessary
    - Would it be acceptable to test the phantom within a +/- measurement variation, e.g., if data do not fall within the acceptable range, the machine would not meet the performance goals of the Profile?
    - Conformance to expected values based on a calibrated phantom is needed, but maybe not for every system
    - Need to define the vendor use of "verify" and how to confirm Doppler Velocity performance
- It was surprising to discover that if previous machine/units were cleared by the FDA based on a reporting "honor system", no additional testing is required on newer models

- At this point in time, Profile claim confirmed status has not yet been achieved, so manufacturers would need to complete more rigorous assessments of performance
- Claim assumptions are based on phantom data, not clinical data; so some amount of testing for the Profile is necessary
- It is not presently known how manufacturers test for product quality assurance
- Since the BC was uncomfortable with no vendor system testing, Dr. Carson proposed that BC leadership have additional discussions with the following industry partners to determine a practical approach to this vendor testing question:
    - Mr. Milkowski (Siemens)
    - Dr. Erpelding (Canon Medical Systems)
    - Dr. MacDonald (GE Healthcare)
    - Dr. Souquet (SSI)
- As this testing question regarding manufacturer conformance with the Profile is complicated, it may not be possible to address it in the current version of the Profile

Next Steps:

- It is hoped that a finalized version of the letter will be ready prior to the next BC meeting, scheduled for March 1st

Profile Approval Process Next Steps:

- See voting and balloting process links http://qibawiki.rsna.org/index.php/Process
- Voting to release the Profile for public comment will be done electronically

QIBA US Schedule:

02/08	CEUS BC
02/22	US Coordinating Committee
03/01	SWS BC
03/08	CEUS BC