

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

Friday, August 2, 2019; 11 AM CT

Call Summary

In attendance

Brian Garra, MD (Co-Chair)

Tim Hall, PhD (Co-Chair)

Michael André, PhD

Paul Carson, PhD

Rik Hansen, PhD

Reinhard Kubale, MD

Nancy Obuchowski, PhD

Mark Palmeri, MD, PhD

Leah Schafer, MD

Jacques Souquet, PhD

Theresa Tuthill, PhD

Keith Wear, PhD

Jim Zagzebski, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Garra

Approval of 05.03.2019 call summary

- The summary was approved as written

IEC Workgroup Overview: (Dr. Hansen)

- Dr. Hansen provided an overview of the IEC Workgroup's plan to standardize the user interface for equipment
- Goal is to improve confidence (data integrity) when scanning difficult patients
 - Selecting metrics that users are comfortable with will raise their confidence that good data is collected
- He is working with colleagues in Germany and China on a protocol for shear wave speed in three parts:
 - Making standardizations to the SWS equipment
 - Tests to evaluate performance of the equipment
 - Quality assurance (QA) testing
- This work coincides with the efforts of the QIBA SWS BC, and with input from QIBA, both groups could benefit
- Dr. Hansen encouraged SWS BC members to help draft this IEC user interface document
- It would include the following areas:
 - User interface
 - Phantom material preparation
 - Protocols to test equipment / QA
- Dr. Hansen would serve as the liaison to both groups by providing updates on QIBA SWS calls
- He hopes that BC members could review documents and provide feedback to him
- Current testing is focused on homogeneous materials that are most currently used in the liver, though future updates will also include dispersive media
- Dr. Garra mentioned that the next version of the SWS Profile would also include dispersion; so, collaboration with the IEC could be a parallel effort
- Dr. Garra asked Dr. Hansen to provide the last meeting minutes or materials, if available
- Any interested volunteers are asked to email Drs. Hall (tjh@wisc.edu), Garra (bgarra@gmail.com), and RSNA Staff (QIBA@rsna.org)

SWS BC Profile internal review comments:

- The Profile has been through a BC internal review and notes have been made regarding what has been addressed and what issues remain outstanding
- Of the three Profile comments received, one was based on formatting
 - Formatting and minor issues will be addressed after public comment; only critical content issues will be addressed now to get the Profile out for public comment as quickly as possible
 - Some modifications to the statistics section were made at the recommendation of Dr. Obuchowski
- Dr. Garra is working on a checklist to accompany the Profile for public comment
- Dr. Garra asks that BC members forward any critical content issues immediately so that he can address them
- Dr. Hall asked for an update on performance statements based on Dr. Palmeri's work

- There is now a citation that can be added, which might be mentioned in the claims section and a few other places
- There is no explicit claim for bias, though it is included in a cross-sectional claim
- As a measurement for bias is not available, it will be necessary to test the Profile robustly to make certain that the claim holds, and the bias will need to be less than 5%
 - When responding to public comments, it was suggested to add a comment regarding the implications for specific thresholds as a cautionary or uncertainty statement and hold revisions to the Profile until public comment has been completed
- Regarding the vote to release the Profile for public comment, Dr. Carson suggested adding the option to suggest time frames for public comment, e.g., 30, 60, or 90 days
- User checklists will be preliminary checklists
 - A conformance checklist will be developed later – after public comment is complete
- Regarding public comment, Dr. Hall would like it to overlap with the IEEE meeting in October, in order to encourage public comment participation at the meeting
 - The recommended time period for public comment was at least 60 days

Phantom manuscript:

- Dr. Palmeri is putting the final touches on the phantom study manuscript and will circulate to BC members soon
- Dr. Hall suggested adding the manuscript reference to the Profile
- Dr. Carson to draft a letter to the editor of *Radiology* again to accompany the manuscript

Medical Device Development:

- Dr. Garra wants to pursue FDA approval/clearance of procedures and devices, under the Medical Device Development Tools (MDDT) pilot program
- He believes that some components of the SWS Profile would qualify for this pilot program
- According to the FDA, “MDDTs are “tools that manufacturers and FDA use to assess and measure the performance, safety, and effectiveness of medical devices.”
- The MDDT qualification process aims to make evaluation more efficient by validating MDDTs for particular uses

Other topics:

- Dr. Carson mentioned that it might be helpful to contact international colleagues to endorse the Profile or explain how their regulatory processes work
- Dr. Carson provided dashboard updates and mentioned that assessment 4 is in progress
- Dr. Hall said that he would review the dashboard for updates
- Dr. Hall mentioned that the 2020 meeting of the Acoustical Society of America is at the same time as the 2020 RSNA Scientific Assembly and Annual Meeting

Profile request:

- Contact email addresses for public comment should be provided to RSNA staff: jlisiecki@rsna.org

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:

08/23	US Coordinating Committee at 11 am CT.	10/04	SWS BC
09/06	SWS BC	10/11	CEUS BC
09/13	CEUS BC	11/08	RSNA 2019 Poster deadline