

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

Friday, November 20, 2020; 11 AM CT

Call Summary

In attendance

Brian Garra, MD (Co-Chair)
Paul Carson, PhD
Jun Chen, PhD
Giovanna Ferraioli, MD
Aiguo Han, PhD

Rik Hansen, PhD
Viksit Kumar, PhD
Stephen McAleavey, PhD
Kathy Nightingale, PhD
Nancy Obuchowski, PhD

Arinc Ozturk, MD
Stephen Rosenzweig, PhD
Michael Wang, PhD, MASc
Keith Wear, PhD

RSNA

Julie Lisiecki

Moderator: Dr. Garra

- The call summary notes from September 11, 2020 were approved as presented

Public Comment Resolution:

- Dr. Garra is finalizing public comment resolution and the conformance checklist for the Profile
- Dr. Garra plans to send the Profile to BC members for a final internal review by the end of December
- A note regarding the ease of use of the checklist will be added to the beginning of the Profile
- A “clean” version of the Profile will be needed, along with the revised spreadsheet format for posting on the QIBA wiki [Comment Resolutions Page](#) before the Consensus vote at the BC and CC levels

Shear Wave Speed Manuscript (Drs. Nightingale and Wear):

- Dr. Palmeri has re-submitted his manuscript to the *Journal of Ultrasound in Medicine (JUM)*
- Minor comments have been addressed

[Non-Invasive Biomarkers of Metabolic Liver Disease \(NIMBLE\) Study:](#)

- The NIMBLE study will implement the full SWS Profile and may help the Profile attain technically confirmed and claim confirmed status
- Dr. Ozturk is in the process of obtaining institutional approvals and will begin recruiting patients for the study in early 2021
- His team will be collecting SWS velocity data but will not be following the phantom section for initial testing and machine verification, though the NIMBLE study will otherwise be following the SWS Profile
- All patients will either have fatty liver or Nonalcoholic steatohepatitis (NASH), and there will be a broad range of disease represented
- Dr. Obuchowski noted that data could be pooled for the reproducibility coefficient over the range of categories
- The anticipated timeline for the study is one year for the first stage only (which incorporates ultrasound), though patient recruitment has not started yet
 - The second stage of the study will have an MRI component
- With regard to the system calibration, it is possible that manufacturers may not test each system before delivery, which is a deviation from the Profile; however, newer digital systems are very stable and require only periodic software updates
- To achieve proper Quality Control (QC) and consistent patient results, Dr. Carson suggested a baseline QC be established prior to using the Profile
 - The QC can be done with less expensive phantoms via the standard method for reproducibility by the operator promulgated by Dr. Barr

Next Version of the Profile:

- Review sources of variability and will double-check these for the next version of the Profile
- The group was asked to consider whether the Profile should be extended to visco-elastic materials
- Dr. Carson asked the group to consider more rigorous standards for the different manufacturers to obtain the same measurements and whether sufficient patient data could be obtained from the NIMBLE study to make stronger claims for the next version of the Profile, as current claims are based on phantom data
- Dr. Obuchowski anticipates that a NIMBLE dataset based on patient data will help identify any necessary adjustment to the claims

- Dr. Ozturk indicated that 6 ultrasound systems and Fibroscan will be tested in the NIMBLE study
 - Correlation with Fibroscan results will be needed along with a comparison of systems to aid in model selection for the Profile, which will aid in making stronger claims
 - Further discussion on upcoming calls may include how to quantify system variability
- Dr. Nightingale favors a linear attenuation model and is not optimistic about extrapolating outside of that range

Retirement Announcement:

- Dr. Garra announced that he is leaving QIBA at the end of the year and asked that anyone who might be interested in Co-Chairing the SWS BC to contact [Dr. Fowlkes](#), [Dr. Carson](#), or [Dr. Hall](#)

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

QIBA US Schedule: *next call – Friday, December 18th at 11 am CT*

12/11	CEUS BC	12/18	SWS BC
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