

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

Friday, January 22, 2021; 11 AM CT

### Call Summary

#### In attendance

Brian Garra, MD (Co-Chair)

Andy Milkowski, MS (Co-Chair)

Karen Alton, BS, RDMS, RVT

Paul Carson, PhD

Anil Chauhan, MD

Todd Erpelding, PhD, MSE

Aiguo Han, PhD

Hendrik Hansen, PhD

Reinhard Kubale, MD

Viksit Kumar, PhD

Stephen McLeavey, PhD

Kathy Nightingale, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Arinc Ozturk, MD

Keith Wear, PhD

#### RSNA

Joe Koudelik

Julie Lisiecki

#### Moderator: Dr. Garra

- The call summary notes from November 20, 2020 were approved as presented

#### Public Comment Resolution:

- Dr. Garra has finalized public comment resolution, and he thanked Ms. Alton and Mr. O'Donnell for their help with editing
- Dr. Garra and Ms. Alton plan to work on minor formatting modifications to the conformance checklist for the Profile
- A "clean" version of the Profile is needed, along with the revised resolution spreadsheet for posting on the QIBA wiki [Comment Resolutions Page](#) before the Consensus vote proceeds at the BC and CC levels
- Once RSNA staff receives the resolution spreadsheet and marked-up version of the Profile, a consensus ballot will be distributed

#### Profile questions:

- Mr. O'Donnell had some questions regarding processes described for the technical performance claim
  - Should the SWS bins or linear interpolation be used in Table 2-1?
  - If frequency speed is 2.2, the coefficient leaps up to 10.2% - is this correct?
- Dr. Garra said that he would add a note to clarify when values may be higher near the boundary
- Dr. Obuchowski explained that current speed ranges were used based on limited data availability at the time of writing
- Dr. Carson to send an email with details for Dr. Garra to add in a footnote to the Profile
- More limitations regarding the boundary were discussed
- Mr. O'Donnell suggested that in parallel with the Consensus vote, the BC should send the Profile to at least 3 sites to conduct feasibility testing; this would speed up advancement to Stage 3 (Technical Confirmation)
- While testing of the Profile is being done in the NIMBLE trial, limited sections of the Profile are being used
- It would be helpful to see if other sites would be willing to use the Profile in its entirety for a more comprehensive review

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

- The NIMBLE study may help the Profile attain technically confirmed and claim confirmed status
- Dr. Ozturk's 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
- Dr. Ozturk indicated that 6 ultrasound systems and Fibroscan will be tested in the NIMBLE study

#### Next Version of the Profile:

- Sources of variability will be reviewed for the next version of the Profile, particularly focusing on machine variability with manufacturer-to-manufacturer differences, which can be a limiting factor for ultrasound, sometimes causing over- or under- diagnosis of fibrotic liver
- Fibroscan and visco-elastic materials will be included in the next version of the Profile (v2.0)
- Dr. Chauhan mentioned a paper by Drs. Giovanna Ferraioli and Richard Barr which provides more detail on fibrotic liver disease and holistic assessment for chronic liver disease

- He also discussed issues related to hepatitis and inflammation, though more factors are involved
- Dr. Chauhan agreed to help with the next version of the Profile
- Presently, there are clinical confounders in current guidelines that impact measurements, making it challenging for clinicians to decide which guidelines to follow
- It is hoped the new version of the Profile will address these clinical confounders or discrepancies, as well as technical / manufacturer confounders

**Retirement Announcement:**

- Dr. Garra announced that he is stepping down from QIBA 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, February 19<sup>th</sup> at 11 am CT? - TBD*

<b>2/11</b>	CEUS BC
<b>2/19</b>	SWS BC – <b>TBD</b>
<b>2/22</b>	US Coordinating Committee @ 1 pm CT