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

Wednesday, November 17, 2021; 2 PM CT

Call Summary

In attendance			**RSNA**
David Fetzer, MD (Co-Chair)	Jun Chen, PhD	Theresa Tuthill, PhD	Joe Koudelik
Stephen McAleavey, PhD (Co-Chair)	J. Brian Fowlkes, PhD	Michael Wang, PhD, MASc	Julie Lisiecki
Stephen Rosenzweig, PhD (Co-Chair)	Kathy Nightingale, PhD	Keith Wear, PhD	
Michael André, PhD	Arinc Ozturk, MD	James Wiskin, PhD	
Peter Chang, PhD, PMP			

Moderator: Dr. Fetzer **(please see Dr. Fetzer's Detailed notes at the end of the summary)**

The following were discussed:

- Dashboard updated per CC and SC request
- High-level updates made to the Profile
- Revisions to Checklist to match numbering in the Profile
- Outstanding questions regarding Profile requirements
- Making protocol guidelines manufacturer and society agnostic
- Encouraging/recommending phantom testing for sites with necessary expertise
- Volunteers helping with Profile/checklist updates
- Interest in pursuing Stage 3 (Technically Confirmed) after Consensus vote

Reference provided:

- Palmeri ML, et al., "Radiological Society of North America/Quantitative Imaging Biomarker Alliance Shear Wave Speed Bias Quantification in Elastic and Viscoelastic Phantoms," *J Ultrasound Med* 2021:9999:1-13 0278-4297 doi:10.1002/jum.15609

Action items:

- Appendix A, committee members and authors, to be updated
- Appendix B (Background Information) and Appendix C (Conventions and Definitions) are blank
    - May not be needed. Co-chairs to check with Dr. Garra (or Ms. Alton)
- Dr. Ozturk agreed to check Profile hyperlinks and request updated manufacturer protocols for Appendix D
- Co-chairs to send their latest version of the Checklist (with tracked changes) to the BC for review – *TBD*
- Co-chairs to follow up with Dr. Garra and/or Ms. Alton re: Appendices B and C

Next Steps per *QIBA Process Committee*

- Clean up the checklist (keep most/all the recommended lines, migrate normative material from Notes into Requirements, clean up any ambiguities)
- Get BC approval of the checklist modifications - via a voice vote
- Resynch the Profile so the table contents match the updated checklists
- Circulate updated Profile & checklist for BC approval– focus on approving technical content of the Profile (Resolve any comments that come in)
- Circulate the resulting Profile & Checklist for formal CC approval (email ballot) – focus on approving the BC is doing everything properly (Resolve any ballot comments that come in)
- Publish as Stage 2: Consensus and move on to Stage 3: Technically Confirmed. (Road test the new checklists.)

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

Next call – *Wednesday, December 15th at 2 pm CT*

12/15	SWS BC – 3rd Wednesday @ 2 pm CT
01/19	SWS BC – 3rd Wednesday @ 2 pm CT

Additional detailed notes provided by Dr. Fetzer:

QIBA SWS BC Agenda
Nov 17th, 2021
(*Minutes italicized)*

- **Go through Dashboard** and update each line item as a group so everyone is on the same page
  - *Updated*

- **Report high-level updates** made to the profile, and provide timeline for re-distributing profile and checklist to all BC members for re-review
  - Steve & Stephen (Section 3)
  - David (Sections 2 and 4; specific comments below)

- **Outstanding questions regarding Profile:**
  - Hyperlinks: this will need to be checked and updated:
    - *Volunteer: Arinc Ozturk*
  - For 2.1, Clinical Interpretation lists the SRU Consensus Statement from 2014. There has since been an updated consensus statement. Should this be incorporated?
    - *Potential out of scope of this profile?*
    - *Change focus on a clinical site having a protocol for interpreting guidelines/cutoffs, but may be different between sites*
  - Section 3, updated charts to reflect changes to Checklist
    - References to subsections within Section 3 will need to be verified, ensure numbering between checklist and Profile subsections are accurate;
  - For 4.1, and other sections discussing use of phantoms, do we need to include "for those sites including phantom-based conformance procedures"?
    - *Use of phantoms is encouraged / recommended for those sites with expertise*
    - *Could be more applicable to manufacturer conformance*
  - The Profile references many AIUM guidelines and technical standards documents. I'm assuming we're sticking with AIUM because no other organization has the same database of documents. Again, we will need to make sure these references are up to date;
    - *Keep checklist society-agnostic*
    - *Keep AIUM references in Profile as a guide, include "such as…" and provide link*
  - For in-vivo SWS data (4.2.1.1c):
    - Requiring imaging of 6 normal subjects--not accounted for in Checklist;
      - *Checklist currently is less prescriptive*
      - *Could include in section that these in-vivo requirements may form the basis for a site-specific training and QA process*
    - The profile specifies 4.5 cm and 7.0 cm from transducer. What if these distances prevent the required distance of 2.0 cm from the liver capsule?
      - *Focus on clinical protocol (2 cm from capsule), and interpolate results between 4.5 cm and 7.0 cm, or assume worst case scenario (based on table 2.1)*

    - The profile requires the transducer-skin contact to be changed, and for the patient to get up and lie back down, between each measurement. This seems like a lot of time-consuming effort. Does the group think this is necessary?
        - *Remove. Normal variability in hand/transducer position and orientation, and changes in liver position between breath holds, should provide needed variability in speckle pattern and noise profile*
- 4.2.1.2A, again, requiring imaging of 6 normal subjects is also not accounted for in the checklist (within subject measurement variation);
- 4.2, Several sections reference an operators+system pair as the "imaging system", and testing appears to be required for each imaging system. Therefore, for a large site (i.e., most clinical sites), the combination of possible operators and systems requiring paired phantom and in-vivo testing is increased exponentially
    - *Based on manufacturer/model/software rev, not every physical system*
    - *Currently covered by bullet point under 4.2.1.1.C*
- Section 5 – description of checklist will need to be updated, and reference to scoring will need to be removed (now using "required" and "recommended" categories).
- How would a QIBA Conformance Statement be organized? Could we include a template? What about a self-attestation letter?
- Appendix A, committee members and authors, will need to be updated
- Appendix B (Background Information) and Appendix C (Conventions and Definitions) are blank.
    - *May not be needed. Check with Brian Garra*
- For Appendix D, given the delay in publishing the profile, do we need to re-approach each listed vendor and ensure the included information is correct and up to date?
    - *Volunteer: Arinc Ozturk to reach out to manufacturers for updated information*