

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

Wednesday, September 14, 2022; 2 PM CT

Call Summary

In attendance

David Fetzer, MD (Co-Chair)

Stephen McAleavey, PhD (Co-Chair)

Stephen Rosenzweig, PhD (Co-Chair)

Peter Chang, PhD, PMP

Jun Chen, PhD

Todd Erpelding, PhD, MSE

Giovanna Ferraioli, MD

J. Brian Fowlkes, PhD

Nancy Obuchowski, PhD

Arinc Ozturk, MD

Mark Palmeri, MD, PhD

Michelle L. Robbin, MD

Keith Wear, PhD

James Wiskin, PhD

RSNA

Julie Lisiecki

Moderator: Dr. Rosenzweig

Agenda items:

- Clinically Feasible (Stage 3) planning, aka Profile feasibility testing
- Public comment resolution document
- Manufacturer attestation and possible solutions

Update on feasibility testing progress:

- Dr. Fetzer received feedback from his team at UT Southwestern (UTSW):
 - The 2016 recommended phantom costs nearly \$3K; a significant expense
 - No suitable scale or means to measure ambient temperature of the phantom is specified
 - Sites can create their own QC system for measuring temperature and weight, but they must follow their own protocol longitudinally, to be noted in the Profile
 - Difference between recommendations vs. requirements will be noted
 - UTSW has 3 different manufacturer scanners, 4 different models, 3 different software versions, and hundreds of transducers
 - Concern was expressed regarding the number of combinations and multisource variability, particularly between users and transducers, with respect to longitudinal tracking
 - QIBA should provide over-arching guidance for these issues
- It is challenging to ask for manufacturer self-attestation of QIBA conformance
 - Without reimbursement, attestation may not be seen as a competitive advantage
- Use of QIBA templates was suggested (to be maintained and updated by manufacturers)
- Dr. Fowlkes and SWS BC leadership to reach out to QIBA Leadership and the QIBA Steering Committee for guidance on how to approach this challenge for manufacturer implementation
- SWS BC leadership to partner with another QIBA BC (any modality) that has experience with manufacture templates or guidance to use as a model for SWS
- Greater manufacturer engagement is needed for Profile development and to support sites seeking conformance

Action items (new and ongoing):

- Dr. McAleavey is compiling resolution comments and will submit a [Public Comment Resolution document](#) for wiki posting soon; he also plans to update the appendices
- Revisit some wording in the checklist re: phantom QC
- BC to clarify what is meant by pre-delivery, delivery, and install, as it relates to an ultrasound system, hardware/software upgrades, and/or even new transducers
- BC to add explicit transducer requirements – perhaps not the same actual physical transducer, but the same type, e.g., 5C1 for each use
- Dr. Fowlkes and QIBA SWS BC leaders to contact QIBA Leadership regarding guidance about manufacturer self-attestation templates
- QIBA Steering Committee / QIBA Leadership to advise what BC (any modality) may have solutions or suggestions about handling manufacturer implementation of self-attestation
- Follow up re: QIBA oversight re: delivery of new software versions (with regard to checklist)
- Manuscript on the SWS Profile to be submitted to the *Journal of Ultrasound in Medicine (JUM)* in progress

Action items (feasibility testing):

- Recruitment beyond local or affiliated sites needed to obtain at least three volunteer sites to implement Profile and provide feedback regarding feasibility of performing requirements on a routine basis
 - Medical physicist at UT Southwestern Medical Center have agreed to participate
 - Unofficial buy-in at University of Rochester (NY)
 - Dr. Ozturk to reach out to network colleagues in Boston
- Discrepancies between Profile requirements and checklist need to be identified
- Reminder that this is not clinical confirmation; it is a practicality assessment
- Consensus was that 1 representative device from each manufacturer that a performance site may have that is performing elastography

QIBA Process Committee feasibility notes:

- All Profile procedures and requirements have been performed/checked on at least two vendor platforms and at three or more sites and found to be clear and not burdensome/impractical
 - Group consensus was that one sonographer per site could provide checklist feedback
 - One-two vendor platforms tested per site would be a useful representation of the entire site
- "External" sites should be recruited to bring "fresh eyes" to better assess the clarity of the Profile and bring different assumptions about routine practice for this biomarker
- At least one of each Profile actor have demonstrated conformance (met all requirements)
- Process links: <http://qibawiki.rsna.org/index.php/Process>

Next call – *Wednesday, October 12th at 2 pm CT {2nd Wednesdays of the month}*

[QIBA Dashboard](#) for updates

[9/14/2022 recording](#): Passcode: z&^Bpg6H