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

Wednesday, September 14, 2022; 2 PM CT

Call Summary

In attendance			**RSNA**
David Fetzer, MD (Co-Chair)	Todd Erpelding, PhD, MSE	Mark Palmeri, MD, PhD	Julie Lisiecki
Stephen McAleavey, PhD (Co-Chair)	Giovanna Ferraioli, MD	Michelle L. Robbin, MD	
Stephen Rosenzweig, PhD (Co-Chair)	J. Brian Fowlkes, PhD	Keith Wear, PhD	
Peter Chang, PhD, PMP	Nancy Obuchowski, PhD	James Wiskin, PhD	
Jun Chen, PhD	Arinc Ozturk, MD		

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, November 9th at 2 pm CT {2nd Wednesdays of the month} – to be confirmed*

QIBA Dashboard for updates