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

Wednesday, November 9, 2022; 2 PM CT

Call Summary

In attendance			**RSNA**
David Fetzer, MD (Co-Chair)	Peter Chang, PhD, PMP	Mark Palmeri, MD, PhD	Julie Lisiecki
Stephen McAleavey, PhD (Co-Chair)	Giovanna Ferraioli, MD	Michelle L. Robbin, MD	
Michael André, PhD	J. Brian Fowlkes, PhD	Keith Wear, PhD	
Jeff Bamber, PhD	Arinc Ozturk, MD		

Moderator: Dr. Fetzer

Agenda items:

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

Clinical Feasibility Update

- Hoping to hear back from U-Rochester and colleagues in the Boston area
- Need a better understanding of section 4 – site qualification / conformance testing
- Need help with recruiting additional sites; to include some non-academic medical centers
- Dr. Robbin to talk with UAB Physics team re: Philips scanner performance or image acquisition protocols or checklist requirements (?)
- Diversity of manufacturers amongst sites is also desirable
- Ask manufacturers to recommend sites that may be willing to participate
- Cross reference with other modality BCs at the same stage may be helpful

Manufacturer Attestation

- The BC has not yet reached consensus regarding manufacturer requirements
- Section 4 – reviewed details / meaning with regard to sonographer's qualification and implications for the site
- Proper scale to gauge phantom weight with high accuracy needed
    - For reference, PEQUS phantoms are about 2 kilos
    - Suggested use of a calibrated kitchen scale
- Is a definition of sensitivity for temperature of probe, phantom, etc. needed or is a basic protocol sufficient?
- Each site should create and maintain their own protocol to be followed longitudinally
- Differentiate between manufacturer and site level
    - Realistic tolerances
    - Reasonable site requirements
    - Check with Dr. Ted Lynch (CIRS) re: temperature dependence
- Definition of a site to remain fluid for protocol that includes spot-checking sites – template needed
- Transducer and system variability discussed
    - Are transducers interchangeable?
    - Multiple combinations add variability
- Consider random spot checks
    - Testing every imaging system is not feasible
    - One site may encompass multiple systems/platforms
- Need to determine how to define site, (e.g., same sonographers, protocols, radiologists, and QA programs to be considered single site / organization)
- Another variable is using transducers that may not match the system manufacturer
- Want to create a manufacturer conformance statement with an easy-to-use QIBA template
- Dr. Fowlkes suggested manufacturers keep statements of conformance updated on their respective websites, using a QIBA template that includes recommended system settings, modes, transducers, software

Action items (new and ongoing):

- Dr. Ozturk volunteered to draft a QIBA template for manufacturers
- Dr. McAleavey to submit a Public Comment Resolution document for wiki posting and update the appendices
- Revisit 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
- 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, January 11th at 2 pm CT {2nd Wednesdays of the month}*

QIBA Dashboard for updates