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

Wednesday, January 11, 2023; 2 PM CT

Call Summary

In attendance			**RSNA**
David Fetzer, MD (Co-Chair)	Paul Carson, PhD	Kathy Nightingale, PhD	Julie Lisiecki
Stephen McAleavey, PhD (Co-Chair)	Peter Chang, PhD, PMP	Arinc Ozturk, MD	
Stephen Rosenzweig, PhD (Co-Chair)	Yuling Chen, PhD	Mark Palmeri, MD, PhD	
Jeff Bamber, PhD	Todd Erpelding, PhD, MSE	Gabriela Torres, PhD	
Richard Barr, MD, PhD	J. Brian Fowlkes, PhD	Keith Wear, PhD	

Moderator: Dr. Rosenzweig

Agenda items:

- Manufacturer attestation and definition clarification
- Clinically Feasible (Stage 3) planning, aka Profile feasibility testing
- Next steps

Imaging System Requirements Discussion

- The co-chairs thanked Dr. Ozturk for drafting initial guidelines for manufacturers
- Leadership have clarified previous confusion regarding site vs. system definitions
- Vendor should provide a statement if there is a software upgrade
- Co-chairs will review this definition and provide for BC review prior to the 2/8 call
- Proposed plan to evaluate sites on an annual basis via self-attestation
- A representative transducer is included in the system but not necessarily the *exact* transducer

Proposed changes/additions to guidance language definitions:

"**Imaging system**" refers to the combination of ultrasound scanner (machine), transducer, software version, and operator. Changing any of these may result in a different imaging system. Given all possible permutations, for the purposes of performance site conformance, an imaging system refers to a particular manufacturer's make/model, and transducer type (e.g., 1-5MHz curved). A manufacturer's conformance statement may allow for a closely associated model to be treated equivalently. In addition, different system software versions may be considered equivalent if specified in the manufacturer's conformance statement. Although the same transducer type (e.g., 1-5MHz) should be used, the *exact* transducer (i.e., same serial number) may not be required for longitudinal follow up. Similarly, the same operator may not be required to perform measurements for longitudinal follow up, if operators have completed all specified requirements.

"**Performance site**" is defined as an institution or organization which may operate multiple physical locations; however, operators are under the same organizational structure of training, evaluation, and quality assurance; SWS measurements follow the same imaging protocol; imaging devices are maintained and evaluated by the same group of medical physicists and/or QA manager; and results are interpreted by the same group of specialists.

- Changing any of these elements will change the system
- The checklist tells the site what it needs to do to become conformant to the Profile Claim
- Guidance needed from Leadership on what needs to be submitted annually to demonstrate conformance
- Dr. Chang asked about how operators would be tracked as part of the system
    - User/ stenographer needs to go through a QA / training process, which is defined and tracked by the site
    - Requirements are specified for each actor in the checklist, and operators are part of the system
        - Variability may occur if there is a change in operator
        - Training and record-keeping for personnel are crucial
- Buildings in multiple locations may equal one site if using the same protocol

Clinical Feasibility Questions

- Stage 3 wording on the QIBA wiki is as follows:
    - Stage 3 (Clinically Feasible) = "Several sites have performed the Profile and found it to be practical and expect it to achieve the claimed performance"
- Clinically Feasible Process

- "Whereas the preceding Public Comment Stage collected feedback based on people reading the Profile document itself, this stage seeks feedback on how well it works in a **pilot implementation**. As such, comments are solicited specifically from those that have used it and only those that have used it."
    - In previous SWS committee calls, it has been suggested that sites do not have to actually run the Profile checklist, but that they could read the Profile/checklist and comment on it -- saying what they would and would not do. The quote from the wiki above sounds like they have to perform the checklist as it is written.
    - BC leadership want to clarify if responding to questions for the checklist is enough, or if real scanning is needed.
- Dr. McAleavey to follow up with Process Committee co-chairs, Kevin O'Donnell, MASc and Michael Boss, PhD

Next steps
- Once the clinically feasible stage is reached, the BC would like to consider options for the future
- Translation of the elastic phantom to the viscoelastic phantom is being considered
- A presentation by a BC member with historical knowledge and special expertise on where the BC has been and where it needs to go was requested
    - Dr. Palmeri has volunteered to give a brief overview presentation at the February 8th meeting

Action items (new and ongoing):
- Dr. Palmeri has volunteered to give a brief SWS BC historical overview presentation at the February 8th meeting
- Dr. McAleavey to submit a Public Comment Resolution document for wiki posting and update the appendices
- Dr. Robbin to talk with UAB Physics team re: Philips scanner performance or image acquisition protocols or checklist requirements
- Need help with recruiting additional sites; to include some non-academic medical centers
- 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
- 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
- Cross reference with other modality BCs at the same stage may be helpful

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, February 8th at 2 pm CT {2nd Wednesdays of the month}*

QIBA Dashboard for updates