

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

Wednesday, February 8, 2023; 2 PM CT

Call Summary

In attendance

David Fetzer, MD (Co-Chair)

Stephen McAleavey, PhD (Co-Chair)

Stephen Rosenzweig, PhD (Co-Chair)

Richard Barr, MD, PhD

Paul Carson, PhD

Peter Chang, PhD, PMP

J. Brian Fowlkes, PhD

Timothy J. Hall, PhD

Nancy Obuchowski, PhD

Arinc Ozturk, MD

Mark Palmeri, MD, PhD

Michelle L. Robbin, MD

Keith Wear, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Fetzer

Agenda items:

- Update: Clinically Feasible (Stage 3) Profile feasibility testing
- Presentation on elastic and viscoelastic phantoms (Dr. Palmeri)

Update on Feasibility Testing

- Feedback has been received from two sites and a third is expected
- Feedback comments to be compiled in the Process Committee's [Feedback Resolution Spreadsheet](#) for eventual wiki posting

Presentation on Elastic and Viscoelastic Phantoms Research (Dr. Palmeri)

- Dr. Palmeri gave a presentation based on SWS BC research which was published in an open access article: [Ultrasound Med 2021:40:569-581](#)
- Research took place over a period of 13 months during which time the phantoms proved to be resilient even in a winter shipping cycle
 - The purpose of the phantom studies was to determine differences between commercial systems
 - Details can be found on GitHub (links are on the [SWS QIBA wiki page](#) under *Tools*)
- **Phase I: Elastic Phantoms**
 - Developed standardized sequences on Verasonics (open source references on GitHub)
 - Phantoms were sent to different measurements sites where increasing focal depths were used
 - There were 2 different batches of 10 phantoms that were sent to different sites for measurement.
 - Two phantoms were made for comparison with MRE, and those phantoms differed from the others in the size of the overall phantom, and also slightly in the associated material properties
- **Phase II: Viscoelastic Phantoms**
 - In the second phase, 3 different viscoelastic formulations were used to nominally represent realistic viscosity in different stages of liver fibrosis
 - There were multiple systems, models, sites, and software to consider but all were anonymized
- The overall project was a protected effort with a deep dive on these topics with a synergy among various academic institutions, where some funding was provided, helping to maintain a steady focus
- It was suggested that a federal agency may need to enforce a requirement to ensure consistent measurements
- Without incentives or consequences, it remains difficult to engage manufacturers to achieve more consistent measurements
- Manufacturers will not make changes or conform to QIBA Profile requirements unless there is a compelling reason, and conformance to the QIBA Profile may not be enough to ensure standardized comparable measurements in clinical settings
- It was suggested that QIBA conformance may become a precursor to FDA regulation, since precedent exists with similar IEC standards documents
- QIBA conformance may eventually extend to CMS payment

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

Action items (new and ongoing):

- [Dr. McAleavey](#) to submit a [Public Comment Resolution document](#) for wiki posting and update the appendices
- Site responses can be compiled using the Process Committee's [Feedback Resolution Spreadsheet](#)
- [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
 - At Rochester:
 - Feedback from one radiologist (Akshya Gupta) received
 - Pending with Nancy Carson (Advanced Practice Sonographer)
 - [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>

Process Committee co-chairs: [Kevin O'Donnell, MASC](#) and [Michael Boss, PhD](#)

Next call – *Wednesday, March 8th at 2 pm CT {2nd Wednesdays of the month}*

[QIBA Dashboard](#) for updates