

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

Friday, March 17, 2017; 11 AM CT

Call Summary

In attendance

Brian Garra, MD (Co-Chair)

Tim J. Hall, PhD (Co-Chair)

Andy Milkowski, MS (Co-Chair)

Michael André, PhD

S. Kaisar Alam, PhD

Jun Chen, PhD

Shigao Chen, PhD

David Cosgrove, MD

Manish Dhyani, MD

Todd Erpelding, PhD, MSE

Joel Gay, MSc

Mike MacDonald, PhD

Ravi Managuli, PhD, RDMS

Nancy Obuchowski, PhD

Mark Palmeri, MD, PhD

Theresa Tuthill, PhD

Matthew Urban, PhD

Keith Wear, PhD

Hua Xie, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Garra

Review prior call summary: January 20th summary approved as submitted

Profile Updates/Open Issues

- Remaining open issues for the Profile were discussed
- Claims and checklists are both in need of some updates
 - Statistical assumptions underlying the claim must be resolved
 - Dr. Garra to follow up with Dr. Obuchowski offline
 - Questions remain regarding how conformance will be monitored
- The Profile format will be modified to reflect the new template and will include all necessary detail
- A preliminary outline demonstrating how actors will assess their performance based on assumptions of the claim is available
- Bias and variance may also require additional details
 - Variance as a function of different variables is available
 - Almost all of the data collected (95%) falls into a $\pm 10\%$ range (grand estimate of performance) for Phase II of the phantom study
 - Measurements were made across three different phantoms, at three different focal depths, across multiple imaging sites
 - There is not a clear trend for net bias though variance is capturing changes
 - Systems, sites, and focal depths were taken into account
- Physicians are concerned about the variance in ultrasound measurements
 - Output variability across scanners is not yet known, but deemed a clinical issue
 - Proposal to set the bar higher at first pass at 5% to be achievable and clinically useful
 - Guidelines needed for creation of a standard phantom for manufacturers to use
 - Bias must still be addressed and the comparison between systems and sites
- Variance among systems is lower if the focal length depth is held constant
 - This can be added to the claim; however, a depth reference is needed for clinical use
 - It would be ideal to tighten up the depth range
 - Manufacturers need to work together to mitigate intra- and cross-scanner variance
- Another issue of concern is that the visco-elastic phantoms are not stable or reliable for long-term use, thus making the coefficient of variation arbitrary
 - Caution voiced regarding pursuit of an arbitrary performance target based on a physical phantom that remains difficult to impossible to manufacture
 - Goal is to develop a simple phantom with an achievable performance that manufacturers can reach
 - Treatment decisions are based on the range of the middle phantom
 - The team is working to resolved site-to-site variability

- Presently, even if the same machine is used in a different lab, different results are obtained
 - Three factors are affecting this variance:
 - Manufacturer
 - Receiver
 - Transducer
 - Greatest variation seen across sites based on phantom stiffness
 - A spectrum of stable and accessible phantoms may help to resolve this issue
 - It was also suggested that manufacturers must deal with the problem measurement linearity
 - If manufacturers are able to test machines at their respective factories, machine variance might be handled prior to distribution to market
 - Profile conformance testing should use a standard phantom and focus on both machines and transducers/probes
 - Phantom reference values must also be identified
 - The coefficient of variation (performance bar) will remain higher at $\pm 5\%$, with the possibility of $< \pm 5\%$ in a future Profile version
- Any further comments regarding the Profile should be sent to Mr. Milkowski, and Drs. Dhyani and Garra:
 - andy.milkowski@siemens.com; Dhyani.Manish@mgh.harvard.edu; bgarra@gmail.com

Action item: Establish whether doing a test-retest with MRE would be reproducible and move forward

Dashboard Updates: Please send Dr. Carson any relevant updates: pcarson@umich.edu. Thank you.

Next QIBA WebEx calls are as follows:

WebEx Calls:

- **Apr 07:** SWS BC (*Dr. Hall, if available*)
- **Apr 14:** CEUS BC

Task Force calls (*if requested*):

- **Apr 21:** SWS TF
- **Apr 28:** CEUS TF