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)  David Cosgrove, MD  Nancy Obuchowski, PhD  RSNA  Joe Koudelik
Tim J. Hall, PhD (Co-Chair)  Manish Dhyani, MD  Mark Palmeri, MD, PhD  Julie Lisiecki
Andy Mikowski, MS (Co-Chair)  Todd Erpelding, PhD, MSE  Theresa Tuthill, PhD
Michael André, PhD  Joel Gay, MSc  Matthew Urban, PhD
S. Kaisar Alam, PhD  Mike MacDonald, PhD  Keith Wear, PhD
Jun Chen, PhD  Ravi Managuli, PhD, RDMS  Hua Xie, PhD
Shigao Chen, PhD

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
  o Statistical assumptions underlying the claim must be resolved
  o Dr. Garra to follow up with Dr. Obuchowski offline
  o 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
  o Variance as a function of different variables is available
  o Almost all of the data collected (95%) falls into a ±10% range (grand estimate of performance) for Phase II of the phantom study
  o Measurements were made across three different phantoms, at three different focal depths, across multiple imaging sites
  o There is not a clear trend for net bias though variance is capturing changes
  o Systems, sites, and focal depths were taken into account
• Physicians are concerned about the variance in ultrasound measurements
  o Output variability across scanners is not yet known, but deemed a clinical issue
  o Proposal to set the bar higher at first pass at 5% to be achievable and clinically useful
  o Guidelines needed for creation of a standard phantom for manufacturers to use
  o 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
  o This can be added to the claim; however, a depth reference is needed for clinical use
  o It would be ideal to tighten up the depth range
  o 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
  o Caution voiced regarding pursuit of an arbitrary performance target based on a physical phantom that remains difficult to impossible to manufacture
  o Goal is to develop a simple phantom with an achievable performance that manufacturers can reach
  o Treatment decisions are based on the range of the middle phantom
  o 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 ±5%, with the possibility of <±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:**

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<td><strong>Apr 07:</strong> SWS BC (Dr. Hall, if available)</td>
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