

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

Friday, July 7, 2017; 11 AM CT

Call Summary

In attendance

Brian Garra, MD (Co-Chair)

Tim J. Hall, PhD (Co-Chair)

Andy Milkowski, MS (Co-Chair)

S. Kaisar Alam, PhD

Paul Carson, PhD

Jun Chen, PhD

Shigao Chen, PhD

Elaine Collins, RDMS

Remko Enserink, PhD

Todd Erpelding, PhD, MSE

Steven Fick, PhD

Edward Jackson, PhD

Eleni Liapi, MD, ScM

Mike MacDonald, PhD

Nancy Obuchowski, PhD

Arinc Ozturk, MD

Mark Palmeri, MD, PhD

Stephen Rosenzweig, PhD

Suraj Serai, PhD

Matthew Urban, PhD

Keith Wear, PhD

RSNA

Joe Koudelik

Susan Weinmann

Moderator: Dr. Hall

Review prior call summary: May 5th summary approved as submitted

Statistical Assumptions Underlying Claims

- Proposal claim language based on data from Round 1 of phantom comparisons; focusing on the repeatability of SWS under a variety of imaging systems
- Dr. Obuchowski provided an overview, clarifying the different statistical assumptions underlying Claims and answering the following questions for each Claim statement:
 - Meaning and interpretation
 - Clinical impact
 - Appropriateness for the US SWS Profile
 - Incorporation into the Profile
- The following Claims were discussed:
 1. Technical performance Claim
 2. (a & b) Longitudinal Claims using the same imaging systems at two time points
 - Dr. Garra to discuss stringent 95% confidence interval (CI) with VA hepatologists to provide a possible lower-bar for Claim 2b, e.g. 60% CI suggested
 - A 95% CI may be too difficult for “mainstream” radiologists
 - Statistical rigor deemed overly complex for end-users; numbers (stats) could be replaced with clear example text, e.g. “likely” or “extremely likely” regarding likelihood of change
 3. (a & b) Longitudinal Claims using different imaging systems within the same site at two time points
 - New cut point was included in Claim 3a, e.g. larger change needed to hit 95% CI
 - Suggestion to incorporate instructions on interpreting tables
 - Suggestion to create online app to help users select appropriate rigor of CI, e.g. 95%, 60%
 4. (a & b) Longitudinal Claims using different imaging systems at different sites at two time points (only constant is the patient)
 5. Cross-sectional Claim: The bias estimates from this study are based on the assumption that the consensus mean of SWS measurements obtained at Duke is 5% across multiple systems
 - This type of claim would be the foundation of future alignment efforts across multiple systems; the claim would not of clinical use today, i.e. a “forward-looking claim”
- RSNA staff to distribute this US Claims document to the US-SWS BC roster once minor editing is completed

US SWS Profile

- Dr. Garra provided three categorizations for the Precision Profile and suggested performance be broken down by shear wave (imaging) depth; Dr. Obuchowski to develop Claims based on this data
- Discussion on whether more phantoms are needed; there are viscoelastic phantoms but not elastic ones
- Suggestion to ask for specific feedback regarding real-world/end-user confidence interval levels when releasing the Profile for public comment
 - The RSNA/QIBA announcement will highlight that recipients may forward the request-to-review to all colleagues who may be interested
 - It was noted that a specialized public comment announcement can be sent to subject matter experts for better engagement
 - Dr. Garra mentioned that he would like to share the Profile with VA hepatologist colleagues for end-user (clinician) feedback
 - At a recent conference, the AAPM Ultrasound Elasticity Imaging technical group was alerted that their input on the US-SWS Profile would be requested when it is sent out for public comment
- Dr. Garra to request a clean copy of the Profile needed from Dr. Dhyani

Next QIBA WebEx calls are as follows:

8/4	US SWS BC
8/11	CEUS BC