

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

Wednesday, August 18, 2021; 2 PM CT

Call Summary

In attendance

David Fetzer, MD (Co-Chair)

Stephen McAleavey, PhD (Co-Chair)

Stephen Rosenzweig, PhD (Co-Chair)

Michael André, PhD

Peter Chang, PhD, PMP

Jun Chen, PhD

Todd Erpelding, PhD, MSE

J. Brian Fowlkes, PhD

Timothy J. Hall, PhD

Reinhard Kubale, MD

Viksit Kumar, PhD

Nancy Obuchowski, PhD

Kevin O'Donnell, MASc

Arinc Ozturk, MD

Mark Palmeri, MD, PhD

Matthew Urban, PhD

Michael Wang, PhD, MASc

Keith Wear, PhD

James Wiskin, PhD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Fetzer

Profile Checklist Update:

- The co-chairs have simplified the checklist for ease of use and to encourage adoption
- Dr. Ozturk described his version of the QIBA checklist modified for the NIMBLE trial and explained that sonographers were trained based on the revised protocol
- The overall goal of the Profile is to optimize precision and accuracy by narrowing down the checklist to items that are **required** (essential to meet the claim) vs. those that are **recommended** (considered best practices)
 - The checklist helps minimize bias and variability and is organized by actor
- Efforts to streamline the checklist continue
- Concerns regarding periodic QA, include how often to perform and what requirements to address.
 - Is B-mode QA sufficient?
 - Most sites are not equipped to perform QA on standardized phantoms – per the current checklist, they are to perform their own QC
 - Long-term scanner stability or drift is a concern, but we do not yet know the impact (if any).
- Focus will remain on items that affect technical performance, and expand its usefulness to clinical sites
- Dr. Fetzer expressed concern that some clinical sites might lack technical and financial resources, phantoms, and personnel necessary for periodic QA and conformance to the Profile, which is why streamlining processes is important to reduce the burden for sites; user burden and scanner performance (QA rigor) must be better balanced for implementation
- Dr. Chang (Hologic) noted that manufacturers are regularly adding tools/components to scanners and transducers to ensure better system performance
 - Manufacturer updates can be added to the Profile and Checklist to remain current as changes are made known
- There are potentially hidden “shalls” in the Notes column of the checklist
 - To avoid confusion, the Notes column should reflect helpful notes only, consolidate any hidden requirements into the Requirements column, and Use Notes will be only for clarifying and helpful information
 - Actual requirements will be moved into column C
- The final version will be circulated for BC review as co-chairs work on matching up checklist edits with the Profile; there should be a 1:1 correlation

Next Steps (per Mr. O'Donnell, QIBA Process Committee Chair):

- Clean up the checklist sheet (keep most/all the recommended lines, migrate normative material from Notes into Requirements, clean up any ambiguities)
- Get BC approval of the checklist modifications - possibly via a voice vote
- Resynch the Profile so the table contents match the updated checklists
 - In the new Profile Template, the checklists become the primary representation of the normative requirements
- Circulate the updated Profile & Checklist for formal BC approval (email ballot) – focus on approving technical content of the Profile
- Resolve any ballot comments that come in

- Circulate the resulting Profile & Checklist for formal CC approval (email ballot) – focus on approving the BC is doing everything properly
- Resolve any ballot comments that come in
- Publish as Stage 2: Consensus and move on to Stage 3: Technical Confirmation. (Road test those new checklists.)

Action items:

- Co-chairs will send their latest version of the Checklist (with tracked changes) to the BC for review prior to the next call on September 15th
- Co-chairs will work to match up the Profile text with latest Checklist revisions
- *Future action item*: Some groundwork via a pilot study may be needed to determine the impact of adjustments to test accuracy, reasonable use of QA, and what is considered *required* vs. *too onerous* to include in the Profile and checklist

Profile Approval Process: See voting and balloting process links: <http://qibawiki.rsna.org/index.php/Process>

Next call – *Wednesday, September 15th at 2 pm CT*

09/15	SWS BC – 3 rd Wednesday @ 2 pm CT
10/20	SWS BC – 3rd Wednesday @ 2 pm CT
11/17	SWS BC – 3rd Wednesday @ 2 pm CT