

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

Wednesday, July 21, 2021; 2 PM CT

Call Summary

In attendance

David Fetzer, MD (Co-Chair)

Stephen Rosenzweig, PhD (Co-Chair)

Karen Alton, BS, RDMS, RVT

Michael André, PhD

Paul Barbone, PhD

Richard Barr, MD, PhD

Paul Carson, PhD

Peter Chang, PhD, PMP

Jun Chen, PhD

Manish Dhyani, MD

J. Brian Fowlkes, PhD

Timothy J. Hall, PhD

Rik Hansen, PhD

Reinhard Kubale, MD

Viksit Kumar, PhD

Kathy Nightingale, PhD

Nancy Obuchowski, PhD

Arinc Ozturk, MD

Mark Palmeri, MD, PhD

Michelle L. Robbin, MD

Matthew Urban, PhD

Tomy Varghese, PhD

Keith Wear, PhD

RSNA

Julie Lisiecki

Moderator: Dr. Fetzer

Profile Checklist Update:

- The co-chairs have simplified the checklist for ease of use and to encourage adoption
- Review is underway to modify and shorten the checklist, without losing its core requirements or significantly altering the claims
- Dr. Ozturk has created a slightly modified version of the checklist for the NIMBLE trial and will share the Word document with the co-chairs and BC members
- 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)
- 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 conformance to the Profile
 - It is possible that the current Profile may only apply to scientific research studies
- The intent of the Profile is to ascertain that the systems are in good working order and performing as expected, ultimately improving patient care
- Though quality control checks are performed periodically, it is unknown how often imaging systems would need to be tested to adhere to the Profile
 - If requirements are too stringent, adjustments to the performance claim might be necessary
 - Requirements must be explicit but not so burdensome that they are beyond the scope of quality assurance and ACR requirements
 - It was suggested that 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
- The co-chairs asked for the guidance of BC members, especially manufacturers, to ensure that the Profile will continue to meet performance claims
- Dr. Barbone suggested using wide margins for initial testing and adding a reporting requirement to assess drift, variability, etc., which may offer a solution
 - Acceptable limits could be tightened over time as data would be accumulated
 - Separate reports for necessary requirements and simple “yes/no” responses could be compiled
- Questions could be consolidated to: “Are you following respective manufacturer guidelines?” with less critical items to be eliminated

Action items:

- Dr. Ozturk to share his slightly modified version of the Checklist in Word with the co-chairs and BC members
- Co-chairs will send their latest version of the Checklist (with tracked changes) to the BC for internal comment prior to the next call on August 18th

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

Next call – Wednesday, August 18th at 2 pm CT

8/17	NM CC – August 17 th @ 10 am CT
8/18	SWS BC – 3 rd Wednesday @ 2 pm CT