

QIBA Contrast Enhanced Ultrasound (CEUS) Biomarker Committee (BC) Call

Friday, August 14, 2020; 11:30 AM CT

Call Summary

In attendance

Mike Averkiou, PhD (Co-Chair)

Todd Erpelding, PhD (Co-Chair)

Paul Carson, PhD

J. Brian Fowlkes, PhD

George Kapodistrias, PhD

Zaiyang Long, PhD

Nancy Obuchowski, PhD

Stephanie Wilson, MD

RSNA

Joe Koudelik

Julie Lisiecki

Moderator: Dr. Averkiou

Approval of 07.10.2020 call summary

- The summary was discussed; Dr. Carson has some minor edits re: the use of groundwork or literature to develop claims that either he or Dr. Averkiou will provide

QIBA Profile – In progress

- Discussion centered around the Profile development plan, particularly clinical context and claims
- Consensus was that both a longitudinal claim (for therapy monitoring) and a cross-sectional claim (for lesion characterization) would likely be needed to achieve the desired aims
- Previous CEUS BC decisions included to address liver lesions as the initial clinical application, bolus transit time as the method of analysis, and using linearized data to extract the 4 important parameters, namely, rise time (RT), mean transit time (MTT), peak intensity (PI) and area under the curve (AUC).
- Dr. Fowlkes noted that the methodology is the same in both cases (longitudinal and cross sectional) with two different usages, even though the outcomes are the same
- A cross-sectional claim requires bias of the measurement and precision, or [within-case coefficient of variation \(wCV\)](#).
- A longitudinal claim requires precision, or [within-case coefficient of variation \(wCV\)](#), linearity, and the known slope of the true value vs. what is being measured
- The wCV is needed for both claim types, but slightly different data are required for each
- Dr. Wilson discussed how tumor response using LI-RADS in monitoring patients over time is a valuable technique
 - This work has demonstrated high value without quantification, which makes the argument for quantification difficult
 - While quantification can be done, it likely will not be done due to the extra time required
 - Caution voiced not to disrupt the current LI-RADS standard of care
- CEUS testing is also done to evaluate and track Inflammatory Bowel Disease (IBD) over time and watch the response to therapy, which does involve quantification and the use of many serial exams
 - This is critical for reviewing the therapy response, though it is uncertain how to incorporate this information into this particular Profile
 - Dr. Wilson mentioned that quantification is used with the IBD population in her practice. However, she is perhaps the only clinician doing so. No other centers are known to perform such studies.
- A claim might be considered solely on longitudinal therapy-monitoring studies
- Dr. Obuchowski suggested making the claim as generalizable as possible across applications
 - If precision is constant, it will not matter what the clinical application is, regardless of therapeutic setting
 - If a change is seen that is a measurable and real, it can be quantified
- Dr. Wilson mentioned that variability amongst manufacturers poses significant challenges for clinicians, which is what drew her to the QIBA effort

Next steps

- Dr. Averkiou asked Dr. Wilson to craft a statement of short-term repeatability on two applications, and to see if enough data are available, as well as to consider claim wording for the next BC discussion
- The BC wants to create a Profile that will increase clinical usability and application, showing broad-reaching potential for CEUS quantification
- Help is needed with clarifying the claims, as well as clinical context in particular; clinician input is vital
- Further discussion is needed regarding whether to focus on liver and IBD, or just one topic
- Determination needed re: whether to base US CEUS claims on the phantom study and/or literature
- Recommendation that Claims be statistically based, succinct, and focus on performance; additional details are addressed in other Profile sections

Action items:

- All are asked to sign up for drafting Profile sections using the [Google form](#)
- All are asked to consider the claims and to forward suggestions to the co-chairs: Drs. [Averkiou](#), [Barr](#), and [Erpelding](#), to be discussed during the next call
- Feedback also needed re: whether to use published data (conduct meta-analysis) or the phantom study
- CEUS BC SMEs are asked to attend more calls to provide their diverse expertise
- Participation from BC members with experience with the QIBA Profile-writing process is also crucial

The next scheduled QIBA ultrasound calls will be as follows at 11 am CT, unless otherwise noted:

08/28	US Qtr. 3 Coordinating Ctte	10/02	SWS BC
09/04	SWS BC - breakout	10/09	CEUS BC
09/11	CEUS BC		

RSNA Staff attempt to identify and capture all committee members participating on WebEx calls. However, if multiple callers join simultaneously or call in without logging on to the WebEx, identification is not possible. Call participants are welcome to contact RSNA staff at QIBA@RSNA.org if their attendance is not reflected on the call summaries.

Helpful Resources:

- Examples of **Profiles** can be found on the QIBA Wiki here: <http://qibawiki.rsna.org/index.php/Profiles>
- Link to the **US Shear Wave Speed Profile** – which recently completed public comment: http://qibawiki.rsna.org/images/b/b7/QIBA_US_SWS_Profile_10.21.19.pdf
- **QIBA Profile template:** http://qibawiki.rsna.org/index.php/QIBA_Profile_Template
- **How to Write a QIBA Profile:** http://qibawiki.rsna.org/index.php/How_to_Write_a_Profile
- **Claim Guidance:** http://qibawiki.rsna.org/index.php/Claim_Guidance
- All Profile Editors are encouraged to join the QIBA Process Committee to learn about QIBA writing tips and processes and network with other Profile Editors to exchange best practices

Contact information for QIBA Process Committee:

- Kevin O'Donnell, MASC (Chair): KODonnell@MRU.MEDICAL.CANON