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

Friday, October 9, 2020; 11:00 AM CT

Call Summary

In attendance			**RSNA**
Mike Averkiou, PhD (Co-Chair)	Timothy Hall, PhD	Nancy Obuchowski, PhD	Joe Koudelik
Todd Erpelding, PhD (Co-Chair)	George Kapodistrias, PhD	Douglas Stone, PhD	Julie Lisiecki
Paul Carson, PhD	Reinhard Kubale, MD	Theresa Tuthill, PhD	
Christian Greis, PhD			

Moderator: Dr. Averkiou

Approval of 08.14.2020 call summary

- The last call summary was approved as presented.

QIBA Profile – In progress

- Focus of the call centered around the Profile development plan, particularly clinical context, and claims
- Dr. Averkiou would like to assign sections to potential authors to begin Profile writing
- Claims may be made based on phantom groundwork done or on literature review related to the clinical problem
- Since characterizing liver lesions with CEUS quantification is not used clinically, liver lesion therapy monitoring (longitudinal studies) was chosen as a focus
- With the bolus injection and CEUS quantification, Profile users could gauge certain blood flow properties
- A longitudinal clinical study would be helpful, however, Dr. Averkiou is suggesting a simple claim for version 1.0 of the Profile based solely on phantom data
- This Profile is an important first step which should "describe clearly the imaging parameters, injection method, acquisition, analysis software, and processing," and it will describe which parameters to extract and how
- Dr. Averkiou noted that he reported on the test-retest variability in his recent *Investigative Radiology* manuscript
- There is no information on measurement bias due to no measurement for ground truth
- It may be possible to use deviation from consensus or from the average of all machines instead of bias, though trying to prove various theories may be too much for version 1.0 of the Profile
- Correlating flow rate and other flow measures with time intensity curve parameters may require additional experiments before being able to include those in the Profile
- It was mentioned that also correlating with therapy outcomes is another option
- Dr. Averkiou to look into finding test-retest studies of correlation with the flow
- A simple clinical study to establish good variability measures in patients may be needed in the near future
- Dr. Carson noted that it would be necessary to show that measurements are linear with volume flow and asked the group to consider how the phantom results related to the clinical data
- Dr. Obuchowski suggested that repeatability might translate to a clinical study
- Dr. Hall reminded the group that the Shear Wave Speed (SWS) Profile is based only on phantom data, and though the perception was that SWS is not as reproducible as Magnetic Resonance Elastography (MRE), the Profile has demonstrated reproducibility better than previous clinical perception
    - The goal was to minimize bias and variance in preparation for human subjects
    - It was noted that bias was not due to the machine variability but rather the variance in techniques used by the clinicians, which is an important takeaway
    - Such Profiles can help clinicians in providing better care
- Dr. Carson suggested that obtaining some coffee break data may be helpful to get short-term clinical reproducibility data to compare to phantom measurements, which may not be needed before writing the Profile
- Dr. Averkiou proposed that a vote may be needed to determine which of the following the group should pursue
    1. A Profile based on phantom data, with additional consideration of some clinical work *or*

2. A Profile based solely on phantom data

- Dr. Kapodistrias suggested establishing the protocol first with a more systematic approach to determine what clinical data might be needed in the future
- Dr. Erpelding would like to proceed with the phantom approach
- The current working title for the Profile is – QIBA Profile: CEUS Quantification
    - An Executive Summary has already been written, along with some clinical context for section 2
- Dr. Wilson has expressed interest in including Inflammatory Bowel Disease (IBD), and Dr. Averkiou asked her to provide some clinical context
- The team does not have clinical data at the present time

Next Steps:

- Determining how to formulate the claim(s) and how to address phantom test-retest variability and deviation from consensus, with possible future correlation with flow in phantoms
- Vote amongst BC members on the next call to select/finalize the direction for the Profile
- Dr. Averkiou to prepare an email highlighting discussed options for RSNA Staff to distribute to BC members
- Help is needed with clarifying the claims, as well as clinical context in particular; clinician input is vital

Action items:

- Dr. Averkiou to provide an email asking BC members to vote on the Profile direction going forward
- All are asked to sign up for drafting Profile sections using the Google form
- All to consider the claims and to forward suggestions to the co-chairs: Drs. Averkiou, Barr, and Erpelding
- 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

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

11/12	US Qtr 4 Coordinating Ctte, 11 am CT
11/13	CEUS BC
11/20	SWS BC - TBD
12/11	CEUS BC
12/18	SWS BC - TBD

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 (**QIBA wiki**):

- **Profiles** | **QIBA Profile template** | **How to Write a QIBA Profile** | **Claim Guidance** | **US Shear Wave Speed Profile**
- 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

QIBA Process Committee: Kevin O'Donnell, MASc (Chair): KOdonnell@MRU.MEDICAL.CANON