

PULSE-ECHO QUANTITATIVE ULTRASOUND BIOMARKER COMMITTEE

Agenda for Friday, February 5, 2021 11:00am – 12:00pm

Attendees: Ivan Miguel Rosado-Mendez (Co-Chair), Anthony Samir (Co-Chair), Michael Wang, (Co-Chair), Stephane Audiere, Cristel Baiu, Jeffrey Bamber, Richard G. Barr, Paul L. Carson, Anil Chauhan, Shigao Chen, Yuling Chen, Guy Cloutier, Chris De Korte, Todd Erpelding, Raul Esquivel, Giovanna Ferraioli, David Fetzer, J. Brian Fowlkes, Jing Gao, Joel Gay, Zaegyoo Hah, Timothy Hall, Jean-Pierre Henry, Viksit Kumar, Amy M. Lex, Jonathan Mamou, Ravi Managuli, Lori Mankowski-Gettle, Stephen McAleavey, Andy Milkowski, Kibo Nam, Gary Ng, Juvenal Ormachea, Arinc Ozturk, Theodore Pierce, Stephen Rosenzweig, Jonathan Rubin, Arun Sanyal, Paul Sidhu, Timothy Stiles, Michael Thornton, Theresa Tuthill, Xiaohong Wang, Keith Wear, James Zagzebski, Nancy Obuchowski

AIUM Staff: Kelly Phillips

AS: Anthony Samir

IRM: Ivan Rosado-Mendez

MW: Michael Wang

TOPIC	COMMENTS	ACTION ITEMS
Introduction	Welcome (IRM)	
Summary of Discussion	Summary of Discussion with Vendors (MW)	
Summary of Discussion	Summary of Discussion with Vendors (WW)	

Work Groups	 Work groups progress reports Attenuation WG (VK, AO, RB) Backscatter WG (AH, RL, TT) Sound Speed WG (SR, TP) Phantom WG (TS, DF) 	
Open Discussion	Open Discussion/Wrap up	
NEXT CALL	Date: March 5, 2021 Time: 11:00am, EST	

IRM: Reminder – deadline for US imaging and tissue characterization symposium – abstract due Feb 12 to Dr. Marie Muller at mmuller2@ncsu.edu

- Topics:
- Phantom design and fabrication challenges for biomarker validation
- Historical perspective of biomarkers and current challenges in clinical translation

MW: Summary of Discussion with Vendors -

- Had a call with manufacturers about status of plans for phantom study
 - o reviewed survey responses on what biomarker implementations are commercially available and reviewed the number of sites interested in participating with each biomarker commercial implementation
 - Discussed options for under-represented vendors to increase measurement sites; collecting RF data at sites with existing systems and processing data offline; provide new software to sites with existing systems
 - o Sent follow up questions to get an idea of the level of interest on vendor and site interest
 - Notes to be aware of when answering
 - Assuming that if willing to receive a system, you have the manpower to take the additional
 measurements with that system; For vendors expectation is that you are responsible for setting
 up any confidentiality agreements

- Concern about measurement protocols should be defined by each biomarker WG and should take into account the measurement capabilities of all the vendor systems; please get info from the manufacturers of what the measurement capabilities are
- Discussed financing asking for \$4000 donation from vendors
- Will have further meetings as needed

Attenuation WG -

- VK: Working document to compile thoughts as predecessor to profile document
 - Added technical section, Echosens, Samsung, Hologic descriptions, basic science
 - Characteristics of ROI
 - Minimum window size
 - Spectrum estimation methods
 - Clinical issues discussed
- RB: Should a site look at these parameters to make sure we pick an appropriate ROI size, depth so that we find out before the study has started? Preliminary testing?
 - o AS: Good observation; encourage that we do this
 - o IRM: define measurement protocol for phantom study; if there is lacking evidence, it should be addressed at the beginning and multiple times during the phantom study
 - o GF: ROI and depth some are fixed by manufacturer
 - o LM: Could start evaluations once we receive phantoms at Univ of Wisc
 - o IRM: Strategy to follow Once first draft of the profile is finished identify the gaps of knowledge regarding factors that influence the measurement that need to be addressed in the phantom study; define a measurement protocol around those gaps and the need to validate the claims included in the first profile draft; after identifying which points need to be addressed, include measurement protocol from each vendor in an effort to answer those points in the phantom study

Sound Speed WG -

- TP: Update on literature review -

- o Of the 3 methods for speed of sound calculation, we are half way finished
- o Less thorough review of other techniques, which don't have clear liver imaging or medical applications
- o Received additional vendor survey from Mindray
- o To do:
 - Complete literature review
 - Determine quantitative parameters to narrow down which methods to be focused on
 - UITC Abstract
 - Complete draft of profile
 - Reach out to e-scopics
- o IRM: Has WG started thinking about questions that will need to be addressed and overall strategy for phantom study for this particular biomarker?
 - SR: Focused on discussion of determining the accuracy and precision of methods overall

Backscatter WG -

- TT: Phantom discussion with WG four phantoms
 - Drafted summary document
 - Sections assigned
 - Incorporates literature search
 - Includes aspects for profile
- KW: Frequency dependence f^4 liver backscatter much closer to linear but we decided that its simpler to predict the theoretical backscatter coefficient with f^4 scatterers; Frequency dependence is very complicated; Try to mimic the magnitude of backscatter at a central frequency
- IRM: If we have a narrow distribution of scatter sizes, helpful to use Faran theory as a prediction of backscatter coefficient that can be used as gold standard; If we go with a broader distribution of glass bead sizes, will have to measure the distribution of glass beads in the phantom and could add another layer of variability
 - -BF Faran theory Is the thought that its ok that whatever the target is has a fairly high amount of shear wave contribution within the targets? Need to know all corresponding properties of phantom to make the comparison to Faran
 - o IRM: Yes useful for Backscatter WG to make a list of properties so that we have them ready to be able to make predictions
 - o GC: Still concerned about possibility of shear wave propagation or multiple scattering with glass

- IRM: Has WG started thinking about questions that will need to be addressed and overall strategy for phantom study for this particular biomarker?
 - o TT: will address at upcoming meeting

Phantom WG -

TS: Meeting with Backscatter WG

- Complete phantom plan
 - At 4MHz
 - Normal liver 1 to 10
 - Fatty 30 to 300
- Most phantoms will have beads similar to their usual beads of about 40 micron diameter
- At least one phantom will have ka approximately 0.8 at 4.0 MHz
 - o Diameter of about 100 microns
- Round 1 of this study work will continue on phantoms that mimic tissue thought oil dispersion in gel
- IRM: Decision about material of beads?
 - o CB: I think we should go with glass
 - o TS: Phantoms with smaller beads decided on glass
- IRM: Are we ready for fabrication?
 - o TS: goal for next phantom WG meeting
- IRM will work with AIUM Liver Fat Quantification Task Force in second stage

Open Discussion

- **CONFIDENTIAL INFORMATION:** RB: have applied for a CPT code for liver fat quantification using ultrasound CPT code 3 (no reimbursement, just tracking its use); should be voted on later today, not officially approved until March 8.
- PC: Effect of food on attenuation coefficient should be qualified to be short term food intake as opposed to glycogen quantity
 - -RB: Can address glycogen
 - DF: pending meeting to address related topics; document through AIUM Liver Fat Quantification Task Force regarding the need for ultrasound based techniques, current status, and to start ground work for highlighting the utility of this QIBA effort

- IRM work on a guidelines document
 - RB: Document has been submitted for publication, not accepted yet
- IRM next week is deadline for UITC share abstracts on Basecamp if you'd like feedback
- AS Likely to see delays in contracting be aware
- MW Agree with plan to have a dry run with the protocols before officially starting the study
- IRM Goal is for phantom study to start in summer; each WG needs to define the questions that need to be addressed in the phantom study, to fill the gaps about accuracy, precision, reproducibility, define measurement protocol that will address those questions suggest each WG add to next call agendas