QIBA Ultrasound Shear Wave Speed (SWS) Biomarker Committee

Friday, April 10, 2015; 11 AM CT Draft Call Summary Notes provided by Dr. Garra

In attendance RSNA

Brian Garra, MD (Co-Chair)Manish Dhyani, MDMark Palmeri, MD, PhDJoe KoudelikTimothy J. Hall, PhD (Co-Chair)Steven Fick, PhDAnthony Samir, MDJulie LisieckiKaisar Alam, PhDGilles Guennette, RDMS, RDCS, RVTDaniel Sullivan, MD

Richard Barr, MD, PhD Zaegyoo Hah, PhD, MBA Theresa Tuthill, PhD
Paul Carson, PhD Mike MacDonald, PhD Matthew Urban, PhD
Jun Chen, PhD Stephen McAleavey, PhD Keith Wear, PhD
Wui K. Chong, MD Yasuo Miyajima, MS Russell Witte, PhD

David Cosgrove, MD Wayne Monsky, MD, PhD

Moderator: Dr. Garra

1. Call Summary Review—no changes

2. Phase II phantom study testing—status and remaining sites.

The status of the phase II phantom study was reviewed. Richard Barr has the second set of phase II phantoms and will forward them to Brian Garra for testing at the VA using the Philips system. After completion the phantoms will go to MGH. The first set of phase II phantoms currently are at Wisconsin and Tim Hall will ship them to MGH where Manish and Anthony will scan them. After MGH completes scanning, all phantoms will be shipped to Duke for recheck, then on to Steve McAleavey at Rochester and finally to Glen McLaughlin for data acquisition. Dr. Samir noted that originally scanning at Boston was to include the Fibroscan, but after discussion with Echosens, it was determined that the Fibroscan would likely damage the phantoms; so, Fibroscan acquisition will be deferred. A new less-damaging instrument is in the works but will not be available for some time.

A log will be kept on the WIKI for each site to record when they have completed scanning. It will be under the US SWS tab -- <u>Combined System Dependencies/ Phantom Task Force</u> page.

- 3. Phase II data processing and data storage In this discussion it was noted that the results are currently being stored in a Box account created by Paul Carson. Most if not all sites received information on accounts.
- 4. Phase I phantoms location for testing. The phase I phantoms are currently in Boston. They will be shipped to DC for scanning there. Tim Hall mentioned that numbers of the phase I phantoms scanned in DC should be recorded so that he could keep track of which phantoms were scanned.

5. Updates on projects

- a. Clinical studies—Dr. Samir gave an overview of the project currently underway—the round IV study NIBIB funded which aims to evaluate the importance of acquisition settings and procedures on SWS results. Patients are being recruited with some difficulty and will be scanned with SSI and Siemens systems. In these acquisitions, radio-frequency data will be also acquired for study by other investigators wanting to test algorithms on real clinical data.
 - This study succeeded the round III funded project which studied about 200 patients exploring the effects of clinical confounding factors such as fatty infiltration and liver inflammation on SWS. Those results are currently being analyzed.
- b. **Simulation studies** Mark Palmeri discussed the creation of simulated RF data using two FEA programs—LS Dyna and Abacus. These calibrated data sets are to be provided to manufacturers for them to adapt to their

algorithms and to test their algorithm's performance Data for 48 configurations have been created and are currently being validated at Duke. These data are intended to simulate data from a purely elastic phantom. A later set simulating RF from a visco-elastic phantom will be created and made available next. At RSNA several manufacturers agreed to look at the simulated data and determine if they had the resources to modify it to fit their processing software. A representative from each company willing to participate has been identified. Echosens, Siemens, Philips, GE, Toshiba, SSI and Samsung have all agreed to participate. This project is being conducted with Round IV NIH funding.

- 6. **Upcoming meeting presentations, papers to write**: Two abstracts have been submitted to IEEE regarding the simulated data and testing using this data by manufacturers. The RSNA poster deadline has passed; so, obtaining space for a second poster to cover new US QIBA activities and biomarkers will not be possible. Some of the new biomarker material can be added to the existing SWS poster material without difficulty. Tim Hall noted that he was responsible for the Phase I paper but working on the document had been delayed. A discussion about other possible presentation venues yielded the ITEC meeting scheduled for 9/20-24/15. A call for abstracts has not yet gone out. Another venue is the UITC meeting in June. Although the deadline for abstract submissions had long passed, Mel Linzer will be asked if he can accommodate one or two additional presentation on SWS. Kaisar Alam will guery Dr Linzer. (Later that day Mel Linzer agreed to allow one or two additional presentations.)
- 7. **Status of Profile Writing**—Brian Garra discussed the status of the SWS profile. The profile has been outlined using the standard template. He noted that the bulk of the document will be written by the profile team (Garra, Dhyani and Samir) but many people will be asked to review sections. He noted that a draft should be ready for review by the QIBA Annual Meeting in May. He also mentioned that the QIBA claims section had already been drafted and will be brought up-to-date.
- 8. Quick review of status of new QIBA projects—Paul Carson summarized activities at AIUM where a number of potential new biomarkers were discussed. Four potential technologies were selected for further review: Contrast Dynamics (working group headed by Richard Barr), Pressure evaluation in large blood vessels using Flemming Forsberg's technique, volume flow using the technique promulgated by Jon Rubin, and spatial measurements. Each group is expected to submit a short white paper for evaluation at the end of April so that a final decision on one or two new biomarkers can be made and preliminary proposals made at the steering committee meeting May 5.

The discussion of funding evolved into a discussion regarding how much of the NIBIB funding would go towards new biomarkers and how much to continue the SWS work. Paul Carson envisioned an approximately 50:50 split between SWS and new biomarker funding.

Prior to adjournment, Tim Hall suggested changing the 15 May meeting to May 1 so that further discussion could be had prior to the QIBA Annual Meeting. This was agreed to. The May 15 meeting will be canceled unless a need arises after the Annual Meeting.

9. Adjourn—at 1:05 PM ET

Upcoming Ultrasound SWS Calls (Fridays, 11 am CT):

- April 24: Clinical Applications Task Force (Dr. Samir)
- May 1: US SWS Biomarker Committee (Dr. Hall)
- May 8: No call (Day after QIBA Annual Meeting)
- May 15: No call
- May 22: System Dependencies/ Phantom Task Force (Dr. Wear, if available)
- May 29: Clinical Applications Task Force (Dr. Samir, if available)