

## QIBA Ultrasound Volume Flow Call

Monday, April 6, 2020 at 12:30 PM ET

### *Draft Call Summary*

#### **Approval of previous call summary**

Summary not available.

#### **Update:**

- The revision manuscript is still in review and waiting on response back from *Radiology* review.
- Abstract from Rubin et al scheduled for presentation at AIUM on Volume Flow Measurements in Umbilical Cord. Comparisons of 2D spectral Doppler and 3D volume flow method
  - Results were positive. The reproducibility (coefficient of variation) of the 3D method was better by factor of ~2.5 over the 2D method. Presentation has been recorded and waiting on AIUM to post at the end of the month or early May. Will forward information as we get it.
- Brian Fowlkes that if there are any other VF abstracts or presentations being completed, please let him know so that the group can be updated.

#### 1. Funding mechanisms for additional QIBA groundwork studies for the future

- It was reported that the QIBA Coordinating Committee and Steering Committee recently met Both discussed possible mechanisms for supplemental funding from the NIH and BCs are encouraged to strategize on this. These supplements require existing R grants, likely R01.
- Baylor College of Medicine and University of Michigan have a collaborative R01 with NIH Perinatal Branch in Detroit – This might be a possible opportunity to request supplemental funding.
  - Single ultrasound platform being used for this fetal imaging but there may be potential to expand
- Jon Rubin has an R21 Grant on placental flow and intraureterine growth restriction but not sure if R21 will qualify for these supplements. Volume waveforms might be used for measuring transfer function effect of the placenta as being examined in this grant.
- QIBA is looking broadly for funding mechanism that will allow additional ground work studies or funding to move QIBA profiles along through various stages.
  - Particular for confirming technically confirmed profile.
  - There may be opportunities within a current NIH to ask for a supplement to expand QIBA activities within such.

#### 2. Strategies for trying to move the profile forward

- Brian Fowlkes gave an overview of the current status of the profile.
  - Very early stage development
  - Clinical applications previously proposed
    - Umbilical cord flow
    - Dialysis graft flow

- Need to determine what claims might be possible.
  - Tim Hall explained the reasons for the range of claims in the SWS profile
    - Depth dependence
    - Range of tissue stiffness
  - Tim suggested that for volume flow there may be performance limits based on vessel size.
  - Current recommendation for developing claims has circled back to making more general claims in performance such that contract research organization (CROs) can manage getting certified as profile conformant.
  - So suggesting point spread function to vessel size relationship may be useful.
  - QIBA phantom study might suggest the parameters that would define performance limitations.
  - Jim Jago commented that it would be useful to have rationale in the profile as to why the claim is defined as it is.
- Reproducibility of 2D method is good in highly trained personnel. It may not be as good more broadly.
- Clinical input will be needed to determine what level of accuracy is required for clinical decisions.
- Brian Fowlkes asked for volunteers interested in working on the profile. They should contact him offline.
- Profile needs to be updated to include specifics learned from groundwork studies.
  - Literature review
  - QIBA phantom study submitted to *Radiology*
- Need a subcommittee to work on updating the profile – Possibly carve out sections to work on so that it is more manageable.
- Paul Carson suggested that some of the background work on 2D method performance could be done by others.
- There is also opportunities for developing QA procedures that could be an area where some will want to work.
- There will be need for individual performance protocols for the various systems.
- Paul Carson suggested that section 3.9 could be drafted early.
- Brian Fowlkes will send the qibawiki link for the profile template and the current SWS profile.
- Tim Hall suggested that there are a variety of profile examples that are at various stages.

#### Additional Discussion

The SWS manuscript is being submitted elsewhere (not *Radiology*) as that journal is requiring the identification of the manufacturer which was not the position of QIBA and the understanding of the manufacturers. This may affect how future reporting is done and the future selection of biomarkers. This may also affect manufacturer participation and drive the QIBA activities to only those where the methodology is commercially available. There was considerable discussion of this topic.