



## AIUM/QIBA Ultrasound Volume Blood Flow Biomarker

### Summary 04-October-2021

#### Attendees:

Brian Fowlkes, Jim Zagzebski, Jing Gao, Stephen Pinter, Jim Jago, Jonathan Rubin, Megan Russ, Michelle Robbin, Nicole Lafata, Oliver Kripfgans, Paul Carson, Rimon Tadross, Shriram Sethuraman

AIUM Staff: Therese Cooper

#### Action items in red.

1. Review of Previous Call Summary – Not available at the time of the meeting. Will be posted later for comment.
2. Action Items
  - 2.1. New phantom drawings should be coming from Cristel soon reflecting suggested changes by the profile working groups.
    - 2.1.1. No drawing were available for this meeting. It was noted that the stenosis was eliminate from the planned phantom design.
    - 2.1.2. **Cristel to provide for the upcoming profile task group meetings in the month of October.**
  - 2.2. Abstracts for Groundwork Studies.
    - 2.2.1. Brian provided an update of the related NIH study that may provide data considered as groundwork for 3D VBF. This is in the application of umbilical venous flow.
    - 2.2.2. **Again, if you have an idea for an abstract let Brian know.**
  - 2.3. Brian reported that there were no updates concerning possible supporting data from Dr. Zonnebeld so we may have to determine if there is any option here.
    - 2.3.1. **Brian to determine if there is any use in further pursuing this.**
3. Update on VBF Profile Discussions
  - 3.1. Review of current draft and updates from Profile Task Group

- 3.1.1. Discussed the need for a follow-up article to the Radiology publication where the statistical basis of the profile claims could be presented in detail.
  - 3.1.1.1. Need to determine if this is to be pursued and in what form it would take. This would in part be based on the length of the document needed to detail this properly.
  - 3.1.1.2. Brian indicated that he was discussing this with Oliver who has the materials associated with such an article.
  - 3.1.1.3. Pursue the writing of such an article.
- 3.1.2. Further discussed how to define pulsatile flow vs. constant flow.
  - 3.1.2.1. Jon Rubin discussed his quick review of the umbilical venous literature finding that at least one case was considered abnormal at an RI of 17%.
  - 3.1.2.2. Jon Rubin to identify the references that could underpin any threshold.
  - 3.1.2.3. Discussed the different methodologies for handling pulsatile flow and decisions that might determine when a given type of flow is present.
  - 3.1.2.4. Discussed the pulsatile setting in the current phantom. Cristel noted the multiplication factor for the phantom in determining the average volume flow.
  - 3.1.2.5. Discussed the level of pulsatility that would determine if pulsatile or constant flow performance can be expected.
  - 3.1.2.6. Acceleration has also suggested as a possible approach to evaluate if the acquisition is sufficiently fast. Todd E. said that the Canon scanner has an acceleration metric. But there may not be sufficient literature to establish a threshold for identifying constant flow.
- 3.1.3. Discussed the possible modification to the profile concerning imaging near a stenosis
  - 3.1.3.1. Some data in the Radiology paper may inform how far downstream from a stenosis would provide for a given performance metric.
  - 3.1.3.2. Jon Rubin pointed out that in theory the methodology should work.
  - 3.1.3.3. Discussed conditions that might affect performance, e.g. theoretical vs. practical performance.
  - 3.1.3.4. Oliver to revisit the data from the Radiology paper to examine any performance differences that be indicated by the change in distance from the stenosis.
  - 3.1.3.5. Brian to look for the terms of laminar, symmetric, parabolic, etc. to make sure these are used correctly.
- 3.1.4. Discussed QA measurements and the type flow phantom that would be needed for a given use.
  - 3.1.4.1. It was decided that a conventional, straight tube phantom could be used for periodic QA test (see changes to 3.5.2 Specifications)
  - 3.1.4.2. Need to be mindful of the depth range of any phantom based on Doppler sensitivity tests and the current commercial phantoms in comparison to the QIBA specifications.
  - 3.1.4.3. Also need to ensure that the blood mimicking fluid has the appropriate backscatter for Doppler testing.
  - 3.1.4.4. More complex phantoms may be useful for training.
    - 3.1.4.4.1. This is particularly important for the “train the trainer” paradigm.
    - 3.1.4.4.2. Brian to add comments to profile indicating this usefulness.

- 3.1.4.5. Testing by the companies would require a more complex phantom to make sure the selected method is robust in a variety of flow conditions.
- 3.1.4.6. Discussed calibration of volumetric flow in phantoms.
  - 3.1.4.6.1. Depends on the design of the phantom (open vs. closed)
- 3.1.5. Need to reach a point with the profile to reach public comment.