

AIUM/QIBA Ultrasound Volume Blood Flow Biomarker

# MINUTES 2016-02-01

## Attendance:

P. Carson, S. Chen, D. Dubberstein, J. Gao, T. Hall, O. Kripfgans, R. Leichner, M. Lockhart, T. Lynch, R. Managuli, K. Minton, S. Pinter, J. Rubin, R. Tadross, M. Trew, T. Tuthill

## I. Profile and Protocol review and subcommittee formation

## Profile:

- 1. QIBA guidelines for profile and protocol creation were reviewed.
- 2. Committee members were encouraged to join the profile/protocol subcommittee headed by Brian Fowlkes.
- 3. A preliminary draft document was provided by Brian Fowlkes.
- 4. The profile document presents the metric, *i.e.* what measurements are being undertaken and information regarding current best practices. In the protocol document, manufacturers specify how to make those measurements on their systems, *i.e.* what are the important configurations, parameters and what are the requirements for each system in order to minimize bias, variance etc. Ultimately to the extent that these descriptions can be generalized across all platforms, they would be inserted into either the general profile and/or the general protocol. The idea is that manufacturers get enough information to know exactly what is being measured so that they can approach the problems with different implementations and/or basic ideas. The information can include guidelines for consensus estimates on known phantoms and variances among the group of manufacturers. So there can be lots of free parameters in the measurement that one is approaching. Particular individuals such as Paul Carson can be excellent resources for our committee along with guidance from existing profile documents that reside are on the QIBA Wiki.
- 5. The question is raised, if one could ask the QIBA steering committee to accept a change in focus and address large vessels in the profile as opposed to specific kidney transplants, yet keeping kidney transplants as a means of verification *in vivo*. Tim Hall agrees in part that as long as one is restrictive to the measurement, and one needs to keep in mind or draw from experience of the other applications.
- 6. 'Current Best Practices' does not refer to clinical practice but to what one has accomplished in their research, *i.e.* a volume flow measurement, UM has shown it works in various cases. Tim Hall adds: It's enough information to get it out into the community, so that they can provide feedback on what the profile states.

It doesn't do much good to put the profile out for public comment if it's not available in several laboratories for people to try it.

### II. Phantom design review

- A tool was introduced that was designed to build geometric 3D tube objects including straight segments, angles, and spirals. These objects can have elliptical cross-sections and tapers. A plastic 3D model in the shape of a corkscrew was presented. This model could be implanted into a poured agar or other phantom and then removed after the mold solidifies. Narrowing and subsequent widening segments could simulate stenoses. Each side of the stenosis is reached by a corkscrew vessel geometry. The point of convergence of the two corkscrews would represent the stenosis. The corkscrew curvatures on each side of the stenosis should reflect some anatomical vascular geometry. The corkscrew model would be printed on a 3D printer. The current model does not pertain to anatomical dimensions; therefore input was solicited from the committee to contribute proper dimensions that are realistic to the case of a renal transplant.
- 2. While lumen diameter and curvatures are found as distributions in vivo, the goal is to obtain measurements in up to the 10<sup>th</sup> or 5<sup>th</sup> percentile not more. Jing Gao agreed to supply literature on kidney transplant vessel geometries (and has subsequently done so, now uploaded to wiki). No consensus was reached with respect to percent stenosis to be simulated.
- 3. Input and output flow connections would need to be designed to fit the helical entries into the phantom. This could be a sleeve, x% larger than the lumen. The phantom will be tubeless, however, arterial lumens have a certain elastic response to the pulsatile flow and this might require a certain stiffness in the phantom or in the immediate phantom materials lining the lumen, *i.e.* a tube like structure. Moreover, arterial walls have different speeds of sound that are not taken into account as well.
- 4. UAB does 225-250 kidney transplants a year.
- 5. Arterial walls could be possibly made out of polyvinyl alcohol, some other hydro gel, gelatin, or rubber (urethane). Hoyt *et al.* (Journal of Ultrasound Medicine, 2009) was recommended as a reference regarding phantom construction. An incremental design maybe the best initial trade-off.
- A cross-reference to lumen diameters in umbilical arteries was suggested. A cross sectional study of 200 patients with singleton gestations, 12 23 weeks gestational age authored by Pridanik *et al.* stated that the mean umbilical arterial diameter was 3.26 mm with the smaller of the 2 arteries averaging 1.43 mm (0.8 2.3mm) and the larger averaging 1.66 mm (0.9 2.8 mm).
- 7. Known or agreed upon parameters:
  - depth of measurement: 3 6 cm
  - volumetric flow rate: 400 mL/min (normal), minimum required was as yet determined
  - angle of incidence:  $0 30^{\circ}$ , 0 being straight down the lumen
  - lumen diameter: 3 9 mm

• overlying tissues: abdominal wall, fascia, kidney parenchyma, hilum of the kidney, vessel.

- ditto: sometimes, depending on kidney orientation: abdominal wall, fascia, vessel.
- 8. <u>Action items</u>: Obtain best estimates on: speed of sound in arterial walls, attenuation coefficient in arterial walls and intervening tissues, and elastic modulus of arterial wall.

III. Previous minutes: Approved by Rubin and Dubberstein.