QIBA Diffusion-Weighted Imaging MR Biomarker Committee (BC) Call

Thursday, April 16, 2020 at 2 p.m. (CT)

Call Summary

Participants			**RSNA**
Thomas Chenevert, PhD (Co-Chair)	Daniel Margolis, MD	Savannah Partridge, PhD	Joe Koudelik
Amita Shukla Dave, PhD	Nancy Obuchowski, PhD	Brian Taylor, PhD	Susan Stanfa
Dariya Malyarenko, PhD			

Moderator: Dr. Chenevert

Review of Previous Call Summary

- The notes from the March 19, 2020 DWI BC t-con were approved as presented

Invicro-QIBA Profile (Self-attestation) Conformance Update

- An overview of the process used to test the DWI Profile checklist to achieve conformance was provided
- Profile conformance was demonstrated using the DWI (ADC) ice-water phantom
- Invicro scanned a phantom at their London imaging site, recording multiple metrics, provided real-world user feedback, and generated a thorough performance report
- The report was used to create a template to be used by other sites that seek SA-conformance; this will help simplify the process and facilitate greater adoption of the DWI Profile
- The SIG reviewed the process, checked the report for completeness, received feedback from the DWI BC subject matter experts and met to discuss whether procedures were successfully followed
- The registration confirmation letter (Conformance Statement) was published on a dedicated QIDW page with restricted access (to QIBA and SIG leadership)
- Invicro to pursue CRO conformance by overseeing the imaging and data analysis of three imaging sites
    - New criteria are needed re: CRO conformance, e.g., data analysis procedures and software package must be considered; modified actor checklists may be required

VERDICT/ Prostate Imaging Reporting & Data System (PI-RADS) v3

- Authors of VERDICT (Radiology 2019; 291:391–397) are interested in collaborating with QIBA, to perform additional within-subject coefficient of variation (wCV) analysis of their data
- The group is considering condensing a multi-parametric approach, possibly invoking the DWI Profile and protocol
- The hope is that VERDICT would be willing to perform analysis with a range of b values in their acquisition
- Intracellular volume fraction (FIC) was mentioned, which is a diffusion technique that purports to determine the cellularity of a voxel
- It was noted that prostate has the largest wCV, though the VERDICT dataset is large and could be grounds to revise the prostate wCV ADC estimate
- The QIBA white paper on test-retest in DWI and DCE-MRI was referenced: Shukla-Dave A, et al. **QIBA recommendations for improved precision of DWI and DCE-MRI derived biomarkers in multicenter oncology trials**. *J Magn Reson Imaging*. 2019; 49(7): e101-e121
- Because bias could not be determined at the time the DWI Profile was first being drafted, a longitudinal Claim was used rather than a cross-sectional (cs) Claim; however, a cs Claim could now be possible by establishing bias using a phantom
- A stronger quantitative element is being advocated for PI-RADS v3; ADC, biopsy results, DROs and phantoms could be used to evaluate bias to inform a cs Claim in the next version of the DWI Profile
    - A physical phantom can be used for mono-exponential work/metrics, whereas a DRO will be needed for exponential metrics

- PI-RADS has been designed to be straightforward for the average radiologist to help qualify study sites, therefore a simpler assessment of ADC with lower b values, and applicability to legacy hardware would be needed
- The next version of PI-RADS needs to include baseline and advanced quantitation levels of performance to provide more value to the community; ADC could be used to help raise/lower suspicion of prostate lesions
- Additional discussion needed re: what would be involved to develop cs Claim for prostate
    - The bias of the measurement would need to be determined, which could be done if a phantom could be used to reasonably provide an estimate
    - Suggestion to assess bias using a DRO
    - Other factors that might affect bias to be determined and estimated as well, e.g., different hardware, technique, etc.

- Discussion re: diffusion phantom work done by the Breast Imaging Research Group at the University of California, San Francisco led by Nola Hylton, PhD
    - Breast diffusion phantom designed at UCSF in collaboration with Kathryn Keenan, PhD (NIST) and Elizabeth Mirowski, PhD (Verellium, LLC, formerly QalibreMD)
    - Sites are considering low-cost alternatives for obtaining phantoms
        - A rental/lease model may be an option for clinical trials
        - Suggestion to use a simpler phantom design that would reduce fabrication costs, but remain robust and reliable and work with a stream-lined protocol
        - Screening, diagnostic and treatment response areas of the field are interested in using a larger sample of scanning subjects to avoid false positives
        - Identification of lesions would benefit from better reads, e.g., fewer false positives
        - Non-contrast screening is another emerging area for diffusion; avoiding DCE-MRI, which would make scanning safer, faster, and more affordable

- Dr. Margolis stated that he/the Society of Abdominal Radiology are interested in learning if there is anything that can be done to support the efforts discussed

Next DWI-MR BC Call: Thursday, May 21, 2020 at 2 p.m. CT
