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

Thursday, March 19, 2020 at 2 p.m. (CT)

Draft Call Summary

Participants RSNA Michael Boss, PhD (Co-Chair) Amita Shukla Dave, PhD Savannah Partridge, PhD Joe Koudelik Dariya Malyarenko, PhD Kristina Sergunova Rajpaul Attariwala, MD, PhD Susan Stanfa Daniel Margolis, MD Brian Taylor, PhD Yoganand Balagurunathan, PhD Nancy Obuchowski, PhD Lisa Wilmes, PhD Ishtiaq Bercha, MSc

Moderator: Dr. Boss

Review of Previous Call Summary

• The notes from the December 19, 2019 DWI BC t-con were approved as presented

DWI Consensus Profile Votes and Publication

- After final edits were made, the Profile was ready for a BC vote to publish it as Stage 2: Consensus
- Dr. Boss made a motion to approve, seconded by Dr. Chenevert, during the December 19, 2019 DWI BC call; this in-person BC vote passed successfully with 8 yeses, 0 abstentions, and 0 noes (n=8)
- The MR CC e-ballot vote passed unanimously with 13 yeses (n=13) and the Profile was published on the <u>Profiles</u> QIBA Wiki page on Jan. 14 as Stage 2: Consensus
- After it was finalized, the <u>DWI Public Comments #2 Resolution Sheet</u> was published on the QIBA Wiki

Planning for DWI Profile Paper

- Discussion occurred, re: Kinahan PE, et al. <u>QIBA Profile for FDG-PET/CT as an Imaging Biomarker Measuring</u>
 <u>Response to Cancer Therapy</u>. *Radiology*. 2020; 294:647-657.
 - The manuscript was a digestible summary of the various FDG-PET Profile sections
 - Overall goal was to promote the QIBA NM efforts and better engage the radiology community
 - It was noted in the paper that the Technically Confirmed Claims were informed by a review of the literature, but were not independently verified by a prospective study that conformed to the Profile
- Dr. Kinahan's paper will be used as an outline for the DWI paper
 - The Profile will be highlighted, including Claims across organ systems, imaging artifacts and new techniques
 - The paper can be written as a guide for new users, demonstrating standards and advanced methodology
 - The imaging community needs to know what QIBA and the Profiles have to offer
- All participants in DWI Profile paper efforts would be listed as co-authors and given credit for their contributions
- The QIBA white paper on test-retest in DWI and DCE-MRI was referenced: Shukla-Dave A, et al. <u>QIBA</u>
 <u>recommendations for improved precision of DWI and DCE-MRI derived biomarkers in multicenter oncology trials</u>.
 J Magn Reson Imaging. 2019; 49(7): e101-e121.

Planning for DWI Profile Stage 3: Technical Confirmation

- Quality control steps in Section 4: Assessment Procedures, will be the focus and it will be determined whether
 protocol specifications are feasible/can be implemented at various sites
- Stage 3 completion and writing the DWI Profile paper may proceed in parallel
- Academic sites to confirm whether they can adhere to specifications listed in Section 3.6: Protocol Design for brain, liver, prostate and breast
- Checklist containing all actors to be evaluated for feasibility by sites with expertise in a particular organ

- Suggestion to consult outside perspectives on checklist feasibility by enlisting sites that have not been actively participating in DWI BC activities
- Dr. Margolis noted that a phantom would be useful for testing interscanner variation across all Weill Cornell scanners (including two major vendors on site, with a third at another location); Dr. Dave agreed to loan Memorial Sloan Kettering Cancer Center's ice water DWI phantom
- It was noted that Dr. Russek (NIST) will be implementing a diffusion phantom lending library; there would be a domestic rental fee of a couple hundred dollars (details unknown re: international lending)
- In the private sector, RadNet, Inc. oversees a couple dozen magnets; a colleague of Dr. Margolis would like to standardize DWI imaging and utilize a phantom for cross-scanner calibration
- Discussion to continue offline and DWI BC members will be updated during an upcoming call

Recent Development re: Invicro-QIBA Profile Conformance

- In response to the SIG Pharma letters sent last year, one iCRO (Invicro) responded with interest re: conducting conformance testing for the DWI-MR Profile
- Drs. Chenevert and Malyarenko at Univ of Michigan helped to obtain DWI phantoms, as well as software analysis tools)
- All Invicro self-attestation (SA) activities were completed, a site checklist was reviewed, and a DWI Profile Conformance test report was created
- By following the Profile checklist, conformance was demonstrated using the DWI (ADC) phantom
- Invicro is drafting a summary report for QIBA/SIG review and will facilitate additional testing by engaging three additional imaging sites in the UK (using GE, Philips and Siemens scanners)

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

- The group is considering condensing a multi-parametric approach, possibly invoking the DWI Profile and protocol
- 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
- Dr. Margolis reported that 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
- 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
- Dr. Margolis to follow up with PI-RADS Chairs regarding a joint PI-RADS/QIBA effort and report back to the DWI BC

Next DWI-MR BC Call: Thursday, April 16, 2020 at 2 p.m. CT

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