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QIBA PET-Amyloid Biomarker Committee
Friday, August 14, 2020 at 9 AM CT
Call Summary
Notes provided by Dr. Smith

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In attendance: **RSNA**

Dawn Matthews, MS (Co-chair)   Tammie Benzinger, MD, PhD   John Sunderland, PhD   Joe Koudelik
Satoshi Minoshima, MD, PhD (Co-chair) Rachid Fahmi, MSc, PhD   Daniel Sullivan, MD   Julie Lisiecki
Anne Smith, PhD (Co-chair)   Adriaan Lammertsma, PhD   Jean-Luc Vanderheyden, PhD
                                       Nancy Obuchowski, PhD   Richard Wahl, MD

Moderator: Dr. Smith

Review of the PET amyloid/tau climate:
- FDA is fast-tracking the Biogen anti-amyloid submission
- Recent findings show possible impact of anti-amyloid therapeutic on ptau217, which has in turn been found to be a specific biomarker for AD
- Increasing body of work showing a linkage between amyloid accumulation and tau spread
- Although plasma-based diagnostics are primarily used due to lower cost, imaging will be needed and may benefit from more stringent QIBA requirements
  - Diffuse type vs. other forms of plaque may be better sorted using imaging
  - There is the possibility that patients may be identified earlier, allowing for better treatment

Profile Progress:
- Recent progress made on the DRO up to this point
  - First iteration of the 30 volume DRO was tested and feedback given
- Planned improvements to the DRO
  - Based on above feedback, next iteration of DRO will change
    - GM/WM SUVRs will be as we specify (were inverted in iteration 1)
    - Noiseless volumes for each GM/WM will be included
    - Added noise will be reduced reflecting better SNR from modern PET scanners
    - MR volume will be included to help registering to common atlas space
- Publish Profile in a suitable journal
- Updates will be made to the checklist to provide a more user-friendly format and volunteers will be contacted to test the checklist

Profile 2.0 Discussion:
- Additional updates on PET tau tracers
  - Tracers with FDA approval
    - Tauvid (flurotaucipir, AV1451) - one of the better ones, but not the best.
      - Label is a visual read, but use display thresholds
      - Has off-target binding
      - 1st generation tracer
      - Need to clarify which tau is being targeted
    - WUSTL (Dr. Benzinger) doing comparisons between tau tracers (e.g. PI2620) on same patients – will publish
  - How different is the acquisition and analysis from the amyloid?
  - Best for PET tau tracers to have their own QIBA Profile
    - Group decided it should not be combined with PET amyloid in a Version 2.0
      - Would need its own Profile
  - Off-target binding for tau tracers is an issue
    - Each tau tracer is different.
    - May not be easy to get a general protocol/Profile
    - Much different than the amyloid tracers (derived from PiB)
      - Target different tau proteins
      - Cannot do a single static image; there are many more caveats

- DRO Improvements to work on in a Version 2.0 of Amyloid Profile
  - Test-retest data for DRO
  - Simulate different head orientations of the same patient
  - Simulate different patients
    - Different uptake
    - Different anatomy
  - If different manufacturers have different gray/white matter ratio slopes, those values must be added when estimating change
  - This may require follow up with Dr. Obuchowski
  - Dr. Minoshima noted that changes may be necessary for version 2.0 of the Profile that take variations into consideration, so that realistic individual variations, both physiological and physical, are represented
    - Test/retest data are needed to determine precision and can be created using the various DROs

Reference for FDG-PET Profile Article in *Radiology*

Kinahan, Paul E., Eric S. Perlman, John J. Sunderland, Rathan Subramaniam, Scott D. Wollenweber, Timothy G. Turkington, Martin A. Lodge, Ronald Boellaard, Nancy A. Obuchowski, and Richard L. Wahl. "The QIBA profile for FDG PET/CT as an imaging biomarker measuring response to cancer therapy." *Radiology* 294, no. 3 (2020): 647-657. https://pubs.rsna.org/doi/full/10.1148/radiol.2019191882

- Dr. Wahl suggested to get a peer-reviewed article published about the PET Amyloid Profile in *Radiology* or the *Journal or Nuclear Medicine* to promote use of the Profile
- While availability on the wiki is helpful, broader distribution and advertising for the Profile are recommended
- Following the white paper format / template used by the FDG-PET team was suggested, as well as considering potential consumers

Action items

- Ms. Matthews to follow up with Dr. Pierce and Mr. Byrd
- Dr. Smith or Ms. Matthews to add a note in the Profile indicating that the data are simulated to ensure that no questions are raised pertaining to HIPAA regulations
- Ms. Matthews to reformat the Profile checklist from Excel to Word for ease of use

Next Steps (ongoing)

- Ms. Matthews to get in touch with Drs. Minoshima and Wahl regarding site testing
  - Actor-specific checklists to be distributed to participating sites
  - Ms. Matthews may also contact Drs. Sunderland and Subramaniam
- It was agreed that there would be no BC call in September to allow for additional DRO updates and testing of iterations with noise level
- A call will be planned for October or November when Profile v 1.0 is finalized; one more review is needed
- The group is considering proposal of a new BC on Tau, or an extension of the existing PET Amyloid BC
  - More specialized expertise would be needed for a Tau working group
  - Leadership to consider possible experts to invite in September, if agreed

QIBA Nuclear Medicine Schedule:

08/27	NM Coordinating Ctte @ 2pm CT
09/25	NM Leadership @ 9 am CT – TBD