QIBA Process Committee Call

Tuesday, March 2, 2021 at 2 pm (CT)

Call Summary

Attendees:			**RSNA Staff:**
Kevin O'Donnell, MASc (Chair)	Nancy Obuchowski, PhD	Daniel Sullivan, MD	Joe Koudelik
Michael Boss, PhD (Vice Chair)	Nicholas Petrick, PhD	Gudrun Zahlmann, PhD	Fiona Miller
Alexander Guimaraes, MD, PhD			Susan Stanfa

Streamlining Profile Document

- Process Cmte leaders have been working offline to revise the Profile template based on a reorganization of section content
- Three Profiles to participate in vetting this streamlining effort: CT Vol (Mr. O'Donnell), DWI (Dr. Boss) and possibly the FDG-PET (tbd) and/or the SWS (tbd); if successful, this would later be recommended to all BC leaders
    - PC leaders to engage FDG-PET BC leaders
- From the Profile user perspective, the goal is to complete the requirements as efficiently as possible to achieve site conformance
- A revised order was proposed to focus on critical information needed for end-users (1) Executive Summary, (2) Conformance, (3) Profile Requirement Checklists, and (4) Assessment Procedures
- With this new format, the Executive Summary, Clinical Context (application of Profile), Claims and Disclaimers would all fit on a single page
- It was recommended that Claims be named, rather than numbered
- Pre-Profile performance (standard of care) vs. Profile performance (expected if the Profile was used) suggested to highlight benefit to all stakeholders
- Information on how to conform to the Profile may be moved to the appendix
- Checklists to be moved from the end of QIBA Profile documents to the beginning (Section 3) and arranged by actor
- Appendix A to include the same requirements as checklists, but also details on patient preparation, acquisition, etc.
- With most details moved to the appendices, it may be possible to reduce the length of the body of the Profile to only 18 pages
- This careful repackaging of Profile information does not eliminate any critical information, it simply moves the most critical information for end users to the front for easier reference, rather than having it scattered throughout a lengthy document
- Including a standardized imaging protocol (i.e., UPICT) was found helpful by FDG-PET Profile implementers
- Dr. Zahlmann suggested that EARL pilot sites testing the FDG-PET Profile could be asked to provide feedback on how they used the Profile, e.g., whether they read the entire Profile, or referenced only the checklist(s)
- Recommendation to have the new format of the Profile implemented by several sites before a complete adoption of a new Profile template is promoted across all QIBA groups
- PC leaders to discuss this on upcoming BC calls to assess committee opinion, then report back to the PC in one month (Dr. Boss will be unavailable on 3/16)

Technical Confirmation (TC) (Stage 3) vs. Claim Confirmation (CC) (Stage 4)

- Clearer delineation is needed re: what both stages entail and how they would be achieved
- CC is seen as a QIBA process to advance the Profiles, where test/retest data may often be needed; TC is targeted to imaging sites and hardware/software vendors to demonstrate conformance to technical specifications within the Profile

    - Conforming to a Profile (TC) would not require test-retest study on patients; the user must only demonstrate that they have completed checklist requirements
    - It was determined that the purpose and processes for TC will need to be solidified before efforts can be shifted toward establishing a TC resolution process
    - Clear TC steps/requirements are needed for sites and HW/SW vendors to follow

- The Technical Confirmation Process QIBA Wiki page was reviewed
- The purpose of TC would be to obtain feedback on the Profile implementation process and assess whether the requirements can be performed - as a result:
    - Issues with user comprehension could be identified and addressed by updating the Profile text
    - Steps can be adjusted if determined that users are either unable to execute them or they are impractical to routinely perform
    - Some requirements may not be 100% necessary to achieve Claims, and it would be helpful to know when this is the case

- A combined requirements checklist with Yes/No responses (can you implement?) and user opinions (is this practical/will you implement?) would address both questions
- A standardized Technical Confirmation Resolution template will be used to compile feedback from TC sites, summarize cmte discussion, and record resolutions
- Engaging non-QIBA members/sites would provide the most useful real-world feedback, but active BC members (i.e., Profile contributors) would still be helpful for assessing the execution step and should not be excluded
- Members who demonstrated engagement by providing Public Comment feedback would be another resource for the TC step
- Input on Profile requirements by international users to be encouraged since regulations may differ by country
    - Links to US, Japanese and European contacts suggested

- *"Can* a user implement" vs. "*Will* a user implement," were debated as the goal for the TC feasibility testing – additional discussion needed
- Additional discussion needed re: TC and CC requirements across multiple organ systems, e.g., DWI Profile

Next Process Cmte Call: Tuesday, March 16, 2021 at 2 p.m. (CT)