QIBA Process Committee Call

Tuesday, July 21, 2020 at 2 pm (CT)

Call Summary

Attendees:

Kevin O'Donnell, MASc (Chair)

Michael Boss, PhD (Vice Chair)

Alexander Guimaraes, MD, PhD

RSNA Staff:

Daniel Sullivan, MD

Gudrun Zahlmann, PhD

Susan Stanfa

Brian Zimmerman, PhD

Process Cmte Agenda Item for Sept. 29 QIBA Virtual Annual Meeting

- "Improving QIBA Profiles" discussion
 - o Brevity, e.g., omit requirements not critical for meeting the Claim
 - Role and use for slightly different, more user-friendly versions of the Profile
 - Structure or specifications are acceptable, but they need to be more readable, e.g., Dr. Ehman received a request for an MRE Profile version for the radiologist in routine clinical practice
 - The CT-SLN and US-SWS Profiles could be shortened for ease of adoption
 - Best practices documents e.g., UPICT Profile draws on the larger FDG-PET Profile, but is abbreviated and easier to implement
 - QIBA Guidance Document, e.g., COVID guidance draws on the SLN Profile

Process Cmte CC agenda item

- As of Q2 2020, CC calls began to be used as forums for disseminating procedural updates, reminders, and requests; this is part of an overall effort to harmonize processes across QIBA biomarker cmtes
- It was reported that BC Co-chairs found this educational information helpful
- The topic for the Q3 Aug. 2020 CC calls will be reviewing the public comment process; the Public Comment Resolutions page and Profiles page of the QIBA Wiki will be referenced
- A representative of the Process Cmte will attend each call to present this agenda item

Draft Guidance Document Process

- Periodically, it may be useful for the QIBA Community to publish a document that is not a Profile but does
 provide guidance from QIBA experts on how to perform imaging that is conducive to quantitative image analysis
- Discussion re: whether QIBA should be involved in offering general imaging guidance
 - Due to the limited number of physicians among QIBA volunteers, content will mainly focus on technical performance, a biomarker, and possibly a related clinical context issue
 - A QIBA Guidance Document (QGD) would not include a performance claim or formal conformance requirements and would not be constrained to the common structure of a QIBA Profile
 - It was suggested that it would probably be best if a QGD had different formatting to avoid confusion with QIBA Profiles
 - A QGD could provide recommendations/best practices related to imaging procedures and associated patient handling, device qualification, etc.
- Motivations for publishing a QGD may be:
 - To address other publications that alleged to report quantitative information from imaging, but may not have been adequately managing acquisitions/image quality; comparability of results needs comparable imaging
 - o Imaging databases (e.g., CT scans for COVID-19) built to help develop and test AI algorithms

- o To address image quality issues that warrant special attention; this may not occur very often (e.g., a new disease, such as COVID-19 calls for guidance, but existing disease might be more stable/covered)
- When other entities have instructed on how to do imaging, but QIBA members can help improve acquisition of quantitative (compatible) data, even if just formatting/data handling
- QGD could serve to draw attention to QIBA Profiles, however, publication efforts should not divert a BC from Profile development progress
- The typical audience of a QGD would include:
 - Radiologists (including supporting staff like physicists, techs, etc.), e.g., guidance was needed to acquire high quality CT images for COVID-19 patients
 - Treating clinicians, e.g., pulmonologists ordering appropriateness, patient handling, quality expectations, diagnostic need
 - Vendors want to provide reference protocol to help with cross-vendor consistency
 - o Imaging Centers educational materials, e.g., to support clinical trial population
 - o Clinical Trials/CROs that want "good imaging" even if there is no quantitative claim
 - Guidance documents may have a broader audience and applicability, e.g., a broader target such as F-18
 PET than its original Profile
 - Hosp Admin/Dept Heads how to make good use of resources re imaging for novel diseases, e.g., COVID
- A QGD would be developed by a dedicated Task Force approved by the Steering/Executive Committee since resources are needed
 - The original idea/proposal may come from a BC or CC
 - Task Force membership ideally includes representation from radiologists, clinical specialists, physicists, equipment/SW vendors, technologists, etc.
 - No summary notes would be provided as these would operate as informal, short term working groups created to meet a specific goal
 - o While a-QGD would benefit from a public comment period, it would not be required
 - If it is desired, a less formal process than the typical Profile public comment would be implemented, i.e., ballot and review periods are brief and public comments do not need to be tracked or published
 - Targeted review by interested, affiliated organizations may be helpful
 - A QGD does not need to be initiated by the SC/EC; a BC member contacts their modality CC leadership with a few bullet points explaining the purpose of its development and how QIBA would benefit
 - Approval of the concept is needed from SC or EC, as some guidance documents may not fall into a single modality
 - Approval of the QGD requires SC/EC sign-off; the SC reserves the right to decline the paper as a "QIBA Guidance document," but it could still be posted on the QIBA Wiki
 - Once the QGD is approved and published, the TF would be dissolved, but may be reconvened to address feedback or update the doc
 - Additional discussion is needed re: terminology, e.g., "guidance" or "consensus" and definitions
 - QIBA to consider whether a QGD would undergo peer review and journal publication (more formal process) vs. being posted on the QIBA Wiki (less formal process)