QIBA Steering Committee T-con Meeting

Thursday, April 16, 2020
10:00 AM – 12:00 PM

DRAFT Call Summary

In attendance:

Daniel Sullivan, MD (Chair)
Alex Guimaraes, MD, PhD (Co-chair)
Timothy Hall, PhD (Co-chair)
Ronald Boellaard, PhD
Michael Boss, PhD
Andrew Buckler, MS
Thomas Chenevert, PhD
Patricia Cole, PhD, MD
Renee Cruea, MPA
Cathy Elsinger, PhD
J. Brian Fowlkes, PhD
Brian Garra, MD
Rudresh Jarecha, MBBS
Paul Kinahan, PhD
Carolyn Meltzer, MD
P. David Mozley, MD
James Mulshine, MD
Robert Nordstrom, PhD
Nancy Obuchowski, PhD
Kevin O'Donnell, MASc
Nicholas Petrick, PhD
Mark Rosen, MD, PhD
Annette Schmid, PhD
Lalitha Shankar, MD, PhD
Anne Smith, PhD
John Sunderland, PhD
Gudrun Zahlmann, PhD
Brian Zimmerman, PhD

RSNA Staff:

Angela Colmone, PhD
Fiona Miller
Joe Koudelik
Tori Peoples

Review and Approval of 03/19/2019 Meeting Summary

The meeting summary was approved as distributed. Later edits should be submitted to RSNA staff at qiba@rsna.org

General Update

Dr. Sullivan noted that the shared agenda was for the next two SC meetings and covers some of the topics that were to be addressed at the April in-person QIBA meeting. The *Value of QIBA* topic will be the focus of the June 18th SC call. To obtain a broad stakeholder opinion, Dr. Sullivan suggested a longer-than-one-hour June call to include representatives from various stakeholder groups, e.g., Cooperative Groups, CROs, Pharma, etc. Staff will poll the SC for availability for a 90-minute call in June.

Improving Members' Experience

Improving Members Experience, incorporating the topic of burnout, was touched on in the last meeting, and suggestions included a survey and letters of appreciation. Concern was expressed about the timing of the survey due to the COVID-19 situation, which might introduce exceptional bias. Suggestion to include an open-ended question: *What would it take to make your participation in QIBA more remunerative* (e.g., academically, financially, professionally, etc.).

Dr. Mulshine expressed concern that letters of appreciation might draw unwanted attention to volunteer time being spent on QIBA efforts. The typical QIBA member is well accomplished and appreciates the critical role QIBA plays and values the opportunity for academic contributions more than letters of appreciation.

Dr. Guimaraes suggested that advancement to a QIBA leadership role could be an incentive, and engaging more junior members also has the potential to invigorate committee energy and drive efforts forward.

- Suggestion made to survey members' engagement in QIBA if greater opportunity existed to take on leadership roles in the current QIBA structure.
    - This would require a more formal mechanism for advancement and encouragement of term limits.

- Asking participants what they find rewarding about their QIBA efforts (personally and to their organization) with the option of identifying long- and short-term benefits would be helpful.

- Timing and wording will need additional input
    - Dr. Sullivan to draft the survey questions and staff will seek input on question structure from the RSNA's survey staff.

AI / QIBA Relationship

Dr. Sullivan noted the relationship of QIBA to AI is a question that often comes up, although no one seems to be clear about what the relationship should be. Since the AI concept is vast, how QIBA efforts could be engaged to satisfy this need and opportunity remains unclear.

- QIBA standards might be one area that is applicable to AI, e.g., identify standards of performance for AI algorithms.
- QIBA could serve in the role of identifying metrics of performance.
- QIBA could provide the basis for making reasonable (clinical) performance assertions beyond those of computer scientists and mathematicians.
- Further discussion will be held on 4/29 SC call.

Mr. O'Donnell noted that, at its core, AI is a family of algorithm technologies. An example within QIBA is segmentation of lung nodules that uses algorithms, and the groundwork studies provide the metrics. A second channel would be to provide the methodology to address sources of variability. Dr. Mulshine reiterated that QIBA is "measurement science" and needs to be distilled among the various stakeholders. Dr. Sullivan noted that he plans to discuss dissemination/marketing of the QIBA message with Ms. Cruea (The Academy) and Dr. Colmone (RSNA).

Re-Assessment of Profile Structure and Writing Process

Mr. Buckler provided feedback received based on real-world CTA Profile review experience. Based on comments from Dr. Michelle Williams, author of a series of Scot-Heart Coronary CTA Study papers on risk stratification and patient management, the Profile appeared to be too complex to be implemented in the field. As a result, Mr. Buckler reduced the Profile by half by removing controversial and/or non-essential detail.

Dr. Sullivan noted the constant push/pull between the desire for a perfect vs. usable Profile. Mr. O'Donnell agreed that the overall goal is to improve user performance but noted this benefit must be balanced by the extra time and effort required by users. He suggested that the top five to ten requirements with the highest performance impact be included for the first pass of a Profile. Dr. Shankar agreed that this targeted format would likely receive more attention in the field. More detail could be included in a larger reference document in future versions (including methodology, statistical and supporting data). Dr. Sunderland voiced concern that this abridged Profile might chip away at the scientific foundation and endanger the statistical rigor and impact the Claims. Dr. Garra noted the importance of appealing to the practicing imaging center that may not have a vested interest in QIBA certification or methodology. This type of user is simply interested in an improvement, rather than meeting the Claim.

Group consensus was that there was a clear need for both (or multiple) Profile versions based on user/audience need. Shorter Profiles could be aimed at specific actors or groups and contain hotlinks to additional reference materials, such as checklists, statistical support details and the full Profile versions. The full Profile would be aimed at clinical trialists that could utilize all the detail provided.

Mr. O'Donnell stressed the importance to release the full Profile for Public Comment, then trim to a more manageable size based on feedback received.

Potential Chokepoints in Profile Development

QIBA is unique in that it often requires groundwork to answer technical questions. Profile formatting, standardization and editing can be time consuming and the lack of experienced editors can slow progress. Noted was the challenge facing Profile development due to infrequent, monthly BC calls. In other words, the flow of discussion, and therefore progress, might be better served by more frequent calls at shorter intervals.

QIBA Profile Conformance Testing and Accreditation

Dr. Sullivan mentioned that the first imaging site (Invicro, London) had recently demonstrated conformance to the DWI Profile. This early adopter had run through the entire DWI conformance process and demonstrated the required system performance. This was a positive advancement for QIBA and the pilot conformance concept. This site paid the fee to be listed as QIBA Registered.

Committee discussion and questions focused on what constitutes conformance testing for various end users, such as clinical sites, core labs and Pharma (clinical trials):

- For site conformance-should this be by Profile or modality (e.g., would a site be "CT Conformant" to all the CT Profiles)? Current thought is that conformance is based on each biomarker/Profile.

- Is it reasonable to expect radiology departments to attain conformance for each biomarker/Profile, e.g., SLN, Advanced Nodule, Lung Density and CTA? Is this practical?

- In a multiple scanner institution, would each scanner need to be certified, or would the entire department be certified?

- Finding a single phantom that applies to multiple Profiles would be convenient to imaging sites but would prove challenging and may not be ideal for each Profile.

- What is the benefit of conformance to imaging sites? QIBA conformance needs to be tied to clinical trials and/or accreditation to engage users. The process must be made easy and the benefit clear.

- Distinct use cases were identified as imaging sites, CROs and Pharma (clinical trials). The conformance process will likely be different for all three. A focus on clinical trials may be the best use case for Profile conformance since these are most likely the first users of quantitative imaging (and are accustomed to detailed protocols). A better understanding of how Profiles can be applied to all users is needed.

- CROs were identified as a use case that might require specific conformance requirements/mechanisms due to their oversight and data analysis role, e.g., Invicro LLC acting as a CRO – the current Profile checklists are based on sites/actors.

- A stronger QIBA onboarding process is needed re: Profiles, checklists, methodology, and terminology to help new users and committee members come to speed faster, with a periodic review of "why we are doing this."

Dr. Guimaraes highlighted the growing interest of ACR and CMS re: the need for better scanner performance and quality metrics in efforts to raise the imaging performance bar. Incentives for radiologists and imaging sites may eventually include a financial "carrot" to participate. There is value in setting meaningful quality metrics that can assure meeting a performance threshold for reimbursement for clinical sites and clinical trial participation.

Next Steps:

- Staff to poll SC members for their availability to attend a 90-minute June SC call.
    - The perceived QIBA value to stakeholders to be a focus -- Pharma, Cooperative Groups and CRO reps to be invited to share their opinions
    - April 29 SC call to include group reports on opportunities re: Profiles
    - Process Committee will follow-up on suggestions about how to improve Profile brevity and user friendliness. Also, the value of editors to draft Profiles (if resources were available); need for guidelines for new BC members and Profile editors.
- Survey of member experience to be drafted with question re: leadership term limits and opportunity to advance
- Reimbursement topic will require a focused SC call at some point in the future, to include leaders
    - Dr. Sullivan requests recommendations for appropriate CMS contacts to invite

Next QIBA Steering Committee Call

Wednesday, April 29th SC (12 PM-1:30 PM CT)