QIBA Steering Committee Conference-Call Meeting

Thursday, September 17, 2020
10:00 am – 11:30 am (CT)

Call Summary

In attendance:

Daniel Sullivan, MD (Chair)
Timothy Hall, PhD (Co-chair)
Michael Boss, PhD
Andrew Buckler, MS
Paul Carson, PhD
Thomas Chenevert, PhD
Caroline Chung, MD
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
James Mulshine, MD
Robert Nordstrom, PhD
Nancy Obuchowski, PhD
Kevin O'Donnell, MASc
Annette Schmid, PhD
Lawrence Schwartz, MD
Lalitha Shankar, MD, PhD
Anne Smith, PhD
John Sunderland, PhD
Gudrun Zahlmann, PhD
Brian Zimmerman, PhD

Guest Speakers:
Christine Lorenz, PhD, MBA
James Jago, PhD
Gregory Sorensen, MD
Jacob (Bram) Stolk, PhD
Peter Weems

RSNA Staff:
Fiona Miller
Joe Koudelik
Tori Peoples

Dr. Sullivan welcomed guest panelists noting QIBA leadership hoped the panelists would help QIBA understand better some of the perspectives of the medical imaging device industry, with respect specifically to quantitative imaging biomarkers (QIB's).

He indicated that while there is no single, unifying industry perspective on this general topic, each of the guests had been asked to provide their own personal perspective, with the understanding that they were not speaking on behalf of their company or as an official spokesperson for the industry.

Dr. Sullivan provided a brief refresher about the goals of QIBA, and some of what it was hoped the meeting discussion would illuminate.

Despite the extensive published literature about variability in radiologist interpretations, there has been little progress toward widespread implementation of QIB's and QIBA hopes to understand the barriers from the perspectives of the medical device industry. Challenges may include push-back from payers and professional organizations that write guidelines and recommendations.

Dr. Sullivan noted that variation in image interpretation is a significant problem in clinical practice, resulting in poorer outcomes and higher costs. One approach that has been existence for many years to reduce variability in radiology is to extract objective quantitative data from scans vs. qualitative interpretation

Gregory Sorensen, MD, President, DeepHealth:
Dr. Sorensen noted that although best practices are known, there is no universal agreement among clinicians regarding what high quality imaging consists of in detail. Even when there is agreement on what good performance is in aggregate, e.g., within mammography, we see that individual reader performance may not meet the recommended goals. For example, according to an Institute of Medicine report in 2015, almost half of MQSA-certified radiologists who are willing to report their performance fall short of some recommended mammography performance thresholds today. Undoubtedly the natural human reluctance to report on our own performance is part of this challenge. Busy clinicians have little incentive, other than their own internal motivation, to report performance.

Given this observation there are two things industry and QIBA might consider doing together:

- QIBA could help quantitate performance to help guide our community. This could standardize guidelines. By helping recognize and document where clinical performance is short of desired standards, we could motivate the need for help e.g., from quantitative tools.
- QIBA could help drive the evolution of QIBs on the clinical side; for many QIBs we need clinician consensus; this in turn can help ensure that QIBA solutions are adopted as best practice.
    - AI and QI usage need clinician consensus to advance

Dr. Sorensen described two new clinical areas that are receiving government reimbursement

1. Retinal scans (not in the field of radiology) - A company (Digital Diagnostics) worked with AMA and CMS to generate a CPT code which CMS will reimburse to carry out AI-operated screening diabetic retinopathy scans. There are Medicare quality mandates for carrying out screening for diabetic retinopathy and AI has now been able to detect the need for referral to specialist care (similar to needing a diagnostic workup after a screening mammogram).
2. A new "Technology add-on payment" (using a mechanism mandated by Congress many years ago) is now available via CMS for a stroke AI tool that detects large vessel occlusion on a head CTA. This is an added payment meant to boost technology adoption. Specifically, if a patient is admitted with a stroke diagnosis, a hospital that uses of the technology (e.g., AI software) can result in a CMS payment of up to $1,043. Patient outcomes and improvements of quality-related metrics were the drivers in this case.

CMS has demonstrated a willingness to pay for higher quality and may be willing to collaborate. QIBA could help the radiology community by staying close to clinical needs to better identify technologies that payers are excited about (e.g., technologies that save the payers money while improving healthcare outcomes). Payers would support such advances through add-on payments and that in turn would be welcomed by vendors and providers. Identifying areas where near-term reimbursement is possible could be one clear goal to chase, for example, in diseases where the use of AI or quantitative measures for screening improves outcomes (e.g., fewer false negatives) while lowering overall costs (e.g., fewer false positives).

Peter Weems, Director of Policy and Strategy for MITA:
As a subdivision of NEMA, MITA is the primary trade association for standards development for medical imaging devices in the US with 55-60 member companies of varying sizes. Most of the work is split across policy, advocacy, and standards development, with an emphasis on ensuring patient access to safe and effective imaging solutions.

MITA's Reimbursement Committee works with CMS to focus on annual payment rules, coordinating with ACR and other groups to assure adequate payment for services rendered. The MITA Coverage & Research Committee is also looking to expand CMS and private payer coverage for new services, e.g., digital mammography.

MITA also advocates for transparent, predictable, and efficient pathways for bringing technologies to market. As a standards development organization, MITA develops industry standards for medical imaging technologies.

Mr. Weems suggested that QIBA should engage industry (via MITA) early and often to discuss common objectives and to promote the value of imaging. Mr. Weems offered to serve as MITA point person.

Christine Lorenz, PhD, MBA, Chief Operating Officer for Cohesic:
Dr. Lorenz indicated that data quality and standardization is key to improving patient care and solving many issues in our global healthcare systems and believes in the mission of QIBA. However, when it comes to scanner vendors, they are driven by their own set of incentives and improving quantification is not necessarily a driving force. Instead vendor emphasis has primarily been on developing technologies that help sell scanners and software. In this case, new and/or different features are often key to sales, which can go against standardization. However, in some areas, such as in PET/CT in oncology, the ability to standardize quantitative measurements is in itself a differentiator for the vendors.

Vendors adapt to the imaging community who are their customers but are often behind in development of features as they wait for consensus of clinical opinion, which sometimes does not happen. However, two examples of industry responding to customer needs are 1) development of features that help improve imaging efficiency, quality and reproducibility to address the pressure on imaging services to increase throughput, and 2) focus on aspects of imaging that support machine learning approaches for scanning, analysis, and interpretation. Imaging that provides data consistency and reproducibility is important in AI tool development and clinical usability. QIBA Profiles are valuable in this space but the commercial benefit to vendors is likely medium to long-term.

Dr. Lorenz encouraged QIBA to continue its current path, but recommended that instead of focusing on the vendors, it is more important to find the "pain-points," of referring physicians, pharma, payers, and other stakeholders of imaging and identify which of those could be addressed by QIBs. When those issues can be solved and be shown to bring real clinical and/or

economic benefit, the vendors will react accordingly and provide the tools demanded by their customers in the imaging community.

James Jago, PhD, Principal Scientist, Phillips Healthcare Ultrasound:
Dr. Jago noted the vision of QIBA helps both industry and patients. Vendor involvement within QIBA demonstrates an ongoing industry examination of needed clinical applications and implementations. The development of phantoms helps implementation for all vendors. Standardization across vendors helps to instill confidence within the clinician community and will eventually drive adoption and development of clinical guidelines. Representation from clinicians is helpful and provides much needed insight and guideline development.

Dr. Jago noted that overall skepticism regarding quantitation exists in industry, especially for ultrasound. Quantitation and implementation of Profiles are regarded as academic in nature; and difficult for community hospitals or outpatient centers. From an ultrasound perspective, it is difficult to know if adoption is clinically useful or drives product sales. Adoption typically requires some change in clinical practice, which takes a long time, is a big investment, and has regulatory hurdles. Without a clinical benefit, it might be hard to accept the higher costs associated with standardization. Although useful, it was not clear if QIBA can help overcome these challenges.

Dr. Jago acknowledged that the shear-wave-speed (SWS) biomarker profile has helped drive a relatively rapid adoption of shearwave elastography for liver assessment, but this may be due to increased clinical community awareness and confidence in the technology, not the Profile. Even though industry may not be aware of QIBA, if the customers are aware, they can drive demand. But, currently, there is no evidence to show that Profile are driving business, e.g., for MR systems. Dr. Jago suggested to focus on payers which might help drive future clinical reimbursement and an increase of sales and equipment.

Jacob (Bram) Stolk, PhD, GM Global Research, GE Healthcare:
Dr. Stolk spoke from an industry and academic perspective based on twelve years with Siemens and five with GE. He stressed that the bottom line for industry is selling equipment. Customers are asking about QI, but it is not clear that QI will be the next technology used. The lack of reimbursement is another hurdle facing QI.

QIBA's work is important to industry (e.g., ASL, SWS, DWI), but follows a different timescale and does not change the vendor product roadmap. QIBA needs to better align itself to the vendor timescale to improve success.

To do:

- QIBA must demonstrate that QI metrics improve clinical outcomes
- QIBA must act faster when addressing a performance parameter/metric (before vendor product release)

- QIBA should work with industry to make radiology become more quantitative in performance by tying QI to the same metric, scanner output, and better clinical outcomes

Discussion

Quality of Radiology

Variability in radiology is broad – perhaps in the ballpark of +/- 30% overall. This large value associated with variability refers to the complete chain of image acquisition and interpretation, not the variability of the scanners per se. The precision of scanners themselves is much better, but how they are used in practice contributes the additional variability. This overall level of variability is much greater than most industries would accept. Thus, scanner manufacturers do not consider the poor level of reproducibility in practice to be their problem. It is a problem for the specialty and its professional organizations to address. How can QIBA help address this issue? If we all use the same metric, how much impact will this have on patient care? Dr. Stolk reiterated that clinical outcomes will drive all QIBA collaborations. Dr. Sorensen recommended identifying more areas that can utilize QI in radiology.

Reimbursement Issues - How can QIBA approach the reimbursement issue (and payers) with very limited resources?

Focusing on payers that reimburse/supplement for quality improvement was deemed a reasonable goal. Associating QIBA to some "payer value" such as clinical outcome was needed to boost the value of QI in general. Dr. Sorensen suggested pursuing studies to demonstrate the benefit to patients by implementing a quantitative tool. Future QIBA goals should focus on patient benefit and a meaningful quantitative metric.

Dr. Sorensen noted a January 2020 change re: QI cardiac ultrasound reimbursement where a "strain" metric was implemented. The combination of the benefit to the patient and the extra work required resulted in a permanent CPT code for reimbursement. Subsequent development of an AI software solution resulted in time saving for physicians.

Dr. Mulshine highlighted the potential tension between innovation and standardization and the overarching need from a clinical perspective to know whether a condition is better, stable, or worse. Vendors need to provide tools to do this and cross-vendor implementation is critical. Innovation and standardization must work in concert to move the field forward.

Dr. Lorenz noted the clinical benefit of measuring disease progression is recognized by all vendors and tools exist now, but there are many opinions and varying metrics to use.
Dr. Jago called for more evidence that a biomarker could address problems reliably across multiple vendors while still offering opportunity for innovation. Dr. Jago also noted that in his opinion, QIBA does not impede innovation.

Dr. Lorenz stated that anything that helps to increase market traction via standards or new outcomes capability would be welcomed by vendors.

Dr. Sullivan asked how industry can be made more aware of QIBA?
Dr. Jago reiterated that if QIBA requirements come from the customer, industry will listen, thus driving standardization. The scientific side of industry may be excited, but the executive side is not aware of QIBA but will listen to the customer. Dr. Stolk agreed that the customer drives vendor decisions, so QIBA must drive their message to the customers first, who in turn will make demands back on the vendors.

How can QIBA interact with the Vendors beyond the Profiles?
Dr. Sullivan noted that no mechanism exists for QIBA to interact with industry directly except through some limited connections with MITA. Are the MITA modality committees the best pathway? Mr. Weems offered to serve as a liaison to the various MITA modality committees and bring the correct SME reps to the discussion table as needed.

Dr. Sullivan mentioned that a new QIBA Task Force is being considered to reach out to potential Profile users, such as Clinical Trials Groups and have them identify QIBs that would be helpful.

Dr. Chung noted that the timing of test-retest data and scanner development are out of sync. QIBA needs to work with vendors earlier in the product development cycle to have any impact. The voice of QIBA must lead, not trail, product development. Dr. Chung added that there is an overall shift across all clinical metrics towards a more quantitative approach, so the timing is right to start and act on this dialogue.

Dr. Carson suggestion hosting equipment buyers' sessions at the RSNA or ACR.

Dr. Garra agreed that a difference between customer use and a biomarker use exists. Ultrasound SWS is in relatively high demand in areas other than radiology, e.g., hepatology. A coordinated marketing effort was suggested since radiologists need to be competitive with other medical specialists and not fall behind.

Dr. Sullivan thanked all the guest speakers for their time, opinions and continued engagement with QIBA in the future.