QIBA vCT Technical Committee Weekly Update
Monday, September 21, 2009
11 am CDT

Call Summary

In attendance

Andrew Buckler (Co-Chair)
P. David Mozley, MD (Co-Chair)
Kristin Borradaille, MS
Patricia E. Cole, PhD, MD
David Gustafson, PhD
Philip F. Judy, PhD
Michael McNitt-Gray, PhD
James Mulshine, MD
Kevin O'Donnell
John Michael O'Neal, MD
Nicholas Petrick, PhD
Daniel C. Sullivan, MD

RSNA staff

Susan Anderson, MLS
Joe Koudelik

Agenda (Mr Buckler)

- Continuation of discussion on QIBA compliance testing
- QIBA Roadmap

QIBA compliance testing

- Discussion of long-term considerations of Connectathon or alternate possibilities for QIBA compliance testing
    - Compliance can be characterized in several ways:
        - Algorithm/software to meet requirements in testing against data set or testing against a phantom for resolution, etc.
        - Would phantom be circulated between sites?
        - Can be described as performance-oriented or integration-oriented
    - Compliance testing has two aspects:
        - Connectivity aspect - longitudinal measurement
        - Performance aspect - one time point or longitudinal
- IHE has used self-certification route or has used an external testing group to certify
    - Process must be concise and streamlined to accommodate vendors
    - $4-8K per system paid by vendor to IHE as participation fee covers infrastructure, testing tools
- Discussion of site accreditation/qualification and vendor compliance:
    - Important to assure vendor understanding and buy-in
    - Proposition that certification of current/new equipment could increase sales might be powerful vendor incentive
    - Both equipment (e.g. scanners) and sites (e.g. acquisition, QC, patient preparation) could be reviewed and accredited
    - Site could be accredited even without a compliant piece of equipment
    - Want to simplify and optimize site behavior
    - How will vendors load protocol?
- Mechanics of certifying compliance:
    - Discussion of levels such as: Ideal—Target—Acceptable

    - Do not want grandfathering and upgrades of older equipment to discourage innovation and investment in new products
- A QIBA 'Gold Standard' could solve QC measures which can be viewed as punitive and demanding of scanner and staff time
- QIBA compliance can mean that vendor costs are pooled (not necessarily reduced) and sites can go through qualification once or use equipment judged to be compliant
- Details can be settled when Profile text is completed

Roadmap

- QIBA Roadmap was drafted in September 2008
    - Long-term goal is to transform clinical practice with roadmap of intermediate steps but current version may contain too much detail
    - Need to have shorter summary version in addition to longer version which preserves detail
    - Would like to have document for 2010 meeting with FDA which is in preparation for FDA 2011 guidance on imaging
    - Decision to use version of Roadmap from NIBIB proposal as short version; RSNA staff will place on wiki for review and comment
    - Preamble and statement of long-term goals and specific aims needed
- Recently released by European Medicines Agency: *Guideline on clinical evaluation of diagnostic agents (cpmp/ewp/1119/98 rev. 1) on imaging agents* and *Appendix 1 to the Guideline on clinical evaluation of diagnostic agents (cpmp/ewp/1119/98 rev. 1) on imaging agents*
    - Logic is welcome but concern that approach may degrade innovation by conflating biological efficacy with cost effectiveness
    - EMEA Guidance on diagnostic agents could be generalized to all diagnostic modalities
    - Published in July 2009 has a logical structure which may be relevant across QIBA
    - FDA may be influenced by the documents but the EMEA documents make cost effectiveness integral to approval and has not separated cost from scientific value
    - Important to consider generic question: examine effect of diagnostic procedure while accounting for risk and patient safety
    - FDA has looked for proof both of safety and efficacy but showing benefit to patient has been difficult
    - Efficacy ideals differ for device and biopharma; less of a link to outcomes needed
    - 'Fit-for-purpose' explicit guidance needed
    - Oncology has been using response rate as surrogate for effectiveness; topic is contentious
    - FDA has generally enforced strictest Level 4 re benefit to patient but may be changing to less strict Levels 2-3

Next steps

- RSNA staff will place version of Roadmap from NIBIB proposal on wiki for review and comment; preamble and statement of long-term goals and specific aims needed