QIBA FDG-PET/CT Update WebEx
Tuesday, January 27, 2009
3:00 pm CST
Draft Call Summary

In attendance:

Richard Frank, MD, PhD (Co-Chair)
Ronald Boellaard, PhD
Michael E. Casey, PhD
David A. Clunie, MBBS
Patricia E. Cole, PhD, MD
Richard Eaton, JD
Igor Grachev, MD, PhD
John M. Hoffman, MD
Yuying C. Hwang, PhD
Paul Kinahan, PhD
Steve Kohlmyer
Eric S. Perlman, MD
Ling X. Shao, PhD
Rathan Subramaniam, MD
Timothy G. Turkington, PhD
Jeffrey T. Yap, PhD

RSNA staff
Fiona Miller
Susan Anderson
Joe Koudelik

Introduction (Dr. Frank)

- There are six active subcommittees:
  - **Software Version Tracking**, Ling Shao, PhD, Chair
  - **Region of Interest (ROI) Definition**, Timothy Turkington, PhD, Chair
  - **Covariate Rationale**, Yuying Hwang, PhD, Chair
  - **Digital Reference Objects-Images**, Paul Kinahan, PhD, Chair
  - **Quantitative Computation**, David Clunie, MBBS, Chair
  - **Quality Control Metrics**, Jeffrey Yap, PhD & Ling Shao, PhD, Chairs
- Dr. Shao has replaced Dr. Gagnion as Chair of the Software Version Tracking subcommittee.
- The Quality Control Metrics subcommittee is new as of RSNA 2008.

Upcoming RSNA meetings

- March 16-17, 2009, Imaging Biomarkers Roundtable, O'Hare Hyatt Hotel
- May 19-20, 2009, QIBA, Oakbrook Terrace Marriott
- July 2009, proposed joint meeting of TQI and Imaging Biomarkers Roundtable

Subcommittee Reports

Digital Reference Objects-Images (Dr. Kinahan)

- Goal: to build a common reference DICOM test image that can be generated by each scanner and read on PET DICOM display stations to check information fidelity (i.e. next step beyond DICOM conformance statement)

- Question: Do we need to have a neutral broker (e.g. NEMA/MITA)?
    - Need for neutral broker depends on what is being shared and the company sensitivity on proprietary material
    - One role for NEMA/MITA may be to help to develop final recommendation to industry
    - Mr. Eaton will be a useful resource person to combat anti-trust concerns and promote vendor buy-in.
    - Suggest Mr. Eaton joins call with Kinahan, Shao, Casey and Kohlmyer
- Completed
    - Collected DICOM PET/CT images of the same reference phantom from scanners from GE, Philips, Siemens
    - Image data collated and compared to w.r.t. DICOM header information
- Next Steps
    - Discussion with scanner manufacturers and 3rd party display systems to find out what information and/or resources can be shared
        - Group agreement that most information related to DICOM is public domain
            - At image level with DICOM, no proprietary issue
            - At data reconstruction and image formation level, may be more sensitive proprietary issues
    - Determine expert(ise) from each company to participate in discussion
    - Key step: First-pass discussion to define test DICOM image set
    - Evaluation and modification
    - Explore IHE process for manufacturer-driven roll-out
    - Explore potential for moving further up the data generation stream, i.e., closer to raw data
    - Within next two weeks, Mr. Casey, Dr. Shao, Mr. Kholmyer and Dr. Kinahan to identify scoping expert
    - Will post image data on QIBA Wiki site
    - Identify expertise or experts in DICOM
    - Produce draft of basic information with input of experts

Region of Interest (ROI) Definition (Dr. Turkington)

- Goal: Assess current ROI methodologies on workstations; move forward with new methods; consider anatomical ROIs in the future
- Survey of current capability for ROIs in current equipment is in production;
    - Consistency is a major issue in drug development trials
    - Reliable comparable input and output is critical for quantitative imaging
- Non-disclosure
    - Confidentiality/non-disclosure is a potential logistical issue as subcommittee reviews survey responses

    - Subcommittee members are from academia and industry
        - Consider review by academic subgroup- need to consider antitrust issues of this approach
    - Options:
        - Separate by class of ROI due to resampling strategy
        - Consider proprietary information versus information the manufacturer may be embarrassed to disclose
        - Ask vendor to contribute what they can, then use non-disclosure if absolutely necessary
        - Start with non-disclosure statement
        - Use term “blinded data” to encourage freer response with statement that data will not be published or shared with other vendors
- Important to identify best and most knowledgeable respondent
- Different approach may be to define a standard for ROI and invite vendors to meet the standard
    - Difficult for larger manufacturers due to long cycle times for development
    - Smaller manufacturers with smaller product line may be able to respond more quickly to meet standard
- Subcommittee members
    - Need for a technical manager or programmer on this subcommittee
    - Funding to recruit members would be helpful
    - Slowly adding names to list, especially manufacturers
        - New contact: Chuck Norman, Philips
- Next steps
    - Dr. Turkington to finalize survey and distribute to group for comments
    - Discussion on non-disclosure statements/agreements will continue off-line

Covariate Rationale (Dr. Hwang)

- Goal: incorporate some covariates, such as blood glucose, patient weight and height, information on injected dose and time of injection, into DICOM header
    - Select covariates that impact SUV measurement.
    - Inclusion would eliminate separate paperwork and reliance on CT tech to enter data
- Dr. Yap has offered help with identifying what is available in DICOM header
- Possible partnering of Drs. Hwang and Kinahan, who is working with three companies on incorporating covariates in DICOM headers
- Issues:
    - Identify the place in header -- issue for DICOM Working Group
    - Vendor implementation and adjustment of user interface

        - Making change to user interface is slow and expensive for manufacturers
        - Need to justify endpoints – rationale for parameters w/impact on precision

    - Would be useful to partner, e.g. Siemens DICOM person with Siemens rep to QIBA
- Another possible approach is to define an ideal and vendors will follow suit
- Next steps
    - Identify members for subcommittee
    - Circulate a short list of covariates requested, reach consensus on priority
    - Identify the ways vendors handle covariates; improve the data already in the DICOM fields

Software Version Tracking (Dr. Shao)

- Goal: To track the traceability of software version of a PET/CT system to ensure the consistency of quantitative output throughout a trial
- Rationale: Due to the continuous improvements to PET/CT systems, vendors upgrade software in different sub-systems. Some upgrades may include quantitation improvements.
- It is difficult to collect data even from software release notes
- May be useful to involve 3rd party imaging workstation vendors
- Three major software components in the quantitative imaging chain should be tracked:
    - Acquisition (include detector)
    - Reconstruction (may be combined with acquisition) and
    - Quantitation tool (Some sites use third party Display/Quantitative Tools, which further complicates the tracking)
- Approach
    1. Manual Tracking (Current)
        - Status: Currently, every vendor should incorporate the ability to obtain the version info for each software component installed.
        - Action: Send out a survey to vendors for instructions on checking the software version (Acquisition, Reconstruction, Quantitative Tool)
        - Some vendors provide multiple Reconstruction methods
    2. Fully DICOM Tracking (5-8 Years)
        - Status: Currently only the attribute for acquisition software version may exist
        - Action: Work with other committees to define a global recommended list of DICOM attributes needed for quantitation
        - Work with DICOM committee to define the timeline for implementing the list

3. One-button software tracking function (8 years and beyond)
    - Status: Currently, vendors provide tools to view all/most DICOM info, but most information which impacts quantitation is missing (No DICOM Attributes). The goal is for vendors to provide a one-button function in the quantitative tool to display all quantitative related info.
    - Action
      Define the quantitative information to be recorded (DICOM)
      Develop guidelines (work with NEMA?)
      Compliance steps

Quality Control Metrics (Dr. Yap)

- Issues in quality control
    - Clinical trials and quantitative longitudinal studies in general require PET/CT scanner consistency from day to day
        - Rigorous QC evaluation is typically performed during scanner acceptance testing and/or qualification/certification for trials and there are various standards (e.g. ACR, ACRIN, core labs)
        - Various core labs require repeat qualification/certification at fixed intervals and/or after hardware/software updates
- There is no standard for how QC is maintained and evaluated on a regular basis or on the day of a particular research patient's scan
- Parts of the information may be available in DICOM headers but are varied by manufacturer and generation of equipment
- Goals
    - Bridge the gap between PET/CT scanner acceptance/qualification/certification and routine (daily) quality control
    - Summarize methods and parameters for evaluating daily PET/CT QC on each vendor's scanner and share with vendors
    - Long term goal: Establish common standards for recording and distributing QC parameters for individual patient scans (e.g. extended DICOM tags). Is there a way to export that confirmatory data in text with patient data?
- Process
    - First answer question: what impact does this have on vendors/cost/CROs? Is the effort worth it?
    - Identify the daily quality control tests that are performed on each vendor's PET/CT scanners, avoiding proprietary information
    - Specify the range of acceptable parameters for each test as recommended by the vendor
    - Describe the methods for obtaining QC parameters and the output format for each vendor

- Ideally, develop standard for daily QC output that could be exported with individual patient scan, e.g. extended DICOM tags or standard file format (CSV, XML)
- Need input on quality controls - do vendors have designated people?
- Include scanner clock errors, for example, test every day, synchronize clocks, add to DICOM header
    - Clocks are important to quantitation in clinical trials
    - Scanner vendors have been slow in addressing the issue
- Discussion of including reference object to be scanned at time of each scan
- Real or digital object?
    - Introduces more radioactivity
- Define items which have biggest impact on quantitation; prioritize issues with input from those involved in clinical trials

Next steps

- Prioritization
  Important to establish priorities among the subcommittees (e.g. covariates, ROI, software tracking) to make best use of limited vendor resources
  Conduct survey on priorities (e.g. ROI, covariates, software tracking) by March 2009
  Start with question: “Is the current state sufficient?”

- Dr. Frank (by Feb 24 tcon) to organize 2-hour March PET CT Tech Cmte tcon to assess sub-teams' "next steps" plan for delivery (milestones) cost, feasibility, impact, and contingencies (needs).

- March 31 tcon
    - Assess survey results
    - Assess sub-teams' "next steps" plan for delivery (milestones) cost, feasibility, impact, and contingencies (needs).

- Dr. Frank (by April 28 tcon) to organize 4- hour breakout session of QIBA annual meeting May 19-20, 2009 at the Oakbrook Terrace Marriott to prioritize requests of Industry partners (across all 6 sub-teams)

- Upcoming QIBA FDG-PET/CT monthly update WebEx:

  February 24, 2009, 3pmEST
  March 31, 2009, TBD
  April 28, 2009, TBD
  May 26, 2009, TBD
  June 30, 2009, TBD