QIBA fMRI Subcommittee
Wednesday, January 13, 2010
11 AM CST

Call Summary

In attendance:

Cathy Elsinger, PhD (co-chair)
Travis Allen
Daniel Barboriak, MD
Rasmus Birn, PhD
Bradley Buchbinder, MD
Paul E. Bullwinkel, PhD
Geoffrey Clarke, PhD
Ted DeYoe, PhD
Sandeep Gupta, PhD
Edward Jackson, PhD
Kathryn M. McMillan, PhD
Heiko Meyer, PhD
Jeffrey Petrella, MD
Jay J. Pillai, MD
James L. Reuss, PhD
Douglas M. Tucker, PhD, MBA
James Voyvodic, PhD
Gudrun Zahlmann, PhD

RSNA
Susan Anderson, MLS
Joe Koudelik

Introduction and Review (Dr Elsinger)

- Dr Elsinger is COO of NordicNeuroLab, a company which provides hardware and software for functional neuroimaging
- Vendors supply clinical stimulation paradigms for use with different scanner platforms and stimulus presentation hardware; there is variability in timing parameters and stimuli used
- No best-practice standards or guidelines have emerged specific to the measurement tool; (however, 2007 ACR Practice Guideline is a good overview of many methodologies and has section on block design paradigm)
- Goal is to develop a process or criteria to evaluate and validate integrity of functional paradigms for use in single-subject clinical studies
- Immediate clinical application is presurgical mapping (e.g. tumor resection, epilepsy surgery) in single subjects. Once process/criteria is developed, can be applied outside pre-surgical mapping to other paradigms, e.g. clinical trials, evaluation and diagnosis of disease such as CNS or psychiatric disease, better patient care in general
- Need better understanding of paradigms and the practical implication of fMRI; large learning curve expected for clinicians
- For discussion: literature reviews, setting up trials, issue of whether group addresses methodology (technical issues, insuring means and statistical inference done correctly) or functionality as a biomarker
    - BIRN project may serve as template for activities determining levels
- Suggestion that committee work towards QC metrics for BOLD, which are currently variable across vendors with focus on one topic for now: pre-surgical mapping
- Determine work at level of scanner performance or at level of subject performance (e.g. recording patient performance)

Introduction to the QIBA organization

- At RSNA 2009, meeting of industry attended by QIBA representatives including Dr Zahlmann
- QIBA has activities at all levels of maturity on path through development and optimization, to application in studies, to validation, qualification, acceptance and reimbursement in clinical practice
- QIBA maintains an open membership format with anyone interested encouraged to participate; would like to have representation from a variety of stakeholders such as ASNR, Human Brain Mapping, BIRN, clinicians, physicists and basic scientists; expert collaboration drives the QIBA process
- QIBA is not a scientific activity but rather is translating existing techniques to larger scale, as well as defining a good quality imaging process, e.g. what is needed for high quality imaging
- The QIBA DCE-MRI group is exploring levels of variability with phantom studies; the co-chairs Drs Zahlmann, Jackson and Gupta represent pharma, academia and industry respectively

- Administration:
- RSNA staff provides administrative support; Dr Daniel Sullivan provides continuity and is liaison to RSNA Board of Directors
- Interested participants may contact Joe Koudelik, RSNA, directly (jkoudelik@rsna.org)
- QIBA wiki (http://qibawiki.rsna.org/) is used to post and review work
- Bi-weekly call schedule, alternating with DCE-MRI committee
- Time and effort commitment for co-chairs varies according to role and projects undertaken

Profile Development

- Committee to discuss drafts:
    - **Initial Claim Sentence:** Goal is to investigate the technical feasibility of creating a method for validating/optimizing design parameters of stimulus paradigms used in single-subject BOLD studies
    - **Initial Objectives:** Characterize the robustness of stimulus-induced MR signal change measurements (a BOLD response) in brain tissue that will lead to an understanding of the minimal threshold required to classify MR signal change in eloquent brain tissue as a medically meaningful surrogate for change in brain activity

American Society of Functional Neuroradiology (ASFNR)

- Both Drs Pillai and Barboriak represent ASFNR; interested in synergistic work with QIBA including both a bottom-up and top-down approach
    - Suggest 2 motor and 2 language paradigms as a beginning
    - ASFNR has collection of paradigms on their website; paradigms selected on basis of collected clinical experiences; methodology of expert consensus needed
- Determine focus: identifying and validating particular paradigms versus establishing criteria to test and validate a variety of paradigms
- ASFNR about to launch a multicenter clinical trials to determine the clinical impact of fMRI on surgical management (not the technical aspects of image acquisition); focus on 3T imaging
    - Culminates 5 years of planning to reach consensus among 7-8 institutions
    - Not attempting quantitative analysis
    - Outcome measure is change in therapeutic decision on part of neurosurgeon (this has been studied in single sites, but not in multi-site study)
- Dr David Mikulis spearheading the trial

Next Steps:

- Identification of co-chairs; ongoing
- Interested participants should contact Joe Koudelik, RSNA (jkoudelik@rsna.org)
- Upcoming Profile activities:
    - Step 1: Claims/set clinical context; drafting an initial sentence to articulate Claims
    - Step 2: understand performance measures and how to know when goal is achieved (may be technological, financial, etc)
    - Step 3: define experimental groundwork to prove performance specified to realize the Claim
    - Some groups need to characterize performance first; other groups have base of work and proceed to optimization (a tech and engineering activity)
    - Identify gaps in performance and level of optimization
    - Stakeholders can articulate their interests, e.g. regulatory, reimbursement, standard of clinical care
- Committee members to offer comments on draft Claim and Objectives statements
- Next call: January 27th, 2010 at 11 am CST