QIBA NM Coordinating Committee Update

Wednesday, May 6, 2015
Richard L. Wahl, M.D
Eric S. Perlman, M.D
Paul Kinahan, Ph.D (SL)

Voting Members (Role) – Max of 15 Non-Voting Members

| Richard Wahl, MD, FACR (Chair, NM CC) | TBD |
| Eric Perlman, MD (Vice Chair, NM CC & Co-chair Amyloid-PET BC) | |
| Rathan Subramaniam, MD, PhD (Co-Chair, FDG-PET BC) | |
| John Sunderland, PhD (Co-Chair, FDG-PET BC) | |
| Scott Wollenweber, PhD (Co-Chair, FDG-PET BC) | |
| Satoshi Minoshima, MD, PhD (Co-chair, Amyloid-PET BC) | |
| Anne Smith, PhD (Co-chair, Amyloid PET BC) | |
| Paul Kinahan, PhD, FIEEE (Scientific Liaison) | |
| (Metrology) | |
| “+” 3 Co-chairs, SPECT BC (pending approval by Steering Comm.) | |
| = 12 members | |
Modality Structure

- **FDG-PET/CT Biomarker Committee**
  John Sunderland, PhD; Rathan Subramaniam, MD, PhD, MPH; Scott Wollenweber, PhD
  - **FDG-PET/CT Profile Conformance Task Force**
    Timothy Turkington, PhD; Ronald Boellaard, PhD, Martin Lodge, PhD
  - **FDG-PET/CT UPICT Task Force**
    Jeffrey Yap, PhD—“Mission Accomplished?” (pub JNMMI 2015)

- **PET Amyloid Biomarker Committee**
  Anne Smith, PhD; Satoshi Minoshima, MD, PhD; Eric Perlman, MD

- **SPECT Biomarker Committee (proposed)**
  - John Seibyl, M.D, Ph.D; David Mozley M.D, Yuni Dewaraja Ph.D
    possible candidates

Current Status: Profile Development

- **Profile(s) in progress:**
  - FDG PET vs 1.0 Published, Public, in Technical Verification Stage
  - Amyloid PET vs 1.0 writing group active
  - Quantitative SPECT: Considerable interest, calls

- **Conformance project(s) in progress:**
  - Groundwork projects exploring FDG PET profile
  - Groundwork projects to inform Amyloid profile
  - Technical proposals for SPECT, FDG and amyloid
### Prior Work

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- **Profile v 1.05**
- **Create ORO**
- **UPICT Protocol v 1.0 publication**
- **Draft Profile 2.0 (informed by Field Test phase I output)**
- **Field Test 1st**
- **Groundwork Project: Field Test phase 2 (Turkington)**

Phase I final actions pending, including individual Manufacturer feedback

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**Summary of the UPICT Protocol for FDG PET/CT Imaging in Oncology Clinical Trials**


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### Amyloid-PET Biomarker Comm.

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- Draft Amyloid-PET Profile v1.0
- Groundwork Project: Physical Phantom Development (Sunderland)
- Groundwork Project: DRO Development (Kinahan)

### SPECT BC (proposed)

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- Exploratory Discussions
- Draft SPECT Profile v1.0
Activities/Projects In Progress

- NIBIB-funded project update(s) (if any), listed according to Round 3, Round 4, etc.
- Future (Round 5) project proposals
- Other significant activities

Proposal for Steering Committee Action

- Endorse creation of SPECT/CT Biomarker WG
  - Proposal submitted—all key elements addressed
- Suggest Process Committee addresses common format for Profile version publication, Including approach for “minor” fixes.
Status of “Round 4” Funded Projects

• FDG-PET
  – Multicenter Field Test phase II (Turkington)
    • Sites identified (n = 9)
    • To deploy checklist from phase I
    • Use phantoms (+/- subject scans) to assess Profile feasibility;

Field (Feasibility) Testing of FDG PET Profile vs. 1.0

• Deliverables provided by FDG-PET Field Test group
  • Checklist of 36 specifications for imaging sites to assess Compliance
  • Items (19) identified to inform revision of Profile
Status of “Round 4” Funded Projects

- Amyloid- PET
  - Create Physical Phantom (Sunderland)
    - Candidate high resolution MRI scans identified
    - Automated segmentation of relevant anatomy begun
    - Gray vs. white matter segmentation underway
    - Testing of porous sheets (Porex)
  - Create ‘Virtual’ DRO Phantom (Kinahan)

ACR and Alzheimer's Association Lead Trial to Inform Medicare Brain Amyloid Imaging Coverage

- April 16, 2015
- A new four-year research study, with an estimated budget of $100 million, was announced April 16 by the Alzheimer’s Association and the American College of Radiology (ACR). The Imaging Dementia - Evidence for Amyloid Scanning (IDEAS) Study will determine the clinical usefulness and value in diagnosing Alzheimer's and other dementias in certain situations of a brain positron emission tomography (PET) scan that detects a core feature of Alzheimer's disease.
• High-resolution brain MRI selected from a population of 250 candidates representative of shrinkage, relevant age, and disease progression
• Tested the 3D Slicer, FSL-BET, and NeuroQuant software packages. None worked for the pre-processing step or removing the skull. The skull-stripping task was performed manually, and the NeuroQuant was to differentiate the gray matter, white matter, and CSF within the brain volume
• This segmented brain is now being incorporated into the DICOM structure and can be shared with the physical manufacturing component of the project (John Sunderland)

**Amyloid-PET Physical Phantom**

Physical Amyloid Phantom: Brain Slices: Grey/White/CSF cut from hygroscopic porous plastics from templates to simulate relative amyloid tracer uptake.
Activities/Projects In Progress

• Future (Round 5) project proposals

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<th>Project Title</th>
<th>Rationale</th>
<th>Deliverable</th>
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<tr>
<td>Assess repeatability of FDG and CT volumetric parameters</td>
<td>SUV max is in profile 1.0 for FDG. MTV, TLG are important and not standardized yet.</td>
<td>Test algorithms on known test re test lung cancer data sets with varying users.</td>
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<td>Develop procedure for standardizing PET spatial resolution</td>
<td>Resolution of PET affects quantitation but isn’t standardized</td>
<td>Cylinder-based method to assess resolution at same time as sensitivity/uniformity.</td>
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<td>Amyloid PET Test-Retest Meta-analysis</td>
<td>No meta analysis of Quantitative Amyloid Imaging</td>
<td>Perform meta analysis and use data to inform claim and possibly groundwork studies</td>
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<tr>
<td>Analyses to Support Amyloid Imaging</td>
<td>Little data on test-retest of software tools with varying amyloid agents</td>
<td>Groundwork data to inform claim as to individual patient variance and claim language</td>
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<td>Multi-site evaluation evaluation of accuracy and variability of Quantitative SPECT/CT</td>
<td>Uncertainty on accuracy of SPECT quantitation across systems for Tc99m, i-123 and ? In-111 vs object size, camera</td>
<td>Design of phantom. Measure accuracy on 4 commercial SPECT/CT systems. Detailed acquisition and reconstruction protocols for the above radionuclides</td>
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Key Updates Since Jan 2015 SC Meeting

- **Any leadership or organizational changes to report?** No
- **Milestones achieved?**
  - Publication of FDG-PET UPICT article (JNM April 2015)
  - Amyloid PET Profile – continued progress of draft creation
  - Progression of SPECT/CT Biomarker WG discussions
    - Proposed leaders (Dewaraja, Mozley & Seibyl)

- **Unanticipated problems or challenges?**
  - Change control mechanism (e.g. for lbm) waiting Process committee and DICOM field change issues?
  - Morphing field test work to conformance work and ?? Compliance??
  - Amyloid PET - Articulating Claim is a challenge
    - Multiple agents
    - Currently qualitative usage/label, but need quantitative
    - Individual repeatability papers lack statistical power – need aggregate
Challenges/Next Steps/Future Plans

• Update FDG PET Profile and move forward toward the “technically and clinically validated” state of vs 1.0. Move towards version 2.0
• Refine the claims based on literature and groundwork data to complete Amyloid 1.0 profile for public comment
• With Steering Committee Support initiate Quantitative SPECT/CT Profile in two possible use cases (I-123 Brain-DAT, Tc99m liver/large organ)
• Continue groundwork data acquisition
• Explore methods for “Conformance” and ? How to assure conformance, i.e. compliance

Thanks

• RSNA Staff
• Technical committee members
• Eric Perlman, Paul Kinahan
• And....
Leadership:

Leadership

• The action of leading a group of people or an organization
• Synonyms: guidance, direction, control, management, superintendence, supervision;

synonyms: directorship, governorship, governance, administration, captaincy, control, ascendency, supremacy, rule, command, power, dominion, influence
Thank you to Dan Sullivan for his vision, patience, wisdom and for demonstrating true leadership in QIBA.