QIBA COPD/Asthma Committee Update Call

Tuesday, October 13, 2009
11 AM CDT
Call Summary

In attendance:

Andrew Buckler, MS (Moderator)
Kristen L. Boedecker, PhD
Harvey O. Coxson, PhD
James D. Crapo, MD
Sean Fain, PhD
David S. Gierada, MD
Eric A. Hoffman, PhD
Philip Judy, PhD
Zachary H. Levine, PhD
Richard Mather, PhD
Michael McNitt-Gray, PhD
John D. Newell, Jr, MD
Berend Stoel, PhD
George Washko, MD

RSNA
Fiona Miller
Susan Anderson, MLS
Joe Koudelik

Agenda

- Review of group discussion Sept 30 at ACRIN meeting
  - Identify groundwork that has been completed
  - Distribution of COPDGene phantom images-reconstruction filter and slice thickness
- Target Profile (Ideal/Target/Acceptable)
- Industry participants

Introduction (Mr Buckler)

- The committee has been meeting biweekly to identify needs and strategies related to:
  - Density measurements
  - Airway thickness/morphology measurements
- Have documented sources of variability
- Claims statements for Profile still under discussion
- Considering nature of experimental groundwork needed to quantify across vendors and sites; appropriate use of phantoms for groundwork still under discussion
  - Looking for density that is achievable and acceptable; value of 1% change/year or 1HU has been cited by several
  - Suggested that there is need to be able to distinguish 1%/year lung density change in a clinical trial

Benchmarking

- Value in using an external benchmark such as RECIST in Vol-CT
  - Use what has already been done as a comparison
  - Four categories include Progressive, Stable, Partial Response and Total Response
- Steps:
  - Define benchmark
  - Try to better the benchmark

    - In COPD/Asthma, want statistically mathematical improvement
        - Want CT imaging to reduce the time of clinical trials, e.g., from 5 yrs to 2 yrs
    - In CT imaging, rate of lung tissue density loss (rate of progression) is 2 - 2½% HU per year (a more sensitive measure than rate-of-loss)
- Will document what we learn for these measures in Profiles (a recipe or protocol on vendor products for users to achieve Claims which indicate accuracy)
- Two measures published in Alpha 1 group 10 years ago:
    - rate of progression
    - presence and distribution of emphysema (more forgiving than rate of loss)
- There is no consensus concerning required accuracy because no standards exist and it is not known how to standardize across scans
- No data on articulated target and whether there is true technology to measure reliably
    - Discussion of highest number that can be reasonably achieved over time
    - What is technically possible is primary question

Experimental groundwork (Dr McNitt-Gray)

- Review of groundwork on tumor volumetrics in VolCT Technical Ctte:
    - Group 1A: in phantom with known size lesion, what variability in tumor volume and morphology with different readers
    - Group 1B: with patient data, e.g. coffee break experiment from MSKCC, with scans where No Change is expected
    - Group 1C: examine variability on phantom scans across manufacturers
- What groundwork has been accomplished in COPD/Asthma?
- Phantom data sets include:
    - Some published work done in Europe on densitometry (reproducibility)
    - Dr Stoell can provide reference(s)
    - Data from ECLIPSE study in which phantoms scanned in different institutions is available (Dr Coxson)
    - COPDGene is analyzing data for QA procedure
- Much data already acquired, but need to determine whether it is possible to extrapolate phantom results to human imaging.
    - Reproducibility study with two analyses to demonstrate degree and source of variability
    - inspiratory respiration is the biggest variable
- Consider two activities:
    - 1. analysis of Coxson ECLIPSE study data based on 42 acquisition sites
    - 2. collect and analyze coffee break data
- Dr Hoffman has coffee break data with TLC and FRC; both on pneumothoraces
- As an intermediate step, conduct detailed review of the literature to formulate specific questions for narrow experimental design
- Discussion on defining what image sets to contribute to an image library and decision on which image library

Phantom design

- Bubble size in phantoms needs to be addressed
- Consider London (thorax) Phantom
    - Contains both lungs; could be circulated between sites to test standardization methods

- Dr Judy to distribute COPDGene Phantom images with recon filter data on DVD if interested
- Use of lung path specimens:
    - Support use of lung tissue in phantoms, e.g. fixed cores of sheep lungs in phantom
    - There are challenges in using lung tissue, e.g. drying, shrinking, stability over time, mold
    - Possible design would be use of tissue in a compressed time study; using multiple vendor scanner systems within close physical proximity suggested; similar to what was done at SARP sites

Next steps:

- Dr Stoell will provide citations for studies relevant to Claims section of Profile
- Dr Coxson to provide citation for study published in Chest
- Dr Judy will collect literature citations for review as a group
- Suggestions of questions requested from group
- Define what image sets to contribute to a public image library and discuss decision on which image library – need image sets in a public domain