The University of Utah
Center for Alzheimer's Care, Imaging & Research
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Quality Assurance in a Multi-Center PET Imaging Trial

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BACKGROUND

- Imaging studies pose added challenges for clinical trials
- Logistical and technical issues raised by imaging are not addressed by current clinical trial monitoring procedures, but are critical to study success
- Such "technical deviations" are usually not apparent to study coordinators and often identified only as images are processed

OBJECTIVE

Classify and determine the frequency and types of technical deviations in a multi-center PET imaging trial

METHODS

- Nine academic centers with variable imaging experience performed 55 scans in patients with suspected frontotemporal dementia using positron emission tomography with ^{18}F-fluorodeoxyglucose (FDG-PET)
- Centralized Data Coordinating Center (DCC) used for image processing and analysis
- Scans performed using a standard technique without restraints
- History of a behavior disturbance was not exclusionary; indeed it was common
- Scan scheduling, completion and processing continuously monitored
- Standards for scan quality and timeliness of data established at outset

RESULTS

- 52 of 55 images (96%) ultimately met full quality standards
- 54 of 55 (98%) were usable in the study
- Timely DCC interventions improved image quality in 6 scans (11%)
- The most frequent technical deviation was a delay in transferring data to the DCC
- The number of technical deviations was variable from site to site and became less frequent as the trial progressed

CONCLUSIONS

- Uniform and comprehensive technical standards should be established at the onset of imaging trials and assessed prospectively using explicit rules
- Timely quality assessment and working closely with sites minimizes problems caused by technical deviations
- Our quality monitoring procedures are effective and feasible for adoption
- High quality FDG-PET studies can be achieved without restraints, even in demented patients with a history of behavior disturbance

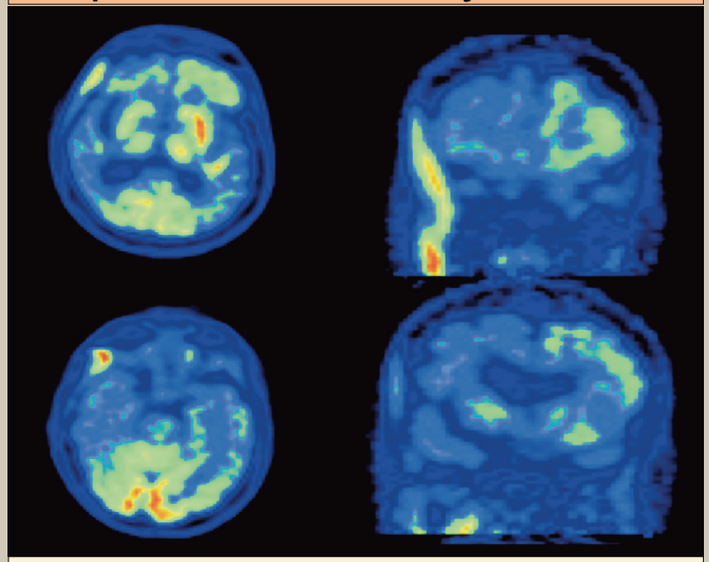
Severity Rating and Frequency of Technical Deviations

Severity Rating	Frequency	% All Scans
Uncorrectable Scan can't be used	**1**	**1.8**
Major Ultimately some image degradation	**2**	**3.6**
Correctable Full image quality achieved	**4**	**7.3**
Minor Scan quality never affected	**31**	**56.3**

Classification and Frequency of Technical Deviations

Classification	Frequency	% All Scans
Acquisition	4	7.3
Processing and Reconstruction	9	16.4
Poor Image Quality (Movement)	0	0
Unexpected Scan Abnormality	1	1.8
HIPAA Violation	1	1.8
Non-Delay Deviations	**15**	**27.3**
Delays in Data Transfer	21	38.2
Delays in DCC Processing	2	3.6
Delay Deviations	**23**	**41.8**

Unexpected Scan Abnormality



Incidental abnormality caused by asymmetric masseter contraction during isotope uptake

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Foster NL, Koeppe RA, Heidebrink JL, Stevenson V, VanHuysen C for the Pilot Collaborative PET Imaging Trial. Quality assurance in a multi-center PET imaging trial. Alzheimer's & Dementia: The Journal of the Alzheimer's Association, 2006, 2(Suppl 1), S322.