Summary

Structure of the FDG PET/CT Profile

- FDG-PET/CT is already in use for quantitatively assessing response to therapy
- Considerable information is already available on bias and variability in FDG PET/ CT measurements

- Technical Subcommittees have focused on five areas of enhancement for profiles
  1. Standardized Uptake Value (SUV)
  2. Covariates data capture
  3. Role of QA/QC procedures
  4. Software version tracking
  5. Region of interest definition and validation

FDG PET/CT Profile Primary Claims

- Quantitation of tumor metabolism via FDG-PET/CT that can be used practically and efficiently as a biomarker.

- This biomarker shall be of known precision and accuracy when used in single- and multi-center, multi-vendor clinical trials and meta-analyses, enhancing its potential for use in patient care and qualification for use in clinical studies of pathophysiology and therapeutic interventions.

Subcommittee 1: Standardized Uptake Value (SUV)

Background: Due to the variability in the implementation of the PET DICOM standard, calculation and verification of correct PET standardized uptake values (SUVs) is challenging.

There is a need for:

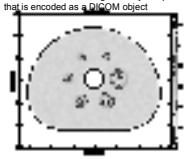
1. Collection of accessible information on DICOM fields and methods used for calculating SUVs
2. A common reference DICOM test image that can be generated by each scanner and read on PET DICOM display stations to check information fidelity

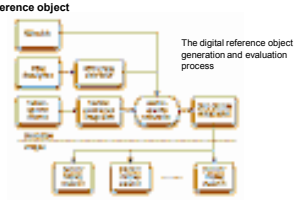
Status: This subcommittee has

1. Completed and published a survey with PET/CT manufactures on their methods for calculation of PET standardized uptake values (SUVs)
2. Provided vendor-neutral guidelines for interpreting DICOM data from all manufacturers
3. Developed and performed initial testing of a generic DICOM digital reference object to ascertain DICOM interpretation by review and analysis workstations

Digital reference object

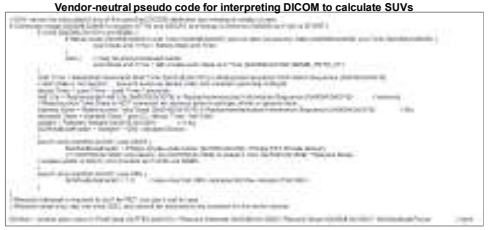
Digital reference object: a synthetic image, based on the NEMA NU-2 Image Quality test phantom, that is encoded as a DICOM object





The digital reference object generation and evaluation process

Vendor-neutral pseudo code for interpreting DICOM to calculate SUVs



Subcommittee 2: Covariates

Background: There are a number of independent variables that affect the measurement of tumor and normal tissue SUVs using FDG-PET. Variations in these covariates should be minimized and/or properly documented

Status: This subcommittee completed a description of the rationale, limitations, and proposed potential solutions for addressing the following critical variables, based in part on EORTC guidelines and NCI consensus recommendations

- patient weight and height
- injected activity
- blood glucose
- time
- fasting time
- hydration
- physical activity
- FDG uptake time

Selected Covariate Descriptions

Patient Weight

Rationale: Patient weight is required for the standard SUV body weight correction and should be measured on the day of the PET/CT scan. Entry of weight is also required for phantom studies to verify accurate scanner calibration and SUV calculation.

Limitations: The precision that can be recorded on some PET/CT scanners is only 1 pound or kilogram. This leads to significant errors for small patients (e.g. pediatric) and more importantly phantom measurements. Patient weight is sometimes automatically imported from medical records and is not necessarily accurate.

Potential Solution: All PET/CT vendors should allow entry of weight with a minimum precision of +/- 0.1 pounds or kilograms. Patient weight should be measured on a properly calibrated scale in the imaging department on the day of each scan.

Injected activity

Rationale: Accurate recording of the net injected activity is essential for measuring accurate tumor SUVs

Limitations: The acquisition software for some PET/CT scanners do not allow the entry of residual activity and calculation of net injected activity. Many customer sites do not measure residual activity and/or properly correct for decay. The assay dose and/or time are often incorrectly used as net injected activity and injection time.

Potential Solution: All PET/CT scanners should record assay activity and measurement time, residual activity and measurement time, and time of injection. PET/CT scanners should automatically calculate the net decay-corrected injected activity. The assay and residual activities and times should be stored in (future) public DICOM tags (in addition to the net injected activity that is currently stored).

Blood Glucose Concentration

Rationale: Blood glucose levels affect the biodistribution of FDG and the quantification of PET SUVs.

Limitations: Most PET/CT acquisition software does not record glucose and there is no public tag for the data.

Potential solution: PET/CT acquisition software should record the glucose value and time of measurement in a (future) public DICOM tag.

Subcommittee 3: Quality Control

Background: Quantitative PET imaging requires more rigorous quality control procedures than might be performed at centers that only perform qualitative clinical imaging. In addition, various regulatory and accreditation agencies (e.g. FDA, Joint Commission, ACR) require documentation of the quality control tests that are performed and the subsequent results.

Status: This subcommittee has:

1. Reviewed the current quality control procedures and output for the 3 major PET/CT vendors and the current technical limitations were identified
2. Described the rationale for addressing limitations
3. Proposed potential solutions

Subcommittee 4: Software Version Tracking

Background:

- Due to the continuous improvements of current PET/CT systems, vendors will upgrade software in different sub-systems from time to time for the same scanner.
- Some of the upgrades include quantitation improvements. It is crucial for users to include these changes into their trial data or clinical results.
- Essential software versioning to be tracked: Typically, three major pieces of SW in the quantitative imaging chain should be tracked:
  1. Acquisition (including detectors)
  2. Reconstruction (may be combined with acquisition)
  3. Quantitation/Analysis tools
- Besides software version tracking, other information, such as reconstruction methods, filtering parameters, and calibration file information, should also be recorded in the image header.

- **Status:** This subcommittee has
  - Initiated a survey of PET/CT scanner manufacturers on software versioning practice
  - Completed recommendations for
    1. Short term: Manual Tracking

       Currently, every vendor should have the ability of obtaining the version info each software installed. The committee will send out a survey to vendors for instructions to check the SW versions (Acquisition, Reconstruction, Quantitative Analysis).
    2. Fully DICOM Tracking (5-8 Years)

       Currently only the DICOM attribute for acquisition SW version exists. The SW version tracking committee will work with other committees to define a global recommended list of DICOM attributes needed for quantitation purpose.
    3. One-button SW Tracking Function (8 Year beyond)

       Currently, vendors provide tools to view most DICOM information. However versioning information is missing (due to non existing DICOM Attributes): The goal is to encourage vendors to provide a one-button function in a quantitative analysis tool to display all quantitative related information after all necessary attributes are are populated in the DICOM image header.

Subcommittee 5: Region of Interest (ROI)

- **Background:** Methods for ROI analysis, even calculating the mean for pixels within an ROI are implementation-dependent. Such methods are sensitive to software details and to operator use.

- **Status:** The Goals of this subcommittee are:
  1. Ongoing participation of vendors of each workstation used for PET image display and analysis
  2. Assessment of the current ROI capabilities of each workstation and software application.
  3. Recommendations for ROI methods that work equivalently on as many current workstations as possible.
  4. Recommendations for implementation of improved ROI methodologies for future availability

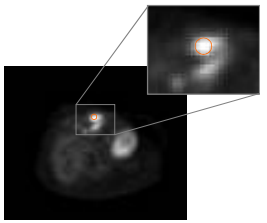


Illustration of some of the details in an ROI calculation at the pixel level

More Information

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