QIBA FDG/PET PROFILE FIELD TEST PHASE I

GOALS:

1. To evaluate the specifications of the QIBA FDG/PET profile in three academic PET imaging centers and then in a larger, more varied field test.
   - *Assess the feasibility and necessity of each item.*
2. To streamline the large list of specifications into a much shorter essential checklist that can be used to ascertain potential for doing quantitative PET imaging optimally.

DELIVERABLES:

1. A list of proposed changes to the Profile
2. A streamlined site checklist (in spreadsheet form, tying each specification to the original profile, and in simple text form).
The potential for widespread deployment of the profile was assessed as part of a clinical feasibility study that evaluated the importance and practicality of the profile recommendations.

*Modification or removal of each specification is based on reassessment of:
1) tradeoff of feasibility and impact on quantitation,
2) actual relevance to quantitation*

**FDG PET/CT Profile Field Test**

**Phase 1: Academic sites (3)**

- For each specification:
  1. Is it current practice (y/n)?
  2. Is spec feasible (y/n)?
  3. Is it feasible but objectionable (y/n)?

- Summarize feasibility by spec

**Phase 2: Additional sites (beyond academic)**

- For each specification:
  1. Is it current practice (y/n)?
  2. Is spec feasible (y/n)?
  3. Is it feasible but objectionable (y/n)?

- Checklist, Profile update
  - Define update process
  - Remove, modify specs as warranted

**Phase 3: Finalize checklist as a “Conformance” tool**

- For each check:
  1. Is it current practice (y/n)?
  2. Is it feasible (y/n)?
  3. Is it feasible but objectionable (y/n)?

- Compliant Site
- Non-Compliant Site

*Feasibility Questionnaire Summary Results*

<table>
<thead>
<tr>
<th>Routine Clinical Care</th>
<th>Clinical Trials</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imaging weight PET/CT</td>
<td>Currently In Practice</td>
<td>Currently In Practice</td>
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<tr>
<td>Manufa scanne</td>
<td>Routine Clinic</td>
<td>Not Feasibl</td>
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</tbody>
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SITES PROVIDED RESPONSES FOR EACH PROFILE SPECIFICATION

Example 1

“The Technologist shall measure and document subject height and weight and enter this information into the scanner during the PET/CT acquisition. Subject body weight shall be measured at the time of each PET/CT scan with standardized measurement devices and with the subject in an examination gown or light clothing. ...”

Responses:
- Current practice
- Feasible
- Feasible but not going to do it
- Not feasible

Outcome:
No change to profile

Example 2

“Technologist shall administer FDG intravenously through a large bore (21 gauge) indwelling catheter placed anatomically remote to any sites of suspected pathology, preferably in an antecubital vein...”

Responses:
- Current practice
- Feasible
- Feasible but not going to do it
- Not feasible

Outcome:
Change to “(24 gauge or larger)”
SITES PROVIDED RESPONSES FOR EACH PROFILE SPECIFICATION

Example 3

“The Technologist shall ensure that the tracer uptake time for the baseline scan is 60 minutes, with an acceptable range of 55 to 75 minutes…”

Responses: Some Phase II sites use 90 minutes uptake.
Comment: 90 minutes is better in some Regards.

Outcome: No Change.

SITES PROVIDED RESPONSES FOR EACH PROFILE SPECIFICATION

Example 4 (manufacturer)

“Shall be able to accept the radionuclide type (i.e. F-18) from the DICOM Modality Worklist either from the NM/PET Protocol Context, if present, or by deriving it from the Requested Procedure Code via a locally configurable tables of values.”

Responses: Most systems can’t
Comment: Is this even necessary?

Outcome: Make “Future Specification”
ASSIMILATION OF RESULTS FROM FEASIBILITY ASSESSMENT

Phase I Feasibility: 3 Academic Sites

- Critical Introspection for all statements and requirements.
- Any unfeasible or unclear components of the FDG PET/CT Profile specification were identified in a written report. The workgroup considered what specifically was not feasible, and if possible, an alternative approach was identified. This phase ended with the development of a preliminary checklist.

Phase II Feasibility: 11 Sites – Academic and Community

- Use Preliminary Checklist from Phase I to evaluate feasibility and plan for Phase II feasibility assessment.
- Collect Comments and assess feasibility of all checklist items. Identify any unfeasible or unclear components.
- Generate Updated Profile with changes informed by feasibility assessment.
- Generate final checklist for Phase II feasibility assessment.

16 Sections had recommended changes

Recommended changes to the QBA FDG PET Profile
From the Phase I Profile Task group: Tim Tuckington, Martin Lodge, and Ronald Broda
Feb. 26, 2015

The field test group recommends a limited number of changes to the FDG PET Profile, after having tested the entire set of specifications in our own centers. For each change, we list the current location in the profile, the new statement, and the possible addition comments in ().

3.1.3.1.1
The technologist shall administer FDG intravenously through a large bore (21 gauge) indwelling catheter placed anatomically remote to any sites of suspected pathology, preferably in an antecubital vein. Intravenous ports should not be used, unless no other venous access is available.

One Field Test site successfully uses 24 gauge. We suggest broadening the allowance to at least 24 gauge.

In the case of mechanical administration, a three-way valve system should be attached to the intravenous cannula so as to allow at least a 10 to 20% injection following the FDG injection.

The profile makes allowances for sites with automated procedures. The specification should reflect that.

Technologist shall
1. Record the exact and expected amount of FDG injected (in ml). Moderately physiological range is less than 7% and less than 20%. Accuracy estimated more than 2%. Estimation will be done based on charges and/or known typical values.
2. Remove the infusion site.
3. The occurrence of substantial (>1%) elimination is extremely rare. Estimation is almost.

Appendix I: QBA FDG PET/CT Imaging Site and Scanner Checklists

The following checklist may be used to ascertain a PET imaging site’s qualification for quantitative imaging according to the QBA FDG PET/CT profile. Answers may be provided either as “current practice” or “feasible”, depending on the context, but it should be made clear both which was expected and how the site answered.

Site and Personnel Qualifications

1. The site is accredited (AQC, ACC, etc) or has Qualified status for clinical trials (GFDG-PET/CT: FMN, GEM, QW, etc.)

2. The site has the support of technologists, physicians, and patient’s personnel in the use of FDG-PET/CT, and meeting the qualifications described below.

3. The technologist’s PET/CT units are verified by physicists who are certified by the respective. Whether the American Society of Nuclear Medicine (ASNM) or the American Society of Radiologic Technologists (ASRT), and should meet all local, regional, and national regulatory requirements for the administration of radiation to patients.

4. The physician’s PET/CT imaging facilities are certified by the American Board of Radiology (ABR) in Nuclear Medicine Physics by the American Board of Nuclear Medicine (ABNM), and is a member of the Canadian Society of Nuclear Medicine in addition to the local, regional, and national regulatory requirements for the administration of radiation to patients.

5. The technologist’s PET/CT units are verified by physicists and/or radiologists. ceiling: PET/CT scanning is performed in a facility certified by the ACR or an equivalent entity.

Imaging Procedures

1. Patient height and weight are entered into scanner during PET/CT acquisition.

2. Blood glucose is measured for each patient within 2 weeks prior to PET/CT administration.

3. If and when glucose threshold is exceeded, the reason will be documented.

4. No specific requirements are specified for the patient’s diet or regular or focal type of exercise.
There was a lot of compliance for imaging sites and manufacturers.

Points of non-compliance were extremely valuable for discussion of Profile and honing it.

Feedback from imaging sites and manufacturers is essential

Essential vs. Good Idea vs. Standard Practice

For manufacturers, future systems will be built with Profile in mind.