<u>Note</u>**: Summary table for three similar studies**

Clinical Area:	**FDG PET for breast cancer: Staging of axilla**
Keywords:	**FDG PET, breast cancer, carcinomas, axilla**
References :	Smith IC, Ogston KN, Whitford P, Smith FW, Sharp P, Norton M et al. Staging of the axilla in breast cancer: accurate in vivo assessment using positron emission tomography with 2-(fluorine-18)-fluoro-2-deoxy-d-glucose. Ann Surg 1998; 228: 220-227.

Avril N, Dose J, Janicke F, Ziegler S, Romer W, Weber W et al. Assessment of axillary lymph node involvement in breast cancer patients with positron emission tomography using radiolabeled 2-(fluorine-18)-fluoro-2-deoxy-D-glucose. J Natl Cancer Inst 1996; 88: 1204-9.

Crippa F, Agresti R, Seregni E, Greco M, Pascali C, Bogni A et al. Prospective staging of fluorine-18-FDG PET in presurgical staging of the axilla in breast cancer. J Nucl Med 1998; 39: 4-8.

Study Type:	Comparison of diagnostic tests
Study Aim:.	To evaluate the diagnostic value of FDG PET for staging the axillary lymph nodes.

<u>Outcomes</u>
- *Primary:* Sensitivity, specificity

<u>Validity</u>
For all 3 studies:
- Sample size of n ≥50
- Prospective
- Blinded assessment of PET findings. Comparison to gold standard (clinical exam/cytopathologic findings/histopathological surgical findings)
- Presented sensitivity and specificity information
- Limitation: Did not present information on impact of FDG PET findings on patient management.
- **Conclusions regarding validity of methods:** Studies had reasonably valid methods for diagnostic test studies. Findings did not include the affect of FDG PET scan findings on patient management decisions. The Smith and Avril studies did not select consecutive patients which may have introduced selection bias.

Smith et al., 1998
<u>Design</u>
Number of subjects: N=50
Description of study population: Mean age=67 (range=26-89); 38% postmenopausal.
Inclusion/exclusion: <u>Inclusion</u>: Women with a diagnosis of breast cancer. <u>Exclusion</u>: younger than 18 years; pregnant; diabetes mellitus; unable to lie still within the PET imager.
Consecutive patients?: Not specified.

Results

	Clinical exam (n=50)	Axillary PET imaging (n=50)
	%	%
Sensitivity	57	90
Specificity	90	97
PPV	80	95
NPV	74	96

Avril et al., 1996

<u>Design</u>
Number of subjects: N=51
Description of study population: Mean age=50 ± 10 years (range=18-74); 22% postmenopausal.
Inclusion/exclusion: <u>Inclusion</u>: Newly discovered breast tumors, scheduled to undergo surgery. <u>Exclusion</u>: pregnant, diabetes mellitus, under 18 years old.
Consecutive patients?: Not specified.

Results

	Clinical exam (n=51)	Axillary PET imaging (n=51)
	% (95% CI)	% (95% CI)
Sensitivity	58 (36-78)	79 (57-93)
Specificity	85 (66-96)	96 (81-100)
PPV	78 (30-70)	95 (75-100)
NPV	70 (51-85)	84 (66-95)

Crippa et al., 1998:

<u>Design</u>
Number of subjects: N=68 (4 had bilateral disease, n=72 breasts)
Description of study population: Mean age=68 years (range 29-84);
Inclusion/exclusion: <u>Inclusion</u>: <u>Exclusion</u>:
Consecutive patients?: Yes.

Results

	Axillary PET imaging (n=72 breasts)
	%
Sensitivity	85 (23/27)
Specificity	91 (41/45)

Reviewer's conclusions

Sensitivity of FDG PET at detecting axillary metastases was 79%, 85% and 90% in the three studies; specificity was 91%, 96% and 97%. In the two studies that compared PET to clinical exams, sensitivity was substantially higher for PET and specificity was somewhat higher (statistical testing was not done).