

Progress in Access to PET Scanning ...but regional differences persist

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The past year has seen some progress in the availability of Positron Emission Tomography (PET) imaging technology to Canadian patients with cancer, although there remain significant regional differences. This overview will provide background to availability of FDG, the radioactive drug required to image most cancers; clinical PET scanning; medical cyclotron facilities; and research sites.

Availability of Fluoro-deoxyglucose (FDG)

One of the major factors limiting the rapid diffusion of PET imaging was the regulatory position of FDG. Health Canada regulations required that each centre producing FDG be considered an independent manufacturing site and that all patient studies had to be performed under a clinical trial application. Over the past year, four centres have made new drug submissions with respect to FDG and have received formal Notice of Compliance documentation from Health Canada. These centres are: IPET in Vancouver, McMaster University in Hamilton, BMS in Sherbrooke and Alberta Cancer Board in Edmonton.

Once the inspection processes have been completed, these four sites will be able to supply FDG for clinical imaging use for the specified indications without a CTA arrangement. In addition, off label use will also be permitted. This will be very helpful in situations where an oncologist believes that a PET scan may be valuable in the management of a less common malignancy. For example, although PET scans will be approved for the staging evaluation of patients with cervical cancer, a less common cancer like vaginal cancer may not appear on the list of approved indicators. In the future it will be possible to order PET scans for patients with less common malignancies provided that the oncologist can justify the request based on his or her ability to show how the result will influence patient treatment and provided that the nuclear medicine physician performing the scan agrees.

Notices of compliance for these four manufacturers

will, over the course of 2008, significantly improve the availability of PET scanning and reduce the complexity of the procedure from the patient point of view. Previously patients were required to agree to be part of a research protocol in order to obtain a scan. The process of giving consent for participation in a clinical trial is significantly more time consuming for both patients and staff. Since in all provinces, except Ontario, most PET scans will be performed as part of routine clinical practice, the process will become as simple as consent to a CT scan or MRI scan.

Clinical PET Imaging

PET imaging continues to be available across the country with Ontario remaining the province with the most limited access (compare Table 1, Ontario, with Table 2, Alberta).

TABLE 1 **INDICATIONS FOR PET SCANNING IN ONTARIO**

ONTARIO ACCESS TO PET IMAGING		
Indication	Clinical Trial	Registry
Non-Small Cell Lung Cancer (early)		+
Non-Small Cell Lung Cancer (late)	+	
Breast Cancer (nodal spread)	+	
Squamous Cell Carcinoma of the Head and Neck	+	
Colorectal Cancer (prior to liver resection)	+	
Thyroid Cancer		+
Solitary Pulmonary Nodule		+
Colorectal Cancer		+
Germ Cell Tumors		+

The gap between Ontario and the rest of Canada appears to be getting wider.

TABLE 2 **INDICATIONS FOR PET SCANNING IN ALBERTA**

CONDITION/ PRIMARY CANCER	INDICATION
LUNG	Diagnosis and staging Solitary pulmonary nodule
LYMPHOMA	CT post-treatment
GYNECOLOGY	Staging after recurrence Assess surgical resectability
RECTAL/ COLORECTAL	Persistent elevated CEA Staging after recurrence
THYROID	Thyroid ca with elevated thyroglobulin, post treatment
BREAST	Local regional recurrence
BRAIN	Recurrence versus radiation necrosis
MELANOMA	Staging after recurrence Assess surgical resectability
ESOPHAGUS	Staging
HEAD AND NECK	Staging Staging after recurrence Assess for surgery Monitoring
INDETERMINATE LIVER LESIONS	All primaries
GERM CELL	Diagnosis of recurrence Differentiation of scar from recurrence
SARCOMAS	Diagnosis of recurrence Differentiation of scar from recurrence
UNKNOWN PRIMARY	Staging/diagnosis Diagnosis of recurrence
EPILEPSY	Refractory; potential surgical candidate

In Ontario there remains very limited access to PET scanning for patients with cancer. There is a movement away from enrollment in Ontario clinical trials, to registration of patients undergoing PET imaging in a specific tumor type registry which will allow evaluation of efficacy at some later date.

Gradually the barriers to cancer patients being able to access PET scanning for approved indications are being lowered in provinces across Canada. For example the indications for PET scanning in Alberta are quite wide-ranging (Table 2).

In contrast, access is very much more limited in Ontario. Access to PET scanning in Ontario continues to be limited to those patients who are either eligible for entry into one of the formal clinical trials, or those patients eligible for being included in the registry. Table 1 outlines those entry points. The gap between Ontario and the rest of Canada reported in last year's Report Card appears to be getting wider.

PET scanners for clinical imaging are available in the following locations:

Vancouver	2 (1 private)
Calgary	1
Edmonton	2
Winnipeg	1
Ottawa	2 (one of these scanners is mainly dedicated to research but does perform some clinical cardiac imaging under the myocardial viability registry).
Toronto	4 (1 private)
Hamilton	1
London	1
Quebec	12 (2 private)

While most PET imaging studies are currently performed under the CTA regulations, there will be an increasing move away from this in all provinces, except Ontario, as the manufacturing sites make their approved products available.

Most PET scanners across the country are performing between 1000 and 1600 images annually.

Clinical scanners are planned for Thunder Bay and Halifax. It is anticipated that these scanners will be installed and operating within the next 18 months.

It is important to note that in Ontario (McMaster), Quebec (BMS), Alberta (Cross Cancer Institute) and British Columbia (IPET), Health Canada product approval for FDG for PET imaging has been obtained. The indications are outlined in Table 3.

With these Health Canada approvals there is no requirement to use the previously required CTA process to perform PET scans with these four products on patients for any indication if, in the opinion of the referring physician the test is important to the care and management of the patient, and of course, if it is funded by the provincial government.

Medical Cyclotron Facilities

Medical cyclotrons are currently installed and operating in the following cities: Edmonton, Ottawa, Hamilton, Toronto (almost entirely dedicated to research use), Sherbrooke, and Montreal. Cyclotron installations are planned over the next one to two year time frame in the following cities: Vancouver, Winnipeg, Toronto, London, Quebec, Halifax and Thunder Bay. Each of these cyclotrons will require the construction of glucose monophosphate (GMP) manufacturing facilities for the production of FDG and for other PET imaging tracers that may be required by the oncology communities.

There continues to be considerable activity on the research front across the country

Research Facilities

There continues to be considerable activity on the research front across the country and many of the cyclotron sites that will be installed over the coming years will support both clinical research and research facilities. PET scanners dedicated to research have been installed in the following sites: Vancouver (UBC), Edmonton (Cross Cancer Institute), Ottawa (Ottawa Heart Institute), Toronto (Princess Margaret Hospital, Centre for Addiction and Mental Health), Montreal (Montreal Neurological Institute), Sherbrooke (CHUS). There continues to be a dialogue across the country about ways in which the research activities of the various PET groups can be integrated and enhanced.

Since last year there has not been a significant enhancement of PET imaging capability across the country, but this has been largely due to no significant change in the access of PET imaging to Ontario patients. There have been a number of new scanner installations and several more are planned which have the potential to increase the availability of this technology to patients with cancer in each province.

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TABLE 3 **PRODUCT APPROVAL FOR FDG FOR PET IMAGING**

Health Canada FDG NOC			
	Non-Small Cell Lung Cancer	Small Cell Lung Cancer	Colorectal Cancer
McMaster	+		
BMS	+		
CCI	+	+	+
IPET	+		