

Bulletin



Bulletin Number	Date	Direct inquiries to
4452	July 12, 2007	Ministry of Health and Long-Term Care Office Locations
Distribution		(address below)
Physicians, Hospitals, Clinics and Laboratories		

Subject: Positron Emission Tomography (PET) Studies/Programs Funded by the Ministry of Health and Long-Term Care, Ontario, Canada

Positron emission tomography is a nuclear medicine diagnostic imaging procedure using positron emitting radiopharmaceuticals, often F18 fluorodeoxyglucose (FDG). Evidence suggests that PET may have a role in the assessment of certain cancers and myocardial viability. The FDG produced by most Ontario PET centres is currently not approved by Health Canada for routine clinical use, but may be used for research purposes. Furthermore, PET scanning is presently not an insured health service in Ontario.

Ontario PET Evaluation Studies (1st Step)

Based on recommendations of the Ontario PET Steering Committee and the Ontario Health Technology Advisory Committee, the Ministry of Health and Long-Term Care (MOHLTC) is funding:

- 5 PET clinical trials, and
- 2 PET registries, one for cancer patients, which includes 4 separate indications and one for cardiac patients.

Physicians may make a referral to a principal investigator of the appropriate clinical trial, or to the nuclear medicine department at the PET Registry Coordinating Centre for a registry study that matches the patient's condition. Eligible patients can receive a PET scan at participating health sciences centres in Toronto, Hamilton, London, or Ottawa. There will be no charge to the patient.

A brief description of each trial and its enrolment status as of May 31, 2007, as well as the contact information for the principle investigator at each centre, are summarized in Attachments 1 (Positron Emission Tomography Trials and Registry Funded by the Ministry of Health and Long-Term Care – 2 pages) and 2 (Ontario Pet Scan Access Program Request – 2 pages) this bulletin. This information is also available at the following website <http://ontariocancertrials.ca/>.

Office locations

Barrie 34 Simcoe St. Suite 102 L4N 6T4	Etobicoke 3300 Bloor St. W., Unit 142 M8X 2W8	Hamilton 119 King St. W 10th fl. P.O. Box 2280, Str. A L8P 4Y7	Kenora 220-808 Robertson St. P9N 1X9	Kingston 1055 Princess St. P.O. Box 9000 K7L 5A9	Kitchener 1400 Weber St. E. Unit B2 N2A 3Z8	London 217 York St., 5th Floor Station A N6A 5P9
Mississauga 201 City Centre Dr. Suite 300 L5B 2T4	Newmarket 465 Davis Dr. Unit 108 L3Y 8T2	North Bay 101-447 McKeown Ave. P1B 9S9	North York 4400 Dufferin St N Unit A4-A5 M3H 6A8	Oakville Oakville Town Centre II 220 North Service Rd. W. L6M 2Y3	Oshawa Exec. Tower, Oshawa Centre. 419 King St. W. P.O. Box 635 L1J 7J2	Ottawa Fuller Building 75 Albert Street K1P 5Y9
Ottawa Government Service Centre 110 Laurier Ave W K1P 1J1	Owen Sound 1400 1st Ave. W Suite # 2. N4K 6Z9	Peterborough 300 Water St, 1st Fl North Tower K9J 3C7	St. Catharines 301 St. Paul St. Mezzanine Level L2R 3M8	Sarnia 452 Christina St. N. N7T 5W4	Sault Ste. Marie Roberta Bondar Place 70 Foster Dr., Ste. 100 P6A 6V4	Scarborough 2063 Lawrence Ave. E. M1R 2Z4
Sudbury 199 Larch St., Suite 801 P3E 5R1	Thunder Bay 435 James St. S., Suite 113 P7E 6T1	Timmins 38 Pine St. N., Suite 110 P4N 6K6	Toronto 47 Sheppard Ave. E. Suite 417 M2N 7E7	Toronto-Downtown 777 Bay St, Suite M212 M5G 2C8	Windsor 1427 Ouellette Ave. N8X 1K1	Head Office P.O. Box 48 Kingston, ON K7L 5J3

Ontario PET Access Program (2nd step if your patient cannot access through Step 1)

If the patient is not identified as a candidate for any of the clinical trials or registry studies, the patient might still be able to receive a PET scan in Ontario, through the Ontario PET Access Program. A review process has recently been established by MOHLTC in conjunction with Cancer Care Ontario (see attachment 2 – Ontario Pet Scan Access Program Request). Through this review process, a radiologist, a nuclear medicine physician, and an oncologist, determine whether the patient is an appropriate candidate for a PET scan. If there is agreement that a PET scan would be appropriate, then the PET Access Office at the Hamilton Health Science Centre is notified and arrangements are made for this patient's referral to an appropriate Ontario PET Centre for the PET scan.

Before requesting a PET scan under the Ontario PET Access Program, it is advisable for the clinician to first review the summary of the clinical trials and registries (See attachment 1 – Step 1 - Positron Emission Tomography Trials and Registry Funded by the Ministry of Health and Long-Term Care). All efforts must be made to have the patient enrolled in one of the clinical studies or registry studies before considering the alternative described above as Step 2.

Attachment 1

PET Clinical Trials

MOHLTC has committed funding for 5 clinical trials coordinated by the Ontario Clinical Oncology Group of Cancer Care Ontario (CCO) (Table 1). Of the 5 clinical trials, PET PREVENT, a trial to evaluate the ability of FDG PET to detect the presence or absence of lymph node metastases in newly diagnosed breast cancer patients completed patient accrual in April 2007 and is now closed. The results of this trial are being analyzed, and will be reported to the Ontario PET Steering Committee shortly. In addition to the current clinical trials, the Ontario PET Steering Committee provides advice to MOHLTC regarding new indications and the need for additional trials based on ongoing international research.

Ontario Cancer PET Registry

The PET registry provides a PET scan to and tracks the outcomes of patients who meet the eligibility criteria for one of the following conditions:

- Solitary pulmonary nodule (SPN) for which a diagnosis has not been established by fine needle aspiration cytology (FNA), is inaccessible to FNA or there is a contra-indication to the use of FNA;
- Thyroid cancer where recurrent or persistent disease is suspected on the basis of an elevated and/or rising thyroglobulin but standard imaging studies are negative;
- Germ cell tumours where recurrent disease is suspected on the basis of elevated tumour markers (beta HCG and/ or alpha fetoprotein) and standard imaging tests are negative, or a mass persists after primary treatment and surgical resection is being considered;
- Colorectal cancer where recurrent disease is suspected on the basis of elevated or rising carcinoembryonic antigen (CEA) during follow-up after surgical resection, but standard imaging studies are negative.

MOHLTC has secured annual funding for the PET Registry, and will be funding up to 700 cases in the 2007/08 fiscal year. To refer patients to the Ontario PET Registry, physicians may contact the Ontario PET Registry Coordinating Centre at Hamilton Health Sciences (905-521-2100 ext. 74445).

Cardiac FDG PET Registry of Ontario

MOHLTC is funding a Cardiac FDG PET Registry at the University of Ottawa Heart Institute. The Cardiac PET registry study is expected to begin patient enrolment shortly to provide a PET scan to and track the outcomes of patients who meet all of the following criteria:

- Have severe ischemic left ventricular dysfunction (Left ventricular ejection fraction LVEF < 35%), and
- Remain symptomatic (New York Heart Association Class II-IV) despite maximal medical therapy, and
- Would be suitable candidates for revascularization if there was viable myocardium or who would be considered for heart transplantation if there is no viable myocardium, and
- For patients referred from centres without direct access to PET, have undergone myocardial viability assessment using other modalities (i.e. SPECT using Thallium or MIBI or dobutamine echocardiography) and the results of those tests are equivocal or negative in terms of the existence of viable myocardium.

Further information will be circulated upon activation of this registry study.

Table 1: Summary of MOHLTC-Funded PET Clinical Trials

Clinical trial	Purpose	Eligible Cancer Types	Target Sample Size	Enrolment as of May 31, 2007	Contacts
PET PREVENT	Prospective cohort study to determine the ability of FDG PET to detect metastatic cancer in neck lymph nodes in patients with head and neck cancer and whether the cancer has responded to treatment. All enrolled patients will receive a PET scan before & after treatment	Advanced N2 or N3 squamous cell carcinoma of the head and neck arising in either the oral cavity, larynx and pharynx (except non-nasopharyngeal cancer) being considered for neck dissection following primary curative radiation therapy.	400	242	<u>Hamilton Regional Cancer Centre:</u> Dr. Ian Hodson (905) 387-9711 ext. 64702 <u>London Regional Cancer Centre:</u> Dr. Alex Hammond (519) 685-8650 <u>Ottawa Regional Cancer Centre:</u> Dr. Libni Eapen (613) 737-7700 ext. 70199 <u>Toronto- Princess Margaret Hospital</u> Dr. John Waldron (416) 946-6522
PET START	A prospective randomized controlled trial to determine (1) whether PET will help detect how far the lung cancer has spread beyond the chest after the patient has undergone all the usual standard diagnostic tests for lung cancer and (2) determine whether PET results will change how much of the chest will need radiation. Half the enrolled patients will receive a PET scan.	Stage III non-small cell lung cancer suitable for combined modality therapy, radical radiation therapy, or trimodality therapy	400	199	<u>Hamilton Regional Cancer Centre</u> Dr. Jim Wright (905) 387-9495 ext. 64417 <u>London Regional Cancer Centre</u> Dr. Edward Yu (519) 685-8500 ext. 53347 <u>Ottawa Regional Cancer Centre</u> Dr. Rob MacRae (613) 737-7700 ext. 70205 <u>Toronto -Princess Margaret Hospital</u> Dr. Alex Sun (416) 946-6522 Toronto Sunnybrook Regional Cancer Centre Cindy Foden (416) 480-5846
ELPET	A randomized controlled trial that compares standard imaging tests to PET in the staging of non-small cell lung cancers. In order to determine whether PET can detect occult metastatic disease and thus help determine which patients with lung cancer have early stage disease that may be treated surgically. Half the enrolled patients will receive a PET scan.	Stage I, II, or IIIA non-small cell lung cancer in which the primary lesion appears technically appropriate for surgical resection based on x-ray or CT.	322	305	<u>London Regional Cancer Centre:</u> Dr. Richard Incelet (519) 667-6679 <u>Credit Valley Hospital:</u> Dr. Donald Jones (905) 813-1100 ext. 1841 <u>Ottawa General Hospital:</u> Dr. Donna Maziak (613) 737-8899 ext. 74035 <u>Toronto Princess Margaret Hospital</u> Dr. Gail Darling (416) 340-3121 <u>Scarborough General Hospital:</u> Dr. Abdollah Behzadi (416) 438-2911 <u>Toronto St. Joseph's Health Centre:</u> Dr. Y. Shargall (416) 530-6653
PET CAM	A prospective randomized controlled trial to determine the impact of pre-operative FDG PET on patients who have been assessed as having resectable colorectal cancer liver metastases by conventional imaging, by determining the proportion of patients who have a change in management resulting from PET imaging. Half the enrolled patients (randomised to the PET arm) will receive a PET scan.	Colorectal adenocarcinoma (excluding carcinoid, squamous cell cancer, gastrointestinal stromal tumour, or lymphoma) with resectable metastasis isolated to the liver.	400	138	Toronto: <u>Princess Margaret Hospital</u> Dr. Steven Gallinger (416) 586-8550 <u>St. Joseph's Health Centre</u> Dr. Richard Hart (416) 530-6841 <u>Sunnybrook Regional Cancer Centre</u> Linda Last (416) 480-5000 ext. 3885 <u>Hamilton St. Joseph's Healthcare & Hamilton Health Sciences Centre</u> Dr. Ved Taqndan (905) 521-6148
PET PREDICT	Patient accrual completed				Study closed

Ontario PET SCAN Access Program Request

TO BE COMPLETED BY THE REQUESTING PHYSICIAN

Referring Physician's Name: _____

Referring Physician's Telephone: _____ and Fax: _____

Provider Number: _____

Patient Name: _____

OHIP Number --- Telephone: _____

Date of birth: ____/____/____ Sex: ☐ M ☐ F
YYYY MM DD

Postal Code ____-____

Indications for the PET Scan: _____

☐ Is your patient a candidate for one of the current PET clinical trials or Registry study?
☐ Yes ☐ No

If not :

☐ Attach a copy of the reports from all relevant imaging studies

List all relevant imaging study	1. Date of: ____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MR
	2. Date of: ____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MR
	3. Date of: ____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MR
	4. Date of: ____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MR
	5. Date of: ____/____/____ YYYY MM DD	☐ CT ☐ US ☐ MR

Please fax this form and any additional documents in support of a PET Scan to Provider Services Branch at (613) 536-3184.

Should you have any questions about this form or the program, please call 1-888-359-8807

Ontario PET SCAN Access Program Request

TO BE COMPLETED BY THE REQUESTING PHYSICIAN

Patient Consent

(to be completed and signed by the patient)

I, _____, consent to my physician disclosing personal health information on, and attached to this form, to the Ministry of Health and Long-Term Care relevant to the medical condition that might qualify me for a diagnostic assessment using Positron Emission Tomography (PET). In addition, I consent to the Ministry's disclosure of this information to Cancer Care Ontario. I understand that the purpose of this disclosure of my personal health information is to determine whether I can participate in a government-funded PET scan clinical trial or registry study in Ontario. If I do not qualify for one of these studies, my personal health information may be used to determine if I could qualify for a PET examination through a review process established by Cancer Care Ontario

Signature of patient

Date

Patient Consent for minor child

(to be completed and signed by parent/legal guardian of patient)

I, _____, (name of parent/guardian) am the parent/ legal guardian of _____ (name of child). I consent to the above- named physician disclosing personal health information on, and attached to this form, to the Ministry of Health and Long-Term Care relevant to the medical condition that might qualify me for a diagnostic assessment using Positron Emission Tomography (PET). In addition, I consent to the Ministry's disclosure of this information to Cancer Care Ontario. I understand that the purpose of this disclosure of _____'s personal health information is to assess and determine whether _____ can participate in a government-funded PET scan clinical trial or registry study in Ontario. If _____ does not qualify for one of these studies, his/her personal health information may be used to determine if he/she could qualify for a PET examination through a review process established by Cancer Care Ontario

Name of parent/guardian

Signature of parent/guardian or patient

Date