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# ***PET SCAN PRIMER***

A Guide to the Implementation of  
Positron Emission Tomography Imaging in Ontario

Executive Summary

Prepared by the Members of the Ontario PET Steering Committee

August 31, 2008

Ministry of Health and Long-Term Care  
Copies of this report can be obtained  
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## ■ Executive Summary

### What is PET?

Positron Emission Tomography (PET) is a nuclear medicine diagnostic imaging exam. Nuclear medicine exams use small amounts of radioactive material (known as radiopharmaceuticals) that are usually injected into a person's bloodstream but are sometimes swallowed by mouth or inhaled as a gas. The most common radiopharmaceutical used in PET scanning is  $^{18}\text{F}$ FDG (Fluorodeoxyglucose). Health Canada regulates  $^{18}\text{F}$ FDG as a new product and authorizes only licensed manufacturers to distribute it to PET scanning centres. The use of  $^{18}\text{F}$ FDG is subject to a Clinical Trials Agreement unless the institution applies for a Notice of Compliance to manufacture the radiopharmaceutical for a specific indication and maintains an Establishment License.  $^{18}\text{F}$ FDG is a form of sugar and is taken up avidly by many cancers because cancers use sugar for growth. However, metabolically active normal tissues like the brain, as well as benign conditions such as inflammation, also take up  $^{18}\text{F}$ FDG. Imaging exams, such as plain radiography, ultrasound, computed axial tomography (CAT or CT) and magnetic resonance imaging (MRI) are routinely used to provide information on the shape and size of anatomical structures and this information is used for both diagnosis and treatment decision-making. However, PET scanning can provide information on both the location and the extent of metabolic activity of abnormal tissues such as cancer and it has the potential to identify areas of abnormal metabolic activity before there is distortion of the anatomy. The key question is does the information from PET make a difference in the clinical management of patients compared to these other tests?

### What do PET Scans do?

A PET scanner works with a computer to create two- and three-dimensional images of the structure and function of organs and tissues. This technology is useful in determining the stage (extent) of some cancers, which in turn may help to define the most appropriate treatment for the stage of cancer.

Like any diagnostic test, PET must be used based on evidence because it can pose risks, as well as benefits. PET scanning can give false results if chemical balances within the body are not normal. As well, cancers that do not take up  $^{18}\text{F}$ FDG may give a negative PET scan. If the PET scan upstages cancer accurately (i.e., the cancer is more serious than it was originally thought to be) patients can avoid aggressive treatments that will not help them. However, if the PET scan upstages the cancer incorrectly, patients with potentially curable cancers risk not getting the most appropriate treatment for their cancer or they may get aggressive treatments they do not need. Of particular concern is the recent report from the U.S. that 70% of patients who were scheduled to have a biopsy (the gold standard for diagnosing cancer is biopsy followed by pathological exam) before a PET scan ended up not having a biopsy and having treatment based on their PET scan results alone. The PET scan was three times more likely to lead to treatment than non-treatment, with physicians changing the management of 36.5% of their patients after the PET scan.

### How Do Patients Access PET Scans In Ontario?

A provincial PET Steering Committee makes recommendations on the appropriate use of PET to the Ministry of Health and Long-Term Care's Ontario Health Technology Advisory Committee. The Committee is made up of representatives of the Institute for Clinical Evaluative Sciences, Cancer Care Ontario, and the

Program for Assessment of Technology in Health, clinical oncologists, nuclear medicine physicians and experts in clinical research trials.

*PET is available in three ways in Ontario.*

1. PET is funded for those cancers where there is enough evidence that the test improves the clinical management of specific cancers or other conditions. To enable Ontarians to have a PET scan where evidence supports its use and to comply with Health Canada's regulations for the use of <sup>18</sup>F<sup>18</sup>FDG, the ministry established cancer and cardiac PET registries. Patients receiving PET scans for their cancer or cardiac conditions must be recorded in a "registry" with information on the reason for and the results of the PET scan.

Over 1,400 patients are enrolled in the PET registries to date.

2. High quality clinical trials are being conducted to determine if PET improves diagnosis and treatment decisions for early stage lung cancer, stage III (locally advanced) lung cancer, women with breast cancer, head and neck cancer, and colorectal cancer that has spread to the liver. The result of the trial in early stage lung cancer was presented at the American Society of Clinical Oncology meeting in June 2008.

It showed that PET is more effective than standard staging studies in determining which patients have the greatest probability of benefit from surgery. As a result, PET is now funded for all Ontario patients with early non-small cell lung cancer who are being considered for surgery. This is projected to increase the number of PET scans in Ontario by over 1,000 in the next 12 months. The breast cancer trial has also been completed and is being analysed, and the other three trials are well on their way to completion.

Over 1,500 patients are enrolled in the clinical trials.

3. Situations where a PET scan may be justified but cannot be obtained through the clinical studies or registries are adjudicated by an expert panel. Physicians who think that their patient might benefit from a PET scan can refer them to the PET Access Program where requests are reviewed by a panel of oncologists, radiologists and nuclear medicine physicians. Between October 2006 and March 31, 2008, 170 applications were made to the Ontario PET Access Program; 68 applications for a PET scan were approved.

### What Does The Research Say About PET Scans?

A review by the Institute for Clinical Evaluative Sciences in 2001 found little evidence to show that PET made a significant difference in most of the clinical conditions that were reviewed. The International Network of Agencies for Health Technology Assessment – after conducting a survey of 19 countries in 2004 – concluded that all countries need to undertake continuous quality improvement to manage the uncertainty about the evidence for PET.

Clinical experts believe there is clear evidence that PET improves the diagnosis and treatment of patients with the following conditions:

- Solitary pulmonary nodules in cancer patients who cannot have a biopsy, who have failed prior biopsy attempts or in whom the potential risk of a biopsy-induced pneumothorax is high.
- Patients with treated thyroid cancer, treated germ cell cancer or treated colorectal cancer who develop positive biomarkers (an elevated biological marker usually indicates that disease is present) but whose CT/MRI does not show that the cancer has recurred.

- Patients being considered for surgical resection of a non-small cell lung cancer.
- Certain specific indications for lymphoma.
- Assessment of the probability of the recovery of heart muscle function after coronary revascularization (Myocardial viability studies).

Ontario has been leading the way in studying the clinical benefits of PET and other jurisdictions are undertaking similar evaluations. For example, the U.S. Centers for Medicare and Medicaid introduced a “Coverage with Evidence Development” policy which requires physicians to provide information on the usefulness of PET to clinically manage cancer conditions that were not previously covered.

### Do All the Other Provinces Provide Access to PET Scans?

Ontario has 10 hospital-based PET scanners, more than any other province. However, the other larger provinces (Quebec, British Columbia and Alberta) perform more scans. Ontario clinical experts believe that some of these PET scans are conducted for indications that do not have sufficient evidence of clinical benefit.

### What Are the Costs Associated with PET?

The current average cost to perform a PET scan in Ontario is \$1,000-\$1,200 per scan which includes the cost of the radiopharmaceutical and a stipend (payment) for the physician reading the scan.

### PET in the Future

Some believe that PET should be widely available based on the claim that this technology improves care and saves lives. Others believe that PET should be used in situations where it has been shown in well conducted studies to add value and provide additional accurate information to improve the diagnosis and subsequent treatment of patients.

Clinical trials research is the best approach to obtain evidence for PET scanning. Ontario's trials are leading to greater understanding of how PET can benefit patients. However, there has been some concern about the pace of the clinical trials in Ontario. Clinical trials take time and involve many steps including the development of a research protocol and quality assurance standards, getting Research Ethics Board approvals and enrolling a sufficient number of patients, which relies on the willingness of physicians to approach their patients and the acceptance of patients to participate in the trial.

Although Ontario's clinical trials are taking time, they are resulting in high quality – and internationally recognised – evidence for the appropriate use of PET in diagnosis and treatment. This evidence is critically important for the safety and care of Ontarians.

To improve access to PET for clinically-proven conditions, Ontario is urging Health Canada to simplify its regulations for accessing <sup>18</sup>F<sub>2</sub>FDG. Health Canada regulates <sup>18</sup>F<sub>2</sub>FDG as a new product and requires a Clinical Trials Agreement for all non-approved indications. Currently, in Ontario, only Hamilton Health Sciences manufactures an approved <sup>18</sup>F<sub>2</sub>FDG product for lung cancer indications, including diagnosis of solitary pulmonary nodules, staging of non-small cell lung cancer and evaluation of recurrence of non-small cell lung cancer. This means that Ontario and other provinces have had to set up PET registries to provide access

for other indications in cancer and cardiac disease of established clinical utility. At present, the process to follow in order to access PET through the registries is not widely known by physicians. Regular communications through OHIP Bulletins and other means should increase physicians' awareness of how to access PET for their patients.

Ontario remains committed to an evidence-based approach to the introduction of new technologies including PET. Given the competing demands for limited health care resources, the risks associated with diagnostic imaging procedures (all procedures have risks including the risk of false positives and false negative results), and the potential for the technology to affect patient outcomes significantly, PET's usefulness needs to be established before it becomes part of routine clinical practice. Ontario is making a valuable contribution to the appropriate and effective use of this new technology in Ontario and internationally.

*Evidence-based advice on technology to advance health*