

The Use of Positron Emission Tomography (PET) for Cancer Care Across Canada

Time for a National Strategy

Susan D. Martinuk



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A TRIUMF-AAPS JOINT PROJECT



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Note: This publication contains only Sections 1 through 3. Please see www.triumf.ca for the full report.

Acknowledgment of Reviewers

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the TRIUMF Board of Management and the AAPS Board of Directors. The independent review provides candid and critical comments that assist in making the published report as sound as possible and ensure the report meets institutional standards for objectivity, evidence, and responsiveness to the task. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

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1

SUMMARY OF KEY FINDINGS



1.0

SUMMARY OF KEY FINDINGS

1.1 Cancer is a Growing Challenge in Canada

One out of every four Canadians will die from cancer. It is the leading cause of premature death in Canadians, and the number of cancer cases will increase each year as the Canadian population grows and ages.

1.2 PET Scans Can Play an Important Role in Cancer Detection and Diagnosis

Studies have shown that PET is a clinically-effective diagnostic modality for cancer and has a significant influence on the management strategies of patients.

Recent economic reviews show that PET is a cost effective diagnostic modality in the following situations:

- The staging of non-small cell lung cancer;
- The differential diagnosis of solitary pulmonary nodules;
- The restaging of colorectal carcinoma after recurrence; and
- The restaging of Hodgkin's and non-Hodgkin's lymphoma.

1.3 PET is Unevenly Deployed across Canada

- a) Canada is far behind the United States and Europe in its adoption of PET and other diagnostic technologies.
- b) The availability and utilization of PET infrastructure varies widely, province by province.
- c) Quebec leads Canada with a well-established and expanding PET infrastructure that offers broad access to PET imaging for cancer.
- d) In sharp contrast to Quebec, the province of Ontario has restricted patient access to PET over the past decade.

1.4 Growth of PET is Constrained by Costs, Infrastructure, and Education

1.4.1 Costs

- a) High operational and capital costs are challenges to Canada's publicly-funded healthcare system.
- b) Limited availability of the radiotracer FDG (18F-fluorodeoxyglucose) currently creates high cost barriers for cancer-care programs integrating PET technology.

1.4.2 Infrastructure and Policy Framework

- a) Canada's geography and population density have constrained the widespread deployment of PET technology.
- b) Health Canada's regulation of FDG is viewed as a hurdle to the efficient use of PET resources.
- c) Canada does not have a national approach or national policies for the use of PET as a clinical tool for cancer care. Indications for the use of PET vary from province to province.
- d) The increasing use of other diagnostic modalities has led to concerns about the potential overutilization of PET.

1.4.3 Education and Training

- a) Physician groups, cancer patients and the general public are uneducated about the utilization and benefits of PET technology in cancer care.
- b) The medical-specialty groups associated with nuclear medicine appear to have different visions as to how scarce healthcare dollars are spent.
- c) There is a critical shortage of HQP (highly qualified personnel) in all areas of nuclear medicine. This demand will increase with growing numbers of PET facilities and cyclotron installations.

1.5 Canada is Ready to Seize the Opportunity

The expansion of PET is critical to Canada's world-wide leadership in nuclear medicine. In the face of the opportunity for full deployment of PET technology to assist in dealing with cancer, Canada has a choice to make. Each province need not deal with this situation on its own, in isolation. Coordinated action, based on a clear business case that outlines action at federal and provincial levels, is required.

1.6 Time for a National Strategy

1.6.1 Costs

- a) A national approach is required to overcome the initial high costs of an expanding PET infrastructure; this approach could include improved access to capital or coordinated/collective purchase agreements with key manufacturers in the supply chain.

1.6.2 Infrastructure and Policy Framework

- a) A key constraint is availability and access to the chief radiotracer FDG. Coordinated investments would allow Canada to develop a network of cyclotrons for distributed and equi-geographic production of FDG.
- b) A national PET Steering Committee would allow establishment of uniform PET policies and indications for all provinces to follow.

1.6.3 Education and Training

A PET-education campaign directed at physicians, medical students, cancer advocacy groups and the general public would facilitate informed, strategic choices by the different elements of the provincial healthcare systems.

2

PREFACE



2.0

PREFACE

The Positron Emission Tomography (PET) scanner is a powerful, non-invasive, nuclear imaging technology that allows detailed diagnostic measurements of physiological and biochemical processes within the body. Since changes in biological function precede structural or anatomic changes in a variety of disease conditions, PET is uniquely capable of detecting cancer before it is evident through other diagnostic imaging tests such as CT (computed tomography) or MRI (magnetic-resonance imaging). In cancer care, early detection prompts earlier treatment, thereby improving the probability of a successful outcome.

Virtually all new PET scanners are bundled with a CT scanner and this hybrid device, known as a PET/CT scanner, is one of the most sophisticated scanning technologies available today. It allows for the simultaneous detection of functional (physiological) changes via PET technology and anatomic (structural) changes via CT technology.

Given that current PET research and clinical studies almost exclusively involve the use of PET/CT technology, this report will use the term 'PET' as a general reference to PET technology or to PET/CT technology. Any research or comments based on PET-only technology will be designated as such.

2.1 Background

This revolution in medical imaging has been particularly significant to the field of oncology where there is a known need to detect the presence of disease (when symptoms are not yet present or minimal), the response to treatment, and improvement or worsening of the disease as early as possible. It is estimated that approximately 95% of all PET procedures performed are related to oncology, and in most developed countries the use of PET technology is the normal standard of care in the diagnosis, staging and treatment planning of cancer patients.

As a result, PET imaging is now essential to cancer care in terms of disease staging, monitoring response to treatment, planning various therapies, and detecting recurrence (Basu and Alavi, 2008).

However, the situation is very different in Canada, where only one province (Quebec) views PET as vital to proper cancer care. Provincial jurisdiction over healthcare decisions has led to a fragmented approach to the use of PET technology and a significant disparity in the availability of PET to Canadians dealing with cancer.

The burden of cancer on Canadians is significant and it is estimated that 177,800 Canadians were diagnosed with some type of cancer in 2011. One out of every four Canadians will die from cancer, while 40% of Canadian women and 45% of Canadian men will develop cancer during their lifetimes (Canadian Cancer Statistics, 2011). Although the accurate and timely diagnosis of cancer through PET is integral to modern oncological care and has gained broad acceptance by oncologists around the world, many Canadian cancer patients do not have ready access to this technology. There are only 29 publicly-funded, clinical scanners across Canada, with the vast majority of these scanners located in Quebec (12) and Ontario (nine).

In 2009, a total of 42,620 scans were performed across Canada. However, the number of scans varied greatly from province to province with a low of about 100 scans in Newfoundland to a high of 22,400 scans in Quebec, the only province where PET is considered to be the normal standard of care for oncology patients.

In a November 2009 news release, the Canadian Association of Nuclear Medicine (CANM) stated that the lack of public funding for PET has impaired the ability of Canadian doctors to diagnose cancer at an early stage and that widespread access to PET was necessary for Canada “to live [sic] to its principles of equality, high standards of wellbeing and responsibilities ...[to provide] all its citizens and residents with equal access to standard of care technology for the management of their diseases, particularly cancer.” It therefore called for the rapid implementation of PET programs across all Canadian provinces to alleviate the suffering of cancer patients by improving the detection, staging, management and follow-up of many cancers. Thus far, most provinces have only responded weakly to the CANM’s call to implement PET technology across Canada.

In an effort to move nuclear medicine forward in Canada, Advanced Applied Physics Solutions (AAPS, Inc.) and TRIUMF determined that a research report should be prepared to outline the benefits of PET (in terms of costs and clinical diagnosis), identify the barriers to expanding PET in Canada, and establish the necessary conditions for increased access to PET in the future.

2.2 Project Plan

The deployment of PET imaging is quite varied across Canada as a standard tool in provincial health systems. Through careful research, a report will be prepared that outlines the issues, analyzes the case for action, provides a clinical and cost-benefit analysis of the use of PET in cancer diagnosis and treatment and an action plan for the future. Consequently, the objectives for this project are to:

- Make the case for the clinical and fiscal advantages of using PET in cancer diagnosis and treatment.
- Analyze the deployment of PET-based imaging within selected provincial health systems across Canada in order to understand barriers, conditions for access, and overall effectiveness.
- Generate a set of coherent findings, conclusions and/or recommendations to enhance the penetration of PET in support of improved cancer-patient care.

This report addresses the healthcare systems in each Canadian province and does not examine in detail the systems in place for the Canadian territories.

This report will serve as the backbone of a strategic communications campaign that will provide a case for action on PET acquisition and deployment across Canada. The work will proceed in the following phases to “follow the story” where it leads:

- **Exploration** – Review of literature, conversations with experts at TRIUMF and BC Cancer Agency.
- **Data-Gathering** – Detailed review of literature for clinical and fiscal advantages of PET. Conversations with clinicians, visits to key medical centres and conversations with nuclear-medicine experts.
- **Analysis and Formulation** – Analysis of PET deployment/penetration in provinces across Canada. Site visits to medical centres, conversations with opinion leaders and/or policy makers. Test marketing of potential findings, conclusions or recommendations.
- **Report Preparation** – Writing and editing final report including an independent review.

The Project Plan was adopted in June 2010 and Susan D. Martinuk (see Appendix E) was contracted as the lead researcher and author. As the project was carried out, it became evident that the plan was quite ambitious in its scope. Given the limited time frame for the project, the scope was tightened to focus on reviewing existing literature, surveying activities across Canada, and preparing a concise, written analysis.

3

EXECUTIVE SUMMARY

3.0

EXECUTIVE SUMMARY

Human health is perhaps the most important public-policy issue for this generation of Canadians. Research breakthroughs are constantly influencing strategies for preventing, detecting, and treating disease. It is therefore critical that public resources be deployed in such a way as to maximize the impact on disease and to provide Canadians with a quality of care that is in keeping with world standards and consistent from province to province.

This report examines one element of cancer-care systems across Canada: the deployment and utilization of PET imaging for enhanced diagnosis and treatment of cancers. In particular, it provides summary statistics about the degree of PET deployment in each province and identifies the key constraints at a national level that need to be addressed in an effort to more fully exploit this technology for the benefit of all Canadians. As PET imaging could improve patient care and reduce associated costs, the expansion of PET technology represents a national opportunity to enhance Canadian healthcare.

3.1 Cancer is a Growing Challenge in Canada

Cancer is the leading cause of premature death in Canadians and the number of cancer cases increases with each year. As Canada's population grows and ages, cancer incidence and mortality rates will continue to rise and place growing pressure on the Canadian healthcare system to provide new technologies and therapeutics that will provide better, more efficient and cost-effective care for cancer patients.

The statistics below present the grim realities of cancer in Canada (Canadian Cancer Statistics, 2011):

- One out of every four Canadians will die from cancer
- Cancer is the cause of almost one-third (30%) of all premature deaths (National Post, 2011)
- 40% of Canadian women and 45% of Canadian men will develop cancer during their lifetimes
- 177,800 new cases of cancer and 75,000 deaths from cancer will occur in Canada in 2011
- Every hour, an average of 20 Canadians will be diagnosed with some type of cancer and another eight will die from cancer
- 42% of new cancer cases and 59% of cancer deaths will occur among Canadians 70 years of age and older.

It has long been known that early detection of cancer and selecting the most appropriate treatment strategy will enhance a patient's chance of survival. New technology exists that is uniquely capable of detecting the source and full extent of cancer before it is evident through other widely-used diagnostic imaging tests such as CT (computed tomography) and MRI (magnetic resonance imaging).

The positron emission tomography (PET) scanner is a powerful, non-invasive, nuclear imaging technology that allows detailed diagnostic measurements of physiological and biochemical processes within the body prior to changes in anatomy. Since changes in biological function precede structural or anatomic changes in conditions such as cancer, PET is capable of detecting cancerous cells at an early stage, before they congregate to form a mass. This early detection is critical to cancer care as it prompts more timely treatment and greatly improves the probability of a successful outcome.

Throughout this report, the core technology is referred to as PET, even though PET technology is typically combined with CT in a single package known as a PET/CT scanner.

3.2 PET Scans Can Play an Important Role in Cancer Detection and Diagnosis

a) Studies have shown that PET is a clinically-effective diagnostic modality for cancer and has a significant influence on the management strategies of patients.

Because PET is a diagnostic and not a therapeutic tool, its clinical effectiveness is typically measured in terms of its impact on the intended management strategy of the physician.

Current data suggest that in as many as one-third to one-half of cancer cases, physicians who do not have access to PET may be choosing the wrong management/treatment strategy for their patients. Three large-scale, national studies published by the National Oncologic PET Registry in the United States have shown that PET imaging changes the intended patient management strategy in 36.5, 38 and 49% of cases (Hillner et al., 2008a; Hillner et al., 2008b; Hillner et al., 2009, respectively). Results were consistent across all cancer types (Hillner et al., 2008b). A recent Canadian study (Worsley et al., 2010) found that the information derived from PET imaging resulted in a change in intended treatment plans in 50% of cases.

In as many as 90% of cases, referring physicians indicated that the scan results allowed them to avoid additional imaging tests or procedures (Hillner et al., 2009), suggesting that PET can significantly reduce the number of testing procedures and result in substantial healthcare savings if it is performed at the beginning of the diagnostic pathway, rather than as a last resort.

PET imaging allowed physicians to avoid costly biopsy surgeries in as many as 70% of cases (Hillner et al., 2008a). This can lead to significant cost savings, as well as prevent patients from undergoing high-risk surgical procedures that will not confer any benefit.

b) Recent economic reviews show that PET is a cost-effective diagnostic modality in the following situations (Buck et al., 2010; Langer, 2010):

- The staging of non-small cell lung cancer;
- The differential diagnosis of solitary pulmonary nodules;
- The restaging of colorectal carcinoma after recurrence; and
- The restaging of Hodgkin's and non-Hodgkin's lymphoma.

Cost savings in lung and colorectal cancer primarily result from avoiding costly surgical procedures in cases where no reasonable chance of cure exists. In Canada, lung and colorectal cancers are the second (14%) and third (12%) most common cancers in both men and women (Canadian Cancer Statistics, 2011). This suggests that PET imaging would be cost-effective in the management of, at minimum, one-quarter (26%) of Canada's cancer patients.

It has been determined that cost savings can be realized by using PET to ensure the most appropriate management of cancer patients. PET imaging at early stages in therapy can reveal when treatments are ineffective; thereby allowing doctors to quickly change to a more effective treatment strategy and reducing healthcare expenditures on ineffective therapies.

Since PET scans typically find that the cancer has spread beyond that demonstrated by conventional imaging, they often provide doctors with an opportunity to avoid futile, costly and invasive interventions such as surgery or radical chemotherapy/radiotherapy. This does not always improve the survival of the patient, but it does improve the patient's quality of life through the use of more appropriate palliative measures. It also ensures the most appropriate use of scarce healthcare resources.

A recent systematic review of PET (Langer, 2010) suggests that personalized medicine using PET may be cost-effective because it generally results in improved care and less exposure to ineffective treatments.

3.3 PET is Unevenly Deployed Across Canada

PET imaging technology is increasingly well established in the Canadian health-research community. Medical cyclotrons distributed across the country regularly provide isotopes to radiopharmacies for the local development and distribution of imaging agents. Highly trained experts in the leading research hospitals (e.g., Université de Sherbrooke and Cross Cancer Institute, among others) use PET imaging information with skill. However, outside of Quebec, PET is minimally integrated into provincial healthcare policy.

a) Canada is far behind the United States and Europe in its adoption of PET and other diagnostic technologies.

Europe currently has 479 PET installations and that number is expected to grow to 742 by 2013 (MEDEC, 2010). The United States has approximately 2,000 PET scanners and a ratio of about 6.5 scanners per million (Buck et al., 2010). In comparison, Canada currently has 29 PET scanners and a ratio of 0.86 scanners per million people.

When compared to the 29 other countries belonging to the Organization for Economic Cooperation and Development (OECD), Canada ranks 22nd and 18th in the availability of CT scanners and MRI equipment, respectively (Skinner, 2009).

b) The availability and utilization of PET infrastructure varies widely, province by province.

Canada currently has 29 publicly-funded, clinical PET scanners and a ratio of 0.86 PET scanners per million people, a figure that is far below the two PET scanners per million ratio recommended by the World Health Organization (WHO; MEDEC, 2010). Twelve of these PET scanners are located in the province of Quebec and nine in Ontario.

Canada conducted 42,620 scans in 2009; 22,400 (51%) of those were carried out in the province of Quebec.

The cost of a PET scan varies significantly from a low of \$956 in Quebec to a high of \$1,800 in Manitoba and Nova Scotia. The average cost of a scan in Canada is \$1,506.20. It should be noted that the province with the lowest cost per scan (Quebec) is also the province that does the most scans. This is consistent with reports that the costs of PET decrease as the number of PET examinations increase (Buck et al., 2010).

c) Quebec leads Canada with a well-established and expanding PET infrastructure that offers broad access to PET imaging for cancer.

A decade ago, Quebec made the decision to make cancer care a priority. It followed the recommendations of a 2001 investigation into PET imaging to deploy PET scanners around the province and make PET a normal standard of care for cancer patients. As a result, Quebec currently has 12 publicly-funded, clinical PET scanners in 12 locations across the province. This results in a ratio of 1.5 PET scanners per million people, the highest ratio of all the provinces and the only ratio that comes close to approximating the two scanners per million recommended by the WHO.

Given that PET imaging can change the management strategy of cancer patients in anywhere from 36.5 to 50% of cases, there is an implication that Quebec cancer patients have a very different standard of cancer care than their counterparts in other provinces.

d) In sharp contrast to Quebec, the province of Ontario has restricted patient access to PET over the past decade.

This has resulted in underutilization of its present PET network and a provincial medical community that appears to be divided in its perception of the usefulness of PET imaging.

In 2009, Ontario funded 553 scans per million people. In comparison, Quebec funded 2,835 PET scans per million and the national average was 1,068 PET scans per million people. That same year, Ontario also carried out 806 scans per scanner – the lowest ratio of any province and far below the national average of 1,643 scans per scanner. Both of these statistics suggest that some of Ontario's PET scanners are poorly utilized for clinical purposes; a fact that was confirmed in numerous interviews with Ontario nuclear medicine physicians.

Ontario's hesitancy to accept PET as a beneficial diagnostic tool has been cited as having a negative impact on the acceptance of PET in other provinces.

3.4 Growth of PET is Constrained by Costs, Infrastructure and Education

The challenge facing Canada today is the transition of PET from primary use as a research tool to PET as a widely-used, clinical tool that is fully integrated into the planning and management of cancer care in each province. The success of this transition is limited by several key factors: relatively few programs to overcome high start-up costs, limited infrastructure for networking, and poor education of doctors, patients and policy makers.

3.4.1 Costs

a) High operational and capital costs are challenges to Canada's publicly-funded healthcare system.

In Canada, PET scanners range in cost from \$2.5 to \$4 million and yearly operating costs are estimated at \$2 million. These costs make PET a significant, ongoing investment for provincial healthcare systems.

b) Limited availability of the radiotracer FDG currently creates high cost barriers for cancer-care programs integrating PET technology.

The costs of FDG (¹⁸F-fluorodeoxyglucose), a critical component of PET imaging, vary widely from lows of \$230 and \$350 per dose (Alberta and Quebec, respectively) to a high of \$800 per dose (New Brunswick). Much of the difference in cost can be attributed to variable distance from the cyclotron facility to the PET clinic. FDG loses one-half of its activity every two hours (approximately) from the time it is produced. Therefore, facilities that have to import FDG from other provinces have to pay for a large amount of FDG in order to have sufficient radioactivity remaining to perform PET exams by the time it reaches the PET facility.

FDG costs are also high because availability in Canada is low. At present, there are only ten cyclotrons (nine academic and one private) producing FDG for oncologic PET imaging across Canada. Because there are so few PET facilities in Canada, the amounts of FDG produced are relatively small and there is no cost reduction due to large volume production.

For all of the above reasons, costs of FDG diminish substantially when PET facilities have their own cyclotrons. Therefore, a well-functioning PET infrastructure in Canada would require a cyclotron network that makes FDG easily available to PET centres in every province.

3.4.2 Infrastructure and Policy Framework

The expansion of PET is limited by gaps in the underpinning infrastructure and policy framework. Other fundamental challenges are Canada's unique geography and the relative absence of PET

policies in the present public-policy environment.

- a) Canada's geography and population density have constrained the widespread deployment of PET technology.

Canada has a sparse population spread over large geographic regions. Most PET scanners are situated in population-dense cities and it is difficult to justify the cost and operation of a PET scanner in small cities, even though they may serve a large geographic area. Geography also makes it difficult to transport FDG over long distances.

- b) Health Canada's regulation of FDG is viewed as a major hurdle to the efficient use of PET resources.

Since Health Canada considers FDG to be a therapeutic drug rather than a diagnostic imaging agent (such as those used in typical CT and MRI exams), clinical trials are required to prove the safety and clinical efficacy of FDG for certain indications. This means that multiple facilities are running identical scientific trials and collecting redundant data. Some proponents argue that Health Canada regulations have moved forward in the past year, although it has been shown that regulatory requirements add a minimum of \$196 to the cost of each PET scan in Canada (Chuck et al., 2005).

FDG has been approved for use in the United States since 2000 and one prospective study of more than 80,000 patients failed to show any adverse events from the administration of FDG (Silberstein, 1998).

- c) Canada does not have a national approach or national policies for the use of PET as a clinical tool for cancer care. Indications for the use of PET vary from province to province.

PET imaging for diagnosis and treatment of cancer patients in Canada has arisen directly from the research programs of leading hospitals, clinics and laboratories. PET research has benefitted significantly from federal investments and Canada has established some global prestige for its aggressive exploration and development of new radiotracers for cardiology, neurology, and oncology. However, thus far, there has not been a coordinated approach to implementing a national strategy for the focused translation of PET technology from research purposes to the clinical care of cancer (e.g. developing a PET network or developing national PET policies and indications for use). The Medical Imaging Trials Network of Canada (MITNEC) is a step in the right direction although it is currently focused on cardiology and the conventional SPECT isotope Tc-99m, rather than oncology and PET.

- d) The increasing use of other diagnostic modalities has led to concerns about the potential overutilization of PET.

There is a perception that CT and MRI are overused modalities and utilized in cases when there is little evidence to support their need. Consequently, there are concerns that PET imaging will follow this path, even though PET has a far more restricted number of indications. While it is beyond the scope of this report to evaluate the use of CT and MRI, this perception (or misperception) suggests it may be time for governments to develop a systematic approach to assess the proper utilization of CT and MRI, rather than limit the expansion, and utilization, of PET technology in clinical care. Governments should consider the merits of PET technology based on its own capabilities, not on the possible overuse of other technologies.

3.4.3 Education and Training

The final category of constraints limiting the full adoption of PET in Canada is the education and training of caregivers, doctors, patients and healthcare officials.

- a) Physician groups, cancer patients and the general public are uneducated about the utilization and benefits of PET technology in cancer care.

Physicians – A lack of physician knowledge (in both specialists and general practitioners) about PET imaging is a growing concern and was commonly cited as a factor contributing to the underutilization of existing PET scanners in some provinces.

An informal survey of 14 medical schools across Canada confirmed that the vast majority of undergraduate medical students receive anywhere from zero to three hours of nuclear medicine education. This statistic is higher in the U.S. by comparison.

Canadian doctors tend to use PET imaging at the end of the diagnostic pathway and this may prevent cost-effective care. Medical literature suggests that PET imaging can result in substantial healthcare savings if it is used as an initial tool in the diagnostic pathway of an oncology patient, rather than a last resort. It can eliminate the need for further tests or procedures in as many as 90% of cases (Hillner et al., 2009), change treatment strategies in as many as 50% of cases and improve decision-making by physicians in 83% of cases (Worsley et al., 2010). Yet many Canadian doctors continue to view PET imaging as a diagnostic tool to be used when all other means have failed.

Cancer patients and the general public – A lack of knowledge among cancer patients and the general public may also be a limiting factor to the expansion of PET imaging. Approximately 82% of Canadians are, at some point, impacted by cancer through illness or the illness of a family member or friend (CCAC, 2011). Yet very few are aware of the potential benefits of PET in determining the most appropriate management of their cancer.

Many physicians credit the people of Quebec with creating a positive environment for the implementation of PET across the province. This heightened cultural awareness of PET was attributed to the high-profile story of PET intervention to better manage the cancer care of a Montreal Canadiens hockey star and to the Quebec PET storyline in an Oscar-winning French movie that became very popular in that province in 2003. Through these two events, Quebec's population became very aware of critical technology that was ready for inclusion in their clinical cancer care.

- b) The medical-specialty groups associated with nuclear medicine appear to have different visions as to how scarce healthcare dollars are spent.

As a result, there has been no unified advocacy for PET by physician groups and there is no consensus on how to move forward and shape healthcare policies that will enhance the deployment and utilization of PET technology in Canada.

Nuclear medicine physicians – are somewhat restricted in their ability to advocate for more PET because they primarily operate on a fee-for-service basis. Consequently, as they advocate for more PET technology, they are often accused of trying to enhance their own billing opportunities.

Oncologists – appear to be more interested in obtaining new therapeutic agents than new diagnostic tools. However, there is growing evidence that future clinical trials of new therapeutic agents in oncology will require PET imaging as a part of their testing protocols. Consequently, there is a legitimate concern that limited access to PET in Canada may prevent Canadian doctors and cancer patients from participating in clinical trials of promising therapeutic agents.

Radiologists – there appears to be some tension between nuclear medicine and radiology specialists and it may impede progress as they advocate for new technology for their hospitals. At the core of this discord is the dual nature of the hybrid PET/CT technology and a dispute over which specialty will control this technology. Different spending priorities suggest that radiologists will advocate for more CT and MRI equipment, while nuclear medicine physicians advocate for PET technology.

Perceptions – and misperceptions – of the billing practices of radiologists also appear to impede the growth of PET. Some worry that radiologists can enhance their incomes by restricting the emergence of newer PET technology and focusing on reading more lucrative CT and MRI scans. An increased emphasis on PET imaging would substantially reduce the income of radiologists. Coordinated policy action at the level of the healthcare system would obviate some of these concerns. Quebec has dealt with this issue by not allowing dual specialties in the province. This has negated the competing interests of radiologists and nuclear medicine specialists over PET technology.

- c) There is a critical shortage of HQP (highly qualified personnel) in all areas of nuclear medicine. This demand will increase with growing numbers of PET facilities and cyclotron installations.

Deployment and uptake of PET technology in clinical care is limited by the number of trained, qualified personnel ranging from radiochemists to perform synthesis and radiopharmacists to formulate and certify radiopharmaceuticals to imaging specialists and cyclotron operators. Additionally, support personnel for regulatory oversight, operations and maintenance, training, and so on are in short supply. Recent conversations about the need for a national preclinical imaging network estimate a gap of more than 60 Ph.D.s alone in this sector (Prato, 2011).

3.5 Canada is Ready to Seize the Opportunity

Canada has centres of global research excellence in PET for oncology, neurology and personalized medicine. Our nation is also considered a world leader in the physics, chemistry and biology of developing new PET agents for applications in human health. It is largely through this prowess on the research side that provinces have developed local strategies for incorporating PET into the healthcare system. A definitive, national approach for including PET imaging as a tool in clinical care for cancer is missing.

When viewed more broadly, the expansion of PET becomes even more critical to Canada's world-wide leadership in nuclear medicine. Traditional nuclear medicine is based on SPECT/CT scans using conventional isotopes such as Tc-99m. This isotope is still sourced from nuclear reactors that are aging and vulnerable to long shutdowns for maintenance and repairs. Thus, the demand for PET isotopes, as an alternative to Tc-99m, is expected to significantly increase. Canada has a leading position in this global discussion, although a nationally-coordinated effort is required to develop a truly competitive edge.

Moreover, Canadian researchers are applying PET to neurological diseases such as Alzheimer's and Parkinson's. Alzheimer's is one of the fastest growing diseases in Canada, and a new case is diagnosed every five minutes. Any technology capable of early detection – and therefore initiating early treatment – of this disease would be in significant demand. PET will undoubtedly play a key role in this, and the demand for PET technology will increase as it becomes the world-wide standard of care for this high-profile disease. Canada cannot afford to fall further behind.

In the face of the opportunity for full deployment of PET technology, Canada has a choice to make. Coordinated action, based on a clear business case that outlines action at a federal level, is required.

3.6 Time for a National Strategy

What would it take for Canada to become more aggressive in exploiting the power of PET in oncology? A national approach. Examples in the United Kingdom and Australia suggest that a coordinated effort to deal with regulatory policies and standards, capital and operating costs for the associated infrastructure, and awareness-raising education can make an enormous difference in the successful implementation of PET technology across a nation.

The province of Quebec serves as an excellent example of taking effective steps to deploy PET more broadly. Quebec's government reviewed cancer statistics in the year 2000 and made a clear decision to make oncology a healthcare priority. The government then undertook a consultation and evaluation via Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS). The AETMIS report recommended a level of infrastructure and policy focus that became the foundation for a provincial plan for investment and deployment of PET across the province. An education and outreach campaign engaged the public, physician groups and other elements of the healthcare system.

Applying this to Canada and considering the chief categories of constraints identified earlier, we conclude that Canada's road to success includes the following:

3.6.1 Costs

- a) A national approach is required to overcome the initial high costs of an expanding PET infrastructure; this approach could include improved access to capital or coordinated/collective purchase agreements with key manufacturers in the supply chain.

The WHO recommends that countries adopt a PET scanner ratio of two scanners per million people (MEDEC, 2010). This suggests Canada would require approximately 60 PET scanners; double the current number of scanners.

Attaining this goal requires a financial commitment commensurate with policy priority that includes resources for hardware; radiotracer production and distribution infrastructure; and the education of physicians and healthcare consumers. The upcoming 2014 Health Accord may provide an opportunity for further discussions of this nature.

3.6.2 Infrastructure and Policy Framework

- a) A key constraint is availability and access to the chief radiotracer FDG. Coordinated investments would allow Canada to develop a network of cyclotrons for distributed and equi-geographic production of FDG.

Cyclotrons should be available to provide FDG to multiple PET facilities in each province. According to Pearcey and McEwan (2006-07), shipping times should be less than three half-lives (or approximately five hours) to allow clinically-useful quantities to be available upon delivery. This would substantially reduce a major component of PET scan costs.

- b) A national PET Steering Committee would allow establishment of uniform PET policies and indications for all provinces to follow.

At present, each province has very different PET policies and indications for use. Coordination of provincial and federal policies regarding PET deployment, regulation and indications for use could be undertaken by a national committee.

3.6.3 Education and Training

- a) A PET education campaign directed at physicians, medical students, cancer advocacy groups and the general public would facilitate informed, strategic choices by the different elements of the provincial healthcare systems.

This education campaign could include:

- Using the media to educate the public about the benefits of PET;
- A public-relations campaign directed by a physician leadership group such as the Canadian Association of Nuclear Medicine;

- A website to educate both the public and physicians about PET and how to access it;
- Educational, advocacy and lobbying initiatives by today's recognized centres of research excellence for nuclear medicine; and
- Enhanced PET education in medical schools.

3.7 Outlook

Cancer is the leading cause of premature death in Canada. Based on Canada's demographics, cancer rates will continue to rise and the Canadian healthcare system will have to find new ways to move cancer patients quickly and efficiently through diagnostic and treatment procedures.

As cancer increases, Canada has a duty to improve cancer care for its citizens and do all it can to ensure a better, more efficient use of scarce healthcare resources. Data in this report suggest that oncologic PET imaging could play a significant role in this process.

- In up to 90% of cases, PET obviates the need for further diagnostic testing prior to devising a treatment strategy
- PET imaging identifies non-responders early in the treatment process and enables doctors to change to a more effective treatment strategy
- In up to 70% of cases, PET imaging leads to a cancellation of costly, high-risk surgical interventions that can confer no benefit

In short, PET leads to a better quality of care for patients and a better utilization of medical resources. It is standard practice because it has been proven to be the best technology for most efficiently managing cancer care. For these reasons, PET imaging has become integral to modern oncologic care and is now the normal standard of care for the diagnosis, staging and treatment planning of cancer patients in the United States, Europe, Japan and other developed nations.

Canada is far behind the rest of the world in its adoption of diagnostic technologies. Based on information contained herein, it is clear that Canada has a responsibility to investigate this new technology that has been proven to be both clinically- and cost-effective.

Barriers exist to the further deployment of PET scanners and a key impediment to overcome is a lack of understanding about the benefits of PET technology in oncologic patient management that is prevalent among physicians, medical students, cancer patients and the general public. The report suggests that a PET education campaign directed at physicians, medical students, cancer advocacy groups and the general public could be accomplished through the media, and public relations/education campaigns by key leadership groups such as the Canadian Association of Nuclear Medicine and centres of excellence such as the University of Alberta, Université de Sherbrooke and TRIUMF.

Obviously, a significant financial commitment is required to move Canada forward in its adoption of new medical technology and this will likely require the cooperation of both federal and provincial governments to remove barriers and reallocate financial resources to nuclear medicine technology.

Canada now stands at a crossroads in its adoption and utilization of PET technology. We can move forward and adopt the technology necessary to provide Canadians with the current world standard for cancer care or, alternatively, we can maintain the status quo and fall further behind other Western nations in providing the most beneficial and efficient cancer care.

The choice is ours.

