

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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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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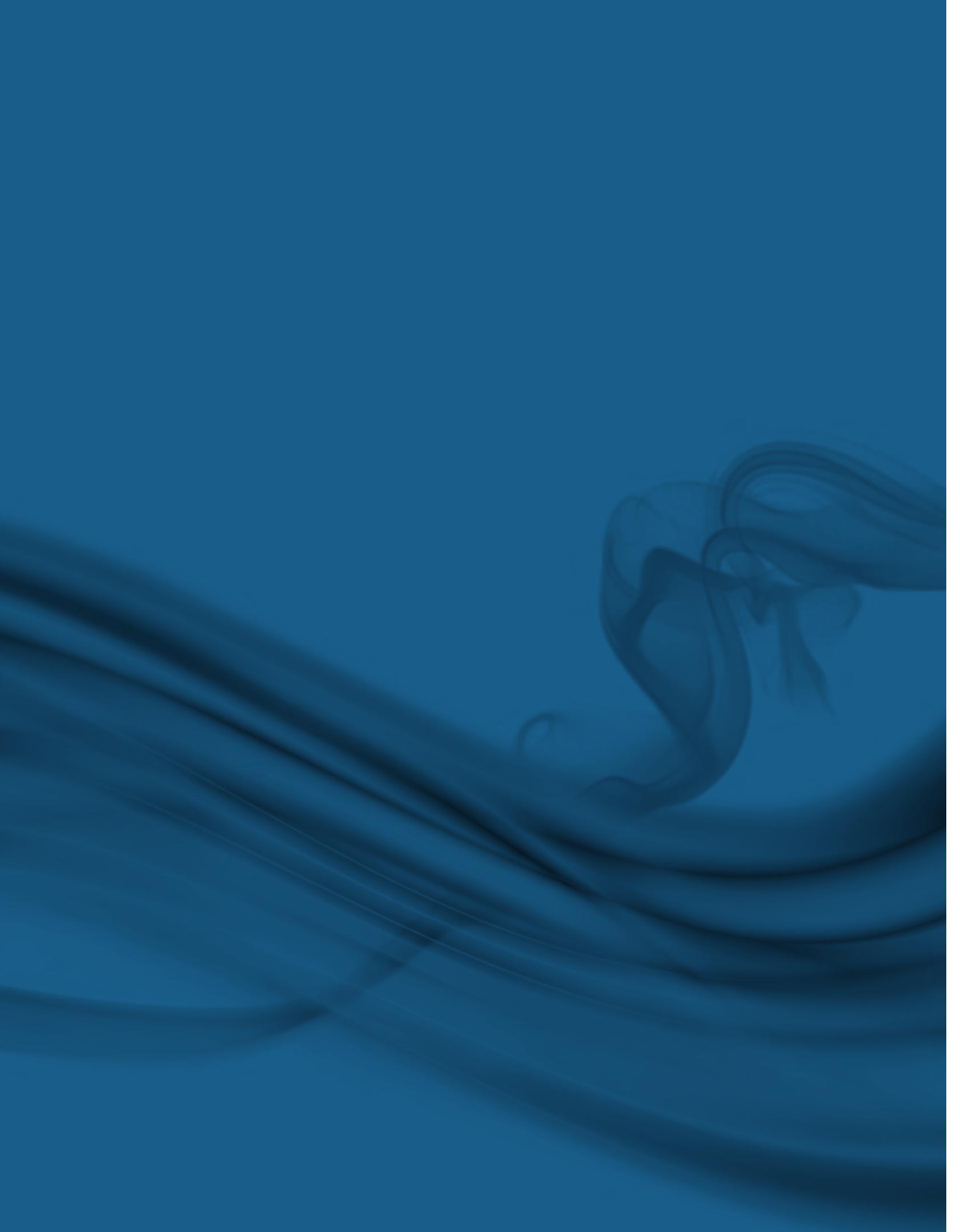
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1

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.

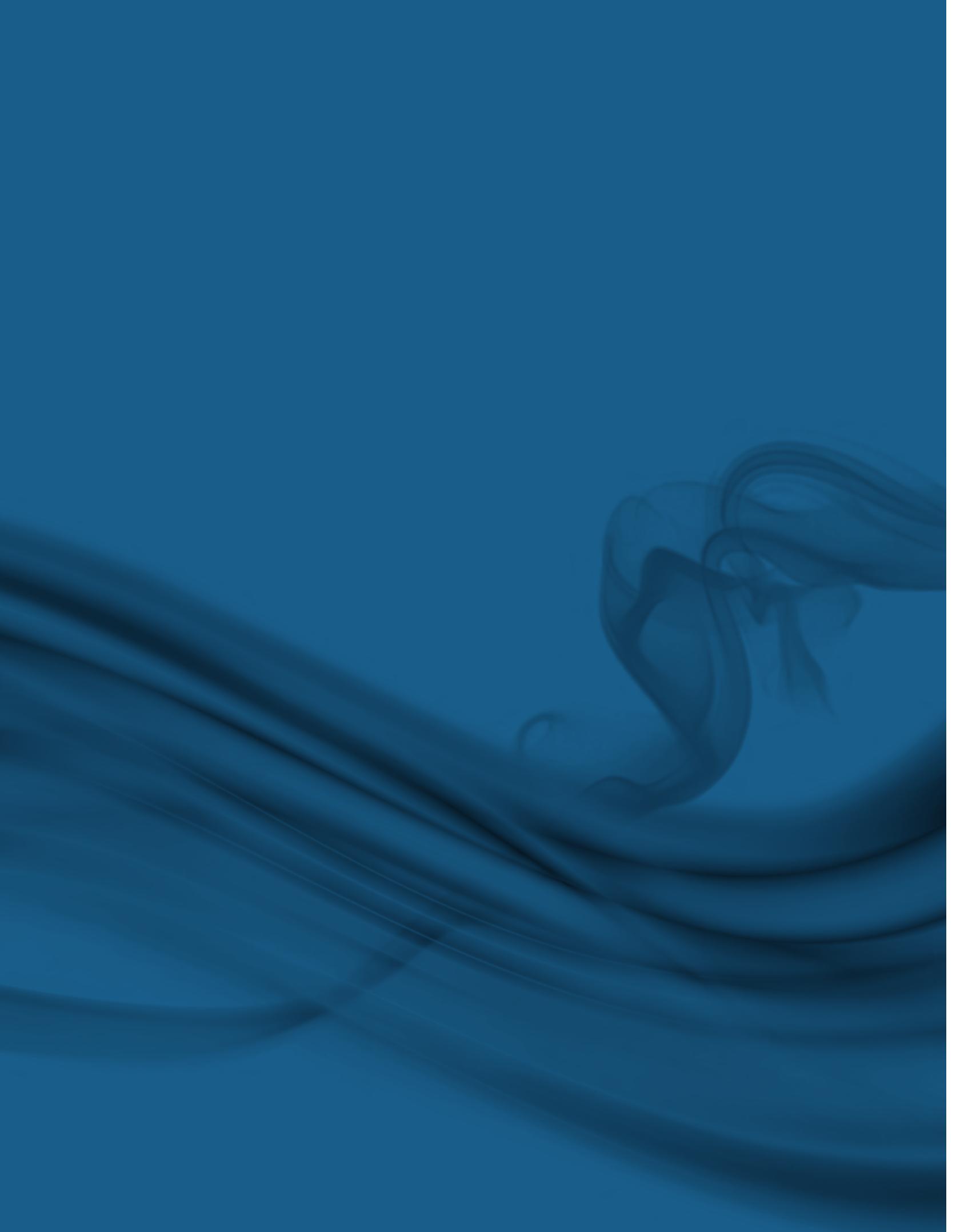
1.6.3 Education and Training

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.

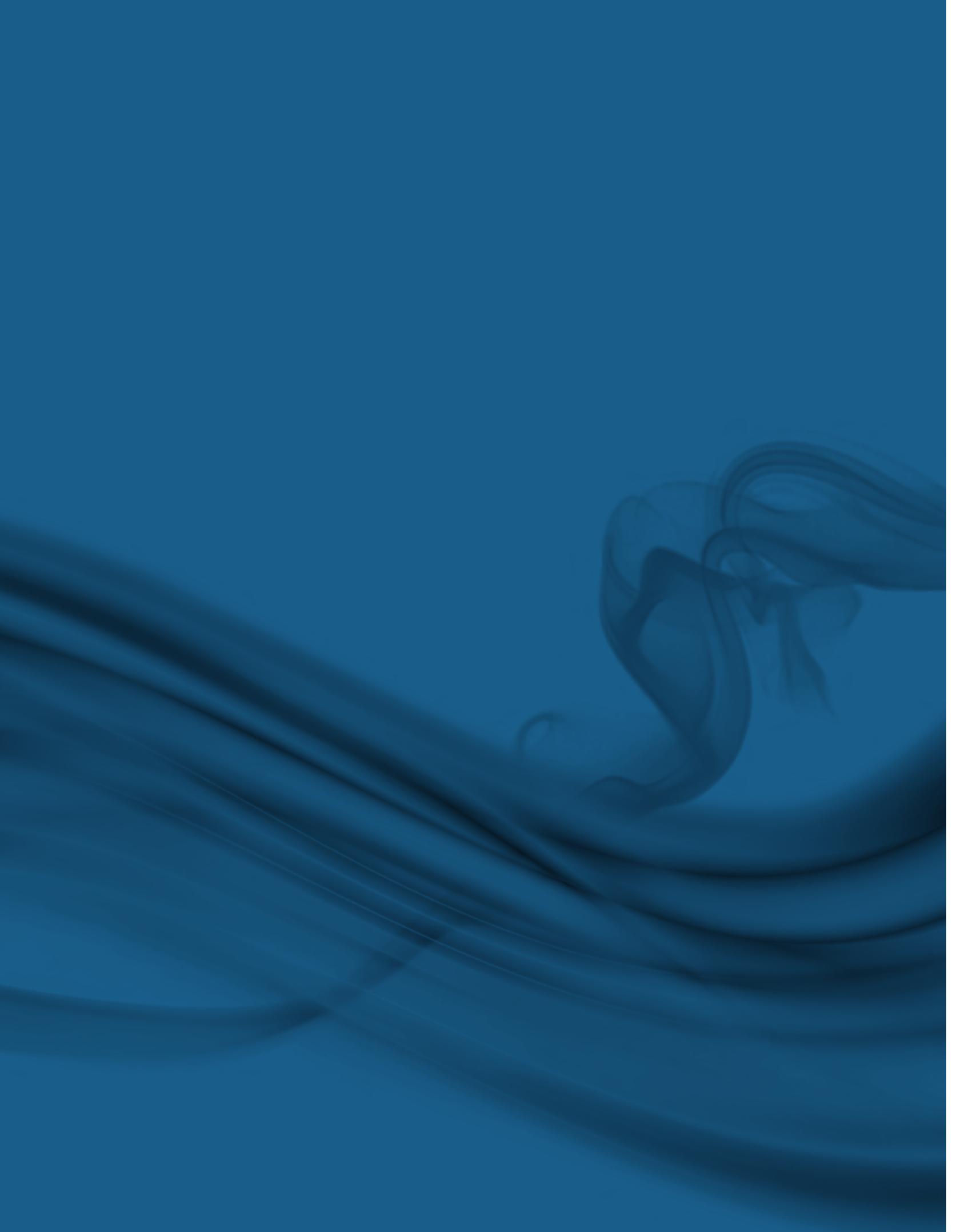
This report will serve as the backbone of a strategic communications campaign that will provide a case for action on PET acquisition and deployment across Canada. The work will proceed in the following phases to “follow the story” where it leads:

- **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 worldwide 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.

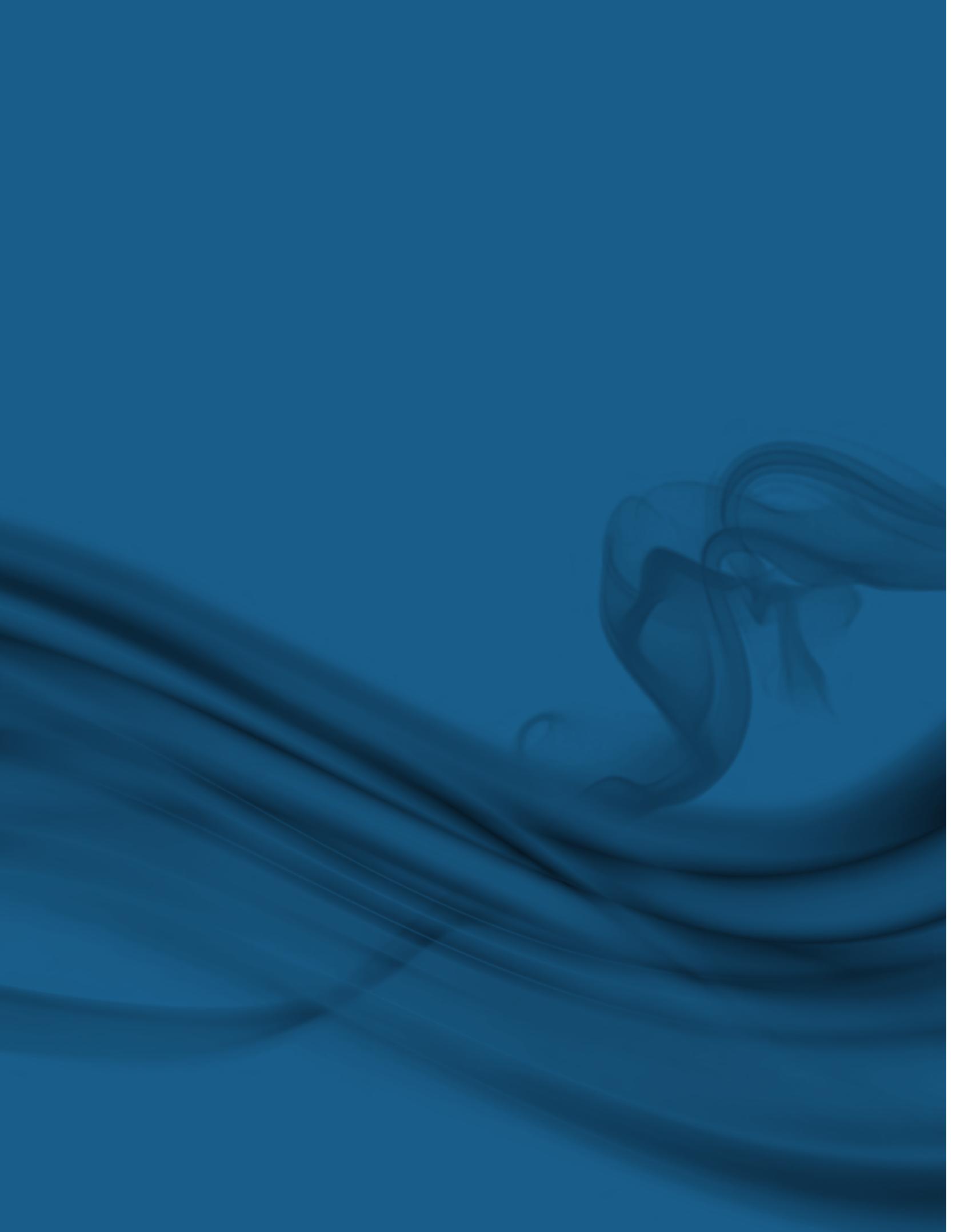
Obviously, a significant financial commitment is required to move Canada forward in its adoption of new medical technology and this will likely require the cooperation of both federal and provincial governments to remove barriers and reallocate financial resources to nuclear medicine technology.

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.

4

INTRODUCTION TO POSITRON EMISSION TOMOGRAPHY (PET)



4.0

INTRODUCTION TO POSITRON EMISSION TOMOGRAPHY (PET)

PET (positron emission tomography) is a non-invasive, nuclear medicine imaging technology that produces three-dimensional images of metabolic processes in the body and therefore allows us to visualize the body at the cellular, or functional, level.

The past decade has been marked by the development of hybrid scanners that allow the integration of PET and CT (computed tomography) technology. The simultaneous acquisition of information from both PET and CT provides observers with the functional (physiological) information from PET and the more precise structural (anatomical) information from the CT. This simultaneous visualization of both physiology and anatomy allows functional abnormalities to be pinpointed within the body with greater accuracy. The hybrid machine also reduces the overall scanning time by 30% to 40% compared with a stand-alone PET scan. This allows higher patient throughput and a more comfortable exam for the patient which can be completed during a single session. As a result of the wide-spread adoption of hybrid PET scanners, stand-alone PET scanners have essentially disappeared from the clinical, diagnostic imaging market.

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.

Although studies directly comparing PET/CT with PET-only are still limited and much of the older literature centres exclusively on PET-only, an exhaustive review by the United States National Comprehensive Cancer Network (Podoloff et al., 2009) states that PET/CT has "been reported to be an improvement over PET alone" and clinicians generally feel comfortable in extrapolating PET findings to PET/CT. For example, a study of 260 patients with cancer showed that the accuracy of PET/CT in tumour staging (84%) was superior to PET plus CT (76%), CT alone (63%) and PET alone (64%; Podoloff et al., 2009).

Further, according to a report by the International Atomic Energy Agency (IAEA, 2008), there is now abundant evidence (validated by pathology or clinical followup) that PET is more accurate (due to superior sensitivity, specificity, or both) than conventional imaging techniques for both the diagnosis and staging of cancer (Gambhir et al., 2001). This improved diagnostic performance of molecular imaging with 18F-FDG has been further enhanced with the advent of PET/CT (Czernin et al., 2007).

As of December 2010, 28 out of 29 (96.6%) publicly-funded, clinical scanners in Canada were combined PET/CT.

4.1 How PET Imaging Works

PET imaging is based on a unique physical process involving the interaction between an electron and a positron arising from the decay of a positron-emitting radiopharmaceutical (PER). A tiny dose of a short-lived PER is injected into the patient approximately one hour prior to a PET scan. It continues to decay as it travels through the blood stream, releasing positrons that collide with nearby electrons in a process known as annihilation. These interactions emit pairs of gamma photons that exit the body and are detected by the external scanner and then reconstructed by a computer to generate three-dimensional, digital images that represent the distribution of the PER compound within the body (Podoloff et al., 2009).

4.1.1 FDG

Radionuclides used in PET scanning are isotopes that are then incorporated into compounds normally utilized by the body, such as glucose. FDG (18F-fluorodeoxyglucose) is a glucose analogue attached to a PET radiotracer (Fluorine-18 or 18F) and is, by far, the most commonly-used PER for clinical PET studies. It functions well because one biochemical characteristic of malignant cancer cells is an enhanced rate of glucose metabolism due to an increased number of cell surface glucose transporter proteins and increased intracellular enzyme levels that promote glycolysis. This enhanced rate of glycolysis means that the fast-growing tumour cells absorb FDG (glucose) more quickly than healthy tissue. Once inside the cell, FDG is phosphorylated into a form of glucose that cannot be further metabolized and is trapped inside the cell. Therefore, the FDG accumulates in malignant tissues and shows up as “hot spots” on the PET scan image. Consequently, FDG-PET scans have become vital to modern oncologic imaging and are used for diagnosis, staging (determining how extensive the cancer is), assessing recurrence and monitoring response to therapy (such as surgery, chemotherapy or radiation therapy) in many cancer (Podoloff et al., 2009; Peterson and Manning, 2009; Kelloff et al., 2005).

PET technology can be used to trace the biologic pathway of any compound in humans, provided it can be labelled with a radiotracer. Therefore, the specific processes that can be probed by PET are virtually limitless and radiotracers for new target molecules and processes are being synthesized all the time. As stated earlier, 18Fluorine (18F) is the isotope most frequently used in the form of FDG. However, there are dozens of other PERs available for clinical scans and hundreds available for various applied research scans. There are PET radiotracers that supply information in heart disease and neurological disorders, including aspects such as enzymatic expression, receptor density, presence and activity of neurotransmitters, blood flow, hypoxia and angiogenesis (Peterson and Manning, 2009).

Most of the positron-emitting isotopes are produced by medical cyclotrons. These machines can make short-lived isotopes by accelerating charged particles in an outward spiralling pattern until the particle eventually collides with a specific target substance. This collision transforms the target substance into the desired isotope (Demeter et al., 2009). The radionuclide is then attached to the relevant biological molecule in a radiopharmacy prior to use in PET.

One half-life is defined as the time it will take the radionuclide to lose one-half of its radioactivity. PERs tend to have relatively short half-lives (ranging from minutes to a maximum of almost two hours) and must be utilized soon after they are created as the radioactive isotopes decay rapidly. 18F has the longest half-life (110 minutes) of the most commonly used ones. This means that the FDG will lose one-half of its radioactivity approximately every two hours post-production. This allows FDG to be transported to sites remote from its production, but additional quantities must be ordered to make up for the lost activity. This can very rapidly drive up the costs of PET scans to the point where distance ultimately makes the endeavour impractical. According to Pearcey and McEwan (2006-07), a general rule of thumb is that shipping times be less than three half-lives (or approximately five hours) to allow clinically useful quantities to be available upon delivery. Clearly, PET scanning is dependent on timely access to FDG. However, it has been shown that 18F-FDG shipments can be managed over long distances through careful establishment of contingency protocols and management of shipments (Ducharme et al., 2009).

Other radionuclides used in PET imaging are isotopes with short half-lives such as Carbon-11 (11C, approximately 20 minutes), Nitrogen-13 (13N, 10 minutes), Oxygen-15 (15O, 2 minutes) and Rubidium-82 (82RB, 1.5 minutes). Because of their extremely short half-lives, many of these PERs must be synthesized in an on-site cyclotron or distributed with generator technology, in close proximity to the PET imaging facility.

4.1.2 FDG Regulation

Access to a regular supply of FDG is critical to the success of any PET program, yet the Canadian regulatory environment for FDG and other radioactive tracers has been described as “complicated” at best (Demeter et al., 2009). Radiopharmaceutical (PER) tracers such as FDG have not been approved for use in Canada and Health Canada has strict regulations governing their use. Since 2003, FDG has been regulated as an investigational radiopharmaceutical drug rather than a general diagnostic imaging agent such as the contrast agents typically used in CT and MRI examinations. Consequently, Health Canada requires each site preparing PER tracers to file a New Drug Submission (NDS) and conduct clinical trials under a Clinical Trials Application (CTA) to gather clinical efficacy and safety data for all patients who receive FDG. As a result, clinical trials are continuously and repeatedly required to prove its safety and clinical efficacy for specific indications. This is a time consuming and costly process. This requirement has not only proven to be a bureaucratic frustration for many clinics across Canada, but it is also considered to be a major factor limiting the rapid diffusion of PET imaging across Canada (Pearcey and McEwan, 2007).

It has been shown that regulatory requirements add significant costs to operating a PET centre in Canada. Chuck et al. (2005) determined that regulatory compliance added \$196 to the cost of each scan. That figure only reflects the cost of personnel and would be even higher if it included the added costs of office space, equipment, data storage and supplies.

Clinical trials are deemed not necessary if institutions apply for a Notice of Compliance (NOC) to manufacture FDG for a specific indication and maintain an establishment license. Until recently, only McMaster University Medical Centre (The Centre for Probe Development and Commercialization) had been granted a NOC for the production of FDG and that FDG is only authorized to be utilized in lung cancer indications (including the diagnosis of solitary pulmonary nodules, staging of non-small cell lung cancer and evaluation of recurrence in non-small cell lung cancer).

FDG-PET has been safely introduced into clinical practice in most regulatory jurisdictions around the world. In those jurisdictions, regulatory authorities have typically acted to facilitate this introduction based on the common scientific knowledge that PET radiopharmaceuticals are safe. The radiopharmaceutical is administered in extremely small, nano- or pico-molar quantities that essentially have no pharmacologic effect. One prospective safety study of more than 80,000 patients, published more than a decade ago, failed to show any adverse events (Silberstein, 1998). In the United States, FDG was approved for use by the Food and Drug Administration in March 2000.

The following table has been adapted from Demeter et al. (2009), and illustrates the approved and clinical trial indications for FDG in Canada, compared to the United States, Europe and Australia. Since most indications in Canada still require a Clinical Trial Application, it is clear that Canada is operating under the assumption that either the safety of FDG has not yet been proven or that its use for certain indications has not been fully validated. As demonstrated in the table below, this is in sharp contrast to the situation in other countries.

TABLE 4.1 Approved International Indications for Clinical Use of FDG

Cancer Indication	Canada ¹	United States ²	Europe	Australia
Brain - primary	CTA	YES		YES
Breast	YES	YES		
Cervix	CTA	YES		YES
Colorectal	YES	YES	YES	YES
Esophagus	CTA	YES		YES
Head and Neck	CTA	YES	YES	
Lung	YES	YES	YES	YES
Lymphoma	CTA	YES	YES	
Melanoma	CTA	YES	YES	
Ovary	CTA	YES		YES
Stomach	CTA	YES		YES
Testicular	CTA	YES		
Thyroid	CTA	YES		

Table adapted from Demeter et al., 2009

¹YES – based on approved indications for five Health Canada approved FDG products circa January 2008

²Since 2006, the CMS will cover PET scanning for almost any malignancy if the appropriate paperwork is submitted

CTA – based on clinical trials in Canada

4.2 History of PET

The following is a very brief summary of the development of PET to give readers some idea of the timeline of significant events; it is not meant to be an all-encompassing retrospective of PET history.

The science of positron emission tomography (PET) dates back to the late 1950s and the work of David E. Kuhl and Roy Edwards at the University of Pennsylvania. Early work by William Sweet at Harvard and Gordon Brownell at Massachusetts General Hospital laid the groundwork for modern PET along with Michael E. Phelps at Washington University. FDG was first successfully synthesized in 1975 at the Brookhaven National Laboratory (BNL) in New York by organic chemist Alfred Wolf and his group of researchers. A collaboration between BNL and the University of Pennsylvania produced the first FDG-PET images in 1976 (personal communication, Dr. Tom Ruth).

During the 1970s and early 1980s, PET was primarily used as a research modality for assessing brain function in physiologic and pathologic states. In Canada, the Montreal Neurological Institute (MNI) acquired a PET instrument from the BNL in 1975. With additional work, this instrument was the first PET scanner in Canada and became known as the “Positome.” McMaster University in Hamilton followed shortly after by building a single-ring PET scanner to study the metabolism of dopamine in the brain. The McMaster group, led by Dr. Stephen Garnett, was the first in the world to utilize ¹⁸F-dopa to study Parkinson’s disease in the brain (personal communication, Dr. Geoff Coates).

In 1982, TRIUMF, Canada's national laboratory for particle and nuclear physics, located on the campus of the University of British Columbia, built a PET scanner and the first PET scan was carried out on February 24, 1983.

By the mid-1980s, McMaster had purchased a multi-slice PET scanner and cyclotron from Siemens and, by 1986, it began to manufacture various radiopharmaceuticals to use as PET tracers. As a result, the PET scanner was soon utilized for both cardiology and neurology investigations. In 1996, McMaster purchased its first full-body PET scanner and became the first centre in Canada to use PET as a diagnostic tool in clinical oncology.

In the late 1980s, Toronto's Clarke Institute of Psychiatry, now known as the Centre for Addictions and Mental Health (CAMH), became the fourth Canadian centre to obtain a PET scanner. A decade later, the Université de Sherbrooke at Fleurimont also had a PET scanner and, in 2003, Quebec became the first province to provide public funding for PET scans and to develop a comprehensive plan to develop a PET imaging network across the province.

In the United States, dramatic improvements in PET technology during the 1990s, including the routine availability of medical cyclotrons to produce the necessary short-lived positron emitters like FDG, led to a tremendous increase in the use of this technology in clinical settings and in the field of oncology. The use of PET also accelerated when the United States Centers for Medicare/Medicaid program and third party payers established reimbursement for numerous indications for PET in 1999 and, subsequently, when the US Federal Drug Administration approved FDG for use in PET scanning in 2000.

The advent of the PET/CT hybrid also gave way to a new era in clinical imaging where PET images could be utilized for clinical practice in the treatment and diagnosis of cancer patients (IAEA, 2008). By combining structure and function in a single diagnostic examination, precise localization of the disease sites became possible for the accurate diagnosis of cancer. Since then, there has been an almost exponential rise in the use of PET technology throughout the world.

4.3 Clinical Uses of PET in Oncology

There are essentially three broad clinical applications of PET technology: oncology, neurology and cardiology imaging. As outlined in the Project Plan (Section 2.2), this report focuses exclusively on the use of PET in oncology.

The broad oncologic applications of PET scanning are based on increased FDG uptake by most malignant tumours. The Warburg effect, which is when cancer cells have abnormally accelerated rates of glycolysis in the presence of oxygen, was first observed in the 1930s (Warburg, 1931). As a glucose analog, FDG is an ideal agent to detect these *in vivo* changes in glucose metabolism. The degree of FDG accumulation within the cell, as measured by PET, is proportional to glucose uptake and metabolic activity of the tissue examined (Delgado Bolton et al., 2008). Therefore, malignant tumours are readily identified by PET as hypermetabolic regions with increased concentrations of FDG.

Various papers (Valk, 2003; England's Department of Health Services, 2005; Delgado Bolton et al., 2007; Buck et al., 2010 and Langer, 2010) have described the various roles of PET imaging in oncology as follows:

Initial diagnosis – distinguishing between benign and malignant disease. Early diagnosis is important in determining and initiating beneficial treatment strategies. However, it is commonly recognized within the oncologic community that a gap may exist between diagnostic capabilities and curative treatment options. In such cases, an early diagnostic PET scan is still beneficial in that it may prevent futile attempts at cure, sparing the patient's physiological reserves and enhancing the patient's quality of life (IAEA, 2008).

Staging – The accurate staging of disease is critical for planning the most appropriate treatment strategy. PET is the only diagnostic imaging modality that is capable of detecting active cancer cells prior to tumour formation and this is particularly helpful in locating metastatic disease in cancer patients. For this reason, PET imaging often reveals that the cancer is more progressive than indicated by other testing.

Monitoring response to therapy (e.g., surgery, chemotherapy or radiation therapy) – When used to monitor response to treatment, PET has the potential to improve the probability of cure through the most appropriate use of resources and reduce the adverse effects and costs of unnecessary or ineffective treatments.

Conventional imaging modalities, such as CT, define response to treatment as a reduction of tumour volume. Since PET detects changes in the biological activity of a tumour that may be apparent earlier than the structural or anatomic changes, it is considered to be superior in determining a patient's response to treatment.

Many studies have shown that an early response to therapy as detected by PET is predictive of the patient's response to treatment and patient outcome (Delgado Bolton et al., 2008; Podoloff et al., 2009; Hillner et al., 2009). To assess early response to treatment, PET can be performed as early as seven days after having begun the chemotherapy treatment. This allows tailoring treatments to the individual patient (in terms of changes in dosage or treatment strategies) depending on the chemosensitivity and radio-sensitivity of the tumour.

Conversely, PET imaging plays a significant role in the early identification of non-responders. This early recognition facilitates earlier termination of ineffective treatment, thereby allowing a change to alternative treatments in the hope that they may be more efficacious. In addition to obviating the costs of ineffective treatment, this may allow a patient to avoid futile side effects that diminish physiological reserves and compromise quality of life (Delgado Bolton et al., 2008).

Assessing recurrence (establishing whether the disease has recurred and the exact site of recurrence) – Early detection of recurrence is clinically important and can improve the prognosis and survival of patients with cancer. Israel and Kuten (2007) showed that the use of PET in determining cancer recurrence can make a significant difference in the diagnosis and care of cancer patients.

Treatment planning for radiotherapy – PET has been demonstrated to have increased accuracy over CT in the precise delivery of high doses of radiation in select patients (Rajagopalan and Heron, 2010).

Identifying the primary site of a tumour – when there are strong clinical indications of the presence of cancer, but the site is unknown.

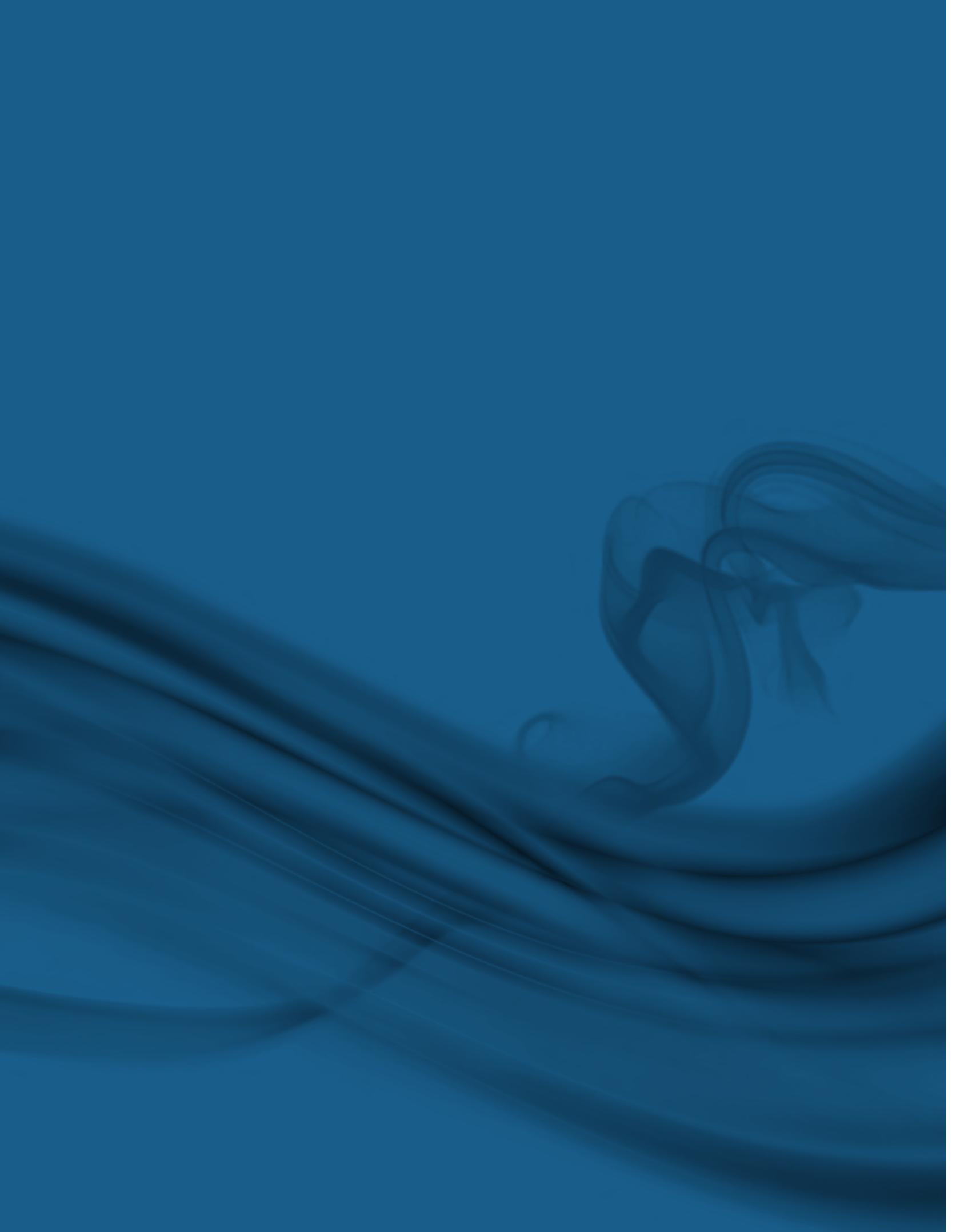
Pharmacology – Non-invasive imaging methods are of great importance in the research and development of new drug therapies. This is particularly true for PET as it supplies functional and molecular information and can be used to assess all the processes related to the development of a new drug. Using PET, the uptake of the drug, the tissues in which it concentrates, and its eventual elimination, can be monitored far more quickly and cost effectively than the older technique of killing and dissecting animals to discover the same information. PET allows the precise determination of the pharmacodynamics resulting from a distribution of pharmaceutical agents (Basu and Alavi, 2008; Kelloff et al., 2005).

Patient management – Because PET can readily identify active metabolic sites in cancer patients, PET imaging provides both the doctor and the patient with more detailed information than other diagnostic tools. It can also be carried out at various points during treatment (diagnosis, staging, detecting recurrence and establishing response to treatment) to provide accurate information

regarding the current status of the patient. As a result, PET improves decision-making at these key points and has been shown to have a direct impact on the clinical management of cancer patients (Hillner et al., 2008a; Hillner et al., 2008b; Hillner et al., 2004; Podoloff et al., 2009; Tucker et al., 2001). Tailoring treatment to the individual patient will result in improved treatment results, reduce unnecessary side effects and reduce the cost of unnecessary and unhelpful treatments (Delgado Bolton et al., 2008). Unfortunately, a more accurate diagnosis of cancer may not necessarily improve the survival of an individual patient, particularly if no effective treatment is available.

5

CLINICAL EFFECTIVENESS OF PET IMAGING IN ONCOLOGY



5.0

CLINICAL EFFECTIVENESS OF PET IMAGING IN ONCOLOGY

The proper role of a diagnostic test is to determine how best to manage the patient's treatment, not to treat the patient or to increase his/her survival rate. Because PET is a diagnostic and not a therapeutic tool, it is difficult to determine its clinical effectiveness. PET may indicate a certain treatment strategy, but too many options for therapeutic treatment exist following the PET diagnosis to assess the direct impact of PET on the survival rate of the patient. Therefore most studies define the clinical effectiveness of PET imaging in terms of its impact on intended patient management by the physician.

According to Hillner et al. (2008a), changes in management strategies after PET are primarily assessed as a change of treatment (e.g. surgery, chemotherapy, radiation) to non-treatment (watching, non-invasive imaging, biopsy or supportive care) and curative to palliative. Some studies also measure changes in the type of intended treatment (e.g. from surgery to chemotherapy). As described below, there is significant data to suggest that the results of PET imaging affect physician decision-making and alter patient management strategies.

5.1 Change in Patient - Management Statistics

A considerable amount of literature is available to describe the impact of PET imaging on the clinical management of cancer patients. By far the largest study ever done to determine management changes after PET imaging comes from the United States, where a unique program called the National Oncologic PET Registry (NOPR, www.cancerPETregistry.org) is in place to gather PET imaging evidence. A basic understanding of the NOPR is necessary to understand the enormity of the data accumulated and to view the data in its appropriate context.

From 1998 to 2005, the CMS (Centers for Medicare and Medicaid Services, previously known as the Health Care Financing Administration) in the United States provided broad coverage for the use of PET in the diagnosis, staging and restaging of lung, colorectal, head and neck, and esophageal cancers, as well as lymphoma (both Hodgkin's and non-Hodgkin's) and melanoma (Fletcher et al., 2008; Podoloff et al., 2009). Reimbursement for PET was also approved for specific indications in breast, cervical and thyroid cancers.

However, in January 2005, the CMS acknowledged that evidence was accumulating for the application of PET in numerous other indications. In response to requests by professional organizations, it announced a new approach to its coverage policy for diagnostic and treatment methods termed "coverage with evidence development" (CED). The goal of CED was to expand the evidence base for evaluating selected technologies such as PET in uncovered indications (Hillner et al., 2009). Under the program, PET scans for all cancers and indications (except for those already covered by, or specifically prohibited by, the CMS) would be reimbursed if the patient and physician agreed to participate in, and provide data to, the CED program.

In response, the Academy of Molecular Imaging, in collaboration with the American College of Radiology Imaging Network, developed a CED program known as the National Oncologic PET Registry (NOPR). This is a nationwide prospective medical registry designed to systematically collect clinical and demographic data on the usefulness and impact of PET imaging in previously non-covered cancer types and indications. The registry opened in May 2006, with the primary goal of evaluating the impact of PET on physicians' plans for patient management. As a condition of reimbursement, providers are required to submit data from pre-and post-PET physician questionnaires to the NOPR. By March 2009, the NOPR had collected data from greater than 130,000 cases in approximately 80% of PET facilities across the United States.

At the end of its first year of operation, the NOPR published results from nearly 23,000 (22,975) scans from 1,178 centres (Hillner et al., 2008a). The main goal of this initial NOPR study was to assess the impact of PET on intended patient management by physicians.

The primary finding of this study is that, overall, investigators changed their intended patient management strategy after PET imaging in 36.5% of cases (Hillner et al., 2008a). In addition, surgical biopsy was avoided in 70% of cases where the pre-PET strategy was planned biopsy. Referring physicians indicated that the PET results enabled them to avoid additional tests or procedures in 76.9% of cases. When the most common pre-PET imaging plan was more imaging, it was found that treatment strategies changed to watching in 37% of cases and treatment in 48% of cases. When determining treatment or non-treatment, the post-PET plan was three-fold more likely (28.3%) to lead to treatment than non-treatment (8.2%). According to Larson (2008), there can “be no doubt from the study that statistically PET had a major impact on ... intended management.”

In a subsequent investigation (Hillner et al., 2008b), NOPR investigators reported on the results from nearly 41,000 (40,863) scans performed at 1,368 centres over two years (2006-2008). In this study, they found that PET imaging resulted in a change in intended clinical management in 38.0% of cases and changes were consistent for all testing indications (staging, restaging and detecting recurrence). See Table 5.1 below.

Table 5.1 Changes in Intended Management for all Cancer Types

Testing Indication	# of Scans	% of Cases with Change in Management
Initial Staging	14,365	39.8
Restaging	14,584	35.9
Detection of suspected recurrence	11,914	38.5
TOTAL	40,863	38.0

Adapted from Table 4, Hillner et al., 2008b

In 2009, Hillner et al. used the NOPR data from 8,240 patients to describe the impact of PET monitoring on the management of patients who were already undergoing cancer treatments such as chemotherapy, radiation therapy or combined modality treatment. It has previously been demonstrated that the findings of PET scans recording a response to treatment are a predictor of progression-free or overall survival for a variety of cancers. In this study, it was determined that PET imaging results during therapy changed the referring physicians’ intended patient management in 49% of cases. In the majority of cases where treatment plans changed, PET studies revealed more active sites of disease than anticipated. PET imaging caused physicians to switch the patient to another therapy in 26-28% of cases. In 16-19% of scans, PET results led to an adjustment of the dose or duration of therapy. In 90% of cases, referring physicians indicated that the scan results allowed them to avoid other imaging or invasive procedures.

Major strengths of the NOPR data are its large sample size, the completeness of the data and the national scale. However, despite its large scale, a major limitation is its inability to determine whether the intended changes in management conferred a benefit to the patient in long-term outcomes. Even though PET imaging led to a change in management in more than one-third of all cases, it should be noted that an impact on, or change in, management does not always translate to a clinical advantage for the patient (Podoloff et al., 2009).

The statistics reported above for change in oncologic patient management (36.5%, 38% and 49%) are highly reflective of the frequencies described in numerous studies on this topic (30-40%, as reported in Hillner et al., 2008a; Delgado Bolton et al., 2008; Seltzer et al., 2002; Podoloff et al., 2009). However, other literature suggests that the impact of PET on patient care may be even more striking.

A large Canadian study by Worsley et al. (2010) evaluated the impact of PET on treatment changes and decision-making in 3,779 consecutive patients at the British Columbia Cancer Agency in Vancouver, British Columbia. Based on a standard physician's questionnaire, it was found that the information derived from PET imaging resulted in a change in an individual patient's treatment plan in 50% of cases and physicians reported an improved decision-making ability in 83% of cases.

These findings are similar to those reported in one of the earliest studies (Tucker et al., 2001) to consider the impact of PET. Physician evaluations of the management of 463 oncologic patients following a PET-only scan in the first year of PET operation in one American medical centre demonstrated that PET-only changed patient management in 45% of cases and improved decision-making ability in another 44% for an overall impact on management in 89% of cases. Surveys showed that PET-only imaging had caused the cancellation of surgery in 33% of cases where surgery was the intended treatment.

In addition, a prospective study of 248 patients at one United States cancer centre (Hillner et al., 2004) found that physicians changed their intended management in 61% of patients following PET imaging. When the pre-PET intended treatment plan involved more testing or biopsy, there was a change of strategy 79% of the time. In 32% of cases, physicians changed to a treatment strategy from a non-treatment strategy.

The following table summarizes the above information on change in patient management statistics:

Table 5.2 Summary of Change in Patient Management Statistics

Study	# of Patients	% Change in Patient Management Reported
Hillner et al., 2008a	22,975	36.5
Hillner et al., 2008b	40,863	38
Hillner et al., 2009	8,240	49
Worsley et al., 2010	3,779	50
Tucker et al., 2001	463	45
Hillner et al., 2004	248	61

5.2 Patient Management Statistics by Cancer Type

NOPR investigators also reported on the impact of PET on the management of patients with pathologically proven cancer of known origin (Hillner et al., 2008b). The intent of the investigation was to evaluate whether important differences in patient management were present as a function of cancer type. The study included results from nearly 41,000 (40,863) scans performed at 1,368

centres over two years (2006-2008) and the NOPR collected questionnaire data from physicians on intended management before and after PET.

As reported above, Hillner et al. (2008b) found that PET imaging resulted in an average change in intended management in 38.0% of cases. Change in management for 18 specific cancer types ranged from a low of 31.4% for non-melanoma skin cancer to a high of 48.7% for myeloma (see Table 5.3), although the results were “strikingly consistent” across cancer types. As previously reported (Hillner et al., 2008a), most of these treatment changes were from non-treatment to treatment (30%), rather than vice versa (8%). This is most likely due to PET’s ability to detect unsuspected lesions.

The efficacy of PET imaging for diagnosing and staging cancer as well as monitoring the progress of treatment continues to be an actively reported topic in research. Each month, new studies add to the growing evidence that PET-based information enhances patient care.

According to a recent study published in the *Journal of Clinical Oncology* (Safar V et al., 2012), patients with newly diagnosed diffuse large B-cell lymphoma who have negative PET scans using FDG after two cycles of anthracycline-based chemotherapy plus rituximab showed higher progression-free survival and overall survival rates than those with positive PET scans. It was concluded that an early PET scan (after two cycles of treatment) can effectively predict the outcome in patients with this form of cancer treated with rituximab and anthracycline-based chemotherapy by using either a visual or quantitative approach.

The utility of PET imaging beyond oncology is important as well; its use in cardiology and neurology is also rapidly expanding. For instance, researchers from Finland have developed a decision-support tool to help improve the diagnosis of Alzheimer’s disease. The tool, developed by a project called PredictAD, uses biomarkers from PET and other methods and compares them with measures in pre-existing databases at hospitals. The system allows for diagnosis to be more accurate and for clinicians to have a higher level of confidence in their decisions.

5.3 Implications of Patient Management Statistics

PET imaging often changes oncology patient management: Previous, small, single-centre studies have reported that PET imaging is associated with a change in management in 30-40% of cases (Hillner et al., 2008a). The NOPR data shown above are based on extremely large sample sizes and are national in scale, and they confirm that patient management changes in 36.5% (based on 22,975 scans) and 38% (based on a study size of 40,863 scans) of cases. Further, these management changes were shown to be remarkably consistent over type of cancer (see Table 5.3). The similarity in management changes between small and large studies suggests the percentages may accurately reflect the realities of day-to-day oncology practice. The data also suggest that current management of cancer patients by CT- or MRI-only results in the ‘wrong’ management strategy in at least one-third of all cases.

PET imaging improves decision-making by doctors: By providing functional images of the cancerous indications in the body, PET imaging is, in many cases, better able to define the extent of the cancer in the patient. This information logically enables both doctors and patients to make more informed decisions about therapeutic options and therefore leads to a more appropriate use of resources. Obviously, better treatment decisions result in more appropriate patient care and a better use of limited healthcare resources.

Table 5.3 Impact of PET on Intended Management by Cancer Type

Type of Cancer	# of Scans	% Change in Intended Treatment
Prostate	5,309	35.1
Ovary	4,509	41.4
Bladder	3,578	37.9
Pancreas	3,314	39.0
Stomach	3,025	36.9
Small Cell Lung	2,983	41.2
Kidney	2,877	35.8
Uterus	2,869	36.5
Myeloma	1,784	48.7
Connective Tissue	1,350	36.4
Nonmelanoma skin	1,057	31.4
Liver and intraphepatic bile ducts	1,038	42.9
Cervix	984	32.7
Gallbladder	806	39.7
Other female genital	709	37.1
Thyroid	629	35.6
All other	4,042	36.6
TOTAL	40,863	38.0%

Table 2, Hillner et al., 2008b

PET imaging frequently eliminates the need for further testing: Studies clearly show that PET imaging can eliminate the need for further tests or procedures in as many as 90% of cases (Hillner et al., 2009). The statistics suggest that PET should be used as a first-line diagnostic tool to diminish the need for further testing. Yet, in provinces other than Quebec, physician interviews suggest that PET imaging is often used as a last resort in the oncology diagnostic pathway.

There is likely a huge disparity in management of cancer patients among the various provinces: Given the changes in patient management that result from PET imaging, it is reasonable to believe that cancer patients without ready access to PET are getting very different management of their cancer care than those with access to PET. It remains uncertain as to whether this results in higher survival rates for cancer patients, although there is good evidence to show that the PET management reduces the adverse effects and costs of unnecessary or ineffective treatment.

PET helps patients to avoid costly biopsies: The above studies show that PET imaging frequently produces results that render surgical biopsies futile. By avoiding costly surgeries in as many as 70% of cases (Hillner et al., 2008a), PET can lead to significant cost savings and prevent patients from undergoing painful, high-risk surgical procedures that have no chance of conferring any benefit.

PET does not always translate into better survival rates for patients: PET leads to better, more-informed decision-making by the patient and the physician, but that does not always translate into benefit for survival rates of patients as there is often a disparity between diagnosis of a disease and therapeutic options to successfully treat it. In many cases, PET's superior diagnostic abilities will upgrade the patient's cancer status. The upgrade may lead the patient to undergo earlier treatment or lead the doctor to conclude that future therapeutic options are not advisable in terms of the patient's quality of life and would provide too great a drain on the patient's physiological resources.

As a result of the NOPR studies, the United States Centers for Medicare and Medicaid Services now allow reimbursement for most clinical indications in oncology: Breast, cervix, colorectal, esophageal, head and neck, lymphoma, melanoma, non-small cell lung and thyroid cancers are all reimbursed by the CMS. It has most recently added ovarian cancer and myeloma to that list. All other cancers are eligible for scans but patients must participate in a registry, with the data going to the NOPR program for "coverage with evidence."

There is a human element to be considered in determining the value of a PET scan: The present report identifies numerous healthcare policies and provides considerable statistical information to describe the impact of PET imaging on cancer treatment. But it is also important to note that the impact of any healthcare policy goes beyond statistics to have a direct impact on individual patients and their families. For that reason, the following personal stories are used to illustrate the plight of patients whose cancer treatment has been impacted by current PET imaging practices and policies. These examples are anecdotal only and, while they cannot be generalized to reflect the experience of the entire population, they do demonstrate the effect that current PET policies can have on individuals in Canada.

CASE #1: In 2002, Saku Koivu, the captain of the Montreal Canadiens, was diagnosed with non-Hodgkin's intra-abdominal lymphoma. He was fortunate in that Quebec had just installed its first clinical PET scanner at the Université de Sherbrooke in Fleurimont, and his doctor sent him there for a PET scan prior to treatment. The scan found that the cancer was localized and Koivu elected to undergo six courses of chemotherapy.

After his second round of chemotherapy, Koivu was sent back to Sherbrooke for a PET scan to determine if he was responding to treatment. Surprisingly, the scan showed that the cancer was completely gone and therefore the chemotherapy was discontinued much earlier than expected. As a result of not having to undergo an additional four rounds of chemotherapy, Koivu's physical resources were conserved and he was able to return to hockey much earlier – and in much better condition – than anticipated.

Koivu was so grateful for the beneficial intervention of PET imaging that he established the Saku Koivu Foundation to raise the \$8 million needed to purchase a PET scan machine for the Montreal General Hospital.

Case 2: In 2010, a 77-year-old Saskatchewan woman was diagnosed with pancreatic adenocarcinoma. Following surgery, a CT exam showed that a two cm lesion remained and opinions were divided as to whether the cells represented scar tissue or active cancer. The oncologist did not believe that a PET scan would resolve the difference of opinion, as he did not understand how a PET scan was any different than a CT scan. It was only through repeated requests by the family that

an out-of-province PET scan was ordered. PET imaging revealed that the lesion was cancerous and the woman began chemotherapy immediately.

Case 3: In Ontario, a 72-year-old male with colon cancer underwent surgery in December 2006. The surgeons identified lesions on the liver that suggested metastatic cancer. CT and MRI exams following surgery both suggested that the lesions were benign hemangiomas, but a repeat CT six months later showed that the lesions were enlarging and therefore metastatic. Three months later, the patient had surgery to remove the lesions. Had the patient undergone a PET scan right after surgery, it would likely have revealed that the lesions were, in fact, active and the patient could have undergone surgery up to nine months earlier, perhaps extending his life and/or quality of life.

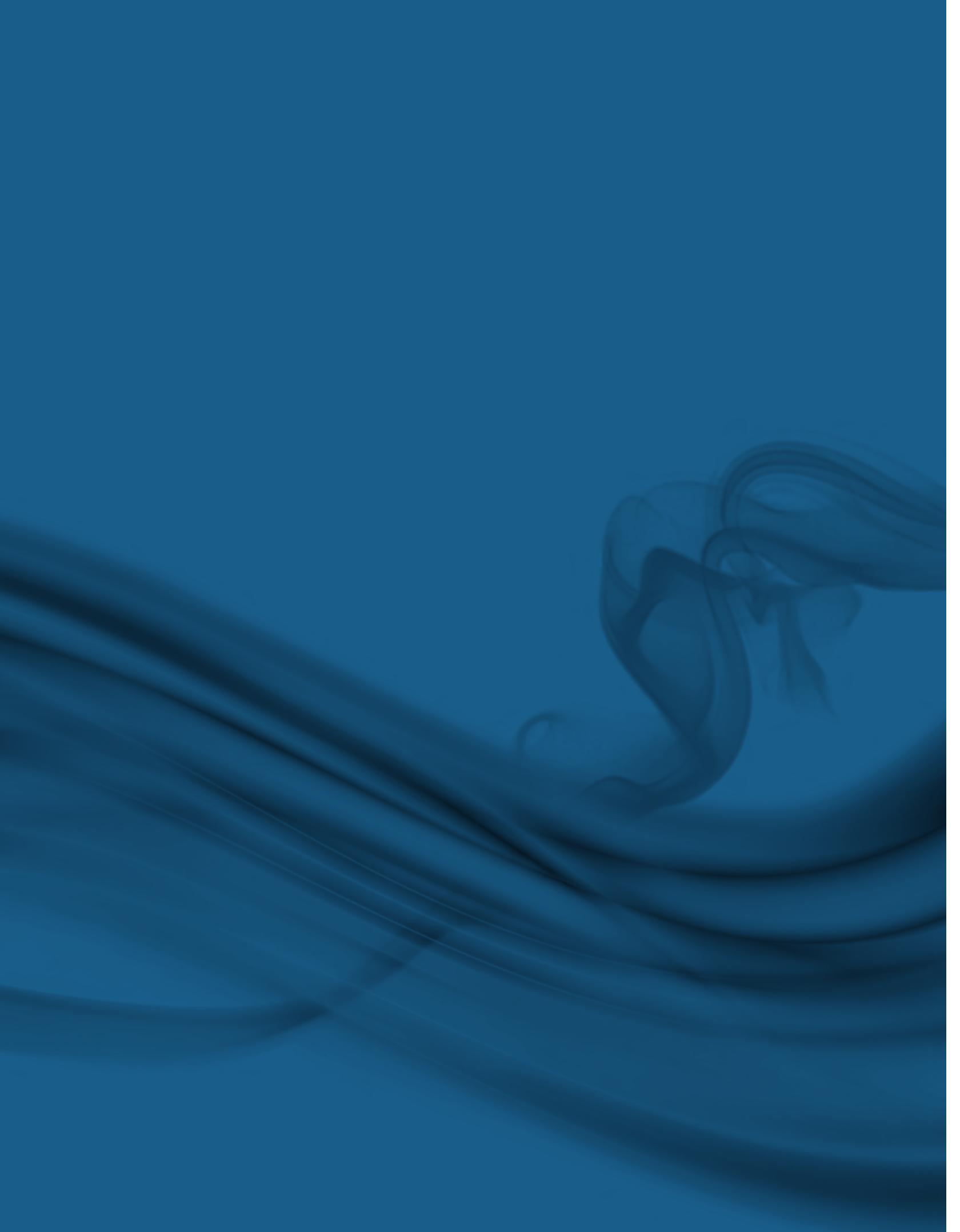
Three years later, a followup CT showed that this same patient had persistent, unresponsive lesions in his liver and, based on this, his prognosis was dire. The patient was distraught and preparing for his life to end. Based on a friend's advice, the patient requested a PET scan. The physician was reluctant, but finally relented. The PET scan showed that the lesions were not taking up FDG and only represented scar tissue. It also revealed that there was one small active lesion at a site that the CT had not detected.

Therefore, rather than preparing for an imminent death as suggested by the CT, this patient underwent surgery for the one lesion. This case study shows the inability of CT to identify metabolically active anatomic lesions.

Case 4: A 46-year-old Ontario patient was diagnosed with lymphoma. Following chemotherapy, the patient underwent two CT scans and they revealed that the mesenteric disease had resolved, but there was a five cm lesion in the spleen that was diagnosed as scar tissue. Based on these results, the patient was told that he appeared to be disease free. Shortly after, the patient and his physician decided to request a PET scan and it revealed a very different story – not only was there active mesenteric disease at the original site, but the spleen lesion was active as were several sites in the neck. Consequently, a patient who thought he was disease-free was placed on a very aggressive course of chemotherapy. This study demonstrates the benefit in using PET rather than anatomic imaging to monitor and direct a patient's cancer treatment.

6

COST EFFECTIVENESS



6.0

COST EFFECTIVENESS

As noted in the previous section, PET imaging has substantially influenced the management of patients with cancer by ensuring the patient undergoes the most appropriate treatment for his current condition – even if that means palliative treatment only. While it is obvious that this is a benefit to the patient, it is much more difficult to determine if this results in a financial benefit to the healthcare system. PET may indicate a certain treatment strategy, but too many options for therapeutic treatment exist post-PET imaging to assess the direct impact of PET on the cost of the treatment.

However, it has been reported that cost savings can be realized by using PET to ensure the most appropriate management of cancer patients (Demeter et al., 2009). 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. The overall cost impact on the health system will depend on whether this alternative care ends up being less or more costly but, in any case, it will likely be a more appropriate use of scarce resources. A systematic review of PET also suggested that personalized medicine using PET may be cost effective because it generally results in improved care and less exposure to ineffective treatments (Langer, 2010).

From a health economic point of view, the literature shows that the use of functional PET in clinical routine is justified in the following situations:

- There is a general consensus in the research that PET is cost effective in the staging of non-small cell lung cancer and the differential diagnosis of solitary pulmonary nodules (Buck et al., 2010; Langer, 2010 and Demeter et al., 2009; Jadvar, 2005). By avoiding costly surgeries in as many as 70% of cases (Hillner et al., 2008a), PET can lead to significant cost savings and prevent patients from undergoing painful, high-risk surgical procedures that have no chance of conferring any benefit.
- Economic reviews suggest that PET is cost effective when it is used for restaging of colorectal carcinoma after recurrence (Buck et al., 2010; Demeter et al., 2009; Jadvar, 2005). When PET is used as a restaging tool, average case cost savings ranging from \$1,785 (CDN) to \$2,301 (AUS) have been realized (Demeter et al., 2009). As with lung cancer, cost savings relate largely to averted interventions such as surgeries when the disease is discovered to have spread beyond the stage where a reasonable chance of cure exists.
- According to a recent economic review by Buck et al. (2010), the clinical use of PET has also been demonstrated to be cost effective for restaging of Hodgkin's disease and non-Hodgkin's lymphoma.

At a time when healthcare costs are escalating and financial resources are limited, there is a growing need to assess the economic benefit of diagnostic procedures. Economic evaluations go beyond pure effectiveness measurements by combining costs and consequences (outcomes) of diagnostic procedures. Three economic evaluation methodologies can be used to assess imaging studies: cost effectiveness analysis, cost-utility analysis and cost-benefit analysis (IAEA, 2008; Buck et al., 2010).

Cost effectiveness analysis (CEA) is performed through a cost-minimization study or by evaluating the cost-effective ratio. The minimization study can be adopted when it is known that the clinical-effectiveness of two diagnostic tests is equivalent. In this case, the only parameter to be considered is the total cost of each strategy and the final choice will reflect the procedure with the lowest cost.

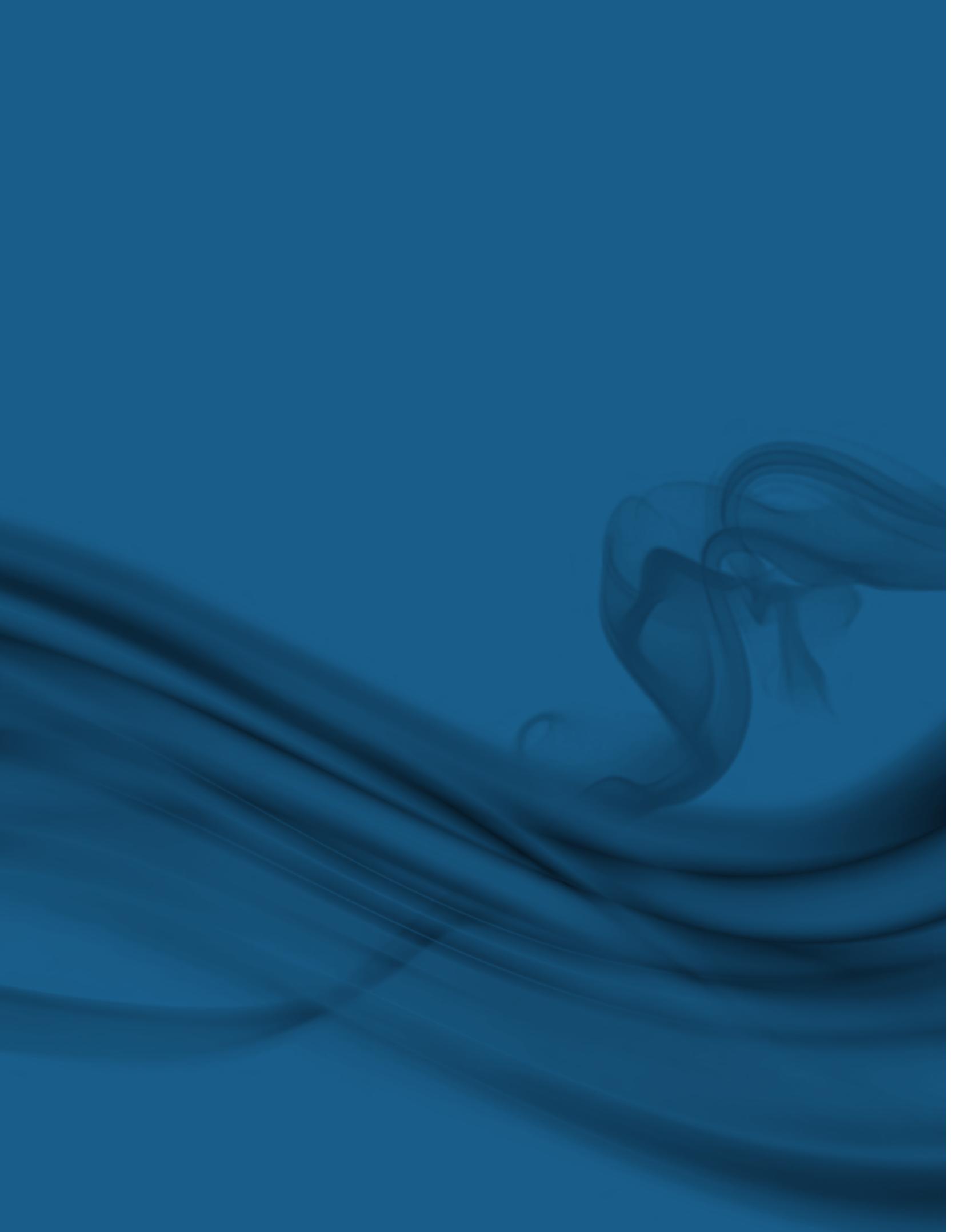
The cost-utility analysis (CUA) is considered to be a form of the cost-effective analysis where adjustments are done for the 'value attached to the benefits.' One of the most widely-used measures of the health outcome is the quality of adjusted life year or QALY. This sets out the change in resource use and the number of quality adjusted life years. QALYs estimate the effect on survival and the changes in quality of life stemming from the introduction of the modality under investigation.

The cost-benefit analysis (CBA) may be regarded as an extension of the cost-utility study where all the measurements of the effectiveness, including quality adjusted life, pain and other negative effects can be expressed as financial value. There are different proposals to calculate the monetary value of life such as earning or willingness to pay.

The number of studies reporting on economic evaluations of PET is limited. However, it should be noted that the number of available publications is higher than that for other widely-utilized imaging modalities such as CT and MRI.

7

STATUS OF PET IMAGING IN CANADA



7.0

STATUS OF PET IMAGING IN CANADA

7.1 Introduction

In the United States and Europe, PET has become the standard of care for the diagnosis, staging, and evaluation of treatment response to a growing number of cancer indications. This is not the case in Canada where, in many places outside of the province of Quebec, diagnostic PET imaging is still considered to be experimental, expensive and unproven technology.

In Canada, healthcare is under the control of each provincial jurisdiction and, as a result, PET policies are fragmented and inconsistent. As demonstrated in the following pages, access to publicly-funded, clinical PET imaging and the number of scans performed in Canada varies greatly by region (Table 7.3). There are currently a total of 29 publicly-funded clinical scanners situated across Canada (see Figure 7.1), and the vast majority (21) of these are located in Ontario (9) and Quebec (12). Alberta has three scanners; British Columbia has two scanners. Manitoba, New Brunswick and Nova Scotia each have one. There are currently no scanners in the provinces of Saskatchewan, Prince Edward Island and Newfoundland, although plans are in place for both Newfoundland and Saskatchewan to have functional scanners by the year 2013. Table 7.2 provides information on the location of these facilities, the type of equipment utilized and any known plans for the future installation of PET services.

The findings and data below are based on 44 interviews conducted across Canada during the latter part of 2010. Interviewees consisted of nuclear medicine physicians, representatives of various provincial cancer agencies (British Columbia Cancer Agency, Saskatchewan Cancer Agency, Cancer Care Manitoba, Cancer Care Ontario and the New Brunswick Cancer Network), administrators of both public and private nuclear medicine programs, one nuclear medicine technician, one lawyer and the Conseiller Scientifique of Quebec's Ministry of Health and Social Services. Overall, 62 individuals were contacted about the project. A total of 46 questionnaires were sent out and 28 were completed and returned.

The data and calculations shown in Table 7.3 reflect provincial PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010.

It should be noted that there were considerable difficulties involved in obtaining and verifying this data. A reluctance to share data as well as debates over the clinical/research use of many devices clearly underscore the observation that Canada has no coherent PET strategy or means of collecting infrastructure data. Further, there are no policies to ensure that cancer patients have adequate access to this technology.

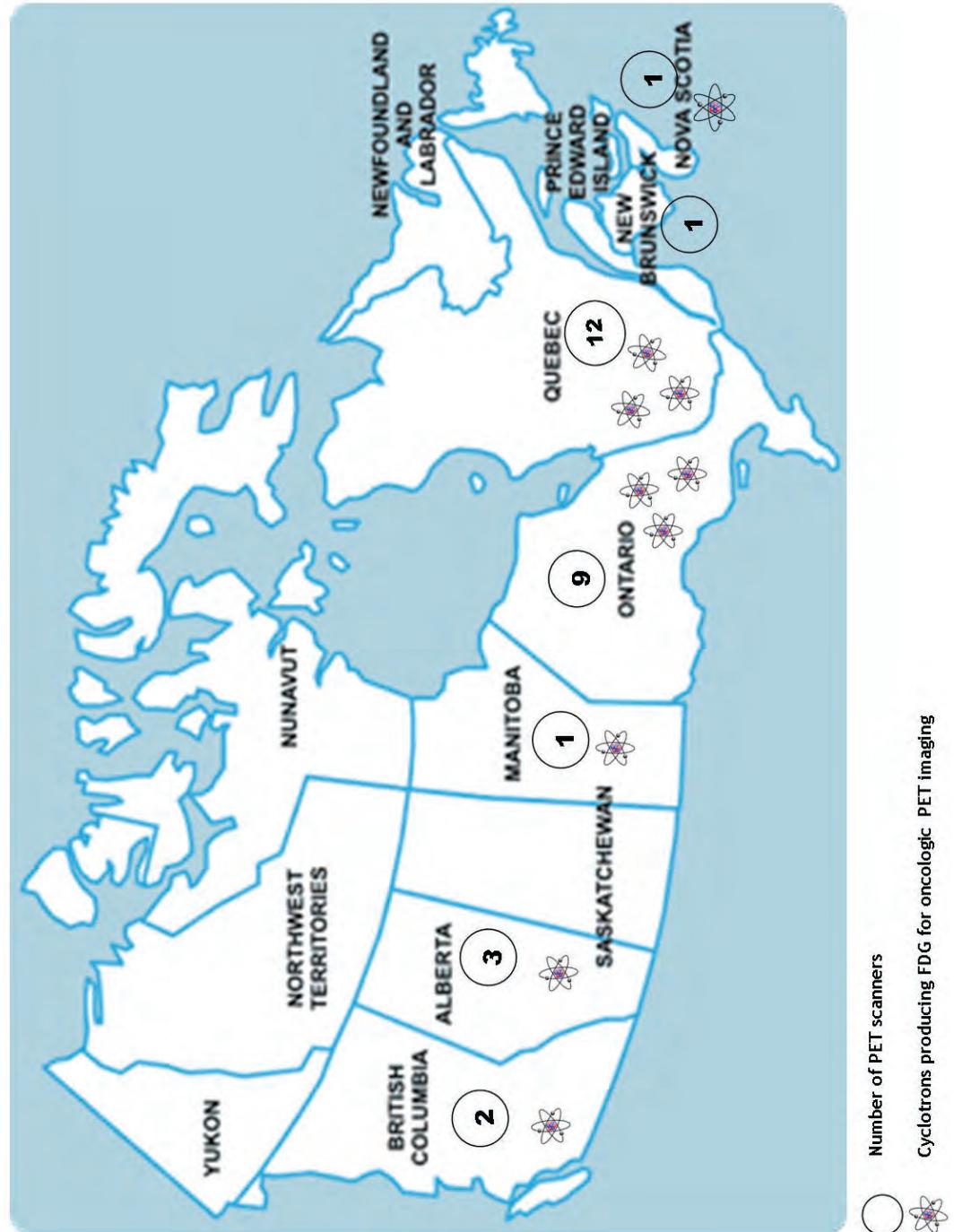


Figure 7.1 Publicly funded clinical PET scanners in Canada.

Table 7.2 Location of Publicly-Funded, Clinical PET Scanners in Canada (2011)

Province	Facility	City	Clinical Scanners
BC	BC Cancer Agency	Vancouver	2 PET/CT
Alberta	Cross Cancer Institute	Edmonton	1 PET/CT
	University of Alberta Hospital	Edmonton	1 PET/CT
	Foothills Hospital	Calgary	1 PET/CT
Saskatchewan	Royal University Hospital	Saskatoon	0** (1 PET/CT expected by 2013)
Manitoba	WPG Health Science Centre	Winnipeg	1 PET/CT
Ontario	McMaster University Health Sciences	Hamilton	1 PET-only
	St. Joseph's Hospital	Hamilton	1 PET/CT
	The Ottawa Hospital	Ottawa	1 PET/CT
	Ottawa Heart Institute	Ottawa	1 PET/CT
	Princess Margaret Hospital	Toronto	1 PET/CT
	Sunnybrook Hospital	Toronto	1 PET/CT
	The Hospital for Sick Children	Toronto	1 PET/CT
	Toronto Western Hospital	Toronto	1 PET/CT to begin operating in 2012
	St. Joseph's Hospital	London	1 PET/CT
Thunder Bay Regional Hospital	Thunder Bay	1 PET/CT	
Quebec	CUSM - Montreal General Hospital	Montreal	1 PET/CT
	CHUM - Hotel Dieu	Montreal	1 PET/CT
	Jewish General Hospital	Montreal	1 PET/CT
	Hospital Ste. Justine	Montreal	1 PET/CT
	Hospital Maisonneuve-Rosemont	Montreal	1 PET/CT
	CHUQ- Hotel Dieu Quebec	Quebec City	1 PET/CT
	Hospital Laval/Inst. Of Cardiology and Pneumology Quebec	Quebec City	1 PET/CT
	CHUS- Université de Sherbrooke	Sherbrooke	1 PET/CT
	Rimouski General Hospital	Rimouski	1 PET/CT
	Chicoutimi General Hospital	Chicoutimi	1 PET/CT
	Trois Rivieres General Hospital	Trois Rivieres	1 PET/CT
	Gatineau General Hospital	Gatineau	1 PET/CT
Nova Scotia	QE II Health Sciences Centre	Halifax	1 PET/CT
New Brunswick	St. John Regional Hospital	St. John	1 PET/CT
	The Moncton Hospital	Moncton	1 PET/CT expected in 2012
Newfoundland	Memorial University	St. John's	0** (PET/CT expected by 2013-14)
Prince Edward Island			0

**expecting a/another scanner

Table 7.3 PET Scanning Statistics for Canada in 2009

	BC	AB	SK	MB	ON	QB	NB	NS	PEI	NF	TOTAL/ Average (AVG)
Population	4.5M	3.7M	1.0M	1.2M	13.1M	7.9M	0.75M	0.94M	0.14M	0.5M	33.73M
#Clinical scanners	1**	3	0***	1	9	12	1**	1	0*	0***	28
#Scans (funded in 2009 (approx))	3,100	5,500	300	1,300	7,250	22,400	1,000	1,600	70	100	42,620
Cost per scan	\$1,400	\$1,350	\$1,250	\$1,800	\$1,220	\$956	\$1,600	\$1,800	\$1,836	\$1,850	\$1,506.20 (AVG)
#Scans per million people	689	1,486	300	1,083	553	2,835	1,333	1,702	500	200	1,068 (AVG)
#PET scanners per million people	0.22	0.81	0	0.83	0.7	1.5	1.33	1.06	0	0	0.83 (AVG)
#Scans per scanner	3,100	1,833	0	1,300	806	1,867	1,000	1,600	0	0	1,643 (AVG)

*Sends patients out of province for scans

**Expecting a/another PET scanner

Note that the data and calculations above reflect PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that these statistics remained essentially the same in 2010.

7.2 PET Scanners

Quebec and Ontario appear to have the best access to PET technology when one considers the numbers of PET scanners and their geographic distribution. However, when population numbers are equalized by evaluating the number of publicly-funded, clinical PET scanners per million people (see Figure 7.4 and Table 7.3), a rather different picture emerges of the penetration of PET scanners by province. Quebec has the highest penetration at 1.5 scanners per million people, followed by New Brunswick and Nova Scotia at 1.33 and 1.06 scanners per million, respectively. In contrast, Ontario (0.7 scanners per million) and British Columbia (0.22 scanners per million) are the provinces with the lowest penetration of PET technology. In July 2011, British Columbia began operating a second scanner. This increases the current ratio to 0.44 scanners per million, but that value still leaves British Columbia with the most limited access to PET services in Canada.

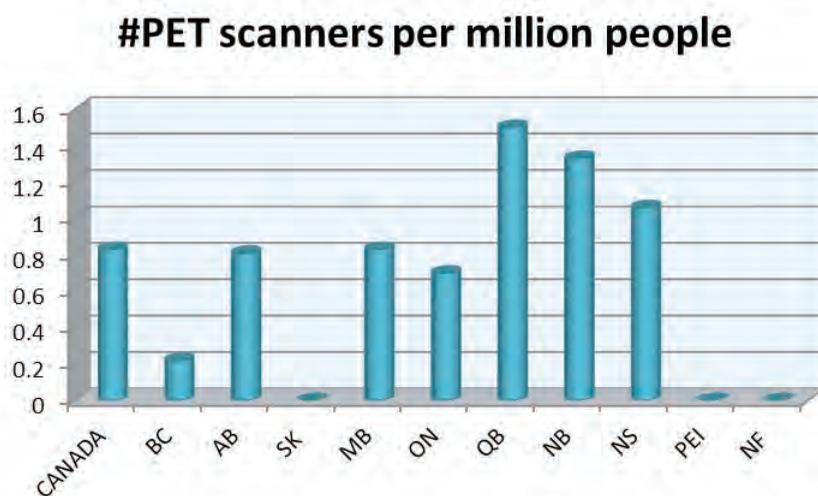


Figure 7.4 Number of PET scanners per million people for Canada and each of its provinces in 2009.

The Royal College of Radiologists in the United Kingdom has recommended that there be one PET scanner per 1.5 million people (Department of Health Services, 2005), while the World Health Organization (WHO) recommends that countries adopt a ratio of two scanners per million (MEDEC, 2010). With 29 scanners operating in 2011, Canada's national average of 0.86 PET scanners per million fails to meet either of these world standards. By way of comparison, the United States has about 6.5 scanners per million people (Buck et al., 2010).

It is interesting to note that New Brunswick and Nova Scotia each have one scanner to serve a population of less than one million. Further, New Brunswick is planning for a second scanner (expected in 2012) to satisfy provincial bilingual requirements. The current PET scanner is located in a predominantly English-speaking hospital in St. John; a second PET scanner will be installed at the French-speaking hospital in Moncton. The province would then have two scanners serving a population of 750,000 people, making it the province with the highest penetration of PET scanners in Canada at 2.67 scanners per million people.

Canadians have access to seven private PET scanning facilities located in British Columbia, Ontario and Quebec. As shown in Table 7.5, costs per oncology PET scan range from a low of \$1,980 in one of the Montreal clinics to a high of \$2,850 in Burnaby, BC. KMH Cardiology and Diagnostic Centres predominantly perform cardiology investigations and, therefore, its prices vary according to procedure. The cost of a mobile PET scan was not available at press time.

There are currently 11 scanners in eight different facilities across Canada that are dedicated to research in oncology, neurology and cardiology. Table 7.6 identifies the facility and the type of scanning equipment available. Please note that some of the Ontario PET scanners listed in Table 7.2 may be utilized for both clinical and research purposes.

Table 7.5 Private PET Imaging Facilities in Canada (2011)

Province	Facility	City	Equipment	Cost
British Columbia	Premier Diagnostics	Burnaby	1 PET/CT	\$2,850
Ontario	Care Imaging	Mississauga	1 PET	\$2,358
	KMH Cardiology and Diagnostic Centres	Markham	1 PET/CT	\$1,500 – 2,500
	Precision Diagnostic Imaging	Windsor	1 mobile PET/CT	Not available
Quebec	Centre d'imagerie Medicale Reso Scan CLM	Montreal	1 PET	\$1,980
	Clinique Radiologique de la Capitale	Quebec City	1 PET/CT	\$2,500
	Centre d'imagerie Nucleaire et TEP/CT Ville Marie	Montreal	1 PET/CT	\$2,500

Table 7.6 Research PET Imaging Facilities in Canada (2011)

Province	Facility	City	Equipment
BC	University of British Columbia	Vancouver	3 PET-only
Alberta	Cross Cancer Clinic	Edmonton	1 PET-only
Ontario	(CAMH) Centre for Addictions and Mental Health	Toronto	1 PET-only
	(CAMH) Centre for Addictions and Mental Health	Toronto	1 PET/CT
	Princess Margaret Hospital	Toronto	1 PET/CT
Quebec	CHUM (University of Montreal) Notre Dame	Montreal	1 PET/CT
	Montreal Neurological Institute	Montreal	2 PET-only
	Université de Sherbrooke	Sherbrooke	1 PET/CT

7.3 PET Scans

In 2009, a total of 42,620 PET scans were funded across Canada (see Table 7.3). Numbers of scans remained essentially the same in 2010. More than half of all the scans in Canada (22,400) were carried out in the province of Quebec. Ontario funded the second highest number of scans (7,250), followed by Alberta (5,500) and British Columbia (3,100). The lowest number of scans (70) was funded by Prince Edward Island, a province without a PET scanner.

But once again a very different picture regarding the regional distribution of scans emerges when the number of scans is calculated per million people, as seen in Figure 7.7 below.

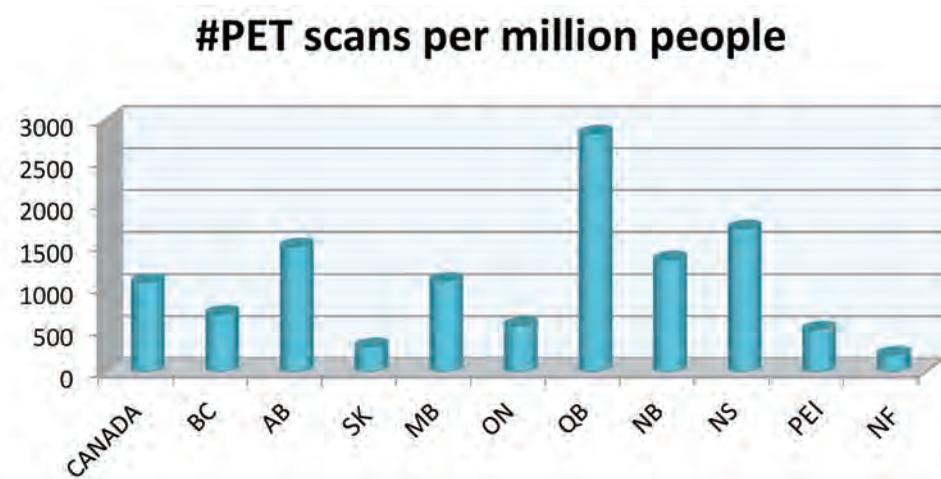


Figure 7.7 Number of PET scans carried out per million people in Canada and each of its provinces in 2009.

In 2009, Canada's national average was 1,068 scans per million people. Quebec remains the province with the most scans at 2,835 scans per million; Nova Scotia is second at 1,702 scans per million, followed by Alberta at 1,486. Ontario funded the lowest number of scans (553 scans per million) of all provinces with PET scanners. By means of comparison, Prince Edward Island, which does not have a PET scanner and has a population base of just 140,000, still managed to fund the equivalent of 500 scans per million people in 2009.

When one considers the number of scans carried out per individual scanner in each province, it is possible to determine which province has the most efficient utilization of its scanners. Table 7.3 and Figure 7.8 below demonstrate that British Columbia has the highest utilization, as that province carried out 3,100 scans with just one PET scanner – a value that is twice the national average. Quebec has the second highest rate of utilization (1,867 scans per scanner), followed closely by Alberta with a ratio of 1,833 scans per scanner. The national average was 1,643 scans per PET scanner.

Once again these ratios suggest that Ontario is somewhat of an anomaly. Even though the province has nine publicly-funded scanners, the clinical utilization of those scanners appears to be extremely poor. Ontario carried out just 806 scans per PET scanner – 74% fewer scans than the sole PET scanner in British Columbia. In other words, Ontario may have a high number of PET scanners, but they do not appear to be efficiently utilized for the clinical care of cancer patients. PET scanners in every other province are performing at least 1,000 scans per year and as many as 3,100 scans per year.

#PET scans per scanner

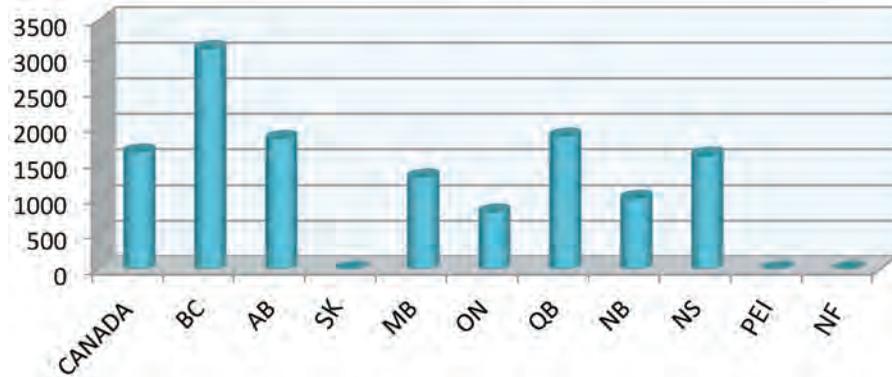


Figure 7.8 Number of PET scans carried out per scanner for Canada and each of its provinces in 2009.

Ontario's low usage statistics can be explained, in part, by the dual clinical/research role that some scanners have. For example, St. Joseph's Hospitals in London and Hamilton may be utilized for research as much as 50% of the time. However, there were multiple verbal confirmations of the chronic underutilization of PET for clinical purposes in some Ontario hospitals.

7.4 FDG Availability

Figure 7.9 shows that the cost of FDG in provinces with PET scanners varies widely across Canada, ranging from \$230 in Alberta to \$800 per dose in New Brunswick. The average cost in Canada is \$505 per dose. Note that although the province of Manitoba does have a PET scanner and a cyclotron to manufacture FDG, it declined to report a cost for FDG.

FDG: cost per dose

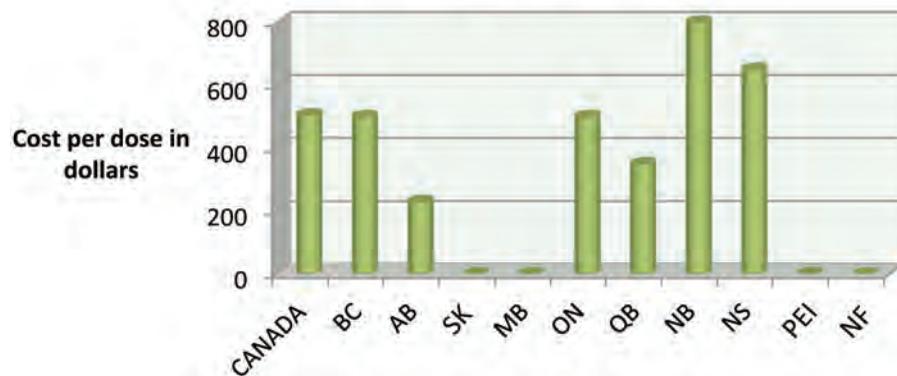


Figure 7.9 Cost of FDG per dose in Canada and each of its provinces in 2009.

A key factor cited in the growth of clinical PET facilities has been the availability of commercial sources of FDG for patient imaging (Ducharme et al., 2009). Canada currently has 10 cyclotrons (nine academic and one private) that are involved in the production of FDG for oncologic PET imaging. As shown in Table 7.10, cyclotrons producing FDG are operating at the following facilities:

TABLE 7.10 Location of cyclotrons involved in the production of FDG for oncologic PET imaging in Canada

Province	Facility	City	Cyclotrons
British Columbia	BC Cancer Agency	Vancouver	1
	Premier Diagnostics – private clinic	Burnaby	0**
Alberta	Cross Cancer Clinic	Edmonton	1 (** in 2012)
Saskatchewan	Royal University Hospital	Saskatoon	0** (expected by 2013)
Manitoba	Winnipeg Health Sciences Centre	Winnipeg	1
Ontario	McMaster University - Hamilton Health Science	Hamilton	1
	Thunder Bay Regional Hospital	Thunder Bay	0** (expected by 2013)
	Ottawa Heart Institute	Ottawa	1
	Lawson Health Research Institute	London	1
Quebec	Pharmalogic PET Services	Montreal	1
	Montreal Neurological Institute	Montreal	1
	University of Sherbrooke	Sherbrooke	1**
Nova Scotia	QE II Health Science Centre	Halifax	1
Newfoundland	Memorial University	St. John's	0** (expected in 2013-14)

**expecting a/another cyclotron

7.5 PET Funding

There is no national funding for PET in Canada as healthcare is under provincial jurisdiction. Consequently, Figure 7.11 shows that the cost of a PET scan in Canada varies greatly from province to province. The average cost of a PET scan in Canada is \$1,506.20. Quebec has the lowest cost at \$956 per scan, while Manitoba (\$1,800), Nova Scotia (\$1,800), Prince Edward Island (\$1,836) and Newfoundland (\$1,850) have the highest costs. Much of this difference can be attributed to the varying costs of FDG, as previously discussed. In Figure 7.11, the cost for scans in provinces that do not have a PET scanner (Saskatchewan, Prince Edward Island and Newfoundland) reflects the amount paid to other provinces for out-of-province scans. 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 findings by Buck et al. (2010), who reported that the costs of PET decrease with increasing numbers of PET examinations.

By way of comparison to other countries, it has been reported that the CMS (Centers for Medicare and Medicaid Services) in the United States reimburses hospitals a median amount of \$952.83 per PET examination. In Europe, costs per scan vary from \$1,030 to \$2,109 in the United Kingdom and from \$885 to \$1,474 in Germany (all figures in US dollars; Buck et al., 2010).

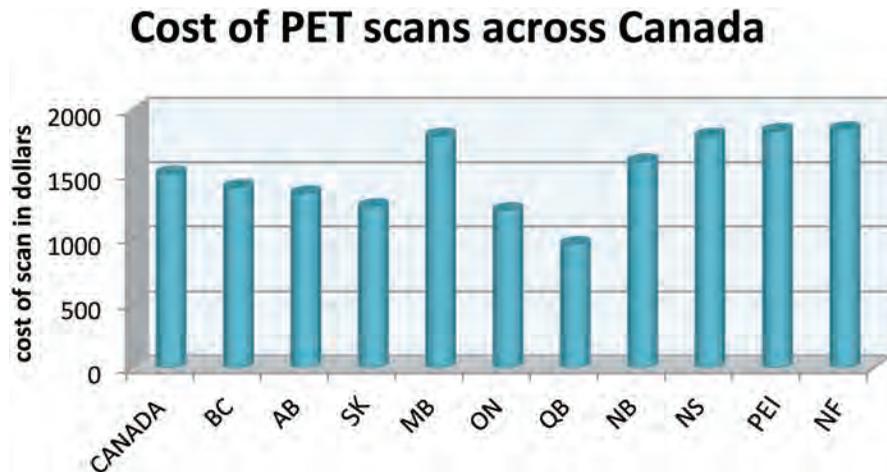


Figure 7.11 Cost of PET scans across Canada in 2009.

7.6 Canada PET Indications

At this point, there are no national indications for PET scanning. Each province sets its own criteria (see Appendix C).

7.7 Canada Cancer Statistics

The following report is filled with statistics and data related to PET scanning in the field of oncology. As this report progresses, it is important to remember that each statistic relates to an individual who suffers from cancer. A March 2011, survey (CCAC, 2011) revealed that 82% of Canadians have been touched closely by cancer (defined as that individual, friend or family member has battled cancer). According to Statistics Canada (National Post, 2011), cancer is the leading cause of premature death in Canadians, accounting for almost one-third (30%) of all deaths. It is estimated that 177,800 new cases of cancer and 75,000 deaths from cancer will occur across Canada in 2011 (Canadian Cancer Statistics, 2011). Figure 7.12 diagrams the incidence and mortality of cancer in each province.

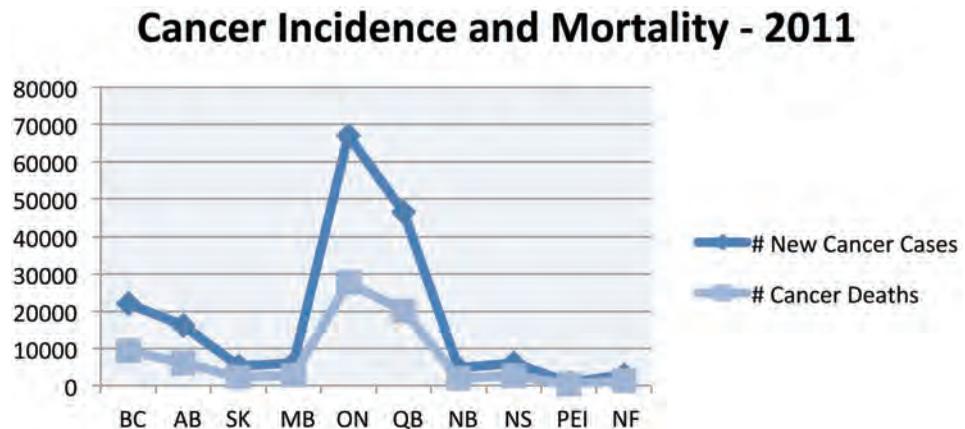


Figure 7.12 Cancer incidence and mortality in Canadian provinces (estimated for 2011) [Source: Canadian Cancer Statistics, 2011].

Increases in the number of new cancer cases are primarily due to a growing and aging population. This suggests that cancer rates will continue to rise and the Canadian healthcare system will have to find new ways to move Canadians quickly and efficiently through diagnosis and treatment procedures. PET scanning, which often obviates the need for further testing prior to devising a treatment strategy, could potentially play a significant role in this process.

Figure 7.13 shows the four cancers with the highest incidence rates in Canada – prostate (men), lung, breast (women) and colorectal, along with their mortality rates. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009). One physician who was interviewed went so far as to state, “In Quebec, it is now a malpractice to not offer patients this technology if they suspect lung cancer.”

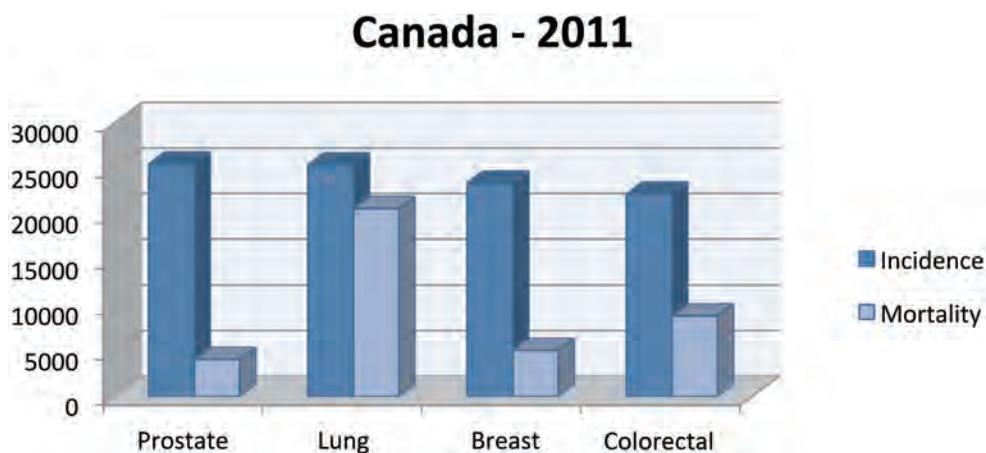


Figure 7.13 Cancers with the highest incidence rates in Canada, and their mortality rates (2011) [Source: Canadian Cancer Statistics, 2011].

8

STATUS OF PET IMAGING IN BRITISH COLUMBIA



8.0

STATUS OF PET IMAGING IN BRITISH COLUMBIA

8.1 Introduction

British Columbia is Canada's third largest province in terms of population (4.5 million) yet, until very recently, there was only one publicly-funded, clinical PET scanner. A second scanner was added in July 2011, but the waiting period for a PET scan remains as long as five weeks.

PET imaging in this province is administered by the BC Cancer Agency (BCCA) and is funded by a global budget provided to the BCCA by British Columbia's Ministry of Health Services. Overall, 11 individuals were contacted as part of this study and the data reported below results from in-depth interviews with nine individuals associated with nuclear medicine in British Columbia (five nuclear medicine physicians, one nuclear medicine researcher, two individuals from British Columbia's only private PET facility and Dr. David Levy, President of the BCCA). Most British Columbia interviews were conducted prior to the PET questionnaire being created. Therefore, almost all data were obtained through personal and telephone interviews. One questionnaire was completed for this province.

8.2 PET Scanners

The provincial data and calculations shown in Table 7.3 reflect PET statistics obtained for the year 2009 when there was only one PET scanner. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010.

In 2009, there was one publicly-funded, clinical PET scanner serving the province of British Columbia and its population of 4.5 million. As outlined in Table 7.2, the PET/CT unit is located at the BCCA in Vancouver and it has been scanning British Columbians since 2005.

With one PET scanner, British Columbia has a ratio of 0.22 scanners per million people – the lowest ratio of all provinces with PET scanners (Table 7.3). This ratio is well below the national average of 0.83 scanners per million and the two scanners per million ratio recommended by the World Health Organization (WHO; MEDEC, 2010). If one calculates this ratio for 2011, based on the province's two PET scanners, the resulting value (0.44 scanners per million) still remains the lowest ratio in Canada.

British Columbia is also home to one privately-owned PET scanner at Premier Diagnostics in Burnaby. It has been operating since June 2010 and the cost of a whole body, oncology scan is \$2,850 (see Table 7.5); its future is quite uncertain, however.

The University of British Columbia in Vancouver has three PET-only scanners that are dedicated to research in neuroscience, movement disorders, and Alzheimer's diseases (see Table 7.6).

8.3 PET Scans

In 2009, the British Columbia Cancer Agency (BCCA) funded 3,100 PET scans at a cost of \$1,400 per scan (see Table 7.3). A similar number of scans were conducted in 2010. When compared to other provinces, British Columbia funded the fourth highest number of scans (behind Quebec, Ontario and Alberta). However, when provincial scan numbers are equalized by calculating the number of scans per million people, British Columbia falls to sixth with just 689 scans per million. In comparison, Quebec has a high of 2,835 scans per million and Alberta conducts 1,486 scans per million. The national average is 1,068 scans per million. Note that even Prince Edward Island,

which does not have a PET scanner, provides sufficient funding for the equivalent of 500 scans per million people.

British Columbia may not fund a high number of PET scans, but the 2009 and 2010 statistics suggest that the one publicly-funded, clinical PET scanner is well utilized. This PET scanner carried out 3,100 scans in both 2009 and 2010, a number that places it far above the national average of 1,643 scans per scanner. Even with a second scanner in place, it still operates nine days out of every 10 and performs an average of 14 scans per day. In comparison, Quebec and Alberta conducted an average of 1,867 and 1,833 scans per scanner, respectively.

The waiting period for a PET scan in British Columbia is approximately five weeks. The wait list seems to build up over time and then plateau at five weeks. At that point, physicians request fewer scans because they do not want to wait five or six weeks to get results that could impact urgent treatment strategies for oncology patients. As fewer physicians make requests, the wait list diminishes and so the cycle continues.

It is estimated that the number of PET scans carried out annually (3,100) will double when the second PET scanner is fully operational.

8.4 FDG Availability

Until very recently, TRIUMF, Canada's national laboratory for particle and nuclear physics, produced the FDG for the PET scanner at the BCCA. However, at the end of 2010, the BCCA's own cyclotron became operational. The BCCA estimates that it paid \$500 per dose for FDG from TRIUMF and it hopes to be able to reduce that cost by producing FDG in its own cyclotron.

Premier Diagnostics, the private PET facility in British Columbia, currently receives its FDG from the Cross Cancer Institute in Edmonton and pays approximately \$500 per dose.

8.5 PET Funding

The government pays \$1,400 per scan (see Figure 7.11). There is no approved billing (MSP) fee for a PET scan in British Columbia. The PET reading service is currently performed by salaried/service contract physicians at the BCCA and the money for the scans comes from a global budget that is given to the BCCA by the provincial government's health ministry.

8.6 Provincial Indications

There are currently 13 indications for adult and pediatric PET scanning in British Columbia. They were developed in consultation with provincial tumour groups and fall within the framework of the BCCA's evidence-based guidelines for PET. The list of indications can be found in Appendix C and includes the following:

- Lung cancer
- Lymphoma
- Head and neck cancer
- Esophageal cancer
- Colorectal cancer
- Gynecological cancers
- Testicular cancers
- Brain cancer
- Thyroid cancer

- Melanoma
- Sarcoma
- Solitary pulmonary nodule

Other reasonable indications where physicians believe that a PET exam will be helpful to treatment strategy

8.7 British Columbia Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for British Columbia in 2011 is 22,100 and the number of cancer deaths (mortality) is estimated to be 9,300. Figure 8.1 shows the incidence of the four most common cancers in British Columbia – prostate, lung, breast and colorectal. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

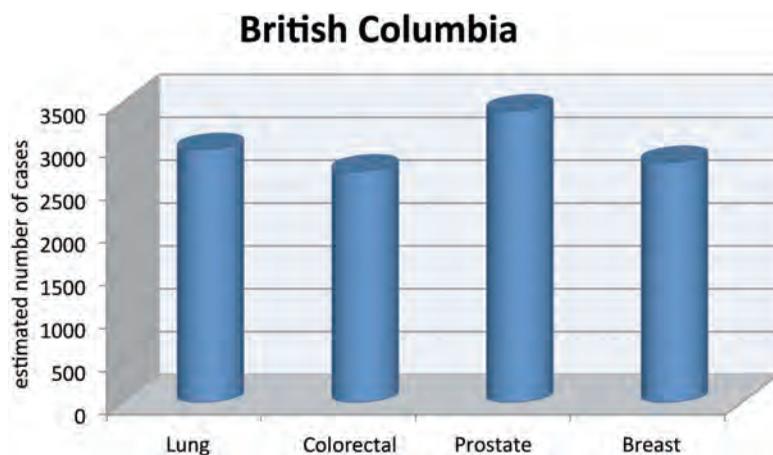


Figure 8.1 Incidence of the most common cancers in British Columbia (estimated for 2011).

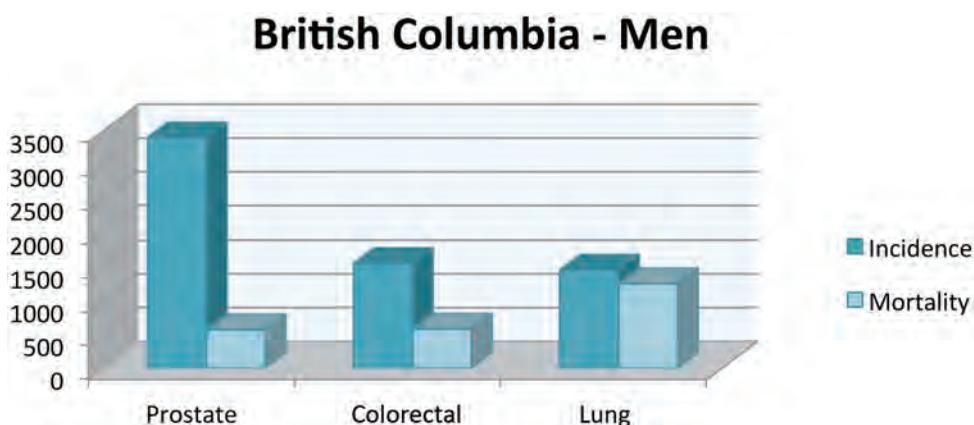


Figure 8.2 Incidence and mortality of the most common cancers for men in British Columbia (estimated for 2011).

British Columbia - Women

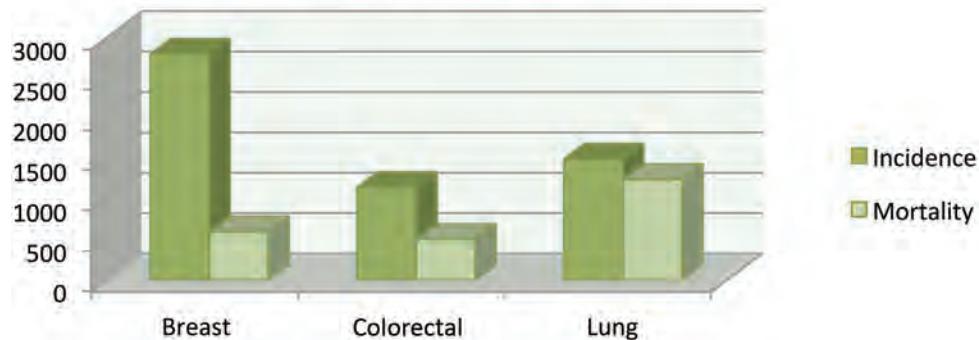


Figure 8.3 Incidence and mortality of the most common cancers for women in British Columbia (estimated for 2011).

In British Columbian men, prostate has the highest incidence, followed by colorectal and lung cancer (see Figure 8.2). For British Columbian women, the most common cancer is breast, followed by lung and colorectal (see Figure 8.3). As shown in Figures 8.2 and 8.3, lung cancer has the highest mortality rate in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011).

8.8 British Columbia Findings

There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0.

The following findings relate to the status of PET imaging in British Columbia:

1. In 2009 and 2010, the province's sole PET scanner was functioning at maximal capacity. Conversations with the BCCA suggest there is a need for a minimum of six scanners to adequately provide access to the province's oncology patients (two in Vancouver, one outside Vancouver in the Fraser Valley, one for Victoria and Vancouver Island, one for the Interior and one in Northern British Columbia).
2. Geography poses an access problem for individuals living outside of Vancouver's Lower Mainland. British Columbia is a large province with vast land space between major cities and outside of Vancouver and the Lower Mainland. People from Northern British Columbia have to travel 10-12 hours by car to access a PET scan in Vancouver; people living in the Interior of the province would similarly have a long journey. There is a high population of senior citizens on Vancouver Island and they would have to endure a two-hour ferry trip in addition to a drive from their home on the Island. For this reason, the BCCA has a mandate to balance patient access with regional accessibility and the efficient use of equipment.
3. The BC Cancer Agency estimates that the province needs to fund a minimum of 10,000 scans per year – three-fold more than the 3,100 funded in 2009 and 2010. The scanner added in 2011 will increase the number of scans to 6,200 when it becomes fully operational. The increase should be reflected fully in the 2012 PET statistics.
4. Cancer patients who are able to pay for private PET imaging are routinely sent to private PET facilities in Washington State and Burnaby (as of June 2010) to bypass the BCCA's long waiting list for PET imaging.
5. The current method of payment for PET may constrain PET services, rather than support their greater adoption and use. In British Columbia, PET services fall under the auspices of the BCCA. It

receives a global budget from the Department of Health Services to administrate all cancer care in the province, including the cost and interpretation of PET exams. There is no MSP (Medical Services Plan) fee schedule item to bill for a PET scan or to interpret a PET scan. Therefore, it is impossible for a hospital to obtain a PET scanner and image patients outside of the realm – and the planning – of the BCCA. As long as there is no fee code item to bill for PET, there can be no reimbursement for PET outside the realm of the BCCA budgets.

6. There are questions about whether the BCCA only should be determining the future of PET in BC. The BCCA has an obligation to ensure that patients in all health regions have, in theory, equal access to cancer diagnosis and treatment. Therefore, it will only implement PET scanners as provided for by provincial budgets and will only assign PET scanners to hospitals in accordance with its stated goals of providing equal access to cancer patients across the province. As a result, there is little chance that a large hospital in Vancouver or Victoria could ever operate a PET scanner – even if they had the money to purchase and operate one – outside of the operating plan of the BCCA. This situation does not appear to be well-liked, as it appears to have been done without proper consultation with the nuclear medicine community and, therefore, some interviewees credit this construct as a major barrier to the enhanced penetration of PET in British Columbia.

7. FDG costs and availability issues that have been problematic in the past have been largely resolved by the new cyclotron installation at the BCCA. The BCCA estimates that it was paying \$500 per dose of FDG when it was acquiring the radioisotope from TRIUMF. That value will now decrease as the BCCA cyclotron operations commence, but the exact cost of FDG from this new source was not available at the time of writing.

9

STATUS OF PET IMAGING IN ALBERTA



9.0

STATUS OF PET IMAGING IN ALBERTA

9.1 Introduction

The province of Alberta is served by three publicly-funded, clinical PET scanners and a provincial PET program that is run under the auspices of Alberta Health Services. However, waiting lists can still be as long as six to eight weeks for an oncologic PET scan.

Overall, six individuals were contacted as part of this study. The data and findings below are based on in-depth interviews with five individuals (two nuclear medicine physicians, one medical physicist, one radiopharmacist and one PET program administrator). Five questionnaires were sent out; three were returned – one for each PET facility in the province (Cross Cancer Institute, University of Alberta Hospital and Foothills Hospital).

9.2 PET Scanners

There are currently three publicly-funded, clinical PET scanners serving the province of Alberta and its population of 3.7 million. As shown in Table 7.2, two of the scanners are located in Edmonton (Cross Cancer Institute and the University of Alberta Hospital) and one in Calgary (Foothills Hospital). All of the scanners are hybrid PET/CT models and it is estimated that 99% of all scans are related to oncology.

In 2009, the three clinical scanners result in a ratio of 0.81 PET scanners per million people. This ratio is just below the national average of 0.83 scanners per million and well below the two scanners per million ratio recommended by the World Health Organization (MEDEC, 2010).

In addition to these three clinical scanners, there is one PET-only scanner that is dedicated primarily to oncology research. It is located in Edmonton at the Cross Cancer Institute (see Table 7.6).

9.3 PET Scans

The data and calculations shown for Alberta in Table 7.3 reflect PET statistics obtained for the year 2009. That year, Alberta Health Services funded 5,500 PET scans at a cost of \$1,350 each. This is the third highest number of scans conducted in Canada (behind Quebec and Ontario), yet it represents only 25% of the number of scans done in Quebec (22,400) – a province with twice the population of Alberta (see Table 7.3).

However, when all provincial numbers are equalized by dividing the number of scans by one million, Alberta funds 1,486 scans per million people, a number that is higher than the national average of 1,068 scans per million and higher than every province except Quebec (2,835 scans per million) and Nova Scotia (1,702 scans per million).

When the number of provincial scans is divided by the number of scanners, Table 7.3 demonstrates that Alberta conducts an average of 1,833 scans per scanner. This is slightly higher than the national average of 1,643 scans per scanner, but still significantly less than the 3,100 scans carried out by British Columbia's sole PET scanner.

One completed questionnaire was received for each PET facility in the province (Cross Cancer Institute, University of Alberta and Foothills Hospital). Questionnaires reveal that each facility scans patients four days per week only. The Cross Cancer Institute in Edmonton scans 10 to 12 people per day, while the University of Alberta and Foothills hospitals each scan eight to 10 patients per day.

Information provided from the PET status questionnaires suggests that the PET scanning equipment is not being maximally utilized because of issues related to funding and the availability of FDG. Foothills Hospital currently conducts about 1,500 scans per year, but states that if conditions were ideal it could scan up to 4,000 per year. Similarly, the University of Alberta Hospital currently performs about 1,700 scans per year and, given sufficient funding, estimates it could conduct as many as 3,000 per year.

Wait periods for a PET scan appear to be quite variable. The Cross Cancer Institute has a wait period of about one week, while the wait for a scan at the University of Alberta Hospital can extend as long as eight weeks. In Calgary, the waiting period at Foothills Hospital is approximately four to six weeks.

9.4 FDG Availability

There is currently one cyclotron producing FDG in Alberta and it is located at the Cross Cancer Institute (see Table 7.10). This institution is expecting a second cyclotron in the near future and it will be used exclusively for research. The Cross Cancer Institute supplies FDG to both the University of Alberta Hospital and Foothills Hospital at an approximate cost of \$230 per dose. PET clinical trials have closed for FDG produced by the Cross Cancer Institute as it has received a Notice of Compliance from Health Canada.

9.5 PET Funding

Alberta Health Services pays a sum total of \$1,350 per scan through a global budget (see Figure 7.11 for comparison). This includes \$835.57 for the PET scan, an interpretation fee of \$286.74 and \$227.69 for a dose of FDG. There is no provincial fee code to charge for a PET scan procedure.

9.6 Provincial Indications

Alberta's list of clinical indications for PET was developed by a provincial PET committee and is periodically reviewed. There are currently 15 indications for PET scanning in Alberta; 14 are related to oncology and one to neurology (epilepsy). The list of indications can be found in Appendix C and includes the following:

- Lung cancer
- Lymphoma
- Gynecological cancers
- Colorectal/rectal cancer
- Thyroid cancer
- Breast cancer
- Brain cancer
- Melanoma
- Esophageal cancer
- Head and neck cancers
- Indeterminate liver lesions
- Germ cell cancers
- Sarcomas
- Unknown primary tumour
- Epilepsy

9.7 Alberta Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for Alberta in 2011 is 16,200 and the number of cancer deaths (mortality) is estimated to be 6,200. Figure 9.1 shows the incidence of the four most common cancers in Alberta – prostate, breast, lung and colorectal. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

Prostate cancer in men has the highest incidence, followed by colorectal and lung (see Figure 9.2). For Alberta women, the most common cancer is breast, followed by lung and colorectal (see Figure 9.3). As shown in Figures 9.2 and 9.3, lung cancer has the highest mortality rate of all cancers in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011).

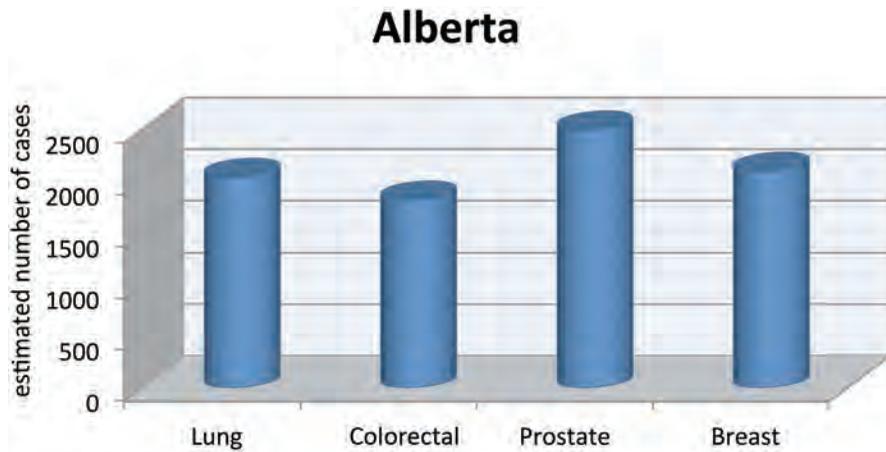


Figure 9.1 Incidence of the most common cancers in Alberta (estimated for 2011).

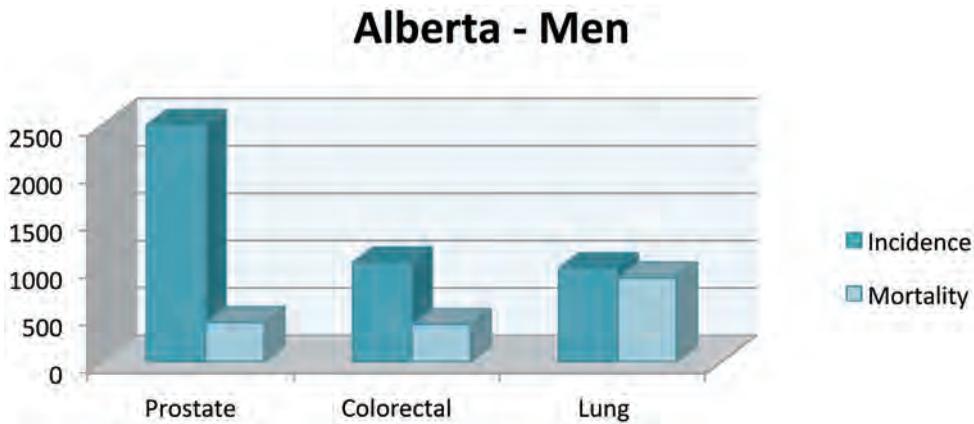


Figure 9.2 Incidence and mortality of the most common cancers for men in Alberta (estimated for 2011).

Alberta - Women

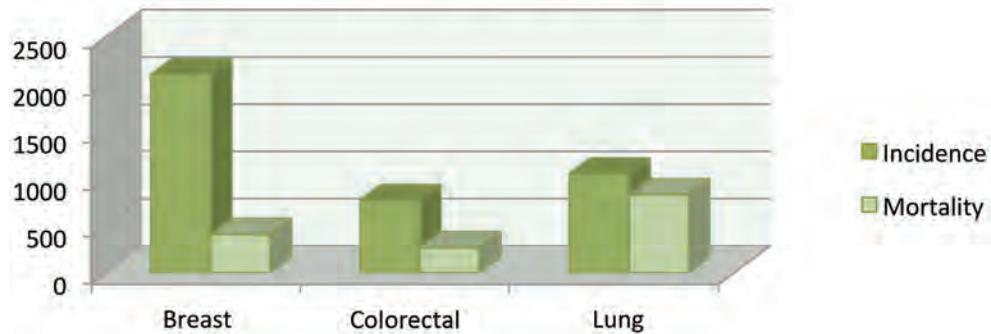


Figure 9.3 Incidence and mortality of the most common cancers for women in Alberta (estimated for 2011).

9.8 Alberta Findings

There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0.

The following findings relate to the status of PET imaging in Alberta:

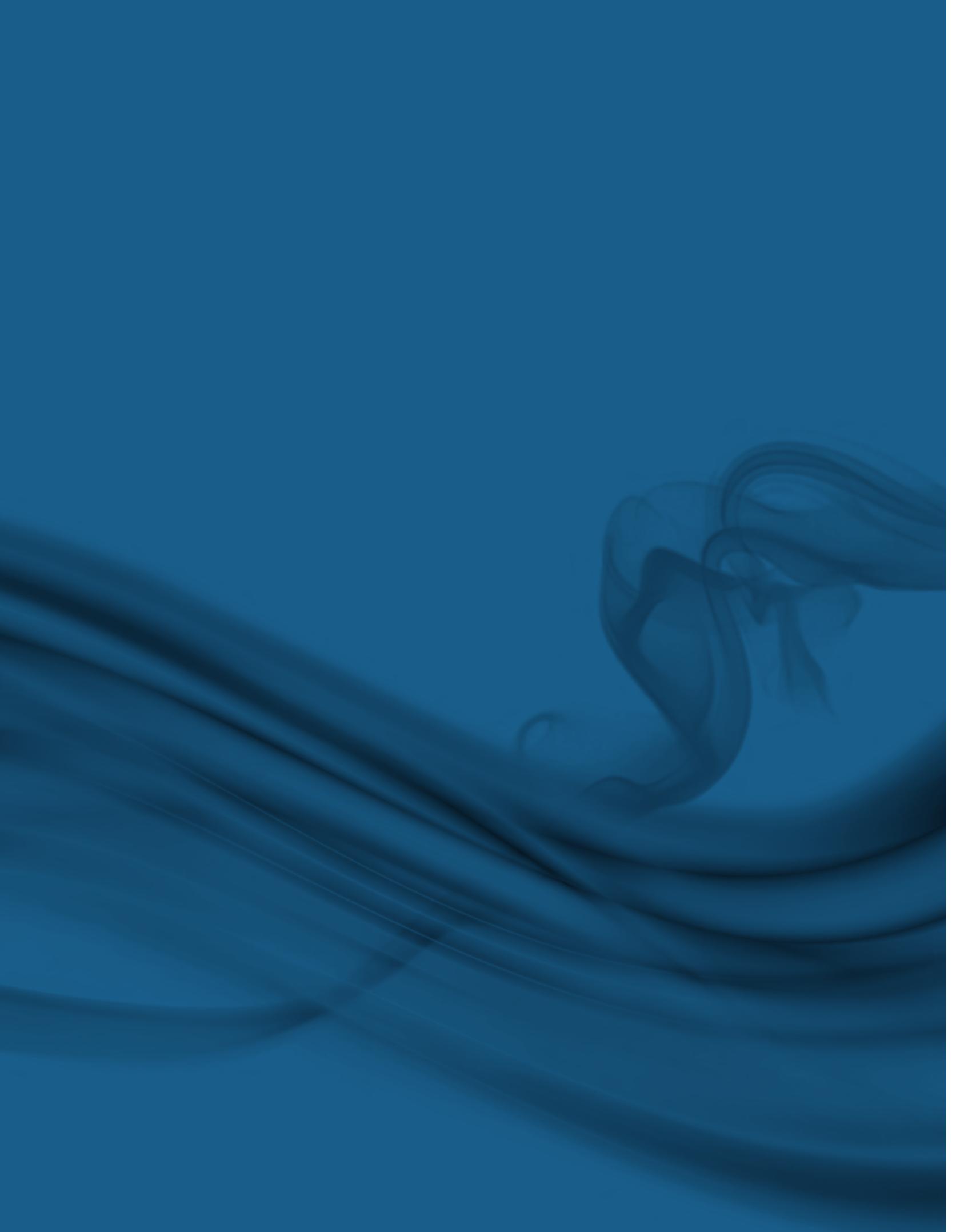
1. Alberta has an active clinical and research PET program. However, interviewees view the current status of PET in Canada (except for Quebec) as being five to 10 years behind the PET services available in other countries (Japan, the United States and Western Europe). The province of Ontario and its restrictive PET policies were mentioned as a critical barrier that is impacting the delivery of PET services in all provinces across Canada.
2. Alberta carries out approximately 5,500 scans per year, however, it was suggested that there is a need for 10,000 or more scans to be funded each year. Foothills Hospital performed 1,600 PET scans in 2009, but says there is a current need to do 4,000 scans per year. In Edmonton, the University of Alberta Hospital carried out 1,700 scans in 2009, yet believes there is a current need to do as many as 3,000 PET scans per year.
3. A lack of funding is a key barrier to more PET scanning in Alberta. Each hospital has a budgeted number of scans that can be done each year but, as discussed above, the demand is much greater.
4. Alberta has the lowest costs of FDG in Canada (\$230 per dose, see Figure 7.9). Yet availability of FDG still appears to be a significant issue that is thwarting an increase in the number of scans performed each year. The University of Alberta Hospital only has access to FDG four days per week and the cyclotron that provides FDG for the province (located at Edmonton's Cross Cancer Institute) is shut down on holidays and approximately seven weeks of the year for maintenance. The Cross Cancer Institute is expecting a second cyclotron that will be utilized exclusively for research purposes, but it has been suggested that Calgary have its own cyclotron. A second cyclotron dedicated to creating FDG would provide some redundancy that would keep PET scanners functioning when one cyclotron is shut down for maintenance.
5. Wait lists are extremely variable but can extend as long as six to eight weeks. At that point, it becomes prohibitive for physicians to order PET as it takes too long to make treatment determinations for cancer patients. In fact, most physicians will not order an oncology test if it takes even three weeks to get the results. The wait lists confirm comments by interviewees that Alberta can utilize more PET scanners to serve its population of 3.7 million, particularly in the city of Calgary.

6. It was suggested that national PET trials be undertaken to build up sufficient evidence for the use of PET in Canada. However, when this was brought up in other provinces, there did not appear to be much support for this idea. There was a strong feeling that the United States has already accomplished this on a large scale and the studies did not need to be repeated in Canada.

7. A lack of trained personnel (nuclear medicine technicians, in particular) was also cited as a factor holding back the expansion of PET in Alberta. It is difficult to attract qualified technicians to a PET program that is limited in the number of scans that it can accomplish each year. This finding is consistent with a high demand for HQP (highly qualified personnel) in nuclear medicine facilities across Canada.

10

**STATUS OF PET IMAGING
IN SASKATCHEWAN**



10.0

STATUS OF PET IMAGING IN SASKATCHEWAN

10.1 Introduction

Saskatchewan is one of the three Canadian provinces that does not have a PET scanner. Patients requiring PET examinations are currently sent out of the province to PET facilities in Calgary, Edmonton or Winnipeg. This is done under the auspices of the Saskatchewan Cancer Agency.

Nuclear medicine physicians in this province have been advocating for a PET scanner since 2002. As PET technology has become more available across the country, the pressure for Saskatchewan to obtain its own PET scanner has intensified. In March 2011, the Saskatchewan government announced that \$6 million (from multiple sources) would be directed towards the purchase and installation of a PET/CT scanner at Saskatoon's Royal University Hospital. In addition, the federal and provincial governments are collaborating to make a \$17 million investment in an advanced research cyclotron at the University of Saskatchewan. The cyclotron would generate the short-lived isotopes used by PET, as well as conduct research into the production of other medical isotopes. It is expected that the PET scanner will be operational by 2013 and the cyclotron at some point thereafter.

Three Saskatchewan physicians were interviewed as a part of this study. Two nuclear medicine physicians (one in Saskatoon and one in Regina) were interviewed, as was the head of the Saskatchewan Cancer Agency, Dr. Colum Smith (a radiation oncologist). Questionnaires were completed by all three interviewees.

10.2 PET Scanners

There are no private, research or clinical PET scanners located in the province of Saskatchewan. It is anticipated that a publicly-funded, clinical PET/CT scanner will be operational at Royal University Hospital in Saskatoon by 2013.

10.3 PET Scans

The data and calculations shown for Saskatchewan in Table 7.3 reflect PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010.

In 2009, the Saskatchewan Cancer Agency funded approximately 300 out-of-province scans (Table 7.3). That translates into a scan per million ratio of 300, a number that places Saskatchewan ninth out of the 10 provinces and well-below the national average of 1,068 scans per million. The Saskatchewan Cancer Agency estimates that about 1,000-1,500 PET scans per year are required for optimal cancer care. In a 2007 business proposal for the acquisition and operation of a PET scanner in Saskatchewan, it is suggested that the province could have a need for as many as 5,100 scans per year once the PET technology and cyclotron are in place (Au, 2007).

Patients are currently sent out of the province for PET imaging with about 30% going to Calgary, 30% going to Edmonton, 30% going to Winnipeg and 10% going to Vancouver. The destination is often dependent on the patient's state of health, family considerations and/or the length of the waiting list at the various PET facilities.

There is no cap on the number of PET scans currently available to Saskatchewan patients, as demand for the examinations is not particularly strong. With no PET technology available

in province, it has been suggested that many of Saskatchewan's doctors and oncologists are unfamiliar with the benefits of PET imaging to the management of cancer patients and/or uncertain about the process of referring a patient for an out-of-province scan.

10.4 FDG Availability

This is not applicable at this time, as there is no PET scanner or cyclotron currently operating in Saskatchewan.

10.5 PET Funding

The Saskatchewan Cancer Agency pays PET facilities in other provinces a sum of \$1,250 per PET scan (this includes the interpretation fee). The fee is paid out of a global budget for the Saskatchewan Cancer Agency; there is no fee schedule item for a PET examination.

10.6 Provincial Indications

At present, there is no provincial list of indications for PET scans. The only criteria are the clinical condition of the patient and the outcome that doctors are trying to achieve in terms of patient management.

10.7 Saskatchewan Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for 2011 in Saskatchewan is 5,200 and the number of cancer deaths (mortality) is estimated to be 2,350. Figure 10.1 shows the incidence of the four most common cancers in Saskatchewan – prostate, colorectal, lung and breast. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

Prostate cancer in men has the highest incidence, followed by colorectal and lung cancer (see Figure 10.2). For Saskatchewan women, the most common cancer is breast, followed by lung and colorectal (see Figure 10.3). As shown in Figures 10.2 and 10.3, lung cancer has the highest mortality rate of all cancers in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011).

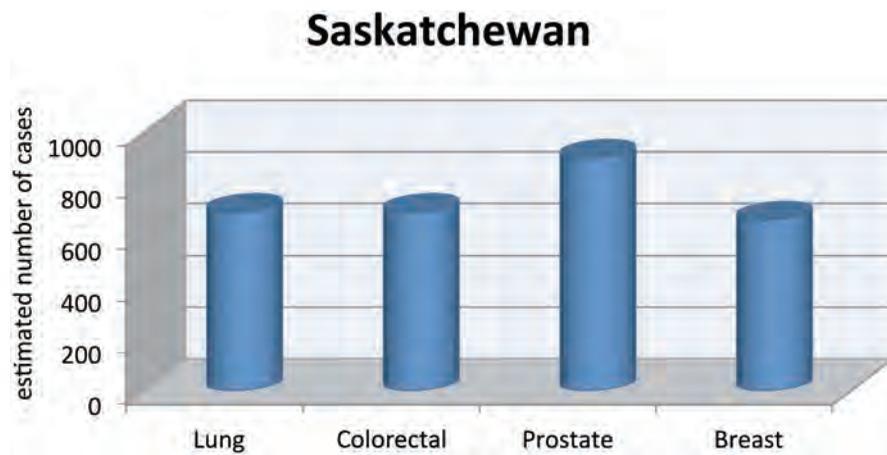


Figure 10.1 Incidence of the most common cancers in Saskatchewan (estimated for 2011).

Saskatchewan - Men

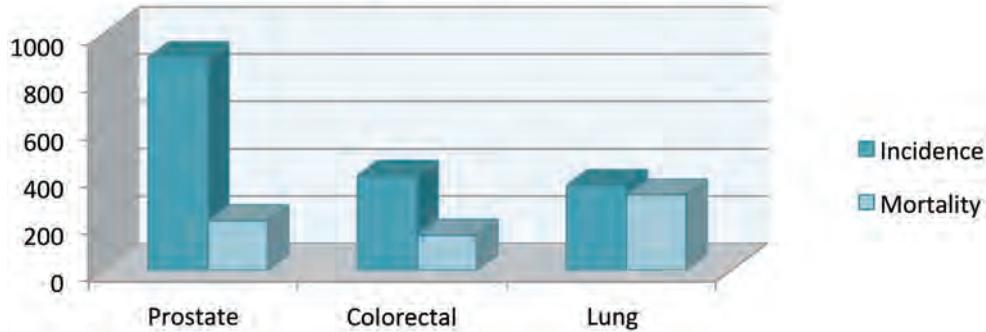


Figure 10.2 Incidence and mortality of the most common cancers for men in Saskatchewan (estimated for 2011).

Saskatchewan - Women

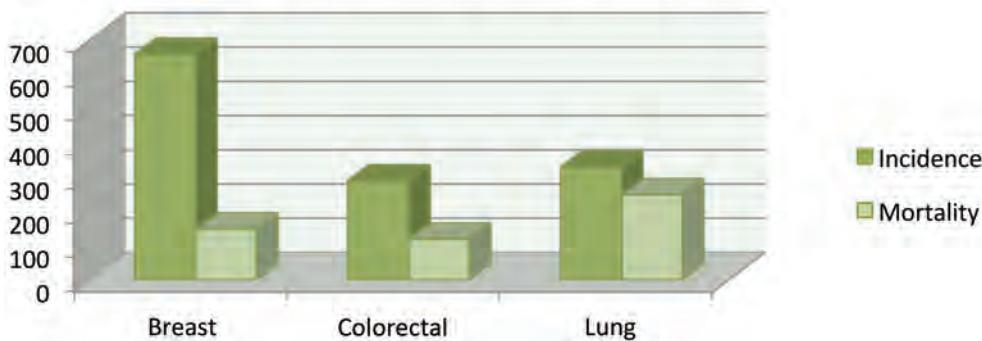


Figure 10.3 Incidence and mortality of the most common cancers for women in Saskatchewan (estimated for 2011)

10.8 Saskatchewan Findings

There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0.

The following findings relate to the status of PET imaging in Saskatchewan:

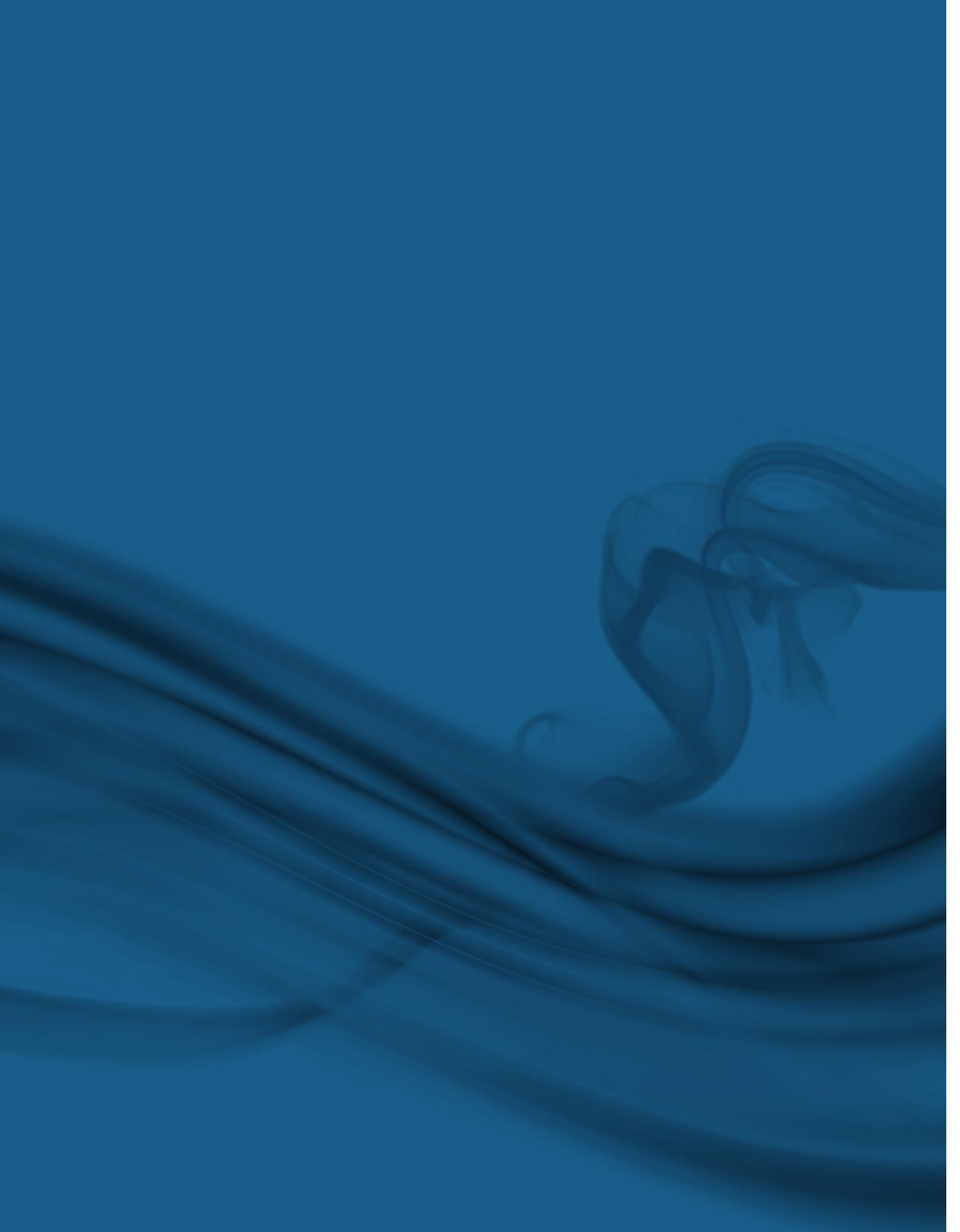
1. The province clearly recognizes the value of PET in oncology treatment management as it is willing to send patients out of province based on their clinical condition alone. At the present time, there are no criteria, funding restrictions or quotas, although that could certainly change once demand increases. In the meantime, clinical condition alone determines a patient's eligibility for a PET scan.

At this point, the number of referrals for PET is relatively low (300 per year in 2009 and 2010). The province has estimated that there is a potential need for as many as 1,500 patient scans per year based on out-of-province travel. That number would increase to 5,100 scans per year if the province had its own PET scanner and cyclotron (Au, 2007). This suggests that a lack of physician and public education regarding the purposes and benefits of PET in cancer management may be a problem, as cited in a case study in Section 5.3. of this report. As discussed in Section 18.0, this problem is prevalent across Canada, although it may be exacerbated in provinces that either do not have PET technology or ready access to PET.

2. PET technology will soon be available, as plans are now in place to have a PET/CT scanner and cyclotron located at the University of Saskatchewan in Saskatoon. However, Saskatchewan is a large province in terms of land mass and geography remains a critical barrier to reasonable access to PET scanning in the province. Saskatoon may be a central location, but patients from the extreme southern or northern parts of the province may still be required to drive as long as eight hours to obtain a PET scan in Saskatoon. Consequently, it may remain more convenient for some patients to have a PET scan in Calgary, Edmonton or Winnipeg. To provide equitable access to all Saskatchewan residents, the province may wish to consider the installation of a second PET scanner in Regina.

11

**STATUS OF PET IMAGING
IN MANITOBA**



11.0

STATUS OF PET IMAGING IN MANITOBA

11.1 Introduction

Manitoba has one publicly-funded, clinical PET scanner to serve its population of 1.2 million and its PET imaging program is run under the auspices of Cancer Care Manitoba.

Three individuals were interviewed as a part of this study – one nuclear medicine physician, one radiation oncologist and one administrator from Cancer Care Manitoba. Two questionnaires were completed.

11.2 PET Scanners

Manitoba has one publicly-funded, clinical PET/CT scanner located at the Winnipeg Health Sciences Centre (see Table 7.2). It has been operating since 2005 and more than 95% of all scans are related to oncology.

With one scanner servicing a population of 1.2 million, Manitoba has a scanner ratio of 0.83, a value equivalent to the 2009 national average of 0.83 PET scanners per million people. It is also significantly lower than the two scanners per million ratio recommended by the World Health Organization (MEDEC, 2010).

There are no research only or private PET imaging facilities in Manitoba.

11.3 PET Scans

The data and calculations shown for Manitoba in Table 7.3 reflect PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010.

Cancer Care Manitoba estimates that it funded 1,300 scans in the year 2009 at a cost of \$1,800 per scan. When provincial scan numbers are equalized by calculating the number of PET scans per million people, Manitoba performs 1,083 scans per million, a number that is very similar to the national average of 1,068 scans per million.

Evaluating the number of scans per scanner reveals how well the PET scanner is utilized. Manitoba carries out 1,300 scans per scanner – less than the national average of 1,643 and considerably less than British Columbia's 3,100 scans per scanner. The Winnipeg Health Sciences Centre currently scans up to eight patients a day, four days per week. The utilization statistics (scans per scanner) confirm comments made by interviewees who estimated that they presently have the capacity (staff and infrastructure) to do as many as 2,000 scans per year. Since this facility has the funding and the infrastructure to handle up to 2,000 scans per year, it appears that the number of referrals may be a limiting factor to optimal scanner use.

The waiting period for a scan at this facility is about two weeks.

11.4 FDG Availability

Until recently, the Winnipeg Health Sciences Centre obtained its FDG from Cross Cancer Institute in Edmonton or Pharmalogic PET Services in Montreal. In August 2010, a cyclotron located at the Health Sciences Centre became operational and it is now providing FDG for PET examinations. The facility was not willing to provide the costs of FDG purchased from its former suppliers or the costs of FDG created by its own cyclotron. However, it is likely that the FDG costs – and therefore the costs of the PET scan – will now diminish and that the cyclotron will greatly enhance the facility's capacity and ability to meet current and future demands.

11.5 PET Funding

Cancer Care Manitoba provides funding for up to 2,000 scans per year by the Winnipeg Health Sciences Centre. At 1,300 scans per year, the average cost per scan is calculated to be \$1,800 (including scan costs, FDG and physician fees). There is no fee schedule item to bill for a PET scan procedure and the money comes from Cancer Care Manitoba's global budget.

11.6 Provincial Indications

Compared to other provinces, Manitoba has the highest number of indications for PET scans. The oncology categories are very broad and all-encompassing. There are currently 19 indications for PET scanning in Manitoba.

- Bladder cancer
- Breast cancer
- Colorectal cancer
- Gallbladder and cholangiocarcinoma
- Head and neck cancers
- Lymphoma
- Myeloma
- Primary unknown tumour
- Testicular cancer
- Other
- Brain cancer
- Cervical cancer
- Esophageal cancer
- Gastric cancer
- Lung cancer
- Melanoma
- Ovarian cancer
- Sarcoma
- Thyroid cancer

11.7 Manitoba Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for Manitoba in 2011 is 6,100 and the number of cancer deaths (mortality) is estimated to be 2,750. Figure 11.1 shows the incidence of the four most common cancers in Manitoba – lung, colorectal, breast and prostate. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

Prostate cancer in men has the highest incidence, followed by colorectal cancer and lung cancer (see Figure 11.2). For Manitoba women, the most common cancer is breast, followed by lung and colorectal (see Figure 11.3). As shown in Figures 11.2 and 11.3, lung cancer has the highest mortality rate of all cancers in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011)

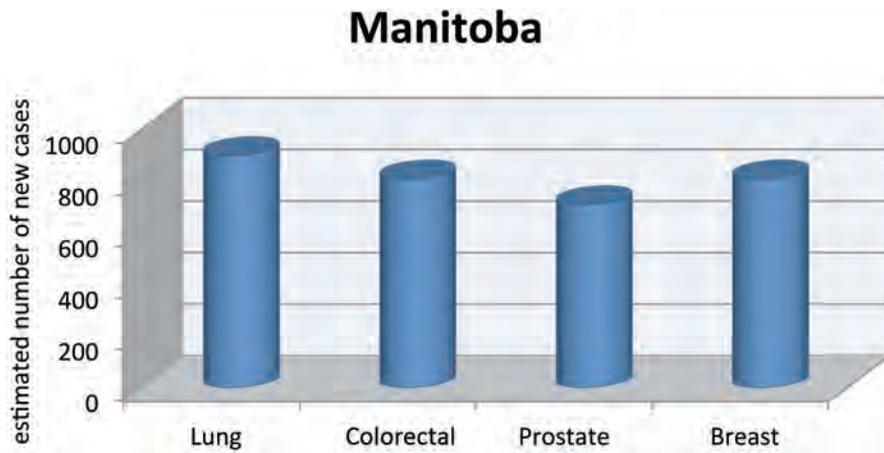


Figure 11.1 Incidence of the most common cancers in Manitoba (estimated for 2011).

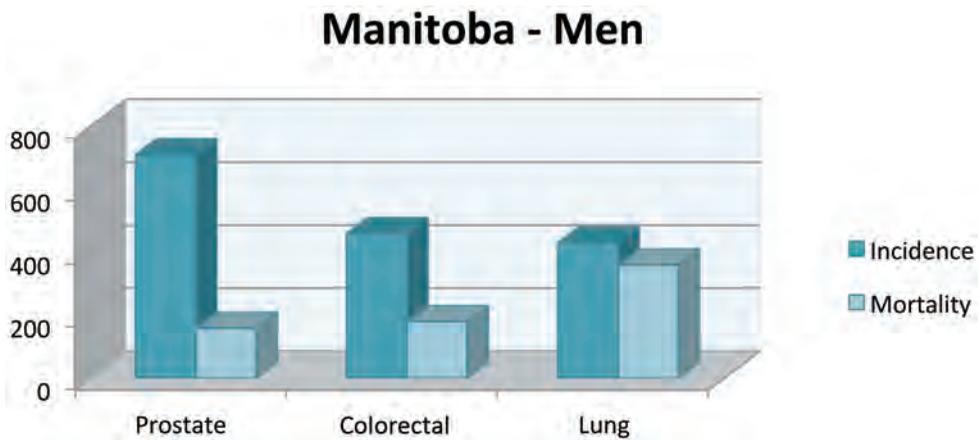


Figure 11.2 Incidence and mortality of the most common cancers for men in Manitoba (estimated for 2011).

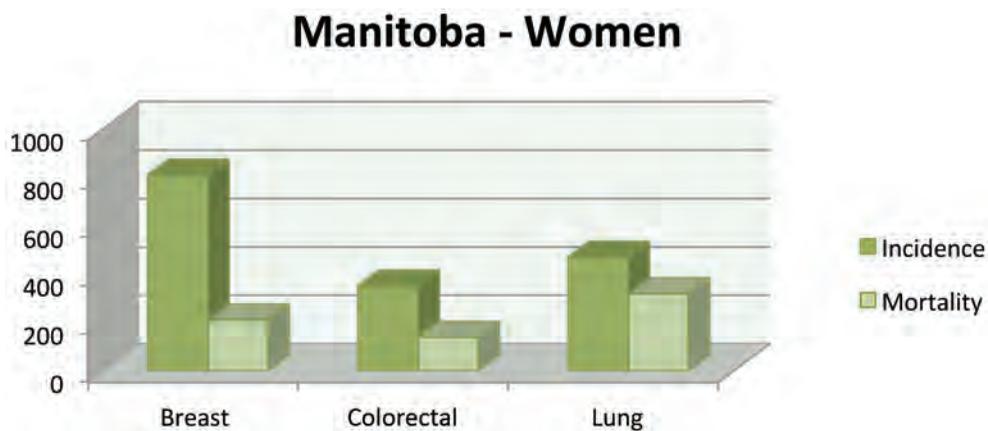


Figure 11.3 Incidence and mortality of the most common cancers for women in Manitoba (estimated for 2011).

11.8 Manitoba Findings

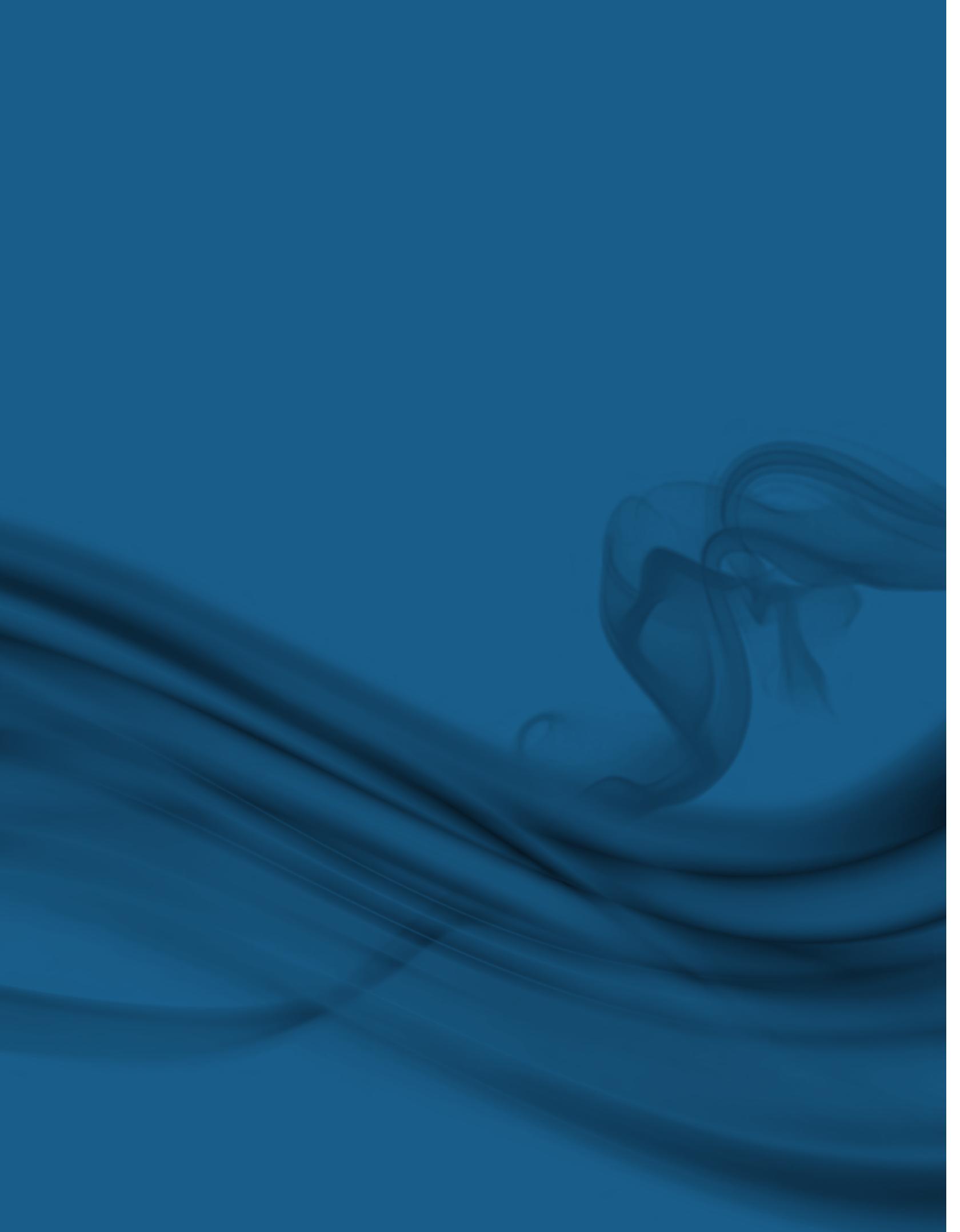
There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0.

The following findings relate to the status of PET imaging in Manitoba:

1. Interviewees suggested that national guidelines be established to dictate indications for the common use of PET across Canada.
2. Manitoba currently carries out 1,300 scans per year. The PET scanner is operational four days per week and scans up to eight patients per day. The Health Sciences PET facility presently has the capacity to expand scanning to five days per week and the budget to do up to 2,000 scans per year. However, at present, there is not sufficient demand to do so. The lack of referrals suggests that proper education of both physicians and the public may be necessary to expand the penetration of PET within Manitoba. As is the case in many provinces, physicians do not appear to understand the benefits of PET in oncology patient management and/or do not know how to access PET. In addition, patients in more isolated areas may not have the resources to attend a PET examination in Winnipeg.
3. The Winnipeg PET facility has been functioning since 2005. The facility did a follow up with the referring physicians of their first 2,600 cases to determine the impact of PET on patient management. The referring physicians reported that the PET was very helpful or helpful for patient management in about 87% of cases and had a neutral impact in about 10%. In 3% of cases, physicians stated that the PET results were not helpful.

12

STATUS OF PET IMAGING IN ONTARIO



12.0

STATUS OF PET IMAGING IN ONTARIO

12.1 Introduction

As Canada's most populated province, Ontario has a high number of scanners relative to all other provinces except Quebec. But the statistics below describe a low number of scans, suggesting that the Ontario government has done little to support PET as a normal standard of clinical care for cancer patients.

The findings and data below are based on in-depth interviews with 11 nuclear medicine personnel and two officials from Cancer Care Ontario, the government agency that oversees all cancer care and PET policies in the province, under the advisement of a PET Steering Committee. Contact was established with 15 physicians and nuclear medicine personnel. A total of 14 questionnaires were sent out; seven were completed. Four physicians who did not complete the questionnaire were interviewed.

Ontario occupies a unique position in Canada's PET community in that it has questioned the legitimacy of existing literature outlining the benefits of PET to oncology care. In 2001, the province developed what it terms an "evidence-based approach" and initiated its own formal clinical trials to evaluate the clinical effectiveness of PET in certain oncology indications.

For much of the past decade, this approach to PET has limited the number of scans carried out each year relative to other provinces. This policy has sparked debate across Canada and led to divergent opinions within the province. Nuclear medicine clinicians have complained that the medical evidence required for PET is unreasonable and much higher than has ever been required for other, more widely-used diagnostic imaging modalities. Many interviewees appear to believe that the government is using the clinical trials and evidence gathering as a means of postponing payment for PET in circumstances where it has already been proven useful and effective. Complaints by both doctors and patients resulted in two provincial Ombudsman investigations into Ontario's PET policies.

During interviews it was evident that the province's medical community and Ministry of Health officials have different visions regarding the implementation of PET practices in Ontario. Dr. Bill Evans, chair of Ontario's PET Steering Committee that advises the government, believes that Ontario has introduced PET into the province in a way that has ensured that it is used appropriately according to the best available evidence. In contrast, Dr. J.L. Urbain, past-president of the Canadian Association of Nuclear Medicine (CANM) and a practicing Ontario physician, believes that "Ontario practices financial-based medicine over evidence-based medicine."

The controversy over Ontario's PET policies and its resulting impact on patient care is further covered in Sections 12.6 (PET Imaging Policies) and 12.9 (Findings).

12.2 PET Scanners

According to Cancer Care Ontario, there are nine publicly-funded, clinical PET scanners currently serving the province of Ontario and its population of 13.1 million. As outlined in Table 7.2, two facilities are located in Hamilton (McMaster University Health Sciences Centre and St. Joseph's Hospital), one in London (St. Joseph's Hospital) and one at Thunder Bay (Thunder Bay Regional Hospital). Three are located in Toronto (Princess Margaret Hospital, Sunnybrook Hospital and the Hospital for Sick Children), while two more are in Ottawa (The Ottawa Hospital and the Ottawa Heart Institute). A tenth PET/CT unit is installed at Toronto Western Hospital and will begin clinical operations at some point in 2012.

All scanners are hybrid PET/CT models except for the 15-year-old PET-only scanner at McMaster University's Health Sciences Centre. All scanners are predominantly utilized for oncology scanning, with the sole exception being the PET/CT scanner at the Ottawa Heart Institute that is primarily utilized for clinical and research investigations in cardiology.

Geography has played a key role in determining where the PET scanners are located as most are clustered around academic centres in the southern portion of the province. A PET scanner began operating in Thunder Bay in 2009 and it has been suggested that Sudbury requires a scanner to adequately service the population in northern Ontario (MEDEC, 2010).

Ontario is also home to three private imaging facilities. Facilities are available in Markham (one PET/CT scanner located at KMH Cardiology and Diagnostic Centres) and Mississauga (one PET-only scanner located at Care Imaging). A mobile PET/CT unit is located in Windsor under the auspices of Precision Diagnostic Imaging (see Table 7.5). The cost of a PET scan appears to vary significantly according to the procedure at KMH, where the vast majority of scans are related to cardiology, not oncology. Cardiology scans can run from \$1,500 to \$2,500 at KMH, compared to \$2,358 for a whole-body oncology scan at Care Imaging.

As shown in Table 7.6, there are three scanners that are dedicated to research in oncology, neurology and cardiology. They are located at the Centre for Addictions and Mental Health (one PET-only and one PET/CT) and Princess Margaret Hospital (one PET/CT).

Table 7.3 demonstrates that Ontario has 0.7 PET scanners per million people, far below Quebec's 1.5 scanners per million and the two scanners per million ratio recommended by the World Health Organization (MEDEC, 2010).

12.3 PET Scans

The provincial data and calculations shown in Table 7.3 reflect PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010. In 2009, Ontario's Ministry of Health funded 7,250 PET scans that were carried out by nine PET scanners (Table 7.3). Although this scanning statistic places Ontario second highest among provinces in Canada, the actual number of scans carried out is quite minimal when all provincial numbers are equalized by population numbers.

In contrast, Quebec, with a smaller population and 12 PET scanners, carried out 22,400 PET scans in 2009; three-fold more than Ontario. When provincial scan numbers are calculated per million people, Quebec funds 2,835 scans per million, while Ontario funds just 553 scans per million. This ratio places Ontario last among all provinces with PET scanners. Note that even Prince Edward Island, Canada's smallest province in terms of population and one which does not have a PET scanner, provides sufficient funding for the equivalent of 500 scans per million people.

The numbers are even more telling about the utilization of PET scanners when the number of provincial scans is divided by the number of scanners in the province. Ontario funds 806 scans per scanner, a number that places it well below the national average of 1,623 scans per scanner and the Quebec average of 1,867. In other words, Ontario may have a relatively large number of PET scanners compared to other provinces, but these scanners appear to be poorly utilized for clinical purposes. There are a number of PET centres across the province, but many are conducting a small number of scans. This inefficiency was confirmed in interviews at various locations in the province, where there were complaints about PET scanners that were not being utilized to their full potential. During an interview, one doctor commented, "it's frustrating to see technology so under used."

For example, Princess Margaret Hospital in Toronto does eight scans a day, five days per week for an estimated total of 2,000 scans per year. In contrast, Hamilton Health Sciences and St. Joseph's Hospital in Hamilton do a total of 1,200 scans per year (combined), yet say they have the capacity

to do 2,500 clinical scans per year. The Hospital for Sick Children in Toronto only carries out 210 clinical scans per year, but states it could do as many as 500. St. Joseph's Hospital in London currently scans about three patients per day, three days per week for a total of about 750 scans per year. It is estimated that this facility could perform up to 2,500 clinical scans per year. Note that some of these scanners have been purchased with research funds and are utilized for research purposes as much as 50% of the time.

One good consequence of limited demand for PET scans is a relatively short waiting period. According to Cancer Care Ontario, there was a median wait of four days for a PET scan in the year 2010.

12.4 FDG Availability

There are currently four clinical suppliers of FDG for PET clinics in Ontario: The Centre For Probe Development and Commercialization at McMaster University in Hamilton, Lantheus in Mississauga, Pharmalogic PET Services in Montreal and the University of Ottawa Heart Institute. The cost of FDG may vary widely, but those who were willing to provide data suggest the price is about \$500 per dose. It is anticipated that St. Joseph's Hospital in London will have all Health Canada approvals and be producing clinical FDG in early 2012.

12.5 PET Funding

According to Cancer Care Ontario, the government pays \$1,220 per scan; \$1,020 includes the cost of the scan and FDG, plus a \$200 reading fee for the physician interpreting the scan. There is no global budget for PET scans; they are paid for on an individual fee-per-scan basis.

12.6 PET Imaging Policies

In the late 1990s, a multidisciplinary committee was established to examine the potential for PET imaging in Ontario. The committee, headed by Dr. Al Driedger, included representatives from various medical disciplines, including nuclear medicine, radiology, surgery, and oncology. In 1998, the committee presented a report to the Ontario Ministry of Health (MOH) urging the province to fund PET imaging for cancer, cardiac disease and neurology investigations. The report argued that the usefulness of PET had already been established for the suggested indications and estimated that there was a need for up to 40,000 PET scans per year in Ontario.

It appeared that the government would be acting on the recommendations until a MOH representative presented an abstract from an Australian conference showing that PET did not change the management of lung cancer. In response to that single abstract, a decision was made to set up a provincial PET Steering Committee, under the direction of Dr. Bill Evans, that would assess all potential roles for PET imaging and advise the MOH in its own evaluation of PET imaging.

In 2000, the government commissioned the Institute for Clinical Evaluative Sciences (ICES) at McMaster University to review the scientific literature and make recommendations regarding the use of PET in cancer, cardiac disease and neurologic disease. In 2001, the ICES published a report advising the Ministry of Health against funding PET as an insured service as "the number of methodologically high quality studies (and the numbers of patients within these studies) is distressingly small" (ICES Investigative Report, 2001). It dismissed any role for PET in cardiac and neurology investigations and also encouraged Ontario to generate its own evidence for the value of PET by undertaking a series of formal clinical trials to gather data.

Subsequently, Ontario's PET Evaluation Program was established. It consisted of three elements: Clinical Trials, a PET Registry and a PET Access Program. Ontarians were able to access PET provided they fit into any of these three elements, as follows:

12.6.1 Clinical Trials

Five clinical trials were designed and carried out between 2004 and the present, with a total enrolment of over 1,700 patients. These trials are described below (Dobranowski, 2009):

PET PREVENT – started in May 2006, to investigate the utility of PET in head and neck cancer. The goal was to determine if PET could detect metastatic cancer in the neck lymph nodes of patients with head and neck cancer who had received radiation treatment. Ultimately, 400 patients were enrolled in the trial. The trial is now closed and data analysis is still underway.

ELPET – started in June 2004. The purpose was to determine whether PET could detect occult metastatic disease and avoid futile thoracotomy in patients with early stage lung cancer. Over time, 337 patients were enrolled and the trial data led to the approval of PET scanning for staging of early lung cancer in patients being considered for surgical resection.

PET START – began to evaluate patients with locally advanced (stage three) lung cancer in June of 2004. Its purpose was to determine (1) whether PET could detect lung cancer spread beyond the chest after the patient has undergone all the usual standard diagnostic tests, and (2) whether PET results would change the radiation treatment volume. A total of 310 patients were enrolled in the trial which closed early due to overwhelmingly positive results. Trial data resulted in the approval of PET for stage three NSCLC (non-small cell lung cancer) patients being considered for combined modality therapy.

PETCAM – started in November 2005, to study patients suffering from colorectal cancer with liver metastasis. Its purpose was to determine the impact of preoperative PET on patients who have potentially resectable colorectal cancer liver metastases as shown by conventional imaging. The study determined the proportion of patients who had a change in management resulting from PET imaging. This trial closed recently with a total enrolment of 400 patients. Data analysis is currently underway.

PET PREDICT – evaluated patients with early breast cancer beginning in January 2005. The purpose of the study was to determine the ability of PET to detect axillary lymph node metastases in newly-diagnosed breast cancer patients with no clinical evidence of disease spread. A total of 336 patients were enrolled in this trial which closed in May 2007. Data demonstrated that PET had an insufficient sensitivity for staging axilla. (See Section 12.9 for controversy regarding this trial.)

12.6.2 The PET Registry

This was established to fund PET scans for patients in oncologic situations where it was deemed there was sufficient evidence to suggest that PET imaging could improve the clinical management of their condition. To be eligible for the PET Registry, patients were asked to sign a consent for their data to be sent to ICES for evaluation. The following oncologic indications were covered by the PET Registry:

- Solitary pulmonary nodule (SPN);
- Thyroid cancer;
- Germ cell tumour;
- Colorectal cancer (where biomarkers suggest recurrence, but recurrence is not found with conventional imaging).

12.6.3 PET Access Program

This was established to cover situations where a PET scan may be justified, but could not be

obtained under the insured indications or through the PET registry. In such cases, physicians who believed their patient might benefit from a PET scan could refer them to a special access program where requests were reviewed on a case-by-case basis by a panel of oncologists, radiologists and nuclear medicine physicians. Referring physicians had to confirm in the application that other diagnostic tests did not provide the clinical information needed and indicate how a PET scan could influence the clinical management of the patient. Between October 2006, and March 2008, 170 applications were received; 68 (40%) were approved.

As described above, the PET Steering Committee initially functioned as an advisory body to the Ontario government's Ministry of Health and Longterm Care (MOHLC). However, in 2009, the major responsibility for PET was shifted to Cancer Care Ontario, under the direction of a radiologist named Dr. Julian Dobranowski. The PET Steering Committee continues to advise Cancer Care Ontario with regard to the current PET registry trials and PET policies. The current terms of reference for the Ontario PET Steering Committee, including its composition and responsibilities, can be found in Appendix D.

In July 2009, Ontario's MOHLC announced that PET scanning would be a publicly-insured health service available to cancer patients under conditions where PET scans had proven to be clinically effective, as well as through a PET Registry and a Special Access Program.

12.7 Provincial Indications

As of October 1, 2009, there are seven insured indications for oncology and one for cardiology (see Appendix C). PET scans can also be accessed through the Ontario PET Registry and a Special Access program.

The oncology indications are as follows:

- Solitary pulmonary nodule (SPN)
- Thyroid cancer
- Germ cell tumours
- Colorectal cancer
- Lymphoma
- Non-small cell lung cancer (NSCLC)
- Limited disease small cell lung cancer

In addition, there are four oncology indications that are not insured, but eligible for reimbursement through the Ontario PET Registry:

- Esophageal cancer
- Pancreatic cancer
- Melanoma
- Testicular cancer

To be eligible for the PET Registry, patients are asked to give consent for their data to be sent to the ICES for evaluation.

The government also recognizes that there are situations where a PET scan may be justified, but cannot be obtained under the insured indications or through the PET Registry. In such cases, physicians who believe their patient might benefit from a PET scan can refer them to a Special Access Program where requests are reviewed on a case-by-case basis by a panel of oncologists,

radiologists and nuclear medicine physicians. Referring physicians need to confirm in the application that other diagnostic tests do not provide the clinical information needed and indicate how a PET scan may influence the clinical management of the patient.

12.8 Ontario Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for Ontario in 2011 is 66,900 and the number of cancer deaths (mortality) is estimated to be 27,800. Figure 12.1 shows the incidence of the four most common cancers in Ontario – prostate, breast, colorectal and lung. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

Prostate cancer in men has the highest incidence, followed by colorectal and lung cancer (see Figure 12.2). For Ontario women, the most common cancer is breast, followed by lung and colorectal (see Figure 12.3). As shown in Figures 12.2 and 12.3, lung cancer has the highest mortality rate of all cancers in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011).

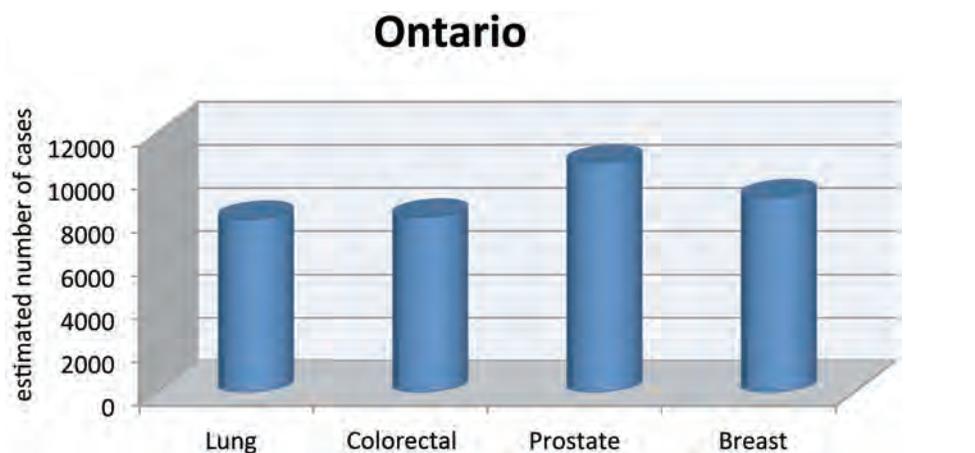


Figure 12.1 Incidence of the most common cancers in Ontario (estimated for 2011).

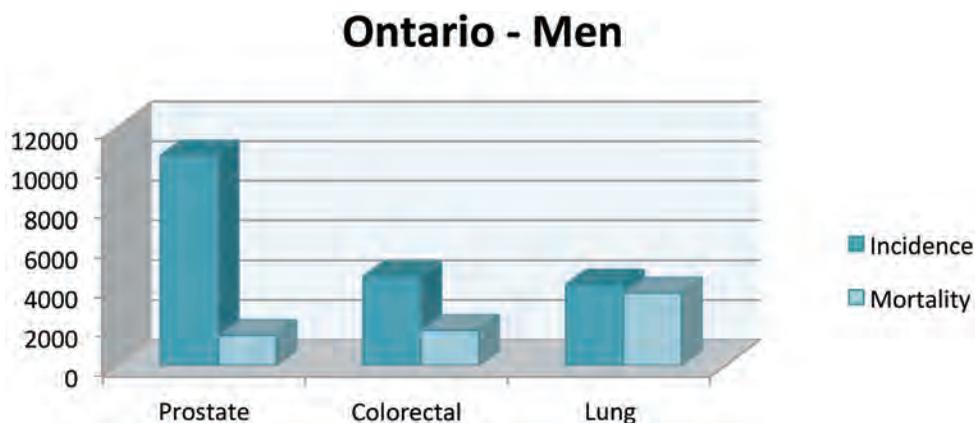


Figure 12.2 Incidence and mortality of the most common cancers for men in Ontario (estimated for 2011).

Ontario - Women

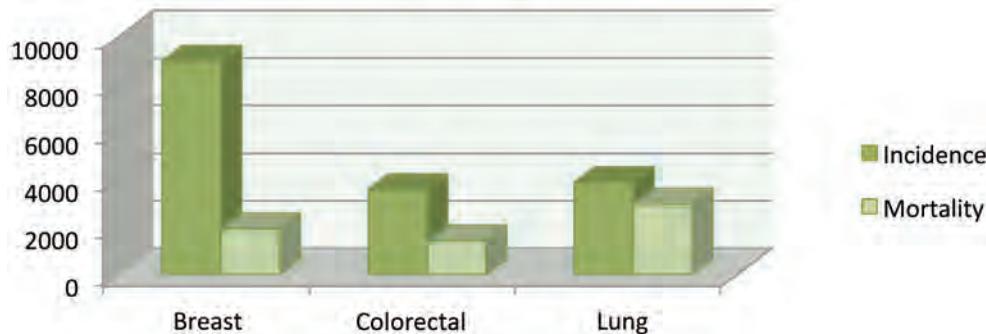


Figure 12.3 Incidence and mortality of the most common cancers for women in Ontario (estimated for 2011).

12.9 Ontario Findings

There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0.

The following findings relate to the status of PET imaging in Ontario:

1. Statistics suggest that Ontario's PET scanners are underutilized in terms of clinical use. Although the province has nine clinical scanners, Ontario funds just 806 scans per scanner – a number that places it far below the national average of 1,643 scans per scanner. When provincial scan numbers are calculated per million people, Ontario funds just 553 scans per million. This ratio places Ontario last among all provinces with PET scanners.

Long wait times do not appear to be an issue (median wait of four days). This is a benefit to Ontario patients, but it suggests that the numbers of patients being referred for PET examinations may be significantly lower than in other provinces. When considered in conjunction with the low number of scans, the short waiting lists also suggest that the scanners are not being heavily utilized.

In interviews, physicians suggested the poor utilization was due to two factors: confusion among referring doctors about the current status of PET in Ontario (with regard to regulations, how to access PET scans and the current indications for PET) and a restricted list of PET scan indications. In contrast, the current Chairman of the PET Steering Committee, Dr. Bill Evans, believes the low utilization is the result of the appropriate use of PET imaging.

It is interesting to note that there have been well-documented problems with the proper utilization of some PET scanners in the province. For example, Princess Margaret Hospital in Toronto did only 18 PET scans in its first year of operation – a fact that was documented by the National Post. In addition, it took more than one year for Thunder Bay's PET scanner to become operational after it had been installed.

It should be noted that many of the PET scanners in Ontario were initially purchased for research and with research funds. These research scanners have since been partially utilized for clinical work. This may explain some underutilization, but interviews confirmed a problem with chronic underutilization in terms of clinical work. A brief survey of Ontario hospitals suggests that most do clinical work 90% of the time or more. Some exceptions are Sick Children's Hospital, and St. Joseph's Hospitals in London and Hamilton, where scanners are dedicated to research 100%, 50% and 50%, respectively.

2. Questions persist about the validity of the ICES Investigative Report. The ICES report (2001) has served as the foundation for all PET policies in Ontario, yet questions about the validity of the

assessment tools used in the report persist a full decade after its findings were submitted. At the core of the issue are questions about the appropriateness of the health technology assessment (HTA) system used by the government in evaluating a diagnostic imaging tool such as PET.

This question was raised in the *Journal of Nuclear Medicine* by prominent Canadian nuclear medicine physician Dr. Sandy McEwan (McEwan, 2006). McEwan used the Ontario situation as an example, saying "... HTA is a policy tool, often used to justify negative funding decisions, rather than a rigorous scientific methodology." He states that the "HTA algorithms have been assigned to assess the evaluation and efficacy of new drugs and medical interventions," but "... they are totally unsuited to the evaluation of the clinical importance of imaging tests."

As an example, he points out that one key outcome assessed by HTA is the survival benefit conferred by an imaging test, even though imaging tests are not designed to improve survival but to direct treatment planning and ensure that the best strategy is followed for the patient's condition. Conversely, the HTA ignores the important role of imaging in "treatment planning and assessment of response, the reductions in downstream costs such as saved operations due to upstaging, and the contribution of imaging to diagnostic confidence." Until these endpoints are incorporated in the HTA, McEwan – and, indeed, much of the nuclear medicine community in Ontario – believes that the results of the HTA of imaging modalities "will remain arbitrary and capricious."

3. Numerous problems have undermined the legitimacy of the clinical trials carried out under the PET Evaluation Program.

Many nuclear medicine physicians that were interviewed claim that the procedures being evaluated by the clinical trials had already been widely accepted in other jurisdictions. As a consequence, they suggest it is unlikely that additional evidence from the Ontario trials would have any impact on the use of PET in other countries or provinces. In fact, one physician stated that, "the volume of literature showing evidence for PET is decreasing because the evidence is now accepted everywhere but in Ontario."

The Ontario PET trials didn't commence until 2004 (ELPET and PET START), 2005 (PETCAM and PET PREDICT) and 2006 (PET PREVENT). Between 1998 and 2005, the CMS in the United States reviewed the scientific literature and determined there was appropriate evidence to approve Medicare reimbursement for PET imaging of nine malignancies, including solitary pulmonary nodule (1998), non-small cell lung cancer (1998), colorectal cancer (1999), lymphoma (1999), melanoma (1999), esophageal cancer (2001), head and neck cancers (2001), breast cancer (2002) and thyroid cancer (2003). Consequently, Ontario began trials to determine PET's utility in head and neck cancer in 2006 (PET PREVENT), five years after the United States CMS had approved that particular indication.

In 2005, a United Kingdom evaluation of the evidence for PET imaging stated, "It is now widely accepted that the evidence of benefit (based on sensitivity/specificity analysis of PET compared with other imaging modalities) is now sufficiently robust to support the establishment of PET facilities across the country, so that all appropriate patients can have access to the technology" (Department Health Services, 2005).

Length of the trials and limited funding have undermined the legitimacy of the PET clinical trials. Two key problems with the Ontario clinical trials were the length of the trials (up to five years in some cases) and the limited funding that was provided to carry out the trials.

There is a known problem in using long-term trials to gather evidence about diagnostic imaging technology. New technology is constantly being developed and it is difficult to ensure that the technology used at the beginning of the trials is the same as the technology used at the end. In this case, the Ontario trials began when PET-only scanners were common. By 2009, more accurate

PET/CT scanners were the standard for oncology imaging. One Ontario interviewee stated, “It’s like changing drugs in the middle of a drug trial.”

According to a September 27, 2004, update written to the Ontario Association of Nuclear Medicine (OANM) by Dr. Christopher O’Brien, then secretary-treasurer of the Association, the funding available for the trials made it logistically impossible to recruit the 1,800 patients required to complete the trial in a timely manner. Approximately \$4.5 million was allotted for the PET trials, but the majority of the money was apparently dedicated to data analysis. Each participating hospital was funded in the amount of \$65,000 per year over a two-year research protocol. Given that a whole-body PET scan costs approximately \$2,500 and FDG costs would be approximately \$500, O’Brien calculated that each hospital would only be able to scan 32.5 patients per year towards the research evaluation. Since four centres took part in the trials, the funding only allowed for about 130 patients to be scanned each year, thereby making it exceedingly difficult to complete this research project (that required 1,800 patients) in a reasonable period of time.

Dr. David Webster, the president of the OANM at the time, publicly stated that the underfunding was a deliberate attempt to ensure that the introduction of PET technology (and its associated costs) would be delayed.

In 2005, the Ontario Association of Nuclear Medicine (OANM) unanimously declared the breast PET trials (PET PREDICT) “unethical” and “unconscionable.” Similarly, the Canadian Association of Nuclear Medicine (CANM) declared that the Ontario trials on cancer patients were “unethical” because they impeded access to patients for whom the technology had been proven to have value. The Association demanded that the trials be suspended and a team of experts in medical ethics and health policy be brought in to evaluate the trials. The Ministry of Health refused and the clinical trials continued.

As mentioned previously, the PET PREDICT trials were established to determine the ability of PET to detect axillary lymph node metastases in newly-diagnosed breast cancer patients with no clinical evidence of disease spread. The data from the trials eventually demonstrated that PET did not have sufficient sensitivity to stage the axilla. However, as the OANM points out, the resolution of PET at that time was five to six mm only and it was not capable of detecting the microscopic disease that it was looking for in the PET PREDICT trial.

In addition, it appears that the patients were not informed that the PET scanner was not capable of detecting the vast majority of potential metastatic disease or that the data analysis tool itself (the HTA) had not been validated for the purposes of this trial. Consequently, patients went through the PET scan and were subjected to radiation to search for something that the PET scanner was not designed to detect.

According to one physician, “It violates fundamental research ethics to design an experiment for which the instrument is incapable of performing.” Many physicians who were interviewed believe that this trial best exemplifies the deliberate course of action taken by the MOH to delay the implementation of clinical PET scanning for Ontario cancer patients. They suggest that the MOH deliberately structured a research protocol that would present PET in a negative light to further delay the introduction of clinical PET in Ontario. The major use of PET in breast cancer is in restaging, determining whether or not the cancer has recurred and monitoring those with known metastatic breast cancer.

Were the lung cancer trials ethical? The Ontario Association of Nuclear Medicine also questioned the ethics of the lung cancer trials (ELPET and PET Start) as they deliberately denied PET scans to a group of control patients at a time when it had already been effectively proven in the world literature that PET was the standard of care for lung cancer. Further to that, the MOH did not inform patients entering the trial that the use of PET in lung cancer had effectively become the

world's standard of care. Ethical trial design demands that patients be given sufficient information to make an informed decision as to whether or not they want to be part of the trial. The PET Steering Committee informed the OANM that it had used an exemption clause that allowed them to not inform the lung cancer trial patients about the status of world opinion on the use of PET in lung cancer.

4. There have been two investigations into the PET trials by Ontario's Ombudsman, yet no findings have been publicly released. The Ontario Ombudsman was involved with two formal investigations into the government's handling of funding for PET technology. The first was initiated at the request of Dr. David Webster, a Sudbury nuclear medicine physician and former head of the OANM. Dr. Webster asked the Ombudsman's office to investigate claims of fundamental government process issues that were affecting Ontario cancer patients. Following a six-month investigation, the Ombudsman concluded that the government had addressed the concerns of Dr. Webster. But Dr. Webster did not receive a copy of the letter wherein the government supposedly addressed the concerns. In answering Dr. Webster's questions about what exactly the government had done to resolve his concerns, the Ombudsman told Dr. Webster that all responses were protected by the Privacy of Information Act.

By 2007, both patients and doctors were complaining to the media that the trials were taking too long and Ontario was deliberately lagging behind other provinces in the provision of publicly-funded PET scans. In September of that year, Ontario Ombudsman Andre Marin responded to a patient's complaint by launching an investigation into the accessibility of PET scans in Ontario and other provinces. He undertook interviews with approximately 50 physicians, as well as patients and other stakeholders. The report was completed in December 2008, and given to the MOHLTC for a response, as required under the Ombudsman Act. Six months later, the Ombudsman announced to the media that the government had yet to respond to the report. Three weeks after that announcement, the government announced that PET scans would be available for cancer and cardiac patients under certain indications where they had proven to be clinically effective. After meetings with senior ministry officials, the Ombudsman determined that the issue had been resolved without the need for a published report.

5. Is patient safety at risk? The rational introduction of PET into the Ontario system can only be accomplished by looking at all tests performed on a cancer patient and effectively establishing an algorithm describing the most appropriate pathway to obtain information. However, Ontario's guidelines for funding PET do not always allow for such logic. For example, one of the current indications for a PET scan is single pulmonary nodules – three cm or less nodules that may be found in the lung through a chest X-ray. Since these nodules have a 30% probability of being malignant, such a finding would typically dictate that a PET scan be done to determine the possibility of cancer and, if so, the extent of the spread to other areas. The PET exam would essentially provide all the information – and more – of a lung needle biopsy.

Yet Ontario PET funding guidelines currently dictate that a lung needle biopsy be done first to determine if the patient is a candidate for a PET scan. The lung needle biopsy is a high risk procedure that can result in serious consequences since it involves sticking a needle into the chest. It is not uncommon to result in collapsed lungs or bleeding that can lead to hospitalization or even immediate surgery to control the bleeding.

An Ontario cancer patient must be subjected to all this – instead of a routine PET exam – when there is a 70% chance that the single pulmonary nodules are benign. If a physician wants to do a PET scan without a biopsy, he/she has to provide an explanation as to why it is not possible to biopsy the nodule.

6. Medical specialists associated with nuclear medicine appear to have different visions as to how scarce healthcare dollars are spent.

Oncologists – interviews and the apparent low number of referrals for PET scans suggest that oncologists are unlikely to join nuclear medicine physicians to advocate for more PET technology and better use of existing technology.

The oncology community seems to be more interested in obtaining new therapeutic agents than new diagnostic tools. Any money spent on PET comes from the same budget that funds treatments and drugs for cancer patients.

In addition, many oncologists are familiar with the use of evidence-based medicine to prove the efficacy of cancer therapies and believe that PET imaging technology should be judged according to that standard. However, evidence-based medicine cannot properly validate PET because it is a diagnostic imaging test, not a treatment that directly impacts patient survival. Without proof that PET improves patient survival, oncologists remained unconvinced of its benefits. This reluctance to support PET likely plays a significant role in influencing an overall confused and negative attitude toward PET among physicians in Ontario. However, this emphasis on obtaining treatment tools rather than diagnostic tools may reflect years of training and experience in an environment where PET has been restricted and discouraged.

There is also growing evidence that future clinical trials of new therapeutic agents in oncology will require PET imaging as a part of their testing protocols (Basu and Alavi, 2008; Kelloff et al., 2005). Consequently, there is a legitimate concern that the limited access to PET in Ontario may well prevent Ontario oncologists from participating in clinical trials of promising therapeutic agents (Laupacis and Evans, 2005).

Radiologists – there appears to be some amount of acrimony between nuclear medicine and radiology specialists 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.

Nuclear medicine physicians are not all trained in reading CT scans and therefore require a radiologist to read the CT portion of the scan. Conversely, most radiologists are only minimally trained to read PET images and, in theory, require a nuclear medicine physician to read that portion.

However, Ontario is unique in that it is the only province where there is not a requirement for those reading PET exams to be qualified nuclear medicine specialists. The Ontario Association of Radiologists has fought any attempt to implement such a rule and, therefore, Ontario allows radiologists to read PET exams. There are still some instances where a grandfathering clause may allow some radiologists to read PET scans in other provinces, but that is increasingly rare.

Billing practices also appear to be a point of contention between nuclear medicine specialists and radiologists. Some worry that radiologists are attempting to enhance their incomes by restricting the emergence of newer PET technology so they can focus on reading more lucrative CT and MRI scans. One physician estimated that radiologists can read (and be paid for) about 30 to 40 CT scans per day. In contrast, they can probably only read 10 to 15 PET exams per day. Therefore, an increased emphasis on PET imaging would substantially reduce the income of radiologists. According to one physician, “It’s all about billing,” while another commented, “If the public knew about the turf wars, they would march all the doctors off the end of the gangplank.”

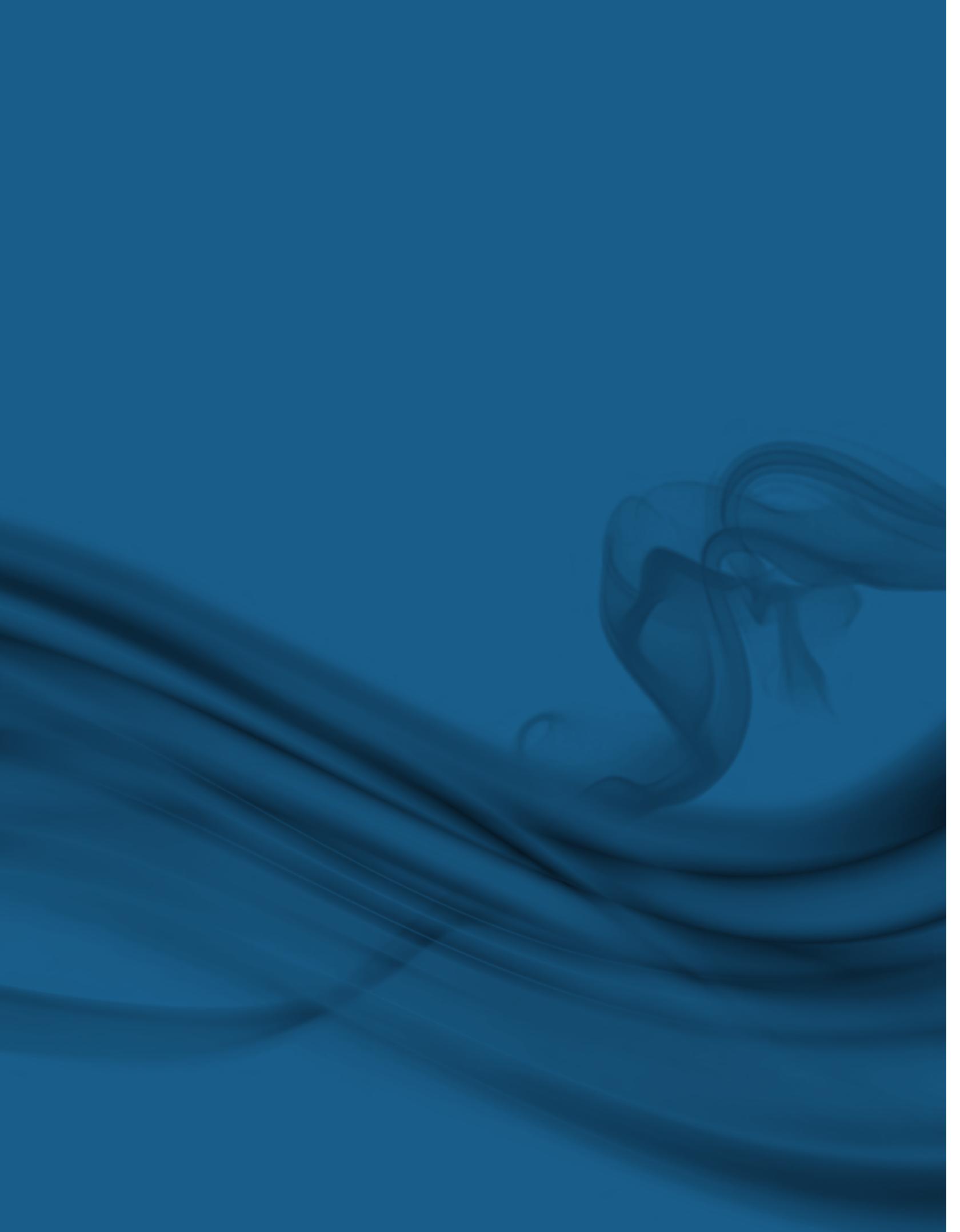
7. It is difficult for the nuclear medicine community to advocate for the proliferation of PET technology in Ontario. Nuclear medicine physicians in Ontario are very frustrated by that province’s restrictive policies toward PET scanning. This frustration has grown over the years as the PET clinical trials have continued while increasingly positive data on PET has been presented – and

accepted – in jurisdictions around the world. As a result, nuclear medicine specialists have now become more vocal in discussions with the media and politicians in an effort to increase the penetration of PET scanning in Ontario.

However, as they have publicly advocated for PET, they have been accused of wanting PET to supplement their income. According to one interviewee (who is not a nuclear medicine physician), nuclear medicine is a discipline in decline as a lot of technology changes have directed imaging business to radiologists (particularly through the heightened use of CT and MRI). Consequently, whenever nuclear medicine physicians advocate for more PET, they are confronted by suggestions that they are primarily concerned about their diminished income and are looking to PET to be their monetary “salvation.”

13

STATUS OF PET IMAGING IN QUEBEC



13.0

STATUS OF PET IMAGING IN QUEBEC

13.1 Introduction

Quebec is a unique province in that it has a well-established and expanding PET infrastructure that offers its 7.9 million citizens broad access to PET imaging. A government technology assessment report on PET imaging was released in 2001 and it came to the opposite conclusion of the 2001 ICES technology assessment report in Ontario. The AETMIS report (2001) confirmed the clinical utility of PET in oncology, neurology and some cardiology applications and encouraged the development of a plan to effectively deploy PET technology throughout the province. Consequently, in 2003, Quebec became the first province to provide public funding for PET scans and to develop a comprehensive plan to develop a PET imaging network across the province. There are currently 12 publicly-funded, clinical PET scanners and it is anticipated that, over time, every nuclear medicine department in the province will have PET imaging equipment.

For this reason, nuclear medicine specialists across the country view Quebec as being a decade ahead of the rest of Canada in terms of its adoption of PET technology. While the rest of the provinces are said to follow Ontario's reluctance to accept the new technology, Quebec is said to follow Western Europe, the United States and Japan – all international leaders in PET imaging.

Given that PET imaging can change the management strategy of patients with cancer in, at minimum, 36.5% of cases (see Section 5.1 of this report), there is an implication that Quebec cancer patients have a very different standard of cancer management than their counterparts in other Canadian provinces.

The information below is based on the completion of five questionnaires and seven in-depth interviews that were conducted with five nuclear medicine physicians, the Conseiller Scientifique for the Minister of Health and Social Services that governs PET services and the president of the Colorectal Cancer Association of Canada.

13.2 PET Scanners

There are currently 12 publicly-funded, clinical PET scanners serving the province of Quebec and its population of 7.9 million (Figure 7.2). This results in a ratio of 1.5 PET scanners per million people, the highest ratio of all the provinces and the only one – at present – that comes close to approximating the two scanners per million ratio recommended by the World Health Organization (WHO).

As outlined in Table 7.2, five clinical scanners are located at facilities in Montreal: (CUSM) Montreal General Hospital, (CHUM) Hotel Dieu, the Jewish General Hospital, Hospital Ste. Justine and Hospital Maissonneuve-Rosemont. It should be noted that the PET/CT scanner at Hospital Ste. Justine is dedicated to pediatric patients. The PET/CT scanner at Hotel Dieu is the most widely-used scanner in Quebec – and in all of Canada. It performs about 4,000 scans per year and operates six days a week.

There are two clinical PET/CT scanners located in Quebec City: (CHUQ) Hotel Dieu Quebec and Hospital Laval/Institute of Cardiology and Pneumology Quebec.

There is one PET/CT scanner at each of the following locations: (CHUS) Université de Sherbrooke in Fleurimont, Rimouski General Hospital, Chicoutimi General Hospital, Trois Rivières General Hospital and Gatineau General Hospital.

All scanners are primarily utilized for oncology scanning, with the exception of the PET/CT scanner at Hospital Laval/Institute of Cardiology and Pneumology Quebec which is utilized for lung and cardiology investigations.

Quebec is also home to three private PET imaging facilities (Table 7.5). Two of these facilities are located in Montreal (one PET-only scanner at Centre d'imagerie Medicale Reso Scan CLM and one PET/CT at the Centre d'imagerie Nucleaire et TEP/CT Ville Marie). One PET/CT is available at a facility in Quebec City (Clinique Radiologique de la Capitale).

In addition, there are four PET scanners in Quebec that are dedicated to research in oncology and neurology (Table 7.6). They are located at (CHUM) Notre Dame at the University of Montreal (one PET/CT that is primarily used for oncology research), the Montreal Neurological Institute (two PET-only scanners that are used for research into neurology) and the Université de Sherbrooke (one PET/CT).

13.3 PET Scans

The provincial data and calculations shown in Table 7.3 reflect PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010.

In 2009, Quebec funded approximately 22,400 clinical scans, a sum that far exceeds every other Canadian province (see Table 7.3). When provincial scan numbers are equalized by dividing the number of scans by one million, Quebec funds 2,835 scans per million, far higher than any other province and the national average of 1,068 scans per million.

When the number of provincial scans is divided by the number of clinical, publicly-funded PET scanners (12), it results in an average performance of 1,867 scans per PET scanner. While this ranks slightly higher than the national average of 1,643 scans per scanner and is the leading ratio of scans per scanner in all provinces, it still falls short of the 3,100 scans carried out on British Columbia's single scanner.

However, completed questionnaires and interviews with personnel at various PET scan facilities show that equipment utilization rates vary widely. For example, the PET scanner at Hotel Dieu is operating six days a week to complete 4,000 scans per year – the highest of any PET scanner in Canada. Montreal General Hospital performs 2,500 to 3,000 scans per year, while the two PET machines at Université de Sherbrooke combined to perform about 4,300 scans per year, even while conducting research studies. In contrast, Ste. Justine Children's Hospital carries out only 700 to 1,000 scans per year.

Waiting lists also appear to be quite variable, although emergency patients can typically access a PET scan within 24 to 72 hours at any facility. Other than priority cases, the waiting list can vary from one week (Ste. Justine) to three or four weeks (Université de Sherbrooke and Hotel Dieu) and even as long as a few months (Montreal General Hospital).

13.4 FDG Availability

There are currently three cyclotrons producing FDG in Quebec (see Table 7.10). They are located at the Montreal Neurological Institute in Montreal, Pharmalogic PET Services of Montreal (a commercial supplier of FDG) and the Université de Sherbrooke (CHUS) in Fleurimont, Quebec. The Université de Sherbrooke is expecting another cyclotron within the next two years and it is expected that one cyclotron will be dedicated to research and the other to clinical production of positron emitting radioisotopes. The average cost of a dose of FDG to Quebec PET facilities is \$350, far less than the national average of \$505 per dose.

13.5 PET Funding

The Quebec government pays PET facilities a sum total of \$956 per scan, including \$700 for the scan and FDG, along with a \$256 interpretation fee. Quebec is the only province with a billing code to cover the physician's interpretation of the scan.

13.6 PET Imaging Policies

1. In 2000, the Federation of Medical Specialists in Quebec (Federation des medecins specialists du Quebec; FMSQ) and the Quebec Council for The Fight against Cancer (Conseil quebecois de lute contre le cancer; CQLC) jointly requested that the Agency for the Evaluation of Technologies and Modes of Intervention In Health (Agence d'evaluation des technologies et des modes d'intervention en santé; AETMIS) undertake a full assessment of the clinical efficacy of PET technology in oncology, neurology and cardiology. The AETMIS report was completed in October 2001, and Quebec's unique and progressive PET policies stem from the recommendations made by this report.

The AETMIS study confirmed the clinical utility of PET in many oncology, neurology and cardiology applications with the statement, "Since the clinical efficacy of PET is recognized in many oncological, cardiological and neurological applications, it would be advisable to promote and sustain the deployment of PET for clinical purposes in Quebec's public healthcare system."

In particular, PET's utility as a diagnostic tool for oncology was recognized in lung cancer colorectal cancer, melanoma, head and neck cancer and lymphomas. Consequently, the report estimated that Quebec could require 15,000 or more scans per year. In order to accomplish this, AETMIS recommended the gradual deployment of 10 to 15 PET scanners, supplied by three or four cyclotrons, across Quebec. The Quebec government, in close consultation with the nuclear medicine specialists in Quebec, developed a plan for the gradual deployment of 12 PET scanners in 12 sites around the province. This initial plan was completed in 2009.

As a result, Quebec now leads Canada in the deployment of PET imaging technology with a total of 12 clinical scanners in 12 locations. An updated AETMIS report is due and the health ministry expects that it will recommend the deployment of more PET scanners. The nuclear medicine specialists in Quebec are working closely with the government in an effort to ensure that, over time, there is a PET scanner in every nuclear medicine department across Quebec.

2. Quebec prides itself in having a patient-centred approach to cancer treatment, whereby technology and treatment initiatives are driven by clinical need rather than cost. Although Quebec does not currently have a cancer agency like the other provinces, the provincial government apparently made a decision around the year 2000 to make cancer treatment a priority for the province of Quebec.

3. Quebec is unique in that physicians cannot practice dual specialties in this province. In other words, a physician cannot practice radiology and nuclear medicine. This policy has led to the development of a very strong provincial association of nuclear medicine specialists that is closely tied to, and in frequent communication with, the provincial government. Their goals are focused on the development of nuclear medicine within the province and their attention is not divided by radiologists who would prefer the government to focus on obtaining more MRI or CT machines. This single policy is seen by many as key to the successful development of the current PET infrastructure in Quebec.

13.7 Provincial Indications

The Quebec indications for PET scans were initially a product of the AETMIS report (2001). They were reviewed by physicians in 2005 and 2007, and a new report is due in 2011. There are currently 15 indications for oncology PET scanning in Quebec. The list of indications can be found in Appendix C and include the following:

- Breast cancer
- Lung cancer
- Esophageal cancer
- Colorectal cancer
- Colorectal – metastases to liver
- Lymphoma
- Melanoma
- Head and neck cancer
- Thyroid cancer
- Uterine cancer
- Ovarian cancer
- Testicular cancer
- Pancreatic cancer
- Sarcoma
- Kidney cancer

There are also three indications for neurology scans and two for cardiology scans (see Appendix C).

13.8 Quebec Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for Quebec in 2011 is 66,500 and the number of cancer deaths (mortality) is estimated to be 20,100. Figure 13.1 shows the incidence of the four most common cancers in Quebec – lung, breast, colorectal and prostate. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

Prostate cancer in men has the highest incidence, followed by lung and colorectal cancer (see Figure 13.2). For Quebec women, the most common cancer is breast, followed by lung and colorectal (see Figure 13.3). As shown in Figures 13.2 and 13.3, lung cancer has the highest mortality rate of all cancers in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011).

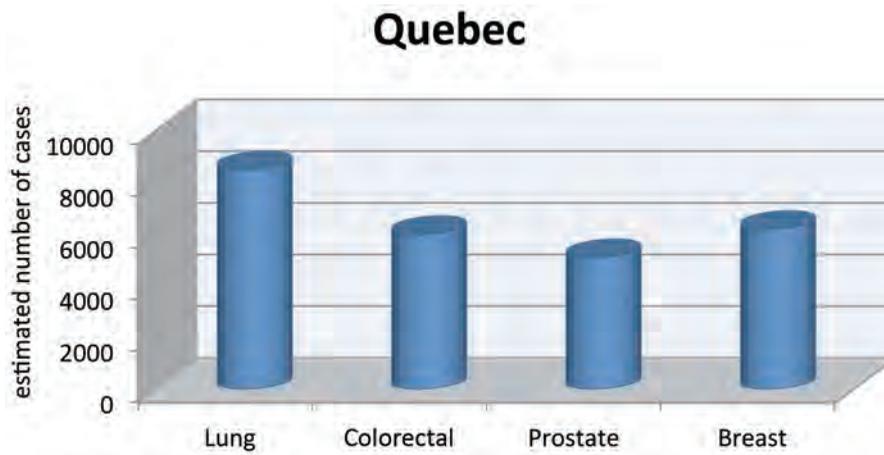


Figure 13.1 Incidence of the most common cancers in Quebec (estimated for 2011).

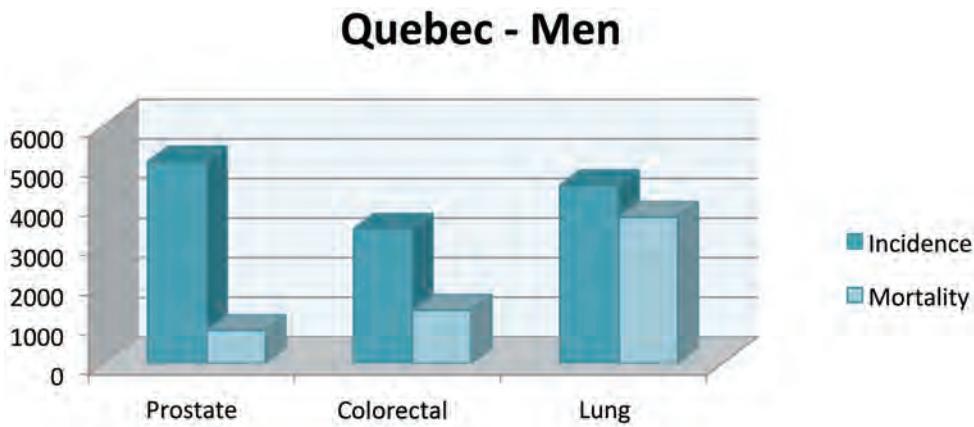


Figure 13.2 Incidence and mortality of the most common cancers for men in Quebec (estimated for 2011).

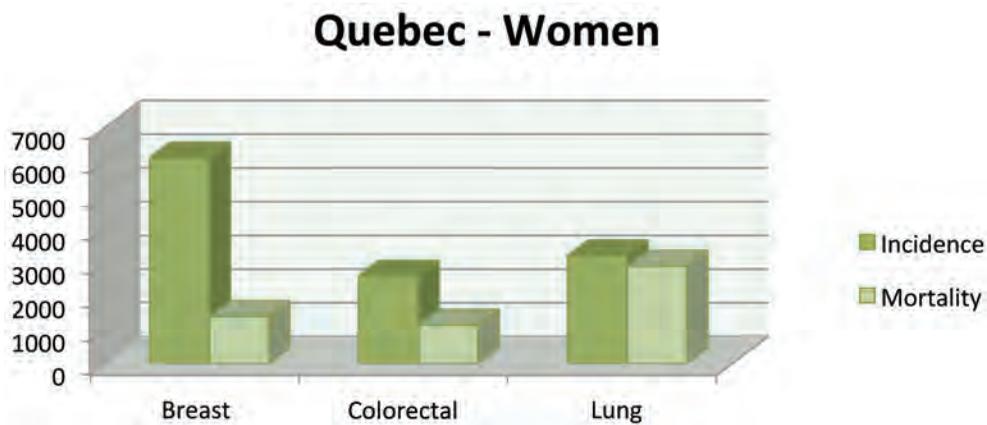


Figure 13.3 Incidence and mortality of the most common cancers for women in Quebec (estimated for 2011).

13.9 Quebec Findings

There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0.

The following findings relate to the status of PET imaging in Quebec:

1. The AETMIS report. Quebec's AETMIS report on the clinical efficacy of PET technology was published in 2001, the same year as Ontario published its ICES report on PET. It is interesting that the reports came to opposite conclusions. A decade later, the impact of these reports on each province is clear. Quebec has 1.5 PET scanners per million, compared to Ontario's ratio of 0.7. Quebec conducts 2,835 scans per million, while Ontario carries out 553 – the lowest ratio of any Canadian province with a PET scanner. Quebec is the Canadian leader in PET imaging, while Ontario's PET policies are viewed as an "embarrassment" and "ridiculous" by its own physicians. One Quebec physician commented on the situation by saying, "if you look around the world, it's time for governments to justify their lack of PET, rather than trying to justify why we should have PET."
2. Quebec has a different standard of care for cancer patients. Given that PET imaging changes treatment strategy at least 36.5% of the time (see Section 5.1), it is logical to assume that the standard of care for managing cancer patients in Quebec is very different than that for cancer patients who cannot access a PET scan in other provinces. According to one Quebec physician, "It's good, ethical, normal practice to use PET for oncology patients. If PET changes treatment strategy in 30 to 40% of cases, is it even ethical to start treatment or do treatment without a PET scan?"

Yet, because PET is a diagnostic tool that has no impact on patient survival, it is very difficult to obtain the statistics necessary to prove that changing treatment results in better cancer outcomes. As outlined in Section 5.3, PET leads to better, more-informed decision making by the patient and the physician, but that does not always translate into a benefit for survival rates of patients as there is often a disparity between early diagnosis of cancer and the therapeutic options available to successfully treat it. Statistics may be hard to come by but, for individual patients, it is always beneficial to have the most information possible and to undergo the most appropriate treatments for their current condition as indicated by PET imaging. One physician stated that a PET scan always results in patients getting into the healthcare system more quickly and therefore getting proper treatment management more quickly; "For \$1,000 it gives you the whole picture to start treatment."

3. Several physicians mentioned that oncologic and thoracic surgeons in Quebec will not operate without first doing a PET scan.
4. Physicians in the province of Quebec tend to follow medical trends in Europe more closely than those in the rest of Canada or even in the United States. This may be partly due to French-speaking physicians following their French-speaking colleagues in Europe more closely, but it has had a large impact on PET. Western Europe has a current total of 479 PET scanners and its PET infrastructure is expected to increase to 742 scanners by 2013.
5. Quebec currently has 12 PET scanners located primarily at academic sites. The nuclear medicine specialists are pushing to have a PET scanner in every nuclear medicine department in the province, but some physicians are concerned that there are not enough specialized personnel to accomplish that goal. A shortage of HQP (highly qualified personnel) has been noted as a challenge to the expansion of PET in Canada.
6. Hospital Ste. Justine. The PET scanner at Hospital Ste. Justine is primarily utilized to scan children, although some overloaded hospitals may send adults for a scan in an emergency situation. In this facility, only 65% to 70% of scans are oncology-related. Instead, the PET scanner is often used to locate sites of infection when the diagnosis is fever of unknown origin; in more than

50% of these cases they are able to locate the source of infection. Ste. Justine is a world leader in using PET for the proper diagnosis of the source of infection.

7. Many physicians credit the people of Quebec with creating a positive PET environment in the province. This heightened cultural awareness of PET was apparently created by two factors. First, the story of Saku Koivu, a former captain of the Montreal Canadiens, is outlined in Section 5.3. The public closely followed his journey with abdominal cancer, including his gratitude for a PET scan that allowed him to stop chemotherapy early and conserve his physical resources for his hockey comeback. Koivu's experience with PET galvanized him to start a high-profile foundation to raise money for a PET scanner at Montreal General Hospital.

Second, an Oscar-winning movie by French-Canadian director Denys Arcand called *The Invasion of the Barbarians* became very popular in Quebec. The film was released in 2003 and tells the story of a man with cancer who must face Quebec's over-crowded, underfunded hospitals. The man is sent to New York for a PET scan by his son. This film demonstrated the value of PET and clearly sent the message that Quebec was offering subpar medicine in not having ready access to the technology.

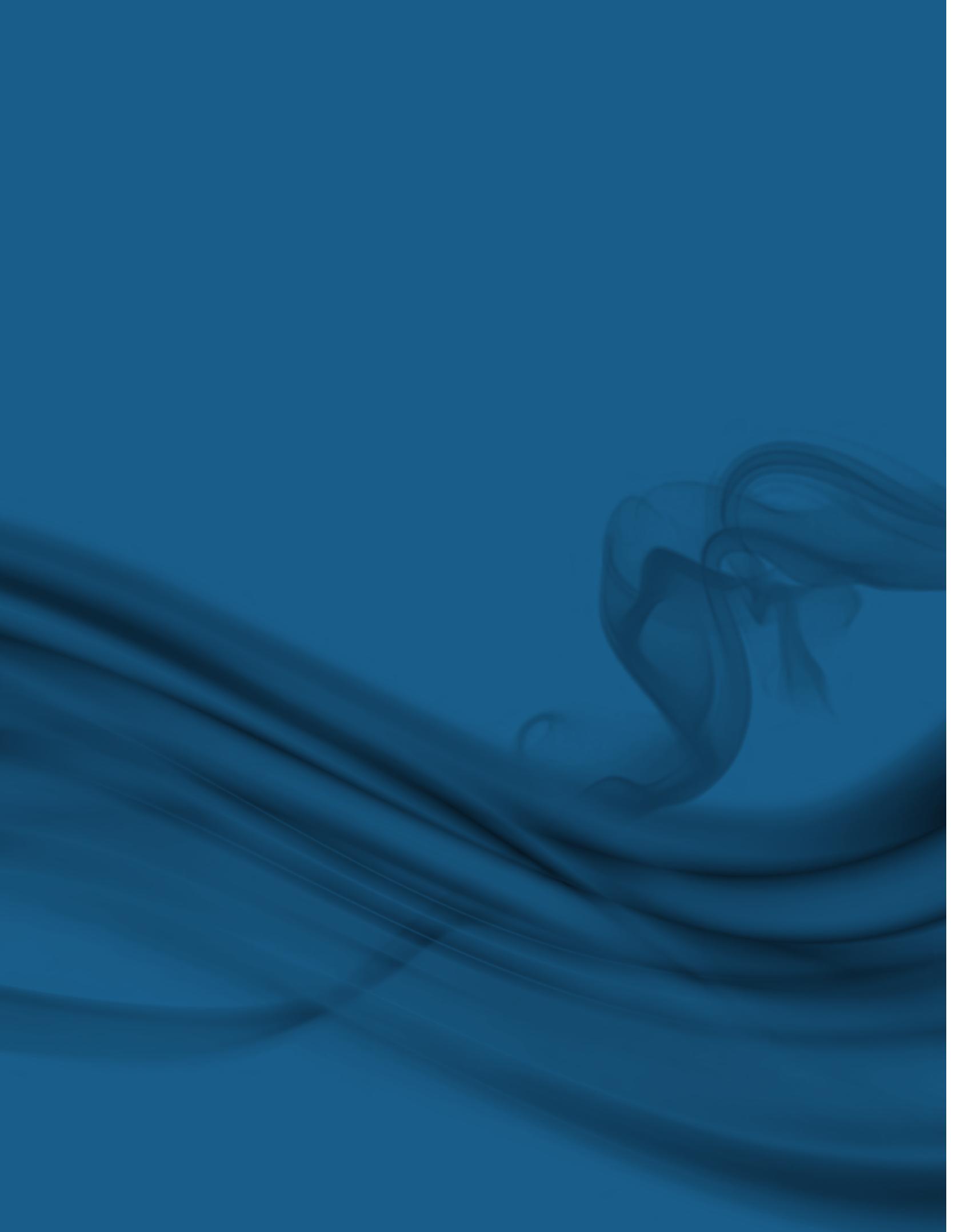
For these two reasons, the people of Quebec are relatively knowledgeable about PET imaging and its benefits in oncology, particularly when compared to citizens of other Canadian provinces.

8. Quebec is unique in that physicians cannot practice dual specialties in this province. In other words, a physician cannot practice radiology and nuclear medicine. This policy has led to the development of a very strong provincial association of nuclear medicine specialists that is closely tied to, and in frequent communication with, the provincial government. Their goals are focused on the development of nuclear medicine within the province and their attention is not divided by radiologists who would prefer the government to focus on obtaining more MRI or CT machines. This also ensures that nuclear medicine specialists only are interpreting PET exams.

By not allowing dual specialties, Quebec has been successful in negating the professional infighting and competing interests of radiologists and nuclear medicine physicians that is problematic across the country, particularly in Ontario. This single policy is seen by many as key to the successful development of the current PET infrastructure in Quebec.

14

STATUS OF PET IMAGING IN NOVA SCOTIA



14.0

STATUS OF PET IMAGING IN NOVA SCOTIA

14.1 Introduction

There is one PET scanner servicing this province and an active PET program has been in place since 2008. This program was further bolstered in August 2010, by the addition of a cyclotron. This should considerably reduce the cost of a PET examination, as a major cost to the PET program had been importing FDG from Montreal.

The PET program in this province is run under the auspices of Cancer Care Nova Scotia. The information below is based on in-depth interviews with two nuclear medicine physicians from Halifax. Two questionnaires were completed.

14.2 PET Scanners

The provincial data and calculations shown in Table 7.3 reflect PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010.

There is one publicly-funded, clinical PET/CT scanner serving Nova Scotia and its population of 0.94 million. It is used for oncology imaging approximately 99% of the time. As shown in Table 7.3, it is located in Halifax at the QEII Health Sciences Centre and has been operating since 2008. This creates a ratio of 1.06 PET scanners per million people – the third highest ratio in Canada, behind only Quebec (1.6 scanners per million) and New Brunswick (1.33 scanners per million). This ratio is also above the national ratio of 0.83 PET scanners per million people. Although the ratio appears to be adequate for serving a population of less than one million, it is still well below the two scanners per million ratio recommended by the World Health Organization (MEDEC, 2010).

14.3 PET Scans

In 2009, the Halifax PET facility carried out 1,600 PET scans at a cost of \$1,800 per scan. This represents approximately 1,500 scans from Nova Scotia and 100 scans on individuals from other Maritime provinces (Newfoundland and Prince Edward Island).

While this ranks Nova Scotia in the middle of the provinces in terms of numbers of scans, a different picture emerges when all provincial numbers are equalized by dividing the number of scans by one million. As shown in Table 7.3, Nova Scotia carries out 1,702 scans per million people, a number that is higher than the national average of 1,068 scans per million and above every other province except for Quebec (2,835 scans per million).

It would appear that Nova Scotia's one PET scanner is well utilized since it carries out 1,600 PET examinations per year. However, that number remains just below the national average of 1,643 scans per scanner and represents only 52% of the number of scans carried out by British Columbia's sole scanner (3,100 scans per year).

Interviews also suggest that the PET scanner is not being maximally utilized. The facility is currently scanning nine to 10 patients a day, three days per week. The interviewees suggested that they simply do not have the demand for more scanning, although they plan to carry out 1,800 scans this year and say they presently have the facilities and infrastructure to carry out approximately 2,500 scans per year.

The waiting period for a PET scan is approximately two weeks.

14.4 FDG Availability

Until recently, FDG cost and availability were key factors influencing the number of PET scans carried out each year. Until August 2010, FDG was obtained from Pharmalogic PET Services in Montreal at a cost of approximately \$650 per dose. At that point, a cyclotron at the QEII Health Sciences Centre in Halifax began operating and producing FDG for PET exams. At time of writing, the cost of FDG per dose had not yet been calculated, but it is likely to be significantly lower than the cost of the FDG flown in from Montreal and will likely enhance Nova Scotia's capacity to undertake a greater number of scans.

14.5 PET Funding

The Nova Scotia government provides global funding to the PET program through Cancer Care Nova Scotia. The funding is adequate to cover about 1,500 PET scans per year based on a cost of \$1,800 per scan (including a \$285 interpretation fee). The cost per scan will likely go down as local FDG is utilized in the PET program.

14.6 Provincial Indications

There are currently 10 provincial indications for PET scanning in Nova Scotia. Nine of the indications are quite specific, but the tenth covers individual cases where the indication is not covered, yet there is a reasonable expectation that a PET scan may be of assistance in diagnosis or case management. The list of indications can be found in Appendix C and includes the following:

- Breast cancer
- Colorectal cancer
- Lung cancer
- Head and neck cancers
- Lymphoma
- Esophageal cancer
- Melanoma
- Thyroid cancer
- Pancreatic cancer

Other individual cases with a diagnostic or management dilemma may be approved on a case-by-case basis by medical services insurance (MSI).

14.7 Nova Scotia Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for Nova Scotia in 2011 is 6,100 and the number of cancer deaths (mortality) is estimated to be 2,650. Figure 14.1 shows the incidence of the four most common cancers in Nova Scotia – prostate, lung, colorectal and breast. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

Prostate cancer in men has the highest incidence, followed by lung and colorectal cancer (see Figure 14.2). For Nova Scotia women, the most common cancer is breast, followed by lung and colorectal (see Figure 14.3). As shown in Figures 14.2 and 14.3, lung cancer has the highest mortality rate of all cancers in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011).

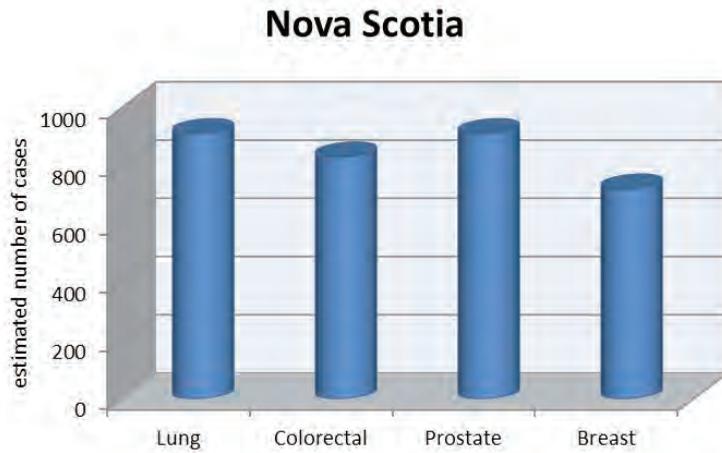


Figure 14.1 Incidence of the most common cancers in Nova Scotia (estimated for 2011).

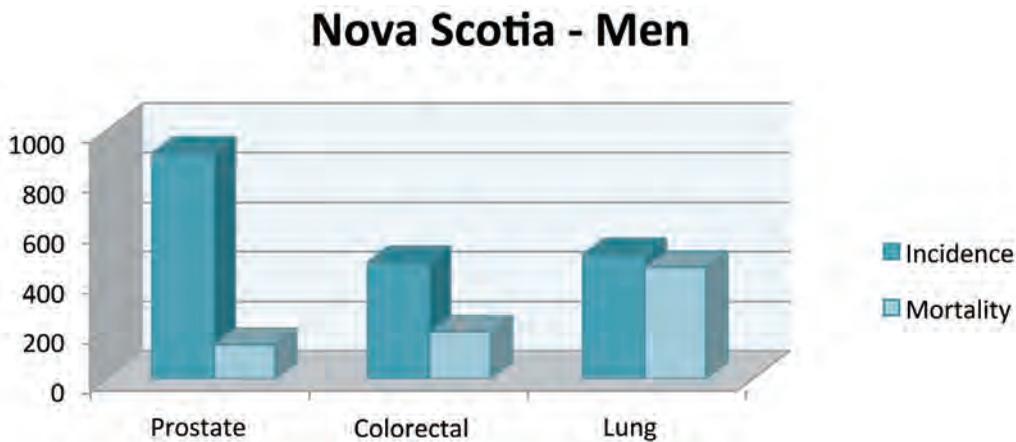


Figure 14.2 Incidence and mortality of the most common cancers for men in Nova Scotia (estimated for 2011).

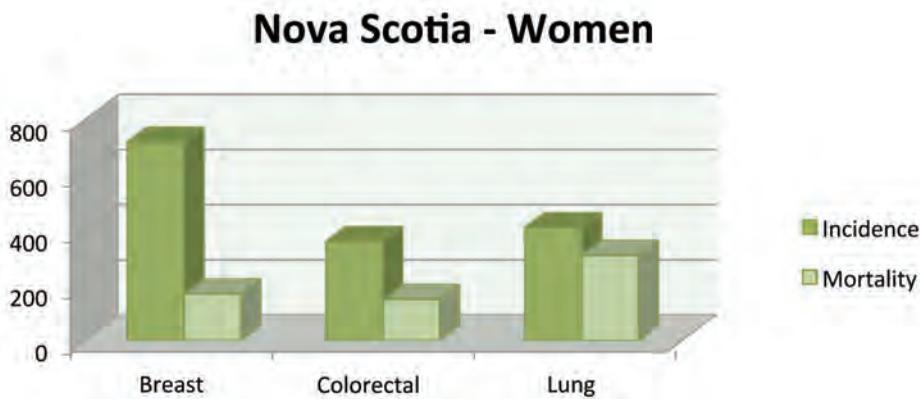


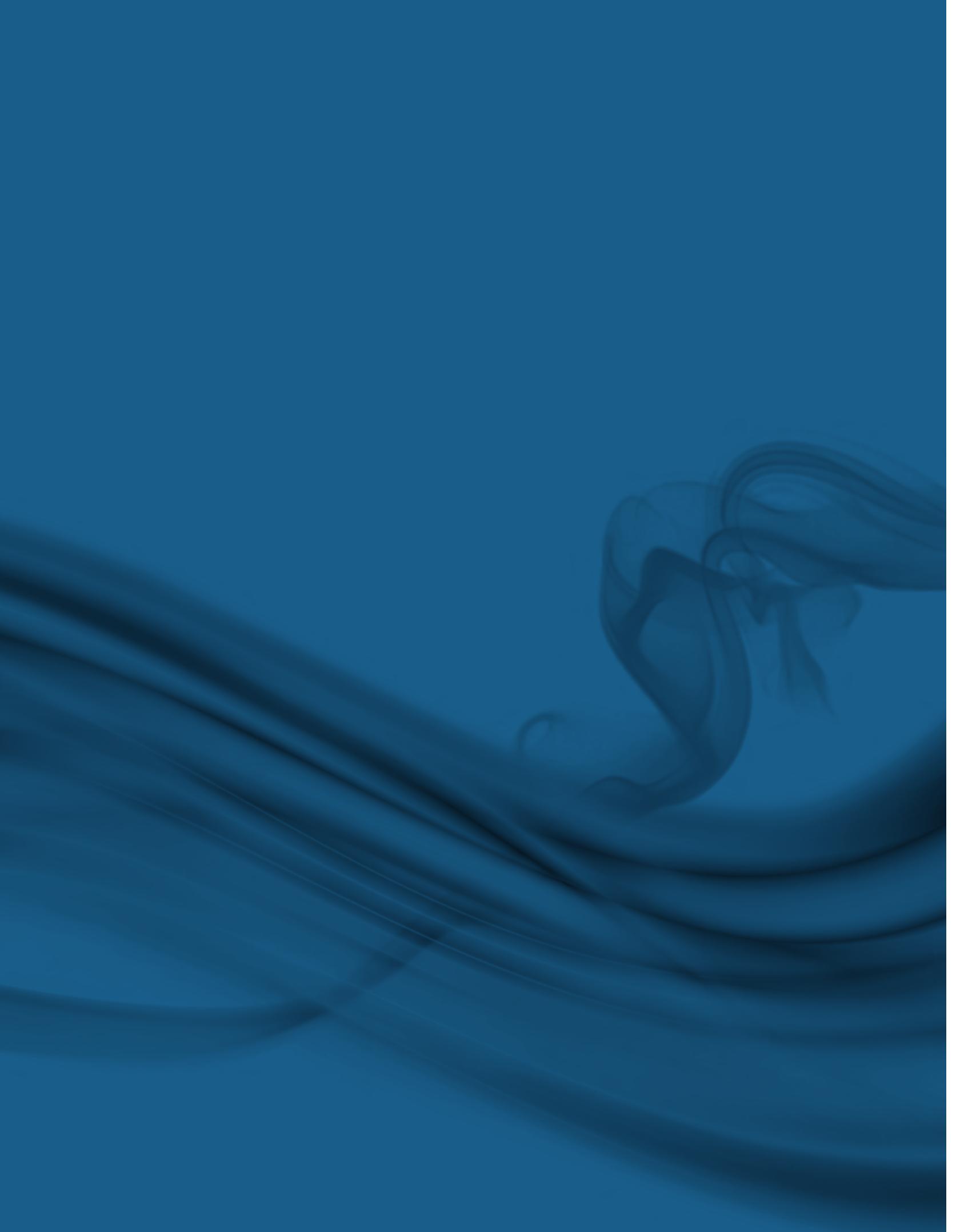
Figure 14.3 Incidence and mortality of the most common cancers for women in Nova Scotia (estimated for 2011).

14.8 Nova Scotia Findings

There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0. There are no findings that are unique to Nova Scotia.

15

**STATUS OF PET IMAGING
IN NEW BRUNSWICK**



15.0

STATUS OF PET IMAGING IN NEW BRUNSWICK

15.1 Introduction

The province of New Brunswick is served by one publicly-funded, clinical PET scanner that is located in St. John and operates on a part-time basis. Yet, as the only officially bilingual province, New Brunswick has an obligation to offer all services in both French and English. As St. John is primarily an English community, the provincial government has made a commitment to install a second PET scanner at a predominantly French hospital in Moncton. It is expected to begin operations as early as 2012. With two PET scanners to serve a province of 0.75 million, New Brunswick would undoubtedly have the most accessible PET program in Canada.

Two individuals from New Brunswick were interviewed as a part of this study: One nuclear medicine physician in St. John and the co-CEO of the New Brunswick Cancer Network that oversees the provincial PET program, Dr. Eshmar Kumar. Two questionnaires were completed.

15.2 PET Scanners

The provincial data and calculations shown in Table 7.3 reflect PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010.

New Brunswick has one publicly-funded, clinical PET/CT scanner located at the St. John Regional Hospital in St. John (see Table 7.2) and 100% of its scans are related to oncology. A second PET/CT has been promised to the community of Moncton to meet the provincial obligation to provide all services in English and French.

As it stands now, New Brunswick has 1.33 PET scanners per million people, an access figure that is higher than every province except for Quebec (1.5). While this figure (1.33) still falls below the WHO recommended ratio of two scanners per million people (MEDEC, 2010), it should be noted that a second scanner would increase that ratio to 2.66.

15.3 PET Scans

The PET facility at St. John completed approximately 1,000 PET scans in 2009 at a cost of \$1,600 per scan. When all provincial numbers are equalized by dividing the number of scans by one million, New Brunswick conducts 1,333 scans per million people (see Table 7.3). This is higher than the national average of 1,068 scans per million, but still lower than the scan per million ratios of Quebec, Nova Scotia and Alberta.

Despite a seemingly high number of scans, the one PET scanner does not appear to be maximally utilized. As shown in Table 7.3, New Brunswick's 1,000 scans per scanner are significantly lower than the national average of 1,643 and far below British Columbia's 3,100 scans per scanner. In fact, New Brunswick ranks behind all provinces except Ontario in terms of PET scanner utilization.

This was confirmed through interviews and questionnaires. The St. John PET machine scans seven patients a day, three days a week for 39 weeks of the year. The scanner is only operational two days per week for the other 13 weeks per year. If sufficient funds were available, it is estimated that the St. John scanner could do about 1,800 PET examinations per year.

The waiting list for a PET scan is quite variable, depending on demand and the number of days the scanner is operating. It can be as short as one week or as long as four weeks.

15.4 FDG Availability

The St. John Regional Hospital currently purchases its FDG from Pharmalogic PET Services in Montreal. It is extremely costly (about \$800 per dose) and involves a six- to eight-hour journey from the production plant to the PET facility. At present, there are no plans to get FDG from Halifax.

15.5 PET Funding

New Brunswick Medicare pays \$1,600 per scan. This includes the cost of the scan, FDG and an interpretation fee. The number of scans is currently capped at 1,000 per year. This province has a fee schedule item to charge for a PET scan examination.

15.6 Provincial Indications

There are currently 14 indications for PET scanning in New Brunswick. The list of indications can be found in Appendix C and includes the following:

- Colorectal cancer
- Lung cancer
- Lymphoma
- Esophageal cancer
- Pancreatic malignancy
- Testicular cancer
- Musculoskeletal (bone metastases with unknown primary tumour)
- Head and neck cancer
- Ovarian cancer
- Melanoma
- Thyroid cancer
- Breast cancer
- Brain cancer
- Neuroendocrine tumours

15.7 New Brunswick Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for New Brunswick in 2011 is 4,800 and the number of cancer deaths (mortality) is estimated to be 1,990. Figure 15.1 shows the incidence of the four most common cancers in New Brunswick – prostate, lung, breast and colorectal. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

Prostate cancer in men has the highest incidence, followed by lung and colorectal cancer (see Figure 15.2). For New Brunswick women, the most common cancer is breast, followed by lung and colorectal (see Figure 15.3). As shown in Figures 15.2 and 15.3, lung cancer has the highest mortality rate of all cancers in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011).

New Brunswick

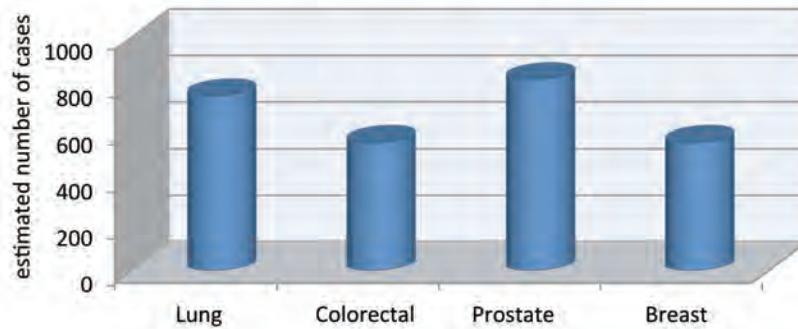


Figure 15.1 Incidence of the most common cancers in New Brunswick (estimated for 2011).

New Brunswick - Men

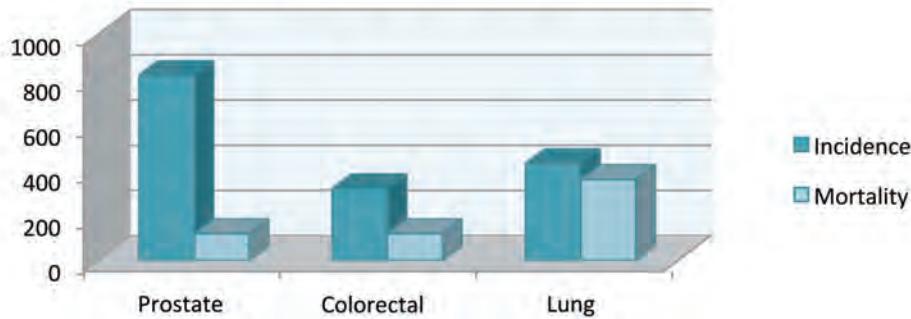


Figure 15.2 Incidence and mortality of the most common cancers for men in New Brunswick (estimated for 2011).

New Brunswick - Women

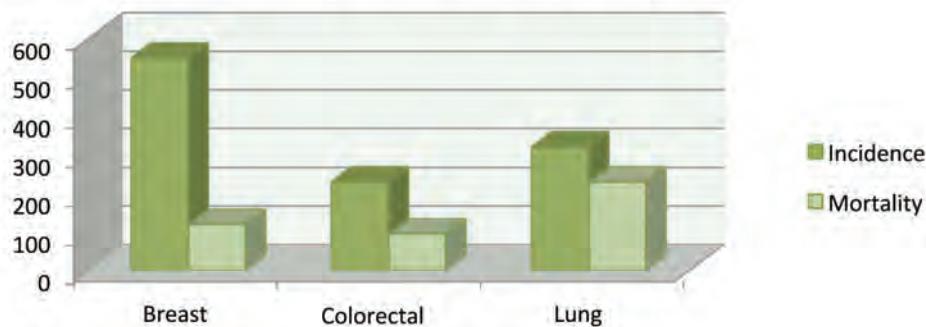


Figure 15.3 Incidence and mortality of the most common cancers for women in New Brunswick (estimated for 2011).

15.8 New Brunswick Findings

There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0.

The following findings relate to the status of PET imaging in New Brunswick:

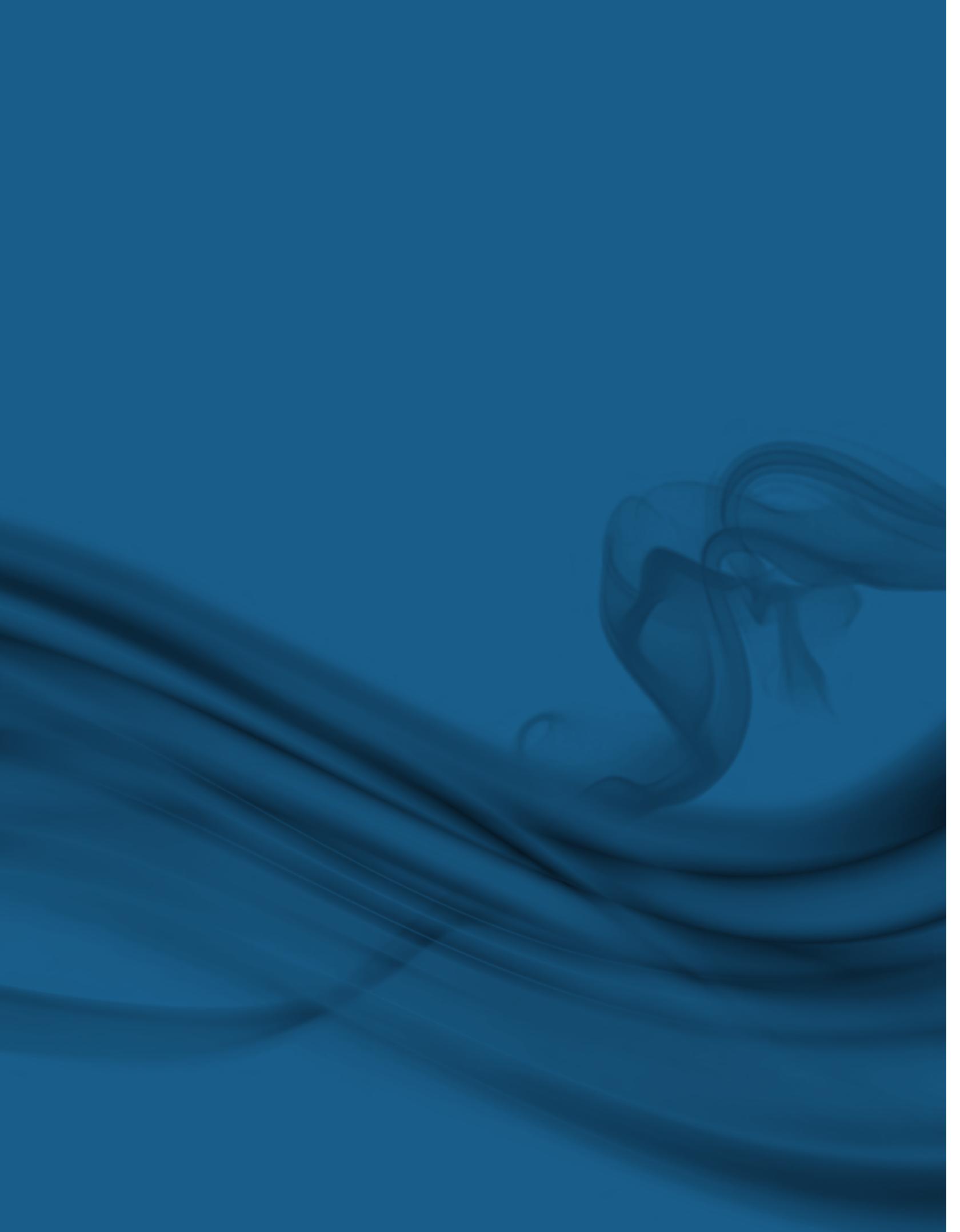
1. The PET scanner in New Brunswick is currently functioning on a part-time (three days per week) basis only and it appears there is not a demand for more PET scans. Yet there is active discussion about a second PET scanner for New Brunswick to satisfy the province's requirement to provide services in both French and English. The first scanner is located in a predominantly English-speaking hospital in the community of St. John; the second scanner is planned for a predominantly French-speaking hospital 155 km down the road in Moncton and may be functioning as early as 2012.

With two scanners serving a population of 0.75 million, there would be a ratio of 2.66 PET scanners per million people, well above the two per million recommended by the World Health Organization. It seems unreasonable to have a second scanner (at a cost of \$2.5–4 million in capital costs and about \$2 million per year for operating costs) when the present scanner is not being optimally utilized.

2. At \$800 per dose plus shipping costs, New Brunswick pays the highest price for FDG of all facilities in Canada. FDG is currently flown in from Pharmalogic PET Services in Montreal – a six- to eight-hour journey during which a significant amount of radioactivity (three to four half-lives) is lost. According to Pearcey and McEwan (2006-07), a general rule of thumb is that shipping times be less than three half-lives (or approximately five hours) to allow clinically useful quantities to be available upon delivery. Therefore, the cost of FDG (and shipping charges) would drop substantially if it could be obtained from the new cyclotron facility in Halifax. This may not be possible for a while, as the cyclotron at Halifax only recently began to produce FDG. However, it is definitely something that should be considered in the future.

16

STATUS OF PET IMAGING IN PRINCE EDWARD ISLAND



16.0

STATUS OF PET IMAGING IN PRINCE EDWARD ISLAND

16.1 Introduction

Prince Edward Island is one of three Canadian provinces that does not have a PET scanner. Patients requiring PET examinations are currently sent out of the province to PET facilities at St. John, New Brunswick or Halifax, Nova Scotia.

However, while Saskatchewan and Newfoundland (the two other provinces without a PET scanner) have active plans to purchase and install a PET scanner, Prince Edward Island does not. It appears difficult to justify such a costly purchase to serve a population of 140,000 people.

As all PET scan activity takes place in St. John or Halifax, there were no interviews conducted with physicians in Prince Edward Island. The statistical information resulted from contact with the province's Out-of-Province Coordinator of Medical Programs, a division of the PEI Department of Health and Wellness.

16.2 PET Scanners

There are no private, research or clinical PET scanners located in the province of Prince Edward Island.

16.3 PET Scans

The provincial data and calculations shown in Table 7.3 reflect PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010.

In 2009, the Department of Health and Wellness funded 70 out-of-province PET scans at a cost of \$1,836 per scan. This translates into the equivalent of 500 scans per million people (see Table 7.3); a ratio that is higher than both Saskatchewan (300 scans per million) and Newfoundland (200 scans per million), the two other provinces without a PET scanner. In fact, it is also not far behind Ontario's 553 scans per million – in a province with 13.1 million.

Patients are sent to St. John, New Brunswick, or Halifax, Nova Scotia, for PET examinations. The destination is often dependent on the patient's state of health, family considerations and/or the length of the waiting list at the various PET facilities.

There is no cap on the number of PET scans currently available to patients in Prince Edward Island.

16.4 FDG Availability

This is not applicable, as there is no PET scanner or cyclotron operating in Prince Edward Island.

16.5 PET Funding

The Prince Edward Island Department of Health and Wellness pays PET facilities in other provinces a sum of \$1,836 per PET scan. The fee is paid out of a global budget for out-of-province patient services. There is no fee schedule item for a PET examination.

16.6 Provincial Indications

There are no criteria for ordering an oncology PET scan other than that the request is made by a medical oncologist.

16.7 Prince Edward Island Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for Prince Edward Island in 2011 is 910 and the number of cancer deaths (mortality) is estimated to be 350. Figure 16.1 shows the incidence of the four most common cancers in Prince Edward Island - prostate, lung, colorectal and breast. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

Prostate cancer in men has the highest incidence, followed by lung and colorectal cancer (see Figure 16.2). For Prince Edward Island women, the most common cancer is breast, followed by colorectal and lung (see Figure 16.3). As shown in Figures 16.2 and 16.3, lung cancer has the highest mortality rate of all cancers in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011).

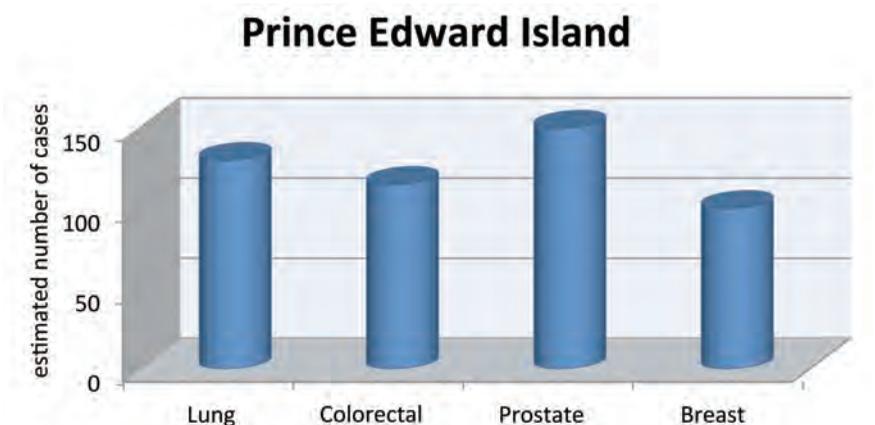


Figure 16.1 Incidence of the most common cancers in Prince Edward Island (estimated for 2011).

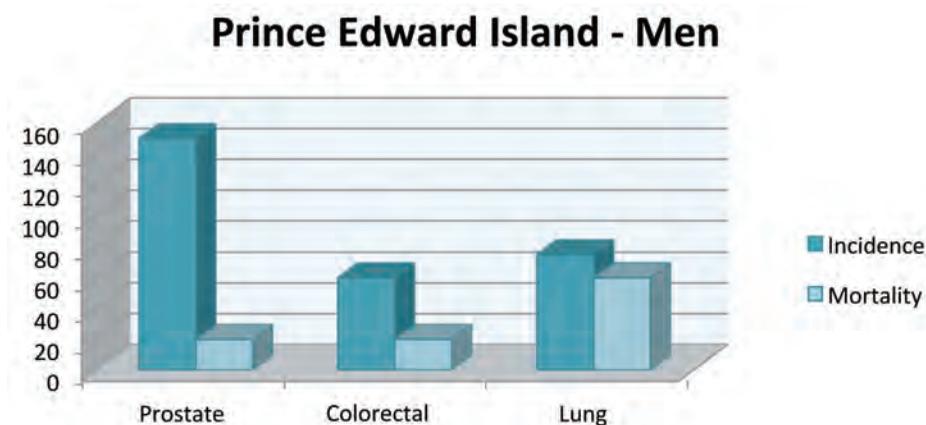


Figure 16.2 Incidence and mortality of the most common cancers for men in Prince Edward Island (estimated for 2011).

Prince Edward Island - Women

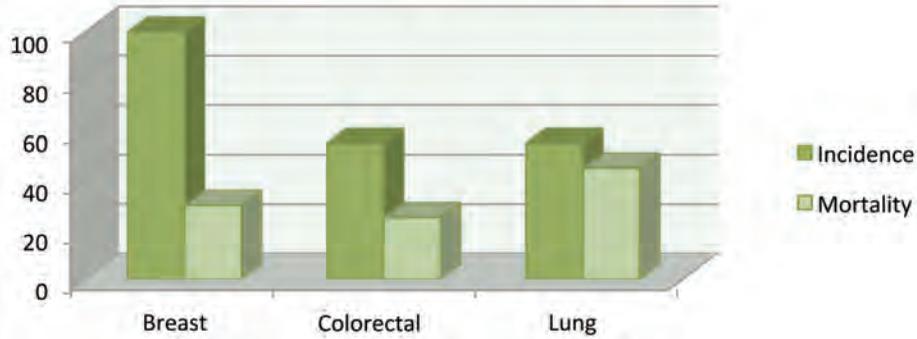


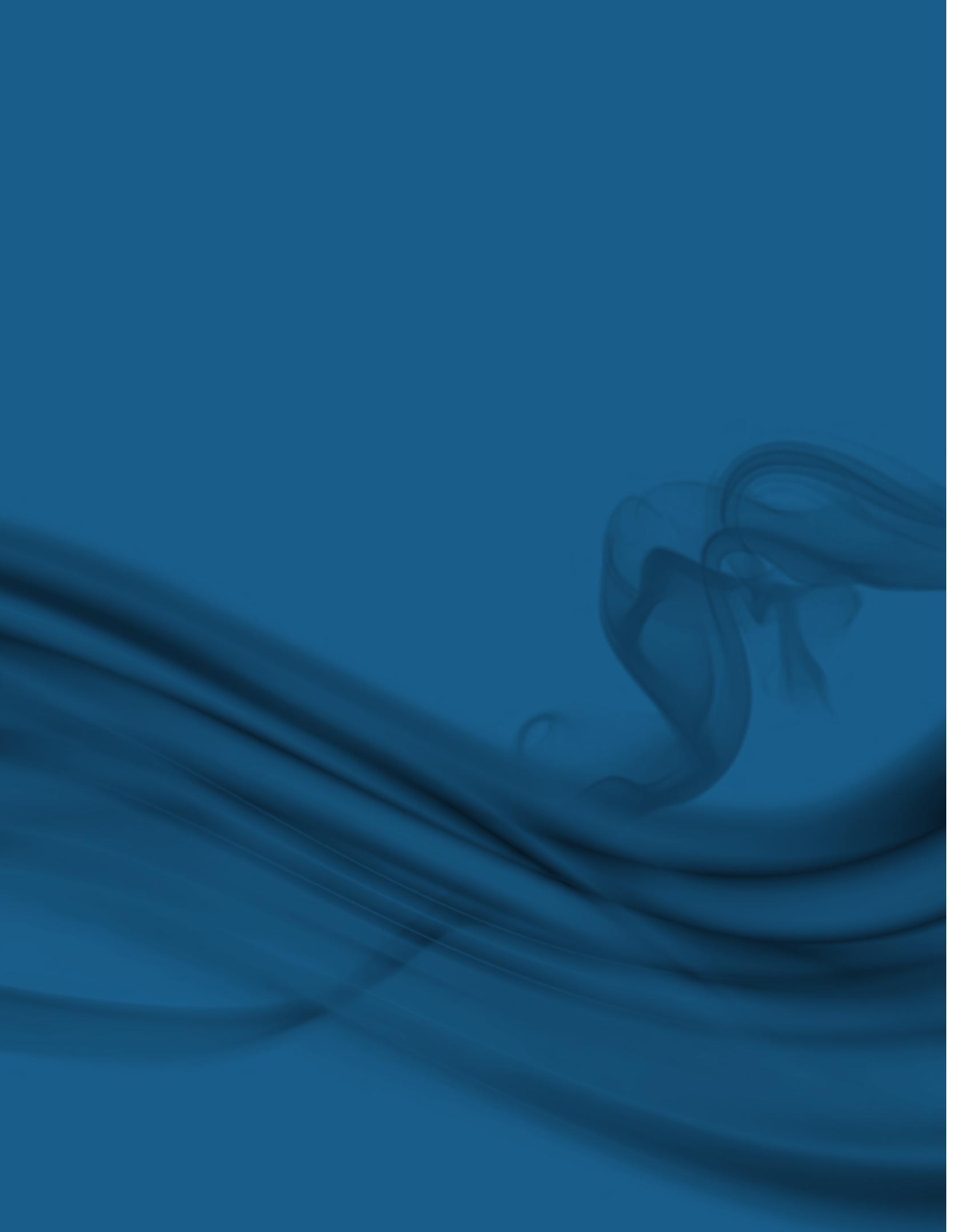
Figure 16.3 Incidence and mortality of the most common cancers for women in Prince Edward Island (estimated for 2011).

16.8 Prince Edward Island Findings

There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0. There are no findings that are unique to Prince Edward Island.

17

STATUS OF PET IMAGING IN NEWFOUNDLAND



17.0

STATUS OF PET IMAGING IN NEWFOUNDLAND

17.1 Introduction

Newfoundland is one of three Canadian provinces that currently does not have a PET scanner (Saskatchewan and Prince Edward Island are the other two). Patients requiring PET examinations are currently sent out of the province to PET facilities at Halifax, Nova Scotia.

In 2009, Demeter et al. produced a report entitled *The Development of a PET/CT Program in Newfoundland and Labrador* which evaluated the evidence for the installation of a PET scanner and cyclotron in Newfoundland. Based on the report, the Newfoundland government has agreed to purchase and install both a PET scanner and a cyclotron to operate out of Memorial University in St. John's. The process is currently being delayed as space is built to house both the scanner and the cyclotron. However, it is hoped that the PET scanner will be operational by 2013–14 and the cyclotron shortly after.

17.2 PET Scanners

There are no private, research or clinical PET scanners currently located in the province of Newfoundland. However, it is anticipated that a publicly-funded, clinical PET/CT scanner will be operational at Memorial University in St. John's by 2013-14.

17.3 PET Scans

The provincial data and calculations shown in Table 7.3 reflect PET statistics obtained for the year 2009. A recent survey of PET facilities confirmed that numbers of scans and costs remained essentially the same in 2010.

In 2009, the province of Newfoundland funded approximately 100 out-of-province scans at a rate of about one to two patients per week. With a current population of 500,000, that translates into a scan per million people ratio of 200 - a number that places Newfoundland last among all provinces. As shown in Figure 7.3, the ratio of 200 scans per million is also substantially below the national average of 1,068 scans per million people.

It is estimated that, once a PET machine is in place, there will be a demand for approximately 870 scans per year (Demeter et al., 2009).

Presently, there is no cap to the number of PET scans that can be funded each year. Patients are currently sent to Halifax, Nova Scotia, and typically have a two to three week wait after referral.

17.4 FDG Availability

This is not applicable at this time, as there is no PET scanner or cyclotron currently operating in Newfoundland.

17.5 PET Funding

Newfoundland pays the PET facility in Halifax a sum of \$1,850 per scan. The money is paid out of a global budget, as there is no fee schedule code at this time. Patients who are eligible may apply for partial reimbursement of their travel and accommodation expenses.

17.6 Provincial Indications

There are no specific indications for obtaining a PET scan in the province of Newfoundland. However, patients must be referred by a specialist and the referral must be accepted by the PET facility at Halifax.

17.7 Newfoundland Cancer Statistics

Cancer continues to be the leading cause of premature death in Canada. As shown in Figure 7.12, the number of new cancer cases (incidence) estimated for Newfoundland in 2011 is 2,750 and the number of cancer deaths (mortality) is estimated to be 1,420. Figure 17.1 shows the incidence of the four most common cancers in Newfoundland – colorectal, prostate, breast and lung. The efficacy of using PET imaging to improve the management of both lung and colorectal cancer patients at various stages of disease has been well established and is recommended in various reviews (Facey et al., 2007; Fletcher et al., 2008; Podoloff et al., 2007; Demeter et al., 2009).

Prostate cancer in men has the highest incidence, followed by colorectal and lung cancer (see Figure 17.2). For Newfoundland women, the most common cancer is breast, followed by colorectal and lung (see Figure 17.3). As shown in Figures 17.2 and 17.3, lung cancer has the highest mortality rate of all cancers in both men and women. All cancer statistics have been reported in Canadian Cancer Statistics (2011).

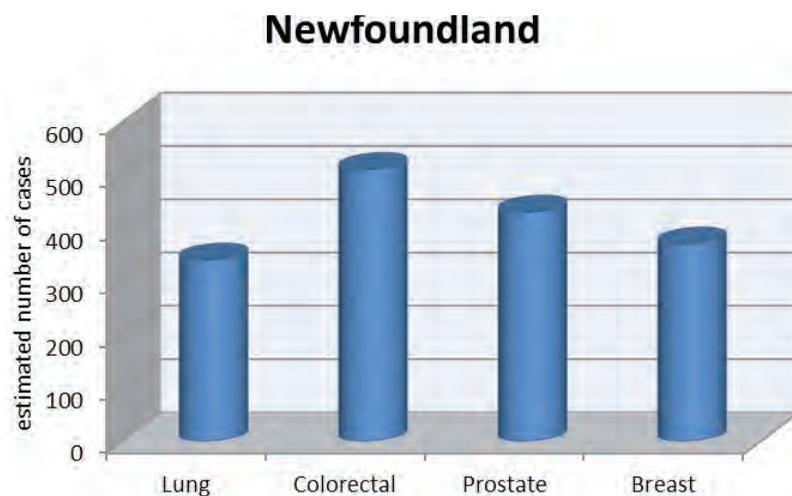


Figure 17.1 Incidence of the most common cancers in Newfoundland (estimated for 2011).

Newfoundland - Men

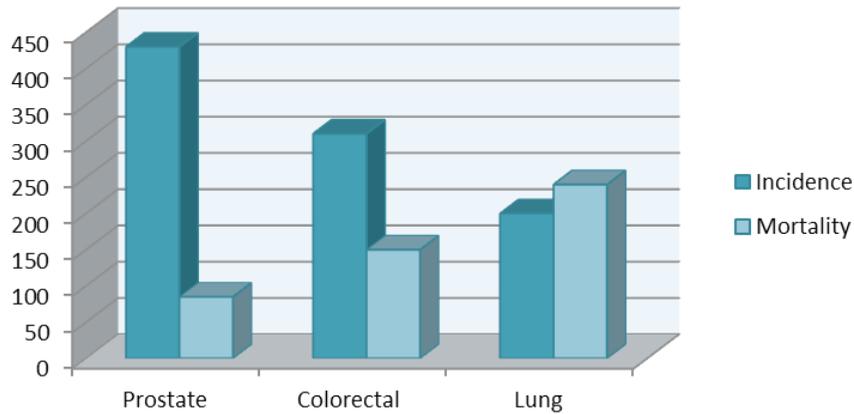


Figure 17.2 Incidence and mortality of the most common cancers for men in Newfoundland (estimated in 2011).

Newfoundland - Women

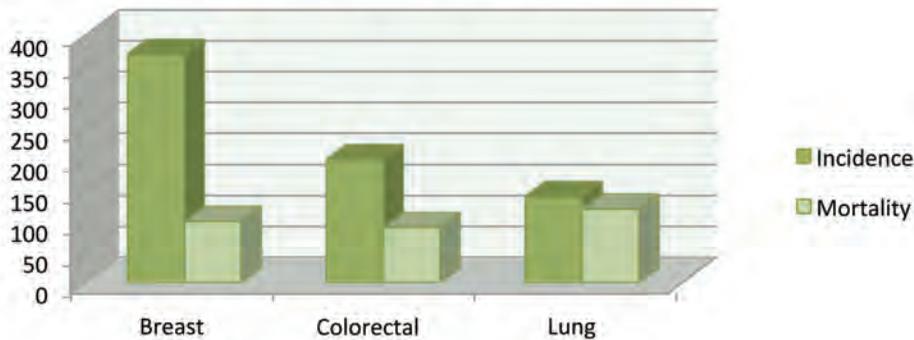


Figure 17.3 Incidence and mortality of the most common cancers for women in Newfoundland (estimated for 2011).

17.8 Newfoundland Findings

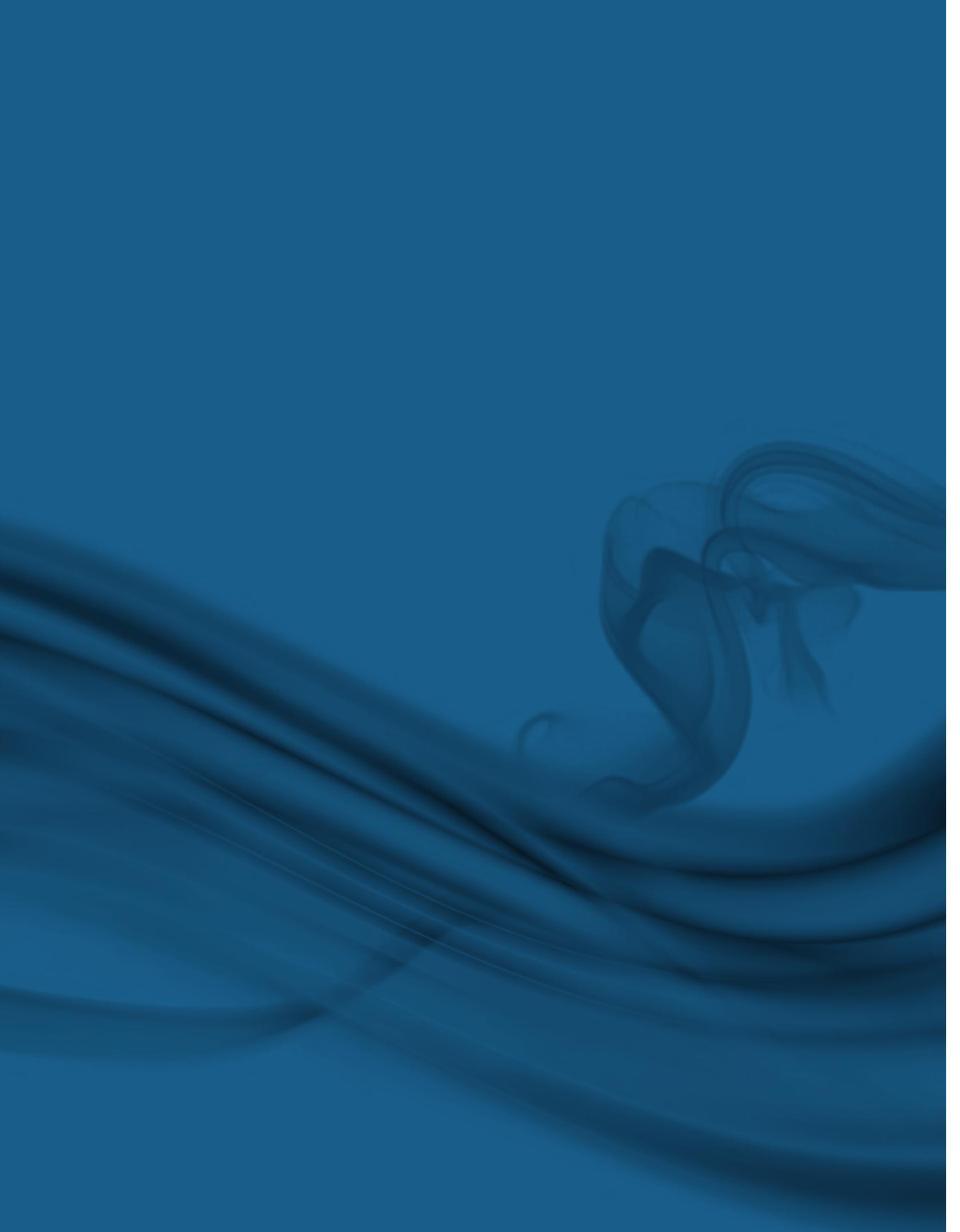
There are a number of issues that are common to every province and impact the success of PET imaging across Canada. These national findings are discussed in Section 18.0.

The following findings relate to the status of PET imaging in Newfoundland:

1. The people of the Maritime provinces will soon be well-served by PET programs. PET scanners are currently located in Halifax, Nova Scotia, and St. John, New Brunswick. Another scanner may soon be operating in Moncton, New Brunswick. Newfoundland is now preparing for the installation of both a PET scanner and a cyclotron and it is expected that the PET will be functional by 2013-14 and the cyclotron shortly after.

18

**FINDINGS: AN
OPPORTUNITY TO
IMPROVE THE CANCER
CARE OF CANADIANS**



18.0

FINDINGS: AN OPPORTUNITY TO IMPROVE THE CANCER CARE OF CANADIANS

Findings that were unique to individual provinces are discussed in the various sections that cover each province. A discussion of this report's findings of national significance that impact the current and/or future status of PET imaging in Canada follows.

18.1 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 measured in terms of its impact on the intended patient management strategy of the physician. Current data suggest that in as many as one-third to one-half of cancer cases, physicians who manage cancer patients by CT- and/or MRI-only may be choosing the 'wrong' management/treatment 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, 38.0 and 49.0% 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), and the large number of cases studied (22,975, 40,863 and 8,240 scans, respectively) suggests that these statistics are highly reflective of the realities of day-to-day oncology practice.

PET imaging allowed physicians to avoid costly and painful surgical biopsies 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.

In as many as 90% of cases, referring physicians indicated that PET 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 used as an initial tool in the diagnostic pathway of an oncology patient, rather than a last resort.

In addition, a recent Canadian study of 3,779 consecutive patients showed that PET imaging resulted in a change in treatment plans in 50% of cases and improved decision-making by physicians in 83% of cases (Worsley et al., 2010).

Treatment decisions that utilize the most appropriate type of patient care result in a better use of limited healthcare resources.

b) Recent economic reviews (Buck et al., 2010; Langer, 2010) 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 both 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 more than 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.

Since better diagnostics lead to better patient management and the more efficient use of healthcare resources, PET imaging appears to lead to a better quality of care for patients and a better utilization of medical services. As a result, PET imaging has become integral to modern oncological 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.

18.2 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.

Canada lags far behind the United States and Europe in terms of its adoption of PET, CT and MRI. 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. (NOTE: In the OECD comparisons, availability is defined as the number of units per million people). For example, while Japan has 92.6 CT scanners per million, Canada has 12. While the United States has 26.5 MRI's per million, Canada has 6.2 (Skinner, 2009).

Similarly, Europe currently has 479 PET installations and that number is expected to grow to 742 by 2013 (MEDEC, 2010). Germany leads with 98 PET scanners, while Italy has 92 and France has 64. The United States has approximately 2,000 PET scanners and a ratio of about 6.5 scanners per million. In comparison, Canada has 29 PET scanners and a ratio of 0.86 scanners per million people. The World Health Organization (WHO) recommends that countries adopt a PET scanner ratio of two scanners per million people (MEDEC, 2010).

A key frustration mentioned in many provinces is that Canada's socialized healthcare system tends to make decisions based on immediate economic benefit, with limited consideration given to long-term economics and benefits for patient management. For this reason, many provinces have chosen to follow Ontario's lead in restricting PET access – even though that decision may not have been made for reasons that are scientifically or morally grounded. In sharp contrast, in 2001, the Quebec government made a decision to make cancer care a priority for its healthcare system. As a consequence, decisions regarding access to PET in Quebec are based solely on a patient's clinical need.

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

Canada 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 WHO. 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 (53%) 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.

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.

This broad deployment of PET scanners stems from a year 2000 decision by the Quebec government to make cancer diagnosis and treatment a priority for its provincial healthcare system. As a part of that decision, it asked AETMIS (Agence d'évaluation des technologies et des modes d'intervention en santé) to review the clinical efficacy of PET technology. The 2001 AETMIS report stated that the clinical efficacy of PET was well recognized in many oncological, cardiological and neurological applications and recommended the gradual deployment of 10 to 15 PET scanners, supplied by three or four cyclotrons, across Quebec. An updated AETMIS report is due in 2011 and it is expected that it will recommend the deployment of more PET scanners.

Given that PET imaging can change the management strategy of cancer patients in, at minimum, 36.5% of cases (Hillner et al., 2008a; 2008b; 2009; Worsley et al., 2010), there is an implication that Quebec cancer patients have a very different standard of cancer care than their counterparts in other Canadian 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 in terms of clinical use; a fact that was confirmed in interviews with Ontario nuclear medicine physicians.

Doctors suggested that the poor clinical utilization was due to Ontario's restrictive PET policies and a low number of referrals from physicians who may be confused by the current status of PET in that province, uncertainty about how to access PET and a restricted list of PET scan indications. In addition, after a decade of controversial PET policies, some doctors may not be aware of the benefit of PET in oncology patients.

Much of the controversy surrounding Ontario PET policies stems from a 2001 report commissioned by the Ontario government. It asked the Institute for Clinical Evaluative Sciences (ICES) to review the scientific literature and make recommendations regarding the use of PET. The resulting

report (ICES, 2001) has served as the foundation for all PET policies in Ontario, yet questions about the validity of the assessment tools utilized by the report – and therefore the results and recommendations of the report – persist a decade later.

The ICES used the health technology assessment (HTA) system to evaluate PET as a diagnostic tool, even though “HTA algorithms ... are totally unsuited to the evaluation of the clinical importance of imaging tests” (McEwan, 2006). Further, McEwan states that HTA ignores the value of PET imaging to the “treatment planning and assessment of response, the reductions in the downstream costs such as saved operations due to upstaging, and the contribution of imaging to diagnostic confidence.” Because of questions about the validity of the assessment tools utilized, the report’s recommendations and resulting policies have been controversial and unsupported by much of the nuclear medicine community in Ontario.

The ICES report (2001) also encouraged Ontario to generate its own evidence for the value of PET by undertaking a series of formal clinical trials to gather data. Five clinical trials were designed and carried out between 2004 and the present, and questions about their legitimacy have persisted since their inception. Many nuclear medicine physicians claimed that the procedures being evaluated had already been widely accepted in other jurisdictions, so it was unlikely that additional evidence would have any impact on PET in other countries or provinces.

Other concerns cited were the length of the trials (some results are still not available six years after trials began) and limited funding that only allowed for 130 patients to be scanned in trials each year.

The Ontario Association of Nuclear Medicine (OANM) questioned the ethics of the lung cancer trials as they deliberately denied PET scans to a group of control patients at a time when it had already been effectively proven in the world literature that PET was the standard of care for management of lung cancer.

Both the OANM and the Canadian Association of Nuclear Medicine called the breast PET trial “unethical” and demanded that the trials be suspended. As mentioned previously, the PET PREDICT trials were established to determine the ability of PET to detect axillary lymph node metastases in newly-diagnosed breast cancer patients with no clinical evidence of disease spread. However, as the OANM points out, the resolution of PET at that time was five to six mm only and it was not capable of detecting the microscopic disease that it was looking for in the trial. In addition, it appears that the patients were not informed that the PET scanner was not capable of detecting the vast majority of potential metastatic disease or that the data analysis tool itself (the HTA) had not been validated for the purposes of this trial. Consequently, patients went through the PET scan and were subjected to radiation to search for something that the PET scanner was not designed to detect.

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

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

18.3.1 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 many cancer care programs integrating PET technology.

FDG is a critical component of PET imaging and the average cost in Canada is \$505 per dose. However, costs vary widely from lows of \$230 and \$350 per dose (Alberta and Quebec) 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 facility. FDG loses one-half of its radioactivity 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.

For that reason, PET facilities generally purchase FDG from the closest FDG producer. New Brunswick is one exception to that rule and the high cost it pays per dose of FDG is the result. The PET facility in St. John currently obtains its FDG from Pharmalogic PET Services in Montreal and it takes from six to eight hours to travel from facility to facility, losing a substantial amount of radioactivity along the way. It would be advisable for St. John to obtain its FDG from the new cyclotron in Halifax and that may be a future possibility that could save significant costs.

FDG costs are also high because availability in Canada is low. At present, there are ten cyclotrons producing FDG across Canada (nine academic and one private; see Table 7.10). 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.

A key challenge is to transition the manufacturing of clinical FDG from research facilities to a nationally-coordinated network of clinical facilities. Currently, a lack of medical cyclotrons means that most FDG in Canada is produced in academic/research centres that sell FDG at prices based on recovering partial costs for the mixed-use and multi-purpose aspects of these facilities. Elevated prices may be necessary to compensate for the additional demands placed on research facilities to produce FDG for clinical use. Using research cyclotrons to produce FDG results in lost time and opportunity for academics to research and synthesize the next generation of radiotracers that are needed to further expand the clinical applications of PET in oncology and other fields. It should also be noted that a full-cost-recovered price for a PET scan at a private clinic is around \$2,500; the cost of acquiring FDG (by purchase or direct production) is a key component but not the dominant expense.

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 strategic cyclotron network that is dedicated to creating FDG for clinical use at PET centres. In addition, allowing private FDG suppliers to operate would protect cyclotrons used for research purposes. This would also provide a cost benefit to PET facilities.

18.3.2 Infrastructure and Policy Framework

- a) Geography and population density are limiting factors in providing PET access to Canadians.

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. As FDG loses half of its radioactivity every two hours, it becomes financially unrealistic to transport it beyond a reasonable distance. Given such logistics, it is impractical to install PET scanners in remote locations unless a FDG source is within reasonable distance.

- 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 CT and MRI examinations), clinical trials are required to prove the safety and clinical efficacy of FDG for certain indications. In Canada, FDG is approved only for lung, breast and colorectal cancer – all other indications require a clinical trial. This means that multiple facilities are running identical scientific trials and collecting redundant data. These trials involve additional bureaucracy, paperwork and costs for PET facilities. In discussions with stakeholders, it was clear that understanding and responding appropriately to the system governing the FDG clinical trials was difficult and created unnecessary bureaucratic burdens. While many believed that the FDG trials were useful at first, they are now considered to be a waste of time and money on an imaging agent that has been proven safe. 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).

It has been shown that regulatory requirements add a minimum of \$196 to the cost of each scan (Chuck et al., 2005). Further, that figure only reflects the cost of personnel and would be much higher if it included the added costs of office space, equipment, data storage and supplies.

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

There is no national PET steering committee to advocate for PET or to create uniform national policies and indications for the use of this technology. Many physicians believe that PET imaging across Canada would benefit from a national PET steering committee composed of nuclear medicine physicians, as well as other stakeholders such as oncologists, thoracic surgeons, radiochemists, and radiopharmacists.

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 focused development of PET technology driven by public-health considerations for 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 initial trials are focused on cardiology and the conventional SPECT isotope Tc-99m.

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

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.

18.3.3 Education and Training

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

Physician groups – 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. The scanning statistics for some provinces demonstrate that the PET equipment is not being optimally utilized. This suggests that doctors are not taking advantage of PET as a diagnostic tool, and many interviewees believe it is due to a lack of knowledge/understanding about PET and how it can benefit oncologic patient care. As an example, refer back to Case #2 in Section 5.3 of this report – the story of a young Saskatchewan oncologist who did not understand the difference between PET and CT imaging and how PET could impact the treatment strategy of his patient.

An informal survey of 14 medical schools across Canada confirmed that the vast majority of undergraduate medical students receive a minimal education in, and exposure to, nuclear medicine. In most cases, the extent of training ranges from zero to three hours. Numerous interviewees blamed outdated curricula at Canadian medical schools for not adequately covering aspects related to new diagnostic technology.

To illustrate the limited understanding that physicians have, it is noted that it is common practice for Canadian doctors to view PET imaging as a diagnostic tool to be utilized when all other means have failed. This practice may prevent doctors from seeing real cost savings and benefits to patient management. The literature described earlier in this report suggests that PET imaging can result in substantial healthcare savings if it is used as an initial diagnostic tool in the diagnostic pathway of an oncology patient, rather than a last resort. It can eliminate the need for further tests and procedures in as many as 90% of cases (Hillner et al., 2009), eliminate costly surgeries in as many as 70% of cases (Hillner et al., 2008a), change treatment strategies in as many as 50% of cases and improve decision-making by physicians in 83% of cases (Worsley et al., 2010).

In some cases, this may compromise patient safety. For example, Ontario PET guidelines dictate that a lung needle biopsy be done first to determine if the patient is a candidate for a PET scan. The lung needle biopsy is a high-risk procedure that can result in serious consequences since it involves sticking a needle into the chest. It is not uncommon to result in collapsed lungs, bleeding that can lead to hospitalization or immediate surgery to control the bleeding. Yet an Ontario cancer patient must be subjected to all this – instead of a routine PET exam – when there is a 70% chance that the single pulmonary nodules are benign. If a physician wants to do a PET scan without a biopsy, he/she has to provide an explanation as to why it is not possible to biopsy the nodule.

The MEDEC (2010) PET Task Force report for Ontario also cites physician education as a concern and calls for clinical information to be disseminated to the Canadian referral base “in a manner that allows the general practitioner, family physician, oncologist or cardiologist to understand the value of this technology...”

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. Most members of the public (82%) 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.

As noted in Section 13.9 (Quebec Findings), 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 movie that became very popular in Quebec in 2003. Through these two events, the people of Quebec became relatively knowledgeable about PET imaging and very aware of critical technology that was missing in their cancer care.

Quebec physicians believe it is absolutely vital that patients/the public understand the value of PET to the diagnosis and treatment of cancer. Many interviewees suggested that the media could/should play a key role in educating Canadians about PET so that they understand it to be a normal standard of care in the management of patients with cancer. Several doctors suggested that a Canadian PET website might be a useful tool in educating a broad range of stakeholders.

The MEDEC (2010) PET Task Force report for Ontario also called for the establishment of a PET Education Task Force to increase the level of awareness among the public, physicians and all relevant parties.

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 to move forward and shape healthcare policies that will enhance the deployment and utilization of PET technology in Canada. The following describe some of the issues that relate to this situation:

Nuclear medicine physicians – The Canadian Association of Nuclear Medicine (CANM) is working hard to promote a pan-Canadian approach to PET based on the Quebec model for PET imaging. Thus far, however, it has had little success. At present, the CANM is composed only of nuclear medicine physicians. Until recently, there was a parallel organization called the Canadian Society of Nuclear Medicine (CSNM) that consisted of nuclear medicine physicians, physicists, chemists and technicians. In late 2010, the CANM determined that nuclear medicine physicians only should be representing, and advocating for, nuclear medicine in Canada and its members essentially voted the CSNM out of existence. However, that move appears to have left the CANM divided and with limited influence as it represents the nuclear medicine community and lobbies governments for PET technology.

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 billing opportunities. This suggests that other medical specialist groups (e.g. surgeons, oncologists and general practitioners) are going to have to join with nuclear medicine physicians to effectively advocate for PET technology across Canada.

Oncologists – It was suggested by many physicians that the oncology community appears to be more interested in obtaining new therapeutic agents than new diagnostic tools. In most provinces, any money spent on PET comes from the same budget that funds treatments and drugs for cancer patients. This emphasis on obtaining treatment tools over PET may reflect years of training and experience in an environment where PET technology has been nonexistent or restricted in terms of access. Consequently, it may mean that oncologists are reluctant to support initiatives that promote PET.

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 the 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 this may be an impediment to 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 imaging equipment and a dispute over which specialty will control this technology. Different spending priorities seem to 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. One physician estimated that radiologists can read (and be paid for) about 30 to 40 CT scans per day. In contrast, they can read only 10 to 15 PET exams per day. Therefore, an increased emphasis on PET imaging would substantially reduce the income of radiologists. According to one physician, “It’s all about billing,” while another commented, “If the public knew about the turf wars, they would march all the doctors off the end of the gangplank.”

Quebec has dealt with this issue by not allowing physicians to practice dual specialties. This has negated the competing interests of radiologists and nuclear medicine physicians that are problematic across the country, particularly in Ontario. It also ensures that only qualified nuclear medicine professionals are interpreting PET examinations. This single policy is seen by many as key to the successful development of the current PET infrastructure in Quebec.

- 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).

18.3.4 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.

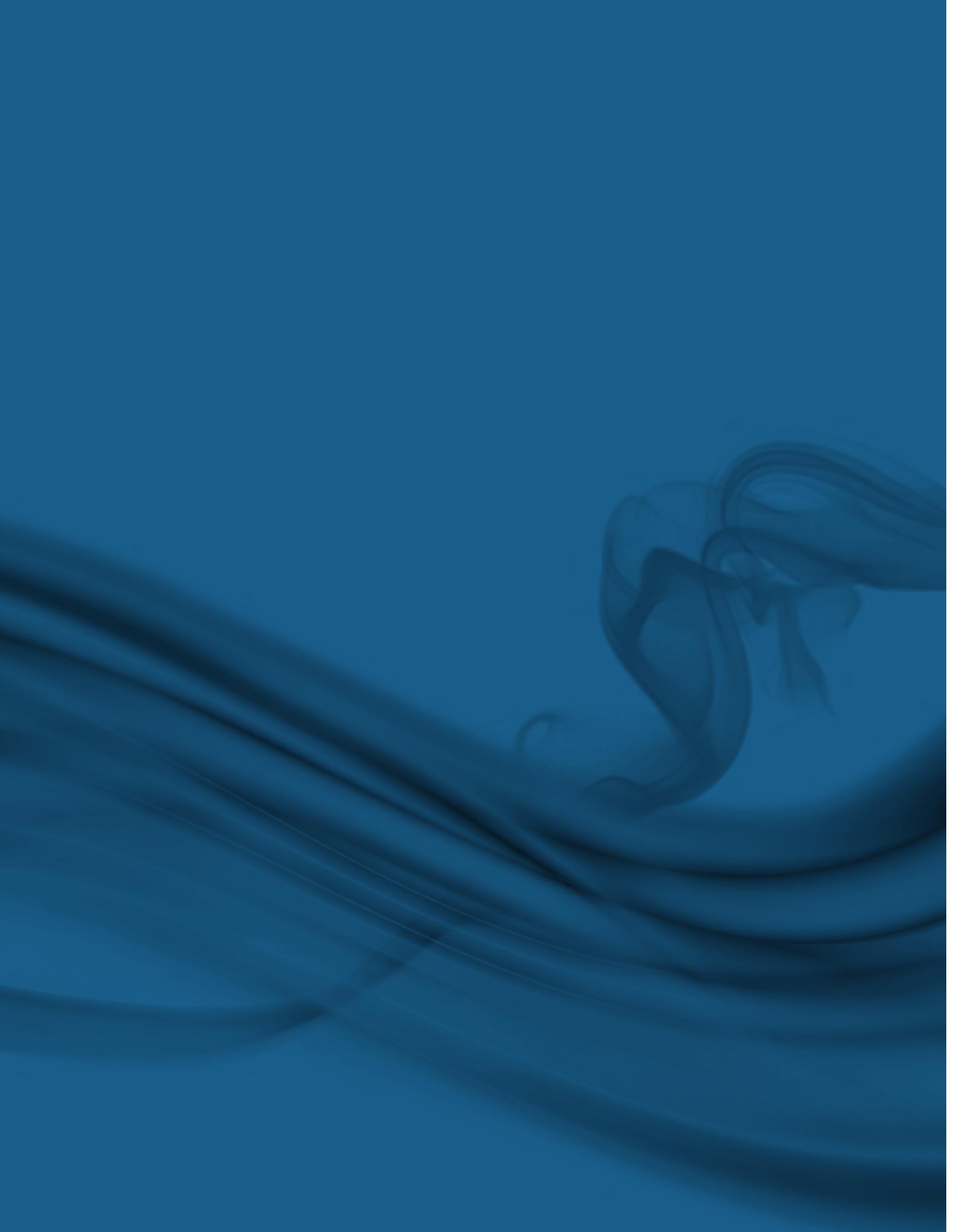
When viewed more broadly, the expansion of PET becomes even more critical to Canada’s leadership in nuclear medicine. Traditional nuclear medicine is based on SPECT/CT scans using conventional isotopes such as Tc-99m. This isotope is still sourced from nuclear reactors that are aging and vulnerable to 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 detect 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 only 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.

19

**CONCLUSIONS: TIME FOR
A NATIONAL STRATEGY**



19.0

CONCLUSIONS: TIME FOR A NATIONAL STRATEGY

There are several constraints confronting the future of PET imaging in Canada. Without intervention, this healthcare technology will likely grow only modestly at the national level, albeit with significant regional variations as noted. The constraints identified by this report include financial costs, access to the PET radiotracer FDG, insufficient training and education within the healthcare delivery system and among healthcare consumers, challenges to building broad advocacy coalitions, Canada's innate dispersed population and a reluctance to accept PET imaging as the normal standard of care for cancer patients.

There is a disconnect between perception and reality as it relates to the cost effectiveness of PET technology. As discussed in Section 6.0 of this report, it is extremely difficult to prove the cost effectiveness of a diagnostic modality. However, economic reviews have demonstrated that PET imaging is cost effective in certain situations, such as lung and colorectal cancer. These cancers are the second and third most common cancers in Canada, and statistics indicate that PET imaging would therefore be cost effective in the management of more than one quarter (26%; Canadian Cancer Statistics, 2011) of Canada's cancer patients.

A national approach is required for Canada to enhance the use of PET technology in cancer care. Examples in the United Kingdom and Australia suggest that a coordinated effort to deal with regulatory policies and standards, capital and operating costs for infrastructure, and an 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 an engaged government working cooperatively with stakeholders to develop and implement a plan for the deployment of PET technology. The following stages are viewed as integral to the successful development of Quebec's PET network over the past decade:

Decision – In the year 2000, the government of Quebec evaluated provincial cancer statistics and decided to make cancer care a healthcare priority.

Consultation – That same year the Agence d'évaluation des technologies et des modes d'intervention en santé (AETMIS) undertook a full assessment of PET technology and recommended the gradual deployment of 10 to 15 PET scanners, supplied by three or four cyclotrons, across Quebec (AETMIS, 2001).

Develop a plan – The Quebec government, in close consultation with the nuclear medicine specialists in Quebec, developed a plan for the gradual deployment of 12 PET scanners in 12 sites around the province.

Generate public interest – As described earlier, the people of Quebec are relatively knowledgeable about PET imaging and its benefits in oncology, particularly when compared to other Canadians. Quebec physicians credit this understanding with creating a positive PET environment in the province.

Cooperation with physicians – Quebec physicians cannot practice dual specialties. This policy has led to the development of a strong provincial association of nuclear medicine specialists that is closely tied to, and in frequent communication with, the provincial government. Their common goals are singularly focused on the development of nuclear medicine within the province.

19.1.1 Costs

A national approach is required to overcome the initial high costs of 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. 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, education of physicians and healthcare consumers.

19.1.2 Infrastructure and Policy Framework

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.

A cyclotron network would further benefit Canadians by accelerating the development of new PET technologies and providing education and training opportunities for professionals and HQP that are required to support a PET infrastructure, including radiochemists, radiopharmacists and imaging physicists.

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.

19.1.3 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.

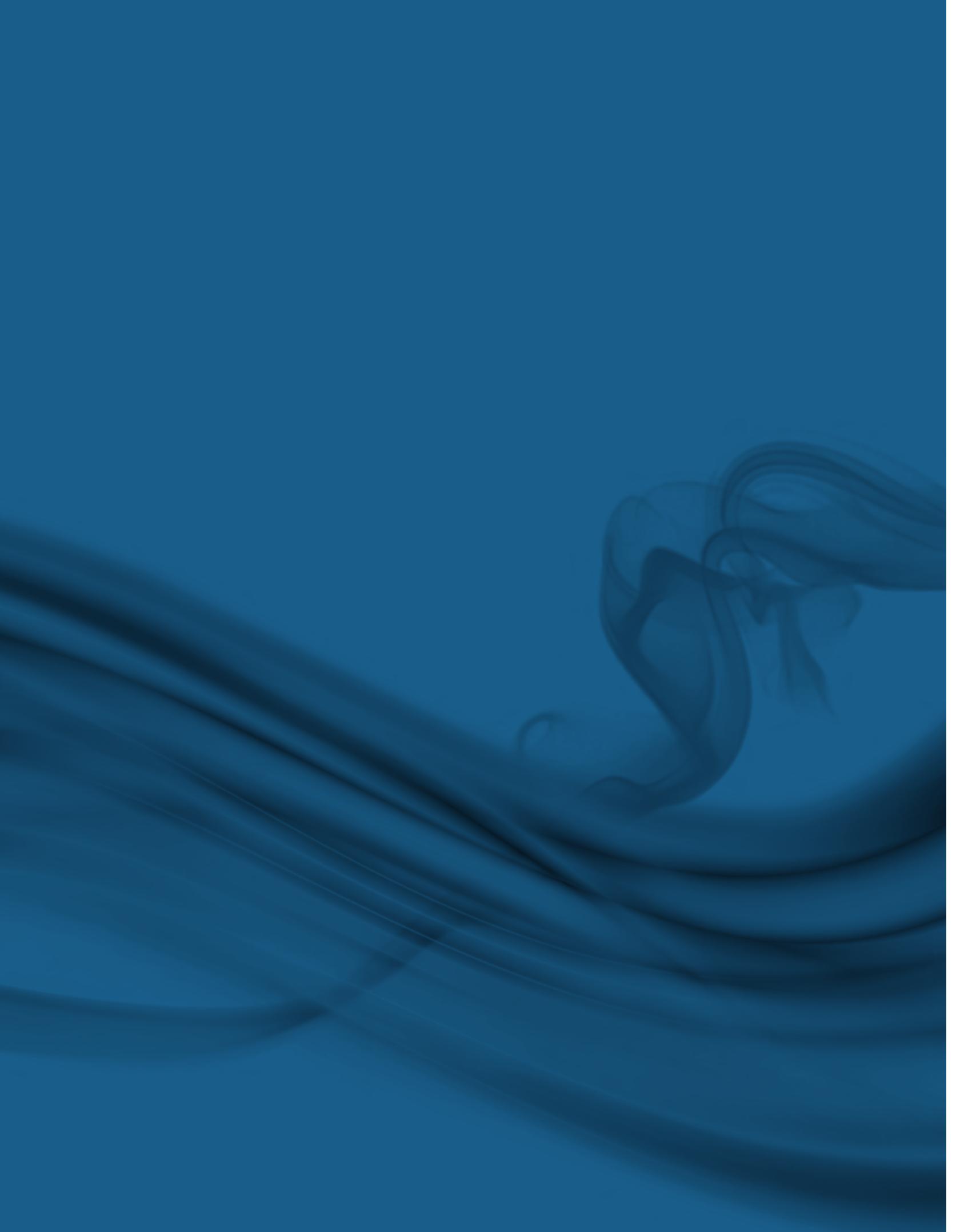
This education campaign could include:

- 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.

20

OUTLOOK





20.0

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.
- Three large-scale, national studies from the United States have shown that PET imaging changes the intended patient management strategy in 36.5%, 38% and 49% of the cases. Results were consistent across all cancer types. A recent Canadian study found that the information derived from PET imaging resulted in a change in intended treatment plans in 50% of cases.

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.

Constraints 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 constraints and reallocate financial resources to nuclear medicine technology.

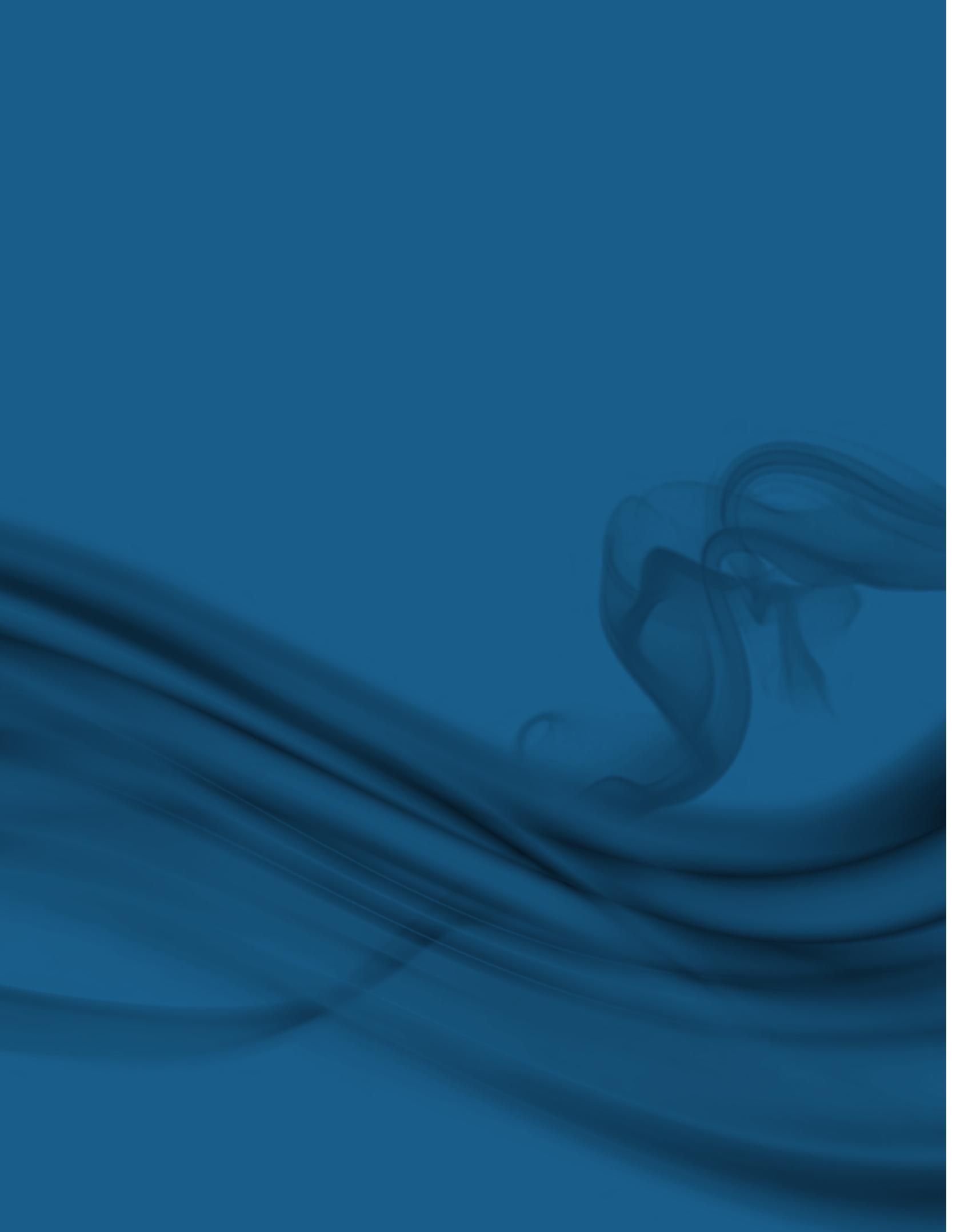
Canada now stands at a crossroads in its adoption and utilization of PET technology. We can move forward and adopt the technology necessary to provide Canadians with the current world standard for cancer care or, alternatively, we can maintain the status quo and fall further behind other Western nations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

The choice is ours.

21

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APPENDICES





APPENDIX A – NAMES OF INDIVIDUALS INTERVIEWED FOR THIS REPORT

The following individuals were interviewed for this report:

British Columbia

Dr. Phil Cohen, Lions Gate Hospital/TRIUMF
Heidi Henderson, Premier Diagnostics
Joe Husar, Premier Diagnostics
Dr. Brian Lentil, Victoria
Dr. David Levy, President, BC Cancer Agency
Dr. John Powe, Vancouver General Hospital, BC Cancer Agency
Dr. Tom Ruth, TRIUMF/BC Cancer Agency
Dr. Don Wilson, Medical Director, BC Cancer Agency
Dr. Dan Worsley, Vancouver General Hospital, BC Cancer Agency

Alberta

Dr. Doug Abrams, Cross Cancer Institute
Lori House, Cross Cancer Institute
Dr. Richard Kloiber, Foothills Hospital
Dr. Sandy McEwan, Cross Cancer Institute
Dr. Steve McQuarrie, Cross Cancer Institute

Saskatchewan

Dr. Edyta Dudzic, Royal University Hospital
Dr. Glenn Ollenberger, Regina Qu'Appelle Health Region
Dr. Colum Smith, Saskatchewan Cancer Agency

Manitoba

Dr. Sandor Demeter, Winnipeg Health Sciences Centre
Dr. Ethan Lynn, Winnipeg Health Sciences Centre
Kathy Suderman, Cancer Care Manitoba

Ontario

Dr. Rob Beanlands, Ottawa Heart Institute
Dr. Martin Charron, Hospital for Sick Children
Dr. Geoff Coates, McMaster University Hospital
Dr. Al Driedger, Victoria Hospital
Dr. Bill Evans, Jurivanski Cancer Center, head of Ontario PET Steering Committee

Dr. Karen Gulenchyn, McMaster University Hospital

Doug Hussey, Princess Margaret Hospital

Dr. Deanna Langer, Cancer Care Ontario

Jillian Ross, Cancer Care Ontario

Dr. Jean-Luc Urbain, St. Joseph's Hospital, former President of the Canadian Association of Nuclear Medicine

Dr. Dave Webster, Sudbury Regional Hospital

Dave Wilson, Princess Margaret Hospital

Quebec

Dr. Christian Cohade, University of Montreal, Hotel Dieu

Dr. Raymond Lambert, Ste. Justine Hospital

Dr. Francois Lamoureux, Santa Cabrini Hospital and head of the Association of Nuclear Medicine Specialists in Quebec

Dr. Robert Lisbona, McGill University, Royal Victoria Hospital

Serge Peloquin, Conseiller Scientifique, Ministry of Health and Social Services

Barry Stein, President, Colorectal Cancer Association of Canada

Dr. Eric Turcotte, University of Sherbrooke Hospital

Nova Scotia

Dr. David Barnes, QEII Health Sciences Centre

Dr. Andrew Ross, QEII Health Sciences Centre

New Brunswick

Dr. Eshwar Kumar, New Brunswick Cancer Network

Dr. Jennifer Martin, St. John Regional Hospital

Newfoundland

Dr. Peter Hollett, Memorial University

APPENDIX B – PET STATUS QUESTIONNAIRE

The following questionnaire was used to collect information from various PET/CT centres around Canada.

1. PET/CT IMAGING

		Response
a)	How many PET/CT scanners are at your facility ?	
b)	List the name, model and specifications of the PET/CT devices in your facility:	
c)	Do you have any PET-only scanners?	
d)	If so, list the name, model and specifications of the PET-only devices in your facility:	
e)	What percentage of scans performed at your facility are related to clinical and research:	Clinical ____% Research ____%
f)	What percentage of all scans performed at your facility are related to oncology?	Oncology ____%

		Response
g)	What is the waiting period for a clinical oncology scan at your facility?	
h)	Do you have a target number of scans per year ? If so, what is the number ? Is that target number adequate for your current and future oncology needs? If not, how many oncology scans are needed per year?	
i)	What factor(s) determine the number of scans done per year?	
j)	How does a patient access a PET/CT scan in your facility?	
k)	What factors determine their eligibility?	

		Response
l)	How were those factors determined? (eg. Cost, number of scanners, personnel)	
m)	How many days per week do you scan oncology patients?	
n)	How many oncology scans do you perform per	Day: ___ Week: ___ Year: ___
o)	Given ideal conditions and adequate funding, how many scans could be done per	Day: ___ Week: ___ Year: ___
p)	How many hours (based on a 24h day) is your scanner not in use per	Day: ___ Week: ___

		Response
q)	<p>What are barriers to doing a greater number of scans? (eg. Costs, FDG availability, personnel)</p>	
r)	<p>What were the barriers in establishing your PET/CT scanning program? (eg. Costs, clinical, regulatory, cyclotron, FDG availability)</p>	

		Response
s)	How many trained personnel are at your facility?	Nuclear medicine physicians _____ Radiochemists _____ Physicists _____ Technologists _____ Other _____
t)	Can you provide to me and data/papers/references on the Clinical Effectiveness of PET/CT? and/or the Cost Effectiveness of PET/CT?	
u)	Did the Chalk River breakdown lead to an increased number of PET/CT scans at your facility?	
v)	Can you provide an estimate of the number or percentage of additional scans?	

2. FDG/CYCLOTRONS

		Response
a)	Where do you get your FDG from?	
b)	How is it transported to your facility?	
c)	How long does it take for the trip from cyclotron to PET/CT facility?	
d)	How often do you receive FDG shipments per	Day _____ Week _____
e)	Can you estimate the percentage of time that you have experienced delivery problems that caused you to change or cancel your scanning schedule? (eg. Late, not shipped, transportation issues)	
f)	How much do you pay per dose of FDG?	\$ _____
g)	Are you currently conducting clinical FDG trials?	

3. ONCOLOGY STATISTICS

		Response
a)	What is the estimated number of cancer cases that come through your facility each year?	
b)	What percentage of those cases receive PET/CT scans?	_____ %

		Response
c)	<p>What kinds of cancer scans are most often performed at your facility? Can you estimate using a percentage?</p>	<p>Head and neck _____ %</p> <p>Brain _____ %</p> <p>Breast _____ %</p> <p>Lung _____ %</p> <p>Lymphoma _____ %</p> <p>Gastrointestinal _____ %</p> <p>Sarcoma _____ %</p> <p>Colorectal _____ %</p> <p>Esophagus _____ %</p> <p>Gynecological _____ %</p> <p>Melanoma _____ %</p> <p>Others _____ %</p>

		Response
d)	By percentage, what are the indications for your PET/CT scans?	<p>Diagnosis _____ %</p> <p>Staging/Re-staging _____ %</p> <p>Assessment _____ %</p> <p>Response to therapy _____ %</p>
e)	How did your facility determine the indications for which PET/CT should be used?	

		Response
f)	<p>Are you aware of the 2010 Vancouver General Hospital study showing that PET/CT scans changed treatment decisions in 50% of oncology cases and improved decision making in 83% of cases?</p> <p>Do you know or can you estimate how often did PET/CT scans lead to a change in treatment protocol (by percentage) or improved care (by percentage) in your facility?</p>	<p>Change in treatment protocol ____%</p> <p>Improved care ____%</p>

4. FUNDING

		Response
a)	How many PET/CT scans does your provincial government cover per year	in province? out-of-province?
b)	How much does the government pay per	in-province scan ? out-of-province scan ?
c)	Is government funding made through a global budget or per scan? If a global budget, what is it?	
d)	What is your facility's cost per scan?	
e)	If you send patients outside of the province, where are they sent?	
f)	Is current funding adequate for oncology PET/CT scanning?	
g)	Ideally, how much funding is needed per year for oncology PET/CT scanning?	

5. GENERAL QUESTIONS

		Response
a)	Why is PET/CT not everywhere across Canada as in the United States?	
b)	What are the key LIMITATIONS to having more PET/CT scanners?	
c)	How do you view the current status of PET/CT across Canada? Where is it heading?	
d)	How do you view the current status of PET/CT in Canada compared to other countries?	

		Response
e)	What is driving changes in PET/CT scan policies across Canada?	
f)	<p>In your view, what would enhance the penetration of PET/CT scanners within your province ?</p> <p>Within Canada ?</p>	
g)	Do you have other information that you would like to share and which you consider to be relevant to this report but has not been included in this questionnaire ?	

Questionnaire for PET/CT facilities across Canada:

NAME: _____ Title: _____
PLEASE PRINT

ORGANIZATION: _____

Address: _____

DATE: _____

APPENDIX C – PROVINCIAL INDICATIONS FOR PET SCANS

BC CURRENT ADULT CLINICAL INDICATIONS FOR PET/CT SCANNING

(as of September 19, 2007)

PET/CT scanning for adults at the BC Cancer Agency is done under a Clinical Trial Agreement with Health Canada. The numbers and types of patients that can be scanned will be limited by operational capacity and approved indications. The currently approved indications were developed in consultation with provincial tumour groups and are within the framework of the evidence based BCCA guidelines for FDG-PET. PET/CT referrals are currently being accepted at our facility for the following indications in adult oncology patients:

1. Non-Small Cell Lung Cancer
 - a) Staging of patients with clinical stage I and IIA lesions
 - b) Staging of potentially resectable stage IIB and III disease
2. Lymphoma
 - a) To plan duration of chemotherapy for patients with limited stage (IA or IIA, non-bulky) Hodgkin's Lymphoma
 - b) To plan duration and type of treatment for limited stage (IA or IIA, non-bulky) aggressive histology (diffuse large B cell, mantle cell, peripheral T cell) lymphoma
 - c) Post-chemotherapy for patients with advanced stage aggressive non-Hodgkin's lymphoma (including primary mediastinal large B cell lymphoma) and Hodgkin's lymphoma with residual CT abnormalities or initial bulky (bulky = 10cm or larger in any single diameter) disease to assess need for radiation therapy
3. Head and Neck Cancer (non-CNS, non-thyroid)
 - a) Diagnosis of primary site in patients presenting with squamous cell carcinoma metastatic to cervical lymph nodes with no obvious primary on conventional work-up
 - b) Staging in patients with nasopharyngeal carcinoma and N2 or N3 nodal disease
 - c) Staging in patients with level IV cervical lymph node metastases
 - d) Diagnosis of suspected recurrence in the absence of other definitive evidence in patients being considered for salvage therapy
 - e) Evaluation of cervical lymph nodes in patients for whom radical neck dissection is a part of the treatment plan for advanced primary disease
4. Colorectal Carcinoma
 - a) Determination of stage in patients with potentially resectable recurrence
5. Testicular Carcinoma
 - a) Post-treatment evaluation of residual masses
6. Gynecologic Cancer
 - a) Staging of recurrent disease in patients being considered for pelvic exenteration. Referrals for other clinical oncology indications will be considered on an individual basis as capacity permits.

BC CURRENT PEDIATRIC CLINICAL INDICATIONS FOR PET/CT SCANNING

(as of September 19, 2007)

PET/CT scanning for children at the BC Cancer Agency is done under a Clinical Trial Agreement with Health Canada. The numbers and types of patients that can be scanned will be limited by operational capacity and approved indications. The currently approved pediatric indications were developed in consultation with provincial tumour groups and are within the framework of the evidence based BCCA guidelines for FDG-PET. PET/CT referrals are currently being accepted at our facility through BC Children's Hospital for the following indications in pediatric oncology patients:

1. Lymphoma

- a) For initial staging of patients to determine extent of disease.
- b) To determine response to chemotherapy or radiation therapy.
- c) Post-chemotherapy for patients with advanced stage aggressive non-Hodgkin's lymphoma and Hodgkin's lymphoma with residual CT abnormalities or initial bulky disease.
- d) To plan duration of chemotherapy for patients with Hodgkin's and non-Hodgkin's lymphoma.
- e) To plan duration and type of treatment for limited stage aggressive histology lymphoma.

2. Sarcoma

- a) To evaluate the primary soft tissue mass prior to biopsy to identify high grade areas and guide biopsy.
- b) For staging of locally advanced high grade soft tissue sarcomas.
- c) For detection of suspected local recurrence of soft tissue sarcoma after definitive treatment.
- d) For staging of Ewing's sarcoma.
- e) For initial staging and evaluation of potential recurrence in osteogenic sarcoma.

3. Neuroblastoma

- a) For evaluation of extent of viable tumour tissue in primary tumour.
- b) For staging and disease evaluation of MIBG-negative tumours.
- c) Post-treatment, to evaluate residual mass or primary site for recurrent or residual tumour, particularly if conventional studies are not helpful or equivocal.
- d) Post-treatment or marrow transplantation, to evaluate for local recurrence or distant metastases.

4. Brain

- a) To evaluate for recurrent tumour.
- b) To differentiate between recurrent tumour and post-treatment necrosis.
- c) For localization of areas of high grade disease to guide biopsy and treatment planning.

5. Thyroid Carcinoma

- a) For detection and localization of suspected recurrence after definitive therapy, in patients with elevated or rising thyroglobulin levels and negative radioiodine scan (papillary and follicular carcinomas).

6. Other cancers given specific clinical indications, as approved by the investigator at the site, on an individual basis.

It is well recognized in clinical practice that there may be clinical scenarios that do not meet specific guidelines but where expert medical opinion indicates the procedure could have a major impact on patient management. PET scan referrals in these cases will be reviewed on an individual basis by physician representatives from the appropriate Provincial Tumour Group and the Functional Imaging department. If approved by consensus, the patient will be offered participation in the study.

ALBERTA CLINICAL INDICATIONS FOR PET

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
Epilepsy	Diagnosis of recurrence Refractory; potential surgical candidate

Indications for PET/CT from Foothills Medical Center (Calgary, AB) 2010

Oncology: Neoplasm of the following systems or anatomic regions (the most common indication(s) are shown in brackets):

1. Hematopoietic System

- a) Hodgkin's Lymphoma (primary staging, therapy / disease monitoring, restaging / local recurrence, radiotherapy planning)
- b) Non-Hodgkin's Lymphoma (primary staging, therapy / disease monitoring, restaging / local recurrence, radiotherapy planning)
- c) Multiple Myeloma (primary staging, therapy / disease monitoring, restaging / local recurrence)

2. Central Nervous System

- a) Brain (local recurrence, grading / biopsy site selection)

3. Head and Neck including Thyroid

- a) Head and Neck (primary staging, therapy / disease monitoring, restaging / local recurrence, radiotherapy planning)

- b) Thyroid (distant metastases, elevated tumour markers, pre-surgical assessment, radiotherapy planning)

4. Thorax

- a) Lung (primary staging, therapy / disease monitoring, restaging / local recurrence, pre-surgical assessment, radiotherapy planning)
- b) Mesothelioma (primary staging, restaging / local recurrence, presurgical assessment, radiotherapy planning)

5. Gastro-Intestinal

- a) Esophagus (primary staging, therapy / disease monitoring, restaging / local recurrence, pre-surgical assessment, radiotherapy planning)
- b) Stomach (distant metastases)
- c) Gastro-Intestinal Stromal Tumour - GIST (primary staging, therapy / disease monitoring)
- d) Colorectal (restaging / local recurrence, distant metastases, presurgical assessment, radiotherapy planning)
- e) Pancreatic (primary staging, restaging / local recurrence, distant metastases)
- f) Hepatocellular (distant metastases)
- g) Cholangiocarcinoma (initial detection / staging)

6. Musculoskeletal system

- a) Bone Sarcomas (therapy / disease monitoring, restaging / local recurrence)
- b) Sarcoma (grading / biopsy site selection, primary staging, therapy / disease monitoring, restaging / local recurrence, pre-surgical assessment, radiotherapy planning)

7. Breast

- a) Breast Cancer (restaging / local recurrence, distant metastases, radiotherapy planning)

8. Dermatologic System

- a) Melanoma (restaging / local recurrence, distant metastases, presurgical assessment for metastases)
- b) Squamous cell (restaging / local recurrence, distant metastases, presurgical assessment for metastases)

9. Neuroendocrine

- a) Neuroendocrine tumours other than MTC (ancillary role in primary staging, therapy / disease monitoring, restaging / local recurrence, elevated tumour markers)

10. Gynecologic Malignancies

- a) Endometrial Cancer (distant metastases)
- b) Ovarian Cancer (elevated tumour markers, pre-surgical assessment)
- c) Cervical Cancer (primary staging, restaging / local recurrence, presurgical assessment for metastases)

11. Urinary and Male Genital Tract

- a) Renal (distant metastases, local recurrence)
- b) Transitional cell (distant metastases)
- c) Prostate (no routine indications)
- d) Testicular (primary staging, therapy / disease monitoring, restaging)

12. Primary Unknown

- a) Primary Unknown (staging)

13. Masses - benign vs. malignant

- a) Pulmonary Nodule > 8mm
- b) Solid Liver Mass
- c) Solid Splenic Mass
- d) Adrenal, pancreatic or other masses not readily amenable to biopsy

ONTARIO INSURED INDICATIONS (PET SCANS ONTARIO)

<https://lwww.petscansontario.ca/cms/One.aspx?portalId=69866&pageId=69897>

Solitary Pulmonary Nodule (SPN): a lung nodule for which a diagnosis could not be established by a needle biopsy due to unsuccessful attempted needle biopsy; the SPN is inaccessible to needle biopsy; or the existence of a contra-indication to the use of needle biopsy.

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 or equivocal.

Germ cell tumours: where recurrent disease is suspected on the basis of elevated tumour marker(s) - (beta human chorionic gonadotrophin (HCG) and/or alpha fetoprotein) and standard imaging tests are negative, or a mass persists after primary treatment for seminoma and curative surgical resection is being considered.

Colorectal cancer: where recurrent disease is suspected on the basis of an elevated and/or rising carcinoembryonic antigen (CEA) level(s) during follow-up after surgical resection but standard imaging tests are negative or equivocal.

Lymphoma: for the evaluation of residual mass(es) following chemotherapy in a patient with Hodgkin's or non-Hodgkin's lymphoma when further potentially curative therapy (such as radiation or stem cell transplantation) is being considered; or for the assessment of response in early stage Hodgkin's lymphoma following two (2) or three (3) cycles of chemotherapy when chemotherapy is being considered as the definitive single modality therapy.

Non-small cell lung cancer: where curative surgical resection is being considered.

Clinical stage III non-small cell lung cancer: where potentially curative combined modality therapy with radical radiotherapy and chemotherapy is being considered.

Limited disease small cell lung cancer: where combined modality therapy with chemotherapy and radiotherapy is being considered.

Ontario Indications Eligible for Reimbursement through the Ontario PET Registry

Esophageal cancer: for the staging of patients who are being considered for potentially curative therapy (esophagectomy + neoadjuvant chemotherapy).

Pancreatic cancer: for staging if the patient is a candidate for potentially curative surgical resection (pancreatectomy) as determined by conventional staging.

Melanoma: for the staging of melanoma patients with localized "high risk" tumours with potentially resectable disease; or for the evaluation of patients with melanoma and isolated metastasis at the time of recurrence when metastectomy is being contemplated.

Testicular cancer: for the assessment of completeness of responses in patients with seminoma and residual mass(es) after chemotherapy/radiotherapy and biopsy is not possible or is inconclusive.

NOVA SCOTIA INDICATIONS FOR PET/CT

Breast: Evaluation of recurrence/residual disease, distant metastases (staging/restaging) and disease/therapeutic monitoring

Colorectal Evaluation of recurrence/restaging, distant metastases and disease/therapeutic monitoring

Lung Diagnosis of single pulmonary nodule, staging distant metastases, recurrence/restaging and disease/therapeutic monitoring

Head and neck diagnosis of occult and synchronous tumours and recurrence/restaging and radiation planning

Lymphoma staging, restaging and monitoring

Esophageal, staging, restaging and monitoring

Melanoma recurrence/restaging, distant metastases

Thyroid limited to recurrent disease not confirmed by ¹³¹I scintigraphy

Pancreas staging or disease recurrence

Other individual cases with a diagnostic or management dilemma may be approved on a case by case basis by MSI.

NEW BRUNSWICK INDICATIONS FOR PET/CT

Colorectal cancer

Lung cancer

Lymphoma

Esophageal cancer

Pancreatic malignancy

Testicular cancer

Musculoskeletal (bone mets with unknown primary tumour)

Head and neck cancer

Ovarian cancer

Melanoma

Thyroid cancer

Breast cancer

Brain

Neuroendocrine tumours

QUEBEC CANCER INDICATIONS FOR PET/CT (APPROVED 2005)

Cancer du sein

Clarification du bilan d'extension quand les autres examens sont équivoques

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

Évaluation de la réponse au traitement

Cancer du poumon

Caractérisation du nodule pulmonaire indéterminé

Bilan d'extension

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

Cancer de l'oesophage

Bilan d'extension

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

Cancer colorectal

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

Évaluation de la réponse au traitement

Clarification du bilan d'extension quand les autres examens sont équivoques

Cancer colorectal (suite)

Évaluation de métastases hépatiques

Lymphome

Bilan d'extension

Évaluation de la réponse au traitement

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

Mélanome

Bilan d'extension métastatique (stade III AJCC)

Évaluation d'une récurrence si une chirurgie est planifiée

Cancers ORL

Bilan d'extension

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

Recherche de primaire inconnu en présence de métastases cervicales

Cancer de la thyroïde

Évaluation d'une récurrence lorsqu'il existe des signes d'appel et que la scintigraphie à l'iode est négative

Évaluation d'une récurrence d'un carcinome médullaire lorsqu'il existe des signes d'appel

Cancer du col utérin

Bilan d'extension

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

Évaluation de la réponse au traitement

Cancer de l'ovaire

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

Évaluation de la réponse au traitement

Cancer du testicule

Bilan d'extension

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

Évaluation de la réponse au traitement

Cancer du pancréas

Évaluation des masses pancréatiques

Bilan d'extension d'un cancer du pancréas

Sarcomes

Détection d'une récurrence

Bilan d'extension

Cancer du rein

Évaluation d'une récurrence lorsqu'il existe des signes d'appel

APPENDIX D – TERMS OF REFERENCE FOR ONTARIO’S PET STEERING COMMITTEE



ONTARIO STEERING COMMITTEE FOR POSITRON EMISSION TOMOGRAPHY (PET) EVALUATION ("PET Steering Committee") TERMS OF REFERENCE

Objective

To assist the Ministry of Health and Long-Term Care ("Ministry") in making decisions regarding new indications for PET* scanning and the introduction, diffusion, and provision of PET scanning in Ontario by providing timely advice based on quality evidence.

Membership (15-25)

One member may cover more than one area of expertise and/or representation.

Nuclear medicine physician who performs PET (2-3)

Radiologist who performs PET (2-3)

Physician who performs cardiac PET (1)

Physicians who refer patients for PET, at least one from each category (4-6):

- Oncologist
- Pediatric oncologist
- Cardiologist
- Neurologist
- Additional categories to be added as evidence for PET in other disease states emerges

Individuals with experience/expertise in:

- Health technology assessment (1)
- Health services research (1)
- Radiopharmaceuticals (1)
- PET instrumentation and PET quality control (1)
- Clinical trial design (2-4)

Senior hospital administrator from PET centre (1)

Senior representatives (total 4-6) from

- Cardiac Care Network
- Cancer Care Ontario
- Pediatric Oncology Group of Ontario
- Each organization conducting studies funded by Ontario's evidence-based PET program (e.g. OCOG)
- Ministry, Provincial Programs Branch, Health Systems Accountability and Performance Division (1, non-voting)

Chair of each Sub-Committee

Members are required to have a commitment to and experience with evidence-based medicine and interpretation of quantitative data.

Effort will be made to ensure province-wide geographical representation.

Responsibilities

Oversee Evaluation of Clinical Effectiveness

1. Advise on processes to facilitate the evaluation of the clinical effectiveness of PET in Ontario in order to acquire high quality evidence necessary for the Ministry to make informed decisions regarding the assignment of PET as an insured service. The evaluation is to utilize the most cost-effective mechanism, including review of the scientific literature and, when warranted, Ontario-based clinical trials and real-world evaluation (e.g. "registries").
2. Advise on the indications to be studied in clinical trials and other evaluations funded by Ontario's evidence-based PET program (PET Scans Ontario). Set priorities for evaluation, endorse research questions, and ensure appropriate study design.
3. Ensure that all evaluations undertaken at the direction of the PET Steering Committee are completed in a timely fashion and are of high quality through compliance with principles, policies, and procedures endorsed by the Committee, which may include:
 - Quality assurance policies and procedures
 - Rules for termination of studies
 - Policies relating to protection of intellectual property, authorship and publication of results, while recognizing that the committee will, in no way, restrict publication of trial results.
 - Data quality
4. Monitor the progress and outcomes of any evaluations undertaken at the direction of the PET Steering Committee. Provide feedback as appropriate, and facilitate resolution of problems that might arise during the evaluation.

Monitor Evidence

5. Continually monitor the published research evidence on PET in order to provide advice to the Ministry and to ensure that the evaluation process continues to be relevant.

Provide Advice to the Ministry

6. Examine and make recommendations on issues relating to PET access in the province, including the availability and location of cyclotron facilities, supply of radiopharmaceuticals, the distribution of PET/CT scanners across the province, and other issues that may be raised by the Ministry from time to time.

7. Make timely recommendations to the Ministry when quality evidence supports the routine funding of PET for clinical use for specific indication(s) or the removal of a specific indication from the insured program.

Advise the PET Access Program

8. Provide advice on policies and processes related to the operation of the PET Access Program.

Provide Research Leadership

9. Provide leadership to encourage and facilitate the development of national and international strategies for PET research through collaboration; identify new foci of PET research.

Review and Approve Reports

10. Guide preparation of and endorse reports from Ontario's evidence-based PET program including:
 - Recommendations for PET as insured services
 - Recommendations for modifications to distribution and access to PET

Attendance

Attendance at each meeting is critical due to the time-sensitive nature of the Committee's work and the importance of having representatives from each area of expertise for decision-making. In an effort to facilitate attendance, meetings will be scheduled a minimum of 3 months in advance. Should a member be unable to attend, he/she is accountable for assigning a delegate with appropriate expertise to attend on his/her behalf (no more than 2 consecutive meetings, 3/year). Delegates must be pre-approved by the Chair.

Sub-Committees

Sub-committees and working groups may be struck at the call of the Chair as needed to fulfill the Committee's work. For example, disease specific sub-committees may be required to ensure appropriate specialist input beyond what can be achieved through Steering Committee membership alone. Establishment of a sub-committee must be approved by CCO VP Clinical Programs and Quality Initiatives or delegate from the perspective of ensuring sufficient secretariat support can be made available.

Term

The Chair and members will serve staggered renewable three year terms. The term may be extended if no suitable new candidate is available following a search process, and the Member in question is willing to continue.

Appointment Process

Senior representatives as outlined in "Membership" will be appointed by the CEO or equivalent of the organization in question. The Committee Chair and remaining members will be appointed by the CCO VP Clinical Programs and

Quality Initiatives, with input from a selection committee that includes the organizational representative members of the Committee.

Reporting

The Committee reports to the Board of CCO, via the VP Clinical Program and Quality Initiatives.

Decision Making

Quorum (2/3 membership) is required for all decisions. Decisions will be made by consensus. If consensus cannot be reached, the method to arrive at a decision will be at the call of the Chair.

Support

Secretariat support to the committee will be provided by Cancer Care Ontario. This support includes evidence-review conducted by the Program in Evidence-Based Care.

Meeting Frequency

Meetings will be held monthly. A meeting may be cancelled at the call of the Chair if there are no issues on the agenda as of two weeks in advance of the meeting. A minimum of 6 meetings will be held each year.

**For the purposes of this document PET refers to PET and/or PET-CT scanning*

APPENDIX E

BIOGRAPHICAL SKETCH OF AUTHOR

Susan D. Martinuk is a freelance writer and speaker on public policy issues and current affairs. Susan is a columnist with The Calgary Herald and has published over 1000 editorial columns in major newspapers across Canada. She has been a frequent contributor to The National Post and her weekly column was featured on the editorial pages of The Province for over 10 years. She has been a syndicated columnist for Hollinger's Sterling News Service and, for five years, hosted a Vancouver radio talk show on social and political issues.

She typically weighs in on such "hot" topics as bioethics (including reproductive, medical and biotechnologies), labour disputes, controversial cultural issues related to societal and political change (aboriginal issues, women's and human rights, healthcare reform, The United Nations, etc.) and issues related to a diminished knowledge of Canadian history.

Susan was formerly a successful researcher in reproductive technologies and infertility. In 1990, she and her colleagues were credited with pioneering a world-first medical breakthrough – the first to visualize and record human ovulation. She received a number of awards and authored numerous scientific publications before personal ethical concerns led her to resign from her Ph.D. studies at an infertility clinic.

Since then, Susan has written and spoken extensively across Canada on issues related to new medical technologies. She is a past member of The Canadian Bioethics Society and has consulted with groups on the ethical implications of the human genome project, as well as on the development of commercial biotechnology projects.

For four years, Susan worked with The Dominion Creative Group to create history education projects for The Dominion Institute (a Toronto-based organization dedicated to promoting Canadian history). She has also worked with the Centre for Cultural Renewal, a public-policy think tank.

She continues to speak nationally on issues related to biotechnology and public policy, and her presentations have made her a frequent speaker at conferences.



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

Time for a National Strategy

