

What's in a Scan?

How well are consumers informed about the benefits and harms related to screening technology (CT and PET scans) in Canada?

By Alan Cassels

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› March 2009



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ISBN 978-1-897569-43-6

This report is available free of charge from the CCPA website at www.policyalternatives.ca. Printed copies may be ordered through the National Office for a \$10 fee.

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Acknowledgements

The authors wish to thank the following for their helpful feedback and review of this paper: Hans Brown, Frances Bryan, Dr. Rick Hudson, Seth Klein, Dr. Brian Lentle, Dr. Joel Lexchin, Malcolm Maclure, Tim Sheaff, and Miriam Sobrino.

The authors also would like to thank the following people for their contributions through interviews and research assistance: Dr. Denise Aberle, Dr. Amanda Burls, Dr. William Casarella, Dr. Joann Elmore, Lisa Garcia, Dr. Mario Garcia, Dr. Peter Gotzsche, Dr. Gordon Guyatt, Dr. Nortin Hadler, Dr. Irwin Hinberg, Dr. Judy Illes, Patricia Lau, Dr. Barnett Kramer, Dr. Brian Lentle, Heather Logan, Dr. Raymond Miralbell, Maryann Napoli, Dr. Harald Ostensen, Dr. Rita Redberg, Dr. Lisa Schwartz, Dr. Silvana Simi, Laura Swaney, Dr. David Vickar, Dr. Gilbert Welch and Dr. Steve Woloshin.

Funding of the research on which this report was based was received from Industry Canada's Contributions Program for Non-Profit Consumer and Voluntary Organizations.

The content, opinions and any errors contained in this report are solely the responsibility of the authors. The views expressed in the report are not necessarily those of the CCPA, Industry Canada or the Government of Canada.

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Executive Summary

Background:

Private medical imaging companies in Canada are marketing health screening services to consumers, and yet the impacts of such screening have not been well studied. When used as tools to diagnose illness, CT (computed tomography) or PET (positron emission tomography) machines can be invaluable aids in determining a patient's best treatment options. But when otherwise healthy people become convinced of the benefits of "pre-disease" screening and pay to have heart, lung, or full body scans performed, they are entering a health-care marketplace that offers very few protections. Screening tests being promoted to Canadian consumers are often marketed under the pretence that such screening can "save your life" despite the fact that neither the scientific literature nor professional or regulatory bodies condone such practices. The potential for false positive results (leading to cascading procedures, unnecessary patient anxiety, patient harm from radiation, as well as the potential harm to community health systems) makes this an area worthy of further study.

***A Body Scan Can
Save Your Life!***

—Advertisement by Ultralife

We set out to:

- assess the regulatory, media and marketing literature pertaining to the use of CT and PET machines in the real world and gather Canadian consumer perceptions of scanning technologies via a public opinion survey;
- assess the evidence-based literature associated with the use of cancer scanning technologies on asymptomatic people, specifically related to CT screening for heart, lung, and full body scans; and

“A false positive is a test result that suggests cancer is present when it in fact is not. It is also known as a ‘cancer scare.’”

—Dr. Gilbert Welch

- produce recommendations for policy-makers on needed regulatory action and a guide for consumers on questions to ask when entering the private imaging marketplace.

Methods:

Our project team assessed the HTA (Health Technology Assessment) literature related to CT and PET screening for asymptomatic patients, analyzed the media and marketing of medical imaging screening tests in Canada, conducted an overview of Canada's regulatory environment in this area, and carried out a series of interviews with 28 key informants, mostly experts in the regulatory, medical, academic, and commercial fields related to screening. We finished with a Canada-wide public opinion survey of 400 Canadians related to perceptions of medical screening in Canada.

Findings:

- Controversial medical imaging procedures are being marketed and sold to Canadians as effective in screening healthy people for early detection of specific diseases, even though such screening is expensive, potentially harmful, and neither supported by the scientific literature nor recommended by professional bodies and regulators.
- We have found no evidence that national, provincial, or professional regulatory bodies have effective policies to protect Canadians from harms arising from such screening (such as increased medical investigations of false positives, increased anxiety and "cancer scares," and cumulative exposure to ionizing radiation from repeat testing).
- The medical imaging industry (including equipment manufacturers, private health-care companies, brokers and radiologists

with investments in clinics) is expanding screening markets through a variety of mechanisms such as commercial advertising to the public, workplace wellness and disability management programs, and privately-financed executive health assessments or pre-employment evaluations.

- Canadian consumers are exposed to deceptive advertising, are generally misinformed about the reliability and safety of different screening tests, and lack access to effective, consumer-oriented guidance around these screening procedures.
- Consumers erroneously believe that Canadian governments actively regulate the marketing and use of these tests, and that medical imaging screening tests provided through private imaging clinics or private health-care companies are prevented from misleading or harming the public.

Conclusion and Recommendations:

This descriptive study was able to determine that there are worrisome gaps in the regulation and monitoring of the use of screening technologies in Canada, and that this situation could seriously affect the health of consumers, public and private payers, and the workload of medical imaging professionals. Our key recommendations are as follows:

- Consumers, health professionals and the media need quality information about the controversies and limitations of the proliferating number of new and sophisticated medical imaging tests. We have started to address this in our "Consumer Guide to Screening" (see appendix), but consumer-oriented information on screening needs to be

enhanced by future research, professional support, and stable public funding.

- Provincial governments must establish meaningful oversight over the marketing and use of these procedures, given that voluntary, professional oversight is ineffective.
- Federal and provincial research organizations and funding agencies should direct resources to gathering systems-level data and determining the full impact of privately purchased screening tests such as heart, lung, and whole body CT or PET scans on Canada's public health system.
- The federal government should take immediate action on the recommendations

of the 2004 Auditor-General's Report on the Medical Devices Program, including providing sufficient resources to the program to ensure the safety of Canadians. (See Appendix D).

Any desire to stimulate greater use of medical imaging technology in Canada should be balanced with knowledge of the downsides of carrying out more and more screening tests on more and more healthy individuals. The market for unsupported and non-evidence-based health screening is dysfunctional and consumers should be able to count on governments and health professionals to implement market interventions that protect Canadians from the worst excesses of the promotion and uses of such machines.



Background

Medical imaging exams can be used for either diagnostic or screening purposes. *Diagnostic* exams are tailored to locate abnormalities after someone has developed a symptom or if his or her health-care provider has discovered a problem. In contrast, *screening* exams are used to look for anomalies in healthy (or asymptomatic) people that indicate the presence of a disease before it becomes clinically apparent. Typically, a screening test does not provide absolute evidence of

disease, but rather provides signs that further evaluation of an anomaly is warranted. The value of any screening test rests in how accurately it can find a condition or sign that strongly predicts a potential clinical problem. **In this study, we are *only* concerned with the use of medical imaging technologies and tests for screening purposes, not for *diagnostic* purposes** — that is, for the purposes of finding suspicious signs (in the absence of symptoms) which may reflect potential or future illnesses.

There is an intermediate form of screening known as case-finding, where a person's risk factors are identified and, if the person is deemed to belong to a particular "high risk" population group (i.e., family history of a particular disease or other risk factors), that person may be offered a screening exam. In this context, the screening of the sub-set of the population of patients at high risk for colon cancer using CT colonography may be justified. In this research, we acknowledge that screening can mean several things, but we emphasize that we are only examining the screening of well persons, not those at particular risk.

What are commonly identified health consumer or patient rights?

- The right to safety and quality;
- The right to be informed;
- The right to be respected related to decisions and choices;
- The right to participate in decision making (personal and system);
- The right to access essential care.

Five common health consumer rights identified by the Consumers Association of Canada, the United Nations, Consumers' International, and Health Action International.

Screening can occur for a number of reasons: the patient may request it, the physician may order it, or an employer may demand it. Why a patient would request a screening test outside a typical medical encounter depends largely on the person's perception of their own risk of disease, and their sense of how much benefit they would achieve by being screened (i.e. achieving peace of mind).

Private medical clinics in Canada are offering and marketing discretionary medical screening procedures, using new technologies to screen healthy people for disease. These procedures are being marketed directly to the public, as well as through corporate executive health checkups and employee pre-employment screening programs. There are undoubtedly many challenges faced by consumers when “shopping” in a retail-oriented medical marketplace or being required to undergo tests as part of work-related programs. Heart, lung, and full body scans are among some of the more controversial screening tests being promoted to Canadian consumers; these are often presented by private facilities in Canada that market CT and PET scanning under the pretence that they are able to screen for early signs of disease, and thus “save your life.”

It is clear that **the information consumers receive from the proponents of such tests is often unbalanced, exaggerating the effectiveness of the screening and downplaying or avoiding discussion of any potential harms.** There is a range of potential problems presented by unapproved, scientifically unsound screening procedures that are being aggressively marketed to the public. As well, the extent to which unanticipated problems arising from such screening may affect the availability and cost of medically necessary physician services for Canadian families is unknown. It is possible that many of these potential problems are being left unaddressed by the regulators and the relevant medical professions.

These are some of the consumer issues addressed by this research:

- How much are high-tech screening technologies (CT and PET scanning machines) being marketed to and used on consumers outside of standard diagnostic encounters?

Private medical clinics in Canada are offering and marketing discretionary medical screening procedures, using new technologies to screen healthy people for disease. These procedures are being marketed directly to the public, as well as through corporate executive health checkups and employee pre-employment screening programs.

- What is the quality of information, specifically related to the benefits and potential harms of these types of scans, that Canadian consumers are receiving?
- If there is a disconnect between what evidence-based recommendations say and how the screening tools are used in actual practice, where do those disconnections lie and in what ways can we address any knowledge gaps so that consumers can be better informed and protected in this confusing and complex marketplace?

The use of medical imaging equipment in Canada is experiencing rapid growth. Spending on medical imaging — MRI, CT scans, and PET scans — in hospitals in British Columbia, Alberta, Ontario, and New Brunswick (where data were available)

went up 44% from 1996 to 2000.¹ Data from the Canadian Institutes of Health Information (CIHI) show the number of MRI scanners in private diagnostic clinics (private businesses) grew from two in 1998 to 32 in 2006 and 41 in 2007, and that the number of clinics with CT scanners increased from two in 2000 to 18 in 2006 and 21 in 2007. CIHI has noted that “Canadian and international researchers have documented both underuse and overuse of medical imaging” and that “recent federal and provincial reports on health care have called for action to address access to diagnostic services and to better understand the appropriate use of these technologies, now and in the future.”²

Any anomalies found as a result of preventative CT-scans, no matter how small, often lead to further investigation, usually in the public system. It is estimated that, for every 100 healthy people who undergo a full body CT scan, somewhere between 30 and 80 of them will be told there is something that needs a workup and it will turn out to be nothing.

As opposed to the public system, there is even greater cause for concern in how private companies may seek out and treat asymptomatic people. The two major potential harms related to the use of “preventative” screening exams are the potential to discover both false positives (minor abnormalities which turn out to be non-disease) and the potential for exposure to unsafe levels of ionizing radiation. Any anomalies found as a result of preventative CT-scans (currently only delivered by private for-profit clinics in Canada), no mat-

ter how small, often lead to further investigation, usually in the public system. It is estimated that, for every 100 healthy people who undergo a full body CT scan, somewhere between 30 and 80 of them will be told there is something that needs a workup and it will turn out to be nothing.³

It is impossible for this report to calculate the scale of the added weight of interventions carried out by the public system stimulated by sales of these screening tests by private imaging facilities in Canada or the drain and diversion of physician and hospital resources for follow-up investigations, but there are indications that it is growing. For example, in 2003, the Medical Advisory Board of the Calgary Health Region passed a motion outlining its concerns about false positives from whole body CT scans and the resulting follow-up tests using and diverting Calgary staff and resources without just cause. Some practitioners felt that private clinics should foot the bill for such investigations.⁴

The impact of such private medical clinics on the public provision of care is also potentially worrisome. According to a report by the Ontario Health Coalition, “for-profit MRI/CT clinics reduced capacity in the public hospital system,” and there is evidence that for-profit MRI/CT clinics have “worsened staff shortages in local hospitals, leading to cuts in the non-profit hospitals.”⁵

These medical imaging devices fall into the higher classifications of risk related to medical devices under Health Canada’s regulatory framework, as they offer direct risk of harm from energy fields, not just loss of money or misdiagnosis. Canada’s federal Auditor-General has noted in a recent audit of Health Canada’s Medical Devices Program:

“While Health Canada has made progress in important aspects of managing risks related to medical devices before they are made available for sale, it needs to better manage risk after they are available for sale. As a result of the gaps in its Medical Devices

Program, Health Canada does not have a comprehensive program to protect the health and safety of Canadians from risks related to medical devices, even though it committed to such a program over a decade ago. Its failure to deliver such a program compromises Health Canada's ability to protect health and safety, which could translate into a growing risk — risk of both injury and liability.”⁶

Background radiation dose is often quoted as a comparator for radiation exposure. The effective dose from radiation-emitting scanners is measured in millisieverts (mSv). An effective dose (ED) of 2.5 mSv is a typical background dose for adults but this value will vary slightly according to altitude, latitude, geological, and other variables. Doses from CT and PET range up to 15 mSv ED, depending on the site and machine used.⁷ As technology has become more sophisticated and advanced, the trend of radiation dosage has increased over time. Dr. Brian Lentle, the former head of the Radiological Society of North America, wrote: “Any radiation exposure is assumed to cause harm in older people beyond the reproductive age. The harm from screening procedures is radiation carcinogenesis – cancer induction. Such cancer induction is related to dose and dose-rate in a linear or linear-quadratic way that is explicit at high doses. There is no safe threshold that can be inferred. The evidence for harm at lower doses is less strong, but such harm may be reasonably assumed in the conservative practice of radiation medicine.”⁸

With the increased use of CT, there has been an increase in average effective dose to hospital patients. For example, at the Vancouver General Hospital, the average annual patient effective dose almost doubled between 1991 and 2002.⁹ An Ontario Auditor-General's report pointed out the problems with potential excessive doses of radiation, especially on children, and the major differences between the dosage levels of similar procedures performed at different hospitals.¹⁰

Radiology

› Incidentalomas: chance findings when you're looking somewhere else

Even screening tests that are justified (CT colonoscopy, for example) may find far too many false positives in other organs. In a letter published in the medical journal, *Radiology*, the senior radiologist at Emory University in Atlanta, Dr. William Casarella, describes the cascading series of medical adventures he encountered after undergoing a routine CT scan of his colon. The scan which is wide enough to examine organs adjacent to his colon found suspicious lesions on his liver, his kidneys and his lungs (his colon was fine). He underwent numerous

biopsies and other medical procedures including a full thoracotomy (major chest surgery) to remove benign nodules from his lungs and was hospitalized for several weeks to recover. Such an experience led him to conclude that: “*The pursuit of false positive findings in the lungs is at best costly, anxiety producing and requires 2 year follow ups. At worst it will lead to painful, costly, potentially risky major surgical procedures.*”

Casarella, W.
*A Patient's viewpoint on a current controversy (2002).
 Letter in Radiology
 vol 224: 861-69.*

There is significant corporate power and interests behind the medical device and medical imaging industry in Canada, including names like Siemens, Philips, and GE Healthcare. Although most medical devices and imaging equipment sold in Canada are imported (according to MEDEC), the national association and lobby group representing the Medical Device Industry (including a new Medical Imaging Sector) employs over 35,000 Canadians in close to 1,500 facilities and contributes nearly \$6 billion in national sales per annum.¹¹ In 1999, Industry Canada supported the development of a *Medical Imaging Technology Roadmap* initiative to improve patient care and enhance the global competitiveness of the Canadian medical sector by strengthening technology development, diffusion and adoption.¹² According to a 2007 U.S. market report, the demand for medical imaging equipment in

Canada has grown at an average annual rate of 7% over the past five years. It is expected to grow between 5% and 10% through 2010.”¹³

There are significant controversies within the medical profession related to the use of these technologies on asymptomatic people. Changes in 1997, which limited federal controls to advertising by manufacturers, and the growth of private medical imaging clinics in Canada (and the closure of many outlets in the U.S.), appear to be leading to increasing commercial and behind-the-scenes marketing of these procedures, often using the media as a vehicle.

There are many different types of machines that can be used for screening, as well as ma-

chines that are hybrids of several different technologies. Combining different technologies can produce PET/CT machines as well as PET/MRI. For the purposes of this report, we focused strictly on the use of CT and PET alone in screening, and on three specific commonly marketed screening procedures which use Computed Tomography (CT) for intensive study. These three screening procedures are heart scans, lung scans, and full body CT scans, all of which are promoted by private clinics in Canada and which do not enjoy the support of a substantive body of evidence (summarized in Appendix C) to prove that the harms outweigh the benefits for individual or population health.



Methodology and Results

We focused on these following six research activities:

- 1. Media:** An analysis of the media regarding CT scans.
- 2. Marketing:** An analysis of the markets and marketing for medical screening tests. (Appendix A: Information Available to Consumers Through Various Clinic Websites.)
- 3. Key Informants:** Interviews of key informants. (See also Appendix B: List of Interviewees.)
- 4. HTA literature:** An assessment of HTA literature. (See also Appendix C: Summary of Screening Recommendations From Various Health Organizations.)
- 5. Regulatory Environment:** A brief review of the regulatory environment. (See also Appendix D: Auditor-General's Recommendations.)
- 6. Polling:** An analysis of polling in this area and our own national public opinion survey of Canadians on Screening. (For full poll see Appendix E.)

Media: A brief analysis of the Canadian media regarding CT and PET scans

“At the moment no one knows how many people in this country develop cancer due to excessive radiation. Until they do, use radiation as the porcupine makes love: very, very carefully.”

— W. Gifford Jones (physician columnist)
Winnipeg Free Press, June 25, 2008.

As part of understanding what messages consumers are exposed to via the media, we conducted a Canadian print media search of all stories related specifically to CT and PET scanning for lung, heart, and full body scans. We utilized a library-based Proquest search engine that includes two major Canadian news indices: Canadian Newstand (which indexes 48 Canadian newspapers back to 1995) and CBCA Business (which indexes 509 magazines in Canada).

A general search of these two databases produced 2,570 stories using the search term “CT scans.” Given the vast number of hits, the results were narrowed to 746 stories by adding the search term “cancer” along with “PET

or CT scans.” A separate search for the terms “full-body scan,” “full body scan,” or “full body CT scan” yielded 74 stories through the online database.

In addition to searching the diagnostic terms described above, we searched the media database to find the term “executive health.” We hypothesized that this search term would retrieve stories centred on the use of preventive CT-screening by corporate executives. A search combining the terms “executive health,” “executive physicals,” or “premium health” yielded 399 stories.

Our media database now consisted of over 1,000 stories mentioning one of the relevant terms. We culled this database to focus specifically on those stories where the CT or PET machines were being used for screening. Most of the stories we found were irrelevant to advancing our understanding of how preventive screening is characterized in the media and, as a result, these stories were eliminated from our research (i.e. the story of hockey star who received a CT scan to examine his injured knee). Following these eliminations and deletions, we were left with approximately 70 stories that related specifically to the technology and its use in screening.

The remaining media reports on the technology of screening could be broadly classified into four major themes: 1) Safety, 2) Access, 3) Controversy, and 4) Marketing or Hype.

The stories in the **SAFETY** category tended to be more recent (after 2005) and focused primarily on the dangers of over-scanning, the controversies around scanning healthy people and the potential danger of radiation exposure. There were very few stories that focused on the regulatory aspects of consumer protection and the regulation of these devices.

The **ACCESS** stories comprised a sub-set of the stereotypical Canadian “public-versus-private” debate story, with compelling human

drama centred on the fact that Canadians are often denied access to high tech medical devices due to an alleged limited availability in the public system. The other main type of access story was the wait-list story — which decried the lack of MRI or CT screening machines in Canada. These might also be classified under Controversy stories.

The **CONTROVERSY** stories found through our media search were a relatively new breed (after 2005) and focused on the disconnect between what the proponents of screening are saying (many pushing full body, CT, or lung screening for smokers) and what the detractors or researchers say. These included several very high-profile stories in the U.S. press, particularly in *The New York Times* and *The Los Angeles Times*, some of which were reprinted in Canadian media.

The stories found in the **MARKETING** or **HYPE** category were typical of industries eager to expand their markets and increase the sale of their newest equipment. Many of these stories focused on the incredible purported benefits of the screening machines, and paid little attention to the potential for harm or the controversies surrounding how they are being used.

More than three-quarters of the stories (45) we found focused on access issues, and, since we were not investigating the access issues, we eliminated them from our database. This left us with 25 stories divided into three types of stories related to CT and PET screening: Controversy, Safety and Marketing stories. This sub-set of stories is small, and cannot be said to represent the full body of media related to CT and PET cancer screening in Canada, so a full content analysis of this small body of stories was not justified. We have included a sample of each containing the first few paragraphs of these stories which we believe represent the flavour of the small body of media stories we found pertaining to our issue.

(I) Example of safety issue story:

The Windsor Star

Full body scans may increase cancer risk

People having full body scans to find potential health problems may wind up creating one, researchers suggest.

Radiation from computerized axial tomography (CAT) scans will result in a modest increase in the risk of cancer, according to research published in the September issue of the journal *Radiology*.

The radiation from a full body scan is only slightly less than the average dose received by survivors of atomic bomb blasts. Full-body CAT scans, for instance, expose people to 100 times more radiation than a mammogram...

[Final Edition] *The Windsor Star*. Windsor, Ont.: Sep 9, 2004. p. B.3.Fro

(III) Example of a marketing or hype story:

The Vancouver Sun

New scanner can see inside arteries, predict heart attacks

A 64-slice scanner records 64 cross-sectional images at the same time. Until recently, the best scanners were 16-slice. St. Paul's Hospital's best CT scanner is a four-slice, [Brett Heilbron] said.

Heilbron predicts CCTA will be covered by insurance in the future: "It's probably less than half the cost of an invasive angiogram."

CCTA does have

limitations. It's expensive and creates poor images of patients with irregular heart rhythms, Heilbron said. As in catheter angiograms, CCTA requires injection of dye which carries risk of kidney damage, and involves radiation...

[FINAL C Edition] Jenny Lee. *The Vancouver Sun*. Vancouver, B.C.: Sep 15, 2005. pg. B.6

(II) Example of a controversy story:

The Vancouver Sun

The unseen fallout from private health care

I have watched with interest your readers' responses to the Oct. 2 editorial, "Private clinics and insurers are part of the Canadian health care system." I wonder whether the public realizes that the patients seeking treatment or diagnosis in private facilities frequently end up back in

the public system. There are also patients, usually business executives, whose privately paid "executive physicals" involve coronary CT scanning or whole-body CT scanning. ...

Dr. Anna Kang. *The Vancouver Sun*. Vancouver, B.C.: Oct 11, 2008. pg. C.3

The Marketing and Market for Medical Imaging Screening Tests

There are numerous ways in which private companies promote a wide variety of private-pay screening exams, and many clinics also provide public or privately paid diagnostic exams. Marketing vehicles include company websites, brochures, and print or radio advertising. Other marketing strategies include the use of referral networks and contracts with private health-care companies offering yearly "executive health assessments" and "pre-employment" health evaluations. Some of the media stories would likely be self-initiated by the clinic making contact with reporters and news outlets.

In terms of what is found on the most easily accessible marketing vehicles — company websites — we wanted to examine how thoroughly the companies described the benefits and risks of the screening procedure, the discussion of po-

tential candidates, references to evidence-based literature, whether or not a referral was required, and the costs of the screening exams.

Based on the above criteria, it was clear that the information provided on these websites ranged from being very comprehensive to very uninformative. The more comprehensive websites included information on benefits and risks, as well as a discussion of potential candidates. While all of the sampled websites discussed the benefits of these screening exams (through patient testimonials, anecdotes and expert opinion), a majority of the sites (8 out of 11) did not mention any risks associated with the screening of healthy individuals. None of the clinic websites made explicit reference to evidence-based literature and only one provided information on cost. Marketing messages ranged from being anecdotal or testimonial to those that played on expert opinion or public fear. Similar patterns were identified in a sample of brochures obtained from these clinics. A sample of website and brochure messaging used to promote and describe these screening tests is included in the boxes on the following three pages.

i) Websites and brochures:

In an attempt to better understand the marketing strategies of private imaging clinics and health-care companies offering health assessments and the quality of information reaching the public, we explored a convenience sample of Canadian clinics and company websites and brochures for trends in the marketing approaches, along with the website of an American company that advertises for Canadian patients. (See Appendix B). We acknowledge that this convenience sample is not an exhaustive list of all private clinics and want to emphasize that these results simply reflect general trends of the available information. The following screen captures have had the text enhanced for legibility. A full listing of these websites can be found in the bibliography. We developed a very simple checklist of eight items, with each item rated satisfactory or not satisfactory. These criteria are described below:

a) Benefits and Risks: Does the website discuss both the benefits and risks of the screening exam? In order for individuals to make an informed decision regarding a screening exam, both the pros and the cons must be clearly laid out. Exaggerating or emphasizing only the benefits or risks of these tests could deliver an unbalanced perspective. All eleven of the sampled websites discussed the benefits of these screening exams and thus received a “satisfactory” result for the ‘benefits’ column. Clinic websites that did not include easily accessible information on screening risks were rated “not satisfactory” on risks, but those that mentioned any risk factors (regardless of whether the risk discussion was complete) received a “satisfactory” rating.

b) Potential Candidates: Does the website provide information on who would most benefit from the screening tests? We considered it important for sites to accurately describe potential candidates and specific patient groups who could benefit most from specific screening exams. These patient groups may include individuals with a strong family history of a given disease or individuals with specific risk factors. Clinic websites that discussed specific target populations or mentioned the necessary traits for potential screening candidates were given a “satisfactory” rating. Those sites that did not discuss the applicability of screening exams to different segments of the general public received a “not satisfactory” rating on this criterion.

c) Reference to Evidence-based Literature: Does the website refer to recent studies, control trials, or health and technology assessments that support the use of specific screening exams in healthy people? Referencing evidence-based literature is an important part of providing information to the public.

Consumers need confidence that medical practices being promoted are supported by a body of scientific evidence. They also need context and to be informed where there are evidence gaps, controversies and debates surrounding medical practices. In addition to mentioning recent studies or reports, it is beneficial to provide the precise references so that potential patients could locate and examine these studies. Several clinics made references to the “latest medical evidence” or “bodies of literature” that supported screening in healthy people, but if they did not provide specific references (so individuals could access this research themselves), those sites were given an “unsatisfactory” rating.

d) *Referral Information:* Does the site indicate whether referrals are required before individuals can access any screening tests? Indicating whether or not a doctor’s referral is required is another important aspect of patient information. Requiring a physician referral and clinical history prior to a screening exam encourages consumers to discuss their desires for a screening exam with a physician who understands their medical history. In addition, a referral alerts both the consumer and radiologist to any medical contraindications or special precautions that must be taken during a screening exam. Those websites that mentioned a referral requirement received a “satisfactory” rating while those that did not require this referral received an “unsatisfactory” rating.

e) *Cost of Screening Exams:* Does the website provide information on the costs of these screening exams? The provision of cost information contributes to a better understanding of what these screening tests entail. Providing this information to patients ahead of time allows them to consider the

cost as part of the pros and cons of a given procedure. Clinic websites that provided any cost information were given a “satisfactory” rating while those that did not indicate any price ranges were rated “unsatisfactory.”

ii) Print and Radio Advertising

Due to the challenges of obtaining transcripts of radio ads and copies of advertisements in

A Body Scan Can Save Your Life!
Heart Disease, Stroke & Cancer are the three leading causes of death in America!

From an Ultralife Advertisement found in the Victoria Times Colonist

MAYFAIR DIAGNOSTICS
 Health Assessment Packages
 Home > Preventative Screening > Health Assessment Packages
 Your Needs
 Preventative Screening
 Diagnostic Imaging
 Frequently Asked Questions
 About Us
 Contact Us
 Patient Resources
 Physician Resources
 Media Resources

“We designed our Preventative Health Assessment Scans to detect serious diseases of the heart, lungs, colon and body areas before they cause symptoms and while they can still be treated to improve your health.”

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Are there any risks?

“During a CT scan, you are briefly exposed to radiation, making the risk similar to that of conventional X-rays; however, the valuable information a CT scan provides typically outweighs the associated risks. Be sure to inform your doctor if you’re pregnant; he or she may recommend another type of exam to reduce exposure of your fetus to radiation.”

*(Imaging clinic) Mayfair Diagnostics
http://www.mayfairdiagnostics.com/index.php?option=com_content&task=view&id=38&Itemid=66#risks*

<http://www.canadadiagnostic.com/>

(Imaging Clinic) Canadian Health Scan
<http://firstbasedirect.com/canadianhealthscan/news.html>

daily newspapers or magazines, we did not carry out a systematic review of these outlets. However, radio advertising appears to be increasingly popular in a number of provinces where private medical imaging companies exist. Key messaging in both print and radio advertising includes statistics implying a high rate of disease and death from a particular disease, as well as statements that most such cases are preventable, that early detection is important, and that the particular test being advertised can discover signs of a disease at the earliest stages while it is preventable.

iii) Referral Networks and Corporate Health Care

While many Canadians refuse to pay for medical services simply to avoid waits in the public system, we assume that many would be also unwilling to pay out-of-pocket for screening tests at private imaging clinics¹⁴. In the U.S., where consumers can simply walk in and purchase an exam from a private clinic (called self-referral), in Canada many Colleges of Physicians and Surgeons require a prior medical assessment from another physician before a radiologist performs a scan, out of concern for patient

Often falling under the rubric of workplace “wellness programs,” these screening programs are sold on the claim that they can help reduce the rapidly rising costs of workplace benefit plans provided by private insurers.

safety. It seems, however, that compliance is poorly monitored and that there are many ways around such rules. Some private imaging clinics often offer customers the opportunity to see their own staff physician and have him or her do a brief history and referral. In 2006, one B.C. clinic’s website offered self-referral for a full body CT scan.

Private clinics offering these services to Canadians often must rely on family physicians and specialists with more regular contact with a pool of patients to refer or recommend these tests to their patients.¹⁵ But, if recent experience with private insurers providing many new models of workplace benefit insurance is any guide (particularly disability income insurance), a key market for selling medical imaging screening exams is through contracts or affiliations with

private health-care companies. These companies provide executive health assessments and pre-employment evaluations as part of overall management of sick time, disability, and absentee programs for employers and disability income insurers, as indicated in one of the clinic advertisements above. Therefore, individuals do not have to bear the cost directly. Often falling under the rubric of workplace “wellness programs,” these screening programs are sold on the claim that they can help reduce the rapidly rising costs of workplace benefit plans provided by private insurers. Keeping people well and working is important for employers, since the cost of sick time and income replacement when someone is off work due to a medical condition can be considerable. Although workers’ compensation programs pay the costs of wage replacement for workers injured on the job, the costs of wage replacement for all other ills are borne through a person’s disability insurance or direct payments.

Over the last decade, the number and scope of these private care management and broker companies has increased significantly. Some simply act as brokers and coordinating agents for various components of executive health assessment and pre-employment evaluations, including a number of “medical tourism companies” which also arrange for treatment out-of-country or in other provinces if any problems are identified in a routine health assessment. Others, such as Medysis Health Group, have their own in-house clinics, imaging facilities, and preferred provider contracts with a major disability insurer such as Sun Life.¹⁶

Once the domain of company CEOs and business partners in legal firms, these employer-paid “executive health assessments” have expanded to include senior level management. Recently, a number of companies such as the Copeman Clinic have sought to expand into the “mass market” by offering “comprehensive health assessments” as part of a yearly enrolment fee to

join a medical practice. These are often called “boutique” health clinics. As well as providing privately paid tests, physicians often order tests covered under Medicare programs.

“State-of-the-art” diagnostic equipment is featured prominently in the advertising for these health assessments,¹⁷ and having these exams within the context of a full medical evaluation by a physician can be very attractive to the public.¹⁸ Lower-cost executive health assessment packages often include both traditional medical imaging-screening exams, such as mammography for women and new ultrasounds of the abdomen. Higher-cost packages include CT heart scans, lung scans, or whole body CT or MRI scans.

A standard “executive health assessment” for senior managers in Canada can range from \$1,200 to \$1,800 and consists of a four-hour visit with an unhurried physician and a team of other health professionals, along with convenient on-site testing. Depending on the availability of in-house imaging and a client’s ability and willingness to pay, other screening scans may also be recommended by the consulting physician if the client expresses a desire and interest in order to put their worries at ease. As well as serving as a direct market for various types of medical imaging scans, these health assessments serve as the gateway for other scans and tests.

Pre-employment physicals have also taken on new importance for employers, particularly for key personnel, as hidden health conditions may lead to both lost productivity and additional drains on a company’s health and disability programs. Dominion Medical Centres in Edmonton offers both corporate health assessments and employee fitness evaluation. An amount of \$1,050 covers the costs of an hour-and-a-half with a doctor and some on-site tests; however, clients are also expected to pay \$1,150 for a pre-booked CT scan of the entire body or of the core body and heart.¹⁹

Examples of marketing pitches by health assessment companies marketing directly to the public include:

Empowerment: enabling you to be in control of your wellbeing

Proactive: acting, not reacting

Preventative: wellness, not illness

Ad from Wellpoint Health Services,
www.wellpointhealthservices.com

Many people are quite healthy. We went to keep it that way. **Unfortunately a disturbing number of people who feel healthy have undiagnosed or misdiagnosed illnesses.** Even more have high, unknown risks for cancer or chronic disease based on family and lifestyle history and their health status isn't being monitored carefully. The Copeman Clinic Health Assessment is comprised of a set of more than 55 tests and examinations, as well as detailed questionnaires to properly assess your health status and your health risks. Tests range from relatively simple blood tests to sophisticated imaging technologies.

(Copeman Clinic website)
http://www.copemanhealthcare.com/success_stories

Interviews of key informants

The issue of screening asymptomatic individuals to detect early signs of cancer and other diseases is both complex and controversial. In addition to investigating the consumer understanding of this issue, we conducted key informant interviews to explore a range of perspectives, including those of regulatory bodies, health professionals, academics, researchers, and private clinic staff. Where possible, both national and international contacts were consulted. While consumer advocates provided us with a better understanding of the consumer

issues at hand, the consulted physicians (i.e., generalists, cardiologists, neurologists, oncologists and radiologists) provided perspectives on the practical aspects of screening and other frontline issues. Individuals in academic medicine shared an invaluable perspective on current research and relevant issues of population screening while private clinic operators provided the perspective of the national and international industry. For the full list of interviewees, see Appendix B.

We classified our data from the interviews according to the interviewee's perspective: whether it was from a consumer advocate perspective, disease group, industry, professional association, medical academic, and so on. In order to preserve the anonymity of the interviewees, we have grouped individual comments without the names of the individuals interviewed. The following main themes emerged from the interviews.

Consumer perspective: For the most part, consumer advocates and organizations agreed that *"the public is pretty much left in the dark when it comes to controversial issues of screening."* By being exposed to marketing information about screening, consumers are given an unbalanced and incomplete perspective of any existing safety concerns and are largely unaware of the potential downsides to a screening exam. As stated by one of our interviewees, *"I would be frankly surprised if you find that people who go into these tests go into it with their eyes wide open and fully informed. I see a strong role for an effort to have information sheets [be generated] by an independent and not by people who own the facilities."*

Health organization's perspective: Generally speaking, the health organizations with an interest in cancer screening suggested that population screening (of asymptomatic individuals) is only beneficial for a few illnesses and cancer types. A representative from a large national organization dealing with cancer indicated that their organization stands behind evidence-based screening programs and that, under this rubric, they approve whole population screening for colon, cervical, and

breast cancer. These are cancers where they “believe that there is sufficient scientific evidence that using these tests on healthy people will not only detect the cancer early... but will reduce mortality.” These groups acknowledge that the need for alternate screening exams (e.g., Prostate Specific Antigen [PSA] and lung screening) should be determined through a discussion with the clinician and the patient and through an understanding of the individual’s risk factors for a given disease.

Industry perspective: With screening exams priced anywhere between \$100 and \$2500, the provision of private screening services could be perceived as a promising source of lucrative business. In one instance, a public hospital in Canada sold full body screening with its CT machine to private payers, a practice that has since been discontinued. Private clinics advertise their services directly to the public and draw in new customers who are willing to pay for these screening procedures. Clinic staff generally suggested that their advertising is completely ethical, and they claim that early detection of potential illnesses is always beneficial for the patient. While individuals pay for these private services out of their own pockets, the private industry maintains that they set standards for determining who they will screen with their machines and that they are not ready to provide a screen to anyone who walks in off the street. Depending on the procedure and the age and health status of a potential patient, some clinics require a doctor’s referral. (For further details see the clinic summaries in Appendix A).

Professional Associations of Radiology perspective: Various professional associations of radiologists such as the Canadian Association of Radiologists (CAR) provide physicians with guidelines for imaging procedures. Specific to the various body parts, these guidelines are designed to assist physicians in choosing the best and most effective imaging procedure for their patients. These guidelines are associated with specific clinical/diagnostic problems and would only be applicable to symptomatic patients. In terms of the screen-

ing of asymptomatic individuals, the professional associations of radiology have varying responses, depending on the available evidence. In general, if solid evidence exists for (or against) a specific screening exam, these associations will side with the evidence. Where there is a lack of evidence for (or against) one of these tests, the tendency is for the associations to avoid taking a side. Referring to the lack of evidence for some procedures, the spokesperson for one professional association said: “*Until we have a good answer, all we can do is advise on the potential risks and those who promote it can advise on the potential benefits. This conversation goes on in the medical literature today.*” Rather than taking a definitive position, these associations leave the decision-making up to the individual practicing radiologists.

Practicing radiologist perspective: The general consensus among practicing radiologists was that full body scans are not justified by the evidence and that these tests are potentially exposing people to harm. Several of the practicing radiologists recognized the divide between

The general consensus among practicing radiologists was that full body scans are not justified by the evidence and that these tests are potentially exposing people to harm.

academic or public-hospital based radiologists and radiologists practicing in private clinics. In terms of CT screening for lung cancer or CT angiography, we found a large spectrum of opinions. Some radiologists were strong advocates of preventative screening whereas others were very cautious about exposing asymptomatic individuals to these tests in the absence of good controlled-trial evidence. While radiologists across the spectrum agreed that some risks may be associated with some of the common forms

of screening (particularly mammography), many pointed out that the potential harm from radiation is minimized through the use of appropriate machinery settings. *“The cautious practicing professionals indicated that for a large majority of people (with no family history or specific risk factors for various conditions), a number of the screening exams are unnecessary and most often serve to find abnormalities that would have gone unnoticed throughout the individual’s lifetime.”*

Regulators’ perspective: Through our conversations with federal health regulators, it was clear that when and how medical imaging is used to screen asymptomatic individuals is not regulated. The World Health Organization (WHO) tries to establish guidelines on the use of imaging technology, especially concerning the potential harm from ionizing radiation, but it has produced no guidelines on the issue of population screening. At the national level, devices are regulated only to the extent that they meet the specifications pertaining to the specific machine. As one national regulator put it, *“All medical devices are regulated in Canada by Medical Device Regulations, and devices have to be safe, effective, and of good quality... We make sure the device does what it was technically intended to do.”* This representative noted that, while *“[radiation exposure] is definitely an issue...we don’t dictate the practice of medicine.”* Once these machines are sold and used on the public, there is no regulation dictating how and on whom these devices can be used. Representatives from device manufacturers in the U.S. maintained that they are unable to advertise their machines for screening purposes, implying that their marketing of the machines was actively regulated. They acknowledged that, while their companies are being prevented by regulation from promoting their devices for unapproved uses, it is usually their customers or buyers (i.e., the private clinics and owners of MRI and CT machines, for example) who actively promote their screening services without any regulatory arm stopping them.

Disease prevention perspective: The individuals working in organizations or departments

of disease prevention generally agree that society’s understanding of imaging technologies is limited and that better research needs to be collected prior to offering these screening exams to uninformed members of the general public. As stated by one of our interviewees: *“We have not yet reached a point of definitive knowledge about benefits, harms or futility.”* Individuals in this field were encouraged by some forms of screening that are undergoing high-quality research programs and collecting data from large randomized control trials such as the National Lung Screening Trial (NLST) in the United States.

Academic medicine perspective: Most academic medical professionals agree that better research is needed before many types of screening can be justified. Individuals in this field spoke with a consistent voice, suggesting that even mammography (the most well-studied area of screening) is not without controversy and that consumers are not aware of the limited research behind the screening programs, such as lung cancer screening or CT angiography, which are heavily promoted and advertised in Canada and the United States. Academic medical professionals stressed the possibility that these screening exams could be associated with more harm than benefit and that our current literature base cannot rule out this pressing possibility.

Summary of HTA Literature related to CT and MRI scanning.

*“Screening for cancer remains a very emotional and hotly debated issue in contemporary medical practice. An analysis of published data reveals a multitude of opinions based on a limited amount of reliable data.”*²⁰

— H. Schoder and M. Gonen,
(radiologist and epidemiologist¹⁷)

A Health Technology Assessment (HTA) is a systematic appraisal of the costs and benefits of a medical treatment, and is an attempt to systematically and

objectively assess which medicines or medical procedures should be accepted. HTA programs from around the world provide high-quality information about the clinical effectiveness, cost-effectiveness, and population-wide impact of the use of drugs, medical technologies, and health systems.

For the most part, the HTAs and systematic reviews (SRs) which focused on CT and PET scanning indicate that the usefulness of the types of procedures depends on the specific condition in question. For the purposes of diagnoses, the use of CT machines to provide a more accurate diagnosis may produce benefits that far outweigh any risks related to radiation exposure. The problem is that radiation effects are cumulative over lifetime, so it is never considered a good idea to expose patients to radiation when the tests are not necessary nor add any value in terms of diagnostic accuracy.

Generally, we found that there is a lack of high-quality studies to address the clinical and cost-effectiveness of CT and PET used for screening purposes, and that more research is needed to fully assess the benefits of these technologies. Some of that research is ongoing, such as research on CT screening programs to detect lung cancer in smokers, and the results are obviously eagerly awaited. But many of the areas in which screening is routinely being recommended by private clinics, such as CT angiograms, have no ongoing, high-quality randomized control trials (RCTs). As their name suggests, RCTs involve the random allocation of different interventions (or no intervention) to the research subjects, a method of allocation that serves to reduce bias and yield more reliable results. In the absence of these types of trials, results from screening-based studies can appear deceptively better than they really are.²¹

CT Heart Scans

The body of HTA literature published in the last four years about cardiac CT screening, for example, clearly suggests that a careful approach to screening for coronary artery disease (CAD) should be followed. Out of the ten HTAs reviewed,

only one report from the United Kingdom (2008) suggested that the use of CT angiography may be able to rule out extreme or very serious cases of CAD. This same report concluded that the proportion of traditional heart disease tests that could potentially be replaced by a CT angiograph is uncertain and requires further investigations.

Three other HTA reports indicated that, although the technology looked promising, there was insufficient evidence available to recommend the use of cardiac CTs in clinical practice (Canada, 2005; Italy, 2008 and USA 2007). These reports stressed that the available literature had limited value for the development of policies and that the evidence base for this procedure was not adequate to suggest that cardiac CT scans are superior to the traditional methods (family history, smoking status, etc) of assessing the presence or absence of CAD.

Two additional reports used the word “cautious” to describe the recommendations concerning cardiac screening (Canada, 2006 and USA, 2008). The 2008 report from the United States indicated that, when used in combination with a pre-CT clinical probability assessment, a cardiac CT may provide some added benefit over standard screening tests. This same report emphasized that, “due to the risk of radiation-induced cancer, patients should be selected carefully for this test and scan protocols should be optimized to minimize risk.”

A few of the recent HTA reports concluded that the use of CT screening for CAD had very little value. The 2004 literature review by the United States Preventive Services Task Force (USPSTF) resulted in a grade D recommendation for routine screening of asymptomatic individuals for coronary heart disease (CHD). The grade D recommendation states that the USPSTF recommends against routinely providing the service to asymptomatic patients. A 2006 systematic review from the United Kingdom suggested that there were no randomized control trials (RCTs) that assessed the value of CT screening in reducing cardiac events. A year later, a Canadian study came to the same

conclusion about the absence of any RCTs. This report clearly stated that “screening the asymptomatic population for CAD using multi-detector CT does not meet WHO criteria for screening [and] hence, it is not justifiable.”

CT Lung Scans

The HTA and SR literature search for the topic of CT lung screening resulted in nine related papers. The results from four of these reports do not support population screening with CT for lung cancer because the use of this technology has not been shown to decrease morbidity or mortality (Canada 2007; UK 2007; Aus/NZ 2007; Canada 2003). While several of these reports indicated the lack of RCTs for lung cancer screening, some of the more recent papers acknowledged and made reference to RCTs that are currently underway. The Canadian Coordinating Office of Health Technology Assessment (now CADTH) report suggested that “multi-slice CT is able to detect lung cancers of smaller size and at an earlier stage when better outcomes *may* be possible.” Even given this, the assessment of current evidence suggests that, even for smokers, screening for lung cancer with multi-slice CT scanning would be premature.

Although fewer in number, HTA of positron emission tomography (PET) scans for lung cancer screening also recommend a cautious approach. The results from these assessments suggest that, although PET screening may have a role in early lung cancer detection, there is insufficient evidence to draw such conclusions. One HTA (Canada 2004) suggested that there is evidence that PET scans are more efficient at distinguishing benign from malignant solitary pulmonary nodules (SPNs). The report concludes that the use of PET in this context could reduce morbidity by reducing the number of unnecessary thoracotomies (major chest surgeries).

Full Body CT Scans

As for full body screening, no HTA assessments have been found on CT full body screening. The

National Cancer Institute, the U.S. Food and Drug Administration, and the American Cancer Society have all concluded that there isn't sufficient evidence to support full body CT scans for patients with no symptoms. There is sufficient concern for harm that the USFDA and Health Canada have both posted notices on their websites warning consumers about the potential harms due to full body screening. In 2003, concerned with the proliferation of private clinics offering healthy people whole body screening exams using MRI or CT technologies, Health Canada published a consumer alert bulletin on the “It's Your Health” section of its website.²²

In summary, the available English language Health Technology Assessment (HTA) literature does not support population screening for heart and lung or full body scans using MRI, PET, or CT scanning modalities. (See Appendix C-Summary of screening recommendations from various health organizations.)

Regulatory Overview

Medical imaging machines are incredibly complex and are increasingly becoming more complex as different modalities (e.g., CT and PET) are merged in single units and the capacity for digital storage and transfer of information grows. Because these are highly complex machines, component parts such as electrical circuitry and computer software can break down over time, necessitating constant evaluation, checking, calibration, and maintenance to ensure safe use.

Responsibility for regulatory oversight of the safety and sales of medical imaging equipment and its maintenance and use by private clinics and hospitals is fragmented. Health Canada is responsible for evaluating, licensing, and monitoring the introduction and sale of medical imaging equipment by manufacturers, distributors, and importers. Responsibility for how these machines are used in practice by clinics, hospitals, and professionals falls technically under provincial jurisdiction. In practice, most responsibilities

default to voluntary professional organizations which produce guidelines. Most major hospitals also have medical engineers to help maintain and manage equipment safety.

Medical imaging devices require a licence before they can be sold in Canada. Devices are categorized through the Risk-Based Classification System as Class I, II, III, or IV, determined by the degree of invasiveness, the hazards of energy transmission, and the potential consequences to a patient in case of device malfunction or failure. Most imaging equipment falls between Classes II and IV.

Manufacturers are required to submit proof that the device has been tested and meets a number of technical standards; however, these standards do not specify how much radiation an operator should expose a patient to for a given procedure, or if that particular procedure is worth it given the radiation exposure. Therefore, Health Canada also requires manufacturers to label medical imaging equipment, identifying the level of radiation a patient will be exposed to for a specific procedure and purpose, although this information is not made public.

Health Canada is also responsible for administering the *Radiation Emitting Devices Act*, aimed at protecting workers, and has developed a Safety Code, which is often referenced in applicable provincial legislation. There is no federal or provincial regulation regarding the cumulative exposure of patients to ionizing radiation.

The 2004 federal Auditor-General's report on the Medical Devices Program at Health Canada provides an important reality check on the ability of Health Canada to meet its obligations and the expectations of the public. It identifies major gaps in the program and a serious lack of human and financial resources to meet identified obligations. The Auditor-General also comments that the federal government's "current approach to regulation, which involves an increased reliance on industry to protect the health and safety of the public," requires more active involvement of Medical Devices

Program staff to ensure compliance. (See Appendix D for the full recommendations.)

Although the Therapeutics Products Directorate of Health Canada has agreed to undertake corrective action, there has been little progress in implementation. The Department is currently awaiting direction from political authorities.²³ Despite this obvious lack of progress, the *Medical Devices Program Strategic Plan 2007-2012* opens with the statement: "Health Canada has a strong regulatory program for medical devices. Canadians can be confident that medical devices sold in this country are safe, effective, and of high quality." Given what we know about how little the use of devices is regulated in actual practice, such statements may deliver a misleading sense of security to Canadian consumers, not only because of the limitations of the federal regulatory program for medical devices, but also because the safety, effectiveness, and quality of this equipment rests heavily on its applied uses, maintenance, and operator skills.

The Practices of Clinics and Hospitals

The authority to regulate professionals, hospitals, and private clinics is vested in provincial and territorial governments. In practice, the maintenance and uses of medical imaging equipment in these settings rests with the individual organizations and the physicians or other professionals ordering the tests and/or using the equipment. In turn, provincial Colleges of Physicians and Surgeons oversee the practice of medicine.²⁴ Specialists such as radiologists also have to meet certain standards to be certified by the Royal College of Physicians and Surgeons.²⁵ In addition, private clinics often seek, or are required to seek, accreditation from private accrediting bodies, and in some provinces these clinics are required to be accredited by provincial Colleges of Physicians and Surgeons. Accreditations are largely process-oriented (i.e., were certain checks are performed at certain intervals) and do not deal with the purpose or appropriateness of testing or marketing claims. In general, oversight is directed to locations as opposed to the companies owning

the location. Private assessment and care management companies appear to exist in a regulatory vacuum, and, practically speaking, colleges struggle to maintain influence over physician practices in the growing corporate health-care sector.

Public Opinion Polling on Screening

Background

In order to inform our study and as a precursor to designing our public opinion survey, we searched extensively for opinion polling of Canadians' awareness of the promotion and use of new medical imaging tests for health screening purposes (e.g., lung scans, heart scans, virtual colonoscopies, and whole body CT and MRI scans). In particular, we were interested in public perceptions of the reliability of these scans in predicting or ruling out specific diseases, as well as the perceived benefits, harms, and desirability of such scans. We were also interested in public perceptions of regulatory controls and protections related to the safety and quality of imaging equipment and its uses, as well as the marketing claims of private clinics.

“They didn't tell me there were any risks from [my scan].”
—Shirley (Ontario)

Our background searches included available polling by Health Canada, the Canadian Public Health Agency, and the Health Council of Canada, as well as the Ontario Provincial Ministry of Health. The Canadian Opinion Research Archive was reviewed and e-mail or telephone contact was made with all major commercial polling companies. Large consulting and marketing research compa-

“One thing that concerns me though, that they don't tell you, is that they are giving you a lot of x-rays, that's a lot of radiation. They don't tell you that.... They used to advertise in the [newspaper] for their clinic and they don't make it clear that you are having a pile of x-rays... I found out after by reading”
—Albert (Alberta)

nies, employer benefit plan managers/insurers, and private clinics or brokers offering employment-related or privately purchased “health checks” were contacted or had their websites searched. In addition, we searched the academic literature and the websites of radiology associations, health technology assessment organizations, mainstream media outlets, consumer groups, and regulatory standards and governance bodies. We also contacted the Canadian Cancer Society (CCS).

Although we were unable to find any Canadian polling that answered our specific areas of inquiry, a number of polls/studies and synthesis reports spoke to underlying issues (e.g., perceptions of risk for specific diseases, belief in personal responsibility for health and the ability of individuals to influence health outcomes, expectations of the public health care system, the growth of private-pay imaging clinics, and wait times for access to CT or MRI technologies inside Medicare).^{26,27} Searches for public polling in other countries, particularly the U.S., produced more results, although they are still limited in terms of their relevance to our area of inquiry.

Following several discussions with pollsters and researchers who conducted similar polls in the past, we developed a series of 16 polling questions that addressed the public perception of preventive screening. We interviewed researchers in the United States (Lisa Schwartz and Steve Woloshin) who conducted a similar study there several years ago, and they shared their polling instruments with us. (For our complete polling results, see Appendix E.) Our aim was to target individuals of both genders across Canada who were above 45 years of age. In addition to providing feedback on our polling questionnaire, Malatest and Associates, a national public opinion and evaluation firm, field-tested and then surveyed, with our approved questionnaire, 400 Canadians nationwide.

What We Found:

While our poll was intended to give us a baseline sense of how informed Canadian consumers are

with respect to the benefits, harms, regulation, and reliability of these medical screening exams, our survey sample was small. With 400 respondents, and a small number of survey questions, we are not claiming our survey was exhaustive. We were able, however, to highlight some important trends in the consumer perspective on the issue of screening in general and in particular the kinds of services offered by private-pay imaging clinics.

a) Perceptions of Benefits and Desirability:

Widespread enthusiasm for screening

Similar to U.S. citizens, Canadians' enthusiasm for screening tests is widespread. Studies from a decade ago indicate that Canadians already had a strong desire for access to a range of screening tests, regardless of official recommendations or the existence of controversy about the benefits and harms of specific tests. For example, a 1996 survey of 682 patients at primary care sites in Ontario and Michigan found that patients' desire to undergo a range of screening tests was similar and high in both jurisdictions, although Canadian patients had lower expectations of actually receiving the tests. Physicians in both jurisdictions underestimated patients' desire for screening tests.²⁸

In the U.S., a 2004 national survey on cancer screening by a team of researchers found that most adults (87%) believe that routine cancer screening is almost always a good thing to do, while less than one-third believed there will ever be a time when they will no longer undergo routine screening. In this same study, a substantial portion of people surveyed thought that an 80-year-old who chose not to be routinely screened for specific procedures (e.g., mammography or colonoscopy) was irresponsible. Almost 4 in 10 had experienced one false positive screening test, but nevertheless admitted they were glad they had the test. More than 7 out of 10 said that, given a choice, they would prefer to receive a whole-body computer tomographic (CT) scan instead of \$1,000 cash.²⁹ Asking this identical question

in our survey, it was evident that Canadians also place a relatively high value on a screening test of dubious value: 61% of Canadians we surveyed would prefer a free full-body CT over \$1,000 cash. We speculated that this enthusiasm for screening may reflect a fear of specific diseases or a perceived substantial health advantage to submitting to a full-body scan.

Fear of disease may be a strong motivator, a thought confirmed in the yearly Sanofi-Aventis HealthCare Survey (2007 and 2008)³⁰ for employers and benefit plan managers which found that Canadian employees worry most about being at risk for cancer (78%), heart disease (70%), and diabetes (54%). These concerns may also be driving the growth of employer-paid "executive health assessments." Common beliefs that "an ounce of prevention is [always] worth a pound of cure," together with the value that physicians and patients place on the early detection of disease (even in the absence of the effectiveness of such screening), may also explain the enthusiasm for screening.

b) Perceptions of Reliability: To err is strictly human

To err in diagnosis is perceived to be a human characteristic in today's medical culture, compared to a machine which is considered more reliable or infallible.³¹ A 1999 Canadian focus-group study found that patients considered test results more accurate than the history or results of the physical examination during routine check-ups. In contrast, physicians generally placed more value on the history and physical examination. Both physicians and patients placed a high value on the detection of insidious diseases, and past polls have shown that patients rarely identified any disadvantages to screening tests. When advised that early diagnosis does not necessarily translate into better chances of survival, patients saw it as contrary to popular wisdom. Finally, perhaps due to cuts to health care budgets in Canada during the 1990s, both

patients and physicians tended to be suspicious of government advice on screening tests (such as the Canadian Task Force on Preventive Care) believing that criticisms of screening must be financially motivated.³²

The results from the 2004 U.S. national survey (mentioned above) indicated that 74% of those surveyed believed that finding cancer early would save a person's life most or all the time³³ (Schwartz, 2004). A similar perception was noted in our results where 65% of people surveyed indicated that the detection of a potential health problem with a private CT scan would contribute to a longer life. That two-thirds of the general

Over 60% of people surveyed either thought that there were no risks/safety concerns associated with screening technologies or indicated that they did not know of any risks. In addition, people largely believed (63%) that CT scanning exposes the patient to less radiation than conventional X-rays.

public assumes an “early detection equals salvation” mindset without much questioning may reflect a general public misunderstanding of the very small and sometimes non-existent mortality benefits that such screening programs provide. Placing a tremendous value on the accuracy of preventive screening exams was also captured in our survey where nearly half of those surveyed believed that CT scans can verify the absence of disease at least 80% of the time.

Surveys from other countries suggest that patients' expectations of the reliability of screening tests depends on community reported experience^{34, 35} and the experience of acquaintances in

terms of missed abnormalities or false positives. The public seems to have a reasonably high tolerance of false positives or “cancer scares” for mammography, as found in recent research; and there is still a very strong motivation to screen for and detect breast cancer in women. The most common cause of court-supported malpractice cases for radiologists in Europe and the U.S. is missing an abnormality in a mammography exam.³⁶

c) Perceptions of Regulation and Safety: The knowledge gap

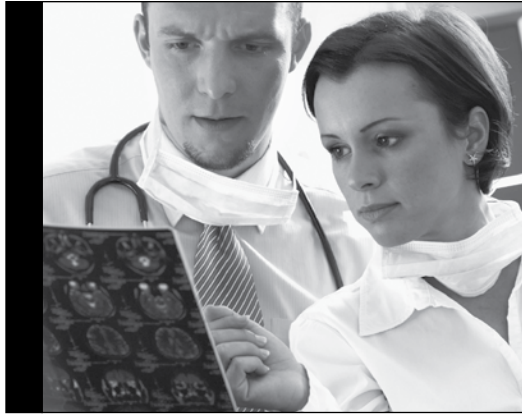
Canadian public polling related to the adequacy of regulation, the function and uses of imaging technologies, or the claims of private imaging clinics related to scanning technologies is sparse and hard to find. However, one poll conducted by Ipsos Reid as part of a 2007 study for Health Canada on communicating risk related to consumer products (excluding medical and food products) provides insights.³⁷ According to this survey, Canadians in general “demonstrate a poor level of knowledge” and “have an unwarranted degree of confidence in the scope of systems currently in place to assure product safety.” For example, large numbers of survey respondents believe that the government and manufacturers test all products sold in Canada (they don't). This belief echoes an earlier Canadian public poll relating to medical devices (e.g., hip implants, glucose monitors, pacemakers, complex diagnostic machines, radiation-emitting devices, blood tests). Conducted in the early 1990s as part of a major review of the regulation of medical devices in Canada, this survey found “that Canadians believe that nearly all medical devices being used in Canada have been subject to government review and approval.” (In fact, only about 5% of medical devices were subject to review.)³⁸

Recent polling of the public in the U.K. (in addition to nurses, pharmacists, and doctors) turned up a similar lack of knowledge about the nature, safety, and regulation of medical products.³⁹

A 2006 Ipsos-MORI poll for the Medicines and Healthcare products Regulatory Agency in that country found that widespread public confidence in medications and medical devices “seems to stem from an overall confidence in doctors,” although polling of nurses, pharmacists, and doctors indicated these groups were also poorly informed about the regulatory system. Another important finding was that many members of the public found the concept of “risk” difficult to conceptualize. Although few members of the public said they knew anything about the way that medicines and medical devices were regulated or who is responsible, two-thirds said they have confidence in the way they are regulated. “The general feeling was that, if you can buy the medicine or device, you can assume it’s safe.” This perspective was echoed, to some extent, in our findings where more than half of those surveyed believed that governments *do* currently regulate the use and advertising of screening exams for healthy people.

As found in the British public survey mentioned above, there is a gap in the public knowledge of safety issues around screening technologies. Our survey found Canadians are relatively misinformed about the risks of screening procedures. Over 60% of people surveyed either thought that there were no risks/safety concerns associated with screening technologies or indicated that they did not know of any risks. In addition, people largely believed (63%) that CT scanning exposes the patient to less radiation than conventional X-rays. (Some CT screening involves the equivalent of up to 500 chest X-rays.)

Despite repeated and highly publicized warnings from the FDA and radiologist associations about the dangers of full body CT scans, a survey of 94 patients in the U.S. who underwent a full-body CT strongly supported statements that “full body CT screening is appropriate for healthy people as well as people with specific disease” and that “this test is one of the best options today for preventive care.”⁴⁰



Discussion

In terms of the major findings of our study, we believe the following points are worthy of note:

- Canadian consumers are being exposed to extensive (and often very misleading) marketing about screening for specific diseases: about 40% of Canadian consumers in our poll indicated that they had seen ads promoting preventive health screening. Some advertising even implies that diseases cannot be effectively treated if someone waits for symptoms to occur.

“The effective dose from CT can be orders of magnitude larger than traditional plain film examinations, depending on the examination type. For example, a typical chest CT (approximately 8 mSv) can result in an effective dose 400 times larger than a plain film chest x-ray.”

Computed Tomography Radiation Safety Issues in Ontario
http://www.ehealthinnovation.org/files/CT_radiation_safety.pdf

- Some of that screening being promoted directly to consumers (with CT or PET scans) may be harmful.
- There is the potential for harm due to false positives: excessive medical procedures and physical harm to people, including death from follow-up procedures as well as the potential for such screening to miss important signs of disease and thus provide a false sense of security to people. Although these screening scans are often advertised as being “non-invasive,” further investigation of minor anomalies often involves serious medical interventions, including the insertion of a tube into the lungs, stomach or bowel, or a needle into an organ such as the liver, kidney, or adrenal gland. And the final result may well be that there was nothing seriously wrong in the first place.⁴¹
- There is potential harm from excess radiation with many screening exams and apparently very little advice or systems in place to shield patients from excessive dosages or cumulative exposure to ionizing radiation,

which is, in itself, a risk for cancer.⁴² While new machines offer lower doses, this can also lead to more casual use of these tests, leading to greater exposure over time.

- There are growing concerns among a number of physicians within the system that excessive medical screening is overloading the public health care system, diverting resources from the lower-paying and more important work diagnosing and treating disease, and leading to additional investigations arising from high rates of false positives (or “incidentalomas”) arising from some highly unreliable screening.⁴³
- The licensing and sale of imaging equipment and related pharmaceuticals are regulated, but the uses of these scanners once licensed (which affects the risk and benefits to consumers) is out of the hands of Health Canada. According to the Auditor-General, there is far too little surveillance of industry compliance with the rules related to investigational testing and reporting of incidents once medical imaging equipment is in use. Provincial and territorial governments are responsible for the people and organizations that buy and/or use medical imaging equipment, but oversight and management are primarily left to institutions, companies, and voluntary initiatives. Professional groups have developed guidelines on dosage for different types of CT scans, but no provincial government has made them a regulatory standard. By contrast, the European Union adopted guidelines for the whole continent about four years ago.⁴⁴
- The screening of healthy individuals is being marketed to Canadians largely by private clinics, health-care brokers, and companies providing services to corporations and insurers. The information provided by the individual clinics is variable in quality, and

some of that information is misleading, falsely reassuring, or outright fraudulent. (See Appendix A.)

- The medical imaging industry is a powerful force pushing the uptake of screening around the world, and this industry has a strong North American presence that is looking to expand its markets.
- The screening is largely being paid for by employers and private disability insurers and others outside the public system, and much of it lacks a sufficient

The medical imaging industry is a powerful force pushing the uptake of screening around the world, and this industry has a strong North American presence that is looking to expand its markets.

base in evidence or proof to ensure the benefits outweigh the harms. There are only a very few types of cancer screening that have an evidence base sufficiently strong to be promoted by public health agencies (pap smear, colorectal cancer, and mammography), and even there much controversy, debate and conflicting beliefs question the claimed population-wide benefits of these screening modalities. Given this controversy, researchers in Australia have been working on a Guide for the Public to help people make informed personal decisions about the value of colon cancer screening.

- Consumers are not fully informed when it comes to being screened. The polling conducted by others, as well as our own survey, revealed a number of misinformed beliefs around screening. Our survey of the quality of information available on

screening found very few sources of quality information (with one exception, the site operated by the Radiological Society of North America at: www.radiologyinfo.org)

- There is a strong belief that “early detection equals salvation.” Our survey found that 65% of respondents believed that the detection of a potential health problem with a private CT scan would contribute to a longer life. Nearly half the people surveyed believed that CT scans can verify the absence of disease at least 80% of the time. The fact that people can place a relatively high value on a screen of dubious value is reflected in our survey result that

found more than 60% of respondents would prefer to get a full body scan rather than \$1,000.

- People largely think scanning is safe (60% of our survey said that they thought there were no risks or safety issues associated with CT scanning or that they didn’t know of any) and erroneously believe (63%) that CT scanning exposes you to less radiation than conventional X-rays.
- People wrongly believe that the government regulates the use and advertising of screening (but are mixed on whether it should or should not perform a regulatory function).



Conclusions and Recommendations

“When you read the hundreds of images of a whole-body [CT] carefully enough, you will find something ‘abnormal’ in any asymptomatic person. Then what do you do? The easiest way out is to overlook that finding or propose a re-examination in six months’ time. [Given the concerns and predications of increased cancers due to increased use of CT], that is unethical.”

—Dr. Peter A. Rinck,
If it moves, radiologists will want to screen it, May 19, 2008.

“After all, *unlike pilots, clinicians* do not share the fate of their patients.”

—Evans et al.⁴⁵

Medical tests and treatments offer great benefit, but can also lead to harm. The more hazardous a good or service, the higher are consumer expectations that such goods and services are managed in ways that will limit harm and maximize benefits. In addition, consumers of medical goods and services are unusually vulnerable consumers, trusting in health professionals and regulators who are assumed to be working in the patients’ best interest.

Although “patient safety” has been the focus of many initiatives in Canada’s health care system in recent years, its lack of visibility in this relatively unregulated private health-care sector in Canada has led to little research in this area.⁴⁶

In our research, we were surprised by both the extent of the market and the lack of protection for consumers as purchasers of both medical imaging exams and private health assessments or pre-employment physicals. This situation, where there is little apparent consumer protection, could pose a significant risk to the public and may also lead to a loss of confidence in both health professionals and governments. There are indications that the marketing of these services is driving public expectations for unproven and unreliable testing, leading to even greater risks of harm to the public through significant demands on limited health human resources.

If public and private markets are to work to the benefit of a society, consumers need to be assured of a reasonable level of safety and have access to information and education to assist them to make informed choices. Given the non-discretionary nature of medical treatment, Canadian consumers also need to be assured that diverting

resources to other purposes (such as screening of little proven benefit) will not compromise the availability of care for the community.

We believe that, in order to begin to improve the quality of services and products sold in the medical marketplace and protect the safety and sustainability of our public health care system, it is important that federal and provincial governments consider these recommendations:

- Consumers, health professionals, and the media need quality information about the controversies and limitations of a proliferating number of screening tests, including new and sophisticated medical imaging tests. In particular, there is a desperate need for information to help the public and professionals understand how health information and studies are generated and disseminated and some of the common heuristic mistakes and deceptions. We have started to address this in our “Consumers’ Guide to Screening,” but admit that consumer-oriented information on screening needs to be further advanced and enhanced by future research, and that the dissemination of such material must be implemented with stable public support and funding.
- To address the disconnect between what the existing HTA literature says about screening asymptomatic individuals with heart, lung, and full body scans, and what is happening in the real world, including executive health assessment and employee fitness-to-work evaluations, provincial governments must establish meaningful oversight over the marketing and use of these procedures outside the publicly-financed system. Clearly the current way oversight is ceded to professional organizations is not working.
- The federal government should take immediate action on implementing the recommendations of the 2004 Auditor-General’s Report on the Medical Devices Program. (Appendix D)
- In the absence of improved controls on this growing sector through a variety of interventions, federal and provincial governments need to consider improved methods of remedies for harm done to both individuals and public assets such as the public health system. Governments must also resist the urge to directly or indirectly subsidize the growth of [these] dysfunctional markets.
- Federal and provincial research organizations and funding agencies should direct resources to find ways to gather system-level data, which would identify the impact of various screening tests on health system resources and accessibility of health care for ill and injured Canadians.

Appendix A

Information Available to Consumers Through Various Private Clinic Websites

Clinic Name	Benefits	Risks	Discussion of Potential Candidates	Reference to Evidence-Based Literature	Referral Required	Costs of Screening Exams	Marketing or Media Outlets	Anecdotal, Testimonial or Expert Opinion Appeal
Canadian Diagnostics Center (Vancouver & Calgary)	S	S	S	NS	S	NS	Health Newsletters	Expert opinion
False Creek Urgent Care Center (Vancouver)	S	NS	S	NS	S	NS	Radio, Television, Magazines	Testimonials
Medisys (Montreal) ¹	S	NS	S	NS	S	NS	unknown	Anecdotal
Insight Imaging (Edmonton) ²	S	S	NS	NS	S	NS	unknown	unknown
Mayfair diagnostics (Calgary)	S	S	S	NS	S	NS	Newsletters	Expert Opinion Testimonials "KNOW NOW!"
Westmount Square Medical Imaging (Montreal) ³	S	NS	NS	NS	unclear	NS	Not a strong marketing sense from this site	unknown
Ultralife (Huntington Beach CA) ⁴	S	NS	NS	NS	NS	S	Newspapers, ads, flyers, radio	"MEDICAL SCREENING SAVES LIVES"
Timely Medical Alternatives (Vancouver) ⁵	S	NS	NS	NS	S	NS	Television, Print Ads	Testimonials "DON'T WAIT!"
WellPoint Health Services (Toronto) ⁶	S	NS	S	NS	S (in addition to a 7-stage screening assessment)	NS	Television, Print ads	Testimonials, "LIVE BETTER LONGER"
Valley Medical Imaging (Abbotsford)	S	NS	NS	NS	S	NS	unknown	unknown
Ville Marie Nuclear Imaging and PET/CT (Montreal)	S	NS	NS	NS	S	NS	unknown	unknown

S= Satisfactory NS= not satisfactory

¹ only the CT and MRI screening departments are privatized and therefore the general public accepts them as a public facility. They do not market themselves for preventative scans but do offer a full body scan.

^{2, 3} Associated with Misericordia Community Hospital and McGill University Health Center, respectively.

⁴ This company is based in California but utilizes mobile facilities that are advertised in Canada. The website suggests that they only offer ultrasound screens but the company ads suggest that they have more advanced technologies like CT and MRIs. These services are offered for ALL body parts including the full body scan.

⁵ This clinic emphasizes wait times and the failures of the current Canadian Health care system. Referrals are required for diagnostics only.

⁶ This company offers health programs that would include diagnostic services. They have a detailed 7-stage screening assessment and require a physician referral before giving patients any screening exam. They focus on heart health.

Appendix B

List of Key Informant Interviewees

- Dr. David Vickar, President of the Canadian Association of Radiologists (CAR), Edmonton, Alberta.
- Maryann Napoli, Center for Medical Consumers, New York, New York.
- Dr. Irwin Hinberg, Health Canada- Bureau of Radiation and Medical Devices, Ottawa, Ontario.
- Dr. William Casarella, Professor of Radiology (Emory University School of Medicine), Executive Associate Dean for Clinical Affairs, Atlanta, Georgia.
- Dr. Barnett Kramer, Associate Director for Disease Prevention, National Institutes of Health, Bethesda, Maryland.
- Dr. Mario Garcia, Professor of Cardiology at Mount Sinai, Toronto, Ontario.
- Dr. Denise Aberle, Professor of Radiology, Vice Chair of Research, Radiological Sciences, Section of Thoracic Imaging. UCLA. Los Angeles, California.
- Dr. Joann Elmore, Section Head, Division of General Internal Medicine, Professor of Medicine and Adjunct Professor of Epidemiology at University of Washington.
- Heather Logan, Director of Cancer Control and Policy at the Canadian Cancer Society
- Dr. Rita Redberg, Director of Cardiovascular Women's Services at the University of California.
- Judy Illes and Patricia Lau, University of British Columbia's Center for Neuroethics
- Lisa Garcia, False Creek Surgical Center, Vancouver, BC.
- Dr. Peter Gotzsche, Director, Nordic Cochrane Centre, Copenhagen, Denmark.
- Dr. Gordon Guyatt, Professor, Department of Clinical Epidemiology & Biostatistics, McMaster University.
- Dr. Silvana Simi, Cell Biology and Cytogenetics Unit, Institute of Clinical Physiology, Pisa, Italy.
- Dr. Raymond Miralbell, Division de Radio-Oncologie, Hôpital Cantonal de Genève.
- Dr. Amanda Burls, Director of Postgraduate Programmes in Evidence-Based HealthCare (EBHC) at the University of Oxford, UK.
- Dr. Nortin Hadler, Professor of Medicine and Microbiology/Immunology at the University of North Carolina at Chapel Hill
- Dr. Gilbert Welch, General Internist at the Department of Veteran Affairs, Professor of Medicine at Dartmouth Medical School, co director of the Center for Medicine and the Media at the Dartmouth Institute for Health Policy and Clinical Practice.
- Drs. Steve Woloshin & Lisa Schwartz, General internists at the Department of Veteran Affairs, White River Junction, Vermont.
- Dr. Brian Lentle, Radiologist and Past President of the Radiological Society of North America, Victoria, BC.
- Dr. Harald Ostensen, Radiologist at the World Health Organization, Geneva.

Appendix C

Summary of Screening Recommendations from Various Health Organizations

Health Organization	Heart Screening	Lung Screening	Other
US Preventative Services Task Force (USPSTF)	The Grade D recommendation indicates that the USPSTF recommends against routine CT screening for coronary heart disease in asymptomatic patients (2004).	The Grade I recommendation indicates that the USPSTF concludes that the current available evidence is insufficient to recommend for or against the provision of routine lung screening using low dose CT technology (2004).	Colorectal Cancer: Recommends colonoscopy for adults between 50 & 75 yrs of age; grade I recommendation for CT colonography as a screening modality. Prostate Cancer: Grade I recommendation for men under 75 yrs; recommends against prostate cancer screening in 75+ years. Breast Cancer: Recommends mammography every 1-2 years for women over 40 (grade B).
National Cancer Institute (NCI)		The evidence is inadequate to determine whether CT lung screening reduces mortality from lung cancer.	Full Body CT: The NCI recommends against these screening exams saying that the harms outweigh the benefits. Breast Cancer: Mammography screening in women aged 40-70 yrs decreases breast cancer mortality. The benefit is higher for older women, in part because their breast cancer risk is higher.
Food and Drug Administration (FDA)			Full Body CT: The FDA recommends against these screening exams in healthy people.
Health Canada (HC)		Routine screening for lung cancer (using any screening modality) is not recommended by HC as there are no tests or techniques currently available that are effective in the early detection of lung cancer	Full Body CT: HC recommends against screening exams in healthy people. Colorectal Cancer: HC recommends that patients discuss family/medical history with their physician and decide whether a colonoscopy is necessary.
Canadian Diagnostic Centres (CDC)	Recommend cardiac CT scans for males patients over 40 years of age and female patients over 50 years.	Suggest lung screening for patients who are over 40 years of age and are smokers, chronic emphysema sufferers, and those exposed to air pollution.	Core Body CT: Include heart and lung CTs and a bone density scan. Suggest for those over 60 years of age. Virtual Colonoscopy (using CT): suggested for patients over 50 years of age.
Canadian Cancer Society (CCS)	Does not recommend cardiac CT screening in healthy individuals.	Does not recommend lung screening (via any screening modality) in healthy individuals.	The CCS suggests that only three tests have sufficient evidence to warrant population-based screening. These tests are breast cancer screening, colorectal cancer screening and pap-tests.
American College of Radiology (ACR)		Says that the evidence is not conclusive as to whether routine lung CT screenings successfully reduce mortality.	Full Body CT: The ACR has concluded that there is not sufficient evidence to support full body CT scans for patients with no symptoms.

Appendix D

The 2004 Federal Auditor-General's Report on Medical Devices⁴⁷

Recommendations include:

- **improved inspection** for regulatory compliance by manufacturers to such things as maintaining distribution records, responding to complaints and adverse events and selling only licensed devices;
- **increased vigilance** regarding the sale of unlicensed medical devices by using logos or bar codes to identify licensed devices and penalizing those who sell unlicensed devices;
- **analysis and interpretation of adverse events**;
- **an improved system for registering implant devices** since registration cards containing contact information used to locate patients are not always completed;
- **introduction of new regulations** covering the reprocessing and reuse of devices that are intended for single use only since there is information that single use devices are being reused to save costs;
- **a greater investment of resources** to deliver the program;
- **greater monitoring of clinical trials** and verification of the quality and integrity of the results of the trials;
- **post-market inspection** to assure that manufacturers or importers are operating adequate surveillance systems, taking appropriate action in response to adverse events or complaints, and reporting all serious adverse events to Health Canada;
- **improved communication** of concerns to health providers, as those surveyed by the Auditor suggested that communications were not timely.
- **an improved surveillance** system for collecting adverse events from health care professionals and patients after medical devices are in use, together with better

While Health Canada has made progress in important aspects of managing risks related to medical devices before they are made available for sale, it needs to better manage risk after they are available for sale.

Chapter 2—Health Canada—Regulation of Medical Devices, *2004 March Report of the Auditor General of Canada*, accessed at http://www.oag-bvg.gc.ca/internet/English/parl_oag_200403_02_e_14894.html

Appendix E

Results from Public Opinion Poll

Question B1. Have you seen or heard any media stories or advertisements encouraging healthy people to get a screening test such as a CT lung scan, a CT heart scan, a virtual colonoscopy or a full body CT scan?

In response to this question, 39% of people surveyed indicated that they had heard these advertisements while 59% percent said they had not.

Question C1. In talking about people with no apparent symptoms, do you think CT scans have the ability to *predict disease* greater than 80% of the time? (i.e. If the test identifies something that looks like cancer it will turn out to be cancer)

35.2 % said 'yes'

22.2 % said 'no'

13.7 % said 'maybe'

28.9 % said that they did not know or did not respond

Question C2. In talking about people with no apparent symptoms, do you think CT scans have the ability to *verify the absence of disease* greater than 80% of the time? (i.e. If the tests shows no cancer in the specific area, no signs or symptoms of cancer will be apparent in next year)?

46.6 % said 'yes'

16.2 % said 'no'

10.7 % said 'maybe'

26.4 % said that they did not know or did not respond

Question C3. When several doctors look at the results for the same full CT body scan, how often do you think they will agree about the diagnosis?

1.0 % said 'always disagree'

21.9 % said 'sometimes disagree'

1.0 % said 'neither disagree or agree'

49.9% said 'sometimes agree'

11.2% said 'always agree'

15.0 % did not respond or did not know

Question C4. If one of these scans detects a potential health problem in someone with no symptoms, do you think that the person will be more likely to live longer?

65.3 % said 'yes'

12.5 % said 'no'

15.0 % said 'maybe'

7.2 % said that they did not know or did not respond

Question C5. Assuming that you are a healthy individual with no signs/symptoms of a medical problem, would you rather receive a free full-body CT or a \$1000 cheque?

60.8 % said 'full body scan'

33.2 % said '\$1000 cheque'

6.0 % said that they did not know or provided no response

Question D1. Based on your knowledge, do you believe there are any risks or safety concerns related to use of CT scans?

- 28.4 % said 'yes'
- 42.4 % said 'no'
- 11.0 % said 'maybe'
- 18.2 % said that they did not know

Question D2. Based on your knowledge do you believe CT scans provide more, the same or less exposure to radiation than conventional X-rays?

- 17.7 % said 'more'
- 19.5 % said 'same'
- 28.4 % said 'less'
- 34.4 % said that they did not know or provided no response

Question E1. Do you think that governments regulate or control the *reason* for which these scans are used on people?

- 47.6 % said 'yes'
- 28.4 % said 'no'
- 9.2 % said 'maybe'
- 14.7 % said that they did not know or did not respond

Question E2. Do you think that governments regulate/control how these scans are *advertised* in the media?

- 33.7 % said 'yes'
- 34.9 % said 'no'
- 10.2 % said 'maybe'
- 21.2% said that they did not know or did not respond

Question E3. Governments in Canada do not regulate the different *reasons* for which CT scans are used by healthcare clinics. Do you think that they should?

- 40.6 % said 'yes'

- 51.6 % said 'no'
- 3.7 % said 'maybe'
- 4.0 % said that they did not know or did not respond

Question E4. Governments in Canada do not regulate the *advertising* of these imaging tests by healthcare clinics. Do you think that they should?

- 44.4 % said 'yes'
- 47.4 % said 'no'
- 4.5 % said 'maybe'
- 3.7 % said that they did not know or did not respond

Question F1a. Have you ever had a CT lung scan, heart scan, virtual colonoscopy or full body CT scan directly paid by either you or your employer in the absence of symptoms or an identified health problem?

- 10.0 % said 'yes'
- 88.8 % said 'no'
- 1.2 % said that they did not know or did not respond

Question F1b. Have you ever considered purchasing one of these CT scans?

- 7.5 % said 'yes'
- 92.0 % said 'no'
- 0.5 % said that they did not know or did not respond

Question F1c. [If Yes to either of the 2 questions above] Would you be willing to participate in a short interview with the researchers of this survey? We would provide you with a \$25.00 gratuity as a thank you for your time.

- 50.0 % said 'yes'
- 46.6 % said 'no'
- 3.4 % said that they did not know or did not respond

Appendix F

To Screen or Not to Screen, That is the Question: A Consumer's Guide to Health Screening

“A good screening test is the one that saves the most lives and harms the fewest healthy people in the process.”

— H. Gilbert Welch, author of *Should I Be Tested for Cancer?* (U of Calif Press, 2006)

Screening in this case refers to looking for signs of disease in an otherwise healthy person, that is, a person without any symptoms. Anyone who has a lump or a bump or anything suspicious related to their health and consults their doctor for further investigation is considered to be undergoing “diagnostic” screening. Here, the physician is looking for the cause or source of a symptom or complaint. The objective of health screening, for the purpose of this guide can be defined as follows: “the early detection of those diseases whose treatment is either easier or more effective when undertaken at an earlier point in time.”¹ Essentially this guide to screening is not directed towards diagnostic investigations, but focuses solely on screening tests: those tests done on healthy people searching for early signs of disease.

An otherwise healthy person has the time to become educated before considering whether they wish to submit themselves to a ‘screen’. A screening test could be as simple as a blood test,

such as a PSA test in men, looking for early signs of prostate cancer; slightly more invasive tests, such as a pap smear for cervical cancer or a mammographic x-ray to search for signs of breast cancer in women, are also common. The screening could involve very sophisticated imaging devices such as CT, PET or MRI scans of internal organs, including hearts or lungs which expose patients to electromagnetic energy or radiation.

The National Cancer Institute of Canada says this about population screening: “because screening involves subjecting apparently healthy individuals to potential risk, population-based screening programs are recommended only when five specific factors are met. We discuss these factors under “Evidence of Benefit.” In constructing this checklist we assume one thing: That any otherwise healthy person presented with a screening test will want to approach the screening decision with as much good information about it as possible. People will want to ask questions and will expect reasonably detailed answers concerning the test’s potential benefits or harms. The decision to get screened is a personal one, and best made with good information and the advice of a trusted health professional. Further quality information can be found in references below.

Criteria	What should you be asking about?	Notes
Evidence of Benefit ²	<ul style="list-style-type: none"> • Is there evidence the test can lead to treatment that reduces overall mortality? • Does the test detect the disease in a 'pre-clinical' phase? • Does the test accurately predict when disease does exist (high sensitivity) and it does NOT exist (high specificity)? • Does the test expose the individual to an unacceptable level of risk? • If a cancer is identified through screening, is effective treatment available? (Treatment that reduces morbidity or mortality to a greater extent than no treatment and that does not have unacceptable risks) 	<p>Good evidence should be the bedrock upon which screening recommendations are built. You need to know how strong the foundation is for the recommended screening test.</p> <ul style="list-style-type: none"> • Does the test detect a disease at a point where, once detected, something meaningful can be done about it? • Does the test have a high degree of accuracy? • How often does it find things that turn out to be false alarms? • Is the test safe?
Quantification of Risk and Benefit	<ul style="list-style-type: none"> • If the screening test is to reduce my risk of becoming sick or dying from a particular disease, what is my risk to start with? • How big is it given my circumstances and age? And how much can a screening test reduce that risk? 	<p>Well-studied, evidence-based screening programs will be able to say how many people may be saved from a harmful outcome if they are screened versus those who are not screened. Not knowing how big your risk is to start with is like seeing a "50% off" sign on a dress but not being told the original price.²⁹</p>
Disease Mongering	<ul style="list-style-type: none"> • Is the particular screening test being oversold? • Are the risks of the disease in question made to look as scary as possible? 	<p>Sometimes promoters of screening may exaggerate or over-sell a condition, turn risk factors into diseases or misrepresent the natural history and/or severity of a disease. Look out for spurious statistics, fear mongering, and treating 'signs' of disease as diseases in and of themselves.</p>
Costs of Testing	<ul style="list-style-type: none"> • What does it cost to do the test and is the cost of the test covered by my health plan? 	<p>Screening tests that aren't a publicly-funded benefit in Canada are likely either not strong on the evidence (i.e. PSA testing) or too expensive and difficult to apply to the entire population (i.e. CT screening for colorectal cancer).</p>
What happens next?	<ul style="list-style-type: none"> • If I get a 'positive' test result, what happens next? (see questions below about harms of testing) 	<p>Here's where you need to hear about what the options you'll likely be presented with. You may hear such terms as: biopsy, surgery, further tests, cumulative radiation exposure and "watchful waiting."</p>
Harms of Testing	<ul style="list-style-type: none"> • What are the potential downsides to being tested? • What is the likelihood of finding false positives? • Is there anyway to mitigate the likely anxiety and further stress that an individual may experience? • Should I be concerned about the exposure to radiation or other hazards or more repeated tests? 	<p>These may be among the most important questions you need to ask. If there is a possibility that the test could harm you, you might want to rethink your desire to submit to the test. You should find out as much as you can before you agree to a test.</p>
Sources of Information	<ul style="list-style-type: none"> • Who is promoting a test (is it a for-profit or a non-profit organization)? • Has the test been approved and recommended by a respected national body? 	<p>Sometimes there may be pressure on your doctor to do a test. You should find out if your doctor is under any pressure to recommend screening tests, or is rewarded for recommending them.</p>
Availability of the test	<ul style="list-style-type: none"> • Is the test available where I usually receive health care? • Is the test paid for through a public health plan? 	<p>Non-coverage of tests is a red flag worthy of further investigation. Health systems typically assess screening tests to see if they are justified on the basis of evidence, safety and affordability. If this information isn't available, you should find out why.</p>
Other options	<ul style="list-style-type: none"> • Are there other things you could do to prevent the disease in question? 	<p>There is a range of sensible advice that a physician could give you to help you avoid the disease in question, and advice you need if you think there is something suspicious that may need further investigation.</p>

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Appendix G

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