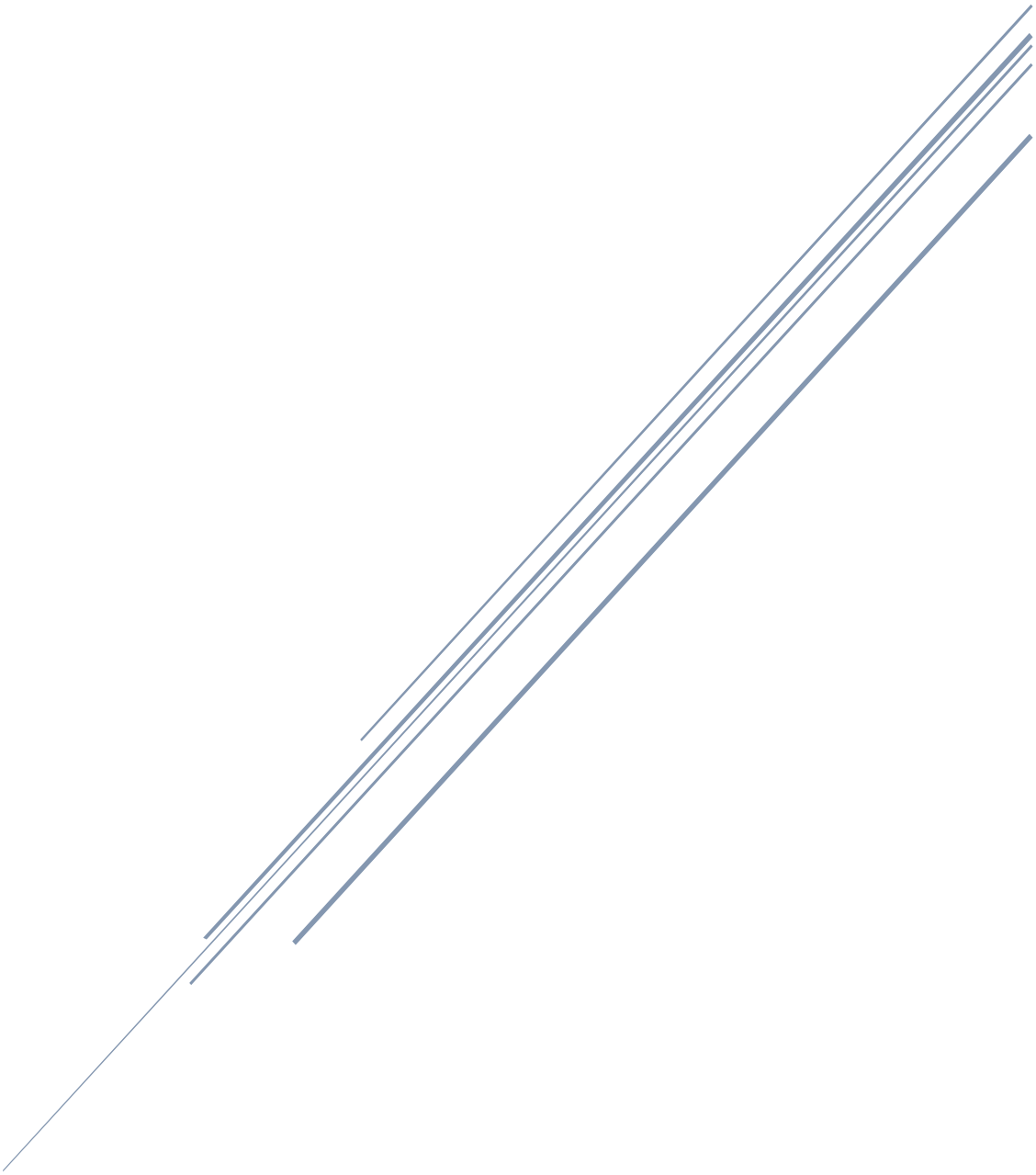
SCREENING TESTS FOR THE PRIVATE PAYER MARKET IN CANADA

A Case of Ovarian Cancer and Alzheimer's Disease Screening Tests



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Executive Summary

The objective of this report is to evaluate the commercial potential of screening tests for ovarian cancer and Alzheimer's disease for the private payer market. The research team was asked to conduct a secondary research based on the review of published reports and statistical data. Due to confidentiality concerns, the team avoided any contacts with prospective users or prescribers of the tests. No technical (i.e., specificity or sensitivity) or commercial data (i.e., price) of the tests were available for the purpose of this research. The research team aimed to analyze and compile the available data about the prevalence of ovarian cancer and Alzheimer's disease in Canada, the economic burden of the diseases, the value of possible solutions and business opportunities from introducing the screening tests for these two diseases.

Both diseases – ovarian cancer and Alzheimer's disease – are among high priority health issues in Canadian society. The early detection of the diseases in patients would be beneficial in terms of patients' survival (in case of ovarian cancer) and the cost-effectiveness in healthcare expenditure. Moreover, the early detection of these diseases could potentially offer financial incentives to patients and their caregivers in terms of significant long-term savings, which would ultimately encourage patients to cover the costs of the screening tests.

Although the early detection of these diseases is encouraged, there is no sufficient evidence to recommend using the existing screening tests for ovarian cancer and Alzheimer's disease in the general population. The lack of accurate sensitivity tests – that can justify the cost of screening at the early stages of the disease in a reasonable number of cases – is the main reason for the reluctance in introducing screening tests in the general population. Therefore, new tests could potentially change the current position in favor of screening. In case of Alzheimer's disease, there is no agreement as to the profile of the high-risk population; this makes the screening more expensive and impractical. Additionally, there has not been any prior screening experience with biomarkers for Alzheimer's disease, adding more skepticism to the effectiveness and efficiency of such screening. Unlike Alzheimer's disease, the market is more ready for the introduction of a screening test for ovarian cancer because of the prior experience with biomarkers and a distinct high-risk population for ovarian cancer.

This research concludes that there is a better market opportunity for ovarian cancer screening. Proper market preparation, including raising awareness of patients and healthcare providers, should precede the introduction of the screening test for Alzheimer's disease. It is also recommended that the media and patients' societies be utilized as a medium to communicate the value of screening for the general population. Collaboration and constant communication with clinical societies will provide valuable input to devising an effective marketing plan and increase the credibility of the test.

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Ovarian Cancer

Cancer is a term used for diseases with uncontrolled division of abnormal cells, which are able to invade other tissues in the body.

Ovarian Cells and Tumours

The ovaries are made up of three main kinds of cells. Each of these types of cells may develop into a different type of tumour.

1. **Epithelial cells** – make up the outer layer of the ovary

   (Cancerous tumours that start from epithelial cells are called epithelial ovarian carcinomas and serous carcinoma is the most common type.)

2. **Germ cells** – found inside the ovary and are the reproductive cells or the egg cells

   (Granulosa cell tumours are the most common type of stromal tumour.)

3. **Stromal cells** – form the structural connective tissue that holds the ovary together

   (Germ cell tumours are cancerous tumours that start in germ cells; these tumours – for example, dysgerminoma and yolk sac tumour – are rare.)

Ovarian tumours may be benign (not cancerous) or malignant (cancerous). Ovarian tumours that are malignant (cancerous) can spread (metastasize) to other parts of the body and can be serious.

Factors That Contribute To Risk for Ovarian Cancer

- **Age** – ovarian cancer is more common in women aged 50-79, the risk increases as one gets older
- **Family History** – the risk is higher among the woman with the history the breast cancer prior to age 50 or ovarian cancer at any age in their close blood relatives
- **Reproductive History** – the risk is higher if a woman has not a child
- **Oral contraceptives/hormone replacement** – the risk is lower for women who have used oral contraceptives and the risk may be higher if they have taken hormone replacement
- **Ethnicity** – Jewish women of Eastern European (Ashkenazi) background have a higher risk. French Canadians of certain ancestry may be at increased risk

- **Other factors** – the risk may be higher if woman have a history of a condition called endometriosis (Ovarian Cancer Canada, 2015).

*These factors are primarily known to **increase the risk for the most common type** of ovarian cancer, epithelial ovarian cancer; the risk factors for other ovarian cancers are not as well known.

Incidence and Mortality:

About 17,000 women live with ovarian cancer in Canada. In 2013, it was estimated that 2,600 new cases of ovarian cancer would be registered in Canada -- 300 cases in Ontario and 1,150 in British Columbia. "Ovarian cancer is the 5th most common cancer for women and is the most fatal women's cancer" (Canadian Cancer Society's Advisory Committee on Cancer Statistics, 2013).

Ovarian cancer incidence has not changed in the last ten years in Canada, including its major provinces (Fig 1&2).

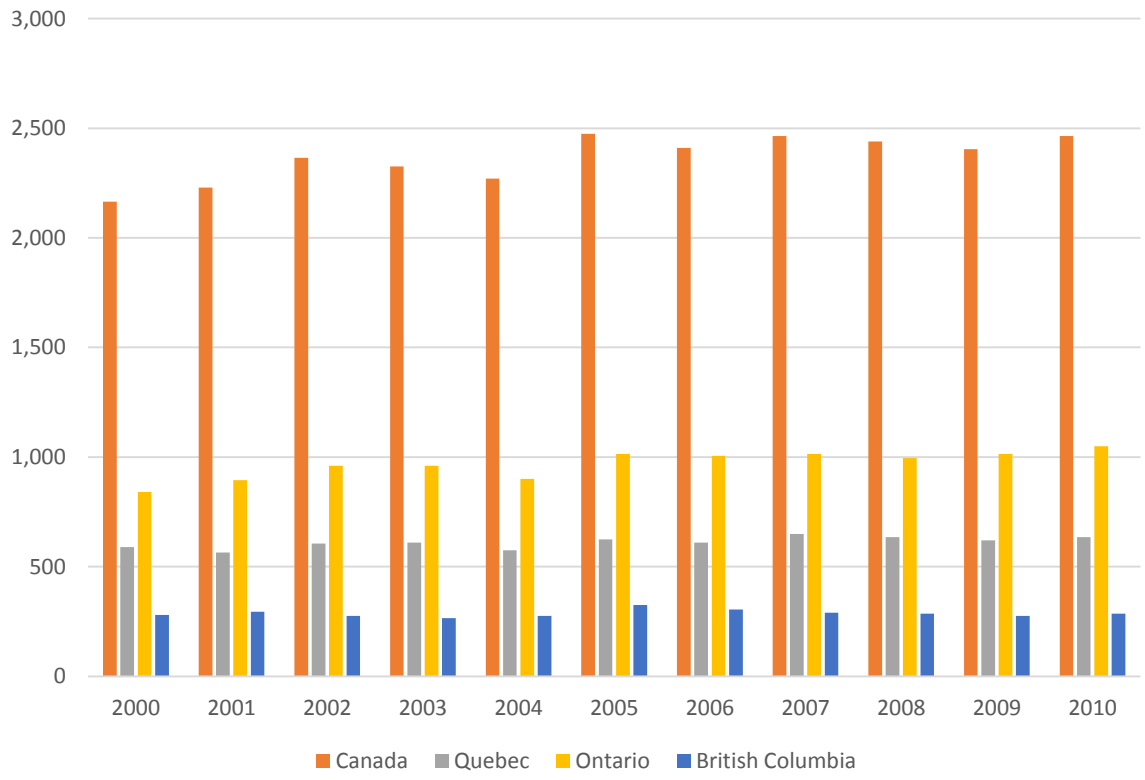


Figure 1: The total numbers of new cases of ovarian cancer (Statistics Canada, 2010)

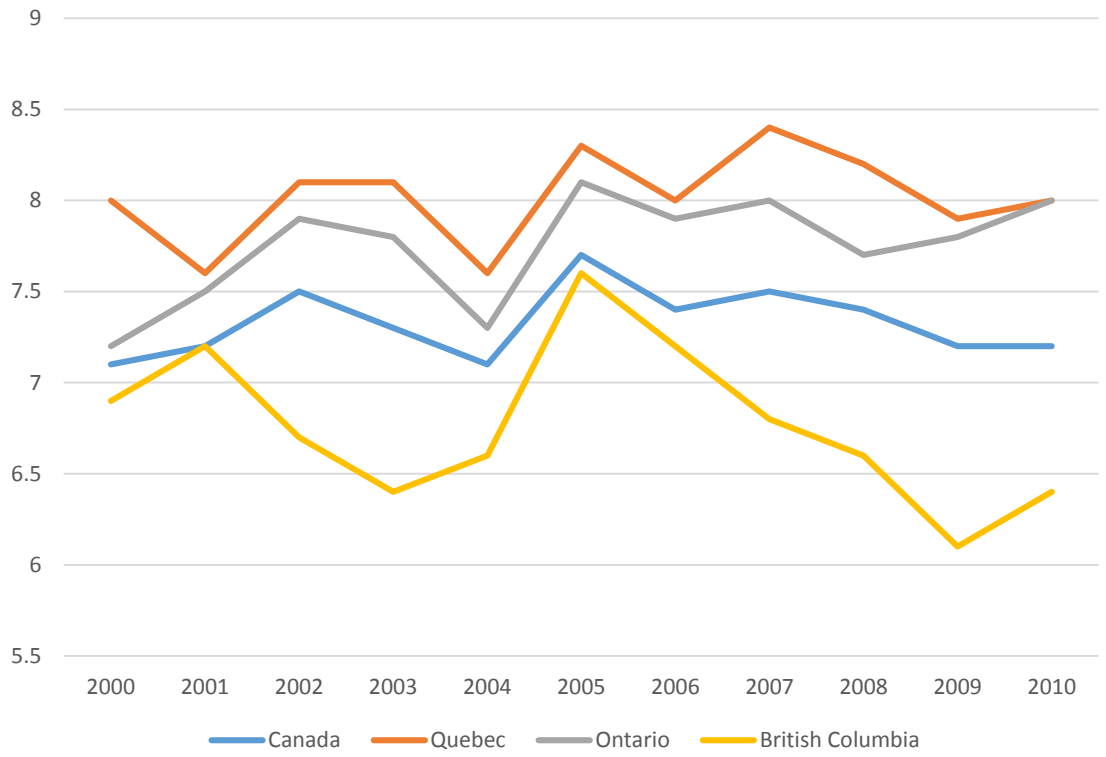


Figure 2: New cases of ovarian cancer per 100,000 population (Statistics Canada, 2010)

It is estimated that in 2014, 2,700 Canadian women will be diagnosed with ovarian cancer and 1,750 women will die from ovarian cancer in Canada. With all the existing advances in cancer treatment, the majority of patients with ovarian cancer will not live for more than five years after diagnosis (See Figure 3).

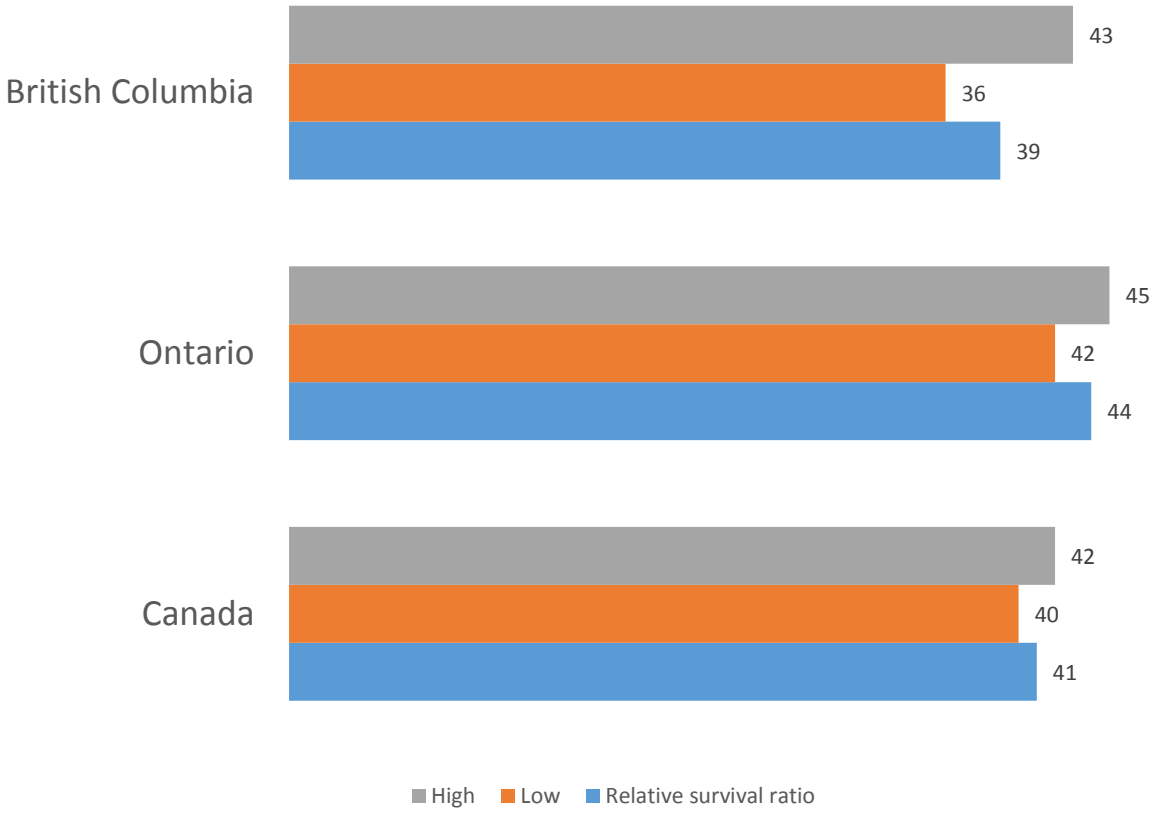


Figure 3: Five-year survival rate of ovarian cancer (Statistics Canada, 2011)

One of the main reasons for the disappointing therapeutic result for patients with ovarian cancer is late diagnosis. Figure 4 explains the importance of early diagnosis in the outcome of the treatment. While 91% of cancer patients live more than five years if they are diagnosed in the localized stage, only 15% of patients are diagnosed in this stage. In other words, 70% of patients are diagnosed in the stages when the chance of five-year survival does not exceed 27%.

Figure 4 illustrates the association between early diagnosis and the survival of patients with ovarian cancer. Diagnosing ovarian cancer in the localized stage – compared with a distant-stage diagnosis – will increase the chance of five-year survival by three times.

Figure 4: The diagnosis and survival of patients with ovarian cancer in different stages (The Surveillance, Epidemiology, and End Results (SEER) Program, 2011)

Early Detection of Ovarian Cancer

The best way to find ovarian cancer at early stages is "to recognize symptoms and get regular health check-ups." Presently, "there are no effective screening tests to find ovarian cancer early in women who are at average risk for the disease." Unfortunately, "ovarian cancer is usually diagnosed at an advanced stage" by the time women have symptoms. "As a result, most women have advanced ovarian cancer at the time of diagnosis (Canadian Cancer Society, 2015)."

The following tests are usually considered for the early detection of the ovarian cancer

The following screening tests are usually considered for the early detection of ovarian cancer.

Pelvic Exam: "Regular pelvic exams may help find an ovarian tumour before it … spread[s] (Canadian Cancer Society, 2015).

Ultrasound: It is used to look for any changes or abnormalities in the ovaries.

Cancer antigen 125, (CA-125) test: CA-125 is a protein cancer that is secreted by cancerous ovarian cells; however, it is released from other cells as well. Therefore, measuring the level of CA-125 in the blood might be a tool to detect and monitor the treatment response in patients with ovarian cancer. However, CA-125 is not recommended for screening of general population for ovarian cancer because:

- CA-125 is not significantly higher in early-stage ovarian cancer; and
- CA-125 is not specific for ovarian cancer and the blood level can be increased in other diseases (Canadian Cancer Society, 2015).

The Burden of the Disease

Based on the epidemiology described above, we can state that ovarian cancer is a comparatively less common type of cancer than, for example, breast cancer: it affects only around 1.3 per cent of women over the course of their lifetime (American Cancer Society, 2015) in comparison to around 12 per cent of women who are diagnosed with breast cancer each year (U.S. Breast Cancer Statistics, 2014, September). The Person's Years of Life Lost (PYLL) due to ovarian cancer is 249 as estimated by the US Cancer Trends Progress Report by the National Cancer Institute in 2011-2012. This is significantly less than, for example, PYLL from lung and bronchus cancers, which stands at 2,378 (ibid). However, according to the American Cancer Society, "ovarian cancer ranks fifth in cancer deaths among women, accounting for more deaths than any other cancer of the female reproductive system (American Cancer Society, 2015).

Challenges associated with diagnosing ovarian cancer during stage one of the disease makes it difficult to cure and, consequently, comparatively costly for the health-care system, family and society as a whole because it requires in-hospital and/or palliative care. Other costs associated with ovarian cancer care -- as any other cancer treatment -- are also quite substantial (Canadian Cancer Action Network and Canadian Cancer Society, Manitoba Division, 2010). According to the CMAJ Open Research, direct costs associated with ovarian cancer treatment in Ontario were on average $29,640 in the year immediately after the diagnosis for patients who survived the first year after the diagnosis (De Oliveria el al, 2013). These costs included cancer-related surgeries, radiation and chemotherapy, hospital and home care (See Appendix 1 for more details). The costs for patients who died in the first year after the diagnosis were $46,270. The charts below

show the increase of the direct health care costs for ovarian cancer patients before and after the cancer diagnosis.

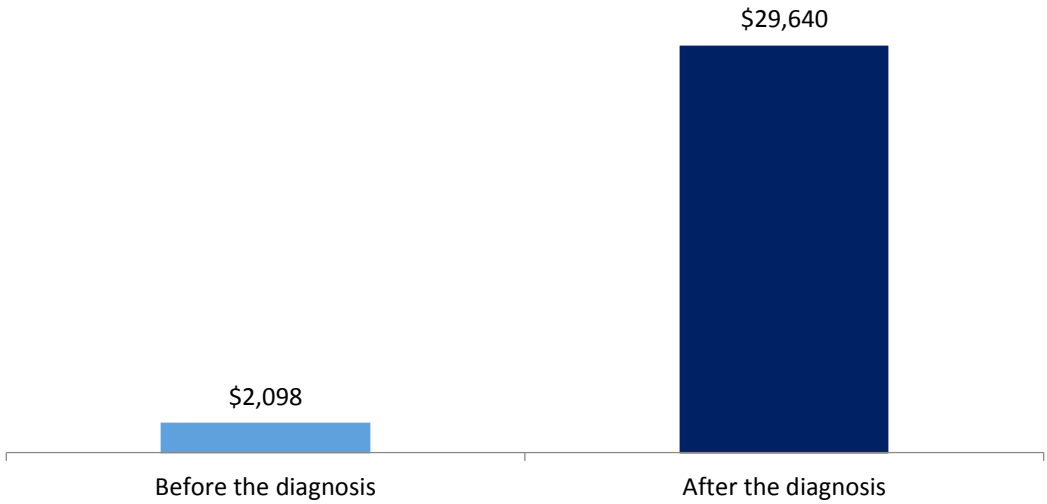


Figure 5: Total direct health care costs for ovarian cancer patients before and after the cancer diagnosis (De Oliveria el al, 2013)

Note from the source: "The pre-diagnosis phase of care is the last 3 months before diagnosis (in light blue). The initial phase of care is the first 12 months following diagnosis (in dark blue)."

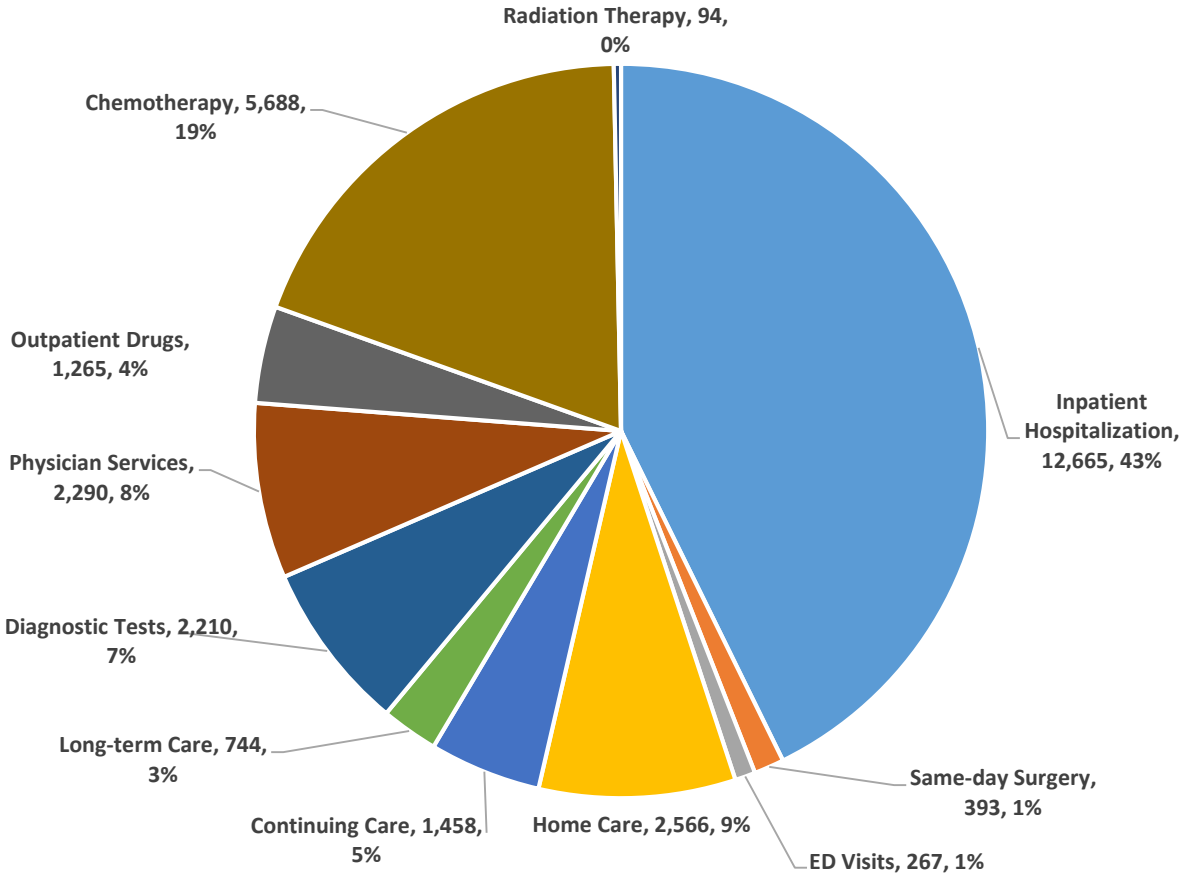


Figure 6: Direct health care costs for ovarian cancer patients before and after the cancer diagnosis by resource for pre-diagnosis phase for cancer patients who survived beyond the first year after diagnosis (De Oliveira, et al., 2013)

Other sources, which include indirect costs such as caregiver's lost wages, indicate an average of $25,000 per month for various types of cancers:

> *"Guerrier et al.'s 2010 study of ambulatory and home-based palliative care at one centre in Toronto reported a total mean monthly cost of about $25,000. This high cost was due in large part to the detailed accounting of caregiver's lost wages and leisure. These costs made up $17,453 – or more than two-thirds — of the $25,000 monthly total. Other costs included $6,400 per month per patient in health care system costs, $172 in third-party insurer costs, and $698 in patient or family out-of-pocket expenses. {Guerrier et al., 2010} This was one of few studies detailing informal caregiving costs. Its findings suggest that families and caregivers may be assuming a large proportion of the burden associated with end-of-life care* (Hodgson, 2012).

According to the Five-Year Action Plan to Address the Financial Hardship of Cancer in Canada: A Call for Action, *"severe financial hardship [of cancer] can be created by two major factors:*

- *Family income may decline dramatically because of the need to stop working during treatment or while caring for a loved one who is ill. Gaps in our public safety nets leave some people with few financial footholds until they have hit rock bottom.*
- *Expenses may skyrocket at the same time as income is dropping. Gaps and inconsistencies in coverage and services can leave individuals responsible for tens of thousands of dollars in additional costs* (Canadian Cancer Action Network and Canadian Cancer Society, Manitoba Division, 2010)*."*

According to the same source "one in six Ontario cancer patients said out-of-pocket costs were significant or unmanageable" and "lost income may have a larger effect than out-of-pocket costs." The document further states that although some governmental support is available to individuals diagnosed with any type of cancer, the assistance is limited. For example, even though Employment Insurance may cover sickness benefits for up to 55 per cent of the salary, it is paid only for 15 weeks and not everyone is qualified for the program.

Furthermore, the application process for the Canada Pension Plan Disability program is quite complicated too, and "…having cancer, even with metastatic disease, is often insufficient to obtain the benefit and the medical criteria are extremely limited.… Before becoming disabled, the individual must have made adequate CPP contributions in at least four of the last six years, or valid CPP contributions for at least 25 years, including three of the last six years. (Canadian Cancer Action Network and Canadian Cancer Society, Manitoba Division, 2010). Consequently "an average annual household wage loss from cancer in Canada is $17,729 per person with the national estimate of household wage loss of $2.95 billion**."** (Canadian Cancer Action Network and Canadian Cancer Society, Manitoba Division, 2010)

Other expenses related to cancer treatment include expenses for medications. "Some medications which are not given in hospitals are not covered by government plans. The Canada Health Act states that only drugs provided for patients in a hospital setting must be provided free of charge. In most provinces [including Ontario], people have to pay all or some of the cost of certain medications that are taken at home, even if they are considered essential as part of

internationally accepted treatment protocols. Today half of the newer cancer treatment drugs are taken at home, which means that the burden of drug costs is shifting to the individual." As CMAJ Open Research indicates, the costs for the drugs related to ovarian cancer care after the diagnosis vary on average between $1,265 to $1,296 for patients who survived the first year after the diagnosis and for those who did not (De Oliveria el al, 2013) (See Appendix 1).

Caregivers' expenses are quite significant too: "The economic contribution of family caregivers was estimated at more than $25 billion for 2009, and one in four Canadians cared for a loved one with a serious illness in the last 12 months."

Additional expenses, which are significant but often overlooked, include travel expenses for patients and their caregivers, accommodation, gas, parking, meals, childcare, and housekeeping (Canadian Cancer Action Network and Canadian Cancer Society, Manitoba Division, 2010).

Ovarian Cancer Screening Tests

A number of tests have been evaluated as potential methods of screening for ovarian cancer. The most studied available screening tests by are trans-vaginal ultrasound and serum CA-125. (Serum markers are substances in the blood that can be detected in blood tests.) Less information is available regarding a number of other bio-markers, used alone or in combination.

CA-125

"CA-125 is a protein released by more than 90% of advanced epithelial ovarian cancer." (Epithelial ovarian cancer is the most common form of the disease.) "As a result, the CA-125 protein has become the most evaluated serum marker for ovarian cancer screening" (Memorial Sloan Kettering Cancer Center, 2015).

Studies have suggested that CA-125 also appears to be elevated in 2-3% of normal post-menopausal women. "Given this fact and the relatively low annual incidence of ovarian cancer, screening using the CA-125 test has not been effective enough to warrant its widespread use." To diagnose one additional case of ovarian cancer "using CA-125 as the primary screening method, another 100 to 150 women would have to … [be tested] and approximately 30 diagnostic operations should be performed" (Memorial Sloan Kettering Cancer Center, 2015).

"To improve the … [effectiveness] of CA-125 measurements for ovarian cancer screening," experts suggest monitoring "the change in CA-125 concentration in the bloodstream over time, as opposed to relying on the absolute value" (Memorial Sloan Kettering Cancer Center, 2015).

Serum CA-125 in Combination with Transvaginal Ultrasound

"Several studies have evaluated the combined use of transvaginal ultrasound and CA-125. These studies have suggested that the combination of these tests result in a higher sensitivity for ovarian cancer detection, but at the cost of an increased rate of false positive results… The positive predictive values for an abnormal test were 1%for transvaginal ultrasound and 3.7% for CA-125. When both were abnormal, this value increased to 23.5%" (Memorial Sloan Kettering Cancer Center, 2015).

Genetic testing

The BRCA1, BRCA2, or PALB2 genetic tests are not used for the screening of ovarian cancer because there is no consensus on "screening guidelines for women at average risk of developing the disease" (Breastcancer.org, 2015).

Genetic testing also has limitations and possible drawbacks, including the following:

- The medical procedure following the positive test has not been determined;
- Removing the breasts and ovaries (prophylactic surgery) does not significantly reduce the risk of breast or ovarian cancer;
- Normal test results do not guarantee healthy genes; and
- An abnormal test result and lack of clear medical advice can trigger anxiety, depression, or anger (Breastcancer.org, 2015).

Test	Pros	Cons
CA 125	The most thoroughly assessed serum biomarker for ovarian cancer	Poor sensitivity and specificity in early stage disease
CA 125+ Trans-vaginal Ultrasound	Improved specificity and sensitivity	Time consuming, costly
Genetic testing	Objective result	Lack of clear practical recommendation following positive tests

Table 1: Summary of available screening tests

Guidelines

The screening for ovarian cancer in the general population is not recommended by clinical guidelines. The main reason is the low sensitivity of available tests. The published guidelines by Cancer Care Ontario (Cancer Care Ontario, 2004), BC Cancer Agency (BC Cancer Agency, 2015) and The National Hereditary Cancer Task Force (Horsman, et al., 2007) would not recommend the screening of ovarian cancer in the general population.

Women without specific risk factors.

- There is no clear evidence to prove the benefit of ovarian cancer screening with currently available methods. “Ovarian cancer screening with serum markers such as CA-125 and/or transvaginal ultrasound is … [recommended] within the framework of research studies (Memorial Sloan Kettering Cancer Center, 2015).

Women with increased risk.

- There is no clear evidence to prove the benefit of ovarian cancer screening with currently available methods. The ovarian cancer screening with serum markers such as CA-125 and/or transvaginal ultrasound is recommended within the framework of research studies (Memorial Sloan Kettering Cancer Center, 2015).

Women with inherited risk.

- The advantages of ovarian cancer screening have not been proven in the women with inherited risk; however, the screening is suggested in "those who have mutations in ovarian cancer susceptibility genes." The recommended screening method is "using a combination of transvaginal ultrasound and CA-125 testing," and this method "should generally begin between ages 30 and 35." Furthermore, genetic counselling is strongly recommended for women in this group to better clarify the risk of ovarian and related cancers (Memorial Sloan Kettering Cancer Center, 2015).

The characteristics of an acceptable biomarker for ovarian cancer screening

Drescher et al. conducted a simulation based on the current available screening tests for ovarian cancer to find the cost-effectiveness of hypothetical modalities. According to their estimation, the prospective biomarker should have a substantially better sensitivity than CA-125 and its cost should not exceed $200. Moreover, the screening should be done twice a year in order to reach a 25% mortality reduction in average-risk women (Drescher, et al., 2012).

Guideline	**Cancer Care Ontario**	**BC Cancer Agency**	**The National Hereditary Cancer Task Force**	
Risk Profile	Recommendation	Recommendation	Definition	Recommendation
General population	N/A	Not recommended	N/A	N/A
Increased risk	N/A	Not recommended	N/A	N/A
Inherited risk	Not recommended	Not recommended	BRCA1 or BRCA2 mutation	With currently available technologies, ovarian cancer surveillance is not routinely recommended

Table 2: Summary of recommendation by guideline

Market potential of ovarian cancer screening

Market size

The market for cancer diagnostics is growing rapidly. The development of new technologies enables healthcare professionals to have more accurate and affordable diagnostic services which result in more demand for diagnostic services. The global cancer diagnostics market is expected to grow from $1.6 billion in 2013 to $10 billion in 2019 (BCC Research, 2014). Cancer biomarkers constituted $4 billion of this market in 2012 and the researches forecast a low single digits growth till 2017 (Insight Pharma Reports, 2013).

Stakeholder analysis

Figure 7 shows the official and unofficial stakeholders involved in the decision-making for disease screening. The solid black lines represent the formal influencers in the process, while the dotted lines determine the unofficial influencers.

1) General practitioners (GPs): They are the main and final decision-makers who can prescribe the screening tests for patients. GPs are usually follow the respective clinical guideline; however, in the absence of clear clinical recommendations, they decide based on patient's characteristics and their clinical judgment.
2) Clinical societies: The aim of clinical associations is to discuss and harmonize the decisions and practices within the medical society. They can be related to specialities such as "The society of Obstetricians and gynecologists of Canada," or cover general medicine such as "the college of physicians and surgeons of Ontario." One of the functions of clinical associations is to publish guidelines to harmonize the clinical practice across the provinces or Canada. Therefore, effective communication with these societies can impact the daily practice of physicians.
3) Payers: Payers refer to institutional payers. They usually only reimburse screening tests' expenses which are endorsed by solid clinical data. Payers usually follow the recommendation of the respective clinical societies; however, payers challenge the clinical societies, if the recommendation is not supported by clinical evidence.
4) Patients: Patients are the user of screening tests; however, the final decisions are made by physicians. They can ask for the tests if they are well informed about the value of screening tests.

5) Patient societies: They are usually non-governmental organizations which represent the patients' interests in the decision-making process. They are usually a part of new products' evaluation for registration or reimbursement. They usually have educational programs for patients or at-risk individuals to inform them about the treatment or diagnostic methods.
6) Media: Media is a visible informal player which can impact all the decision-making process by publishing relevant information. The media can challenge both the governmental and non-governmental authorities in case of incoherent decisions.

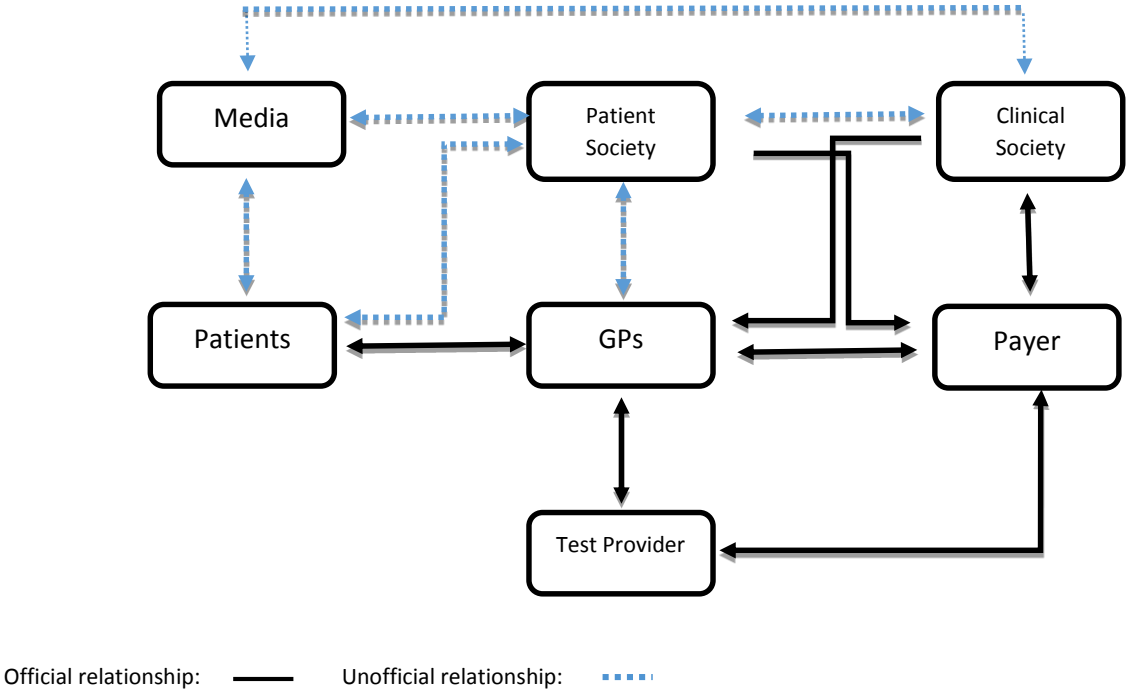


Figure 7: The map of Stakeholders

SWOT Analysis

		Helpful to achieving the objective	**Harmful** to achieving the objective
Internal origin	(attributes of the system)	*Strengths* • Availability of several relevant biomarkers in Ovarian cancer • Prior experience of biomarkers in Oncology	*Weaknesses* • Lack of proven ovarian cancer biomarkers • Lack of long-term studies about the bio-markers • Failed prior experience of biomarkers in the ovarian cancer
External origin	(attributes of the environment)	*Opportunities* • Clear definition of high risk population • Proven benefits of early diagnosis • A high demand for screening tools • Low competition	*Threats* • Screening is not recommended by experts or practice guidelines • No direct communication channel with end users • Regulatory restrictions about the marketing of ovarian cancer screening

Conclusion:

Although there is a huge opportunity for the early detection of ovarian cancer, the readiness of the market for ovarian cancer screening tests is in question for two main reasons: the lack of evidence and lack of accurate sensitive tests. The available data shows that the early detection of ovarian cancer would be beneficial for patients and societies in terms of survival and the cost of disease management.

It seems that the lack of accurate screening tests is central to the uncertainty about the screening of ovarian cancer. The existing practice guidelines consider the current technologies when they recommend a specific medical intervention. Because of the inefficiency of the current tests in the early detection of ovarian cancer, the existing guidelines will not recommend the screening in the general population. The entrance of an effective screening test will change the practice guidelines and the behavior of healthcare professionals toward the screening.

The main challenge for promoting screening tests for the private payer market is the absence of direct communication with end users who are the ultimate payers for the service. Therefore,

conveying the value of the screening test will likely be among the decisive factors that will affect the purchase rate of the service. However, other stakeholders can be utilized as an opportunity to enhance the communication of the value of the screening test with the public. Interested stakeholders such as the media and disease organizations can be used as the marketers of the value of the screening test.

Targeted market segmentation will also help to increase the efficiency of introducing ovarian screening tests to the private payer market. To have a better understanding of the target market, it is essential that stakeholders consider the risk profile of the general population for ovarian cancer. Such a comprehensive approach will result in a more effective communication of the value of the screening tests to the general population and relevant stakeholders.

Alzheimer's disease

Epidemiology

Discovered in 1907 by Alois Alzheimer, a German neuropathologist (Norris 2007), Alzheimer's disease is a fatal, progressive and degenerative disease that destroys brain cells. Today, it accounts for 64 per cent of all dementias in Canada. It affects men and women of all races, religions and socio-economic backgrounds.

As many diseases have been eliminated, particularly those that used to affect children and young, the life expectancy of Canadians has increased. The proportion of the Canadian population over 65, which accounted for only 4% in 1900, is expected to stand at 20% by 2026 (Norris, 2007). As a result of the longevity, there is an increase in the number of Canadians affected by conditions associated with dementia, most commonly by Alzheimer's disease (AD).

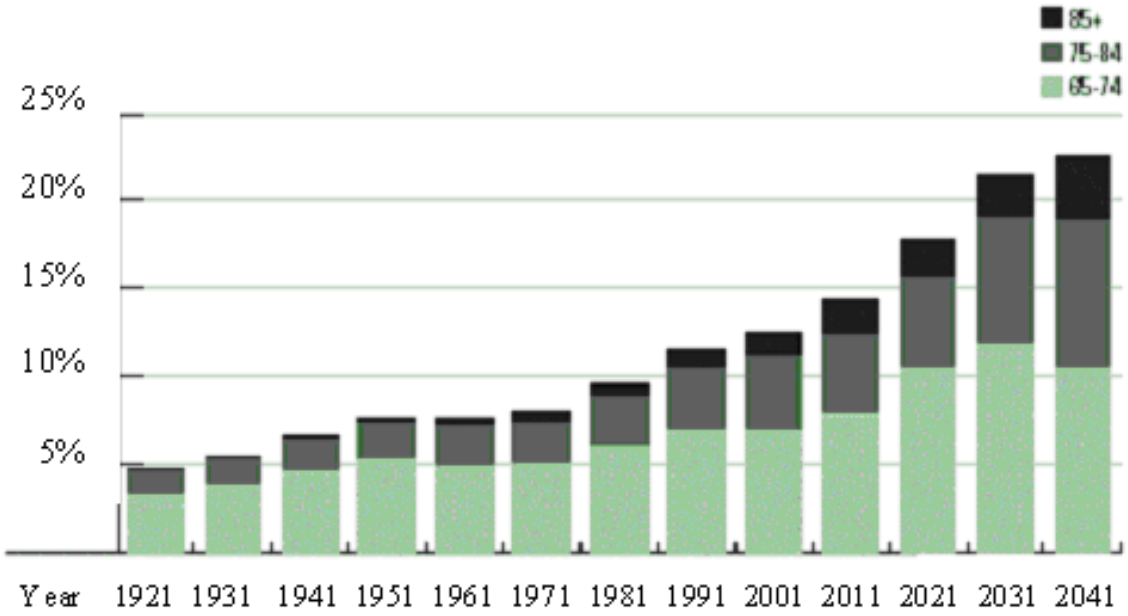


Figure 8: Seniors by age subgroup, as % of the total population, Canada, 1921-2041 (Division of Aging and Seniors, 2002)

Figure 8 demonstrates that the population of seniors (+65 years) is rapidly growing as a result of increasing life expectancy (Division of Aging and Seniors, 2002). According to *Public Health Agency of Canada* (Norris, 2007), a Canada's National Population Health Study of Neurological Conditions was initiated in 2009 and presented the following results:

1. An estimated 3.6 million Canadians are affected by neurological conditions (Public Health Agency of Canada, 2015);

2. Over the next 20 years, Canada will see a significant increase in the number of people diagnosed with a neurological condition as a result of the aging population, particularly Alzheimer's disease and other dementias, as well as Parkinson's disease (Public Health Agency of Canada, 2015); and

3. Over the next 20 years, it is projected that hospitalization will remain the largest contributor to total direct health care costs for many neurological conditions except for Alzheimer's disease and other dementias, where facilities-based long-term care will remain the largest contributor (Public Health Agency of Canada, 2015).

Figure 9 presents that in both in Ontario and British Columbia – the provinces targeted by Life Labs – the growth of aging population is fast, and there is a potential for age-related diagnostic services.

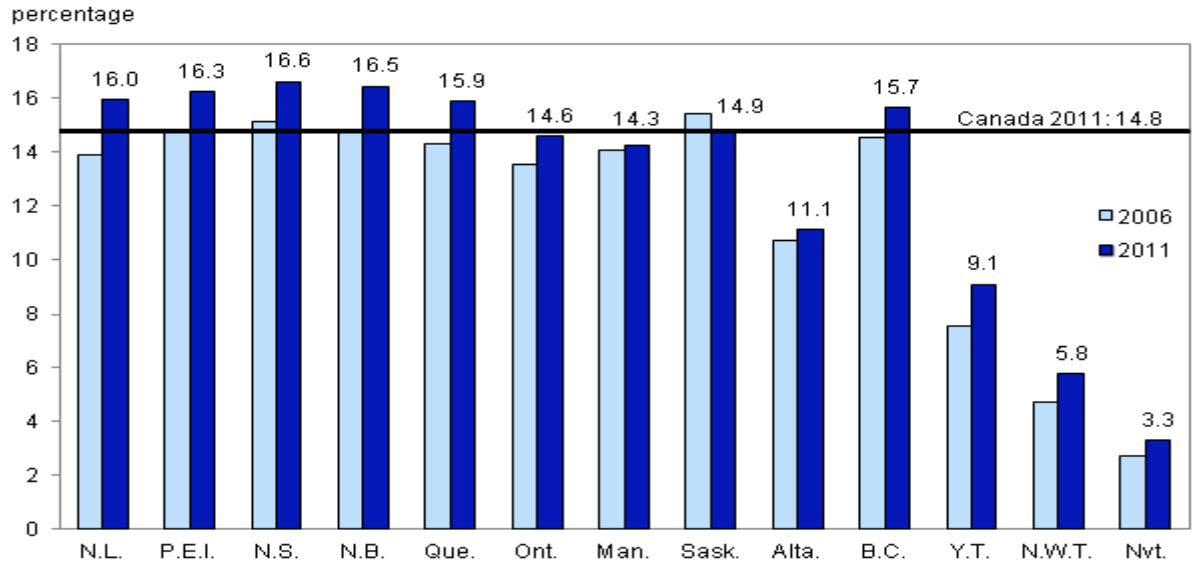


Figure 9: Proportion of the population aged 65 and over, Canada, provinces and territories, 2006 and 2011 (Statistics Canada, 2011)

Incidence and Prevalence

As the Baby Boomer population ages, the number of seniors with dementia is expected to increase dramatically. Nearly 200,000 Ontarians over the age of 65—or one out of ten—are now

living with this disease, an increase of 16% over the past four years. By 2020, close to 250,000 seniors in Ontario will be living with dementia[1].

Although the disease is not of epidemic proportions, the estimated number of Canadians living with AD in 2007 was 300,000, while almost 450,000 suffered from either AD or a related dementia (Alzheimer Society of Canada, 2015). Roughly 7% of Canadians over the age of 65 have AD; therefore, the number of people affected is projected to exceed three-quarters of a million by the year 2031. Although the percentage of the population suffering from AD has been found to fluctuate between studies and countries, the rapid rise in both incidence and prevalence are quite consistent. It is generally agreed that there is a doubling in both parameters for every five years after age 65 (McDowell, 2011).

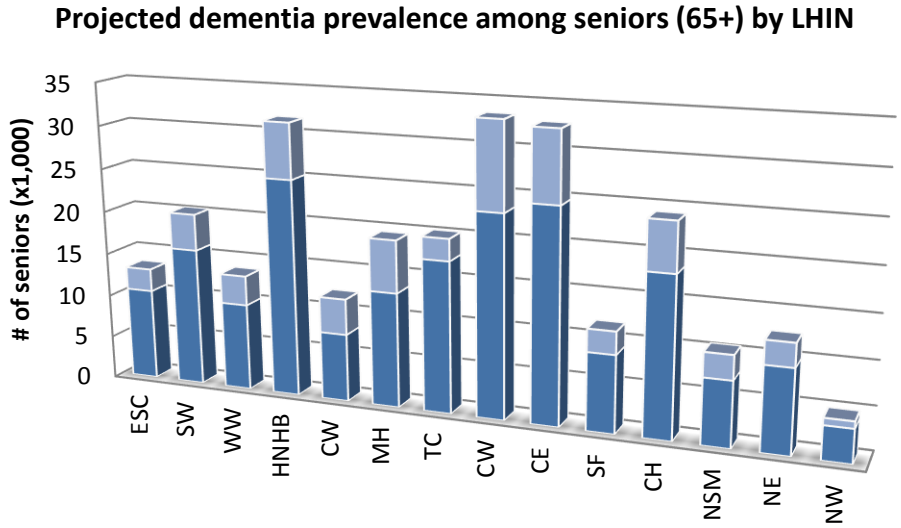
In order to understand the magnitude of the AD in Canada, it is very important to understand how many Canadians are living with this condition. Furthermore, focusing on the prevalence (extent of the population affected) and incidence (new occurrence) of the AD in Canada are presented as a highlight of how this disease has been evolving through the past years.

Increases in dementia prevalence will vary among different regions in Ontario depending on the demographics of its population. As age is a primary risk factor for dementia, those regions expecting substantial increases in the number of people aged 80 and above will experience the highest growth in dementia prevalence (Alzheimer Society of Ontario, 2012).

The number of new cases of dementia in 2038 among Canadians (65+) is expected to be 2.5 times than for 2008. In 2008, 103,700 new cases of dementia were registered in Canada: in 2038, it is estimated that 257,800 new dementia cases will be registered (Alzheimer Society of Canada, 2010).

Figure 10 indicates the difference of senior population in different regions of GTA which should be considered for marketing and promotion of services for this age group.

[1] Dementia prevalence was calculated using 2006 Census-based Ministry of Finance Population Estimates (2001-2010) & Projections (2011-2036) for Local Health Integration Networks (unpublished, updated May 2011) and prevalence rates from the Alzheimer Society of Ontario, “Projected Prevalence of Dementia: Ontario's Local Health Integration Networks,” April 2007 (based on the Canadian Study of Health and Aging, 1994).



	ESC	SW	WW	HNHB	CW	MH	TC	CW	CE	SF	CH	NSM	NE	NW
2020	2.6	4.2	3.4	6.4	4.1	6	2.5	10	8.1	2.6	5.6	2.8	2.7	0.8
2012	10.6	16	10.1	25.1	7.9	13.3	17.5	23.3	24.6	9	18.4	7.6	9.7	3.9

Figure 10: Projected dementia prevalence among seniors (65+) by LHIN (Alzheimer Society of Ontario, 2012)

Ontario LHINs: Erie St. Clair (ESC), South West (SW), Waterloo Wellington (WW), Hamilton Niagara Haldimand Brant (HNHB), Central West (CW), Mississauga Halton (MH), Toronto Central (TC), Central (C), Central East (CE), South East (SE), Champlain (CH), North Simcoe Muskoka (NSM), North East (NE), North West (NW), cited in Dementia Evidence Brief: Ontario, Alzheimer Society Ontario, August 2012

Looking Ahead: 2011 to 2031

The number of Canadians aged 40 and over who have Alzheimer's disease and other dementias (based on prevalence numbers) will almost double (Public Health Agency of Canada, 2015); similarly, there will be at least twice as many, if not more, Canadians aged 65 and over who are living with each of the seven modelled neurological conditions (based on prevalence numbers) (Public Health Agency of Canada, 2015).

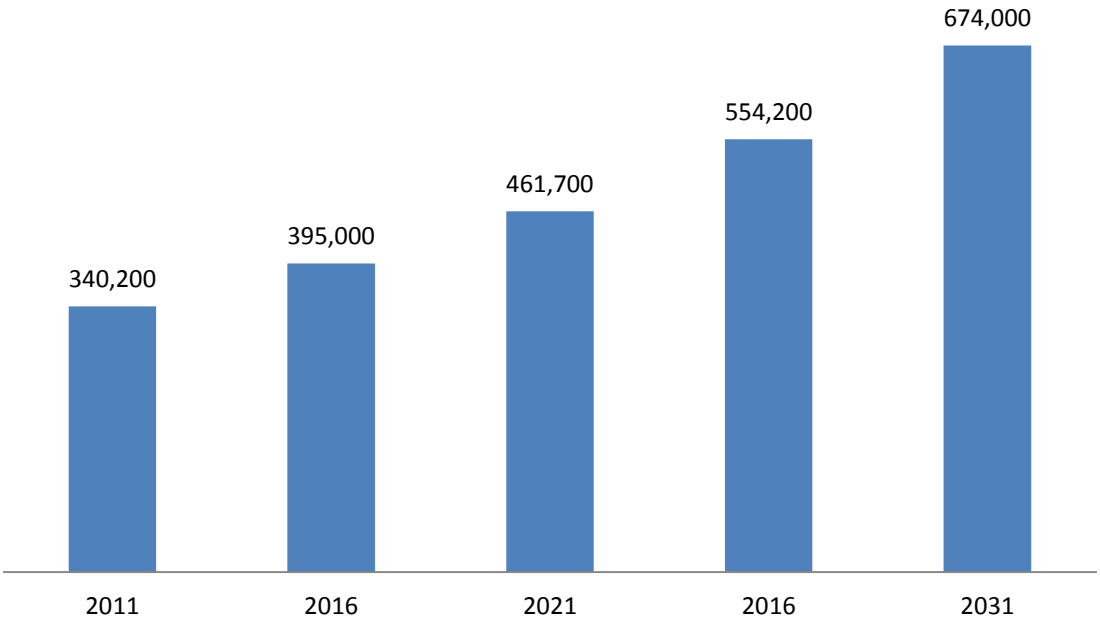


Figure 11: Projected prevalence number of Canadians age 40+ living with AD, Canada (Public Health Agency of Canada, 2015)

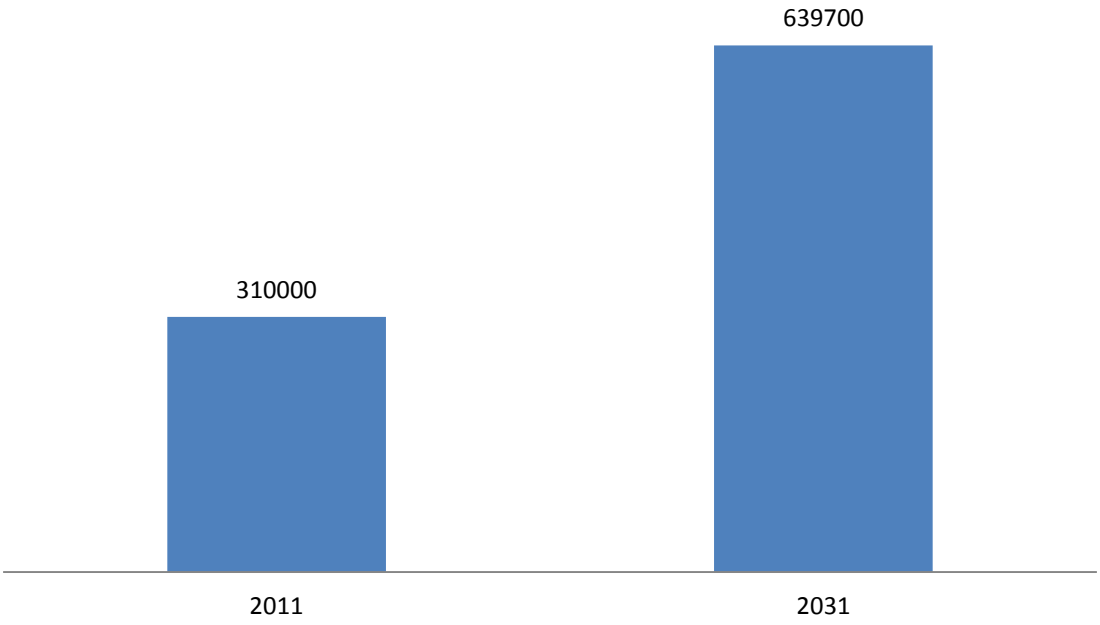


Figure 12: Projected number of Canadians age 65+ living with AD, Canada (Public Health Agency of Canada, 2015)

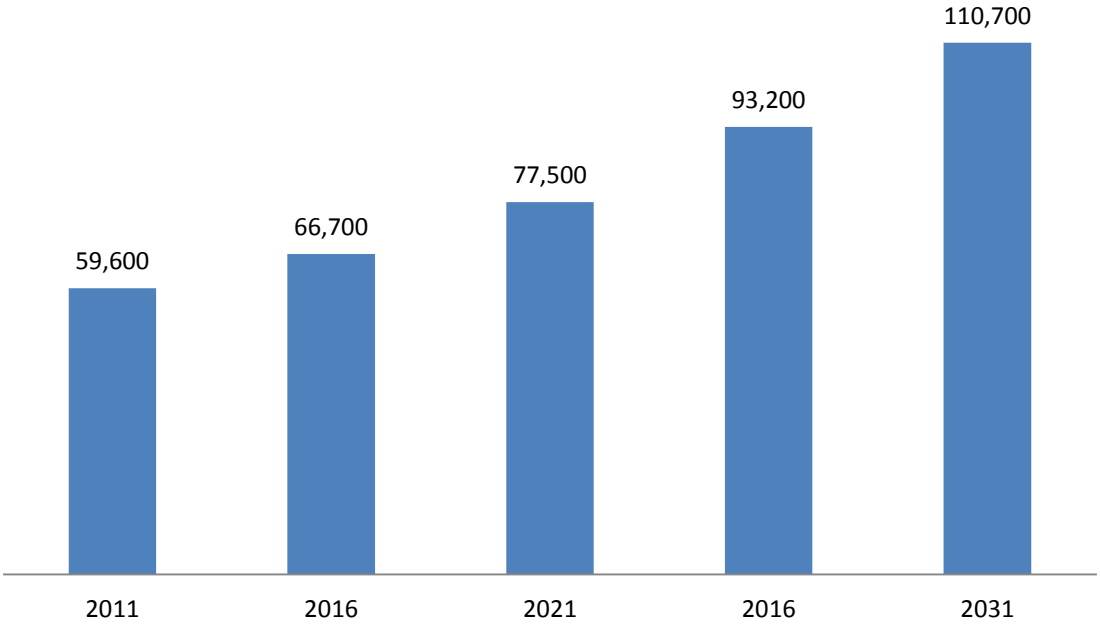


Figure 13: Projected incidence (New cases), age 40+ with AD, Canada (Public Health Agency of Canada, 2015)

The death rate among Canadians with a neurological condition will increase. The total number of deaths for those living with Alzheimer's disease and other dementias, which is already the highest of the modelled conditions in 2011, will increase by a further 70% by 2031.

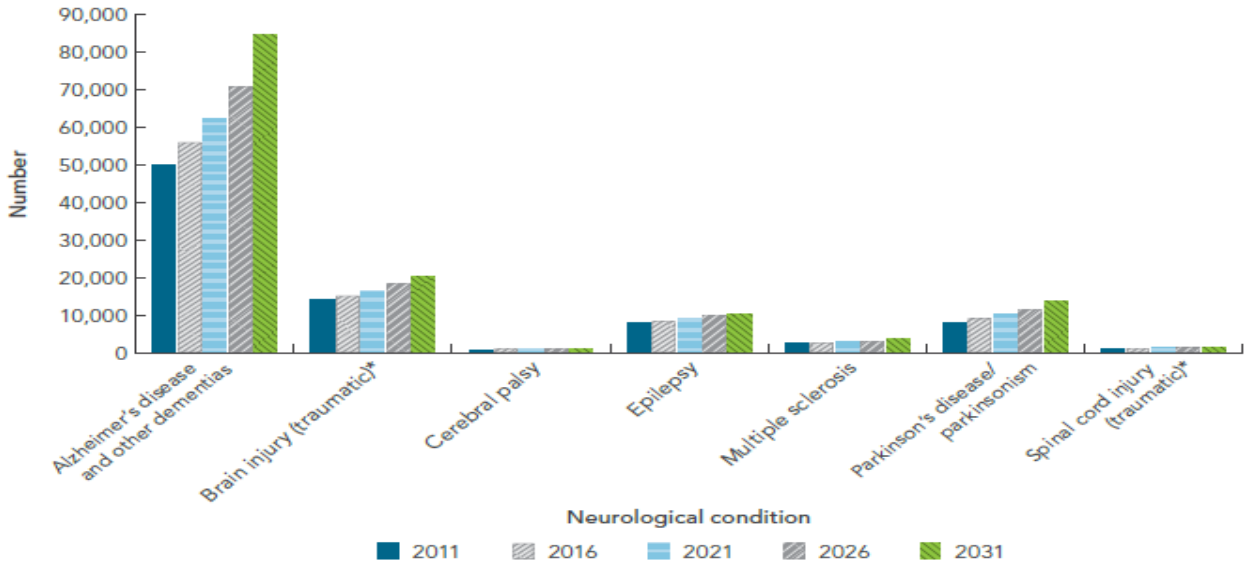


Figure 14: Projected number of deaths, by select neurological condition, Canada, 2011, 2016, 2021, 2026, and 2031 (Public Health Agency of Canada, 2015)

The economic burden of Alzheimer's disease

The human and financial costs of Alzheimer's disease are huge. For the disease to progress from "mild" to "severe," it usually takes many years. Caring for patients with severe Alzheimer's disease in a home-based environment often results in substantial expenses associated with medical and other types of care. When home care is no longer possible due to patient's deteriorating condition, the patient must be relocated to a long-term care facility, which results in higher than normal expenses.

Even using the most conservative estimates of prevalence and of the average number of years spent in institutional care -- typically three to four years -- the costs of the health care system are immense. Estimates of the annual public costs per patient include costs for home care, institutional care, medications, community support and the medical team, and range from $9,451 for mild AD to $16, 054 for mild to moderate, $25, 724 for moderate, and $ 36, 794 for severe AD. This amounts to approximately $5.5 billion annually (Alzheimer Society of New Brunswick, 2015).

Stage	**Duration (y)**	**Global Deterioration score[2]**	**MMSE score[3]**	**Global autonomy**
Mild	2-3	3-4	26-18	Independent living
Moderate	2	5	10-17	Supervision required
Severe	2-3	6-7	9-0	Total dependence

Table 3: The progression timeframce and need for assitance (Gauthier, 2012)

Based on the 2007 report of the Alzheimer Society of Canada, total direct and indirect costs (De Oliveria el al, 2013) per person are shown in the below chart:

[2] The Global Deterioration Score measures progressive need for assistance in daily activities (e.g., choosing clothes, dressing); scores range from 1 to 2 (normal) and 6 to 7 (severe dysfunction)

[3] Mini-Mental State Examination (MMSE): a brief psychological test designed to differentiate among dementia, psychosis, and affective disorders

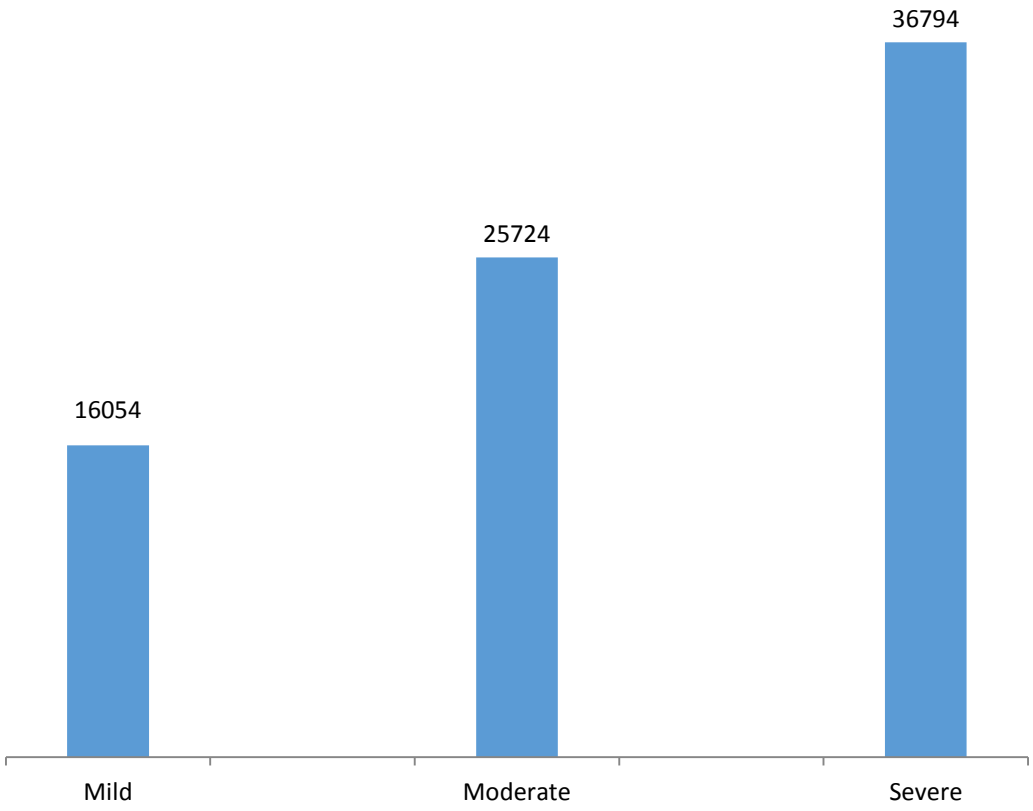


Figure 15: Direct and indirect annual costs per person(Canadian Dollar) (Alzheimer Society of Canada, 2010).

Annual Total Economic Costs:

The annual Total Economic Burden, expressed in future dollars, increases substantially from approximately $15 billion in 2008 to $153 billion by 2038.

- The Monetary Burden of dementia (direct plus indirect costs) will reach approximately $97 billion by 2038.
- Opportunity costs of informal caregivers will add a further $56 billion to the annual Economic Burden by 2038.

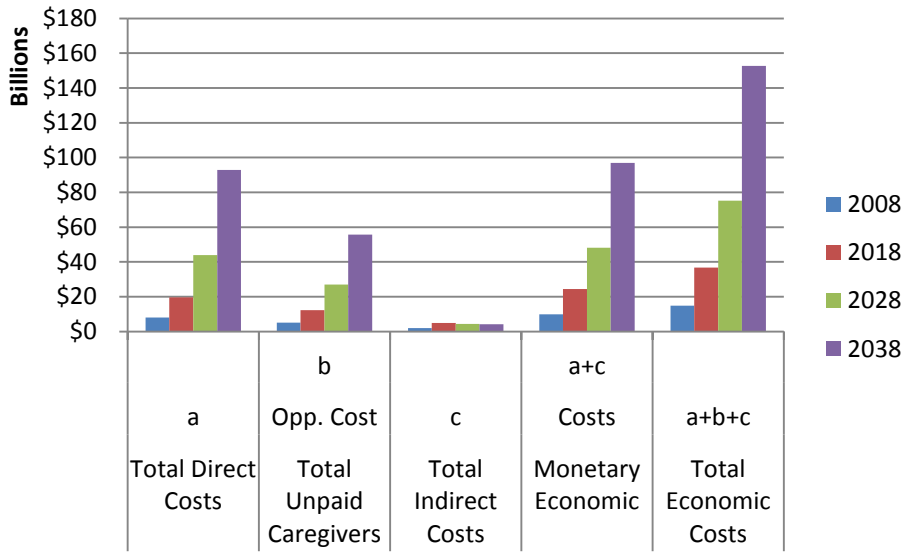


Figure 16: Total annual economic burden attributed to dementia, future values: 2008-2038 (Alzheimer Society of Canada, 2010)

Annual Total Indirect Costs

The Life at Risk® economic simulation module evaluates the indirect impact of a health condition by examining its effect on production. Dementia negatively impacts production in two ways:

- A lower productivity level for Canadians living with dementia than for otherwise healthy individuals. This reduced productivity translates into a reduction in output.
- Reduced productivity faced by employed informal caregivers due to the fatigue and stress associated with providing care. This reduced productivity is also measured in terms of lost production.

Lost production is translated into lost wages and reduction in corporate profits. The sum of lost wages and reduction in corporate profits yields the Indirect Cost of disability associated with dementia and the provision of informal care.

- Lost production attributed to dementia was approximately $3 billion in 2008.
- Lost production attributed to dementia is estimated to rise to $6.8 billion per year by 2038.

The burden of Alzheimer's disease on caregiver

In 1998, three American researchers Andrea Manca, Linda Davies and Alistair Burns published a report on Alzheimer informal care cost per person. In that report, they stated that in Canada, a

mild stage AD patient's informal care cost range (private household) was $8,120-$14,784 (USD) annually.

In 2003, Dementia-Caring, Ethics, Ethical and Economical Aspects mentioned that a mild stage AD patient's direct care cost range per person was $ 7,873 - $12,100 (USD) annually.

Therefore, based on the above data, in 2003 a mild stage AD patient's total direct and indirect cost range per person was $15,993 - $26,884 (USD).

Referral to the Alzheimer Society for support and services

People diagnosed with dementia, their families and health-care providers who support them recognize that early access to ongoing, reliable support and information is critical to handle many challenges associated with dementia. To address this need, the Alzheimer Society developed First Link®, a referral program for physicians, health and community services providers that connects individuals and their families to learning, services and support as early as possible in the disease process. Cognitive impairment and dementia are present in about 20% of the elderly population and are consistently rated among the top 3 health concerns of older adults.

The major hurdles to diagnosing dementia in family practice are:

- the complexity of the diagnostic process;
- physicians' lack of familiarity with cognitive screening;
- the pressures of time (the diagnostic process requires multiple visits to complete); and
- the lack of general conviction that an accurate diagnosis of dementia warrants the requisite effort

Undetected dementia places older adults at risk for delirium, motor vehicle accidents, medication errors and financial difficulties. Early detection of dementia provides an opportunity for the individual to adjust to the diagnosis and to participate actively in planning for the future, which can reduce the heavy societal costs associated with institutionalization. When you know something is wrong, it is important to push until you are satisfied. The answer may be frightening, but it is better to have a diagnosis, find out what help is available and have time to plan for the future with family members and caregivers.

Early detection of cognitive impairment

Although primary care physicians are in an ideal position to diagnose dementia, cognitive impairment is often undiagnosed by family physicians. Many barriers to recognition have been identified, including lack of time and ability to screen for dementia, lack of knowledge about dementia, lack of symptom recognition and belief that early detection increases patient and caregiver distress. Tool outlining questions have been developed to help family physicians detect early signs of dementia.

Main diagnostic methods for Alzheimer's disease

A number of various screen tests for cognitive impairment have been developed and practiced by specialists for decades, which are still relevant nowadays.

The most popular options are listed below:

Brief cognitive screening tests (Mental status testing, office-based cognitive assessment)

Pros: Brief cognitive tests can be completed in 5 to 15 minutes (depending on the test) in almost any setting. They can help flag possible Alzheimer's cases that may warrant further examination. They are also used to track changes in cognitive function over time in people with dementia.

Cons: These are preliminary tests; brief cognitive screenings can't diagnose Alzheimer's disease. An abnormal result can have many explanations other than Alzheimer's. They can also miss cognitive impairment in those who are highly educated or very intelligent. Nor can cognitive screens paint a detailed view of which functions (language, reasoning, etc.) are most affected.

Cost: These are nominal or free, other than the cost of a memory workup or medical checkup.

Neuropsychological tests

Pros: Neuropsychological testing is especially useful for identifying very early or subtle cognitive changes. It also identifies in detail what areas of mental functioning are affected, which can help distinguish Alzheimer's disease from other forms of dementia. This information can help tailor individualized therapies.

Cons: Testing can take two to eight hours and is usually done separately from a standard neurological or medical exam. It can be tiring and stressful for the person being tested.

Cost: The costs vary; they can run from $500 to $5,000 (usually the cost of the test plus an hourly clinician fee). Some testing is usually covered by HealthCare System and may be covered by other insurance.

Clock Drawing Test (CDT)

Pros: Quick and easy to administer. Becoming more widely known and accepted with a body of research to support its validity. Independent of culture, gender, or the level of education.

Cons: Various ways to score and different opinions on the most effective scoring method.

Test	Pros	Cons
Brief cognitive screening tests	Completed in 5 to 15 minutes flag possible Alzheimer's cases	Can't diagnose Alzheimer's disease; Does not work in highly educated patients
Neuropsychological	Detects very early or subtle cognitive changes; Distinguishes Alzheimer's disease from other forms of dementia	Takes 2-8 hours
Clock Drawing Test (CDT)	Quick and easy Independent of culture, gender, or the level of education	Difficult to interpret

Table 4: Summary of available screening tests

Evidences and propositions for Alzheimer's disease testing

Dementia may be the most important health problem for the baby-boomer generation and healthcare system. As new disease-modifying drugs become available in the next decade, it will be critical to have strategies and mechanisms in place to diagnose dementia at its earliest, even preclinical, stage. These strategies include public and professional awareness, reorganization of primary care to facilitate enhanced roles of nurses and nurse practitioners, and targeted screening of high-risk seniors.

The value of early detection:

According to recent modeling and generation of four intervention scenarios by Alzheimer Society of Canada, the scenarios demonstrate that

- Increasing by 50% the activity level of Canadians (65+), who are already active would yield a 30-year reduction in Direct Health Costs of $31 billion and a reduction in Total Economic Burden of $52 billion;
- Delaying onset of dementia with improved healthy diet and lifestyle strategies by two years would yield a 30-year reduction in Total Economic Burden of $219 billion, along with 410,000 fewer prevalent cases;
- Helping caregivers develop coping skills and build competencies in their caregiving roles would yield a 30-year value of $63 billion; and
- Providing system navigation support for people with dementia and their caregiver would yield a 30-year value of $114 billion (Alzheimer Society of Canada, 2010).

Impact of Intervention 1 and 2 on Dementia Prevalence

Years 2008 through	Intervention 1 Prevention: Increased Physical Activity		Intervention 2 Prevention: Hypothetical Program to Delay Dementia Onset	
	Simulated Value	% of Base Case	Simulated Value	% of Base Case
2018	-32,454	-5.1%	-137,502	-21.6%
2028	-64,189	-7.6%	-269,736	-31.8%
2038	-96,412	-8.6%	-409,647	-36.4%

delaying onset of dementia by two years would yield a 30-year reduction in Total Economic Burden of $219 billion, along with 410,000 fewer prevalent cases, i.e. a 36% reduction from the Dementia Base Case

Figure 17: The economic impact of the early detection of dementias (Alzheimer Society of Canada, 2010)

The financial support of informal care costs comes from family members and requires further commitment based on the Alzheimer disease stage.

Stage	Duration (yr.)	Global autonomy	Hours of care
Mild	2-3	Independent living	1.6
Moderate	2	Supervision required	4.2
Severe	2-3	Total dependence	24

Table 5: the spent time by informal caregivers based on the stage of Alzheimer's disease

Based on the latest research of the Alzheimer Society (Alzheimer Society of Canada, 2015), the earlier screening test on dementia and Alzheimer's diseases can save 5-8% on direct costs and 21-36% on care giving costs. Therefore, there is a strong incentive for individual for paying for measures that can postpone the beginning of the disease or minimize its progress.

Medical literature and the screening of Alzheimer's disease

Although population screening for dementia is generally not recommended in developed high income countries, screening in high risk population can help the early detection (Alzheimer's Disease International, 2011).

The Canadian practice guideline for diagnosis and treatment of dementia does not recommend the use of biomarker in clinical practice. Moreover, the guideline does not have clear recommendation about the population screening for dementia or Alzheimer's disease (Gauthier, 2012). A guideline published by the Ministry of Health of British Colombia clearly states that the screening of asymptomatic population for cognitive impairment (including Alzheimer's disease) is not recommended (Guidelines & Protocols Advisory Committee, 2014). In summary, the current practice guidelines do not specify the necessity of screening or the target population for prospective screening.

Market potential of Alzheimer's disease screening

Market size for Alzheimer's disease

Alzheimer's disease is one of the most complex sectors in the life science market. The aging population of industrialized countries creates a huge demand for services for this sector, while

the compound annual growth rate (CAGR) is -1.5%. Therefore, a $10.2 billion market in 2012 will reach $9.5 billion in 2017 mainly due to the drop in sales of disease modifying medications (Pre Diagnostics, 2015).

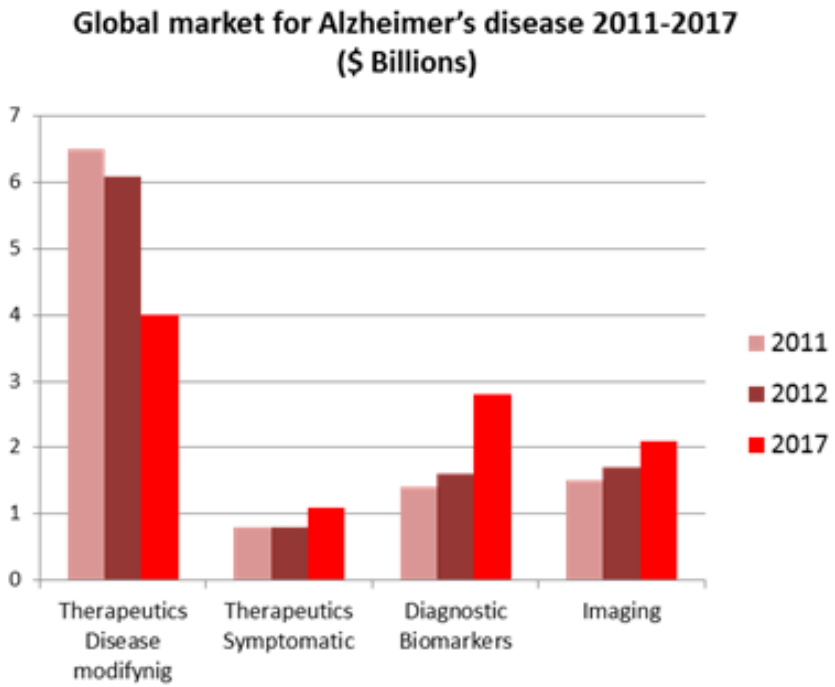


Figure 18: Global Market for Alzheimer's disease ($ Billion) (Pre Diagnostics, 2015)

AD biomarkers are the segment of the market with the highest growth in the next years and will reach three billion USD in 2017 (Pre Diagnostics, 2015).

Alzheimer's disease cost the Canadian economy $14.9 billion in 2008 that will increase to $36.7 billion in 2018 and 75.1 billion in 2028.The annual burden attributed to Alzheimer's disease is compound from direct costs (60%), informal care costs (35%) and indirect costs (5%). Therefore, there is a strong incentive for any measure which might improve the chance of early detection and save money for tax payers.

Stakeholder analysis

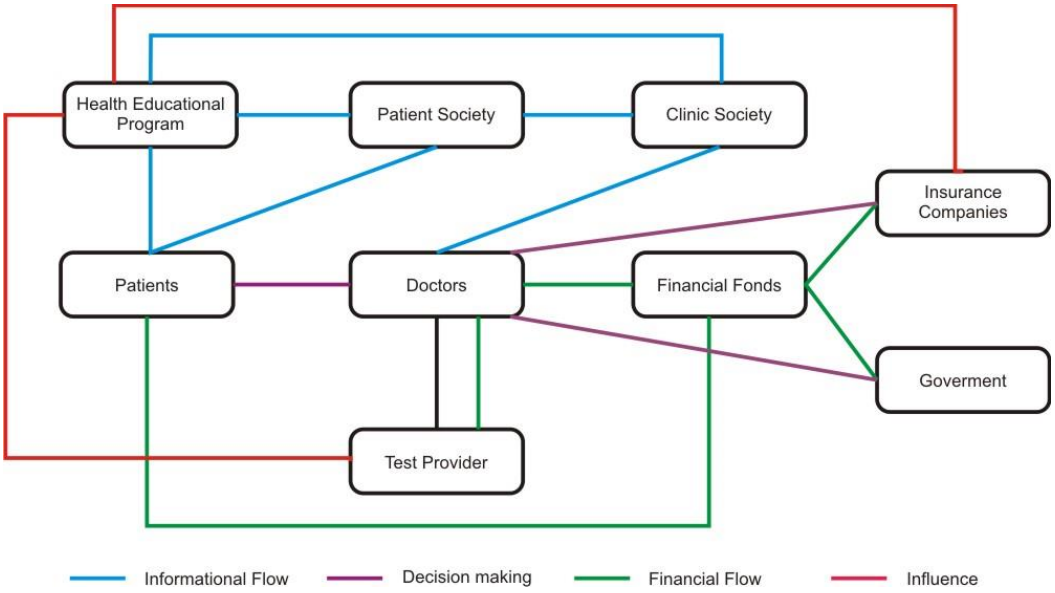


Figure 19: The map of stakeholders for Alzheimer's disease

The influence flow is the key factor of the marketing process of test providers. Creating the Health Educational Program as a non-governmental body allows the test providers to influence the decision-making process in the stakeholder's relationship.

The Health Educational Program focuses on early diagnosis of the Alzheimer disease and on health prevention programs. First symptoms of the Alzheimer's disease can be detected by the age of 54. Currently, the retirement age for Canadians is 65, and the government plans to increase it to 67 by 2023. Thus, the gap between early diagnosis and retirement age is 11 years. Test providers can use this gap as an opportunity for developing health education and/or promotion programs. These programs can persuade and help insurance companies to develop saving plans that would include early testing for Alzheimer's disease for people in the risk group. As a result high risk population will change their financial and health behavior to avoid financials debts. It is expected that they will start to invest more in their private disability insurance plans that will reduce financial burden to their families and government

SWOT Analysis

		Helpful to achieving the objective	**Harmful** to achieving the objective
Internal origin (attributes of the system)		*Strengths* • First objective tools for diagnosis of Alzheimer's disease (AD) • Cost-effective compared to current subjective test	*Weaknesses* • No prior experience of biomarkers in the field of AD • Lack of long-term studies about biomarkers
External origin (attributes of the environment)		*Opportunities* • Huge market with high degree of awareness • Clear benefit of early diagnosis • Lack of easy, objective diagnostic test • Healthy aging is the focus of policy-makers and the public	*Threats* • Minimum support for screening program for AD • Lack of scientific evidence for screening of AD • Not known high risk population • The majority of AD patients are non-productive

Conclusion

A number of specific plans and frameworks should be developed for dealing with dementia in Canada, as it has been done in such countries as the Netherlands, France and the UK. These plans are directed at:

- increasing the integration of health and social policies;
- establishing more home-based programming;
- adapting care facilities to better meet the needs of residents with dementia;
- providing education programs for people with dementia, their families, health professionals and the public; and
- Investing in research.

With the aging demographics and society of specialists in dementia, the predicted 250,000 new cases in the next five years indicate that the primary-care system will need to take a larger role

in the early identification, diagnosis and management in the more straightforward cases of persons with dementia. Targeted screening for seniors who are at high risk for cognitive impairment can facilitate earlier recognition of dementia. Treatment options used earlier can lead to improved outcomes. These include the use of specific anti-dementia drugs, treatment of vascular risk factors, strategies to improve adherence in other chronic diseases and enhanced support and education for caregivers. Therefore, there is a growing market for the therapeutic and diagnostic services for Alzheimer's disease, however there are challenges for a screening test for Alzheimer's disease.

The use of a biomarker for the screening of Alzheimer's disease has not been tested in the market. Therefore, the available data evaluating the effectiveness of the screening by a biomarker is very limited. Moreover, the screening for Alzheimer's disease is not recommended by current practices guidelines, because the current tests are not sensitive enough to detect patients early. The lack of distinct high risk population vulnerable for Alzheimer's disease is another barrier in suggestion a practical screening policy.

The substantial market size and the distinct financial impact on caregivers are the opportunities for an emerging screening test especially in private payer market. The huge size of the market for Alzheimer's disease makes the launch of new services commercially viable even with the low market penetration rate. Moreover, Alzheimer's disease, as long-term debilitating disease, involves all the family members as informal caregivers. This long-term commitment may vary between a part-time involvement in mild cases of Alzheimer's disease to full-time commitment in severe cases and give a strong financial incentive to informal caregivers to invest in tests which can postpone the beginning of the disease.

Recommendations:

- Market preparation is essential for the commercial success of these tests. Communicating the added value of the screening tests to all relevant stakeholders should be an integral part of the business/marketing strategy before the launch of the tests.
- Media and patients' societies can be used as a medium for indirect communication with patients and their caregivers, where the possibility of direct communication with patients is limited.
- The involvement of the relevant clinical societies will boost the credibility of the tests and will increase the chance of commercial success.
- The communication with the public payer will not be beneficial at this stage because of the lack of supporting evidences.
- Market acceptance of an ovarian cancer screening test is higher than that of Alzheimer's disease.
- The launch of the Alzheimer's disease screening test is not recommended now. It should be done after the preparation of Canadian market for a biomarker for the diagnosis of Alzheimer's disease.
- The emerging test should have substantial superior sensitivity (<2 folds) than CA-125 and be available at same price.
- Well-studied market segmentation for ovarian cancer screening test based on the socio-economic status as well as the geographic and risk profiles of the target market is recommended.
- The results of the following projects should be used in the development of the marketing plan for the ovarian cancer screening test:
    - Primary market research aiming at analyzing healthcare providers and determining primary target market
    - Market research analyzing the experience in the promotion of a similar product/service for the private payer market
    - A study evaluating innovative business models for financing products for the private payer market

Appendix:

Appendix I: The detailed cost of ovarian cancer in Canada

	Hospital-based Care			Tertiary Care			Other		
Total Cost	**Inpatient Hospitalization**	**Same-day Surgery**	**ED Visits**	**Home Care**	**Continuing Care**	**Long-term Care**	**Diagnostic Tests**	**Physician Services**	**Outpatient Drugs**
2,098	361	53	79	46	-	59	1,081	308	110

Table A – Mean (95% confidence interval) direct ovarian cancer care costs by resource for prediagnosis phase for cancer patients who survived beyond the first year after diagnosis (in 2009 Canadian dollars) (De Oliveria el al, 2013)

	Hospital-based Care			Tertiary Care			Other		
Total Cost	**Inpatient Hospitalization**	**Same-day Surgery**	**ED Visits**	**Home Care**	**Continuing Care**	**Long-term Care**	**Diagnostic Tests**	**Physician Services**	**Outpatient Drugs**
2,936	779	63	153	186	65	11	1,142	296	243

Table B – Mean (95% confidence interval) direct ovarian cancer care costs by resource for prediagnosis phase for cancer patients who died within the first year after diagnosis (in 2009 Canadian dollars)

	Hospital-based Care			Tertiary Care			Other			Cancer-specific Care	
Total Cost	**Inpatient Hospitalization**	**Same-day Surgery**	**ED Visits**	**Home Care**	**Continuing Care**	**Long-term Care**	**Diagnostic Tests**	**Physician Services**	**Outpatient Drugs**	**Chemotherapy**	**Radiation Therapy**
29,640	12,665	393	267	2,566	1,458	744	2,210	2,290	1,265	5,688	94

Table C – Mean (95% confidence interval) direct health care costs for initial phase cancer patients who survived beyond the first year after diagnosis (in 2009 Canadian dollars)

	Hospital-based Care			Tertiary Care			Other			Cancer-specific Care	
Total Cost	**Inpatient Hospitalization**	**Same-day Surgery**	**ED Visits**	**Home Care**	**Continuing Care**	**Long-term Care**	**Diagnostic Tests**	**Physician Services**	**Outpatient Drugs**	**Chemotherapy**	**Radiation Therapy**
46,270	29,854	315	547	3,750	3,186	143	1,438	2,211	1,296	3,496	35

Table D – Mean (95% confidence interval) direct health care costs for initial phase cancer patients who died within the first year after diagnosis (in 2009 Canadian dollars)

Appendix II: The direct and indirect cost of Alzheimer's disease

Direct Costs:

The Life at Risk® economic framework calculates the Total Economic Burden of dementia as the sum of direct health costs, opportunity costs (foregone wages) of unpaid informal caregivers and indirect costs. The Monetary Economic Burden reflects only actual monetary outlays and, hence, ignores opportunity costs.

Total Economic Burden = Direct Health Costs + Opportunity Costs of Informal Caregivers + Indirect Costs

Monetary Economic Burden = Direct Health Costs + Indirect Costs

Direct health costs are costs incurred while treating a particular disease and can accrue within or outside the formal health care system.

Opportunity costs of informal caregivers are the wages informal caregivers could have earned had they been able to participate in the labor force.

Indirect costs are costs that have no direct connection to dementia, but are a consequence of it.

a) Direct health costs pertaining to dementia within the formal health system include the cost of prescription medication, long-term care staff costs, support staff costs, long-term care administrative costs, and physician and hospital costs. Direct health costs outside the formal health care system include the cost of over-the-counter medication, long-term care accommodation and out-of-pocket expenses.

They include the loss in wages (e.g. days off or sick time) and in corporate profits that result from the reduction in labor productivity for both the individual with dementia and the provider of informal care (Burden of AZ in Canada).

b)

	Total Economic Burden of Dementia, Future Values				
Year	Total Direct Costs a	Total Unpaid Caregivers Opportunity Cost B	Total Indirect Costs c	Monetary Economic Costs a+c	Total Economic Costs a+b+c

2008	$8,063,733,967	$4,995,340,836	$1,864,955,665	$9,928,689,632	$14,924,030,467
2018	$19,573,547,540	$12,303,233,856	$4,845,163,396	$24,418,710,937	$36,721,944,792
2028	$43,842,755,134	$26,921,613,083	$4,380,174,051	$48,222,929,184	$75,144,542,267
2038	$92,832,808,780	$55,708,854,294	$4,097,831,931	$96,930,640,711	$152,639,495,005

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