CARE IN OUR CONTROL:

Managing Innovation in Ontario's Multi-Payer Health Care System

PART IV OF THE ONTARIO CHAMBER OF COMMERCE'S 2016 HEALTH TRANSFORMATION INITIATIVE

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LETTER FROM THE PRESIDENT AND CEO

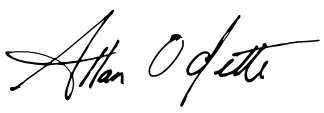
It is a notion not regularly discussed in Ontario, but we possess a multi-payer health care system. Public and private health coverage work in tandem to provide much-needed treatment to Ontarians, and do so in a balanced way that prevents undue financial hardship while allowing for timely access to cutting-edge care. However, as public budgets benefit from innovative drugs and devices that can move patients away from expensive touchpoints like hospitals and emergency rooms, individuals are now responsible for that level of care. This shift has increased pressure on private payers like employers, especially as private benefit plans are more likely to include innovations than their public counterparts.

As health technology advances and patient needs evolve, we must acknowledge the new challenges in meeting the goals of fiscal sustainability and best-in-class care, as well as the challenges of ensuring continued affordable access for Ontarians. Our health care system cannot be one in which we are able only to offer a small selection of lowest-cost treatments to Ontarians; it must be one in which we are able to offer a diverse selection of best-in-class care that is right for individual patients.

It is true that innovation comes with an up-front price, but research has shown that effective innovations are able to reduce system costs and relieve pressure on the most expensive points of care. Today, we do not sufficiently measure the full value of adopting new innovations; for example, how they perform against multiple budgets, or save money in the long term by reducing repeated hospital visits. Measuring that kind of value requires data that we do not sufficiently collect. How can our public system be accountable to its mission if we are unable to measure the extent to which it is or is not achieving value for money? At the same time, much of the cost of innovation is ultimately borne by private payers, including employers through the workplace benefits plans they sponsor, and working Ontarians who pay premiums for that coverage, or pay out of pocket. The private payer system has worked well, but is impacted by rising costs.

In this report, we examine the challenges and opportunities that health innovation in the medical device and pharmaceutical sectors present the Ontario health care system, as well as how the failure to adopt these innovations is putting pressure on the public/private coverage relationship.

Both the Ontario government and businesses must work closely with government to acknowledge the rapid pace of change within health care, collaborating on new visions and new approaches to keep our system delivering high-quality care.



Allan O'Dette
President and CEO
Ontario Chamber of Commerce

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GLOSSARY

Innovation: A new technology, technique, process, model, or other solution that adds value and provides a meaningful benefit over the status quo. The impact of innovation should be measureable.

Health innovation: An innovative medical device or pharmaceutical, that is, advanced treatments used at home or in a formal health care setting that are intended to aid in diagnosis, treatment, or mitigation of diseases and conditions. There has been increasing convergence in recent years between these industries, as their products become more high-tech and individualized, leading to a rapid and disruptive pace of innovation within the health care sector.

Incremental innovation: An improvement in the cost or functionality of a product in an existing market.

Payer: Payers are the individuals and institutions who are responsible for financial decision-making in health care. This includes public payers (government ministries and agencies; large health institutions), and private payers (insurance companies, employers and individuals).

Value: In the health care context, value is a return on investment that considers patient outcomes alongside cost. It is demonstrated through long-term savings to the system as a whole, not just an immediate reduction in the cost of a good or service.

INTRODUCTION:
The Struggle to Manage Innovation

This century, we have already seen considerable advancement and convergence within the realm of health innovations. Medical devices and pharmaceuticals have become more sophisticated, facilitating a move towards personalized medicine and out-of-hospital care. As a result, patient wellness and quality of life has improved. However, both public and private payers are struggling to evaluate and afford new innovations that are entering the market with increasing rapidity. These innovations are capable of bringing large-scale value to the health care system and to society, but have disrupted the traditional models of assessment and cost management. Innovation whose cost exceeds the ability of the system to pay will ultimately not be realised; a balance must be struck between encouraging innovation while recognising that the absolute affordability of health care is a challenge. As the nature of health care moves from population to personal and from disease management to preventative wellness, our approach to paying for that health care cannot continue to be a simple price and volume equation. In order to adopt innovation while ensuring sustainability and affordability, we must accurately measure and unlock its value to the system as a whole.

In Ontario today, there is greater competition for scarce health care resources, increased patient empowerment and demand for services, and a growing availability of innovative treatments. This has created an environment in which payers must make difficult decisions about how and when to adopt innovation within the traditional criteria of cost management. Payers also struggle to quantify the broader value of health innovations beyond a single condition or a single node within the health care system. However, research has shown that innovations like medical devices and pharmaceuticals can bring about improved patient outcomes, and with them reduced demand on public services. If payers were able to view an innovation's value beyond the initial purchase price, cycle of treatment, or procurement budget, a longer-term story of improved patient outcomes and fiscal sustainability would be revealed.

While innovative drugs and devices can move patients away from expensive touchpoints like hospitals and emergency rooms, the consequence of this shift is that patients and their employers are now largely responsible for the cost of that care. Unfortunately, both private and public health expenditure is rising, resulting in Ontarians simply spending more on care regardless of the vehicle of payment. Therefore, as we capitalize on the changes wrought by innovation, the government must ensure they are creating savings through improved efficiency, rather than merely shifting spending.

In this report, we examine the two major categories of health innovation: medical devices and pharmaceuticals. Both industries represent a frontier in personalized medicine and both have struggled to communicate. We also discuss how a broader definition of value impacts the reality of our multi-payer health care system, in which private and public payers experience similar challenges when deciding how to pay for and adopt innovation. Finally, we outline a series of solutions to the problems of value definition, performance tracking, and measuring value in a system of siloes.

CONTEXT: A VALUE-BASED APPROACH

There is an understandable tension between those who would seek faster and more significant innovation within our health care system (usually patients, providers, and manufacturers) and payers (public, as well as employers, individuals, and insurers), who must not only devote scarce resources to purchasing new products and services but also manage their disruptive effects. We must find a better way of negotiating this tension, by more effectively measuring the value of innovation to resolve the uncertainty it brings, and adopting an approach that improves sustainability for all stakeholders.

Payers, particularly those within the public health care system, are tasked with the difficult choice of if and when to adopt innovation. Choosing the wrong innovation, or implementing it poorly, could result in wasted resources and poor patient outcomes if the treatment fails to deliver on its promises.[1] Meanwhile, failing to innovate could similarly result in poor outcomes and a delay in capturing valuable real-world data.[2] Similarly, restrictive formularies or benefits lists can limit adoption or scaling of innovation, impacting cost and quality of care.[3]

In order to prevent an undesirable outcome, industry and researchers must reduce the uncertainty inherent within payer decision-making processes, by providing the tools and evidence necessary to answer questions like: What is the clinical benefit of the innovation? How can we adopt and scale an innovation? What is the 'value for money' calculation? What is the economic impact of this innovation?[4]

VALUE-BASED HEALTH CARE: WHERE CANADA RANKS

In their global assessment of health systems alignment with the standards of value-based health care, The Economist Intelligence Unit ranked Canada as having moderate alignment, largely because the presence of "enabling elements" for value-based health care was strong. Canada's ranking was negatively affected by the fact that those elements have yet to be reflected formally in legislation, strategy or policy-making.[8]

Ontario is not the only jurisdiction to struggle with these tensions and uncertainties. As a result, there is a global trend towards the concept of value-based health care. Value-based health care is an approach intended to help decision-makers adjust to rising expenses and deliver high-quality care while managing finite resources.[5] This is accomplished through "the creation and operation of a health system that explicitly prioritises health outcomes that matter to patients relative to the cost of achieving those outcomes."[6] Decision-making within value-based health care is characterized by a large-scale view of value, defining it relative to not merely a procurement or department budget, but to patient experience, system sustainability, and even the social and economic impacts of a given treatment.[7]

Reflecting this broader view of value, the Ontario Health Innovation Council (OHIC) stated that value "...should take into account social impact, health system benefits, and economic benefits".[9] Enacting value-based health care in this province will require a paradigm shift from our inputs-focused model to one that is patient-centric in its definition of value.

OHIC VALUE EQUATION

Value = Social Impact + Health System Benefits + Economic Benefits

In order to calculate value, the inputs and outputs of a system must be measureable and comparable. With respect to patient outcomes, this requires tools like disease registries and electronic patient records. Unfortunately, data collection, standardization, analysis, sharing, and utilization is low across Canadian health care systems. In a global analysis of value-based health care, Canada received the lowest possible score for the indicator "Patient outcomes data standardization".[10]

While Ontario has made some headway in building the necessary tools to improve data usage, they lack universality, ease of use, and technical interoperability.[11] The Ontario Personalized Medicine Network (see sidebar) has found there is poor utilization of data platforms intended for public use: government is actively collecting data on some treatment areas, but it is not comprehensive nor is that information being put to use to assess patient needs, treatment efficacy, or cost-effectiveness.[12] This is due in part to database administrators lacking the resources to develop effective service models and target patient needs. Collaboration is sporadic and what resources do exist are under-used. Furthermore, these databases are poorly linked and the capacity for analysis is limited.[13]

THE ONTARIO PERSONALIZED MEDICINE NETWORK

In a partnership between the Ministries of Health and Long-Term Care, Research, Innovation and Science, and the Ontario Genomics Institute, the network was founded in order to create a road map for research, policy and economic development related to personalized medicine. In their consultations, they identified a clear need for improved use of health data, including formal mechanisms for collecting and evaluating data at a system level, particularly to determine cost-effectiveness and efficacy of emerging technologies.[14]

One of the consequences of this environment is that hospitals are unable to consistently and accurately perform case costings (also known as patient-level costing). This impacts not only their own understanding of their performance, but it also limits vendors from presenting a more fulsome evidence case to buyers. Imagine a scenario in which a vendor hopes to sell a surgical device to a hospital, one that is proven to reduce patient recovery time in the intensive care unit. If that vendor does not know how much a bed in that ICU costs per day, how can they provide a value proposition for larger benefits of their product to payers?

This challenge is magnified by siloed budgeting: at the institution level, at the health system level, and at the ministerial level. If an innovation's value proposition is spread over multiple budgets, that proposition lacks power with payers. Without a system in place to consider the value of an innovation across multiple budgets, decisions that are made with only an individual budget in mind could miss positive or negative impacts on others. The payer's understanding (and capture) of an innovation's value will therefore be limited.

Managing Innovation:
Medical Devices

Medical devices are instruments that aid health care delivery through diagnosis, treatment, or prevention of a condition. They exist on a continuum of complexity, with some as simple as a thermometer and others as complex as an imaging device. Certain devices – such as surgical gloves – are treated as commodities, as their innovation is slower and less disruptive. However, many medical devices are not commodities but technologies, and so require a different approach to assessment and procurement. This paper will focus on the more disruptive innovations.

As the medical device sector is so diverse, it is difficult to quantify the value of medical devices to both patient outcomes and health systems costs. However, studies on particular classes of devices have found that innovative products can provide significant improvements to patient outcomes and budget savings.[15] For example, the concept of value for a drug-eluting stent (a device that, implanted into an artery, slowly releases a drug) can be expressed by that device's ability to reduce the need for coronary bypass surgery in favour of less invasive cardiology procedures, resulting in savings at both the hospital and system level, as well as a better experience for the patient.[16] With such a large-scale impact on both patient and fiscal outcomes, medical devices require a new approach to calculating their value relative to price.

CHALLENGES TO A VALUE-BASED APPROACH TO MEDICAL DEVICES

The most fundamental challenge to the medical device industry in Ontario is the speed and disruptive power of their own innovation. While public payers may wish to procure and adopt the latest medical device, innovation moves faster than government decision-making. Across Canada, over 4000 medical devices are licensed each year.[19] This places real limitations on the ability of government agencies to thoroughly assess each new technology. Additionally, an innovation may change a point of care in a way that is not always aligned with health system structures or priorities. Introducing one innovation could demand further innovation throughout the nexus of care. There are fewer incentives for government to invest in incremental innovation, even as incremental innovation is the most common way we reach breakthroughs.[20] Finally, public benefits lists and fee schedules are either infrequently updated or insufficiently reviewed to reflect device innovation. If devices are unable to be properly assessed by payers against these lists, access to innovative technologies for patients is either limited or costly.

Additionally, there is currently no clear link between payers and manufacturers for collaborative problem-solving or managing adoption. The Ontario Medical Technology Working Group noted that there is "an insufficient and sub-optimal exchange of knowledge and information" between industry and public decision-

THE MEDICAL DEVICE INDUSTRY

The medical device sector in Ontario has revenues of approximately $10.5 billion, with consistent growth in employment even during the recent economic downturn.[17] While these numbers are impressive, there are concerns that without a re-alignment around value within the public health care system, Ontario will lose out on both the economic and clinical advantages of our local medical device industry.[18] The province needs an innovation ecosystem to support the health science sector from researchers through start-ups to established, global firms, anchored by a collaborative public health system. This will continue to drive the economic success of the sector while speeding access to safe and efficacious innovation for Ontarians. This topic is explored in more detailed in a previous OCC report, *Adopting our Advantage: Supporting a Thriving Health Science Sector in Ontario.*

makers.[21] The consequence is an industry that is unable to understand the needs of health providers, and providers who are unaware of what solutions currently exist.[22]

One of the most common tools in Ontario for helping decision-makers understand the potential value of a new medical device are health technology assessments (HTAs). These documents examine the economic, medical, ethical, and social implications of a health technology, based upon credible, evidence-based methodologies; as such, they are valuable tools for both government and industry. However, HTA protocols differ across Canada, based on regional decision-making processes. This influences how HTAs are conducted, as well as how they are used by payers. What is consistent, though, is the length of time it takes Canadian assessors to complete their HTAs – often over a year.[23] In that span of time, technology may change, patients who would have benefited from innovation are left without access, and potential cost savings are lost. Part of the challenge is the sheer number of devices that are licensed each year, taxing the capacity of evaluators to complete their assessments. Unfortunately, without the seal of approval that comes with an HTA, both manufacturers and payers face uncertainty and delay.

CASE STUDY: ESIGHT AND THE ASSISTIVE DEVICES PROGRAM

While most medical devices are sourced by, and used in, hospitals, innovative technologies are increasingly available for personal use. In Ontario, a major touchpoint for those who require personal medical devices is the Assistive Devices Program (ADP). ADP provides funding for appropriate assistive devices to Ontarians who have long-term physical disabilities. Notably, the challenge of assessing value and adopting innovation is just as relevant to ADP as it is to a hospital.

As a government payer, ADP administrators are acutely aware of having to demonstrate value for money to the public. While they hope to serve their clients best through provision of life-improving technologies, they are leery of innovations that may be short-lived. Payers do not want to purchase a treatment that will become quickly outdated, or whose support systems may no longer exist should a problem arise in the future. As Ontario has a robust medical device sector, this contributes to a chicken-and-egg problem: our medical technology start-ups need a market in order to grow to a size where they are seen – and are able to operate as – reliable companies.

Innovative devices are further locked out from ADP by the limitations of their device funding categories. For many devices, there are no OHIP or ADP fee codes to cover the cost of the patient's assessment (which is necessary to determine which device(s) is appropriate), limiting adoption.[24] The device categories and approved prices that currently exist were set decades ago, and so may not accurately cover the cost of a device. As industry cannot simply "go around" fee codes and bid rules, they may be unable to apply for ADP coverage.

These challenges are particularly acute for one Ontario company, eSight Corporation. eSight designs and manufactures electronic glasses that allow individuals with vision loss to experience great improvement in their ability to see. This company's innovation allows legally blind clients to make use of their remaining sight to an extent that no other traditional device can match, providing enhancements such as real-time digital magnification and contrast enhancement at distance, intermediate and near.

ADP support for low-vision clients is generally a collection of devices: those necessary for orientation and mobility (e.g. canes), optical aids (e.g. magnifiers, specialized glasses, telescopes), or reading/writing systems (e.g. closed-circuit televisions, Braillers). Clients can obtain funding for devices based on their day-to-day needs. However, most items usually address only one or two aspects of a low vision patient's visual needs. As eSight's technology can provide visual function at varying distances and in various settings in a more seamless manner, users are therefore able to function in their work and personal life with greater ease This reduces the need for other accommodations, and allows many users who are unable to work or go to school to do so again, and with increased activity in those environments.

Unfortunately, eSight's technology does not fit into ADP's predetermined funding categories; ADP's assessment methodology is not constructed for value-based assessment, so a single device that costs approximately $19,500 will be evaluated against a different standard of criteria than the outcomes it can provide users and savings it will create over time. As eSight has a small user base, they are unable to take advantage of the cost-lowering impact of volume, nor are they able to collect the valuable real-world evidence that would lead to further innovation.

Correspondingly, the total cost to Ontario of the Ontario Disability Support Program (ODSP) is approximately $20,000 per client per year. An estimated two-thirds of low vision Ontarians are outside the workforce. With innovative devices like eSight, there is potential for great savings to ODSP and similar programs if low-vision users were able to return to work. Initial adoption of eSight has already begun along these lines in the United States through Vocational Rehabilitation programs, but Ontario has not developed similar programs. Unfortunately, the government is unable to act on those potential savings thanks to current budgetary silos. If eSight was adopted today, ADP (operated by the Ministry of Health and Long-Term Care) would spend more on low-vision clients while the savings would largely be realized by the Ministry of Community and Social Services.

RECOMMENDATIONS

- ✓ **Increase understanding between the medical device community, health care providers, and public decision-makers.** Industry needs to better grasp the priorities of health care decision-makers, while the system itself must be better educated about global trends and best practices with regards to medical technology innovation. This could be accomplished through formal relationship-building in the pre-procurement stage, e.g. with reverse trade shows where health institutions present their challenges to industry to tackle. Similarly, providers, prescribers, and other authorizers have a broader knowledge base vis-à-vis patient needs, which would provide input into a device's clinical utility and value.
- ✓ **Support efforts to harmonize HTA regimes with other jurisdictions, not just within Canada but across countries with industrialized health care systems.** Collaborate with those partner provinces or countries who share value definitions similar to our own, increasing the number of HTAs available and reducing duplicated efforts.
- ✓ **Create an advanced technology category within each of ADP's equipment/supply categories, where applicable.** This could be established in tandem with a grant system based on personal income to prevent a short-term spike in costs, while ensuring Ontarians would be able to access a necessary device. Similarly, the provision of an innovative device could be made in tandem with enrollment in a vocational or training program to support individuals seeking to return the workforce.

Managing Innovation:
Pharmaceuticals

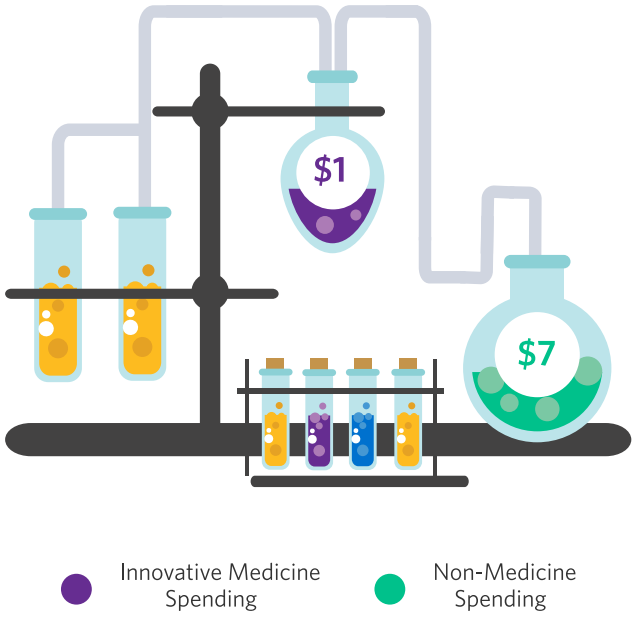
Since the inception of our publically-funded health care system, use of prescription drugs as a tool for restoring and maintaining wellness has grown.[25] This transition has had an impact on the way Canadians receive health care, as well as who pays for that care, revealing a symbiotic relationship between innovative medicine and other forms of care. Broadly, the Province has recognized its budgetary constraints and voiced concern with its ability to afford innovation. We acknowledge these efforts, and want to work with all payers in order to address these challenges.

The research behind the system-level value of innovative pharmaceuticals is robust: Across the world, for every $1 spent on innovative medicine, non-medicine spending drops by $7.[26] Research from the US has also found that while reducing the average age of a medicine will increase prescription drug spending, it will lower other medical spending.[27]

Closer to home, a recent Conference Board of Canada study found that Ontario recoups approximately twice as much in varied benefits as it spends on pharmaceuticals.[28] In a national study of six drug classes, the $1.22 billion Canada spent on pharmaceutical treatment within those classes resulted in offsetting health and social benefits of approximately $2.44 billion.[29] Appropriate use of pharmaceuticals can reduce the need for surgery, hospitalization, or other costly interventions as well as the quantity of complications and the incidence and impact of disease more broadly.[30] They have the ability to move patients out of the public system, saving public money, improving patient experience, as well as allowing them to re-enter the workforce and become more productive.[31] In this way, appropriate use of pharmaceuticals can create increased efficiencies within the public health care system.

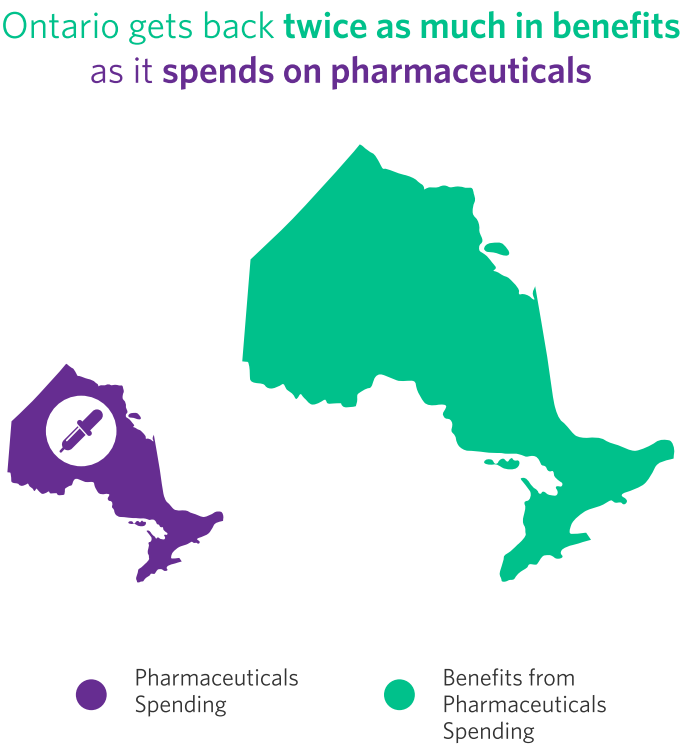
Figure 1.a:

Across the world, **for every $1 spent on innovative medicine, non-medicine spending drops by $7**



Source: Lichtenberg, 2002; Hermus et al., 2013.

Figure 1.b:



Source: Lichtenberg, 2002; Hermus et al., 2013.

The implication for those institutions that purchase pharmaceuticals is that an expansive, long-term view is required when assessing medicines, both throughout the product's life cycle and across the entire health system. Despite the value that pharmaceuticals can provide, the primary focus of conversation about drugs in Canada tends to be price and cost, and their impact on budgets. Rarely is there a dialogue about how drugs impact other types of health care treatment and spending.

It must be noted that the conversation about value in pharmaceutical reimbursement is not merely one about old vs. new drugs. Evidence demonstrates the benefits to society of improving patient compliance for drugs that are currently accessible.[32] Improvement in the way we utilize existing medicines, such as through adherence, can also create value in the system, or extract the true value of the original innovation, whether or not a drug is patented.

However, understanding how drugs are currently performing within the system requires real-world evidence collected through improved monitoring and evaluation. Currently, we lack a consistent and evidence-based process for de-listing drugs and de-funding out-of-date treatments. Even if a drug is no longer the most effective treatment (or effective at all), it is difficult to de-list and to change clinical or patient habit, and so the system continues to pay for that intervention. Even when there is no evidence that a drug is harmful – merely ineffective – the continued funding of that drug can have a serious impact on system costs.[33]

RECOMMENDATIONS

- ✓ **Engage in real-world evidence collection and analysis to support an improved understanding of a drug's value once it is in use within the system,** and to promote efforts to de-list drugs that are no longer effective.
- ✓ **Expand drug assessments to include tertiary factors,** those that have an impact on health and cost within a larger scope. These factors could include improvements in social or economic outcomes for patients, provider and patient preference, convenience, benefits for payers outside of safety, operations, and maintenance and across multiple budgets.

CASE STUDY: RISPERIDONE AND SYSTEM SAVINGS

Schizophrenia is a chronic disease that is characterized by recurrent relapses and, consequently, a significant use of public resources.[34] One of the contributing factors to relapse is non-adherence to medication, which results in hospitalization and negative patient outcomes.[35] Many challenges with adherence are a result of oral treatments for schizophrenia, as they demand consistent use by patients at home. In contrast, a treatment in the form of a long-acting injectable requires less patient follow-up and provides fewer opportunities for missed doses. In a study of one of these injectables, risperdicone, and its use at Brampton Civic Hospital in Ontario, researchers found a significant cost savings over oral medication. Analysis revealed that a patient treated with risperidone in the hospital injection clinic saved the hospital itself $22,778 annually and saved the health care system more broadly $17,355 thanks to its improved adherence performance.[36] Though a long-acting injectable comes with a higher up-front price, the savings achieved by the system and the lowered risk of relapse for the patient are results of the greater value provided by this innovation.

Managing Innovation:
The Multi-Payer System

While we generally refer to Ontario's health care system as "single-payer", this implies a universality that is not entirely accurate. There is a single payer in the sense that Ontarians – whether through taxes, insurance premiums, or out-of-pocket – are the ones who pay for health care.[37] However, access to and coverage for that health care is the purview of a network of public and private payers.

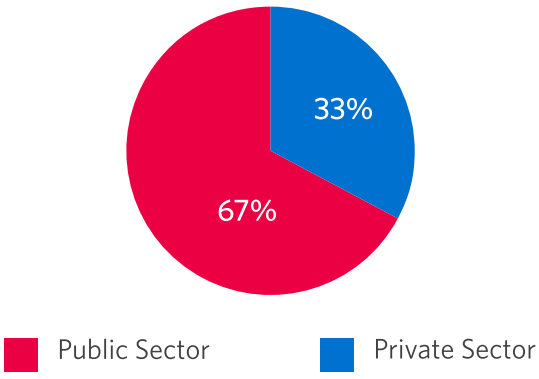
Figure 2:

59% of Canadian employers have some kind of **health care spending account** in place for their employees. The average contribution to **health care spending** was **$943 per employee** (in 2014)

Source: Stewart, Nicole. 2015. "Benefits Benchmarking 2015". Conference Board of Canada.

Coverage for out-of-hospital pharmaceuticals and medical devices is not accounted for under the Canada Health Act, resulting in private payers covering a notable share of the expenditure (on pharmaceuticals, especially). The Ontario government provides coverage for health innovations to some vulnerable groups but these coverage programs are slow to change, contain inefficient evaluation metrics, and come with application procedures that are difficult to parse. Most Ontarians who are not eligible for such programs rely on private insurance, usually through their employer or union.

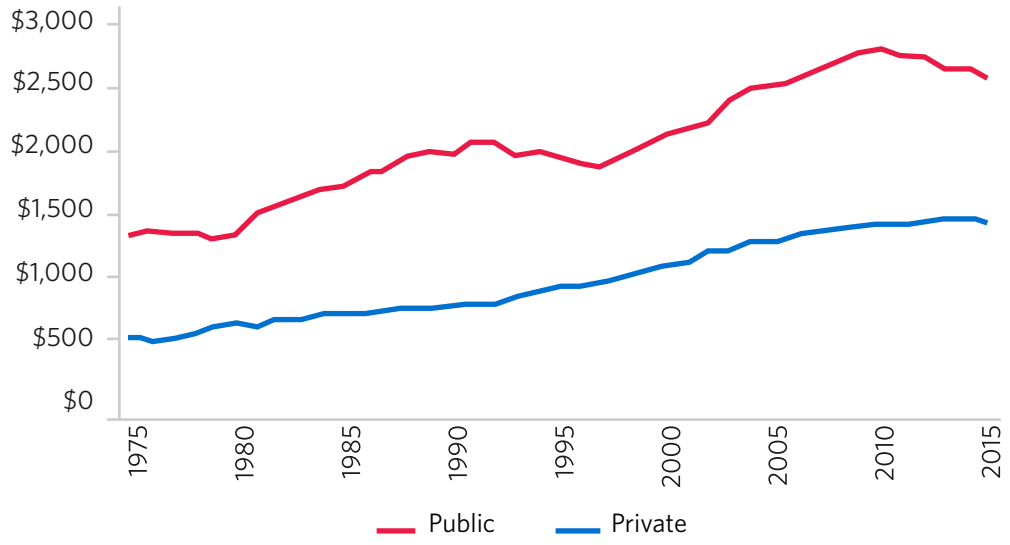
Figure 3: Health Care Expenditure in Ontario by Source of Funds (2015, Estimated)



Source: *Canadian Institute for Health Information,* 2015. https://www.cihi.ca/en/spending-and-health-workforce/spending/national-health-expenditure-trends

As noted earlier in this report, innovative drugs and devices are capable of moving patients out of the expensive public system, which is a boon to public budgets. However, the unintended consequence of this shift is that patients are now moving from health coverage that is mandated as public to care that is not accounted for under the Canada Health Act, and so is largely paid for by employers and individuals. Costs associated with some innovative drugs and devices are the responsibility of the private sector, while the public system sees (but rarely measures) related savings.

Figure 4: Health Expenditure Per Capita in Ontario, by Source of Funds



Source: *Canadian Institute for Health Information*, 2015. https://www.cihi.ca/en/spending-and-health-workforce/spending/national-health-expenditure-trends

Since the 1970s, private spending has increased alongside public spending (Fig. 4). While larger benefits from innovation (i.e. social benefits) are well within government's reach to capture, they are often less tangible for private payers. The value calculation for employers who provide benefits packages, for example, is quite different from that of a hospital. Although the common perspective is that this cost is expended by large insurance firms, it is in fact largely borne by Ontario's employers. The result is that higher-cost innovations are impacting the sustainability of employer benefit plans, which may lead to some Ontarians seeing a reduction in their coverage.

Plan sponsors, typically employers, are also increasingly responsible for paying for health innovations because newer products are more likely to be offered under insurance plans than public programs.[38] They include robust drug benefits, particularly, in order to remain competitive through attracting and retaining talent and ensuring a healthy and productive workforce. It must be noted that offering a supplementary health plan is voluntary, and so with the rising price of treatment the sustainability of benefit plans has become stressed and far from assured. This is evidenced by the increasing share of plans that now have annual or lifetime caps. Moreover, coverage costs are not distributed equally across all sizes of employer: smaller businesses may pay more per capita than larger businesses. Large businesses can take on more risk and have lower insurer expense loads; they also offer more benefits with lower reimbursement levels. For these reasons, they are able to introduce more flexible benefit systems which affords better control to their employer contributions.[39]

There are, however, benefits to employers to offering supplementary coverage: a competitive compensation package is appealing to talent, and increasingly expected in certain industries or positions. Additionally, in Ontario, benefits plans are a form of non-taxable compensation.

There are also considerable advantages for employees: private plans provide a broader range of products and services to choose from and tend to take less time to offer them than government coverage.[40] Individuals with employer-based coverage experience timelier treatments than those who rely on supplemental public health coverage programs, as well as reduced financial strain and improved drug compliance because their coverage is consistent. This in turn leads to less sick leave taken, reduced days caregiving to family members also on the plan, and a reduced risk of long-term absenteeism. The impact is greater productivity and a happier workforce.[41]

As expected, employers want to pay for devices and drugs that will provide positive health outcomes for their employees. They also want to ensure they are getting good value for the innovations their employees use. Similar to governments, employers are looking for ways to ensure both value for money and their ability to continue to offer benefits to those who depend upon them.

However, employers are growing increasingly concerned about the sustainability of their plans. Currently, private payers are looking to various mechanisms to appropriately assess the price and cost of new pharmaceuticals entering the market as well as whether and how they may be accessed on a drug plan. In response, the pharmaceutical industry has recognized this challenge and has expressed a desire to work with private payers to explore potential solutions to ensure that best value can be achieved for their plans.

Successful resolution of this question is one component in the management of costs in both the public and private markets, and the enduring sustainability and viability of our multi-payer system. Broadly, it is critical that both public and private stakeholders align behind what is demonstrably best for Ontario patients.

STRENGTHENING THE MULTI-PAYER SYSTEM

In an environment where private health care coverage has been on the rise, gaps have opened in the coverage enjoyed by many Ontarians. These gaps have formed around the self-employed, those operating in the "gig" economy, those on contract, individuals with pre-existing major illnesses, and households that earn slightly too much to qualify for government programs. Since the need for greater coverage now extends beyond merely seniors and the truly vulnerable, this raises the question of whether or not the public system of support is working.

While this multi-payer system creates a patchwork of coverage that can lead to gaps, there are benefits to a system in which there is more than one purchaser and adopter of innovation. What is of value to one payer may be of different value to another, providing patients with greater access to a diversity of treatments. Private insurers tend to have longer formularies, granting access to more innovations, often faster than the public formulary.[42] Treatment can slow disease or reduce the likelihood of disability, thereby leading to reduced spending on both in- and outpatient resources.[43] Similarly, private spending may be offset by reduced absenteeism, increasing productivity.[44] Without private coverage, individuals who are not covered by supplementary public programs face longer wait times for innovative treatments and higher out-of-pocket costs for those treatments.[45] Furthermore, insurance coverage is also customizable for both employers and individuals, and is therefore able to be nimbler than public programs. As it is in their interest to keep their clients healthy, insurers are often active proponents of preventative medicine, including promoting wellness in the workplace.

This multi-payer system has recently prompted discussion at the federal level about the need for a national pharmacare program. While the goal of providing drug coverage to all Canadians is laudable, we would caution this impulse. The cost to government to design and administer such a program would be steep, while the outcomes are less than guaranteed. Canadians tend to envisage pharmacare as universal, "free" access to all Health Canada approved drugs.[46] However, programs generally result in access to a small selection of low-cost drugs, amplifying the challenges public payers already have with timeliness and innovation. A recent analysis of 248 pharmaceuticals found that only 74% were approved for market in New Zealand, a country that recently enacted a national pharmacare plan. In comparison, 90% of those drugs are available in Canada today.[47] The literature suggests that the adoption of innovative drugs declines within a universal pharmacare program because of a "race to the bottom" created by government as they attempt to supply necessary treatment to all residents, but can only afford to do so by purchasing the lowest-price drugs. As illustrated within this report, access to innovative medications both improves patient outcomes and can save money in the long-term. If governments intend to spend on a pharmacare program, they may find their overall costs will increase as access to, and use of, innovative drugs declines. For Ontario, a more successful approach may be re-examining the mission and scope of the Trillium Drug Program.

RECOMMENDATIONS

- ✓ **Examine the gaps that exist between current public and private coverage** and determine what can be done to fill them through a collaborative, patient-oriented effort. A possible arrangement would be a more formalized, integrated public/private strategy that addresses not only the ongoing financial sustainability of medical plans but also ensures we implement needed innovation.
- ✓ **Improve provincial integration** to ensure that individuals with private health insurance coverage have applied for any appropriate government programs first, and before reimbursement is paid by the insurer, reducing wasted public resources and the burdensome shifting of financial responsibility onto employers or individuals.[48]
- ✓ **Currently, there is a review of the Trillium Drug Program underway. We encourage that review to consider the mandate of the program:** What are the needs in society today, given both the changing nature of work and the rise of innovative, individualized treatments? Now is the time to refresh the protocols for those who require supplementary public coverage, and ensure that coverage is appropriate and easy to access.

SOLUTIONS

1. FIND NEW WAYS TO DEFINE AND RECOGNIZE VALUE

METRICS

In order to re-align our system towards value-based health care, legislators, policy-makers and payers need to create tools that can address two fundamental questions: How do we define value in a way that makes it a workable concept for decision-makers? How do we assess innovation against that definition? The best way to begin to tackle these questions is by creating adaptable metrics that reflect the outcomes we wish our system inputs to achieve.

A metric in this context is a set of criteria used to assess an innovation's impact on the health care system. These criteria should include big-picture considerations, such as how the innovation can be scaled, in what geographic or population settings is it most likely to have a positive impact, the conditions necessary for the innovation to succeed, its economic value (e.g. reducing costs, enhancing productivity, generating revenue), and how to generate provider buy-in to lead uptake.[49] This is more than just proof of concept; it is "proof of relevance, proof of value and proof of reimbursement".[50] These value-based metrics then give payers the criteria against which to measure evidence and make decisions in order to spend effectively while achieving system goals.

To ensure that metrics are able to provide the guidance needed to tackle innovation and disruption-related challenges, they should also include broader health and wellness measures.[51] Rather than merely assessing cost or safety inputs, (e.g. readmission, errors, adverse events, and mortality) positive outcomes should be evaluated (e.g. patient quality of life, convenience, relevance to integrated care delivery).[52] In this way, innovation assessment can be used as part of a larger shift from the current paradigm of disease management to one of health management.

With the ideal scope, metrics would also include measures for value across the "continuum of health services".[53] This means evaluation across silos (e.g. budgets, team or department performance) but also how an innovation would impact, for example, a hospital's interaction with home and community care, if that is where their outpatients go.

Opportunely, work on the creation of metrics to measure value and aid assessment of innovation is already underway, with leadership from academia as well as payers, health care providers, and manufacturers (such as dedicated efforts from the World Health Innovation Network, the Institute for Health Metrics and Evaluation, and the International Consortium for Health Outcomes Measurement).

PERFORMANCE-BASED RISK-SHARING ARRANGEMENTS

Performance-based risk-sharing arrangements (PBRSAs) are agreements between manufacturers and payers that "attempt to balance the benefits of timely patient access to new health care technologies while addressing the clinical uncertainties and/or economic risks associated with their use", though reduced complications and more efficient, directed resource use.[54] They are mechanisms for purchasing, leasing, or reimbursing technology that promote the use of value-enhancing innovations by reducing the uncertainly that may come with a new health innovation. The agreements include a more significant investment in evidence collection and analysis while the innovation is in use within the health care system.[55] PBRSAs are supported by performance tracking in a set patient population across a set period of time, with level of reimbursement or continuation of contract based on the economic and health outcomes achieved by the product or service.[56] They can also be used to capture real-world evidence, which can be used to support further decision-making in both the clinical and health care

delivery realms. Fundamentally, they provide payers with greater certainty about their purchases and an improved understanding of where their investment has gone.

The motivation for a PBRSA is the differing definition of value that exists between payers and manufacturers, including the willingness of payers to accept uncertainty around the efficacy (or cost-efficacy) of an innovation.[57] PBRSAs are an excellent tool because they address two of the challenges holding payers back from embracing health innovation:

- Payers want to see manufacturers take on more of the accountability and risk that was traditionally their responsibility, particularly as innovation comes with both greater disruption and higher up-front expenses than the status quo; and
- Payers need evidence-based reasons to purchase an innovation, particularly if the value is to be found in the long-term or is expected to be spread across the system. A PBRSA is designed to both share risk and develop evidence.

CASE STUDY: BENEFITS OF PBRSAS

Patients	Focus on their health outcomes, not just treatment
	Improved access to technology, including earlier in the innovation cycle
	Increased treatment options
Manufacturers	Overcome payer's risk aversion
	Increased market access
	Faster time to market
	Closer to desired price point
	Builds value proposition
	Expands evidence base
	Injects innovation by appropriately recognizing and rewarding value
	Demonstrates accountability
	Links innovation to health system decision-making
Payers	Reduces decision-making uncertainty
	Gains access to innovation, and reduces bias against early-stage innovation
	Expands formulary/benefits list
	Supports move to value-based health care
	Minimizes financial risk
	Meets health outcome-based goals, on both patient and population levels
	Reduces risk that they may be denying patients access to effective treatment
	Links health research to decision-making and vice-versa
	Realize broader (i.e. system-wide) savings[58]

It should be noted that there are some challenges to the creation of a successful PRBSA. These include:

- Parties have to work around/break down existing silos.
- May require a major administrative or delivery change, including increased resource use due to change management.
- Involves complex and challenging negotiations surrounding how to determine the measurable outcomes to design the arrangement and the timeline against which they will be measured.
- Costs associated with establishing the systems necessary to appropriately track and measure outcomes.
- A limited capacity to collect, analyse, or share the necessary data to capture whether or not outcomes are being met.[59]
- Payers will need to ensure that an innovation can be withdrawn if it is not effective, to ensure they do not become path dependent with each new innovation.[60]

There may be a question of who bears the responsibility for, and shoulders the cost of, data collection, as well as uncertainly regarding how that data will be used and shared. These responsibilities may pass to the manufacturer, though many may choose to take on this role so as to demonstrate accountability and trust within the relationship with the payer, and to build normalcy (i.e. encourage PBRSAs to become more common). Similarly, at least at the beginning, funding responsibility may be shared between payer and manufacturer in order to ensure the initiative will move forward.[61]

In order to answer some of these questions, guidance should come from health authorities with a system-level view of innovation assessment, pricing, and adoption. While currently facing challenges in their relationships with industry, institutions such as CADTH and the pan-Canadian Pharmaceutical Alliance could include PBRSA guidance within their mandates, demonstrating leadership at the policy level to encourage other stakeholders to experiment.

RECOMMENDATIONS

- ✓ **Public system decision-makers should work to redefine value** through the creation of metrics and benchmarks. This effort should be done in collaboration with manufacturers, and make improved use of real-world evidence. They should build on current collaborations between universities and providers to develop metrics for collecting and analyzing the data necessary to make value-based decisions. Payers should also utilize academics as indifferent third parties in collaborations with industry.
- ✓ **Outcomes measurement should incorporate multiple sources of value,** such as patient and provider convenience, increased compliance, reduction of in-hospital treatment, savings across budgets, and other societal and/or long-term considerations.
- ✓ **Non-traditional agreements between payers and manufacturers should be utilized** in order to reduce risk, improve data collection, and tie product performance to patient outcomes and/or system goals.

2. DEVELOP REAL-WORLD EVIDENCE AND BETTER UTILIZE PATIENT DATA

REAL-WORLD EVIDENCE

Becoming truly patient-centred is not merely about the move to personalized medicine – it means making use of a diversity of data sources to better understand the patient experience and care pathways.[62] Tapping into patient outcomes data and conducting cost-benefit analyses are critical to value-based health care.[63] Unfortunately, our current capacity to do this is limited, as electronic records are not shared across health care institutions, with manufacturers or insurers, and the system lacks the requisite IT infrastructure to facilitate this level of connectivity.

Traditional sources of evidence, such as clinical data, internal industry data and academic studies are currently the most common information sources used to assess health innovations. However, there is a wealth of data that could be similarly valuable but is not consistently or effectively being collected, including outcomes data from providers, outcomes data from payers, electronic health record data, and qualitative patient data.[64] This real-world evidence base may be able to demonstrate what types of patients respond better to particular treatments in particular contexts, providing data to better understand where and when value is achieved.[65]

Providers and payers should be able to track treatment patients receive, the products used in that treatment, the outcomes of the treatment, and the risks associated with the treatment.[66] With this knowledge, payers can analyze what is and is not effective, benchmark results, and discover opportunities for improvement. For manufacturers, real-world evidence can provide confirmation that their product generates greater value.

SUPPLY CHAIN REFORM

An effective way to improve our data richness is through supply chain reform. A supply chain is the network of finances, information and supplies related to the acquisition and movement of goods and services (from supplier to end user, e.g. provider or patient). Effective use of supply chain practices, including intelligent use of the data they provide, can raise patient outcomes and control costs through improved resource distribution.[67] Incorporating modern supply chain management into the public health care system would result in increased knowledge about patient health, safety, and recovery time linked to product and procedure use and quality, case costing, economic impacts of adverse events, rate of shortages/stock-outs, and inventory costs/savings.[68] Payers could track both the positive and the negative, to know what is working and what needs to be improved.

The adoption of global supply chain standards (such as barcoding) is the first step in supply chain reform. Increasingly, health care systems around the world are adopting GS1, the most common global standard, in order to better track inputs. For manufacturers, GS1 standard use can improve their understanding of the needs of their customers within the health care system. Currently, industry lacks access to health system data, including evidence related to product performance.[69]

Within Canada, Alberta has taken the lead on the adoption of GS1 standards for medical devices; their Canadian Healthcare Medical Device Standards Project is intended to demonstrate the value of these standards. GS1 creates data synchronization that allows for sharing of standardized product data between supplier and distributor stakeholders, and Alberta Health Services. GS1 data will be accessed in real time through digital tools that allow for tracking, confirming, and tracing products and procedures. These will provide a more accurate accounting of what is being used, how often, and

when. Knowing this information – and being able to link it to the patient and their experience – can help determine the value of an item related both to resource use and patient outcomes.[70] Tracking and tracing can mean more efficient procurement practices as information about product performance could be built into purchase or renewal decisions. The intention is better use of resources in the Alberta health care system through better understanding of the ROI of a purchase.[71]

However, in the conversation about data, we must remember that as manufacturers are facing pressure to deliver more data, and more in-depth data, this can increase administration and costs. Depending on the organizations asking for data, and how many are doing so, and how they want their data delivered, this can also be duplicative and constraining.[72] Supply chain reform should be enabled by government, but ultimately left to the manufacturers to decide their approach to implementing GS1 use.

RECOMMENDATIONS

- ✓ **Revisit data sources used for assessment to allow for continual evidence-generation through health innovation's use within the system.** Increase use of real-world data to better recognize a deeper definition of value across the providers, departments, institutions and Ministries.
- ✓ **Within the Ministry of Health and Long-Term Care's on-going efforts at supply chain reform, provide opportunities and leadership for health institutions to adopt GS1 standards.** The use of these standards should be integrated with manufacturers to improve tracking of data for safety, performance, and value measurement purposes.
- ✓ **The Government of Canada should help build common data access policies** that are capable of enhancing the utility of public platforms, and create frameworks that allow for the flow of patient information between various points in the health care system, protected by forward-looking privacy legislation (e.g. HIPPA in the United States).[73] The federal government should also help build linkages to international databases and evidence review bodies, to share health technology assessments and similar research without duplication.

3. BREAK DOWN BUDGET SILOS

As noted in *Patients First,* "Health services are fragmented in the way they are planned and delivered. This fragmentation can affect the patient experience. It can also result in inefficient use of patient and provider time and resources, and can result in poor health outcomes."[74] What's missing from this assessment of system fragmentation is budgetary silos. Value-based health care and the effective integration of disruptive innovation require high-level budget decision-making, which in Ontario means silo-breaking collaboration between the Ministries of Health and Long-Term Care, Government and Consumer Services, Research, Innovation and Science, Finance, and the Treasury Board. All will need to assess where spending in one part of the system results in savings in another, and how the value proposition of a promising innovation can be accurately captured across the public sector (e.g. in the social determinants of health that extend into community and social services). Each should have a view to spending and saving that captures the overlapping impact of health on Ontarians' lives, and each should possess the willingness to demonstrate how a broader definition of value can be measured and its benefits captured.

CASE STUDY: INSPIRED AND CROSS-SILO ACTION

INSPIRED is an example of a public/private partnership that identifies a broader value context across budgetary silos and works to achieve goals in a patient-centric way. The Canadian Foundation for Healthcare Improvement (CFHI) and pharmaceutical firm Boehringer Ingelheim partnered to scale a program designed to support patients living with late-stage chronic obstructive pulmonary disease (COPD), and transition them from the hospital to care in their community. INSPIRED teams are made up of a variety of health and social care providers, from respirologists to nurses to social workers to COPD educators. Together, they deliver support through individualized action plans, home visits, telephone help lines, self-management support education, and other care planning. Currently, a series of major hospitals across Ontario are associated with the program, and all have demonstrated improved care outcomes for COPD patients, such as a reduction in hospital admissions, ER visits, and length of stay. INSPIRED costs approximately $1000 per patient, but the CFHI estimates that a five-year, nationwide program could save $688 million in ER visits and hospitalization costs alone.[75] We know that organizing treatment around health outcomes rather than medical speciality, the way INSPIRED has done, can "generate efficiencies, reduce duplication, cut costs and provide better care to patients".[76] However, this requires policy and legislative change in order to move away from siloed provision of care, as well as improved support for electronic medical records and interoperable IT systems.[77] It also requires a consideration of multiple budgets, across hospital departments, providers, community services, and private organizations. Nonetheless, INSPIRED has demonstrated that scaling of innovative solutions can be efficiently and ethically achieved by collaboratively leveraging the resources and expertise of the traditional health care community and partners in the private sector.

RECOMMENDATIONS

- ✓ **The Government of Ontario should create a Health Cabinet.** In 1995, the governor of Maine created a "Children's Cabinet" in which all government departments that had some responsibility for children's services came together to coordinate their activities. The initiative was so successful that it was made permanent in 2001.[78] Today, there are more than 16 Children's Cabinets across the United States.[79] An Ontario Health Cabinet would include representatives from the Ministries of Health and Long-Term Care, Finance, Community and Social Services, Community Safety and Correctional Services, Labour, Housing, Indigenous Relations and Reconciliation, Government and Consumer Services, Research, Innovation and Science, the Treasury Board, and the Seniors' Secretariat to understand how their decisions impact one another and to determine how to assess budgets in a way that recognizes and captures the value of their activities. Like some Children's Cabinets, the Ontario Health Cabinet could also include private sector stakeholders, in order to take advantage of the knowledge and capacity of non-government actors in the health sector.

CONCLUSION

Management of our public health care system is primarily concentrated on measurement of cost inputs and safety outputs. Measurement of system effectiveness – value – is not part of the equation, even when this concept is needed most in order to ensure sustainability. Unfortunately, government's current notion of value is not agile; it cannot manage the changes wrought by innovative medical devices and pharmaceuticals. As a result, shortcomings in public health coverage have emerged, and it is private payers who are increasingly shouldering the burden for innovation.

In order to transition to value-based health care, we need "an ecosystem of institutional and policy structures that support value-based approaches".[80] There is growing buy-in to this idea from health care providers, patients, and some payers. However, without leadership at a higher level, value-based health care is not achievable in Ontario.

This leadership must come in the form of an inclusive approach to system-wide thinking and acting:

- **Leadership from policy makers,** who must create the conditions for adoption of innovation, including the means for successful change management of any resultant disruption and a systems approach to health care delivery. They must do so in the context of how innovative technologies can be used to realize a patient-centered health care system.
- **Leadership from manufacturers,** through the creation of innovation that drives economic value and an improved ability to address the specific uncertainties and issues that prevent payers from choosing innovative treatments.
- **Leadership from private payers,** who could work more closely with government to identify and fill gaps between public and private drug and device coverage, while maintaining broad and timely access to innovation for Ontarians.
- **Leadership from clinicians, providers, and patients,** as they are the end-users of innovation, and as such require a say in its management.
- **Leadership from academics and researchers,** who can create the evidence base and metrics needed for measuring and evaluating innovation, and who can help decision-makers determine how we act on the concept of value.

While leadership is necessary from all stakeholders, it is policy-makers who must demonstrate a willingness to tackle reform through an effective value-based health care strategy. In order to succeed, this strategy must embrace the three solutions outlined in this report: Find new ways to define and recognize value, develop real-world evidence and better utilize patient data, and break down budget silos.

Based on the current challenges we face evaluating, adopting, and paying for innovation, Ontario needs immediate action to enshrine value-based health care within the *Patients First* strategy. Without that, we will not succeed in transforming our system.

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