

Spotlight on the Canadian Specialty Pharmaceutical Market

Do Better? Yes, We Can

As much as the Covid-19 pandemic has challenged Canada, it has also opened up new opportunities in specialty medicine and healthcare delivery.

Our performance during Covid gave us a glimpse of what's possible and invites us to do better.

Lessons learned from the pandemic to improve innovation and access to specialty medicines.

Carlene Todd of Roche Canada discusses how to achieve optimal patient access to medicines.

Covid the Change-Maker: Lessons for Specialty Healthcare

Before and after. The Covid-19 pandemic is one of those events that slices through time and divides it forever. The pandemic has changed not only the way people engage with the world, but the very fabric of society. As the national and global emergency settles into its post-vaccine phase, the specialty pharmaceutical ecosystem can use the lessons learned from the event to boost innovation and improve access to specialty medicines.

What we saw during the pandemic

First and foremost, we saw heart. Canadians of all stripes came together to keep the healthcare system running through one of the country's greatest health challenges. Healthcare providers, policymakers and the pharmaceutical industry came together to maintain continuity of care for patients requiring specialty medicines. The numerous individuals and groups involved in keeping the specialty medicine wheel turning during Covid deserve a loud and enthusiastic thanks.

At the same time, Covid laid bare the pre-existing gaps in the specialty pharmaceutical ecosystem and the need to build greater resilience into the healthcare system. The fact

that Canada ranks 10th out of 11 peer countries in overall healthcare performance, including a 10th-place ranking for health outcomes and 9th place for access to care,¹ speaks to the need for improvement and presents an opportunity to learn from better-performing countries.

The fault lines in Canada's resilience to the Covid-19 crisis inspired the formation of new group called the Resilient Healthcare Coalition.¹⁵ In an October 2021 [joint mandate letter](#), the Coalition and its supporters urged the Minister of Health and the Minister of Innovation, Science and Industry to ensure that "Canada doesn't simply return to a pre-pandemic status quo, but instead builds a stronger and more interconnected healthcare and life sciences ecosystem."¹⁶

One of the group's members, Quebec Cancer Coalition Executive Director Eva Villalba, draws on the concept of "antifragility"¹⁷ as inspiration for a more resilient system. "Antifragile systems actually grow and improve under pressure," says Villalba. To become antifragile, "you need to balance risk management with innovation so you can benefit from unpredictable events."

WHAT EXACTLY IS HEALTHCARE INNOVATION?

Dr. Zayna Khayat, who teaches a course on the subject at the University of Toronto, lists three criteria that, in combination, characterize a healthcare innovation¹⁸:

- **New:** A fundamentally new approach compared to the existing standard of care.
- **Better:** An overall five-fold improvement over the existing standard, taking outcomes, patient experience, healthcare experience, and costs into account.
- **Used:** Implemented at scale, at a minimum level of 35% of potential adoption.

According to Dr. Khayat, a medical advance that fails to meet these criteria is "just a new and interesting thing."

For example, life-changing innovations in specialty medicine include the discovery of antiviral drug regimens that cure hepatitis C and the development of tumour-agnostic drugs, accompanied by genomic testing to predict who will benefit from specific medications – advances that seemed impossible until they became reality.

SO WHAT'S THE BIG IDEA?

Our response to Covid has shown us that change can happen faster and more dramatically than previously thought possible. Carrying this mindset to the realm of specialty medicine could inspire equally bold changes. Here, we offer some ideas that could help accelerate innovation and improve care for Canadians who depend on specialty medications.

Data from the real world

Imagine this scenario: a patient with a serious condition presents to the doctor, who taps into an AI-enabled database to make a diagnosis, to identify the best treatment choice for this particular version of the condition, or both. Or how about this one: a patient goes to the hospital for an MRI. Before a doctor or technician reviews the images, an algorithm interprets the data and flags every irregularity, which helps focus the healthcare provider's efforts and ensures nothing significant is overlooked.

Making such scenarios a reality will require a major shift in how we think of data: who owns it, how we access it, and how we can use it to drive behaviour change. We're clearly not there yet. As the pandemic brought to light, Canada's ability to collect, share and use health data leaves a lot to be desired. The list of barriers includes archaic technologies

for collecting data and excessive fears of privacy breaches, leading to siloed data repositories.¹⁹

In an effort to solve such data collection problems, the federal government has begun moving toward a pan-Canadian Health Data Strategy, with stakeholder consultations under way.²⁰ The Strategy's priorities include modernizing the data infrastructure, updating privacy standards for the digital age, and clarifying accountability and governance.

In terms of specifics, however, the path forward still looks muddy. Take breast cancer data, for example. "We got very excited when the SEER database in the States announced they would begin collecting recurrence data but after further exploration, this seems nearly impossible in Canada," says MJ DeCoteau, founder and executive director of Rethink Breast Cancer, noting that real-world evidence research "has long been considered unfindable."²⁰ On a positive note, DeCoteau says that "interest in using big data and artificial intelligence to help understand metastatic breast cancer is growing and could be a way forward."

A group called CREATE [Centre for Data Science and Digital Health] is on the case. With help from the artificial intelligence firm Pentavere, the Hamilton-based group is working to translate unstructured clinical data on breast cancer patients into real-world evidence that clinicians can use to make treatment decisions.²¹ On the diagnostic front, the detection of breast cancer lesions is getting a boost with an AI-enhanced system called QuantX, which can also support biopsy procedures.²²

Canadian patients have their own visions for health data, as outlined in a Declaration of Personal Health Data Rights in Canada. Jointly drafted by 20 patient associations, the declaration asserts that patients "have a right to benefit from the processing or sharing of their personal health data for research or any other purposes" and that patients must have the ability to "access complete and usable copies of the data."²³ Seems like a reasonable ask.

BIG IDEAS IN THE MAKING

The Apple Watch, known to many as a fitness device, is shapeshifting into a diagnostic tool. In a joint project called the Heartline study, Apple and Johnson & Johnson hope to harness the Apple Watch to detect atrial fibrillation before symptoms become obvious or dangerous.²⁴ A new commercial venture called Isomorphic Labs, meanwhile, is betting that AI can revolutionize the entire process of drug discovery. Noting the commonalities between biology and information science, Isomorphic Labs founder and CEO Demis Hassabis maintains that "AI methods will increasingly be used not just for analysing data, but to also build powerful predictive and generative models of complex biological phenomena."²⁵

Going digital

When the pandemic hit, health centres across the country scrambled to meet the urgent need for remote care services. This happened at great speed: by October 2021, a single centre of excellence had provided more than 100,000 virtual care visits to Canadians over the first 18 months of the pandemic.²⁶ The Canada Health Infoway created a Rapid Adoption of Virtual Care Fund to give the paradigm shift to digital health a further push.²⁷ With this vision in mind, the government of Alberta has invested in a Digital Health Integration Readiness Platform to help health technology startups meet the complex data and security requirements critical to success in Alberta's health system.²⁸

While this fast reaction time is to be commended, Eva Villalba cautions against "rushing in to fit a round peg in a square hole" and suggests we take the time to "define the problems we want digital tools to solve."²⁹ To get full value from a digital health ecosystem, Villalba maintains, we will also need to transition from "a sick model (break and fix) to a true health model (predict and prevent)."

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Eva Villalba, Executive Director, Coalition Priorité Cancer au Québec Co-Chair, Resilient Healthcare Coalition

In the meantime, digital technology is making promising inroads into complex care. In one recent Canadian study, 905 adults received either virtual or standard care after discharge from hospital for non-elective surgery. A month after randomization, fewer patients in the virtual care group reported pain, suggesting new avenues for virtual follow-up.¹¹

Patient support programs (PSPs), for their part, have integrated such offerings as virtual scheduling and video injection training into their services. Recognizing that technology can intimidate some patients, design teams have taken pains to create simple interfaces that even tech-naïve patients can comfortably manage.

Looking ahead, we can expect PSP providers to redouble their efforts to meet patients on their own turf, with an expanding array of apps or other tools to help patients access various services. While this sea change will require

an investment, it will reward PSP stakeholders with more streamlined and cost-effective operations, while giving patients greater control over their healthcare.

The pandemic has demonstrated that remote services previously considered impractical can work very well. It has also inspired us to streamline the exchange of health data so we can act on it more quickly. Banks have already achieved this cross-talk, while maintaining a high level of security. There is no reason our health infrastructure can't get there, too.

FASTER ACCESS

Covid has also proven that we can dramatically shorten the time to drug access. Can we not do the same thing for patients waiting for life-saving medications for their complex diseases and conditions?

With the average time from NOC to public reimbursement of drugs currently languishing at 21 months (19 months for oncology drugs and 22 months for orphan/rare-disease drugs), we admittedly have a steep hill to climb.³⁰ To this end, the Resilient Healthcare Coalition drafted a letter urging the Canadian government to "create a coordinated and synchronized regulatory regime that reduces the time between when innovative drugs, vaccines, and medical devices are submitted to Health Canada and their access by patients and clinicians."¹⁶ But how? In a report on precision medicine, the Canadian Breast Cancer Network recommends "using performance standards to enable a more flexible, proactive approval process that allows for nimbler access to both therapies and testing."³¹ This could entail setting targets for accelerated drug reviews or committing to timelines for all drug reviews in Canada.

All too often, delays in the approval process end up stalling the commercialization of novel innovations, leaving patients waiting too long for products that could change their lives. To address this gap, the Canadian government is moving forward with a "regulatory sandbox" to fast-track approval of disruptive health technologies that current regulations are not equipped to handle, from 3D-printed organs to personalized cell therapies.³² The program will allow companies to work with Health Canada to establish individualized standards, rather than having to follow preset rules. What remains to be seen is whether the program can speed up access without compromising safety.

Value-based healthcare

Back in 2006, a book called *Redefining Health Care* introduced the notion of value in healthcare.³³ Since then, researchers and healthcare leaders around the world have developed tools to implement the value agenda.

In Canada, this effort has seen mixed results. Our current system rests on compensation for interventions, rather than outcomes. Shifting from an input-based system to an outcome-based system will spur innovators to create value for patients and encourage better stewardship of

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**Resilient Healthcare Coalition
Letter to the Government of Canada**

system-level costs. As noted by Harvard Business School professor Robert Kaplan in a video interview about healthcare costs, "the remedy to the cost crisis... simply requires a new way to accurately measure costs and compare them with outcomes."³³ Outcomes-based agreements (OBAs), defined as performance-based contracts that divide risk between manufacturers and payers, offer an avenue to this destination.³⁴

Value lies at the core of all healthcare. All of our efforts – solving the data problem, digitizing services, accelerating and streamlining access, and rewarding outcomes rather than activities – must culminate in value to the patient.

This endpoint comes through loud and clear in a November 2021 summit called *The Way Forward: Patients Redefining the Future of Healthcare in Canada*. Dominant themes in the summit include the importance of identifying the most valuable outcomes for different patient populations and the need for accessible data to help understand those outcomes.³⁵

Dr. Harindra C. Wijeyesundera, chief of the Schulich Heart Program at the Sunnybrook Health Sciences Centre, makes the link between clinical and commercial value. "Innovation must be deliberate about its value and impact on how patient care is delivered, which sometimes doesn't happen enough," he said in a September 2021 webinar on innovation in Canadian healthcare.¹⁷ Keeping a steady eye on these objectives – value and impact – will help us "make the argument that innovation is worth paying for."

The pandemic has offered a glimpse of what is possible in innovation, access, and care. Bringing this vision to fruition will require ingenuity and tenacity – and above all, a belief that we can do it. Perhaps we can draw inspiration from science writer and inventor Arthur C. Clarke, who famously stated that "the only way to discover the limits of the possible is to go beyond them into the impossible." **Or maybe Nike has it right: "Just do it."**

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**CREATING VALUE FROM
PATIENT EXPERIENCES²¹**

A group called CREATE [Centre for Data Science and Digital Health], housed in the Hamilton Health Sciences Centre, is harnessing AI to help clinicians obtain a clear picture of patient populations before, during and after treatment. According to McMaster University oncology professor Dr. Mark Levine, one of the project's leaders, this capacity is long overdue. Thirty-five years ago, if Dr. Levine wanted to obtain information about breast cancer patients with a particular profile, he would "either do a chart review myself or ask a resident to do it." Today it's "the same thing – and with all the technology now available, that's unbelievable."

With help from the Toronto AI firm Pentavere, CREATE is working to digitally recreate breast cancer patients' experiences throughout the treatment arc, with the eventual goal of using the data to support personalized breast cancer care. With funding from Roche Pharmaceuticals, CREATE and Pentavere are now collecting anonymized information about diagnosis, tumour type, and treatment in 3,000 breast cancer patients. "Until now, this data has been locked away in charts and in silos," says Dr. Christopher Pettengell of Pentavere, who envisions funneling the data into "a dashboard that guides clinical decisions by enabling clinicians to identify patients with similar profiles."