Volume 1 Issue 3 Fall 2024

Hypothesis

PERSPECTIVES INSIGHTS & THOUGHT LEADERSHIP IN THE LIFE SCIENCES

Is AI Revolutionizing Health Care, or Sitting at the Sidelines?

A Conversation with AI Guru Dr. Tom Davenport

INSIDE THIS ISSUE

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15 years

Medical minds gather here.

As the largest independent medical publisher in Canada, our peer-reviewed open access scientific journals are a practical resource for Canadian healthcare practitioners. We currently publish specialty journals in the areas of allergy & immunology, dermatology, hematology, ophthalmology, diabetes & endocrinology, gastroenterology, primary care, women's health, rheumatology, oncology, respirology and our press is constantly growing with new titles planned for 2025.

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Hypothesis
PERSPECTIVES INSIGHTS & THOUGHT LEADERSHIP IN THE LIFE SCIENCES
Volume 1 Issue 3 Fall 2024

Letter From Our Editor-in-Chief

Well, it's been a great first year for the magazine! We couldn't be happier with the readership numbers, the feedback, and the reach of the magazine. Our Summer 2024 issue was mailed to close to 200 life-sciences companies and the journal was deployed electronically to over 1,000 Canadian industry professionals. Open rates and web visits are up, as are organic subscriptions! Please share the journal link with a friend: www.hypothesismag.com.

Before I forget, we want to take a moment to thank all our contributors in 2024 and we also want to take a moment to wish everyone a safe, healthy, and prosperous holiday season. We can't wait to see you back in 2025!

This issue features a great interview with Tom Davenport, a regular contributor to Harvard Business Review and a world-renowned management consultant. We also sat down with Lucie Rousseau from Servier Canada and spoke with Susan Waserman from McMaster University' s Division of Allergy & Immunology. Our patient interview helps shed light on the daily challenges faced by migraine sufferers. And of course, we top it all off with news about your products and the people in the industry!!

We hope you enjoy this issue and that you'll share it with your peers. We welcome your feedback ---let us know what you want to see more (and less) of!

Happy Holidays!

Lea

Lea Prevel Katsanis, PhD
Lea Prevel Katsanis is a professor in the Department of Marketing at the John Molson School of Business at Concordia University. Katansis, who spent many years working around the world for major global pharmacy brands, is the author of Global Issues in Pharmaceutical Marketing.

A Clear and Present Danger

Consulting is a dangerous business. Maybe never more so than now.

By Rohit Khanna, MBA, MSc, MPH

If I asked you to name the most dangerous healthcare company in the world (you can decide for yourself how you define 'dangerous'), which company would you choose? OpenAI. Meta. Google. Apple. Any EMR software vendor on the planet. Any pharmacy benefits manager in the universe. Any health insurance company in the galaxy.

Go on. Keep thinking. Probably a ton of companies that I haven't mentioned and an equal number that I've probably never even considered.

Well, a bunch of U.S. state attorneys general and the U.S. Justice Department want us to believe that the answer to the question is McKinsey & Company or Publicis Health. Old news you say.

Indeed. You are right.

McKinsey paid nearly $1B in settlements for their role in the opioid crisis over the last few years and Publicis Health's role has been known for some time. Over the last few months, however, there has been a resurfacing of news related to these companies during that crisis. In February 2024, Publicis Health agreed to pay $350M to settle claims over its involvement in the opioid crisis. And in April 2024, several news outlets reported that McKinsey was under criminal investigation by the U.S. Justice Department for helping clients devise ways to accelerate opioid sales.

I've got no particular sympathy for either firm and there are plenty of examples that shed light on their questionable business practices and motivations.

To wit, in 2021, Multnomah County in Oregon, the state's most populous and which includes the city of Portland, sought to hold fossil fuel companies and their "misinformation agents" accountable for the unprecedented 2021 heat dome that saw temperatures in the county reach 116° Fahrenheit.[1] One of those misinformation agents was McKinsey. According to another lawsuit, Paine Schwartz drained over $24 million in cash from the largest peach farming outfit in America in less than four years and used its control of that company to enrich McKinsey & Company, who had long-standing ties to the investment firm.[2] They have also been implicated in racketeering lawsuits,[3] settled lawsuits over excessive fees,[4] and worked with Big Tobacco (need I say more).

I mean consulting is a tough business at the best of times. You've got to earn your fees. And then you must earn more fees. And to earn more fees, you need to think about new pain points and problems, where in some cases none ever existed before, that could potentially earn you those fees.

Let's be clear: I'm not a lawyer. I haven't seen the charges or accusations, or any paperwork related to any of these cases. And most importantly, I'm not trying to defend any criminal behaviour if it took place.

However, on the basis of what's been reported, which is that these firms helped their clients maximize the sales of opioids and develop predatory and deceptive marketing strategies, there must be incontrovertible evidence that this was done with malice and with the full knowledge that this was harmful or lethal to patients.

Otherwise, we have a problem. Because then we have to go after every company "that's just doing their job" or "is at the wrong place, at the wrong time." In many case, there actually may be premeditated intent, in which case the punishment fits the crime. But what if there's not?

This means that we must go after all the aforementioned fossil fuel companies and their misinformation agents for failing to inform us about the ravages of climate change brought on by their respective industries.

And we must also go after all the social media companies and their misinformation agents for creating addictive social media platforms and helping to fuel and maximize the screen time of young adolescents, which we know is harmful to a developing brain. I'm looking at you Tik Tok.

And we must have the food industry and their coterie of consultants and ad firms in our crosshairs too, because they've been feeding us deceptive marketing strategies for decades about the role of trans fats and fructose and other lethal ingredients in their products.

Let's not forget that we're definitely going to have to sue the fast-food companies and their merry band of 'misinformers' too. Haven't they been knowingly brainwashing us to fuel the sales of their hamburgers, fries, and desserts, despite knowing about an ever-growing obesity epidemic?

Maybe we should sue the cell phone manufacturers and their misinformation agents too. Encouraging us with free minutes and cell phone plans that have no limits, while knowing there may be a potentially lethal link to low levels of radio frequencies and prolonged cell phone use.

And we should definitely go after every municipality and county and their consultants for 'luring' us to live in their communities whilst continuing to ignore the known health concerns with lead- and asbestos-lined water pipes that deliver the drinking water to the residents in those very same communities. Ask the people of Flint, Michigan.

You all get my point.

Healthcare is a high-profile area. No matter what happens, if it's related to healthcare, it is sure to garner attention.

So be it.

If this is our new standard, then let's make sure it's applied fairly across the board.

Rohit Khanna, MBA, MSc, MPH
Rohit Khanna is the Managing Director of Catalytic Health, a leading life-sciences communication, publishing, and strategy firm. He holds a B.A. from McGill University, an M.B.A. from Queen's School of Business, an MSc. from the London School of Economics & Political Science and a Master of Public Health in Epidemiology from Harvard School of Public Health. His first book entitled *Misunderstanding Health: Making Sense of America's Broken Health Care System* was published in October 2021 by Johns Hopkins University Press. His second book is due for release in 2025. He can be reached at:**rohit@catalytichealth.com** or you can learn more about him at **rohitkhanna.com**

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The Canadian Life Sciences Top 20 Under 40 Awards puts a spotlight on the young movers and shakers in the life sciences industry. Nominations for this award are currently open. Anyone affiliated with the life sciences industry can nominate a life sciences professional who is under the age of 40.

Go to **top20under40lifesciences.com** to nominate.

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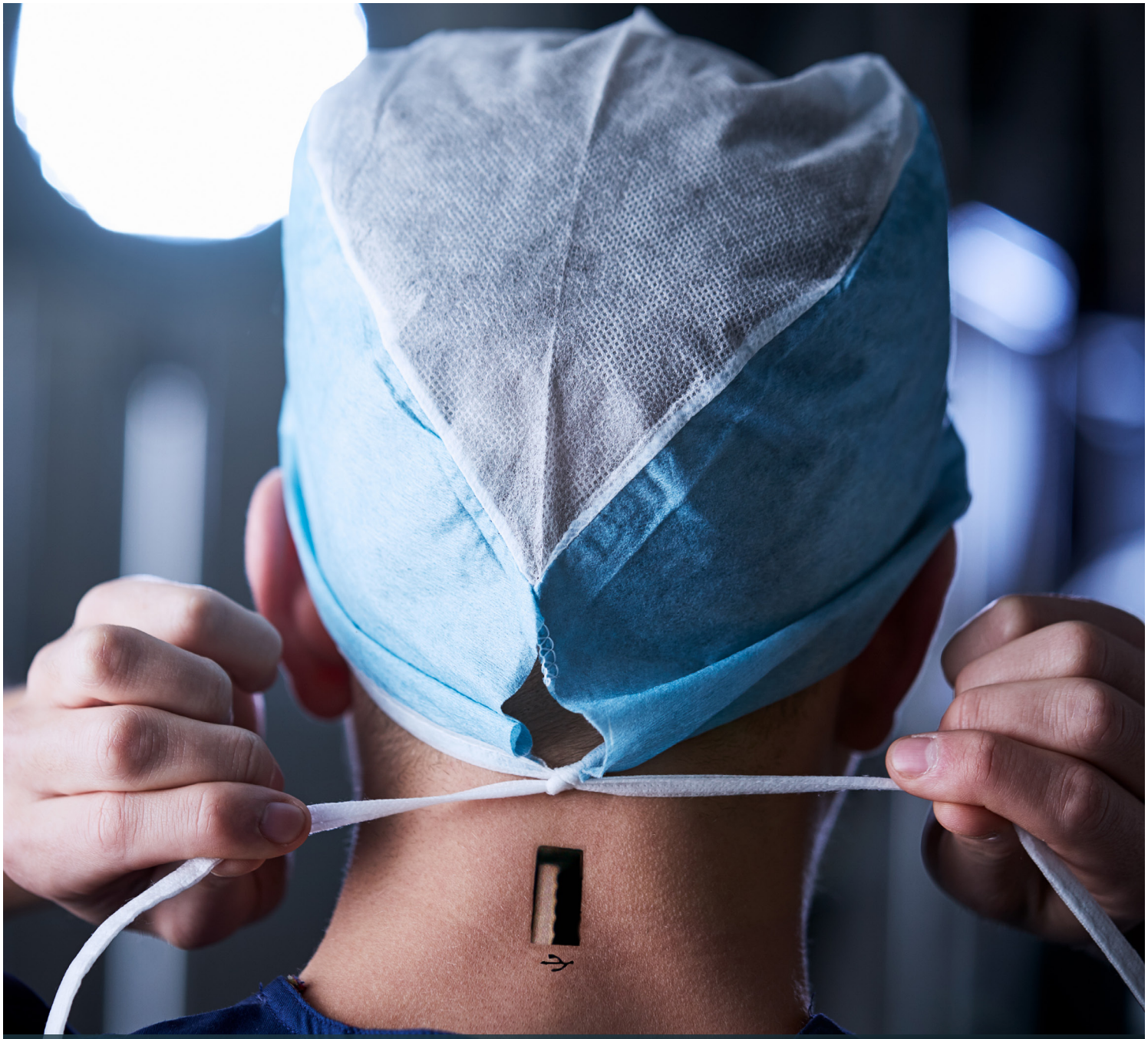

Is AI Revolutionizing Health Care, or Sitting at the Sidelines?

A Conversation with AI Guru Dr. Tom Davenport

Dr. Tom Davenport is the President's Distinguished Professor of Information Technology and Management at Babson College, cofounder of the International Institute for Analytics, and a fellow at the MIT Initiative on the Digital Economy. Dr. Davenport has written and edited 19 books and over 200 articles on big data, AI, healthcare, and business. He spoke with Hypothesis about some of the most innovative companies merging healthcare and AI, how smaller life sciences organizations can compete with analytics, his perspective on AI, and medicine's thorny ethical challenges.

The Nobel Prize for physics was just awarded a few days ago to Geoffrey Hinton, of the University of Toronto, and John Hopfield, of Princeton University, for their foundational work in machine learning. Is this overdue or premature, considering so much of the potential of artificial intelligence (AI) has not yet been realized?

There were actually two Nobel Prizes this past week for AI technologies. The people behind Google DeepMind, Demis Hassabis, John Jumper, and David Baker, were awarded the Nobel Prize for their work using machine learning to predict the 3D shape of proteins. I think these prizes are a recognition that AI is now mainstream in the sciences and also how important it is to our society. It may be a while before the Nobel Prize in literature is awarded for something generated by AI, at least I hope so.

You published a seminal review entitled Competing on Analytics in Harvard Business Review. When using analytics to drive business decisions, how should companies consider the nuances of human behaviour and the rapidly evolving social media and political landscape?

A sentiment analysis can assess whether posts on social media about a company are generally positive or negative. We can also analyze how many people are paying attention to various messages, but it's still difficult to really understand what drives consumer behaviour. Unless we can analyze neural networks, we can't understand individuals' motivations and the various factors that play into their decisions.

What are the top areas where you see AI being deployed in healthcare?

AI for drug discovery is still in the early days. Proteins and amino acids come in sequences, just like words come in sequences. Those sequences could be used for generative AI models, and many companies are trying to apply generative AI models to drug discovery. So far, however, there aren't any drugs in clinical trials that were discovered by generative AI. There are some drugs in clinical testing that came out of more predictive machine learning, however.

> ***"In imaging it seems like every day we hear about a new breakthrough in AI-based image recognition."***

In imaging, on the other hand, it seems like every day we hear about a new breakthrough in AI-based image recognition. AI can now recognize cancers and diagnose various ophthalmological diseases through retinal images, for example. Yet, if you go to a hospital or a doctor's office, it's unlikely that AI would be involved in your care at all. There are too many regulatory and financial obstacles. Insurance companies and governments have to agree to pay for the technology. Another barrier is that it can be challenging to wedge AI into the workflow of clinicians.

I hope these obstacles will be overcome soon. Already, AI that summarizes recorded conversations and produces clinical notes could free up physicians from the tyranny of the electronic health record system, at least to a degree. I recently heard that 80% of a physician's time is spent in front of an electronic health record system, which is rather tragic.

Photo courtesy of freepiks.com.

I'd also like to see AI being applied more broadly to the administrative burden in healthcare. In the US, we spend 30% or more our healthcare resources on administration. If we could use AI to lower that cost, we'd have more money for more valuable things.

Are you concerned about the errors that could result from an AI system transcribing and interpreting conversations between clinicians and patients?

Generative AI does a pretty good job of recognizing words in context, so it would be able to distinguish the word 'rash' when describing a skin rash from, "I made a rash healthcare decision", for example. Generative AI systems can also identify the differences between the patient's understanding and the physician's understanding of what may be causing their symptoms. Generative AI can even detect sarcasm and humour. If the doctor says, "How are you feeling?" And the patient says, "Well, I died last week, but I'm feeling much better now," generative AI can understand the patient's words are meant as a joke.

> ***AI that summarizes recorded conversations and produces clinical notes could free up physicians from the tyranny of the electronic health record system.***

We know that AI hallucinates. In healthcare, when the predictive model is wrong, that could cost lives. Does this concern you?

Traditional machine learning, like generative AI, made predictions. These models could assess a dataset and predict, based on a simple algorithm, how likely it would be that a person who had a certain body mass

index, age, and exercise level would get diabetes or sepsis. Generative AI tries to predict new content, so it can make a bad prediction about what word comes next in a sequence or what image should fit a prompt. That's what people call a hallucination. This is why we still need a human in the loop. We still need the doctor to say, yes, that's consistent with my understanding of the conversation with a patient. That does mean that the productivity advances from generative AI are not quite as dramatic as we might have hoped.

> ***We still need a human in the loop. We still need the doctor to say, yes, that's consistent with my understanding of the conversation with a patient.***

Do clinicians owe it to patients to tell them how AI was involved in their care?

Academics have studied situations where an AI system diagnoses cancer, and the radiologist disagrees. What generally happens in those circumstances is the radiologist usually doesn't disclose to the patient that the AI system identified cancer, because that information may unnecessarily frighten and confuse the patient. In other words, the clinician trusts their judgement more than the model. I think as AI systems are developed with so many different parameters, it will be impossible to interpret why an AI system diagnoses cancer. In the future, clinicians may need to be comfortable saying, "the AI system says you have this disease, even though I don't see it myself."

Based on your expertise, are there any particular healthcare or life sciences companies you think are really 'hitting it out of the park' on using analytics in their day-to-day operations?

There is a company in China called Ping An Good Doctor, which offers a telemedicine app used by more than 400 million people, which is mind-boggling. They've assembled doctors and pharmacists to create a whole ecosystem. In Japan, Sampo is the second largest owner of nursing homes and now they're integrating all the data, including sensor data and electronic medical record data, to determine when patients need more attention from nurses or doctors.

Photo by Cedric Fauntleroy via pexels.com.

Some of the U.S. hospital systems are also experimenting with AI. Mayo Clinic may be the furthest along. They have developed products that use AI to identify particular cardiological problems, for example.

Among the large pharmaceutical companies, the one that is all in with AI is Sanofi. They're using AI in different areas in drug development. But many pharmaceutical companies have now set up partnerships to incorporate AI much more aggressively.

The vast majority of companies can't hire teams who can lead data analytics in their business. What advice do you offer to these companies?

The whole area of data science, analytics, and AI once required rare and expensive computing resources, but now it's become much more democratized. There is an OpenAI tool called Code Interpreter, and you can say, "Analyze this dataset and predict who is going to die of diabetes." With a two-line prompt, it will give you three pages of data analysis. It will tell you what it did with missing data, how it transformed some of the variables to make them more effective, and which of those variables are most important in making the prediction. An OpenAI subscription is $20 a month, so it's not expensive. What is required is an awareness of what's out there and a willingness to experiment with it, even if you're not a data scientist.

Always my final question: if you could invite any three people, dead or alive, out to dinner who would you want at your table?

During COVID, I tried to learn more about my ancestry, and I found out the first person with the name Davenport to come to the United States since 1620 was named Lancelot Davenport. He was an indentured servant. Even though he was the son of a rich father, he was not the first son, so he had to make his own way in the world. He would be number one. I've always been impressed by Gandhi and Martin Luther King, so I'd like to include them as well. If I'm going to put an analytics and AI-oriented person in, I guess it would be Geoff Hinton. Over the years, he's become more concerned about the ethical implications of AI, and he's trying to do something about it. Plus, it would be nice to have a Nobel prize winner at your table.

Tom Davenport, Professor of Information Technology and Management at Babson College
Dr. Tom Davenport is the President's Distinguished Professor of Information Technology and Management at Babson College, the co-founder of the International Institute for Analytics, a Fellow of the MIT Initiative for the Digital Economy, and a Senior Advisor to Deloitte Analytics. He has written or edited twenty books and over 250 print or digital articles for *Harvard Business Review (HBR)*, *Sloan Management Review*, the Financial Times, and many other publications. He earned his Ph.D from Harvard University and has taught at the Harvard Business School, the University of Chicago, the Tuck School of Business, Boston University, and the University of Texas at Austin.

One of HBR's most frequently published authors, Tom has been at the forefront of the Process Innovation, Knowledge Management, and Analytics and Big Data movements. He pioneered the concept of "competing on analytics" with his 2006 *Harvard Business Review* article and his 2007 book by the same name. Since then, he has continued to provide cutting-edge insights on how companies can use analytics and big data to their advantage, and then on artificial intelligence. Tom's book, co-authored with Julia Kirby, Only Humans Need Apply: Winners and Losers in the Age of Smart Machines, offers tangible tools for individuals who need to work with cognitive technologies and in his latest book, The AI Advantage: How to Put the Artificial Intelligence Revolution to Work, he provides a guide to using artificial technologies in business. You can read a review of The AI Advantage on MIT Press.

Harvard Business Review editors highlighted his latest ideas in the 10 Must Reads 2017: The Definitive Management Ideas of the Year and again in the 2019 issue. One of his articles is also in the new 10 Must Reads on AI, Analytics, and the New Machine Age. Tom was also named one of ten "Top Voices" by LinkedIn in 2016 for Education, and in 2018 for Technology. He has also been named one of the top three business/technology analysts in the world, one of the 100 most influential people in the IT industry, and one of the world's top fifty business school professors by *Fortune* magazine.

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Why Allergies Are On the Rise, and What We Can Do About It

Dr. Susan Waserman is the Professor of Medicine and the Division Director of Clinical Immunology and Allergy at McMaster University. A prolific trialist, Dr. Waserman has published in many high-profile journals and also serves as the President of the Canadian Allergy Asthma and Immunology Foundation. She spoke to Hypothesis about the effects of climate change on allergies, the major developments in food allergy treatment in recent years, and more.

Can you start by telling us about your background?

I was born and raised in Montreal, where I did my internal medicine residency, followed by a residency in allergy and immunology. Shortly after finishing my master's degree in respiratory allergy at the Meakins-Christie Laboratories, I was presented with an opportunity to join McMaster University Children's Hospital by two of my great mentors. I moved to Ontario with my husband and four children. I've been here ever since, and I now have nine grandkids.

I'm always amazed at the spectrum of disease that an allergist and immunologist treats. What about the specialty do you think is underappreciated by the public?

The breadth of what we see in allergy and immunology is huge. Other specialties turn to us for cases that are less straightforward and don't fit into any other subspecialty. The bread-and-butter issues are rhinitis and asthma, for which we have some amazing new biologic therapies; food allergy, which is one of my personal passions; drug allergy; and hives and eczema. In terms of some of the less well-known diseases we treat, we see hereditary angioedema and other causes of angioedema that are quite rare, affecting one in 50,000 people. I also see a lot of patients who are suffering from recurrent infections and it's my job to figure out why that's happening and whether we can treat that immunodeficiency. Finally, we see a lot of patients with anaphylaxis. We're the detectives who try and figure out why people have severe allergic reactions.

"We see a lot of patients with anaphylaxis. We're the detectives who try and figure out why people have severe allergic reactions."

I love the term detective. That's so apropos to the role of the allergist. You're also the head of the new Schroeder Allergy and Immunology Research Institute, based at McMaster. Can you talk about the research you're most excited about?

The Institute is the first of its kind in Canada. We're looking at the immune mechanisms that drive allergic disease, namely by studying IgE, the antibody that causes allergies. Our hope is to identify targets that can be blocked by certain medications, especially for food allergy, for which there are not many therapeutics available. An exciting development for us, which recently got a lot of attention, is that we identified a new type of memory B-cell involved in IgE production. We believe this rare memory B-cell is responsible for the persistence of allergy, so it could be a good target for food allergy, and possibly for all allergies.

Photo by courtesy of via freepikcom.

> ***Our knowledge is evolving and we hope for a cure on the horizon.***

You've worked on allergy for decades. How close are we to finding a cure for food allergy?

There have been a lot of improvements in food allergy treatment over my career, but a cure has been elusive. For instance, we've learned that infants need to be fed allergenic foods early to avoid becoming allergic. It may sound obvious, but really this was a big pivot. When I initially started training, the messaging was that parents should avoid peanuts and avoid allergenic foods for their infants.

For those infants who do become allergic, we now have a treatment. It's called oral immunotherapy, or OIT for short, and its usage has skyrocketed in the past few years. In this approach, infants and children are fed small amounts of the food that they are allergic to, so that they become desensitized to it and they don't react to it. Some children will become tolerant to the food, especially if we start OIT early.

Another development is a biologic medication called Xolair® (omalizumab). This is a biologic that was first approved to treat asthma and hives and it has recently been approved in the U.S. to treat food allergy. (The medication is not yet approved for the treatment of food allergy in Canada.) It prevents acute allergic reactions from accidental exposure to an allergen. It's not a cure, but it's certainly progress. Our knowledge is evolving and we hope for a cure on the horizon.

Photo courtesy of freepik.com.

That's wonderful to hear. It's not easy to get donations and funding, but if I gave you a lump sum of money, with the only caveat being that it had to be directed within allergy and immunology, what would you do with that lump sum?

We would love to have the resources to support a clinical challenge unit, to perform food challenges and test new therapies on large numbers of people with allergies. Right now, we don't have the infrastructure for that, as space and trained personnel are at a premium. As it stands now, in most cases, the only way to test for many food allergies is through an oral challenge, essentially exposing patients to the allergen, to test them. Ideally, in the future, we could develop better diagnostics. I'd like to be able to do genetic testing on many patients with allergies, to see if we could identify certain mutations that could be used in a diagnostic test in the future.

I'd like to talk about the impact of a recent announcement from the Ontario government that international students will be barred from Canadian medical schools starting in 2026. As a leader in medical education, what do you predict will be the impact of this decision?

Our job is to look after our local community and national community, but we also have an obligation, as one of the best countries in the world in which to practice medicine, to educate people from around the world. That's been a very rewarding part of what I do. The other consideration is that international residents pay a high tuition, which fuels a lot of exciting activity at the university. I hope this policy doesn't become permanent.

While we're talking on policy, can you talk about the association between climate change and allergic disease?

As allergists, we're becoming more aware about the effects of climate change. The pollen season is starting earlier. The pollen counts are frequently higher. The season may last longer. Plants that would never find our part of the world hospitable will start to grow here because of warming temperatures, and these are pollen-emitting plants as well.

Because of the higher exposure, we're already seeing higher rates of environmental allergies in children all the way up to geriatric patients. What can we do about it? We need to increase awareness, improve

treatment and diagnostics, and expand access to specialists, but we also know that there will not be an overnight fix to this problem. While it's noble to want to move to only having electric cars, or ending the use of fossil fuels, we must also roll these changes out in a way that mitigates negative impacts to the economy and to individuals.

We're trying to do our part at the hospital. We've eliminated paper and we're trying to move away from plastic products as much as possible.

Let's move on to another global trend influencing health care. Where do you see artificial intelligence playing a role in allergy and immunology?

There's tremendous potential in clinical medicine, but we're not yet there. Many clinicians are not yet comfortable with using artificial intelligence in their own practice. Others, like myself, are enthusiastic, but we're somewhat limited in how much we can incorporate AI into our day-to-day clinical practice. In the hospital, new technologies aren't integrated quickly into our electronic health records, in part due to understandably stringent rules around privacy and security.

Nonetheless, in the short term, AI is going to be extremely useful in patient communications, by improving language or fixing errors in dictated letters, for instance. Clinicians can also prompt AI tools to include information relevant to a patient's diagnosis or test results. AI is also going to be very important in interpreting spirometry tests. In fact, in some studies, artificial intelligence performs better than the respirologist. I think AI could also help differentiate between asthma versus chronic obstructive pulmonary disease (COPD) or between atopic dermatitis versus another rash, based on data from the electronic health record. We still don't know the extent of the medical-legal implications, however, including whether there will be more or less medical errors with AI in the near term.

My final question, what book is on your nightstand?

On the advice of my daughter, who is a psychiatrist, I'm reading a book called *The Anxious Generation* by Jonathan Haidt. The book speaks about the effects of social media and excessive screen time on children and youth. It's very sobering to learn about the growing prevalence of anxiety, depression, and self-harm. It is a strong rallying cry to protect and return to healthy socialization and it's extremely well written.

Susan Waserman, MD
Dr. Susan Waserman is a Professor of Medicine, Director of the Division of Clinical Immunology and Allergy at McMaster University and the Adverse Reactions Clinic at the Firestone Institute of Respiratory Health, St Joseph's Healthcare.

Dr. Waserman is extensively involved in medical education in both academic and community settings, in addition to an active hospital-based clinical practice in adult and pediatric allergy and clinical immunology. Her research interests are focused on mechanisms of peanut allergy and its treatment.

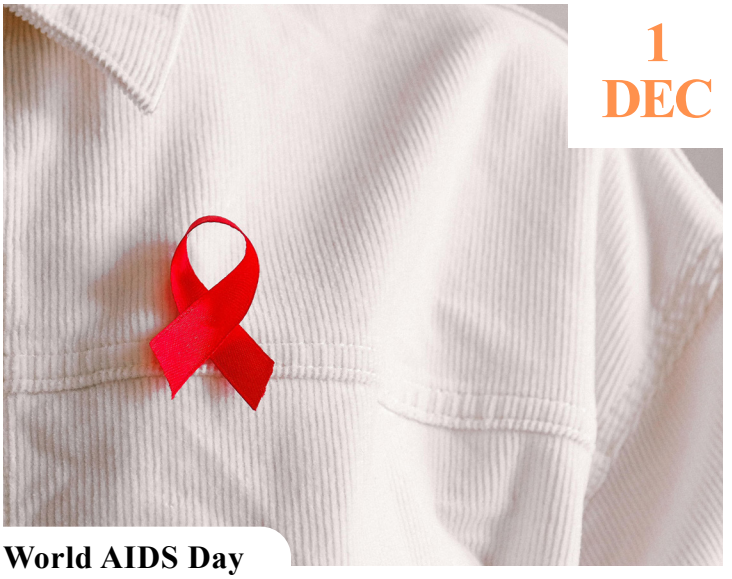
She is President of the Canadian Allergy, Asthma and Immunology Foundation and past President of the Canadian and Ontario Societies of Allergy and Clinical Immunology.

DECEMBER 2024

World AIDS Day – December 1*
Women's Brain Health Day – December 2*
International Day of Persons With Disabilities – December 3*

JANUARY 2025

Alzheimer's Awareness Month
Firefighter Cancer Awareness Month



1 DEC

World AIDS Day

December 1st, is World AIDS Day, a global movement to fight HIV/AIDS and support those living with the disease.
Photo by Anna Shvets via pexels.com.

FEBRUARY 2025

AMD Awareness Month
World Cancer Day – February 4*
Congenital Heart Disease Awareness Week – February 7 to 14*
International Childhood Cancer Day – February 15*
Mental Health Nurses Day – February 21
Rare Disease Day – February 28

JAN

Alzheimer's Awareness Month

During the month of January, Canadians are encouraged to take the time to learn about the impacts of dementia and fight the stigma associated with Alzheimer's.
Photo by Kampus Production via pexels.com.

4 FEB

World Cancer Day

Held on February 4th, World Cancer Day is an international movement to raise awareness about the worldwide epidemic of cancer, and how we can help encourage its prevention.
Photo from freepik.com.

Source: www.canada.ca/en/health-canada/services/calendar-health-promotion-days.html
Events marked with an asterisk (*) take place on the same day every year.

MARCH 2025

MAR

Multiple Myeloma Awareness Month

March is Multiple Myeloma Awarness Month, a time to inform people of the signs of myeloma and how to detect it early on.
Photo by Karolina Grabowska via pexels.com.

Brain Health Awareness Month
Colorectal Cancer Awareness Month
Epilepsy Awareness Month
Liver Health Month
Multiple Myeloma Awareness Month
Pharmacy Appreciation Month (PAM)
Kidney Health Month – March 1 to 31
World Obesity Day – March 4
World Lymphedema Day – March 6*
International Women's Day – March 8*
World Glaucoma Week – March 10 to 16
Brain Awareness Week – March 11 to 17
World Down Syndrome Day – March 21*
World Tuberculosis Day – March 24*

APRIL 2025

APR

IBS Awareness Month

IBS Awarness Month takes place in April. Special attention is given to spreading awareness for those living with irritable bowel syndrome, what the symptoms are, and what resources are out there.
Photo from freepik.com.

IBS Awareness Month
Parkinson Awareness Month
Rosacea Awareness Month
World Autism Awareness Day – April 2*
World Health Day – April 7*

Source: www.canada.ca/en/health-canada/services/calendar-health-promotion-days.html
Events marked with an asterisk (*) take place on the same day every year.

Spotlight Article

Prevalence and Nature of Manufacturer-sponsored Patient Support Programs for Prescription Drugs in Canada: A Cross-sectional Study

Quinn Grundy: PhD, RN, Ashton Quanbury: BScN, Dana Hart: MA, Shanzeh Chaudhry: BSc, Farideh Tavangar: MA, Joel Lexchin: MS, MD, Marc-André Gagnon: PhD, Mina Tadrous: PharmD, PhD

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Background: Globally, pharmaceutical companies offer patient support programs in tandem with their products, which aim to enhance medication adherence and patient experience through education, training, support and financial assistance. We sought to identify the proportion and characteristics of such patient support programs in Canada and to describe the nature of supports provided.

Methods: We conducted a cross-sectional study to identify and characterize all marketed prescription drugs available in Canada as of Aug. 23, 2022, using the Health Canada Drug Product and CompuScript databases. To describe the nature of supports provided, we conducted a content analysis of publicly available patient support program websites and Web-based documents. Using logistic regression, we identified characteristics of drugs associated with having a patient support program including brand-name or branded generic (generic medications with a proprietary name), orphan (medications for rare diseases) or biologic drug status; estimated total cost of prescriptions dispensed at retail pharmacies; and price per unit.

Results: Of the 2556 prescription drugs marketed by 89 companies in the study period, 256 (10.0%) had a patient support program in Canada. Many of the 89 drug manufacturers (n = 55, 61.8%) offered at least 1 patient support program, frequently relying on third-party administrators for delivery. Brand-name and branded generic medications, biologic agents and drugs with orphan status were more likely to have a patient support program than generic drugs. Compared with drugs priced $1.01–$10.00 per unit, drugs priced $10.01–$100.00 per unit were nearly 8 times more likely to have a patient support program (adjusted odds ratio 7.54, 95% confidence interval 4.07–14.64). Most sampled patient support programs included reimbursement navigation (n = 231, 90.2%) and clinical case management (n = 223, 87.1%).

Interpretation: About 1 in 10 drugs marketed in Canada has a manufacturer sponsored patient support program, but these are concentrated around brand-name, branded generic, biologic and high-cost drugs, often for rare diseases. To understand the impact of patient support programs on health outcomes and sustainable access to cost-effective medicines, greater transparency and independent evaluation of patient support programs is necessary.

"If you're playing in the specialty medicines field," argued a pharmaceutical industry consulting firm, "a patient support program is the price of admission."[1] Pharmaceutical company–sponsored patient support programs, designed to lessen financial and clinical barriers for patients and prescribers to starting and sustaining treatment, exist in high- and middle-income countries globally.[2-7] Once prescribed the treatment, patients are referred to the program by their health care provider or they may self-enroll. They are then contacted by a program coordinator, typically a registered nurse who may help the patient navigate insurance coverage options, coordinate home drug delivery, teach self-injection techniques, answer questions on an on-call basis and conduct follow-up to support patient treatment adherence.[8–10] Neither patients nor insurers pay for these services; thus, the cost of the medicine likely includes these supports.

In an era where policy-makers are grappling with escalating drug prices and budgetary impacts globally,[11] the pharmaceutical industry promotes patient support programs as adding complementary value to a drug through supporting medication adherence and enhancing clinical outcomes, patient experience or quality of life.[3] Industry stakeholders have also identified patient support programs as a valuable opportunity to collect patient-level data as a means to evaluate clinical, quality-of-life and economic outcomes, and, thereby, define a drug's value to payers more clearly.[12]

Because patient support programs are proprietary, understanding of these programs and their outcomes relies on studies funded and conducted by the drug's manufacturer using proprietary patient data collected through the patient support program. These studies are typically focused on the evaluation of patient-reported outcomes (e.g., adherence, persistence) and economic impacts (e.g., health resource use), and usually report positive outcomes,[3,13,14] as seen in a longitudinal study of patients in Canada prescribed adalimumab and enrolled in the manufacturer's patient support program, AbbVie Care.[15,16]

Other details about the types of supports offered by patient support programs have emerged from litigation. In 2020, AbbVie settled a California suit in which the state alleged that the patient care and insurance authorization assistance provided by the nurses of the patient support program constituted a kickback because it provided "free and valuable professional goods and services to physicians," contingent upon prescription of the drug.[17,18]

Overall, industry-sponsored patient support programs and the extent or nature of the services provided are not well understood,[17] making it difficult to assess their value to patients or their impact within health systems. Canada offers a useful case study to conduct a national survey of industry-sponsored patient support programs. Patient support programs began to appear in Canada when biologics first came on the market in the early 2000s.[9] Funded by drug manufacturers, patient support programs are typically administered by third-party service providers.[19]

Canada has among the highest drug prices and per-capita spending on biologics among Organization for Economic Cooperation and Development (OECD) countries and, for many products, lower uptake of biosimilar medicines, which are cost-effective alternatives to biologics.[20,21] The extent to which patient support programs are offered for biologics and nonbiologics, or for biosimilar or generic drugs is unknown. We sought to identify the proportion and characteristics of marketed prescription drugs available in Canada that had accompanying manufacturersponsored patient support programs and the prevalence and nature of supports provided.

Methods

Study design

We conducted a cross-sectional study to quantify the proportion of prescription drugs with a patient support program on the Canadian market as of Aug. 23, 2022, and describe their characteristics. We defined a patient support program as services (including but not limited to financial assistance) offered to patients prescribed a specific drug that were started and funded by the manufacturer.[3,4] We then conducted a structured content analysis of Web-based sources to understand the types and range of supports provided to patients through these programs.

We chose to rely exclusively on publicly available data sources to identify and describe

manufacturer-sponsored patient support programs as these are sources currently available to patients when making program enrolment decisions and to policy-makers seeking to understand the extent and impact of this model of care.

We report the study according to the Strengthening the Reporting of Observational studies in Epidemiology checklist.[22]

Setting

Specialty medicines are characterized as highly complex and high cost, and have complicated handling, storage, administration and monitoring regimens that often require the involvement of nurses and pharmacists.[23] Many are manufactured in laboratory-grown cells and are known as biologics.[24] Typically priced at more than $10 000 for a 1-year course of treatment, specialty medicines (biologics in particular) account for an increasing share of public and private drug spending.[20]

Sampling frame

Because the European Medicines Association defines a patient support program as services for a specific drug offered by the company holding the marketing authorization,[3] we first sought to identify all drug companies with currently marketed prescription products in Canada. Between June 27, 2022, and Aug. 23, 2022, 2 authors (A.Q. and D.H.) independently extracted the names of all member companies listed on the websites of the 3 main trade associations for the Canadian pharmaceutical industry, namely Innovative Medicines Canada, representing the research-based pharmaceutical industry (typically including manufacturers of brand-name medications);[25] BIOTECanada, representing the biotechnology industry;[26] and the Canadian Generic Pharmaceutical Association, representing generic drug manufacturers.[27] Because trade association membership is voluntary, we supplemented this list with nonmember drug manufacturers identified in previous research by an author (J.L.)[28]

Using the Health Canada Drug Product Database,[29] 2 authors (A.Q. and D.H.) independently screened the list of companies and included those with marketed prescription products. We excluded companies that were not drug manufacturers (e.g., law firms) and those without marketed prescription drugs (e.g., products under development) at the time of the study. Screeners resolved discrepancies through discussion or adjudication by a third author (Q.G.).

Sample and variables

Using the Health Canada Drug Product Database,[29] 1 investigator (A.Q. or D.H.) searched each identified drug manufacturer and extracted the product and active ingredient names for all marketed prescription drugs. We counted a single drug as all dosages, formulations or routes of administration with the same active ingredients and manufacturer since industry patient support programs are brand-specific and do not typically differentiate among these factors.

We selected and extracted variables that reflected known characteristics of drugs and that may be associated with having a patient support program,[3,19] including brand status, biologic status, orphan drug status (i.e., whether the drugs are for rare diseases), route of administration, therapeutic indication, estimated total cost of and number of prescriptions dispensed at retail pharmacies (a measure of market share) and price per unit.

On the basis of the type of Health Canada regulatory review,[30] clinical expertise and knowledge about the manufacturer, 2 authors (Q.G. and M.T.) independently identified the brand status of each drug as brand-name (i.e., innovator products first to market), branded generic (i.e., subsequent entry products that contain identical medicinal ingredients or are highly similar to an existing product on the market, but given a proprietary name by the manufacturer) or generic (i.e., subsequent entry products that contain identical medicinal ingredients to an existing product on the market, but not given a proprietary name by the generic manufacturer). We classified biosimilars, which are biologic drugs that are highly similar to an existing product on the market,[31] as branded generic drugs. We resolved discrepancies through discussion or adjudication by a third author (J.L.), as required.

Using the Health Canada Drug Product Database and the drug's product monograph,[32] 1 investigator (A.Q. or D.H.) extracted verbatim routes of administration, the Level 1 Anatomic Therapeutic Chemical (ATC) code and whether the drug is a biologic and thus listed as Schedule D of the *Food and Drug Act*,[33] meaning the drug comes from

living organisms or from their cells. The investigator also identified whether the drug had orphan drug status, meaning the drug was indicated for a life-threatening, seriously debilitating or serious and chronic condition affecting a fairly small number of patients and, depending on the jurisdiction, may be subject to an adapted regulatory pathway, or eligible for tax incentives or additional market exclusivity.[34,35] Although Health Canada has reported approvals of orphan drugs since 2017, we used the searchable United States Food and Drug Administration Orphan Drug Designation database, which includes approvals since 1983, to identify these drugs.[36]

Using national dispensing data from IQVIA's Canadian CompuScript database, 1 investigator (A.Q., D.H. or S.C.) extracted each drug's estimated total cost and number of prescriptions dispensed at retail pharmacies in Canada for the year 2021. The estimated total cost of prescriptions reflects the sum of all estimated costs of the prescriptions dispensed by community pharmacists, including pharmacy mark-up and dispensing fees. The total number of units sold represents the number of standardized units based on the most common purchasing formats (e.g., tablets, capsules, mL) for total prescriptions dispensed. We calculated the price per unit for each drug by dividing the estimated total cost of prescriptions for all formulations of the drug by the estimated total number of prescription units for all formulations of the drug dispensed in 2021.

The CompuScript database includes only drugs dispensed through retail pharmacies (i.e., does not include drugs administered in hospital), and manufacturers can opt out of data collection. However, the CompuScript database does not provide specific reasons why data are missing. If we could not identify the estimated total cost and number of prescriptions for a sampled drug in the database, 2 investigators with clinical knowledge (Q.G. and M.T.) independently judged likely reasons (e.g., low prescription counts, recent market entry) that price per unit data were missing from the CompuScript data to provide readers additional context.

Identifying Patient Support Programs and Their Characteristics

We identified whether a drug in our sample had an associated manufacturer-sponsored patient support program for patients in Canada. Based on recent systematic and comparative reviews of patient support programs in North America and Europe,[3,4] and an exploratory, empirical study in Australia,[5] we defined a patient support program as any combination of services or resources related to medication access, administration, adherence, education, storage or disposal for patients prescribed a specific product and started and sponsored or operated by the company holding the product's marketing authorization.

We distinguished patient support programs from patient assistance programs, choosing to exclude patient assistance programs because they exclusively provide financial assistance (e.g., coupons, co-pay coverage) and no other categories of supports, and are considered a distinct pharmaceutical company activity.[3,4,37] We also excluded expanded access or compassionate access programs, risk management programs outlined in the product monograph (required by the regulator rather than started by the manufacturer) and programs delivered solely for a clinical study.

Building on effective methods for sampling industry Internet documents,[38,39] 2 authors (A.Q. and D.H.) independently performed structured searches on Google ("[company name] AND patient support program AND Canada" and "[drug brand name] AND patient support program AND Canada") to identify industrysponsored patient support programs in Canada, resolving discrepancies through discussion, with a third author (Q.G.) adjudicating any outstanding discrepancies.

Using Zotero, a reference management software, 2 authors (A.Q. and D.H.) independently downloaded and catalogued public-facing web pages and documents (e.g., web pages for the program, patient portals and apps, educational materials, press releases, enrolment forms) that explicitly mentioned the patient support program, the sponsoring company and the specific drug, and were intended specifically for a

Canadian audience. The authors met to reconcile any discrepancies, with another (Q.G.) adjudicating as necessary. We excluded web pages directed exclusively at health professionals.

Using REDCap,[40] we created a data extraction form based on the existing empirical research describing patient support programs (**Appendix 1**, available here).[3-5] We extracted characteristics of the sampled patient support programs, including target population (adult, pediatric or both), evidence of third-party administration, the nature of supports offered (including financial assistance, reimbursement navigation, injection training, infusion coordination, education, clinical case management, pharmacy services and material resources) and other relevant details (e.g., modalities, availability and access, clinician involvement). Because the definition of a patient support program continues to evolve within the literature and no expert recommendations or jurisdictional regulations are available to guide the development, components or administration of patient support programs,[3] we included the option to select and specify other types of supports to ensure comprehensiveness. Coders were prompted to extract, verbatim, illustrative evidence for the presence of a particular type of support.

Two authors (A.Q. and D.H.) independently piloted the data extraction form on a random sample of 10% of the patient support programs. Through discussion (Q.G., A.Q., D.H.), we resolved all discrepancies and refined the data extraction form to ensure consistency. The remainder of the sample was coded by a single author. Because we did not validate these data with drug manufacturers directly, we coded variables dichotomously as either having evidence of the existence of particular supports or no information.

Data Analysis

We conducted a descriptive analysis on the full sample of marketed prescription drugs, generating crude descriptive statistics using frequencies and percentages for categorical characteristics. Based on the distribution of the data, 2 authors (Q.G. and M.T.) categorized variables, merging categories with very small sample sizes, including merging Level 1 ATC codes into 7 categories, grouping them by broad physiologic system or clinical area into other (sensory organs, various, dermatologicals, and musculoskeletal system); antiparasitics and anti-infectives; genitourinary and hormones; nervous system; cardiovascular, blood and respiratory; alimentary tract and metabolism; and antineoplastic and immunomodulating agents. We also grouped medications by route of administration into 3 categories (oral, injection and other), coding drugs with multiple formulations according to the most common route of administration. If more than 1 route was commonly used, we coded for the most complex route, defining this as the route of administration requiring the greatest clinical support (e.g., intravenous, subcutaneous).

Based on the data distributions, we also categorized estimated total cost (i.e., a measure of market share) of prescriptions dispensed at a retail pharmacy and price per unit into 4 categories (e.g., price per unit <$1, $1.01–$10.00, $10.01–$100.00, ≥ $100.01). These costs were calculated for calendar year 2021.

We conducted logistic regression analyses to assess the relationship between having a patient support program and a drug's characteristics. Because the CompuScript database includes only drugs dispensed through retail pharmacies and manufacturers can opt out of data collection, some drugs had missing data for estimated total cost of prescriptions and price per unit; we excluded these drugs from the regression analyses. We conducted univariable logistic regression analyses to assess the relationship between having a patient support program and a drug's characteristics, including brand, biologic or orphan drug status, ATC classification (Level 1), route of administration, estimated total cost of prescriptions dispensed at retail pharmacies and price per unit. We also conducted a multivariable logistic regression analysis to assess how the presence of these drug characteristics reflected the existence of a patient support program. We assessed multicollinearity among predictor variables in the multivariable regression using the variance inflation factor, whereby values that exceed 5 or 10 indicate a problematic amount of collinearity.[41] Because generic drugs are more numerous and more likely to be lower cost, we conducted 2 sensitivity analyses replicating the univariable and multivariable logistic regression models for only brand-name drugs, and then only brand-name and branded generic drugs. In all logistic regression models, we reported the odds ratio (OR) with profile or likelihood-based 95% confidence intervals (CIs).

We conducted a directed content analysis to describe the prevalence and nature of supports offered through identified patient support programs.[42] Based on the

literature describing patient support programs[3-5] and the extracted data, we (Q.G., A.Q., D.H., J.L., M.T.) deductively derived 6 broad categories of support (i.e., financial, clinical, educational, pharmacy, material or not specified). The team, through discussion and review of extracted data, inductively derived subcategories or types of support within each broad category. Two investigators (D.H., A.Q. or Q.G.) then independently reviewed the extracted data and source materials for each program to dichotomously code for evidence of each category of support or whether the program had no specified supports. Investigators resolved discrepancies through discussion or adjudication by a third author (D.H., A.Q. or Q.G.). We calculated the prevalence for each category and subcategory of supports, and selected verbatim examples from the coded programs to qualitatively illustrate the nature and range of supports.

Ethics Approval

This study did not include human participants or their data and thus was exempt from ethics review as per the University of Toronto Health Sciences Research Ethics Board.

Results

We identified 2556 prescription drugs marketed by 89 companies, including all prescription drugs administered in hospital and outpatient locations. We identified evidence of an accompanying patient support program for 256 (10.0%) marketed prescription drugs; 55 (61.7%) of the 89 companies offered a patient support program (**Figure 1**). Nearly all of the 263 data sources describing patient support programs were created and disseminated by the sponsoring manufacturer (*n* = 249, 94.7%), such as dedicated websites, press releases, enrolment forms and brochures. Patient associations or hospitals authored and published the materials identifying and describing the other 14 (5.3%) patient support programs.

Characteristics of all 2556 marketed prescription drugs, with and without patient support programs, are outlined in **Table 1**. Most drugs were generic (*n* = 1535, 60.1%) and administered orally (*n* = 1647, 64.4%). A relatively small proportion of marketed prescription drugs were biologics (*n* = 251, 9.8%), had orphan drug status (*n* = 275, 10.7%) or were a biologic with orphan drug status (*n* = 102, 3.9%).

More than half of the 256 drugs with a patient support program were biologics (*n* = 138, 53.9%) or had orphan drug status (*n* = 118, 46.1%); one-quarter had both designations (*n* = 67, 26.2%). Most drugs with associated patient support programs had original market dates after 2012 (*n* = 183, 71.5%), with 104 (40.6%) marketed after 2018. Most drugs with a patient support program were indicated for adult populations only (*n* = 168, 65.6%).

Data on estimated total cost of prescriptions were available for 2214 drugs dispensed through retail pharmacies, including 210 (82.0%) of 256 drugs with a patient support program and 2004 (87.1%) of 2300 drugs without a program. Among drugs with missing data were those dispensed only in hospital (*n* = 126), blood products (*n* = 52), drugs with very low prescription counts (*n* = 45) and those with recent market entry, after 2021 (*n* = 9).

Of the 2214 drugs dispensed through retail pharmacies, most (*n* = 1632, 73.7%) cost $10.00 per unit or less. Drugs with a patient support program had a median price per unit of $208.4 (interquartile range [IQR] $38.1–$716.3) versus $1.47 (IQR $0.58–$6.51) for drugs without programs. **Figure 2** shows the distribution of patient support programs for high-cost drugs (≥$100.01 per unit, *n* = 222).

The 256 drugs with patient support programs represented 234 unique combinations of active ingredients. For 22 of the active ingredient combinations, 72 patient support programs were offered by different manufacturers for the same therapeutic indications, including adalimumab (*n* = 7), fingolimod hydrochloride (*n* = 6), rituximab (*n* = 5), dimethyl fumarate (*n* = 5), infliximab (*n* = 4) and teriflunomide (*n* = 4) (**Appendix 2**, available here).

Table 2 presents the results of univariable and multivariable logistic regression models, predicting the likelihood of drugs dispensed through retail pharmacies having a patient support program. The univariable and multivariable regression models included 2210 drugs dispensed through retail pharmacies with complete data for all drug characteristics, excluding 4 outlier drugs with prices per unit greater than $14 000. Like the univariable analysis, the multivariable logistic regression showed that brand-name, biologic and orphan drugs, and those with higher prices per unit, were more likely to have associated patient support programs. In our multivariable regression model, all

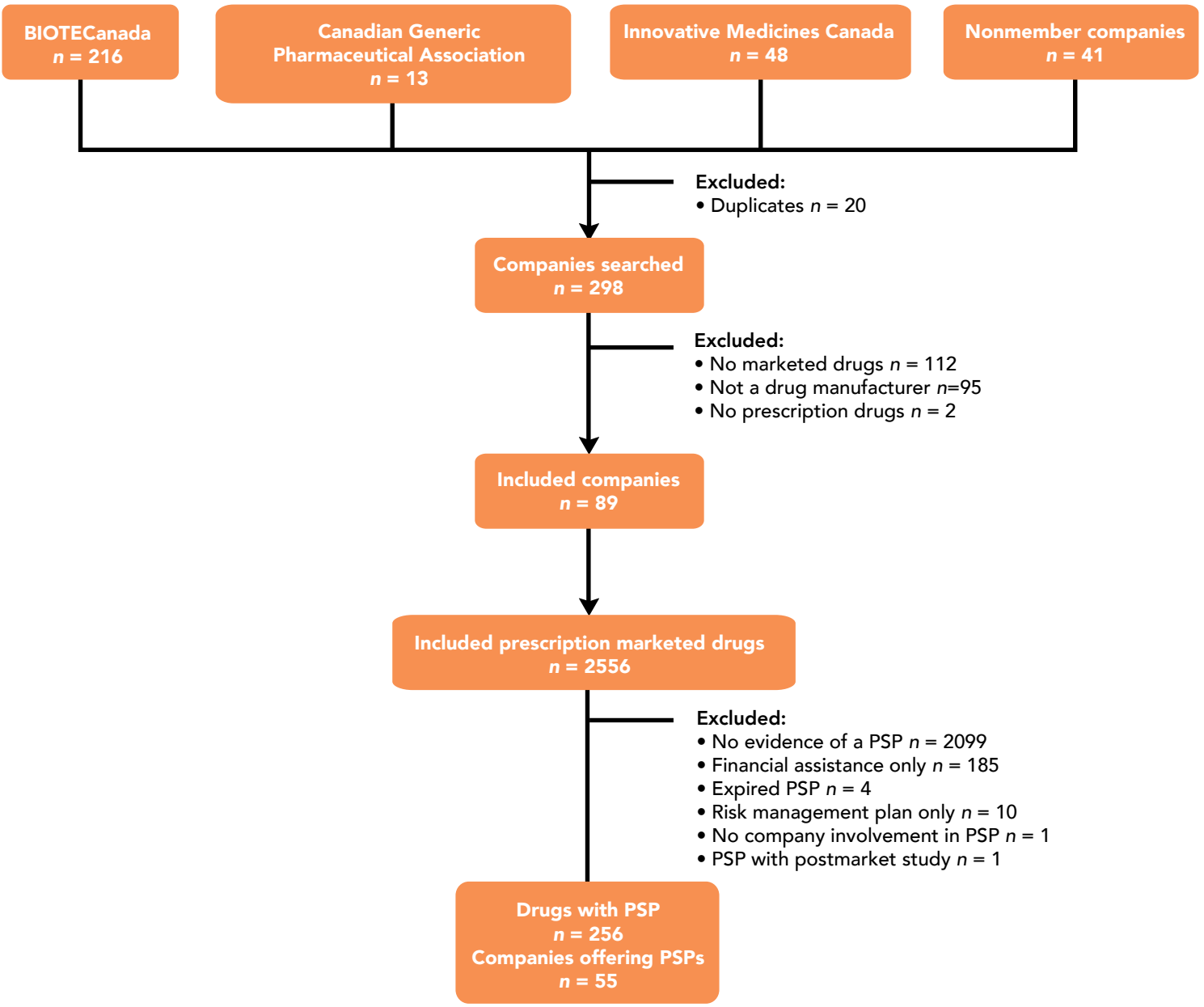

Figure 1: *Flow diagram for identifying patient support programs (PSPs).*

variance inflation factors were less than 1.5, suggesting no evidence of collinearity.

Compared with drugs priced $1.01–$10.00 per unit, drugs priced $10.01–$100.00 were 8 times more likely (adjusted OR 7.54, 95% CI 4.07–14.64) to have a patient support program; drugs costing $100.01 or greater per unit were 11 times more likely (adjusted OR 10.58, 95% CI 5.10–22.72) to have a patient support program. Sensitivity analyses excluding generic drugs were consistent with our main results (**Appendix 3**, available here).

Characteristic	Total n = 2556	No. (%) of drugs* With PSP n = 256	Without PSP n = 2300
Brand Status			
Generic	1535 (60.1)	25 (9.8)	1510 (65.6)
Branded generic	98 (3.8)	32 (12.5)	66 (2.9)
Brand	923 (36.1)	199 (77.7)	724 (31.5)
Biologic			
No	2305 (90.2)	118 (46.1)	2187 (95.1)
Yes	251 (9.8)	138 (53.9)	113 (4.9)
Orphan Drug			
No	2282 (89.3)	138 (53.9)	2144 (93.2)
Yes	274 (10.7)	118 (46.1)	156 (6.8)
Level 1 ATC†			
Other *(including sensory organs, various, dermatologicals and musculoskeletal system)*	342 (13.4)	14 (5.5)	328 (14.3)
Antiparasitics and anti-infectives	350 (13.7)	12 (4.7)	338 (14.7)
Genitourinary and hormones	222 (8.7)	21 (8.2)	201 (8.7)
Nervous system	465 (18.2)	12 (4.7)	453 (19.7)
Cardiovascular, blood and respiratory	532 (20.8)	32 (12.5)	500 (21.7)
Alimentary tract and metabolism	220 (8.6)	25 (9.8)	195 (8.5)
Antineoplastic and immunomodulating agents	425 (16.6)	140 (54.7)	285 (12.4)
Route of Administration‡			
Oral	1647 (64.4)	92 (35.9)	1555 (67.6)
Injection	632 (24.7)	160 (62.5)	472 (20.5)
Other	277 (10.8)	4 (1.6)	273 (11.9)
Price Per Unit, $§			
Low *(≤1.0)*	827 (37.3)	1 (0.5)	826 (41.2)
Medium–low *(1.01–10.0)*	805 (36.4)	16 (7.6)	789 (39.4)
Medium–high *(10.01–100.0)*	360 (16.3)	69 (32.9)	291 (14.5)
High *(>100)*	222 (10.0)	124 (59.0)	98 (4.9)
Estimated Total Cost of Prescriptions Dispensed at a Retail Pharmacy,$§			
Low *(≤1 000 000)*	744 (33.6)	48 (22.9)	696 (34.7)
Medium–low *(1 000 001–5 000 000)*	714 (32.3)	41 (19.5)	673 (33.6)
Medium–high *(5 000 001–10 000 000)*	297 (13.4)	25 (11.9)	272 (13.6)
High *(>10 000 000)*	459 (20.7)	96 (45.7)	363 (18.1)

Table 1: *Characteristics of drugs with and without patient support programs (PSPs)*

**Column percentage.*

†Level 1 ATC codes are grouped into 7 categories to ensure sufficient cell sizes.

‡Route of administration was coded as oral (oral, buccal, sublingual, dental), injection (subcutaneous, intramuscular intravenous, intravenous, intra-arterial, intracerebroventricular, intracavernosal, intraintestinal, intracervical, intrasynovial, epidural, intrathecal) and other (inhaled routes [inhalation, intranasal, instillation, intratracheal], droppers [otic, ophthalmic], dermal [transdermal, topical], vaginal, intrauterine, urethral and rectal).

§Data on estimated total cost of prescriptions dispensed and price per unit (in 2021) were available for 2214 drugs dispensed through retail pharmacies, including 210 with a PSP and 2004 without a PSP.

Abbreviations: ATC: *Anatomic Therapeutic Chemical code.*

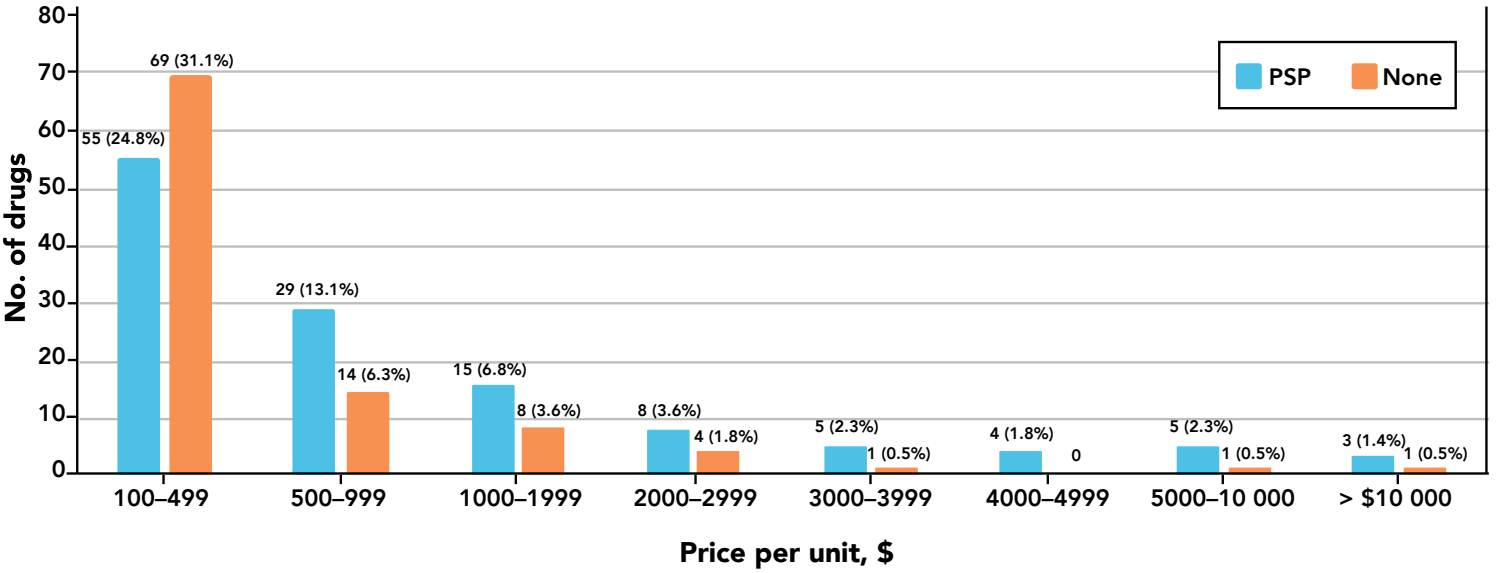

Figure 2: *Number and proportion of patient support programs (PSPs) by cost for high-cost drugs (n = 222).*

Characteristics of Drug Manufacturers and Third-party Administrators

The 256 patient support programs were funded or delivered by 55 (61.7%) of the 89 companies. Of those offering patient support programs, most were members of the brand-name drug manufacturers or biotechnology trade associations or both (*n* = 38, 69.1%). For half (*n* = 128, 50.0%) of the 256 patient support programs, we found evidence that manufacturers contracted a third-party to administer or deliver the patient support program (**Table 3**). Two companies, Innomar Strategies and McKesson Canada, accounted for more than 40% of third-party delivery (*n* = 54, 42.2%).

Characteristics of Patient Support Programs

Table 4 outlines the type and prevalence of supports offered by patient support programs. Most sampled patient support programs included financial assistance or reimbursement navigation (*n* = 231, 90.2%), or clinical case management provided by a nurse (*n* = 223, 87.1%).

Interpretation

We identified and studied 256 industry patient support programs, which accompanied about 10% of marketed prescription drugs. Most sampled pharmaceutical companies (61.7%) offered patient support programs for their marketed drugs, including members of the research-based, biotechnology and generics industries. Patient support programs were concentrated among brand-name, branded generic, biologic and high-cost drugs, often for rare diseases.

Our finding that 10% of marketed prescription drugs had an accompanying manufacturer-sponsored patient support program is likely an underestimate, given our reliance on materials available to the public and patients; for example, we may have missed patient support programs for drugs that are highly specialized and used in rare instances, and thus may not be publicly advertised. A 2023 report published by 20Sense, a specialty medicines consulting company in Canada, estimated that 400 patient support programs were available in Canada, citing unpublished research;[19] however, they did not explicitly define what constituted a patient support program.

Recent reviews — including a systematic review of 20 studies of 8 industry patient support programs in Europe[3] and a scoping review of 70 studies of 56 patient support programs offered by industry, government and health care organizations globally[52] —have synthesized findings on the types of supports offered within programs. However, these reviews examined only patient support programs described within the peer-reviewed literature. Although previous reviews documented heterogeneity among patient support programs,[3,52,53] our study found that patient support programs typically included financial supports (including reimbursement navigation) and nursing care in the form of case management, health teaching and counselling—although the degree and intensity of service provision is an important question

Characteristic	Univariable OR (95% CI)	Multivariable* adjusted OR (95% CI)
Brand status		
Generic	1.00	1.00
Branded generic	31.32 (16.57–60.14)	5.26 (1.87–1.49)
Brand	18.16 (11.58–30.06)	2.45 (1.33–4.61)
Biologic		
Yes	41.22 (27.88–61.80)	6.23 (3.11–12.81)
Orphan drug		
Yes	14.69 (10.43–20.74)	1.68 (1.02–2.76)
Level 1 ATC†		
Other *(including sensory organs, various, dermatologicals and musculoskeletal system)*	1.00	1.00
Antiparasitics and anti-infectives	0.85 (0.34–2.09)	0.56 (0.18–1.73)
Genitourinary and hormones	2.72 (1.29–6.04)	1.20 (0.44–3.40)
Nervous system	0.65 (0.27–1.55)	1.00 (0.32–3.10)
Cardiovascular, blood and respiratory	1.23 (0.58–2.70)	1.26 (0.45–3.60)
Alimentary tract and metabolism	3.04 (1.45–6.72)	1.19 (0.42–3.46)
Antineoplastic and immunomodulating agents	17.72 (9.71–35.66)	2.92 (1.21–7.52)
Route of administration‡		
Oral	1.00	1.00
Injection	7.51 (5.53–10.24)	0.64 (0.33–1.18)
Other	0.28 (0.08–0.67)	0.26 (0.69–0.80)
Price per unit, $§		
Low *(≤1.0)*	0.06 (0.003–0.29)	0.07 (0.004–0.38)
Medium–low *(1.01–10.0)*	1.00	1.00
Medium–high *(10.01–100.0)*	11.69 (6.85–21.16)	7.54 (4.07–14.64)
High *(>100)*	61.51 (36.04–111.70)	10.58 (5.10–22.72)
Estimated total cost of prescriptions dispensed at a retail pharmacy in 2021, $§		
Low *(≤1 000 000)*	1.00	1.00
Medium–low *(1 000 001–5 000 000)*	0.88 (0.57–1.36)	0.98 (0.54–1.77)
Medium–high *(5 000 001–10 000 000)*	1.34 (0.80–2.19)	1.63 (0.79–3.27)
High *(>10 000 000)*	3.71 (2.58–5.42)	2.42 (1.39–4.26)

Table 2: *Univariable and multivariable logistic regression for the association between presence of a patient support program and drug characteristics (n = 2210)*

**In multivariable regression, we adjusted for brand status, biologic status, orphan drug status, level 1 ATC code, route of administration, price per unit and estimated total cost of prescriptions dispensed retail pharmacies in 2021.*

†Level 1 ATC codes are grouped into 7 categories to ensure sufficient cell sizes.

‡Route of administration was coded as oral (oral, buccal, sublingual, dental), injection (subcutaneous, intramuscular intravenous, intravenous, intra-arterial, intracerebroventricular, intracavernosal, intraintestinal, intracervical, intrasynovial, epidural, intrathecal) and other (inhaled routes [inhalation, intranasal, instillation, intratracheal], droppers [otic, ophthalmic], dermal [transdermal, topical], vaginal, intrauterine, urethral and rectal).

§Data on estimated total cost of prescriptions dispensed and price per unit (in 2021) were available for 2210 drugs, excluding 4 outlier drugs with prices per unit greater than $14 000.

Abbreviations: ATC: *Anatomic Therapeutic Chemical code*, **CI:** *confidence interval*, **OR:** *odds ratio.*

Company	Description*	No. (%) of patient support programs administered *n = 128*
Innomar Strategies	"As an AmerisourceBergen company, we are part of a global network that drives innovative partnerships with manufacturers, providers and pharmacies to improve product access and efficiency throughout the healthcare supply chain."[43]	29 (22.6)
McKesson Canada	A subsidiary of multinational drug distributor, McKesson Corporation, "in addition to providing specialty financial and reimbursement assistance, [McKesson Canada] offers programs that assure patients remain adherent to their medications to ensurethey receive optimal benefit and outcome."[44]	25 (19.5)
Bayshore Healthcare	A Canadian company providing home and community health care service, Bayshore "provides patient assistance programs for specialty medications that are fully customizable to patient needs."[45]	15 (11.7)
Shoppers Specialty Health Network	Owned by Loblaws, a supermarket and pharmacy corporation, Specialty Health Network by Shoppers "aims to help patients and their caregivers manage their health, when health needs become complex. This can include helping gain access to medication; learning how to take medication; managing side effects; and staying on track with medications."[46]	11 (8.6)
STI Technologies Limited	An IQVIA company, STI Technologies Limited "enables and builds intelligent solutions that help our stakeholders support the healthcare system by delivering financial reimbursement, patient engagement, and patient management solutions that improve health outcomes."[47]	10 (7.8)
Bioscript Solutions	Canadian specialty pharmacy and distributor, "providing access to complex, specialty drug therapies and delivering full-service specialty care solutions."[48]	4 (3.1)
Medicum	A privately held Quebec-based company, which "assists Canadian patients in navigating provincial formulary or private insurance barriers so as to fully access needed medications, medical devices or treatments, focusing on the individual patient and acting as a hands-on support resource for patients and their families."[49]	4 (3.1)
Sentrex Health Solutions	A Canadian company that serves as a "fully integrated specialty distributor and patient support provider."[50]	1 (0.8)
Unspecified third party	"External (third-party) service providers are assisting [manufacturer] with the provision of the Services and administration of the Program: a third party service provider handles the Program registration process and call centre, and another has been appointed as administrator of the Program (i.e., rendering the Program's Services)."[51]	29 (22.6)

Table 3: *Third-party patient support program administrators.*

**Illustrative quotations from third-party company websites.*

for future research. Compared with a previous review,[3] our study found a higher prevalence of clinical supports, including nursing care and pharmacy coordination, suggesting the value of this type of care to patients, prescribers and payers.

These findings have several policy implications. The provision of these supports may have inefficiencies. Our study documented the duplication of services across companies marketing drugs with the same active ingredients. In the context of global shortages in health human resources, the impact of patient support programs on health human resources should be considered.

The prevalence and nature of patient support programs lack public transparency. As proprietary offerings generating proprietary data, the impact of these programs is currently not clear to decision makers. Thus, decision-makers may find it challenging to independently evaluate value for money and health system impacts, including access to medicines and medication-related care.

Finally, although manufacturers may be filling important gaps within publicly funded health systems,[9,19] whether manufacturer sponsored patient support programs are the optimal model to address health needs related to medicines is an open question.

The delivery of health care should be organized around a health need, not a particular therapeutic product. For example, participants in an Australian study endorsed the value of holistic nursing care for chronic disease within the health system rather than referral to multiple industry patient support programs.[5] In 2007, the French government commissioned an independent investigation into patient support programs, which suggested that direct contact between the pharmaceutical industry and the public be prohibited because of role confusion and misaligned incentives.[54]

Despite these policy concerns, few documented policy responses have addressed the regulation of industry patient support programs, a challenge exacerbated by the lack of transparency around their prevalence or activities. In 2009, the French government passed a law, in response to the independent investigation, that formalized industry patient support programs, requiring approval by the health regulator and prohibiting the involvement of company representatives; programs could instead be implemented by industry-sponsored clinicians.[55] In the United States, the government has taken legal action against pharmaceutical companies at the state and federal level under the Anti-Kickback Statute, alleging that the services provided under patient support (e.g., nursing services) and patient assistance programs (e.g., cost-sharing mechanisms) constitute an inducement to providers or patients to use a particular drug kickback; however, legal cases have been settled out of court or remain pending, and no additional regulation has been imposed on these activities to date.[10,56]

No literature exists on the attitudes of patients, health care providers, payers or policy-makers toward these programs or their experiences navigating care systems that involve patient support programs, suggesting an important avenue for future work. Studies of the prevalence and characteristics of patient support programs in other jurisdictions would provide useful comparative information to understand what might be unique to the Canadian context or the extent to which the global pharmaceutical industry employs patient support programs.

Limitations

The cross-sectional design and reliance on publicly available sources mean we may have missed drug manufacturers or their marketed drugs. However, we conducted all sampling and searches for patient support program data in duplicate, triangulating several search strategies and Web-based sources; thus, it is likely that any missed medicines are those without patient support programs during the study period.

Because the definition of a patient support program is evolving,[3] our identification of patient support programs is 1 possible interpretation. The study relied on publicly available documents; since we did not verify this information with companies, we may have missed some supports offered by a patient support program or incorrectly classified a program as a patient assistance program if we found evidence of only financial supports. However, although we relied on publicly available information, most included data sources were manufacturer-produced content, primarily web pages, brochures and enrolment forms, and coding for the presence and absence of supports was done in duplicate, using the source materials for verification.

The European Medicines Agency classifies some therapeutics as orphan drugs that do not receive this classification from the US Food and Drug Administration and, therefore, we may have undercounted the number of orphan drugs approved by Health Canada. Finally, we lacked information regarding the discounts that manufacturers extend to payers and buyers, as these agreements are secret. These reductions in cost can be quite substantial. However, our findings encompass the entirety of purchases within the drug system and total spending is still a good approximation of the market size; we anticipate that drugs that were categorized as high cost or having large market sizes would still fall into the same categories if all rebates were considered.

Conclusion

Industry-sponsored patient support programs routinely offer financial, clinical and educational supports to patients, and are primarily available for high-cost drugs. To understand the impact of patient support programs on patient and public health outcomes, and sustainable access to cost-effective medicines, greater transparency and independent evaluation of patient support programs is necessary.

Category*	No. (%) of PSPs† *n = 256*	Subcategory	No. (%) of category†	Illustrative examples‡
Financial supports	231 (90.2)	Reimbursement navigation	218 (85.2)	"We consider your financial needs, explore all your options for reimbursement, and handle the paperwork for you." (PSP2)
		Co-pay coverage and other financial assistance	132 (51.6)	"You can get individualized help from trained insurance specialists at the toll-free [PSP] number. They can help you verify your insurance coverage or help you to find programs that may allow you to obtain coverage for [drug]." (PSP32)
		Compassionate access or free sample	34 (13.3)	"Copay assistance, bridging and compassionate drug for qualified patients." (PSP33)
		Reimbursement of cost difference between brand and generic	15 (5.9)	"1-month supply free." (PSP47)
Clinical and case management supports	223 (87.1)	Access to a nurse for questions about program or treatment	132 (51.6)	"We will help coordinate injection training with a healthcare professional for you, your child, and/or a caregiver of your choice." (PSP16)
		Synchronous injection or infusion training	59 (23.0)	"We keep your health care team informed about how you are doing." (PSP5)
		Care coordination (finding a clinic, bookings, laboratory coordination)	40 (15.6)	"Your regional support nurse will work with you to ensure blood collection is accessible and convenient." (PSP54)
				"Live support, available from our dedicated team and your care coach (nurse), for questions about the program or treatment; access to a [PSP] care coach — a registered nurse — and all our associated services to help you get the most out of your treatment plan." (PSP185)
Educational supports	163 (63.7)	Brochures and patient handbooks	80 (31.3)	"If you have been prescribed [drug] in a [brand] autoinjector, you can watch a [brand] autoinjector how-to-inject video below." (PSP16)
		Injection or infusion training videos or instructions	76 (29.7)	"[Drug] app offers reminders and useful tips, coaching, and access to educational resources to help you stay motivated throughout your treatment." (PSP171)
		Informational web pages	70 (27.3)	"Download our patient handbook that contains helpful information on your condition, [drug] and [PSP]." (PSP6)
		Links to third-party resources	39 (15.2)	"Nutrition counseling video capsules by a team of registered dieticians." (PSP142)
		Emails or newsletters	1 (0.4)	"Patient advocacy groups information is shared." (PSP64)
		Other	28 (10.9)	
		Not specified	83 (32.4)	
Pharmacy supports	148 (57.8)	Home drug delivery	108 (42.2)	"Coordinate the delivery of your medication and any additional supplies." (PSP229)
		Pharmacy coordination	75 (29.3)	"[PSP] can also arrange for you to receive a reminder call when it's time to receive your next box of medication." (PSP5)
		Refill reminders	20 (7.8)	"We also dispose of all product packaging relating to your home delivery." (PSP1)
		Waste disposal	1 (0.4)	"In-depth product counselling by a certified pharmacist if dispensed through the program." (PSP129)
		Other	13 (5.1)	
		Not specified	7 (2.7)	

Category*	No. (%) of PSPs† *n = 256*	Subcategory	No. (%) of category†	Illustrative examples‡
Material supports	48 (18.8)	Medication-related supplies	34 (13.3)	"You get your welcome kit after your first call with [PSP]! This kit contains some tools to help you get started with [drug], including a cooler bag, some ice packs, and an injection mat." (PSP6) "The [PSP] also offers essential medical supplies required during treatment; these additional supplies available include [brand] needles." (PSP165)
		Pharmaceutical waste management supplies	12 (4.7)	"Access to a travel kit." (PSP196)
		Travel supplies	10 (3.9)	"Sharps disposal container." (PSP142)
		Other	15 (5.9)	"Medical alert bracelet for patients." (PSP65)
Not specified‡	9 (3.5)	Evidence of patient support program, but types of supports unspecified	9 (3.5)	"[Company] offers a number of patient support programs designed to help patients by providing services and secure access to the treatment prescribed by their healthcare professional." (PSP154) "Canadians prescribed [drug] will have the opportunity to request to be enrolled in the [PSP] … . Call [#], fax [#] or e-mail [address] for more information." (PSP155)

Table 4: *Types and frequency of supports offered within patient support programs (PSPs)*

**We define the mutually exclusive categories of supports as financial, defined as services or supports that decrease or eliminate the cost of a drug for patients; clinical and case management, defined as synchronous health teaching, medication administration, patient monitoring or care coordination performed by a nurse or case manager; education, defined as asynchronous health information or training; pharmacy, defined as any services or supports provided by a pharmacist or through a pharmacy; material, defined as provision of any supplies, tools or other tangible resources; and not specified, defined as descriptions of a PSP that did not include details about types of support.*

†*Patient support programs could have multiple support categories and subcategories, thus percentages do not add to 100.*

‡*Illustrative examples are direct quotations from sampled data sources; the code (i.e., [PSP#]) refers to the particular program from which the quotation was extracted.*

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Data sharing: All data underlying the analysis are publicly available with no restrictions at doi.org/10.5683/SP3/LYCQUR, except for variables related to estimated total cost of prescriptions dispensed at a retail pharmacy and price per unit in 2021. Variables related to estimated total cost of prescriptions and price per unit were obtained under licence from IQVIA Canada. The raw data cannot be publicly shared as it was obtained from a third party and as per signed agreement. Requests for data can be sent to IQVIA Solutions Canada and may carry a cost.

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Information on the Latest Drug Approvals and Reimbursement Milestones

NORDIMET® (methotrexate) Self-Injection Pen by **Nordic Pharma** is now available in Canada for treatment of rheumatoid arthritis and psoriasis/psoriatic arthritis.

Quebec expands public reimbursement of **Abbott**'s **FreeStyle Libre® 2 Flash Glucose Monitoring System** to more adults with diabetes.

First public drug plans provide reimbursement for **CAMZYOS™** developed by **Bristol-Myers Squibb Canada** for adults with symptomatic obstructive hypertrophic cardiomyopathy.

Abbott's **AVEIR™ DR**, the world's first dual chamber leadless pacemaker system, is now available in Canada.

AbbVie announces Ontario and Quebec are the first provinces to reimburse subcutaneous **EPKINLY™ (epcoritamab)** for the treatment of diffuse large b-cell lymphoma under a new early access process.

KYE Pharmaceuticals announces the availability of **QUILLIVANT® ER Oral Suspension** for the treatment of children with ADHD.

Quebec is the first province to list **Bristol-Myers Squibb Canada's OPDUALAG™** on its public drug plan for the treatment of adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma.

Organon Canada and the Alberta Women's Health Foundation unite to raise awareness and advocate for **universal access to contraception** in Canada.

Vertex Pharmaceuticals Canada Inc. announces Health Canada acceptance of the new drug submission for **vanzacaftor/tezacaftor/deutivacaftor**, a next-in-class triple combination treatment for cystic fibrosis in patients 6 years of age or older.

Health Canada grants marketing authorization of first CRISPR/Cas9 gene-edited therapy, **CASGEVY®** (**Exagamglogene Autotemcel**), developed by **Vertex Pharmaceuticals Canada Inc.**, for the treatment of sickle cell disease and transfusion-dependent beta thalassemia.

Pfizer Canada and **BioNTech** receive Health Canada approval of **Omicron KP.2 variant adapted COVID-19 vaccine.**

ABRYSVO™, **Pfizer Canada**'s newly publicly funded vaccine, is a step towards national RSV prevention in older adults.

Biogen Canada Inc.'s new drug submission for **Omaveloxolone** is accepted for priority review by Health Canada for the treatment of Friedreich's Ataxia.

DUPIXENT® (**dupilumab injection**) developed by **Sanofi Canada** is approved in Canada for the treatment of children aged 1 year and older with eosinophilic esophagitis (EoE).

Health Canada approves **Merck Canada Inc.**'s **KEYTRUDA®** as monotherapy for the treatment of adult and pediatric patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumours that have progressed following prior treatment and who have no satisfactory alternative treatment options.

Pendopharm announces public drug coverage plan listings for **Octasa®** (**oral mesalamine**).

Health Canada approves **AbbVie's CONSTELLA®** (**linaclotide**) for the treatment of functional constipation in pediatric patients 6 to 17 years of age.

Merck Canada and the pan-Canadian Pharmaceutical Alliance (pCPA) successfully complete negotiations for **WELIREG®** (**belzutifan**).

WINREVAIR® (**sotatercept**) developed by **Merck Canada** is now authorized for use in Canada for adults with pulmonary arterial hypertension.

AbbVie's VRAYLAR® (**cariprazine**) receives positive reimbursement recommendation by Canada's Drug Agency for the treatment of schizophrenia.

Eli Lilly Canada and the pan-Canadian Pharmaceutical Alliance (pCPA) successfully complete negotiations for **OMVOH®** (**mirikizumab**) for adults with moderately to severely active ulcerative colitis (UC).

Viatris launches **PrViagra® ODF** in Canada: a new oral dissolving film form of the erectile dysfunction treatment.

Arrayus Technologies Inc. announces Health Canada approval of its **Focused Ultrasound Therapy System**.

Health Canada approves **VORANIGO™** (**vorasidenib tablets**) first and only oral targeted treatment for brain cancer developed by **Servier Canada**.

Arcutis announces Health Canada approval of **ZORYVE® (Roflumilast) foam 0.3%** to treat seborrheic dermatitis in individuals 9 years of age and older.

Alnylam Canada signs letter of intent from pan-Canadian Pharmaceutical Alliance for the public reimbursement of **AMVUTTRA®** for the treatment of hereditary Transthyretin-Mediated (hATTR) Amyloidosis in adults.

Incyte announces Health Canada approval of **OPZELURA®** (**ruxolitinib**) cream for the treatment of atopic dermatitis (AD) and nonsegmental vitiligo.

Eli Lilly Canada and the pan-Canadian Pharmaceutical Alliance (pCPA) successfully complete negotiations for **Verzenio®** (**abemaciclib**) in expanded early breast cancer (EBC) indication.

AbbVie's VRAYLAR® (**cariprazine**) is now publicly reimbursed in Ontario.

Small Subsidiary, Big Global Moves: Lucie Rousseau on Servier's Recent Acquisitions

Lucie Rousseau is the general manager of Servier Canada, the Canadian subsidiary of the global Servier Laboratories, headquartered in France. She spoke about the company's recent big acquisitions, AI in drug discovery, the qualities she looks for in new hires, the role of pharmacists, and Servier's groundbreaking new brain cancer therapy.

Can you tell us about your background?

I was born in Montreal and raised in a region of Quebec called La Mauricie, which is located between Montreal and Quebec. My dad was an entrepreneur, and my mom was a teacher. Many of my aunts and uncles held positions in pharmacy, dentistry, and medicine. I chose pharmacy because I felt it was a good blend between medicine and entrepreneurship. After my pharmacy degree, I completed a post-graduate diploma in management in Montreal, and then moved to Europe to pursue post-graduate studies in international commerce. I started my career in the pharmaceutical industry in Europe. I'm now married, with a ten-year-old daughter, living in Montreal, and I'm still very much enjoying my career.

The role of pharmacists is rapidly evolving. For example, in Ontario and many other provinces, pharmacists can prescribe medication. How do you see the pharmacist's role continuing to change, going forward?

In addition to prescribing medication, pharmacists could be more central in immunizations and infectious disease management. I think pharmacists should be able to administer more immunizations than they currently do. They could play a larger role in preventing disease, such as by providing screening and resources for patients struggling with their mental health or raising awareness about common conditions. For example, cardiovascular disease in women is under-diagnosed. With more screening tools at their disposal, pharmacists could catch the issue earlier, leading to quicker interventions.

"This expansion has definitely enriched the company's culture by introducing more diverse perspectives and a stronger, customer-centric focus."

These are great ideas. In the shadow of the pandemic, it would indeed be helpful if pharmacists could screen and triage patients who may be in need of mental health counseling and referral to psychiatry or psychology. I want to talk now about your role at Servier. What's the biggest change you've seen over your time at Servier?

I joined Servier in 2006, when its operations were largely concentrated in France. With the acquisition of the oncology units of Shire in 2016 and Agios in 2021, our presence in North America has grown exponentially. This expansion has definitely enriched the company's culture by introducing more diverse perspectives and a stronger, customer-centric focus.

In August of 2024, Servier received approval from Health Canada for VORANIGO™, indicated for brain cancer in patients who have a specific mutation. Can you tell me a little about this?

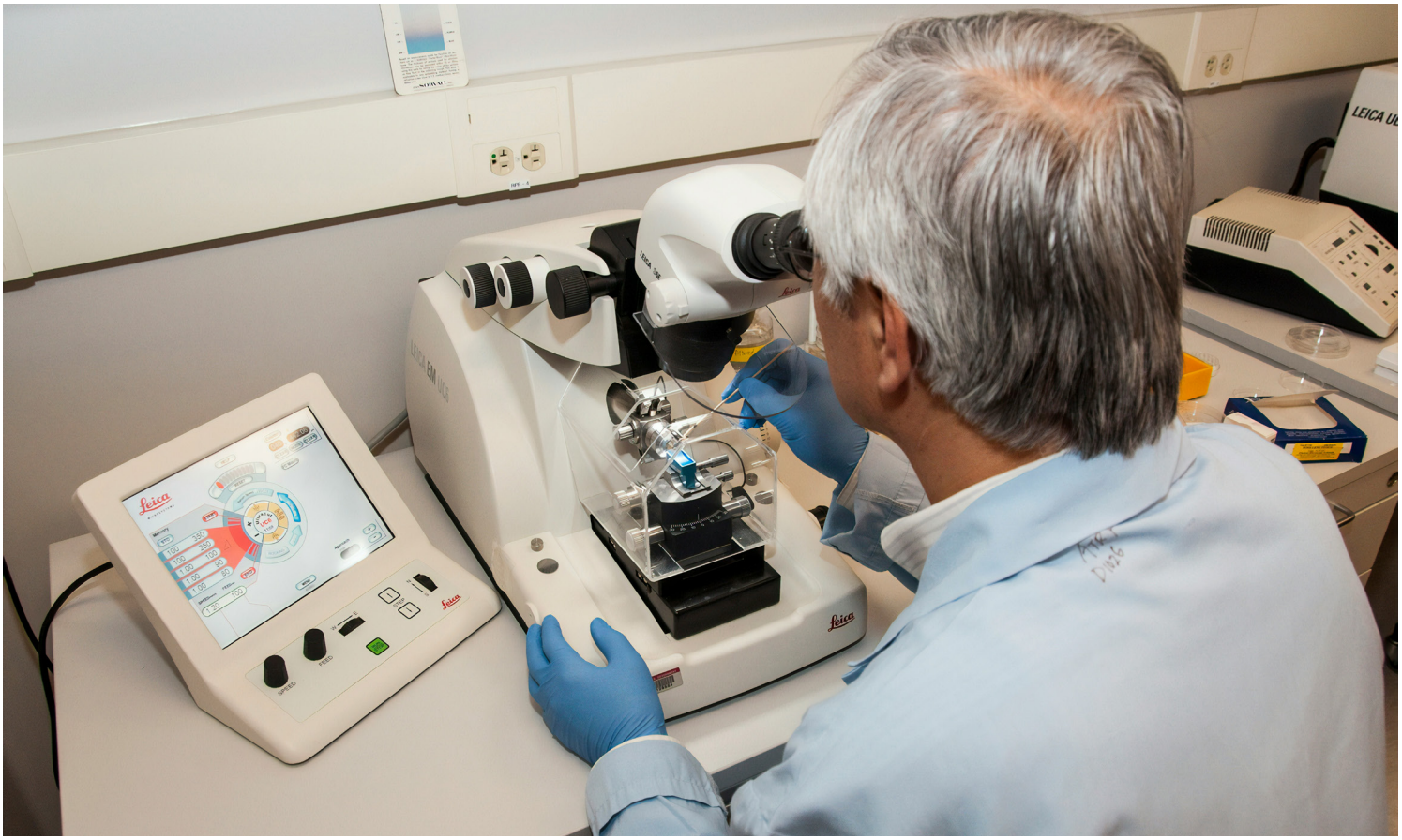

Photo by the The National Cancer Institute on unsplash.com.

We're quite proud to bring VORANIGO to market for the benefit of Canadian patients, in a space where there hasn't been any innovation in the last 25 years. VORANIGO specifically targets the IDH mutation, and diagnostic tests are already part of the standard of care to identify IDH-mutated glioma. When patients are diagnosed with this mutation, it greatly increases the probability of response for VORANIGO.

Indeed, the VORANIGO launch was possible because, in 2021, Servier acquired the commercial, clinical, and late-stage assets of Agios's oncology portfolio. Servier is always on the lookout for acquisitions.

In May of last year, Servier entered into a collaboration with a company called Aitia, which is a leader in AI drug discovery for pancreatic cancer. Just last month, this partnership was extended to novel drug candidates discovered using AI Aitia's "digital twins" technology. Digital twins are computational models that reproduce disease processes that occur in the body, including genetic and molecular interactions. This is a very concrete example of an external partnership focusing on cancer treatment, and it aligns very well with our goal of expanding our U.S. footprint.

I was struck to read in Servier's most recent annual report that the company has 20 products in clinical development for solid tumors and hematologic malignancies. Oncology represents 60% of the of company's development program. Can you share more about the oncology development program?

Servier, which is governed by a non-profit foundation, is committed to investing over 20% of its brand revenue into research. Most of that goes toward oncology. Our focus remains therapeutic spaces where there are very few or even no treatments available. VORANIGO is a good example. To speed up innovation, we combine our internal research expertise, with start-ups, universities, and even other pharmaceutical companies, such as Aitia.

Just over a year ago, Servier opened a Research and Development Institute, an hour away from our global Paris headquarters. It's a research hub that's quite unique. It's a high-tech facility that enables entrepreneurs to test and develop their ideas independently, while benefiting from the scientific support and the technological expertise of Servier.

Currently the oncology group's research focuses on myelodysplastic syndrome, brain cancer, and other types of cancers that may express specific mutations, both in hematology and solid tumors.

I recognize that within the Canadian market, and within oncology, advancing access and reimbursement is challenging. Can you share what you've learned about Canada's reimbursement process?

Access is difficult in Canada, even more so when you innovate in the rare disease space, including oncology. It is a lengthy and complex process that results, unfortunately, in inconsistent provincial access. There's no way to speed up access to medicines in rare diseases for which there are no alternative treatments available. An analysis that was conducted by Innovative Medicines Canada a few years ago found that Canada was one of the slowest countries to publicly reimburse therapies. Despite the fact that we approve a similar number of new therapies as the OECD average, in recent years, we've reimbursed 45% fewer therapies in comparison to the OECD average. There is a clear need to do better in Canada.

I fully agree with you. Let's switch gears and talk about the opportunity in a smaller pharmaceutical environment like Servier. What are the top three character traits you look for when hiring?

Here in Canada, Servier has just over 50 employees, but across the globe we have over 22,000 employees. In small subsidiaries like ours in Canada, one of the top traits we look for is a self-starter attitude. Individuals who demonstrate a strong sense of initiative will likely enjoy this type of environment. Secondly, we need people with a collaborative mindset – individuals who are willing to work openly across functions are particularly valuable in smaller teams. Finally, adaptivity is a key asset. We often need to pivot and help other teams.

Where do you think we're going to see the biggest bang for our buck in terms of AI in the next five to ten years?

AI will be critical in drug discovery, which is something we're well aware of at Servier. AI can also play a huge role in clinical trials, by identifying the right patients and speeding up recruitment.

AI could probably play a role, at the subsidiary level, in analyzing market trends and patient needs. Machine learning could potentially optimize our supply chain, by forecasting demand, managing and tracking inventory, and rebalancing stock based on predictions. Related to this, AI can predict equipment failure at manufacturing sites and help maintain efficient manufacturing systems. While the potential is astounding, we need to remind ourselves about the importance of guardrails. It is really our responsibility to make sure that AI is used in a way that is ethically acceptable, and that's not yet a given.

> ***AI will be critical in drug discovery, which is something we're well aware of at Servier. AI can also play a huge role in clinical trials, by identifying the right patients and speeding up recruitment.***

On that thought, do you think we owe it to patients to tell them if AI was involved in their diagnosis?

That's a tricky question. I'm not sure if it would change anything for me, if I knew that my imaging scan was read by an AI machine, as opposed to a radiologist. I hope that, at some point in the near future, we'll have guidelines that give patients all the context they need to manage their health. I see when I use Microsoft Copilot or ChatGPT that there are limitations to those platforms. I can imagine that similar limitations affect health care applications too, including AI diagnostics.

I always like to save this question for last because it says so much about people. Let's say I give you my personal credit card to go out for dinner with three guests, dead or alive. Who would you want to have dinner with?

One guest would be someone who has been to space. Maybe Chris Hatfield, because he's a musician too. I've always been fascinated by space. The second person is Jerry Seinfeld, because I like to laugh. I am from the generation where I would get back from my university classes and turn the TV on and watch a Seinfeld show before studying. Thirdly, I'd want to

bring together all Canadian women who fought for women's rights over the last 150 years. I'm extremely grateful to those women who led the way and opened doors for millions of Canadian women like me, and I would love to show them how impactful their actions have been, and to discuss how we can preserve these gains in the future for all those young girls, so they have the possibility to become tomorrow's leaders.

Thank you! That's more than 3 people, but I'll let you have that third group. And that would be an interesting dinner – all those incredible women, plus Jerry Seinfeld and Chris Hatfield in the mix. It was a pleasure to learn about Servier, and about VORANIGO, which is a tremendous accomplishment for your organization.

Lucie Rousseau, General Manager of Servier Canada

Lucie Rousseau studied in Montréal, where she obtained a bachelor's degree in pharmacy and a post-graduate certificate in management. She later pursued her studies in Europe in international management. At Servier, she was able to grow professionally and hold various positions. Lucie has been working at Servier Canada since 2006. In her early years at Servier, she was Product Manager, Cardiology, and later assumed several major strategic roles, such as Group Product Manager, Marketing Director, Market Access Director and Head of the Oncology business unit. In January 2023, she became responsible for the Canadian subsidiary as General Director at Servier Canada. Lucie works in close collaboration with all the teams to reach the goals of the organization by taking every necessary action in the company to ensure that all collaborators can develop their full potential, for the benefit of patients who remain at the centre of our mission.

Not a Headache: How Stigma Stops Migraine Patients from Getting the Help They Desperately Need

A Conversation with Migraine Patient Melissa Saunders

When Melissa Saunders experienced her first migraine at age 15, she was terrified, as she had no idea what was happening to her. She spoke with Hypothesis about the lack of awareness about the diverse symptoms of migraines and how debilitating the neurological condition can be. Her journey to finding the right treatment reveals the stigma and barriers that migraine patients face, in their workplaces and in the healthcare system.

Can you start by telling our readers about yourself?

Sure, I was born and raised in Ottawa. I have an undergraduate degree in psychology and a Master of Social Work. I worked as a social worker at the Ottawa Hospital before returning to school, which is a great love of mine, to study law. Migraine has been a big part of my life for the last two decades. Through my journey to understand my own migraines, I've learned that my dad also suffers migraines. Until I started doing research, we didn't realize that the symptoms he experienced were from migraines.

Could you tell me more about your migraine journey? When did you realize you had migraines, as opposed to run-of-the-mill headaches?

The first time I can recall experiencing a migraine was when I was 15. I lost vision in my left eye, which is what usually happens when I experience an aura, though I didn't know that at the time. I remember where I was and who I was with, because I was terrified. I was lying on my couch thinking, 'What is happening?' My family doctor eventually diagnosed me with migraines, after several episodes.

Photo by Anna Shvets on unsplash.com

Many people aren't aware of the strange symptoms that migraines can cause. For example, my friend once suddenly had difficulty speaking, due to a migraine aura. She had no idea why, so she called 911.

How often would you experience migraines, and how did you manage them?

At first, I would take over-the-counter medications like Tylenol and Advil to manage the pain. In my 30s, my migraines became more frequent and severe. I was prescribed triptans and Tylenol 3, which worked for a while but my migraines continued to worsen. As workplace stress was a trigger for my migraines, I had to resign from a job that I loved.

A few years ago, I was getting migraines two or three times a month and each migraine would last three to four days. I would call Telehealth and the nurse would recommend I go to the emergency department. I didn't feel it was appropriate for me to use emergency department resources. I became extremely depressed and hopeless, because my quality of life was so poor, and I didn't know if life would get better.

> ***"Many people aren't aware of the strange symptoms that migraines can cause."***

That must have been an incredibly frightening time. When did things change for you?

I eventually saw a neurologist who prescribed Qulipta, a daily medication that prevents migraines. When I went to pick up the prescription from the pharmacy, I learned the cost was close to $3,000 for a three-month supply. I burst into tears, because I couldn't afford it. Fortunately, the manufacturer offered compassionate access to the drug, which means the manufacturer provided me the drug for free.

Within a month, I stopped having migraines. I don't experience side effects with the medication. It's been life-changing for me. It's shocking to think that I almost didn't get to try this medication.

Migraine patients struggle to get coverage for medication, because many don't recognize that this can be such a debilitating disease. Can you talk about the stigma migraine sufferers face?

This is something I feel very strongly about. So many of the migraine sufferers I know talk about this stigma, about not being taken seriously. Migraines are seen as headaches when they should be seen as a neurological condition. Migraine sufferers are required to advocate for themselves and spend time

educating people in their lives and at their workplaces about the debilitating effects of migraines. Migraine is an invisible disability. People don't see the effects, so they don't understand what having a migraine feels like.

It's also difficult for people who don't suffer migraines to understand the psychological and quality-of-life impacts. For me, my migraines coincided with my menstrual cycle. I experienced extreme anxiety when I knew I was about to experience a migraine, as I knew I would have to miss work to get an injectable medication. My supervisor often asked me to return to work after having a migraine, despite the fact that it was mentally and physically impossible for me to work. Migraine sufferers face huge barriers in getting medication coverage, sick leave, and disability benefits.

You describe the stigma very well. What more can the pharmaceutical industry do for migraine sufferers like yourself?

I would love it if industry could fund an awareness campaign about migraines. The stigma migraine sufferers face is similar to the stigma that people with mental illness face. I think in both cases, it comes down to a lack of education.

> ***Migraine is an invisible disability. People don't see the effects, so they don't understand what having a migraine feels like.***

An awareness campaign should highlight the migraine symptoms that aren't known as classic migraine symptoms. This could speed up the time to diagnosis and treatment. For example, I thought I had allergies for years, until I saw a specialist and found out that my sinus pressure and congestion was a migraine symptom. Many people don't seek help for migraines because they don't realize the symptoms that they're experiencing are due to migraines, and that treatments are available. We can do a much better job at raising awareness about a common, and often very severe, condition.

Melissa Saunders
Melissa Saunders is a neurodivergent social worker and lawyer. Melissa earned a BA (Honours) from Carleton University, an MSW from Wilfrid Laurier University, and a JD from the University of Ottawa. She is passionate about social justice and mental health advocacy, loves Broadway musicals and her two Yorkies, and is an ardent believer in kindness and karma.


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Who's Doing What and Who's Going Where

Ryan Bradley has started a new position as Associate Medical Director at ***Novo Nordisk.***

Nicole Loblaw has embarked on a new role as Head of Sales (Oncology, Rare Disease, Blood Disorders) at ***Sanofi***.

Mark Surka has begun a new position as Head - Medical Affairs (Oncology, Rare Disease, Blood Disorders) at ***Sanofi***.

Jennifer Barbusci has started a new position as Senior Brand Manager (Hematology/Oncology) at ***AbbVie.***

Jenelle Brecevic has assumed a new role as Continuing Medical Education Manager at ***Pfizer***.

James Thompson is now the National Health Policy & HCA Manager, Canada at ***Boehringer Ingelheim.***

Sarah Holdridge has started a new position as Director, Marketing (Lung Cancer) at ***AstraZeneca***.

Lea Moutounet has embarked on a new role as Medical Education Manager at ***GSK***.

Jeff Tam has assumed the role of Marketing Lead (Hematology) at ***Eli Lilly and Company***.

Dustin Cavida has started a new position as Medical Director at ***Amgen***.

Melissa Piccininni taken up a new role as Associate Marketing Director (HIV) at ***Gilead Sciences.***

Matthew Bergamin has joined ***GSK*** as an Oncology Systems Solutions Manager.

Laura Tió has been hired by ***Philips*** as a Field Sales Representative.

Marie-Claude Fortin has embarked on a new role as Marketing Lead for ***Roche Diabetes Care Canada.***

Elliot Madden has joined ***Arjo Medical Canada*** as Sales Director.

Vatroslav Mateljic has been appointed General Manager of ***Takeda Canada.***

Geneviève Gauthier is emabarking on a new role as Executive Director (Corporate Affairs and Community Engagement) with ***Organon Canada***.

Jeffrey Malawski has assumed the role as Executive Director (Women's Health and Established Brands) with ***Organon Canada.***

Dimitri De Mel is now the Senior Product Manager (Dupixent Dermatology) at ***Sanofi***.

P. James Scrivens is starting a new postion as Regulatory Affairs Manager (Oncology) at ***GSK.***

Manon Petit has assumed a new role as Regional sales Manager at ***Applied Medical***.

Sindi Skenderi has joined ***Bausch + Lomb*** as Senior Marketing Manager for the Rx portfolio.

Christophe Guile has assumed the role of Brand Manager of Pluvicto at ***Novartis***.

Please submit your selection for our "People on the Move" section, celebrating the advancements of your colleagues, for upcoming issues via email to info@catalytichealth.com.