

The
Research
Institute
of St. Joe's Hamilton



2020

Annual Report

Introduction

The Research Institute of St. Joe's Hamilton

The Research Institute of St. Joe's – Hamilton oversees the work of over 700 researchers, staff members, learners, and fellows as they carry out clinical, translational, evaluative, and fundamental research. Our Hospital has a long and celebrated history of impactful research, which continues to improve diagnostics, care, and treatment for patients in our

community and across the globe.

Since its inception in 2014, The Research Institute has become a leader in collaborative translational research. Known as the bench-to-bedside approach, this innovative method of conducting research allows scientists working in our labs to make the latest advancements available to clinicians for patient care, all within the walls of our Hospital.

St. Joe's researchers are helping to improve patient quality of life and the quality of care provided by health care professionals. We are an integral partner within Hamilton's growing health innovation community, where we are working to transform the way medicine is practiced.



The Research Institute is a Proud Member of St. Joseph's Health System

Publication Credits

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A Word from Dr. Gail Martin

Messages from Our Leadership

This has been a year unlike any other. The ongoing coronavirus pandemic has taken a terrible toll on our society, and in particular on our most vulnerable – the elderly, those living with pre-existing conditions, and people experiencing homelessness.

The virus has tested the mettle of every individual working in our Hospital. It has altered the dynamic of research and clinical care and added stress to the health care system that may last for years to come.

Though vaccines have been approved in Canada and other jurisdictions, marking the start of the largest immunization program in history, it will still take time to return to some semblance of our pre-pandemic lives.

But where there has been tragedy, there has also been triumph. Through the resilience and resourcefulness of our research community, we've overcome many challenges both internally and externally.

Early on in the pandemic, our research coordinators managed to transition many study participants to virtual check-ins, allowing many studies to continue. Several coordinators and investigators also worked together to manage patient access for the dozens of COVID-19 research projects that were initiated. Our researchers embraced remote work, performing their data analyses, preparing grant proposals and literature reviews, connecting with their students and participants, and editing manuscripts from home.

We also transitioned some of our events to virtual sessions. This marked a dramatic change for our biggest event of the year, Celebrate Research, which was presented with great online engagement from our community. We plan to incorporate these virtual event successes into future events, even as public gatherings become possible once again.

From a broader perspective, The Research Institute became a major contributor to the province's response to COVID-19 diagnostic testing. Our researchers developed and deployed critical solutions to supply shortages, processing bottlenecks, and other key obstacles that threatened Ontario's ability to engage in testing on an unprecedented scale. Second only to a vaccine, reliable mass testing is our greatest tool for reducing the spread of the virus.

I am proud to present the stories of our 2020 Annual Report. They offer a glimpse of what St. Joe's researchers have accomplished over the course of this arduous year.



Gail Martin, PhD, BSc
Executive Director, The Research Institute of St. Joe's Hamilton

A Word from Dr. Jack Gauldie

Messages from Our Leadership

The unwavering commitment to care for our community is the foundation upon which St. Joe's is built. It has been so ever since the early days when, in the midst of a deadly cholera outbreak, the Sisters of St. Joseph began their health care mission in earnest.

Over the last 130 years, St. Joseph's Healthcare Hamilton has grown into an academic research hospital, affiliated with the world-renowned McMaster University. Within these walls, life-changing research and innovation benefits patients. We educate the world's best and create a healthier community.

Our Hospital has faced many great challenges over the years, and the COVID-19 pandemic might prove to be the toughest one yet. Managing it has been an enormous effort by everyone involved, and the work continues. Despite these difficulties, we've remained committed to achieving our long-term goals and have made steady progress in many key areas.

In 2020, The Research Institute launched a new program called Access Research, designed to reduce the inequities that exist in clinical research recruitment. This program will provide more occasions to share research opportunities with interested patients by utilizing the power of Dovetale, our state-of-the-art electronic medical record system.

We have also been making progress towards our new Institute for Chronic Lung Disease, as we work to bring its blueprint into reality. With the support of multiple donors, Canada Research Chairs, the Faculty of Health Sciences, and our Hospital and Foundation, this new research centre will expand on the vital work of the Firestone Institute for Respiratory Health. It will solidify St. Joe's as a leader in respirology, thoracics, pathology, diagnostic imaging, and much more.

At the close of 2020, I will take my retirement from St. Joe's. I'm grateful to have had the opportunity to lead the Hospital's research enterprise these past few years, and I'm confident that The Research Institute will continue its fast-paced growth, fostering innovation and discovery that ultimately changes lives. Through its stories, our 2020 Annual Report can attest to these qualities.

I have always advocated for collaboration. There is nothing that cannot be achieved if we are working together – within the walls of St. Joe's, with our public and private sector partners across Hamilton, and with the people of this fine city.

The COVID-19 pandemic will one day be a distant memory for our Hospital, like SARS and cholera before it. For now, we must remain steadfast in our resolve and let our motto guide us as it always has before. *It is an honour to serve our community.*





COVID-19: The fight against the pandemic

COVID-19

Research at St. Joe's is not limited to our labs and offices – it occurs in almost every clinical space across our three campuses. Research is interdisciplinary and translational, utilizing the bench to bedside approach. The interconnectedness of clinicians and their patients with researchers and study participants has been one of our greatest strengths, though it does present challenges in the midst of a pandemic.

By January 2020, scientists at St. Joe's virology research lab were paying close attention to the novel coronavirus that was spreading across Asia and moving into Europe. When the SARS-CoV-2 genome was first published, Dr. David Bulir designed a robust clinical test for the virus. His test – called an assay – would soon be used by several labs in Ontario, one of the many innovations to come out of our research laboratory.

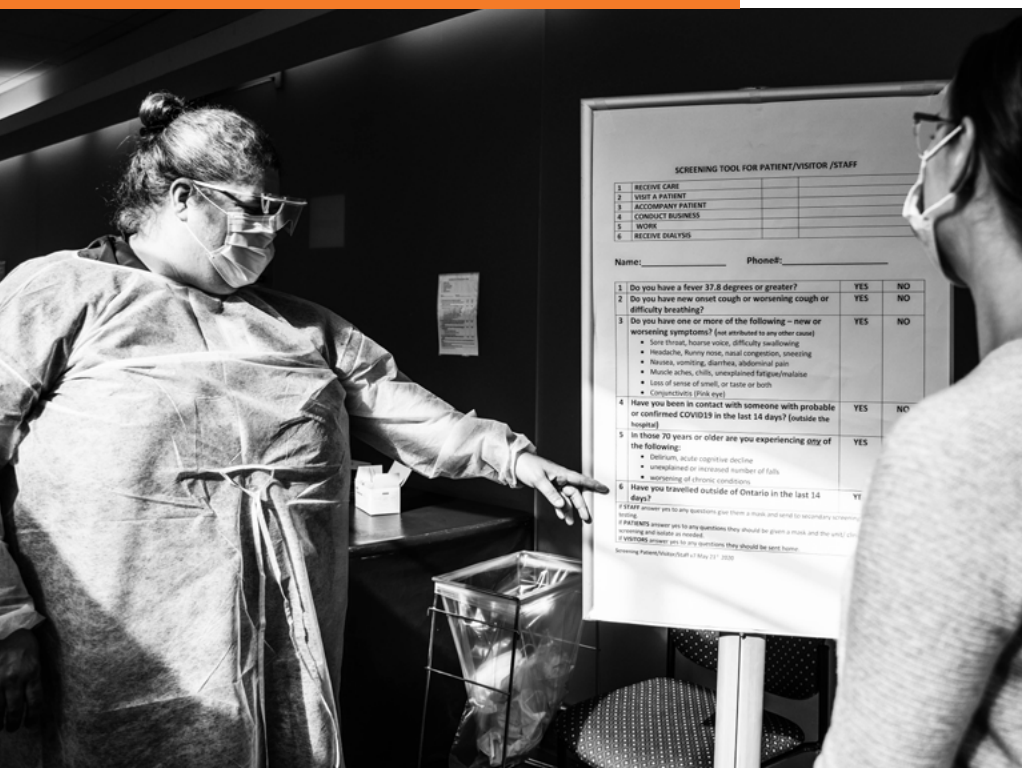
Realizing what was coming, The Research Institute administration team shifted to offsite work in advance of the Ontario government's first lockdown mandate. Our executive team worked closely with McMaster University to develop and implement pandemic protocols for research. Ultimately, study recruitment was put on hold and research learners were affected.

On March 17, 2020, St. Joe's implemented an active screening protocol and began to limit the premises to essential workers only. This also meant postponing elective surgeries and halting visitors in an effort to protect vulnerable patients under our care.

St. Joe's worked quickly to establish a new COVID-19 care unit. The Hospital maintains a stockpile of personal protective equipment (PPE), but it was uncertain how long these precious supplies would last in the event of a massive surge in COVID-19 hospitalizations. Similarly, laboratory testing supplies were dwindling as manufacturers struggled to meet global demand.

Through the unpredictable first

Active screening for staff began on March 17, 2020





Clinical and research staff comforted patients, particularly as visitor restrictions were implemented

wave, our community rallied in support of health care workers by sending in donations of meals, coffee, gifts, and PPE supplies. Our Hospital received more than \$700,000 in donations to cover the costs of our most pressing research, equipment, and supply needs. Local distilleries gifted us with hand sanitizer that they created using the WHO formulation and our research partners in Guangzhou, China managed to send a large shipment of N95 masks and gloves to our Hospital, along with a message of hope and solidarity.

As cases began to climb, some researchers worked to publish urgently needed guidance. Dr. Catherine Clase published a

review of 100 years of evidence that indicated the efficacy of multi-layer cloth masks. Dr. Derek Chu's comprehensive review of existing literature supporting the use of face masks, eye protection, and physical distancing – funded by the World Health Organization – was published in *The Lancet*. As well, physical therapist and researcher, Dr. Michelle Kho, collaborated on a new set of guidelines for performing physical therapy during a pandemic.

Like many other sectors, health care and research went digital. Virtual meetings allowed key stakeholders to communicate without the added risk of

spreading the virus. Research coordinators connected with study participants through digital means, allowing them to forgo a research visit at the Hospital. As the pandemic has continued, we found new ways to engage with our community, such as bringing events like Celebrate Research to virtual platforms.

Most importantly, our researchers and clinical partners have persevered through what has been perhaps the most challenging year of their careers. The stories presented here are only a small snapshot of the dedication, commitment, and bravery of everyone who has worked to ensure St. Joe's can continue its Mission of Discovery.



The D3 Group: A story of innovation

COVID-19

The Disease Diagnostics and Development (D3) Group at The Research Institute of St. Joe's Hamilton, led by Dr. David Bulir, has been hard at work developing innovative solutions to the biggest challenges involved in COVID-19 diagnostic testing. Large-scale testing continues to offer the best opportunity of reducing the spread of the virus.

The D3 Group began working on testing solutions in January 2020. Scientists had just published the full genome of the pathogen responsible for COVID-19 – a novel coronavirus called SARS-CoV-2. Dr. David Bulir, a physician and researcher in the D3 Group, began developing a molecular test for this new virus. Knowing that it was likely to mutate as it continued its race across the continents, he designed his molecular test – called an assay – to detect a region of the virus that was believed to be relatively stable.

Just as predicted, SARS-CoV-2 experienced several mutations. Thankfully, Dr. Bulir's robust assay remained effective in detecting the mutated forms of the virus. The assay was also designed to

detect and differentiate between eight other respiratory viruses, including influenza A/B and SARS-CoV-1 (the virus that caused the SARS outbreak of 2003).

By March 2020, the D3 Group had acquired two high-throughput liquid handling robots, which would be used to increase test processing to thousands of samples per day. These two Hamilton Microlab STAR units enabled Dr. Bulir's new assay and the D3 Group to begin the next phase of development – sample pooling to further increase testing capacity.

By combining samples into batches of two, four, or even eight and testing them as a single specimen, sample pooling offers massive increases in throughput since the majority of tests are negative. Any positive batches are re-tested individually to isolate the positive sample.

The Hamilton Regional Laboratory Medicine Program (HRLMP) is responsible for processing diagnostic tests for St. Joseph's Healthcare Hamilton, Hamilton Health Sciences, and other partnering clinics in the

Hamilton region. Early on, the HRLMP worked with the D3 Group to implement Dr. Bulir's assay. By April 2020, the assay was licensed for confirmatory testing, eliminating the need to send positive samples to Hamilton Public Health. Ultimately, this helped to conserve scarce testing supplies.

Just as supplies of personal protective equipment became scarce during the first wave of the virus, so too did the supply of critical laboratory materials as demand for testing skyrocketed. Key producers of specimen swabs, transport materials, and lab reagents were not prepared to meet the needs brought on by a global pandemic, and labs everywhere faced imminent supply chain issues that threatened their ability to sustain long-term testing. Luckily, the D3 Group had been working on solutions to these supply challenges.

The team began to secure alternative suppliers that would not only allow testing to continue, but to reliably expand to the capacity across the whole province as the virus spread. In a race against time, researchers led a major effort towards supply

chain independence. They worked relentlessly to secure a new supplier of flocked swabs, which were validated at St. Joe's research lab as well as other labs in Ontario for use in COVID-19 diagnostic testing.

But swabs are only one piece of the puzzle. The specimen tubes that hold the samples, for instance, were another crucial aspect that were in short supply. Specimen tubes contain a liquid to preserve the integrity of the sample, called the transport medium. As demand for commonly used transport media increased, many suppliers were not able to provide while others increased dramatically in price.

“Our most standard transport medium was not available and the cost of our alternate transport medium increased substantially, so we hastily began searching for a reliable and affordable solution,” says Dr. Bulir. “Ultimately, we decided to develop our own transport medium in our lab, and the McMaster Molecular Medium (MMM) was born.”

Many commonly used transport media do not inactivate the samples, creating an exposure risk for lab technicians who must manually inactivate each sample in a biosafety cabinet before processing them. By design, the MMM inactivates samples in the tube at the point of collection,

reducing risk to lab technicians and simplifying and speeding up the testing process. Samples can then be loaded directly onto liquid handling machines for immediate processing.

Through the McMaster Industry Liaison Office, the D3 Group partnered with Bay Area Health Trust to license the rights to production and sales of the MMM for research and clinical purposes, ensuring a steady supply would be available.

The D3 Group also worked with an interdisciplinary team of researchers and industry professionals in Ontario to produce required plastic

Continued >

Dr. David Bulir prepares specimens for testing in the high-throughput robotic liquid handling system





Specimen tubes containing the newly developed McMaster Molecular Medium are prepared for processing

components for the in-lab testing process. The design, fabrication, testing, and scaling of production for these materials usually takes 3 to 4 months. Fortunately, they managed to achieve these goals in only 5 weeks.

The innovative solutions developed by the D3 Group have impacted labs across Ontario, since each solution was designed with the entire province in mind. Even health authorities from outside of Ontario were reaching out to the D3 Group to improve testing in their own jurisdictions.

One prime example of this enormous impact is from Shared Hospital Laboratory (SHL), which had a weeks-long testing backlog affecting six Toronto hospitals. They were receiving

specimens in nearly a dozen different types of transport media and tube formats, slowing down the testing process. By September 2020, the number of daily samples arriving at SHL had skyrocketed, and the need to manually inactivate each specimen exacerbated the problem. That's when, with the help of Dr. Bulir, they switched to the MMM.

“Prior to implementing the MMM, we struggled to complete 3,500 to 4,000 tests per day,” says Dr. Christy Vermeiren, deputy director of SHL. “We rolled out the revamped workflow, eliminated the preprocessing bottleneck, and redeployed staff. The following day we completed just over 5,200 tests and then 6,500 tests the day after that – all with our existing staff

complement. It's a win-win-win.”

SHL managed to clear their backlog within 48 hours of implementing new protocols, which included the MMM as their standardized transport medium.

The solutions developed by the D3 Group have also been used in several clinical research projects. One study, conducted during Ontario's first wave of the virus, saw researchers partnering with Hamilton's Shelter Health Network to perform surveillance testing on vulnerable populations. Researchers were able to monitor and help control the spread of COVID-19 among groups of people experiencing homelessness in Hamilton.

A novel pilot study of incoming travellers was conducted in partnership with Air Canada, the Greater Toronto Airports Authority, and McMaster HealthLabs. Researchers performed thousands of COVID-19 tests on incoming international travellers, collecting samples at Pearson Airport. Participants also submitted self-collected samples at 7 and 14 days after their arrival during their mandated quarantine period. The study was later boosted by a \$2.5 million grant from Health Canada and the Canadian Institutes of Health Research.

Interim results of this study, released in November 2020, showed that only 1 percent

of incoming travellers tested positive for SARS-CoV-2. Of those positive cases, 70 percent were detected during the initial test at the airport. Self-collected samples taken 7 days after arrival found 30 percent of positive cases, and samples taken 14 days after arrival found less than 10 percent of all positive cases.

With several vaccines now being distributed in Canada and around the world, there is light at the end of the tunnel. Yet fast and accurate COVID-19 testing will remain key to fighting the pandemic, as mass vaccinations will take time. Testing will also remain critical in limiting the size of outbreaks in low-income countries where access to vaccines is delayed or

hampered.

By developing critical diagnostic solutions and ensuring Ontario has the supplies it needs to continue testing, the D3 Group is further proof that St. Joe's conducts research that changes lives.

Funding for the work of the D3 Group was provided by the Juravinski Research Institute, the Ontario COVID-19 Rapid Research Fund, and The Research Institute of St. Joe's Hamilton. Additional funding for the COVID-19 Study of International Travellers was provided by Health Canada and the Canadian Institutes of Health Research.

The D3 Group worked diligently to secure, validate, and translate their solutions to labs across Ontario and beyond





Collaboration Culture: How St. Joe's research coordinators are managing dozens of concurrent COVID-19 studies

COVID-19

As news of a novel virus spread amongst the scientific community, the immediate need to build a body of knowledge became apparent. Since then, an immense volume of COVID-19 research has been conducted around the world, as researchers have sought to assess a variety of potential treatment options, determine risk factors, study the virus's long-term effects, improve diagnostic testing, and much more.

In Canada, multiple levels of government and various funding agencies provided several emergency research grants. Research ethics boards prioritized and expedited their reviews of COVID-19 study protocols, and research coordinators prepared to initiate new studies in record time.

As Ontario experienced its first wave of COVID-19 in the spring of 2020, dozens of pandemic-related clinical research projects emerged at St. Joe's. But researchers soon found themselves in a unique situation – a handful of studies were all simultaneously targeting the same population of inpatients for study recruitment.

Outpatients are rarely, if ever, enrolled in more than one study

at a time, which helps eliminate unknown factors that may affect study findings. However, co-enrolment in critical care research studies is much more common compared to other departments.

“St. Joe's critical care researchers have a lot of experience with co-enrolment, but the degree of which we've seen during the pandemic has been unprecedented,” says Sarah Culgin, a critical care research coordinator at St. Joseph's Healthcare Hamilton and the executive coordinator of St. Joe's GUIDE Group. “The logistics of managing patient consent alone was a challenge, and that was only the beginning.”

Culgin is part of a group of interdisciplinary research coordinators and physicians who are responsible for managing dozens of COVID-19 studies at St. Joe's. During Ontario's first wave of the pandemic, the newly formed group began working closely together to oversee co-enrolment, as there was a need to regulate access to patients admitted with COVID-19.

Balancing patient access for research consent and follow-up while minimizing the use of scarce personal protective equipment was a priority. In

addition, determining the use of multiple medications and disease management strategies, as well as post-discharge follow-up, further complicated matters. The research group worked closely to address these new challenges.

“We've built a unique culture of collaboration at the research coordinator level here at St. Joe's,” says Culgin. “It's certainly helped manage the influx of pandemic studies that have arisen, allowing our Hospital to contribute to pandemic research efforts on so many levels.”

The group created visualizations to help them track the needs of each study and identify overlap between study timelines. The needs of over two dozen concurrent studies were stratified by hospitalization stage – including hospital admission, admission to the ICU, transfer to a ward, discharge, and out of hospital follow-up.

It began in critical care, with coordinators and principal investigators meeting to collaborate on approaching patients. As further studies were established, particularly those related to diagnostic testing and long-term outcomes of the virus, more research coordinators joined

the group.

“It’s crucial that we avoid overwhelming patients and their families with a barrage of research coordinators doing recruitment and follow-up,” says Culgin. “The model we’ve developed has been working well and has received a lot of positive feedback from our clinical partners and patients. We’re also able to reduce patient interactions and the amount of PPE needed, while allowing much needed research to continue.”

Research coordinators France Clarke, Laurel Kelly, Jodi Gilchrist, Liz Johnson, and Sarah Culgin have covered most inpatient recruitment for COVID-19 studies at St. Joe’s. The

team has also maintained steady contact with their counterparts at Hamilton Health Sciences (HHS) to help manage any St. Joe’s studies being conducted at participating HHS sites.

Efforts towards the continuation of research – at St. Joe’s and beyond – have contributed much to our understanding of the virus. In fact, St. Joe’s GUIDE Group, which develops critical care guidelines, has been working to coalesce findings from hundreds of COVID-19 studies as part of their work with the Society of Critical Care Medicine and the Surviving Sepsis Campaign.

In June 2020, an international team of researchers led by

GUIDE Group co-chair, Dr. Waleed Alhazzani, published new guidelines in *Critical Care Medicine*. The extensive document summarizes the best evidence and makes treatment recommendations for physicians caring for COVID-19 patients in hospital.

Since pandemic research is ongoing, an updated version of these guidelines will be published in early 2021 to incorporate the latest evidence.

By conducting dozens of pandemic research projects, St. Joe’s joins research institutions around the world looking for evidence-based guidance in the fight against COVID-19.

Kate Nelson, Sarah Culgin, and Dr. Alhazzani prepare packages for hospital sites participating in the Awake Prone study





New Realities: Understanding addiction during the pandemic

COVID-19

In March 2020, the provincial government made the difficult decision to temporarily close many businesses that were deemed non-essential. The introduction of infection control protocols and reduced capacities allowed essential businesses – food retailers, pharmacies, etc. – to continue operating. Naturally, public debate over which businesses should be deemed “essential” ensued.

To the surprise of many, LCBO stores were allowed to remain open. Surely Ontarians could go without liquor for a short period. After all, alcohol is Canada’s most commonly abused addictive substance, causing hospitalizations at a rate comparable to heart attacks. So why were these Crown-operated liquor stores deemed essential?

The decision may have seemed counterintuitive to those unaware of the realities of alcohol dependence. With bars and restaurants temporarily shuttered, an LCBO closure would have increased the risk to those suffering from alcoholism, leading to a rise in withdrawal-related hospitalizations. This was already a crucial time for hospitals, which were busy preparing for a surge

in COVID-19 patients. Even though keeping LCBO stores open meant a slightly increased risk of community spread, effective safety measures like physical distancing, masking, and hand sanitizing addressed those risks.

Without proper medical supervision, alcohol withdrawal can lead to symptoms that include anxiety, nausea, high blood pressure, fever, hallucinations, and much more. A medically supervised detox program can help reduce and manage side effects during recovery from alcohol dependence.

Ultimately, when public policy is guided by science, society is better able to understand and address the nuances of many key issues. Without an evidence-based approach, unintentional harms can be introduced, even with the best of intentions.

The Peter Boris Centre for Addictions Research (PBCAR) at St. Joseph’s Healthcare Hamilton conducts state-of-the-art research on the causes, consequences, and treatment of addiction. Researchers conduct empirical investigations across four broad domains: psychological

science, cognitive neuroscience, behavioural genetics, and clinical research. Their work impacts the development of addiction interventions as well as public policy.

Since the pandemic began, researchers at the PBCAR have paid close attention to its impacts on mental health and addiction.

“The most troubling impact of the pandemic is the spike in opioid overdose deaths. This is because public health measures like physical distancing and quarantining lead to social isolation and solitary drug use,” explains Dr. James MacKillop, Director of the PBCAR and Professor in the Department of Psychology and Behavioural Neurosciences at McMaster University. “Using alone is a major risk factor for overdose because the rescue medication naloxone can’t be used. Unfortunately, what’s happening is that the existing problem with highly toxic opioids being present in the drug supply is being significantly exacerbated by the pandemic.”

Researchers at the PBCAR have been busy developing and adapting studies to incorporate the effects of COVID-19 across

a broad range of addictions. For example, prior to the pandemic Dr. MacKillop began conducting a longitudinal study called PATH Cann, which aims to characterize patterns of change in a number of different areas over the course of cannabis legalization. In June 2020, the PATH Cann team was awarded over \$400,000 from the Canadian Institutes of Health Research to expand the study, allowing supplementary data collection related to the impacts of COVID-19. Researchers have recently completed their third follow-up as part of this study, which will help them develop pandemic-related insights.

“It is critical that we systematically examine pandemic impacts on

substance use because so much of what we are hearing is based on anecdote,” says Dr. MacKillop.

It has been nearly a year since Ontario was first hit by the coronavirus pandemic, and individuals across the board have been affected to varying degrees, both mentally and physically. Surprisingly, some aspects of the pandemic and accompanying social restrictions have had unexpected effects on some populations typically affected by addictive substances.

“One of the things we are learning in Peter Boris Centre studies is that not all news is bad,” adds Dr. MacKillop. “Although it is certainly the case that some

people are increasing their alcohol or cannabis use, in other cases, such as in heavy drinking young adults, levels are going down. In addition, among people in recovery, we are also seeing reports of stories of resilience and unanticipated coping strategies.”

The complex social aspects that are intertwined with addiction have become even more enigmatic as the constantly evolving pandemic continues to run its course. Fortunately, researchers at the PBCAR are expediting their work – identifying risk factors and effective coping strategies with the goal of helping patients weather the challenges of the pandemic as successfully as possible.

Researchers at the PBCAR are helping to understand the effects of the COVID-19 pandemic in relation to addiction



A Year in Numbers

Facts and Figures about Research in 2020

213 Total Number of Researchers

774 Research Staff & Learners



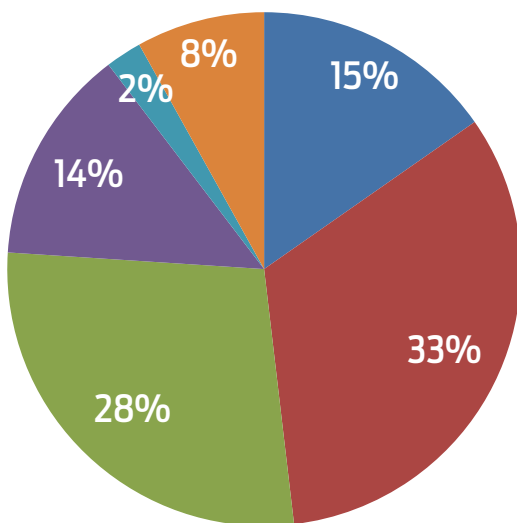
4,059 ft²
Wet Lab Space Added in 2019

135

New Clinical Research Projects Started

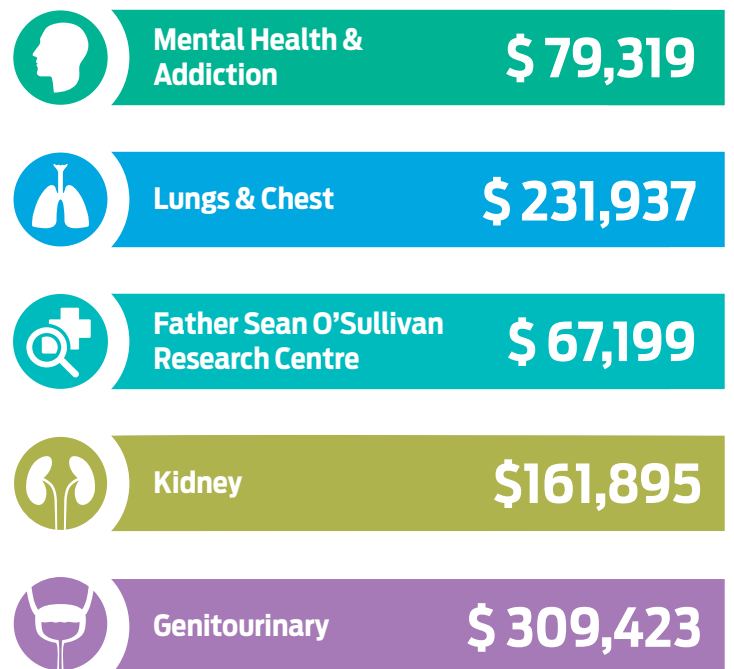
77,040 ft²
Total Dedicated Research Space

Funding Source by %



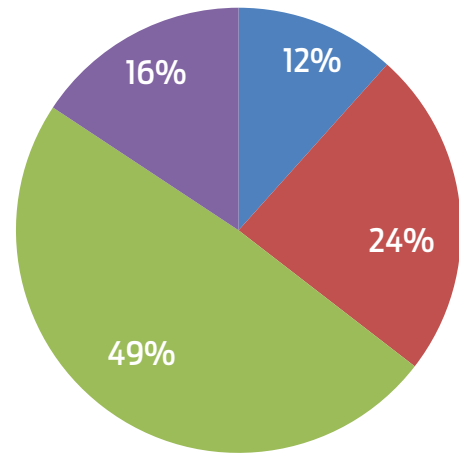
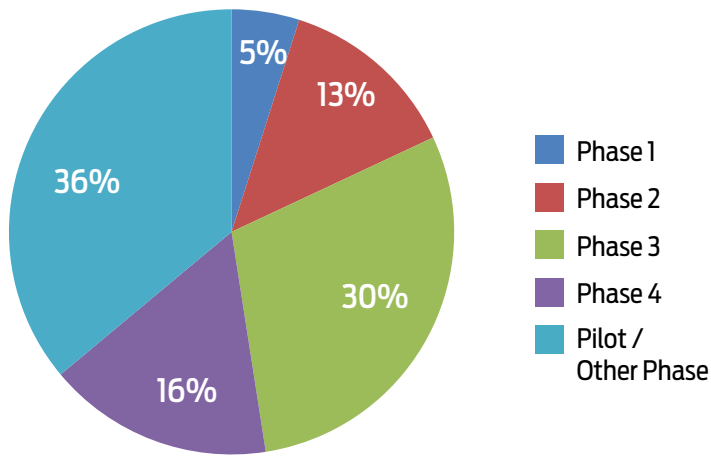
■ Corporate ■ Not for Profit
■ Federal ■ Provincial
■ Internal ■ Regional

Average Research Funding per Investigator by Program



61 New Clinical Trials

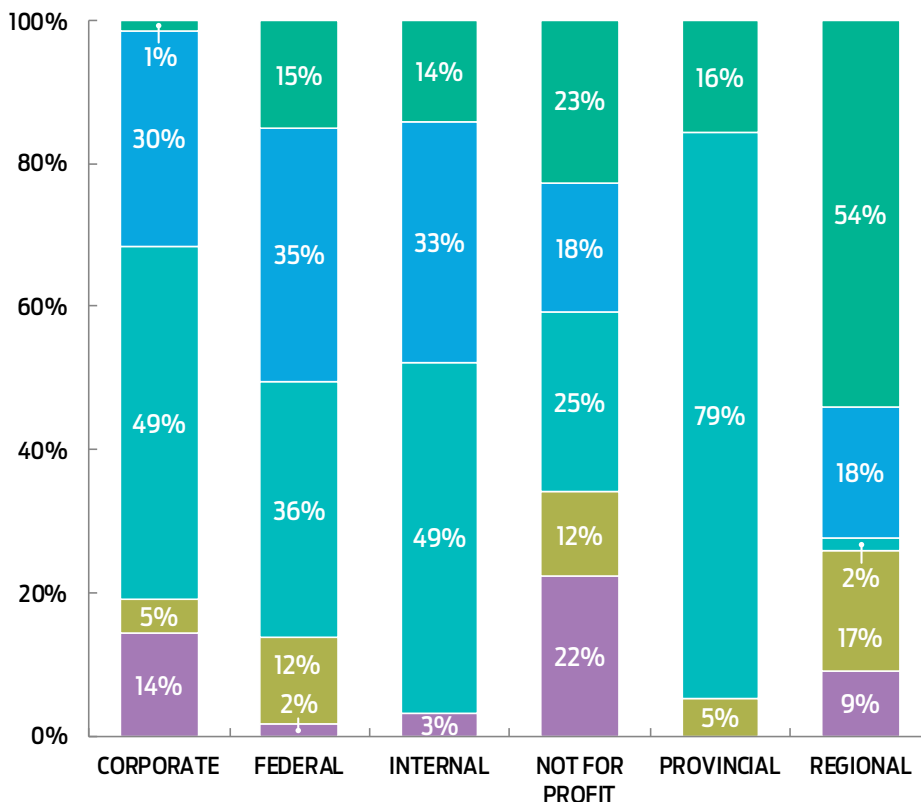
172 Ongoing Clinical Trials



Total Funding

\$27,941,569

Funding Source by % per Program



7

Events

(in-person & online)



1104

Publications





Mood Disorders: Curbing the early burden of disability

Mental Health & Addiction

The 2015 Global Burden of Disease Study revealed a startling statistic: depressive disorders and anxiety disorders are, respectively, the third and ninth leading causes of disability worldwide. In fact, mental illness accounts for one third of all years lived with disability – a staggering toll on the quality of life of so many individuals.

There are also economic impacts of mental illness, which include the direct costs associated with the health care system as well as the indirect economic costs related to loss of productivity and disability support services. In Canada, this represents an annual economic burden of approximately \$50 billion.

Dr. Benicio Frey is an associate professor in the Department of Psychiatry and Behavioural Neurosciences at McMaster University. At St. Joe's, Dr. Frey is the academic head of the Mood Disorders clinic and medical director of the Women's Health Concerns clinic. His research focuses on the neurobiological mechanisms involved in bipolar

disorder and major depressive disorder, with an emphasis on women's mental health.

To better understand the trajectory towards disability for those living with mental illness, Dr. Frey and his team conducted an analysis on a massive cohort study of Ontario residents. The study examined the time between the first diagnosis of a mental disorder and the receipt of disability services. Entry into the Ontario Disability Support Program (ODSP) and admission to a Long-Term Care (LTC) facility were used as indicators of disability.

The study consisted of nearly 300,000 participants with and without mood disorders, such as major depressive disorder and bipolar disorder, as well as over 1.6 million participants with and without common mental disorders, such as anxiety. A balanced ratio of participants with and without a diagnosed mental disorder was used.

In October 2020, the team's findings were published in *JAMA Network Open*.

Dr. Frey and his team found a significant elevated risk of receipt of disability services early in the course of illness. The study also showed that individuals with bipolar disorders had the greatest ODSP utilization rates.

“This study really reinforces the case for further investment into the early stages of mental health care,” says Dr. Frey. “We know that early intervention strategies achieve better long-term outcomes among individuals with mood disorders. These results demonstrate the added importance of effective, early intervention from an economic point of view.”

Prior to the study, policy makers lacked a large, population-based study to ground their efforts towards increasing and improving access to early interventions in mental health treatment. Dr. Frey and his colleagues believe that better institutional supports to address acute mental health challenges will ultimately lead to a lower long-term economic burden of disability support programs, such as ODSP, since

the number of patients on the trajectory towards disability would be reduced.

“With effective early interventions, we can ‘flatten the curve’ of the disabilities caused by mental illness and improve the quality of life for so many individuals experiencing mental health challenges, while also reducing the long-term economic burdens caused by these diseases – that’s a win-win scenario.”

In 2020, Dr. Frey received the title of University Scholar at McMaster, an honour granted to those who have distinguished themselves as international scholars and have demonstrated a commitment to discovery, communication and preservation of knowledge, excellence in education and pedagogy, and service to local and global communities.



Psychiatry &
Behavioural
Neurosciences

Dr. Benicio Frey and his team are pushing for greater access to early mental health interventions





Taking aim at cystic fibrosis

Lungs & Chest

In Canada, cystic fibrosis (CF) is the most common fatal genetic disease affecting children and young adults. An estimated 1 in every 3,600 children born in Canada are affected by CF.

Cystic fibrosis affects multiple systems throughout the body, though symptoms manifest primarily within the digestive and respiratory systems. Mutations of the CFTR gene affect fluid transport in the lungs, resulting in complications that include increased mucus viscosity, susceptibility to pathogens, and changes to lung immunity. As a result, individuals with CF experience respiratory symptoms that include persistent cough, wheezing, shortness of breath, and frequent chest infections including pneumonia.

Though research has helped many individuals with CF live longer by managing their symptoms more effectively, there remains no cure and the efficacy of available treatments varies greatly between individuals. In addition, parents who care for children affected by CF may suffer from symptoms

of depression and anxiety, as caregivers can sometimes lose focus on their own mental health needs.

Jenny Nguyen is a graduate student at McMaster University, studying cell biology and the molecular mechanisms of cystic fibrosis. She is working towards a doctorate under the supervision of Dr. Jeremy Hirota, who holds the Canada Research Chair in Respiratory Mucosal Immunology, and is co-founder and CEO of Infinotype, a start-up biotechnology company focused on lung diagnostics. Dr Hirota is also Chair of the College of Health Inventors at McMaster University, which advocates for bringing university research to the marketplace for maximal social and economic benefits.

“With the specialized equipment necessary to grow and culture primary cells from healthy and CF donors, Dr. Hirota’s Lab provides me with all the necessary resources. It’s also the perfect environment for me to pursue my research and learn how to bring it to market,” says Nguyen. “This research will not only improve

the current limited therapeutics for CF but could have potential applications for other lung diseases that are affected by acquired CFTR dysfunction.”

The Hirota laboratory at St. Joseph’s Healthcare Hamilton is uniquely poised to facilitate Nguyen’s research. With access to quantitative PCR and western blot equipment, as well as the ability to culture primary cells, Dr. Hirota’s graduate students have the tools they need to pursue their novel research projects. In addition, the lab’s ongoing collaboration with The Hospital for Sick Children (SickKids) offers Nguyen access to donors, providing the lab with human airway epithelial cells from both healthy individuals and patients with CF, which is critical to her work.

The development of single drug therapeutics that directly target CFTR function has led to the ability to treat a larger CF patient population. However, with over 2000 known mutations to the CFTR gene, some patients remain unresponsive to this type of therapy. This led Nguyen

to look for alternative drug pathways. Instead of targeting CFTR directly, she is working on an alternative strategy that targets an intracellular messenger molecule called cAMP as well as other proteins.

Nguyen's hypothesis is based on prior work with these proteins from the Hirota lab. She will use highly specialized equipment to grow cell cultures from a variety of CF donor cells. From there, she will identify samples with high expression levels of three specific proteins and genes involved in

CFTR activity. The samples will be tested with a combination of protein inhibitors to observe any effects on CFTR activity, and to determine the optimal dosage of these inhibitors.

Nguyen also sees potential for her research to be applied beyond cystic fibrosis. For instance, her work may benefit non-CF patients with COPD who have acquired CFTR dysfunction through smoking.

"It's crucial that we cultivate our young scientists with the skills they

need to conduct groundbreaking independent research, while also encouraging their creativity," says Dr. Hirota. "We don't want our students to be pigeonholed to one specific problem, when their work may have broader impacts in other areas as well. Encouraging imaginative thinking is a priority."

The work of Jenny Nguyen and the Hirota lab is just one example of many that demonstrate how St. Joe's researchers are educating the world's best.

Jenny Nguyen prepares to conduct an experiment in the Hirota Lab at St. Joe's





RoboKnees: Using motion capture technology to optimize partial knee arthroplasty

Father Sean O'Sullivan Research Centre

As osteoarthritis of the knee progresses, patients frequently experience pain when walking, running, bending over, and kneeling. Joint stiffness, particularly in the morning, is also common. If left untreated, further wear on knee cartilage will lead to increased pain.

Total knee arthroplasty (TKA) is the second most common surgical procedure performed in Canada. Commonly known as knee replacement surgery, this procedure is used to treat patients suffering from end-stage knee osteoarthritis. TKA can successfully restore much of a patient's lost knee function, depending on their level of physical activity.

However, no artificial replacement can yet replicate the fidelity of a natural knee. Since TKA procedures affect the entire knee, all three compartments – medial, lateral, and patellofemoral – are replaced whether or not they are all compromised. Any healthy areas of the knee are sacrificed during a TKA procedure and replaced entirely by an artificial knee implant. Ultimately, the way the knee moves when walking or bending will be affected.

Researchers are exploring novel alternatives to TKA. This includes unicompartmental knee arthroplasty (UKA) and bicompartmental knee arthroplasty (BiKA) – both of which are partial knee replacement procedures affecting one or two compartments, respectively. These partial replacements are much more technically challenging compared to a total replacement, necessitating the use of robotic surgery.

For years, St. Joseph's Healthcare Hamilton has been a leader in the use of surgical robotics, with a focus on genitourinary and thoracic cancers. In January 2019, St. Joe's orthopedic surgeons performed Canada's first robot-assisted knee replacement surgery, using the state-of-the-art Mako RIO surgical platform. Our Hospital was the first in Canada to acquire the Mako RIO platform, thanks to donations from our community.

"The robot allows surgeons to place implants with extreme precision," says Dr. Kim Madden, an orthopedic researcher at St. Joe's and assistant professor in the Department of Surgery at McMaster University,

whose research is focused on osteoarthritis, orthopedic surgery, and biomedical aspects of human health. "We believe this technology could enable us to save healthy knee compartments rather than replace the whole knee, leading to improved outcomes for our patients."

To determine whether robotic surgery for knee and hip procedures is superior to conventional techniques, a team of St. Joe's orthopedic researchers, including Dr. Madden, are conducting a major study with the Mako RIO. The team will consider a number of factors, including function, recovery time, patient satisfaction, surgical time, complications, implant survival, and cost-effectiveness.

Complementing this work, Dr. Madden is leading a study called RoboKnees that will assess the efficacy of both UKA and BiKA partial knee replacement procedures. To achieve this, she is working with Dr. Janie Wilson, a professor in the Department of Surgery and an Integrated Biomedical Engineering & Health Sciences instructor at McMaster University.

Drs. Wilson and Madden have built a new biomechanics laboratory at St. Joe's that uses industry-grade cameras combined with motion capture technology. It will allow researchers like Dr. Madden and her team to analyze the walking patterns, or gait, of patients before and after knee replacement procedures. The technology will enable researchers to accurately assess the biomechanical changes caused by each procedure and help to optimize implants used in future surgeries.

"If we are able to demonstrate better outcomes with partial knee

arthroplasty, up to 40 percent of our current total replacement procedures could meet the requirements for a partial replacement instead," says Dr. Anthony Adili, Chief of Surgery at St. Joe's and the first surgeon to perform an orthopedic robotic knee replacement in Canada, which was done on the Mako RIO platform.

The research is being supported by several awards and groups, including the Constantine Douketis New Researcher Award, the Canadian Institutes of Health Research (CIHR), and the Hamilton Academic

Health Sciences Organization (HAHSO).

"Our goals for this study are to optimize partial knee replacement surgery and position our Hospital as a teaching centre for this new robotic platform," says Dr. Madden.

The new biomechanics laboratory will help St. Joe's researchers develop innovative procedures as well as offer further opportunities to use motion capture technology in future studies on hip, knee, and shoulder disorders. The possibilities are vast.

Dr. Madden (left), Dr. Adili (middle) and Dr. Wilson (right) inspect and test the new motion capture equipment





An HIV Game-Changer: Expanding access to PrEP

Father Sean O'Sullivan Research Centre

Since the early, unpredictable days of the HIV/AIDS pandemic, effective treatments, knowledge, and attitudes towards the virus and those suffering from it have come a long way. When taken regularly, modern medicines can effectively reduce an HIV infection to undetectable levels, and recent studies have shown that individuals who maintain an undetectable viral load cannot infect others.

Effective management of HIV is not all that has changed. The development of pre-exposure prophylaxis (PrEP) has been described as a game-changer. PrEP is a medication that, when taken daily, can prevent HIV infection if an exposure occurs. In fact, a 2020 report showed that new HIV infections among high-risk groups were at a 20-year low, due in part to the increasing use of PrEP.

Dr. Kevin Woodward is an infectious diseases physician and researcher at St. Joe's, specializing in the prevention and treatment

of sexually transmitted infections, including HIV. Since 2013, Dr. Woodward has been prescribing PrEP for HIV prevention at the Hamilton PrEP Clinic, which accepts physician- and self-referrals for at-risk individuals.

Access to PrEP can be lifesaving, but unfortunately Ontario lacks the clinical capacity it needs to prescribe it across the entire province. Many patients in Ontario can't access PrEP outside of large cities like Hamilton, Toronto, and Ottawa. To expand access to PrEP and ultimately reduce new HIV infections in Ontario, Dr. Woodward is focusing on three key areas: clinical implementation, research, and education.

Locally, Dr. Woodward has been working with clinicians to expand referral opportunities. This includes intercepting patients during hospital stays related to intravenous drug use, since shared needles can be a vector for HIV transmission. His clinic's efforts have also inspired change at Hamilton Public Health, where

PrEP referrals are now offered to at-risk patients.

Extensive research has been conducted on the efficacy and safety of PrEP. Dr. Woodward and his colleagues are now focusing their research on implementation and logistics, prioritizing studies on how to best train primary care physicians to prescribe and manage PrEP.

“Our current challenge is to get more primary care physicians comfortable in prescribing PrEP and managing the follow-up,” says Dr. Woodward. “Physicians need to be prepared to schedule regular testing for their patients every 3 months as well as develop a level of comfort in diagnosing and treating STIs.”

Health Canada's PrEP guidelines recommend testing every 3 months for HIV and other sexually transmitted infections, as well as testing for kidney function. The most widely available iteration of PrEP (due to its availability as a generic drug) can have a minor effect on the kidneys. Fortunately,

the latest form PrEP, sold as Descovy®, appears to have fewer kidney-related side effects and has just been approved by Health Canada. Regular blood tests can help physicians track any changes in kidney function.

To further drive change and increase clinicians' knowledge of PrEP, Dr. Woodward has been travelling across Ontario to various community health centres, offering PrEP education talks focused on primary care providers. Part of the larger strategy also

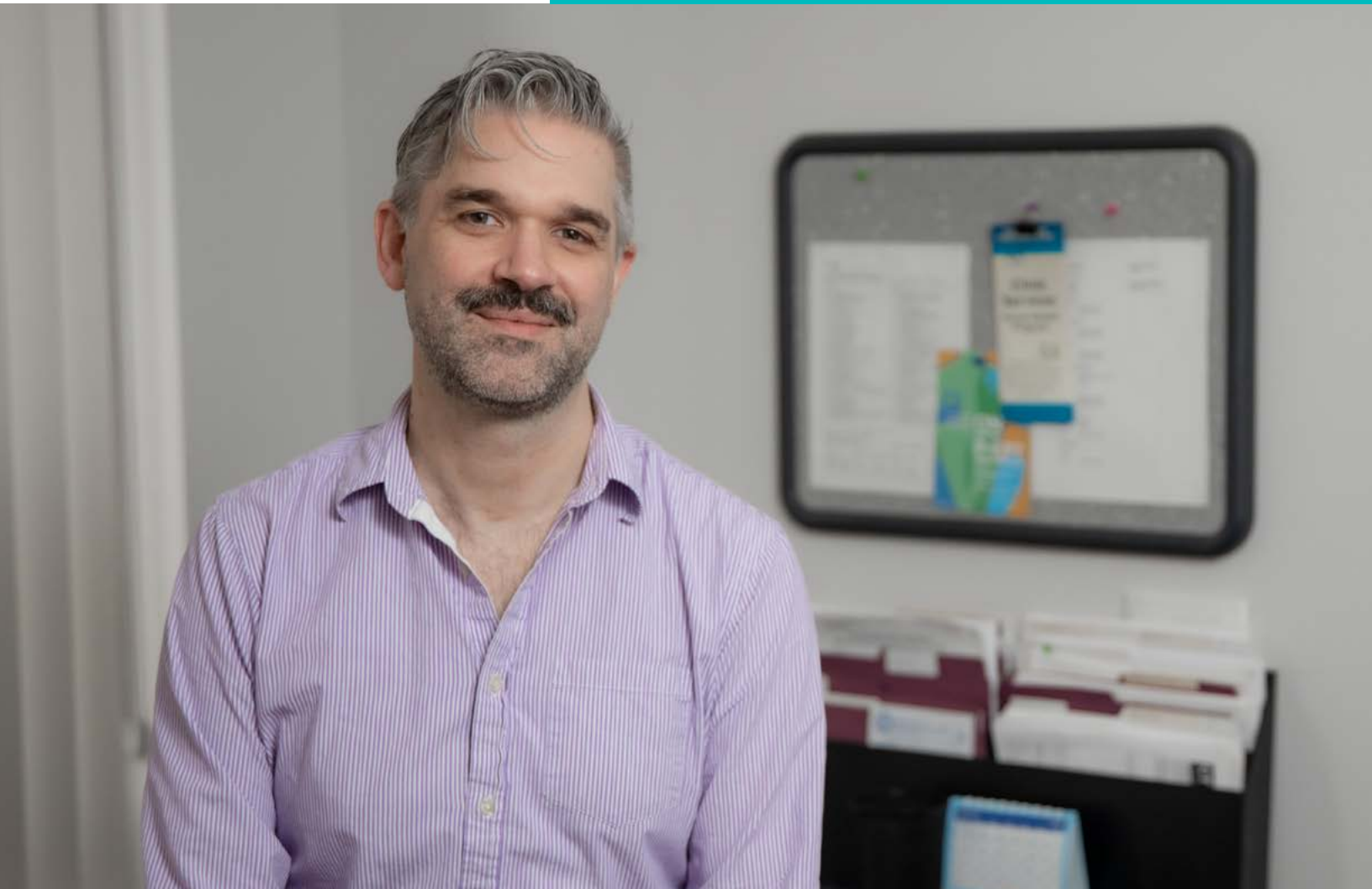
includes understanding missed opportunities for discussing PrEP with patients. For example, at-risk patients who have been newly diagnosed with a bacterial STI by their primary care physician would benefit by learning how PrEP can help reduce their risk of HIV infection. With the challenges of COVID-19, these educational sessions have moved online for 2020.

Collectively, these efforts aim to eliminate the inequities that are preventing many Ontarians from

accessing this powerful tool in the fight against the HIV/AIDS pandemic.

“Where you live shouldn't negatively affect the health care services you receive,” says Dr. Woodward. “Right now, expanding the use of PrEP is the most effective strategy we have to prevent new HIV infections.”

Dr. Kevin Woodward specializes in the management of infectious diseases



Events

Making the Virtual Transition

In March 2020, the pandemic changed almost every facet of our lives. As researchers and staff transitioned to working from home, in-person meetings became virtual sessions and live events everywhere were cancelled. Physical distancing protocols, which are crucial in reducing the spread of the virus, meant that event gatherings had to be put on hold.

Many among us were now using virtual platforms that we had previously never heard of, such as Zoom or Microsoft Teams. The transition to virtual work was not without its hiccups – “you’re on mute” was dubbed the 2020 Phrase of the Year by several online news outlets.

As the pandemic progressed, The Research Institute managed to transition many of our events to virtual platforms. For instance, the popular Coordinators CONNECT! moved to Zoom, where topics such as remote monitoring

and virtual research visits were discussed.

Throughout the month of October, The Research Institute held a series of online events and a social media campaign in recognition of Research Month. It began with our largest event of the year, Celebrate Research, which went ahead as an online ceremony that premiered live

hosted virtually in 2020. Judging was completed online and the announcement of the winners occurred during the live premiere of Celebrate Research.

The winner of the Anne & Neil McArthur Research Award traditionally gives an academic presentation. Typically, this occurs at our Celebrate Research event. However, this year’s winner, Dr. Lehana Thabane, was given the opportunity to present in a separate, dedicated presentation held via Zoom. This allowed for greater audience engagement.

Though we look forward to the time when we can once again meet in person, we are finding success in online events, seminars, and virtual conferences.

Necessity is the mother of invention, and the pandemic has certainly created an explosion of new ideas in the realm of virtual events. We plan to incorporate some of our virtual successes into future in-person events when it is once again safe to do so.



via YouTube. Many tuned in to watch the live stream, engaging in the audience chat to congratulate each other on their successes. Our student poster competition, which for years has been held during Celebrate Research, was

We transitioned our popular Coordinators CONNECT! event to an online format with great success, and may continue this online model, or a hybrid in-person and online model, after the pandemic has ended.



Access Research

An Innovative, Equitable Approach to Research Study Recruitment

Access Research is a process that allows researchers to request basic patient contact information in order to reach out to patients who may be eligible for participation in a research study. Similar systems have been put in place by other hospitals in Ontario, including CAMH, Holland-Bloorview, as well as Baycrest, with overwhelming success.

Thanks to the implementation of an electronic medical record system – Dovetale – St. Joe's is

able to deliver a similar system for research contact called Access Research.



Access Research empowers patients with the knowledge of research participation opportunities in groundbreaking

studies at St. Joe's. The program increases equitable access to research and offers patients a way to support local research that can have a global impact.

Access Research represents the future of equitable and efficient study recruitment at St. Joseph's Healthcare Hamilton.

With over 10,000 annual patient visits, and an average of 150 participants per study, Access Research will benefit patients and researchers alike.





New guidelines to treat ANCA-associated vasculitis

Kidney

Research teams often strive to include as many participants in their studies as possible, since larger sample sizes can offer more reliable results. But clinical trial recruitment is never an easy task – and it becomes even more challenging when a study involves a rare disease. To increase enrolment, researchers must leverage large international networks as well as conduct their studies over longer periods of time.

St. Joseph's Healthcare Hamilton is home to several researchers who have led or are currently leading large international trials, including Dr. Michael Walsh, a nephrologist and researcher. In 2020, Dr. Walsh and his team published the results of a major international study that was years in the making.

The findings of the PEXIVAS study (“Plasma Exchange and Glucocorticoids for Treatment of Anti-Neutrophil Cytoplasm Antibody [ANCA]-Associated Vasculitis”) were published in the *New England Journal of Medicine* in February 2020. It was largest clinical trial ever conducted for

this type of vasculitis, and the first to test two treatments at the same time. PEXIVAS has provided physicians around the globe with crucial guidelines needed to treat this disease.

ANCA-associated vasculitis is considered to be on the more common end of the rare disease spectrum, which still presents challenges for study recruitment. Ultimately, the St. Joe's team engaged with 94 other recruitment centres across 16 countries in order to increase its participant enrolment. Remarkably, almost 10 percent of the study participants were enrolled from St. Joe's – a testament to the incredible effort of the study team of Dr. Walsh, Dr. Nader Khalidi, and Andrea Mazzetti.

One of those participants is Tom Salisbury. Before participating in the PEXIVAS study, Tom was a 54-year-old firefighter who developed joint pain and a lingering cold. His family grew concerned when he began to cough up blood, and he soon found himself in St. Joe's emergency care. There, Dr. Khalidi diagnosed Tom with this rare

disease and he immediately began immunosuppressant therapy.

Steroids like prednisone are used to treat vasculitis by suppressing the immune system and reducing inflammation, but they also put patients at higher risk of acquiring opportunistic infections. The PEXIVAS study examined two types of vasculitis treatments: plasma exchange and steroids. Though steroids were already known for their ability to slow the progression of the disease, the ideal dosage to balance infection risk was a mystery prior to this study.

Days after he was first admitted, Tom was introduced to Dr. Walsh, who asked if he would like to participate in the PEXIVAS study. Tom was fortunate not to develop a serious infection during his treatment.

“Infection is the most common cause of death associated with this kind of vasculitis disease, with one in three patients ending up in the hospital with a serious infection within their first year of treatment,” says Dr. Walsh. “Our study found that lower

doses of steroids are as effective as higher doses in controlling the disease, while at the same time significantly reducing the risk of serious infections for patients.”

Findings from PEXIVAS proved that the steroid dose can be reduced gradually, reducing the likelihood of developing an opportunistic infection while properly addressing the inflammation caused by vasculitis. In addition, the study found that plasma exchange did not reduce the incidence of death or end-stage kidney disease.

Funding for the study was provided by the Canadian Institutes of Health Research, the National Institute of Health Research (UK), the Food and Drug Administration (US), the National Health and Medical Research Council of Australia, Assistance Publique (France), and the Agency for Medical Research and Development (Japan).

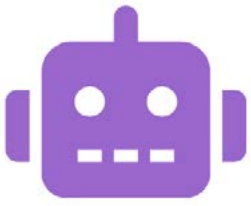
By playing a leading role in large international studies, St. Joe’s researchers are giving hope to those suffering from rare and complex diseases – in Hamilton and around the world.

“I was so captivated by the type of life-changing research going on at St. Joe’s, I jumped at the chance to work with Dr. Walsh on studies like the one that helped save my dad’s life.”

– Maddie Salisbury,
Research Coordinator

Dr. Walsh (right) discusses the PEXIVAS findings with Maddie and Tom Salisbury





Robotic surgery and the case for public funding

Genitourinary

Prostate cancer is the most common non-skin cancer and the third-leading cause of cancer-related death among Canadian men. Over 20,000 Canadians are diagnosed annually with prostate cancer, many of whom will need a prostatectomy during the course of their treatment.

Robot-assisted technology used in prostate cancer surgery has become a global standard, with 82 percent of prostatectomies performed worldwide in 2017 using this technology. However, in stark contrast with the global statistic, only 27 percent of prostatectomies performed in Canada in that same year were robot-assisted, since many provinces do not fund this technology. The crux of the issue comes down to its perceived cost-effectiveness, but new research is providing a more complete understanding of the financial side of this innovative technology.

“St. Joe’s urologic surgeons prefer to use robot-assisted technology for radical prostatectomies and some other complex procedures that can be performed robotically,” says Dr. Jen Hoogenes, a

genitourinary research fellow at St. Joe’s Urologic Cancer Centre for Research & Innovation (UCCRI). “This technology can result in safer outcomes, faster recovery times, and a lower risk of adverse events such as infection, urinary incontinence, and erectile dysfunction. Robot-assisted surgery also greatly reduces surgeon fatigue during the procedure.”

Generous donations from our community have helped St. Joseph’s Healthcare Foundation to provide funding for three robotic platforms – the da Vinci Si and its Xi successor, as well as the Mako RIO. While the new robot has arrived, St. Joe’s continues to raise funds for specialized instruments required for each surgery. Philanthropic donations and funding from the Hospital have helped to cover the costs of over 400 robotic-assisted surgeries each year, in addition to paying for the cost of purchasing and maintaining the robotic systems.

Robotic procedures performed through the Boris Family Centre for Robotic Surgery at St. Joe’s include urologic, thoracic,

orthopedic, and other surgeries. With public funding, the program could be further expanded while also reducing the cost of each procedure, since robot-assisted surgery benefits massively from economies of scale.

Health care equity is another key issue to consider. Those living in the Hamilton region and in need of a prostatectomy benefit from St. Joe’s ability to provide this innovative technology, whereas patients in other parts of the province may not have access to robotic technology at their local hospitals.

The alternative to a robot-assisted prostatectomy – open prostatectomy – is an older technique that is used far less commonly today in the health systems of developed nations due to higher instances of adverse events. Currently, the Ontario government will only fund open surgeries, despite widespread adoption of robotic technology in other jurisdictions. For instance, the Alberta government recently began to fund this procedure after it concluded that it would be cost-effective.

In 2017, the procedure was first considered for coverage by Health Quality Ontario, which assesses the costs and benefits of new health treatments and technologies. However, the results of its Health Technology Assessment (HTA) led to the recommendation against funding robotic technology in the province.

Yet findings from a 2020 study conducted by St. Joe's researchers are once again making the case for public funding in Ontario. The study, published in the *Canadian Urological Association Journal*, found that robot-assisted radical prostatectomy could be cost-effective, aligning with findings

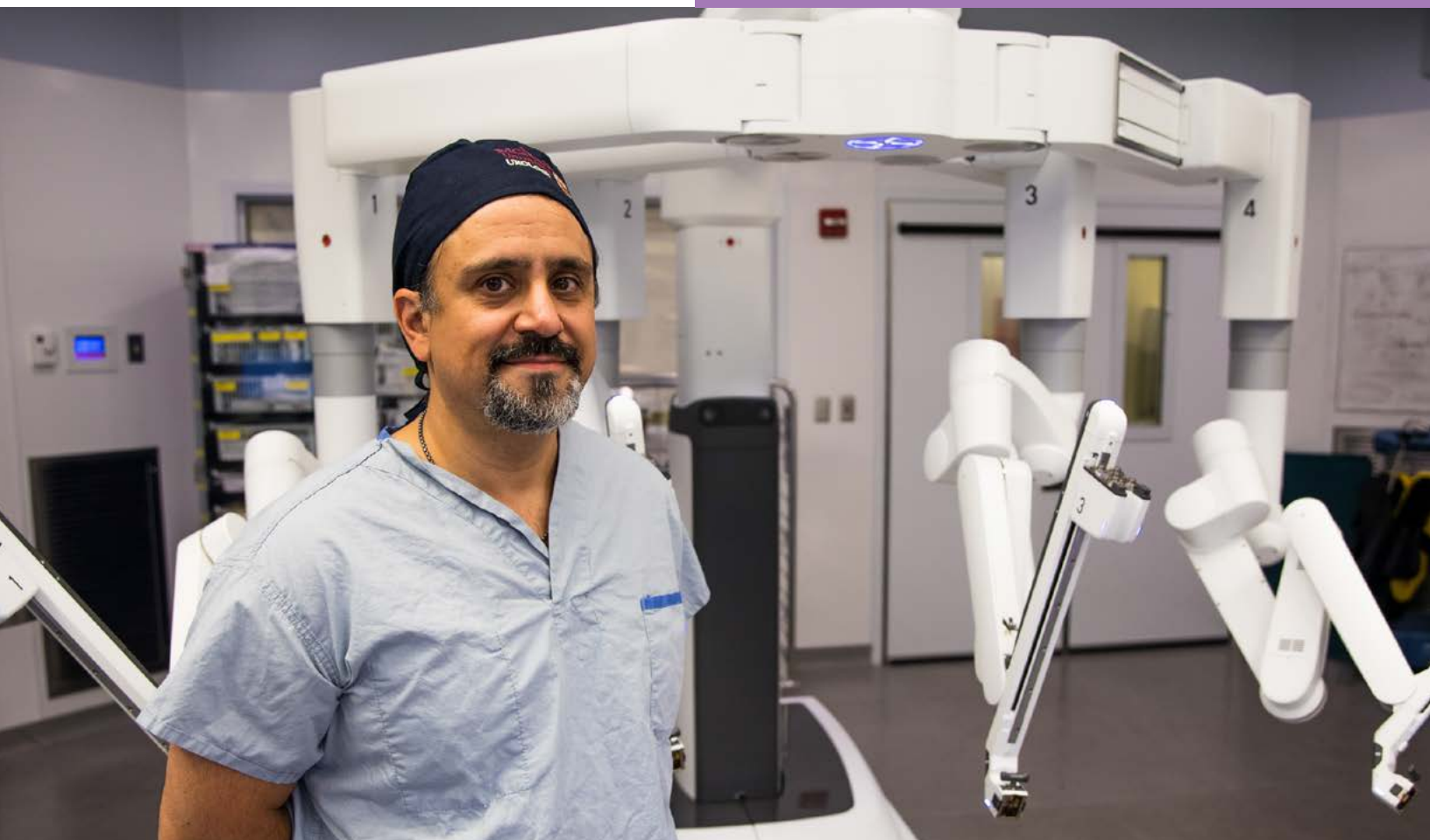
from the Alberta government and many other jurisdictions around the world.

The two-part study, led by St. Joe's surgeon Dr. Bobby Shayegan, re-analyzed Health Quality Ontario's HTA and performed its own in-depth analysis. Using a comprehensive dataset that included multiple randomized controlled trials, more precise estimates of annual patient volume, and a realistic 10-year time horizon (i.e., lifespan) for the robotic surgery system, St. Joe's researchers found that the cost per procedure would be over 100 times smaller than the Ontario government had previously determined.

"We believe our findings offer a much more precise, real-world analysis of the cost-effectiveness of robot-assisted radical prostatectomy," explains Dr. Hoogenes, who is also a co-author of the study. "We're hoping the Ontario government will see this as an indication to revisit funding for these innovative robotic surgical systems."

For now, St. Joseph's Healthcare Foundation continues to raise funds for robotic surgery, allowing our Hospital to continue to provide this innovative technology to our community.

Dr. Shayegan stands with the new da Vinci Xi surgical robot





NEW Discoveries & NEW Hope, Made Possible by You.

Last year, our Foundation granted \$2.6 million to the **Research Institute of St. Joe's Hamilton** to help fund numerous studies and clinical trials currently underway. From asthma to schizophrenia, addictions to robotic surgery, microbiology to palliative care, and so much more; **your gift helps our researchers** make new discoveries – so they can give our patients new hope.

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