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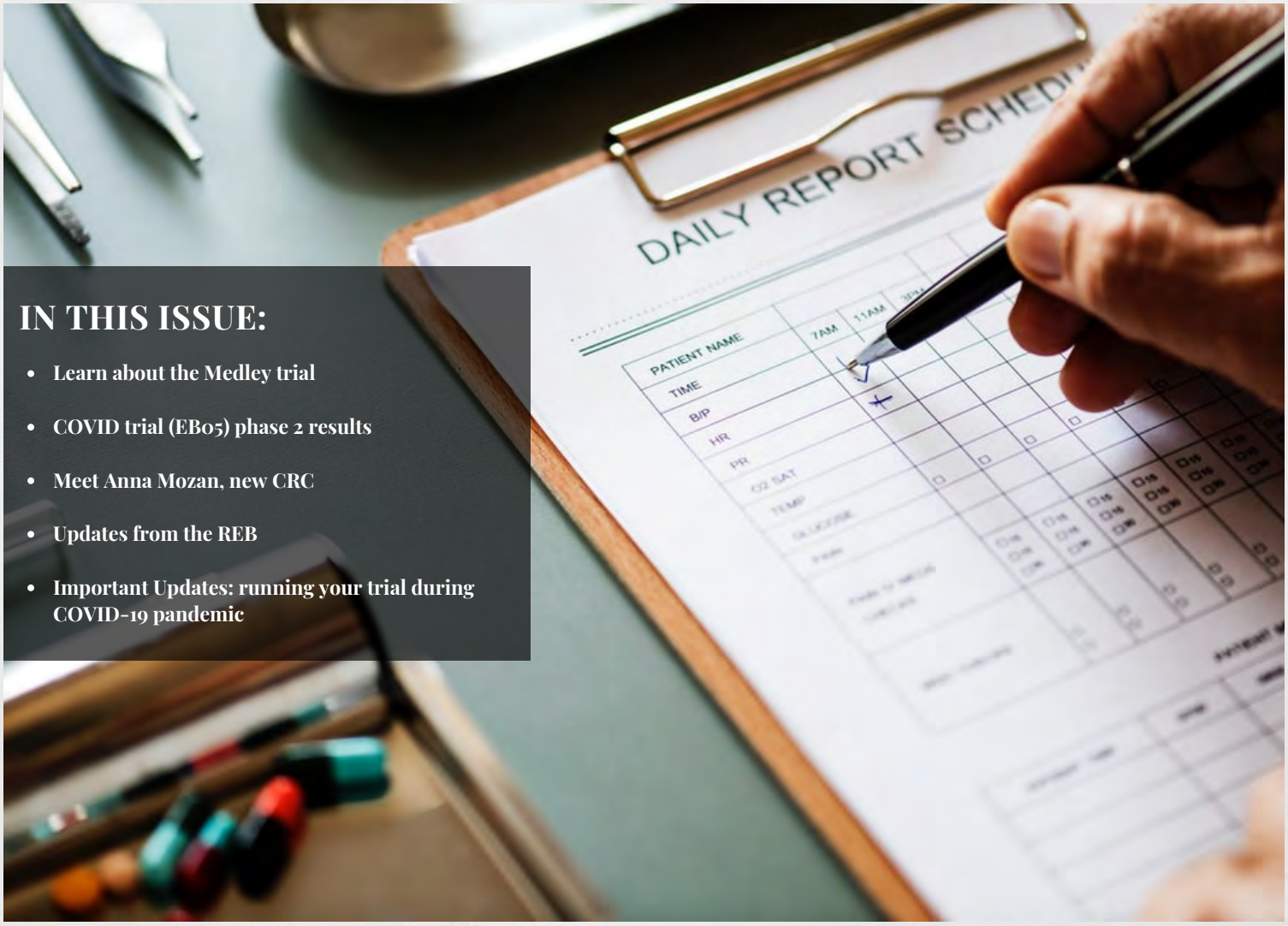
QUARTERLY RESEARCH NEWS

THE OFFICIAL NEWSLETTER OF THE OFFICE OF RESEARCH



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UPDATES FROM THE OFFICE OF RESEARCH

BY MICHELLE DIMAS, MANAGER OF RESEARCH

As we embark on a new year, the Office of Research would like to obtain your feedback on our research program, how we can improve and what we are doing that works.

We invite all staff, physicians and volunteers to help make the Oak Valley Health research program the best it can be! We kindly ask that you provide your feedback by completing a short online survey accessed online here.

Our goal for the upcoming year is to continue improving our research program by building on trial education and awareness among staff, volunteers and the research community.

During the COVID-19 pandemic we have modified some procedures to ensure limited face-to-face interactions with patients and staff. We encourage staff, volunteers and the research community to remain up-to-date on research practices by following the Research blog on acorn. Please review our latest post on research activities during the 5th wave.

PATIENT EXPERIENCE IN A CLINICAL TRIAL

SURVIVOR TO THRIVER, BY REVEREND KAREN HAMMOND CROXALL

We have an expression in Newfoundland where I was born, it is: "oh, me nerves!". I was diagnosed with Her 2 positive breast cancer on February 14th, 2019. I will never forget that day. I cried and my husband almost fainted as the Doctor shared the news. We still went out for our Valentine's Day dinner. People were laughing and talking around us and we sat there in shock. I assumed I was going to die and even started thinking about writing my funeral service. Well that is depressing!

I went through surgery, chemotherapy, and radiation. All the horror stories I had been told were wrong. Yes, there are side effects to cope with, but medicine is so advanced now, you don't have to put up with suffering. I was tired and it is lonely at 3am when you are in the bathroom. It was difficult to accept that I had cancer. Didn't that happen to other people? One horrid day in chemo I had a drug reaction, witnessed by my adult children. It was very painful. I feel terrible still that two of my kids were there. Please take the medication exactly how you are advised. Cancer is hard on your whole family and friends.

I was pleasantly surprised who the supportive friends were, and saddened that ones I thought would be around were not. You know, not everyone can cope with your diagnosis for many reasons, be kind.

Along with my husband Rob, and kids David, Ryan and Olivia, my Doctors, nurses, radiation therapists, social workers, colleagues and volunteers were very supportive! I love my Doctors and nurses! They are the most hard-working and compassionate people I know. My husband, kids, and a few friends came to treatment with me. My Church friends arranged meals, and little fun packages for me to open. At the hospital my daughter and I were given little gifts from a volunteer. Other supports were art classes by amazing social workers. I would advise you to speak to someone who isn't a family member or friend, it really helps. I didn't get to do the Look Good, Feel Better program but would like to. Getting used to the bald version of me was hard. It took awhile to realize I was still me.

At first I was reluctant to participate in a research trial. I'm glad I said yes and encourage you to do so. The team is amazing! I am monitored closely and I feel so good about being part of something to help myself and others. When you have rung the bell, there is life and happy times again, I promise! I work part-time, volunteer, and enjoy my hobbies. Our cats Nala and Cicu are also wonderful therapy. Eat well, (with the odd treat) and stay fit. If you think about dying, you miss out on living. Don't let anyone tell you how to think or feel. With love, I'm cheering you on!

CLINICAL TRIAL SPOTLIGHT

<u>Medley Study:</u> Nurse-led Integrated Care of Complex Patients Facilitated by Telemonitoring: Implementation and Effectiveness

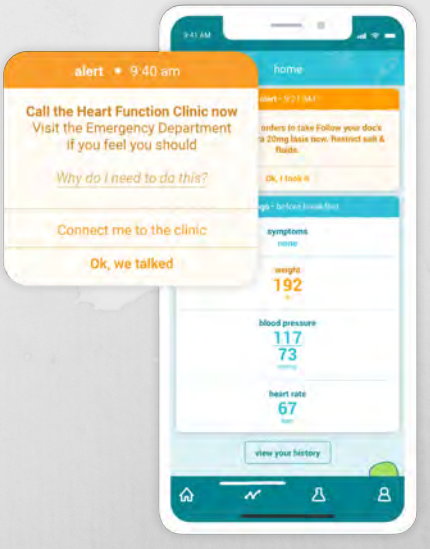
Nurse-led Integrated Care of Complex Patients Facilitated by Telemonitoring: Implementation and Effectiveness

Caring for complex patients who usually have multiple chronic conditions (MCC) is one of the biggest challenges facing our healthcare system. For patients, the lack of coordination and continuity of care as they transfer between healthcare settings and healthcare providers (HCP)s often results in a higher risk of readmission, suboptimal and fragmented care plans, delays in required medical intervention, inadequate self-care, and confusion on whom they should contact when they have questions.

In order to address this increasing need to bridge the current gap in clinical management and self-care of complex patients during their transition from healthcare settings to home care, this trial aims to design, implement and evaluate the SMaRT (Safe, Managed, and Responsive Transitions) Clinic, a nurse-led integrated care model facilitated by telemonitoring (TM). Specifically, the SMaRT Clinics aim to meaningfully introduce a nurse (or nurse practitioner) role to improve clinical coordination across patient care teams and reinforce proper self-care education through the use of telemonitoring.

The study involves enrolling 350 patients with complex chronic conditions into SMaRT clinics across four study sites. The Canadian Institutes of Health Research (CIHR) is funding this trial led by the University Health Network and will be conducted in two phases. Phase I involves Design and Development, and Phase II involves Implementation and Effectiveness Evaluation. The implementation and effectiveness of the SMaRT clinics will be evaluated through a mix of semi-structured interviews, ethnographic observation, patient questionnaires, and analyses of health utilization outcomes using propensity matched controls from the ICES provincial database.

The Oak Valley Health study will be supported by our GIM clinic and outpatient clinics. Questions about the SMaRT trial can be directed towards Dr Paul Lee (PI). To learn more about Medley please visit the following link.



Phase 2 EB05 Results

In 2021 Oak Valley Health participated in a Phase 2 trial evaluating Edesa Biotech, Inc monoclonal antibody candidate, designated EB05, as a single-dose treatment for hospitalized COVID-19 patients.

The Phase 2 data was preemptively unblinded by the study's Data and Safety Monitoring Board (DSMB) due to a clinically important efficacy signal detected among the most critically ill patients. Edesa believes EB05 regulates the overactive and dysfunctional immune response associated with Acute Respiratory Distress Syndrome (ARDS) - the leading cause of death in COVID-19 patients.

The DSMB reported the following results:

- Critically ill hospitalized patients treated with EB05 + Standard of Care treatment (SOC) had a 68.5% reduction in the risk of dying when compared to placebo + SOC at 28 days.
- Severe Acute Respiratory Distress Syndrome (ARDS) patients receiving supplemental oxygen at baseline had "a clinically important efficacy signal" with a 28-day mortality rate of 16.7% (2/12) in the EB05 + SOC arm versus 42.9% (6/14) in the placebo + SOC arm
- Survival analysis among ARDS patients showed that the subjects treated with EB05 + SOC had a 66.0% reduction in the risk of dying when compared to placebo + SOC at 28 days (HR: 2.94 placebo vs. EB05; 95% CI: 0.59-14.60; p=0.19).
- Patients with mild to moderate ARDS receiving oxygen support beyond supplemental oxygen demonstrated a 50.7% reduction in the risk of dying in the EB05 + SOC arm compared to placebo + SOC at 28 days (HR: 2.03 placebo vs. EB05; 95% CI: 0.61-6.74; p=0.25).

A total of four patients were enrolled in the Phase 2 trial from our site, and we will be participating in a the Phase 3 trial in January 2021.

The Phase 3 trial we continue with the EB05 study drug and add additional pharmacokinetic and genotype testing.

If you have any questions about the EB05 trial please contact Dr. Anthony LaDelfa (PI) or Anna Mozan (Research Coordinator).

Please see a brief snapshot, you can also find detailed results from the Phase 2 trial here.

CHANGES TO RESEARCH ACTIVITIES DURING COVID-19 PANDEMIC

Due to the 5th wave, the Office of Research has released a guideline to assist researchers with research activities during the COVID-19 pandemic.

We ask all staff, students and volunteers involved in research to review the Research during COVID FAQ document for updates and changes to research practices at Oak Valley Health.

We encourage all researchers to remain up-to-date with the Command Centre: COVID-19 updates posted daily on the internal acorn page.

If you have any questions about the new guidelines please contact the Office of Research. You can find information on acorn here.

Summary of Key Results

Baseline Characteristics

COVID-19 Scale	ARDS Criteria	N	Signal Detected	
ECMO and/or IMV with Add. Org. Supp. (Level 7)	Mild to Severe	33	**28-day mortality:**	• 14.3% (2/14) for EB05 • 36.8% (7/19) for Placebo; • **Hazard Ratio** = 3.17 (p=0.15) • Odds ratio = 3.50 (p=0.16)
Supplemental Oxygen (Level 4)	Severe	26	**28-day mortality:**	• 16.7% (2/12) for EB05 • 42.9% (6/14) for placebo; • **Hazard Ratio**: 2.94 (p=0.19) • Odds ratio: 3.75 (p=0.16)
High-flow oxygenation or worse (Levels 5,6,7)	Mild to Moderate	76	**28-day mortality:**	• 10.8% (4/37) for EB05 • 20.5% (8/39) for placebo; • **Hazard Ratio**: 2.03 (p=0.25) • Odds Ratio: 2.13 (0.25)
			Mean difference in days alive and free of IMV	• 6.1 more days for patients treated with EB05 versus placebo (95% CI, p<0.05)

COVID-19 Scale: 4 = Hospitalized requiring Oxygen supplementation; 5 = Hospitalized, requiring nasal high-flow oxygen therapy, noninvasive mechanical ventilation, or both; 6 = Hospitalized Severe Disease - intubation and invasive mechanical ventilation; 7 = Extracorporeal Membrane Oxygenation (ECMO) and/or invasive mechanical ventilation with additional organ support; **Berlin ARDS Criteria:** Mild = PaO_2/FiO_2 between 200 and 300 mm Hg; Moderate = PaO_2/FiO_2 between 100 and 200 mm Hg; Severe = PaO_2/FiO_2 <100 mm Hg

OUR MARK ON THE RESEARCHCOMMUNITY

Oak Valley Health recently participated in a research study lead by UHN PI Dr. Rima Styra titled **Surviving SARS and Living Through COVID-19: Healthcare Worker Mental Health Outcomes and Insights for Coping**. The study received funding from the Toronto COVID-19 Action Initiative Grant - University of Toronto.

This was a cross-sectional, multi-centered, hospital-based online survey conducted in two tertiary and two community care hospitals to explore the psychological effects of the COVID-19 pandemic on clinical and non-clinical HCWs and to assess the impact of work during a previous novel pathogen outbreak, namely the 2003 SARS outbreak in Toronto (MSH PI: Dr. Nadarajah).

Data was self-reported and included such variables as the HCWs' professional roles, category of institution (tertiary or community care), area of work, age, sex, marital status, education, isolation or quarantine history, deterioration in sleep, and sedative and alcohol use. HCW's also reported whether they had worked during the 2003 SARS outbreak. The following self-report scales were embedded in the survey to evaluate the psychological impact of the COVID pandemic: Impact of Event Scale-Revised (IES-R), Generalized Anxiety Disorder Scale (GAD-7) and Patient Health 96 Questionnaire (PHQ-9).

The results of this study demonstrate that HCWs with previous work experience during SARS did not have worse mental health outcomes compared to those without any previous experience. These findings have significant implications for staff wellness, the prevention of burnout and promotion and maintenance of staff retention—all of which are ongoing challenges in this current and in future pandemics. Findings can also provide guidance for healthcare systems seeking to provide appropriate, targeted, and timely support to HCWs especially those at greater risk, in order to promote

More information on the study and results can be found at the following locations: study publication and MSH Academic Day Poster

If you have questions regarding the study, please contact Dr. Rima Styra at rima.styra@uhn.ca

MEET ANNA MOZAN - NEW CRC

My name is Anna, I have B.Sc.N and I am an IEN. I have more than 8 years of experience in OR nursing and surgery. I have been introduced to Research in 2020. It was always my passion and career goal for many years and I'm finally fulfilling my dream. As a clinical research coordinator I am hoping to be involved in major breakthrough studies and be able to help improve quality of life for patients.

I have experience as a CRC in Parkinson's and Huntington's disease and I am especially interested in research focusing on chronic health problems as it is very challenging for individuals to manage their symptoms or disease.

Anna is the CRC for: EB05-04-2020, SCHOLAR-2, Navigating the Grey Zone, MVASI Trial

E: amozan@msh.on.ca
T: x6292

UPDATES TO THE RESEARCH WEBSITE

The Research Office now as a dedicated 'research' tab at the top of the Oak Valley Health website. This feature allows for internal and external researchers to easily access REB and Research Office information.

The Oak Valley Health REB continues to run as normal during the 5th wave. Please ensure that you are submitting the most up-to-date REB application form. Forms, templates and guidelines can be found on the acorn page or our external website.

Revisions to the Research website now make it accessible for staff to see what clinical trials are active at Oak Valley Health under our 'clinical trials' page.

If you have any questions about changes to the website or where to find resources please contact the Research Office at ResearchAdministration@msh.on.ca

RESEARCH COMMUNITY SPOTLIGHT

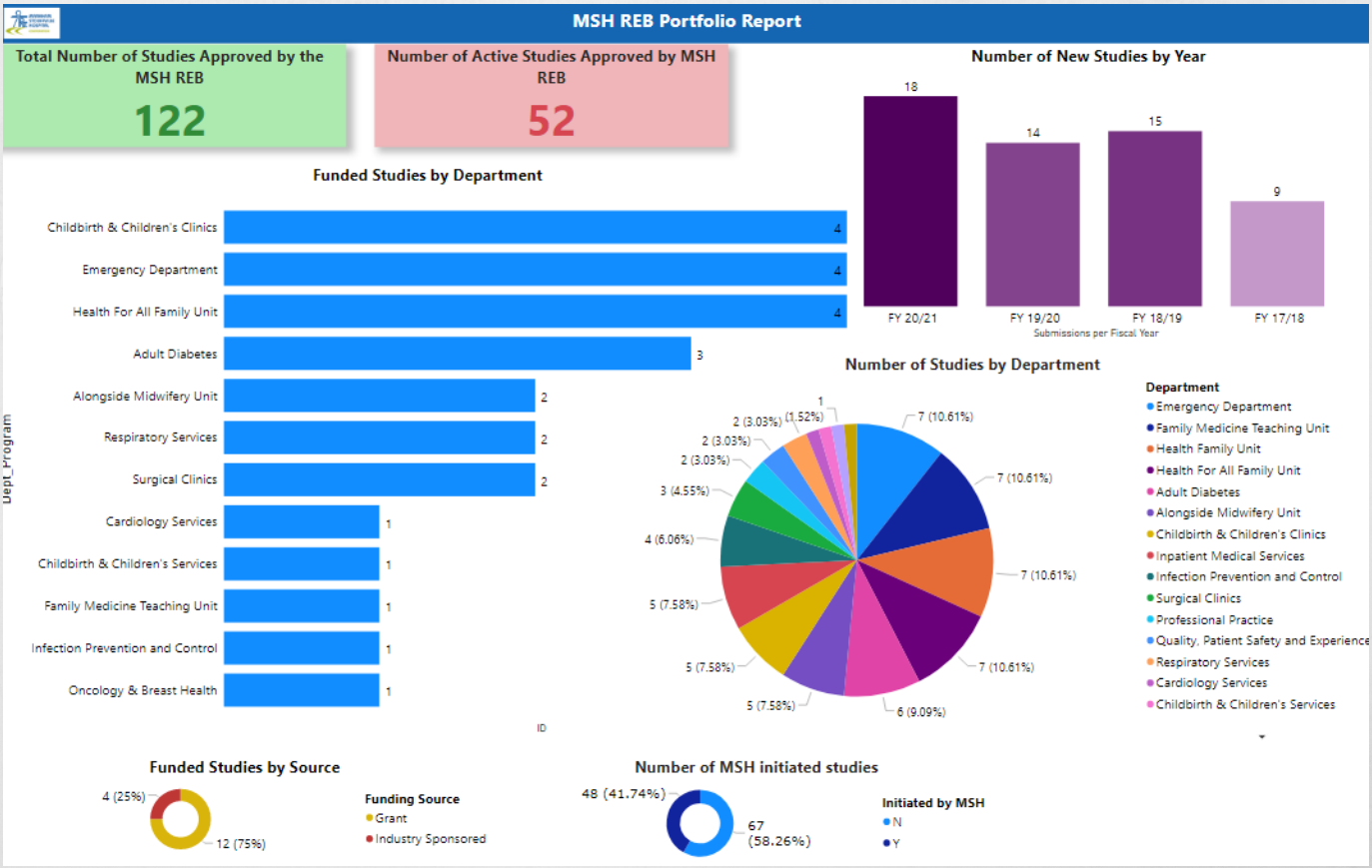
In-patient pharmacy:

In-patient pharmacy support all clinical trials that involve study drug across Markham Stouffville Hospital.

Our pharmacist support the trials by recieving and verifying study drug shipments/supply, help to create orders for the study product and activities, prepare and dispense the drug, and assist with questions from clinical staff regarding drug administration and handling.

Alice Hogg and **Karen McFarlane** have supported numerous trial including: CATCO, CONCOR-1, EB05, and more. Karen and Ally also provide support for these trials by completing dispensing and labelling logs for Sponsors, attending SIV and monitoring meetings and assist our research team by helping create study budgets for pharmacy impact on trials. Without Ally and Karen majority of our trials would not have fast time to activation or be able to run without their support.

On behalf of the research team, thank you for all your hard work and support!



TRIAL EDUCATION AMONG STAFF

The Office of Research utilized multiple modalities of trial education, awareness and training.

During Trial Rollout:
Before a trial is activated and enrolling patients at Oak Valley Health, the research team will educate all staff that may be impacted by the trial in the following ways:

- Attending huddles and rounds
- Placing laminated flyers on the huddle boards
- Update the research website active trials list
- Ask Managers to distribute short educational videos to their staff

Each unit has a Research Binder located in the nursing stations with more information of all trials active in the unit.

During Trial Enrolment:

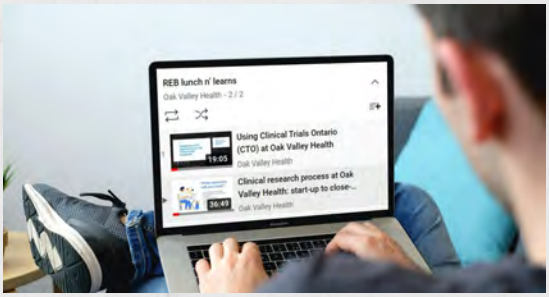
- The research team places a note into Meditech on enrolment
- Laminated signs may be placed at the entrance of patient rooms
- Laminated sign is placed within the patients physical chart
- In the ICU: "clinical trial patient" magnets are used in the team room to identify patients that are enrolled

Throughout the Study

- Notes are continuously placed in Meditech
- Research team attends huddles periodically to educate/answer any concerns or questions

When trials are copleted and results are available, the Office of Research will communicate interim analysis or study findings on the acorn blog or through the research newsletter.

If you have ideas on how to improve trial education or awareness, or want to learn more about how to get started in research, please contact Michelle Dimas at mdimas@msh.on.ca



SIMULATION AND RESEARCH

The simulation program at Oak Valley Health is growing! Apart from its use as a modality for clinical education, simulation can also be used to study how to improve quality and safety in health care. Linked below is an article that provides an overview of simulation-based research (SBR), how it can be deployed and which study designs it may support. SBR is capable of accommodating multiple research designs and allows the study of certain situations that would otherwise escape scientific evaluation, for instance high risk, low frequency events or where direct observation or experiments are not possible for ethical or other reasons. Furthermore, simulation has the advantage of providing researchers with a controlled environment to test their hypotheses and to do so safely for patients and participants (Lame & Dixon-Woods, 2018). More recently, organizations are including SBR in their programs of work as the use of simulation in research is a flexible technique and can be integrated easily into multiple designs. If you are interested in exploring research through simulation, please contact the simulation team at simulation@msh.on.ca and Michelle Dimas at mdimas@msh.on.ca.