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QUARTERLY RESEARCH NEWS

Official Newsletter of the Office of Research



Updates from the Office of Research

BY MICHELLE DIMAS, MANAGER OF RESEASRCH

The Office of Research has made exciting strides to further our research agenda for this fiscal year. We have created a Research Council to help improve and direct the growth of research at Oak Valley Health. The members consist of an interprofessional group of research stakeholders to discuss support for researchers, bring forward issues, and develop a research plan to strive towards a research institute. The first item on the agenda is to help create a 2, 5 and 10 year research plan including discussion for financial support for Oak Valley Health investigators. Our goal is to help financially support new research ideas from our investigators and assist with knowledge translation from the studies being conducted. We look forward to sharing exciting updates with our research community.

The Office of Research would also like to announce the creation and launch of the new **Clinical Research Toolkit**. The toolkit is a consortium of clinical research templates and information needed for investigators to conduct their trial. For example, you can find templates for essential documents and everything you need to retain in your regulatory binder, checklists in the event of an audit, and a Health Canada guidance documents for conducting clinical trials. The Clinical Research Toolkit is now available on the Acorn page under 'Research'. If there are templates or resources you would like to see added to the toolkit, please contact mdimas@msh.on.ca

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CLINICAL TRIAL SPOTLIGHT

HIP ATTACK-2

Millions of adults globally (1 in 1000) Canadians suffer a hip fracture annually and have devastating consequences that can lead to death. In an attempt to improve the care of these patients, the Hip ATTACK 1 trial set out to determine how accelerated surgery compared to the current standard of care. Hip ATTACK-1 demonstrated that accelerated surgery was feasible and safe, even in patients with acute medical conditions. Specifically, mortality was more than doubled as compared to patients that underwent accelerated surgery.

Hip ATTACK-2 is a multicenter, international, open-label, parallel group randomized controlled trial that will include 1100 patients. The study objective is to determine whether accelerated surgery for hip fracture, in patients with acute myocardial injury, is superior to standard care in reducing death at 90 days after randomization. The secondary objective will focus on mobilization, cardiovascular outcomes, delirium, and pain.

Patients will be randomized to accelerated medical assessment and surgical repair (i.e., goal of surgery within six hours of hip fracture diagnosis) or standard care (i.e., medial management of the heart injury and then surgery when the acute heart injury has stabilized). All patients will receive the same structured follow-up. For the first seven days after randomization, while in hospital, we will perform daily troponin measurements to screen for myocardial injury and myocardial infarction, and daily creatinine to screen for acute kidney injury. Patients will be contacted by phone 90 days to determine trial outcomes.

The Canadian Institutes of Health Research (CIHR) is funding the trial. The trial will be managed and led scientifically as an investigator-initiated study (IIS) through the Population Health Research Institute (PHRI). The trial is taking place at Hamilton Health Sciences, St. Joseph's Healthcare, Victoria Hospital, and the Ottawa Hospital to name a few.

The trial is supported with by our lab, DI, and inpatient surgery department as well as our orthopedic surgeons, ED physicians and nurses. Questions about the Hip ATTACK-2 trial can be directed to Dr. Steve McMahon, Lisa McLean (Co-PIs).

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Dr. McMahon and I are committed to improve the health of patients with hip fractures by understanding the benefits of treating patients expeditiously and lowering the risk of complications

– **LISA MCLEAN MN, BSCN, RN, CMSN(C)**

Lunch n' Learn Series

The Office of Research will be holding the next educational webinar on **Monday November 22nd at 12:00pm**. Calendar invites will be sent out to researchers and the research community.

During this webinar you will learn about the research process at Oak Valley Health from start-up to close out, including all required approvals for conducting research (impact assessment, contracts, REB), how studies are reviewed for feasibility, and the study negotiation process with the Sponsor.

If you would like to request a topic for a future lunch n' learn, please email Michelle Dimas at mdimas@msh.on.ca



Upcoming Trials at Oak Valley Health

HIP ATTACK-2 (PI: Dr. McMahon). A randomized control trial investigating whether accelerated surgery for hip fracture in patients with acute myocardial injury is superior to standard care in reducing death at 90 days after randomization.

SCHOLAR-2 (PI: Dr. Kumar). A randomized clinical trial evaluating the safety and efficacy of a strategy of continuing trastuzumab/pertuzumab/T-DM1 in patients with stage I-III HER2 positive breast cancer who develop systolic LV dysfunction

MVASI/ABP 215 (PI: Dr. Trinkaus). An industry sponsored (AMGEN) Canadian retrospective observational study of MVASI in metastatic colorectal cancer patients.

Trial Update

EB05 INTERIM ANALYSIS

Markham Stouffville Hospital is currently participating in a COVID treatment trial -EB05 - investigating the safety and efficacy of EB05 vs. standard of care in adult hospitalized patients (PI: Dr. Anthony La Delfa).

Interim analysis provided by the Sponsor were **positive**:

- A clinically important signal was detected between the groups that were on EB05 + SOC and SOC alone.
- Among the findings, the DSMB reported a 28-day death rate of 14.3% (2/14) in the EB05 arm versus 36.8% (7/19) in the placebo arm in critically severe patients on ECMO therapy (extracorporeal membrane oxygenation).
- EB05 has been generally well-tolerated and consistent with the observed safety profile to date.
- The DSMB members have concluded that the study has met its objective and should continue further into a Phase 3 study.
- The link to the press release by Edesa: <https://www.accesswire.com/664687/Edesa-Biotech-Announces-Positive-Phase-2-Data-of-Its-Monoclonal-Antibody-in-Hospitalized-COVID-19-Patients>

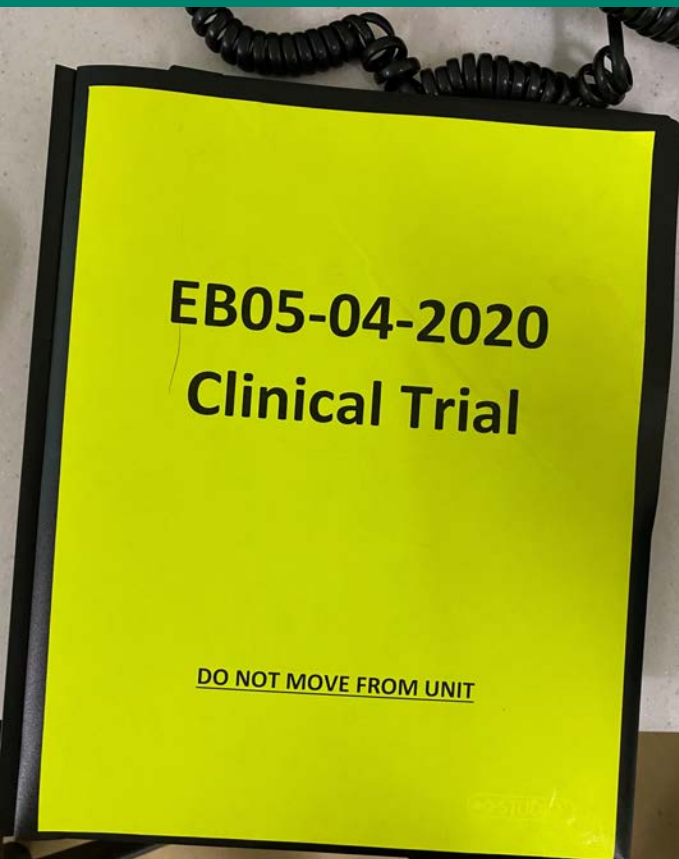
EB05 is a monoclonal antibody with high affinity and specificity to human TLR4. To date, 4 patients have been enrolled and our site is looking to recruit 8-10 patients to the study.

Research Community Spotlight

3WG CRITICAL CARE NURSING STAFF

Oak Valley Health is currently participating in a COVID-19 clinical trial called EB05-04-2020 (PI: Dr. La Delfa). The trial involves administration of an investigational product and daily COVID-19 symptom assessment. The Office of Research would like to express our sincere gratitude for **Sandeep Yakub** (Manager, Intensive Care Unit), **Cece Pastor** and **Diane Schmidt** (Charge Nurses), and all of the **nursing staff in 3WG** for their support and assistance with the trial.

With their help, the study has currently enrolled four patients and is on target to reach 8-10 patient enrolment as scheduled. The EB05 trial is the only in-patient COVID-19 trial active at Oak Valley Health that offers an alternative treatment for patients with moderate to severe COVID. To learn more about the EB05 trial you can visit the clinicaltrials.gov website (NCT04401475).



Meet Albie Law

CLINICAL RESEARCH COORDINATOR, ONCOLOGY

Albie holds a Bachelor's degree in Psychology and is a Certified Clinical Research Associate from McMaster University. Recently, Albie achieved her Society for Clinical Data Management designation. She has 8 years of experience in clinical research and has been involved in studies related to Huntington's Disease, Parkinson's Disease, Alzheimer's Disease and Stroke. Further, Albie has experience conducting research specializing in allergy and oncology.

Albie is the coordinator for: ReACT Trials, CO.29, Bridging the Gap, and MA.40



Meet Karen Croxall

PATIENT REPRESENTATIVE - ONCOLOGY TRIALS

Karen has joined our oncology clinical trials team as a Patient Representative (PR). A PR acts as the “patient voice” to help improve the clinical trial patient experience. Karen will liaise directly with the Office of Research and will serve as an active and fully integrated member our team by participating in meetings, reviewing clinical trial materials, providing input on clinical processes and patient support strategies, engaging with our website re-design, as well as assisting with identifying new areas for meaningful and effective patient and public involvement (PPI). We look forward to improving the patient experience of our oncology clinical trials.



Our Mark on the Research Community

PUBLICATION HIGHLIGHTS

In July 2018, Canada's first midwife-led alongside midwifery unit (AMU) opened at Markham Stouffville Hospital (MSH) in Markham, Ontario. **Anne Malott** (contributing author) and support from **Carol Cameron**, partnered with the McMaster Midwifery Research Center to conduct a study to examine how the conditions at MSH made it possible for the hospital to create the first AMU in Canada and to identify lessons to inform spread by examining how characteristics of the intervention, the inner and outer settings, the individuals involved, and the processes used influenced the MSH-AMU implementation process. Between November 2018 and February 2019, fifteen key informant interviews took place identifying thirteen relevant documentary sources of

evidence, including news media coverage, website content, Ontario parliamentary records, and hospital documents. While several unique features of MSH supported innovation, factors that could be adopted elsewhere include organizational investment in the development of midwifery leadership skills, intentional use of change management theory, broad stakeholder involvement in the design and implementation processes, and frequent, open communication. The example of the MSH-AMU illustrates the value of utilizing best practices with respect to change management and system transformation and demonstrates the potential value of using implementation theory to drive the successful implementation of AMUs. **Lessons learned from the MSH-AMU has informed development of a Hamilton AMU, with consultation provided by Carol Cameron and Anne Malott.** Access to the publication: <https://authors.elsevier.com/sd/article/S0266613821002266>



Meet Anne Malott

PRINCIPAL INVESTIGATOR FOR SEVERAL AMU STUDIES

Anne Malott is a part-time hospitalist midwife in the Alongside Midwifery Unit (AMU) at Oak Valley Health, an associate professor at McMaster University and a fellow in the McMaster Midwifery Research Centre.

Anne's funded research has included community engagement and outreach in marginalized communities (\$35,553 and \$52,695); formative evaluation in midwifery education (\$3,606); the scholarship of teaching and learning and curriculum development (\$8,769 and \$4,251); and the evaluation of interprofessional team OSCEs and other interprofessional education events (\$5,745 and \$3,500).

Anne is the Principal Investigator for two collaborative studies with the McMaster Midwifery Research Centre and a study evaluating the new midwife mentorship program.

Anne is a co-investigator of studies exploring the built environment of the AMU; experiences of healthcare providers working in the unit and a recently published study on lessons learned in creating the AMU. She is also a co-investigator in and a study examining the experiences of midwifery patients undergoing induction of labour.

Anne is passionate about learning with and from her midwifery, nursing and obstetric colleagues, and leads education and simulation in the AMU. She is engaged in coordinating learning opportunities for midwifery students across the Children's and Childbirth Services with the goal of offering comprehensive experiences for learners while supporting client centred care. Anne employs a strengths-based educational pedagogy that positions learners as essential members of the healthcare team who can contribute to clinical care and facilitate patient flow.

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I am so privileged to be part of this incredible team of clinicians and researchers here at Markham Stouffville Hospital, and I truly am grateful for this opportunity to support normal birth and evidence-based care

– ANNE MALOTT

OFFICE OF RESEARCH INTERNS

The Office of Research is excited to welcome two new interns joining our team from Seneca College. **Sahil Kothari**, Clinical Research Intern, will be supporting our team by assisting on ADDAM,

Bridging the Gap, and Hip-Attack-2 research studies. **Sarah Rubin**, Research Ethics Intern, will be supporting our Research Ethics Board by assisting with reviews and operations.



UPDATE FROM THE TRANSFORMATION PMO TEAM

Launch of Telemetry Monitoring System

The new Telemetry Monitoring System has launched at Markham Stouffville Hospital and Uxbridge Hospital!

At Oak Valley Health, delivering exceptional patient care is our focus. Having the right equipment is key to delivering the best care. The Phillips Telemetry system was launched on, September 28 2021 at Markham Stouffville Hospital and at Uxbridge Hospital on October 5, 2021.

Oak Valley Health has revitalized a crucial tool that keeps our cardiac care patients safely monitored through their stay. The Phillips Telemetry system offers critical monitoring of vital statistics such as a patient's heart rhythm. There will also be a web viewing of patient vital statistics for off-site health care team members, which means improved access to data and enhanced functionality.

Phase 2 of the project will focus on sending telemetry alarms to mobile phones. The current system only allows staff to hear patient alarms when they are close to the centralized station. The new model will have the alerts go directly to phones that are carried by nursing staff. This new technology will help support patient care and patient safety.

UPDATES FROM THE REB

The REB has released several new documents and tools for investigators:

- Internal and external SAE reporting form
- Protocol deviation form
- Guideline for email communication in research
- Minimal risk consent form (ICF) template
- Personnel Change form

Effective September 1, 2021 all new forms should be used. Any outdated forms will be turned away and ask to be re-completed. You can find all of the REB forms, guidelines and templates on the Acorn page.

The REB has officially changed its name to the Oak Valley Health Research Ethics Board. Investigators with active studies at Oak Valley Health are asked to make the following administrative changes to participant-facing material:

1. Update the hospital logo on all participant-facing material (i.e., consent forms, posters, information sheets, etc.). New logos can be found on the Communications Acorn page (intranet page). We suggest that investigators review the Which logo do I use? Guidance document provided by Communications available on the Acorn page.

2. Update the new corporate name to Oak Valley Health on all participant-facing material.

The REB has released a formal 'Research Ethics Board Name Change' guidance document to assist investigators with their active studies. If you have any questions about the new name change or the impact to your study, please contact the Oak Valley Health Research Ethics Board at ResearchAdmin@msh.on.ca