TrialScribe
Clinical Research News
at University Health Network

Welcome to the November 2014 edition of *TrialScribe*, a bi-monthly e-newsletter designed to inform researchers and trainees about clinical research news and information at UHN. Included in this issue:

- Charles Chan, FACP, FRCPC, MD, Vice President, Medical Affairs and Quality, and Christopher J. Paige, PhD, FCAHS, Vice President, Research

Research Spotlights

Prostate Cancer: Accurately Pinpointing Tumours

Within five years of being treated for prostate cancer with radiation, 20-30% of men display symptoms that suggest that their cancer has recurred. The standard treatment for recurring prostate cancer is to target the entire prostate, which is associated with severe complications.

To help improve current treatments and address this issue, UHN researchers have developed a new procedure that uses high resolution magnetic resonance imaging (MRI) to pinpoint cancerous cells. The procedure creates detailed three-dimensional images that are used to guide the removal of small tissue samples (biopsies) from the prostate and to more accurately distinguish between healthy and cancerous tissue.

To evaluate this new procedure, Dr. Cynthia Ménard, a Clinical Researcher at PM Cancer Centre and Affiliated Faculty at Techna, led a clinical trial that enrolled 30 men suspected of recurrent prostate cancer. Researchers found that recurrent tumours could be identified more accurately when MRI images were taken using multiple techniques. They also found that the MRI-guided biopsies enabled more accurate identification of the boundary of the tumour in three-dimensions.

This procedure represents a new, higher resolution diagnostic tool that, if adopted, could enable men with recurrent prostate cancer to keep as much healthy prostate tissue as possible, while ensuring that the cancer is treated.

This work was supported by the Office of the Assistant Secretary of Defense for Health Affairs, Ontario Ministry of Research and Innovation, the Ontario Institute for Cancer Research and the Princess Margaret Cancer Foundation.

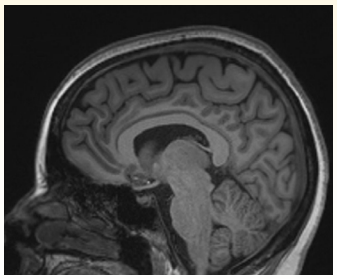
Ménard C et al. Radiology. 2014 Sep 8. [Pubmed abstract]

Stroke: Development of a Powerful New Imaging Technique

Vessel wall magnetic resonance imaging (VW-MRI) is a medical imaging technique being developed to more accurately diagnose an ischemic stroke—a stroke caused by a blocked blood vessel in the brain. Traditionally, physicians have determined the cause of a stroke using images of the blood flowing inside of a blood vessel. However, many of the diseases that cause stroke alter the wall of the vessel and not the blood per se. VW-MRI generates detailed three-dimensional images of the wall of a blood vessel, enabling radiologists to see more clearly what the underlying disease is: a blood clot, fatty plaques, or inflammation or constriction of the blood vessel. Ischemic stroke can be treated with different medications and/or surgery, depending on its cause.

TWH neuroradiologist Dr. Daniel Mandell is developing VW-MRI and focusing on improving the clinical interpretation of its images. Recently, he discovered that the minimally invasive surgical removal of a blood clot (to treat ischemic stroke) can cause changes in the blood vessel wall which mimic other artery diseases.

As part of his clinical study, 16 patients who had suffered an ischemic stroke underwent VW-MRI within days of being treated. The imaging showed a thickening and brightening of the blood vessel wall more frequently in stroke patients treated with surgery than in those treated with medications alone. These same features are also observed on VW-MRI images of blood vessels damaged by inflammatory diseases.



The findings may help to prevent the misdiagnosis of artery disease in people who have been treated for ischemic stroke. Furthermore, the accurate interpretation of VW-MRI images will help clinicians to make better diagnoses of ischemic stroke and prescribe the most effective therapies to treat it.

This work was supported by The Association of University Radiologists and the Toronto General & Western Hospital Foundation.

Power S et al. Stroke. 2014 August [Pubmed Abstract]

Research Policy Corner

Several projects have been initiated by the Clinical Research Support Services Planning and Implementation (CRSSPI) team, chaired by Lisa Alcia, Executive Director of Research Operations. In this section you will find the new research policies available on the Corporate Intranet.

Privacy Policy

UHN and its personnel, including staff, students and volunteers, are responsible for maintaining the confidentiality of a patient's personal health information (PHI). These responsibilities are described in detail in UHN's Privacy Policy, which is compliant with the Personal Health Information Protection Act (PHIPA). To help personnel meet PHIPA standards, UHN provides tools, training and support and has implemented safeguards such as requiring that all new personnel sign a confidentiality agreement.

Violations of the Privacy Policy include, but are not limited to, the following actions: accessing information that you do not require to fulfill the purpose of your job; misusing, disclosing without authorization, or altering patient or personnel information; and disclosing to another person your RIS username and password or leaving your account active such that another person may access electronic patient records they would not otherwise have had access to.

Breaches of the Privacy Policy will result in disciplinary action up to and including a loss of privileges or the termination of employment or of a contract. Furthermore, in accordance with the penalties set out by PHIPA, the Office of the Privacy Commissioner can fine individuals $50,000 and institutions (UHN) $250,000 when a breach is reported.

Quality Improvement and Best Practices

The Research Quality Integration (RQI) program focuses on areas critical to maintaining subject safety, data integrity and regulatory compliance. Through internal quality auditing and site support, the QI team assists researchers in recognizing opportunities for enhancing effective processes and operations, and identifies best practices that can be shared throughout the organization. The following is a continuation of a series of case studies highlighting examples of how to manage gaps in procedure and improve research best practices.

What does privacy mean?

Patients and research participants at UHN are entitled to privacy—meaning that their PHI should be kept confidential and should be treated with respect and sensitivity. PHI is defined as any information that can be used to identify an individual and relates to their health or to the care that they receive. PHI can include any information related to an individual's physical state or mental health, the surgical procedures or treatment they received, information related to their eligibility or payment for participation in research, and their health card number. PHI can be in written or verbal form. The knowledge and express written consent of a person is required before their PHI can be collected, used or disclosed for research purposes.

Privacy—Case Study

Note: the following is a fictional case concerning the responsible conduct of research

Dr. X initiated a research study to test the effectiveness of aerobic exercise at regulating mood in young adults with bipolar disorder. In the study protocol submitted to the research ethics board (REB), Dr. X requested that the study coordinator be given authorization to access patient health records to pre-screen potential participants for eligibility criteria. The REB accepted the protocol under the condition that the study coordinator must first obtain written consent from each participant prior to reviewing their medical history (a type of PHI).

Shortly thereafter, Dr. X and the coordinator attended a local charity event, at which Dr. X met his favourite celebrity. After exchanging niceties, their conversation turned towards bipolar disorder—Dr. X's research specialty. The celebrity, Mr. Y, explained that he had been recently diagnosed with the disorder and was currently seeking treatment at the same hospital where Dr. X is employed and conducting the new bipolar disorder study. The following day, the study coordinator accessed Mr. Y's medical records to determine his eligibility for Dr. X's study. Unfortunately, Mr. Y was not eligible and was never contacted.

While conducting a random audit, the Privacy Office discovered that Dr. X's study coordinator had inappropriately accessed Mr. Y's medical records, by viewing them without first obtaining his written consent.

Quality Improvement and Best Practices

Breaching Privacy—What are the Risks?

The study coordinator violated Mr. Y's privacy and breached UHN's Privacy Policy by accessing his medical records without express written consent. Accordingly, the Privacy Office notified Mr. Y of the inappropriate access by the study coordinator. The privacy breach was leaked to the media, which portrayed UHN and Dr. X as being dishonest and lacking integrity. The reputation of UHN as a premier research institution was compromised. In response to the incident, UHN terminated the study coordinator's employment and the Privacy Commissioner fined the study coordinator $50,000 and UHN $250,000 for the privacy breach.

Effective Ways to Maintain Privacy

- Ensure that you, your staff and your colleagues attend UHN privacy training.
- Review a patient's medical record only if you are in their circle of care or have REB approval and the patient's express written consent to do so.
- Do not disclose patient or participant PHI to anyone who does not require it to fulfill the responsibilities of their job.
- Store PHI on the secure UHN network and use encrypted laptops and mobile devices so that, if stolen or lost, the PHI cannot be accessed.
- Keep participant files in a secure location (eg, a locked cabinet and/or a locked office), so that they are accessible to authorized personnel only.
- Do not share your RIS username or password.
- Log off before leaving a public workstation; you will be held responsible if someone else uses your credentials to inappropriately access patient information.

Why is it Important to Maintain Privacy?

Maintaining the confidentiality of PHI is an essential part of ensuring that patients, research participants and UHN personnel are comfortable and trust UHN's staff, students and volunteers. Every time a patient's or research participant's privacy is violated, there is a risk that UHN's reputation will be tarnished. Privacy breaches can result in lost funding opportunities. The disclosure of PHI to certain parties (eg, employers or insurance companies) could impact a patient's or research participant's employment or insurance benefits. Finally, negative media coverage could also affect a person's willingness to seek treatment at UHN or participate in research studies conducted at UHN.

News and Events

UHN Named Canada's Top Research Hospital of 2014

For the fourth year in a row, UHN is Canada's top-funded research hospital in RE$EARCH Infosource Inc.'s Top 40 Research Hospitals in Canada List 2014. The annual study ranks participating research hospitals across the country according to research funding, which includes grants, contributions and contracts from all internal and external government and non-government sources. The list was launched in 2011 as a component of RE$EARCH Infosource Inc.'s Canada Innovation Leaders publication to emphasize the importance of hospitals in shaping Canada's research ecosystem. Since the inauguration of the list, UHN has remained the country's leader with research expenditures of $312M for the 2013 fiscal year.

Annual Clinical Research Training Program

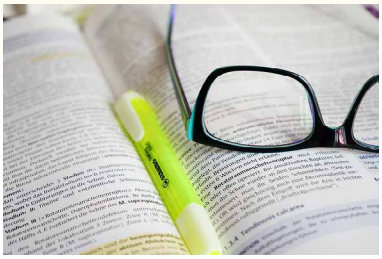
Does your research involve human participants?

If it has been a year or more since you have last completed the mandatory training listed in UHN's Clinical Research Training Policy, then you must complete the 2014 Annual Clinical Research Training (ACT) Program no later than February 2015.

The ACT Program contains a combination of updated as well as refresher modules to ensure that personnel are up-to-date on knowledge and skills around good clinical practice. Accordingly, the modules found within the annual program may change from year to year.

In order to complete the ACT program, you must do the following:

1. Complete all modules
2. Complete and pass the test
3. Print the test results and retain them as a record of completion
4. Complete the course attestation



The new and updated 2015 ACT Program will be available starting in January.

TrialScribe is brought to you by UHN Research Communications. We hope you have enjoyed reading this newsletter.
Please note: this newsletter is designed for UHN internal purposes and, as such, contains links to some documents that can only be accessed through UHN's Research or Corporate Intranet.
The next issue of *TrialScribe* will be released in January 2015.
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