

January 2010

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In This Issue

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About Us

The ICTCR facilitates patient-centered research through the combined strengths of its founders: Mercy Medical Center and Des Moines University along with its partners, Drake University College of Pharmacy and Health Sciences and Mercy College of Health Sciences and welcomes inquiries from interested clinicians and scientists.

For more information, please call (515) 247-4435.
www.iowatranslationalresearch.org

Mercy Family Medicine Physician Begins New Influenza Study as Public Health Officials Anticipate Emergence of Seasonal Flu

Dr. Dean Moews, faculty member in the Mercy Family Practice Residency Program will be conducting a study in which patients hospitalized for seasonal or pandemic influenza that is serious enough to warrant inpatient care will be randomized to one of two dose levels of oseltamivir. While the drug has been available in oral form, in this study it will be administered intravenously to individuals age 13 and above and who meet other inclusion criteria. Although the study drug is part of the World Health Organization's strategy for dealing with potential world-wide outbreaks, there remains a need to explore the use of intravenous forms of neuraminidase inhibitors as some influenza patients may become critically ill and may be unable to swallow or tolerate existing oral forms of the medication.

The announcement of the study is timely because in last week's epidemiology newsletter from the Iowa Department of Public Health, the agency provided a reminder that the flu season is still with us and it will not be surprising to see seasonal cases of this illness as winter continues. While plans are in place for a state diagnostic effort (www.uhl.uiowa.edu/services/influenza/) it is good to know that Mercy Medical Center will be able to contribute to advancing understanding of a therapy that may potentially fill a gap in therapeutic approaches to the sickest of influenza patients. The study will benefit from documentation of virus shedding and viral loads during the course of the study as well as indicators of safety and clinical efficacy of each of the two dose levels studied. Enrollment of hospitalized patients will be permitted up to 96 hours after clinical diagnosis. The study is registered with clinicaltrials.gov and is built on a foundation of 3 previous IV oseltamivir studies.



Dr Moews (left) will be assisted by Judi Greene, BS, RN in this study. Her assistance with this study is also significant as it represents a new opportunity for sponsored research at Mercy. In the case of this clinical trial, coordination of the administrative aspects of the study will rely on a coordinator who has been supplied to the study by an arrangement with the contract research organization handling the study.

Questions about this study may be directed to Dr. Moews (Mercy Family Practice) or to Judi Greene. She may be reached at 515-643-2682. The study will consider enrolling patients who are referred by other practitioners.

Featured Investigators:

Craig Mahoney, MD



John Nettrour, MD



Vassilios Vardaxis, PhD



Laura Covill, DPT



Comparative Effectiveness Research in Action

Inter-institutional Research Group Compares Outcomes Following Total Hip Arthroplasty by Two Minimally-Invasive Approaches

In last month's issue of the ICTCR update, the heightened importance being placed on Comparative Effectiveness Research was discussed. Mercy and DMU investigators are starting a new study that illustrates how Comparative Effectiveness Research can be carried out within a busy clinical practice for the benefit of patients undergoing hip replacement surgery. An estimated 200,000 hip replacement surgeries occur each year in the U.S.

Craig Mahoney, MD, and John Nettrour MD, of Iowa Orthopedics will join with Vassilios Vardaxis, PhD and Laura Covill DPT from Des Moines University and will conduct a prospective study of the short and long-term functional performance, physical activity level, health status, radiographic outcomes and physical outcomes of total hip arthroplasty (THA) patients receiving total hips through one of two commonly used minimally invasive surgeries (MIS): either by the posterolateral (PLA) or direct anterior (DAA) surgical procedure and contrast these measures to those of a gender and age-matched control group.

The result of surgical procedures can be favorable in the short term, but later, different procedures may show divergent results over time. The opposite may also be true with short term differences resolving over time. So, this team will engage in objective assessment of everyday activities (walking, balance, curb - step up and down, stair ascend/descend, and sit-to-stand), the physical activity level will include assessment of the everyday activity maintained (using portable wearable activity monitors), the health status assessment will be done using patient reported and physician completed survey tools (WOMAC and Harris Hip Score), radiographic outcomes will be assessed using measures from the pre and post surgery X-rays, and the physical outcomes will be assessed by a licensed physical therapist (manual muscle strength and ROM).

Dr. Vardaxis, who heads the DMU Human Performance Laboratory (a state-of-the-art human motion analysis center) stated that this study "will determine whether the short and long-term functional performance differs between surgical approaches, and whether the short and long-term functional performance of the THA patients is directly related to the THA procedure, the health status, the physical outcomes, or the physical activity maintained during the respective post surgical period."

The follow up of patients over time is one of the strong attributes of this research program, and being able to assign consistent measures at both times after surgery will provide opportunities to compare across time and surgical approach.

In the short term (3 months), it is hypothesized that there will be differences between the 2 procedures in terms of function in everyday tasks (gait, balance, ascend/descend stairs and sit-to-stand), mechanical energy used for ambulation, muscle activation pattern timing, and physical measurements (strength and flexibility). However, there will be no differences in bilateral asymmetries in the post operative radiographic measures.

In the long-term (12 months), it is hypothesized that these differences will no longer persist, thus nullifying this short term surgery effect. However, regardless of the surgical technique we hypothesize that the functional ability of the patients in the long term will be strongly related to the physical activity level maintained throughout the post surgery period and the improvement in the physical outcomes.

To learn more about this study, contact Vassilios.Vardaxis@DMU.edu

Bruce Hughes, MD



James Andrikopoulos, PhD



Michael Jacoby, MD



Planned topics for ICTCR future issues:

Generating qualitative research data through focus groups.

Top statistical issues every physician should know.

Current research on telemedicine technology mapping medical hazards using Geographical Information Systems.

Maximizing the value of clinical research participants:

How Ruan Neurology Clinic and Research Center Investigators Are Advancing the Frontiers of Multiple Sclerosis Research on Two Fronts Using a Single Patient Cohort

In many fields of research, valid assessment tools are used to establish degrees of physical disability or cognitive function to accurately measure both disease severity and changes following treatment. A new version of the Minnesota Multiphasic Personality Inventory is such a tool, but has not been validated in a Multiple Sclerosis population, a project soon to begin locally.

Bruce Hughes, MD, is joined by Jim Andrikopoulos, PhD and Michael Jacoby, MD (all pictured at left) in evaluating this newly revised tool that will help determine the degree to which cognitive and emotional conditions contribute to the patient's sense of having a physical disorder (somatization). Among MS patients who have definite physical disability and physical symptoms of the disease, it would be of value to determine what contribution to the overall clinical picture may be associated with the emotional and cognitive condition of the affected individuals. And because there is currently no validated tool to tease out the cognitive and non-cognitive contributions to the psychological aspects of MS manifest among MS patients, this research group will be venturing into important new territory. Among the new findings that are expected is establishing upper limits for the somatic symptoms that distinguish between somatization and strictly physical elements of the patient psychological profile and an ability to gauge the degree to which the patient has made psychological adjustment to this important disease.

This research team, however, merits special attention for the innovative way in which they are recruiting a study population. Because the Ruan group has a strong reputation for MS research, they already have ongoing MS treatment trials. One study requires patients to undergo prolonged intravenous infusion. Inviting persons already attending their clinic for these infusions to participate in the revised MMPI evaluation, allows data to be obtained to support two very different research studies. Moreover, the program described illustrates the potential value of having one disease entity studied from vantage points other than medicine alone.

Research teams of the future will be expected to be increasingly interdisciplinary, allowing a greater breadth of discoveries from individuals with the same condition. Investigators at Ruan Neurology Clinic and Research Center are showing leadership in this type of interdisciplinary discovery.

Statement of Purpose

The ICTCR is a research enterprise that facilitates productive research collaboration between its partners by sharing intellectual and infrastructure resources for the purpose of advancing patient-centered research that seeks better health for our communities and education and research opportunities for our faculty, staff, students and trainees. We believe the comprehensive training of medical students, residents and other health care professionals must be accompanied by a working knowledge of clinical research methods and best practices and that the best way to accomplish this is through active research endeavors. The ICTCR is dedicated to ethical and compassionate care for all individuals who participate in clinical research studies and actively supports the principles of autonomy, beneficence and justice in clinical research programs.