

## June-July 2009

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### **In This Issue**

Cover story: Mercy Clinics Inc. and Foundation for Informed Medical Decision Making. The NIH: Changed and Changing (p2) and featured research: Perinatal Center of Iowa

### **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](http://www.iowatranslationalresearch.org)

## **Mercy Clinics Participate in a Major International Program Integrating Shared Decision Making into Patient Care**

Increasing levels of patient autonomy, participation in one's own care, better health outcomes, personal responsibility, and reduced health costs are all positive goals for outpatients, but what is the evidence that these can be achieved in a real-world setting? A new project undertaken through the Mercy Clinics system may demonstrate just how these goals may be integrated into everyday practice.

The pursuit of these goals is being aided by a major, national, grant-supported study sponsored by The Foundation for Informed Medical Decision Making that is aimed at preparing patients to take a more active and informed role in their care. Work with this foundation puts the Mercy Clinics in the company of other major institutions such as Dartmouth-Hitchcock, Massachusetts General, UCLA and other well-known programs in primary care and specialty medicine who are also pursuing quality improvement in patient care.

This work is based on a forward-thinking program in which 15 Mercy primary care clinics have employed nurse-coaches to educate patients and support them in meeting their health goals. Staff clinicians will build on this resource to create a shared decision-making program, relying significantly on the health coaches. The coaches provide patients with decision aids during face to face patient-coach meetings. The patients are able to get their questions answered and additional materials such as videos or booklets are made available to them. After viewing the decision aid the patients can discuss concerns about their medical decision. Coaches will help patients complete surveys on knowledge and feelings about decision making before and after using the decision aids. Results will be linked with information on claims, cost of care and services used to evaluate program effectiveness.

The project will not immediately encompass all patient decision making situations, but will begin with six decision aids for topics of hip or knee osteoarthritis, chronic and acute low back pain, spinal stenosis, and herniated disk which will be implemented at four clinics. Additional decision aids related to abnormal uterine bleeding, menopause management and uterine fibroids will be deployed additionally at one of these sites.

Dave Swieskowski, MD, MBA, the principal investigator, and Del Konopka, RN MS, study coordinator, are primarily responsible for managing the integration of these programs into the clinic system and may be contacted for more information at [dkonopka@mercydesmoines.org](mailto:dkonopka@mercydesmoines.org), 643-7393.

**Combined Issue of "Update"**

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Undoubtedly, summer is a season when time seems to move at a different pace – and not necessarily slower. We know that families have vacations, summer camps, or just more time with kids at home.

So realizing that many of our colleagues are occupied with things other than ICTCR research news, we combined our June and July issues with the plan to return to a monthly schedule for the "Update" starting in August.

Those of us directly involved with the ICTCR have lately been pre-occupied with a new community based consortium that has been assembled to develop new far-reaching re-search training programs in clinical research. This effort has involved much relationship building, planning and urging of our professional colleagues to commit to help make this a success.

Later, mention will be made of the many partners in this venture, but for now, we want to recognize Dr. Ted Rooney who worked tirelessly on the intricate relationships involved.

We have submitted a major grant seeking support for this venture and we will be giving much more detail in the months ahead through the ICTCR "update". So the time saved by eliminating one summer issue of the "update" has given us welcome time to put the finishing touches on what may become a very important program of research training for Central Iowa and the health professionals who practice here or who are training to practice in the state.

**Information on NIH**

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Office of Extramural Research:  
<http://grants.nih.gov/grants/oer.htm>  
And the "Extramural Nexus"  
<http://grants.nih.gov/grants/nexus.htm>  
ERA Commons (<http://era.nih.gov/>)

**The National Institutes of Health:  
Extramural Granting-- Changed and Changing**

As I prepare to go to NIH this summer to participate in the review of extramural grant applications, I have been faced with a new mechanism for reviewing and scoring grant applications. This new evaluation paradigm is part of a year long process the NIH has engaged in to streamline and improve the granting process. Because all of our ICTCR partner institutions are increasingly involved with NIH-supported research and certainly with the quest for additional NIH funding, I thought it might be an opportune time to mention some of these changes and give tips on keeping up with future changes.

The new scoring system for overall impact/priority on grant applications, called 'enhanced peer review' will require that reviewers evaluate each of the key criteria of Significance, Investigators, Innovation, Approach and Environment on a 1-9 criterion scale. The NIH has also given descriptors that go along with the numerical values to help reviewers select an appropriate scoring level. Applicants will be able to see scores for individual areas making the process more transparent and useful to applicants as they try to determine the true strengths and weaknesses noted by the reviewers. This system will be phasing in and the NIH will create percentile rankings to a new base after 3 rounds of review have been completed.

Electronic submission of grant applications has been in place for a few years, but even so, some grants are still submitted in paper form. Paper submission will continue to disappear and eventually all grant applications will be submitted through ERA (Electronic Research Administration) Commons. Anyone who is submitting a grant electronically for the first time should work with an experienced sponsored programs officer for guidance as the process can be a little complicated the first time, even though the grant application may have all the same elements as the paper application. Some applicants might be surprised to know that electronic submissions are not necessarily more efficient for the applicant as hundreds of applicants may be accessing NIH servers simultaneously at or near the deadline and the submissions must go through an error checking process that may involve multiple rounds of correction and resubmission. For your first submission, start early to allow plenty of time for the unexpected.

Applications will be changing in the future. Anyone who has submitted a regular investigator initiated research project to NIH is familiar with the 25 limit on the Research Plan portion of the application. NIH will be phasing in a new streamlined version in which the Research Plan will be limited to 12 pages instead of 25. Some grant applications (those related to the ARRA or stimulus money) have used the shorter form and some institutes will be phasing in the new version with some being required in early 2010. If you are submitting a grant application in the coming year, watch for changes. Is the shorter form good or bad? On one hand it means the writing task is smaller, but on the other hand, it means you have just 12 pages in which to make your case that you are a strong investigator with an innovative project, an outstanding approach and are working in a suitable environment. To keep up with developments, subscribe to the RSS feeds from the Office of Extramural Research and the NIH (see sidebar).

– *This article was contributed by Bryan Larsen, PhD, ICTCR.*

## **Obstetrical Research and Premature Birth Prevention**

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**Joseph K. Hwang, MD  
FACOG**



For additional information about this study, please contact Dr. Hwang through the Perinatal Center of Iowa: <http://www.perinataliowa.com> where a full description of this project can be found, or call 515 643-6888

Dr. Joseph Hwang along with the staff at the Perinatal Center of Iowa will join an international study that is cooperatively sponsored by the National Institutes of Health and Columbia Laboratories to examine the efficacy of a progesterone gel that may decrease the risk of premature labor and birth in a cohort of women who have sonographically demonstrable reduced cervical length. The study will be a placebo-controlled trial and will be open pregnant women who have singleton pregnancy and are not scheduled to undergo a cerclage procedure. (Additional criteria apply.)

Preterm birth is a significant public health problem worldwide and despite the availability of a high level of medical technology in the US, 12.7% of births in the US in 2007 were occurred before 37 weeks of completed gestation. World-wide, the figures are sobering, as an estimated 4 million deaths occur as a result of premature birth, and 98% of these occur in developing countries according to World Health Organization estimates.

While many aspects of the causes of premature birth remain poorly understood, one definable risk factor that can be measured with minimally invasive methods is the distance from the cervical os to the amniotic sac. If this distance is especially short, it places microorganisms of the normal flora in proximity to the fetal membranes. Some evidence suggests that certain types of microbial flora are more likely than others to elicit obstetrical complications either through direct invasion of the fetal membranes, by eliciting an inflammatory reaction leading to preterm labor or by elaborating enzymes that weaken the barrier provided by the amnion and chorion. Thus far, no antibiotic regimen has proven reliable in preventing premature birth despite the direct or indirect role of bacteria in preterm birth, premature rupture of the fetal membranes or other complications.

Research has indicated that progesterone treatment may be beneficial in decreasing the risk of preterm birth. Fortunately, progesterone is a naturally-occurring steroid hormone found throughout pregnancy, although it drops precipitously at term. The study which will be conducted by the Perinatal Center of Iowa applies a progesterone containing gel (or placebo gel) to the cervix, and because the active ingredient is a normal hormone of pregnancy it carries less concern that a completely novel drug compound would. In fact this is not the first time progesterone gel has been used in pregnancy.

The Perinatal Center of Iowa is also collaborating with the NIH-sponsored National Children's Study which will be a topic of a future "update" issue. Dr. Hwang is also serving as a guest editor on a special edition of *Infectious Diseases in Obstetrics and Gynecology* which will focus on infectious diseases relationships with preterm birth. The high volume and complexity of cases managed by PCI makes it an ideal venue for advancing knowledge in high-risk obstetrics.

### **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.