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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

Comparative Effectiveness Research (CER) Takes Center Stage

The American Recovery and Reinvestment Act (ARRA) has become a well known term as new funds have been directed at broad range of purposes intended to create economic stimulus in a time of economic downturn. A \$1.1 billion allocation for CER was announced by the US Department of Health and Human Services (HHS) and these funds will be distributed as follows: \$300M Agency for Healthcare Research and Quality (AHRQ), National Institutes of Health (\$400M) and the Secretary of HHS (\$400M). The program will have the input from a panel of 15 experts representing government and independent organizations with an interest in effective health care. Details of the announcement and information on committee members is at: [www.hhs.gov/recovery/programs/os/cebios.html]

Although the term, Comparative Effectiveness Research, may be largely self-explanatory, it might also require definition as it could be conflated with Evidence-Based Medicine, or Cost-Benefit Analysis. According to a December, 2007 paper by the Congressional Budget Office entitled "Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role," CER is defined as "...a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risks of each option, or it may also weigh both the costs and the benefits of those options. In some cases, a given treatment may prove to be more effective clinically or more cost-effective for a broad range of patients, but frequently a key issue is determining which specific types of patients would benefit most from it. A beneficial treatment is only of value to a subset of patients upon rigorous study.

While not necessarily a household term, the concept of CER captures public attention as reports which have become hot topics in the lay press (comparison of different cholesterol lowering regimens, or mammography screening frequency, to mention only a couple of very recent examples) underlies studies that seem to have high relevance for the public which is concerned about both what is the best care and what is cost-effective care. Professionals might be intrigued because some of the discoveries made in CER are counter-intuitive, unexpected and occasionally suggest that the newest treatments may not be the most efficacious or cost-effective.

Medical centers interested in CER initiatives, should find ARRA funds an important new opportunity and should stimulate thinking about local projects that are within the scope of CER. Perhaps most important is the fact that even smaller medical centers (see sidebar on page 2) can be involved in this area of research as stand-alone investigations or as part of multi-center studies. – *B. Larsen*

**Comparative Effectiveness
Research at Mercy Medical
Center (follow-up to page 1):**

The increasing importance the US Public Health Service is placing on Comparative Effectiveness Research was described on page 1. But is this kind of research going on at Mercy Medical Center?

The ICTCR is currently engaged in an ongoing evaluation of the Mercy Health Network project known as eICU-Connect. This will be the first ever study of a clinical unit that uses technology to remotely monitor critical care patients that is independent of vendor sponsorship and is also unique in that data will be compared between the remotely monitored intensive care units and control hospitals that do not have remote monitoring. A more comprehensive description of this project will appear in a forthcoming issue of the ICTCR update.

Another notable comparative effectiveness project is illustrated by the efforts Mercy Clinics Inc. have expended in developing the Patient Centered Medical Home (PCMH) in various parts of their organization. The clinic system is highly data driven and this lends itself to opportunities for careful and thorough analysis of the effectiveness of clinical sites where the PCMH concept is fully operational to those clinical sites where it is only partly or not operational at all.

These examples (there are others) reveal the richness of information available for Comparative Effectiveness Research within the medical center.

The discussion at the right is based on: G. O. Schaeffer, E. J. Emanuel and A. Wertheimer which appeared in JAMA 2009; 302 67-72. The editor is indebted to Dr. Ron Torry (Drake Liaison to the ICTCR) for calling this provocative paper to our attention. →

**Controversial Thoughts on Human Subjects Research
Participation: Duty or Choice**

There is no doubt that the literal life-blood of clinical research studies is the patients who voluntarily join studies that are offered to them. In a recent article appearing in JAMA, authors Schaeffer, Emanuel and Wertheimer (1) posit that participation in research studies is an obligation in contrast to the more prevalent view that patients who participate in research are going above and beyond the call of duty that faces all of society. Because this concept is a significant departure from what the authors refer to as the "standard view", it is certain to be controversial. Undoubtedly, clinical research investigators are grateful to those patients who are willing to be research participants, but it would be unlikely – almost unthinkable - that a researcher would tell a patient that they have an obligation to participate. Indeed, it would be interesting to contemplate the reaction of IRB members if they heard that an investigator included "duty" in the informed consent discussion.

This is certainly not what the authors of the opinion are implying, but their reasons for suggesting the existence of an obligation on the part of qualified research subjects deserves hearing and possibly discussion among the public that is a potential beneficiary of clinical research. The authors of the JAMA article appeal to the concept of beneficence which obligates people to do good or prevent ill if they can. Yet they recognize limitations to the concept as it is not reasonable that people's beneficence will be without bounds as it is unrealistic to believe it is rational to become entirely self-impooverished to contribute to those who are unfortunate. The authors also invoke the idea that anyone who does not contribute to the greater good is taking a free ride – in other words obtaining potential future benefits from research for which others are volunteering, without sharing in the risk intrinsic to all research studies. Although not mentioned specifically, the Belmont principle of justice, which states that those who accept the risks of research should also have its benefits available to them, seems very much related to the free ride argument. Interestingly, while the principles of beneficence and justice are invoked as obligations of researchers toward those who are research subjects, the arguments of Owen et al appear to reflect a requirement on the public to practice those principles toward their fellow creatures when given opportunity.

An additional appeal is made to a concept that individuals should contribute to public good – so called because the good embodied in better medical knowledge is available to all and is not expended when one person partakes of it. It is interesting to note that in the informed consent document, this is one principle that comes through very strongly as investigators frequently tell the potential research participant that the study may not benefit you personally, but the knowledge gained in the research may help others with a similar condition in the future.

Questions and objections are addressed in the JAMA paper and deserve mention. For example, while suggesting participant obligation, the authors do not indicate there should be an enforcement mechanism to require participation. In addition, they do not believe that the sense of duty obviates the role of consent in biomedical research. (See additional notes in sidebar at left). – Update Editor

Featured Researchers:

Dr. Geoffrey Wall



Dr. Bernard Leman



Justin Costello



Dr. Richard Deming



Dr. E. P. Finnerty



Dr. Dev Puri



Collaboration Culminates in Published Case Report

Dr. Geoffrey C. Wall of the Drake University College of Pharmacy and Health Science and Dr. Bernard I. Leman of the Iowa Inflammatory Bowel Disease Center, recently published an unusual case of mucormycosis that surfaced in a patient who was being treated with an immunosuppressive (including a TNF inhibitor) regimen for long-standing Crohn's disease. (Pictured left sidebar)

The report appeared in "Digestion" September 2009. The authors reported that the patient's symptoms led to imaging studies and endoscopic biopsy that allowed them to identify the uncommon mucormycosis. This fungal infection can be fulminating and presents a serious and possibly increasing risk due to expanding use of immunosuppressive therapy including biological response modifiers as occurred in this case. The authors reported that the patient responded to antifungal therapy and removal of the immunosuppressive regimen which was accomplished without immediate exacerbation of the Crohn's disease.

We congratulate Drs. Wall and Leman for a timely reminder that the learning opportunities gained from unexpected cases with unusual presentations ought to be reported on and shared with the larger medical community. The success in managing this potentially devastating condition may be of substantial value to physicians who are faced with a similar problem and illustrates the complexity inherent in the polypharmacy that can accompany multiple chronic diseases and that complications of therapy often arise in systems or sites other than those being directly treated. (Digestion 2009; 80: 182-184)

Med Student Radiotherapy Research Unites Mercy Physicians, DMU Faculty

Justin Costello, Des Moines University Medical Student is first author on an abstract that presents results of a novel retrospective review of the use of the Cyberknife® stereotactic radiotherapy instrument in a study on its compassionate use in non-small cell lung carcinoma. Joining Justin Costello as co-author is Mercy Medical Center physician, Dr. R.L. Deming and DMU faculty member E. P. (Pat) Finnerty. The senior author on the paper is Dr. Dev Puri of the Mercy Radiotherapy Program who served as the chief clinical mentor for this project. This research is both interdisciplinary and inter-institutional. Such collaboration fulfills the purpose of translating the theoretical value of potential therapies into sound evidence. This type of research brings value to individual patients and populations while advancing the research skills of participating medical students. The abstract, entitled "Cyberknife Stereotactic Body Radiotherapy: A Retrospective Review of Local Control, Marginal Failures, and Early Toxicity in Inoperable Stage I Non-Small Cell Lung Cancer" is expected to be presented at the 9th Annual Cyberknife® Scientific Meeting in Dallas, Texas.

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.