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About The ICTCR

We exist to facilitate 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. Web address is www.iowatranslationalresearch.org

Iowa Diabetes And Endocrinology Research Center (IDERC) Joins The International TECOS Study

Iowa Diabetes and Endocrinology Research Center's (IDERC) commitment to providing diabetic patients in Iowa with the latest diabetes research and leading edge treatment has led to an invitation to join the TECOS study. The landmark international study is intended to compare the impact of Januvia (sitagliptin) as part of usual care for Type 2 diabetes patients versus usual care without the drug with respect to cardiovascular outcomes. A double-blind placebo-controlled paradigm for persons with inadequate glycemic control on mono or dual combination oral antihyperglycemic therapy will be utilized. The study is expected to last approximately four years and enroll 14,000 patients in 33 countries.

Dr. Anuj Bhargava and the IDERC staff will direct the portion of the study that will occur at Mercy Medical Center—Des Moines. The patient population recruited for this study will include individuals with Type 2 diabetes and those who have heart or vascular disease—including heart attacks, stroke or peripheral vascular disease. Dr. Bhargava indicates that the study may last between three and six years depending on the rate of recruitment.

IDERC is interested in recruiting patients who meet the inclusion criteria: greater than 50 years of age; not currently on insulin; and have a glycosylated hemoglobin level of 6.5 percent to -8 percent three months prior to enrollment. Study participants will be seen four times during the first year of the study and twice yearly thereafter, with telephone interviews every six months. The study team will be responsible for detailed evaluation to determine individual eligibility. Qualified participants will receive study-related care and study medication(s) at no charge. They may also receive payment for time and travel expenses.

IDERC is also seeking providers who may be willing to collaborate on the trial. Providers could help with recruitment or could become a sub-investigator. Interested providers may contact Dr. Bhargava by emailing anujmd@yahoo.com.

Study personnel for the TECOS study may be reached at the IDERC office, which is located at Iowa Diabetes and Endocrinology Center at Mercy Medical Center—Des Moines, 1111 6th Ave, Suite 450, Des Moines, Iowa, 50314. Additional information may be obtained by calling (515) 643-5122 or emailing iderc@mercydesmoines.org or visiting www.iderc.org.

What the Human Genome Project has to say about Pharmacogenomics...

The US Department of Energy was the lead agency in completing the sequencing of the human genome and continues to pursue genomic research. The promise of pharmacogenomics, according to the agency, "Pharmacogenomics holds the promise that drugs might one day be tailor-made for individuals and adapted to each person's own genetic makeup."

Expected benefits from the application of pharmacogenomics are:

- More powerful medicines
- Better, safer drugs the first time
- More accurate methods for determining appropriate drug dosages
- Advanced screening for diseases
- Better vaccines
- Improvement in the drug discovery and approval process
- Decrease in the overall cost of health care

Further Reading

<http://publications.nigms.nih.gov/medbydesign/> This piece by the National Institute of General Medical Sciences of the National Institutes of Health is suitable for lay audiences.

**Pharmacogenomics:
Research that Supports Individualized Medicine**

Pharmacogenomics, the branch of science that bridges genetic variation to therapeutic applications is one of the rapidly growing areas of research. As a result, personalized medicine, considered to be the future of healthcare, is already here. This contention is supported by several lines of evidence. During the past 8-9 years, the number of peer reviewed publications in this general area has increased five fold - from about 210 in the year 2000 to over a thousand in 2008 and over 370 articles in the first quarter of this year alone. A recent FDA study states that that out of about 33 million prescriptions filled in the US during 2006, 8.8 million prescriptions contained biomarker information in the drug labels. That is a staggering 24% of prescriptions filled with pharmacogenomic information!

The same report documents a five to six fold increase in the number of FDA approved drugs that contain genetic information in their labels. This number keeps growing as new research unravels association of genetic variation with adverse drug reactions or improved dose monitoring, and is not limited to newly approved drugs, but also applies to drugs already in use. Thus, prompted by new research documenting severe hypersensitivity reactions to Abacavir treatment, in July 2008 FDA issued a boxed warning on the Abacavir (marketed as Ziagen®, Trizivir® and Epzicom®) label recommending that patients be screened for HLA-*B 5701 allele. In Feb. 2009, the International Warfarin Consortium comprised of 21 research groups across six countries from four continents published a very comprehensive study comprised of over 4000 patients. This research clearly establishes the benefits of using pharmacogenomic algorithms for estimating appropriate initial dose of warfarin, a drug known to have significant adverse effects as a result of large variation in appropriate doses.

Finally, the April 15th issue of NEJM has published a study describing association of a locus on chromosome 12p13 with increased risk for stroke. We can go on citing many more examples of the phenomenal increase in pharmacogenomics research. As described above, translation of this fundamental knowledge into clinical applications is also growing, but not as rapidly. Lack of trained health care professionals is one of the many challenges that contribute to this slower bench to bedside translation.

We as members of ICTCR have an important role to play in further improving the abilities of current and future health care professionals in this area. Simultaneously, we have an obligation to increase awareness of the consumers about the science, business and ethics of individualized medicine. More on that in the near future!



This article was provided by Pramod Mahajan, PhD (pictured at left). Dr. Mahajan is Associate Professor of Pharmaceutical Science at Drake University's College of Pharmacy and Health Sciences.

Dr. Mahajan is beginning a new program in pharmacogenomics at Drake University and has also submitted a grant to the National Institutes of Health to seek funding for the program. You may get further information: pramod.mahajan@drake.edu

*Anuj Bhargava MD,
MBA, CDE, FACP, FACE
is the Founder of the
IDERC*



For more information about participating in, or referring a patient to a research study, call (515) 643-5122 or visit www.iderc.org



The center is located at the Central Campus of Mercy Medical Center:

1111 6th Ave, Suite 450, Des Moines, Iowa 50314.

Featured Research Program: The Iowa Diabetes and Endocrinology Research Center.

Iowa Diabetes and Endocrinology Research Center (IDERC) was founded in 2007 by Dr. Anuj Bhargava M.D., MBA, CDE, FACP, FACE to bring the latest diabetes research to Iowa and benefit Iowans with diabetes. IDERC is a part of the Iowa Diabetes and Endocrinology Center (IDEC, the largest endocrinology practice in Central Iowa with seven board-certified endocrinologists. IDERC is committed to improving the health and lives of Iowans with diabetes through participation in clinical research.

IDERC Mission: To improve the health and lives of patients with diabetes.

IDERC has participated in 22 research studies since its inception. IDERC is currently screening participants for a variety of studies. One study is looking for post menopausal women with pre-diabetes, while additional ongoing studies are looking for persons with uncontrolled Type 2 diabetes who are not currently on medications.

IDERC is also seeking providers who may be willing to collaborate on the trial. Providers could help with recruitment or could become a sub-investigator. Interested providers may contact Dr. Bhargava by emailing anujmd@yahoo.com.



IDERC Research Team (L-R) June Felice Johnson PharmD, FASHP-CDM-Diabetes; Dr. Bhargava; Debra Iverson ARNP-CNS,CDE,FACE; Natalie Young, CCRC and Lisa Borg, CCRC

Recent publications:

1. Attaining glycemic control by self-titrating biphasic insulin in type-2 diabetes (INITIATEplus trial). David S. Oyer, MD, Mark D. Shepherd, MD, Franklin C. Coulter, MD, Anuj Bhargava, MD, Jason Brett, MD, Pei Ling Chu, PhD, and Bruce S. Trippe, MD, accepted for publication for August 2009, American Journal of Medicine
2. Anuj Bhargava, June Felice Johnson, and Joseph P. Weir. Premixed Insulin Dosing in Actual Practice: Two-Thirds in AM, One-Third in PM, or Half and Half? Clinical Diabetes March 20, 2009 27:91-95

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.