Mayo Professor in the School of Public Health Russell Luepker, M.D., is leading a multidisciplinary team to help transform clinical and translational research education at the University of Minnesota. Training the next generation of scientists working in this increasingly competitive and collaborative field will require new strategies in approaching clinical and translational research—which means starting early and thinking broadly, says Luepker.

“It’s crucial that we become better at engaging young students—as undergraduates or even in high school—to the potential of clinical research,” says Luepker. “We’re good at doing this on a basic science level, but many students interested in the health sciences don’t realize there are fulfilling careers in clinical research as well as bench research.” Toward this aim, new introductory courses in clinical research and internships will be offered at the undergraduate level.

Biostatistics is a crucial component in any clinical research project. Biostatisticians provide important input into the entire research process—from developing the research question and drafting the grant application, to conducting the study and analyzing the data. Fortunately, the University has an excellent cadre of biostatisticians with a strong track record in clinical and translational research. However, we are working to make their expertise even more accessible with the creation of the Biostatistical Design and Analysis Center (BDAC), an AHC-wide facility specializing in clinical and translational research support.

With the formation of BDAC, we are responding to several issues identified in the 2003 AHC Task Force on clinical research. These included: statistical and coordinating support that was not well-integrated with other AHC researcher activities, and an insufficient number of both statisticians available to plan and write grant applications and biostatisticians needed to assist with the analysis of data from current projects.

BDAC will be staffed by experienced biostatisticians who will guide clinical and translational researchers in study design, design innovation, data analysis, and results reporting. In addition, the center will offer statistical consulting and analysis for clinical trials and smaller-scale studies, as well as provide initial consultations to help investigators develop new ideas for review.

(continued on page 2)
Director’s Update, continued.

John Connett, Ph.D., professor and head of the Division of Biostatistics in the School of Public Health is interim director of BDAC. There are currently open searches for a director, up to three Ph.D.-level faculty, two master’s level research fellows, and two bachelor’s level statistical assistants. For complete job descriptions, or to apply, go to: http://employment.umn.edu or contact Sue Jackson at 612-625-1652 or sjackson@umn.edu.

BDAC is just one initiative sponsored by the Office of Clinical Research to ensure that clinical and translational researchers receive the support needed to truly succeed. As we continue to transform the research enterprise at the University, we welcome your comments and suggestions. Please feel free to contact me at ahecocr@umn.edu.

Education Initiatives, continued.

Luepker also recognizes that clinical research must be a multidisciplinary venture. “The field is too complex for any one discipline,” he says. Both the NIH-funded K12 program and the M.S. in clinical research are multidisciplinary, involving students from across the AHC’s schools and colleges.

“We’re also reaching out to health professionals in the community,” he adds. “In addition to providing continuing education and career development opportunities, we are working to engage health professionals at organizations such as Fairview, HCMC, Abbott Northwestern, and HealthPartners in potential research collaborations.”

Finally, there is a need to inform the general population about clinical research. Although the public may regard medical discovery favorably, explains Luepker, concerns about drug safety or treatment of clinical participants may make many people unwilling to participate. “Issues in clinical research typically are not black and white. We need to do a better job helping the public understand these complex issues.” One way to do this is to build on existing successful programs. For example, Mini Medical School, a popular community outreach program designed to help educate Minnesotans about new and emerging health-related issues, is taught by an interprofessional team of leading faculty members over the course of four weekly sessions, focusing on topics such as cancer, neuroscience, and women’s health.

New on the team is Nancy Johnson, education coordinator, who will work with the Office of Clinical Research in the areas of clinical and translational research education. Together the team will develop creative approaches, increase interprofessional efforts, and reach out to the community at large.

Available resources for those interested in clinical research include:

- a new undergraduate introductory class in clinical research;
- a graduate course for clinical research coordinators (see below);
- and a variety of courses within the Master’s of Science in Clinical Research, which can also be taken by those not formally enrolled in the program. For more information, contact Nancy Johnson at (612) 625-1651 or nancyj@umn.edu.

Register now for a graduate course on clinical research.

PubH 6305, Introduction to Clinical Research for Health Professionals, will be offered Spring 2007. Taught by Russell Luepker, M.D., M.S., and Alan Berger, M.D., the course is designed for nurses, coordinators, and other professional staff working in or preparing to work in a clinical research setting. For more information on the course, obtain the syllabus from Spring 2006, or to register, contact Kathryn Schwartz at schwartz@epi.umn.edu.
**SPOTLIGHT**

**Bench to Bedside:**
**Pioneering Treatment for Leukemia**

From the basic science discovery of a new drug therapy to conducting Phase I clinical trials, a team of Cancer Center scientists and physicians hopes to provide pioneering treatment for acute lymphoblastic leukemia—a collaboration representing bench to bedside research at the University of Minnesota.

It began in the laboratory of Daniel Vallera, Ph.D., a basic science researcher focusing on experimental drug therapies for cancer patients. Vallera and colleagues radiolabeled an antibody that can specifically bind to cancer cells. These radioactive antibodies can kill cancer cells on contact.

Vallera hopes that delivering the radiation directly to the cancer cell will eradicate the cancer while leaving surrounding tissue unharmed. He and his colleagues are beginning to investigate this drug as an alternative treatment for patients with acute lymphoblastic leukemia (ALL).

Hematology oncologist Linda Burns, M.D., specializes in treatment of adults with leukemia and other blood cancers. Interested in Vallera’s discovery, she began a Phase I clinical trial in the spring of 2005. This trial uses Vallera’s antibody treatment to target CD45, which is present on cancerous blood cells. Vallera and Burns worked together to obtain an Investigational New Drug (IND) application through the FDA for use of the drug in this Phase I setting. This study is actively enrolling patients at this time.

In the meantime, Vallera developed another antibody treatment that targets CD19. This antibody is present in only 10 percent of normal blood cells; however, in patients with ALL, it is present in all leukemia cells. Pediatric oncologist Brenda Weigel, M.D., will use this antibody therapy in a clinical trial involving children whose cancer has not responded to conventional therapies or for whom conventional therapies have failed.

“We’re hopeful this antibody will ultimately be a way of delivering an effective leukemia therapy without a lot of side effects and may help children with little or no other options,” says Weigel. “For instance, this treatment may help move children to remission so they can obtain a bone marrow transplant.” The team worked with Harvey Arbit, Ph.D., in the University’s Research Services Organization to obtain FDA approval and will begin patient recruitment pending final approval from the University’s IRB.

Vallera, Burns, and Weigel’s work illustrates the University’s commitment to moving basic science discoveries into meaningful treatments, giving doctors new tools to fight challenging diseases, and patients the hope for a cure.

**NEWS**

**Training for electronically submitting proposals to Grants.gov**

Using EGMS System-to-System begins in November. This system will enable users to prepare and submit R01 applications to NIH through Grants.gov for the February 2007 deadline. To register for System-to-System training, e-mail help@egms.umn.edu with “EGMS S2S” in the subject line or call Frances Spalding at (612) 625-0848. Training schedules will be posted at: [http://www.ospa.umn.edu/GrantGov/Schedules%20and%20Calendars/trainingschedule.html](http://www.ospa.umn.edu/GrantGov/Schedules%20and%20Calendars/trainingschedule.html).

**The Body Composition Human Performance (BCHP) laboratory**

of the General Clinical Research Center (GCRC) has a Lunar Prodigy densitometer used to evaluate body composition and bone density in pediatric and adult populations. The lab has recently obtained an updated software version which has new normative data for lean body mass in pediatric patients. GCRC staff can assist with studies requiring total body, lumbar spine, and femur scans. Contact Susan Raatz, Ph.D., at raatz@med.umn.edu or (612) 624-6642 for your densitometry needs.
CAPS Profile:
Heather Vezina, Pharm.D.

Heather Vezina, Pharm.D., came to the University of Minnesota in 2000 to pursue a two-year fellowship in antiretroviral clinical pharmacology at the College of Pharmacy. During her fellowship Vezina became active in the Minnesota AIDS Clinical Trials Unit (ACTU) where she met her senior mentor, Henry H. Balfour, Jr., M.D. Balfour is the P.I. of the Minnesota ACTU and also has an active Epstein-Barr virus (EBV) research program. In 2002 Vezina accepted a joint faculty appointment in the Medical School’s Department of Laboratory Medicine and Pathology and the College of Pharmacy’s Department of Experimental and Clinical Pharmacology. As an assistant professor she became interested in antiviral-EBV and antiviral-host interactions and is now an integral part of Balfour’s EBV research program.

Vezina oversees the antiviral pharmacology research laboratory in the Department of Laboratory Medicine and Pathology, which develops drug assays to support her clinical research. As part of CAPS, the NIH-funded K12 program at the University of Minnesota, Vezina is studying whether there is a role for antivirals in the management of primary EBV infections such as infectious mononucleosis (IM), which can occur in otherwise healthy young adults. Her first study will evaluate the pharmacokinetics and pharmacodynamics of the antiviral drug valacyclovir when used as an experimental treatment for primary EBV IM. She is also a co-investigator for a prospective study to evaluate risk factors for the severity of primary EBV IM in University freshmen. Data from these and earlier studies conducted by Balfour’s research group could help explain complex interactions observed among EBV, the host, and antiviral drugs. In addition, these data may provide clues into the pathogenesis and management of more serious EBV infections that can occur in individuals with weakened immune systems, such as those who have undergone transplantation.

In addition to Balfour, professor of laboratory medicine and pathology and pediatrics in the Medical School, Vezina’s mentoring team includes Richard Brundage, Pharm.D., Ph.D., associate professor of experimental and clinical pharmacology in the College of Pharmacy, and William Thomas, Ph.D., associate professor of biostatistics in the School of Public Health.

Regarding CAPS, Vezina says, “I enjoy the multidisciplinary approach to clinical research and look forward to collaborating with other scholars and faculty through this program.”

For more information on CAPS go to: www.epi.umn.edu/CAPS.