

COLORADO HEALTH OUTCOMES PROGRAM ANNUAL REPORT: YEAR 8

November 1, 2007 – October 1, 2008

The Colorado Health Outcomes Program (COHO) was established in 1998 by Dean Richard Krugman of the School of Medicine at the University of Colorado Denver. John Steiner, MD, MPH was appointed as the first permanent director of COHO in 2000. In 2005, the Dean's Strategic Initiatives Review Committee approved an additional 5 years of core funding for COHO through June, 2010. A detailed description of the COHO mission, projects and staff is available on the program website at www.uchsc.edu/coho.

Research initiatives

In 2007-08, COHO continued its research in several focus areas. In the area of health communication and information technology, Dr. Sheana Bull and colleagues have completed their R01-funded internet-based HIV prevention for youth, and learned that, while the initiative had moderate effects, existing options such as social networking sites may be better alternatives than independent websites for HIV prevention. Dr. Bull is continuing an R01 to develop and test an HIV prevention initiative for social networks on My Space.com, and an R21 to pilot test a mobile phone-based HIV prevention initiative for young black men in Philadelphia. In addition, she is a co-investigator on a R01 to develop and test Internet-based HIV prevention interventions for youth in Uganda.

In the area of organizational assessment, Dr. Debbi Main has recently completed a multi-year evaluation of the impact of quality improvement interventions on adult immunizations in Denver Health and childhood immunizations among health care sites on the Western Slope. In the area of chronic disease outcomes, Dr. Diane Fairclough continues her long-term national collaboration in pediatrics, with ongoing studies that include an investigation of depression and anxiety in adolescents with irritable bowel disease, how families make the dual decisions for one child to undergo a bone marrow transplant and a sibling to be the donor, comparison of the social behavior of children who have received treatment for brain tumors with their peers, and cognitive interventions for children who have received CNS treatment for brain tumors or leukemia. She is also involved locally in two investigations of long term outcomes for adult leukemia/ lymphoma and colon cancer survivors. She and Dr. John Steiner have started collaboration with an investigator from Kaiser Permanente on a new R21 study assessing the effect of new onset depression, treatable cancer, and exacerbations of pulmonary disease on guideline-concordant diabetes care.

In the area of cardiovascular outcomes, Dr. Steiner continues his NHLBI-funded cooperative agreement with Denver Health to reduce disparities in cardiovascular disease prevention for Latinos. Ongoing collaborations with investigators at Denver Health, Kaiser Permanente, and the CU Boulder campus led to a new NHLBI R01 award to Irene Blair, PhD (Boulder), to assess physician stereotypes and prejudice as a possible contributor to disparities. Dr. Steiner also received a planning grant to combine BMI data from the electronic health records of Denver Health, Kaiser, and Children's Hospital in order to identify neighborhoods at high risk for adult and childhood obesity in metropolitan Denver. Dr. Debbi Main is now completing her NHLBI-funded study to assess the impact of the built and social environments on health and health disparities among people living in and around the Stapleton redevelopment. She is also actively involved in 2040 Partners for Health, a community-academic partnership that received initial funding from the Colorado Health Institute to develop community-based participatory research programs and evaluations in collaboration with people living in diverse

neighborhoods in and around Stapleton. One of Dr. Main's doctoral students is leading a 2040 Partners for Health project on physical activity and obesity in children; they are currently collecting community-based surveys of children and their parents to be completed in the fall of 2008. Dr. Sheana Bull continued to contribute her expertise in community participatory research, health disparities and qualitative methods to new studies of approaches to improving physical activity and nutrition in community members, and treating hypertension, heart failure, and improving cardiac rehabilitation.

In surgical outcomes, Dr. Bill Henderson is collaborating with investigators throughout the US on 15 funded studies using the National Surgical Quality Improvement Program database, including 13 funded by the VA Health Services Research & Development Service, 1 funded by NIA, and 1 SBIR grant funded by NIH. COHO continues to serve as the coordinating center for the National Surgical Quality Improvement Program (NSQIP), the pre-eminent surgical outcomes improvement and research program in the U.S. Over 300 VA, Department of Defense, and private sector hospitals participate in the program.

Dr. Karl Hammermeister developed and obtained funding for two new SBIR grants, one of which is developing a surgical bed management software system, while the other is collecting NSQIP data in real-time and using that data to provide decision-support to the surgical team. Drs. Hammermeister and Elaine Morrato are working closely with members of the American Pediatric Surgical Association in developing an NSQIP for pediatric surgery. With the Collaboration of Mori Ziegler, MD, chief of pediatric surgery, Phase 1 will begin in four children's hospitals, including TCH, on October 1, 2008.

In child health outcomes, Dr. Allison Kempe, the director of the Childrens' Outcomes Research (COR) program, continues to lead the CDC-funded Vaccine Policy Collaborative Initiative project (which was recently re-funded through 2011), a national, rapid-response survey program of physicians regarding new vaccines, new vaccine recommendations, and policy issues related to vaccination. Additionally, Dr. Kempe received new CDC funding to evaluate vaccination reminder/recall systems for adolescent patients in public and private pediatric offices and school based health centers.

Dr. Matthew F. Daley continues his work in the areas of immunization delivery, immunization safety, and prevention of early childhood caries. Drs. Daley and Kempe constitute the evaluation team on 2 newly funded projects from the CDC, in which the Denver Public Health Department will work with the Denver Public School system to implement large-scale school-based vaccination. Dr. Daley is the lead investigator on a CDC-funded grant to explore adolescent vaccination in non-traditional medical settings, and a co-investigator on the CDC-funded Vaccine Safety Datalink project, a study involving large linked databases that allows rigorous study of issues related to actual or potential adverse events following immunization. In the area of preventive oral health, Dr. Daley also leads a Delta Dental Foundation-funded trial of the feasibility and effectiveness of co-locating dental hygienists in primary care offices to deliver preventive dental care to low-income children.

Dr. Elaine Morrato has initiated a cohort study investigating the prevalence of periodontal disease in adolescents with type I diabetes compared to non-diabetic controls. This study will determine the frequency of oral health self-care, periodontal health knowledge, and correlation of periodontitis severity with cardiovascular risk markers, in collaboration the School of Dental Medicine and The Barbara Davis Center for Childhood Diabetes. Pilot funding was obtained from Procter & Gamble and the Children's Research Institute. Drs. Henderson and Morrato are also investigators in the Center for Native Oral Health Research (CNOHR) in

collaboration with the School of Dental Medicine and the American Indian and Alaska Native Programs. CNOHR is one of four Cooperative Research Centers awarded funding by the National Institute for Dental and Craniofacial Research to reduce oral health disparities. Dr. Morrato continues to lead a Pfizer-sponsored study on the impact of FDA warnings and the American Diabetes Association Consensus Statement on the need for metabolic screening in patients initiating atypical antipsychotic drugs. In 2008, she was also a consultant to the FDA Risk Communication Advisory Committee and an invited speaker on risk management evaluation for the FDA Center for Drug Evaluation and Research.

COR is developing new areas of research in general surgery and in orthopedic surgery. Currently COR investigators are helping orthopedic surgery to assess national trends in spinal fusion surgery using secondary databases, and examining surgical outcomes of spinal fusion and hip surgeries in both prospective and retrospective studies at The Children's Hospital. They are also studying national trends in surgery for gastro-esophageal reflux as well as outcomes for these surgeries at The Children's Hospital, including quality of life and functional measures in children and families. COR is also conducting a qualitative research study to understand the surgical experience and impact of spine fusion for high-risk children with neurological impairment and their families from the perspective of The Children's Hospital clinical team and the child's caregivers.

In pharmaceutical outcomes research, the COHO master contract entered Year 4 for the DEcIDE network, a group of 13 centers nationally with expertise in pharmacoepidemiology. In September 2008, AHRQ designated David West as the Principle Investigator/Director of CO-DEcIDE, replacing Dr. Steiner. Investigators in the Department of Family Medicine, led by Dr. West and Dr. Wilson Pace, are continuing a task order to develop the Distributed Ambulatory Research in Therapeutics Network (DARTNet) - a prototype network of eight organizations representing over 200 clinicians and over 350,000 patients coming together to share electronic health record (EHR) data. The prototype now captures, codifies and standardizes over 200 data elements per patient for use in comparative effectiveness and other outcomes studies. Dr. Rob Valuck (School of Pharmacy) completed the first Observational Comparative Effectiveness Study (OCER) under the Task Order comparing patterns of use, comparative effectiveness, and safety of oral diabetes medications (ODM) in the treatment of type 2 diabetes. Dr. Valuck is currently conducting a confirmatory study using "live" data from DARTNet as a test of the prototype. AHRQ has committed another \$1.3 million to this effort for 2009, with an emphasis on taking the prototype to scale on a national level.

Publications

A list of COHO publications in 2007 and 2008 (to date) is provided on the COHO website at <http://www.uchsc.edu/coho/abstracts.htm>. COHO investigators published over 138 papers in these years.

Educational initiatives

In July 2008, Anne Libby, PhD, became the new director of the CFSP, and oversight for the program was transferred to the new CCTSI. The CFSP enrolled the fifth cohort of junior faculty members into its Clinical Faculty Scholars Program, to assist them in obtaining career development awards or independent funding in outcomes research. The new Clinical Faculty Scholars are: Tim Bernard, MD (Pediatric Neurology), Angela Czaja, MD, MPH (Pediatric critical care), Adit Ginde, MD, MPH (Emergency Medicine/Surgery), and Anusha Streubel, MD, MPH (Neonatology). Five other faculty members continue in the CFSP: Greg Austin, MD, MPH (Gastroenterology), Ingrid Binswanger, MD, MPH (General Internal Medicine), Stacie Daugherty, MD, MSPH (Cardiology), Tom Maddox,

MD, MPH (Cardiology), and Judy Zerzan, MD, MPH (General Internal Medicine). Through May, 2008, the 21 current and former participants in the CFSP have received grants with direct costs of over \$4.6 million. This represents approximately \$24 in grants awarded for each \$1 of AEF investment and over \$7 in grants awarded for each \$1 in total (AEF + departmental) program costs. In September 2008, Dr. Adit Ginde was awarded one of 4 inaugural K12 grants through the CCTSI (out of 31 applicants).

Dr. Kempe continues to direct the training of 10 primary care research fellows who are supported by two HRSA-funded programs: a NRSA (T32) award and a faculty development grant. Both programs are housed in COHO, and were refunded for the 2008-2011 time period. These fellows are conducting research in vaccine delivery to adults and children, treatment of hypertension, prevention of obesity in children, treatment of obesity in adults, interventions to increase exercise in diabetic and overweight adults, preferences regarding the medical home in low-income families, the relationship of exercise and osteopenia, management of reflux in children with special needs, prevention of dental caries in childhood, risk assessment and medical decision-making by primary care physicians, and increasing the effectiveness of primary care teaching.

COHO continues to offer monthly research seminars in Methods and Applications in Health Outcomes Research, a weekly primary care faculty research conference, a monthly statistics “brown bag” conference, a joint COHO/DH research conference for DH investigators as part of its cardiovascular partnership grant, a SAS “users group” under the direction of Brenda Beaty, MSPH, and a working group on qualitative research methods under the direction of Carolyn Nowels, MSPH, in collaboration with the Health and Behavioral Science Department at the downtown campus.

In 2007, COHO leadership and senior investigators devoted substantial time to the successful application for a CTSA award from NIH. The initiation of the Colorado Clinical Science Translation Institute (CCTSI) will more fully integrate our agenda of community translational research with traditional “discovery translation” research efforts on campus. Dr. Steiner led the development of the Education, Training, and Career Development programs, and Drs. Bull and Main will have a major role in the Scientific Staff of the Community Engagement component of the CTSI. Dr. Bull and Charlene Ortiz, senior PRA, were instrumental in obtaining funds to establish a training program in community engagement through the CCTSI. The program will train academics and community members how to improve partnerships that will contribute to better translational research.

Financial report

Current COHO research projects are summarized in Table 1 for the period July 1, 2007 to June 30, 2008, and in Table 2 for 2008-09 (to date). Table 3 demonstrates that COHO has achieved this growth while remaining a careful steward of AEF resources, due largely to the ability of COHO senior investigators to offset their time charged to the AEF with extramurally funded research. At this point, AEF reserves of \$278,000 are sufficient to fund another year (Year 11) of operation beyond the original budget when AEF funding was renewed in 2005. Table 4 summarizes the growth in the number of COHO investigators, staff, projects, and funding since 2000. In 2007-8, COHO funding grew to over \$6.2 million, despite the harsh funding climate for federal grants. In the current fiscal year, COHO has already received over \$5.2 million in funding with nine months remaining, suggesting that the COHO budget will remain stable this year.

Challenges and plans, 2008-9

Over its first 8 years, COHO faced several perennial challenges. The negotiated division of ICR between COHO and departments continues to run smoothly, although new agreements are under negotiation for COHO faculty with primary appointments in the new School of Public Health. The demand for mentorship continues, but has been met by the development of the

Clinical Faculty Scholars program. With the inauguration of the CCTSI, much of the prior mentoring demand will be met institutionally by UCD, rather than within COHO. Mentorship of surgical outcomes researchers remains an ongoing concern, and Drs. Bill Henderson and Karl Hammermeister continue to discuss strategies for this problem with senior surgical leadership. Funding for administrative infrastructure remains an issue, since the return of indirect costs to COHO is insufficient to support all administrative activities, and the AEF remains the only other source of support (in the absence of an endowment) for such costs. While the renewal of COHO AEF support in 2005 provides stability, COHO investigators continue to seek alternative sources of revenue that can contribute to the administrative costs of the program. The decline in federal research support has been of substantial concern nationally, but COHO and COR continue to grow despite this downturn.

The impending departure of Dr. Steiner in November, 2008 has brought into focus the need for a comprehensive reassessment of the goals and directions of COHO. This effort is timely for several reasons. First, COHO will need to renew its AEF support in 2010 or 2011, and a clear plan for program development will assist that process. Second, as new initiatives in health services and health outcomes research develop within UCD and the broader Denver research community, COHO needs to reassess its relationships with these entities. These include the community engagement, informatics, biostatistics, and education/training components of the CCTSI, departments within the new School of Public Health, the Division of Healthcare Policy and Research in the Department of Medicine, the REAP at the Denver VAMC, collaborating academic departments on the UCD downtown campus (particularly the Department of Health and Behavioral Science) and Boulder (Department of Psychology), and other departments/divisions within the School of Medicine, particularly the primary care academic units (Department of Family Medicine, Division of General Internal Medicine, Section of General Pediatrics). Since Dr. Steiner will assume the leadership of the Institute for Health Research at Kaiser Permanente Colorado, a reassessment of that relationship is also timely.

To address these issues, Dr. Frank DeGruy has agreed to lead a strategic planning process, and the search for an interim director for COHO, who has not been appointed at the time of this writing. The goal for this process is to define strategic objectives to guide the recruitment of a new COHO director in 2009.