

COLORADO HEALTH OUTCOMES PROGRAM ANNUAL REPORT: YEAR 7

November 1, 2006 – October 31, 2007

The Colorado Health Outcomes Program (COHO) was authorized 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 September 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. This report summarizes COHO progress from November, 2006-October, 2007.

Research initiatives

In 2006-07, COHO continued its research in several focus areas. In the area of health communication and information technology, Dr. Sheana Bull and colleagues are finishing analyses of their R01-funded internet-based HIV prevention for youth. As a consultant to technology-based prevention studies in the US and internationally, Dr. Bull is helping to design a prevention website for persons with HIV and to develop a site to help STD clinicians promote prevention initiatives. In 2007 Dr. Bull was awarded 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 will be a co-investigator on a R01 to develop and test Internet-based HIV prevention interventions for youth in Uganda. Dr. Steve Ross received a grant from the Robert Wood Johnson Foundation to design a "next-generation" prototype personal health record to assist older adults with complex medical conditions, and their caregivers, with medication management across care transitions.

In the area of organizational assessment, Dr. Debbi Main is collaborating with Drs. Ally Kempe and Matt Daley on their grants to understand primary care office adolescent immunization practices. In the area of patient-centered outcomes measurement, Dr. Diane Fairclough continues her long-term national collaboration in pediatric cancer, with ongoing studies that include an investigation of factors contributing to perception of quality of life among cancer patients enrolled in hospice, assessment of the trajectories of adjustment in mothers of children with newly diagnosed cancer, and a comparison of the social behavior of children who have received treatment for brain tumors with their peers.

In the area of cardiovascular outcomes, Dr. John Steiner continues his NHLBI-funded cooperative agreement with Denver Health to reduce disparities in cardiovascular disease prevention for Latinos. He has collaborated with investigators at Denver Health, Kaiser Permanente, and the CU Boulder campus on pending applications that assess physician stereotypes and prejudice as a possible contributor to disparities, and studies of patient empowerment interventions to reduce disparities. Dr. Debbi Main continued her NHLBI-funded study to assess the impact of the Stapleton redevelopment on physical activity and cardiovascular risk. She is also the Co-Director of Stapleton 2040, a community-academic partnership recently funded by the Colorado Health Institute to develop community-based participatory research programs and evaluations in collaboration with people living in neighborhoods in and around Stapleton. 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. Drs. Karl Hammermeister and John Steiner completed a project to assess the effectiveness of isosorbide-hydralazine on heart failure outcomes in veterans, through a AHRQ task order awarded under a DEcIDE master contract.

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. The results of the AHRQ-funded Patient Safety in Surgery Study, which demonstrated that the NSQIP, developed in the VA, could be applied in the private sector as well, were published by Dr. Henderson and colleagues in a series of 20 articles in the June, 2007 issue of *Journal of the American College of Surgeons*.

Dr. Karl Hammermeister developed two SBIR grants, one of which was funded to develop a surgical bed management software system, while the other, to collect NSQIP data in real-time and to use that data to provide decision-support to the surgical team, has received a very promising priority score. Drs. Hammermeister and Elaine Morrato are working closely with members of the American Pediatric Surgical Association in developing an NSQIP for pediatric surgery.

In child health outcomes, Dr. Allison Kempe became the director of the Childrens' Outcomes Research (COR) program, replacing its founder, Dr. Steve Berman. She 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. Matt Daley obtained a CDC-funded grant to explore the feasibility and acceptability of adolescent vaccination in non-traditional medical settings. Dr. Daley also leads a Delta Dental Foundation-funded RCT of the effectiveness of delivering preventive dental care children in conjunction with primary care to low-income children. In 2007, Dr. Daley assumed a new position as a co-investigator in the CDC-funded Vaccine Safety Datalink, a studying involving large linked databases that allows rigorous study of issues related to actual or potential adverse events following immunization.

Dr. Elaine Morrato is initiating 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 Dentistry and The Barbara Davis Center for Childhood Diabetes. She 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.

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.

In pharmaceutical outcomes research, AHRQ renewed the COHO master contract in the DEcIDE network, a group of 13 centers nationally with expertise in pharmaco-epidemiology. Dr. John Steiner is the principal investigator. Dr. David West is the Operations Director for CO-DEcIDE and was the primary investigator responsible for obtaining this master contract. Drs. Steiner and Hammermeister completed the first task order (as noted above), and investigators in the Department of Family Medicine, led by Dr. West, received a second 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 system will capture, codify and standardize over 200 data elements per patient for use in comparative effectiveness and other outcomes studies.

Publications

A list of COHO publications in 2005, 2006 and 2007 (to date) is provided on the COHO website at <http://www.uchsc.edu/coho/about.php>. COHO investigators published over 90 papers in each year.

Educational initiatives

In July 2007, COHO enrolled the fourth 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: 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). Four other faculty members continue in the CFSP: Liron Caplan, MD, MPH (Rheumatology), Lorraine Dugoff, MD (Obstetrics/Gynecology), Stephen Ross, MD, (General Internal Medicine), and Jeannie Zuk, PhD (Pediatric Anesthesia). Since February, 2004, the 17 current and former participants in the CFSP have received 15 grants (out of 26 submitted) for total awarded direct costs of over \$3.5 million.

Dr. Kempe continues to direct the training of 10 faculty development and primary care fellows who are supported by HRSA-funded programs including a NRSA (T32) award, and are housed in COHO. These fellows are conducting research in vaccine delivery to adults and children, treatment of hypertension, screening for colorectal cancer in rural areas, health care for undocumented patients with renal failure, prevention of obesity in children, antibiotic overuse in primary care, injury prevention, and interventions to increase exercise in diabetic and overweight adults. Renewal applications for both programs are being submitted in 2007-08.

COHO continues to offer monthly research seminars in Methods and Applications in Health Outcomes Research in collaboration with the Denver VA Medical Center, a weekly primary care faculty research conference, a weekly research seminar for Clinical Faculty Scholars, 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, in collaboration with the Health and Behavioral Science Department at the downtown campus. In 2007,

Ms. Beaty was honored by being named Chair of the Denver SAS User Group and was appointed Secretary and Communications Coordinator of the Western Users of SAS Software (WUSS).

Dr. Bull and Charlene Ortiz, senior PRA, continue to lead a cultural proficiency working group within COHO. In addition, they have developed a training program to address cultural proficiency issues in conducting research, with a goal of increasing investigator skill in recruiting diverse participants into research studies and in increasing participant satisfaction with and understanding of the research process. In March 2007, Ms. Ortiz was honored with a President's Diversity Award from the University of Colorado in recognition of her many contributes to diversity education and enhancement at University of Colorado Denver and in the community.

Financial report

Current COHO research projects are summarized in Table 1 for the period July 1, 2006 to June 30, 2007, and in Table 2 for 2007-08 (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. Table 4 summarizes the growth in the number of COHO investigators, staff, projects, and funding since 2000. In 2006-7, COHO funding grew to over \$5.9 million, despite the substantially reduced funding climate for federal grants. In the current fiscal year, COHO has already received over \$5.8 million in funding with eight months remaining, suggesting that the COHO budget will grow again this year. Under Dr. Kempe's leadership, COR has experienced particularly strong growth in 2006-7, with approximately a doubling of funding since 2005.

Challenges and plans, 2007-8

Several long-term challenges identified over the seven years of COHO have largely been addressed. The negotiated division of ICR between COHO and departments continues to run smoothly. The demand for mentorship continues, but has been met more systematically by the development of the Clinical Faculty Scholars program. 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 have been able to obtain new grants from NIH and other sources despite this downturn.

Dr. Allison Kempe has increased the service provided by COR to investigators in the Department of Pediatrics and The Childrens' Hospital who are interested in developing research in child health outcomes. Of particular importance was her recruitment of Dr. Elaine Morrato in 2006 as a methodologist to work with these investigators in conducting pilot and preliminary studies that will lead to grant applications. COR is expanding research in the area of preventive pediatrics with a new focus on preventive dental care. In addition, COR is collaborating with COHO in building a research focus in the area of prevention of obesity and cardiovascular disease. A multidisciplinary working group has been formed in this area to bring together interested investigators.

In 2006-07, COHO successfully recruited a new epidemiologist (Elaine Morrato, DrPH, MPH), and biostatistician (Max Min, PhD). Our recruitment of new faculty continued into 2007-08 with the recruitment of Dr. Patrick (Jud) Blatchford, a recent graduate of the biostatistics doctoral program at the University of Colorado Denver. Under Dr. Diane Fairclough's mentorship, he will develop his career interests in cancer outcomes research and clinical trials, as well as providing statistical consulting to COHO and external investigators. COHO also continues to build relationships with social/behavioral scientists. In 2007, Drs. Debbi Main and Sheana Bull obtained joint appointments with the Department of Health and Behavioral Sciences to provide didactic teaching and research mentorship, and Dr. Main supervised our first post-doctoral fellow, a graduate of the HBS program. Their affiliation with HBS is already providing opportunities for doctoral students in the HBS program to participate in COHO-sponsored research. Drs. Steiner, Bull, and Fairclough continue to collaborate actively with Drs. Irene Blair and Geoff Cohen of the section of social psychology, Department of Psychology, at the CU Boulder campus. Dr. Bonnie Lehmann-Castillo from the Colorado Prevention Center (a junior faculty member and HBS graduate) is also collaborating actively with Dr. Bull.

In 2007, COHO leadership and senior investigators devoted substantial time to the application for a CTSA award from NIH. This institutional award will more fully integrate our agenda of community translational research with the traditional "discovery translation" research efforts of the adult and pediatric GCRCs, and other investigators on campus. If awarded, Dr. Steiner has been designated as Associate Director for Education, Training, and Career Development programs, and Dr. Bull will have a major role in the Community Engagement component of the CTSI.

As noted, new collaborations with the School of Dentistry have been initiated by Drs. Matt Daley and Elaine Morrato, and Dr. Henderson has collaborated with Dr. Judith Albino of Dentistry and Dr. Spero Manson from the Native American Center in a just-submitted grant to National Institute of Dental and Craniofacial Research.

COLORADO HEALTH OUTCOMES PROGRAM ANNUAL REPORT: YEAR 6

November 1, 2005 – October 31, 2006

The Colorado Health Outcomes Program (COHO) was authorized by Dean Richard Krugman of the School of Medicine at the University of Colorado at Denver and Health Sciences Center in 1998. John Steiner, MD, MPH was appointed as the first permanent director of COHO in September 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. This report summarizes COHO progress from November, 2005-October, 2006.

Research initiatives

In 2005-06, COHO continued its research in several focus areas. In the area of health communication and information technology, Dr. Sheana Bull and Dr. Art Davidson are collaborating with Kaiser Permanente and Denver Health on three new grants awarded from the Colorado Department of Public Health and Environment (CDPHE), the Centers for Disease Control, and the NIH. In the area of organizational assessment, Dr. Debbi Main is collaborating on a new NIDDK-funded assessment of the impact of diabetes learning teams. In the area of patient-centered outcomes measurement, Dr. Diane Fairclough continued her long-term national collaboration in pediatric cancer, with new funding from the National Cancer Institute assessing sibling and parent bereavement.

In the area of cardiovascular outcomes, Dr. Debbi Main received NHLBI funding to assess the impact of the Stapleton redevelopment on physical activity and cardiovascular risk, while Dr. Sheana Bull is contributing her expertise in community participatory research, health disparities, and qualitative methods to 2 new studies of approaches to treating hypertension, heart failure, and improving cardiac rehabilitation, funded by CDPHE. Drs. Karl Hammermeister and John Steiner initiated a project to assess the effectiveness of isosorbide-hydralazine on heart failure outcomes in veterans, through a AHRQ task order awarded under a DECIDE master contract.

In surgical outcomes, Dr. Bill Henderson is collaborating on four new merit review grants awarded to national and local investigators by the VA HSR&D service, in the areas of improving surgical informed consent, the impact of transfusion practices on outcomes, the long-term outcomes of hip fracture, and the effect of intra-operative changes in vital signs on surgical morbidity. 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, and for a private-sector NSQIP initiative sponsored by the American College of Surgeons. The COHO surgical outcomes group is also completing the preparation of 21 manuscripts for a special supplement to the Journal of the American College of Surgeons, with data from a recently-completed, AHRQ-funded study that initiated the private-sector NSQIP.

New grants in the areas of cancer and palliative care outcomes include participation by Drs. Fairclough and Main on a grant led by Dr. Peter Raich of Denver

Health in collaboration with the University of Colorado Cancer Center to test the efficacy and cost-effectiveness of a patient navigator program for improving cancer care and patient outcomes, and collaboration in a NCI-funded R21 grant to develop information system capacity in hospices to improve symptom management (Jean Kutner, PI).

In 2006, Dr. Steve Berman announced that he is stepping down as the director of the Childrens' Outcomes Research program, which he has headed since its founding in 2001. Dr. Allison Kempe serves as interim director of COR. She has recruited a new faculty member, Dr. Elaine Morrato, who recently received a DrPH in epidemiology from Johns Hopkins, to help investigators at The Childrens' Hospital and the School of Dentistry develop agendas in outcomes research. Dr. Kempe continues to lead a CDC-funded national center for survey research in immunization policy. Findings from surveys conducted by her group were presented to the national Advisory Committee on Immunization Practices in 2006. Dr. Matt Daley received new CDC funding to assess alternative sites for adolescent immunizations, given the recent approval of new vaccines that target this age group. Dr. Daley also received funding from the Delta Dental Foundation to conduct a randomized controlled trial of the effectiveness of delivering preventive dental care children in conjunction with primary care to low- income children.

A new emphasis area in pharmaceutical outcomes research was initiated in September 2005, with the award of a master contract with AHRQ for membership in the DEcIDE network, a group of 13 centers nationally with expertise in pharmaco-epidemiology. Dr. John Steiner is the principal investigator. Dr. David West is the Operations Director for CO-DEcIDE and was the primary investigator responsible for this award. COHO was awarded its first task order under this network, a 14-month, \$170,000 award to assess the impact of isosorbide/hydralazine therapy on outcomes for congestive heart failure. Karl Hammermeister, MD, is the task order leader. Dr. Elaine Morrato received new funding to evaluate the impact of "black-box" notifications of drug safety concerns.

Publications

A list of COHO publications in 2005 and 2006 (to date) is provided on the COHO website at <http://www.uchsc.edu/coho/abstracts.htm>.

Educational initiatives

In July 2005, COHO enrolled the third cohort of junior faculty members into its Clinical Faculty Scholars Program, to assist them in obtaining career development awards or project support in outcomes research. The new Clinical Faculty Scholars are: Liron Caplan, MD, MPH (Division of Rheumatology), Lorraine Dugoff, MD (Department of Obstetrics/Gynecology), Stephen Ross, MD, (Division of General Internal Medicine), and Jeannie Zuk, PhD (Section of Pediatric Anesthesia). The second cohort, Tamara Stoner, MD (anesthesiology), David Bekelman, MD (GIM) and Pamela Peterson, MD, MSPH (cardiology) continues in the program. Since February, 2004, the 12 participants in the CFSP have written 18 grants, of which 9 have been funded, with total direct costs of \$2,545,000. These individuals have also published 43 scientific papers.

Dr. Kempe continues to direct the training of 10 faculty development and primary care fellows who are supported by HRSA-funded programs including a NRSA (T32) award, and are housed in COHO. These fellows are conducting research in vaccine delivery to adults and children, treatment of hypertension, screening for colorectal cancer in rural areas, health care for undocumented patients with renal failure, prevention of obesity in children, antibiotic overuse in primary care, injury prevention, and interventions to increase exercise in diabetic and overweight adults.

COHO continues to offer monthly research seminars in Methods and Applications in Outcomes Research in collaboration with the Denver VA Medical Center, a weekly primary care faculty research conference, a weekly research seminar for Clinical Faculty Scholars, a monthly statistics “brown bag” conference, a joint COHO/DH research conference for DH investigators as part of its cardiovascular partnership grant, a working group in cultural proficiency under the direction of Charlene Ortiz, and Sheana Bull, PhD, a SAS “users group” under the direction of Brenda Beaty, MSPH, the COHO data analysis coordinator, and a new working group on qualitative research methods under the direction of Carolyn Nowels and Dr. Carol Darr.

Dr. Bull and Charlene Ortiz, senior PRA, continue to lead a cultural proficiency working group within COHO. In addition, they have developed a training program to address cultural proficiency issues in conducting research, with a goal of increasing investigator skill in recruiting diverse participants into research studies and in increasing participant satisfaction with and understanding of the research process. They received CDPHE “health disparities” funds to disseminate this curriculum in 2006.

Financial report

Current COHO research activity is summarize in Table 1 for the period July 1, 2005 to June 30, 2006, and in Table 2 for 2006-07 (to date). Table 3 summarizes the growth in the number of COHO investigators, staff, projects, and funding since 2000. In 2005-6, COHO funding remained essentially stable at over \$5.1 million, despite the substantially reduced funding level for federal grants. In the current fiscal year, COHO has already received over \$5.0 million in funding with six months remaining, suggesting that the COHO budget will remain stable or grow slightly again this year. COHO has been able to maintain its research funding by an increase in funding from the Department of Veterans affairs, the CDPHE, and private foundations to offset declines in funding from NIH, CDC, and AHRQ.

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.

Challenges and plans, 2006-7

Several long-term challenges identified over the six years of COHO have largely been addressed. The negotiated division of ICR between COHO and departments continues to run smoothly. The burgeoning demand for mentorship continues, but has been met more systematically by the development of the Clinical Faculty Scholars program.

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 over the next few years, COHO investigators continue to seek alternative sources of revenue that can contribute to the administrative costs of the program.

The 2005-6 and 2006-7 COHO development plans continue to reflect several external forces, particularly the continued decline in federal research support. As discussed above, we have been successful in developing alternative revenue sources to support COHO faculty and staff, and will continue that process in 2006-7, while continuing to pursue federal funding in our areas of emphasis.

As interim COR director, Dr. Allison Kempe has increased the service provided by COR to investigators in the Department of Pediatrics and The Children's Hospital who are interested in developing areas of research in child health outcomes. Of particular importance was her recruitment of Dr. Elaine Morrato as a methodologist to work with these investigators in conducting pilot and preliminary studies that will lead to grant applications. Musculoskeletal surgery and general surgery have been identified as areas of commitment by Children's Hospital faculty and several studies are underway in these areas. COR is expanding research in the area of preventive pediatrics with a new focus on preventive dental care. In addition, COR is collaborating with COHO in building a research focus in the area of prevention of obesity and cardiovascular disease. In collaboration with Dr. Steve Daniels, the new chair of Pediatrics, a multidisciplinary working group has been formed in this area to bring together interested investigators in this area.

In 2005-6, COHO made important progress in recruiting junior faculty methodologists. Dr. Morrato brings new expertise in epidemiology and research design, with a particular emphasis on pharmaco-epidemiology. Dr. Max Min, our third biostatistician, is working primarily with the surgical outcomes group, and continues to receive support from his prior academic "home" in the Division of Healthcare Policy and Research. He is also a valued addition to COHO's biostatistical consulting capacity, with particular expertise in research design and econometrics. COHO has also recruited its first post-doctoral fellow, Dr. Carol Darr, a recent graduate of the Health and Behavioral Sciences doctoral program at UCDHSC.

Over the next 2 years, COHO leadership and senior investigators will devote substantial time to the application for a CTSA award from NIH. This institutional award will more fully integrate our agenda of community translational research with the traditional "discovery translation" research efforts of the adult and pediatric GCRCs, and other investigators on campus. COHO investigators are participating in 6 of the writing groups that are preparing the CTSA application for submission in the fall of 2007.

COLORADO HEALTH OUTCOMES PROGRAM ANNUAL REPORT: YEAR 5

November 1, 2004 – October 31, 2005

Program history and mission

The Colorado Health Outcomes Program (COHO) was authorized by Dean Richard Krugman of the University of Colorado School of Medicine in 1998. Richard Hamman, MD, DrPH, served as interim director until September, 2000, when John Steiner, MD, MPH was appointed as Director, with start-up funding from the Dean's Academic Enrichment Fund (AEF) from September 2000-August 2005. The institutional goal for COHO has been to expand health outcomes research efforts within the University of Colorado School of Medicine and to provide mentorship and infrastructure for new and existing faculty members and trainees dedicated to careers in outcomes research. A COHO request to the Dean's Strategic Initiatives Review Committee (SIRC) for core funding from July 1, 2005-June 30, 2010 was approved in June 2005.

The COHO mission is: **to conduct and evaluate interventions to improve population health and the quality of health care.** To accomplish this mission, COHO has developed expertise in: 1) the deployment of health communication tools and health information technology; 2) assessment of the organization and function of health care delivery systems; and 3) measurement of patient-centered health outcomes. Consistent with the call of the current NIH roadmap for interdisciplinary models of research, COHO projects consistently rely on collaborations among clinicians, health services researchers, behavioral scientists, and statisticians. A detailed description of the COHO mission, projects and staff is available on our website at www.uchsc.edu/coho.

In its first five years, COHO research has addressed a wide array of research topics with multiple collaborators inside and outside the School of Medicine. COHO has achieved rapid growth in extramurally funded research, faculty, staff, and research training programs. This report summarizes COHO progress from November, 2004-October, 2005, and our development plan for November, 2005 to October, 2006.

Research initiatives

Current COHO research activity is summarize in Table 1 for the 2004-05 fiscal year, and in Table 2 for the 2005-06 year (to date). Table 3 summarizes grants that have been submitted and are under review at the time of this report. The following section highlights accomplishments in specific areas.

Health communication and information technology

Under the leadership of Art Davidson, MD, MSPH, and David Kaplan, MD, the clinical informatics working group at COHO/COR has continued its work on a system for transporting clinical information electronically between health care delivery systems in Colorado. Funding from the Agency for Healthcare Research and Quality (Arthur

Davidson, MD, MSPH, PI - \$5,000,000) and the Foundation for eHealth Initiative (David Kaplan, MD, PI - \$600,000) supports this effort. Dr. Davidson was awarded \$364,593 in November 2005 from the CDPHE Amendment 35 grant program to develop infrastructure for guideline implementation within COHIE.

Sheana Bull, PhD continues to lead an active program of research, with participation as PI or Co-PI on three federally funded grants and one foundation funded grant to assess the application of health communication and information technology to STD prevention, reproductive health and diabetes self-management. She also leads a project to develop novel approaches to community-based cardiovascular prevention in Latinos, as a sub-study of the COHO/DH partnership to reduce cardiovascular disparities described below. In addition, in an effort to consider opportunities to increase minority participation in research related to health disparities, Dr. Bull is working with COHO staff to develop a curriculum related to Cultural Proficiency for researchers. This effort is described in more detail below.

In October 2004, Dr. Debbi Main received a \$461,972 grant from the Agency for Healthcare Research and Quality (AHRQ) to test the feasibility of a patient-centered diabetes registry that uses health information technology (web and telephony) to activate patients and support evidence-based diabetes care and self-management within six primary care offices. Her collaborators include Dr. Bennett Parnes (family medicine), Dr. Steve Ross (GIM) and Dr. Russ Glasgow from Kaiser Permanente. The patient-centered feature of this registry as well as its technological platform (IVR, web) have served as the basis of additional pending diabetes-related grant proposals to the American Diabetes Association, and Colorado Department of Public Health and Environment and funded grants to enhance symptom management in palliative care (Kutner, NCI) and behavioral screening and counseling in primary care (Dickinson, RWJ). Steve Ross, MD, in collaboration with Dr. Bull and Dr. Debbi Main, continues his randomized controlled trial of a web-based “portal” for patients with diabetes in the UCH clinic system (GIM, family medicine, and endocrinology clinics). By October 2005, 320 patients have been enrolled into this study, which was funded by the Robert Wood Johnson Foundation.

Organizational assessment

Dr. Main is completing the final year of an AHRQ Measuring Readiness to Translate Research into Practice grant, a multi-method study aimed at developing a measure of a primary care office’s structural, strategic, technical and cultural capacity to translate research into practice. This grant used the research network of primary care practices developed by Dr. Wilson Pace and colleagues in the Department of Family Medicine. Dr. Main’s practice-level measure (OVS – Office Vital Signs) has been proposed or used in pending (Pace, AHRQ) and funded projects (Main, AHRQ; Main, The Colorado Trust; Pace, RWJ) to describe organizational structures and processes that influence a primary care practice’s readiness to change and to understand how diverse primary care offices are able to adopt and adapt evidence-based interventions.

Patient-centered outcomes measurement

Diane Fairclough, DrPH, continues to lead COHO efforts in this area. During 2005 she obtained new funding from a NIH grant to study Sibling and Parent Bereavement in Childhood Cancer and from Boehringer-Ingelheim to examine outcomes in two clinical trials of HIV patients. She continues with work on long-term outcomes for childhood survivors of brain tumors and an intervention in mothers of newly diagnosed children with cancer. The exploration of changes in symptoms and cytokines and symptom clustering continues with MD Anderson Cancer Center. Dr. Jean Kutner (GIM) continues her NIH-funded program of research in interventions to reduce symptom burden in palliative care patients, in collaboration with Dr. Fairclough and Dr. Bill Henderson.

Cardiovascular outcomes

A COHO-sponsored working group in this area has been in existence since 2001. In 2004-5, we completed the first year of a large cooperative agreement funded by NHLBI that established a partnership between COHO (John Steiner, MD, MPH, PI) and Denver Health (Ed Havranek MD, PI) to reduced cardiovascular disparities by a series of studies to improve primary prevention of cardiovascular disease in Latinos. This 5-year grant provides \$2,981,011 in total costs to COHO and \$2,985,310 to Denver Health. Currently, COHO is developing an application with Irene Blair, PhD, a social psychologist at the CU Boulder campus, and with DH and Kaiser Permanente for a NHLBI R01 grant to assess the impact of implicit racial/ethnic attitudes on the outcomes of care for patients with hypertension in those delivery systems. COHO also provided methodological support for two successful applications for Amendment 35-supported cardiovascular prevention grants. In 2004-5, COHO faculty participated in the successful awards of career development grants to Michael Ho MD, PhD from the Denver VAMC (American Heart Association and VA Research Career Development awards) and Pamela Peterson MD, MSPH, (AHA outcomes career development award).

Surgical outcomes

COHO serves 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. Under the leadership of William Henderson, Ph.D., the coordinating center supports the NSQIP in the Department of Veterans Affairs' 123 hospitals. In collaboration with the American College of Surgeons, the NSQIP is expanding into the private sector, with private hospitals participating on a subscription basis. In November 2005, the ACS-NSQIP contracted with its 50th private hospital, and additional hospitals are in the process of signing contracts. Blue Cross-Blue Shield of Michigan has recently funded 15 Michigan hospitals to participate in the ACS-NSQIP. Three Department of Defense hospitals are also participating in the NSQIP on a pilot basis. NSQIP coordinating center staff are collaborating with CMS in their national SCIP

(Surgical Care Improvement Program), and with the Anesthesia Patient Safety Foundation in incorporating anesthesia data into the NSQIP.

Two AHRQ-funded NSQIP projects have completed data collection and now are in final analysis. One involves application of the NSQIP in 14 university surgical centers and 4 community hospitals, and the other involves a study of the effects of resident working conditions on risk-adjusted surgical outcomes. Several new research grants using the NSQIP database have been funded this year—one by NIH, and four by the VA. The NIH-funded study is a Phase 1 SBIR project that is using the NSQIP data to estimate post-surgical length of hospital stay. Results from this study might be used to develop a software product for hospitals to help them manage their bed capacity. The four VA-funded research projects are examining the effect of transfusion usage on postoperative cardiovascular outcomes; the effect of reduced resident work hours on surgical outcomes; predictors of outcomes of bariatric surgery; and the benefits of “repeat back” protocols within a computer-based informed consent program to improve patient comprehension, compliance, and satisfaction with surgical care. Another research study was recently funded by an anesthesia foundation to investigate the use of beta blockers, statins, and other drugs to prevent postoperative cardiac complications. Five research grants using the NSQIP database are being submitted to the VA on December 15, 2005, on hip fracture operations, incorporating anesthesia data into the NSQIP, outcomes of breast cancer surgery comparing the VA to the private sector, effect of alcohol intake on surgical outcomes, and effect of operative duration on surgical outcomes.

Several important manuscripts have been published from the NSQIP database in 2005. One manuscript showed that risk-adjusted postoperative mortality is higher in the American Indian veteran population compared to the white veteran population. Another study showed that the short-term risk-adjusted outcomes are superior for endovascular AAA surgery compared to open AAA surgery. A third paper showed that a postoperative complication is an important determinant of the patient’s long-term survival.

Cancer and palliative care outcomes

Close collaborations between COHO, the University of Colorado Cancer Center, and AMC Cancer Research Center continued during 2004. Dr. Steiner is a co-investigator on an ongoing grant led by Dr. Gail Eckhardt from the Division of Medical Oncology to improve recruitment of elderly patients into early-phase cancer chemotherapy trials, and a Komen-Foundation-funded project led by Betsy Risendal PhD from the Cancer Center on the work experiences of Latino breast cancer survivors. COHO also provides mentorship and research support to Tom Denberg MD, PhD (GIM), who holds a DOD career development award for research in prostate cancer treatment decision-making, and was awarded a 5-year American Cancer Society career development award in 2005 for his research in decision-making in colorectal cancer screening. Drs. Fairclough and Main are co-investigators on a grant led by Dr. Peter Raich of Denver Health in collaboration with the Colorado Cancer Center (Drs. Byers and Risendal) and AMC Cancer Center (Drs. Marcus and Kilbourn) to test the efficacy and cost-effectiveness of a patient navigator program for improving quality of cancer care and patient outcomes. Dr. Jean Kutner was

awarded a NCI-funded R21 grant in 2005 to develop information system capacity in hospices to improve symptom management.

Child health outcomes

COHO and COR (directed by Steve Berman, MD in the Department of Pediatrics) have shared space on the Fitzsimons campus since 2000. In April 2004 COHO and COR consolidated many administrative functions to avoid duplication of infrastructure. COR continues to manage the Colorado Immunization and Information System (CIIS) with CDC funding passed through the Colorado Department of Health and Environment as well as private sector support (project manager, Elaine Lowery, JD, MSPH). As of November 2004, 52% of Colorado children under age 6 years had immunization information entered into CIIS. This immunization information system provides COR investigators Allison Kempe and Matt Daley with the infrastructure to carry out CDC funded influenza immunization outcomes research in 6 pediatric private practices in the Denver metro area.

COR/COHO investigators led by Allison Kempe, MD, MPH, in collaboration with the Prevention Research Center in the Department of Preventive Medicine, are operating a CDC-funded national center for survey research in immunization policy issues. They have received CDC and Colorado state health department funding for an innovative telephone-based trial to support breast-feeding (Kempe, PI). Other ongoing COR research in child health outcomes is summarized in Table 1. COHO continues to support the RWJ-funded faculty development award of Simon Hambidge MD, PhD, who is conducting studies of strategies to improve immunization rates for disadvantaged children.

Pharmaceutical Effectiveness Research

In September 2005, COHO was awarded a master contract with AHRQ for membership in the DEcIDE network, a group of 13 centers nationally with expertise in pharmaceutical outcomes research. John Steiner, MD, MPH is the principal investigator. David West, PhD is the Operations Director for CO-DEcIDE, and was the primary investigator responsible for this award. Also in September, 2005, COHO was awarded its first task order under this network, a 9-month, \$120,000 award to assess the impact of isosorbide/hydralazine therapy on outcomes for congestive heart failure. Karl Hammermeister, MD, is the task order leader.

Other areas

Debbi Main PhD continues her evaluation, funded by the Colorado Trust, of the Colorado Clinical Guidelines Collaborative, a unique joint venture of payers and health care delivery systems to develop and implement common clinical guidelines throughout Colorado. Dr. Steiner continues to provide consultation to investigators in the Kaiser Permanente Clinical Research Unit. COHO and COR investigators (Steiner, Kempe, Davidson) continue to participate in a HRSA-funded grant to develop and expand a

primary care research unit, which was formally incorporated into COHO in 2005. The PCRU is led by Frank DeGruy, chair of the Department of Family Medicine.

Publications

A list of the 68 publications in 2005 (to date) by COHO investigators is provided in Appendix I.

Educational/faculty development initiatives

In 2004, COHO received additional AEF funding to begin a Clinical Faculty Scholars Program designed to assist promising junior faculty members to obtain career development awards or project support in outcomes research. The five initial Faculty Scholars are Tom Denberg MD, PhD (GIM), Meica Efird MD, MPH (neonatology), Lisa Forman MD, MS (adult hepatology), Marion Sills MD, MPH (pediatric emergency medicine) and Stephanie Teal MD, MPH (gynecology). All have submitted applications for career development awards and/or federally funded grants and two (Denberg, Forman) have received career development awards. The second cohort, Tamara Stoner, MD (anesthesiology), David Bekelman, MD (GIM) and Pamela Peterson, MD, MSPH (cardiology) began the program in July, 2005. Dr. Peterson was recently awarded both a 4-year AHA outcomes research career development award and Amendment 35 funding from the Colorado Department of Public Health and Environment for her research in chronic disease management for disadvantaged patients with heart failure at Denver Health. The CFSP continues to administer a grant writing curriculum led by Anne Libby, PhD of the Department of Psychiatry and Allison Kempe, MD, MPH, director of the primary care research fellowship, which is also housed administratively in COHO/COR. Currently 10 faculty development and NRSA (T32) primary care fellows are housed in COHO through these HRSA-funded programs.

COHO continues to offer monthly research seminars in Methods and Applications in Outcomes Research in collaboration with Kaiser Permanente. COHO sponsors a weekly primary care faculty research conference in conjunction with the PCRU, a weekly research seminar for clinical faculty scholars, a monthly statistics “brown bag” conference, a joint COHO/DH research conference for DH investigators as part of the cardiovascular partnership grant described above, a working group in cultural proficiency under the direction of Charlene Ortiz, and Sheana Bull, PhD, and a SAS “users group” under the direction of Brenda Beaty, MSPH, the COHO data analysis coordinator.

In addition, Sheana Bull and Charlene Ortiz, have developed and pilot tested a multi-session training program to address cultural issues in conducting research, with a goal of increasing investigator skill in recruiting diverse participants into research studies and in increasing participant satisfaction with and understanding of the research process. Dr. Bull and Ms. Ortiz are applying for CDPHE/Amendment 35 “health disparities” funds to disseminate this curriculum.

Affiliated institution and community initiatives

Developing relationships with community partners has been a COHO priority from the outset. Among the ongoing partnerships with DH are the NHLBI-funded cardiovascular health disparities grant, the cancer “navigator” grant, the AHRQ information technology grant, the PCRU, and the primary care fellowships. Relationships with KP continued their steady growth through joint research projects, the shared Methods and Applications conference, and mutual representation on advisory committees. The VA partnership is primarily national, and focuses on the NSQIP and surgical outcomes research arising from that database. Dr. Steve Ross’s diabetes patient portal and Dr. Main’s patient-centered diabetes registry are expanding linkages with the University of Colorado Hospital, the primary academic hospital for the UCHSC, and with the Salud health centers. Ongoing eHealth and AHRQ information technology grants promote clinical information-sharing between DH, TCH, KP, and UCH, and will, over the next four years, expand the prototype systems developed among these institutions to a far larger array of payers and delivery systems in the state of Colorado as a whole.

Administrative initiatives

The administrative consolidation of COHO and COR continues to function well. The COHO administration now supports the grants of 16 principal investigators, and provides HR support for 39 staff. The current membership of the COHO executive committee is: John Rumsfeld MD PhD from the Denver VA, Richard Hamman MD, DrPH (Preventive Medicine), David Magid, MD, MPH (Kaiser Permanente), Paul Fennessey, PhD (Department of Pediatrics), Andrew Kramer (Healthcare Policy and Research) and Frank DeGruy (Family Medicine).

Financial report

Through December 2005, COHO has experienced a leveling off in its grant support, as shown in Table 4. COHO annual revenue from grants, contracts, and AEF was about \$5.2 million in fiscal year 2004-05 and is slightly over \$5.1 million in thus far in fiscal year 2005-06, with about \$1.4 million in direct costs on submitted grant applications pending in this fiscal year. Thus, it is likely that by the end of the fiscal year, COHO will show a slight overall increase in its grant revenue for the year. We have seen a slight decrease in sponsored projects, and a modest increase in service projects. Overall, COHO and COR have obtained over \$20 million (total costs) in new funding since September 2000.

Table 4 shows the rapid growth in COHO since September 2000. The number of principal investigators has increased from 7 to 16. The number of staff has grown from 2 to 39. The number of projects managed by COHO and in collaboration with other HSC investigators and community partners has risen from 4 to 50. The annual direct costs of COHO research projects (excluding AEF support and other income) has risen from \$432,000 to \$5.1 million. The annual ICR generated for the Health Sciences Center has increased from approximately \$110,000 to over \$870,000 in 2005-06.

Table 4 also demonstrates that COHO has achieved this growth while remaining a careful steward of AEF resources. Through its first five years, COHO expended less of the AEF allocation than budgeted, due largely to the ability of COHO senior investigators to support their time on extramurally-funded research. As a result, COHO was able to carry forward approximately \$100,000 of unexpended AEF funds into its next cycle of AEF support from 2005-10.

Development plan, 2005-6

The 2005-6 COHO development plan reflects several external forces. We were fortunate (in tight times) to receive a renewal of core resources from the Dean's AEF, but that renewal came with a clear message that we should plan for other sources to replace AEF support for COHO infrastructure by 2010. This message was reinforced by the roughly 20% decrease in yearly core funding we received from the AEF. Thus, the first element in the COHO development plan for this year is:

1. Develop alternative revenue sources to support COHO infrastructure

To this end, we have already developed and enacted a plan for bidding "service" projects to organizations (such as payers, foundations, and government agencies) that want to contract for specific COHO skills. Dr. Steiner and other COHO investigators are expending more effort to "market" these services locally and nationally. Although infrequent, some federal funding is available for infrastructure development. If funding is made available in the HRSA budget, we will also apply in collaboration with GIM, Family Medicine, and General Pediatrics for a third three-year cycle of infrastructure funding for our interdisciplinary primary care research unit.

The slowdown in federal research funding leads to the second element of the COHO development plan:

2. Continue to actively pursue research funding

The 5-year COHO business plan (through 2010) projected a 10%/yr growth in grants housed at COHO, and a 20%/yr growth in collaborative grants with other partners. While this rate of growth may still be achievable in 2005-6 pending the outcome of numerous grants under review (Table 3), the overriding goal for this year will be to maintain the excellent team of investigators and staff that we have assembled since 2000. To this end, all investigators have increased their number of grant submissions, and are applying to new funding sources, such as Amendment 35 ("tobacco tax") funds for prevention programs in cardiovascular disease and for reduction in health disparities. In December 2005, COHO was successful in three of these awards, for joint programs with KP/DH in hypertension control, with DH for heart failure disease management, and with Denver Public Health for a COHIE informatics grant. Our ability to receive competitive funding is exemplified by the award of the NCI navigator grant (in collaboration with DH

and the Cancer Center), one of 2 awarded out of 40 applications, and by Dr. Pam Peterson's career development award (one of 4 awarded out of 32 applications).

One COHO new initiative in 2005-6 will stem from the September 2005 award of a master contract for pharmaceutical outcomes research through the AHRQ-funded DEcIDE network:

3. Develop core expertise in pharmaceutical outcomes research

Dr. David West assembled a superb cast of local and national collaborators for the successful master contract application, which was rewarded by the immediate award of a \$120,000 task order related to heart failure treatment. This task order will allow us to gain more familiarity with VA pharmacy databases and analytic methods related to non-experimental assessments of therapeutic outcomes (in collaboration with Dr. Dick Hamman in Preventive Medicine). The COHO goal for this year is to identify individuals with a career interest in pharmaceutical outcomes who can lead the response to future task orders and maintain continuity across task orders under this master contract.

Another new initiative will be undertaken with the Division of Rheumatology:

4. Become the data coordinating center for the National Databank for Rheumatic Disease

With COHO assistance, Dr. Mike Holers, chief of the Division of Rheumatology recruited Liron Caplan MD, as a new faculty member from Washington University beginning in November 2005. Dr. Caplan's expertise is in outcomes research in rheumatology. Drs. Holers and Caplan are exploring the transfer of the data coordinating center for a well-established national databank of rheumatology outcomes from Kansas City to Denver. Given our expertise in serving this role for the NSQIP and for Dr. Diane Fairclough's multi-site clinical trials, COHO is providing methodological expertise to support this effort.

Current challenges

The challenges identified in prior annual reports have largely been addressed. The negotiated division of ICR between COHO and departments continues to run smoothly. The burgeoning demand for mentorship continues, but has been met more systematically by the development of the Clinical Faculty Scholars program. Funding for administrative infrastructure remains an issue, since the return of indirects 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. The need to develop a long-term space plan for COHO has become even more acute with the influx of research funding and new staff. It is now apparent that, even without substantial further growth, COHO is likely to outgrow building 406 on the Fitzsimons campus within the next 2 years.

A larger, long-term challenge that will occupy COHO leadership over the next several years is to integrate outcomes research with the NIH translational research agenda, and with other clinical/translational research activities at the UCDHSC and its partners. The first component of this effort will be our active involvement in developing an application for a planning grant for NIH Roadmap funding through its CTSA initiative. This planning grant will be submitted in March 2006, with an anticipated submission of a grant for a full CTSA award in 2007.