U.S. Department of Health and Human Services (HHS) Inventory of Programs, Activities and Initiatives Focused on Improving the Health of Individuals with Multiple Chronic Conditions (MCC)

Compiled By the HHS Work Group on Multiple Chronic Conditions

Office of Public Health and Science

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DISCLAIMER

This publication does not constitute medical advice; individuals seeking health care advice should consult their personal physicians. The purpose of this inventory is to provide basic information about existing (as of March 2009) HHS programs for researchers, providers, and organizations concerned about improving the quality of care for patients with multiple chronic conditions (MCC). This inventory consists of information self-reported by HHS agencies and includes programs that are primarily focused directly on the MCC *population*. There are many other programs at HHS that may serve *individuals* who have more than one chronic health condition but are not included in this collection. Thus, this inventory should not be considered an exhaustive collection of Federal activities for people with MCC.

U.S. Department of Health and Human Services (HHS) Inventory of Programs, Activities and Initiatives Focused on Improving the Health of Individuals with Multiple Chronic Conditions

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Foreword

By Anand Parekh, MD, MPH
Deputy Assistant Secretary for Health (Science and Medicine)

Although the U.S. health care system focuses extensive resources on diagnosing and treating acute health problems (such as heart attacks, trauma, and acute infections), the U.S. population more often experiences chronic health conditions[1] (like hypertension, diabetes, cancer, depression, substance abuse and addiction, and HIV/AIDS). Moreover, the management and treatment of a particular chronic health condition may become even more complex for the almost 75 million people who have two or more chronic health conditions at the same time – the population with multiple chronic conditions (MCC). In a given patient, as the number of chronic conditions increases, the following unfortunate outcomes also escalate: mortality, poor functional status, unnecessary hospitalizations, adverse drug events, duplicative tests, and conflicting medical advice. In addition, multiple chronic conditions can contribute to frailty and disability and conversely, the vast majority of older persons who are frail or disabled have multiple chronic conditions.

Patients with multiple chronic conditions also experience significant demands on their time and financial resources just to obtain health care. For example, the nearly one-fourth of Medicare beneficiaries who now have five or more chronic conditions see 14 different physicians on average each year, make 37 office visits and have 50 prescriptions filled [2] [3]. To pay for this care, individuals with MCC face substantial challenges related to the out-of-pocket costs of their care, including high prescription drug and total out-of-pocket health care spending.

To determine how to improve the health of this heterogeneous population with multiple chronic conditions, in mid-2008, the Assistant Secretary for Health (ASH) of the U.S. Department of Health and Human Services (HHS) convened a Work Group (WG) on Multiple Chronic Conditions. Directed by the Deputy Assistant Secretary for Health for Science and Medicine in the Office of Public Health and Science (OPHS), the Work Group includes representatives from the following divisions in HHS:

- the Administration on Aging (AoA);
- the Agency for Healthcare Research and Quality (AHRQ);
- the Office of the Assistant Secretary for Planning and Evaluation (ASPE);
- the Centers for Disease Control and Prevention (CDC);
- the Centers for Medicare and Medicaid Services (CMS);
- the Food and Drug Administration (FDA);
- the Health Resources and Services Administration (HRSA);
- the Indian Health Service (IHS);
- the National Institutes of Health (NIH);
- the Office of the National Coordinator for Health Information Technology (ONC);

[1] Chronic illnesses are "conditions that last a year or more and require ongoing medical attention and/or limit activities of daily living." Hwang, W., et al. 2001. "Out of Pocket Medical Spending for Care for Chronic Conditions." *Health Affairs* 20: 268-9.
[2] Anderson, G. F. 2005. "Medicare and Chronic Conditions." *New England Journal of Medicine* 353: 305-9.
[3] Berenson, R. & Horvath, J. "The Clinical Characteristics of Medicare Beneficiaries and Implications for Medicare Reform," prepared for the Partnership for Solutions, March, 2002.

- the Office of Public Health and Science (OPHS); and,
- the Substance Abuse and Mental Health Services Administration (SAMHSA).

This inventory, a first effort of the Work Group, is a collation of the major HHS programs, activities, and initiatives related to MCC. This inventory will assist HHS by creating linkages and synergy between existing programs as well as by delineating what gaps exist in addressing and improving the health of people with multiple chronic conditions.

U.S. Department of Health and Human Services (HHS) Inventory of Programs, Activities and Initiatives Focused on Improving the Health of Individuals with Multiple Chronic Conditions

Introduction

This inventory of programs, activities, and initiatives related to people with multiple chronic conditions (MCC) includes a brief description of more than 50 efforts at the Federal level in the U.S. Department of Health and Human Services (HHS). The majority of endeavors included in this inventory are directed primarily to the health care needs of people with two or more chronic health conditions. In addition to a description of each effort, the inventory names a contact person for each item in the inventory. Interested readers desiring additional information about specific entries in the inventory may start by contacting this person.

The items in the inventory are divided into four summary areas:

- Assisting health care providers care for individuals with MCCs;
- Assisting individuals with MCCs with self-care management;
- Health system changes to improve the health of individuals with MCCs; and,
- Research to fill knowledge gaps about individuals with MCCs.

The items summarized under the first category focus on helping health care providers improve the care delivered to patients with multiple conditions. Similarly, the items in the second category emphasize how patients with MCC can manage their own health. Under the third category, efforts are directed at changes to the health system that could result in improved health for people with MCC. Finally, the fourth category includes research projects designed to fill gaps in knowledge about people with MCC.

U.S. Department of Health and Human Services (HHS) Inventory of Programs, Activities and Initiatives Focused on Improving the Health of Individuals with Multiple Chronic Conditions

I. Assisting Healthcare Providers Care for Individuals with MCCs

I.A. Enhancing Evidence-Based Decision-Making

I.A.1 AHRQ - Optimizing Prevention and Healthcare Management for Complex Patients

This funding will support projects to expand the understanding of how to optimize decisions about preventive care and management of chronic diseases in complex patients, especially in primary care. Exploratory research studies will contribute evidence to help guide the appropriate integration (i.e., prioritization, timing, provision and coordination) of therapeutic and preventive services in individuals with multiple chronic conditions. This work should improve our understanding of which interventions provide the greatest benefit to patients with multiple conditions, how the safety and effectiveness of specific interventions may be affected by co-morbid conditions, and how interventions may need to be modified for specific patient populations with multiple conditions. This information should help clinicians better integrate care provided to such individuals, help patients make informed decisions about health care choices, and help policy makers identify better ways to measure and promote quality care for complex patients. Specific information is available at: http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-08-003.html.

Contact Mary Barton, AHRQ, 301-427-1638, Mary.Barton@ahrq.hhs.gov.

I.A.2 HRSA – Incorporating multi-morbidity in clinical guidelines – Patients with HIV/AIDS and Hepatitis and/or TB

Patients with HIV/AIDS are susceptible to other infections which may lead to chronic conditions. Thus, to help providers care effectively for HIV/AIDS patients, several divisions of the U.S. Department of Health and Human Services (HHS) publish and regularly update clinical guidelines for prevention and treatment of opportunistic infections, such as Hepatitis B or Hepatitis C, in HIV/AIDS patients. The current version of the guidelines[4] is available at: http://aidsinfo.nih.gov/contentfiles/Adult_OI.pdf.

HHS publishes other guidelines related to complex care for HIV/AIDS patients. For example, guidance for use of antiretroviral medicines, first line treatment for HIV/AIDS, may need revision for application to special patient populations.

[4] "Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents." Recommendations of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and the HIV Medicine Association of the Infectious Diseases Society of America (HIVMA/IDSA) available at http://AIDSinfo.nih.gov. June 18, 2008.

Guidelines are available for use of antiretroviral agents in HIV/AIDS patients with co-infections (such as Hepatitis B or C, active Mycobacterium Tuberculosis, or latent Tuberculosis)[3], in HIV/AIDS patients who use injection drugs,[5] and in HIV-infected women who are pregnant[6].

Contact: Dr. Faye Malitz, HRSA, 301-443-3259, fmalitz@hrsa.gov.

I.A.3 OPHS (in collaboration with USDA) - *Dietary Guidelines for Americans*

The *Dietary Guidelines for Americans* provide science-based information to help health care providers counsel their patients (and/or their parents) two years and older about how good dietary habits can promote health and reduce risk for major chronic diseases. The T*oolkit for Health Professionals*, which is based on the Dietary Guidelines, provides specific resources to assist health education experts, such as doctors and nutritionists, in offering the latest science-based nutrition and physical activity recommendations to their patients and the public.

Diet and physical activity are two of the cornerstones of the HealthierUS Initiative and apply to every person with no, one, or multiple chronic conditions. The Dietary Guidelines, which are revised and updated with the newest nutrition science every five years, are an inter-departmental effort to enhance evidence-based decision making, and they serve as the authoritative reference for healthcare providers and nutrition professionals on nutrition and diet. The Dietary Guidelines can be found at: http://www.health.gov/DietaryGuidelines/.

Contact: Kathryn McMurry, OPHS, 240-453-8260, Kathryn.McMurry@hhs.gov.

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[5] Panel on Antiretroviral Guidelines for Adults and Adolescents. "Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents." U.S. Department of Health and Human Services. November 3, 2008; 1-139. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf, Note: the most recent information is available at http://AIDSinfo.nih.gov.

[6]Perinatal HIV Guidelines Working Group of the Public Health Service Task Force. "Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States." U.S. Department of Health and Human Services. July 8, 2008. Report available at: http://aidsinfo.nih.gov/contentfiles/PerinatalGL.pdf. Note: most recent information available at: http://AIDSinfo.nih.gov.

I.A.4 OPHS – healthfinder.gov

Healthfinder.gov is a website resource for healthcare providers who seek accurate information for their patients in terms which are understandable, actionable and prevention-oriented. People with multiple chronic conditions can locate useful information about each of their conditions on the website. Health care providers can use the website to obtain health information to counsel their patients and as a source to facilitate shared decision-making between providers and patients. The website can be found at: http://www.healthfinder.gov/.

Contact: Linda Harris, OPHS, 240-453-8262, Linda.Harris@hhs.gov.

I.A.5 OPHS – 2008 *Physical Activity Guidelines for Americans*

The *2008 Physical Activity Guidelines for Americans* provides science-based guidance to help health care providers counsel their patients (and/or their patients' parents) aged 6 and older about how to improve their health through appropriate physical activity. Physical activity recommendations are also provided for older adults with chronic conditions (in general) and for adults with disabilities, osteoarthritis, or type 2 diabetes, and for adult cancer survivors. The guidelines can be found at: http://www.health.gov/PAGuidelines/.

Contact: Rachel Hayes, OPHS, 240-453-8255, Rachel.Hayes@hhs.gov.

I.B. Developing Measures to Assess Quality of Care of Services to Individuals with MCCs

I.B.1 AHRQ - Development of Quality Measures for the Medicaid Home and Community-Based Services Population

Medicaid beneficiaries with high health care needs, multiple physical and behavioral problems, disabilities and/or frailty are responsible for a disproportionate sum of Medicaid spending. Persons with at least $5,000 in annual Medicaid expenditures represent 15 percent of the Medicaid beneficiary population but account for 75 percent of the expenditures[7] . Among the top one percent of the most expensive Medicaid beneficiaries, approximately 83 percent have three or more chronic conditions and more than 60 percent have five or more chronic conditions; among persons with disabilities, each additional chronic condition is associated with an average increase in expenditures of $8,400 per

[7] Sommers and Cohen, Kaiser Commission, March 2006.

year[8] . Medicaid beneficiaries living in the community with disabilities, multiple chronic conditions, and high care needs (including the need for personal assistance services) tend to use Medicaid home and community based services (HCBS).

In the "Deficit Reduction Act of 2005," Congress mandated that AHRQ develop measures for assessing the quality of home and community-based services provided by States under their Medicaid programs. Section 6086(b) of the Act, "Quality of Care Measures," specifies that by the end of 2010, AHRQ, in consultation with stakeholders:

- Develop program performance and client function and satisfaction indicators;
- Assess each state's HCBS delivery system and outcomes; and,
- Report best practices and a comparative analysis of system features for each State.

AHRQ's efforts are initially focused on monitoring the health and welfare of all Medicaid HCBS users. Subsequent anticipated efforts (pending funding) will develop measures of performance of Medicaid HCBS at the state level.

Contact D.E.B. Potter, M.S., AHRQ, 301-472-1564, d.e.b.potter@ahrq.hhs.gov.

I.B.2 HRSA - Clinical Performance Measures

Community Health Center patients, including the poor, racial and ethnic minorities, and the uninsured, experience higher rates than average of multiple chronic diseases such as hypertension and diabetes. Access to appropriate care can improve the health status of patients with multiple chronic diseases and thus help reduce or eliminate health disparities. However, effective control of multiple conditions is a particularly ambitious undertaking since health improvements often require treatment with both lifestyle modifications, usually as the first step and, if needed, with medication management, coordination, and control.

To evaluate and track the quality of care in Community Health Centers (CHC), the Health Center Program has established a core set of clinical performance measures for all (CHC). These clinical performance measures, which all Health Center grantees will begin to report in 2009, are aligned with those of national quality measurement organizations and are consistent with the overarching goals of Healthy People 2010. Core measures will include: immunizations; prenatal care; cancer screenings; cardiovascular disease and hypertension; and, diabetes. In addition, Health Centers will also report some of the measures (low birth

[8] Kronick et al., Center for Health Care Strategies, October 2007.

weight, diabetes and hypertension) by race and ethnicity in order to evaluate progress towards eliminating disparities in health outcomes.

Contact: Dr. Deborah Willis-Fillinger, HRSA, 301-443-6614, dwillis-fillinger@hrsa.gov.

I..C. Tools to Reduce Adverse Drug Events

I.C.1 AHRQ - The Centers for Education and Research on Therapeutics (CERTs) – Decision Aid for Medication Reviews

The Centers for Education and Research on Therapeutics demonstration program is a national initiative to conduct research and provide education that advances the optimal use of therapeutics (i.e., drugs, medical devices, and biological products). The program consists of 14 research centers and a Coordinating Center and is funded and run as a cooperative agreement by the Agency for Healthcare Research and Quality (AHRQ) in consultation with the U.S. Food and Drug Administration (FDA).

The CERT is developing and disseminating a decision aid for medication reviews for seniors. This decision aid will be a useful tool for pharmacists and other health professionals to focus medication reviews on the Top 25 medication problems among older adults with a goal to increase the likelihood of identifying clinically important medication-related problems. The decision aid will be disseminated at health professional meetings and in the scientific literature accessible to geriatricians, family physicians, pharmacists,, and nurses.

In addition, the CERT will translate the geriatric medication review guideline into care of elderly patients in a community pharmacy network. In partnerships with Albertson's and Outcomes Pharmaceutical Health Care, the CERT will test the usefulness and translate the Decision Aid for Reviewing Medications into a training program and computerized tools. The CERT also will develop partnerships with local pharmacists to conduct the demonstration.

Contact: Chunliu Zhan, AHRQ, 301-427-1225, Chunliu.Zhan@ahrq.hhs.gov.

I.C.2. CMS – Drug Safety.

The 9th Scope of Work (SOW) was launched August 1, 2008. Within the Patient Safety component, Quality Improvement Organizations (QIOs) are required to work with provider organizations seeking assistance to reduce the number of potentially inappropriate medications (PIMs) and drug-drug interactions (DDIs).

PIMs and DDIs have been shown to be prevalent in the elderly and among patients with multiple chronic conditions. This opportunity allows providers seeking to improve their PIM and DDI rates to work with experts in quality improvement to quickly implement practices shown to improve these rates.

Contact: Paul McGann, CMS, 410-786-6825, Paul.McGann@cms.hhs.gov

II. Assisting Individuals with MCCs with self-care management

II.A Promoting Prevention & Self-Care Management

II.A.1 AoA - Evidence-Based Disease and Disability Prevention Program

The Administration on Aging (AoA) and the Aging Services Network (ASN) play a key role in delivering evidence-based disease and disability prevention programs for persons with multiple chronic conditions in community settings. AoA's goal is to make it easier for seniors to maintain and improve their own health by giving them simple and effective tools that they can use to reduce their risk of disease and disability. The Stanford University Chronic Disease Self-Management Program (CDSMP), which is designed to help people who have multiple chronic conditions, is one of the primary models AoA is promoting under the Initiative.

AoA launched its Evidence-Based Disease and Disability Prevention Initiative in 2003 in collaboration with the Centers for Disease Control and Prevention (CDC), the National Institute on Aging (NIA), the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare & Medicaid Services (CMS), and the John H. Hartford and Robert Wood Johnson Foundations. Twelve community projects received grants to demonstrate the efficacy of delivering science-based programs, including the CDSMP, through community-based aging services provider organizations, such as senior centers, congregate and home-delivered meal programs and senior housing projects. The funded projects all included low-cost programs that had proven effective in empowering seniors to better manage their chronic conditions, reduce their risk of falling, and improve their physical and mental health. AoA funded a national technical assistance center to help the communities implement their projects. As of January 2009, over 7500 individuals have completed the CDSMP.

Contact: Don Grantt, AoA, 202-357-3447, donald.grantt@AoA.hhs.gov

II.A.2 CMS - Senior Risk Reduction Demonstration

The Senior Risk Reduction Demonstration will evaluate whether risk reduction programs that have been developed and tested in the private sector can also be tailored to, and work well with, Medicare beneficiaries (majority have multiple chronic conditions) to improve their health and reduce avoidable health care use. Rather than taking a single risk factor approach to health management and risk reduction, this demonstration will address multiple health risks that have been shown to contribute to the onset of a number of chronic conditions or lead to exacerbations from poor management of existing diseases. The demonstration will

address the risk factors targeted by HealthierUS, which include physical inactivity, obesity, poor diet, tobacco and alcohol use, medication issues, and inappropriate use of clinical preventive services.

Three organizations, selected through a competitive process, will implement the demonstration: Focused Health Solutions, Pfizer Health Solutions, and StayWell Health Management. The demonstration will begin in April 2009 and run for 3 years.

Contact: Pauline Lapin, CMS, 410-786-6883, pauline.lapin@hhs.gov.

II.A.3 OPHS (in collaboration with USDA) - *Dietary Guidelines for Americans*

The *Dietary Guidelines for Americans* provide authoritative advice for people two years and older about how good dietary habits can promote health and reduce risk for major chronic diseases. Consumer materials based on the Dietary Guidelines, including *Finding your Way to a Healthier You, A Healthier You*, and *El Camino Hacia una Vida Saludable (The Road to a Healthier Life)* provide information in a format which assists individuals in making informed and healthy decisions about nutrition and physical activity. Accurate information about diet and physical activity is critical to helping all individuals, including those with multiple chronic conditions, make healthy choices, undertake self-management of health issues and share decision-making with providers. The guidelines can be found at: http://www.health.gov/DietaryGuidelines/

Contact: Kathryn McMurry, OPHS, 240-453-8260, Kathryn.McMurry@hhs.gov.

II.A.4 OPHS – healthfinder.gov

Healthfinder.gov is a resource for consumers who seek accurate health information in understandable and actionable language. As a resource for patients seeking credible, comprehensible health information, healthfinder.gov helps patients to inform their own health choices and to facilitate their communications with providers, both of which are vital to patients with multiple chronic conditions. The website has recently been redesigned so that information can be personalized, prevention-oriented, and clear to people with low health literacy; as a result, patients can put in their age and gender and receive specific health advice, based on national guidelines, which is easy to comprehend. The website is located at: http://www.healthfinder.gov/.

Contact: Linda Harris, OPHS, 240-453-8262, Linda.Harris@hhs.gov.

II.A.5 OPHS – 2008 *Physical Activity Guidelines for Americans*

The *2008 Physical Activity Guidelines for Americans* provide science-based guidance to help Americans ages 6 and older improve their health through appropriate physical activity. Accurate information about diet and physical activity is critical to helping all individuals, including those with multiple chronic conditions, make healthy choices, undertake self-management of health issues, and participate with providers in shared decision making. The guidelines are available at: http://www.health.gov/PAGuidelines/

Contact: Rachel Hayes, OPHS, 240-453-8255, Rachel.Hayes@hhs.gov.

II.A.6 OPHS - The President's Challenge

The President's Challenge is a motivational physical activity tracking tool that offers incentives for participants to reach certain physical activity goals. Individuals, healthcare providers, and organizations, can use the online program to track both individual and group activity and to effectively set and achieve physical activity goals. An awards system is built into the program.

People can earn Presidential Active Lifestyle Awards or bronze, silver, and gold Presidential Champions Awards. The President's Challenge is one way to help individuals achieve the goals set forth in the *Physical Activity Guidelines for Americans*. Additional information about the program is available at: www.presidentschallenge.org.

Contact: Christine Spain, OPHS, 202-690-5148, christine.spain@hhs.gov.

II.A.7 HRSA - Patient Navigator Program

The Patient Navigator Outreach and Chronic Disease Prevention Demonstration Program (PNDP) strives to improve health care outcomes for individuals with cancer and/or other chronic diseases, with a specific emphasis on health disparity populations. Demonstration grants are made to organizations such as health centers, hospitals, and non-profit groups for the development and operation of patient navigator services.

Specifically, funds are used to recruit, train and employ patient navigators, who can be nurses, social workers, community health workers or anyone with first-hand knowledge of the communities they serve. The grants focus on improving health outcomes through the coordination of comprehensive health services for patients in need of chronic disease prevention, care, and management. Patient

navigators carry out a range of activities including: coordinating health care services, facilitating involvement of community organizations, notifying individuals about clinical trials, overcoming barriers to quality health services, coordinating with health insurance ombudsman programs, and conducting outreach to health disparity populations.

Contact: Erica Pearson, HRSA, (301) 443-5794, epearson@hrsa.gov.

II.A.8 CDC – WISEWOMAN

The Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) Program helps uninsured and underinsured, 40- to 64-year-old women reduce their risks for heart disease, stroke, and other chronic diseases. The women are screened for various risk factors including high blood pressure, high blood cholesterol, and diabetes. Local programs partner with community-based organizations to help expand the reach of their services and coordinate patient health care referrals. WISEWOMAN participants can then take advantage of healthy lifestyle counseling and interventions tailored to address their identified risk factors.

CDC funds WISEWOMAN programs in nineteen states and two tribal organizations. While offerings vary from program to program, all funded programs are expected to partner with their State or Tribal Breast and Cervical Cancer Early Detection Program, Tobacco Control Program, and Heart Disease and Stroke Prevention Program. Other partnerships are also encouraged as WISEWOMAN's ultimate goal is to promote lasting, healthy lifestyle changes among women.

Contact: Nancy B. Watkins, CDC, 770-488-8004, nwatkins@cdc.gov.

II.B. Programs to Assist Individuals with Specific Multiple Chronic Conditions

II.B.1 CDC - Using Distance Technology for Treating Depression in People with Epilepsy: Project UPLIFT: Using Practice and Learning to Increase Favorable Thoughts

Depressive disorders, the most common co-morbidity with epilepsy, affect between 30-50% of people with epilepsy. The suicide rate in people with epilepsy is between 5-25 times higher than in the general population. However, mood disorders are often under-recognized and remain untreated in people with epilepsy. The stigma associated with both epilepsy and depression can also interfere with people's ability to seek care. Added to this are transportation

barriers that many people with epilepsy face due to driving restrictions and limited access to public transportation.

With CDC Epilepsy Program support, Emory University's Prevention Research Center is developing and testing telecommunications technology to use in treatment of depression in people with epilepsy. The result is a small-group, cognitive-behavioral therapy and mindfulness intervention to help alleviate and manage symptoms of depression. The intervention is delivered to patients with epilepsy via conference call or the internet.

Conducting intervention groups via telephone or the internet makes it possible for people with epilepsy to attend the sessions with other individuals in similar circumstances, enabling them not only to learn from each other, but also to provide each other with support. Through innovative uses of technology, the barriers of stigma and transportation are addressed, affording people with epilepsy access to much needed mental health services.

Contact: Rosemarie Kobau, MPH, CDC, 770-488-5269, RMK4@cdc.gov.

II.B.2. CDC - PEARL Intervention to Reduce Depression Among Adults With Epilepsy

Compared to individuals with epilepsy who are not depressed, people with epilepsy and depression have significantly higher rates of suicide, lower social and occupational functioning, decreased quality of life independent of seizure frequency, and higher non-psychiatric health care utilization. Adults with epilepsy also are more likely to be homebound as a result of reduced function and restrictions in driving. Thus, opportunities for people with epilepsy to obtain high quality care for depression may be limited.

With CDC Epilepsy Program support, the University of Washington's Prevention Research Center is testing the effectiveness of a home-based multi-modal depression treatment intervention called Program to Encourage Active, Rewarding Lives (PEARL). PEARL consists of problem solving treatment, social and physical activation, pleasant events scheduling, support and education regarding antidepressant medication use as well as psychiatric consultation and recommendations regarding initiation or adjustment of antidepressant medications. PEARL is based on the original PEARLS program, which was found to significantly reduce depressive symptoms and improve health status in homebound chronically ill older adults with minor depression and dysthymia (Ciechanowski, et al. JAMA 2004).

By providing a multi-modal, home-based stepped collaborative care intervention for adults with depression and epilepsy, this program will offer practical alternatives to usual care. In addition, PEARL will provide an opportunity for improving depression outcomes, quality of life and potentially, epilepsy outcomes.

Contact: Rosemarie Kobau, MPH, CDC, 770-488-5269, RMK4@cdc.gov.

II.B.3 SAMHSA – Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS Services

The purpose of the Targeted Capacity Expansion for HIV (TCE/HIV) program is to augment and expand substance abuse treatment, outreach, and pretreatment services in conjunction with HIV/AIDS services for African American, Latino or Hispanic, and/or other racial or ethnic communities affected by the twin epidemics of substance abuse and HIV/AIDS. Target populations include women and their children, adolescents and youth, injection drug and other illicit drug users, men who have sex with men, and individuals who have been released from prisons and jails.

TCE/HIV grants increase access to and availability of outreach or treatment services to more clients, improve the quality and/or intensity of services by adopting state-of-the-art treatment, or add a new service to address emerging trends or unmet needs. TCE/HIV grantees are expected to provide referrals for sexually transmitted diseases, tuberculosis, and hepatitis B and C treatment via linkages with organizations experienced in providing services to ethnic and racial communities. Outreach and pretreatment programs refer clients and facilitate entry into substance abuse treatment. Pretreatment services include brief interventions such as providing literature and other materials to support behavior change, facilitating access to drug treatment, HIV/AIDS testing and counseling, plus other medical and social services available in the local community.

To identify new cases of HIV for referral to care, recent grantees are required to offer all program participants rapid HIV testing; grantees are also expected to complete HIV rapid testing for a minimum of 80% of participating individuals. SAMHSA is also working closely with the Centers for Disease Control and Prevention through a Memorandum of Agreement to develop a web-based rapid testing guide for use in substance abuse treatment settings. In FY 2008, SAMHSA awarded 49 new TCE/HIV grants totaling approximately $21 million a year for five years ($105 million over 5 years).

Contact: Jack Stein, SAMHSA, 240-276-2950, Jack.Stein@samhsa.hhs.gov.

II.B.4 IHS - The Healthy Heart Program – Diabetes and Cardiovascular Disease

The IHS Division of Diabetes Treatment and Prevention, with funding from the *Special Diabetes Program for Indians,* supports 30 grant programs in the Healthy Heart Demonstration Project that are implementing intensive clinical, team-based case management approaches to treat risk factors for cardiovascular disease in American Indians and Alaska Natives who have diabetes. The IHS is conducting a rigorous evaluation of the funded projects to assess effectiveness and to determine how to disseminate the lessons learned throughout the Indian Health Service (IHS).

Contact: Tammy Brown, MPH, RD, IHS, 505-248-4182, Tammy.Brown@ihs.gov.

II.B.5 CDC – Addressing Arthritis in the Context of Co-Morbid Conditions

The CDC Arthritis Program is using two different approaches to address the needs of people with arthritis as well as another chronic condition. The CDC has strengthened 12 state arthritis programs by providing states with more funds (average of $500,000/year per state during the period 2008-2011) to extend effective, evidence-based interventions to reach more to people with arthritis within funded states. In addition to arthritis-specific physical activity and self management education programs, these funds are used to disseminate and implement the Chronic Disease Self-Management Program (CDSMP) and EnhanceFitness, a multi-component physical activity program appropriate for people with chronic conditions http://www.cdc.gov/arthritis/state_programs/index.htm).

In addition to funding state arthritis programs, the CDC Arthritis Program, in collaboration with the National Association of Chronic Disease Directors, has funded 9 state health departments to integrate self-management education or physical activity guidance into the activities of other state programs. In this project, CDC awards arthritis funds to state arthritis, diabetes, and aging programs to disseminate CDSMP and/or EnhanceFitness to constituents with MCC.

The CDC Arthritis Program is also sponsoring a centralized evaluation of both the state arthritis programs and the arthritis integration grants. This evaluation also will identify model efforts that can be replicated in other state agencies and paradigms for working with partners at the state, regional and national level.

Contact: Teresa J. Brady, PhD, CDC, 770-488-5269, TBrady@cdc.gov.

III. Health System Changes to Improve the Health of Individuals with MCCs

III.A Demonstration Projects to Enhance Coordination of Care

III.A.1 CMS - Office of Research, Development, and Information (ORDI) Chronic Disease Demonstrations - Medical Home Demonstration.

Section 204 of the Tax Relief and Health Care Act Balanced Budget Act of 1997 (TRHCA) required the Secretary of the U.S. Department of Health and Human Services (HHS) to conduct the Medicare Medical Home demonstration project "to redesign the health care delivery system to provide targeted, accessible, continuous and coordinated, family-centered care to high need populations." A medical home is a physician practice that organizes and coordinates health care for its patients, based on their needs and priorities, through direct communication with patients and their families and integration of care from the patients' physicians. Under the Medicare Medical Home Demonstration, participating physician practices will receive a monthly care management fee payment for each Medicare beneficiary with a chronic disease who is enrolled. CMS plans to implement the demonstration in eight States. CMS will recruit physician practices in Spring 2009, with payment beginning January 1, 2010 and continuing for 3 years.

Contact: Jim Coan, CMS, 410-786-9168, james.coan@hhs.gov

III.A.2 CMS- The End Stage Renal Disease (ESRD) Disease Management Demonstration.

The ESRD Disease Management demonstration provides the opportunity for Medicare beneficiaries with ESRD to enroll in Medicare Advantage (MA) plans that focus on their chronic illness and associated co-morbid conditions through the use of disease management models. Dialysis organizations are partnering with MA plans to offer comprehensive services to enrolled members with ESRD. The plans rely on care managers to coordinate the overall care of the members and to ensure they receive appropriate care for their MCCs. Typical disease management approaches focus on reducing hospitalizations and on management of diabetes which affects a significant number of ESRD beneficiaries. Enrollment began on January 1, 2006, and the demonstration is scheduled to end December 31, 2010.

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III.A.3 CMS – The North Carolina Community Care Network (NC-CCN)

The North Carolina Community Care Network (NC-CCN) is one of five prospective sites to be considered for the Medicare Health Care Quality (MHCQ) Demonstration Program. NC-CCN will use comprehensive care management for individuals with chronic and co-morbid conditions. Initial care includes assessment, identification of needs, and development of a plan of care. The types of services needed depends on the characteristics of the patient but may include: disease, pharmacy, or social case management; mental health referral; interdisciplinary team review; medical home assignment; patient empowerment and education; family/caregiver involvement; and, collaboration with community providers. This project is expected to start in 2009.

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III.A.4 CMS - LifeMasters Demonstration.

LifeMasters is a Medicare Disease Management Demonstration providing services to certain chronically ill beneficiaries, who are enrolled in both Medicare and Medicaid (dual-eligibles). LifeMasters will test whether disease management in the traditional fee-for-service (FFS) program leads to improved outcomes and lower total costs to the Medicare program. Up to 30,000 dual-eligible Medicare fee-for service (FFS) beneficiaries in seven counties in the State of Florida who have congestive heart failure (CHF) and any combination of CHF, coronary heart disease, or diabetes are eligible to participate in the project. Disease management services, designed to prevent complications and to provide patients with information and support, help manage symptoms between doctor visits.

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III.A.5 CMS - Care Management for High Cost Beneficiaries (CMHCB) Demonstration

The CMHCB Demonstration provides disease management services for thousands of Medicare beneficiaries.. The 3-year demonstration tests if provider-based intensive care management services improve quality of care and reduce costs for fee-for-service (FFS) beneficiaries who have one or more chronic diseases and generally incur high Medicare costs. The sites were chosen in different areas of the country with the primary focus on the disease states of congestive heart failure, diabetes, and chronic kidney disease. Although CMS pre-selects beneficiaries for the demonstration projects according to eligibility criteria, participation in the demonstration is voluntary. Program services are intended to increase adherence to physician prescribed care, reduce unnecessary hospital stays

and emergency room visits, and help participants avoid costly and debilitating complications. At this time three of the sites have been awarded extensions.

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III.B System-Wide Initiatives to Enhance Care

III.B.1 IHS – Chronic Care Initiative

The Indian Health Service (IHS) Director's Chronic Care Initiative is a major effort to redesign the delivery of care for chronic conditions, targeted at improved care across conditions and in clinical preventive services. The IHS is working in partnership with the Institute for Healthcare Improvement (IHI) in an innovative collaboration with 40 sites to develop and sequence the changes that will result in improved outcomes for patients with chronic conditions. The Chronic Care Model provides the framework for the changes being tested in the Innovations in Planned Care for the Indian Health System. These changes include an emphasis on patient self management, patient centered care, integration of behavioral health into primary care, and use of a patient registry to track patients with multiple morbidities and to assist in planned, proactive care.

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III.B.2 HRSA – Patient Safety and Clinical Pharmacy Services Collaborative

In May 2008, HRSA launched the Patient Safety and Clinical Pharmacy Services (PSPC) Collaborative. The Collaborative focuses on reducing medication errors and improving health outcomes by integrating clinical pharmacy services into primary care. In its efforts to protect patient safety, the collaborative targets one area of significant risk: "the experience of high-risk patients" (such as individuals with MCC) "as they encounter multiple providers and different medication practices"[9].

The PSPC is designed to spread leading practices proven to improve patient safety and health outcomes. During the 18 month process of the PSPC, learning sessions, action periods, web training, and list serves will be used to measure, report, and track improvement. Expert faculty will be on hand to help teams adapt, test, and implement successful practices. Additional information is available at http://www.hrsa.gov/patientsafety/default.htm.

Contact: Rebecca Hines at rhines@hrsa.gov or Krista Pedley at kpedley@hrsa.gov.

[9] Health Resources and Services Administration (HRSA). "The Patient Safety & Clinical Pharmacy Services Collaborative (PSPC) Overview" @ ftp://ftp.hrsa.gov/patientsafety/PSPCoverview.pdf. Accessed on 1/8/2009.

III.B.3 HRSA - Children with Special Health Care Needs (CSHCN)

A large percentage of individuals with chronic conditions have both "primary" and "secondary" conditions. Most require a wide range of health services, consult multiple providers, and are at risk of poor health outcomes because of inadequate access to or inadequate coordination of needed services. For example, children with special health care needs (CSHCN) account for an estimated 14% of the child population, but they account for 40% or more of medical expenditures for children overall. Ninety-one percent of CSHCN have one or more conditions and 25% of CSHCN have three or more conditions. Eighty-five percent of CSHCN experience one or more functional difficulties and 28% of CSHCN have four or more functional limitations as a result of chronic conditions.

HRSA has legislative authority: (1) to provide rehabilitation services for blind and disabled individuals under the age of 16 years receiving benefits under Title XVI (the Social Security Act), to the extent medical assistance for such services is not provided under Title XIX (Medicaid); (2) to provide and promote family-centered, community-based, coordinated care for children with special health care needs; and, (3) to facilitate the development of community-based services for such children and their families. HRSA accomplishes this mission through multiple programs:

- the Title V Block Grant Program for Children with Special Health Care Needs, which targets 30% of the State Maternal and Child Health Block Grants to support care for CSHCN, a large percentage of whom have multiple chronic conditions; and,
- the Discretionary Grant Program, which provides funding to support services and infrastructure for individuals with specific diagnoses (e.g., Traumatic Brain Injury program, Hemophilia) and the general population of individuals with special health care needs, many of whom have multiple chronic conditions.

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III.B.4. SAMHSA – Screening, Brief Intervention, and Referral to Treatment (SBIRT) Initiative

The specialist treatment system is often not appropriate for persons at risk for a substance use disorder (i.e., substance abuse or dependence), nor can that system alone address the needs of all those persons diagnosed with either substance abuse or dependence. According to SAMHSA's National Survey on Drug Use and Health (NSDUH), in 2007 approximately 21 million people needed treatment for a substance use disorder but did not receive it. Of those, 95 percent did not even

recognize they had a problem. Therefore, most people with or at risk for a substance use disorder are unlikely to seek help from the specialty treatment system (such as a behavioral health specialist or an addition specialist). They are far more likely to turn up in some other medical setting. The SBIRT approach provides effective early identification and intervention in primary care and general medical settings. Early identification can decrease total healthcare costs by arresting progression toward addiction. SBIRT also can identify persons with more serious problems and encourage them to obtain appropriate specialty services.

SAMHSA's SBIRT Initiative has consisted of a systems-level approach to screening and brief intervention within primary care, general medical and community settings including physician offices, hospitals, educational institutions, and mental health centers. Grantees have implemented SBIRT in primary and general practice settings including: trauma centers or emergency rooms; community clinics; federally qualified health centers; tribal communities; and, school clinics. Preliminary data suggest the SBIRT approach is successful in modifying the use patterns of those who consume five or more alcoholic beverages in one sitting and those who use illegal substances.

As of October 2008, a total of 750,987 clients received SBIRT services over the past 5 years. Of these individuals, 576,813 screened negative while 124,315 screened positive and received brief intervention. In addition, for those who screened positive, 22,938 received brief treatment and 26,921 were referred to specialty treatment.

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III.C Using Health IT to Improve Care for Individuals with MCC

III.C.1 AHRQ - Ambulatory Safety and Quality Program: Improving Management of Individuals with Complex Healthcare Needs through Health IT

This funding supports the development of health information technology (health IT) that assists clinicians, physician practices, health care delivery systems, and patients and families improve the quality and safety of health care for individuals with complex healthcare needs (e.g. multiple chronic diseases). The long-term goal of this effort is to ensure that patients receive the appropriate care and management for the prevention and treatment of priority conditions. Detailed information about this program is available at: http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-08-002.html.

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III.C.2 ONC - Secure Messaging Pilot

The Office of the National Coordinator (ONC) of Health Information Technology (HIT), through this pilot project in 2-3 sites, expects to demonstrate the value of and best practices associated with secure messaging between patients with chronic conditions and their providers. It is anticipated that regular access to a physician's care any place, any time will result in better management and improved health care outcomes.

This project supports public and private sector efforts to promote the use of interoperable health information technology (HIT) in post-acute and long-term care settings. The project will link HIT standards that have been (i) required for use by the Secretary of HHS and (ii) identified by the Health IT Standards Panel (HITSP) to federally-required patient assessment instruments. It will also support the electronic exchange of standardized assessments.

Such interoperable health information exchange will improve quality and continuity of care and decrease inefficiencies inherent in a paper-based system. In addition, the work completed under this contract is being used by HL7 (Health Level 7) as the foundation for the standard for the exchange of patient assessments that include functional status. Finally, the work under this contract provides the Federal Government with the opportunity to implement health information systems that are consistent with the emerging interoperable Nationwide Health Information Network (NHIN).

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IV. Research to Fill Knowledge Gaps about Individuals with MCCs

IV.A Clinical Research

IV.A.1 NIH/NCI – Cancer and Renal or Hepatic Organ Dysfunction

Cancer patients with renal (kidney) or hepatic (liver) organ dysfunction may require dose reductions or modifications of their medications. Gathering organ dysfunction data has traditionally been a post-marketing function. No information has been available concerning use of the newest, potentially most effective investigational therapies or chemotherapies for these patients, and clinicians tend to make dose adjustments for these and the tried-and-true standard therapies empirically. Oncologists have had little scientific evidence—a few small cohort and case studies—to guide dosing for chemotherapeutics in patients with hepatic or renal impairment. The number of protocol-eligible cancer patients with impaired organ function is limited. Involving well-coordinated, multi-center groups with access to experienced phase 1 investigators can and does shorten accrual time significantly.

The National Cancer Institute's Organ Dysfunction Working Group, the Southwest Oncology Group Early Therapeutics Committee, and the Cancer and Leukemia Group B (CALGB) were formed to address the paucity of information for patients with organ dysfunction and to accrue patients efficiently. This effort has been able to involve as many as 12 centers, reducing the accrual time to as little as 15 months.

Given the recognition that hepatic and renal impairment can affect chemotherapeutic drug metabolism and clearance unpredictably, the National Cancer Institute-sponsored Organ Dysfunction Working Group and others are leading structured efforts to assess promising or recently approved agents in patients who have organ dysfunction. The program evaluates different cohorts of patients defined by their degree of organ dysfunction using phase 1 dose-escalating studies; the pharmacokinetic (PK) and clinical toxicity data collected is then used to develop formal guidelines for dosing in these specific populations.

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IV.A.2. NIH/NCI - CTEP Initiatives to Include Individuals with HIV and Cancer onto NCI-sponsored Cancer Clinical Trials

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute has initiated a new research program to improve the approach to cancer therapy in individuals with HIV infection. Since the beginning of the AIDS epidemic, participation in clinical trials for those with HIV and non-AIDS-defining cancers

has been severely restricted. Modern therapy for HIV infection has transformed the disease into a chronic manageable condition. However, cancer has become the leading cause of death when successful therapy for HIV is widely available. The risk of many cancers is higher in HIV+ patients compared to the background population, so exclusion of this population is not justified. CTEP has three new initiatives to enhance access to cancer clinical trials for those with HIV. A major concern is that anti-HIV therapy and cancer therapy will have dangerous interactions that are harmful. A new consortium is funded to study these potential drug interactions and define safe and effective use of anti-HIV therapy and anti-cancer therapy. Participation in clinical trials of potentially curative therapy such as bone-marrow transplantation and other phase II and III cancer clinical trials will also be made available to HIV patients under this program.

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IV.A.3. NIH/NCI – AIDS Malignancy Consortium

This clinical trials consortium was established in 1995 to evaluate clinical trials interventions for the treatment and prevention of malignancies in HIV. The consortium conducts multi-site clinical trials across many medical centers across the nation and has strong collaborations with NIAID-supported AIDS Clinical Trials Networks and other collaborative non-HIV NCI clinical networks. This consortium is the only network in the country that develops, validates, and evaluates anti-cancer therapies for HIV associated malignancies. In addition, the consortium is set to study drug-drug interactions of anti-cancer/anti-HIV therapeutics and to formulate treatment guidelines for these cancers.

Despite dramatic declines in HIV mortality rates due to the success of highly active anti-retroviral therapy (HAART), cancer continues to be among the leading causes of death among HIV-infected patients. The introduction of HAART led to an initial decline in the incidence of those AIDS-defining cancers that occur with very low CD4 cells, leading to the perception that cancer had been markedly reduced as a problem in this population. However, as AIDS patients live longer, the number of patients with AIDS has increased in the United States and they are at risk for cancer for a longer period of time. An increase in non-AIDS defining cancers is now becoming evident in this population, as well as the late occurrence of Kaposi's sarcoma and other AIDS-related cancers.

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IV.A.3 NIH/NHLBI - Cardiovascular Disease and Type 2 Diabetes

Two major trials are testing approaches to reducing the burden of cardiovascular disease (CVD) in people with type 2 diabetes. ACCORD (Action to Control Cardiovascular Risk in Diabetes) is studying patients who have CVD or two or more risk factors for developing it. Three strategies are being compared with conventional treatments: intensive lowering of blood sugar levels, intensive lowering of blood pressure, and use of a fibrate in addition to a statin to modify blood cholesterol levels. The blood-sugar-lowering intervention was stopped in February 2008 because of safety concerns; results of the other interventions will be reported in 2010.

BARI 2D (Bypass Angioplasty Revascularization Investigation in Type 2 Diabetes) is studying patients with established coronary heart disease. The trial is evaluating whether revascularization via bypass surgery or angioplasty, in addition to aggressive medical therapy, confers a survival advantage. The trial is also evaluating the effectiveness of insulin-providing medications versus insulin-sensitizing medications in preventing deaths, heart attacks, and strokes. Results are expected in 2010.

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IV.A.4 NIH/NHLBI – Obesity, Hypertension and Metabolic Syndrome

Obesity increases risk of developing cardiovascular disease (CVD), both independently and by influencing other CVD risk factors such as hypertension. An NHLBI-initiated program titled Weight Loss in Obese Adults with Cardiovascular Risk Factors—Clinical Interventions is evaluating weight-loss strategies to lessen CVD risk. Three trials are under way in obese adults who have either hypertension or at least two elements of the metabolic syndrome (i.e., large waistline, elevated triglycerides, low HDL cholesterol, hypertension, high blood sugar). Although the primary emphasis is on developing and evaluating weight-loss programs that are effective in routine clinical practice, an important secondary focus is on improving application of evidence-based guidelines to reduce other CVD risk factors.

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IV.A.5 NIH/NIA – Developing Interventions for Multimorbidities

The association of multi-morbidity with increasing age and functional compromise suggests that, as the general population ages, the public health burden of co-occurring diseases will increase significantly. Diseases that are

common in older adults, such as hypertension and arthritis, may occur together by chance. However, the impact of co-occurrence on functional status is often greater than the "sum" of the impacts of the individual chronic diseases. Recognition and exploration of "common pathways" of co-occurring conditions offers the potential for improved medical management as well as for targeted interventions to decrease the synergistic interaction of impairment and disability among older populations. This National Institute on Aging (NIA) initiative supports planning projects for clinical trials that establish a scientific basis for future interventions to improve health outcomes related to interactions of multiple co-occurring conditions in elderly patients. Specific projects include Patient-Centered Care Management for Seniors with Multiple Morbidities, Walking Activity and the Burden of Multiple Morbidities, Nursing Home Co-morbid Depression Care Management, Osteoporosis in Women with Rheumatoid Arthritis, and Tailored Clinical Trials for Hypertension and Fall Risk.

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IV.A.6 NIH/NIA - Action to Control Cardiovascular Risk in Diabetes - Memory in Diabetes (ACCORD-MIND)

ACCORD-MIND, a clinical trial funded by the National Institute on Aging, is a sub-study nested within the National Heart, Lung, Blood Institute's Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial. ACCORD-MIND will test over a four year period whether the intensive glucose, blood pressure, and lipid management being conducted in ACCORD can also reduce the rates of cognitive decline and structural brain change in a sub-sample of 2,800 people with diabetes. Participants will undergo periodic cognitive testing and magnetic resonance imaging (MRI) scans to assess change over time. Tests of cognitive function measure memory and executive function, which includes speed of processing, attention, planning, and concentration. The tests are indicators of how well a person performs various tasks in daily life. Cognitive impairment is also predictive of future onset of dementia. In diabetes, cognitive impairment may compromise an individual's ability to manage his or her disease, an important factor to be incorporated into an analysis of clinical trial efficacy.

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IV.A.7 NIH/NIDA - Co-occurring Psychiatric Illness and Substance Abuse

Drug abuse rarely occurs in isolation and is frequently accompanied by other psychiatric conditions, which can complicate the diagnosis and treatment of the drug abuse. The National Institute on Drug Abuse (NIDA) supports research that explores causality and/or directionality for co-morbid drug abuse and other mental disorders (i.e., which comes first) and that identifies common mechanisms that

may lead to both, such as shared genetic vulnerabilities or similarities in brain circuits and chemical messengers. Specific activities are:

- *Epidemiological research* on mental health and drug abuse including support and secondary analyses of data from the National Epidemiologic Survey on Alcohol and Related Conditions (NESARC) and the National Comorbidity Survey,[10] which bolster efforts to better understand the prevalence and variety of co-morbidities.

- *Clinical trials* testing new and existing treatment options in co-morbid populations to assess the actions of combined or dually effective behavioral and medication treatments. For example, because a substantial proportion of patients with attention deficit/hyperactivity disorder (ADHD) also suffer substance abuse problems, NIDA is supporting clinical trials in its National Drug Abuse Treatment Clinical Trials Network (CTN) to examine whether treating adolescent drug abusers and adult smokers with ADHD using osmotic-release methylphenidate will enhance the benefits of concurrent substance abuse treatment.

- *Call for studies* on co-occurring mental illness, alcohol, and/or drug abuse and medical conditions**,** in partnership with the National Institute of Mental Health (NIMH) and the National Institute on Alcohol Abuse and Alcoholism (NIAAA). NIDA also intends to publish a request for applications to study trauma, stress, and substance use and abuse among U.S. military personnel, veterans, and their families.

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IV.A.8 NIH/NIDA - Co-occurring Drug Abuse and HIV

The National Institute on Drug Abuse (NIDA) supports research to learn more about how drug abuse and HIV interrelate and to further promising primary and secondary prevention and treatment for co-occurring drug abuse and HIV infection. NIDA has established that drug abuse treatment *is* HIV prevention. Examples of activities in this area include calls for studies on changing trends, research to explore underlying biological mechanisms, and education/outreach to patients, the general public, and scientists.

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[10] These are nationally representative surveys in the U.S. that assesses the prevalence and correlates of DSM-III-R disorders including substance use and mental health disorders.

IV.A.9 NIH/NIDA - Co-occurring Drug Abuse/Addiction and Chronic Pain

Approximately 10 to 20 percent of the general population suffers with chronic non-cancer pain.[11] While the use of prescription opioids provides needed relief for most of this group, for some, opioid analgesics can produce drug dependence and addiction. Thus, the National Institute on Drug Abuse (NIDA) has embarked on a research program to examine the intersection of pain treatment with abuse and addiction to opioid medications. Major goals are to develop alternative pain medications with reduced addiction potential, and to elucidate risk or protective factors related to opioid abuse and addiction.

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IV.A.10 NIH/NIMH - A Randomized Trial in Liaison Psychiatry in Primary Care

Recent clinical trials focusing on depression treatment among persons with diabetes and heart disease have failed to show improved diabetes or cardiovascular outcomes. Benefits for depression outcomes have varied in these trials, as diabetes and cardiovascular disease are also correlated with less favorable depression prognosis. Therefore, an integrated approach may be needed to improve both depression and medical outcomes.

In this study, National Institute of Mental Health (NIMH) researchers use a Chronic Disease-Focused Depression Treatment model to enhance both major depression and co-morbid chronic disease management. In this randomized controlled trial, 300 persons with poorly controlled diabetes or coronary heart disease and major depression or dysthymia are assigned to either: a depression treatment program that addresses management of co-morbid disease; or, depression treatment with a primary care physician. The principal measures of treatment effectiveness are depressive symptoms and the percentage of diabetes and coronary heart disease patients with successful management of all three disease control measures (glycemic, blood pressure, and lipid control) over a 2-year period.

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IV.A.11 NIH/NIMH - Stepped Care for Depression and Musculoskeletal Pain

[11] Sullivan et al. Regular use of prescribed opioids: association with common psychiatric disorders. Pain 119:95–103, 2005.

Pain costs the nation billions of dollars each year for health care and lost productivity. Patients with pain often suffer from concomitant depression. Comorbid pain and depression have reciprocal adverse effects on both symptom-specific outcomes (reduction of pain and depression) as well as health-related quality of life (HRQL) outcomes. To establish whether treatment strategies shown to improve outcomes for depression in primary care are effective in patients with co-morbid pain and depression, the National Institute of Mental Health (NIMH) developed the Stepped Care for Affective disorders and Musculoskeletal Pain (SCAMP) study.

Stepped care strategies account for variability between patients by assigning different levels of treatment based on personal characteristics. SCAMP will enroll 500 patients with musculoskeletal pain of the low back, hip, or knee - half of which suffer from clinically significant depression and half of which are not depressed. The 250 depressed patients will be randomized to either stepped care or usual care. The stepped care group will receive 12 weeks of standard antidepressant treatment (step 1) administered by a Depression Pain Clinical Specialist (DPCS) nurse case manager. Patients not achieving adequate pain improvement after 12 weeks will receive a series of 6 evidence-based pain self-management sessions (step 2) from the DPCS. This study aims to test whether stepped care is more effective than usual care in improving the outcomes of depression and pain. In addition, the study will test the intervention's impact on HRQL, pain beliefs and behaviors, and health care costs. Finally, longitudinal assessment of the non-depressed cohort will establish the frequency and risk factors for incident depression.

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IV.4.12 NIH/NIMH - The Safety and Efficacy of Using Sertraline for Treating Depression in Patients with Congestive Heart Failure

Patients who suffer from chronic illnesses including vascular disease (cerebrovascular and coronary artery disease) are more likely to suffer from mood disorders compared to the normal population. In patients with vascular disease, depression also is associated with increases in inpatient hospitalizations, healthcare costs, morbidity, and mortality. Despite this knowledge, little is known about the association between congestive heart failure (CHF) and depression. The rate of depression may be high in the CHF population, but studies have not specifically addressed the impact of treating depression on morbidity and mortality in CHF patients.

Therefore, the National Institute of Mental Health (NIMH) is supporting a clinical trial to study the safety and efficacy of using sertraline (Zoloft) to treat depression in patients with CHF. In this randomized trial, 500 patients with CHF and

clinically diagnosed major depression are administered either sertraline or placebo. The acute treatment phase lasts twelve weeks and is followed by a six-month assessment. The investigators hypothesize that sertraline treatment will improve depression symptoms, reduce the rates of mortality and re-hospitalization in patients with CHF and depression, and improve daily functioning and quality of life.

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IV.A.13. NIH/NIMH – Prevention of Post-Stroke Depression and Mortality

Numerous studies have demonstrated an increased death rate associated with post-stroke depression. An important research question is whether prophylactic antidepressants are an effective way of preventing mortality associated with post-stroke depression. In this study, National Institute of Mental Health (NIMH) researchers are conducting a follow-up assessment of patients who received 12 months of antidepressant treatment compared to placebo or to problem solving therapy following a stroke.

The aim of the follow-up study is to determine whether those who received the antidepressant treatment have significantly different measures of cardiac physiology compared to the placebo group. In addition, researchers will enroll 90 new patients in order to obtain a prospective study of baseline cardiac physiology following stroke and the effect of depression and antidepressant medication on these cardiac measures. Prospectively studied patients who have had an acute stroke within three months will be given a three month trial using double blind methodology of the antidepressant, escitalopram, or placebo. All patients will be followed for the duration of the study at yearly intervals to determine whether exposure to antidepressants or depression status has any immediate or long-term effect on cardiac physiology or mortality. This study will determine the utility of the antidepressant medication in reducing long-term mortality as well as potential cardiac-related mechanisms, which may be producing this increased mortality.

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IV.A.14. NIH/NICHD – Down Syndrome, Other Intellectual and Developmental Disabilities and Co-occurring Chronic Medical Conditions

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) supports a broad range of research to advance fundamental and clinical knowledge about intellectual and developmental disorders (IDDs) in childhood and through the lifespan. Many individuals with IDD may also experience one or more co-occurring, chronic medical conditions.

For example, infants and children with Down syndrome (DS), the most common cause of mild to moderate intellectual disability, are more likely to have health conditions like hearing loss, heart malformations, hypertension, digestive problems and vision disorders. Leukemia, heart disease, sleep apnea, seizure disorders and mental health problems are also more common in individuals with DS who experience premature aging and heightened incidence of adult diseases.

Other IDD conditions, associated with co-occurring chronic medical and/or behavioral problems are also of central interest to NICHD. These conditions include Williams Syndrome, Fragile X Syndrome, Rett Syndrome and Prader Willi Syndrome. The goal of the NICHD research is to understand how to ameliorate adverse effects of these complex disorders, how to lengthen the lifespan, how to improve functional capacities, how to enhance the health of individuals with IDDs, and, ultimately, how to reduce the incidence of these conditions.

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IV.A.15 CDC – Chronic Fatigue Syndrome

In the Chronic Fatigue Syndrome Research Program (CFSRP), the Centers for Disease Control and Prevention (CDC) maintains an inventory of research programs focused on individuals with MCCs. To model Chronic Fatigue Syndrome (CFS) the CFSRP supports studies of chronic fatiguing illnesses following acute infectious mononucleosis, Q fever, Ross River, and West Nile Virus, illnesses associated with military basic training, and chronic hepatitis C. The CFSRP continues to evaluate co-morbidities associated with CFS and conducts cohort studies to evaluate the effects of stress (physical, mental, infectious) over the life-time as a risk factor for CFS, other unexplained unwellness, and premorbid conditions such as metabolic syndrome. CDC's CFSRP also conducts cutting-edge molecular epidemiology studies of CFS and unexplained unwellness in order to identify the pathophysiology and potential biomarkers of CFS. The results of these studies are published in the peer reviewed medical literature, posted on the CFS website, incorporated in continuing education materials, and used in educational lectures.

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IV.A.16 FDA – Guidance to Incorporate Individuals with MCCs in Drug Clinical Trials

FDA has long recognized the need for including diverse patient populations in clinical trials that assess a drug's safety and effectiveness. FDA reviews effectiveness and safety data by gender, age, and racial subgroups, as well as by

other criteria such as patients with renal failure, different levels of severity of disease, or the presence of other co-morbid conditions.

In many guidance documents, FDA has advised on clinical trial design on the need to study drugs in patients that mirror the general population that will receive the drug. For example, safety review includes exploring drug-demographic interactions, drug-disease interactions (i.e., co-morbidities or MCCs), and drug-drug interactions. To enhance the general applicability of safety and efficacy findings, FDA encourages applicants (drug manufacturers) to broaden Phase 3 clinical trials to include, for example, patients with concomitant diseases (the MCC population) and patients taking medications for other conditions.

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IV.B Health Services Research

IV.B.1 CMS: Availability of special purpose linked data base for study of Medicare Beneficiaries with Chronic Conditions

The CMS Chronic Condition Data Warehouse (CCW) provides researchers with Medicare beneficiary, claims, and assessment data linked by beneficiary across the continuum of care (see http://ccwdata.org/). In the past, researchers analyzing Medicare data files were required to perform extensive analysis related to beneficiary matching, de-duplication, and merging of the files in preparation for their analysis. With the CCW data, this preliminary linkage work is already accomplished and delivered as part of the data files sent to researchers. For additional information about CMS data, see the website of the CMS Research Data Assistance Center (ResDAC) at www.resdac.umn.edu.

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IV.B.2 ASPE - Constructing Sample Weights for the National Long-Term Care Survey

The National Long-Term Care Survey (NLTCS), the longest running survey of older persons with chronic disabilities, was fielded first in 1982 and then every five years beginning in 1984. This survey is among the most important sources of information for determining trends in elderly disability and the use of post-acute and long-term care services. ASPE has funded special supplements to the core NLTCS (e.g., the Next-of-Kin Survey and Informal Caregiver Survey), but the vast majority of funding has been provided by the National Institute on

Aging. Researchers working on several ASPE projects to document trends in health status, disabilities, and health care use among the elderly identified inconsistencies between their estimates and earlier estimates published by others. This led to uncertainty about the accuracy of the 2004 NLTCS cross sectional weights as well as uncertainty about the consistency of the weighting process across time. To address these issues, this project provides resources for a sampling statistician to review the NLTCS documentation, weighting methodology, and sample weights; construct a new set of sample weights that are consistent across waves of the NLTCS; analyze the validity of the new weights; and, produce user-friendly documentation.

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IV.B.3. ASPE – Cost Evaluation of Nurse Delegation Pilot Project for the Medicaid Home and Community Based Services (HCBS) Population

The State of New Jersey will launch a small pilot program in which registered nurses (RNs) employed by licensed home care agencies will be permitted to delegate the performance of specific nursing tasks (such as medication administration) to home care aides who are employed by the same licensed home care agency. Currently, the New Jersey Nurse Practice Act (NPA) does not permit home care agency aides to administer medications to home care agency clients, even if the aides are trained and supervised by registered nurses. The requirement that all medications administered in home care settings by home care agency personnel must be administered by licensed nurses precludes the provision of cost-effective HCBS alternatives to institutionalization for some Medicaid beneficiaries.

The New Jersey State Board of Nursing (BoN) has authorized the pilot project and an evaluation. If results demonstrate that quality of care is maintained, the BoN will modify the NPA and associated regulations to permit RNs to delegate medication administration and other routine health tasks to home care agency aides. The Robert Wood Johnson Foundation (RWJF) sponsors the pilot program and the quality of care evaluation. The ASPE contract will fund an independent evaluation of the Medicaid cost impact of nurse delegation in HCBS.

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IV.B.4. ASPE - Effect of Reducing the Incidence of Falls on Long-Term Care Expenses

The risk of falling increases substantially with age: one in every three Americans age 65 and older living in the community falls during a year and the ratio increases to one in two by age 80. While the risk of falling is high for older

Americans, most of whom have chronic conditions, public health experts have increasingly come to view falls as a preventable outcome associated with aging. In 2004 and 2005, ASPE contracted with Abt Associates and LifePlans to design a demonstration to reduce the incidence of falls and associated acute health and long-term care services utilization and costs. After further refinement of the falls prevention intervention, methodological approach and assessment instruments, ASPE is now beginning the next phase of the demonstration - the implementation and evaluation of the falls prevention program. The work will be performed over four years and in discrete pieces. The purpose of this project is to fund the first major component: further instrument/assessment refinement, information system development, and field testing of the falls prevention program. Future work will include full-scale data collection as part of the demonstration and evaluation of outcomes.

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IV.B.5 CDC - Examining Prevalence and Implications of Arthritis for Adults with Co-morbid Chronic Conditions.

The Centers for Disease Control and Prevention (CDC) Arthritis Program is conducting epidemiologic analysis to characterize the co-occurrence of arthritis with other chronic conditions. For example, arthritis is common among adults with diabetes, heart disease, and obesity. In May 2008, CDC published results of the first such analysis in the May 9, 2008 Morbidity and Mortality Weekly Report (MMWR), examining arthritis among people with diabetes. This report can be found at: http://www.cdc.gov/mmwr/previewithmmwrhtml/mm5718a3.htm.

The results of this analysis indicated that, during 2005 and 2007, doctor-diagnosed arthritis affected approximately half of the estimated 20.6 million adults with doctor-diagnosed diabetes. The prevalence of self-reported physical inactivity was significantly higher among those with arthritis and diabetes than among those with diabetes alone. This association remained significant after adjustment for age, sex, and BMI, factors that might have otherwise explained the association. State-specific estimates were consistent with the overall findings, with state-to-state differences likely attributable to differences in the distribution of factors associated with both arthritis and physical inactivity in the state population. Because BRFSS data are cross-sectional, they can only demonstrate associations; the temporal sequence of condition onset is unknown.

The associations between arthritis and physical inactivity among adults with diabetes found in this analysis suggest that arthritis might be a special, unaddressed barrier to recommended interventions (physical activity) in this population. Health-care providers interested in improving diabetes management

should especially consider arthritis-related barriers among persons with diabetes who are physically inactive.

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