Domestic Pharmaceutical Policy

The Medicare Modernization Act of 2004 is the latest and most comprehensive of a series of legislative and regulatory initiatives intended to expand access to medicines while controlling medication use and costs. Remarkably these policies are rarely based on convincing evidence of efficacy in achieving objectives related to access to effective medications, expenditures, quality of care, and health outcomes.

Over the last two decades, DACP's Drug Policy Research Group (DPRG) has conducted seminal research evaluating insurance benefit limits, affordability of health care and medications, and the impacts of interventions to improve clinical care or reduce costs. In addition to publishing the results of these research studies in the medical literature, the group has worked closely with national and state policymakers as well as voluntary health agencies to translate their research findings into improved health policies.

CORE PROGRAMS

a. Effects of benefit limits on drug utilization. DPRG faculty have a primary emphasis on investigating the impacts of changes in insurance coverage on use of medicines, affordability, and clinical outcomes. For example, Dr. Soumerai and colleagues conducted the first well-controlled studies of the effect of a limited prescription drug benefit on low income elderly and disabled individuals in New Hampshire Medicaid.[1,2,3,4] While such a policy reduced use of nonessential drugs, it had the unintended effect of causing a substantial decline in use of essential medications and doubled the risk of permanent institutionalization in nursing homes.[2] Similarly, such limits also reduced use of effective antipsychotic medications and increased use of acute care for patients with schizophrenia, at a cost 17 times higher than the drug savings.[3]

b. Affordability and burden of medical and pharmaceutical costs. Affordability of health care and medicines and the burden of medical expenditures for the elderly and disabled is a major current theme in DPRG's policy research. An example is their unique collaboration with the Center for Medicaid and Medicare Services to assess the impact of the Medicare Part D benefit on changes in cost-related nonadherence (CRN) to pharmaceutical therapy. With NIA funding, DPRG investigators developed and validated measures of CRN, integrated the measures into the annual Medicare Current Beneficiary Survey,[5] and used them to assess the prevalence of CRN and the impact of free drug samples.[6,7] In a study of the early impacts of the Medicare Part D benefit, Dr. Jeanne Madden and DPRG colleagues showed decreases in reported CRN and spending less on basic needs to afford medicines following Part D that were modest in absolute terms (<4%), but substantial relative to baseline prevalence.[8] However, these changes were not observed among those in poor health or with multiple comorbidities.

c. **Impacts of interventions to improve clinical care or reduce costs.** DPRG faculty have a long history of research on evaluating interventions or policy changes intended to improve clinical care or reduce costs. These studies have spanned a range of issues (e.g., prescribing quality improvement, formulary changes, patient self-management, disparities in care, adherence to treatment, etc.) and outcomes (e.g., medicines use, clinical status, institutional care, out of pocket or systems costs, etc). As an example,

DPRG investigators have recently shown that a PA and step therapy policy affecting choice of atypical antipsychotics for Medicaid patients with schizophrenia had potentially harmful effects on treatment initiation and medication discontinuities without producing substantial program cost savings.[9,10]

IMPACT

DPRG's research findings have been used by many states to reject strict limits on drug coverage for vulnerable populations and to expand state-funded pharmacy assistance programs. Congress, the Department of Health and Human Services, and patient care advocates used DPRG's published work to argue successfully for subsidies to the drug coverage under Medicare Part D for low income individuals. The National Alliance for the Mentally Ill and AARP, in written statements to the Agency for Health Care Research and Quality, said that DPRG studies helped to increase nationwide access to essential medications among the chronically ill.

DPRG publications were a major factor in recent legislation to allow coverage of appropriate use of benzodiazepines and barbiturates in the Medicare drug benefit. CMS recently incorporated DPRG measures of cost-related medication nonadherence into its major national survey of Medicare beneficiaries in order to evaluate the Medicare drug benefit. Based in large part on DPRG studies, the Government of Australia rejected proposed drug benefit limits and Quebec, Canada agreed to reverse a province-wide high deductible medication plan for welfare patients. Finally, a recent DPRG study resulted in the cessation of an ineffective HPHC program to encourage adherence to depression treatment.

Dr. Soumerai has been an expert witness in two federal court suits by AARP that resulted in exemptions of individuals with specific chronic illnesses from a drug prescription cap in Tennessee, and at state level, has worked closely with the Massachusetts Health Care Reform Connector Board to ensure prescription drug coverage and affordable cost sharing as part of its universal health insurance program.. Dr. Soumerai also co-developed a physician quality improvement method, academic detailing, that has been adopted in several countries' universal health plans, U.S. Medicaid, and numerous private health plans.

PROGRAM COMPOSITION AND SUPPORT

The DPRG consists of 9 faculty members (Soumerai (Director), Madden, Ross-Degnan, Simon, Trinacty, Wharam, Vialle-Valentin, Wagner, and Zhang). The DPRG offers a coveted drug policy fellowship to approximately four pre- and post-doctoral fellows each year. In the period 2003-2007, the DPRG received grants totaling over $10.4 million from a variety of sponsors including AHRQ, NIA, NIDDK, NIMH, the Robert Wood Johnson Foundation, the American Diabetes Association, the Commonwealth Fund, the Kaiser Family Foundation, and public-private partnerships with Eli Lilly and Astra Zeneca.

FUTURE DIRECTIONS

The DPRG continues to develop research that has policy relevance and potential impact on pharmaceutical utilization, costs, quality of care, and health outcomes. Faculty are currently involved in long-term studies of the effects of the Medicare Part D benefit, prior authorization of mental health drugs, disparities in diabetes care and outcomes, cost-related nonadherence to pharmaceutical treatment, and the affordability and burden of health and medicines expenditures in low income and elderly populations. Given the Drug Policy Research Group's active collaboration with the Center for Medicare & Medicaid Services, health plans, health delivery systems, and policymakers, it will continue to influence health policy and the health of vulnerable populations during the next decade and beyond.

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