DPRG DOMESTIC PHARMACEUTICAL POLICY RESEARCH

For decades, the Drug Policy Research Group (DPRG) has conducted seminal research evaluating the impacts of insurance coverage, affordability of health care and medications, and the impacts of interventions to improve clinical care or reduce costs in both the US and globally. In addition to publishing the results of these research studies in the medical literature, the group has worked closely with institutional, state, national, and international policymakers to translate their research findings into improved health policies.

DPRG has 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 demonstrating the unintended harmful effects of a limited prescription drug benefit on low-income elderly and disabled individuals in New Hampshire Medicaid. More recently, Dr. Madden and DPRG colleagues have found that, in states with strictly limited Medicaid drug benefits, patients with severe mental illness who were shifted into more generous Medicare Part D coverage experienced substantial increases access to treatments and improvements in guideline concordant therapy.

Affordability of health care and medicines and the burden of medical expenditures for the elderly and disabled is another major theme in DPRG’s policy research. An example is our 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 and used them in multiple studies of the prevalence and risk of CRN and a range of companion measures, integrated them into the annual Medicare Current Beneficiary Survey and_Concordant therapy.

In studies of

5 Madden JM, Adams AS, LeCates RF, Ross-Degnan D, Zhang F, Huskamp HA, Gilden DM, Soumerai SB. Changes in drug coverage generosity and untreated serious mental illness after Medicare Part D. JAMA Psychiatry. [In press]
the early impacts of the Medicare Part D benefit, Dr. 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. However, program impact was delayed among beneficiaries with poorer health. DPRG’s most recent analyses show that the increased access to medications was not accompanied by detectable improvements in health outcomes or by cost offsets in other services, a finding that stands in contrast to other oft-cited reports, which did not take into account secular decreases in hospitalization rates. In addition, the study team identified worrisome reversals in trends for CRN several years after Part D, whereby multi-morbid beneficiaries, in particular appear to be having increasing difficulties paying for medications. This may be a consequence of economic stagnation or the gradual shifting of health care and prescription costs onto patients by private sector insurers.

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 prior authorization 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. Dr. Lu recently completed a national study published in BMJ of FDA warnings and

widespread media reporting of suicidality among youth taking antidepressants. She and colleagues found substantial reductions in antidepressant use and small increases in suicide attempts by poisoning among young people following the FDA warnings and media reports. In one week, the study was downloaded over 22,000 times from the BMJ website.

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 DHHS, 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 legislation to allow coverage of appropriate use of benzodiazepines and barbiturates in the Medicare drug benefit. CMS and the Canadian government incorporated DPRG measures of cost-related medication nonadherence into their major national surveys of Medicare beneficiaries. Based in 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.

DPRG faculty members are also known for advancing methods for quasi-experimental research. An early publication by Drs. Wagner, Soumerai, Zhang, and Ross-Degnan on the use of interrupted time series analysis for pharmaceutical policy and intervention research is one of the most widely-cited in the field. Subsequent articles by the group have expanded on the design and reporting of ITS research. The team has also shown that a strong ITS quasi-experimental ITS design produces results that are very similar to those of randomized controlled trials, offering great potential savings in studies of health care delivery. A June, 2014, article in Annals of Internal Medicine convincingly showed that instrumental variables, one of the most popular adjustment methods in comparative effectiveness research (CER), are likely biased in

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20 Soumerai SB, Zhang F, Ross-Degnan D, Ball DE, LeCates RF, Law MR, Hughes TE, Chapman D, Adams AS. Discontinuities in atypical antipsychotic therapy following a prior authorization and step therapy policy among Medicaid beneficiaries with schizophrenia. Health Affairs 2008; April 1 [Epub ahead of print]


almost all studies published during the last two decades.\textsuperscript{27} Drs. Garabedian and Soumerai have been invited to participate in training of PCORI methods staff. 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 academic detailing, a physician quality improvement method that has been adopted in several countries’ universal health plans, U.S. Medicaid, and numerous private health plans.

The DPRG comprises 10 faculty members (Drs. Garabedian, Lu, Madden, Nekhlyudov, Ross-Degnan, Soumerai (Director), Stout, Wagner, Wharam, Vialle-Valentin, and Zhang). The DPRG offers a coveted drug policy research fellowship to approximately four pre- and post-doctoral fellows each year. In the period 2008-2014, the DPRG received grants from a variety of sponsors including AHRQ, CDC, NCI, NIA, NIDDK, NIMH, the American Cancer Society, the Commonwealth Fund, and the Kaiser Family Foundation.

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 in patients with somatic and mental illness,\textsuperscript{28} 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 DPRG’s active collaboration with CMS, health plans, health delivery systems, policymakers, and international organizations, it will continue to influence health policy and the health of vulnerable populations during the next decade and beyond.


\textsuperscript{28} Madden JM, Adams AS, LeCates RF, Ross-Degnan D, Zhang F, Huskamp HA, Gilden DM, Soumerai SB. Changes in drug coverage generosity and untreated serious mental illness after Medicare Part D. JAMA Psychiatry. [In press]