

OUTCOMES RESEARCH

Visions of Efficacy and Economics

BY RANDOLPH FILLMORE



“What happens after an intervention?” asks Linda Simoni-Wastila, MPH, PhD, associate professor and director of the Long-Term Care Initiative in the School of Pharmacy’s Peter Lamy Center for Drug Therapy and Aging.

“We, of course, need to know what happens after the prescription is written and the patient has been in treatment. However, outcomes related to reduced drug access, costs and financing of prescription drug benefits, as well as appropriateness of prescribing, are also among the topics addressed by outcomes research.”

In addition to analyzing data about patient outcomes in terms of compliance, spending, and utilization, pharmaceutical outcomes assessment is aimed at answering myriad questions that surround interventions. Knowledge about the relationship between costs and outcomes, gleaned through accurate measurement, could not be more important in today’s health care climate—and how policy, costs, utilization, and consumer patterns figure into the total health care picture are of interest to many players in the health care constellation.

For example, Simoni-Wastila has been engaged in a study funded by the Robert Wood Johnson Foundation that examines the impacts of gaps in prescription drug benefits for Medicare beneficiaries with serious mental illnesses.

“In our first phase of research, we found that individuals with no drug benefits or gaps in coverage used markedly fewer medications to treat their mental illnesses than did their fully insured peers,” says Simoni-Wastila. “The next phase in our study will examine whether reduced use of mental health drugs due to poor benefits translates into increased and more costly use of other services, including emergency room visits and admissions into long-term care facilities.”

According to Simoni-Wastila, when there are gaps in their

prescription coverage the vulnerable elderly fall into a “doughnut hole.”

“People with coverage gaps of six months or more suffer the most serious consequences,” she said. “Gaps appear to be worse for those with chronic conditions and for those whose prescription drugs are really necessary.”

Also looking at outcomes is Van Doren Hsu, PharmD, director of the School’s Pharmaceutical Research Computing (PRC), a research center within the Department of Pharmaceutical Health Services Research. In a study recently published in *Health Affairs*, Hsu and colleagues examined variability and growth in spending for outpatient “specialty pharmaceuticals” such as injectables, infusions or aerosolized products that require special handling, administration, or both. Insurance companies are among the health care players who want to know how much they are spending on specialty pharmaceuticals—regardless of the benefit design, said Hsu.

“It can be eye opening for plans,” she said.

For example, in the specialty pharmaceuticals study, Hsu and colleagues studied 10 Blue Cross and Blue Shield plans and 18 million covered individuals. The researchers identified spending in 2002 and 2003 on 20 classes of specialty pharmaceuticals that are costly or expected to increase in use among two demographic groups—those under 65 years and 65 years and older. They found that the average annual cost per patient for hemostatics, essential drugs for patients with hemophilia, was \$96,302 in 2003. This represents an increase of 19.4 percent from 2002.

Simoni-Wastila also looked at similar variables in her study of drug benefit gaps for Medicare beneficiaries with serious mental illnesses. She and her colleagues looked at the 1997-2001 Medicare Current Beneficiary Survey as linked to Medicare Parts A and B

claims and use of total mental health drug use by class of drug and spending.

“We found that coverage gaps did not influence use of and spending on newer drugs, such as atypical antipsychotics or SSRI/SNRIs, but when we examined the probability of receiving a newer drug, spending was less likely among those with gaps in coverage or no coverage relative to those with full coverage.”

Also engaged in outcomes study is Fadia Shaya, PhD, MPH, associate director of the Center on Drugs and Public Policy in the Department of Pharmaceutical Health and Services Research. Shaya’s work, often involving formulary management and managed care issues with a focus on developing clinical, economic, decision, and budget models, aims at assessing outcomes through prospective as well as retrospective studies and analyzing and handling large data sets such as those used by health care plans.

“We are currently involved in a five-year study funded by the National Heart, Lung and Blood Institute (NHLBI) examining cardiovascular care issues with a focus on assessing the impact of interventions on health care outcomes on patients with hypertension who are being seen at various clinics in Maryland,” explains Shaya, co-recipient of a \$6 million grant from the NHLBI. “We are also examining barriers to accessing care and

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the impact of interventional education to improve outcomes for patients with diabetes.”

Outcomes studies are often comparative, and results can guide therapy and affect treatment models. For example, when Shaya and colleagues conducted an observation study of a high-risk, Medicare population examining outcomes comparing the effects of COX-2 inhibitors with nonspecific nonsteroidal anti-inflammatory agents (NSAIDs), they found that the COX-2 inhibitors did not show increased cardiovascular risk over NSAIDs in this population

(*Archives of Internal Medicine* 2005).

“We are working with commercial and Medicaid managed care organizations and their formulary committees to apply pharmacoeconomic tools to information necessary for making coverage decisions,” said Shaya.

Hsu, Simoni-Wastila and Shaya share concerns about the relationships between costs, outcomes, access and efficacy, and they also agree on the importance of keeping people and their health in the outcomes equation.

“I spend much of my time looking at output from our analyses of large databases and sometimes you forget that these are not just numbers, these are real people,” said Simoni-Wastila. “That is what keeps me engaged and interested in the field of health services

research—understanding that real people have serious mental and substance use disorders and that my work may help improve the quality of treatment they receive.”

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