Funding Woes Curb Childhood Vaccination Efforts

BY HEIDI SPLETE Senior Writer

ATLANTA — The current vaccine financing system in the United States continues to derail vaccinations for underinsured children, based on new survey data from state immunization program managers.

"Limitations in 317 funding and state funding are clearly contributing to this gap," said Dr. Grace M. Lee of Harvard University, Cambridge, Mass. "We estimate about 3.9 billion children are unable to receive Menactra in the private sector and 1.1 billion are also unable to receive Menactra in the public sector."

The explosion in the number and cost of vaccines for children and adolescents in recent years prompted the study. In 1985, there were 7 vaccines in the routine childhood and adolescent immunization schedule; in 1995, there were 10; and in 2006, there were 16, said Dr. Lee, who presented results from a study of states' vaccine financing activities at a meeting of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices. "In 1985, it cost \$45 to fully vaccinate a child. In 2006, the estimated cost to vaccinate a female child is about \$1,200."

Many underinsured children must pay out of pocket for vaccines. Alternatively, private providers may refer them to the pub-



More and costlier vaccines are thwarting immunization goals, says Dr. Grace M. Lee.

lic sector for vaccines bought by the state government with 317 funds or through the federally funded Vaccines for Children (VFC) program. But neither of these sources has kept up with the growth in suggested vaccinations.

The Section 317 program is a discretionary federal grant given to each state (plus all U.S. protectorates, territories, and six cities) to be used for vaccines for underinsured children and adolescents who do not meet the criteria for the VFC program or whose parents or guardians can't afford the out-of-pocket costs for full vaccination. Most of the Section 317 funds are used for routine childhood and adolescent vaccinations, although any remaining funds can be used to pay for vaccinations for underinsured adults.

Dr. Lee and her colleagues conducted a two-phase study that included qualitative interviews with 48 state immunization program managers followed by a national survey and interviews with the state managers plus two city immunization program managers. The survey and interview questions asked how and whether the cities and states provided vaccines to underinsured children.

Overall, about 50% of underinsured children

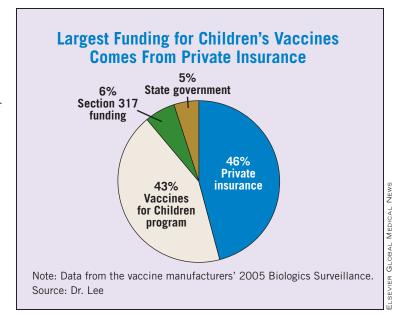
could not be vaccinated in their medical homes unless they could pay out of pocket, according to the survey results. The meningococcal vaccine (Menactra) was the least-covered vaccine. Menactra was not covered by private providers in nearly 70% of states in the study and it was not covered in public clinics in about 40% of the states. The ACIP recently recommended expanding meningococcal vaccination to include all adolescents aged 11-18 years.

The respondents expressed discomfort at having to turn away children who could not afford to pay for new vaccines, Dr. Lee noted. The respondents cited insufficient state funding as a primary barrier to vaccination, and they reported using several strategies to address the lack of funds.

A total of 27 states' managers reported limiting provider vaccine choice, and 25 used annual state appropriations to address financing limitations. A total of 13 managers reported expanding their definitions of federally qualified health care centers (FOHCs) so more underinsured children would be eligible for the VFC program. In addition, 11 managers negotiated state contracts with vaccine manufacturers, 9 decreased their purchases of adult vaccines, and 4 designated annual health plan appropriations.

Of the 13 states that reported expanding FQHC designations, 9 designated some public VFC providers in their states as FQHCs; 3 designated all public VFC providers as FQHCs; and 1 state manager designated all public and private VFC providers as FQHCs. Dr. Lee said she was unable to disclose which states had expanded the FQHCs because interviewees' names were kept confidential.

But the study did not address reimbursement, which remains a hot-button issue for physicians. "A bigger issue is reimbursement. Even if a vaccine is covered, you won't necessarily get paid for all your expenses," said Dr. Jonathan Temte, a family physician at the University of Wisconsin, Madison, and the American Academy of Family Physicians' liaison to ACIP, in a discussion. For more information, visit www.cms. hhs. gov/center/fqhc.asp.



GENOMIC MEDICINE

Redefining the Personal Approach

s a primary care provider, I am skepti-As a primary care provider, "personalized medicine" is new. Every day, we sit down with our patients, listen to their concerns, make diagnoses, and try to tailor treatment to their physical and psychosocial

needs. In short, we personalize medicine. But do we do this as well as we could? Although we rationalize our medication choices to ourselves and our patients, much of how we prescribe medicine relies on trial and error. This is inefficient, and even dangerous in some cases.

Today's vision of personalized medicine, as touted by academia, industry, and others probably could be better described as "genomically

personalized medicine." In many ways, such a vision truly represents a revolution in health care. A central axiom of the movement is "the right drug at the right dose for the right person at the right time." For example, assume you have a patient with a certain diagnosis that can be effec-

BY GREG FEERO,

tively treated with both drug X and drug Y, each of which is toxic if it is not metabolized effectively. Currently, because you have no idea how the patient might respond, you may well choose drug X, say, because it happens to be generic. Now con-

sider the value of knowing a priori, through genetic testing, that your patient can metabolize drug Y, but not drug X. Given the toxicity of the unmetabolized drug X, this knowledge would dictate your choice of drug Y, thereby avoiding causing harm to the patient and saddling him or her with higher costs.

Advances in pharmacogenomics-the science of studying how genetics and genetic variation influence

drug therapy—are rapidly narrowing the gap between vision and reality. Already, specialty medicine is using FDA-approved tests such as the UGT1A1 gene assay, which measures a patient's ability to metabolize the chemotherapeutic irinotecan, to make more rational drug choices.

Primary care won't be far behind. This is perhaps best illustrated by current clinical trials in which researchers are examining whether preemptive genetic testing for the ability to metabolize warfarin improves outcomes in patients requiring oral anticoagulation. Warfarin has frustrated health care providers for many years, largely because of its narrow therapeutic index, high toxicity, and the wide variability in patient response to a given dose. Recent findings have shown that knowledge of variations in two genes (CYP2C9 and VKORC) can help predict a patient's metabolism of warfarin, which can effectively guide selection of the starting dose.

Genetic testing technology has advanced so that it now is feasible to conduct a point-of-care analysis of the genes affecting an individual's metabolism. Many have suggested that such testing could greatly reduce the burden of suffering associated with warfarin use, as well creating health care cost savings. Others have been less sanguine, given the cost of introducing this technology into mainstream health care.

In ongoing trials, researchers are examining whether the incorporation of genetic test results into warfarin management protocols enhances outcomes. The results from these trials will likely be out before the year's end. Other clinical trials are looking at whether genetic testing that predicts selective serotonin reuptake inhibitor metabolism improves clinical outcomes.

The use of genetic information to predict how patients will metabolize drugs that currently are available is but one facet of personalized medicine. Over a longer time frame, primary care providers will likely be able to use at least a few drugs that target the molecular consequences of a patient's disease-causing gene variants

Fantasy? No—this already is true for the choice of Herceptin in breast cancer therapy. An increasingly sophisticated form of personalized medicine is here to stay.

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