New Pediatric Vaccines Add Up to Costly Burden

BY BETSY BATES
Los Angeles Bureau

HONOLULU — A complex regimen of 21 vaccines added to the routine child immunization schedule since 2000 has left many health care providers shaking their heads.

Dr. Andrew D. Racine took his frustration one step further, and took out his calculator.

By his calculations, administration of the new vaccines recommended for pediatric patients from infancy through adolescence by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians has added up to 17.8 weeks of salary for a full-time nurse in a busy practice, as well an up-front inventory cost of $100,000-$200,000.

"The instigation for this [study] was just looking at our nursing staff," said Dr. Racine following the oral presentation of his results at the annual meeting of the Pediatric Academic Societies.

"They were going crazy."

Dr. Racine, chief of clinical pediatrics at Albert Einstein College of Medicine, New York, noted that 10 childhood vaccines were recommended in 1983. That number now stands at a mean 27 vaccines per healthy child, depending on their gender and risk profiles.

Added to the schedule since 2000 are pneumococcal 7-valent conjugate vaccine (PCV7) at 2, 4, 6, and 12 months; influenza vaccine at 6 and 7 months, then annually to all patients up to 5 years and to 50% of 6- to 21-year-olds; meningococcal polysaccharide conjugate (MCV4) vaccine and tetanus/diphtheria toxoid/acellular pertussis (Tdap) vaccine at 11 years; hepatitis A vaccine at 18 and 24 months; rotavirus vaccine at 2, 4, and 6 months; 3 human papillomavirus (HPV) vaccines to girls at 11 years; and a second varicella vaccine at 5 years.

To find out how much staff time was needed to administer these added inoculations, Dr. Racine conducted an observational time-flow analysis of nurses in a busy urban academic practice as they simulated the tasks required to deliver one childhood inoculation.

He then multiplied the mean time to deliver a shot by the number of vaccines required per one pediatric patient over the course of childhood and calculated the total time cost to practices of various sizes.

The study was designed to be widely applicable to many types of practices: large or small, private or academic, staffed by experienced or relatively inexperienced nurses.

Tasks in the simulation included checking the chart for a vaccine order, obtaining the vaccine from storage and drawing up the medication, accessing the examination room, counseling parents, administering the shot and, finally, recording the immunization on the child's personal immunization card and on the chart.

The analysis used conservative assumptions, Dr. Racine noted.

Even so, the time added up to a substantial burden, even for a small panel of 1,000 patients, he reported.

"We've got anywhere from about 4.5 weeks of nursing time for a small panel that gave shots quickly to almost 18 weeks for a full-time equivalent nurse just to give these vaccines to a large panel of patients," said Dr. Racine. (See box.)

The potential implications of the study are profound, he added.

"We think this incremental cost [in terms of nursing time and up-front outlays for vaccine stock] presents significant challenges for the pediatric community and to the public policy goal articulated in Healthy People 2010 of increasing the proportion of all children and adolescents who receive all of their recommended vaccines," he said. ■

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"The instigation for this study was just looking at our nursing staff. ... They were going crazy," said Dr. Andrew D. Racine, chief of clinical pediatrics at Albert Einstein College of Medicine. He is shown here with just some of the required vaccines.

Full-Time Nurse Equivalent Time per Year to Administer New Vaccines Added to Schedule Since 2000

Patients	Additional vaccines	5 minutes/ vaccine	10 minutes/ vaccine
1,000	1,999 doses	4.5 weeks	9 weeks
1,200	2,399 doses	5.3 weeks	10.6 weeks
1,500	2,999 doses	6.7 weeks	13.4 weeks
2,000	3,998 doses	8.9 weeks	17.8 weeks

Source: Dr. Racine

ELSEVIER GLOBAL MEDICAL NEWS

GENOMIC MEDICINE

Keep an Eye on Direct-to-Consumer Testing

In the last 3 years, the advent of genome-wide association studies (GWAS) has facilitated the discovery of more than 180 markers for risk of a growing list of common chronic diseases, such as cancers, diabetes, coronary heart disease, and Alzheimer's.

A number of companies have moved to make these markers available to consumers through genome-wide scans that can be obtained over the Internet at a cost of $1,000-$2,500. The companies emphasize that all results from these scans are preliminary and that their products represent information, rather than medical advice. However, if one takes a look at some of these sites, one could conclude that the companies—implicitly or explicitly—are suggesting to consumers that they might be able to use the results to improve their health.

BY GREG FEERO, M.D., PH.D.

No direct evidence shows that providing patients with genetic risk information improves health outcomes, though this likely will change in the next few years. Yet patients already are taking their results to health care providers with the expectation that some form of clinical action or intervention will follow based on the results.

Though direct-to-consumer (DTC) testing for more traditional genetic conditions, such as hereditary colon cancer syndromes or factor V Leiden deficiency, has been around for some time, the sophistication, scale, and potential reach of this new crop of scans has piqued the interest of state and federal regulatory bodies. And, not unexpectedly, they have also been subject to intense criticism from the scientific and medical communities.

Among those voicing concerns, the central message is that the health care implications of this embryonic realm of genetic testing is unknown at this time, and that over-, under- or misinterpretation of the results could be harmful.

The debate has grown intense. The state of California sent cease-and-desist letters to 13 providers of DTC genetic services to California residents. At the federal level, there is ongoing congressional scrutiny of the topic. On June 12, Sen. Gordon H. Smith (R-Ore.) of the U.S. Senate Special Committee on Aging held a roundtable discussion with researchers as well as representatives of regulatory and policy bodies and the biopharmaceutical industry to discuss scientific, regulatory, and ethical issues pertaining to genetic testing. On July 7-8, the Secretary's Advisory Committee on Genetics, Health, and Society, which advises the Department of Health and Human Services on issues relating to the development of genetic technologies, also examined DTC services in some depth. From the proceedings, it was clear that opinions about the availability of genome-wide scans vary greatly.

This scrutiny has brought an unexpected windfall to those in primary care. Individuals from the most technology-driven reaches of medicine are discussing the need for increased research on determinants of health behaviors and a reevaluation of how our system values preventive interventions.

The core questions are not new to medicine: First, when is a new technology ready for clinical use; and second, how much regulation is appropriate to ensure its safe and effective application while fostering innovation and minimizing the risk of disparities?

One side of this debate argues that consumers should be empowered with every possible bit of information about their health and that to deny them direct access to their genetic make-up through overly strict regulation is dated and paternalistic. The other side argues that this type of genome-wide scanning is still a research tool and that to offer it in a loosely regulated manner might substantially mislead the public and health care providers and incur costs in terms of morbidity and inadequate health care resources. Both sides have valid points.

The American Medical Association and the American College of Medical Genetics have developed official positions that are critical of DTC genetic testing. Much hinges on consumer demand and opinion—and, to some extent, the ability to shape that demand rests in the hands of health care providers. ■

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