

# Physician Autonomy, Patient Choice, and Immunization Performance Measures

The immunization of children against an assortment of infectious diseases is clearly one of the most exciting medical success stories of the 20th century. Never before has scientific knowledge been translated so quickly into tangible benefit. As a result of almost universal agreement among physicians about the importance of compliance with immunization, immunization rates within health care systems have become a classic performance measure in population-based pediatric health care.

Nevertheless, even this simplest of performance measures may elicit controversy and subtly but measurably influence the practice of medicine. Because physicians have a predictably wide range of beliefs about such variables as the optimum age at which various vaccinations should be given, the relative importance of herd immunity, and the ethical value of shared decision making with families, it is not surprising that physicians may question the merit of using immunization rates as performance measures, particularly when newer and sometimes controversial immunizations are included in those rates.

In the early 1990s, the Health Plan Employer Data and Information Set (HEDIS) was established to give employers a way to compare prospective health care insurers. Developed by a collaborative group of major employers and health plans, HEDIS has been used increasingly by employers as an aid in the selection of health care insurance offerings for employees.<sup>1</sup> The National Committee for Quality Assurance (NCQA) recently became the custodian of HEDIS measurement development and health care system data.

As new childhood immunizations have been introduced and as rates of these immunizations have been sequentially incorporated into HEDIS measures, we have gained insight into the evolving influence of performance measures on the behind-closed-doors world of medical practice. This is the story of three newly recommended immunizations (Table 1) and of three fictitious physicians who administer the immunizations in an imperfectly measured health care world.

## Hepatitis B Vaccine: James Hansen, MD

In 1991, the Advisory Committee on Immunization Practices published its recommendation that all newborns be immunized against hepatitis B.<sup>2</sup> Sitting at his office desk over lunch, Dr. James Hansen viewed the published recommendation with curiosity. He was a fanatical supporter of childhood immunizations and had seen the ravages of hepatitis B in a physician colleague who had acquired the disease during a surgical procedure. Acutely aware that his own risk for occupational exposure would probably exceed any unknown or future problems that might result from the vaccination, Dr. Hansen had been one of the first physicians in his community to receive the hepatitis B vaccine some 10 years earlier.

Dr. Hansen also took pride in being a student of public health issues. Having seen (in his West Coast training program) the high incidence of hepatitis B among

See related editorial on pages 284–286 and the primer on pages 287–288.

*This paper is available at [ecp.acponline.org](http://ecp.acponline.org).*

TABLE 1

**Summary of Newer Early Childhood Immunizations**

TYPE OF VACCINE (YEAR OF INTRODUCTION)	DESCRIPTION	RECOMMENDED DOSING SCHEDULE	NATURAL HISTORY OF TARGET DISEASE	EFFECTIVENESS OF IMMUNIZATION	SIDE EFFECTS
Hepatitis B (1989)	Recombinant injection	0, 1 to 2, and 6 to 18 months	90% resolve 1 in 10 new carrier 1 in 100 fatal	Near 100%	Site irritations and malaise; other side effects are rare
Varicella (1995)	Live virus injection	One dose at 1 year	95% self-limited 1 in 500 hospitalized 1 in 50,000 fatal	70% to 95%	Pox-like rash, fever, and later zoster infection
Rotavirus (1998)	Live virus oral vaccine	2, 4, and 6 months	95% self-limited 1 in 80 hospitalized 1 in 100,000 fatal	70% to 80%	Fever, fus- siness, and diarrhea

Asian immigrants and having been disillusioned by the juxtaposition of American affluence and immigrant poverty in his community, his initial reaction to the new recommendation for immunization against hepatitis B for all newborns in the United States was predictable. “Great idea, wrong country,” he thought to himself. Nevertheless, he began recommending the series of injections, a faithful foot soldier in the war against childhood illness.

Dr. Hansen’s patients, however, sometimes assessed the known and unknown risks differently.

“This vaccination is new, at least new in its more broadly recommended distribution,” the father of a tiny infant would reason.

“This is our newborn baby, and we would hesitate at even the smallest risk, known or unknown, until the vaccine has been more widely used,” the mother might add.

“And you indicated that this is really a disease of young adults, and that vaccination at age 10 or 12 would be almost equally effective in preventing the disease,” the father rejoined.

Dr. Hansen might have countered that when population-based immunization penetration is considered, infants more reliably return for multiple scheduled visits and that completing a series of three shots in pre-teenagers would be problematic. But when assured by the parents that at some later date—when other children had received a few million doses of the vaccine without complications—they would guarantee compliance with completion of the series, Dr. Hansen couldn’t argue from the viewpoints of either public health or individual risk.<sup>3,4</sup>

Over the next 2 years, however, health care delivery systems began requiring Dr. Hansen’s office to provide data on immunization rates for all recommended childhood immunizations. From an audit of records,

Dr. Hansen’s success rate for completion of the hepatitis B series was 60%. This rate was better than those of some but significantly lower than those of other colleagues in the pool of comparison. He redirected the auditors to his meticulous documentation: “Hepatitis B vaccination offered and discussed but declined,” his note might read.

“Not good enough—the audit measures completion of the series only,” he would hear in response.

His knowledge of public health notwithstanding, he reluctantly changed his approach. Unless asked, he would no longer discuss the disease as a threat to young adults. He would imply by his brevity that the immunization is commonplace and that it would prevent illness in children of all ages. He favored all childhood immunizations, but being forced to accept imperfect measures of his practice performance demanded a bastardization of his public health knowledge. He realized that childhood immunization had taken on a new morbidity: The child’s physician would have to bite his tongue.

### Varicella Vaccine: Paula Bradley, MD

Dr. Paula Bradley sat at the table of the “new technology committee” as a guest invited to discuss the newest pediatric immunization: the varicella or “chicken pox” injection. Trained in pediatric infectious disease, Dr. Bradley was uniquely qualified to advise her 80-member multispecialty group about the pros and cons of the newly available immunization.

Dr. Bradley’s philosophy in medical practice tended toward the conservative. Her knowledge of new antibiotics was encyclopedic, but she more often prescribed older, inexpensive medications with known rather than unknown side effects, saving the newest, expensive antibiotics for her sickest patients. This

approach was valued highly in an era of utilization management, and she was single-handedly responsible for holding in check the group's increasing prescription antibiotic costs. She also held a seat on the group's medical ethics committee where, despite her extensive training in evidence-based medicine, she consistently defended the patient's right to informed choice in accepting or rejecting a physician's advice.

Dr. Bradley presented to the committee a detailed review of the new recommendation, which stated that physicians should begin to offer varicella immunizations to all children at the age of 1 year.<sup>5</sup>

"To summarize," she concluded, "the immunization preparation seems to be very safe. It is, however, a live virus injection with some potential for future effects not yet identified." Earlier, she had outlined assorted concerns about the new immunization, including the possibility of waning immunity and infection in adulthood or increased rates of subsequent zoster eruption.<sup>6</sup>

"The immunization may cause a pox-like rash from which live virus can be recovered in a small portion of cases, and there is the remote possibility that secondary transmission could adversely affect another family member or contact. In the absence of childhood immunization," she continued, "the disease is without serious morbidity in the vast majority of cases, but there are nevertheless occasional cases with serious or even fatal outcomes."

With Dr. Bradley's assistance, the committee voted to recommend adding the varicella injection at 1 year of age to the panel of routine childhood immunizations. Dr. Bradley designed a detailed informed consent form, and the physicians implemented a model program of shared decision making with parents.

The group's computerized immunization database monitored the slowly increasing penetration of the varicella immunization. Initially, only 10% to 20% of families accepted the injection, but as the immunization gained increasing attention in the medical literature and at local medical education seminars, physicians and families demonstrated slowly increasing acceptance.

After 18 months of experience with the shared decision-making model, the medical group's quality assurance committee requested that Dr. Bradley attend an urgent meeting.

"We have been asked to address our significant shortcomings on immunization compliance, as measured by the HEDIS requirements," the committee chair began. "In the measure of complete immunization at the age of 2 years, only 41% of children enrolled as our patients have achieved this goal."

"I can explain," Dr. Bradley answered, in a reassuring tone. "Our immunization rates for all of the previous-

ly established vaccines are well over 90%. We are currently immunizing 46% of children with the newer varicella injection at age 1, using the shared decision-making model that the medical group approved early last year."

"I'm afraid you don't understand, Dr. Bradley," responded the chairman. "This HEDIS measure doesn't care how well we perform on a single injection, only on the rate of complete age-appropriate immunization, including varicella immunization!" Regardless of how efficient the medical group had become at recalling children who missed shots, sending for outside records to confirm completeness, and even encouraging physicians to immunize children who had concurrent minor illnesses, their measured rate of compliance would hinge on their choice not to accept varicella immunization with open arms.

Dr. Bradley grudgingly began to push compliance with the varicella immunization. Within a week, the detailed consent form had been removed from every examination room and had been replaced by a shorter, perhaps even biased form emphasizing the merits of immunization and making minimal reference to possible risks. The importance of achieving a HEDIS measure that more accurately reflected the group's exemplary performance in administering other immunizations was emphasized to physicians, who sometimes found themselves retracting their own previously spoken words of hesitation about the varicella immunization.

Dr. Bradley, reading a newsletter published by a vaccination resistance group with whom she vehemently disagreed, couldn't help but recognize the irony as she read a sentence she had previously interpreted as extremist: "Without being provided with accurate and complete information about disease and vaccine risks, citizens cannot exercise informed consent, which becomes a human right when an individual considers undergoing a medical procedure that could cause injury or death."<sup>7</sup>

The group's varicella immunization rate began to increase more steeply; physicians invented language designed to redirect families who had previously declined the varicella injection. Months later, Dr. Paula Bradley, for reasons known only to herself, elected to resign from the ethics committee.

### **Rotavirus Vaccine: Fred Taylor, MD**

The medical director stood at the podium, addressing the combined departments of pediatrics and family practice physician shareholders in a 500-physician staff-model HMO. Trained as a pediatrician, Dr. Fred Taylor had earned the first half of his gray hair caring for the sickest of children in the hospital inpatient setting; the

remaining silver-gray locks had resulted from his now long-held position of administrative responsibility. After his update on organizational finances, he concluded his remarks, surprisingly, with his newly held opinions about the latest of pediatric immunizations, the recently released rotavirus oral immunization.<sup>8</sup>

“You may already be familiar with this oral preparation, designed to prevent the most common form of dehydrating viral diarrhea in infants and toddlers. The board has discussed the significant costs of adding this immunization to those currently administered.

“Quite frankly, the board finds the literature concerning the cost–benefit ratio of this immunization to be unconvincing,” he continued.<sup>9</sup> “We feel that in our current patient population, the cumulative costs of rotavirus immunization will easily exceed the potential savings in prevention of dehydration, hospital admission, and intravenous fluid administration. We on the board of directors view ourselves as stewards of our members’ health care dollars, and in a world of limited resources, it is difficult to justify this kind of expense when other technical advances will as a result go unfunded.

“Nevertheless,” Dr. Taylor continued, “you already know that the board has always supported quality in medical care delivery and has particularly supported disease prevention through immunization in both children and adults. You may not realize, however, that as we meet with employers who are considering offering our health plan to their employees, our compliance with HEDIS measures can make or break our ability to demonstrate our commitment to quality. Now, rotavirus immunization is not yet included in these HEDIS measures, but the board has every expectation that it will be viewed as routine and expected in the near future.

“Therefore, please,” he pleaded, “in return for our investment of these precious health care dollars, I ask only this: If you as an individual physician have any hesitation about giving this immunization to your patients, I suggest you get over it now rather than 2 years from now. We are known for our preventive medicine expertise, and I am not interested in having a poor rate of immunization against rotavirus undermine our exemplary immunization efforts in other areas.”

The attendees filed out slowly, returning to a dozen neighborhood medical offices. The debate was over before it had started. The medical director wasn’t interested in the individual physician’s opinion about this well-intended but perhaps overly expensive public health decision. When parents questioned the need for this new oral immunization, the physicians had been coached ahead of time. “It’s new, but it is routine,” one would reply. “We expect it to prevent many hospitalizations,” another might exaggerate. And an imperfect means of

measuring performance would, once again, erode the sacred trust between patients and their physicians.

### Problems with Performance Measures

The physicians described above are composite representations of real doctors who face real dilemmas in their approach to the practice of medicine. In these examples, the simplicity of an immunization rate as a performance measure contributes to the perceived validity of that measure. The shortcomings of this measurement tool can clearly interfere with physician autonomy and patient choice; in other words, the simplified immunization-rate measure currently in use falls short of the desired blend of immunization penetration and respect for the judgment of families and physicians in three distinct areas.

First, in their current form, complete age-appropriate immunization rates overvalue the most recently added immunization recommendations. Predictably, parents and physicians alike will only gradually accept any new and lesser-known intervention. Any meaningful comparison of penetration rates for older vaccines will be overshadowed by the rate of a single newer immunization, and current methods of comparisons will encourage rapid deployment rather than long-term commitment. Couldn’t the rates for individual immunizations be measured separately to avoid overemphasizing the newest immunizations?<sup>10</sup>

Second, physicians practice in diverse environments, and the extent to which patients feel empowered to question their physician’s advice varies. Providing information and educating families rather than withholding information is a respected attribute of physician excellence. Even when a physician feels strongly that immunization is desirable and warranted, our society nevertheless emphasizes that patients or families should have an informed choice in accepting or rejecting the physician’s recommendation and that the physician should respect even those choices with which he or she does not agree. Wouldn’t it be possible to honor a patient’s autonomy by giving credit to physicians who offer or recommend an immunization but subsequently respect the family’s wish to decline?

Third, most physicians recognize that a conservative, hesitant approach to the implementation of new recommendations is not always detrimental but instead can be a balancing influence on those persons eager to implement the latest technology despite potential unknown risks or limited justification of high costs. An acknowledgment of this widely held belief leads logically to an open, respectful discussion with patients about newer interventions and their known, potential, or

unknown risks—the hallmark of shared decision making in medicine. Yet the inclusion of each newly recommended immunization in oversimplified performance measures no longer allows the conservative physician's voice to receive equal weight. Are we ready to concede that, at least in the area of childhood vaccination, the shared decision-making model is no longer acceptable?

*Postscript:* A final example looms on the immunization horizon and may be a graphic illustration of the dilemmas physicians will continue to face. An immunization to prevent Lyme disease in humans was recently approved by the U.S. Food and Drug Administration.<sup>11</sup> The frequency of Lyme disease in children and adults is far less than that of measles or varicella before widespread vaccination. Furthermore, Lyme disease is probably significantly overdiagnosed, and even patients with proven infection may have little subsequent morbidity. Finally, Lyme disease is geographically clustered: Many states almost never report it in humans. Nevertheless, physicians may soon be faced with a new recommendation that this immunization join the ranks of performance measure requirements. Someday, I might very well face a unique challenge as I enter the introspective debate of how much to disclose or withhold from families about the new immunization—an injection that I have, to date, refused to administer to my dog.

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## Note added in proof:

In the preceding article, the author cautions against overemphasizing newer immunizations in current measures of vaccination compliance. Interestingly, since the manuscript's acceptance in June 1999, two of the three vaccines discussed have met with controversy.

In clinical trials prior to widespread release, the rotavirus vaccine was noted to have a possible association with increased intussusception rates, although the difference between vaccine and placebo groups was not considered statistically significant. Subsequent monitoring has revealed that intussusception is a real and significant risk of the vaccine—it occurs in as many as 1 in 5000 recipients during the week after the first dose. Use of the vaccine has been suspended, and after a multistate case-control study by the Centers for Disease Control and Prevention, the pre-

vious recommendation for use of the vaccine has been withdrawn.

Similarly, recommendations for immunization against hepatitis B have recently been modified. A review by the Food and Drug Administration revealed that the addition of this series of shots to the existing schedule for infants created a new potential risk. The hepatitis B immunization, like several others administered to infants, contains the preservative thimerosal, a derivative of ethyl mercury. Although no adverse effects have been documented, the newly recommended schedule of vaccinations has resulted in a potential mercury exposure that exceeds the guidelines published by the Environmental Protection Agency. Until thimerosal-free preparations of these vaccines are widely available, a revised schedule with delayed vaccination for hepatitis B has been proposed.