

SUPPLEMENT TO

M A N A G E D

Care

Improving Quality by Encouraging Providers To Use Pediatric Combination Vaccines

HIGHLIGHTS

- Use of combination vaccines to improve immunization coverage rates and timeliness of administration

- National recommendations from the Centers for Disease Control and Prevention on combination vaccines

- Potential effects of combination vaccines on quality and cost

- Barriers to broader use of combination vaccines

- Managed care strategies to improve utilization of combination vaccines

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INTRODUCTORY MESSAGE

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DAVID B. NASH, MD, MBA

Doing the Right Thing

It is not every day in the health care business where an investment of \$1 results in savings of more than \$18. We now have good evidence to support widespread pediatric vaccinations — especially combination vaccines — to achieve such cost saving. Goldfarb and colleagues have analyzed the promotion of pediatric combination vaccines in a managed care setting and have given us a road map to improve our current performance.

First, evidence of their cost effectiveness makes the combination vaccination of pediatric patients a policy imperative. National organizations have established appropriate evidence-based guidelines and reimbursement policies.

What's needed is a managed care commitment to improve coverage rates by harnessing the tools of quality measurement and improvement. For example, managed care organizations should undertake a review of current immunization data for their covered populations; they should identify any administrative and financial barriers to combination vaccines; they should review the immunization cost experience to justify the promotion of combination vaccines; they should disseminate educational materials and combination vaccine guidelines to both providers and patients; and they should strive to eliminate any financial barriers that providers may face.

Goldfarb and colleagues have also demonstrated that what is essential is leadership and political will among all stakeholders to significantly increase the number of pediatric patients receiving appropriate and timely combination vaccines.

What of the future? The challenge of vaccinating children from low-income families will remain. We must redouble our efforts in vaccinating pediatric patients at risk and collectively commit ourselves to doing the right thing for all our patients, regardless of age. After reading this analysis, I am confident that our readers will have an increased understanding of these challenges as they begin to participate in the work that lies ahead.

Improving Quality by Encouraging Providers To Use Pediatric Combination Vaccines

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ABSTRACT

In the last 4 decades, the number of diseases that vaccines can prevent has quadrupled, and, correspondingly, so has the number of immunizations that is to be administered before a child's second birthday. Based on current recommendations, a child may receive as many as six vaccine injections in a single visit. Vaccine technology has advanced significantly since the introduction of the first combination vaccine, diphtheria-tetanus (DT), in the 1950s. In the United States today, as many as five antigens can be administered in a single injection, and additional combination vaccines are in the pipeline. Increasing the number of antigens delivered with a single injection minimizes physical discomfort for the child, reduces associated stress for the parent, saves time for the provider, and is likely to improve vaccine coverage and timeliness of administration rates. While national immunization guidelines from the Centers for Disease Control and Prevention call for use of combination vaccines where available, provider and parent perceptions can act as barriers to their optimal use. Managed care organizations (MCOs) have the opportunity to improve quality of care and immunization rates by educating providers on the use of combination vaccines in accordance with the national guidelines. This article examines the evidence for pediatric combination vaccines, discusses barriers to their use among parents and providers, presents quality and cost implications of a managed care policy to broaden their use, and suggests ways in which MCOs can more actively promote appropriate use of combination vaccines by providers.

Key terms: combination vaccines, cost-effectiveness, immunizations, managed care, multivalent vaccines, pediatric, quality

INTRODUCTION

Current national guidelines for childhood immunizations include requirements for 22 injections (including optional hepatitis A and influenza vaccines) in the first 2 years of life (CDC 2004a), with as many as six

injections in a single visit. Since the 1950s, diphtheria-tetanus (DT) combination vaccines have become increasingly available (Parkman 1995). Despite the broad availability of multivalent vaccines today and the national recommendations from the Centers for Disease Control and Prevention (CDC) stating preference for combination vaccines over single-antigen vaccines, immunization statistics suggest that use of combination vaccines has not been optimized in the United States.

Although public and private health plans throughout the U.S. health care system cover the newer combination vaccines, the potential effects of these agents on cost and quality have yet to be fully recognized. Managed care organizations (MCOs) that proactively decide how to incorporate combination vaccines into standard practices and protocols are most likely to realize the full range of quality benefits from these new agents.

As with the assessment and diffusion of other new medical technologies, MCOs need to make benefit coverage decisions based on cost and quality criteria, establish appropriate care guidelines and reimbursement policies, and develop quality and utilization management activities as needed — including the implementation of strategies to overcome barriers to acceptance and adherence to guidelines by health plan providers and parents.

This article examines the role of pediatric combination vaccines in improving immunization coverage and timeliness rates, barriers to their broader usage, the quality and cost implications of a managed care policy to further their use, and strategies that health plans can implement to increase utilization of these vaccines.

This policy analysis is based on a review of published literature, including these search terms: combination vaccines, pediatric immunization, managed care, and reimbursement. Additionally, these terms were used in an Internet search for relevant information.

Childhood immunization: the current situation

Burden of preventable disease. Historical experience shows that the best way to reduce the incidence of preventable disease is to have a highly immune population.

Universal vaccination has become well recognized as a critical indicator of quality health care. Achieving 100 percent childhood immunization is by no means easy; in the United States, for example, this means immunizing 4 million children annually against 11 preventable diseases before the age of 2 — approximately 11,000 infants per day (Mell 2005). Nationwide, nearly 25 percent of these children have not received all the recommended vaccine doses by the age of 2 (ASTHO 2004), and the U.S. childhood immunization rate was estimated at 80 percent in 2003 (HHS 2004). Data from the Health Plan Employer Data and Information Set (HEDIS) for 2003 (Figure 1) show a wide range in immunization rates by state, which suggests room for improvement.

Childhood immunization rates have risen steadily across the country in the last decade, although the minority of children and young adults who have not been immunized — or whose immunizations are incomplete — represents a significant public health concern. The inadequacy of immunizations among children has been cited as one reason for the increasing cases of pediatric pertussis since the 1980s (CDC 2002).

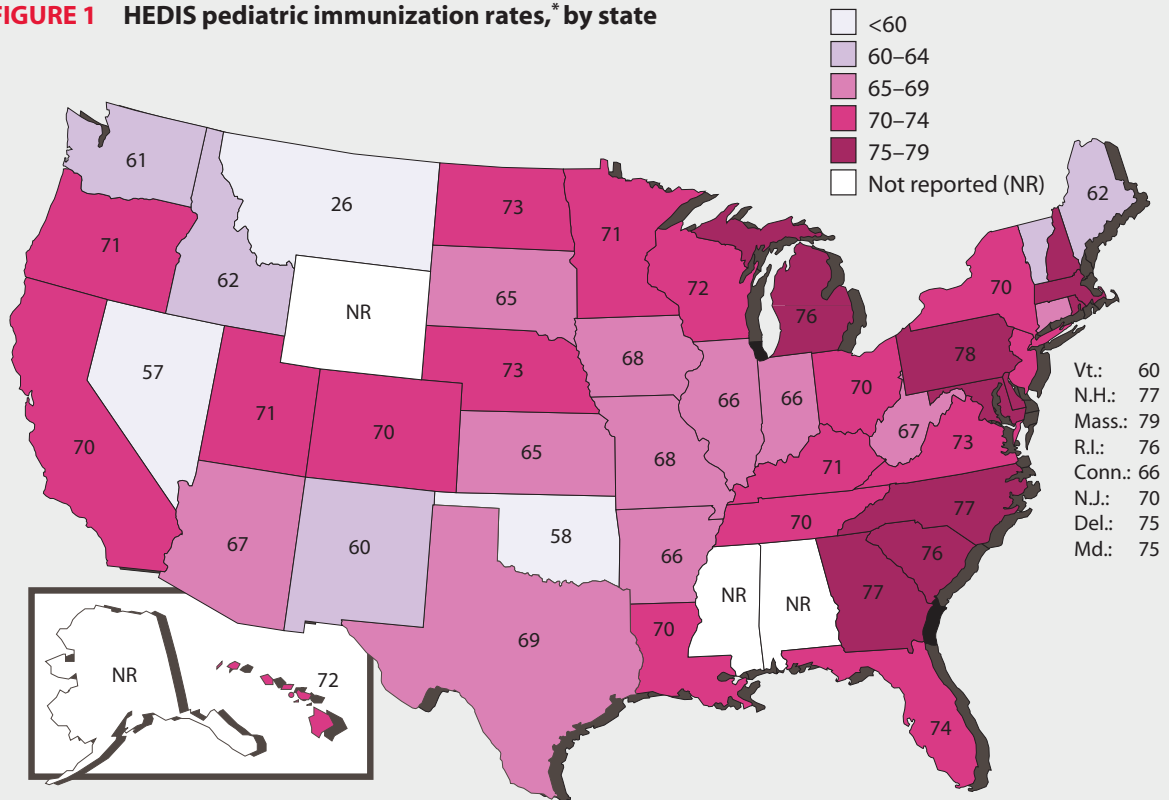
Burden of multiple injections. In the 1960s, routine childhood immunizations consisted of vaccinations

against 5 preventable diseases — diphtheria, tetanus, pertussis, polio, and smallpox — necessitating a total of eight injections by the age of 2 (Humiston 2003). Today, “routine” translates into vaccinations against 11 preventable diseases, with as many as 22 injections by the age of 2 (including hepatitis A and influenza vaccines, which are given as necessary) (Dodd 2003). Combination vaccines, some currently available and others in the pipeline, provide the means for reducing the burden of multiple injections. Table 1 shows the pediatric combination vaccines that are currently available or under development.

Logistical issues. Ensuring that all children are fully immunized against preventable diseases in a timely manner is a difficult assignment for parents, health care providers, and health plans alike. Recordkeeping and the tracking of children’s vaccination histories are significant challenges, particularly in poor urban populations — where parents migrate with greater frequency among providers and health plans — and in rural areas that have sophisticated computer systems.

Two studies illustrate these problems. In the first, investigators examined the correlation between parental recall of their child’s immunizations and documentation of immunizations in providers’ records. They found that

FIGURE 1 HEDIS pediatric immunization rates,* by state



*Pediatric immunization rate defined as percentage of health plan members immunized fully by second birthday.

SOURCE: NCQA 2004a

TABLE 1 Pediatric combination vaccines currently licensed or under development*

Combination vaccine [†]	Licensed in U.S.	Licensed outside U.S.	Under development [‡]
Td-IPV		AvP-Fr, AvP-Ca, AP MSD	
DT-IPV		AvP-Ca	
DT-HepB		AvP-Fr	
DTP-IPV		AvP-Ca, AvP-Fr	
DTP-Hib	AvP-US, WL	AvP-Ca, AvP-Fr, GSK, WL	
DTP-Hib-IPV		AvP-Ca, AvP-Fr, AP MSD	
DTP-HepB		GSK	
DTP-Hib-HepB		GSK	
DTaP-IPV		AvP-Ca, AP MSD, NAVA, GSK	
DTaP-Hib	AvP-US [§]	AvP-Fr, GSK	
DTaP-IPV-Hib		AvP-Ca, AP MSD, GSK	
DTaP-HepB		GSK	
DTaP-HepB-IPV	GSK	GSK	
DTaP-Hib-HepB			Yes
DTaP-Hib-IPV-HepB		AP MSD, GSK	
DTaP-Hib-IPV-HepB-HepA			Yes
HepB-Hib	Merck	AP MSD	
HepB-HepA	GSK	GSK	
MMR-V			Yes
PnC-MnC			Yes
PnC-MnC-Hib			Yes

aP=cellular pertussis vaccine; AvP=Aventis Pasteur (Ca, Fr, US, and AP MSD designate, respectively, vaccines sourced from the Canadian, French, and U.S. subsidiaries or the AvP-Merck European joint venture); D=diphtheria toxoid vaccine; GSK=GlaxoSmithKline; HepA= hepatitis A virus vaccine; HepB=hepatitis B virus vaccine; Hib=*Haemophilus influenzae* type b conjugate vaccine; IPV=enhanced inactivated trivalent poliovirus vaccine; MMR-V=measles, mumps, rubella, and varicella vaccine; MnC=meningococcal conjugate vaccine; MSD=Merck Sharp and Dohme; NAVA=North American vaccine; OPV=oral polio vaccine; P=whole-cell pertussis vaccine; PnC=pneumococcal conjugate vaccine; T,Td=tetanus toxoid vaccine; WL=Wyeth Lederle Vaccines and Pediatrics.

*Products combining only multiple serotypes of a single pathogen are excluded, as are DT, DTP, DTaP, OPV, IPV, and MMR. Only manufacturers that distribute products globally are listed; other manufacturers may produce some products (e.g., DTP-IPV) for local and regional use. Some products represent components derived from, or joint efforts of, more than one manufacturer; in such cases, the principal distributor is shown.

[†]No discrimination is made between products distributed in combined form and those distributed in separate containers for combination at time of use.

[‡]Indicated vaccines may be under development by more than one company.

[§]Licensed for the fourth (booster) dose only.

SOURCE: ADAPTED WITH PERMISSION FROM SEWELL 2001

42 percent of parents underestimated and 24 percent overestimated the number of diphtheria, tetanus, and pertussis (DTP) injections a child had received (Suarez 1997). In the second study, Askew (1995) demonstrated that 40 percent of immunization data were inconsistent when the patient's medical record was compared with computer-order entries.

Timeliness of immunizations. Vaccination providers are encouraged to administer vaccines as close to the recommended intervals as possible. Every visit to a physician or other health care provider is an opportunity to

update a patient's immunization status with needed vaccinations (Lieu 1996). Failure to immunize or to immunize in a timely fashion are associated with both an increased risk of the preventable disease and an increased cost for treating the preventable disease.

Experimental evidence and extensive clinical experience have strengthened the scientific basis for simultaneous administration of all vaccines for which a child is eligible. Simultaneous administration increases the probability that a child will be immunized fully at the appropriate age (King 1994).

In 2003, 11,647 cases of pertussis were reported in the United States, with the highest incidence seen in infants younger than 6 months (CDC 2004b). At least 44 percent of the infants who had contracted pertussis during the 1990s were undervaccinated (Vitek 2003), and all were too young to have received a full series of pertussis vaccine. Researchers postulate that the infants may have experienced indirect protection from transmission of pertussis through the ensuring of their sibling's timely vaccinations (Izurieta 1996).^{*} In addition, the risk of hospitalization due to pertussis was found to be lower for infants immunized with 1 or 2 doses of the DTaP[†] vaccine (Tanaka 2003). These data underscore the importance of timely administration of vaccines.

In 2004, the CDC reported an increase in the number of pertussis cases compared with the previous year. Historically, the inability to vaccinate within the suggested time period has contributed to a rising number of pertussis cases (Kenyon 1996). A study evaluating compliance with national immunization guidelines ascertained that only 11 percent of the children received their fourth DTP/DTaP vaccine dose prior to completion of the minimal acceptable interval between doses (Mell 2005). On further investigation, it was determined that late administration of the third DTP/DTaP dose was responsible for the short interval (less than 6 months) between the two doses. This suggests that timeliness in administering vaccines may have an effect on full immunization coverage rates as well.

A study published in *JAMA* investigated the extent of delay of vaccination within the first 2 years of life (Luman 2005). The authors reported that of the 74 percent of children who experienced delays in receiving at least one vaccination, 52 percent were undervaccinated for longer than 6 months. Looking at DTP/DTaP rates, 16 percent and 14 percent were undervaccinated for more than 6 months and 3 months, respectively. Another study conducted during a measles outbreak demonstrated that approximately one third of measles cases among unvaccinated but vaccine-eligible preschool children could have been prevented if measles-mumps-rubella vaccine (MMR) had been administered during a visit at which another vaccine was administered (Atkinson 1992).

Coverage of immunizations. Traditionally, immunization coverage was considered complete if a child received all recommended doses by the second birthday, regardless of timing of the individual doses. Clinical studies have reported that the recommended ages and intervals between doses of multidose antigens provide optimal

^{*}Because pertussis vaccine is generally not administered after the age of 4, young adults who no longer have immunity also contribute to the increased incidence of pertussis.

[†]DTaP is a safer version of the vaccine that used to be called DTP. DTP is no longer used in the United States. For more information, see «<http://www.cdc.gov/nip/publications/VIS/vis-dtp.pdf>».

protection or have the best evidence of efficacy. Although longer-than-recommended intervals between doses do not reduce final antibody concentrations, full protection might not be attained until the recommended number of doses has been administered. Luman (2005) demonstrated that 1 in 4 children had experienced delays in receiving 4 of the 6 recommended childhood vaccines. These findings suggest that conventional measures of immunization coverage do not reflect significant delays in vaccination.

A study by Lieu (1996) established that 6 percent and 2 percent of children, respectively, missed the DTP and MMR vaccines between the ages of 15 and 24 months. This failure to administer all the eligible vaccines simultaneously (i.e., deferring them to future visits) corresponded to a 9 percent chance of a child remaining under-immunized. The authors concluded that success in raising immunization coverage rates relies heavily on concurrent administration of all eligible vaccines in one visit.

Deferred doses negatively affect overall immunization coverage rates at age 2 years. One recent study established that avoidance of deferred doses is a predictor of complete coverage at age 24 months, based on an immunization coverage rate of 73 percent resulting from deferred vaccine doses between ages 2 months and 8 months (Meyerhoff 2004).

Impediments to full immunization coverage include deferred doses and missed opportunities to immunize, as well as delays in administering vaccine doses. The ability to deliver multiple antigens in a single injection (through increased use of combination vaccines) may reduce the occurrence of deferred vaccination doses and aid in the timely administration of the recommended doses, thereby positively affecting immunization coverage rates.

Importance of combination vaccines to managed care

In joint policy statements issued since 1999, the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) have stated a preference for the use of combination vaccines to reduce the number of injections required at an office visit.

“To minimize the number of injections children receive, parenteral combination vaccines should be used, if licensed and indicated for the patient’s age, instead of their equivalent component vaccines.”

— American Academy of Pediatrics Policy Statement
May 1999

The policy endorses the use of licensed combination vaccines whenever any one component of the combination is indicated and its other components are not

contraindicated, and it explicitly establishes a preference for the use of combination vaccines over separate injections of their equivalent component vaccines (Newacheck 1988).

Multivalent vaccines are aligned with an MCO's goals of improving quality of care, HEDIS scores, and immunization rates for its members at a neutral or reduced cost. Potential secondary gains from improvements in HEDIS immunization rates and quality of care include improved patient satisfaction and better marketing plans directed at both employers and individuals.

Increased use of combination vaccines may help to alleviate some of the problems that are associated with immunizations (i.e., relative to the timeliness of vaccine administration and immunization coverage rates) in commercial MCO populations, but the benefits of combination vaccines may be especially pronounced for MCOs with Medicaid members. The literature suggests that children from low-income families are less likely to keep appointments with physicians and more likely to utilize acute health care services than their higher-income counterparts (Dodd 2003). The low level of preventive care accessed by this population helps to explain its relatively low immunization rates.

In a study that examines the barriers to vaccination in socioeconomically challenged children, Bates (1998) reported that 47 percent of patients had not received all the recommended vaccinations in the first 2 years of life. Additionally, investigators observed that patients visiting nonprivate providers were less likely to complete vaccination series. The implication for Medicaid MCOs is that use of multivalent vaccines may result in improved immunization coverage of this vulnerable population.

Results for 2000 HEDIS and HEDIS/Consumer Assessment of Health Plans (CAHPS) measures show that complete immunization rates for the Medicaid population fall well below those for the general population (NCQA 2000). The potential for multivalent vaccines in improving the timeliness and coverage rates of immunizations is of particular interest in the wake of the recent resurgence of pertussis. Surveillance data for 1997–2000 demonstrated only a 67 percent use of DTP/DTaP in children who are less than or equal to 18 months of age. The greatest rise in cases of pertussis was observed in infants under 1 year old (12 percentage-point increase), thus giving rise to increased hospital and medical services utilization and increased risk of complications, including pneumonia, seizures, encephalopathy, and death (CDC 2002). More recently, the 2004 surveillance report rates suggested that 16 percent of children between the ages of 6 months and 6 years had received 2 or fewer of the recommended 5 vaccine doses against pertussis (CDC 2004c).

Stakeholder perspectives

Physician/provider. The opportunity to deliver more antigens with fewer sticks appeals to pediatricians and family practitioners for reasons that include:

- Fewer visits are needed to achieve full immunization status.
- Timeliness of immunizations may be improved.
- Likelihood of missed immunizations may be reduced.
- Improved adherence to the immunization schedule is often an element in pay-for-performance systems.
- Both child and parent may experience less injection-related anxiety, leading to improved satisfaction with the physician's care.
- With fewer injections — and fewer entries in medical records and databases — the number of inaccuracies in immunization records may be reduced.
- Lower risk of needle-stick injuries (CDC/MMR 2002).

Increased use of combination vaccinations translates to greater efficiency in a pediatric provider's office. Converting from single antigen to multivalent vaccines decreases the frequency of shipping and makes more cold storage space available. Administering multiple antigens via one syringe reduces the likelihood of accidental needle sticks to the person dispensing the vaccine.

Cost savings may be realized from the reduction in time expenditures related to preparation and administration of injections, completion of related paper work (coding, tracking, record keeping), and the scheduling of additional visits. Another potential positive outcome associated with the use of multivalent vaccines is a reduction in the rate of an MCO's intrusions into a provider's office for collection of HEDIS data. A single documentation of a combination vaccine is more efficiently located within administrative data or a chart review than is the documentation of multiple single antigens.

A common goal for all stakeholders is to improve coverage rates. In a study of deferred-dosing practices and consequences, Meyerhoff (2004) looked at the relationship between the number of vaccine doses scheduled versus the number of doses administered between the ages of 2 and 8 months, the frequency of such "deferred-dose visits," and the effect of a deferred dose visit on immunization coverage rates at ages 1 year and 2 years. The results showed a persistent, positive relationship between avoiding a deferred dose between ages 2 months and 8 months and improvement in immunization coverage at ages 1 year and 2 years. These results suggest a strategy whereby administration of required vaccine doses in a timely fashion at visits occurring between the ages of 2 months and 8 months is encouraged and facilitated.

Parent/child. Parents are reluctant to subject their children to fear and discomfort resulting from multiple injections, but deferring immunizations is costly and places the child at risk for vaccine-preventable diseases. A child's emotional distress is a predominant concern for the parent. The pain and psychological trauma suffered by children during immunization visits is amplified with each additional needle stick. One study demonstrated that a reduction in needle sticks considerably reduced infant crying time per shot (Pellissier 2000). Thus, a latent advantage of combination vaccines is reduced trauma from fewer needle sticks leading to (or resulting in) fewer postponed vaccinations.

Multivalent vaccines offer children protection against more diseases with fewer sticks, less discomfort, and less fear — a benefit to the parent as well as to the child. Additional benefits to parents may include potentially fewer trips to the child's doctor, a reduced likelihood of missed vaccinations, ease in keeping track of the child's vaccination types and dates, and improved satisfaction with the child's physician.

Lieu (1996) conducted a survey to analyze total costs borne by parents of children receiving multiple vaccine injections. The study revealed a direct medical expense of \$0.90 per infant per vaccination visit incurred, due to telephone calls to a nurse for advice on symptoms related to vaccinations. Intuitively, the reduced number of visits associated with combination vaccines implies that nurses will receive fewer phone calls. Indirect costs associated with multiple vaccine injections include parents missing work to take the child for additional physician visits.

In another study, Meyerhoff (2001) used a willingness-to-pay approach to estimate the economic value of pain avoided by reducing the number of needle sticks to a child. Results revealed that parents were willing to bear a mean cost of \$30.28 per injection avoided.

Employer/individual health care purchaser. For the health care purchaser, often a parent's employer, combination vaccines afford better quality per dollar spent on childhood immunizations. Improved immunization rates with fewer physician visits can translate to decreased parent absences from work (because of fewer physician visits) and improved parent satisfaction with the child's physician and the health plan.

Perceived barriers to multivalent vaccine use

Physician/provider. Practitioners incorporating the use of multivalent vaccines initially may face issues ranging from practice administration changes to clinical concerns. Financial barriers are sometimes linked to purchase and storage of additional vaccines, but most focus on the loss of per-antigen payment for administering single-antigen vaccines. For example, a pediatrician in primary care receives a \$10 administration fee per injection, on average. Use of combination vaccines repre-

sents a significant loss in profit margin in an average pediatric practice with more than 1,000 patients. Many physicians argue that the administration fee for administering a combination vaccine should be commensurate with the administration fees for separate injections because the amount of time spent educating the parent about each antigen is the same.

Another commonly perceived barrier among providers against the integration of multivalent vaccines is the change it may represent in common practice. With existing immunization schedules organized around single antigens, multivalent vaccines are viewed by many practitioners as adding complexity. A particularly frustrating issue is that the paper records and electronic medical records used by offices often lack up-to-date templates for notating combination vaccines. While the transition from single to multivalent vaccines will necessitate revised templates for immunization record-keeping, a recent study examining the broad European experience concluded that combination vaccines are an efficient means of simplifying the pediatric immunization schedule (Bogaerts 2003).

The main clinical concern relates to the potential for extra or unnecessary doses of one or more antigens in a given combination. For example, a child who received a first dose of hepatitis B vaccine at birth will receive an extra dose of that antigen if a combination vaccine that includes hepatitis B is used for subsequent immunizations. While national and clinical guidelines permit extra doses, and studies assessing the safety and efficacy of 4 doses (rather than 3) of hepatitis B found no increase in reactogenicity (Lieu 2000), some physicians remain skeptical.

Combination vaccines have been in existence for more than 50 years and, during that time, concerns about the potential for heightened adverse events have persisted. The evidence shows that such concerns may be largely unfounded. For example, the rates of fever, rash, or both at 3 weeks after the administration of the MMR vaccine are similar to those associated with the measles vaccine alone (Halsey 2001). Studies examining the safety and efficacy of newer combination vaccines revealed that the most frequently reported adverse events were local redness and swelling, and a systemic response of mild fever (Mallet 2004, Zepp 2002). In the case of one multivalent vaccine, 98 percent of episodes of fever resolved by post-administration day 4 (Zepp 2002).

Physicians respond to parental perceptions and concerns, as well as their own, when administering multiple vaccines simultaneously. This is particularly true if immunizations are due at the time of a "sick visit." In a study of how practitioner policies and beliefs relate to their practice immunization rates, investigators found that accepting fewer contraindications to vaccination, administering all vaccines for which a child is eligible at each visit, and adopting recommended changes in immu-

nization schedules may be most helpful for providers in fully vaccinating a higher percentage of their patients (Lieu 2000).

Parent/child. Perceptions about adverse effects may lead nurses, physicians, or parents to object to administration of multiple antigens at a single well-child visit, thus delaying completion of immunizations. Approximately 23 percent of parents believe that a large number of immunizations may result in adverse reactions, and 25 percent believe that a child's immune system may be compromised by an immunization (Gellin 2000).

Economic considerations for MCOs

At 2004 federally negotiated prices, the cost of fully immunizing one child is \$472. Despite the likelihood that new vaccines for additional diseases and new multivalent vaccines under development will drive this cost upward in the future, the CDC reports that vaccines are cost-effective (AHIP 2004). Results of an extensive cost-benefit analysis show that every \$1 spent on immunization saves \$6.30 in medical costs, with an aggregate savings of \$10.5 billion. When indirect societal costs, such as missed workdays, death, and disability, are added to direct medical costs, every \$1 spent on immunization saves \$18.40, with an aggregate savings of \$42 billion (Trust for America's Health 2004).

A slightly higher per-antigen cost (generally less than \$1 per antigen) is associated with combination vaccines (Hepatitis Control 2001). For MCOs, the higher direct cost may be offset, fully or in part, by the projected indirect cost outcomes, noted in Table 2 (page 10).

A cost-benefit analysis should take into account not only the direct costs of vaccines, but also the potential savings in terms of cost avoidance and quality improvement. A recent economic study estimated that direct medical costs for each injection are \$5 in a large HMO, with overall savings for elimination of excessive injections of almost \$23 (Jacobson 2003).

Implications for MCO strategies

Given the strongly positive positions taken by the ACIP, the AAP, and the AAFP with respect to combination vaccines, and the potential quality and cost benefits associated with their broadened use, what actions might private and public payers take to reduce or eliminate the perceived and real barriers?

Combination vaccines increase the likelihood of administering a greater number of vaccines in fewer visits, potentially generating an increase in HEDIS childhood immunization rates.

Developed by the National Committee for Quality Assurance (NCQA), HEDIS is a set of performance stan-

dards created to assess the quality of managed care across public and private sectors. The HEDIS measures were designed to standardize the way health plans report data, enabling employers to use them as a guide for comparing plans. Continuous improvement in performance on HEDIS measures has become a top priority for MCOs in the fulfillment of their common mission (i.e., providing higher-quality health care without increasing costs) and in terms of successfully competing for corporate and individual members.

Childhood immunization, one of the first HEDIS performance measures, continues to be an important marker for health plans, their members, and potential subscribers. Improved immunization coverage rates are beneficial to all stakeholders. Strategies health plans use to reach target HEDIS scores include methods that are both labor-intensive and cost-prohibitive, such as reminder phone calls to patients and mass mailings. Because combination vaccines are associated with a diminished frequency of missed doses, such costly activities may become less necessary with increased utilization of multivalent vaccines.

Comprehensive, up-to-date record-keeping is vital for assuring timely and complete immunization for children. For MCOs, fragmented records not only contribute to reductions in immunization coverage, but also amplify the problems inherent in determining individual immunization status for the reporting of HEDIS measures.

The recent resurgence of pertussis has been attributed to either missed vaccination doses or incomplete immunization series (CDC 2004c).

Combination vaccines have the potential to improve Medicaid childhood immunization rates across a greater number of antigens in fewer visits.

Improvement of childhood immunization rates in the Medicaid population is one of the goals of the Government Performance and Reporting Act (HHS 2003). Despite improvements in immunization rates, the childhood immunization status for the Medicaid managed care sector (62.0 percent in 2003) is more than 10 percentage points lower than for the commercial population (74.4 percent in 2003.) (NCQA 2004b). Many state Medicaid managed care plans are now reporting HEDIS measures, including antigen-specific calculations of national mean rates for childhood immunizations. The Medicaid environment is particularly challenging because of frequent changes in eligibility for the program, and children often receive immunizations at sites other than those included in their health plan — making documentation and tracking difficult. Further impeding the immunization process is the increased incidence of missed well-child visits for this population.

By encouraging the use of combination vaccines, Medicaid and private managed care plans may be able to improve timeliness of vaccine administration and immunization coverage rates for children. Any potential increase in direct costs may be offset by reductions in the number and frequency of population management initiatives (e.g., mailed and telephoned reminders) and decreased administrative costs. Because recordkeeping problems and member eligibility issues are magnified in this population, precautions should be instituted to minimize the potential for overimmunization (IOM 2000).

Recommended steps for MCOs

Given the CDC's recommendation that combination vaccines be used for pediatric immunization whenever possible, as well as the many associated arguments in favor of their use, MCOs should consider designing quality improvement campaigns to actively promote their use. Specific steps in this process might include:

1. **Review current immunization data**, including HEDIS rates. Is there room for improvement? To what ex-

tent do missed immunization opportunities (e.g., physician visits during which some schedule-recommended immunizations were not done or not recorded) or immunizations that are not administered in a timely manner affect the overall immunization rate? How do rates compare with regional and national averages, as well as optimal goals? Given these data, can an argument be made for more actively promoting the use of combination vaccines?

2. **Identify current administrative and financial barriers to use of combination vaccines**. Do administrative and/or reimbursement strategies discourage providers from using combination vaccines?

3. **Review immunization cost experience to justify the promotion of combination vaccines**. Review the current cost structure, considering direct medical costs such as those that are for vaccines and those related to vaccine-preventable illness. Consider other costs discussed above, such as the cost of conducting HEDIS record reviews and the costs of processing multiple immunization claims.

4. **Review population-management programs and**

TABLE 2 Direct and indirect MCO cost offsets when shifting from single-antigen to combination pediatric vaccinations

Direct costs

Per-antigen cost increase

- Approximately \$1 per antigen additional

Medical-cost avoidance

- Reduced incidence of vaccine-preventable illnesses requiring emergency and/or inpatient admissions
- Reduced frequency of office visits for immunizations (for noncapitated primary care providers)
- Reduced total nurse time devoted to vaccine administration
- More examination rooms available, due to fewer visits associated with combination vaccines

Pay for Performance

- Increasingly used by MCOs as incentives for providers to adhere to immunization schedules, thereby improving the quality of care provided, increasing patient satisfaction, and managing costs more appropriately (Endsley 2004)

Indirect costs

Administrative cost reduction

- Data collection for HEDIS reporting:
Reduced time required for review nurse to locate one combination vaccine on a patient chart
- Reduced costs for claims processing with fewer injections

Population management cost reduction

- Less spending necessary for member immunization reminders and other initiatives to increase compliance with immunization guidelines

Potential avoidance of monetary fines and negative media reports associated with immunization rates that fall short of:

- Contractual expectations
- Regulatory standards
- Regional and national (HEDIS) averages

Potential increase in health care purchaser retention secondary to:

- Increased parent productivity (i.e., more vaccines administered to child in fewer physician visits results in less missed work hours for parent)
- Increased parent satisfaction with health plan

the cost-benefit impact of programs currently in place.

Immunization outreach programs typically consist of mail and phone reminders, education, and incentives. Disseminate information to all new parents, emphasizing not only the importance of immunizations, but also the possibility of receiving all necessary vaccines in a single injection per visit. The American Nurses Association, the American College of Nurse Practitioners, and the National Association of Pediatric Nurse Practitioners have developed a tip sheet for parents, "Voices for Childhood Immunization." It offers suggested questions that parents can pose to health care providers regarding the availability of combination vaccines to reduce the number of sticks their child receives at each visit (ACNP/ANA 2002).

5. Disseminate educational materials and combination vaccine guidelines to providers. These materials should address providers' concerns and alleviate apprehensions and uncertainties about administering multivalent vaccines. Other related provider strategies might include the following:

- Distribute CDC advisories that are suitable for posting in an office (for benefit of office staff and parents).
- Redesign immunization schedule/grid to show combination vaccines in less complex/more prominent fashion.
- Offer provider office assessment and in-office education on strategies to reduce missed vaccination opportunities (e.g., standing orders whereby non-physician personnel vaccinate children via a protocol without direct physician involvement).

6. Eliminate financial barriers for providers. Suggested strategies include:

- Build appropriate use of combination vaccines into pay-for-performance and other provider incentive systems. One recent study found that 71 percent of health plans with pay-for-performance programs use some subset of HEDIS measures (Med-Vantage 2003).
- Consider paying an increased administration fee for combination vaccines with the goal of making combination vaccines cost-neutral for the MCO and reimbursement-neutral for the provider.
- Consider a per-antigen payment scheme for combination vaccines.

Conclusion

Throughout this supplement, we have examined the evidence relative to combination vaccines, discussed barriers to their use, presented quality and cost implications of a managed care policy to broaden their usage, and suggested ways that MCOs can more actively pro-

mote their appropriate use by providers. Achieving timely and complete immunization status for the pediatric population should be an important policy priority for MCOs. This priority is reflected in the significant attention that is paid to pediatric immunization rates by MCOs, NCQA, and the media. Despite significant strides in recent years to improve the nation's immunization rates, room for improvement remains.

Pediatric combination vaccines provide many potential benefits. Among these are improved timeliness of vaccine administration and immunization coverage rates—resulting in reduced risk of disease, reduced administrative time and cost for providers, as well as less discomfort for children and less stress for their parents. As the prime agents for health care quality improvement, MCOs have the opportunity and the responsibility for reviewing their preventive care guidelines, immunization program activities, and provider-reimbursement policies to ensure that barriers to use of pediatric combination vaccines are eliminated.

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