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## **Child and Adolescent Immunizations: New Recommendations, New Standards, New Opportunities**

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# Does Iron-Deficiency Anemia Affect Child Development?

ABBREVIATIONS. IDA, iron deficiency anemia, RCTs, randomized, controlled trials.

The global prevalence of iron-deficiency anemia (IDA) is extremely high. The possibility that IDA affects children's development is therefore a serious public health problem and has implications not only for individuals' development but also for national development in countries with high prevalence. Although infants with mild-to-moderate IDA have poor development both concurrently and in later childhood,<sup>1,2</sup> a causal link is not well-established.<sup>3</sup>

A major problem is that IDA is associated with many socioeconomic disadvantages<sup>1,2</sup> that are likely to have independent effects on children's development. Therefore randomized, controlled trials (RCTs) of iron supplementation are essential to allow causal inferences. Trials of treating IDA indicate whether the effects are remediable whereas preventive trials provide the strongest evidence of causality.

Surprisingly few RCTs of iron supplementation have been conducted in infants. Previous treatment trials have often lacked randomized designs and failed to find benefits; however, 2 RCTs found benefits. One was extremely small<sup>4</sup> and the other involved children highly infected with parasites and very low initial levels of hemoglobin.<sup>5</sup> Preventive trials have had small samples and inadequate measures of IDA and/or been confounded by other dietary components.<sup>3</sup>

The study by Lozoff and colleagues<sup>6</sup> comprises the largest preventive trial of iron supplementation in infants to date. Furthermore, the investigators used adequate measures of iron status and more comprehensive developmental measures than previous studies. They found no effect on the children's scores on the Bayley Scales or a test of recognition memory but a benefit was found in speed of information-processing, behavior, and the age of creeping. As planned, the study should have provided definitive answers. It is a tragedy and a classic example of false economy that their funding was reduced and the investigators had to abandon their randomized design and resort to a quasi-experimental approach. The low- and high-iron groups were separated by time and consumed different amounts of cows' milk. We, therefore, cannot infer with confidence that iron deficiency caused these small differences. Furthermore, as in nearly all studies, high-risk infants (low birth weight or IDA at 6 months) were excluded but

may be the most vulnerable and form a large proportion of children in low resource countries.

There is consensus that severe anemia is harmful, and these findings increase the suspicion that IDA affects children's development. However, considering the expense and difficulties of large treatment programs, there remains an urgent need to know whether mild to moderate anemia affects children's development and to what extent. The authors correctly call for more RCTs.

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## Child and Adolescent Immunizations: New Recommendations, New Standards, New Opportunities

ABBREVIATIONS. VFC, Vaccines for Children (Program); NVAC, National Vaccine Advisory Committee; AAP, American Academy of Pediatrics, VIS, vaccine information statements.

In the movie *Spiderman*, Peter Parker's guardian, Uncle Ben, tells him, "With great power there must also come great responsibility." Over the past decade, pediatricians, family physicians, nurse practitioners, physician assistants, office nurses, and the entire primary care staff have been handed increased power and responsibility. The power to protect our children from vaccine-preventable diseases and the responsibility to ensure that every child receives all necessary vaccines in a safe and effective manner.

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More children receive a greater number of vaccines today than ever before in our history and the majority of these are given in primary care settings. Children receive an increased number of vaccines with up to 23 injections given for 11 different diseases. The US immunization rates are at the highest level ever for 2-year-olds with almost 74% of children up-to-date for the 4:3:1:3:3 schedule.<sup>1</sup> Primary care practice teams provide 73% to 85% of the immunizations for children (personal communication, Pennsylvania Department of Health Immunization Program, Harrisburg, PA).<sup>2-4</sup> For many children and families the Vaccines for Children (VFC) Program has been the key to receiving immunization services in a medical home. The VFC Program has meant an end to the fragmented system of care that required families to have a preventive care visit with their pediatrician and then schedule another visit with the local public health center to receive vaccines. Children still receive immunizations from public health clinics, but many clinics are now primary care settings and not just immunization-only shot clinics. So over the last decade and a half, since the measles epidemic, the health system has made significant progress in protecting children and adolescents through immunization services provided by medical home.

The primary care practice is not alone in the immunization process and this adds to the complexity. Primary care practices are the delivery point for vaccines that are produced by industry with federal agency oversight of vaccine safety before, during, and after production. Vaccines are often purchased, distributed, and monitored by federal and state government agencies. Federal agencies also provide liability protection. Finally, the primary care practitioner has to seek reimbursement from numerous third-party payers. Each stakeholder in the immunization system requires the practice to expend financial and staff resources.

In addition to recognizing that the primary care practice is the principle provider of immunizations, health services research has documented that better quality care comes from continuous, comprehensive care provided by a medical home.<sup>5,6</sup> With this recognition comes the increased responsibility for each practice to ensure that every child receives timely, high-quality immunizations and preventive care. Managed care organizations, integrated delivery systems, state Medicaid agencies, and other credentialing entities also hold practices accountable and use immunizations as a quality measure for preventive and primary care.

In this month's issue of *Pediatrics*, the National Vaccine Advisory Committee (NVAC) presents the revised "Standards for Child and Adolescent Immunization Practices" and the American Academy of Pediatrics (AAP) releases a policy statement titled "Increasing Immunization Coverage" by the Committee on Community Health Services and the Committee on Practice and Ambulatory Medicine.<sup>7,8</sup> Both articles contain recommendations for primary care practice teams that can help improve quality of immunization services.

## THE OPPORTUNITY

Why should busy pediatricians and family practitioners review these recommendations? Because we have the opportunity to do even better. The only way to do improve is first to know how we are performing today. What is the gap between how pediatric and other primary care practices perform now and what we could be doing?

Pediatricians and other child health care providers are doing something right with more children immunized today than ever before. Yet >25% of children in the United States have not received all the recommended doses of diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, *Haemophilus influenzae*, and hepatitis B by 18 to 35 months. If a child is black, living in the inner-city and in poverty, the risks of not being immunized increase significantly with only 60% up-to-date for the 4:3:1:3:3 schedule.<sup>9</sup> If this child has many siblings, his mother is young and did not graduate from high school, he has an even greater chance of not being immunized.<sup>10</sup>

Are there other gaps? Do suburban practices with immunization rates of 90% to 100% have gaps? Studies have documented that pediatricians and family physicians overestimate the practices immunization rates, lack adequate knowledge of catch-up schedules and valid contraindications, do not use vaccine information statements (VIS) forms as required by federal law, and do not use recall/reminder systems, even in the face of vaccine shortages and the need for recall.<sup>11-14</sup>

There are also challenges both in and outside the practice: racial/geographic disparities, vaccine shortages, adding new vaccines and combinations, educating parents and practice staff about vaccines and vaccine-preventable diseases, reeducating parents with vaccine misinformation, and receiving proper reimbursement for providing vaccine services.

Practices vary and the communities they serve vary. The challenges for practices in the inner cities with families living in poverty are the most critical and will require intensive efforts. Primary care practices in the suburbs and rural areas face different, but very real challenges in providing immunization services.

## TRANSLATING THE STANDARDS AND POLICY STATEMENT RECOMMENDATIONS

The NVAC "Standards for Child and Adolescent Immunization Practices" and the AAP policy statement contain specific recommendations and an extensive list of Internet sites with resources and practical tools. Most primary care practices have developed very good systems to provide immunization and other preventive services. Many practices do not think of their preventive services as a system and many systems were developed without formal planning and continue without review. The new recommendations provide the opportunity to review the systems, processes, and protocols that the practice has developed over time and through quality-focused techniques, improve the practice's preventive care system. How can the recommendations be

implemented and what specific steps should practice teams take tomorrow?

### TEAMS, SYSTEMS

Immunization and other preventive care services are delivered by the entire practice, not just the clinician. Every facet of the immunization process needs to be considered and every group in the primary care practice needs to be involved in the review and dialogue about preventive care.

- First, the practice should determine who is or will be the immunization leader and who are the members of the practice immunization or preventive care team. The team consists of 3 to 4 members representing physician, nursing, practice management and billing, or reception staff. The team should meet on a regular basis to develop, review, and rewrite, if necessary, the practices, processes, and protocols.
- Next, each team needs to review the internal practice systems for access, assessment, systems and knowledge. Many practices will need to collaborate with the external health care environment and their community agencies and associations.

#### Access

The NVAC's "Standards for Child and Adolescent Immunization Practices" and the AAP recommendations focus on ensuring children access to immunizations in a medical home with minimal costs to families. Every pediatric and family practice should participate in the VFC Program and avoid the fragmented care that occurs when children are referred to a state, county, or city health department to receive immunizations.

#### Assessment

Both the AAP and the NVAC call for practices to assess their immunization rates. The VFC Assessment Feedback Incentives Exchange and quality assurance program in most states will determine the practice's rates at least once every 3 to 4 years. The NVAC calls for practices to assess rates annually. The practice can either perform a Clinic Assessment Software Application assessment or use a continuous visit methodology. The Clinic Assessment Software Application is available from the Centers for Disease Control and Prevention.

The practice should assess the vaccine status of every child at every visit. This requires that immunization records are a summary of all immunizations given by all providers. Obtaining records can be a laborious process without an active immunization registry. Participation in a registry is encouraged when it is practical for the practice. Vaccine records should be prominently displayed and easily found in the chart. Parents should have a portable record, (credit card size) and are encouraged to carry the record at all times.

#### Systems

The immunization team should examine each component of the practice's immunization system. The following components should have written pro-

ocols developed, taught to all staff and reviewed on a regular basis.

- *Reminder/Recall* processes are developed and used so that parents are notified by phone or mail to schedule appointments for preventive care or immunization only appointments and reminded to keep or reschedule missed appointments.
- *Provider reminder tools* are used by the staff. Computer-generated encounter forms (billing slips) can add immunization due to remind all the staff that a child is due for an immunization at the visit. Receptionists and nursing staff can place simple flags in the chart. Posters can be placed in the waiting and examination rooms to remind parents to ask the staff if their child needs a vaccine.
- *VIS* protocols are followed so that every family is given a VIS at every visit for every vaccine provided. Most families do not want repeat copies so practices can develop practical methods to meet the federal regulations.
- *Vaccine protocols* are readily accessible, cover valid and invalid contraindications, administration sites, and techniques including simultaneous multiple injections.
- *Documentation protocols* are developed so that all vaccines and immunization services are documented appropriately in the chart for parents and for other agencies, including the VFC Program and Vaccine Injury Compensation Program, and to ensure appropriate billing and reimbursement. Refusal to Vaccinate and Vaccine Adverse Events Reporting System forms are completed.
- *Storage and handling guidelines* are easily accessible so that refrigeration of vaccines is appropriate and staff is prepared for emergency situations.
- *Reimbursement protocols* are in place to be sure that whenever an immunization is given, both the vaccine, when appropriate, and the vaccine administration fee are billed.

#### Knowledge

The entire office staff, clinical and nonclinical, needs to be knowledgeable about vaccine-preventable diseases, administration and storage techniques, and all aspects of immunization. The practice immunization team can be the teachers or use local infectious disease experts. Many states, counties and cities now have public-private partnerships between the state AAP/American Academy of Family Physicians chapter and the Department of Health to provide immunization education and quality improvement. Many of these programs, such as the Pennsylvania and Georgia Chapters' Educating Physicians In Their Communities Immunization Education Program provide education for the entire practice staff in the office at convenient times. Other practices in Vermont, New York City, and North Carolina have worked with the National Initiative for Child Healthcare Quality in an intensive quality improvement process focused on all aspects of preventive care.

Education can focus on a number of topics from the most recent schedule to how to give multiple vaccines. Many practices request information on

how to talk with parents about vaccine safety. Parents also need information and education. The biggest barrier with parents is finding the time to provide education during the visit. Using the VIS and using your staff to explain much of the information will help, but parents still rely on their clinician to answer their questions.

#### External Health Care Environment and Community Agencies and Associations

Pediatricians, family physicians, and other primary care clinicians in all communities need to collaborate with the local health department, the Special Supplemental Nutrition Program for Women, Infants, and Children, and community agencies and associations to determine how to reach underserved populations. This is especially true in the large metropolitan cities, but also in small cities and rural areas. Szilagyi et al<sup>15</sup> demonstrated how a city-wide reminder, recall, and outreach program can increase immunization rates and decrease disparities for an inner-city population. Lay outreach workers were recruited to work with 1 or more city practices and apply a staged intervention with increasing intensity from simple reminders to outreach home visits. The concept of joining the outreach program to a practice or practices was successful at decreasing disparities between the inner-city and the suburbs from 18 to 21 percentage points to 4 to 5 percentage points over 6 years. This model of public-private partnerships between practices and city health departments/community associations can and should be applied in other communities.

Many practices are concerned about inadequate reimbursement for immunizations from third-party payers. Today very little income is generated from vaccines and vaccine administration fees often do not cover the expense of providing immunizations. The AAP has been working diligently to have the physician work component for pediatric immunizations recognized by the AMA/CPT editorial panel. Until this effort is successful, practices may find it beneficial to determine the average amount of physician and nurse time they spend on immunizations. Although immunization administration fees are set for most third-party payers, the only way to begin the negotiation process if the reimbursement is too low is with practice specific data. This information is also useful on a state and national basis, not to negotiate fees, but to clearly demonstrate the amount of physician work in providing vaccines.

Practices also need to work with their state, county, and city departments of health and state AAP and American Academy of Family Physicians chapters to create immunization registries that are practical and beneficial for all stakeholders.

Finally, pediatricians need to communicate with their state and national leaders about what works and what does not work. During the past year the AAP has created an Immunization Advisory Team composed of representatives from several key committees within the AAP. This effort was initiated to help the practitioner implement immunization recommendations. The Committee on Infectious Dis-

eases will continue to use the best scientific information to develop recommendations concerning new vaccines or combination vaccines. The AAP Childhood Immunization Support Program also has multiple resources available for parents and all members of the practice staff.

Pediatricians, family physicians, and other primary care clinicians are encouraged to take advantage of this opportunity to review the NVAC "Standards for Child and Adolescent Immunization Practices" and the AAP policy statement, "Increasing Immunization Coverage" with their practice staff. Begin the dialogue, examine what is currently done, what needs to change, and how to make it happen. Pediatricians and others providing health care for children have always been responsible, now hopefully, we will realize that we have the tools and power to ensure that every child is immunized.

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