Counting the Shots: A Model for Immunization Screening and Referral in Nonmedical Settings

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ABSTRACT. Background. Clinics of the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) have become important partners in efforts to improve vaccination coverage in low income children. However, the time required to assess all antigens in each child's vaccination record may exceed the capacity of many of these clinics. Seeking a solution, experts recommended assessing up-to-date (UTD) status only for the diphtheria-tetanus-acellular-pertussis (DTaP) vaccine and treating this as a proxy measure for all vaccines in the childhood schedule. Whether this single vaccine screening method represents an acceptable alternative to the traditional multiple-vaccine method as a basis for improving overall immunization coverage levels in this vulnerable population has not been demonstrated.

Objective. **To evaluate the validity of the proposed simplified method for assessing immunization status in a nationally representative population of infants and children who had ever been enrolled in WIC before 35 months old.**

Methods. **This was a cross-sectional analysis of the 2000 National Immunization Survey representing children ages 3 to 24 months who had ever been enrolled in WIC. For the 6277 children in the study population, we compared personal records of completion status for DTaP with personal records of completion status for all immunizations appropriate for age in the combination 4:3:1:3 schedule to see which of the 2 (single vs multiple screening) methods would better predict the child's *true* (provider-reported) status for the 4:3:1:3 series. The main outcome measures were the comparative sensitivity, specificity, and overall test efficiency of the 2 methods in correctly identifying underimmunized WIC children.**

Results. **Completion status for DTaP was less sensitive than completion status for all vaccinations in correctly identifying truly underimmunized children (sensitivity = 70% and 77%, respectively). However, it was more specific in correctly identifying children who were truly UTD for age (specificity = 86% and 82%, respectively). The 2 methods were essentially identical with respect to overall test efficiency (82% and 81% for DTaP assessment and assessment of all vaccines, respectively).**

Conclusions. **Given limited resources to do immunization screening and referral in nonmedical settings such as WIC, simplifying the process by using DTaP from the personal vaccination record as a proxy for the 4:3:1:3 series is a viable option. Loss in sensitivity may well be offset by gains in the capacity of WIC clinics to screen more children.** ***Pediatrics*** **2003;111:1297–1302;** ***immunization, Women, Infants and Children, evaluation, underserved, sensitivity, specificity, policy, evaluation, preventive services.***

ABBREVIATIONS. WIC, Special Supplemental Nutrition Program for Women, Infants, and Children; DTaP, diphtheria-tetanus-acellular-pertussis; MMR, measles-mumps-rubella; Hib, *Haemophilus influenzae* type b; NIS, National Immunization Survey; UTD, up-to-date.

"The task of the public health agency has been not only to define objectives for the health care system . . . but also to find means to implement health goals within a social structure."[1]

Despite increases in national childhood immunization coverage since the measles resurgence of 1989–1991, preschool children in poverty continue to be significantly underimmunized.[2] To reach these children, state immunization programs collaborate with the US Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), which is the single largest point of access to economically disadvantaged preschoolers.[3]

Vaccination-promoting initiatives in WIC clinics have improved completion rates for the "4:3:1:3" series of childhood immunizations, which includes 4 doses of diphtheria-tetanus-acellular-pertussis (DTaP), 3 of polio, 1 of measles-mumps-rubella (MMR), and 3 of *Haemophilus influenzae* type b (Hib) vaccines administered within recommended age ranges and completed by 19 months old.[4–6] WIC clinics assess children's vaccination progress by reviewing the handheld record brought in by the parent. Children with missing doses (immunization delays) are referred to a vaccine provider, ideally to the child's medical home.

This complex and time-consuming process is 1 of many challenges that WIC programs have faced in providing nutrition services and, at the same time and without additional funding, functioning as the gateway to a variety of health and welfare programs that, over the past decade, have undergone considerable change.[7] In 2001, realizing that taking the time to review all vaccines listed on each child's record may exceed the capacity of many WIC clinics, an interagency team of experts from national immuni-

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zation and WIC programs proposed a less time-consuming method for assessing vaccination status. By this method, WIC staff will assess completion, or up-to-date (UTD) status for the DTaP vaccine as a proxy for UTD status of all vaccines in the 4:3:1:3 schedule. That is, instead of reviewing all documented vaccinations in the child's record, WIC clinic staff may elect to review only the number of DTaP doses received. The child would be classified as being UTD for age for the entire 4:3:1:3 series if the record shows that he or she is UTD for age for DTaP. Only those children late for a DTaP dose would be referred to an immunization provider.

It is not known whether these time-saving benefits outweigh the risks of failing to identify children who lack doses, or of inappropriately referring children for vaccines who are already UTD. A condition of the proposed new procedure is that all assessments be based on a printed document of the child's vaccination history rather than on parental recall. However, because the accuracy of handheld records presented by parents has not been consistently demonstrated, relying on these records may also introduce error.

In this study, we used data from the 2000 National Immunization Survey (NIS), which includes children enrolled in WIC as well as those not enrolled. For enrolled WIC children, we determined whether age-specific UTD status as shown on the parent-held vaccination record accurately reflects physician-verified UTD status at 6 milestone ages for the 4:3:1:3 combination schedule. Furthermore, we evaluated the extent to which using a single vaccine (DTaP) to represent multiple vaccine completion status would correctly identify children in WIC who were not UTD as well as those who were on schedule. Finally, we compared the Hib and polio vaccines with the DTaP vaccine as potential proxy predictors of true status.

METHODS

Data Sources

The NIS is a large, ongoing, population-based telephone survey of US children ages 19 to 35 months that is conducted by the Centers for Disease Control and Prevention to obtain national, state, and municipal area population statistics on vaccination coverage rates at milestone ages. The survey consists of a household component and a provider component. Parents of surveyed children provide sociodemographic and social services usage information (including WIC participation), detailed information on the children's immunization histories, and consent to contact the children's immunization providers. The named providers are then contacted and asked to complete a form documenting dates and types of vaccinations from the surveyed children's medical records. Reports from providers are synthesized, and are considered the "gold standard" of immunization completion status for survey participants.[8–10]

We included in our analysis the subset of year 2000 NIS records for which 1) the child's WIC participation status was determinable; 2) parental response to the immunization history component of the interview was based on a documented vaccination record rather than on recall alone; and 3) complete provider-reported vaccination history data existed as part of the record.

Classification of Age-Specific UTD Status

We classified each study participant's immunization completion status using guidelines established by the Advisory Committee on Immunization Practices (Table 1). These guidelines describe the types of vaccines to be given, the number of doses required, and the age recommendations for each dose in the 4:3:1:3 series.[11]

TABLE 1. Vaccination Schedule for the Universally Recommended 4:3:1:3 Pediatric Immunization Series

Antigen	Total No. of Doses	Criterion Age (mo)				
		3	5	7	16	19
DTaP	4	x	x	x		x
IPV	3	x	x			x
MMR	1				x	
Hib*	3–4*	x	x	x	x	

IPV indicates inactivated poliovirus vaccine.
Xs indicate the age deadline by which each dose must be received to be considered on-time.
* No. of doses depends on the type of vaccine used.

We assessed timeliness and completion status from the NIS provider reports for our study population at ages 3, 5, 7, 13, 19, and 24 months. Next, we used the NIS household record to construct 2 predictors of provider-reported, age-specific completion status—1 based on the DTaP series (the proxy method) and the other based on the entire 4:3:1:3 series.

According to the proposed new method, if the parent does not provide a documented record of the child's vaccination history, WIC staff members will not attempt to classify the child's immunization completion status at that visit. Correspondingly, in our study when the data necessary to calculate age-specific UTD status were missing from the NIS household record, we classified household-reported status as indeterminate at that age.

Statistical Analyses

We calculated the sensitivity, specificity, and test efficiency of UTD status from parent-held records in predicting true immunization status as reported by providers. In keeping with a risk-assessment approach, the condition screened for was immunization delay. Therefore, the sensitivity of each of the 2 household-based tests was defined as the percentage of truly immunization-delayed children according to provider records who were correctly classified as delayed by the test. Specificity was defined as the percentage of children who were truly UTD and were classified as such by the test. Test efficiency was defined as the percentage of times the screening test gave the correct answer, whether positive or negative, out of all times the test was applied. Nationally representative population estimates of immunization completion rates as well as sensitivity, specificity, and test efficiency were analyzed with the SAS-callable SUDAAN crosstab procedure for complex survey designs (Research Triangle Institute, Research Triangle Park, NC).

RESULTS

Population Characteristics

Household questionnaires were completed for 34 087 children in the 2000 NIS. Complete provider data were available for 22 958 (67%) of them. Nationwide 4:3:1:3 immunization coverage rates were estimated to be 76% for all children ages 19 to 35 months. WIC participation status could be determined for 22 767 (99%) of the records that had complete provider data, allowing us to estimate 4:3:1:3 immunization coverage rates of 73% for children ever enrolled in the WIC program and 81% for those never enrolled. Completion rates nationwide were lowest for the 4th DTaP vaccination (82%) and highest for the 3-dose Hib series (93%). Disparities between WIC and non-WIC children mirror this trend, with greatest disparities in the DTaP4 series (86% completion rates for non-WIC children vs 78% for WIC children) and least disparities in the Hib3 series (95% vs 92% for non-WIC and WIC children, respectively).

Figure 1 shows differences in coverage rates at milestone ages between WIC and non-WIC children.

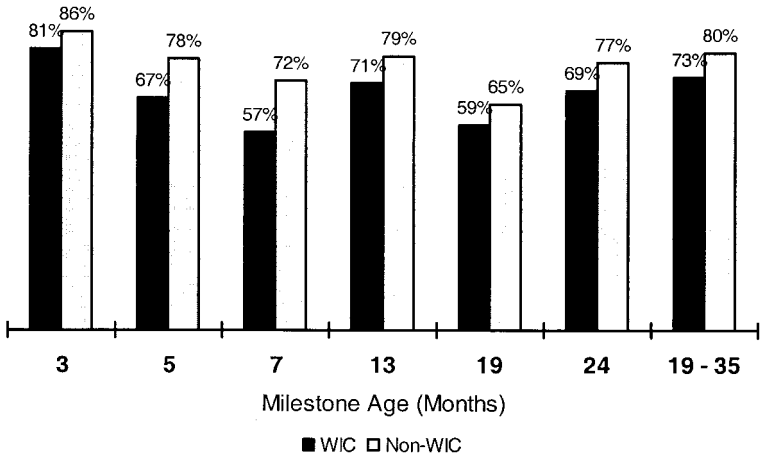

Fig 1. Differences in completion rates by age for the 4:3:1:3 immunization schedule: WIC versus non-WIC participants, 1999.

These differences were statistically significant at every age ($P < .0001$), and were consistently lower for WIC participants. Timely completion for both groups is highest at age 3 months, decreased steadily across the milestone ages through the first year, then increased through the second year so that by the beginning of the third year coverage levels were almost as high as they were at the 3-month milestone.

Comparison of the Sensitivity and Specificity of Household Records

Figure 2 shows the sensitivity, specificity, and overall test efficiency of the 2 household-based predictors of UTD status for 6 milestone ages among children who were ever enrolled in WIC. With the exception of 24 months old, DTaP is consistently a less sensitive predictor of true 4:3:1:3 completion status, with differences in sensitivity ranging from 15% at 3 months old to 4% at 7 months old. Our estimates show that on average, 30% of vaccine delayed WIC children will be incorrectly classified as UTD when the household DTaP series alone is used to predict true UTD status, and that 23% will be misclassified in this way when all 4 vaccines are counted from the household record.

With the exception of the 24-month milestone age, DTaP provides a more specific estimate of true 4:3:1:3 UTD status than assessing all 4 vaccines. Use of this single vaccine method tends to increase the probability of correctly classifying truly UTD children, but marginally so. Specificity of the DTaP test varies less than sensitivity across the milestone ages, with differences ranging from 9% at 7 months old to 2% at 13 months old. When DTaP alone is used to assess status, an average of 14% of truly UTD children will be incorrectly classified as vaccine-delayed; 18% will be misclassified in this way when all vaccines are counted.

Like specificity, test efficiency tends to be higher for the DTaP predictor. On average, use of either the DTaP series or the entire 4:3:1:3 series for screening will result in accurate classification of UTD status ~81% to 82% of the time. Test efficiency, like specificity, is fairly uniform across the milestone ages but tends to be highest for assessments of children <13 months of age. Disparity in the efficiency of the 2 household tests is greatest at 24 months old.

The accuracy of the 2 household-based tests in predicting true UTD status varies widely across the milestone ages. Sensitivity is highest for both tests at 7 months old, and lowest at 24 months old. Specificity is highest at 19 months old for the DTaP-based test and at 24 months old for the 4:3:1:3-based test. Specificity is lowest for both tests at 13 months.

Comparison of DTaP With Other Antigens

The Hib series was a more sensitive predictor of provider-reported UTD status than both DTaP and polio. However, its specificity and overall test efficiency were poor relative to both of the other vaccines. Polio had very high specificity, but poor sensitivity (Table 2).

We found that the combination of DTaP and MMR produces significant improvements in sensitivity at both 19 and 24 months of age. In fact, sensitivity at 24 months old for this combination was almost twice that obtained by the use of DTaP alone (79% vs 41%). However, specificity dropped by ~15% at both ages when the DTaP-MMR combination is used, and overall test efficiency declined by ~8% as well.

DISCUSSION

Based on information in the parent-held immunization record, we found that counting only a single vaccine (DTaP) to determine "true" (provider-reported) UTD status compared with counting all doses in the entire 4:3:1:3 combination series was less sensitive in identifying truly underimmunized children, slightly more specific in identifying truly UTD children, and had similar efficiency. Sensitivity varied depending on the child's age, with relatively more underimmunized children being missed at ages 3 and 13 months when DTaP alone was used. Sensitivity was lowest at 24 months, regardless of which screening method was used.

Although the finding is not new that children participating in WIC remain less well-immunized than children never participating in WIC, our results show that this finding holds true at all milestone ages from 3 to 36 months and is most pronounced at 5 and 7 months of age. This, together with our observation that timely completion is highest at 3 months old and then decreases steadily across the milestone ages through the first year before increasing during the

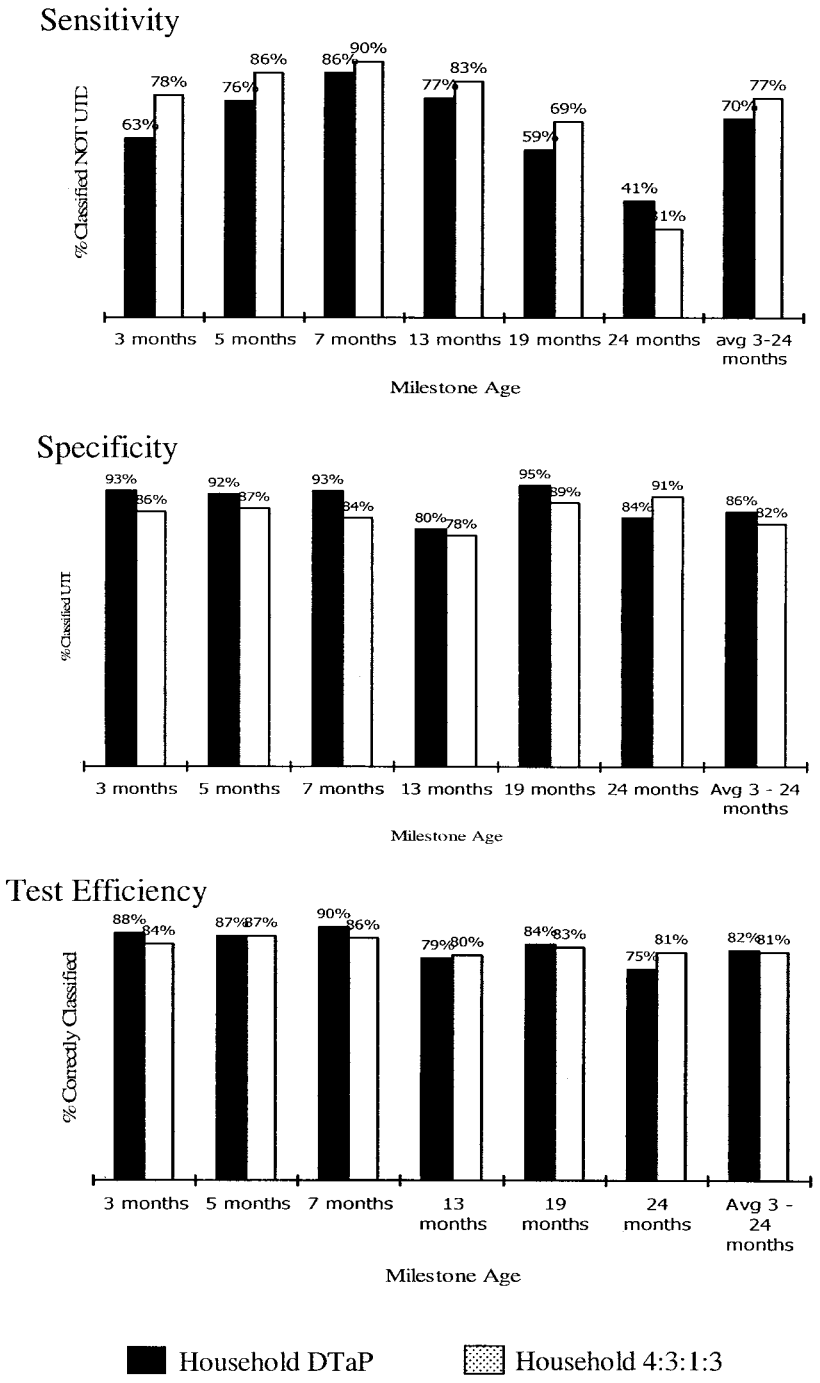

Fig 2. Sensitivity, specificity, and overall test efficiency by milestone ages for 2 different methods of assessing the immunization completion status of WIC children.

second year, has special significance for WIC clinics, where 88% of infants are <3 months old at the initial visit and >33% of enrolled children are <1 year old.[12] It suggests that opportunities for identifying underimmunized children will be greatest between the ages of 7 and 19 months. WIC thus remains a good capture point for underimmunized poor children in this country, and is especially important for vaccination promoting interventions being conducted in WIC during the first year of life, when immunization status is even more discrepant between WIC and non-WIC, and before the large dropout (~30%) from the WIC program, which occurs between the first and second year of life.[3]

Deliberations about the use of a single vaccine to represent true UTD status for all antigens included considerations about which 1 of the 4 might have the best predictive validity. Studies had not yet been performed to provide empirical evidence for this decision, but the DTaP series seemed a good candidate because it has been a long-established component of the 4:3:1:3 series; it is typically initiated at the same time for all infants regardless of birth weight, disease history, or other potential contraindications; and the spacing of the sequential components of the 4-dose series affords an opportunity to check immunization status periodically throughout the months of infancy and early childhood when WIC services are most often sought. However, recent shortages in the supply of DTaP vaccine highlight a potential

TABLE 2. Comparison of DTaP With Other Antigens in Predicting Provider-Verified 4:3:1:3 Completion Status at Milestone Ages

Age (mo)	Household DTaP4 (%)	Household 4:3:1:3 (%)	Household Hib (%)	Household Polio (%)
Sensitivity				
3	63	78	72	65
5	76	86	79	77
7	86	90	74	56
13	77	83	82	48
19	59	69	60	23
24	41	31	51	18
3–24	70	77	72	49
Specificity				
3	93	86	72	95
5	92	87	79	95
7	93	84	74	92
13	80	78	82	86
19	95	89	60	99
24	84	91	51	95
3–24	86	82	72	49
Test Efficiency				
3	88	84	88	90
5	87	87	88	89
7	90	86	85	78
13	79	80	85	75
19	84	83	64	74
24	75	81	59	77
3–24	82	81	80	81

problem for this method. Although these shortages occurred after the 2000 NIS survey and thus did not affect the results of this study, the possibility of future shortages suggests that other vaccines should be evaluated in terms of their usefulness as markers for UTD status.

We found that Hib is a more sensitive predictor of true UTD status than DTaP, but its specificity and test efficiency are lower. Moreover, assessments based on this antigen would be complicated by the fact that the dosage schedule depends on the type of Hib vaccine given: some products require a 3-dose series and others, a 4-dose series. For these reasons we believe that Hib is not a viable candidate vaccine to use in a simplified assessment procedure.

The DTaP-MMR combination for children ages 19 and 24 months certainly deserves further consideration. Most children have dropped out of WIC participation by these ages; the addition of a single vaccine to the screening procedure for the small number of children remaining in WIC may make a slightly more complex assessment feasible.

We did not include hepatitis B vaccine in our assessments because the timing of the initial dose differs depending on the physician's preference and hospital convention. For most infants, the initial dose is given shortly after birth while the infant is still in the hospital nursery; but for others, the first dose is delayed. Consequently, although some of these initial hepatitis B vaccinations become part of the outpatient immunization providers' records, many of them are retained in the hospital record and not readily available for routine outpatient chart review. The pneumococcal conjugate vaccines were not part of the routine immunization schedule for our study population, but given their importance in the current schedule, we will monitor the extent to which they track with the DTaP series and will evaluate their suitability as a potential alternative representative of age-specific completion status for all vaccines in the routine schedule. Meanwhile, for all ages combined and considering the 3 statistical measures of sensitivity, specificity, and efficiency together, DTaP appears, at least for now, to be the most reliable of the 3 candidate vaccines as a proxy measure of true UTD status.

The finding that both the DTaP count and the 4:3:1:3 count were imperfect predictors of true 4:3:1:3 status has important implications for clinical practice. It most likely results from administered vaccines not being recorded appropriately on the child's personal vaccination record. From our analysis we know that the personal record will be insensitive to true immunization delay whenever the child has completed the DTaP series but missed 1 or more of any of the other 3 vaccines, ie, either polio, Hib, or MMR. Conversely, it will be nonspecific to true 4:3:1:3 status whenever the child is UTD for all 4 vaccines and any of them are missing from the child's personal vaccination record. As the child progresses through the schedule of immunizations during the first 18 months of life, problems associated with incomplete updating of the personal vaccination record become more pronounced. Therefore, professional organizations who contemplate using single vaccine screening methods such as the one we describe will need to place more emphasis on accuracy of these records and to encourage both parents and providers to make sure that they are updated with the receipt of each vaccine.

Comparisons With Previous Studies

For preschool children 19 to 35 months of age, 1999 NIS analysis found that when the personal vaccination record shows the child to be UTD then there is agreement with the provider records $\geq$90% of the time; if the personal vaccination record indicates that the child is not UTD, then agreement with the provider is $\leq$29%.[13] Our findings are similar for the subset of children that we studied. However, ours is the first study to evaluate the correspondence between household and provider reports at milestone ages and the accuracy of counting DTaP as a proxy for the combination 4:3:1:3 series.

Limitations

The study is limited by the process used by the NIS to collect immunization histories, which relies not on inspection of the personal vaccination record but rather on parents' "reading" of the immunization dates over the telephone, which may result in some loss of accuracy. This highlights the fact that in the applied setting, possession of a personal vaccination record does not necessarily mean that this record will be brought to all provider visits, especially visits to providers of nonmedical services such as WIC. Accuracy of the single-vaccine model that we evaluated is dependent on the extent to which the parent or caregiver presents a complete and UTD record for review. As the childhood vaccination schedule becomes more complex with the addition of new vac-

cines, future research in single-vaccine screening methods might assess sensitivity and specificity associated with links to immunization registries in comparison to those associated with personal vaccination records.

Policy Implications

Our results suggest that given limited resources to conduct immunization screening and referral in nonmedical settings such as WIC, simplifying the process by using DTaP as a proxy for the combination series is a viable option. When compared with screening methods that involve assessing all doses of all antigens, this method is less sensitive in identifying children who are in need of vaccinations but more specific in that fewer children would be referred to a provider for vaccinations already received. It is important to recognize the need to balance sensitivity and specificity in weighing the merits of this method. Optimizing sensitivity may lead to the identification of more children with vaccine deficiencies, but if this is achieved at the cost of reduced specificity, other problems ensure. In particular, as the link between WIC clinics and the health care system has become weakened, the need to maintain good communications with private-sector immunization providers has become more important. Inappropriately referring fully immunized children to these providers compromises the credibilty of the WIC clinic staff and places the child at risk for receiving duplicate vaccinations.

This assessment model may be useful for programs serving populations that are at risk not only for delayed immunizations but also other preventive services, such as vision and hearing screening. Reports that underimmunized inner-city preschoolers are significantly more likely to be anemic and to have elevated lead levels than their UTD counterparts confirm that these children are at risk for more than just vaccine-preventable diseases.[14] Programs such as Medicaid and Housing and Urban Development that, like WIC, are in regular contact with low income, inner-city children, may have particular interest in this streamlined approach to immunization screening. Because it is a practice that can lead to the identification of other pediatric primary care conditions, it offers the potential for improving the overall health status of these children.

We endorse the use of the single vaccine screening method only by nonmedical providers. Although their contact with children at risk for immunization delay is often more frequent and predictable than that of medical service providers, their objectives are different. In nonmedical settings such as WIC clinics, immunization screening activities are seen as ancillary to the primary mission of the organization; the focus of these activities is to make appropriate referrals to vaccine providers. By contrast, because immunization screening activities in medical settings are directly related to the organization's mission to provide preventive health care services, the objective is assessment and administration of needed vaccines. Comprehensive immunization screening more likely represents standard operating procedure in medical settings, where staff are equipped with the knowledge and the resources to conduct professional assessments. For these reasons, in our study we modeled the medical service provider as the "gold standard" of knowledge of true immunization status and of responsibility for assuring appropriate standards of medical care.

WIC programs are currently directed to conduct immunization screening and referral at all WIC sites nationwide (White House Executive Memorandum, December 11, 2000). Effective October 1, 2002 (US Department of Agriculture policy memorandum, June 2001), use of DTaP alone to ascertain vaccination status has been recommended as a viable option for those WIC sites not able to conduct full antigen screening. The loss in sensitivity associated with this simplified method may well be offset by increases in the number of WIC clinics that can integrate immunization assessment as a component of routine WIC certification, with consequent gains in the number of children assessed. The findings that we report here have implications for the feasibility and the potential cost effectiveness of this simplified immunization assessment procedure, not only in the WIC clinic setting but also in other nonmedical settings such as federal and state family health and social service programs, child care centers, and schools.

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