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CDC'S NATIONAL IMMUNIZATION SURVEY

Methodological Problems Limit Survey's Utility



**Program Evaluation and
Methodology Division**

B-272491

September 19, 1996

The Honorable Dale Bumpers
United States Senate

Dear Senator Bumpers:

Recommendations for childhood immunization indicate that children should receive most of their immunizations before they are 19 months old. (See appendix I.) To monitor the extent to which this goal is met at the national level, the Centers for Disease Control and Prevention (CDC) has, since 1991, administered a supplement to the National Health Interview Survey (NHIS). States have also monitored this goal with their own methods.

In 1994, CDC decided to centralize the collection of immunization coverage data for preschoolers in each state and certain urban areas. The purposes CDC cited for this effort included monitoring state progress in achieving childhood immunization objectives, permitting comparison of current coverage rates across states, and awarding incentive funds available to CDC grantees based on their immunization of certain percentages of preschool children.

Thus, to augment the national estimates provided by the NHIS, in 1994, CDC initiated the National Immunization Survey (NIS) to produce current and comparable immunization coverage estimates for children aged 19 to 35 months in each state and 28 urban areas receiving CDC funds to implement immunization action plans (IAPS).¹ (See appendix II.) Unlike the NHIS, which is a face-to-face household survey, the NIS is conducted by telephone. Unlike the other state immunization surveys, the NIS is conducted under a federal contract jointly managed by CDC's National Immunization Program (NIP) and National Center for Health Statistics (NCHS) and financed directly by the CDC rather than through the grant funds received by each state and urban area. CDC has noted that the NIS is the largest survey ever conducted to assess vaccination coverage levels of children in the United States.

¹The decision to develop coverage estimates for children up to 35 months is grounded in methodological realities rather than disease prevention objectives. The NHIS sample reaches only a limited number of households with children; thus, to allow a sufficient sample size, the immunization supplement measures coverage in children up to 35 months. Other age ranges might have been chosen in designing the NIS; however, this age range was carried over from the design for the NHIS.

Although national, antigen-specific immunization rates are generally high, there are still areas and communities at continued risk of disease outbreaks (sometimes called “pockets of need”) because they have concentrations of children who have not received timely immunizations.² This report responds to your request that we assess (1) the cost of the NIS, (2) the methods used by CDC to conduct the survey, and (3) the utility of the survey in identifying “pockets” of children in need of more timely immunization.

Results in Brief

The cost of the NIS for the most recently completed fiscal year—1995—was about \$13 million, using estimates provided by the Department of Health and Human Services (HHS) on the costs of the data collection contract and other survey-related expenditures. These expenditures are large relative to the incentive awards the survey results are used to distribute, for which approximately \$33 million was available in fiscal 1996. For fiscal 1997, CDC has requested \$16 million for the survey and its administration, as it requested and received in fiscal years 1995 and 1996. However, even with the extraordinary expenses incurred in 1995, survey costs did not reach \$16 million.³ CDC officials indicated that the balance of funds received for the NIS (about \$3 million) was spent on other assessment activities. However, we did not independently verify this statement.

With respect to survey methodology, a number of difficulties are inherent in applying telephone survey methods to the estimation of preschool immunization coverage. Although the random-number telephone survey permits rapid centralized data collection, it also has some widely recognized weaknesses, including the exclusion of households that lack a telephone, lower response rates than typify other survey methods, and inefficiencies in identifying particular types of households. Recognizing the biases inherent in the survey technique and problems with respondents’ recall of children’s immunization history, CDC has made various adjustments to the results of the NIS. The accuracy of the coverage estimates, consequently, depends to some extent on the validity of a highly complex set of assumptions undergirding these adjustments.

The precision of survey estimates and their narrow range raise additional concerns about the utility of this approach. The precision of survey

²See U.S. General Accounting Office, *Vaccines for Children: Reexamination of Program Goals and Implementation Needed to Ensure Vaccination* (GAO/PEMD-95-22; June 15, 1995).

³In fiscal 1995, CDC had to reinterview fiscal 1994 survey respondents in order to obtain their consent to contact their children’s immunization providers.

estimates (or their “margin of error”) governs the survey’s capacity to detect differences in immunization coverage levels over time and across immunization projects. For a variety of reasons, coverage estimates did not achieve planned levels of precision, and the survey can detect only very large changes from quarter to quarter. Moreover, although large differences were anticipated across states, the range of actual results is comparatively narrow. It is doubtful that the precision of survey estimates is adequate for detecting the modest changes that occur from year to year in most coverage levels. Yet CDC uses the survey to measure, quarterly, states’ progress toward early childhood immunization objectives and to reward, annually, those that have reached the highest levels of coverage.

Finally, CDC officials told us that the NIS was not designed to identify pockets of children in need of more timely immunization, and consequently, it does not do so. HHS officials indicated that their previous statement to the contrary was in error.⁴ Furthermore, the NIS was not designed to suggest specific programs or interventions to boost immunization rates, and our survey of state immunization program managers confirmed that it did not.

The survey was never intended to identify pockets of children in need of more timely immunization, and state estimates are higher and closer together than originally anticipated. Moreover, in view of the survey’s cost and its methodological limitations for the purposes of comparing state performance, monitoring progress toward immunization objectives, and distributing incentive funds, we have serious concerns about its utility and efficiency. At your request, we are continuing to study the various means of identifying pockets of need.

Background

CDC’s Immunization Program

The CDC’s National Immunization Program provides grants to states and 28 urban IAP areas for the purpose of controlling vaccine-preventable diseases. The Congress made available at least \$142 million for these grants in fiscal 1995. The portion of these funds received by a particular grantee is based largely upon the amount received the previous year. In addition to these funds, consistent with statements of the Senate Appropriations Committee, CDC has awarded annual incentive grants to

⁴See Office of the Assistant Secretary for Management and Budget, “Department of Health and Human Services: The Fiscal Year 1997 Budget,” March 19, 1996, p. 28.

states since fiscal 1994 to improve the immunization levels of 2-year-olds.⁵ For awards in fiscal 1994, CDC allocated incentive grants based on state-supplied estimates of the percentage of fully immunized 2-year-olds. To establish a common basis for awarding subsequent grants and to monitor progress toward early childhood immunization objectives, the CDC designed, and starting in fiscal 1994 began to conduct, the National Immunization Survey. In fiscal 1996, \$33 million was allocated for such incentive grants.

States' Previous Methods for Measuring Immunization Among Preschoolers

With the advent of the NIS, states had no further obligation to produce statewide coverage estimates and were able to use the grant funds formerly devoted to such measurement for other activities. However, most states' former methods for estimating immunization coverage were much less expensive than the NIS, which CDC has heretofore financed at no cost to the states. Lately, CDC has made inquiries of state health officers regarding their willingness to devote certain percentages of grant funds to support the NIS (see p. 9).

To meet CDC's former requirement for measuring preschoolers' immunization coverage, all states used either school retrospective surveys or other population-based methods to estimate immunization coverage. Most states estimated immunization coverage among preschoolers through reviewing the immunization records of children entering first grade or kindergarten to determine whether their immunizations were up-to-date when the children were younger, typically when they were 2 years old.

This method has both disadvantages and advantages. It produces estimates that are about 3 years old by the time the data are gathered, and immunizations may be selectively collected on school records relative to the minimum state requirements for school entry, which vary to some extent across states and may not include the newer vaccines.⁶ Because the retrospective method uses data that are already collected for the purpose of verifying immunization at school entry, it is fairly inexpensive and enables some states to develop estimates of immunization coverage at

⁵S. Rept. 143, 103d Cong., 1st Sess. 63 (1993), accompanying the fiscal 1994 HHS appropriation; S. Rept. 318, 103d Cong., 2d Sess. 56 (1994), accompanying the fiscal 1995 HHS appropriation; and S. Rept. 145, 104th Cong., 1st Sess. 53 (1995), accompanying the fiscal 1996 HHS appropriation.

⁶See T.V. Murphy, P. Pastor, S.B. Turner, et al., "Estimating immunization coverage from school-based childhood immunization records," *Pediatric Infectious Disease Journal*, 14:7 (1995), 561-67.

substate levels for the use of counties or state health districts.⁷ Records for those immunizations required for school entry should provide more accurate dates of immunization than can be obtained in interviews with parents, who frequently do not have ready access to immunization information.

Those states that did not use the retrospective method used others, such as birth certificate surveys and registry-based methods, that required more original data collection than the retrospective survey, but produced more current coverage estimates while providing the states with other benefits or additional information about their specific activities. In 1995, CDC dropped its requirement that grantees produce an independent assessment of preschool immunization coverage with the view that the estimates from its new NIS would supplant the data that had formerly been gathered by grantees.⁸

Sources of Survey Error

In general, in assessing the quality of survey findings, analysts should consider a variety of types of error that may affect a survey result.⁹ These include errors that arise because (1) surveys only involve a sample of the population of interest, (2) some of the sampled individuals may not respond to the survey, and (3) some of the population of interest may not be covered by the group from which the sample was chosen. In addition, there are problems associated with interviewers, the respondent, or the questionnaire, such as unclear questions or respondents' difficulty in recalling the answers. What is commonly quoted in the reporting of poll results as the "margin of error," typically plus or minus 3 percent for a random sample of 1,500, represents only the error attributable to the first factor named above. Assessing the quality of survey results also requires

⁷See L.E. Rodewald, K.J. Roghmann, P.G. Szilagyi, et al., "The school-based immunization survey: An inexpensive tool for measuring vaccine coverage," *American Journal of Public Health*, 83:12 (1993), 1749-51.

⁸Some states have continued to conduct the retrospective survey to preserve the capacity to compare current coverage levels against older data derived from retrospective methods. The retrospective surveys generally measure immunization coverage on the 2nd birthday (24 months), while the NIS measures immunization coverage between 19 and 35 months of age. Since the measured immunizations are due by 18 months, the estimates provided by the NIS are based on an age range allowing a median of 9 (and as many as 17) additional months to obtain immunizations, while the retrospective surveys allow only 6 additional months to reach up-to-date status. Consequently, the estimates of up-to-date rates derived from the NIS will tend to be higher owing to methodological differences between the surveys rather than changes in the immunization status of preschoolers. It should also be noted that the NIS measures immunization coverage in areas (states and cities) defined by political boundaries. Very different coverage estimates may emerge from surveys of particular areas or populations incorporated in these states and cities.

⁹See P.E. Converse and M.W. Traugott, "Assessing the accuracy of polls and surveys," *Science*, 234 (1986), 1094-98.

considering the extent to which the other sources of error may have affected the accuracy of survey findings.

Scope and Methodology

To respond to your request, we met with officials of the National Immunization Program and the National Center for Health Statistics and with staff of the CDC contractor conducting the National Immunization Survey. We reviewed documents describing the structure, performance, and results of the survey. We also reviewed literature on telephone survey methodology and parental recall of children's immunization status. The methodology report for the 1995 survey was not available as of June 18, 1996, when we conducted our exit conference with CDC, and thus, our review of survey methodology was limited to the procedures employed in the 1994 survey and reports of NIS findings issued through June 1996. We understand from NCHS officials that, since issuance of the 1994 methodology report, procedures for using provider data to adjust survey results have been documented and sensitivity analyses have been conducted to measure the impact of changes in various assumptions inherent in the adjustment of survey results.

To provide information on survey costs, we requested that agency officials provide data on total payments under the survey contract and estimates of the costs of related agency activities. We also reviewed the survey contract and trends in the costs billed under the contract. We did not independently verify the payments for the survey or the CDC cost estimates, though we did review the invoices from the survey contractor and assess the agency's cost estimates for their consistency with the activities the agencies conducted. With this exception, our work was conducted in accordance with generally accepted government auditing standards between March 25 and June 18, 1996.

Finally, we surveyed state immunization program managers regarding how they had used the results of the NIS and their costs for previous survey approaches. In addition, CDC provided a list of six former CDC contractors, officials, and current grantees that they recommended we contact. We contacted some of these individuals and asked them to provide comments consistent with their familiarity with the survey's cost and methodology.

Principal Findings

Survey Costs

The cost of the survey includes three major components—expenditures under the contract issued to conduct the survey and the costs of survey-related activities conducted by NCHS and NIP. Both NCHS and NIP were involved in managing the data collection contract and providing statistical analysis of survey data. In addition to these roles, NIP gathered and reviewed data from the survey respondents' immunization providers. When problems with survey software created a need for a larger interviewing staff, some work was done by the Bureau of the Census, but costs for this work are included in estimates provided by NCHS. Table 1 shows the costs of the NIS contract, survey assistance provided by NCHS and the Bureau of the Census, and NIP's survey-related activities. Only two quarters of data were collected in fiscal 1994; 1995 was the first fiscal year in which the survey operated in all four quarters. Extraordinary expenses were incurred in fiscal 1995 when the agency discovered it needed to reinterview 1994 survey participants in order to identify their immunization providers.

Table 1: Estimates of Total NIS-related Expenditures^a

Fiscal year	Cost			Total
	Survey contract ^b	NCHS and Census Bureau ^c	NIP ^d	
1994 (2 quarters) ^e	\$4.0	\$1.8	\$0.1	\$5.9
1995 (4 quarters)	11.3	1.2	0.4	12.9
1996 (2 quarters) ^f	4.9	0.7	0.2	5.8
Total (8 quarters)	\$20.2	\$3.7	\$0.7	\$24.6

^aIn millions.

^bBased on an NCHS summary provided to us in April 1996. These amounts cover contractor billings through March 30, 1996.

^cEstimates taken from an NCHS summary memo on administrative costs provided to us in April 1996. For purposes of consistency, the estimate provided for fiscal 1996 has been halved in order to approximate the costs for the first two quarters.

^dRevised estimates provided to us by NIP on June 17, 1996.

^eJanuary 1, 1994 to September 30, 1994; in fiscal 1994, only two quarters of survey data were collected (between April and September).

^fFirst two quarters of fiscal 1996.

Source: Data from NCHS and NIP.

The contract to conduct the NIS provides the recipient with a fixed fee and all reasonable costs for conducting the survey. Expenditures under the survey contract have risen at twice the rate anticipated at its signing, reaching nearly the full face amount of the contract halfway through the 54-month performance period. Contractor and agency representatives attribute the higher rate of expenditures to difficulties arising from the need to replace survey management software; the higher-than-expected number of calls required to identify households in the sampling frame; and the addition of a study to check parents' responses against provider records, which increased the complexity of estimating survey results because of the need to adjust them with provider-derived information. The number of calls required to identify eligible households will continue to be an important determinant of survey costs.

According to estimates from CDC and invoices from the contractor, costs for the NIS have been roughly \$25 million through March 30, 1996, including the \$13 million for fiscal 1995, the first complete year of data collection. Insofar as a number of extraordinary expenses were incurred in fiscal 1995, CDC officials anticipate that final survey costs will decrease in fiscal 1996 and future years. However, for fiscal 1997, the agency has requested \$16 million for the survey and its administration, as it requested and received in fiscal years 1995 and 1996 based on expenditures in the early implementation stage of the survey. CDC officials indicated that the balance of funds received in 1995 for the NIS (about \$3 million) was spent on other assessment activities, such as the NHIS and its provider record check study, the Clinic Assessment Software Application, and the provision of technical assistance to the states. However, we have not independently verified this information.

In its report accompanying the fiscal 1996 appropriations, the Senate Appropriations Committee noted its concern that the national findings of the NIS duplicate the findings from the NHIS and that the annual cost of the survey cannot be justified by its utility.¹⁰ The Committee noted particularly that the survey does not provide significant information on high-risk communities for targeting purposes, and in some respects, it duplicates surveys conducted by each state. In the justification for its fiscal 1997 budget request, CDC acknowledged these concerns and noted that it was holding ongoing discussions with, among others, the Association of State and Territorial Health Officials (ASTHO) and the Council of State and Territorial Epidemiologists in which "various options related to the NIS" were being considered.

¹⁰S. Rept. 145, 104th Cong., 1st Sess. 55 (1995).

For example, CDC explored with ASTHO the level of willingness among state health officers to finance the survey through state grant funds distributed by CDC rather than directly through CDC appropriations. However, ASTHO surveys of its members found that many of the larger states and urban areas were not prepared to devote 6-10 percent of their immunization infrastructure grants to support of the survey.¹¹ This is consistent with the findings of our survey of state immunization program managers, which indicated that while the NIS findings were widely used to communicate with the news media and respond to legislative inquiries, they were not used by most states for targeting their activities or designing interventions.¹²

Methodological Challenges

Survey Design Incorporates Inefficiencies

NIS surveyors identify households with children between 19 and 35 months old by dialing random telephone numbers and asking a short set of screening questions to assess the presence of children in the correct age range. Surveyors ask for the number of doses of various vaccines the child has received and a variety of demographic information. Even with sampling refinements implemented by the contractor, only a small proportion of randomly generated telephone numbers results in contacting a residence that includes children between 19 and 35 months old. CDC reported that roughly 1.2 million telephone numbers were called to complete 25,247 interviews during the first three quarters of data collection (47 numbers per respondent, with an average of 4-5 calls per number required to reach a respondent). Thus, roughly 200 calls are initiated per completed interview. In view of the size of this undertaking, there was some thought at the time the survey was planned of using it to gather additional health data, but these plans never came to fruition and the final survey addressed only immunization issues.

With the view that the data provided by parents and other household contacts would be sufficient to produce accurate immunization coverage estimates, the NIS was initially designed as a telephone survey of households using a modified random digit-dialing technique. When it later became clear that the data derived from household interviews would not, on their own, be sufficient to produce accurate estimates of immunization

¹¹The total financing available from those who indicated a willingness to support the NIS through the donation of 10 percent of infrastructure funds was \$4.6 million.

¹²Thirty-four states told us they had not used the NIS results to target program activities, and 36 told us they had not used them to design programs or interventions.

coverage, a second phase of the survey was added—the Provider Record Check Study. In this second phase, household contacts are asked for the names of medical providers, who are then approached for independent information on the dates of immunization for children identified through the household survey. Thus, to some extent, the NIS was reconceptualized as a survey of providers using a two-phase design. However, two-phase designs are usually most efficient

“only when the first-phase element survey costs are smaller than those for the second phase by a large factor . . . [as when] the first-phase sample identifies the members of the rare population inexpensively, and the survey items are then collected from them in the second phase.”¹³

For the NIS, the reverse is true. It appears that CDC is spending a large sum of money on the first phase of the survey, which provides low-quality immunization data but identifies the sample for the second phase, which provides high-quality immunization data from provider records, albeit for a smaller number of children. Although the provider-supplied data improves the accuracy of survey results, earlier recognition of the problems with relying solely on household data might have led to consideration of more efficient data collection methods.

As of June 1996, summary coverage estimates had been published for the first five quarters of NIS data collection (April 1994-June 1995).¹⁴ CDC shares the survey results with state programs shortly before their publication in *Morbidity and Mortality Weekly Report*. Thus, the survey findings are available to states and the general public about a year after data are collected.

Households Without a Telephone Are Excluded From the Survey

The telephone survey technique that CDC adopted for the NIS has certain inherent biases, notably exclusion of any household without a working telephone. The Department of Commerce’s National Telecommunications and Information Administration has recently noted that more than 6 million households still lack a telephone and that low-income and minority communities are substantially below the national average for

¹³Graham Kalton, *Introduction to Survey Sampling* (Beverly Hills, Calif: Sage, 1983), p. 48.

¹⁴See CDC, “State and national vaccination coverage levels among children aged 19-35 months—United States, April-December 1994,” *MMWR*, 44 (August 25, 1995), 613, 619-23; “National, state, and urban area vaccination coverage levels among children aged 19-35 months—United States, April 1994-March 1995,” *MMWR* 45 (February 23, 1996), 145-50; and “National, State, and Urban Area Vaccination Coverage Levels Among Children Aged 19-35 Months—United States, July 1994-June 1995,” *MMWR*, 45:24 (June 21, 1996), 508-13.

telephone penetration.¹⁵ The methodology report prepared for NCHS by the survey contractor notes that

“The high nontelephone noncoverage rates in many of the IAP areas and the large differences between telephone and nontelephone children’s vaccination rates indicate that the potential for noncoverage bias is considerable in several IAP areas. Any candidate estimation technique for the NIS must recognize this potentially large bias, and attempt to adjust for differences between the telephone and nontelephone groups.”¹⁶

Appendix III shows the estimated percentage of households with a 2-year-old child that lack a telephone in each of the IAP areas, and table 2 provides national data from the 1992 and 1993 National Health Interview Surveys detailing the difference in reported immunization rates between children in households with and without telephones.

Table 2: NHIS Estimates of Children With Up-To-Date Immunizations in Households With and Without Telephones^a

Respondents have a shot card?	1992			1993		
	With a telephone	Without a telephone	Total	With a telephone	Without a telephone	Total
Yes	64.8%	47.8%	62.9%	65.2%	49.1%	63.6%
No	53.3	38.3	52.3	71.3	58.1	70.2
Total	58.2	42.3	56.6	68.6	53.9	67.3

^aUp-to-date immunization is defined as the receipt of at least 4 doses of diphtheria and tetanus toxoids and pertussis vaccine/diphtheria and tetanus toxoids, 3 doses of oral polio virus vaccine, and 1 dose of measles-mumps-rubella vaccine.

Source: Abt Associates, Inc., The National Immunization Survey (NIS) 1994 Annual Methodology Report, chapter VIII, table 1. (Submitted to NCHS under contract no. 200-94-7009.)

Although only about 5 percent of all U.S. households lack a telephone, the absence of one is more than twice as common in households with children under 2 years old (11.7 percent). However, these national data mask the wide variation among IAP areas in the percentages of households with children under 2 lacking telephones, which ranges from 2 to 25 percent across the 50 states and 28 urban IAP areas. Exclusion of households without a telephone requires that the survey results be adjusted to account for the positive bias that may result. However, there is no consistent source of information on the immunization rates among children in

¹⁵See National Telecommunications and Information Administration. *Falling Through the Net: A Survey of the “Have Nots” in Rural and Urban America* (Washington, D.C.: U.S. Department of Commerce, July 1995).

¹⁶See Abt Associates, Inc., The National Immunization Survey (NIS) 1994 Annual Methodology Report, prepared for the National Center for Health Statistics and the National Immunization Program of the Centers for Disease Control and Prevention under contract no. 200-94-7009, p. 159.

households without telephones in each area where the NIS is conducted. Consequently, the adjustment for noncoverage of children without telephones is based on a complex procedure involving the application of a statistical model of the probability that a fully vaccinated child in a related national survey resides in a household with a telephone. It is not possible to know whether these adjustments are accurate in each of the states and urban areas covered by the NIS.

Response Rates Vary Widely

The response rate is the estimated proportion of the target group (in this case, households with telephones and age-eligible children) that actually provided data.¹⁷ This rate is important in evaluating survey findings because, to the extent that nonrespondents might have answered differently from those who completed the survey, a large nonresponse rate indicates that survey findings will incorporate bias and require adjustment. For example, CDC analyses of NIS respondents indicated that, as a group, they differed in some respects from census and vital statistics estimates for the population; they slightly overrepresented mothers with more than 12 years of education and in some areas were more likely to report household incomes exceeding \$50,000 and less likely to report income below \$10,000. Thus, answers from those types of respondents who tended to be underrepresented were weighed more heavily in adjusting survey results to arrive at final coverage estimates. Such adjustments will remove bias to the extent that immunization coverage is similar between respondents and demographically similar nonrespondents. However, there is no clear way to test this assumption in the various areas surveyed.

For the calendar year 1994 survey, contractors estimated that the overall response rate was 69.5 percent. Appendix III identifies the overall response rates reported for each surveyed area. Although households determined to be eligible through their completion of the screening questions had high rates of cooperation with the full interview, they represented a smaller portion of the potential households than would have been expected based on census data, indicating that some 17.3 percent of eligible households with telephones were never reached, refused

¹⁷Assessing the extent of error introduced by nonresponse is somewhat complicated in a random digit-dialing telephone survey of the type employed for the NIS. This is true because surveyors are not simply calling a list of houses with children in the appropriate age range, but a list of random telephone numbers. If every telephone number drawn into the sample could be categorized according to its business or residential status and, if residential, according to whether the household included a child in the appropriate age range, calculation of response rates would be a simple matter. However, nonresponse may occur well before this is accomplished, as when a sampled number results in reaching an individual who hangs up before any information can be gathered. Some of these instances may represent eligible households who refused participation before it could be determined that they contained children in the correct age range. Others may represent numbers that did not belong to households, but to businesses or numbers that were not assigned.

cooperation during the screening phase, or inaccurately responded to the questions about age-eligible children. Although a response rate in this range is not atypical of telephone surveys, nonresponse rates tend to run higher for telephone interviewing than for personal visitation.¹⁸ Also, while overall response rates varied tremendously across states and urban areas, nonresponse to particular questions ranged as high as 26 percent. When combined, these factors sometimes reduce to below 50 percent the effective response rates for key questions (for example, how many times has your child received a polio vaccine?), raising concerns about the accuracy of resulting estimates.

Household Respondents Have Difficulty Providing Accurate Data

The potential to use household surveys for the collection of childhood immunization data is limited by the accuracy with which household respondents can supply information on children's immunization status.¹⁹ Data available to CDC before the initiation of the NIS, including a report commissioned by the agency in 1975 to review the United States Immunization Survey, questioned the assumption that parents could accurately recall immunization history.²⁰ Even as the NIS was initiated in 1994, NCHS had a study in progress to assess the accuracy of responses to the immunization supplement of the NHIS.²¹ It is well documented that

¹⁸See, for example, NCHS, An Experimental Comparison of Telephone and Personal Health Interview Surveys, Data Evaluation and Methods Research, Series 2, No. 106 (Washington, D.C.: U.S. Government Printing Office, August 1987).

¹⁹See, for example, K.P. Goldstein, F.J. Kviz, and R.S. Daum, "Accuracy of immunization histories provided by adults accompanying preschool children to a pediatric emergency department," Journal of the American Medical Association, 270:18 (1993), 2190-94. This study indicated that only 8 percent of adults questioned in an inner-city emergency room could accurately recall how many of each vaccine their preschool child had received and that many did not know whether the child had received a measles vaccination despite a recent epidemic in the city. See also M.D. Joffe and A. Luberti, "Effect of emergency department immunization on compliance with primary care," Pediatric Emergency Care, 10:6 (1994), 317-19.

Reports from other countries include: M.A. Soljak, "How many children are fully immunised?" New Zealand Medical Journal (January 25, 1984), 37-39; P. Hawe, A. Wilson, P. Fahey, et al., "The validity of parental report of vaccination as a measure of a child's immunisation status," The Medical Journal of Australia, 155 (1991), 681-86; P.A. McKinney, F.E. Alexander, C. Nicholson, et al., "Mothers' reports of childhood vaccinations and infections and their concordance with general practitioner records," Journal of Public Health Medicine, 13:1 (1991), 13-22; and J.J. Valadez and L.H. Weld, "Maternal recall error of child vaccination status in a developing nation," Journal of the American Public Health Association, 82:1 (1992), 120-22.

²⁰See J. Bean, L. Burmesister, P. Isaacson, et al., "Estimation of Community Immunization Levels," report based on CDC Grant No. 21-74-545 (PIC ID number 0436), July 1, 1975. The specific recommendations of this study of the methods used in the United States Immunization Survey included, "To institute as soon as practicable additional studies of validity of immunization history by both record search and comparison with serum antibody levels."

²¹Elizabeth R. Zell, James T. Massey, and Trena M. Ezzati-Rice, "An Overview of the National Health Interview Survey and the State and Local Area Immunization Coverage and Health Survey," presented at the National Immunization Conference, Los Angeles, May 1995.

survey respondents have trouble accurately recalling the occurrences of, distinctions among, and number of, events that are not particularly salient, or that are similar in nature, or that are repeated more than a few times over a long time period. As a result, when surveyed, they sometimes forget when the events occurred and are confused as to how many of which types of events occurred. As a rule, if events are socially desirable, respondents tend to overreport them.

The NIS asks about the receipt of 14 different immunizations, given in repeated sets, varying in number, over a 1- to 3-year period. Respondents may not understand the differences among the various types of shots and probably consider getting shots socially desirable. As noted, these elements are among the factors associated with inaccurate reporting. To the extent that a parent is able to answer from an up-to-date vaccination record, few of these errors would occur, but significant portions of NIS respondents did not have a shot card and consequently reported from memory.²² Others apparently used shot cards that were not up-to-date.

In December 1994, after the first two quarters of NIS data collection, CDC acknowledged the need to check parents' responses against provider records. At that time, NCHS had determined from its surveys assessing the accuracy of parental responses to immunization questions in the NHIS that household respondent reports of vaccinations contain a number of errors that result in underestimation of the "true" vaccination coverage levels. NCHS concluded that, although respondent information was necessary for estimation and demographic analysis, household respondent records of immunizations are often not sufficiently up-to-date to provide accurate information, errors in reports from recall exist, and the household information must be adjusted using provider data. Using the findings from the NHIS substudy, NCHS and NIP attempted to adjust the NIS estimates. However, these adjustments resulted in estimates that did not differentiate the IAP areas. Therefore, CDC determined that a provider substudy similar to the one being conducted in connection with the NHIS was needed to produce accurate vaccination coverage level estimates from the NIS. We reviewed the level of agreement between household reports and physician records from the NIS substudy and confirmed that it was generally only "poor" or "fair" based on the application of recognized statistical criteria.²³

²²As combination vaccines are introduced and children receive immunizations on an increased variety of schedules, the task of obtaining accurate data on receipt of particular antigens from records or recall may increase in complexity.

²³See D.G. Altman, *Practical Statistics for Medical Research* (New York: Chapman and Hall, 1991), p. 404.

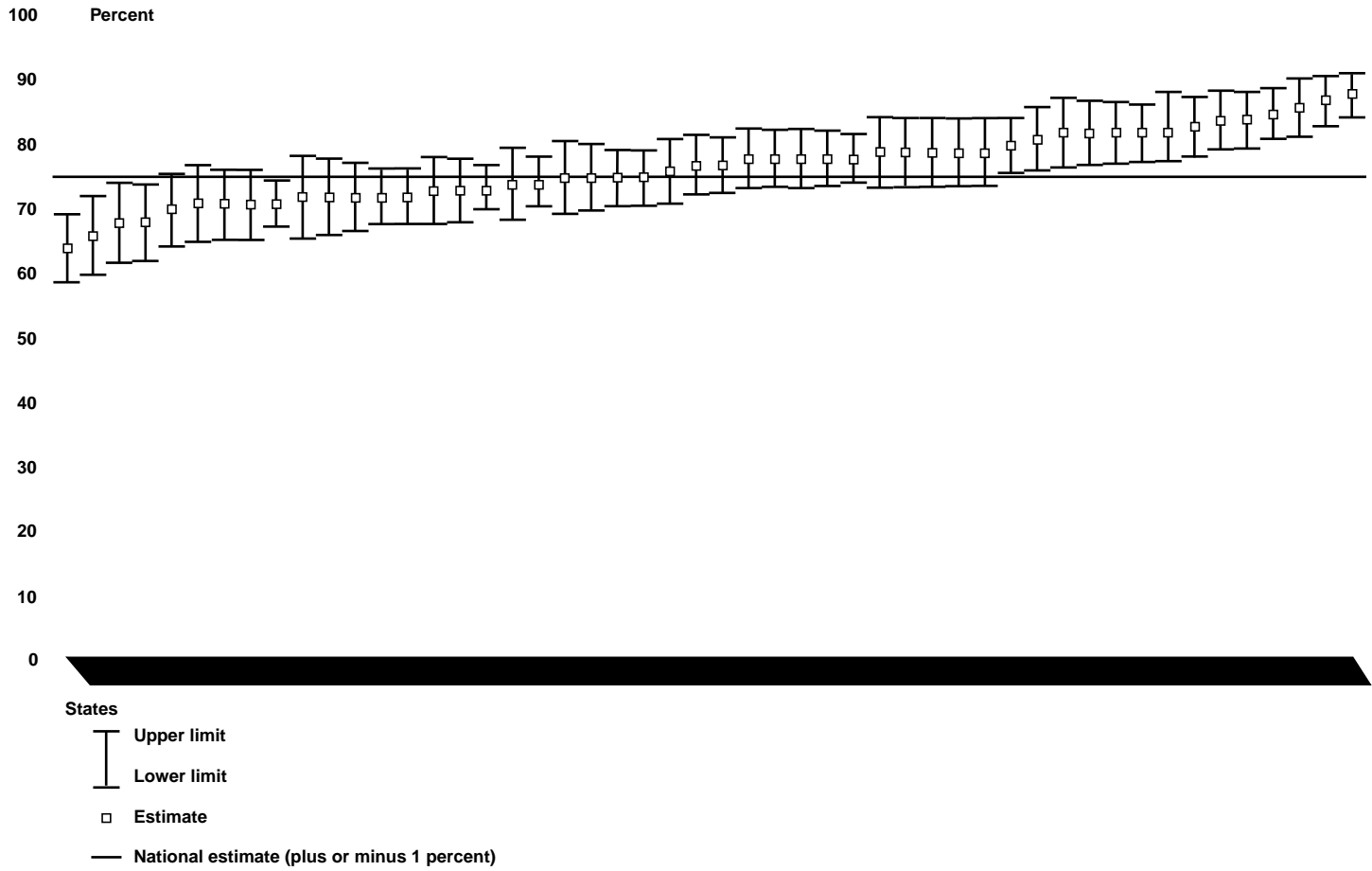
Coverage Estimates Failed to Meet Desired Levels of Precision

Earlier recognition of this problem might have led to more serious consideration of other survey methods.

The survey plan called for precision of plus or minus 5 percent for a coverage estimate of 50 percent, meaning that the margin of error would have been narrower for more extreme coverage estimates. Owing to various factors, the actual estimates produced by the survey in its first year had margins of error that were often larger. As these margins of error increase, the survey's capacity to detect changes in immunization coverage decreases: it becomes more difficult to distinguish a change of a particular size from simple error in the estimates.

CDC officials have indicated that the survey is useful in that it permits them to rank states and helps to motivate the lower ranking states to take positive action to improve immunization coverage. However, partly because survey estimates did not meet planned levels of precision, there appear to be remarkably few differences across states. For example, for the most recently published four quarters of NIS data (quarter 3 of 1994 through quarter 2 of 1995), in 31 states, the estimated percentage of children up-to-date in their immunizations could not be statistically distinguished from the national percentage of children up-to-date. (See figure 1.)

Figure 1: Estimated Percentages of Children in Each State Whose Immunizations Are Up-To-Date and 95-Percent Confidence Boundaries for Each Estimate^a



^aFrom July 1994 through June 1995 for children 19-35 months old. Up-to-date immunization is defined here as having received at least 4 doses of diphtheria and tetanus toxoids and pertussis vaccine/diphtheria and tetanus toxoids, 3 doses of oral polio virus vaccine, and 1 dose of a measles-mumps-rubella vaccine.

Source: Based on NIS data published in "National, State, and Urban Area Vaccination Coverage Levels Among Children Aged 19-35 Months—United States, July 1994-June 1995," *MMWR*, 45:24 (June 21, 1996), 508-13.

Moreover, the survey is unlikely to show change from quarter to quarter. The Final Sampling Plan for the survey notes, “it will only be possible to detect very large changes between adjacent annualized estimates.” For example, a move from 50- to 70-percent coverage would have been the smallest detectable change had the planned level of precision been achieved.²⁴ As a result, there are no statistically significant changes in full coverage across the first three sets of survey results published by CDC for any of the 78 states or urban areas surveyed.

The smallest change that the survey is likely to detect between successive years for a particular IAP area (for example, quarters 1-4, 1995, versus quarters 1-4, 1996) may in some areas approach the size of the largest change observed between successive years in recent years’ data from the NHIS for antigens that had been recommended before every child in the survey cohort was born.²⁵ Thus, even if changes of a typical size were occurring, the survey results might create the false impression of a lack of progress. At a minimum, the survey’s broad margins of error indicate that reporting such statistics each quarter is neither necessary nor advisable. Moreover, the imprecision of the survey estimates combined with their narrow range raises questions about whether the survey provides an improved basis for distribution of incentive funds across states.

NCHS officials acknowledged that they had considered reporting the results only semi-annually. However, even this may be too frequent. For those vaccines that have been recommended for a number of years—measles, polio, 3 doses of diphtheria, tetanus, and pertussis—coverage is 80 percent or higher, limiting the size of any increases that might occur.

Identification of Pockets of Need

CDC officials have indicated that they view identification of pockets of children in need of more timely immunization as a state responsibility rather than a federal one. Although a departmental statement accompanying the fiscal 1997 budget request had indicated the NIS would be useful in identifying pockets of need, HHS officials told us that the statement was in error. CDC has indicated that the National Immunization Survey was not designed to identify such “pockets of need,” and consequently, it does not do so. Our survey of state immunization program

²⁴See Abt Associates, Inc., State and Local Area Immunization Coverage and Health Survey: Final Sampling Plan (March 7, 1994), p. 19. (Submitted to NCHS under contract no. 200-94-7009.)

²⁵For more newly recommended vaccines, such as Hib and Hep-B, the NHIS has estimated that coverage only increased 15 and 14 percent, respectively, from the third quarter of 1993 to the second quarter of 1994. Sales or distribution reports might also be used to monitor uptake of newer vaccines.

managers confirmed that they generally drew upon other data for this purpose.

Instead, the primary objectives CDC has for the NIS have been monitoring state progress in achieving childhood immunization objectives, permitting comparison of current coverage rates across states, and awarding incentive funds available to CDC grantees based on their immunization of certain percentages of preschool children. In this connection, we note that the accomplishment of national immunization goals is simultaneously tracked through supplements to the NHIS and that the cost of mounting the NIS (roughly \$13 million in fiscal 1995) has been large relative to the total amount of incentive funds it is used to distribute (\$33 million in fiscal 1996). We have noted above the survey's limitations for monitoring changes in immunization coverage.

Although the NIS can produce national statistics for some nongeographically defined subgroups, the sample size of the NIS is not large enough to provide subgroup statistics for each state or urban area. On a national basis, the NHIS provides these same subgroup statistics with the exception of immunization coverage estimates for persons of Hispanic and Asian origin. CDC has suggested that the NIS can be used to evaluate immunization activities; however, the NIS does not currently collect information that could link immunization coverage to specific programs. For example, CDC has encouraged immunization among in participants in the Special Supplemental Food Program for Women Infants, and Children (WIC). However, state estimates of immunization coverage by WIC participation derived from the NIS would have unacceptably large sampling error unless the survey sample size were increased at substantial expense.

Conclusion and Matters for Consideration

We have not had the opportunity to assess the NIS in light of the list of additional purposes for the survey provided to us by HHS after our exit conference on this study. Further, our survey of state immunization directors turned up anecdotal evidence that a few states view the NIS favorably even though they are unable to use it to target pockets of underimmunized children. However, while the NIS has provided estimates of current state-specific immunization levels for awarding incentive grants and monitoring progress toward early childhood immunization objectives, it has significant limitations when used for these purposes.

First, of the appropriation that it has requested for fiscal 1997, CDC has requested \$16 million for the survey and its administration. However, the

actual costs of the NIS are now expected to be between \$12 and \$13 million, and even these amounts would render it an inefficient method of allocating incentive grants expected to total \$33 million. Second, the NIS does not provide useful quarterly measurements of statewide immunization levels, and even annual estimates may not be suitable for monitoring the level of annual change that is likely to occur in immunization coverage. Third, the NIS does not assist in the systematic targeting of underimmunized children, a particular concern if HHS is to achieve levels of disease reduction and elimination established as goals for the end of this decade. To follow up on this report, we intend to continue to study the various means of identifying pockets of children in need of immunization.

State officials did make use of the NIS findings in communicating with their legislators and the press; however, these objectives could be met by previous methods at markedly lower cost. Moreover, the survey provides only a statewide or citywide indicator of immunization coverage. Insofar as this indicator is not linked to any specific component of the unique set of immunization initiatives pursued by a particular CDC grantee, it is not surprising that it is not useful in helping states to diagnose problems in their ongoing activities, target their efforts, or design interventions.

CDC has also stressed the motivational benefit of ranking states. Apart from the concerns we have raised about the survey's capacity to rank states, it is difficult to quantify the benefits of this ranking.

In view of these limitations, the Congress may wish to reconsider the NIS's benefits relative to its cost. At a minimum, the Congress may want to ensure that the CDC appropriation reflects a more accurate estimate of the survey's cost.

Agency Comments

We provided a draft of this report to CDC officials for their comments, which are reprinted in appendix IV. CDC does not dispute the cost we reported for the NIS or that CDC's fiscal 1997 budget request for the survey exceeds by at least \$3 million the survey costs the agency anticipates in fiscal 1997. CDC disagrees with some of our findings regarding the survey's methodology and our suggestion that the Congress may wish to consider NIS' benefits relative to its costs. However, the agency bases some of its objections on statements that incorporate inaccurate representations of our findings regarding the validity of survey estimates and factual and technical errors, which we have identified in appendix IV.

CDC indicates that following our presentation of our findings to the agency in late June, we failed to assess all the benefits of the survey that they had identified. However, the additional benefits asserted by CDC after our work was completed break no new ground. Each of these putative benefits stems from the use of the survey findings to compare state performance, monitor changes in immunization coverage across time, or evaluate intervention efforts. However, with few exceptions, our findings cast doubt on the appropriateness or practicality of such uses of survey results in view of the survey's broad margins of error for particular states and urban areas, the generally high level of coverage for individual vaccines, and the difficulty of attributing changes across time or place to any particular causal factor.

CDC asserts that the survey provides an early warning of precipitous changes in immunization coverage; however, we are concerned that the survey may lend a false sense of security by obscuring the existence of substantial pockets of underimmunized children. For example, a recent household survey of central and southeast Seattle found an immunization coverage rate of 57 percent, in contrast to the 79 percent reported by the NIS for the King County area incorporating Seattle. Further, NIS data are not generally analyzed and released until a year after data collection. We agree with the CDC that the survey is technically capable of detecting changes in use of newly introduced vaccines, but CDC already monitors these changes on a national basis through its NHIS. Other means, such as sales and distribution reports, may be available for monitoring the initial uptake of newer vaccines at less expense.

Some data from the late 1980s indicated that immunization coverage levels in the preschool population were quite low and highly variable across areas. While the NIS might have been more useful under those circumstances, it appears the situation has changed. Coverage for particular diseases is now quite high, and coverage for long-recommended vaccines has not been highly variable across states. While the survey does provide more timely immunization coverage data than the retrospective surveys that were formerly used for such data collection, it does so at much higher cost. Thus, in the interest of using immunization resources most efficiently, we have suggested that the cost of collecting and analyzing these data be weighed against their continued utility.

As we agreed with your office, we are sending copies of this report to other interested congressional committees, the Secretary of HHS, the

Director of CDC, and other federal and state officials. We will also make copies available to others upon request.

If you have any questions or would like additional information, please contact me, at (202) 512-3092, or Sushil K. Sharma, Assistant Director, at (202) 512-3460. Other major contributors to this report are listed in appendix V.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Kwai-Cheung Chan'. The signature is fluid and cursive, with a large initial 'K' and a long horizontal stroke at the end.

Kwai-Cheung Chan
Director of Program Evaluation
in Physical Systems Areas

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Abbreviations

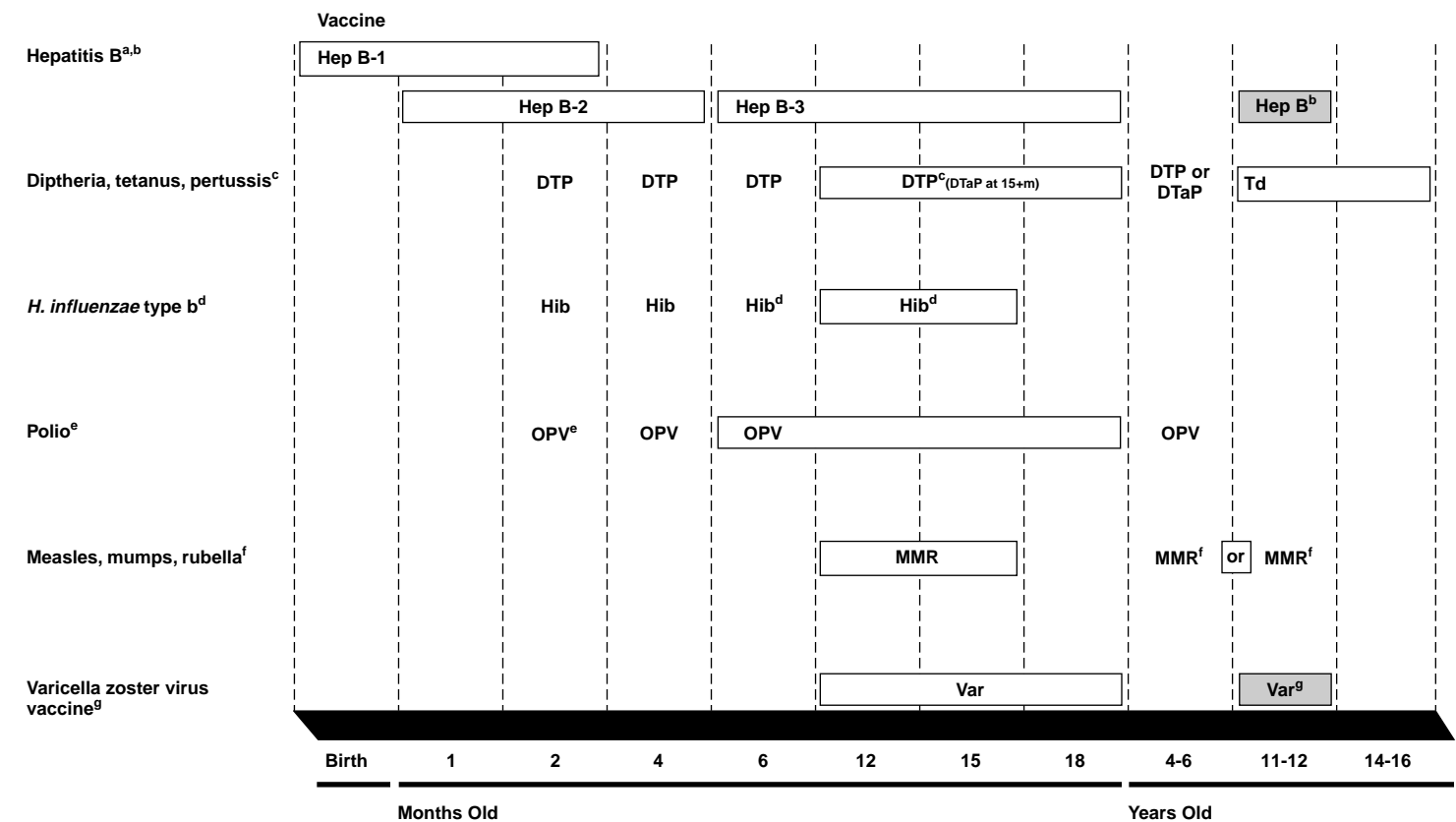
ASTHO	Association of State and Territorial Health Officials
CDC	Centers for Disease Control and Prevention
HHS	Department of Health and Human Services
IAP	Immunization action plan
NCHS	National Center for Health Statistics
NHIS	National Health Interview Survey
NIP	National Immunization Program
NIS	National Immunization Survey
WIC	Special Supplemental Food Program for Women, Infants, and Children

Recommended Childhood Immunization Schedule

This schedule was approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians.

Vaccines are listed under the routinely recommended ages. Bars indicate the range of acceptable ages for vaccination. Shaded bars indicate catch-up vaccination: at 11-12 years of age, hepatitis B vaccine should be administered to children not previously vaccinated, and varicella zoster virus vaccine should be administered to children not previously vaccinated who lack a reliable history of chicken pox.

Figure 1.1: Recommended Childhood Immunization Schedule for the United States, January-June 1996



Appendix I
Recommended Childhood Immunization
Schedule

^aInfants born to HBsAg-negative mothers should receive 2.5 µg of Merck vaccine (Recombivax HB) or 10 µg of SmithKline Beecham (SB) vaccine (Engerix-B). The 2nd dose should be administered 1 month after the 1st dose.

Infants born to HBsAg-positive mothers should receive 0.5 mL hepatitis B immune globulin (HBIG) within 12 hours of birth, and either 5 µg of Merck vaccine (Recombivax HB) or 10 µg of SB vaccine (Engerix-B) at a separate site. The 2nd dose is recommended at 1-2 months of age and the 3rd dose at 6 months of age.

Infants born to mothers whose HBsAg status is unknown should receive either 5 µg of Merck vaccine (Recombivax HB) or 10 µg of SB vaccine (Engerix-B) within 12 hours of birth. The 2nd dose of vaccine is recommended at 1 month of age and the 3rd dose at 6 months of age.

^bAdolescents who have not previously received 3 doses of hepatitis B vaccine should initiate or complete the series at the 11- or 12-year-old visit. The 2nd dose should be administered at least 1 month after the 1st dose, and the 3rd dose should be administered at least 4 months after the 1st dose and at least 2 months after the 2nd dose.

^cDTP4 may be administered at 12 months of age, if at least 6 months have elapsed since DTP3. DTaP (diphtheria and tetanus toxoids and acellular pertussis vaccine) is licensed for the 4th and/or 5th vaccine dose(s) for children aged 15 months and may be preferred for these doses in this age group. Td (tetanus and diphtheria toxoids, absorbed, for adult use) is recommended at 11-12 years of age if at least 5 years have elapsed since the last dose of DTP, DTaP, or DT.

^dThree H. influenzae type b (Hib) conjugate vaccines are licensed for infant use. If PRP-OMP (PedvaxHIB [Merck]) is administered at 2 and 4 months of age, a dose of 6 months is not required. After completing the primary series, any Hib conjugate vaccine may be used as a booster.

^eOral poliovirus vaccine (OPV) is recommended for routine infant vaccination. Inactivated poliovirus vaccine (IPV) is recommended for persons with a congenital or acquired immune deficiency disease or an altered immune status as a result of disease or immunosuppressive therapy, as well as their household contacts, and is an acceptable alternative for other persons. The primary 3-dose series for IPV should be given with a minimum interval of 4 weeks between the 1st and 2nd doses and 6 months between the 2nd and 3rd doses.

^fThe 2nd dose of MMR is routinely recommended at 4-6 years of age or at 11-12 years of age, but may be administered at any visit, provided at least 1 month has elapsed since receipt of the 1st dose.

^gVaricella zoster virus vaccine (Var) can be administered to susceptible children any time after 12 months of age. Unvaccinated children who lack a reliable history of chicken pox should be vaccinated at the 11- or 12-year-old visit.

Source: Adapted from American Academy of Pediatrics, Committee on Infectious Diseases, "Recommended Childhood Immunization Schedule," *Pediatrics*, 97(1), 143 and 145-a.

The Urban IAP Areas for Which the NIS Produces Immunization Coverage Estimates

The urban IAP project names are listed below in roman type; the names in bold identify the largest city in the IAP county project.

Atlanta, Georgia (Fulton/DeKalb Counties)
Baltimore, Maryland
Birmingham, Alabama (Jefferson County)
Boston, Massachusetts
Chicago, Illinois
Cleveland, Ohio (Cuyahoga County)
Columbus, Ohio (Franklin County)
Dallas, Texas (Dallas County)
Detroit, Michigan
El Paso, Texas (El Paso County)
Houston, Texas
Indianapolis, Indiana (Marion County)
Jacksonville, Florida (Duval County)
Los Angeles, California
Memphis, Tennessee (Shelby County)
Miami, Florida (Dade County)
Milwaukee, Wisconsin (Milwaukee County)
Nashville, Tennessee (Davidson County)
New Orleans, Louisiana
New York City, New York
Newark, New Jersey
Philadelphia, Pennsylvania (Philadelphia County)
Phoenix, Arizona (Maricopa County)
San Antonio, Texas (Bexar County)
San Diego, California (San Diego County)
San Jose, California (Santa Clara County)
Seattle, Washington (King County)
Washington, DC (District of Columbia)

Households With 2-Year-Old Children That Lack a Telephone and Overall Response Rates for Households With Telephones^a

Area	Households with 2-year-old children that lack a telephone	Overall response rate among households with telephone ^b
U.S. total	11.72%	69.5%
Alabama	20.30	
Jefferson County (Birmingham)	9.03	64.5
Rest of state		66.3
Alaska	9.73	100.0
Arizona	25.41	
Maricopa County (Phoenix)	11.79	69.8
Rest of state		67.5
Arkansas	22.11	62.2
California	6.09	
Los Angeles	6.94	78.2
Santa Clara	2.21	85.4
San Diego	3.86	73.7
Rest of state		79.5
Colorado	8.21	68.5
Connecticut	5.92	60.2
Delaware	7.49	67.3
District of Columbia	7.36	52.1
Florida	11.91	
Duval County (Jacksonville)	10.68	71.8
Dade County (Miami)	9.05	58.8
Rest of state		51.6
Georgia	16.96	
Fulton/DeKalb County (Atlanta)	8.31	64.2
Rest of state		75.0
Hawaii	3.24	81.8
Idaho	11.81	85.1
Illinois	7.16	
Chicago	17.14	69.2
Rest of state		71.0
Indiana	13.53	
Marion County (Indianapolis)	12.63	76.0
Rest of state		71.6
Iowa	7.25	65.8

(continued)

Appendix III
Households With 2-Year-Old Children That
Lack a Telephone and Overall Response
Rates for Households With Telephones^a

Area	Households with 2-year-old children that lack a telephone	Overall response rate among households with telephone^b
Kansas	8.91%	73.4%
Kentucky	19.94	57.7
Louisiana	14.97	
Orleans Parish	15.31	60.6
Rest of state		70.0
Maine	7.09	62.4
Maryland	4.00	
Baltimore City	16.34	62.9
Rest of state		77.8
Massachusetts	3.42	
Boston	8.89	53.5
Rest of state		66.5
Michigan	7.38	
City of Detroit	12.75	80.2
Rest of state		72.4
Minnesota	3.98	71.4
Mississippi	23.25	71.2
Missouri	11.15	71.7
Montana	12.13	71.9
Nebraska	7.75	76.3
Nevada	8.31	67.6
New Hampshire	6.33	67.3
New Jersey	6.50	
City of Newark	23.32	68.3
Rest of state		56.0
New Mexico	23.65	73.3
New York	6.63	
New York City (5 counties)	13.93	61.2
Rest of state		68.8
North Carolina	14.44	67.5
North Dakota	5.95	77.8
Ohio	10.99	
Cuyahoga County	7.59	64.8
Franklin County	4.67	65.1
Rest of state		69.1
Oklahoma	18.39	60.1
Oregon	9.34	65.1

(continued)

**Appendix III
Households With 2-Year-Old Children That
Lack a Telephone and Overall Response
Rates for Households With Telephones^a**

Area	Households with 2-year-old children that lack a telephone	Overall response rate among households with telephone^b
Pennsylvania	5.02%	
Philadelphia	10.25	62.0%
Rest of state		68.3
Rhode Island	7.24	61.0
South Carolina	15.86	63.9
South Dakota	11.37	78.3
Tennessee	17.33	
Shelby County (Memphis)	9.43	80.0
Davidson County (Nashville)	9.67	60.8
Rest of state		66.6
Texas	18.46	
Dallas County	13.10	67.1
City of Houston	17.73	71.9
El Paso County	17.22	100.0
Bexar County (San Antonio)	14.49	71.8
Rest of state		83.3
Utah	4.93	100.0
Vermont	7.64	69.0
Virginia	11.07	68.2
Washington	7.64	
King County (Seattle)	2.09	69.2
Rest of state		76.7
West Virginia	23.61	56.9
Wisconsin	4.45	
Milwaukee County	9.47	69.0
Rest of state		73.0
Wyoming	9.32	85.4

(Table notes on next page)

Appendix III
Households With 2-Year-Old Children That
Lack a Telephone and Overall Response
Rates for Households With Telephones^a

^aBy area surveyed, for quarters 2 through 4, 1994.

^bThe overall response rate is defined as ratio between the number of households completing the interview for at least one child and 0.0508 times the total number of households identified in the sample. (Census data indicate that 5.8 percent of telephone households contain 2-year-old children.) The total number of households identified in the sample is defined as the total of (1) households identified as ineligible; (2) households determined to be eligible; (3) households for which eligibility was not determined; (4) 90 percent of the numbers that reached an answering machine or service, but did not result in determination of eligibility; and (5) 90 percent of the numbers that were categorized as likely households but for which household status was not clearly determined. The overall response rate calculated in this fashion is slightly higher than the response rate derived when all possible households are used in the calculation.

Source: Abt Associates, Inc., State and Local Area Immunization Coverage Health Survey: Final Sampling Plan (March 7, 1994), Exhibit I pp. 4-6, submitted to the National Center for Health Statistics under contract number 200-94-7009; and The National Immunization Survey (NIS) 1994 Annual Methodology Report, Table 12 Appendix, Chapter V, submitted to the National Center for Health Statistics under contract no. 200-94-7009.

Comments From the Department of Health and Human Services

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

JUL 22 1996

Mr. Kwai-Cheung Chan
Director, Program Evaluation
in Physical Systems Areas
United States General Accounting Office
441 G Street Northwest, Room 4083
Washington, D.C. 20548

Dear Mr. Chan:

This is in response to the draft General Accounting Office (GAO) report on "CDC's National Immunization Survey - Methodological Problems Limit Survey's Utility."

The Centers for Disease Control and Prevention (CDC) does not agree with this draft report's conclusion that in view of the National Immunization Survey's (NIS) methodological limitations, "the Congress may wish to reconsider the NIS' benefits relative to its costs." GAO has underestimated the accuracy and value of the NIS. Many of the techniques employed by the NIS including the complex procedures and adjustments are well-accepted approaches customarily used in the survey field. The major groups involved in public health programs, the Council of State and Territorial Epidemiologists and the Association of State and Territorial Health Officials and the major immunization advisory committees, the National Vaccine Advisory Committee and the Advisory Committee on Immunization Practices, support the NIS. In addition, no adequate alternative to the NIS is available.

For the first time, the NIS provides a standardized measure of the performance of 50 States and 28 large urban areas in meeting immunization coverage targets for two-year-old children. These results are accurate. The approaches employed in the NIS represent decades of careful research as well as major advances in telephone survey methodology. The CDC's National Health Interview Survey (NHIS) is widely considered the "gold standard" in national survey technology. It involves "face-to-face" household interview methodology; however, it does not provide State-specific data. When the NIS' 78 State and local surveys are combined, the aggregated results are virtually identical to those of the NHIS. The NIS also provides the only national data on immunization coverage of certain minority groups, such as Hispanics and Asian-Americans.

See comments 1 and 2.

See comment 3.

See comment 4.

See comment 1.

See comment 1.

See comment 5.

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Comments From the Department of Health
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Fundamentally, the NIS is a powerful public health management tool for States and the Nation. Governors of several States are already using NIS information to take aggressive action to increase immunization coverage. For example, NIS data indicated that Missouri ranked 49th in the Nation in coverage. This led the governor to propose legislation, that was enacted, to provide "first dollar" coverage (no deductibles or co-payments) for children up to 5-years-old. Missouri estimates this law will save the State about \$900,000 annually. Publication of NIS data in Arizona stimulated the Arizona Medical Association to sponsor legislation that was enacted to require that all vaccinations be reported to the State registry. In Idaho, district health departments designated immunization as the number one priority. This included implementation of a reminder system to contact parents when their baby's shots are due.

See comment 6.

The GAO draft report identifies only three of the 11 or more major benefits of the NIS and, therefore, fails to make a comprehensive analysis of the survey. CDC discussed several of these benefits during the kickoff conference and later provided GAO a list of 11 major NIS benefits within the requested time frame. In the report, GAO acknowledges that it did not assess the NIS based on the broader list of NIS benefits. Therefore, the GAO conclusions regarding the NIS are misleading and based on incomplete information.

See comment 2.

GENERAL COMMENTS

The Value of the NIS

The NIS is cost-effective and serves as the most useful means to monitor immunization coverage. Major NIS benefits to the Nation and the States include the following:

See comment 7.

- (1) Provides a standardized measure of the performance of 50 States and 28 large urban areas in meeting immunization targets for two-year old children. Previous State-conducted surveys did not allow CDC to accurately compare differences between States and did not guarantee unbiased results.
- (2) Acts as the Nation's early warning system to avert potential vaccine-preventable disease epidemics by detecting small changes in immunization coverage.
- (3) Ranks State performance and fosters competition among States to achieve the highest immunization coverage because State's can be confident that their rankings are based on valid, accurate, and timely survey results.
- (4) Focuses CDC's technical assistance on areas most in need.

See comment 8.

See comment 9.

See comment 10.

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See comment 11.

(5) Enables CDC to compare the coverage of one area or subgroup with other areas or subgroups to analyze interventions.

See comment 12.

(6) Monitors the rate that new vaccines, such as hepatitis B and varicella, are introduced.

(7) Allows States to swiftly evaluate the impact of changes in their intervention efforts and make adjustments if needed.

See comment 11.

(8) Monitors changes quarterly in national coverage as small as one percent to help policymakers detect the impact of policy changes on immunization coverage levels.

See comment 13.

(9) Furnishes coverage estimates, even for small States, where separate surveys could be prohibitively costly.

See comment 14.

(10) Provides the basis for fair distribution of Federal immunization incentive funds to States.

See comment 15.

(11) Stimulates States and urban areas to target their own intervention efforts better.

The NIS as an Early Warning System

See comment 8.

The NIS is unsurpassed as an early warning system to help States avert disease epidemics through the continuous and timely measure of immunization coverage. In the 1970s, the pertussis vaccination rate in the United Kingdom dropped from 79 to 30 percent and resulted in an epidemic of several hundred thousand cases. A similar situation occurred in Japan. The NIS can detect up to one percent change in immunization coverage, and the data can be available in a timely fashion. The NIS also allows monitoring of the potential impact of policy changes on coverage as recommended by the Advisory Committee on Immunization Practices.

See comment 11.

Additional Use of the NIS System

See comment 16.

The NIS can be modified to collect non-immunization data. The Department of Health and Human Services will soon pilot a modification to NIS to track health factors, such as changes in health information, access to care, insurance coverage, and the impact of managed care at the State and local levels.

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CDC's RESPONSE TO SPECIFIC FINDINGS

Survey Cost

GAO Finding: GAO is concerned with the cost of the NIS.

CDC Response: The NIS measures the immunization performance of the Nation overall, the 50 individual States, and 28 large urban areas. Thus, it comprises 79 separate surveys. In this context, each survey costs only about \$165,000. As experience with the survey grows, costs are expected to decrease. Furthermore, NIS accounts for only about one percent of CDC's immunization budget and is critical for assessing immunization performance and stimulating States to take action to increase coverage.

Any NIS budgeted funds not directly used for the survey have been used for other assessment-related activities, such as the NHIS and its provider record check study, the Clinic Assessment Software Application, and provision of technical assistance to States.

See comment 17.

Households without Telephones

GAO Finding: The adjustment for noncoverage of children in households without telephones is based on a complex procedure.

CDC Response: This is true. The source of data for the adjustment is the NHIS, a survey that includes face-to-face household interviews of residences without telephones. In fact, the sophistication of the approaches employed by the NIS represents decades of careful research as well as major advances in telephone survey methodology. Furthermore, such an adjustment is well-accepted and customarily used in the survey field. CDC believes that the adjustment for noncoverage of children in households without telephones helps make the NIS the most accurate preschool immunization survey in existence.

See comment 3.

Response Rates Vary Widely

GAO Finding: There is no clear way to test the assumption used by CDC in adjusting for potential nonresponse bias.

CDC Response: The NIS response rates are comparable to other telephone surveys involving a hard-to-find subgroup of the population such as two-year-old children. The NIS' accuracy can be supported by comparing the national vaccination coverage levels in the NIS with those from the NHIS. They are virtually identical. Moreover, none of the evaluations to assess NIS' data quality have indicated the presence of any major biases.

See comment 1.

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Comments From the Department of Health
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Household Respondents Had Difficulty Providing Accurate Data

GAO Finding: Immunization data are limited by the accuracy with which household respondents can supply information on children's immunization status.

CDC Response: The NIS record check study indicated that household information enhanced with provider information greatly improved the quality of the estimates. This is why provider surveys, which involve actual provider immunization records, were added to both the NHIS and the NIS.

See comment 18.

Coverage Estimates Failed to Meet Desired Levels of Precision

GAO Finding: The actual estimates produced by the survey in its first year had margins of error that were considerably larger than called for in the survey plan.

CDC Response: This is incorrect. Seventy-one of the 78 areas met or exceeded the requirement that the margin of error be within five percent of the value of the estimate itself. In four of the seven areas where the margin of error was greater than five percent, it was less than six percent. In addition, the original design of the NIS has been strengthened to include immunization record information from providers. This modification in survey design has substantively increased, up to 20 percent, the accuracy of the estimates.

See comment 19.

GAO Finding: There appear to be remarkably few differences in immunization coverage rates across States.

CDC Response: This is incorrect. The most recent NIS identified a 24 percentage point spread among States' coverage levels. The urban areas identified a 31 percentage point spread. Virtually all differences in coverage levels in the range of 10 percent, or possibly even less, are statistically significant. For example, Alabama, which is near the national coverage level of 75 percent, was statistically different from 21 of the other 77 areas.

See comment 20.

GAO Finding: The survey is unlikely to show change from quarter to quarter and the survey results might create the false impression of a lack of progress.

CDC Response: This is incorrect. At the national level, the NIS can detect changes as small as one percentage point between consecutive four-quarter annualized estimates. This is important in tracking progress on newly introduced vaccines or on major changes in the vaccination schedule. Within an area, virtually

See comment 21.

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all differences between two coverage estimates which are five percent or higher will be judged statistically significant.

See comment 21.

Before the NIS, it was impossible to accurately measure differences among States and urban areas because differences observed might have been due to variances in survey methods and not to differences in the quality of the immunization programs. NIS provides the first consistent methodology for collecting immunization data among States and large urban areas.

See comment 22.

Survey Not Designed to Identify Pockets of Need

GAO Finding: NIS was not designed to identify (geographic) pockets of need.

CDC Response: The NIS was not designed to address geographic pockets of need because other CDC interventions are more appropriate and efficient in addressing this issue. For example, CDC is working to address pockets of need by linking immunization services to the WIC program, assessing coverage in public clinics, targeting technical assistance to areas with low rates, and other interventions.

In addition, the NIS does make considerable contributions to identifying population subgroups in need, and this data is useful in targeting interventions. The NIS allows for classifying and combining telephone exchanges to produce estimates for minority children in urban areas.

Previous Surveys May Be Effective at Lower Cost

GAO Finding: With the exception of providing comparable immunization coverage data among States, previously used surveys, such as retrospective surveys, could meet NIS objectives at lower cost.

See comment 23.

CDC Response: CDC and States need an accurate and timely measurement of immunization coverage to evaluate effectiveness of immunization programs. The NIS' ability to provide data among States is, itself, a powerful rationale for the NIS. CDC's evaluation of alternative methods has documented that no cheaper and better method is currently available. In fact, retrospective and other types of surveys have serious flaws and were abandoned in favor of NIS for reasons including:

- (1) Retrospective surveys provide seriously outdated coverage data (at least 3 years old). Among other serious shortcomings, retrospective surveys cannot provide timely

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monitoring of new vaccines and cannot serve as an early warning system. The retrospective survey approach will not provide any data on 1996 immunization coverage until the year 2000.

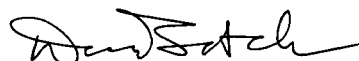
- (2) Birth certificate follow-back surveys are fairly timely but can miss the large percentage of children who move from their residence of birth. More than 20 percent of preschool children move into or out of a given area each year.
- (3) Household interviews are considerably more costly than telephone surveys.

To implement surveys of the same quality as NIS at the State and local levels would require 78 separate contracts and would lose the advantage of "pooling resources". Implementing an effective State survey would be particularly difficult for smaller States. Many States could also be forced to reassign staff who may be engaged in immunizing children to conduct State and local surveys.

The immunization of children in this country could be compromised if this draft report's findings are accepted without critical review.

In conclusion, CDC appreciates the opportunity to comment on the draft report and expects that the complete text of this letter will be included in the final report.

Sincerely,


David Satcher, M.D., Ph.D.
Director

See comment 24.

See comment 25.

See comment 26.

See comment 27.

See comment 28.

See comment 29.

The following are GAO's comments on the Department of Health and Human Services' letter dated July 22, 1996.

GAO Comments

1. CDC has mischaracterized our findings. Although we have identified several issues that raise questions about accuracy, neither we nor CDC can validate the accuracy of survey results. The accuracy of the NIS results depends on the accuracy of the assumptions inherent in CDC's adjustment of the survey results, some of which are untestable. The results of the NHIS are used to adjust the results of the NIS. Thus, while the similarity of the two surveys is reassuring, the NHIS cannot provide an independent assessment of the NIS' accuracy. In any event, the agreement of the national estimates does not ensure that the local estimates are accurate.

2. The various benefits asserted by CDC derive from the application of the NIS to monitoring immunization rates and to comparing them across states. We acknowledged both of these objectives in the second paragraph of our report.

Many potential benefits or purposes could be asserted for the survey, but its use in any of these capacities is limited by the low precision, narrow range, and unverified accuracy of the survey estimates.

3. It is true that surveys, to varying degrees, customarily require the types of adjustments applied to the NIS to correct for biases introduced by nonresponse and limitations in survey coverage. However, the adjustment of NIS results for exclusion of households without telephone service required a somewhat greater leap of faith than customary adjustments for telephone noncoverage.

The success of such adjustments usually depends on the extent to which the variable being measured can be accurately predicted by demographic characteristics that are available or can be inferred for both nontelephone and telephone households. As we have noted in the report, based on data from the NHIS, which is an in-person survey, there are large differences in immunization coverage between children in households with and without telephones. These differences are not completely explained by demographic differences between telephone and nontelephone households.

Furthermore, although telephone ownership varies substantially across the surveyed areas, there are no consistent sources of state and local data

on differences in immunization coverage between telephone and nontelephone households. Consequently, the extent to which this adjustment improved the accuracy of state and local survey results is unclear.

4. CDC has acknowledged that the NIS does not identify pockets of children in need of more timely immunization, and most state immunization program managers have told us that the NIS does not help them in targeting their efforts or designing interventions, although it does relieve them of CDC's previous requirement that they collect statewide coverage data on their own. We are studying alternative means for identifying pockets of need.

Although there is currently no other means of comparing statewide immunization coverage data, the NHIS, as we have noted, tracks coverage changes at the national level. In addition, other methods were used in the past to collect statewide coverage information, albeit through a variety of methods across states.

5. It is true that the sample size of the NIS should afford the calculation of rates for such subgroups on a national basis. The NHIS is not currently large enough to provide childhood immunization coverage information on these two groups.

6. CDC states that the NIS is an "important public health management tool" and notes that Missouri, Arizona, and Idaho have taken steps intended to improve immunization coverage in the wake of NIS results. However, we have some concern that the NIS provides no guidance on the type of action that is appropriate or where it is appropriate. It is not necessarily clear that placing special emphasis on the states with the lowest survey estimates for coverage with a combination of four vaccines is the most appropriate way to prevent a disease outbreak. States with high estimates may nonetheless include significant pockets of underimmunized children.

7. CDC provides no evidence that the NIS is cost-effective. As we note in our conclusion, it is markedly more expensive than the retrospective surveys previously used to generate statewide coverage data. Presuming that the capacity to measure differences between states is an important objective, the NIS' capacity to meet this objective is limited by the broad margins of error in survey estimates and variations in survey participation and coverage. It is similarly limited with respect to monitoring changes in immunization coverage across time. As with previous state surveys, there

is no guarantee that the NIS provides unbiased estimates of immunization coverage.

8. The NIS can detect small changes on a quarterly basis only at the national level. Survey results are not released until roughly a year after data collection, and it is doubtful that a 1-percent change in national coverage should or would be construed as an early warning in the context of very high vaccine-specific rates. In any case, national coverage statistics are also available from the NHIS. Availability of the NIS results did not prevent the recent outbreak of measles in Utah.

Sudden drops in immunization levels for a particular disease in other countries have been associated with problems, such as sudden concerns about vaccine safety, that were evident apart from immunization measurement. There was concern and widespread publicity in the mid-1970s in both the United Kingdom and Japan about reports of encephalitis following the receipt of pertussis vaccine. The reduced utilization of this vaccine was precipitous and observable from sources other than national survey data.

9. While states with lower immunization estimates may be motivated by the NIS findings to improve coverage, the findings do not indicate where the problem lies within these states or what corrective actions are needed. We remain concerned that they may provide a false sense of security to other areas that actually face significant problems (for example, specific pockets of low immunization within states with generally high coverage rates). In addition, the motivational effects of such quarterly ranking may diminish over time. Finally, CDC's argument presumes that states will be more motivated to act by data collected through the NIS than they would have been by data collected locally or through other means. We disagree.

10. The CDC has indicated that the NIS was not intended to identify pockets of need and consequently does not do so. The NIS may actually deflect attention from some serious problem areas because they are incorporated in larger areas for survey purposes. For example, the Seattle-King County Department of Public Health and the University of Washington conducted a separate household survey of Central and Southeast Seattle using the same age group and reference dates as the NIS, but finding that 57 percent of children in this part of the city were fully immunized, in contrast to the

NIS rate of 79 percent up-to-date for all of King County in the same time period.¹

11. Because of the wide margins of error of survey estimates, the NIS is probably not sufficiently sensitive to permit evaluation of interventions or policy changes in particular areas or subgroups. Although national changes in immunization coverage may be monitored with greater precision, changes in national or local immunization coverage might be attributable to factors other than policy changes (for example, trends in the demographic characteristics of children to be immunized). Moreover, policy changes typically occur in groups and are implemented gradually, which would make it quite difficult to attribute any observed movements in immunization coverage to a single change or a combination of changes.

In this context, it seems inadvisable to draw conclusions about particular state activities based solely on the results of the NIS. Similarly, with cross-state comparisons, multiple interventions are linked to each area and subgroup, as well as variations in demographic and other factors, making it difficult to disentangle the reasons for any differences observed across states and cities in the NIS findings.

12. We agree that the NIS is technically capable of detecting the rapid and dramatic changes in coverage that typically accompany the recommendation of new vaccines. However, on a national level, the NHIS also reports on the uptake of newly recommended vaccines. Sales and distribution reports may provide a less expensive means of monitoring the uptake of such vaccines in particular areas.

13. Even small states had produced statewide coverage estimates using previous methods. However, it is difficult for small states to justify the use of \$165,000 in infrastructure funding for a random digit dialing immunization survey such as the NIS. Under a proposal CDC has floated with states, surveys in small states would be subsidized by “contributions” of a percentage of federal grant funds from larger states. However, in view of immunization needs, 20 state health officers surveyed by ASTHO could not justify devoting 6.5-10 percent of their infrastructure funds to survey support. Twenty-four states told ASTHO they were willing to contribute 10 percent of their 1995 infrastructure grant toward the survey in the event that federal funding was discontinued, but their prospective contributions

¹See Seattle-King County Department of Public Health and The University of Washington School of Public Health and Community Medicine (February 1996). “Household Immunization Survey of Central and Southeast Seattle April-August 1995: Final Report.”

would have totaled \$4.6 million—much less than the survey’s reported annual cost.

14. As we have noted, the precision of current estimates raises questions about whether the survey does, in fact, provide an improved basis for the distribution of incentive funds. Moreover, the amount expended on the survey is substantial in comparison to the amount of such funds available for distribution.

15. Most state immunization program managers indicated that the NIS results were not useful in targeting their activities. Although a low result may provide some states with a general incentive to do better, it provides no guidance as to how to accomplish any improvement.

16. The collection of such data will enhance the information derived from the tremendous number of phone contacts with ineligible households made in conducting the NIS. However, the collection of immunization data may continue to drive the number of calls required (and hence the cost of the survey) because households containing two-year-olds would likely continue to be the rarest population sampled. In any case, the utility of the survey for collecting other data does not bear upon its usefulness for collecting information on immunization.

17. CDC agrees with the cost we reported for the NIS. We did not verify CDC’s claims regarding its use of the funds that were not applied to the survey. While CDC anticipates that future costs will be lower, it has not requested modification of its fiscal 1997 budget request to reflect these lower costs.

18. The poor quality of immunization data gathered from household respondents had been documented before the NIS was planned. Thus, although the provider surveys may have reduced the inaccuracies contained in these household data, the survey might have been more efficiently designed had the limitations of household data been acknowledged in survey planning. Earlier recognition of this problem would have supported more serious exploration of other survey methods.

19. It should be noted that CDC’s comments compare the survey estimates to a standard different from the target established in the contract and survey plan. Survey plans are ordinarily drawn by determining the sample size necessary to achieve an acceptably precise result if the value of the measured variable is near 50 percent, the point at which the largest sample will be required to achieve a given level of precision (for example, plus or

minus 5 percent with 95-percent confidence). This is exactly the sampling target specified in CDC's contract with the survey organization. Insofar as the immunization levels measured by the survey are well above 50 percent, had the targets established in the contract been met, the estimates would show precision better than plus or minus 5 percent.

Further, CDC's statement that, "Seventy-one of the 78 areas met or exceeded the requirement that the margin of error be within five percent of the value of the estimate itself," does not conform to the first four quarters of survey results published by CDC (see MMWR, Feb. 23, 1996, pp. 148-49). These indicate that, for 4:3:1 coverage, only 23 of the 78 estimates met or exceeded the criterion that the margin of error be within 5 percent of the value of the estimate itself. For 4:3:1:3 coverage, the number meeting or exceeding this criterion was only 16 of the 78.

Whether the survey estimates met this or any other criterion is less important than the fact that their precision, if not improved, is generally only sufficient to detect, reliably, changes of a size larger than has typically been observed on an annual basis.

While the addition of provider data has helped correct some substantial errors incorporated in household responses, it has not reduced the margins of error for survey estimates.

20. We do not find that the survey documents high levels of variability in results across IAPS. Although CDC correctly states that Alabama's result was statistically different from the result for 21 other IAP areas (11 states and 10 cities), it cannot be statistically distinguished from the results in 56 others. CDC is correct that, in most cases, differences of at least 10 points can be statistically distinguished, as we show in figure 1 for 4:3:1 coverage, but there is only a 24-point range in the state estimates for full coverage, so the majority of the state estimates—31—are not far enough apart for their difference from the national estimate to be confidently attributed to anything more than sampling error. The range of estimates for coverage with particular vaccines is generally narrower.

21. The NIS can detect reasonably small changes in national coverage between consecutive four-quarter annualized estimates, though the first two successive annualized estimates for 4:3:1 coverage were not different. However, even at the national level, for most of the antigens and series, the smallest reliably detectable change (at conventional levels of significance) is slightly larger than 1 percent.

At conventional levels of significance, it is impossible to judge differences as small as 5 percent to be statistically significant when most estimates have 95 percent margins of error of 5 percent or greater. Our report quotes a statement in a document issued by the survey contractor noting that the survey can detect only very large changes (for example, a 20-percent increase from 50 percent) between successive quarterly annualized estimates in the various areas surveyed. The margins originally planned would have been no larger than plus or minus 5 percent. However, survey documentation NCHS provided to us notes that “Confidence intervals for the vaccination coverage estimates are somewhat wider than originally planned because provider information is not available for all children in the sample.”² In addition, for data collected in quarters 2 through 4 of 1994, the number of completed child-level interviews was less than 90 percent of the sample size called for in the design specifications for roughly a third of the IAPS. This too, would have the effect of increasing the margins of error for survey estimates.

22. While the NIS applies the same methodology across states, the range of state results is not as broad as expected and the performance of many states cannot be differentiated. In any case, in making such comparisons with the NIS, it is important to take into account the wide variations in survey coverage and response rates across states and urban areas.

23. We noted that the retrospective survey approach has both advantages and disadvantages, including the timeliness of data. Retrospective surveys do not produce results as quickly as the NIS; however, even the NIS issues results about a year after data collection, and thus it appears equally ill-suited to provide an early warning.

24. As we have noted in appendix III, the NIS in some areas excludes a similar proportion of children living in households without telephone service.

25. This is generally true, although the costs of a household survey can be comparable in some urban areas, as suggested by recent experience in Norfolk and Seattle.

26. There may be some economies of scale in centralizing the surveys under a single contract, but these must be weighed against the costs of limiting potential bidders to firms equipped to handle a task of this large scale. Conducting separate surveys would have the advantage of

²“National Immunization Survey: EZGuide to Estimation” (undated), p. 7.

permitting the questions to be tailored to provide additional data about state and local initiatives.

27. It is true that the full cost of a random digit dialing survey such as the NIS would be more difficult for smaller states to bear. ASTHO officials reported that many smaller states were unwilling to continue participation in the survey if it meant funding the full cost of their own random digit dialing survey through their infrastructure funding. However, it should be noted that all states have recent experience conducting other types of statewide immunization surveys.

28. Minimal staff hours are generally involved in retrospective surveys. While this is not true of household surveys, states may also contract for such services if they continue to be required.

29. As noted in our report, the Congress may wish to weigh the cost of the NIS against its benefits in order to ensure the most efficient use of immunization resources.

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