
Measuring Immunization Coverage

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Objective: Information about immunization coverage comes from five major sources: the National Immunization Survey, the National Health Interview Survey, retrospective school-entry surveys, the Health Plan Employer Data and Information Set (HEDIS) measures reported by managed care plans, and assessments performed on clinics and private practices. In this article, we describe the methodology of the major surveys, discuss technical and policy issues in measuring immunization coverage, and identify issues that must be addressed to harmonize immunization rates calculated from different sources.

Methods and Topics: We describe the (1) design and methodology of the five major sources of immunization coverage assessments, (2) issues and controversies in measuring immunization coverage, and (3) preliminary efforts to harmonize calculation of immunization coverage. Technical and policy issues involve dose and interval requirements, which vaccines are included in the series-completion calculations, and who is excluded from each method of calculation.

Conclusions: The purpose of measuring up-to-date immunization coverage determines the way that it is measured. The tension between measuring immunization coverage to monitor population protection against disease and measuring immunization coverage to determine how well the health care delivery system is working leads to different ways of selecting a sample and reporting coverage. These differences create confusion for the public policymakers who try to identify problems and to set priorities for immunization efforts. Although some unavoidable differences may occur because of differences in purpose of the measurement, greater harmonization is possible.

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Introduction

The Recommended Childhood Immunization Schedule in the United States approved by the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics, and the American Academy of Family Physicians calls for 16 doses of six vaccines to be given before age 2 years.¹ The six vaccines are diphtheria, tetanus toxoid, and pertussis (DTP); poliovirus; measles, mumps, rubella (MMR); *Haemophilus influenzae* type b (Hib); hepatitis B (HepB); and varicella-zoster virus (varicella). The Recommended Childhood Immunization Schedule also specifies minimum ages to administer doses and minimum spacings between doses. Because of the require-

ments for minimum spacing between doses, a child must make at least five visits to a health care provider to receive the entire immunization series.

Immunization coverage rates indicate the extent to which the total population of children (or a subgroup within the total population) has received these vaccines. Immunization coverage is an important indicator of vulnerability of a population—or a pocket within a population—to vaccine-preventable disease. However, in part because five or more encounters with a health care provider are needed to fully immunize a child, immunization coverage has a second important function: as a proxy for how well the health care system—or portion of the system—performs. Many of the differences in design, reporting decisions, and even results in the various sources of immunization coverage are based on whether their purpose is to assess vulnerability to disease or to measure system function.

Immunization coverage rates are reported through five major surveys or sources: the National Immunization Survey (NIS), the National Health Interview Survey (NHIS), state-based school-entry surveys, Clinic Assessment Software Application (CASA) assessments performed on clinics and private practices, and the Health

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Table 1. Overview of purpose and policy/management goals of the sources/surveys of immunization data

| Name of survey/source | Conducted/sponsored by | Purpose of survey/source | Yields information on immunization rate for | Policy/management goals |
|---|---|--|---|--|
| National Immunization Survey (NIS) | CDC | To measure coverage for nation, states, and major urban areas | Population | Disease prevention |
| National Household Interview Survey (NHIS) | NCHS | To measure coverage for nation | Population | Disease prevention |
| Retrospective school-entry surveys | States and other IAP grantees | To determine whether new student meets immunization requirement for school entry; assess coverage retrospectively at 24 months | Population | Disease prevention |
| HEDIS (managed care plan assessments) | Managed care plans according to NCQA criteria | To measure coverage for health plans | Health plans | Hold health plans accountable; allow purchasers to make business decisions |
| CASA (Clinic Assessment Software Application) assessments | States and other IAP grantees | To measure coverage at clinics and private practices | Individual providers | Hold providers accountable for care of children; provide information to improve practice |

CDC, Centers for Disease Control and Prevention; IAP, Immunization Action Plan; NCHS, National Center for Health Statistics; NCQA, National Committee for Quality Assurance

Plan Employer Data and Information Set (HEDIS) measures that managed care plans report on enrolled children. The NIS, NHIS, and school-entry surveys estimate the coverage of the population in specific geographic areas. They estimate up-to-date coverage rates for a population or subgroup within a population primarily to determine vulnerability to disease. In contrast, the CASA and HEDIS assessments estimate coverage for particular organizational entities responsible for children's care. They measure primarily how well the system works. The CASA assessments evaluate how well providers immunize children in their care, whereas HEDIS assessments determine how well the health plans immunize children for whom they have responsibility. Providers use the results of CASA assessments to help improve their service, whereas purchasers and consumers use the results of HEDIS assessments to make choices among health plans. Table 1 gives an overview of the purposes and policy or management goals of these surveys and sources of immunization data.

Differences in coverage levels reported by these surveys and sources cause confusion among parents and frustration for policymakers attempting to monitor coverage and take action if necessary. For example, in 1997 the NIS reported a 78% national average immunization rate² whereas HEDIS reported 65% coverage for commercial plans.³ Conclusions drawn and actions taken on the basis of the two figures would be substantially different. The NIS coverage rate of 78% is not statistically different from the *Healthy People 2010* goal

of 80%.⁴ Policymakers and the general public would most likely conclude that the health care system adequately delivers immunization services, no problem exists, and no intervention is needed. On the other hand, the 65% coverage reported by commercial managed care plans might suggest a need for action. Furthermore, policymakers and the general public may wonder whether the differences are real—that is, were children in managed care really less well immunized than children in general—whereas those knowledgeable in the data collections undertaken suspect the variation was caused by differences in measurement methods.

As it turns out, much of the difference was caused by measurement differences. One source of difference was the fact that different vaccines were used in the up-to-date calculation. The 78% NIS figure, their most widely cited, measures coverage for four doses of DTP, three doses of poliovirus, and one dose of measles-containing vaccine, whereas the HEDIS figure is for these three vaccines plus one dose of Hib and two doses of HepB. The differences do not end with vaccines used: The NIS and HEDIS also use different age and spacing criteria. The NIS methodology provides optimal information on the proportion of children who receive immunizations for public health tracking, whereas the HEDIS has more rigorous requirements for minimum thresholds and spacing between doses that are appropriate for systems assessment.

These differences in measurement can make a profound difference in coverage levels. When the criteria

Table 2. Who is included in the calculation: population sampled, sampling strategy, and inclusion/exclusion criteria

| Name of survey/source | Target population | Sampling strategy | Inclusion/exclusion |
|---|--|---|--|
| National Immunization Survey (NIS) | All children 19–35 months | Random-digit-dial telephone survey; complex, multistage sampling from telephone banks | None |
| National Household Interview Survey (NHIS) | All households with 12–35-month-old children | Complex, multistage sampling of households | None |
| Retrospective school-entry surveys | School entrants (for some states kindergarten, for others first grade) | Cluster sample of ~35 randomly selected schools; random or systematic sample of entrants within schools | None |
| HEDIS (managed care plan assessments) | Children who turn 2 years of age during the reporting year | Systematic sample of 411 children planwide | Children excluded unless continuously enrolled for 12 months (with no more than one break for up to 45 days) |
| CASA (Clinic Assessment Software Application) assessments | Children 24–35 months | Random or systematic sample of 100 children aged 12–23 months and 100 children aged 24–35 months | Children included who have one well-care visit recorded and no acceptable “Moved or Gone Elsewhere” note in medical record |

used in the HEDIS calculation were applied to NIS data, the coverage rate fell by 20%, from 78% to 58%.⁵ Policymakers looking at the 58% up-to-date figure would draw conclusions markedly different from those formed from the previously reported 78% up-to-date coverage.

This example shows that differences in immunization coverage levels reported by two particular sources were in large measure caused by differences in methodology (which, in turn, flows from differences in goals and purposes). These methodologic differences can be divided into those that affect *who is included* (the denominator) in the up-to-date calculation and those that affect *how the determination of up-to-date is made* (the numerator), and how the data are collected (survey vs chart abstraction). The differences in who is included, summarized in Table 2, involve differences in target population, sampling strategy, and other special criteria for who is included and excluded. The differences in how the determination of up-to-date is made, summarized in Table 3, involve differences in immunizations included, sources of immunization information, and spacing requirements. Taken together, these differences lead to variability in coverage levels and make comparisons difficult among surveys with different coverage assessment methods. Although different goals and purposes make some differences unavoidable, the opportunity exists for greater comparability and subsequent efficiency and harmony in educating the public and informing policymakers. Regardless, it is important to understand the nature of the differences and reasons for differences.

An overview of the major sources and the determinants of immunization rates follows. A discussion of

measurement issues and a description of current efforts to harmonize results of the various surveys follows the overview.

National Immunization Survey

The NIS conducted by the Centers for Disease Control and Prevention (CDC), is the primary vehicle for monitoring immunization coverage levels for the nation's preschool children.^{6,7} It provides estimates of coverage for the nation as a whole, for all 50 states, and for major metropolitan areas from a random-digit-dialing telephone survey. Data collection involves quarterly surveys in each of the 78 Immunization Action Plan (IAP) areas (50 States, the District of Columbia, and 27 other large metropolitan areas) combined to provide annualized estimates at established levels of precision. The children included in the up-to-date calculation are aged 19 months to 35 months who live in households selected from telephone banks within the IAP areas, using complex, multistage sampling techniques. The NIS reports coverage for these children as of the day of the interview. To calculate up-to-date levels, it counts doses without regard to whether required spacing between doses or minimum ages were observed.

Data on immunizations received comes from the responses to the household telephone survey as well as from immunizations in the records of providers the children have seen. In the telephone survey, the respondent reads vaccinations and dates of administration from the parent's copy of the immunization card. If, however, the respondent does not have a card or if the respondent reports that additional immunizations

Table 3. Who is considered up-to-date: vaccines included, source of data, age/interval requirements, and reporting

| Name of survey/source | Vaccines included | Source of immunization data | Provider record check | Age/interval requirements | Coverage reported for | UTD calculated at |
|---|--|--|-----------------------|---|--|--|
| National Immunization Survey (NIS) | DTP, polio, MCV*, Hib, HepB, varicella | Respondents to telephone survey | Yes | No | Single antigens, 4:3:1, 4:3:1:3 | Day of interview for children 19–35 months |
| National Household Interview Survey (NHIS) | DTP, polio, MCV, Hib, HepB, varicella | Respondents to household survey | Yes | No | Not currently reported | Currently not reported |
| Retrospective school-entry surveys | Varies by state/locality | School immunization records | No | No, only for MMR, which must be given after 12 months | Varies by state; often 4:3:1 or 4:3:1:3 | 24 months |
| HEDIS (managed care plan assessments) | DTP, polio, MMR, Hib, HepB, varicella | Administrative data and medical record reviews | No | Yes, but slightly different from Recommended Schedule | Usually series completion for: 4 DTP 3 Polio 1 MMR 2 HiB 2 HepB | 24 months |
| CASA (Clinic Assessment Software Application) assessments | DTP, polio, MMR, HepA, Hib, HepB, varicella, pneumococcal, other | Medical record reviews | No | No, only for MMR, which must be given after 12 months | Usually 4:3:1 or 4:3:1:3; can be customized | 12 and 24 months |

4:3:1 is 4 doses DTP, 3 doses polio, and 1 dose MMR or MCV; 4:3:1:3 is 4 doses DTP, 3 doses polio, 1 dose MMR or MCV and 3 doses Hib; DTP, diphtheria, pertussis, and tetanus toxoid; HepA, Hepatitis A; HepB, hepatitis B; Hib, *Haemophilus influenzae* type b; *MCV, measles-containing vaccine; MMR, mumps, measles, and rubella; polio, polio virus; UTD, up-to-date; varicella, varicella-zoster virus

have been given but not listed on the card, the interviewer asks how many. The interviewer will accept a number or simply the response “all.” The parent or guardian then lists providers who have given the child immunizations and the surveyor asks for permission to contact the providers. These providers are surveyed for immunizations and dates from their medical records. Some providers fail to respond, but NIS reported that in 1996 provider data were obtained for about 65% of the children for whom interview data were available. Adjustment factors are calculated based on answers from the providers who can be contacted and are used to approximate coverage if data from all sources were combined.

The resulting immunization rates in each of the IAP areas are weighted to approximate coverage for the population in that area. In addition, statistical adjustments are made to correct for nonresponse and for “telephone bias,” occurring because immunization coverage for children in households without telephones is lower than coverage for children in households with telephones. Currently, this adjustment involves using data from the NHIS (described below), a household survey that includes households with and without telephones, to weight data from the NIS.

Up-to-date coverage is calculated from the number of children who have completed the series for various combinations of six antigens (DTP, poliovirus, MMR, Hib, HepB, and varicella). Coverage rates are reported separately for single antigens and for several combinations of antigen, the most widely cited being four doses of DTP, three doses of poliovirus, and one dose of measles-containing vaccines (4:3:1).⁸

NHIS

The NHIS, one of the major data collection activities of the National Center for Health Statistics (NCHS), is a continuing nationwide sample survey concerning the health of the U.S. civilian, non-institutionalized population and is collected in household interviews throughout the United States.⁹ Like the NIS, the major purpose of the immunization portion of this survey is to estimate coverage for the population. However, unlike the NIS, the NHIS covers many health topics beyond immunization. It includes information on personal and demographic characteristics as well as on illnesses, injuries, impairments, chronic conditions, use of health resources, and other topics. The household question-

naire is reviewed each year and special health topics are added or deleted.

The NHIS has collected data continuously since 1957. The current data collection instrument has three components: a basic health and demographic "core" questionnaire, a condition list, and one or more supplemental questionnaires that address health topics of special public health interest.¹⁰ Since 1991, a subsample of NHIS respondents has received a supplemental immunization questionnaire. Questions about immunizations are similar to those used in the NIS and described above. Since 1994, the NHIS has used a provider record check, similar to that of the NIS, to both verify and extend information on the immunization card.¹¹

The NHIS is designed to produce data for the nation as a whole and not to produce state-specific statistics. Because of this limitation, immunization data collected as part of the NHIS have not been reported since 1994.

School-Entry Surveys

State laws require that children be immunized by the time they first enter school. To monitor compliance, immunization records of all children entering school are reviewed each fall. In addition, states and other IAP areas conduct retrospective school-entry studies in a sample of schools.^{12,13} The CDC developed the guidelines for conducting these surveys, and they involve collecting data from approximately 35 randomly selected schools in each state or major metropolitan area. From a sample of 25 children selected within each school, the survey determines coverage from immunizations documented on the children's school-held immunization cards. An immunization and date of delivery (at least month and year) must be documented on the immunization card for the dose to be "counted." Immunization status is determined for each child at school entry and retrospectively to age two. The latter figure is most widely reported and comparable with other surveys.

States and localities may vary which immunizations they use in calculating up-to-date status, but most base calculations on the number of children with four doses of DTP, three doses of poliovirus, and one dose of MMR (4:3:1) or these three plus three doses of HepB, (4:3:1:3) at aged 24 months. Because of variation in school-entry laws across the various states concerning which antigens are required, some variation occurs in which immunizations are included in the overall series completion rates.^{14,15}

Because this survey reports immunizations retrospectively, when the school entrant was aged two, a three- to four-year lag time occurs in data reported. That is, data collected in fall of 2000 on 5-year-old kindergarten entrants reports coverage 3 years ago, when these children were aged 2. Thus, it measures the effective-

ness of policies in place between the time the school entrants were born and the time they were aged 2, and not the effectiveness of policies currently in place to increase age-appropriate immunization coverage.

HEDIS Performance Measures Used by Managed Care Plans

The HEDIS measures the performance of managed care plans and includes a number of clinical indicators, one of which is childhood immunization status for enrolled 2-year-old children.¹⁶ Unlike the previous three surveys, all of which measure coverage of a population, this assessment measures how well health plans immunize children in their care. The National Committee on Quality Assurance (NCQA), a non-governmental, not-for-profit organization founded to assess and report on the quality of care provided in managed care plans, developed the HEDIS.^{17,18} The need for such a body emerged in the 1980s and early 1990s as competition among health plans increased and plans began trying to prove merit to purchasers by presenting data on performance. Initially, methods used to determine performance varied by plan, and purchasers could not make comparisons among plans with confidence. This situation created pressure to standardize methodologies to give purchasers comparative information on quality of care among health plans. In response to this pressure, NCQA developed the measures that now constitute the HEDIS set. Since 1991, the NCQA has continued to develop standardized quality-assessment measures and protocols to provide information to both purchasers and consumers of health care regarding the performance of health plans. Decisions about measures and methodology are made in NCQA's Committee on Performance Measurements, a body with representation from purchasers, consumer advocates, providers, health plans, the CDC, and others, and thus is able to balance scientific merit with feasibility considerations and attend to the needs of the multiple stakeholders.

The HEDIS sample is designed to yield a group of children for whom managed care plans can clearly and uncontroversibly be held accountable. As a result, HEDIS applies inclusion criteria to each member to assure that the health plan had a reasonable opportunity to provide the care for which it is being held accountable. To be included, the child must have been continuously enrolled for 12 months before his or her second birthday, thus allowing the plan an opportunity to get completely un-immunized children fully up-to-date.

This continuous-enrollment criterion was originally put in place to allow purchasers of care to make business decisions. Including in the calculation only those children who had been continuously enrolled in a plan for 12 months was designed to give health plans ample opportunity to bring a child up-to-date. Specifi-

cally, if a purchaser were contemplating dropping a plan for reasons of poor performance, the purchaser would need, and the plan would demand, concrete information documenting poor performance. Poor immunization rates for children who have been in a plan for 12 months or more clearly represents poor management by the plan or poor delivery by its providers.

Currently, the 12-month continuous-enrollment criterion is the subject of discussion. At the core of this discussion is the question of whether this criterion is too restrictive. Critics of the 12-month criterion assert that it may result in the exclusion of some of those most at risk for missed immunizations. Supporters point to the need for health plans to have the opportunity to get new members in and up-to-date on their immunizations if they are to be held accountable.

However, this is not the first time that managed care plans have considered the issue of the continuous-enrollment criterion. Before 1997, the continuous-enrollment criterion was even stricter for commercial plans—children had to be enrolled for 24 months—and much more lax for Medicaid plans—children had to be enrolled for only 6 months. To support secondary uses of the HEDIS information, the current 12-month standard was applied to both populations. This resulted in continued performance assessment within commercial or Medicaid systems of care, permitted comparison of Medicaid and commercially insured children, and eliminated redundant efforts within plans that resulted from use of two different measurement specifications. However, the transition came with a cost: The ability to follow trends from previous years in the commercial sector was lost.

For the HEDIS, the sample used in the up-to-date calculation consisted of 411 children sampled systematically from the enrollment cohort who reached their second birthday in the reporting year and who met the continuous-enrollment criterion.¹⁹ The protocol used in the HEDIS calculation of up-to-date is different from that used in the other surveys. Although NIS and CASA report series completion for the same five vaccines if all doses in the Recommended Childhood Immunization Schedule have been delivered, the HEDIS requires fewer doses for Hib and HepB. In addition, HEDIS calculations impose rules for minimum spacing between the doses that NIS calculations do not require.

Examples of potential for confusion and methodologic dissonance are frequent; to be counted in the HEDIS up-to-date calculation, the MMR vaccine must have been given between the first and second birthday and one of the two Hib vaccines must have been given between the first and second birthday. These spacing rules generally conform to the spacings on the Recommended Childhood Immunization Schedule but are more rigid than those used in the NIS. This results in a more accurate assessment of whether the immunizations were given on time (a performance indicator) but

underestimates the proportion of the population completely immunized (a public health indicator).

In addition, variations occur in the HEDIS schedule from the Recommended Schedule. For example, the HEDIS imposes the extra requirement that the two HepB vaccines must be administered by the second birthday, with one of the two administered after the sixth month. In contrast, the Recommended Schedule calls for three HepB immunizations, administered at intervals between birth and 18 months. The Recommended Schedule changes frequently; lags occur in incorporating the changes in the HEDIS requirements, which accounts in large part for the differences.

CASA Assessments

The CASA is a CDC-developed software program and standard methodology for assessing coverage levels for a clinic or practice.^{20,21} States and some localities use it to assess immunization coverage levels in provider sites. Its ultimate goal is to improve immunization coverage in a particular provider site by supplying data that shows the quality of immunization practices in that site. It is an integral part of the Assessment, Feedback, Incentives, eXchange (AFIX) strategy promoted by CDC to give providers the information they need to improve practice.²²

The 2-year sample consists of children aged 24 months to 35 months; coverage is calculated for those immunizations required at age 24 months. Revised sampling recommendations in 1997 call for selecting two samples of children, aged 12 months to 23 months and aged 24 months to 35 months, to evaluate the impact of more recent provider practices. The random sample consists of 100 children in both of the specified age ranges (200 children in all).

Because the purpose of the CASA assessment is to determine coverage within a provider's practice, as opposed to determining coverage for a population in a geographic area, decisions need to be made as to which children the provider is to be held accountable. Unlike HEDIS criteria, which make it difficult to include a child, CASA criteria make it difficult to exclude a child. A child is included in the sample if he or she has a record of at least one medical or immunization visit to that provider; to exclude a child an "absolute confirmation" (emphasis in the original) that the child has moved or gone elsewhere must exist.²³ Specifically, a child can be excluded from the sample only if (1) the records were transferred to another provider, (2) the chart indicates that the child moved or has gone elsewhere, (3) a mailed reminder card was returned without a local forwarding address, (4) the chart indicates that the parent says the child is seeing another provider, or (5) the chart indicates that a home or telephone visit determined that the child was seeing another provider. The CASA software permits customi-

zation when reporting results by allowing users to calculate coverage for children with a specified number of visits or length of time followed. However, CDC staff members report that in practice, most states do not use this option and simply report coverage for the children who meet the one-visit criterion (personal communication, John Stevenson, March 2000).

Unlike NIS requirements, dates of administration for each immunization must be present in the chart to be counted as up-to-date. Notations such as "child up-to-date" are ignored. The CASA software allows providers to calculate up-to-date status for a customized set of immunizations and to impose their own spacing interval requirements. One exception is MMR, which must be given after the first birthday. However, CDC reports that most states and localities count doses delivered without regard to spacing or interval in their up-to-date calculation.

Issues and Controversies in Measuring Immunization Coverage

As is clear from the preceding discussion, major differences exist in design, sampling, vaccines used, and methodologic requirements imposed in the major surveys or sources of data on immunization coverage. Moreover, the differences can translate into enormous differences in immunization coverage rates, as shown in the earlier example of a 20% drop in coverage occurring when HEDIS criteria were applied to 1997 NIS data.⁵

Further, the differences may have profound policy and practical implications, such as whether the nation's children are adequately protected against vaccine-preventable diseases and whether the health care system is working for vulnerable children. In addition, design decisions have implications for assigning responsibility for immunization coverage levels.

Some of the major issues are discussed below. The issues can be divided into those that affect which children are included or excluded from the calculations and those that affect how children are classified as up-to-date (e.g., which vaccines are used in the series completion calculation and age/interval requirements). Although the discussions of these issues can be technical, the questions that lie at the heart of the discussion are not. Rather, they have a profound impact not only on the calculation of coverage but also on who is seen as responsible for the care of poor children. Finally, because NIS is the major survey used to monitor coverage of the nation's children, in-depth discussion of this topic follows.

Who Is Included in the Calculation

Who is included becomes the denominator in the up-to-date calculation, which, in turn, indicates the

population to which the coverage level applies. The differences in purposes and policy goal of the various sources of immunization are seen most sharply in the decisions of whom to include. The NIS, NHIS, and retrospective kindergarten surveys measure coverage for a population in a specified geographic area to monitor protection from disease and, thus, include all children in a given age range in the geographic area from which the sample is drawn. In contrast, CASA measures coverage at a specified provider site and, thus, includes only children at that provider site. The HEDIS measures the coverage of children in a given managed care plan or group of managed care plans, and thus includes only children in the health plan. However, within the universe of children associated with a provider or health plan, debate occurs over which children are legitimately "theirs" and for whom they should be held accountable. For example, is the health plan accountable for a child who enrolled in the last month? Is a provider accountable for a child who came once? Twice? When is a provider accountable? The CASA and HEDIS protocols have inclusion/exclusion criteria that implicitly give answers to these questions.

These inclusion/exclusion criteria have been controversial, with complaints that HEDIS excludes too many children and CASA excludes too few. The CASA criteria hold providers responsible for children and assure medical homes for all children. The guidelines state: "By using one medical or immunization visit as the basis for determining an active user we are encouraging the provider to accept responsibility for a patient."²³ The HEDIS criteria were also developed for accountability reasons, but the concern was that purchasers should not penalize health plans for performance unless children had been in the plan long enough to receive the specified services. Of course, the children in the sample are always current members of the plan (in contrast to children in the CASA sample); the issue is for how long.

Providers sometimes complain that the CASA requirements for sampling are unreasonably stringent. The requirement to include children with only one visit and to exclude only if certain strict criteria are met, such as having the chart bear a notation that the child has moved or gone elsewhere, appear unreasonable. (Examples are based on personal communication with providers in the New York inner city, 1998.) They report that parents often fail to notify providers when they move. When this happens, the chart does not bear a "moved or gone elsewhere" notation. The added restriction that unsuccessful telephone attempts are not acceptable documentation also appears unreasonable to some providers. Further, providers in birthing hospitals say that patients may come to the hospital's outpatient clinic for the first or second visit after birth and then move to a neighborhood health center or private provider. The CASA sample, then, includes children who were seen by that hospital clinic 24

months to 35 months earlier and not since. The providers in these clinics object to the implication that they should be held accountable for the care of such children. Drawing a sample of children using criteria that yield children who are more clearly active raises coverage by almost 10% over that generated by the CASA sample.²⁴

The CASA eligibility criteria and norms were developed with an orientation to the public sector and an eye toward making certain that public providers were held responsible for vulnerable children. Further, and most important, the definitions were designed so that children who saw different providers would not fall through the cracks. The guidelines make these intentions clear: "these definitions imply that clinicians that concurrently serve the same children share responsibility for these clients as they switch back and forth."²³ However, as more and more children are seen in the private sector and health departments use CASA criteria to monitor coverage in the private sector, the need to modify eligibility criteria is even more apparent. A recent effort to monitor private provider coverage rates in Maine began with consensus building around criteria for inclusion of children. The consensus was that a child must have three visits to be included, because providers believed they could then be held accountable for care given to that child.²⁵

The CDC has recognized the need to modify the inclusion criteria, at least for the private sector, and is now pilot testing a protocol with more relaxed inclusion criteria for assessment of coverage (personal communication, John Stevenson, March 2000). It might be desirable to extend the modified criteria to the public-sector CASA surveys as well, because the criteria are stringent and because proliferation of different standards is counterproductive.

Criticism of the HEDIS criteria for sampling is the opposite of that leveled at CASA: Here, the issue is that HEDIS criteria exclude too many children with the 12-month continuous-enrollment criterion. Advocates point out that with high levels of disenrollment from health plans—approximately one third disenroll every year, according to some state reports²⁶—the children who remain in a plan for 12 continuous months represent the most stable and not the norm. There is also concern that vulnerable children are falling through the cracks and are the responsibility of no one. These considerations do not drive purchasing decisions, however, and purchasers were the prime audience for HEDIS results, including childhood immunization rates.

The technical differences between CASA and HEDIS criteria for inclusion should not obscure the fundamental policy question of when a provider or health plan takes responsibility for a child and when that provider or plan should be held accountable for immunization coverage.

Who Is Deemed Up-to-date: Dose and Spacing Requirements, Series Completion Calculations

The numerator in the up-to-date calculation is the number of children who have received all doses of specified vaccines. The rules for determining who is up-to-date vary in the different sources and surveys; the more stringent the rule, the more difficult to be up-to-date. For example, one of the rules deals with which of the 16 doses of six vaccines on the Recommended Childhood Immunization Schedule are included in the calculations. The more vaccines included, the harder it is to be up-to-date. Further, some of the surveys impose the Recommended Schedule's rules about the minimum ages at which the doses can be delivered and the minimum spacing between doses and others do not. Issues in deciding which children are considered up-to-date deal with whether to include doses that are delivered too early or too soon, whether to report coverage for individual immunizations or for a series, and if the latter, which of the six vaccines to include in the up-to-date calculation.

Vaccines used in calculating series completion. The debate over which vaccines to include in the up-to-date calculation goes on, but recently it was conducted in the context of deciding which vaccines to include in the *Healthy People 2010*⁴ goal statement. A policy paper by Rodewald and colleagues²⁷ presents a detailed analysis of this issue. Issues involve the value and benefit of presenting coverage for individual vaccines versus coverage for a combination as well as which vaccines to include in the combination. Presenting a combined series has an advantage in communication: only one number to convey and monitor over time. The disadvantages of using a combination have both technical and policy components. As to the technical component, the vaccine with the lowest coverage determines up-to-date coverage level. As to the policy consideration, as a result, a combined coverage rate does not convey the true protection of a population against vaccine-preventable diseases. Rodewald illustrates the dilemma by showing that the 1997 NIS coverage rate of 78% for four DTP, three poliovirus, and one MMR was determined primarily by the 81% coverage for the fourth dose (and least important dose) of DTP, the vaccination with the lowest coverage in the series. Coverage for all other vaccines was 90% or higher. This example also illustrates the fact that the 78% series completion coverage masks the high level of population protection indicated by 87% to 93% coverage for poliovirus, Hib, and MMR.

Because the vaccine with the lowest coverage determines overall up-to-date rates, inclusion of the newest vaccine, varicella, with its coverage of 43% would cause the overall series coverage to plummet, and possibly convey a misleading message about protection of the

population against disease. As more and more vaccines are added to the schedule, which to include in series-completion calculations will be an ongoing issue. In addition to continual increases in the number of immunizations recommended on a national basis, the recent emergence of regional immunization recommendations further complicates calculating immunization rates. For example, hepatitis A vaccine is recommended for children who live in communities with high rates of hepatitis A infection and periodic hepatitis A outbreaks.²⁸ The question arises whether different measurement standards for up-to-date immunization status should exist in those communities where the recommendation is in force.

The vaccines used in the up-to-date coverage calculation markedly affect the coverage level that will be reported. As an example of this, 10% of the 20% decrease in NIS coverage rates when HEDIS criteria were applied were due to the inclusion of HepB (with its age requirement) in HEDIS, but not in NIS.⁵ Decisions about which vaccines to use revolve, in part, around the purpose of the survey. If the purpose is to monitor trends in up-to-date coverage for a given population over a period of years, then the up-to-date equation needs to use vaccines that have been incorporated into routine practice for a reasonable period of time. The six vaccines now on the recommended schedule vary widely in terms of their introduction into routine use. The oldest (diphtheria, tetanus toxoid, and pertussis vaccines) were introduced into routine childhood immunization in the 1940s, whereas the most recent, varicella, became part of the recommended schedule in 1995. Thus, although the appeal of using the vaccines that have been recommended for a number of years is clear, this calculation does not show incorporation of new vaccines into routine care. With the ever-increasing number of vaccines in the recommended schedule, measurements of new vaccine uptake becomes increasingly important. Including newer vaccines makes it more difficult to monitor trends; however, excluding vaccines from the series creates a hierarchy and conveys an implicit message that some vaccines are more important than others.

The NIS reports coverage for single vaccines and two combined series: four DTP (or DTaP), three poliovirus, and one MMR or measles-containing vaccine (4:3:1), and these three plus three Hib (4:3:1:3), all of which have been on the recommended childhood immunization for more than a decade. The retrospective kindergarten surveys generally report the same way, and the vaccines measured and reported are linked to school-entry laws. The CASA can be customized to report any combination that states and localities wish. In practice, states appeared to follow NIS series. The HEDIS reports up-to-date for five vaccines, but requires fewer doses than the recommended schedule for Hib and HepB. It

reports completion for each vaccine singly and for three combinations.²⁹

Spacing requirements. The requirements for dosage spacing also influences the up-to-date calculation. The spacing requirements used by the various surveys in reporting up-to-date status vary enormously and are the subject of much debate. The ACIP recommends minimum spacing between doses based on available data on immunogenicity conferred. For example, the recommended schedule for four doses of DTaP is at 2, 4, 6, and 12 to 15 months. However, an accelerated schedule may be used, provided that the following minimum age/interval requirements are observed: the first dose must be given at aged 6 weeks or older, the second and third doses 4 to 8 weeks after the previous dose, and the fourth dose a minimum of 6 months after the third.³⁰ Giving doses as soon as possible is recommended if the child is unlikely to return at the recommended times.

The minimum age and spacing requirements are a source of contention between providers of vaccines and enforcers of school-entry requirements (health departments and school nurses), who may disallow doses given 1 or 2 days outside of the age range. It is also a source of contention between managed care providers and managed care plans, because strict adherence to the spacing requirements may not make the best sense from a practical or biologic point of view. For example, if a vulnerable child with a history of missing appointments comes to the doctor at 11 months and 30 days, should a provider administer the MMR vaccine that is technically not due until 12 months? Providers are faced with a dilemma: If they administer the dose, the computer programs used by managed care plans will not count it, and this will hurt the provider's (and plan's) reported coverage level. However, if the provider fails to administer the vaccine, the child might not receive protection from measles until much later.

To continue with this example, suppose that the provider decided to administer the MMR on that visit at 11 months and 30 days. The provider then records the date and vaccine in the chart and on the child's immunization card. Four years later when it is time for entry into kindergarten, the school nurse needs to decide whether the child has had the required immunizations. The decision "by the book," and according to school-entry laws in some states, is that the MMR dose should not be included because it was given too early.

This has been a particularly contentious issue because, although the need for a cut-off date is clear, the biologic significance of a few days difference is unknown in most cases. Because of the contentiousness of this issue, CDC and ACIP have reviewed the issue of cut-off dates to see whether a grace period could be applied. The ACIP has moved to accept a grace period of 4 days to be applied to all doses of all vaccines

(personal communication, William Atkinson, MD, March 2000).

Currently, calculations of up-to-date coverage used by NIS, CASA, and retrospective kindergarten surveys count doses and do not impose age/interval requirements for vaccines other than MMR. In contrast, HEDIS does impose age/interval requirements, but the HEDIS requirements do not conform exactly to the recommended schedule. Efforts are underway to harmonize NIS and HEDIS.

Efforts to harmonize NIS and HEDIS. Because the NIS and HEDIS are the most widely published and used sources of immunization coverage, their sharp differences in coverage rates are a particular source of confusion. Further, with the increase in the number of children in managed care, there is a desire to compare coverage in managed care with another standard. In response to this, efforts have been initiated to harmonize methodologies for determining coverage rates from these two major sources.

The CDC, with the support of NCQA, recently convened an external committee of experts to recommend ways to harmonize. The recommendations of this committee will be forwarded to the NCQA for their consideration. For its part, NCQA will review protocols on a regular basis to keep them in line with scientific developments, appropriately reflecting the additions and updates in the Recommended Schedule for the age cohort and the needs of health plans, purchasers, and consumers. These activities will stimulate continued discussions and have the potential to catalyze changes in the childhood immunization measures and to allow greater harmonization.

If consensus can be achieved in up-to-date calculations in NIS and HEDIS, the next step would be to regard this consensus as the standard and apply it to CASA and retrospective kindergarten surveys as well. Currently these count doses without imposing age/interval requirements.

Issues Concerning the NIS Methodology

Coverage levels reported in the NIS are often higher than those in retrospective school-entry surveys conducted for the same years. Several factors can account for this difference, including the fact that NIS validates and combines data from the immunization card (and recall) with provider data. It is not surprising that coverage is higher when immunizations from multiple sources are used. Analyses of 1995 NHIS data showed that coverage levels determined by using only immunizations recorded by the most recent provider were from 9.6% to 13.4% lower than the coverage levels determined by using all provider-verified immunizations.²⁷

Another major difference between NIS and all other forms of assessment is in the criteria for selection. The NIS uses children aged 19 to 35 months and calculates

coverage at the time of the survey. Children aged 35 months at the time of the survey have had 12 extra months in which to become up-to-date for all vaccines required at aged 2 years, whereas those assessed at 19 months have had 6 months less. The extra time makes a difference in coverage; not counting doses given after 24 months has caused the overall coverage rate to drop by 4%.⁵

In a 1996 report, the General Accounting Office (GAO) criticized NIS methodology, cost, and outcomes in response to congressional concerns about its usefulness, particularly in monitoring coverage in pockets of need.³¹ The major methodologic concerns were that the NIS is a telephone survey, and as such, gathers data only from households with telephones and permits respondent recall if the immunization card is not present. The lack of telephones was especially troubling to the GAO because of the wide variation in the number of households without telephones in the states and metropolitan areas in the NIS (2% to 25%). The GAO acknowledged that CDC had made statistical adjustments to compensate for the biases inherent in a telephone survey and problems with respondent's recall, but noted that the "accuracy of the coverage estimates, consequently, depends to some extent on the validity of a highly complex set of assumptions undergirding these adjustments."³¹ The CDC has responded that they are using well-established and standard telephone survey methods to make the adjustments. They further point out that estimates of coverage are virtually identical in the NIS, which uses telephone methodology, and the NHIS, which is a household interview.

The GAO also questioned the value of the NIS in relation to its cost, particularly because the NIS does not provide estimates of coverage in pockets of need. The criticism stems from the fact that the survey was not intended to identify pockets of children in need of more timely immunization, and the sample is not large enough to permit estimation of coverage in a geographic pocket of need within the states and localities. Rather, the NIS sampling strategy was designed to allow precise estimates of coverage at the national level, and below that only for the 78 IAP sites.

The CDC has responded to these concerns by providing additional analysis of special subgroups within a state or locality, such as coverage for children in poverty, minority children, and children receiving U.S. Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children benefits. The NIS was not designed to monitor coverage, and still does not monitor coverage, in geographic pockets of need within states and localities. The large increase in sample size needed to assess coverage in pockets of need would make the NIS even more costly. Further, to the extent that proportion of households without telephones is even larger in "pockets" than in the general population and because the use of multiple

providers may be greater as well, reliance on statistical adjustments for data collected in pockets of need will increase.

Conclusions

The variability in ways up-to-date immunization coverage is measured flows directly from the purpose for which it is being measured. The basic tension between measuring immunization coverage for purposes of monitoring population protection against disease and measuring immunization coverage to determine how well the health care delivery system is working leads to different ways of selecting a sample and reporting coverage. This, in turn, leads to differences in the coverage rates reported, which creates confusion for policymakers trying to identify problems and to prioritize immunization efforts. The confusion obscures issues of who is responsible for the health care of children, including their immunization status. Decisions about which children to include in the sample imply who is responsible for these children and who is responsible if a problem exists. Although some of the differences in how coverage is measured may be unavoidable because of difference in the overall purpose of the measurement, greater harmonization is possible. Just as a "harmonized" immunization schedule has been created from the separate schedules adopted by the ACIP, the American Academy of Pediatrics, and the American Academy of Family Physicians, there is a need for a harmonized method for calculating up-to-date coverage.

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