THE NATIONAL IMMUNIZATION SURVEY: DESIGN OF A STUDY ON KNOWLEDGE, ATTITUDES AND PRACTICES (NIS-KAP)

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I. Introduction

The National Immunization Survey study on Knowledge, Attitudes and Practices (NIS-KAP) will be conducted by the National Immunization Program (NIP) to help identify public and health care provider perceptions and their influence on the immunization status of young children. Although high coverage rates have been achieved for most recommended immunizations in the U.S. (Centers for Disease Control and Prevention, 1999), increased exposure to vaccine safety concerns may affect general public and vaccination provider attitudes and be a precursor to decreased vaccination rates and disease epidemics (Gangorosa, Galazka, Wolfe, Phillips, Gangarosa, Miller and Chen, 1998). In addition, provider and parents' knowledge and practices regarding vaccines in general can potentially impact vaccination status of children (Orenstein, Atkinson, Mason and Bernier, 1990; Szilagyi, Rodewald, Humiston, and Hager, 1994; National Vaccine Advisory Committee, 1999). Identifying public and provider perceptions and their influence on immunization status of children is important in assessing potential risks to maintaining protection against vaccine-preventable diseases.

The study will assess exposure to vaccine-safety-related information, concerns regarding vaccine safety, and immunization-related knowledge, attitudes, and practices of parents and providers of children in the 2000 and 2001 National Immunization Survey (NIS). The impact of these factors on up-to-dateness with the hepatitis B vaccine, the diphtheria, tetanus, and pertussis (DPT) or the diphtheria, tetanus, and acellular pertussis (DTaP) vaccine, the measles containing vaccine (MCV), and the varicella vaccine will also be examined. This paper will describe the NIS-KAP study design, which was developed to address issues of response error, survey burden and maximization of sample efficiency for key statistics. The household data collection is scheduled to begin in November 2000 contacting households interviewed during the first quarter of 2000.

A. Background

Perceptions of vaccine safety may affect public acceptance of immunization. For example, concern over the safety of whole cell pertussis vaccine resulted in decreased vaccine uptake in Europe, with several countries stopping routine pertussis vaccination. Consequences included increased numbers of cases and deaths (Gangorosa et al., 1998). During the past year, vaccine safety concerns have emerged around the hepatitis B and measles vaccines as potential causes of autoimmune diseases (e.g., multiple sclerosis or diabetes). Media reports questioning vaccine safety – suggesting that potential harms may exceed benefits – have recently appeared on television and in major newspapers. There has also been a proliferation of anti-vaccine information presented on many Internet web-sites, which is accessible to millions of persons in the U.S.

Anti-vaccine messages may also affect support by health care providers for immunization. Recommendation by health care providers is a key factor in whether or not a person is immunized (Fedson, 1992; Keane, 1996). Thus, any decrease in support for immunization by providers could have a substantial impact on vaccination rates. Concern by providers also was cited as a contributing factor to a recent decision in France to narrow recommendations for hepatitis B vaccination.

In addition to vaccine safety, other factors also may affect provider recommendation of vaccination (Pathman, Konrad, Freed, Freeman and Koch, 1996). For example, physician's perception about the need for and efficacy of the hepatitis B vaccine as well as the specialty of the provider have been shown to be associated with physician agreement with and adoption of universal infant hepatitis B vaccination recommendations (Freed, Bordley, Clark, and Konrad, 1994; Pathman et al., 1996). Identi-fying these types of factors is important both to char-acterize the independent impact of safety concerns and to develop strategies to improve immunization coverage.

B. National Immunization Survey Study on Knowledge, Attitudes and Practices (NIS-KAP)

The National Immunization Survey study on Knowledge, Attitudes and Practices (NIS-KAP) was funded to help meet the following analytic goals:

1. Assess exposure of parents and providers to safety concern-related information about the DTP/DTaP (with

emphasis on pertussis), hepatitis B, measles, and varicella vaccines.

2. Identify parent and provider beliefs regarding the risks and benefits of vaccination, in general, and with respect to DTP/DTaP, hepatitis B, measles, and varicella vaccines, in particular.

3. Assess how parent and provider beliefs regarding the benefits and safety of DTP/DTaP, hepatitis B, measles, and varicella vaccines impact the child's immunization status. The independent association between parent and provider beliefs and the child's immunization status will be assessed by controlling for potential confounders and effect modifiers.

4. Assess whether providers' beliefs regarding the benefits and safety of vaccines are associated with their participation in systems or programs, such as Vaccines for Children (VFC) program and community-wide immunization registries that aim to raise immunization coverage among children.

5. Monitor trends in public and provider attitudes regarding vaccine safety.

6. Assess how other provider characteristics (i.e., use of computerized tracking) independently impact immunization status.

This study, by focusing on vaccines for which safety questions are most pervasive (e.g., pertussis and hepatitis B) and coverage rates currently are relatively low (e.g., hepatitis B and varicella), can best assess whether beliefs are affecting behaviors. Moreover, understanding why providers may or may not recommend a specific vaccine to parents — whether related to safety concerns or other factors — is critical to improving the uptake of new vaccines. The ability of the American College of International Physicians and the American Academy of Pediatrics recommendations alone to per-suade providers to offer vaccines is becoming much less reliable, as suggested by the plateau at a level below national coverage goals for the hepatitis B vaccine and the slow uptake of varicella. By contrasting providers who are and are not recommending the hepatitis B or varicella vaccine, this study will provide information about the provider decision-making process that will help CDC's advisory bodies make more effective recom-mendations or better promote existing recommendations.

II. NIS-KAP Study Design

A. Sample Design

The NIS-KAP sample design involves recontacting a subsample of households that participated in the NIS survey. The NIS is a random-digit-dialing sample that is conducted on a quarterly basis. The NIS collects vaccination information from households as well as vaccination-provider-reported immunization histories for the age eligible children in the sample households (Zell, Ezzati-Rice, Battaglia, and Wright, 2000). For a given quarter, the provider-reported immunization histories will be used to draw a stratified subsample of NIS children for the NIS-KAP study. The children's households in the subsample will then be re-contacted for an interview, and additional information will also be collected from the children's vaccination providers.

The NIS-KAP population of interest is parents/guardians of children 19-35 months of age at the time of the NIS interview. Given the study's interest in what factors are associated with immunization status, children missing certain immunizations given their age constitute the "study" group, while children with all the recommended vaccinations given their age and children without provider-reported vaccination histories constitute the two "comparison" groups. In total, the surveyed children will be classified into one of eight groups. The eight classification groups for the study and the estimated number of sample children falling into these groups over the study period are as follows:

Table 1: Study Classification Groups and Sample Size

Group	Expected sample size (6 quarters)	Group Definition
A	1,548	Children who received 2 or fewer doses of hepatitis B vaccine, otherwise UTD[1]
B	798	Children who received 0 doses of varicella vaccine, otherwise UTD
C	318	Children who received 0 doses of MCV, otherwise UTD
D	66	Children who received 2 or fewer doses of DTP/DTaP vaccine, otherwise UTD
E	2,424	Children who fall into any two of the low vaccine study groups (Groups A to D)
F	1,392	Children who fall into any three or more of the four vaccine study groups (Groups A to D)
G	4,884	Children who are 4:3:1:3:3:1 UTD[2]

[1]UTD = up-to-date – 3 or more Hepatitis B doses, one or more varicella dose, one or more MCV dose, 3 or more DTP doses.

[2]4:3:1:3:3:1 means the child received 4 or more DTP doses, 3 or more poliovirus vaccine doses, one or more MCV doses, 3 or more Hib doses, 3 or more Hep B doses and one or more doses of varicella.

H	630	Children without provider-reported vaccination data
Total	12,060	

Using information from the most recent 6 quarters of data collection in the NIS (likely to be Quarter 1, 2000 - Quarter 2, 2001), parents or guardians of children whose vaccinations were not found to be up-to-date in the NIS will be identified. Additionally, a sample of children who were found to be up-to-date on all of their immunizations and a sample of children whose providers did not respond to the NIS immunization record request will be included in the NIS-KAP.

During the design stage, several issues were examined. The data collection instruments for the household and the provider both contain general questions on knowledge and attitudes about childhood vaccination. Additionally, there are vaccine-specific questions for providers and vaccine-specific modules for households. To minimize the sample size of children needed for the NIS-KAP, it was decided to administer the core house-hold questions plus each applicable vaccine-specific module to a sample household. For the comparison group of children who are up-to-date on all of their vaccines, the core questions will be asked along with two randomly assigned vaccine-specific modules. The provider survey collects information about the provider's practices and attitudes regarding childhood immunization, and all con-tacted providers will receive the same questionnaire.

The following data collection process will be used for the NIS-KAP study on a quarterly basis:

1. NIS immunization history data are collected from a nationally representative sample of households with children aged 19-35 months and the immunization records for those children provided by medical providers.
2. Based on immunization data from the NIS, children will be assigned to appropriate study groups (A to F) and randomly selected using differential sampling rates for the desired statistical reliability. Additionally, a random sub-sample of all NIS children found to be up-to-date on all their vaccinations (Group G) and children without provider-reported vaccination data (Group H) will be selected.
3. Households will be re-contacted by telephone by interviewers to administer the supplementary NIS-KAP questionnaire via a CATI interview. Based on an expected 80 percent response rate from the attempted NIS-KAP household interview, 9,648 completed child interviews are expected over 6 quarters. The expected number of completed child interviews per quarter is 1,608.
4. Providers identified for NIS-KAP sample children will be contacted by mail to collect information about their immunization knowledge, attitudes and practices.
5. Data from the NIS household and provider components, from the NIS-KAP household interview and from the NIS-KAP provider survey will all be gathered together into a robust analytical data file.

In the NIS-KAP household interview, parents of children in all groups will be administered the core module questionnaire. Additionally, parents of children in each of the individual study groups will be administered the appropriate vaccine-specific module(s) for hepatitis B, varicella, measles and DTP if their children were not found to be up-to-date in those vaccinations. Finally, parents of up-to-date children will be assigned two vaccine-specific modules at random, while parents of those children who did not have a provider response will not complete any vaccine-specific modules. Vaccine-specific module order will be rotated.

Immunization providers of children included in the household survey component for whom the child's parent or guardian grants consent to contact constitute the provider data collection target group. Providers will be contacted for the six study groups of interest (A through F) and the one comparison group (G) of children who are up-to-date on all of their immunizations. The comparison group of children who have no provider-reported vaccination information will not have a provider contact component. After consent is obtained from the guardian of surveyed children, the provider questionnaire will be mailed to associated providers. Providers who only ad-ministered the birth dose of Hepatitis B vaccine will be excluded since they are not likely to have had a strong influence on parents' vaccination decisions. If a provider completes the questionnaire and returns it, he/she will not be re-contacted. The provider information will be used for subsequent children associated with the provider so long as the parent/guardian consents to contact with the provider. The maximum number of completed provider surveys is ex-pected to be 9,258. The actual number may be less de-pending on how many sample children are served by the same provider.

Using information from the most recent 6 quarters of data collection in the NIS, parents or guardians of children in the eight groups described above will be placed into seven analytic categories. These seven categories with their estimated counts of completed child interviews are shown in Table 2 for six quarters. The table also shows the level of precision expected for each analytic group based on an assumed proportion of 50 percent of the population with some characteristics of interest. The analytic categories differ from the study classification groups in that the child's status vis-a-vis each specific vaccine will determine his or her analytic

group (meaning that a child who is not up-to-date for three vaccines would fall into three analytic groups) while a child can only fall into one classification group (based on overall vaccination status).

Table 2: Estimated Number of Completed Interviews for Children in the Seven Analytic Categories*

Analytic Category	Expected Number of Completed Child Interviews Over 6 Quarters	95% Confidence interval - Half-Width for p=50%
2 doses of Hep. B	2,652	±2.1%
0 doses of Varicella	2,940	±2.0%
0 doses of MCV	1,542	±2.7%
2 doses of DTP/DTaP	492	±4.8%
4:3:1:3:3:1 up-to-date	3,906	±1.7%
Close to no vaccinations (2 Hep. B & 0 Varicella & 0 MCV & 2 DTP)	588	±4.4%
No provider-reported vaccination data	504	±4.8

*A child may be placed into as many as three of the first four analytic categories.

B. Questionnaire Development

1. Process

The design of the NIS-KAP requires development of separate data collection instruments for parents of NIS children and their immunization providers. Parents of NIS children will be asked to reflect back to the time when a specific child was being immunized and identify their attitudes and knowledge about immuniza-tions in general and specific vaccines at that particular time. The vaccines of interest to the NIS-KAP are the same for both parents and immunization providers. Immunization providers will be asked to consider all children in their patient caseloads when identifying their attitudes toward and knowledge about immunizations in general and specific vaccines. Therefore the focus of the instruments differs although the content and process for development of the instruments were similar.

After construction of both questionnaires by the principal investigators at NIP, a panel of nationally recognized experts in questionnaire construction and survey data collection was convened for a series of discussions about both the household and provider questionnaires. Individual items were evaluated for effectiveness in obtaining the desired information, impact on participants, and relationship to project analysis goals. The questions were reformed and reworded.

The questionnaire for parents of NIS children retains separate modules for specific vaccines of study interest.

This is possible because the composition of the sample is known from the NIS results ahead of the telephone re-contact. The Computer Assisted Telephone Interview (CATI) system can present any or all of the vaccine specific modules during a given interview based on knowledge about the child's immunization history. The sample for the different combinations is fixed because the NIS child's immunization history is known from the prior interview and the desired modules will be included for the NIS-KAP interview.

Based on discussions among the investigators and experts, all provider vaccine-specific modules were combined into a single instrument as opposed to individual module questionnaires being mailed to providers. While combining all the modules into a single questionnaire increased the length of the questionnaire to every provider, this was preferable to multiple contacts with a given provider to complete individual modules.

Following additional revisions, the questionnaires were passed to the Questionnaire Design Research Laboratory (QDRL) at the National Center for Health Statistics (NCHS). The laboratory conducted full scale cognitive testing for both questionnaires. For 15 participants in the household questionnaire test, QDRL staff conducted structured cognitive debriefing sessions with each participant about individual questionnaire items and the interview experience. These debriefing sessions were videotaped.

Cognitive testing of the provider questionnaire was completed with respondents from multiple professional medical categories. Provider participants were video-taped as they completed paper questionnaires. A follow-up, structured, cognitive interview then addressed each item on the questionnaire and the overall experience. Suggested changes from the cognitive tests were incor-porated into the questionnaires.

In addition, the first quarter of data collection will be considered a pilot test of the questionnaires and the data collection methods. Given the national scope of the data collection during the pilot test, subgroups with problematic reactions to the questionnaire or survey that did not arise during cognitive testing will be identified and steps taken to alter procedures or modify questions. The pilot test will be the final opportunity to make alterations to ensure a high quality data collection effort.

2. Content

Phrasing of items in each questionnaire was designed to facilitate responses by the target population. While parents are encouraged to report their own knowledge at the time a specific child was being immunized, physicians are instructed to reply in reference to all children in their patient case load.

For both parents and immunization providers, investigators from NIP were interested in respondents' knowledge about reported possible adverse events connected to specific vaccines and the sources of information about those adverse events. Investigators were also interested in determining attitudes about the overall need for immunizations and the effectiveness of vaccines for preventing specific illnesses. Items were written and rewritten to refine wording and phrasing that would gather the desired information without alarming parents about possible immunization side effects. It is particularly difficult to ask if a parent has heard about a connection between a vaccine and an adverse outcome without mentioning the adverse event and leading the individual. Investigators also sought ways to inquire about several individual vaccines without creating undue repetitiveness for both parents and providers.

C. Nonsampling Issues

During the design discussions for the NIS-KAP sample and questionnaires, it became clear that efforts were needed to minimize error in the study due to several potential nonsampling issues. This section summarizes how the study investigators addressed these nonsampling issues during the design phase and plans to minimize such errors during the implementation phase of the study.

One type of error of concern involved response error and was specifically related to recall. Parents/ guardians of children in the sample will be asked questions about their past experiences in taking their child for vaccinations, such as whether they were worried about the safety of vaccines, reasons for non-vaccination, and whether vaccination information was sought and if so from what source. Cognitive testing and the pre-test will enable an assessment of whether parents/guardians have difficulty with accurate recall.

A second response error of concern relates to the validity of the questions and the question response categories. Questions related to opinions and attitudes in particular are subject to being interpreted very widely without clear grounding, context and anchoring of response category scales. During questionnaire development, close attention was given to these issues, resulting in many modifications of the original questions to reduce the potential for these errors.

However, perhaps the major hurdle to implementing the NIS-KAP study involved accurately assigning the children in the household sample to the study groups of interest, which are then sampled at rates specified to meet a certain level of reliability. Originally, the NIS-KAP household questions were to be administered during the regular NIS interview as additional questions. However, because household reports of a child's

immunization history are substantially less reliable than records from their health care providers, this design would have led to inaccurate sample assignment resulting in less reliable estimates of interest.

Table 3 presents information from Quarter 4, 1998 and Quarter 1, 1999 indicating the levels of household vaccine status misreporting when compared to provider vaccination status information (the "gold" standard).

Table 3: Percentage of Children Where Provider Immunization Status Did Not Support Household Reported Immunization Status

Household-reported vaccination status	Percentage of children where provider information indicated reporting error	Number of children with provider information
2 hepatitis B	87.8	3,479
0 varicella	20.1	5,220
0 measles containing	84.3	1,898
2 DTP/DTaP	92.2	2,347
4:3:1:3:3:1 UTD	25.7	2,333

According to Table 3, households most often report DTP/DTaP status erroneously, followed by hepatitis B and measles. Respondents appear to most often correctly report the child's status for the varicella shot.

To address this response error issue, the investigators decided to wait until provider data are collected on the NIS household sample to determine the immunization status of the children. The NIS-KAP followup survey will then select sample children for its study groups based on the provider reports of immunization for more accurate classification and control of the sample allocation.

Survey burden is an issue that affects response rates and inevitably the quality (variance and bias) of survey data. In the design of the NIS-KAP household and provider questionnaires, an attempt was made to keep the number of questions to a minimum and to ensure that there is no redundancy between the core set questions and any of the study group specific questions.

Since the NIS-KAP is a follow-up interview with households who participated in the NIS, it is anticipated that 10 to 20 percent of the NIS sample may have moved between the time of the NIS and NIS-KAP contacts. Therefore, measures to locate the original NIS respondent are crucial to ensure maximum response rates. This is one area that will be tracked closely during the pilot test phase of the survey.

Pertaining to collection of the provider data, there are several important issues. The first emanates from the fact that without the consent of the child's parent/guardian, health care providers cannot be contacted to ask about their immunization practices. In the NIS, 83 percent of parents consent to have their immunization providers contacted. The NIS-KAP study anticipates a comparable success rate since the request really will be for a re-consent from the original NIS sample case. If the NIS-KAP consent rate is substantially lower, the mean square error of NIS-KAP estimates will be affected. The pilot test will indicate likely consent rates in the study and enable procedures to be adopted to improve consent rates if necessary.

The second provider issue has to do with finding the "correct" health care provider. The target population for the NIS-KAP provider questionnaire is the actual physician, nurse practitioner, etc. who administered the child's shots. The NIS-KAP study protocol includes a few techniques to get to the "correct" health care provider. During the household interview, the interviewers will verify with the respondent the name/address of the health care providers they named in the NIS, then ask if there is a specific physician, nurse or physician in charge who should be contacted. This should provide the name of the physician/nurse to whom the provider questionnaire should be directed in most cases. For those cases that still have no name associated with the provider after the household interview, provider offices will be contacted prior to mail-out to collect the name of the physician in charge so that the mailing will be directed to a specific person and not just be mailed to the office for uncontrolled distribution. These efforts will hopefully allow identification and data collection from the physicians/nurses who had the most influence on the sample child's vaccination history.

Finally, there are concerns about obtaining cooperation from physicians/nurses. Ensuring provider response is critical because many surveys of this target group have been unable to obtain high response rates. The NIS-KAP hopes to achieve adequate response rates by designing an easy to complete questionnaire, allowing multiple modes of response such as mail-out/mail-back, fax reporting and reporting over the phone, and including an endorsement letter of the survey from respected medical organizations such as the American Academy of Pediatrics to enhance the survey's legitimacy.

III. Conclusion

The NIS-KAP survey is an excellent opportunity to use the NIS information and expand the available knowledge

with the outcome of helping shape policy and communication messages in the U.S. This attempt to re-contact both participating households and immunization providers and elicit additional information will indicate the usefulness of this strategy to inform other health areas of interest. Given the importance of both the procedures and substantive findings, great care has been given to the design and development of the NIS-KAP study and instruments. Results of this data collection effort will be available from CDC upon the study's completion.

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