Abt Associates Inc.

Documentation and Codebook for the Child Vaccination Histories File:

The Study of Prenatal and Infant Exposure to Thimerosal and Neuropsychological Outcomes at Ages 7-10 Years

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Documentation and Codebook for the Child Vaccination Histories File

1. Introduction to the Vaccination Histories File

The *Vaccination Histories File* contains the vaccination histories of the n=1,047 children in the analysis data set[1]. Each row of the Vaccination Histories File represents a record of a vaccine received on a particular day. Thus, the file has many records per child. The file includes each child's "resolved vaccine history", and also includes the raw, original, non-cleaned vaccine data from each of three data sources. The resolved vaccine histories were obtained from cleaning the raw, original data and resolving any discrepancies among the three data sources and any discrepancies between the records and recommended childhood vaccination schedules. Data cleaning procedures are described subsequently.

All previous analyses and any future analyses should be based on resolved vaccine histories. The raw, non-cleaned records of vaccination receipts are known to contain errors. The primary rationale for providing the raw data along with the resolved histories is for documentation purposes and transparency. Data users can compare the raw data to the resolved vaccine histories to gain a better understanding of the data cleaning process that was used, and to make their own judgments as to the appropriateness of the techniques.

The resolved vaccine histories include only vaccine receipts during the age range spanning from birth to one year. Although the raw, non-cleaned records include records of receipts at older ages, the data cleaning process focused exclusively on receipts that occurred between birth and age one-year. Therefore, if any analyses in the future were to be based on vaccines received by children older than one year, then the analysts would have to clean the raw data using procedures similar to those described in this document.

Exhibit 1.1 shows an example resolved vaccine history for one child. The column "Res_Vacdays1" shows the child's age in days at the time of each vaccine receipt. The exhibit shows that the child received vaccines on the day she/he was born (day 1), and at ages 63, 126, and 183 days. The next three columns to the right show the type of vaccine received, the manufacturer, and the ethyl mercury amount contained in each vaccine. Additional detail is provided subsequently in this document regarding vaccine types and the assignments of mercury amounts associated with each receipt. For most vaccine types, the assignment of a mercury amount was straightforward. For *H. influenzae type b* (HIB) receipts, however, the mercury amount was dependent on the manufacture and type of HIB received. Therefore, a code is provided in the column labeled "HIB_AmtCode", which can be cross-referenced to a look-up table to provide an explanation as to why a particular amount was assigned to each HIB receipt. The column labeled "RecptWtKG1" shows the child's weight (in kilograms) at the time of vaccine receipt. And the final column ("Amt_wt1") shows the mercury amount for each receipt divided by the child's weight at the time of the vaccine receipt. To create the exposure variables used in the analyses, the values of "Amt_wt1" were summed over particular age ranges.

[1] See Documentation and Codebook for Main Analysis File

Exhibit 1.1 Example of a Resolved Vaccine History

ChildID	Res_Vacdays1	Res_VacType	Res_MFR	MercAmt	HIB_AmtCode	RecptWtKG1	Amt_wt1
0001	1	HepB	SKB	12.50		3.65	3.42
0001							
0001	63	DTP	CON	25.00		5.90	4.24
0001	63	HIB	MSD	12.50	3	5.90	2.12
0001	63	HepB	SKB	12.50		5.90	2.12
0001	63	Polio	LED	0.00		5.90	0.00
0001							
0001	126	DTP	CON	25.00		7.17	3.49
0001	126	HIB	MSD	12.50	3	7.17	1.74
0001	126	Polio	LED	0.00		7.17	0.00
0001	183	DTP	CON	25.00		8.51	2.94
0001	183	HepB	SKB	12.50		8.51	1.47
0001	183	Polio	LED	0.00		8.51	0.00

2. Overview of Steps from Raw Data to Creation of Analysis Variables

Data on early childhood exposure to ethyl mercury from thimerosal containing vaccines and immune globulins were obtained from three sources: From computer-automated data files, from abstractions of each child's medical records, and from records provided by parents at the time of the parent interview. An overview of the data processing steps from the receipt of raw data files to the creation of the exposure variables used in analyses is as follows:

1. The master list of study IDs was merged to each of the three vaccine files (computer-automated, chart abstraction, and parent provided immunization records). Any problems with ID discrepancies were resolved at this stage. Each of the three files contained many records per child ID, where each record represented a single vaccine receipt. Each file contained fields for child's ID, type of vaccine received, and either the date the vaccine was received or the child's age in days at the time of vaccine receipt. The computer-automated and chart abstracted data sets also contained fields for vaccine manufacturer and lot number. The master list of study IDs contained each child's ID and date of birth.
2. For each of the three files (chart, computer automated, parent records) a new *VacType* (vaccine type) variable was created, where the possible values taken by the variable, and the spelling of each vaccine type were standardized across all three files. For example, in the computer-automated data set, the codes 08, 43, and 45 took the value "HepB" on the *VacType* variable. In the chart data set, entries originally recorded as "HEP B", "HEP-B", "HEP B RECOMB", and several others were assigned the value "HepB" on the *VacType* variable. In the parent records data set, entries originally coded as "hepb", "HepB", and several others were assigned the value "HepB" on the *VacType* variable. The common coding of the *VacType* variable made possible the merging and alignment of the three data

sources on receipts of particular types of vaccines. All recodes were discussed and confirmed during weekly conference calls with the whole study team (the team included CDC staff, principal investigators from each of the HMOs, many of whom are pediatricians, data managers from each of the HMOs, and Abt staff).

3. For the chart abstraction and parent provided immunization records files, each child's age in days corresponding to each vaccine receipt was calculated. The computer-automated data set was delivered to Abt Associates with a field for child's age in days at time of vaccine receipt.
4. The three files were merged by child's ID, child's age in days at time of vaccine receipt, and vaccine type.
5. The next step was to resolve discrepancies in vaccine histories. Discrepancies included differences between the three data sources regarding the receipt of a vaccine on a particular day, or between the vaccine history indicated in the data set and the recommended vaccine schedule. An example of the former is a case where the medical chart abstraction data set indicated receipt of hepatitis-B vaccine for a child on day 1 (i.e. on day child was born), but where the computer-automated data showed no receipt on that day, and where the parent did not provide a vaccine record. An example of the latter is when a particular data source (e.g. chart or computer automated) indicated receipt of two full series of DTaP, HIB, and HepB only two days apart. Receipt of two full series separated by only two days represents a major discrepancy from recommended vaccine schedules. It is exceedingly unlikely that a child would have received these series two days apart. It is much more likely that the duplicate records are due to clerical errors. Resolution of discrepancies was a major task and is considered in greater detail in Section 3. This data cleaning phase focused exclusively on vaccines and immune globulins received during the age range from birth to one year. Resolution of discrepancies resulted in a "resolved vaccine history" for each child.
6. In the next step we assigned a mercury exposure amount corresponding to each vaccine receipt shown in each child's resolved vaccine history. For example, polio vaccine receipts were assigned an exposure amount equal to zero micrograms of ethyl mercury, hepatitis-b vaccines were assigned an exposure amount equal to 12.5 micrograms of ethyl mercury, and HIB vaccines were assigned values of 0, 12.5, or 25 micrograms depending on the type of HIB vaccine received. Additional details on the exposure amounts corresponding to each vaccine type are provided in Section 4.
7. Next, we needed to obtain the child's weight (in kilograms) corresponding to each age (in days) that the child received a vaccine. For most records the process was straightforward because children's weights are often recorded in medical records at the same time that vaccines are administered. In some cases, however, the data on children's weights were incomplete or did not align perfectly to the dates of vaccine receipt. When a vaccine receipt did not have a corresponding weight, one of two methods was used to impute a weight. If there were recorded weights before and after the vaccine receipt, then linear interpolation was used to predict the child's weight on the day of vaccine receipt. If there were no recorded weights after the vaccine receipt, then all of the child's recorded weights were used in a

growth curve model to predict the child's weight at the time of the vaccine receipt. The predictions from the growth curve models aligned very closely with the growth curves published in the *2000 CDC Growth Charts for the United States: Methods and Developments*. Children with no recorded weights were excluded from the analysis data set.

8. For each vaccine receipt, the mercury exposure amount (expressed as micrograms of ethyl mercury contained in the vaccine) was divided by the child's weight (in kilograms) at the time of vaccine receipt, resulting in a measure of *exposure per kilogram per vaccine receipt*. For example, if a child weighed 8 kilograms at the time of receipt of a vaccine containing 12.5 micrograms of ethyl mercury, then the value on this variable corresponding to this vaccine receipt would be equal to 12.5 / 8 = 1.56 micrograms per kilogram.
9. Finally, for each child, the variables representing *exposure per kilogram per vaccine receipt* were summed over all vaccines and immune globulins received within each of three age ranges (0 to 7 months; 0 to 1 month; 1 to 7 months) to produce the following three variables that were used in the analytical models:
    - Exp07mos = "Exposure zero to 7 months" = Exposure per kilogram per vaccine receipt summed over all vaccines and immune globulins received during the age range from birth to seven months of age (1 to 214 days).
    - Exp01mos = "Exposure zero to 1 month" = Exposure per kilogram per vaccine receipt summed over all vaccines and immune globulins received during the age range from birth to one month of age (1 to 28 days).
    - Exp17mos = "Exposure one to 7 months" = Exposure per kilogram per vaccine receipt summed over all vaccines received during the age range from one to seven months of age (29 to 214 days).

Three additional variables were created that were not used in the analytical models, but were used for descriptive purposes. These three variables were similar to those above, except that there was no division by the child's weight at the time of vaccine receipt. They are:

- Amt07mos = "Amount zero to 7 months" = Amount of ethyl mercury per vaccine receipt summed over all vaccines and immune globulins received during the age range from birth to seven months of age (1 to 214 days).
- Amt01mos = "Amount zero to 1 month" = Amount of ethyl mercury per vaccine receipt summed over all vaccines and immune globulins received during the age range from birth to one month of age (1 to 28 days).
- Amt17mos = "Amount one to 7 months" = Amount of ethyl mercury per vaccine receipt summed over all vaccines received during the age range from one to seven months of age (29 to 214 days).

3. Data Cleaning for Child Vaccination Histories

Data on early childhood exposure to Thimerosal from vaccines and Hepatitis-B immune globulins were obtained from three sources: From computer automated data files[2], from abstractions of each child's medical records, and from records provided by parents at the time of the parent interview. Section 2 provided an overview of the data processing steps from the receipt of raw data files to the creation of the exposure variables. The purpose of the current section is to provide detail on the data cleaning procedures used to derive a "resolved vaccine history" for each child. We use the term "resolved vaccine history" to mean the final vaccine history for a child after having resolved any discrepancies among the three data sources regarding the receipt of a vaccine on a particular day, or between the vaccine history indicated in the raw data set and the recommended vaccine schedule.

In the sections that follow we describe each of several data cleaning procedures that were applied to the combined data set. Explanations of these procedures are accompanied by examples. The data cleaning procedures were developed in close consultation with data managers and investigators at each of the four participating HMOs, and with investigators at the CDC. This team included several pediatricians with firsthand experience in administering childhood vaccinations and in-depth knowledge of vaccination policies and practices used during the time period covered by the study. The team also included data managers and analysts from the HMOs who had a great deal of experience in the use of vaccination data for research purposes.

In a process spanning several months, the entire team scrutinized countless records to help develop and validate the data cleaning procedures. As computer automated cleaning algorithms were developed, samples of resulting vaccine histories, shown along with the raw data from each of the three data sources, were sent out to all team members and were discussed during weekly telephone conferences. Near the end of the process, in order to validate that the computerized algorithms did not generate any unexpected results, Abt staff scrutinized printouts showing the resolved histories and the raw data for every child in the data set.

3.1. Step 1: Preliminary Vaccine History

After combining vaccination data from all three sources (chart, computer-automated, parent provided immunization records) we preliminarily assumed, when a vaccine receipt appears in one or more, but not all three data sources, that the vaccine was received by the child. In other words, a vaccine did not need to appear in all three data sources in order to be counted. As will be shown later, the assumption is preliminary because

[2] Each HMO that participated in the study maintains computer-automated vaccine records for administrative use and for research purposes. These computer-automated files are part of the Vaccine Safety Datalink system.

subsequent cleaning rules may remove one or more of the vaccines from the resolved history. An example of the application of this assumption is shown in Exhibit 3.1, where the resolved vaccine history includes a hepatitis-B vaccine receipt at age 2-days. The right-hand panel of the exhibit shows the vaccine records from the chart, computer-automated and parent provided immunization records data sets. The relevance of the columns for manufacturer and lot number will become apparent in subsequent examples. As shown in the exhibit, the hepatitis-B receipt on day 2 was indicated in the chart data, but was not present in the computer-automated data. There were no parent provided immunization records data for this child. The left-hand panel of the exhibit shows the resolved vaccine history for ID # 258. This child received hepatitis-B vaccines at ages 2, 54, and 282 days, and several other vaccines on ages 60, 178, and 233 days. The resolved vaccine history includes only vaccines received during the age range spanning from birth to 365 days, i.e. from age (in days) = 1 to 365. The columns of the middle panel of the exhibit are for indicators for decision rules. None of those rules were applied in this example, but will be discussed in a subsequent section.

3.2. Step 2: Application of 30-day and 15-day Algorithms

A set of algorithms was developed to detect duplicate records of receipts of HepB, Hib, DTP, DTaP, combined DTP-Hib, combined DTaP-Hib, and polio vaccines within the first year of life. Since polio vaccines did not contain thimerosal, it was not strictly necessary to include them in the cleaning processes, but they were included nonetheless. However, for the other vaccines listed above, failure to identify and remove duplicate records from the resolved vaccine history would result in an overestimate of a child's mercury exposure. Checks for other, less commonly administered childhood vaccines are described in a subsequent section of this document.

For all of the vaccine types listed above, except HepB, the algorithms were based on an assumption that two receipts of a single type of vaccine separated by a period of 30 days or less, represents a major discrepancy from the recommended vaccination schedule. When such cases were detected, the algorithms marked one of the assumed duplicates for removal, and retained the other in the resolved vaccine history. The process for deciding which to keep and which to remove is described subsequently. These algorithms were created with the full awareness that, in the rare instance that a child was mistakenly administered one or more of these vaccines twice in a period of less than 30 days, the application of the algorithm would result in an underestimate of the child's actual exposure. However, there was consensus among the study team that those instances were expected to be exceedingly rare, whereas duplicate entries of the same vaccine were known to be common. Therefore, the algorithms focused on solving the common problem, hence preventing overestimates of exposure, while simultaneously, in rare instances, potentially causing underestimates.

The assumptions underlying the algorithms for HepB were similar to those described above, except that, when one of the receipts is a HepB that was received in the first month of life, it is plausible for two doses to be separated by a period of less than 30 days. This occurs, for example, in cases when a child receives a late birth dose of HepB,

or an early month-1 dose of HepB. Examples include records of children who received HepB vaccinations on days 1 and 29, on days 15 and 43, and on days 2 and 31. The team considered it to be implausible to receive two doses within a period of 15 days or less when one of the receipts occurs in the first month of life, so the algorithm was programmed accordingly. When neither receipt fell within the first 30 days of life, the 30-day algorithm as previously described was applied for HepB vaccinations.

Detecting duplicate records for DTPs and Hibs was complicated by the fact that some discrepancies were caused by situations such as a record of a combined DTP-Hib vaccine in one data source, but separate DTP and Hib vaccines in another source, or entry of a DTP in one source, but entry of a DTaP in another source. The algorithms were designed to detect duplicates in all permutations of individual DTP, DTaP, DT TD, TT, experimental DTaP, and HIB vaccines, and combined DTP, DTaP, and HIB vaccines.

When duplicate records were detected, a set of decision rules was applied to determine which of the two records should be omitted and which should be retained in the resolved vaccine history. The first decision rule was dependent on which of the two records had non-missing information on manufacturer and/or lot number. The record containing information on manufacturer and lot number was deemed to be more reliable and was therefore retained. In order to facilitate the comparisons, a ***manufacturer and lot number information score*** was computed for each record as follows. The combined data set included two variables from the chart data set that listed vaccine manufacture and lot number, and two additional variables listing vaccine manufacture and lot number from the computer-automated data set. For each of those four variables, we created a corresponding dummy variable that took the value "1" if the manufacturer or lot number was non-missing, and took the value "0" otherwise. We then calculated the sum of the four dummy variables to obtain the *manufacturer and lot number information score* for each vaccine record. Possible values on this score were 0, 1, 2, 3, or 4. If one of the two duplicates had a higher score, it was retained, and the other was omitted.

Exhibit 3.2 shows an example where combined DTP-HIB vaccines were retained on days 121, and 185, while separate DTP and HIBs were omitted from the same days because the former had non-missing manufacturer and lot number, while the latter did not. This example also shows same-day-duplicate HIBs that were omitted on day 63. In the "decision rules" columns of the exhibit, "1"s indicate omitted duplicates.

In cases of a tie on the *manufacturer and lot information score*, a second decision rule was implemented. Many duplicates were caused by slight discrepancies between the computer-automated and Chart data sources on the child's age in days at the time of vaccine receipt. If either of the two duplicates matched the parent provided immunization records data regarding the age in days at time of vaccine receipt, and the other did not, the record with the match in the parent data set was retained and the other was omitted.

An example of the application of the second decision rule is presented in Exhibit 3.3 where HIB and polio vaccines recorded on day 117 were omitted from the resolved history because the same vaccine types were recorded on day 120, and the latter had

matching parent provided immunization records data. This exhibit also has an example of an application of the first decision rule. The exhibit shows DTaPs on days 62, 120, and 174 that were omitted because the records of DTPs on the same days had non-missing manufacturer and lot numbers.

Finally, if neither of the two previous rules produced a decision of which to retain and which to omit, then one was chosen at random to retain, and the other was omitted. An example is presented in Exhibit 3.4, where records of HIB and polio receipts on day 130 were omitted, but records of the same vaccines received on day 131 were retained in the resolved vaccine history. The choice of which to omit and which to retain was random.

3.3. Step 3: Check, Verify or Fix

This section summarizes a set of checks that were carried out on the children's vaccine histories to identify potential errors. Vaccine histories identified by this set of checks were scrutinized by the study team during weekly phone conferences and decisions were made either verifying that the history was already correct, or that fixes were needed. Often a decision was made that a child's medical records should be pulled and studied for clues on how to resolve potential discrepancies. The process of checking and fixing was iterative, such that after programming code was written and executed resulting in a change in a set of resolved vaccine histories, the set of checks was run again. The programming code used to make changes was applied only to the resolved vaccine history. The original data from the chart, computer-automated, and parent provided immunization records sources were never changed. A summary of the set of checks is as follows:

1) Verify that there are no two receipts of a single type of vaccines of a single type separated by less than 30 days, unless one is a HepB that was received during the first month of life.

2) Check for any receipts shown as having occurred before the child was born.

This type of error was caused by incorrect date entries. These errors were rectified by examination of the child's full vaccine history, followed by a decision regarding the most likely correct date of receipt. For example, in one case a DTP-HIB vaccine was shown as having been received 180 days prior to the birth of the child. By changing the date of receipt by one year, the vaccine lined up with other vaccine receipts that occurred when the child was 185 days old.

3) Check for receipts of anything other than HepB during first 30 days of life.

Receipts of anything other than HepB or HepB immune globulin were treated as data entry errors. Examples include a record of a receipt of HIB at age 2-days, and for a different child, a receipt of DTP at age 1-day. In both cases the children received HepB

vaccinations on those days. In both cases it was believed that the entries of the HIB and DTP vaccines were inadvertent.

4) Identify and check any histories indicating more than 3 HepB receipts in the first year of life.

The vaccine histories of children with more than three HepB receipts during the first year of life were examined by the study team. In instances where the receipts occurred around birth, 2 months, 4 months, and 6 to 12 months, the histories were deemed to be plausible and no further action was taken. When the four receipts deviated considerably from that pattern, staff from the relevant HMO went back to the child's medical charts to look for clues as to what might have happened. In one example, receipts were listed at birth, around 1 month, around 6 months, and around 7 months. Review of the charts indicated that the record of receipt near 7 months was an error. That receipt was omitted from the child's resolved vaccine history.

5) Identify and check any histories indicating more than 3 DT receipts (including DTPs, DTaPs, TT, experimental DTaP vaccines, DTaP-HIB or DTP-HIB combinations, etc) in the first year of life.

The vaccine histories of children with more than three DT receipts during the first year of life were examined by the study team. In instances where the receipts occurred around 2, 4, 6, and 12 months, the histories were deemed to be plausible and no further action was taken. When the four receipts deviated considerably from that pattern, staff from the relevant HMO went back to the child's medical charts to look for clues as to what might have happened. In one example, receipts were listed at days 66, 121, 154, and 188. Review of the charts indicated that the record of receipt at 154 days was an error. That receipt was omitted from the child's resolved vaccine history.

6) Identify and check any histories indicating more than 4 HIB receipts (including combination vaccines with DTP or DTaP) in the first year of life.

A finding that a child's vaccine history indicated more than 4 HIB receipts triggered a chart review by staff at the relevant HMO. In one case, the receipt of 5 HIBs by a single child within the first year of life was deemed to be accurate.

7) Identify and check any histories indicating a receipt of an influenza vaccine in the first 120 days of life.

It would be unusual to receive a flu shot in this age range. None were found.

8) Checks for Hepatitis-A, MMR, varicella and polio vaccines.

These vaccines never contained thimerosal, so obtaining clean histories was not critical for these vaccines. However, checks were run to help identify anomalies in the children's histories. Checks included identification of histories where either varicella or MMR

vaccine was received in the first 180 days of life, histories where any hepatitis-A vaccine was received before age 1 year, and histories indicating more than three polio receipts in the first year

A list of all vaccine types remaining in the resolved vaccine histories of all children, and the amount and the mercury amount assigned to each receipt is shown in Section 4.

Exhibit 3.1
Example Vaccine History: Record of HepB Vaccine Receipt at Age 2-Days Shown in Chart Data, but no Corresponding Record in Computer-Automated Data.

Resolved Vaccine History				Decision Rule Indicators							Chart, Computer-automated, and Parent Provided Immunization Records Data							
ID	Age Days	Res. Vac.	Res. Mfr.	HepB Polio R1	HepB Polio R2	DTP HIB R1	DTP HIB R2	Same Day Dup.	Bad Date	Look up	Age Days	Chart Vac.	Cmptr Vac.	Parent Vac.	Chart Mfr.	Cmptr Mfr.	Chart Lot	Cmptr Lot
258	2	HepB	MIS								2	HepB			MIS		MIS	
258	54	HepB	SKB								54	HepB	HepB		ENG	SKB	ENG	110
258	60	DTP	CON								60	DTP	DTP		CON	CON	2B4	2B4
258	60	HIB	PRX								60	HIB	HIB		PRA	PRX	M13	M13
258	60	Polio	LED								60	Polio	Polio		LED	LED	67	67
258	178	DTP	LED								178	DTP	DTP		LED	LED	350	350
258	178	HIB	PRX								178	HIB	HIB		PRA	PRX	M13	M13
258	178	Polio	LED								178	Polio	Polio		LED	LED	352	352
258	233	DTP	CON								233	DTP	DTP		CON	CON	3J4	3J4
258	233	HIB	PRX								233	HIB	HIB		PRA	PRX	M13	M13
258	233	Polio	LED								233	Polio	Polio		LED	LED	352	352
258	282	HepB	SKB								282	HepB	HepB		ENG	SKB	128	128
258											465	DTP	DTP		CON	CON	3F5	3F5
258											465	HIB	HIB		PRA	PRX	M71	M71
258											465	MMR	MMR		MSD	MSD	116	116

Notes: For brevity, manufacturer and lot numbers are truncated to three characters. Actual values span more characters and may include blank spaces. Resolved vaccine history includes only vaccines received in the age range of 1 to 365 days.

Exhibit 3.2
Example Vaccine History: Combined DTP-HIB Vaccines Retained on Days 121, and 185 While Separate DTP and HIBs Omitted from Same Days Because Former Had Manufacturer and Lot Number. Same-Day-Duplicate HIBs Omitted on Day 63.

	Resolved Vaccine History			Decision Rule Indicators							Chart, VSD, and Parent Provided Immunization Records Data							
ID	Age Days	Res. Vac.	Res. Mfr.	HepB Polio R1	HepB Polio R2	DTP HIB R1	DTP HIB R2	Same Day Dup.	Bad Date	Look up	Age Days	Chart Vac.	Cmptr Vac.	Parent Vac.	Chart Mfr.	Cmptr Mfr.	Chart Lot	Cmptr Lot
26	1	HepB	MIS								1	HepB	HepB		MIS	UNK	MIS	
26								1			63		HIB			MSD		136
26								1			63		HIB			UNK		
26	63	DTP	CON								63	DTP	DTP		MIS	CON	MIS	3D5
26	63	HIB	MSD								63	HIB	HIB		MIS	MSD	MIS	136
26	63	HepB	SKB								63	HepB	HepB		MIS	SKB	MIS	ENG
26	63	Polio	LED								63	Polio	Polio		MIS	LED	MIS	71
26	121	DTP-HIB	LED								121		DTP-HIB			LED		390
26						1					121	DTP	DTP		MIS	UNK	MIS	
26						1					121	HIB	HIB		MIS	UNK	MIS	
26	121	Polio	LED								121	Polio	Polio		MIS	LED	MIS	71
26	185	DTP-HIB	LED								185		DTP-HIB			LED		390
26						1					185	DTP	DTP		MIS	UNK	MIS	
26						1					185	HIB	HIB		MIS	UNK	MIS	
26	185	HepB	SKB								185	HepB	HepB		MIS	SKB	MIS	ENG
26	185	Polio	LED								185	Polio	Polio		MIS	LED	MIS	71
26											371		DTP-HIB			UNK		
26											371		MMR			UNK		
26											371	DTP	DTP		MIS	UNK	MIS	
26											371	HIB	HIB		MIS	UNK	MIS	

Notes: For brevity, manufacturer and lot numbers are truncated to three characters. Actual values span more characters and may include blank spaces. Resolved vaccine history includes only vaccines received in the age range of 1 to 365 days.

Exhibit 3.3
Example Vaccine History: Day 117 HIB and Polio Vaccines Omitted from Resolved History Because Same Vaccines on Day 120 Have Matching Parent provided immunization records Data. DTaPs on Days 62, 120, and 174 Omitted Because DTPs on Same Days Have Manufacturer and Lot Numbers.

	Resolved Vaccine History			Decision Rule Indicators							Chart, VSD, and Parent Provided Immunization Records Data							
ID	Age Days	Res. Vac.	Res. Mfr.	HepB Polio R1	HepB Polio R2	DTP HIB R1	DTP HIB R2	Same Day Dup.	Bad Date	Look up	Age Days	Chart Vac.	Cmptr Vac.	Parent Vac.	Chart Mfr.	Cmptr Mfr.	Chart Lot	Cmptr Lot
373	1	HepB	MIS								1	HepB	HepB	HepB	MIS		MIS	
373						1					62			DTaP				
373	62	DTP	CON								62	DTP	DTP		CON	CON	400	400
373	62	HIB	PRX								62	HIB	HIB	HIB	PRA	PRX	M00	M00
373	62	HepB	SKB								62	HepB	HepB	HepB	SKE	SKB	ENG	173
373	62	Polio	LED								62	Polio	Polio	Polio	LED	LED	428	428
373							1				117		HIB			PRX		M00
373					1						117		Polio			LED		432
373						1					120			DTaP				
373	120	DTP	LED								120	DTP			LED		431	
373	120	HIB	PRA								120	HIB		HIB	PRA		M00	
373	120	Polio	LED								120	Polio		Polio	LED		432	
373						1					174			DTaP				
373	174	DTP	CON								174	DTP	DTP		CON	CON	M56	5M6
373	174	HIB	PRX								174	HIB	HIB	HIB	PRA	PRX	M23	M23
373	174	Polio	LED								174	Polio	Polio	Polio	LED	LED	430	430
373	306	HepB	SKB								306	HepB	HepB	HepB	SKB	SKB	ENG	ENG

Notes: For brevity, manufacturer and lot numbers are truncated to three characters. Actual values span more characters and may include blank spaces. Resolved vaccine history includes only vaccines received in the age range of 1 to 365 days.

Exhibit 3.4
Example Vaccine History: HIB and Polio Receipts from Day 130 Omitted, Same Vaccines Received on Day 131 Retained. Choice of Which to Omit and Which to Retain was Random.

	Resolved Vaccine History			Decision Rule Indicators							Chart, VSD, and Parent Provided Immunization Records Data							
ID	Age Days	Res. Vac.	Res. Mfr.	HepB Polio R1	HepB Polio R2	DTP HIB R1	DTP HIB R2	Same Day Dup.	Bad Date	Look up	Age Days	Chart Vac.	Cmptr Vac.	Parent Vac.	Chart Mfr.	Cmptr Mfr.	Chart Lot	Cmptr Lot
300	11	HepB	SKB								11	HepB			SKB		139	
300	60	HIB	PRX								60	HIB	HIB		PRA	PRX	M17	M17
300	60	HepB	SKB								60	HepB	HepB		SKB	SKB	ENG	ENG
300	60	Polio	PMC								60	Polio	Polio		PAS	PMC	J06	JO6
300							1				130	HIB			PRA		M28	
300					1						130	Polio			PAS		J11	
300	131	HIB	PRX								131		HIB			PRX		M28
300	131	Polio	PMC								131		Polio			PMC		J11
300	183	HIB	PRX								183	HIB	HIB		PRA	PRX	M28	M28
300	183	Polio	PMC								183	Polio	Polio		CON	PMC	J11	J11

Notes: For brevity, manufacturer and lot numbers are truncated to three characters. Actual values span more characters and include may blank spaces. Resolved vaccine history includes only vaccines received in the age range of 1 to 365 days.

4. Mercury Amount Assigned to Each Childhood Vaccine or Immune Globulin Receipt

Each vaccine or immune globulin listed in each child's resolved vaccine history was assigned a mercury amount. Our reference sources for determining the amount of mercury contained in each receipt included the 1995 and 2000 Physician's Desk References (PDRs), Pediatrics (1999), Plotkin & Orenstein (1999), Plotkin & Mortimer (1994), the Food and Drug Administration (FDA) website (accessed on 2/28/2003), and personal communication with vaccine experts at the FDA. The mercury amounts contained in experimental vaccines were provided by the participating HMOs, using data from their own records.

Exhibit 4.1 shows all of the vaccine types listed in the children's resolved vaccination histories, their frequency of occurrence, and the mercury amount assigned to each. For the time frame in which these vaccines were administered (all were received between 01/03/1993 and 01/08/1998), most of the vaccines had a single, constant mercury amount that did not vary by manufacturer. For example, all hepatitis-b vaccines available during that time contained 12.5 micrograms of ethyl mercury per dose. Exceptions were DTaP, TD, pneumococcal, HIB vaccines, and experimental vaccines. Smithkline Beecham licensed a thimerosal-free DTaP vaccine under the name Infanrix on 1/29/1997. Prior to that all available DTaP vaccines contained 25 micrograms of ethyl mercury per dose. The database of resolved vaccine histories include two receipts of Smithkline Beecham DTaPs after 1/29/1997, but both were so soon after the license date that we made the assumption that these two instances were not receipts thimerosal-free vaccine. We therefore assumed these two doses contained 25 micrograms of ethyl mercury each. The receipt dates were 2/19/97, and 3/21/97.

Almost all of the tetanus/diphtheria (TD) in use during that time frame contained 25 micrograms of ethyl mercury per dose. An exception was a TD vaccine manufactured by Massachusetts Biologic Laboratories, which contained only 8.3 micrograms per dose. However, the database contained no TD receipts where the manufacturer was Massachusetts Biologic Laboratories.

Lederle made two pneumococcal vaccines in that time frame, one of which contained 25 micrograms of ethyl mercury (product name = Pnu-Imune 23), while the other contained zero micrograms of mercury (product name = Prevnar). The resolved vaccine histories do include pneumococcal receipts where the manufacturer was Lederle. We know, however, that at the one HMO where these pneumococcal receipts occurred, that the only product in use at the time was the Prevnar product. Therefore, all pneumococcal receipts from that HMO were assigned a mercury amount equal to zero micrograms. Children from other HMOs with pneumococcal receipts in their resolved vaccine histories were known or assumed[3] to have received the Merck product, which contained zero micrograms of ethyl mercury.

[3] Of the 92 pneumococcal receipts in the resolved vaccine histories, only 1 receipt did not have any information on manufacturer. We assumed this receipt contained zero micrograms of ethyl mercury.

HIB vaccines in use at that time contained zero, 12.5, or 25 micrograms of ethyl mercury, depending on the type and manufacturer. The HIB PRP-T vaccines made by Connaught, Aventis Pasteur, Pasteur Merieux Connaught, and Smithkline Beecham with product names ActHIB and OmniHIB contained zero micrograms of ethyl mercury per dose. The HIB PRP-OMP manufactured by Merck & Company with product name PedvaxHIB contained 12.5 micrograms of ethyl mercury per dose. And HIB HbOC vaccine made by Lederle / Praxis with product name HibTITER contained 25 micrograms of ethyl mercury per dose.

Exhibit 4.1
Vaccine Types in Resolved Vaccine Histories and Amount of Ethyl Mercury in Each Receipt

Vaccine Type	Mercury Amount (Micrograms)	Frequency	Comment
DT TD	25	23	Diphtheria and tetanus
DTP	25	1477	Diphtheria, tetanus, pertussis
DTP-HIB	25	1328	Combined DTP-HIB
DTaP	25	135	Diphtheria, tetanus andacellular pertussis
DTaP-HIB	25	4	Combined DTaP-HIB
DTaPHepB	12.5	6	Experimental combined DTaP-HepB
Flu	12.5	4	Influenza
HBIG	25	7	Hepatitis B immune globulin
HIB	0	47	H. influenzae type b MercAmt=0 if Connaught/Merieux/Pasteur PRP-T ActHIB, or SKB/GSK PRP-T OmniHIB
HIB	12.5	472	H. influenzae type b MercAmt=12.5 if MSD PedVax-HIB
HIB	25	983	H. influenzae type b MercAmt=25 if Lederle/Praxis/WAL HbOC Hibtiter.
HepA	0	5	Hepatitis A
HepB	12.5	2828	Hepatitis B
MMR	0	17	Measles, Mumps, Rubella
Pneumo	0	92	Pneumococcal
Polio	0	2740	Polio
TT	25	3	Tetanus toxoid
Varicel	0	3	Varicella
X01DTaP	0	9	X01 Experimental DTaP
X02(DTaP	25	9	X02 Experimental (Acelimune)
X03	25	3	X03 Experimental (Tetracel)
X03(D-H)	25	3	X03 Experimental (Tetracel)
X10	0	6	X10 Experimental Meningicoccal
		10204	

5. File Formats and Variable Descriptions

The Childhood Vaccination Histories File is provided in three formats: 1) ASCII text format, 2) SAS transport file, and 3) Excel spreadsheet. For analysis purposes, the first two formats are recommended. The excel spreadsheet is provided because it is in a convenient format for visual inspection of the vaccine histories.

Exhibit 5.1
Variables Included in the Childhood Vaccination Histories File

#	Variable	Type	Len	Label
1	ChildID	Char	4	Child ID
2	Res_Vacdays1	Num	8	Resolved: Age in days at vaccine receipt
3	Res_VacType	Char	8	Resolved: Type of vaccine received
4	Res_MFR	Char	8	Resolved: Vaccine manufacturer
5	MercAmt	Num	8	Mercury amount (in vaccine received)
6	HIB_AmtCode	Num	8	Explanatory codes for HIB Merc. amounts
7	RecptWtKG1	Num	8	Child weight in KGs at time of vaccine receipt
8	Amt_wt1	Num	8	Mercury amount / Weight in KGs at vaccine receipt
9	HepBPolio_R1	Num	8	Cleaning rule: HepB/Polio Rule 1
10	HepBPolio_R2	Num	8	Cleaning rule: HepB/Polio Rule 2
11	DTPHib_R1	Num	8	Cleaning rule: DTP - HIB Rule 1
12	DTPHib_R2	Num	8	Cleaning rule: DTP - HIB Rule 2
13	SameDayDup	Num	8	Cleaning rule: Same day duplicate
14	BadDate	Num	8	Cleaning rule: Bad date
15	Lookup	Num	8	Cleaning rule: Special case lookup
16	Ch_VacDays1	Num	8	Chart: Age in days at vac receipt
17	Ch_Vactype	Char	8	Chart: Type of vaccine received
18	Cmptr_VacDays1	Num	8	Computer-automated: Age in days at vac receipt
19	Cmptr_VacType	Num	8	Computer-automated: Type of vaccine received
20	PR_VacDays1	Num	8	Parent Rept: age in days at vac receipt
21	PR_VacType	Char	8	Parent Rept: type of vaccine received
22	Ch_VacText	Char	25	Chart: Original text on vaccine type
23	Ch_Mfr	Char	25	Chart: Manufacturer
24	Ch_Lot	Char	25	Chart: Lot number
25	Cmptr_VacCode	Num	8	Computer-automated: Vaccine code
26	Cmptr_mfr	Num	8	Computer-automated: Manufacturer
27	Cmptr_lot	Num	8	Computer-automated: lot number
28	PR_VacText	Char	50	Parent Rept: Original text on vaccine type
29	SortDays1	Num	8	Age in days at receipt

5.1. Variable Descriptions

Variable Name	Label	Data Type	Length
ChildID	Child ID	Char	4

Description
ChildID is an ID variable that can be used to link files. The values of ChildIDs are sequential from 0001 to 1047.

5.1.1. Resolved Vaccine History Variables

Variable Name	Label	Data Type	Length
Res_Vacdays1	Resolved: Age in days at vac receipt	Numeric	8

Description
Resolved -- child's age (in days) at the time of vaccine receipt.

Source
Child chart abstraction, computer-automated data, and parent provided vaccine records.

Codes and Valid Values
Minimum=1
Maximum=365

Variable Name	Label	Data Type	Length
Res_VacType	Resolved: Type of vaccine received	Character	8

Description
Resolved – type of vaccine received.

Source
Child chart abstraction, computer-automated data, and parent provided vaccine records.

Codes and Valid Values
All valid vaccine types are shown in Exhibit 4.1.

Variable Name	Label	Data Type	Length
Res_MFR	Resolved: Vaccine manufacturer	Character	8

Description
Resolved – Vaccine manufacturer

Source
Child chart abstraction and computer-automated vaccine records.

Variable Name	Label	Data Type	Length
MercAmt	Mercury amount (in vac receipt)	Numeric	8

Description
Amount of ethyl mercury (measured in micrograms) associated with a vaccine receipt.

Source
1995 and 2000 Physician's Desk References (PDRs), the September 1999 AAP, Plotkin & Orenstein (1999), Plotkin & Mortimer (1994), the Food and Drug Administration (FDA) website (accessed on 2/28/2003), and personal communication with vaccine experts at the FDA.

Codes and Valid Values
0, 12.5, 25 micrograms.

Variable Name	Label	Data Type	Length
HIB_AmtCode	Explanatory codes for HIB Merc. amounts	Numeric	8

Description
Numeric code indicating why ethyl mercury amounts of 0, 12.5, or 25 micrograms were assigned to each HIB receipt.

Codes and Valid Values
Code values ranged from 1 to 37. Decision rules and codes are listed below.

Exhibit 5.2
Decision Rules for Assigning Mercury Amounts to HIB Vaccine Receipts

Decision Rules

- If the manufacturer was Merck (MSD), then assume product is PedVax-HIB and assign 12.5 as the mercury amount.
- Con = Merieux = Pasteur = Past. Assume these are PRP-T ActHIBs and assign 0 as the mercury amount.
- SKB = GSK. Assume these are PRP-T OmniHIBs and assign 0 as the mercury amount.
- LED = WAL = Praxis. Assume these are HbOC Hibtitier, multidose, and assign 25 as the mercury amount.
- In cases where the chart and the computer automated data sources have conflicting information regarding the manufacturer, try to resolve the discrepancy by examination of the lot numbers (there are often recognizable differences in the form of the lot numbers for different manufacturers). If all else is equal, place greater trust in the chart abstraction records over the computer-automated records. If a determination cannot be made on the basis of manufacturer or lot number, use the computer-automated vaccine type to make the assignment. If the only information is that a HIB was received, but manufacturer, lot, and type are unknown, then assign the most frequently occurring amount for HIB receipts within each HMO.

Exhibit 5.3 Explanation of HIB Amount Codes

Abbreviations: Ch = chart abstracted data; Cmptr = Computer-automated data. MFR = Manufacturer; => points to mercury amount assigned.

HIB_AmtCode		Description
1	=	"1)HIB Ch+Cmptr MFR in(MERIEUX,PASTEUR,CONN) =>0"
2	=	"2)HIB Ch+Cmptr MFR in(LED,PRAXIS) =>25"
3	=	"3)HIB Ch+Cmptr MFR in(MSD,MERCK) =>12.5"
4	=	"4)HIB Ch MFR in(MERIEUX,PASTEUR,CONN) Cmptr in(SKB) =>0"
5	=	"5)HIB Cmptr_MFR in(MSD), Ch_MFR=missing =>12.5"
6	=	"6)HIB Ch_MFR in(MSD), Cmptr_MFR=missing =>12.5"
7	=	"7)HIB Ch_MFR in(PASTEUR), Cmptr_MFR=missing =>0"
8	=	"8)HIB Ch_MFR in(PRAX), Cmptr_MFR=missing =>25"
9	=	"9)HIB Cmptr and Lot #s look like MSD =>12.5"
10	=	"10)HIB Cmptr in(SKB) Ch=missing =>0 "
11	=	"11)HIB Ch+Cmptr MFR missing, Chtype=OMPPRP =>12.5 "
12	=	"12)HIB Ch_MFR in(CONN), Cmptr_MFR=missing =>0 "
13	=	"13)HIB Lot # lookS like MSD =>12.5"
14	=	"14)HIB Individual vaccine history lookup"
15	=	"15)HIB No MFR or LOT Info, this site assume =>12.5"
16	=	"16)HIB Ch+Cmptr MFR in(LED,PRAXIS) =>25"
17	=	"17)HIB Cmptr in(OTH) Ch MFR in(LED,PRAXIS) =>25"
18	=	"18)HIB Cmptr in(LED,OTH) Ch=miss Lot looks like PRAX=>25"
19	=	"19)HIB Cmptr=PMC Ch=PAST =>0 "
20	=	"20)HIB Ch_MFR in(LED,PRAXIS), Cmptr=missing =>25"
21	=	"21)HIB Ch=PAST Cmptr=missing =>0 "
22	=	"22)HIB Cmptr_MFR in(PRAXIS), Chart=missing =>25"
23	=	"23)HIB No MFR or LOT Info, this site assume =>25"
24	=	"24)HIB Ch+Cmptr MFR in(LED,PRAXIS) =>25"
25	=	"25)HIB Ch_MFR in(LED,PRAXIS) Cmptr missing =>25"
26	=	"26)HIB Cmptr_MFR in(LED,PRAXIS) Ch missing =>25"
27	=	"27)HIB Cmptr_MFR in(LED,PRAXIS) Ch in(53124,58160) =>25"
28	=	"28)HIB Cmptr_MFR in(LED,PRAXIS) Ch=NDC lot looks like PRx=>25"
29	=	"29)HIB HMO LOOKUP: These are HIB Praxis =>25"
30	=	"30)HIB Cmptr=miss Ch=53124 lot looks like PRX=>25"
31	=	"31)HIB Cmptr=miss Ch=Biologics, lot looks like PRX=>25"
32	=	"32)HIB No MFR or LOT Info, this site assume =>25"
33	=	"33)HIB Ch_MFR in(Con,Merieux,Pasteur) =>25"
34	=	"34)HIB Assume Praxis: Cmptr/Ch=MSD But LOT+ChType=PRAXIS =>25"
35	=	"35)HIB Ch_MFR in(LED,PRAXIS) =>25"
36	=	"36)HIB Ch/Cmptr=miss, Ch_type =HbOC assume PRAXIS =>25"
37	=	"37)HIB Individual lookup - Experimental HIB with 0 ethyl merc.=>0"

Variable Name	Label	Data Type	Length
RecptWtKG	Chld weight in KGs at time of vac receipt	Numeric	8

Description
Child's weight (measured in kilograms) at the time of vaccine receipt.

Source
Child's medical chart abtraction.

Codes and Valid Values
Minimum = 2.525
Maximum = 13.948

Variable Name	Label	Data Type	Length
Amt_wt1	Merc amount / Weight in KGs at vac receipt	Numeric	8

Description
Mercury amount from vaccine receipt divided by child's weight (in kilograms) at time of vaccine receipt.

Source
Calculated as MercAmt / RecptWtKG.

Codes and Valid Values
Minimum = 0
Maximum = 6.621

5.1.2. Indicators for Application of Data Cleaning Decision Rules

Any record where there is a receipt indicated any of the three source files (chart abstracted, computer automated, or parent provided immunization records) but that is not included in the resolved vaccine history, is marked with one of the indicators described in this section.

Variable Name	Label	Data Type	Length
HepBPolio_R1	Cleaning rule: HepB/Polio Rule 1	Numeric	8

Description
This indicator implies that the HepB or Polio record was omitted from the resolved vaccine history because it was less than 30 days from a receipt that was retained in the resolved vaccine history (or less than 15 days if it was close to a HepB that was received in the first 30 days of life). This rule was marked if the decision on which to retain and which to omit was based on the "manufacturer and lot number information score". See Section 3.2 for details

Codes and Valid Values
1 = decision rule applied resulting in omission from resolved vaccine history.
. = decision rule not applied for this record.

Variable Name	Label	Data Type	Length
HepBPolio_R2	Cleaning rule: HepB/Polio Rule 2	Numeric	8

Description
This indicator implies that the HepB or Polio record was omitted from the resolved vaccine history because it was less than 30 days from a receipt that was retained in the resolved vaccine history (or less than 15 days if it was close to a HepB that was received in the first 30 days of life). This rule was marked if the decision on which to retain and which to omit was based either on which of the records was corroborated using parent provided immunization records, or based on random selection. See Section 3.2 for details.

Codes and Valid Values
1 = decision rule applied resulting in omission from resolved vaccine history.
. = decision rule not applied for this record.

Variable Name	Label	Data Type	Length
DTPHib_R1	Cleaning rule: DTP - HIB Rule 1	Numeric	8

Description
This indicator implies that the DTP, HIB, DTaP, DTP-HIB, or DTaP-HIB record was omitted from the resolved vaccine history because it was less than 30 days from a receipt that was retained in the resolved vaccine. This rule was marked if the decision on which to retain and which to omit was based on the "manufacturer and lot number information score". See Section 3.2 for details.

Codes and Valid Values
1 = decision rule applied resulting in omission from resolved vaccine history.
. = decision rule not applied for this record.

Variable Name	Label	Data Type	Length
DTPHib_R2	Cleaning rule: DTP - HIB Rule 2	Numeric	8

Description
This indicator implies that the DTP, HIB, DTaP, DTP-HIB, or DTaP-HIB record was omitted from the resolved vaccine history because it was less than 30 days from a receipt that was retained in the resolved vaccine history. This rule was marked if the decision on which to retain and which to omit was based either on which of the records was corroborated using parent provided immunization records, or based on random selection. See Section 3.2 for details.

Codes and Valid Values
1 = decision rule applied resulting in omission from resolved vaccine history.
. = decision rule not applied for this record.

Variable Name	Label	Data Type	Length
SameDayDup	Cleaning rule: Same day duplicate	Numeric	8

Description

This indicator implies that the record was omitted from the resolved vaccine history because a record of the same vaccine type occurring on the same day was included in the resolved vaccine history.

Codes and Valid Values
1 = decision rule applied resulting in omission from resolved vaccine history.
. = decision rule not applied for this record.

Variable Name	Label	Data Type	Length
BadDate	Cleaning rule: Bad date	Numeric	8

Description

This indicator implies that the record was either omitted from the resolved vaccine history because there was an apparent error in the recorded date of receipt, or that the value shown in the "Res_Vacdays1" was altered to correct an apparent error in the date recorded in the chart abstracted, computer-automated, or parent provided immunization records data set.

Codes and Valid Values
1 = decision rule applied resulting in omission from resolved vaccine history or correction to resolved age in days at time of vaccine receipt (Res_Vacdays1).
. = decision rule not applied for this record.

Variable Name	Label	Data Type	Length
Lookup	Cleaning rule: Special case lookup	Numeric	8

Description

This variable indicates that the checking routines had identified the record as a potential problem, leading to scrutiny of the child's vaccine history by the study team. Usually the scrutiny involved pulling the child's medical record to look for clues to resolve the problem. The "Lookup" variable takes the value "1" if it was determined that the record should be omitted, and takes the value "2" if the team determined that the record should be included in the resolved vaccine history.

Codes and Valid Values
1 = decision applied resulting in omission from resolved vaccine history.
2 = decision applied resulting in inclusion of record in resolved vaccine history.

. = decision rule not applied for this record.

5.1.3. Variables Created to Standardized Vaccine Types and Children's Ages at Time of Receipt

There was variation within and across the three data sources (chart abstracted, computer-automated, and parent provided immunization records) in the codes and text used to indicate the type of vaccine received. There are two types of variables described in this section. The first were created to standardize the vaccine types to a common set with common spellings, and the others were created to standardize the child's age in days at the time of vaccine receipt across the three data sources.

Variable Name	Label	Data Type	Length
Ch_VacDays1	Chart: Age in days at vac receipt	Numeric	8

Description
For vaccine receipts indicated in the chart abstracted data set, this variable shows the child's age in days at the time of receipt.

Source
Chart abstracted data

Codes and Valid Values
Minimum = -1033 (This is non-cleaned variable. Records indicating vaccine receipts prior to day 1 obviously contain errors).
Maximum = 4099

Variable Name	Label	Data Type	Length
Ch_Vactype	Chart: Type of vaccine received	Character	8

Description
This variable contains standardized text codes of vaccine types for receipts indicated in the chart abstracted data.

Source
Child chart abstracted data.

Codes and Valid Values
The list of standardized vaccine types is shown in Exhibit 4.1.

Variable Name	Label	Data Type	Length
Cmptr_VacDays1	Computer-automated: Age in days at vac receipt	Numeric	8

Description

For vaccine receipts indicated in the computer-automated data set, this variable shows the child's age in days at the time of receipt.

Source
Computer-automated data

Codes and Valid Values
Minimum = -14 (This is non-cleaned variable. Records indicating vaccine receipts prior to day 1 obviously contain errors).
Maximum = 3625

Variable Name	Label	Data Type	Length
Cmptr_Vactype	Computer-automated type of vaccine received	Character	8

Description
This variable contains standardized text codes of vaccine types for receipts indicated in the computer-automated data set.

Source
Computer-automated data.

Codes and Valid Values
The list of standardized vaccine types is shown in Exhibit 4.1.

Variable Name	Label	Data Type	Length
Pr_VacDays1	Parent Report: Age in days at vac receipt	Numeric	8

Description
For vaccine receipts indicated in the parent report data set, this variable shows the child's age in days at the time of receipt.

Source
Parent provided immunization records data.

Codes and Valid Values
Minimum = -868 (This is non-cleaned variable. Records indicating vaccine receipts prior to day 1 obviously contain errors).
Maximum = 3898

Variable Name	Label	Data Type	Length
Pr_Vactype	Parent report: Type of vaccine received	Character	8

Description
This variable contains standardized text codes of vaccine types for receipts indicated in the parent provided immunization records data set.

Source

Parent provided immunization records data.

Codes and Valid Values
The list of standardized vaccine types is shown in Exhibit 4.1.

5.1.4. Raw, Unaltered Data Fields from Chart, Computer-automated, and Parent Provided Immunization Records Data Sets

The variables described in this section are the original, unaltered data fields for vaccine type, manufacture, and lot number from the chart abstracted, computer-automated, and parent report data sets.

Variable Name	Label	Data Type	Length
Ch_VacText	Chart: Original text on vaccine type	Character	25

Description
This variable contains the original text from the chart abstraction describing the type of vaccine received.

Source
Chart abstracted data.

Variable Name	Label	Data Type	Length
Ch_Mfr	Chart: Manufacturer	Character	25

Description
This variable lists the vaccine manufacturer as recorded on the chart abstraction form.

Source
Chart abstracted data.

Variable Name	Label	Data Type	Length
Ch_Lot	Chart: Lot number	Character	25

Description
This variable lists the vaccine lot number as recorded on the chart abstraction form.

Source
Chart abstracted data.

Variable Name	Label	Data Type	Length
Cmptr_VacCode	Computer-automated: Vaccine Code	Character	4

Description
This variable contains Vaccine Safety Datalink (VSD) codes used in the computer-automated data indicating the type of vaccine received. Exhibit 5.4 shows the vaccine types indicated by each code.

Exhibit 5.4.
Codes Used in Computer-automated Data Set to Indicate Vaccine Type

Cmptr_VacCode		Vaccine Type
1	=	DTP (diphth, tet, pertussis)
2	=	OPV (poliovirus, live, oral)
3	=	MMR (measles/mumps/rubella)
8	=	Hep B, adolescent or pediatric
9	=	Td (adult) (tetanus/diphtheria)
10	=	IPV (poliovirus, inactivated)
100	=	Pneumococcal conjugate, polyvalent
101	=	Typhoid Vi capsular polysaccharide
14	=	IG, NOS
15	=	Influenza, split
16	=	Influenza, whole
17	=	Hib, NOS
20	=	DTaP (diphth., tet. andacel. pert.
21	=	Varicella
22	=	DTP-Hib
28	=	DT (peds) (diphtheria and tetanus)
30	=	HBIG (hepatitis B IG)
31	=	Hep A, pediatric, NOS
32	=	Meningococcal
33	=	Pneumococcal
35	=	Tetanus toxoid
36	=	VZIG (varicella zoster IG)
37	=	Yellow fever
41	=	Typhoid, parenteral
43	=	Hep B, adult
45	=	Hep B, NOS
46	=	Hib (PRP-D)
47	=	Hib (HbOC)
48	=	Hib (PRP-T)
49	=	Hib (PRP-OMP)
50	=	DTaP-Hib (DTaP-Haemophs fluB)
51	=	Hib-Hep B
52	=	Hep A, adult
83	=	Hep A, ped/adol, 2 dose
83R	=	Hep A
85	=	Hep A, NOS
88	=	Influenza, NOS
91	=	Typhoid, NOS Unnn = Comb. vaccine
999	=	Unknown vaccine or immunoglobin
DHB	=	Experimental DTaP-HepB
None	=	No vaccines received
X01	=	X01 Experimental DTaP
X02	=	X02 Experimental (Acelimune)

Exhibit 5.4.
Codes Used in Computer-automated Data Set to Indicate Vaccine Type

Cmptr_VacCode		Vaccine Type
X03	=	X03 Experimental (Tetracel)
X10	=	03 Experimental (Tetracel)

Source
Computer-automated data.

Variable Name	Label	Data Type	Length
Cmptr_Mfr	Computer-automated: Manufacturer	Character	3

Description
This variable lists the vaccine manufacturer as recorded in the computer-automated data set.

Source
Computer-automated data.

Variable Name	Label	Data Type	Length
Cmptr_Lot	Computer-automated: Lot number	Character	15

Description
This variable lists the vaccine lot number as recorded in the computer-automated data set.

Source
Computer-automated data.

Variable Name	Label	Data Type	Length
PR_VacText	Parent Rept: Original text on vaccine type	Character	50

Description
This variable contains the original text from the parent report data set describing the type of vaccine received.

Source
Parent provided immunization records data.

5.1.5. Sorting Variable

Variable Name	Label	Data Type	Length
SortDays1	Age in days at receipt	Numeric	8

Description
This variable is convenient to use for sorting the data set. For example excel version of the Child Vaccination Histories file was sorted by childID and SortDays1. This variable indicates that child's age in days corresponding to any receipt indicated in any of the three data sources.

Source
Chart, computer-automated, parent report.

Codes and Valid Values
Minimum = -1033 (This is non-cleaned variable. Records indicating vaccine receipts prior to day 1 obviously contain errors).
Maximum = 4099

6. References

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