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**Documentation and  
Codebook for the  
Prenatal  
Ethylmercury  
Exposures 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 Prenatal Ethylmercury Exposures File

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# 1. Introduction to the Prenatal Ethylmercury Exposures File

Two sources of prenatal vaccination data (maternal medical chart abstraction, and maternal interview) were combined to create a *Prenatal Ethylmercury Exposures File*. This file contains data on maternal exposure to ethylmercury from thimerosal-containing vaccines and immune globulins received by the mothers of study participants during their pregnancies with the focus children. The file contains one record per mother (n=1,054). Each record lists the types of vaccines and immune globulins received, the amounts of ethylmercury corresponding to each receipt, and the timing of each receipt. The timing of receipt is expressed as the number of months from the receipt to the birth of the focus child.

Examples of several prenatal records are shown in Exhibit 1.1. The first record (ID = “x1”) corresponds to a mother who received a Gamulin injection (an immune globulin) 3.0 months prior to the birth of the focus child. The mercury amount corresponding to a Gammulin receipt was assigned as 50 micrograms of ethylmercury. The example in the second row (ID= “x2”) is a mother who received a rhogam injection (an immune globulin) 2.8 months prior to the birth of the focus child. Rhogam is assumed to have contained 12.75 micrograms of ethylmercury per receipt<sup>1</sup>. ID “x3” received two immune globulin injections during her pregnancy, each containing 50 micrograms of ethylmercury, resulting in a total prenatal exposure amount equal to 100 micrograms.

ID “x4” received an immune globulin 2.6 months before the focus child was born, and received another on the day the child was born. Receipts on the day of the birth of the focus child were assumed to have occurred after delivery, and are therefore not counted in the total prenatal exposure amount. ID “x5” received adult dose influenza and tetanus vaccines during her pregnancy, resulting a total exposure amount equal to 50 micrograms. ID “x6” received a hepatitis-B vaccination resulting in 12.5 micrograms of ethylmercury exposure. And, ID “x7” did not receive any vaccinations or immune globulins during her pregnancy with the focus child.

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<sup>1</sup> Additional detail is provided in Section 3

**Exhibit 1.1**

**Example Records of Prenatal Ethylmercury Exposures from Thimerosal-containing Vaccines and Immune Globulins**

ID	Prenat-thimer	Immune Globulin 1				Immune Globulin 2				Flu		HepB		Tetanus		DT	
		Type	Amt	Mos	Dose	Type	Amt	Mos	Dose	Amt	Mos	Amt	Mos	Amt	Mos	Amt	Mos
x1	50	GAMULIN	50	3.0	1CC												
x2	12.75	RHOGAM	12.75	2.8	SINGLE DOS												
x3	100	GAMULIN	50	5.3	UNK (FULL)	GAMULIN	50	2.5	UNK (FULL)								
x4	50	GAMULIN	50	2.6	J23003	GAMULIN	0	0	J24110								
x5	50									25	7.0			25	0.8		
x6	12.5											12.5	6.6				
x7	0																

PrenatThimer = total ethylmercury exposure from vaccines and immune globulins during pregnancy with focus child.

Columns labeled "Amt" show the ethylmercury amount corresponding to a vaccine or immune globulin receipt.

Columns labeled "Mos" show the number of months between receipt and birth of the focus child.

"Flu" = influenza vaccine, "HepB" = hepatitis-B vaccine, "Tetanus" = tetanus, and "DT" = diphtheria-tetanus. Records indicated that these were the only types of thimerosal-containing vaccines received by the mothers of study participants during their pregnancies with the focus children.

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

Data on prenatal exposure to ethylmercury from thimerosal containing vaccines and immune globulins were obtained from two sources: From abstractions of maternal medical charts covering the period that the mother was pregnant with the focus child, and from questionnaire items from 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 the maternal medical chart and parent interview files. Any problems with ID discrepancies were resolved at this stage. The master list of IDs, the maternal medical chart, and the parent interview data files each contained one record per child ID. The master list of study IDs contained each child's ID and date of birth. The maternal chart file contained a field for Rh-blood group status of the mother. It also contained fields for the date, dosage, manufacturer, and product names of immune globulins received, and for dates and types of vaccines received by the mother. The parent interview file contained data from questionnaire items that explained that women with Rh-negative blood types often receive rhogam or other immune globulins during pregnancy to prevent problems with blood incompatibility, and asked the mother if she had received any rhogam or other immune globulins during her pregnancy with the focus child.
2. For chart records, all entries indicating the type of immune globulin received were recoded to correct spelling errors and variations in abbreviations. For example, an incorrectly spelled entry indicating receipt of "rhogan" would have been recoded to take the value "RHOGAM".

3. Next, we calculated the number of months between vaccine or immune globulin receipt and the date of delivery. Only those receipts that occurred within the period spanning ten months (256 days) prior to the delivery date were counted towards the total amount of prenatal exposure to ethylmercury from thimerosal. Immune globulins received on the day of delivery were assumed to have occurred after delivery, and were therefore not counted in the calculation of prenatal exposure.
4. In the next step, discrepancies between the maternal chart-abstracted data and the parent interview data on receipt of immune globulins during pregnancy were resolved. During the weekly conference calls, the entire study team reviewed all available data for discrepant cases. If the mother was rh-negative, and either of the two data sources indicated receipt of an immune globulin during pregnancy, then it was assumed that a receipt had occurred. Additional details on this step are provided in Section 4 of this document.
5. A mercury exposure amount was assigned to each vaccine or immune globulin receipt. See Section 5 for details.
6. Finally, a measure of total ethylmercury exposure from vaccine and immune globulins received during pregnancy was created. For example, a child whose mother received two vaccines during her pregnancy that each contained 25 micrograms of ethylmercury, e.g., a flu shot and a tetanus shot, would have received a value of 50 micrograms on this measure. This measure was used in the analytical models and was defined as follows:
  - *PrenatThimer* = “Prenatal exposure to ethylmercury from thimerosal” = The sum total of mercury amounts from all thimerosal containing vaccines and immune globulins received by the mother during her pregnancy with the focus child.

### 3. Cleaning of Prenatal Ethylmercury Exposures Data

The chart-abstracted data on vaccine receipts during pregnancy were straightforward. The records listed the types of and dates of vaccine receipts. Using the date of vaccine receipt and the child’s date of birth, we calculated the number of months from receipt to birth and assigned an exposure amount to the vaccine receipt only if the receipt occurred before the child was born, and less than 10 months prior to the birth of the child. Although the rule we applied would have counted receipts 10 months prior to birth (to account for the possibility of late births) there were no receipts listed in the data set that were near 10 months. In these data we found one occurrence of a diphtheria-tetanus (DT) receipt that was 9.2 months prior to the birth of the child. All other vaccine receipts that were counted toward the total exposure amounts were less than 9 months prior to birth.

The chart-abstracted data included records of receipts of the following thimerosal-containing vaccines: Influenza, tetanus, diphtheria-tetanus, and hepatitis-B. There were also records of rubella vaccine receipts, but the rubella vaccines did not contain thimerosal and were therefore of no consequence to the analyses.

The data on immune globulin receipts were less straightforward for several reasons. The first was that the information on the product name and manufacturer sometimes

conflicted with one another, or was sometimes missing entirely. This was a problem because the amount of mercury included in a dose varied according to the product received. A second potential conflict was between the mother's recorded rh-status and immune globulin receipt. The expectation is that rh-positive mothers would not receive immune globulins and rh-negative mothers would usually receive immune globulins. Finally, there was the potential for discrepancy between the mother's recollection of immune globulin receipt, as reported in the parent interview, and the data recorded in the medical charts. The resolutions for each of these types of discrepancies are described below.

An example of a discrepancy between a product name and the product manufacturer is a record that indicates that the product received was Rhogam and the manufacturer was Armour. The product made by Armour was called Gamulin, and thimerosal content in Gamulin was different than that of Rhogam. This discrepancy probably occurred because, even though Rhogam is a specific product, the name "rhogam" is often used as a generic term similar to the way "kleenex" is often used as a generic term to refer to facial tissues, even though Kleenex is a specific product. Therefore, whenever a manufacturer or lot number was listed in the record that pointed toward the receipt of a specific product, that information took precedence over the information listed in the product type field. The Prenatal Ethylmercury Exposures File includes the original text for product type and manufacturer, as well as the resolved product type. The resolved product type represents our best estimate of what was actually received, and was used for the purpose of assigning a mercury exposure amount.

Rhogam was the most commonly listed type of immune globulin at all four HMOs. In cases where the evidence pointed to the receipt of an immune globulin, but where there was no information on product type, manufacturer, or lot number, we assumed the receipt was Rhogam. Section 4 describes variables that were created and analyses that were conducted to evaluate the sensitivity of the model results to this assumption.

For each record we had to make a judgment, based on the available evidence, as to whether the mother received an immune globulin during her pregnancy with the focus child, and if so, what type of immune globulin was received. A set of codes was developed to document the decisions that were made. The codes are shown in the column labeled "Decision code" of Exhibit 3.1 and are defined as follows:

- Decision code 1 = prenatal immune globulin received: The chart indicated that the mother was rh-negative, the mother reported having received an immune globulin during her pregnancy with the focus child, and the chart abstraction listed an immune globulin receipt within the period spanning ten months prior to the birth of the child.
- Decision code 2 = prenatal immune globulin received: Although the mother did not know whether she had received an immune globulin during her pregnancy with the focus child, the chart clearly indicated that the mother was rh-negative,

and the chart abstraction listed an immune globulin receipt within the period spanning ten months prior to the birth of the child.

- Decision code 3 = prenatal immune globulin received: For these records there was a discrepancy between the mother report and the chart-abstracted data. Although the mother reported that she did not receive an immune globulin during her pregnancy with the focus child, the chart clearly indicated that the mother was rh-negative, and the chart abstraction listed an immune globulin receipt within the period spanning ten months prior to the birth of the child. We assumed the mothers' memories were in error and the chart data were correct.
- Decision code 4 = prenatal immune globulin received: The mother and the chart agreed that there had been an immune globulin receipt, but the type of immune globulin was not recorded in the records. Receipt of Rhogam was assumed.
- Decision code 5 = prenatal immune globulin received: The mother indicated that she had received a prenatal immune globulin. According to the chart abstracted data, these mothers were either rh-negative or their rh-status was not recorded. The types and dates of receipts were not recorded. For these records we assumed the mother report was correct and assumed Rhogam receipts were prior to the birth of the child.
- Decision code 6 = prenatal immune globulin received: For this record, we assumed that the chart data indicating that the mother was rh-positive was an error, and assumed the remaining data from both the mother report and the chart were correct. The mother and the chart agreed that there had been an immune globulin receipt, and the chart indicated the type and date of receipt.
- Decision code 7 = no prenatal immune globulin received: For each of these records, the mother indicated that she had received a prenatal immune globulin, but the chart indicated that she was rh-positive and that no receipts had occurred. We assumed the mother's recollection was in error and that the chart was accurate.
- Decision code 8 = no prenatal immune globulin received: The charts indicated that the mother was rh-positive and contained no indication of immune globulin receipt. The mothers in this group either said 'no' or they did not know whether they had received and immune globulin during their pregnancies with the focus children.
- Decision code 9 = no prenatal immune globulin received: For each of these records, both the mother and the chart indicated receipts of immune globulins, but the chart showed that the receipts occurred after the birth of the child. Note that receipts that occurred on the day of the child's birth (indicated as *Months Prior to Birth* =0 in Exhibit 3.1) were assumed to have occurred after delivery and were not counted as prenatal exposures.



- Decision code 10 = no prenatal immune globulin received: Although the chart indicated that the mother was rh-negative, a check-box on the chart abstraction form indicated that no immune globulins had been received. The mother also reported that she had not received an immune globulin during her pregnancy with the focus child.
- Decision code 11 = no prenatal immune globulin received: The mothers in this group indicated that they had not received an immune globulin during their pregnancies with the focus children. The chart data fields were mostly missing or incomplete. The assumption of no prenatal immune globulin receipts was based primarily on the maternal report.
- Decision code 12 = no prenatal immune globulin received: Notes written on the chart indicated that no immune globulins were needed. In one case the mother’s husband was rh-negative, in the other case there was no note about the father rh-status but the child was rh-negative so there was no issue of incompatibility.

**Exhibit 3.1**  
**Data Cleaning Decision Codes for Prenatal Immune Globulin Receipts**

Decision Code	Chart Rh Status	Mother Reported IG Receipt	Original Chart Text for IG Receipt	Cleaned Text for IG Receipt	Assigned Months Mercury Amount	Assigned Months Prior to Birth	Chart Check Box IG Received	Freq.
1	RhNeg	Yes	GAMULIN	GAMULIN	50	2.83	Yes	1
1	RhNeg	Yes	GAMULIN	GAMULIN	50	3.03	Yes	1
1	RhNeg	Yes	HYP RHO-D	HYPRHO-D	50	1.61	Yes	1
1	RhNeg	Yes	HYPRHO-D	HYPRHO-D	50	2.47	Yes	1
1	RhNeg	Yes	J24211	GAMULIN	50	2.66	Yes	1
1	RhNeg	Yes	MISSING	RHOGAM	12.75	2.14	Yes	1
1	RhNeg	Yes	MISSING	RHOGAM	12.75	2.57	Yes	1
1	RhNeg	Yes	MISSING	RHOGAM	12.75	2.93	Yes	1
1	RhNeg	Yes	MISSING	RHOGAM	12.75	2.96	Yes	1
1	RhNeg	Yes	MISSING	RHOGAM	12.75	3.09	Yes	1
1	RhNeg	Yes	MISSING	RHOGAM	12.75	5.56	Yes	1
1	RhNeg	Yes	RHL174	RHOGAM	12.75	2.89	Yes	1
1	RhNeg	Yes	RHL228	RHOGAM	12.75	5.72	Yes	1
1	RhNeg	Yes	RHO GAM	RHOGAM	12.75	2.3	Yes	1
1	RhNeg	Yes	RHOD	HYPRHO-D	50	2.57	Yes	1
1	RhNeg	Yes	RHOGAM	GAMULIN	50	2.11	Yes	1
1	RhNeg	Yes	RHOGAM	GAMULIN	50	2.6	Yes	1
1	RhNeg	Yes	RHOGAM	GAMULIN	50	5.33	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	1.71	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	1.74	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	1.84	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	1.97	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.04	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.14	Yes	1

**Exhibit 3.1**  
**Data Cleaning Decision Codes for Prenatal Immune Globulin Receipts**

Decision Code	Chart Rh Status	Mother Reported IG Receipt	Original Chart Text for IG Receipt	Cleaned Text for IG Receipt	Assigned Mercury Amount	Months Prior to Birth	Chart Check Box IG Received	Freq.
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.17	Yes	2
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.24	Yes	2
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.34	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.4	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.57	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.76	Yes	4
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.8	Yes	3
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	2.89	Yes	4
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	3.03	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	3.06	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	3.09	Yes	2
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	3.26	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	3.29	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	3.42	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	3.45	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	3.55	Yes	2
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	4.87	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	5.3	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	5.69	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	5.72	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	6.74	Yes	1
1	RhNeg	Yes	RHOGAM	RHOGAM	12.75	4.47	Yes	1
1	RhNeg	Yes	Rhogam	RHOGAM	12.75	2.5	Yes	1
1	RhNeg	Yes	Rhogam	RHOGAM	12.75	2.83	Yes	1
1	RhNeg	Yes	Rhogam	RHOGAM	12.75	3.03	Yes	1
1	RhNeg	Yes	UNK	RHOGAM	12.75	2.8	Yes	1
2	RhNeg	DK	MISSING	RHOGAM	12.75	2.04	Yes	1
2	RhNeg	DK	RHOGAM	RHOGAM	12.75	1.22	Yes	1
2	RhNeg	DK	RHOGAM	RHOGAM	12.75	2.93	Yes	1
2	RhNeg	DK	UNK	RHOGAM	12.75	2.76	Yes	1
3	RhNeg	No	MICROHOGAM	MICRHOGAM	11.25	5.66	Yes	1
3	RhNeg	No	MISSING	RHOGAM	12.75	3.16	Yes	1
3	RhNeg	No	MISSING	RHOGAM	12.75	5.39	Yes	1
3	RhNeg	No	MISSING	RHOGAM	12.75	6.61	Yes	1
3	RhNeg	No	RHOGAM	GAMULIN	50	5	Yes	1
3	RhNeg	No	RHOGAM	RHOGAM	12.75	2.01	Yes	1
3	RhNeg	No	RHOGAM	RHOGAM	12.75	2.53	Yes	1
3	RhNeg	No	RHOGAM	RHOGAM	12.75	2.73	Yes	1
3	RhNeg	No	RHOGAM	RHOGAM	12.75	3.22	Yes	1
4	RhNeg	Yes		RHOGAM	12.75	2.34	Yes	1
4	RhNeg	Yes		RHOGAM	12.75	3.03	Yes	1
4	RhNeg	Yes		RHOGAM	12.75	5.26	Yes	1

**Exhibit 3.1**  
**Data Cleaning Decision Codes for Prenatal Immune Globulin Receipts**

Decision Code	Chart Rh Status	Mother Reported IG Receipt	Original Chart Text for IG Receipt	Cleaned Text for IG Receipt	Assigned Mercury Amount	Months Prior to Birth	Chart Check Box IG Received	Freq.
4	RhNeg	Yes		RHOGAM	12.75	7.3	Yes	1
4	RhNeg	Yes		RHOGAM	12.75	7.83		1
5	RhNeg	Yes		RHOGAM	12.75	3		1
5	Unk	Yes		RHOGAM	12.75	3		6
6	RhPos	Yes	RHOGAM	GAMULIN	50	2.66	Yes	1
7	RhPos	Yes			.	.	No	2
8	RhPos	DK			.	.		1
8	RhPos	DK			.	.	No	13
8	RhPos	No			.	.		113
8	RhPos	No			.	.	No	748
9	RhNeg	Yes			.	-21.18	Yes	1
9	RhNeg	Yes	MISSING		.	-0.03	Yes	1
9	RhNeg	Yes	RHIMGLOB		.	0	Yes	1
9	RhNeg	Yes	RHL241A		.	-0.03	Yes	1
9	RhNeg	Yes	RHOGAM		.	0	Yes	1
9	RhNeg	Yes	Rhogam		.	-0.03	No	1
9	RhNeg	Yes	UNKNOWN		.	0	Yes	1
10	RhNeg	No			.	.	No	7
11	Unk	No			.	.		64
11	Unk	No			.	.	No	2
12	RhNeg	Yes			.	.	No	2
Total:								1047

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

Each vaccine or immune globulin received during the prenatal period was assigned a mercury amount. Our reference sources for determining the amount of mercury contained in each vaccine 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).

Final determination of the amounts of ethylmercury in prenatal immune globulins were made in consultation with experts at the FDA and with the manufacturers of immune globulin products. The amounts assigned were as follows:

- Rhogam: Between 1993 and 1997 the fill volumes ranged from 0.5 to 1.2 milliliters (*ml*), with an assumed average fill volume of 0.85 ml. Thimerosal was present in Rhogam at 0.003% w/v, which is equivalent to 30 micrograms ( $\mu\text{g}$ ) per *ml*. Thimerosal was 50 percent ethylmercury by weight. Multiplying the three quantities gives  $30 \frac{\mu\text{g}}{\text{ml}} \times 0.85\text{ml} \times 0.50 = 12.75\mu\text{g}$  of ethylmercury per receipt.
- MicRhogam: Between 1993 and 1997 the fill volumes ranged from 0.3 to 1.2 milliliters (*ml*), with an assumed average fill volume of 0.75 ml. Thimerosal was present in MicRhogam at 0.003% w/v, which is equivalent to 30  $\mu\text{g}$  per *ml*. Thimerosal was 50 percent ethylmercury by weight. Multiplying the three quantities gives  $30 \frac{\mu\text{g}}{\text{ml}} \times 0.75\text{ml} \times 0.50 = 11.25\mu\text{g}$  of ethylmercury per receipt.
- Gamulin and Hyprho-d: The average fill volumes for Gamulin and Hyprho-d used between 1993 and 1997 are assumed to be 1.0 ml. Thimerosal was present in each type at 0.01% w/v, which is equivalent to 100 micrograms  $\mu\text{g}$  per *ml*. Thimerosal was 50 percent ethylmercury by weight. Multiplying the three quantities gives  $100 \frac{\mu\text{g}}{\text{ml}} \times 1.0\text{ml} \times 0.50 = 50\mu\text{g}$  of ethylmercury per receipt.

Exhibit 4.1 lists all of the thimerosal-containing vaccines and immune globulins received by the mothers during their pregnancies with the focus children. The exhibit also shows the amount of ethylmercury assigned to each receipt.

As described previously, the word “rhogam” is often used as a generic term even though it is a specific product. Since lot numbers and manufacturers were infrequently listed in the medical charts, there are many instances where the product type was listed as “rhogam”, but where we are uncertain whether the term was being used generically or was referring to the specific product “Rhogam”. If the term was being used generically,

then we may have assigned the wrong mercury amount to the receipt. For example, if a Gamulin was administered, but the administering physician wrote in the chart that “rhogam” was given, then we would have mistakenly assigned the receipt a mercury amount equal to 12.75, instead of 50. The data set includes two variables, corresponding to IG receipts 1 and 2, that each reflect the level of uncertainty regarding the type of immune globulin received. Recall that up to two immune globulins were listed in the chart abstracted data.

For receipt number 1, we defined a variable named *PN\_ProductInfo1* that could take the values “1” or “0”. A value of “1” reflects a high level of confidence that we have correct information on the type of product that was administered. The variable took the value “1” if the lot number or the manufacturer, or a product other than “rhogam” was recorded in the chart. These pieces of information provided specifics about the product that was received. Immune globulin receipts where *PN\_ProductInfo1* takes the value “0” are those where we lack the specific information on the product received. In several cases we assumed that rhogam was received because we had no information on product type, and in the remaining cases the chart listed the type as “rhogam”, but we are unsure of whether the term “rhogam” was being used generically or was a reference to the specific product. For receipt number 2, the same type of variable was created and named *PN\_ProductInfo2*.

We used the variables *PN\_ProductInfo1* and *PN\_ProductInfo2* in the following way. Our primary set of analyses utilized the prenatal mercury amounts listed in Exhibit 4.1. This is equivalent to an assumption that all receipts with low levels of certainty about the product types were Rhogam receipts, and hence contained 12.75 micrograms of ethylmercury. To evaluate the sensitivity of the model results to the potential misspecification of the type of immune globulin received (and hence the total prenatal mercury exposure amount) we fit an alternate set of models where we made an alternative assumption that all receipts with low levels of certainty about the product types, were Gamulin or Hyprho-d receipts, with 50 micrograms of ethylmercury. In these alternative models, if *PN\_ProductInfo1* or *PN\_ProductInfo2* was equal to zero, than mercury amount for the corresponding immune globulin receipt was set to 50 micrograms.

Exhibit 4.2 shows a three-way cross-tabulation of the variable *PN\_ProductInfo1* with the variable containing the primary mercury amount assignments for immune globulin receipt number one (*PN\_IG1\_Amt*), and with the variable containing the alternate mercury amount assignments for immune globulin receipt number one (*PN\_IG1\_Amt\_Alt*). The exhibit shows that there were 75 immune globulin receipts where the value of *PN\_ProductInfo1* was 0 and the primary mercury amount was assigned as 12.75 micrograms. The alternate value for these 75 receipts was set to 50 micrograms. The same type of cross-tabulation for variables corresponding to immune globulin receipt number two are shown in Exhibit 4.3. Finally, Exhibit 4.4 shows a cross-tabulation of the primary variable measuring total prenatal mercury exposure from thimerosal (*PreNatThimer*), with the variable measuring total exposure calculated using the alternate amounts (*PreNatThimer\_Alt*).

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**Exhibit 4.1****Thimerosal-containing Prenatal Vaccines and Immune Globulins and Amount of Ethylmercury in Each Receipt**

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<u>Vaccine or Immune Globulin Type</u>	<u>Mercury Amount (Micrograms)</u>	<u>Freq.</u>	<u>Comment</u>
Rhogam	12.75	88	Immune globulin
Michrogam	11.25	1	Immune globulin
Gamulin	50	11	Immune globulin
Hyrrho-d	50	3	Immune globulin
Influenza	25	9	Influenza (Adult Dose)
Tetanus	25	3	Tetanus
DT	25	8	Diphtheria-tetanus
HepB	12.5	1	Hepatitis – B

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**Exhibit 4.2****Cross-tabulation of PN\_ProductInfo1, PN\_IG1\_Amt, and PN\_IG1\_Amt\_Alt Variables**

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<u>PN_ProductInfo1</u>	<u>PN_IG1_Amt</u>	<u>PN_IG1_Amt_Alt</u>	<u>Frequency</u>	<u>Cumulative Frequency</u>
.	.	.	959	959
0	12.75	50	74	1033
1	11.25	11.25	1	1034
1	12.75	12.75	2	1036
1	50	50	11	1047

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**Exhibit 4.3****Cross-tabulation of PN\_ProductInfo2, PN\_IG2\_Amt, and PN\_IG\_Amt\_Alt Variables**

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<u>PN_ProductInfo2</u>	<u>PN_IG2_Amt</u>	<u>PN_IG2_Amt_Alt</u>	<u>Frequency</u>	<u>Cumulative Frequency</u>
.	.	.	1032	1032
0	12.75	50	10	1042
1	12.75	12.75	2	1044
1	50	50	3	1047

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**Exhibit 4.4****Cross-tabulation of PreNatThimer and PreNatThimer\_Alt Variables**

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<u>PreNatThimer</u>	<u>PreNatThimer_Alt</u>	<u>Frequency</u>	<u>Cumulative Frequency</u>
0	0	936	936
11.25	11.25	1	937
12.5	12.5	1	938
12.75	12.75	4	942
12.75	50	65	1007
25	25	18	1025
25.5	100	9	1034
50	50	10	1044
62.75	100	1	1045
100	100	2	1047

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## 5. File Formats and Variable Descriptions

The Prenatal Ethylmercury Exposures 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 data.

**Exhibit 5.1**  
**Variables Included in the Prenatal Ethylmercury Exposures File**

#	Variable	Type	Len	Label
1	ChildID	Char	4	ChildID
2	PreNatThimer	Num	8	Total prenatal merc from thimerosal
3	PN_IG1_Type	Char	10	Type of prenatal IG (recpt 1)
4	PN_IG1_Amt	Num	8	Merc amt prenatal IG (recpt 1)
5	PN_IG1_Mos	Num	8	IG1: # months from receipt to birth
6	PN_IG2_Type	Char	9	Type of prenatal IG (recpt 2)
7	PN_IG2_Amt	Num	8	Merc amt prenatal IG (recpt 2)
8	PN_IG2_Mos	Num	8	IG2: # months from receipt to birth
9	PN_Flu_Amt	Num	8	Merc amt from prenatal flu
10	PN_Flu_Mos	Num	8	Flu: # months from receipt to birth
11	PN_HepB_Amt	Num	8	Merc amt from prenatal HepB
12	PN_HepB_Mos	Num	8	HepB:# months from receipt to birth
13	PN_Tet_Amt	Num	8	Merc amt from prenatal Tet
14	PN_Tet_Mos	Num	8	Tet: # months from receipt to birth
15	PN_DT_Amt	Num	8	Merc amt from prenatal DT
16	PN_DT_mos	Num	8	DT: # months from receipt to birth
17	IG1_OrigText	Char	50	IG1: Original Text Recorded in Abstract
18	IG1_Man	Char	50	IG1: Manufacturer
19	IG1_Dose	Char	10	IG1: Dose
20	IG2_OrigText	Char	50	IG2: Original Text Recorded in Abstract
21	IG2_Man	Char	50	IG2: Manufacturer
22	IG2_Dose	Char	10	IG2: Dose
23	RH_Status	Char	5	Rh status of mother
24	IG_Recvd	Char	3	Chart checkbox IG received
25	MoRept	Char	3	Mother reported receipt of IG during pregnancy
26	PN_IG_Code	Num	8	Prenatal IG data cleaning decision code
27	PN_ProductInfo1	Num	8	=1 if specific IG product information
28	PN_ProductInfo2	Num	8	=1 if specific IG product information
29	PN_IG1_Amt_Alt	Num	8	Alternate IG1 mercury amount assignment
30	PN_IG2_Amt_Alt	Num	8	Alternate IG2 mercury amount assignment
31	PreNatThimer_Alt	Num	8	Alternate prenatal merc from thimerosal



## 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. Prenatal Exposure Variables

Variable Name	Label	Data Type	Length
PreNatThimer	Total prenat merc from thimerosal	Num	8

### Description

This variable gives the total amount of prenatal ethylmercury exposure from thimerosal in vaccines and immune globulins received by the mother during her pregnancy with focus child.

### Source

PreNatThimer was calculated as the sum of the following variables (each is described subsequently): PN\_IG1\_Amt, PN\_IG2\_Amt, PN\_Flu\_Amt, PN\_HepB\_Amt, PN\_Tet\_Amt, and PN\_DT\_Amt.

### Codes and Valid Values

Min: 0

Max: 100

Variable Name	Label	Data Type	Length
PN_IG1_Type	Type of prenatal IG (recpt 1)	Char	10

### Description

The chart-abstracted data listed as many as two prenatal immune globulins. This variable lists the “cleaned and standardized” type of immune globulin received for receipt number 1.

### Source

Maternal chart abstraction, and parent interview.

### Codes and Valid Values

Possible values are:

GAMULIN, HYPRHO-D, MICRHOGAM, RHOGAM, and No (for no receipt).

Missing values imply no prenatal receipt.

Variable Name	Label	Data Type	Length
PN_IG1_Amt	Merc amt prenatal IG (recpt 1)	Num	8

**Description**

This variable gives the amount of ethylmercury corresponding to immune globulin receipt number 1 (of up to two receipts).

**Source**

Maternal chart abstraction, and parent interview.

**Codes and Valid Values**

Missing values imply no receipt and are equal to zero exposure. Other exposure amounts are 11.25, 12.75, and 50.

Variable Name	Label	Data Type	Length
PN_IG1_Mos	IG1: # months from receipt to birth	Num	8

**Description**

This variable gives the number of months from receipt of an immune globulin number 1 (of up to 2 receipts) to the birth of the child.

**Source**

Maternal chart abstraction,

**Codes and Valid Values**

Min: -21.18 (negative values are receipts that occurred after the birth of the focus child)

Zero Values: 0 (0 = receipt on day of child's birth – these receipts are assumed to have occurred after delivery).

Minimum positive value: 1.2

Max: 7.8

Missing values imply no receipt.

Variable Name	Label	Data Type	Length
PN_IG2_Type	Type of prenatal IG (recpt 2)	Char	9

**Description**

The chart-abstracted data listed as many as two prenatal immune globulins. This variable lists the “cleaned and standardized” type of immune globulin received for receipt number 2.

**Source**

Maternal chart abstraction, and parent interview.

**Codes and Valid Values**

Possible values are:

GAMULIN, HYPRHO-D, MICRHOGAM, RHOGAM, and No (for no receipt).

Missing values imply no prenatal receipt.

Variable Name	Label	Data Type	Length
PN_IG2_Amt	Merc amt prenatal IG (recpt 2)	Num	8

### Description

This variable gives the amount of ethylmercury corresponding to immune globulin receipt number 1 (of up to two receipts).

### Source

Maternal chart abstraction, and parent interview.

### Codes and Valid Values

Missing values imply no receipt and are equal to zero exposure. Other exposure amounts are 11.25, 12.75, and 50.

Variable Name	Label	Data Type	Length
PN_IG2_Mos	IG2: # months from receipt to birth	Num	8

### Description

This variable gives the number of months from receipt of an immune globulin (number 2 of up to 2 receipts) to the birth of the child.

### Source

Maternal chart abstraction,

### Codes and Valid Values

Min: -0.2 (negative values are receipts that occurred after the birth of the focus child)

Zero Values: 0 (0 = receipt on day of child's birth – these receipts are assumed to have occurred after delivery).

Minimum positive value: 1.2

Max: 6.8

Missing values imply no receipt.

Variable Name	Label	Data Type	Length
PN_Flu_Amt	Merc amt from prenatal flu	Num	8

### Description

This variable gives the amount of ethylmercury corresponding to a prenatal receipt of a flu vaccine.

### Source

Maternal chart abstraction.

**Codes and Valid Values**

Missing (.) implies no receipt

25 = 25 micrograms of ethylmercury.

Variable Name	Label	Data Type	Length
PN_Flu_Mos	Flu: # months from receipt to birth	Num	8

**Description**

This variable gives the number of months from receipt of an influenzae vaccine to the birth of the child.

**Source**

Maternal chart abstraction.

**Codes and Valid Values**

Min: 2.4

Max: 8.9

Missing values imply no receipt.

Variable Name	Label	Data Type	Length
PN_HepB_Amt	Merc amt from prenatal HepB	Num	8

**Description**

This variable gives the amount of ethylmercury corresponding to a prenatal receipt of a hepatitis-b vaccine.

**Source**

Maternal chart abstraction.

**Codes and Valid Values**

Missing (.) implies no receipt

12.5 = 12.5 micrograms of ethylmercury.

Variable Name	Label	Data Type	Length
PN_HepB_Mos	HepB:# months from receipt to birth	Num	8

**Description**

This variable gives the number of months from receipt of a hepatitis-b to the birth of the child.

**Source**

Maternal chart abstraction.

**Codes and Valid Values**

Min: 6.6

Max: 6.6

Missing values imply no receipt.

Variable Name	Label	Data Type	Length
PN_Tet_Amt	Merc amt from prenatal Tet	Num	8

**Description**

This variable gives the amount of ethylmercury corresponding to a prenatal receipt of a tetanus vaccine.

**Source**

Maternal chart abstraction.

**Codes and Valid Values**

Missing (.) implies no receipt

25 = 25 micrograms of ethylmercury.

Variable Name	Label	Data Type	Length
PN_Tet_Mos	Tet: # months from receipt to birth	Num	8

**Description**

This variable gives the number of months from receipt of a tetanus vaccine to the birth of the child.

**Source**

Maternal chart abstraction.

**Codes and Valid Values**

Min: 0.8

Max: 7.7

Missing values imply no receipt.

Variable Name	Label	Data Type	Length
PN_DT_Amt	Merc amt from prenatal DT	Num	8

**Description**

This variable gives the amount of ethylmercury corresponding to a prenatal receipt of a diphtheria-tetanus vaccine.

**Source**

Maternal chart abstraction.

**Codes and Valid Values**

Missing (.) implies no receipt  
25 = 25 micrograms of ethylmercury.

Variable Name	Label	Data Type	Length
PN_DT_mos	DT: # months from receipt to birth	Num	8

**Description**

This variable gives the number of months from receipt of a diphtheria-tetanus vaccine to the birth of the child.

**Source**

Maternal chart abstraction.

**Codes and Valid Values**

Min: 0.8  
Max: 9.2  
Missing values imply no receipt.

**5.1.2. Original Values and Text from Chart Abstraction and Parent Interview**

Variable Name	Label	Data Type	Length
IG1_OrigText	IG1: Original Text Recorded in Abstract	Char	50

**Description**

This variable gives the originally recorded text in the maternal abstracted data set of the type of immune globulin received (receipt number 1 of up to two listed).

**Source**

Maternal chart abstraction.

Variable Name	Label	Data Type	Length
IG1_Man	IG1: Manufacturer	Char	50

**Description**

This variable gives the originally recorded text in the maternal abstracted data set of the manufacturer of the immune globulin received (receipt number 1 of up to two listed).

**Source**

Maternal chart abstraction.

Variable Name	Label	Data Type	Length
IG1_Dose	IG1: Dose	Char	10

**Description**

This variable gives the originally recorded text in the maternal abstracted data set of the dose of the immune globulin received (receipt number 1 of up to two listed).

**Source**

Maternal chart abstraction.

Variable Name	Label	Data Type	Length
IG2_OrigText	IG2: Original Text Recorded in Abstract	Char	50

**Description**

This variable gives the originally recorded text in the maternal abstracted data set of the type of immune globulin received (receipt number 2 of up to two listed).

**Source**

Maternal chart abstraction.

Variable Name	Label	Data Type	Length
IG2_Man	IG2: Manufacturer	Char	50

**Description**

This variable gives the originally recorded text in the maternal abstracted data set of the manufacturer of the immune globulin received (receipt number 2 of up to two listed).

**Source**

Maternal chart abstraction.

Variable Name	Label	Data Type	Length
IG2_Dose	IG2: Dose	Char	10

**Description**

This variable gives the originally recorded text in the maternal abstracted data set of the dose of the immune globulin received (receipt number 2 of up to two listed).

**Source**

Maternal chart abstraction.

Variable Name	Label	Data Type	Length
RH_Status	Rh status of mother	Char	5

**Description**

This variable lists the rh-status of the mother.

**Source**

Maternal chart abstraction.

**Codes and Valid Values**

Valid values are: “RhNeg”, “RhPos”, “Unk”

Variable Name	Label	Data Type	Length
IG_Recvd	Chart checkbox IG received	Char	3

**Description**

A checkbox on the chart abstraction form indicated whether an immune globulin had been received during pregnancy with the focus child. “Yes”, “No”, and missing values were present.

**Source**

Maternal chart abstraction.

**Codes and Valid Values**

Valid values are: “Yes”, “No”, “ ” (single blank space of missing).

Variable Name	Label	Data Type	Length
MoRept	Mother reported receipt of IG during pregnancy	Char	3

**Description**

This variable gives the maternal report of whether she received an immune globulin for rh-incompatibility during her pregnancy with the focus child.

**Source**

Parent interview.

**Codes and Valid Values**

Valid values are: “Yes”, “No”, “DK”.

### 5.1.3. Data Cleaning Documentations Codes



Variable Name	Label	Data Type	Length
PN_IG_Code	Prenatal IG data cleaning decision code	Num	8

### Description

This variable documents the decisions regarding receipts of prenatal immune globulins. See Section 3 of this document for details and codes.

Variable Name	Label	Data Type	Length
PN_ProductInfo1	=1 if specific IG product information	Num	8

### Description

For this variable a value of “1” reflects a high level of confidence that we have correct information on the type of immune globulin product that was received (number one of up to two listed), a value of “0” reflects uncertainty. See Section 4 for details.

Variable Name	Label	Data Type	Length
PN_ProductInfo2	=1 if specific IG product information	Num	8

### Description

For this variable a value of “1” reflects a high level of confidence that we have correct information on the type of immune globulin product that was received (number two of up to two listed), a value of “0” reflects uncertainty. See Section 4 for details.

## 5.1.4. Alternate Amount Variables

Variable Name	Label	Data Type	Length
PN_IG1_Amt_Alt	Alternate IG1 mercury amount assignment	Num	8

### Description

Alternate mercury amount assigned to prenatal immune globulin receipt number one when PN\_ProductInfo1 was equal to zero. Used for sensitivity analysis. See Section 4 for details.

Variable Name	Label	Data Type	Length
PN_IG2_Amt_Alt	Alternate IG2 mercury amount assignment	Num	8

### Description

Alternate mercury amount assigned to prenatal immune globulin receipt number one when PN\_ProductInfo2 was equal to zero. Used for sensitivity analysis. See Section 4 for details.

Variable Name	Label	Data Type	Length
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PreNatThimer_Alt	Alternate prenatal merc from thimerosal	Num	8
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**Description**

Alternate total amount of prenatal ethylmercury exposure from thimerosal in vaccines and immune globulins received by the mother during her pregnancy with focus child. Calculated using alternate prenatal immune globulin amount variables (PN\_IG1\_Amt\_Alt, PN\_IG2\_Amt\_Alt). See Section 4 for details.

**Source**

PreNatThimer was calculated as the sum of the following variable (each is described subsequently): PN\_IG1\_Amt\_Alt, PN\_IG2\_Amt\_Alt, PN\_Flu\_Amt, PN\_HepB\_Amt, PN\_Tet\_Amt, and PN\_DT\_Amt.

**Codes and Valid Values**

Min: 0

Max: 100

## 6. References

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