

Date: 10/23/2002

Agenda

Department of Justice Request in August

Discussed results with Melinda Wharton on September 3rd

Reprimand of Bob Chen on September 18th

Politically sensitive study which requires support of NIP Management

Review Bill Thompson E-mail Dated October 18th

Author List - MADDSP MMR/Autism Study Team

Review Additional Documents for DOJ

I won't have time to make my files available immediately
Will provide them to Beverly the 1st week of November

Review Preliminary Results

Next Steps

Continue to clean up data set
Set up meeting to review SAS program with Tanya and Margarete Kolczak
Construct final analysis data set with minimal amount of identifiable data
Consider fast track to distributing final data set externally

Request from the Department of Justice
National Center on Birth Defects and Developmental Disabilities
MMR and Autism Study

Index of Materials

- 1) Emails between MMR/Autism Study Team
- 2) Folder of the July 26th Autism Working Group Meeting
 - a. Contains the transcript from that meeting and subsequent working group meeting agendas
- 3) Folder with materials for abstractors for the study
 - a. Commonly asked questions/situations
 - b. MMR/Autism Study script which is used for scheduling appointments with individual school systems
- 4) Folder with abstraction updates
 - a. Abstraction updates between the Project Coordinator of the study and the Principal Investigator- in the form of memos
 - b. Abstraction Updates-tables describing the number of children abstracted in each system.
- 5) Folder with data collection instrument
 - a. The document is a hard-copy of the abstraction instrument used for the MMR/Autism study.
- 6) Folder with IRB materials
 - a. IRB renewal for 2002
 - b. Original IRB approval
- 7) Folder with Protocol that was distributed to the participating nine-school systems
- 8) Folder with approved protocol for the study
- 9) Folder with Analysis Plan of the study
 - a. To do list for the MMR/Autism Analysis Plan
 - b. Analysis plan draft dated 5/10/2001 that was sent to outside reviewers who are autism and epidemiology experts
 - c. Current analysis plan-after reviewers' comments were incorporated
- 10) Folder with the reviewers' comments of the analysis plan
 - a. Comments from reviewers
 - b. Summary of all of the reviewers comments
- 11) Folder containing documents describing the MMR record review process
 - a. Summary of record review process for delay less than one year or indication of pre-existing conditions
 - b. Instructions for MMR/Autism record review
 - c. MMR record review format outline
 - d. Example of record review form used by each reviewer
 - e. Hard copy of data instrument used to enter in data from the record review
 - f. List of birth defects had by some of the cases
- 12) Folder with preliminary draft of manuscript

Request from the Department of Justice
National Center on Birth Defects and Developmental Disabilities
MMR and Autism Study

Items not currently included in this request:

- 1) Preliminary results
 - a. This includes current and past drafts of the manuscript which contains preliminary results and any other results-containing information
- 2) Dataset
 - a. A dataset has not been provided as it is not yet finalized.
 - b. Edit reports regarding the data
 - c. Other data edits (i.e., misspelling of the names of children which is important for linkages with birth certificate files).
- 3) Emails from some members of the study which are dated from 1999-2000.
 - a. Gaining ability to obtain these emails off of archived files from the Center's computer network is underway. They were not readily available at the time of request.
- 4) All documents containing identifying information such as names of cases or controls and the participating schools.
 - a. Hard copies of each of the abstracted records
- 5) All flagged items either contain personal identifiers or are components of the dataset or relate directly to the dataset.

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Comment: These documents must be provided ASAP for review prior to the DOJ visit on 10/22.

Comment: DOJ may want to see how this data is kept. In addition, they need to know how much data is here, how long it would take to produce ALL of it, not just parts.

Comment: I will work with Angela on this.

Comment: Need to find out who has all of this. How much is there? How long would it take to produce, and what would be the best format to provide access?

Table 1: Descriptive Statistics Unmatched Birth Certificate Sample

Variable	Category	Total Sample				Birth Certificate Sample			
		Controls		Cases		Controls		Cases	
		N	Percent	N	Percent	N	Percent	N	Percent
Age in 1996	3 - 5 yrs	623	34%	214	34%	376	37%	127	36%
	6 - 10 yrs	1201	66%	410	66%	644	35%	228	13%
Sex	Male	1462	80%	500	80%	809	44%	282	15%
	Female	362	20%	124	20%	211	12%	73	4%
Race	White	918	50%	333	53%	571	31%	199	11%
	Black	636	35%	230	37%	384	21%	137	8%
	Other	174	10%	40	6%	65	4%	19	1%
	Missing	96	5%	21	3%	0	0%	0	0%
Maternal Age	< 20 yrs					95	9%	15	4%
	20 - 34 yrs					803	79%	280	79%
	35+ yrs					122	12%	60	17%
Maternal Educ	<= 12 yrs					466	46%	135	38%
	13 - 15 yrs					253	25%	100	28%
	16+ yrs					301	30%	120	34%
Birth Weight	0 - 1499 gms					11	1%	12	3%
	1500 - 2499 gms					52	5%	37	10%
	2500 + gms					957	94%	306	86%
Multiplicity	Singleton					990	97%	329	93%
	Twin +					30	3%	26	7%
Parity	1st Born					452	44%	149	42%
	2nd or Higher					560	55%	204	57%
	Missing					8	1%	2	1%
Total		1824	100%	624	100%	1020	100%	355	100%

* All subjects reported in this table either received an MMR vaccine or had a DTP vaccine by the age of 2

** All cases are confirmed cases

*** The birth certificate sample presented in this table is the unmatched sample.

Background Table

1) Total Sample	Age Group	Controls	%Controls	Cases	%Cases	OR	- 95% CI	+ 95% CI
Updated	0 - 11 mo	36	2.0%	8	1.3%	1.0	0.4	2.2
	12 - 17 mo	1232	67.5%	440	70.5%	1.5	1.1	2.2
	18 - 23 mo	260	14.3%	90	14.4%	1.5	1.0	2.2
	24 - 29 mo	86	4.7%	29	4.6%	1.4	0.8	2.5
	30 - 35 mo	38	2.1%	16	2.6%	1.8	0.9	3.6
	36+ mo	172	9.4%	41	6.6%	--	--	--
	Total	1824	100.0%	624	100.0%			

* Overall test of distribution is not statistically significant

2) Matched BC Sample	Age Group	Controls	%Controls	Cases	%Cases	OR	- 95% CI	+ 95% CI
	0 - 11 mo	8	1.4%	2	0.6%	0.7	0.1	3.8
	12 - 17 mo	406	70.5%	218	70.1%	1.4	0.7	2.5
	18 - 23 mo	87	15.1%	52	16.7%	1.5	0.7	3.0
	24 - 29 mo	27	4.7%	13	4.2%	1.3	0.5	3.2
	30 - 35 mo	8	1.4%	9	2.9%	2.3	0.7	7.3
	36+ mo	40	6.9%	17	5.5%	--	--	--
	Total	576	100.0%	311	100.0%			

* Overall test of distribution is not statistically significant

Figure 2: Age of 1st MMR Vaccination by Case Status
For Total Sample

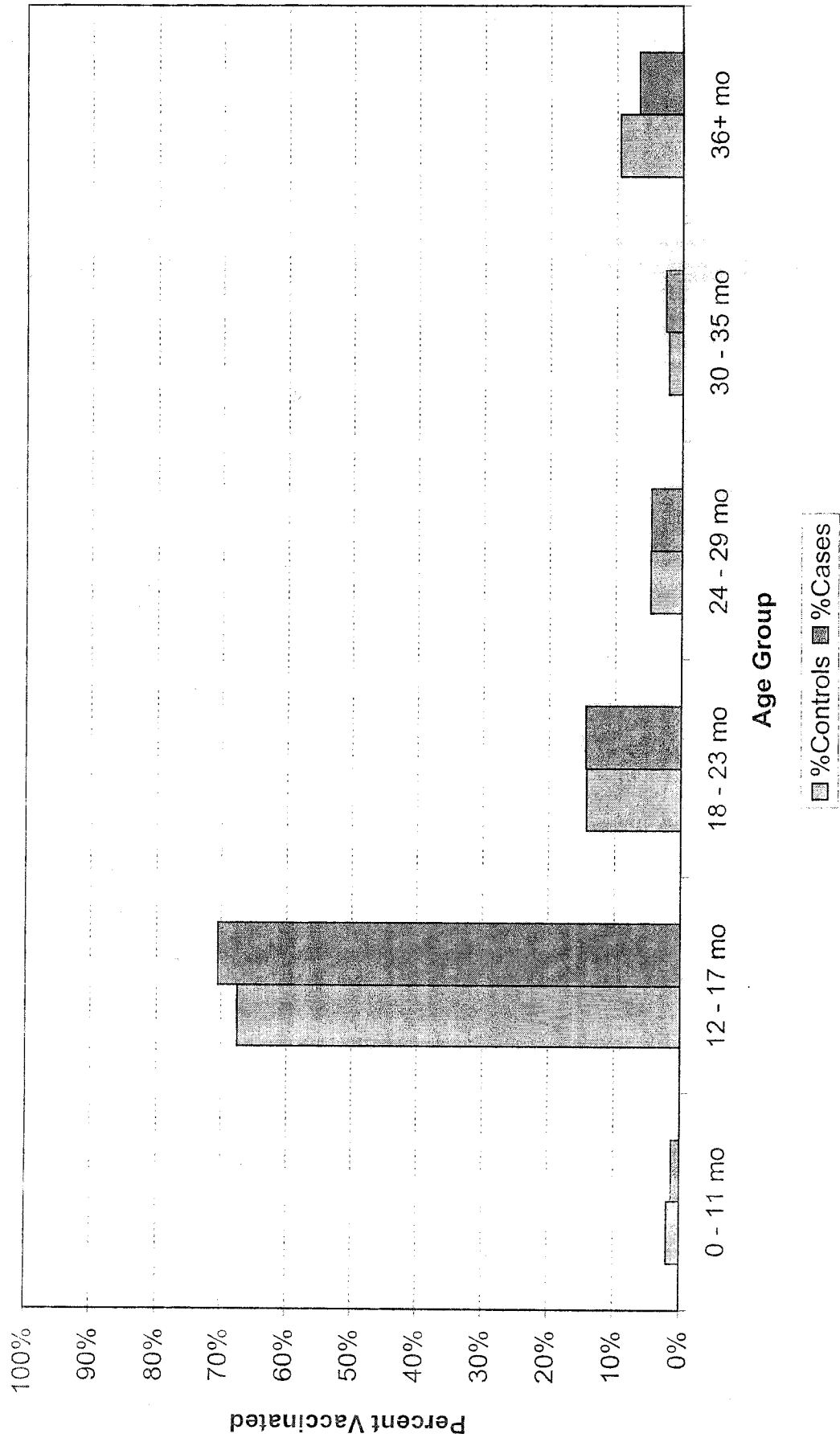


Table 2: Matched Statistical Analyses for Demographic Subgroups

Sample	Case Subgroup	Cases	< 18 Months			< 24 Months			< 36 Months		
			OR	L95CI	U95CI	OR	L95CI	U95CI	OR	L95CI	U95CI
Total Sample	All Cases	624	1.12	0.91	1.38	1.21	0.93	1.57	1.49	1.04	2.14
	Males	500	1.22			1.29			1.60		
	Females	124	0.83			0.96			1.06		
	Aged 3 - 5 Years	214	1.08			1.66			2.34		
Unadjusted Analyses	Aged 6 - 10 Years	410	1.14			1.10			1.33		
	All Cases	311	0.93	0.66	1.30	0.99	0.63	1.55	1.23	0.64	2.36
	Males	243	0.94			1.01			1.64		
	Females	68	0.79			0.84			0.24		
Adjusted Analyses	Aged 3 - 5 Years	112	0.77			1.67			2.63		
	Aged 6 - 10 Years	199	0.98			0.87			1.09		

Table 3: Matched Statistical Analyses for Clinical Case Subgroups

Sample	Case Subgroup	Cases	< 18 Months			< 24 Months			< 36 Months		
			OR	L95CI	U95CI	OR	L95CI	U95CI	OR	L95CI	U95CI
Unadjusted Analyses	No Pre-Existing Conditions < 1 Year	390	1.07	0.83	1.39	1.14	0.82	1.59	1.51	0.96	2.37
	Regression or Plateau	80	1.37	0.78	2.41	1.30	0.64	2.66	1.45	0.54	3.93
	With Mental Retardation	376	1.06	0.82	1.38	1.09	0.79	1.51	1.21	0.79	1.84
	Without Mental Retardation	248	1.23	0.87	1.73	1.46	0.93	2.30	2.45	1.20	5.00
Adjusted Analyses	No Pre-Existing Conditions < 1 Year	187	1.05	0.68	1.61	1.02	0.56	1.86	1.82	0.77	4.31
	Regression or Plateau	31	0.83	0.23	3.09	0.41	0.07	2.29	0.69	0.14	3.30
	With Mental Retardation	179	1.13	0.72	1.79	0.96	0.54	1.71	0.82	0.38	1.79
	Without Mental Retardation	132	0.68	0.40	1.16	1.02	0.47	2.22	3.55	0.74	17.07 *

* OR based on 3 cases vaccinated >= 36 months

Table 4: Unmatched Statistical Analyses for Demographic Subgroups with Birth Certificate Data

Case Subgroup	Cases	< 18 Months			< 24 Months			< 36 Months		
		OR	L95CI	U95CI	OR	L95CI	U95CI	OR	L95CI	U95CI
All Cases	355	0.83	0.63	1.10	0.87	0.60	1.25	1.26	0.74	2.12
White/Other	218	0.87	0.59	1.27	0.78	0.45	1.35	0.89	0.41	1.94
Black	137	0.79	0.52	1.20	0.93	0.56	1.55	1.60	0.78	3.26
Maternal Age < 35 Years	295	0.89	0.66	1.20	0.91	0.62	1.34	1.20	0.70	2.05
Maternal Age 35+ Years	60	0.57	0.27	1.20	0.56	0.16	2.00	2.42	0.21	27.62
Maternal Education <16 Years	235	0.91	0.66	1.25	0.90	0.60	1.34	1.14	0.65	1.98
Maternal Education 16+ Years	120	0.65	0.36	1.15	0.78	0.29	2.07	3.28	0.63	17.07
Birth Weight < 2500 gms	49	0.49	0.21	1.15	0.42	0.14	1.25	1.13	0.28	4.54
Birth Weight >= 2500 gms	306	0.90	0.67	1.21	0.91	0.61	1.36	1.23	0.70	2.17

Table 5: Factors Associated with Case Selection

Sample	Case Subgroup	Cases	< 18 Months			< 24 Months			< 36 Months		
			OR	L95CI	U95CI	OR	L95CI	U95CI	OR	L95CI	U95CI
Total	Records in School Sources Only	253	1.31	0.96	1.79	1.34	0.92	1.96	2.80	1.51	5.22
	Records from Multiple Sources and/or Clinics	371	1.00	0.76	1.31	1.10	0.77	1.57	0.96	0.61	1.50
	Previous ASD Dx	395	1.05	0.81	1.36	1.10	0.80	1.52	1.25	0.82	1.92
	No Previous ASD Dx	229	1.26	0.90	1.78	1.43	0.92	2.23	2.15	1.11	4.17
Birth Certificate	Records in School Sources Only	125	1.25	0.72	2.15	0.82	0.42	1.59	1.69	0.64	4.45
	Records from Multiple Sources and/or Clinics	186	0.78	0.50	1.22	1.21	0.63	2.32	0.85	0.34	2.13
	Previous ASD Dx	199	0.92	0.60	1.39	1.11	0.63	1.95	1.04	0.47	2.29
	No Previous ASD Dx	112	0.90	0.49	1.65	0.78	0.36	1.69	1.81	0.54	6.05

Table 1: All Subjects

The CORR Procedure

2 Variables: age2_5 mrcased1

Variable	N	Mean	Std Dev	Simple Statistics		
				Sum	Minimum	Maximum
age2_5	624	0.34295	0.47508	214.00000	0	1.00000
mrcased1	624	0.60256	0.48976	376.00000	0	1.00000

Pearson Correlation Coefficients, N = 624
 Prob > |r| under H0: Rho=0

	age2_5	mrcased1
age2_5	1.00000	-0.02724
Age 2-5 Yrs		0.4970
mrcased1	-0.02724	1.00000
MR - Low Functioning		0.4970

Table 1: All Subjects

The FREQ Procedure

Table of age2_5 by mrcased1

age2_5(Age 2-5 Yrs)
 mrcased1(MR - Low Functioning)

Row Pct	Frequency		Total
	NO	YES	
NO	159 38.78	251 61.22	410
YES	89 11.59	125 58.41	214
Total	248	376	624