- 1) MADDSP Case versus MMR/AUTISM CASE
  - a. Clarification
    - i. 567 MMR/Autism Cases
    - ii. 540 MADDSP Cases
  - b. 29 subjects are listed as cases in study but not MADSSP cases
  - c. 2 subjects are listed as controls in study listed as MADDSP case
- 2) Missing Data on Matching Variable
  - a. 22 subjects have no matched subjects
- 3) Sex Variable
  - a. No Missing Data
- 4) Age Variable
  - a. 1 control subject born in 1994
  - b. 2 subjects are missing birth year
- 5) School System Variable
  - a. 7 subjects missing School System Variable
  - b. Should we check or should we wait for update?
- 6) MMR Exposure Variable
  - a. MMR vaccination data missing for 63 cases
  - b. Similar missing across cases and controls
  - c. Can we check these values ?????
  - d. Vaccination Dates
    - i. Unusual values ??
    - ii. Changed categories see handout
- 7) Vaccine Exemption Variables no positive values in the current data set
  - a. Excode1
  - b. Excode2
  - c. Excode3
- 8) Race Variable
  - a. Missing 12% of subjects (N=265)
  - b. Creating missing data variable
  - c. Not statistically associated with cases/control variable
- 9) Birth weight is normally distributed reasonable

# 10) Gestational Age Variable

- a. Data for last menses
  - i. Incorrect data
  - ii. Outliers will not be used

# 11) Preliminary Analyses

a. MMR Age of Vaccination

ii. Maternal Race

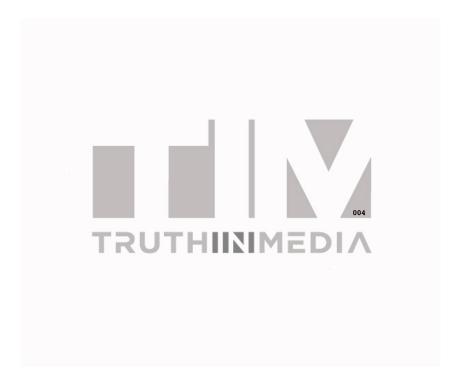
	i. Categorical Age Distribution	+
	ii. < 18 Months	NS
	iii. < 36 Months	+
b.	RACE	NS
c.	Birth Certificate Variables	•
	i Maternal Age	+

iii. Maternal Education NS iv. Birth Weight +



NS

- 1) Use the confirmed autism case definition for cases
- 2) Age in 1996 for cases was based on end of year calculation
  - a. 1 control 2 years of age
  - b. 2 controls 11 years of age
- 3) State Variable
- 4) Birth Certificate Variable
- 5) Missing Data Issues
  - a. Entire Sample
    - i. Cases with missing state variable that have Birth Cert (N=10)
  - b. Sample with Birth Certificates
- 6) SES should we pursue the zipcode matching?



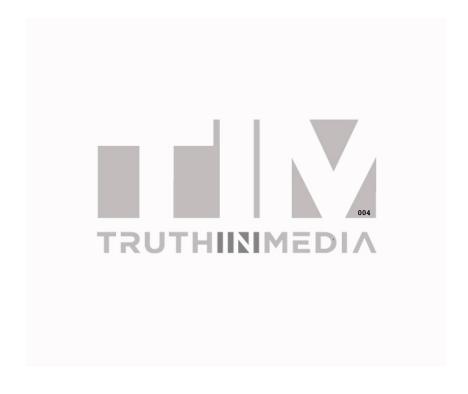
- 1) Confirmed Cases = 620
- 2) Birth Day
  - a. Outliers Day = 91
- 3) MMR Variable
  - a. Negative vaccination dates N=2
  - b. Probably due to incorrect birth date
- 4) All EXCODE data missing
- 5) Race Variable
  - a. Race
  - b. C\_Race
  - c. M Race
  - d. CDCRace
- 6) H\_Plive
  - a. Outliers = 198
- 7) H lbordr
  - a. Outliers = 199
- 8) School System
  - a. N=7 Controls = 900
- 9) SES should we pursue the zipcode matching?
  - a. Coleen Boyle suggested we should pursue
- 10) Statistically Significant Effects
  - a. Born in GA
  - b. MMR 36+ Months

004

# TRUTHIIZIMEDIA

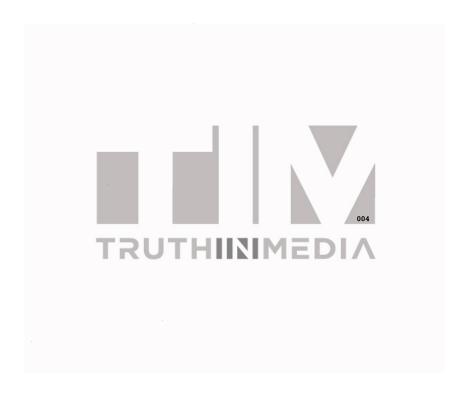
# Agenda 12/05/2001

- 1) Data Privacy Issues
- 2) December 13 Seminar
- 3) Update on availability of Final Database
- 4) Analysis/Data entry for preexisting conditions and parental concern
- 5) Draft Intro and Methods for Paper
- 6) Discussion of Preliminary Descriptive Statistics



# Agenda 10/31/2001

- 1) Data Privacy Issues
- 2) Update on availability of Final Database
- 3) Analysis/Data entry for preexisting conditions and parental concern
- 4) Draft Intro and Methods for Paper
- 5) Discussion of Preliminary Descriptive Statistics



## Agenda 12/12/2001

- 1) Data Privacy Issues
- 2) Update on Final Database
  - a. Original controls are in database
  - b. Exclusion criteria
    - i. Cases
    - ii. Controls
  - c. Missing immunization forms and/or data
    - i. Tanya will be following up on missing forms
    - ii. Will get both MMR data as well as other vaccine data
  - d. Birth certificate matching
  - e. Missing data by School System
- 3) Discussion of Preliminary Descriptive Statistics
  - a. Total Sample
  - b. Birth Certificate Sample
- 4) Additional Analyses
  - a. Run analyses examining influence of school systems
  - b. Others



Date: January 9, 2002

- 1) Data Privacy Issues
- 2) Update on Data Checks / Final Database
  - a. Original controls are in database
  - b. Missing immunization forms/data
    - i. Tanya will be following up on missing forms
    - ii. Will be getting both MMR data as well as other vaccine data
  - c. Will review exclusionary criteria once new data is available
  - d. Check why Isolated Autism cases without Delay < 1 all appear to be vaccinated < 36 months
  - e. New Variables Added
    - i. Developmental Delay < 1
    - ii. Plateau/Regression will not be very useful for analyses
    - iii. Pre-existing Condition was previously subset of DD < 1
    - iv. Age of 1st Concern uncorrelated with age of vaccination
- 3) Discussion of Preliminary Descriptive Statistics
  - a. Total Sample
  - b. Birth Certificate Sample
- 4) Additional Analyses

a. Run analyses examining influence of each school system

- a. Run analyses examb. Delay < 1</li>
- c. Age of 1st Concern

Date: January 23, 2002

- 1) Data Privacy Issues
- 2) Update on Data Checks / Final Database
  - a. Original controls are in database
  - b. Missing immunization forms/data
    - i. Tanya will be following up on missing forms
    - ii. Will be getting both MMR data as well as other vaccine data
  - c. Will review exclusionary criteria once new data is available
  - d. Check why Isolated Autism cases without Delay < 1 all appear to be vaccinated < 36 months
  - e. New Variables Added
    - i. Developmental Delay < 1
    - ii. Plateau/Regression will not be very useful for analyses
    - iii. Pre-existing Condition was previously subset of DD < 1
    - iv. Age of 1st Concern uncorrelated with age of vaccination
- 3) Discussion of Preliminary Descriptive Statistics
  - a. Total Sample
  - b. Birth Certificate Sample
- 4) Additional Analyses

004

- a. Run analyses examining influence of each school system
- b. Delay < P
- c. Age of 1st Concern

Date: February 13, 2002

- 1) Data Privacy Issues
- 2) Update on Data Checks / Final Database
  - a. Original controls are in database
  - b. Missing immunization forms/data
    - i. Tanya will be following up on missing forms
    - ii. Will be getting both MMR data as well as other vaccine data
  - c. Will review exclusionary criteria once new data is available
  - d. Check why Isolated Autism cases without Delay < 1 all appear to be vaccinated < 36 months
  - e. New Variables Added
    - i. Developmental Delay < 1
    - ii. Plateau/Regression will not be very useful for analyses
    - iii. Pre-existing Condition was previously subset of DD < 1
    - iv. Age of 1<sup>st</sup> Concern uncorrelated with age of vaccination
- 3) Discussion of Preliminary Descriptive Statistics
  - a. Total Sample
  - b. Birth Certificate Sample
- 4) Additional Analyses
  - a. Isolated Autism
  - b. Delay < 1
  - c. Pre-existing Condition
  - d. Age of 1<sup>st</sup> Concern
  - e. Examine influence of each school system

Date: February 20, 2002

- 1) Data Privacy Issues
  - a. 308(d) Exemption
  - b. Will we be creating a public use database?
  - c. What variables will be included in that database?
- 2) Update on Data Checks / Final Database
  - a. Original controls are in database
  - b. Review exclusionary criteria
  - c. Isolated autism cases without Delay < 1 all vaccinated < 36 mo ???
- 3) Discussion of Preliminary Descriptive Statistics
  - a. Total Sample
  - b. Birth Certificate Sample
- 4) Analyses
  - a. Discussion of MMR Exposure Variable
  - b. Analysis of Total Sample
    - i. Isolated
    - ii. Non-Isolated
    - iii. Delay < 1 and Pre-existing Condition
    - iv. Age of 1<sup>st</sup> Concern
  - c. Analysis of Birth Certificate Sample
- 0

- i. Isolated
- ii. Non-Isolated
- iii. Delay < 1 and Pre-existing Condition
- iv. Age of 1<sup>st</sup> Concern
- d. Examine influence of each school system

Date: April 16, 2002

- 1) Update on Data Checks / Final Database
  - a. Original controls are in database
  - b. Added new data from Marshalyn/Tanya on pre-existing conditions
- 2) Discussion of Descriptive Statistics
  - a. Total Sample
  - b. Birth Certificate Sample
- 3) Analyses
  - a. Discussion of MMR Exposure Variable
  - b. Analysis of Total Sample
    - i. Isolated
    - ii. Non-Isolated
    - iii. Delay < 1 and Pre-existing Condition
    - iv. Age of 1st Concern
  - c. Analysis of Birth Certificate Sample
    - i. Isolated
    - ii. Non-Isolated
    - iii. Delay < 1 and Pre-existing Condition
    - iv. Age of 1<sup>st</sup> Concern

. . .

TRUTHIIZIMEDIA

Date: May 22, 2002

- 1) Update on Data Checks / Final Database
  - a. Added new data on pre-existing conditions
- 2) Descriptive Statistics
  - a. Cases
  - b. Total Sample
  - c. Birth Certificate Sample
- 3) Statistical Analyses
  - a. Analysis of Total Sample
    - i. 18 Months
      - 1. All Cases
      - 2. Cases with No Delay or Pre-existing Condition
      - 3. Regression Cases
    - ii. 24 Months
      - 1. All Cases
      - 2. Cases with No Delay or Pre-existing Condition
      - 3. Regression Cases
  - b. Analysis of Birth Certificate Sample
    - i. 18 Months
      - 1. All Cases
      - 2. Cases with No Delay or Pre-existing Condition
    - ii. 24 Months
      - T P1. All Cases N M E D | A
        - 2. Cases with No Delay or Pre-existing Condition

Date: June 28th, 2002

## Agenda

- 1) Review Analysis Plan
  - a. Update Power Calculations
    - i. Birth Certificate Sample
      - 1. Original Controls with Birth Certificate N=1049
      - 2. Matched Controls with Birth Certificate N=576
    - ii. Subgroup Analyses
      - 1. Matched Analyses
      - 2. Unmatched Analyses
- 2) Review Data Issues
  - a. Sample Selection See Table
  - b. Descriptive Data for Cases Table 2
    - i. Subgroups
    - ii. Dropped epilepsy from table
- 3) Preliminary Results
  - a. Table 4 Primary Analyses
  - b. Table 5 Unmatched Subgroup Analyses
- 4) Creation of Public Use Data Set
  - a. Data privacy Issues
    - i. NCHS Model
    - ii. Other Model
  - b. Code Book
  - c. SAS Programs

5) Select Data to Present Preliminary Results to Bob Chen and David Shay

IRUIHIIXIMEDI/

Date: October 2<sup>nd</sup>, 2002

## Agenda

- 1) Update on Data Analysis and Statistical Issues
  - a. Started to rewrite and document SAS programs for public use database
  - b. Reviewed Statistical Analyses with Margarette Kolczak
    - i. Suggested testing demographic subgroups as interactions with exposure similar to earlier analyses of race
  - c. Corrected MMR vaccination data
    - i. 1st MMR Vaccination and 2nd MMR Vaccination had coding errors
      - 1. Coding errors were fixed
      - 2. Results change slightly
- 2) Review Preliminary Results
  - a. Results are very similar to previous analyses

b. Any MMR < 36 Months:

OR = 1.476 (prev OR = 1.53)

c. Any Measles < 36 Months:

OR = 1.492

d. Any Measles, Mumps, and Rubella:

OR = 1.482

- 3) Review Case Selection Models and Results
  - a. See Tanya Handout
- 4) Revise analysis plan to include:
  - a. Any measles containing vaccines
  - b. Any measles, mumps, or rubella containing vaccines
- 5) Select Date to Present Preliminary Results to Bob Chen and David Shay

004

TRUTHIIZIMEDIA

Date: October 9th, 2002

## Agenda

- 1) Update on Data Analysis and Statistical Issues
  - a. Started to rewrite and document SAS programs for public use database
  - b. Reviewed Statistical Analyses with Margarette Kolczak
    - i. Suggested testing demographic subgroups as interactions with exposure similar to earlier analyses of race
  - c. Corrected MMR vaccination data
    - i. 1<sup>st</sup> MMR Vaccination and 2<sup>nd</sup> MMR Vaccination had coding errors
      - 1. Coding errors were fixed
      - 2. Results change slightly
- 2) Review Preliminary Results
  - a. Results are very similar to previous analyses

b. Any MMR < 36 Months:

OR = 1.476 (prev OR = 1.53)

c. Any Measles < 36 Months:

OR = 1.492

d. Any Measles, Mumps, and Rubella:

OR = 1.482

- 3) Review Case Selection Models and Results
  - a. See Tanya Handout
- 4) Revise analysis plan to include:
  - a. Any measles containing vaccines
  - b. Any measles, mumps, or rubella containing vaccines
- 5) Select Date to Present Preliminary Results to Bob Chen and David Shay

004

TRUTHINIMEDIA