

- 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
  - i. Categorical Age Distribution +
  - ii. < 18 Months NS
  - iii. < 36 Months +
- b. RACE NS
- c. Birth Certificate Variables
  - i. Maternal Age +
  - ii. Maternal Race NS
  - iii. Maternal Education NS
  - iv. Birth Weight +



- 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

## 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



## MMR/Autism Agenda

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 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. Run analyses examining influence of each school system
  - b. Delay < 1
  - c. Age of 1<sup>st</sup> Concern



## MMR/Autism Agenda

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 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. Run analyses examining influence of each school system
  - b. Delay < 1
  - c. Age of 1<sup>st</sup> Concern

## MMR/Autism Agenda

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

## MMR/Autism Agenda

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
    - 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

## MMR/Autism Agenda

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 1<sup>st</sup> 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



## MMR/Autism Agenda

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
      1. All Cases
      2. Cases with No Delay or Pre-existing Condition

Date: June 28<sup>th</sup>, 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

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 Margarete 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

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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 Margarete 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
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