The Vaxxed team, CDC Whistleblower, and More

Dorit R. Reiss
Conflict of Interest Statement:

- The family owns stock (regular) in GSK.
Presentation Plan

• Vaxxed:
  – CDC Whistleblower claims

• Activism examples:
  – Stories
  – Legislative activism
  – HHS effort
Vaxxed’s three parts

- CDC Whistleblower
- Vaccines cause autism
- Vaccines’ oversight lacking
CDC Whistleblower Makes Official Statement: Admits CDC Hid Vaccine Link to Autism

Source: dcclothesline.com  Aug 28, 2014
CDC Whistleblower: The claims

- Two alleged results hidden:
  - MMR causes autism in African-Americans
  - MMR causes autism in those with isolated autism

- Two claims of wrongdoing:
  - Deviation from analysis Plan
  - Data/document destroyed to hide wrongdoing.

- None hold up to scrutiny.
ISOLATED AUTISM
The claim:

– Paper omitted a result for isolated autism.

– Isolated autism = children who were not exhibiting problems earlier:
  “children of all races who were developmentally normal to age 12 months (‘isolated’ autism)…”

Correction:

- Isolated autism result reported in paper – and regression/delay reported separately.
AFRICAN AMERICAN MALES
The claim:

- Initial results showed statistically significant link MMR/Autism in early group, in African Americans.

<table>
<thead>
<tr>
<th>Sample</th>
<th>Cases</th>
<th>Variable</th>
<th>Matched Analyses</th>
<th>Unmatched Analyses</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>All Subjects</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OR</td>
<td>L95CI</td>
</tr>
<tr>
<td>Total</td>
<td>596</td>
<td>MMR &lt; 18</td>
<td>1.14</td>
<td>0.92</td>
</tr>
<tr>
<td></td>
<td></td>
<td>MMR &lt; 36</td>
<td>1.61</td>
<td>1.10</td>
</tr>
</tbody>
</table>

MMR Categories

<table>
<thead>
<tr>
<th>Category</th>
<th>OR</th>
<th>L95CI</th>
<th>U95CI</th>
<th>OR</th>
<th>L95CI</th>
<th>U95CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 - 11 mo</td>
<td>1.16</td>
<td>0.51</td>
<td>2.65</td>
<td>1.08</td>
<td>0.37</td>
<td>3.16</td>
</tr>
<tr>
<td>12 - 15 mo</td>
<td>1.74</td>
<td>1.18</td>
<td>2.56</td>
<td>0.99</td>
<td>0.58</td>
<td>1.70</td>
</tr>
<tr>
<td>16 - 18 mo</td>
<td>1.42</td>
<td>0.94</td>
<td>2.15</td>
<td>0.69</td>
<td>0.39</td>
<td>1.24</td>
</tr>
<tr>
<td>19 - 23 mo</td>
<td>1.55</td>
<td>0.96</td>
<td>2.49</td>
<td>0.83</td>
<td>0.41</td>
<td>1.67</td>
</tr>
<tr>
<td>24 - 35 mo</td>
<td>1.61</td>
<td>0.97</td>
<td>2.68</td>
<td>0.96</td>
<td>0.45</td>
<td>2.08</td>
</tr>
<tr>
<td>36+ mo</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
</tbody>
</table>
The claim:

• This result was replicated by a published analysis by Hooker.

**Table 2**

<table>
<thead>
<tr>
<th>Age cut-off</th>
<th>Total cohort</th>
<th></th>
<th>Males only</th>
<th></th>
<th>Females only</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Relative risk</td>
<td>95% CI</td>
<td>p-value</td>
<td>Relative risk</td>
<td>95% CI</td>
</tr>
<tr>
<td>18 months</td>
<td>1.24</td>
<td>0.90-1.70</td>
<td>0.184</td>
<td>1.36</td>
<td>0.95-1.95</td>
</tr>
<tr>
<td>24 months</td>
<td>1.47</td>
<td>0.99-2.19</td>
<td>0.0562</td>
<td>1.73*</td>
<td>1.09-2.77</td>
</tr>
<tr>
<td>36 months</td>
<td>2.30*</td>
<td>1.25-4.22</td>
<td>0.0060</td>
<td>3.36*</td>
<td>1.50-7.51</td>
</tr>
</tbody>
</table>

• Note: Hooker’s analysis was retracted. Movie doesn’t say that.
Correction A: Thompson

- Initial association appears spurious:
  - No biological basis
  - African Americans generally receive lower rates of autism diagnosis than Caucasians.
  - Disappeared in birth certificate model that allowed controlling for confounders.
  - **Explanation:** result of enrollment in early intervention plans that require MMR.
Correction B: Hooker

- Results significant only in African American males that got MMR late.
- Numbers supporting result very small.
- Wrong statistical tool.
- Not controlling for confounders.
- Retracted: Non-disclosure of COIs and bad methods.
Even if ignore issues -

Honda et al, Japan, 2005, over 300,000 children

Madsen et al, Denmark, 2002, 537,303 children

Destefano et al, 2004, 2448

Jain et al, United States, 2016, 95,727 children

Fombonee et al, Canada, 2006, 27,749 children

Mäkelä et al, Finland, 2002, 535,544 children

Wrongdoing 1:

DEVIATION FROM ANALYSIS PLAN
The claim:

- To hide result linking early MMR to autism in African Americans, authors deviated from analysis plan, by only publishing analysis for birth certificate group.
Introduction

Autism is a serious life-long developmental disorder characterized by marked impairments in social interactions, and communication skills; and repetitive, restrictive, or stereotyped behaviors. A recent review of studies conducted since 1985, shows an estimate of the prevalence to be 1-1.4 per 1,000 for classic autism, and possibly as high as 4-5 per 1,000 for all autism spectrum disorders (ASD) combined (1,4). While these rates are 3-4 times higher than rates found in studies conducted 15-20 years ago (1), there are several recent studies, including a study done by Baird et al. (2000) and an investigation in Brick Township NJ, which suggested that the rate of autism may be higher still with rates of 3.1 per 1,000 and 4 per 1,000, respectively (CDC,
We will use conditional logistic regression stratified by matched sets to estimate the odds ratios for the association between age at MMR vaccination and autism. In the main analyses, we will include all ASD cases. The factors that will be examined in the analyses will be race, age of MMR vaccination, thimerosal exposure (DTP and hepatitis B), weight adjusted thimerosal exposure, and number of vaccines received.

Each of the above variables will be individually evaluated for their association with the ASD case definition. Those with an odds ratio p-value < 0.20 will be included as covariates in a conditional logistic regression model to estimate adjusted odds ratio for the association between age at vaccination and ASD.

For the children born in Georgia for whom we have birth certificate data, we will perform several sub-analyses similar to the main analysis, and will include several additional potentially confounding variables. The variables that will be evaluated will include:

- Birth weight: 
  - < 1500
  - 1501-2499
  - 2500-2999
  - ≥ 3000
- Gestational age: 
  - ≤ 32
  - 32-36
  - 37+
- Birth type (singleton, twin, triplet)
- Birth order (1, 2, 3 or ≥ 4)
- APGAR scores (1 and 5 minutes)
Comments Analysis
Plan:

• According to Thompson’s statement, analysis of race started September 2001 at the earliest.

• Analysis plan: April 2001.

• Should authors have included and explained results for full sample, after seeing?
  – Maybe.
  – Professional disagreement=/= fraud.
Wrongdoing 2:

DATA/DOCUMENTS DESTROYED TO HIDE WRONGDOING
The claim:

• Authors got together and threw documents/data in trashcan.

16. Sometime soon after the meeting where we decided to exclude reporting any RACE effects, also between August 2002 and September 2002, the coauthors scheduled a meeting to destroy documents related to the study. Dr. Coleen Boyle was not present at the meeting even though she was involved in scheduling that meeting. The remaining 4 coauthors all met and brought a big garbage can into the meeting room and reviewed and went through all our hard copy documents that we thought we should discard and put them in the large garbage can. However, because I assumed this was illegal and would violate both FOIA laws and DOJ requests, I kept hard copies of all my documents in my office and I retained all the associated computer files. This included all the Word files (agendas and manuscript drafts), Excel files with analysis and results, and SAS files that I used to generate the statistical findings. I also kept all my written notes from meetings. All the associated MMR-Autism Study computer files have
Correction I:

- Data not destroyed:
  - Used by Hooker for reanalysis.
  - Available for qualified researchers under conditions:

Correction II:

- Thompson claimed he kept original documents & provided them.

- Provided documents don’t show wrongdoing.

- If duplicates of meeting notes etc’ trashed, that’s not wrongdoing.
Conclusion:

A. No good evidence anything that needed to be hidden.
B. No good evidence of wrongdoing.
C. Numerous studies on MMR and autism: lack of link demonstrated even without this study.
THE VAXXED TEAM SINCE

Bang Public Health! You’re dead!
Stories and Interviews:

VAXXED
WE ARE NOT GOVERNMENT PROPERTY
Ongoing actions:

- Vaxxed II
- Testimony to legislators –
  - West Virginia.
  - Mississippi
- Del Bigtree’s Highwire
- Traveling to other countries.
HHS Notice:

  - Question: standing.
- Claim: Vaccines are not properly tested.
  - No proper placebos.
  - Short Followups (Both wrong).
- Demand: Automate VAERS.
HHS Notice:

• Claim: post licensure studies not performed:
  – Based on misunderstanding IOM reports – focused on their inconclusive sections.
• Claim: there is not enough study of vulnerable sub-populations.
• Demand: remove from CDC website statements that vaccines do not cause autism.
• Demand: do vaccinated/unvaccinated study.
HHS Notice:

- Demand: Reduce conflicts of interests in ACIP.
- Claim: The CDC foundation is a conflict of interests and the CDC shouldn’t promote vaccines.
- Claim: HHS’s role in VICP is a conflict of interest.
Thank you!

Questions? Comments?

reissd@uchastings.edu
415-5654844
Exercise:

A legislator sympathetic to anti-vaccine groups proposes an “informed consent” bill which requires doctors to give parents the vaccine insert before vaccinating.

What strategies would you suggest?