Summary of two retracted Mawson papers comparing health outcomes in vaccinated vs unvaccinated children from a survey of homeschooled children

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Paper 1 - Vaccination and Health Outcomes: A Survey of 6- to12-year-old Vaccinated and Unvaccinated Children based on Mothers' Reports

Submitted to: *Frontiers in Public Health* – abstract published in September 2016 then withdrawn as the paper was rejected by the journal "The rejection was due to severe limitations in the validity of the results." The paper was re-submitted to the *Journal of Translational Research* on 22 March 2017, entitled "Pilot comparative study on the health of vaccinated and unvaccinated 6- to 12-year-old U.S. children". It was accepted on 21 April 2017 and published on 24 April 2017. Links to the paper were removed temporarily whilst stories about the paper's retraction were checked. Once these were found to be incorrect links to the paper were restored.

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Conflicts of interest: None declared.

Aim of Study: 1) null hypothesis of no association between vaccination status and health outcomes and 2) determine whether any association found between vaccination and neurodevelopmental disorders remained significant.

Partnership: the researchers formed a partnership with the National Home Education Research Institute (NHERI)

Study population: survey of homeschooling mothers on their vaccinated and unvaccinated biological children aged 6-12.
415 questionnaires were received providing data on 666 homeschool children.

The children were mostly white (88%), with a high proportion of girls (52%) with an average age of 9 years.
261 (29%) were unvaccinated, 208 (31%) were partially vaccinated and 197 (30%) had received all recommended vaccinations.

Contact with families: indirect through NHERI using a link to an online questionnaire (no personal identification sought on questionnaire). No financial incentives were offered to complete the questionnaire.

Classification of vaccination status:

- *unvaccinated* (no previous vaccinations), *partially vaccinated* (received some but not all recommended vaccination) and *fully vaccinated* (received all recommended age-appropriate vaccines).
- Categories were developed with the view that long-term effects of vaccines would be more evident in fully-vaccinated than in partially-vaccinated children and rare or absent in unvaccinated.
- Respondents were asked to refer to vaccination records for vaccination info. Information on AEs was not requested.
- Respondents were asked to indicate on a list of 40+ acute & chronic illnesses all those for which their child had received a physician diagnosis.

Acute Illness:

- Vaccinated children (N=405), combining the partially and fully vaccinated, were significantly less likely than the unvaccinated to have had chickenpox (7.9% vs. 25.3%, p <0.001; Odds Ratio = 0.26, 95% Confidence Interval: 0.2, 0.4) and whooping cough (pertussis) (2.5% vs. 8.4%, p <0.001; OR = 0.3, 95% CI: 0.1, 0.6), and less likely, but not significantly so, to have had rubella (0.3% vs. 1.9%, p = 0.04; OR = 0.1, 95% CI: 0.01, 1.1). However, the vaccinated were significantly more likely than the unvaccinated to have been diagnosed with otitis media (19.8% vs. 5.8%, p <0.001; OR = 3.8, 95% CI: 2.1, 6.6) and pneumonia (6.4% vs. 1.2%, p = 0.001; OR = 5.9, 95% CI: 1.8, 19.7). No significant differences were seen with regard to Hepatitis A or B, high fever in the past 6 months, measles, mumps, meningitis (viral or bacterial), influenza, or rotavirus (Table 2).

Chronic Illness

- Vaccinated children were significantly more likely than the unvaccinated to have been diagnosed with the following: allergic rhinitis (10.4% vs. 0.4%, p <0.001; OR = 30.1, 95% CI: 4.1, 219.3), other allergies (22.2% vs. 6.9%, p <0.001; OR = 3.9, 95% CI: 2.3, 6.6), eczema/atopic dermatitis (9.5% vs. 3.6%, p = 0.035; OR = 2.9, 95% CI: 1.4, 6.1), a learning disability (5.7% vs. 1.2%, p = 0.003; OR = 5.2, 95% CI: 1.6, 17.4), ADHD (4.7% vs. 1.0%, p = 0.013; OR = 4.2, 95% CI: 1.2, 14.5), ASD (4.7% vs. 1.0%, p = 0.013; OR 4.2, 95% CI: 1.2, 14.5), any neurodevelopmental disorder (i.e., learning disability, ADHD or ASD) (10.5% vs. 3.1%, p <0.001; OR = 3.7, 95% CI: 1.7, 7.9) and any chronic illness (44.0% vs. 25.0%, p 11 <0.001; OR = 2.4, 95% CI: 1.7, 3.3).
- No significant differences were observed with regards to cancer, chronic fatigue, conduct disorder, Crohn's disease, depression, Types 1 or 2 diabetes, encephalopathy, epilepsy, hearing loss, high blood pressure, inflammatory bowel disease, juvenile

rheumatoid arthritis, obesity, seizures, Tourette's syndrome, or services received under the Individuals with Disabilities Education Act (Table 3).

Partial versus Full Vaccination

- Partially vaccinated children had an intermediate position between the fully vaccinated and unvaccinated in regard to several but not all health outcomes. For instance, as shown in Table 4, the partially vaccinated had an intermediate (apparently detrimental) position in terms of allergic rhinitis, ADHD, eczema, and learning disability.

Gender Differences in Chronic Illness

- Among the vaccinated (combining partially and fully vaccinated children), boys were more likely than girls to be diagnosed with a chronic condition – significantly so in the case of allergic rhinitis (13.9% vs. 7.2%, p = 0.03; OR = 2.1, 95% CI: 1.1, 4.1), ASD (7.7% vs. 1.9%, p = 0.006; OR = 4.3, 95% CI: 1.4, 13.2), and any neurodevelopmental disorder (14.4% vs. 6.7%, p = 0.01; OR = 2.3, 95% CI: 1.2, 4.6) (Table 5).

Use of Medications and Health Services

- The vaccinated (combining the partially and fully vaccinated) were significantly more likely than the unvaccinated to use medication for allergies (20.0% vs. 1.2%, p <0.001; OR = 21.5, 95% CI: 6.7, 68.9), to have used antibiotics in the past 12 months (30.8% vs. 15.4%, p <0.001; OR = 2.4, 95% CI: 1.6, 3.6), and to have used fever medications at least once (90.7% vs. 67.8%, p <0.001; OR = 4.6, 95% CI: 3.0, 7.1).
- The vaccinated were also more likely to have seen a doctor for a routine checkup in the past 12 months (57.6% vs. 37.2%, p <0.001; OR = 2.3, 95% CI: 1.7, 3.2), visited a dentist during the past year (89.4% vs. 80.5%, p <0.001; OR = 2.0, 95% CI: 1.3, 3.2), visited a doctor or clinic due to illness in the past year (36.0% vs. 16.0%, p <0.001; OR = 3.0, 95% CI: 12 2.0, 4.4), been fitted with ventilation ear tubes (3.0% vs. 0.4%, p = 0.018; OR = 8.0, 95% CI: 1.0, 66.1), and spent one or more nights in a hospital (19.8% vs. 12.3%, p = 0.012; OR = 1.8, 95% CI: 1.1, 2.7) (Table 6).

Factors Associated with Neurodevelopmental Disorders

- The second aim of the study focused on a specific health outcome and was designed to determine whether vaccination was associated with neurodevelopmental disorders (NDD). Because of the relatively small numbers of children with specific diagnoses, NDD was a derived variable combining children with a diagnosis of one or more of ASD, ADHD and a learning disability.
- There is a close association and overlap of these diagnoses in the study. The single largest group of diagnoses was learning disability (n=15) followed by ASD (n=9), and ADHD (n=9), with smaller numbers comprising combinations of the three diagnoses.
- *Factors associated with NDD* in unadjusted logistic regression analyses were as follows: vaccination (OR 3.7, 95% CI: 1.7, 7.9); male gender (OR 2.1, 95% CI: 1.1, 3.8); adverse environment, defined as living within 1-2 miles of a furniture manufacturing factory, hazardous waste site, or lumber processing factory (OR 2.9, 95% CI: 1.1, 7.4); maternal use of antibiotics during pregnancy (OR 2.3, 95% CI: 1.1, 4.8); and preterm birth (OR 4.9, 95% CI: 2.4, 10.3). Two factors that almost reached statistical significance were vaccination during pregnancy (OR 2.5, 95% CI: 1.0, 6.3) and three or more fetal ultrasounds (OR 3.2, 95% CI: 0.92, 11.5). Factors that were not associated with NDD in

this study included mother's education, household income, and religious affiliation; use of acetaminophen, alcohol, and antacids during pregnancy; gestational diabetes; preeclampsia; RhoGam shot (for Rh negative mothers) during pregnancy; and breastfeeding

- *After adjustment for all other significant factors*, those that remained significantly associated
  with NDD were: vaccination (OR 3.1, 95% CI: 1.4, 6.8); male gender (OR 2.3, 95% CI: 1.2, 4.3); and preterm birth (OR 5.0, 95% CI: 2.3, 11.6). The apparently strong association between both vaccination and preterm birth and NDD suggested the possibility of an interaction between these factors.
- In a final adjusted model designed to test for this possibility, controlling for the interaction of preterm birth and vaccination, the following factors remained *significantly associated* with NDD: vaccination (2.5, 95% CI: 1.1, 5.6), non-white race (2.0, 95% CI: 1.1, 5.5), and male gender (OR 2.3, 95% CI: 1.2, 4.4). Preterm birth itself, however, was not significantly associated with NDD, whereas the combination (interaction) of preterm birth and vaccination was associated with 6.6-fold increased odds of NDD (95% CI: 2.8, 15.5)

Discussion

- Vaccinated children were *significantly less likely* than the unvaccinated to have had chickenpox and pertussis
- Vaccinated children were *significantly more likely* to have been diagnosed with otitis media, pneumonia, allergic rhinitis, eczema, ADHD, ASD and a learning disability
- Vaccinated children were *significantly more likely* to have been diagnosed with otitis media, pneumonia, allergic rhinitis, eczema, ADHD, ASD and a learning disability. This finding is consistent with a 2016 study [http://www.jpands.org/vol21no2/miller.pdf] of 38,801 reports to the Vaccine Adverse Event Reporting System (VAERS) of infants who were hospitalised or died after receiving vaccinations. The *greater the number of vaccinations* and the *younger the infant* at time of vaccination, the *higher the rate* of adverse event, hospitalisation or death
- A comparison of unvaccinated, partially and fully vaccinated children showed that the partially vaccinated had increased but intermediate odds of chronic disease, between those of unvaccinated and fully vaccinated children, specifically for allergic rhinitis, ADHD, eczema, a learning disability, and NDD as a whole.
- Fully vaccinated children showed that the partially vaccinated had increased but intermediate odds of chronic disease, between those of unvaccinated and fully vaccinated children, specifically for allergic rhinitis, ADHD, eczema, a learning disability, and NDD as a whole.

Strengths of study

- The relatively large sample of unvaccinated children (N=261), which made it possible to compare health outcomes across the spectrum of vaccination coverage.
- Information was provided anonymously by biological mothers

Limitations of study

- Because of the absence of a defined sampling frame, neither the number of homeschool families contacted nor the survey response rate is known or can be validated.
- To minimize recall bias, respondents were asked to use their child's vaccination records. To enhance reliability, closed-ended questions were used.
- To enhance validity, parents were asked to report only physician-diagnosed illnesses and about facts such as whether a child had been hospitalized or fitted with ventilation eartubes.
- Self-reported health outcomes were not validated by clinical records or reports.

Paper 2 - Preterm birth, vaccination and neurodevelopmental disorders: a cross-sectional study of 6- to 12-year-old vaccinated and unvaccinated children

Download: **http://www.cmsri.org/wp-content/uploads/2017/05/MawsonStudyPretermBirth5.8.2017.pdf**

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Conflicts of Interest: None declared.

Aim of study: to study the possible role of vaccination in NDD among children born pre-term.

Study population: As per Study 1. This study used data gathered from Study 1 above.

Interactions between preterm birth, vaccination and NDD
Given the apparent synergism in the combination of vaccination and preterm birth on NDD found in regression analyses [48], and the relatively small numbers available for analysis, this report presents additional findings on the association and interaction between preterm birth (yes, no), vaccination status (yes, no) and NDD (yes, no). Stratified analyses with Odds

Ratios and 95% Confidence Intervals were used to quantify the strength of the associations. The analytic process can be envisioned as a 2 X 2 table with the cells in Row 1 labeled A and B, and those in Row 2 labeled C and D. The odds ratio is calculated by the formula AD/BC. Here we examine different combinations of preterm birth and vaccination and their association with NDD. Calculations based on the data in Table 4 (below) suggest a complex picture of the association between prematurity, vaccination and NDD. Most children in the sample were vaccinated and not preterm (n=367; 55%). The second largest group comprised those who were neither vaccinated nor preterm (n=249; 37%); the third largest comprised those who were preterm and vaccinated (n=37; 6%), and the smallest group those who were preterm and unvaccinated (n=12; 2%). While acknowledging that our study group is relatively small and not a representative sample of U.S. children, the following observations are noted. First, of the 37 children who were both preterm and vaccinated (P/V), 12 (32%) had an NDD, consistent with studies suggesting that a high proportion of preterm infants are later diagnosed with ASD [18-20]. Second, of the 12 children who were preterm but unvaccinated (P/V-), none had an NDD. Third, among the 367 children in the sample who were not preterm but vaccinated (P-/V), 30 (8%) had an NDD. Fourth, of the 249 children who were neither preterm nor vaccinated (P-/V-), only 8 (3%) had an NDD. These observations suggest that birth history strongly affects the likelihood of NDD in vaccinated children, given that the combination of preterm birth and vaccination accounts for a substantial proportion of NDD diagnoses in the overall sample. In contrast, cases of NDD are under-represented in preterm but unvaccinated children. These suggestions are further supported and amplified by analyses of the odds of NDD given various combinations of preterm birth and vaccination.

Association between combinations of preterm birth and vaccination status, and neurodevelopmental disorders (NDD)

1) Preterm birth without vaccination (P/V-) was not associated with NDD.
2) Term birth with vaccination (P-/V) was associated with a significant 2.7-fold increase in the odds of NDD.
3) Preterm birth with vaccination (P/V) was associated with a significant 5.4-fold increase in the odds of NDD compared to the odds of NDD given term birth and vaccination (P-/V).
4) Preterm birth with vaccination (P/V) was associated with a nonsignificant 12.3-fold increased odds of NDD compared to preterm birth without vaccination (P/V-) (not technically significant because no child in the sample with an NDD was both preterm and unvaccinated).
5) Preterm birth with vaccination (P/V) was associated with a significant 14.5-fold increased odds of NDD compared to being neither preterm nor vaccinated (P-/V-).

Conclusions

This study compared the birth histories and health outcomes of vaccinated and unvaccinated children and sought to determine the association, if any, between vaccination, preterm birth and neurodevelopmental disorders (NDD). *Vaccination* (i.e., receipt of one of more of the recommended vaccines) *was significantly associated* with NDD, while *preterm birth without vaccination was not*. Preterm birth coupled with vaccination, however, was associated with a synergistic increase in the odds of NDD, suggesting the possibility that

vaccination could precipitate adverse neurodevelopmental outcomes in preterm infants. These results provide clues to the epidemiology and causation of NDD but question the safety of current vaccination programs for preterm infants.