Reanalysis of CDC Data on Autism Incidence and Time of First MMR Vaccination

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This study is a re-analysis of Centers for Disease Control and Prevention (CDC) data pertaining to the relationship of autism incidence and the age at which children got their first measles-mumps-rubella (MMR) vaccine. Statistically significant relationships were observed when African-American males were considered separately while looking at those individuals who were vaccinated prior to and after a 36-month age cut-off. CDC officials observed very similar relationships as early as November 2001, but failed to report them in their final publication. In addition, a relationship is seen when specifically considering children who received a diagnosis of autism without mental retardation. Although this was reported in the original 2004 paper, it was not discussed, nor was any follow-up study conducted. Preliminary results also suggest the possibility of a synergism between thimerosal exposure and MMR timing leading to a greater risk of autism.

Introduction

The Centers for Disease Control and Prevention (CDC), using data from the Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP), examined the incidence of autism in children who received their measles-mumps-rubella (MMR) vaccine either before or after 36 months of age. A 2004 paper by DeStefano et al.[1] showed a strong, statistically significant relationship between the age of MMR administration and the diagnosis of autism. When comparing children receiving the MMR before and after 36 months of age, an odds ratio of 1.49 (95% CI 1.04 – 2.14) was observed for autism incidence, with children receiving the vaccine earlier having greater odds for having an autism diagnosis. When looking at boys only, an odds ratio of 1.67 (95% CI 1.10 – 2.53) was found, whereas no statistically significant relationship was seen for girls (OR = 1.06, 95% CI 0.51 – 2.20).

The authors of this study explained that the significant relationship was most likely due to vaccination requirements for earlier intervention programs for autistic children. This would mean that special-education students would be vaccinated earlier than their neurotypical counterparts. However, if that was the case, a consistent relationship would be seen, regardless of the gender of the subject. This is simply not true, as the association is seen in boys but not girls. Further, it is doubtful that subjects in the sample would have an autism diagnosis prior to vaccination given that the average age for receiving an autism diagnosis in the 1990s was around 50 months.[2] Unfortunately, no additional study was completed by the CDC authors to explore the importance of vaccine timing.

When considering the entire sample and males and females separately, DeStefano et al.[1] completed an analysis on all children in each sample and sub-sample as well as only children who had valid state of Georgia birth certificates. The use of the "birth-certificate" sample was to provide access to birth records on child's birth weight and gestational age as well as maternal race, parity, age, and education. In general, when significance was seen in the overall sample, it was not obtained in the birth-certificate sample. However, when considering race as a category, only the results for the "birth-certificate" sample were presented—even though the school records for all children in the sample contained information on race. The only explanation given by the authors for this curious omission was that "race, birthweight, maternal age and maternal education" were used in this particular analysis. No statistically significant relationship was found between MMR timing and autism for either of the race categories considered (White/other, and Black) in this sub-sample. (Whites are considered in the same category as "others," such as Asian, Hispanic, and Native Americans, because there were very few children in the "other" category.) There was still a trend for a higher incidence of autism in black children vaccinated before 36 months, but it did not reach statistical significance, likely because the "birth-certificate" sample was approximately 41% smaller than the sample of all blacks in the MADDSP database. The odds ratio was 1.68 (95% CI 0.82 – 3.47).

In this study, the relationship between the age of MMR vaccination and autism is again examined using the same MADDSP data set used by DeStefano et al. Special attention is given to gender and race effects as well as the presence of comorbidities accompanying autism. Given that race data were available for all children in the sample, analyses regarding race were not limited to the birth-certificate sample.

Materials and Methods

The data set was obtained from the CDC under a data use agreement. In the MADDSP, autistic "case" and non-autistic control children were selected from school districts in five counties. Children considered in the data set were born between 1986 and 1993 and evaluated in 1996 and 1998. Vaccination data were abstracted from the children's medical records, and race data, intelligence quotient (IQ), and autism diagnoses were abstracted from school records. Cases were matched to controls in strata based on gender, age, and school attended.

A conditional logistic regression analysis was completed on autism incidence modeled against the age when the child received the first MMR vaccine (in years) with cases matched with appropriate controls. Analyses were run by segregating males and females in groups of African-Americans and "whites and others." Autism is more prevalent in males, and some studies[3] have shown a possibly greater sensitivity of males to vaccine injury. Conditional logistic regression was also performed in a separate analysis for African-American males, where the data were categorized into three age groups for the first MMR vaccination: 18, 24, and 36 months.

A similar analysis was completed on the entire sample, considering autism without mental retardation (MR), and autism with MR separately. MR was defined as having an IQ score of less than 70. Odds ratios were obtained for the same three age groups for receiving the first MMR vaccine.

Results

MMR Timing in African-American Males

As noted above, DeStefano et al.[1] reported a statistically significant relationship between the age of receipt of the first MMR vaccine and autism incidence in school-aged children in their case-control study, which used a 1:3 case-control matching. They used a dichotomized conditional logistic regression with matching based on gender, age, and school attended.

To test the hypothesis that the relationship was an artifact of early "health-seeking behavior" to qualify for a special early-intervention program, rather than a possible effect of early MMR vaccination, the current study performed conditional logistic regression with matching based on birth year and school of attendance, with individual analyses of separate categories of white and other males, black males, white and other females, and black females.

Table 1 shows the descriptive statistics for the sample to be considered. Because DeStefano et al. did not match cases and controls by race, there is a slight deviation from 1:3 matching in each separate sample to be considered.

Table 1. Descriptive Statistics for the Sample

Category	Controls (n)	Controls (%)	Cases (n)	Cases (%)
Total*	1824	74.5	624	25.5
White and other males	901	75.3	296	24.7
1st MMR < 18 months	683	75.0	228	25.0
1st MMR 18 to 36 months	151	75.5	49	24.5
1st MMR > 36 months	67	77.9	19	22.1
Black males	480	72.2	185	27.8
1st MMR < 18 months	290	69.9	125	30.1
1st MMR 18 to 36 months	139	72.4	53	27.6
1st MMR > 36 months	51	87.9	7	12.1
White and other females	191	71.3	77	28.7
1st MMR < 18 months	145	72.9	54	27.1
1st MMR 18 to 36 months	36	66.7	18	33.3
1st MMR > 36 months	10	66.7	5	33.3
Black females	156	77.6	45	22.4
1st MMR < 18 months	96	78.7	26	21.3
1st MMR 18 to 36 months	41	75.9	13	24.1
1st MMR > 36 months	19	76.0	6	24.0

*96 controls and 21 cases were missing race information

Unlike in the analysis by DeStefano et al., the first analysis in this study treated age of first MMR vaccination as a continuous independent variable reported in years of age. Also, unlike the original DeStefano et al. analysis,[1] in this study the presence of autism diagnoses was evaluated without using covariates. Cases were matched to controls based on birth year and school attended. The results for these four analyses are shown in Table 2.

Table 2. Effect of race/gender category on relative risk of autism based on the age of first MMR administration (conditional logistic regression with cases matched to controls based on birth year and school attended)

Race/gender category	Odds Ratio	*p*-value	95% Confidence Interval	N (number of cases/number of controls)
White and other males	1.11	0.214	0.94 – 1.32	1197 (296/901)
Black males only	1.38	0.012	1.07 – 1.77	665 (185/480)
White and other females	0.99	0.964	0.75 – 1.32	268 (77/191)
Black females only	1.05	0.738	0.80 – 1.37	201 (45/156)

The only race/gender category showing a statistically significant relationship is black males, who appear to be 38% more likely to receive an autism diagnosis if they received the first MMR vaccine one year earlier than the controls. This relationship is still statistically significant ($p = 0.048$) when applying the Bonferroni correction to multiple comparisons within the same data set, although this type of correction is arguably not necessarily appropriate in multiple analyses of related outcomes.[4]

Following the method of DeStefano et al.,[1] conditional logistic regression was performed for black males only, except that the age category was dichotomized for first vaccine receipt before or after 18 months, 24 months, or 36 months, instead of just for before or after 36 months. Separate conditional logistic regressions were performed for each age categorization; cases were matched to controls based on birth year and school attended. Results are shown in Table 3.

Table 3. Odds ratio for receiving an autism diagnosis for African-American males receiving the first MMR vaccine before or after different age cutoffs

Age cut-off for first MMR vaccine	Odds Ratio	*p*-value	95% Confidence Interval	Number of Cases/Controls: Before
				After
18 months	1.49	0.066	0.98 – 2.26	125/290
				60/190
24 months	1.82	0.029	1.06 – 3.11	162/381
				23/99
36 months	3.86	0.005	1.49 – 10.0	178/429
				7/51

In this instance, an increase in the odds ratio is seen with increasing age of first MMR vaccine, with statistical significance achieved at the 24-month and 36-month cutoffs.

The odds ratios for receiving a diagnosis of autism without mental retardation (Table 4) or with mental retardation (Table 5) were also determined for the entire data set for receipt of the first MMR vaccine before or after the three different age cut-offs. Cases were matched to controls based on birth year, gender, and school attended. The only statistically significant finding was for autism without MR for the 36-month cut-off.

Table 4. Odds ratio for receiving an autism diagnosis without mental retardation for all subjects receiving the first MMR at specific age cut-offs

Age cut-off for first MMR vaccine	Odds Ratio	*p*-value	95% Confidence Interval	Number of Cases/Controls Before
				Cases/Controls After
18 months	1.23	0.227	0.87 – 1.73	190/1275
				58/549
24 months	1.47	0.094	0.94 – 2.32	222/1535
				26/289
36 months	2.52	0.012	1.23 – 5.17	239/1659
				9/165

Table 5. Odds ratio for receiving an autism diagnosis with mental retardation for all subjects receiving the first MMR at specific age cut-offs

Age cut-off for first MMR vaccine	Odds Ratio	*p*-value	95% Confidence Interval	Number of Cases/Controls Before
				Cases/Controls After
18 months	1.06	0.687	0.82 – 1.37	260/1275
				116/549
24 months	1.08	0.646	0.78 – 1.49	318/1535
				58/289
36 months	1.19	0.431	0.78 – 1.82	346/1659
				30/165

The effect of birth year (before or after 1990) was also explored by conditional logistic regression based on age of first MMR vaccine in years (see Table 6). There was a statistically significant effect for the entire group and for the sub-group born in 1990 or later.

Table 6. Odds ratio for receiving the MMR vaccine one year earlier for African-American (AA) males born prior to 1990 or in 1990 and thereafter

Category	Odds Ratio	*p*-value	Number of cases / Number of matched controls
All AA males	1.379	0.0120	185/480
AA males born prior to 1990	1.187	0.2315	96/231
AA males born in 1990 or after	1.720	0.0325	89/249

Discussion

The analysis of the MADDSP data by DeStefano et al.[1] did not consider gender separately and considered race only in the 41% smaller "birth-certificate" sample. This obscured the statistically significant observation of the apparent effect of vaccine timing on the incidence of autism in black males. Their methodology departed substantially from the original analysis protocol, laid out by the study co-authors and finalized on Sep 5, 2001, which indicated that race information was to be abstracted from school records for all individuals in the sample. It further stated, "The only variable available to be assessed as a potential confounder using the entire sample is child's race."[5] The earliest analyses completed subsequent to finalizing the analysis plan included the entire sample for the race analysis, and showed a statistically significant effect for blacks, yet no such effect for whites and others.

A data table generated as a part of an analysis dated Nov 7, 2001, was obtained from a coauthor and lead statistician of the paper, Dr. William Thompson (see Figure 1).[6] The data show statistically significant odds ratios for all subjects in the sample for the matched analysis (conditional logistic regression, dichotomized at 36 months of age, OR 1.61, 95% CI 1.10 – 2.34) and for blacks only, including both boys and girls, in the unmatched analysis (also conditional logistic regression, dichotomized at 36 months of age, OR 2.25, 95% CI 1.25 – 4.03). The former results were presented in the final paper by DeStefano et al.,[1] but the latter results for African-Americans were omitted in favor of results for the "birth-certificate sample" only. Further, when using those blacks vaccinated after 36 months as a reference group, subgroups vaccinated between ages 12–15 months and 16–18 months also had statistically significant effects.

In the CDC's table, "matched" means that cases and controls were matched together if they were the same gender, age, and went to the same school. "Unmatched" means that cases were clustered with controls without any of those stipulations. Thus, males could be considered against females, etc. "Isolated autism" is a term that DeStefano et al. used for autism with no other diagnoses within the first year of life. "Nonisolated autism" means that the children had comorbidities within the first year of life. The unusual intervals were determined by the CDC for unexplained reasons.

			Matched Analyses						Unmatched Analyses					
Sample	Cases	Variable	All Subjects			White Model			Black Model			Other Model		
			OR	L95CI	U95CI	OR	L95CI	U95CI	OR	L95CI	U95CI	OR	L95CI	U95CI
Total	596	MMR<18	1.14	0.92	1.40	0.96	0.71	1.29	1.23	0.91	1.57	1.41	0.63	3.13
		MMR<36	**1.61**	**1.10**	**2.34**	0.89	0.52	1.52	**2.25**	**1.25**	**4.03**	1.97	0.64	6.09
		MMR Categories												
		0-11 mo	1.16	0.51	2.65	1.08	0.37	3.16	1.42	0.36	5.59	NA	NA	NA
		12-15 mo	1.74	1.18	2.55	0.99	0.58	1.70	**2.17**	**1.18**	**4.00**	2.33	0.72	7.57
		16-18 mo	1.42	0.94	2.15	0.69	0.39	1.24	**2.65**	**1.43**	**5.05**	1.71	0.46	6.35
		19-23 mo	1.55	0.96	2.49	0.83	0.41	1.67	2.02	1.00	4.10	3.00	0.63	14.17
		24-35 mo	1.61	0.97	2.68	0.96	0.45	2.08	2.03	0.99	4.14	1.11	0.11	11.43
		36+ mo	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Isolated	222	MMR<18	1.12	0.78	1.61	1.01	0.67	1.52	1.35	0.77	2.36	NA	NA	NA
		MMR<36	**2.48**	**1.16**	**5.31**	1.26	0.55	2.84	3.85	0.92	16.09	NA	NA	NA
		MMR Categories												
		0-11 mo	1.01	0.19	5.43	0.51	0.06	4.45	3.30	0.28	39.16	NA	NA	NA
		12-15 mo	**2.61**	**1.20**	**5.64**	1.31	0.58	2.96	4.12	0.96	17.65	NA	NA	NA
		16-18 mo	**2.34**	**1.05**	**5.25**	1.20	0.51	2.83	3.86	0.86	17.41	NA	NA	NA
		19-23 mo	2.13	0.85	5.35	0.86	0.29	2.53	4.15	0.87	19.83	NA	NA	NA
		24-35 mo	**3.09**	**1.20**	**7.99**	1.99	0.71	5.59	2.68	0.51	14.23	NA	NA	NA
		36+ mo	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Non-Isolated	374	MMR<18	1.14	0.87	1.49	0.91	0.62	1.35	1.21	0.86	1.69	NA	NA	NA
		MMR<36	1.35	0.87	2.09	0.70	0.37	1.31	**1.99**	**1.06**	**3.73**	NA	NA	NA
		MMR Categories												
		0-11 mo	1.25	0.48	3.24	1.43	0.44	4.66	1.12	0.23	5.55	NA	NA	NA
		12-15 mo	1.49	0.95	2.35	0.82	0.43	1.57	1.85	0.96	3.58	NA	NA	NA
		16-18 mo	1.16	0.71	1.89	0.42	0.20	0.86	2.51	1.28	4.35	NA	NA	NA
		19-23 mo	1.39	0.80	2.44	0.81	0.35	1.86	1.66	0.76	3.64	NA	NA	NA
		24-35 mo	1.20	0.64	2.23	0.45	0.15	1.38	1.91	0.89	4.13	NA	NA	NA
		36+ mo	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00

Figure 1. Results of analysis of Dr. William Thompson on all children, African-Americans, whites, and others, from Nov 7, 2001.

Autism is a very significant problem in African-Americans, and there are conflicting data on autism incidence in this population, relative to whites and other races. However, one study showed that prevalence of autism in African-Americans was approximately 25% higher than that of whites when the data were adjusted for socioeconomic factors.[7] All potential causes of or contributors to autism incidence should be investigated, regardless of their bearing on U.S. vaccination rates. The effect originally observed by the CDC and affirmed in this paper, showing a greater risk specifically for African-Americans, deserves additional, immediate investigation.

MMR Timing Related to Mental Retardation

Another feature reported by DeStefano et al.[1] is a statistically significant association between MMR timing and autism incidence when considering autism cases with or without a diagnosis of mental retardation (MR). MR was defined in the original paper as an IQ less than 70, measured between 1996 and 1998. Specifically, Table 4 in DeStefano et al. shows an odds ratio of 2.45 (95% CI 1.20 – 5.00) when looking at the risk of autism without MR, using at the 36-month "cut-off" age. This means that those individuals receiving MMR vaccine prior to age 36 months were at a statistically significant greater risk of autism without MR as compared to those who received the vaccine at 36 months or thereafter. This analysis was completed on the total sample (with 248 cases and age, gender, and school-matched controls). Curiously, this analysis was repeated on the birth-certificate sample, consisting of 132 cases and age, gender, and school-matched controls, with adjustments for birth weight, multiple gestation, maternal age, and maternal education. DeStefano et al. had 1,824 control subjects with 1:3 case control matching, but they do not report the number of controls used in each of these particular analyses. With the limited power associated with the smaller sample, statistical significance was avoided in the second analysis, with an odds ratio of 3.55 (95% CI 0.74 – 17.07).

In the current analysis, this association was revisited for the entire sample for cases of autism with and without mental retardation. In each case, conditional logistic regression was used on cases matched to controls by birth year, gender, and school attended. Results for cases without MR are shown in Table 4, where no statistically significant effect is seen at 18 months, a marginal effect is seen at 24 months (OR = 1.47, $p = 0.094$), and a significant effect is seen at 36 months (OR = 2.52, $p = 0.012$). This

contrasts with cases of autism with MR (results shown in Table 5), in which no effect is observed.

DeStefano et al.[1] mentioned the effect regarding autism without MR only in passing, stating: "The only exception was that case children without MR were more likely to have been vaccinated before 36 months of age than their matched control children." No discussion of any potential reason for this effect is offered. Neither is this result contrasted to any of the other statistically significant results, in which the coauthors suggest that the effect may result from the requirement that children with an autism diagnosis are required to receive their first MMR early in order to qualify for special education services. The obvious problem with this argument, in light of the results, is that no consistent effect is observed across all the demographics studied (boys versus girls, different races, etc.), all of whom face the same requirement.

It is notable that a significant portion of the U.S. autism population has no intellectual disability. The Autism and Developmental Disability Monitoring (ADDM) network in 2014 reported a prevalence of autism without concurrent intellectual disability of 10.2/1000, whereas the prevalence of autism with concurrent disability was 4.7/1000. Authors of the report concluded that "a large proportion of the observed ASD prevalence increase can be attributed to children with average or above average intellectual ability (IQ >85)."[8] Several other recent studies affirm this.[9]

MMR Timing When Considering Underlying Thimerosal Exposure

One aspect of the vaccine schedule that was not studied by DeStefano et al. was the effect of thimerosal exposure on developmental outcomes in light of timing of the MMR vaccine. Many previous studies have shown a relationship between autism incidence and thimerosal exposure from infant vaccines.[10] Gallagher et al.[3] have reported that "non-white" males bear a greater risk from exposure to thimerosal from the hepatitis B vaccination series.

The birth dates of the MADDSP sampling, between 1986 and 1994, yielded a unique opportunity for comparison, given the rise in thimerosal exposure starting in the early 1990s with the addition of the hepatitis B and *Haemophilus influenza* type b (Hib) vaccine series to the CDC's infant vaccination schedule.

Since insufficient information was available in the data set to directly calculate infant thimerosal exposure, the sample was split into two exposure groups: those born before 1990, as a surrogate for lower thimerosal exposure, and those born in 1990 and thereafter, as a surrogate for higher thimerosal exposure. Then, rather than dichotomizing each sub-sample by age of first MMR vaccine (e.g., before and after 36 months of age), a conditional logistic model was run based on the odds associated with receiving the MMR vaccine "one year earlier," i.e. where the timing of the first MMR vaccine was treated as a continuous variable. Results for African-American males are shown in Table 6 and clearly demonstrate that statistical significance is achieved only for the sample taken after the 1990 birth year cut-off (OR = 1.720, p-value = 0.0325). These would include infants subjected to the three-shot hepatitis B vaccine series, with a total mercury exposure of 37.5 micrograms from thimerosal, and the four-shot Hib series, with a mercury exposure of 100 micrograms from thimerosal, in addition to the four-shot diphtheria-tetanus-acellular pertussis (DTaP) series (which was recommended prior to 1990), with a mercury exposure of 100 micrograms from thimerosal. Thus, infants compliant with the CDC recommended schedule, born in 1990 and thereafter, were exposed to an additional 137.5 micrograms mercury by age 18 months. The results, which are preliminary, suggest some type of synergism between thimerosal exposure and MMR timing leading to a greater risk of autism. However, this more complex "effect" requires additional study for confirmation, and to understand the role of thimerosal and the MMR in the onset and etiology of autism, especially given the limited nature of the MADDSP data set.

Conclusion

The data set used by DeStefano et al.[1] represents a huge lost opportunity to understand any role between the timing of the first MMR vaccine and autism. The re-analysis presented here elucidates effects that should at least merit further investigation. Specifically, increased risks of earlier vaccination are observed for African-American males and among cases of autism without MR. Both phenomena deserve additional study that could yield important clues regarding the current enormous increase in autism.

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