MMR Vaccination and Febrile Seizures
Evaluation of Susceptible Subgroups and Long-term Prognosis

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The safety of the measles, mumps, and rubella (MMR) vaccine is of major public health interest because millions of children are vaccinated every year. Fortunately, the vaccine is generally well-tolerated, rarely associated with serious adverse effects, and may even have nonspecific health benefits. However, MMR vaccination is followed by a transient increased risk of febrile seizures compared with nonvaccinated children, probably due to vaccine-induced fever. It may have clinical implications if susceptible children could be identified before the vaccination but no study has been large enough to identify such subgroups. For example, it is unknown whether children with a personal or a family history of seizures are more prone to MMR-induced febrile seizures than children without such history. Febrile seizures are in general associated with an increased risk of epilepsy but it remains unclear if febrile seizures following MMR vaccination carry a particularly high risk. To address these questions, we performed a large population-based cohort study.

Context The rate of febrile seizures increases following measles, mumps, and rubella (MMR) vaccination but it is unknown whether the rate varies according to personal or family history of seizures, perinatal factors, or socioeconomic status. Furthermore, little is known about the long-term outcome of febrile seizures following vaccination.

Objectives To estimate incidence rate ratios (RRs) and risk differences of febrile seizures following MMR vaccination within subgroups of children and to evaluate the clinical outcome of febrile seizures following vaccination.

Design, Setting, and Participants A population-based cohort study of all children born in Denmark between January 1, 1991, and December 31, 1998, who were alive at 3 months; 537,171 children were followed up until December 31, 1999, by using data from the Danish Civil Registration System and 4 other national registries.

Main Outcome Measures Incidence of first febrile seizure, recurrent febrile seizures, and subsequent epilepsy.

Results A total of 439,251 children (82%) received MMR vaccination and 17,986 children developed febrile seizures at least once; 973 of these febrile seizures occurred within 2 weeks of MMR vaccination. The RR of febrile seizures increased during the 2 weeks following MMR vaccination (2.75; 95% confidence interval [CI], 2.55-2.97), and thereafter was close to the observed RR for nonvaccinated children. The RR did not vary significantly in the subgroups of children that had been defined by their family history of seizures, perinatal factors, or socioeconomic status. At 15 to 17 months, the risk difference of febrile seizures within 2 weeks following MMR vaccination was 1.56 per 1000 children overall (95% CI, 1.44-1.68), 3.97 per 1000 (95% CI, 2.90-5.40) for siblings of children with a history of febrile seizures, and 19.47 per 1000 (95% CI, 16.05-23.55) for children with a personal history of febrile seizures. Children with febrile seizures following MMR vaccinations had a slightly increased rate of recurrent febrile seizures (RR, 1.19; 95% CI, 1.01-1.41) but no increased rate of epilepsy (RR, 0.70; 95% CI, 0.33-1.50) compared with children who were nonvaccinated at the time of their first febrile seizure.

Conclusions MMR vaccination was associated with a transient increased rate of febrile seizures but the risk difference was small even in high-risk children. The long-term rate of epilepsy was not increased in children who had febrile seizures following vaccination compared with children who had febrile seizures of a different etiology.

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METHODS

Study Population

This population-based cohort study was based on a previously described study population and includes all children born in Denmark between January 1, 1991, and December 31, 1998, who were alive at the age of 3 months (N = 537,171). The cohort was established by means of data from the Danish Civil Registration System and 4 other national registries. All live-born children and new residents in Denmark are assigned a unique personal identification number (civil registry number), which is stored in the Danish Civil Registration System together with information on vital status, emigration, address, and family structure (link to mother and father). The registry is updated every week and all changes regarding the status of the above-mentioned variables are required by law. The civil registry number can be used to link individual information in all national registries. We obtained permission from the Danish Data Protection Board before the study was initiated.

MMR Vaccination Status

We determined MMR vaccination status from vaccination data reported to the National Board of Health by general practitioners, who provide MMR vaccinations in Denmark. The general practitioners are reimbursed by the state based on these reports.

We retrieved information on vaccinations from January 1, 1991, through December 31, 1999. The MMR vaccine was introduced in Denmark in 1987 and a single-antigen measles vaccine has never been recommended. The MMR vaccine used in Denmark during the study period was identical to that used in the United States and contained the following vaccine strains: Moraten (measles), Jeryl Lynn (mumps), and Wistar RA 27/3 (rubella). The national vaccination program recommended during the entire study period that children should be vaccinated twice, at 15 months and at 12 years. Only the first vaccination is relevant to the end point under study. Because the vaccination data are transferred to the National Board of Health once a week without specifying the day of vaccination, we had to select 1 day as the day of vaccination in our analyses and we chose Wednesday. Since 1996, vaccination information has been recorded with the child’s own civil registry number and the information directly linked with other registries. Before 1996, vaccination information and the age of the child were recorded with the civil registry number of the accompanying adult. We used information from the Danish Civil Registration System to identify the link from the accompanying adult to the child; therefore, 98.5% of the children were identified with the use of the child’s civil registry number or the civil registry number of the mother or father and the age of the child at vaccination. The remaining 1.5% of vaccinated children were identified based on the civil registry number of other relatives and the child’s address at the time of vaccination.

Febrile Seizures and Epilepsy

Information on febrile seizures and epilepsy was obtained from the National Hospital Register (NHR), which contains information on all patients discharged from Danish hospitals since 1977; outpatients (visits to emergency department and hospital clinics) have been included in the register since 1995. All treatments in Danish hospitals are free of charge for all Danish citizens. Diagnostic information was classified according to the Danish version of the International Classification of Diseases (ICD) as follows: ICD-8 was used from 1977 to 1993 and ICD-10 was used from 1994 to the end of 1999. We classified children as having a febrile seizure when they were registered with ICD-8 code 780.21 or ICD-10 code R56.0, aged between 3 and 60 months at the time of discharge, and had no recorded history of nonfebrile seizures, cerebral palsy, severe head traumas, intracranial tumors, meningitis, or encephalitis. The febrile seizures could not be classified as simple or complex because the NHR contains no information on number of febrile seizures occurring within the febrile episode, duration of the febrile seizures, and type of febrile seizures (generalized or focal onset). Children were categorized with epilepsy if they had ICD-8 code 345 or ICD-10 code G40.

Potential Effect Modifiers and Confounders

We obtained information on febrile seizures and epilepsy in siblings from the NHR during the period January 1, 1977, to December 31, 1999. Children were labeled with a family history of seizures from the day a sibling was admitted to a Danish hospital or had been in outpatient care with febrile seizures or epilepsy. We obtained information on birth weight and gestational age from the Danish Medical Birth Register and the NHR. Information on socioeconomic status (as indicated by the employment status of the head of the household) and maternal education was obtained from Statistics Denmark at the time the child was aged 15 months.

Statistical Analysis

To study the association of MMR vaccination with a first episode of febrile seizure, we followed the children from the age of 3 months until the first diagnosis of febrile seizure registered in the NHR, death, emigration, a diagnosis of epilepsy, cerebral palsy, severe brain injury, brain tumor, meningitis, encephalitis, aged 5 years, or until December 31, 1999, whichever came first. The resulting person-years at risk were aggregated and analyzed using Poisson regression, producing incidence rate ratios (RRs). We considered MMR vaccination a time-varying covariate; the children were assigned to the nonvaccinated group until they received the MMR vaccine. From that day, they were included in the vaccinated cohort. We evaluated whether the RR of febrile seizures following MMR vaccination varied between subgroups of children by testing for statistical interaction. All RRs were adjusted for age (3-month categories) and calendar.
period (1-year categories). In multivariable analyses, we considered con-founding by sex, number of siblings with febrile seizures (no siblings, no sib-
lings with febrile seizures, 1 sibling with febrile seizures, ≥2 siblings with febrile seizures), number of siblings with epi-lepsy (no siblings, no siblings with epileps-
y, ≥1 siblings with epilepsy), birth order (1, 2, 3, ≥4), gestational age in weeks (≥36, 37-41, ≥42), birth weight in grams (≥2499, 2500-2999, 3000-
3499, 3500-3999, ≥4000), maternal education (postgraduate education, col-
lege, vocational training, secondary school, primary school), and socioeco-
omic status as indicated by the employment status of the head of the house-
hold (managers [very high], wage earner [high], wage earner [medium], wage earner [low], wage earner [minimal], unemploy-
ed). We had no information on birth weight, gestational age at birth, socioeco-
nomic status, and maternal education for 6.2%, 31.7%, 2.7%, and 0.3% of the children, respectively. Data on gestational age at birth was not avail-
able for children born after December 31, 1996. When evaluating confound-
ing, we used 2 different strategies for the handling of missing values. First, we used the method of single imputa-
tion, replacing a missing value with the most common value of that variable: 3000 to 3499 g for birth weight, 37 to 41 weeks for gestational age at birth, wage earner (standard level) for socioeco-
nomic status, and vocational training for maternal education. Second, we anal-
alyzed only those children with complete information on all variables (358702). A priori, we decided to add all variables to the final model that changed the estimate of interest by at least 10% using either strategy. None of the variables with missing data qualified. Only age and calendar period were included in the final model. When evaluating effect modification, we ana-
lyzed only those children with complete information on the variable of interest.

To study the association of MMR vac-
cination and a second episode of fe-
brile seizures in children with a per-
sonal history of febrile seizures, we con-
structed a cohort of 10541 children who were nonvaccinated at the time of the first febrile seizure. These children were followed up prospec-
tively from the day of the first regist-
ered febrile seizure until the second ep-
isode of febrile seizure registered in the NHR, death, emigration, a diagno-
sis of epilepsy, cerebral palsy, severe brain injury, brain tumor, meningitis, encephalitis, aged 5 years, or until December 31, 1999, whichever came first. The RRs were adjusted for age, calendar period, age at first febrile sei-
zure, and current vaccination status.

All analyses were conducted using SAS statistical software version 8.2 (SAS Institute Inc, Cary, NC). P<.05 was considered statistically significant.

RESULTS
We followed up 537171 children for a total of 1.9 million person-years and identified 17986 children who developed febrile seizures at least once; 973 of these febrile seizures occurred within 2 weeks of the MMR vaccination. During the study period, 439251 children (82%) received MMR vaccination.

RRs of Febrile Seizures After MMR Vaccination
Overall, we found that the rate of first febrile seizures was 10% higher among vaccinated children (7445; person-
years at risk, 1151661) compared with nonvaccinated children (10541; per-
son-years at risk, 793568) during the study period (RR, 1.10; 95% CI, 1.05-1.15), after adjusting for age and calendar period. However, the rate of febrile seizures increased during the first (RR, 2.46; 95% CI, 2.22-2.73) and second (RR, 3.17; 95% CI, 2.89-
3.49) week following vaccination only (FIGURE 1); thereafter the rate was close to that for nonvaccinated children.

Overall, the RR of febrile seizures within 2 weeks of MMR vaccination was 2.75 (95% CI, 2.55-2.97) compared with nonvaccinated children. We found no statistically significant difference in the RR of febrile seizures in the 2 weeks following vaccination between subgroups of children characterized by family history of seizures, sex, birth or-
der, gestational age at birth, birth weight, or socioeconomic factors, com-
pared with nonvaccinated children within the subgroup under study (FIGURE 2). The highest RR was found
among siblings of children with a history of epilepsy who had a 4-fold increased rate of febrile seizures in the 2 weeks following vaccination compared with a 2.7-fold increased rate of febrile seizures following vaccination in siblings of children with no history of epilepsy (P value for interaction = .09).

Among the 10541 children with a personal history of febrile seizures, 175 children had a recurrent febrile seizure within 2 weeks of the MMR vaccination. The RR of febrile seizures in the 2 weeks following vaccination was 2.75 (95% CI, 2.32-3.26) after adjusting for age, age at the first febrile seizure, and calendar period, compared with nonvaccinated children with a personal history of febrile seizures.

**Risk Difference of Febrile Seizures Among Subgroups of Vaccinated Children**

The risk difference of febrile seizures in the 2 weeks following MMR vaccination compared with nonvaccinated children was 1.56 per 1000 (95% CI, 1.10-1.91) for children vaccinated at 18 to 20 months, and 0.64 per 1000 (95% CI, 0.22-1.40) for children vaccinated at 21 to 23 months.

The highest risk difference was found among children with a personal history of febrile seizures (19.47 per 1000; 95% CI, 16.05-23.55) and for children with a family history of febrile seizures (3.97 per 1000; 95% CI, 2.90-5.40; TABLE 1).

**Long-term Prognosis of Febrile Seizures Following MMR Vaccination**

We found that children who experienced febrile seizures within 2 weeks of MMR vaccination had a 19% increased rate of recurrent febrile seizures (RR, 1.19; 95% CI, 1.01-1.41) but no increased rate of epilepsy (RR, 0.70; 95% CI, 0.33-1.50) during up to 105 months of follow-up. The reference group consisted of children who had not been vaccinated when having their first febrile seizure (TABLE 2).

**COMMENT**

The incidence rate of febrile seizures was increased in the 2 weeks following MMR vaccination and thereafter the rate was close to that observed for nonvaccinated children. This finding is consistent with previous reports6-10 and is expected since MMR vaccination often induces fever,1 a necessary cause of febrile seizures. Farrington et al7 found an increased rate of febrile seizures up to 35 days after vaccination with the Urabe mumps strain but the rate was increased no longer than 2 weeks for the Jeryl Lynn vaccine, which was used in our study.

Family history of seizures, preterm birth, low birth weight, and male sex are risk factors for febrile seizures23 but the RR of febrile seizures following MMR vaccination did not vary significantly according to these factors in this study. The highest RR was found among siblings of children with epilepsy; a 4-fold increased rate of febrile seizures following MMR vaccination was observed compared with nonvaccinated siblings of children with epilepsy. However, our statistical power in this subgroup was limited and further studies are needed to determine whether the siblings of children with epilepsy are more likely to experience a febrile seizure after MMR vaccination than other children, or the finding is merely due to chance. The RR of febrile seizure was not modified by a family history of febrile seizures.

Overall, our data suggest that MMR vaccination and the other indicators for febrile seizures follow a multiplicative model; the rate of febrile seizures in all subgroups of children is approximately 2.75 times higher within 2 weeks of MMR vaccination than it would have been had the children not been vaccinated. The absolute increase in incidence of febrile seizures following vaccination depends therefore on the underlying risk of febrile seizures in each subgroup. In Denmark, most children are vaccinated against MMR at age 15 to 17 months when the incidence rate of febrile seizures is peaking.24 At this age, the number of children experiencing febrile seizures within 2 weeks was 1.56 more per 1000 vaccinated children compared with nonvaccinated children. No previous studies have cal-
culated the risk difference according to age at vaccination, but 2 studies found that approximately 0.33 febrile seizures were attributable to 1000 doses of MMR vaccine overall.6,7

As expected, we found the highest risk difference in children with a personal history of febrile seizures. The underlying risk of febrile seizures in these children is high; approximately one third will have at least 1 episode of recurrent febrile seizures before they reach 5 years of age.25 In this very high-risk group, we found 19 additional febrile seizures within 2 weeks of the vaccination per 1000 children compared with nonvaccinated children aged 15 to 17 months. The Advisory Committee on Immunization Practices has suggested that the benefits of administering MMR vaccine to children with a personal or family history of convulsions substantially outweigh the risks, and these children should be vaccinated following the recommendations for children who have no contraindications.26,27

We found no increased rate of epilepsy among children who had febrile seizures after MMR vaccination compared with children who had febrile seizures of a different etiology. The rate of recurrent febrile seizures was slightly increased, possibly because the MMR vaccination introduced an extra febrile episode during the window of highest susceptibility and the total number of febrile episodes is a well known risk factor for recurrence.9,8 We know of only 1 study9 evaluating the clinical outcome of children with febrile seizures following MMR vaccination. No increased rate of subsequent seizures was found in 41 children with febrile seizures following MMR vaccination compared with 521 children who had febrile seizures in the absence of vaccination.6 However, the statistical power of this study was limited, in particular when evaluating the rate of subsequent epilepsy.

The strengths of our study include its size and population-based nature. The follow-up was virtually complete, which eliminates bias due to nonresponse. Information on MMR vaccinations and febrile seizures was collected prospectively and independent of parental recall. We expect the data quality of the MMR vaccination to be high because the general practitioners are reimbursed only after reporting immunization data to the National Board of Health.

The information on vaccination was reported to the National Board of Health on a weekly basis but without information on the exact day of vaccination. We chose Wednesday as the day of vaccination. Because children in Denmark are vaccinated Monday thru Fri-

<table>
<thead>
<tr>
<th>Strata</th>
<th>Rate Ratio (95% Confidence Interval)</th>
<th>P Value for Interaction</th>
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<tbody>
<tr>
<td>All Children</td>
<td>2.75 (2.55-2.97)</td>
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<tr>
<td>Siblings With Febrile Seizures</td>
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<td>2.78 (2.51-3.07)</td>
<td>.69†</td>
</tr>
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<td>2.64 (2.33-3.00)</td>
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<td>Siblings With Epilepsy</td>
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<tr>
<td>No Siblings</td>
<td>2.68 (2.40-2.99)</td>
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<tr>
<td>1 Sibling With Epilepsy</td>
<td>2.73 (2.48-3.06)</td>
<td>.09</td>
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<tr>
<td>2 Siblings With Epilepsy</td>
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<tr>
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<tr>
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<tr>
<td>Girl</td>
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<tr>
<td>2</td>
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<tr>
<td>3</td>
<td>3.21 (2.67-3.85)</td>
<td>.54†</td>
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<td>4</td>
<td>2.47 (1.75-3.49)</td>
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</tr>
<tr>
<td>Postgraduate Education</td>
<td>2.59 (1.93-3.48)</td>
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</table>

MMR indicates measles, mumps, and rubella. Vertical dashed line represents the overall rate ratio (RR) for febrile seizures within the 2 weeks following MMR vaccination compared with nonvaccinated children. Point estimates are given with error bars representing 95% confidence intervals.

*The RRs are adjusted for age and calendar period. The analyses including siblings were additionally adjusted for the total number of siblings. Children with missing values were excluded when the effect of the variable concerned was evaluated.

†Test for interaction was performed by a test for trend. When evaluating the possible effect modification by siblings with febrile seizures or by siblings with epilepsy, children without siblings were not included in the test for interaction.

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day, we have misclassified some vaccinations by up to 2 days. Previous studies have shown that the attenuated viruses in the MMR vaccine cause fever in approximately 10% of nonimmune vaccinees between 5 and 12 days after immunization.\textsuperscript{1,29} Thus, the rate of febrile seizures is probably not elevated during the first 4 days following vaccination.

We have previously validated the quality of febrile seizure registration in the NHR in a cohort of 6624 children born between 1991 and 1992 and followed up until age 10 years.\textsuperscript{30} We collected information about febrile seizures in the cohort using a parental questionnaire. All potential febrile seizures were confirmed by diagnostic telephone interview or review of medical records. We found that 323 children (4.9%) in the cohort fulfilled the criteria for febrile seizures and were 231 of those were registered in the NHR (completeness, 71.5%; 95% CI, 66.3%-76.4%). Among the 249 children registered with febrile seizures in the NHR, we confirmed the diagnosis in 231 children (predictive value of a positive registration, 92.8%; 95% CI, 88.8%-95.7%). We believe it is unlikely that MMR vaccination status influences the threshold for hospitalization or the coding of febrile seizures. Any misclassification of febrile seizures is likely to be nondifferential and will therefore bias the RR toward 1.0.\textsuperscript{21} In fact, we found that the RR of febrile seizures following MMR vaccination was virtually the same during the period 1991 to 1994 (2.68; 95% CI, 2.38-3.02) compared with the period 1995 to 1998 (2.79; 95% CI, 2.55-3.05), although outpatients were included in the latter period only.

The Danish national vaccination program recommends that children be vaccinated with MMR at age 15 months and provides vaccinations free of charge. Overall, vaccination coverage was found to be 82%, which increased during the study period. The effect of vaccination may be confounded by variables related both to avoidance of vaccination and to the outcome of interest. We adjusted our results for several potential confounders but found little change in the estimate of interest. However, the strongest argument against serious confounding is that the risk of febrile seizures was almost the same for nonvaccinated and vaccinated children outside the time frame of 2 weeks following vaccination.

MMR vaccination is an effective health intervention. The 3 diseases and their neurological sequelae are rarely observed today in countries with high vaccination coverage.\textsuperscript{31,32} Our study showed that the transient increased rate of febrile seizures was restricted to 2 weeks following vaccination, the risk difference was small even in children at high risk of febrile seizures, and the long-term rate of epilepsy was not increased in children who had febrile seizures following MMR vaccination compared with children who had febrile seizures of a different etiology.

Author Contributions: Dr Melbye had access to all of the data in the study and takes full responsibility for the integrity of the data and the accuracy of the data analysis. Study concept and design: Vestergaard, Hviid, Madsen, Wohlfahrt, Melbye, Olsen.
REFERENCES


