Reports of sensorineural deafness after measles, mumps, and rubella immunisation

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Abstract
There have been nine reports of sensorineural hearing loss after measles, mumps, and rubella (MMR) immunisation. In three cases the deafness was unrelated to MMR immunisation. In six cases the cause was unknown and MMR remained a possible aetiology. Any risk associated with attenuated viruses must be weighed against the risks of the natural diseases.

(Measles, mumps, and rubella (MMR) immunisation was introduced in the UK in October 1988. To date six million doses of vaccine have been distributed. Phase II clinical trials had shown that the adverse effects were similar in type and frequency to the measles alone vaccine. However, rare events may not be detected by these trials. In 1988, a Danish case of unilateral deafness after MMR was reported and a bilateral case has subsequently been described. In both cases the mumps component was considered to be causal. The other components of MMR have also been implicated in case reports. The yellow card scheme was introduced in 1964 and has an important role in surveillance after marketing. It covers the whole of the UK and there are specific instructions for reporting for both new and established vaccines.

Subjects and methods
Since introduction, nine yellow card reports have been received of deafness after MMR immunisation (personal communication, Committee on Safety of Medicines, CSM). These reports were forwarded to the Department of Health and to us for further evaluation. Additional information was obtained from the reporting doctor and immunisation details were requested from the general practitioner or the child health department.

Results
The table shows the type of deafness, the type of vaccine received, time from immunisation to recognition of deafness, and brief clinical details. In no case was there a history of infection in pregnancy, jaundice, use of ototoxic drugs, or preceding natural mumps infection. Additional clinical information is summarised below for the three children who developed bilateral deafness after this immunisation.

CASE 1
This girl developed a rubelliform rash 25 days after immunisation. Three days later she developed vomiting and malaise. On review, a week later, she exhibited poor balance. Nine weeks later she was found to respond poorly to sound. She had also stopped speaking for the preceding two weeks.

CASE 2
This boy’s father suffered a flu-like illness at the same time that the boy was unwell after immunisation. His mother noticed his poor hearing but attributed it to inattention and did not seek medical advice. He also has amblyopia and learning difficulties.

CASE 9
This boy became deaf four months after immunisation. Mumps antibody titres measured at this time and one month later showed a significant rise.

Sensorineural hearing loss after MMR immunisation: adverse drug reaction reports

<table>
<thead>
<tr>
<th>Case No</th>
<th>Age of child taken immunised (years)</th>
<th>Sex</th>
<th>Vaccine used</th>
<th>Site and degree of sensorineural deafness</th>
<th>Interval from immunisation to documentation of sensorineural deafness</th>
<th>Audiogram recorded before immunisation</th>
<th>Screening tests passed, result of audiograms, and other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Possible cases</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1-2</td>
<td>F</td>
<td>Pluserix</td>
<td>Bilateral profound</td>
<td>9 weeks</td>
<td>No</td>
<td>Acute illness at 25 days</td>
</tr>
<tr>
<td>2</td>
<td>3-8</td>
<td>M</td>
<td>Pluserix</td>
<td>Bilateral moderately severe</td>
<td>6 months</td>
<td>No</td>
<td>Other abnormalities</td>
</tr>
<tr>
<td>3</td>
<td>1-1</td>
<td>F</td>
<td>Pluserix</td>
<td>Right profound</td>
<td>12 months</td>
<td>No</td>
<td>Distraction 9 months</td>
</tr>
<tr>
<td>4</td>
<td>6-2</td>
<td>F</td>
<td>Pluserix</td>
<td>Left profound</td>
<td>8 months</td>
<td>No</td>
<td>Distraction 6 months</td>
</tr>
<tr>
<td>5</td>
<td>4-3</td>
<td>M</td>
<td>Pluserix</td>
<td>Left profound</td>
<td>14 months</td>
<td>No</td>
<td>Distraction 9 months, secretory otitis media present</td>
</tr>
<tr>
<td>6</td>
<td>4-8</td>
<td>M</td>
<td>Pluserix</td>
<td>Right severe</td>
<td>6 months</td>
<td>Yes</td>
<td>Distraction 6 months, normal audiogram 4-8 years, secretory otitis media present</td>
</tr>
<tr>
<td>Unrelated cases</td>
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<td></td>
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</tr>
<tr>
<td>7</td>
<td>5-8</td>
<td>F</td>
<td>Pluserix</td>
<td>Right severe</td>
<td>3 weeks</td>
<td>Yes</td>
<td>Abnormal sweep audiogram 4-9 years</td>
</tr>
<tr>
<td>8</td>
<td>-</td>
<td>F</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>4-5</td>
<td>M</td>
<td>Pluserix</td>
<td>Bilateral profound</td>
<td>4 months</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
Discussion

Doctors are asked to report all suspected reactions for both new and established vaccines. A proved causal relationship is not required before reporting. For cases 7 and 8, the deafness was unrelated to MMR immunisation. One child was deaf before immunisation and the other had not received MMR vaccine.

For six of the children, the cause of deafness is unknown and MMR immunisation remains one possibility. It is difficult to disentangle causal and temporally associated events. The incidence of sudden hearing loss in adulthood is 5–20 per 100,000 person years and it is bilateral in 2% of cases. If these figures applied to children, then more than six cases should have been reported, simply by chance, within a year of MMR immunisation. Unfortunately, there are no equivalent data for children.

All the children with unilateral deafness were over 3 years old when immunised. Unilateral deafness is difficult to diagnose in young children. The side effects of natural mumps are known to increase with age. However, if unilateral deafness has occurred in children immunised between 12–18 months of age, it has been missed. It is timely that the children, immunised at 15 months when the vaccine was introduced, will have started school in September 1992. The school entry sweep audiogram is still recommended. The prevalence of sensorineural hearing loss in a cohort of these children could be compared with a historical cohort of children who did not receive MMR at 15 months or 4 years. However the sample size required is greater than the number of school entrants in one district and so cooperation between several districts would be needed.

The six children reported, whose deafness may have been related to MMR immunisation, had received a vaccine containing the Urabe strain of mumps vaccine. Altogether 85% of the vaccine distributed contained the Urabe mumps (personal communication, NHS supplies authority). It is not statistically significant that no cases have been reported to the CSM among those who received the Jeryl Lynn strain (Fisher’s exact test p=0.6). Both mumps strains have previously been reported to cause deafness. The Urabe strain is no longer supplied in the UK because of the increased risk of aseptic meningitis. The deafness due to natural mumps results from endolymphatic labyrinthitis and is independent of meningitis.

Case 9 had a natural mumps infection despite immunisation. This illustrates the devastating effect of the natural mumps virus and that vaccine efficacy must be considered in addition to reactogenicity. No other child had acute viral titres measured, so other ototoxic viruses were not excluded. To doctors, the effects of congenital rubella, measles, and mumps infection are well recognised. Mumps causes deafness in 50–230 per million cases. One third of parents, seen as part of the nationwide follow up of vaccine associated meningoencephalitis, were unaware of this risk of natural mumps (Dr Stewart and Dr Prabhu, in preparation).

The epidemiology of childhood deafness needs detailed study not only to put adverse events in perspective but also to evaluate rubella prevention and screening programmes. Any risk of deafness after MMR immunisation is small and must be weighed against the risks of the natural diseases.

We thank Dr DM Salisbury of the Department of Health, the Medicines Control Agency, and the reporting doctors for allowing us to present these cases. Dr Prabhu and Dr Stewart have been funded by the Department of Health as part of the active surveillance of meningoencephalitis within six weeks of MMR immunisation.

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