Compiling Safety Reference Data for Maternal Outcomes in Pfizer’s Maternal Immunization Trials

Dave Mix, Mailman School of Public Health ’20
Mentors: Negar Alibabadi, MD; Eileen Farnon, MD; Iona Munjal, MD
Pfizer, Vaccine Clinical Research and Development

Research Question: What are the background rates and case definitions for maternal outcomes in pregnancy?

RESPIRATORY SYNCYTIAL VIRUS (RSV) is a virus that causes mild symptoms in adults but can cause very severe symptoms in infants and children, especially those under the age of 1 year. It is the single most common cause of pneumonia for children under 1 year, hospitalizing thousands of children each year with bronchiolitis and pneumonia. It can also cause very severe symptoms in older adults.

Currently, there is a monoclonal antibody prophylaxis for RSV. However, it is only indicated for those who were born premature, those with a history of bronchopulmonary dysplasia, or those with a history of congenital heart disease, and it can cost tens of thousands of dollars per patient. There is no treatment for RSV.

Scientists have been working on various vaccine candidates since 1967, but recently, maternal vaccinations have been thought to have the potential for protecting infant children through transplacental transmission of antibodies from the mother. However, maternal immunization is an emerging field and background safety data is lacking globally.

METHODS

In order to compile case definitions and background rates for maternal outcomes, a landscape review was conducted to document rates for maternal outcomes, including Cesarean section, stillbirth, and maternal mortality.

Data sources included peer-reviewed literature, governmental health reports, governmental data from national statistics offices, internationally funded health reports, and global meta-analyses conducted by WHO.

DISCUSSION

Overall, rates for maternal outcomes varied widely in the sources reviewed and may be due to non-standardization of case definitions in addition to economic and cultural factors. For example, Japan documents “elective” Cesarean sections, whereas Brazil documents Cesarean sections “without labor.” Further studies are warranted to elucidate these differences.

REFERENCES


A full list of references used in the table is available upon request: dcm2181@cumc.columbia.edu

<table>
<thead>
<tr>
<th>NORTH AMERICA</th>
<th>EUROPE</th>
<th>LATIN AMERICA</th>
<th>AFRICA</th>
<th>ASIA/PACIFIC</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>Canada</td>
<td>Mexico</td>
<td>Finland</td>
<td>Netherlands</td>
</tr>
<tr>
<td>Cesarean-section</td>
<td>31.7%</td>
<td>29.4%</td>
<td>45.3%</td>
<td>14.6%</td>
</tr>
<tr>
<td>Elective</td>
<td>--</td>
<td>14.5%</td>
<td>23.9%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Emergency</td>
<td>--</td>
<td>10.0%</td>
<td>16.8%</td>
<td>10.0%</td>
</tr>
</tbody>
</table>