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MMR Vaccine and Autism: No Evidence of Association

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Executive Summary

Recently, there has been public interest in a theory that suggests the Measles-Mumps-Rubella (MMR) vaccine, may be associated with autism. In a 1998 UK study of 12 children with autism, an initial observation linking autism and MMR vaccine was reported.[1] Several epidemiological studies investigating whether the MMR vaccine may be causally associated with autism have been undertaken. The British Committee on Safety of Medicines, Taylor, et al., and an analysis on data from California and Finland have concluded that evidence does not support the hypothesis that the MMR vaccine, or any combination of vaccines, causes the development of autism, including regressive forms of autism.[2-5]

The benefits of being vaccinated greatly outweigh the risk of contracting the disease being vaccinated for. However, while vaccines may be effective, they are not without possible side effects. The risk of having an adverse reaction from a vaccine is far less than having serious consequences from an infectious disease. The Centers for Disease Control (CDC) tracks any unusual epidemiological trends associated with vaccine safety. Federal monitoring supplies public health professionals with the information they need to ensure the safest strategies of vaccine administration.

While the U.S. is experiencing record low cases of vaccine preventable diseases, the viruses and bacteria that cause them still exist. Diseases that have a low prevalence or have been eliminated in the U.S, are still common in other parts of the world and can easily be imported into the U.S. Persons not vaccinated are at high risk for contracting and transmitting a disease.[6,7]

Prior to vaccinations, infectious diseases were extremely prevalent and brought devastating levels of permanent injury and death to countless individuals in the U.S. Measles, mumps, and rubella are all serious, contagious diseases, which spread rapidly, especially in populations that are not immune. The CDC has stated that if vaccination against measles, mumps and rubella were to stop, the number of cases would return to the pre-vaccine levels.[8]

Autism is a complex, life-long, developmental disorder that has no cure. Experts believe genes control early brain development and that two genes, identified as HOXA1 and HOXB1, may be the underlying factors in a large number of autism cases.

Conclusion
There is no scientific evidence that supports the hypothesis that the MMR vaccine, or any combination of vaccines, causes the development of autism. Both the CDC and the British Committee on Safety of Medicines found no association between the MMR vaccine and autism.

Background

Recently, there has been public interest in a theory that suggests the MMR vaccine, or that immunizations in general, may be linked to autism. In a 1998, UK study of 12 children with autism, an initial observation linking autism and MMR vaccine was reported.[1] The study suggested that the MMR vaccination led to intestinal Abnormalities, resulting in impaired intestinal functions and developmental regression within 24 hours to a few weeks of vaccination. Researchers suggested that the live, weakened measles virus in the vaccine attacked the children's intestines and prevented them from absorbing nutrients critical to brain development. Subsequent studies and reviews have refuted the findings of the study and have found no evidence for casual association between the MMR vaccination and autism.[2-5,9-11]

Findings

A huge blow to the efforts of measles eradication was dealt, when in 1998, Dr. Andrew Wakefield from the Royal Free Hospital, UK, argued that because of uncertainty about its safety, the MMR vaccine should be withdrawn and the components given separately. He presented a theory that there was an association between autism and intestinal abnormalities and a possible relation, as recalled by some parents, with the MMR vaccination, in 12 children who had autism. Wakefield, et al., investigated a consecutive series of children with chronic enterocolitis

and regressive developmental disorder. There were 12 children (mean age 6 years [range 3-10], 11 boys) with a history of normal development followed by loss of acquired skills, including language, together with diarrhea and abdominal pain. All 12 underwent gastroenterological, neurological, and developmental assessment, and had a review of developmental records. Each had Ileocolonoscopy and biopsy sampling, magnetic resonance Imaging (MRI), electroencephalography (EEG), and lumbar puncture. The parents associated the onset of behavioral symptoms with the MMR vaccination in eight of the 12 children. All 12 children had intestinal abnormalities, ranging from lymphoid nodular hyperplasia to aphthoid ulceration. Behavioral disorders included autism (nine), disintegrative psychosis (one), and possible postviral or vaccinal encephalitis (two). Although there were no focal neurological abnormalities and MRI and EEG tests were found to be normal, the authors concluded an association of gastrointestinal disease and developmental regression in a group of previously normal children. Therefore, Wakefield's theory of an apparent onset of autism within a few weeks after the administration of the MMR vaccine, may simply be an unrelated chance occurrence or temporal related event.[1]

Criticisms of both the study and its interpretation followed. A different research group from the same institution published epidemiological evidence contradicting this alleged association. In 1999, Taylor et al.,3 undertook an epidemiological study to investigate whether MMR vaccine may be causally associated with autism. This population-based study involved all children with known cases of autism born since 1979 in a district of London. The researchers looked for evidence of a change in the trend of incidence or age at diagnosis associated with the introduction of MMR vaccination to the UK in 1988. Clustering of onsets within defined post vaccination periods was investigated by the case series method. The investigators reported identifying 498 cases of autism (261 of core autism, 166 of atypical autism, and 71 of Asperger's syndrome). In 293 cases, the diagnosis was confirmed by the criteria of the International Classification of Diseases, tenth revision. They reported that there was a steady increase in cases by year of birth with no sudden "step-up" or change in the trend after the introduction of MMR vaccination. There was no difference in age at diagnosis between the cases vaccinated before or after 18 months of age and those never vaccinated. Also, there was no temporal association between onset of autism within 1 or 2 years after vaccination with MMR (relative incidence compared with control period 0.94 [95% CI 0.60-1.47] and 1.09 [0.79-1.52]). Developmental regression was not observed to be clustered in the months after vaccination (relative incidence within 2 months and 4 months after MMR vaccination 0.92 [0.38-2.21], and 1.00 [0.52-1.95]). The authors concluded that the study did not support a causal association between MMR vaccine and autism. On April 3, a report from a subgroup of the British Medical Research Council concluded that, "between March 1998 and September 1999, there had been no new evidence to suggest a causal link between MMR and inflammatory bowel disease/autism."[2]

The British Committee on Safety of Medicines convened a “Working Party on MMR Vaccine” to conduct a systematic review of reports of autism, gastrointestinal disease, and similar disorders of children after being vaccinated with the MMR vaccine. Of the 95 cases of reported autism evaluated, there were 81 confirmed cases, 11 possible cases, and 3 unconfirmed cases of autism/pervasive developmental disorder (PDD). Detailed evaluation of the 92 confirmed or possible confirmed cases, revealed no extraordinary features, which supports a causal association with MMR.[2]

Another study utilizing data from the National Childhood Encephalopathy Study (NCES), examined 770 cases in children who were previously apparently neurologically normal to see if there was any link between the MMR and neurological events. Researchers found no indication that the MMR vaccine contributes to the development of long-term neurologic damage, educational, or behavioral deficits. In addition, it found no evidence of clustering after vaccination, nor, was there a change in the rate of autism in the general population.[10]

In a report from Finland, a large prospective follow up of the MMR vaccination program has concluded that serious adverse events are rare and greatly outweighed by the risks of disease. The study followed 1.8 million individuals for 14 years from the start of the MMR vaccination program in 1982. By the end of 1996, almost three million vaccine doses had been given, and 173 potentially serious reactions were recorded as having possibly been caused by the vaccine. The most common event was febrile seizure. Forty-five percent of these events proved to be probably caused by some other factor, giving an incidence of serious adverse events of 3.2 per 100,000 vaccine doses. No case of inflammatory bowel disease or autism were detected, and experts concluded that if there were an association between either of these conditions and the MMR vaccine, this prospective study design would undoubtedly have disclosed at least some cases.[5]

In a recent report from the UK, the incidence of newly diagnosed autism was reported to have increased seven-fold, from 0.3 per 10,000 person years in 1988 to 2.1 per 10,000 person years in 1999. The peak incidence was reported among 3 and 4 year olds, and 83 percent were boys. The incidence of autism among 2 to 5 year olds increased markedly among boys (nearly fourfold), from 8 per 10,000 in 1988, to 29 per 10,000 in 1993, while MMR vaccine coverage was over 95 percent for successive annual birth cohorts. The investigators conclude that the data from this study provides evidence that no correlation exists between the prevalence of MMR vaccination and the rapid increase in the risk of autism over time.[11]

In another recent retrospective analyses from California, both the MMR immunization coverage rates among children born in 1980-1994, and autism caseloads among children born in these years who were diagnosed with autism, were reviewed. The study found that for the 1980-1994 birth cohorts, a marked, sustained increase in autism case numbers was noted, from 44 cases per 100,000 live births in 1980 cohort to 208 cases per 100,000 live births in 1994 cohort (a 373% relative increase), but changes in early childhood MMR immunization coverage

over the same time period was much smaller and of shorter duration. Immunization coverage by the age of 24 months increased from 72 to 82 percent, a relative increase of only 14 percent, over the same period. The authors conclude that there seems to be no association between MMR immunization among young children and an increase in occurrence of autism.[4]

Both the CDC and American Academy of Pediatrics (AAP) believe that the current scientific evidence does not support the hypothesis that the MMR vaccine, or any combination of vaccines, causes the development of autism.[12,13] The CDC statement is based on research from the British Committee on Safety of Medicines Working Party on MMR Vaccine, research findings from the Taylor, et al., and Gillberg, Heijbel studies, where hundreds of cases of autism were reviewed for any possible relationship. AAP conclusions were based on current epidemiological data. In summary, the CDC and AAP believe the weight of the evidences does not support an association between the MMR vaccine and autism. See Appendix I for a summary of studies.

Safety

There have been extraordinary measures taken to ensure vaccine safety and effectiveness, however, there remains a certain level of fear, confusion, and hesitation among some of the public about their use. Experts believe that the best defense against infectious diseases is a strong immunization program. Most medical experts agree that the risk of having adverse reaction from a vaccine is far less than having serious consequences from an infectious disease (see Appendix II, misconception number 4).[14] The fall 1998 newsletter of *The National Alliance for Autism Research* stated that the MMR vaccine has already saved some children from autism.[15] Currently, the one and only known cause of autism, Congenital Rubella Syndrome (CRS) has been virtually wiped out by MMR vaccinations. Immunization is credited with the decrease in the number of cases, complications, and deaths of Measles, Mumps, and Rubella.

MMR vaccine is effective in up to 95% of persons who have received a single dose of the vaccine at 12 months of age or older. Vaccine failure after the 2nd dose administered after 12 months of age is uncommon. While vaccines may be effective they are not without possible side effects.[16]

In the interest of safety, the CDC requires vaccines to be safer than the disease. Vaccines, by definition, are a suspension of a whole or fractionated, live or inactivated bacteria or virus that has been rendered nonpathogenic and is given to induce a specific immune response. Thus, stimulating immunity in the body and preventing, or in some cases lessening, an infectious disease. No vaccine is entirely safe or completely effective. However, the use of such vaccinations to prevent infectious disease is undisputable and strongly supported by the demonstrated benefit-to-risk ratio.

The MMR vaccine is not without side effects, most are mild, and of short duration. These include: fever (5% to 15%), febrile seizure caused by fever (1 in 3,000 doses), mild rash (5%), swelling of neck or cheek glands (rare), temporary pain and stiffness in joints (postpubertal and adult females, up to 25%), and thrombocytopenia, temporary low platelet count (1 in 30,000 doses). Severe problems occur very rarely, with serious allergic reaction (less than 1 in a million). Other problems occur so rarely that experts cannot determine if they are associated with the vaccine or not.[16,17]

While the U.S. is experiencing record low, or near record low, cases of vaccine preventable diseases, the viruses and bacteria that cause them still exist. Even diseases that have been eliminated in the U.S., such as polio, are still prevalent in other parts of the world and can easily be imported into the U.S. Those who are not vaccinated are at high risk for contracting and transmitting a vaccine preventable disease and experiencing needless morbidity or mortality related consequences.[6,7]

The Food and Drug Administration (FDA) requires extensive testing of vaccines prior to making them available to the public. In addition, the CDC, the FDA, and the NIH monitor and conduct research on vaccines. A number of steps can be taken when the FDA observes a trend having negative consequences. If the consequences are severe, the FDA can suspend the use of the vaccine.[18]

The Vaccine Adverse Event Reporting System (VAERS),[19] established in 1990, receives reports about adverse events associated with vaccines. This system provides database collection and analysis in order to serve as early warning for adverse events not detected during pre-market testing of vaccines. The FDA continually monitors these reports to determine whether any vaccine or vaccine lot has a higher than expected rate of event.[20] The CDC tracks any unusual epidemiological trends. Health care providers, vaccine manufacturers, and vaccine recipients or their parents/guardians are those most commonly reporting. For a VAERS reporting form or assistance in filling one out, call VAERS at 1-800-822-7967 or visit the VAERS web site at http://www.cdc.gov/cber/vaers/vaers.htm

In 1995, out of the 13 million childhood vaccinations given, only 10,595 adverse events were reported to the VAERS. The adverse events occurring, while unpleasant or frightening, do not give a true picture of events that permanently harm a child's life.[15] In contrast, if no measles vaccine were used, 1 out of every 15 individuals stricken by measles would develop ear problems, bronchitis, pneumonia, and seizures; 1 in 5,000 would develop encephalitis. One to three deaths would occur in every 1,000.[16,17]

The CDC has written a fact sheet for persons who have reservations about receiving vaccinations for themselves or their children. The fact sheet titled, *Six most common misconceptions about immunization,*[14] can be found in Appendix II.

Measles, mumps, rubella, and autism

Measles, mumps, and rubella are all serious diseases, which spread rapidly, especially in populations that are not immune.(Appendix III) Measles is a highly contagious, acute viral infectious disease. Thirty percent of measle cases have one or more complications. More than 90 percent of people not immune will get the measles if they are exposed to the virus. According to the World Health Organization, in 1998, nearly 900,000 deaths from measles occurred among persons in developing countries. In recent years, death from measles in the U.S. occurs in 1-3 per 1000 cases.[16,17] Before measles vaccinations were available, nearly everyone in the U.S. contracted the disease. In the U.S., widespread use of the measle vaccine has led to a greater than 99 percent reduction in prevalence compared with the pre-vaccine era.[16,17] The CDC has stated that if immunization stopped, measles would increase to pre-vaccine levels.[8]

Mumps is an acute viral disease. Before the vaccine was introduced, mumps was a major cause of deafness in children. Rare complications, such as encephalitis or meningitis, can lead to serious side effects such as paralysis, seizures, and fluid on the brain. For women who developed mumps during the first trimester of pregnancy, there is an increase in spontaneous abortions. An estimated 212,000 cases of mumps occurred in the U.S. in 1964. After the licensure of a vaccine in 1967, reports of mumps decreased rapidly. In 1999, the incidence of mumps had declined to 352 reported cases per year. This decline is believed to be the result of administering a second dose of the vaccine and the development of immunity in those who did not gain protection from the first vaccination.[16,17] The CDC has stated that if vaccination were to stop, the number of mumps cases would return to the pre-vaccine levels.[8]

Symptoms of rubella are often mild and while complications are uncommon, they tend to occur more often in adults than in children. Prevention of Congenital Rubella Syndrome (CRS) is the main objective of rubella vaccinations. Women who contract rubella while pregnant risk miscarriage, fetal death, or in the fetus developing serious birth defects. Up to 85 percent of infants born to women infected with rubella during the first trimester of pregnancy will develop CRS, which results in heart defects, cataracts, mental retardation, deafness, and liver and spleen damage.[16,17] Prior to the 1969 U.S. licensure of a vaccine, there was an epidemic of rubella. The 1964 epidemic resulted in an estimated 20,000 infants born with CRS. Of these infants, 11,600 were deaf, 3,580 were blind, and 1,800 were mentally retarded. Sites of exposure for several outbreaks have included work places and communities. The CDC warns that if the rubella immunization stopped, immunity to rubella would decline, resulting in an increase of pregnant women becoming infected and giving birth to infants with CRS.[8] The incidence of rubella and CRS has declined dramatically since wide spread use of the vaccine. However, many developing countries do not include rubella in the childhood immunization schedule.[16,17]

Autism is a serious, life-long, complex developmental disorder that is behaviorally defined. Behavioral characteristics include qualitative deficits in social interaction, communication, restrictive, repetitive, and stereotyped patterns of behaviors, activities, and interest, and body movement difficulties. [13,21-25] Symptoms of autism generally begin to appear between the ages of 1½ to 3 years. The affected children may then start to fall behind in social skills, communication, and cognition. A variety of factors can be associated with some forms of autism, including infections, metabolic abnormalities, and environmental exposures.[22] Some research has shown autism to be a neurobiological difference in the brain prior to birth. Further evidence indicates that autism is highly genetic and geneticists believe that autism is a “multifactorial, polygenic” disorder.[15] A National Institutes of Health (NIH) study has identified two genes, HOXA1 and HOXB1, as playing a critical role in early brain development.[26] The study suggests that these genes control early brain development and may be the underlying factors in a large number of autism cases. Diagnosis of autism is difficult because of its multifarious characteristics. There is no diagnostic test and observation of behavior to identify all the disabilities often requires crossing disciplinary boundaries in order to rule out or confirm given symptoms.[13,25] There is no cure for autism, nor, is there any established treatments. [23,24]

An estimated 400,000 - 500,000 individuals in the U.S. have autism. Early statistics (1966-1988) estimated autism occurring in 4.3 per 10,000 births. However, current (1989-1998) estimates place the prevalence rate at an estimated 7.2 per 10,000 children.[13,22] The increase in the autism rate has been attributed to the changes in definitions, improved recognition of autism, and children being diagnosed at an earlier age. Autism is one of the fastest growing disabilities in Minnesota. The incidence of autism has increased an average of 32 percent a year in each of the last nine years.[27] Autism is three times more likely to affect males than females.[23]

Vaccines

Prior to widespread vaccination, infectious diseases were extremely prevalent and brought devastating levels of permanent injury and death to countless individuals in the U.S. In the late 1700s and during the 1800s, substantial

achievements were made in the development of immunobiologic agents. In 1798, the first vaccine was developed for smallpox. The development of the smallpox vaccine was followed by a great number of other vaccines such as: rabies, 1885; typhoid and cholera, 1896; plague, 1897; diphtheria, 1923; tetanus, 1927; influenza, 1945; measles, 1963; mumps, 1967; and in 1969, rubella.[28]

Dramatic declines in morbidity and mortality have been reported for vaccine preventable diseases. Morbidity associated with tetanus, measles, mumps, rubella, and haemophilus influenza type b, has declined by nearly 100 percent while morbidity associated with smallpox and polio (caused by wild type virus) has declined 100 percent. In the U.S., from 1900 to 1904, an average of 48,164 reported cases and 1,528 deaths per year were caused by smallpox. However, by 1977, smallpox had been eradicated and the administration of the vaccine was no longer necessary. Smallpox is the only disease to have been eradicated to date.[28]

While the U.S. is experiencing record low, or near record low, cases of vaccine preventable diseases, the viruses and bacteria that cause them still exist. Even diseases that have been eliminated in the U.S., such as polio, are still prevalent in other parts of the world and can easily be transported into the U.S. Therefore, vaccine preventable diseases are only controlled by the use of recommended vaccines. Unfortunately, those who are not vaccinated are at high risk for contracting and transmitting a vaccine preventable disease and experiencing needless morbidity or mortality related consequences.[6,7]

Cost

Vaccinations are covered under most basic health plans. In addition, federal, state, and local communities have special programs that provide access to low-cost or free vaccinations. The Minnesota Department of Health's Immunization Information Consumer Information Line for Minnesota Residents is 612-676-5100 or 1-800-657-3970. Contact your state health department, or the CDC at 1-800-232-2522.

Conclusion

There is no scientific evidence that supports the hypothesis that the MMR vaccine, or any combination of vaccines causes the development of autism. Both the CDC and the British Committee on Safety of Medicines found no association between the MMR vaccine and autism.

Appendix I: Summary of Studies

Study	Type	Number Pt.	Vaccine/Disease	Findings
Dales, et al.[4] 2001	Retrospective analysis of immunization coverage rates among children in Californian.	Samples of 600-1900 children each year from 1980 to 1994. The samples were from Kindergarten immunization records.	MMR autism	Essentially no correlation between secular trend of childhood MMR immunization rates in California and the secular trend in numbers of children with autism enrolled in California. For the 1980-1994 birth cohorts sustained increase in autism case numbers was noted from 44 cases per 100,000 live births in the 1980 cohort to 208 cases per 100,000 live births in the 1994 cohort. Coverage in early childhood MMR immunization coverage over the same time period were smaller and of shorter duration. Immunization coverage by the age of 24 months increased from 72% to 82%, a relative increase of 14%.
Peltola, et al.[5] 1998	Prospective follow up of Measles, Mumps, and Rubella vaccination program in Finland.	1.8 million individuals were followed for 14 years from the start of the vaccination program in 1982 to 1996.	MMR Autism Inflammatory bowel disease.	3 million vaccine doses have been given and 173 potentially serious reactions have been recorded as possibility having been caused by the vaccine. The most common event was febrile seizure. 45% of the events proved to probably have been caused by

				some other factor. No case of inflammatory bowel disease or autism was detected. The authors felt that if there was an association between MMR and autism there would have been at least some cases.
Committee on Safety of Medicines.[2] 2000 Report of the working party on MMR vaccine.	Retrospective analysis of completed parent and Physician questionnaires.	126 reports of autism evaluated as follows: 55 with autism alone, 52 with autism and gastrointestinal disease, and 19 with Crohn's disease alone. 15 reports of autism with gastrointestinal disorder and 3 Crohn's disease only were excluded.	MMR • Autism alone. • Pervasive developmental disorder (PDD). • Autism with gastrointestinal disease. • Crohn's disease.	Of the 95 cases of reported autism, diagnosis was confirmed in 81, possibly in 11 but not confirmed in 3. Of the 92 reports considered confirmed or possible cases included 78 (85%) males and 14 (15%) females. All but one of the 92 children had received MMR vaccine, one having received monocomponent measles vaccine. Detailed evaluation of the 92 cases revealed no extraordinary features, which suggested a novel syndrome. The Working group reported finding no evidence to suggest or support that administration of MMR vaccine was associated with autism/ pervasive developmental disorder or inflammatory bowel disease.
Taylor, et al.[3] 1999	Epidemiological study.	498	MMR Autism	The number of autism cases did not change after the introduction of MMR vaccine. The age diagnosis of autism was not influenced by the vaccination date or status of the study patients, nor was there an increase in new cases in the months immediately following vaccination. Results do not support the hypothesis that MMR vaccination is causally related to autism.
Wakefield, et al.[1] 1998	Cases Investigation of children with chronic enterocolitis and regressive developmental disorder.	12	MMR Crohn's disease.	All 12 children had intestinal abnormalities and 8 had behavioral symptoms, which parents associated to the MMR. The authors concluded that they identified chronic enterocolitis in children and that may be related to neuropsychiatric dysfunction. In most cases, the onset of symptoms was after the MMR vaccination.
Miller, et al.[10] 1997	Matched Case-Control study on Measles vaccination and neurological events.	770 cases of children who were apparently normal.	Measles vaccine. Various acute encephalopathic illness and severe convulsions.	16 of the 770 had received measles vaccine within 7-14 days before onset of their illness. Two matched controls for every case recruited and 18 of these had received measles vaccine within the same period before a comparable reference date. When children with febrile

				convulsions were excluded there were only six cases and 10 controls immunized during the same period. The findings showed no significant association between measles vaccination and the onset of acute neurological events in previously healthy children.
Kaye et al.[11] 2001	Time trend analysis of data from general practice database (UK).	Annual and age specific incidence for first recorded diagnoses of autism in children aged 12 or younger; annual, birth specific risk of autism diagnosed in the 2 to 5 year old boys; coverage (prevalence) of MMR vaccination in the same birth cohorts.	MMR Autism	Incidence of newly diagnosed autism increased sevenfold, from 0.3 per 10,000 person years in 1988 to 2.1 per 10,000 person years in 1999. There was a marked increase in the incidence of autism among boys born in each year separately from 1988 to 1993 while MMR vaccine coverage was over 95% for successive annual birth cohorts. The data provides evidence that no correlation exists between the prevalence of MMR vaccination and the rapid increase in the risk of autism over time.

Appendix II: Six Common Misconceptions about Immunization[14]

This list of six common misconceptions was originally written by the Centers for Disease Control in the United States primarily for use by practitioners giving vaccinations to children in their practices. But we in WHO think an edited version is useful for all staff giving vaccinations as well as concerned parents.

In this modern age of communication, we will encounter patients who have reservations about getting vaccinations for themselves or their children. There can be many reasons for fear of or opposition to vaccination. Some people have religious or philosophic objections. Some see mandatory vaccination, as interference by the government into what they believe should be a personal choice. Others are concerned about the safety or efficacy of vaccines, or may believe that vaccine-preventable diseases do not pose a serious health risk.

All health workers giving vaccines have a responsibility to listen to and try to understand a patient's concerns, fears, and beliefs about vaccination and to consider them when offering vaccines. These efforts will not only help to strengthen the bond of trust between staff and the patient but will also help determine which, if any, arguments might be most effective in persuading these patients to accept vaccination.

These pages address six common misconceptions about vaccination that are often cited by concerned parents as reasons to question the wisdom of vaccinating their children. If staff can respond with accurate rebuttals perhaps, we can not only ease their minds on these specific issues but also discourage them from accepting other anti-vaccine "facts" at face value. Our goal is not to browbeat parents into vaccinating, but to make sure they have accurate information with which to make an informed decision.

- **Misconception 1**
  "Diseases had already begun to disappear before vaccines were introduced, because of better hygiene and sanitation."
- **Misconception 2**
  "*The majority of people who get disease have been vaccinated."*
- **Misconception 3**
  "There are "hot lots" of vaccine that have been associated with more adverse events and deaths than others. Parents should find the numbers of these lots and not allow their children to receive vaccines from them."
- **Misconception 4**
  "Vaccines cause many harmful side effects, illnesses, and even death – not to mention possible long-term effects we don't even know about."
- **Misconception 5**
  Vaccine-preventables dieseases have been virtually eliminated from my country so there is no need for my child to be vaccinated."

- **Misconception 6**
  "Giving a child multiple vaccinations for different diseases at the same time increases the risk of harmful side effects and can overload the immune system."

Misconception 1

"Diseases had already begun to disappear before vaccines were introduced, because of better hygiene and sanitation."

Statements like this are very common in anti-vaccine literature, the intent apparently being to suggest that vaccines are not needed. Improved socio-economic conditions have undoubtedly had an indirect impact on disease. Better nutrition, not to mention the development of antibiotics and other treatments, have increased survival rates among the sick; less crowded living conditions have reduced disease transmission; and lower birth rates have decreased the number of susceptible household contacts. But looking at the actual incidence of disease over the years can leave little doubt of the significant direct impact vaccines have had, even in modern times.

There were periodic peaks and valleys throughout the years, but the real, permanent drop coincided with the licensure and wide use of measles vaccine beginning in 1963. Graphs for other vaccine-preventable diseases show a roughly similar pattern, with all except hepatitis B showing a significant drop in cases corresponding with the advent of vaccine use. Are we expected to believe that better sanitation caused incidence of each disease to drop, just at the time a vaccine for that disease was introduced?

Hib vaccine is another good example, because Hib disease was prevalent until just a few years ago, when conjugate vaccines that can be used for infants were finally developed. (The polysaccharide vaccine previously available could not be used for infants, in whom most of cases of the disease were occurring.) Since sanitation is not better now than it was in 1990, it is hard to attribute the virtual disappearance of Hib disease in children in recent years (from an estimated 20,000 cases a year to 1,419 cases in 1993, and dropping) to anything other than the vaccine.

Finally, we can look at the experiences of several developed countries after they let their immunization levels drop. Three countries - Great Britain, Sweden, and Japan cut back the use of the pertussis (whooping cough) vaccine because of fear about the vaccine. The effect was dramatic and immediate. In Great Britain, a drop in pertussis vaccination in 1974 was followed by an epidemic of more than 100,000 cases of pertussis and 36 deaths by 1978. In Japan, around the same time, a drop in vaccination rates from 70% to 20%-40% led to a jump in pertussis from 393 cases and no deaths in 1974 to 13,000 cases and 41 deaths in 1979. In Sweden, the annual incidence rate of pertussis per 100,000 children 0-6 years of age increased from 700 cases in 1981 to 3,200 in 1985. It seems clear from these experiences that not only would diseases not be disappearing without vaccines, but if we were to stop vaccinating, they would come back.

Of more immediate interest is the major epidemic of diphtheria now occurring in the former Soviet Union, where low primary immunization rates for children and the lack of booster vaccinations for adults have resulted in an increase from 839 cases in 1989 to nearly 50,000 cases and 1,700 deaths in 1994. There have already been at least 20 imported cases in Europe and two cases in U.S. citizens working in the former Soviet Union.

Misconception 2

"The majority of people who get disease have been vaccinated."

This is another argument frequently found in anti-vaccine literature - the implication being that this proves vaccines are not effective. In fact, it is true that in an outbreak those who have been vaccinated often outnumber those who have not - even with vaccines such as measles, which we know to be about 98% effective when used as recommended.

This apparent paradox is explained by two factors. First, no vaccine is 100% effective. To make vaccines safer than the disease, the bacteria or virus is killed or weakened (attenuated). For reasons related to the individual, not all vaccinated persons develop immunity. Most routine childhood vaccines are effective for 85% to 95% of recipients. Second, in a country such as the United States the people who have been vaccinated vastly outnumber those who have not. How these two factors work together to result in outbreaks in which the majority of cases have been vaccinated can be more easily understood by looking at a hypothetical example:

In a high school of 1, 000 students, none has ever had measles. All but 5 of the students have had two doses of measles vaccine, and so are fully immunized. The entire student body is exposed to measles, and every susceptible student becomes infected. The 5 students not vaccinated will be infected, of course. But of the 995 who have been vaccinated, we would expect several not to respond to the vaccine. The efficacy rate for two doses of measles vaccine can be as high as >99%. In this class, 7 students do not respond, and they, too, become infected. Therefore, 7 of 12, or about 58%, of the cases occur in students who have been fully vaccinated.

As you can see, this doesn't prove the vaccine didn't work - only that most of the children in the class had been vaccinated, so those who were vaccinated and did not respond outnumbered those who had not been vaccinated.

Looking at it another way, 100% of the children who had not been vaccinated got measles, compared with less than 1 % of those who had been vaccinated. Measles vaccine protected most of the class; if nobody in the class had been vaccinated, there would probably have been 1,000 cases of measles.

Misconception 3

"There are "hot lots" of vaccine that have been associated with more adverse events and deaths than others. Parents should find the numbers of these lots and not allow their children to receive vaccines from them."

This misconception often receives considerable publicity. First, the concept of a "hot lot" of vaccine as it is used in this context is wrong. It is based on the presumption that the more reports of adverse events a vaccine lot is associated with, the more dangerous the vaccine in that lot; and that by consulting a list of the number of reports per lot, a parent can identify vaccine lots to avoid.

This is misleading for two reasons:

1. Most surveillance systems report events that are temporally associated with receipt of vaccine; these reports should not be interpreted to imply causality. In other words, an adverse report following vaccination does not mean that the vaccine caused the event. Statistically, a certain number of serious illnesses, even deaths, can be expected to occur by chance alone among children recently vaccinated. Although vaccines are known to cause minor, temporary side effects such as soreness or fever, there is little, if any, evidence linking vaccination with permanent health problems or death. The point is that just because an adverse event has been reported by the surveillance system does not mean a vaccine caused it.
2. Vaccine lots are not the same. The sizes of vaccine lots might vary from several hundred thousand doses to several million, and some are in distribution much longer than others. Naturally, a larger lot or one that is in distribution longer will be associated with more adverse events, simply by chance. Also, deaths that are more coincidental are associated with vaccines given in infancy than later in childhood, since the background death rates for children are highest during the first year of life. So knowing that lot A has been associated with x number of adverse events while lot B has been associated with y number would not necessarily say anything about the relative safety of the two lots, even if the vaccine did cause the events.

Reviewing published lists of "hot lots" will not help parents identify the best or worst vaccines for their children. If the number and type of adverse event reports for a particular vaccine lot suggested that it was associated with more serious adverse events or deaths than are expected by chance, most countries have a system which results in the lot being recalled.

All vaccines purchased through the UNICEF vaccine procurement system meet World Health Organization standards for safety and quality of production.

Misconception 4

'Vaccines cause many harmful side effects, illnesses, and even death - not to mention possible long-term effects we don't even know about."

Vaccines are actually very safe, despite implications to the contrary in many anti-vaccine publications. Most vaccine adverse events are minor and temporary, such as a sore arm or mild fever. Paracetamol taken after vaccination can often help control these reactions. Rarely do more serious adverse events occur (on the order of one per thousands to one per millions of doses), and some are so rare that risk cannot be accurately assessed. As for vaccines causing death, again so few deaths can plausibly be attributed to vaccines that it is hard to assess the risk statistically. Each death reported to ministries of health is generally thoroughly examined to determine whether it is really related to administration of vaccine, and if so, exactly what is the cause. When, after careful investigation, an event is felt to be a genuine vaccine-related event, it is most frequently found to be a program error, not related to vaccine manufacturer.

DTP Vaccine and SIDS
One myth that won't seem to go away is that DTP vaccine causes sudden infant death syndrome (SIDS). This belief came about because a moderate proportion of children who die of SIDS have recently been vaccinated with DTP; and on the surface, this seems to point toward a causal connection. But this logic is faulty; you might as well say that eating bread causes car crashes, since most drivers who crash their cars could probably be shown to have eaten bread within the past 24 hours.

If you consider that most SIDS deaths occur during the age range when 3 shots of DTP are given, you would expect IDTP shots to precede a fair number of SIDS deaths simply by chance. In fact, when a number of well-controlled studies were conducted during the 1980's, the investigators found, nearly unanimously, that the number of SIDS deaths temporally associated with IDTP vaccination was within the range expected to occur by chance. In other words, the SIDS deaths would have occurred even if no vaccinations had been given. In fact, in several of the studies children who had recently gotten an IDTP shot were less likely to get SIDS. The Institute of Medicine reported that "all controlled studies that have compared immunized versus non-immunized children have found either no association ... or a decreased risk of SIDS among immunized children" and concluded that "the evidence

does not indicate a causal relation between [DTP] vaccine and SIDS."

Comparing the risk from disease with the risk from the vaccines

DISEASE	VACCINES
MEASLES: Pneumonia: 1 in 20 Encephalitis: 1 in 2,000 Death: 1 in 3,000 industrialized countries and as many as 1 in 5 for outbreaks in developing countries.	**MMR:** Encephalitis or severe allergic reaction: 1 in 1,000,000
MUMPS: Encephalitis: 1 in 300	
RUBELLA: Congenital Rubella Syndrome: 1 in 4 (if woman becomes infected early in pregnancy)	
DIPHTHERIA: Death: 1 in 20	**DTP:** Continuous crying, then full recovery: 1 in 100
TETANUS: Death: 3 in 100	Convulsions or shock, then full recovery: 1 in 1,750
PERTUSSIS: **Pneumonia: 1 in 8** **Encephalitis: 1 in 20** **Death: 1 in 200**	Acute encephalopath: 0-10.5 in 1,000,000 Death: None proven

The fact is that a child is far more likely to be seriously injured by one of these diseases than by any vaccine. While any serious injury or death caused by vaccines is too many, it is also clear that the benefits of vaccination greatly outweigh the slight risk, and that many, many more injuries and deaths would occur without vaccinations. In fact, to have a medical intervention as effective as vaccination in preventing disease and not use it would be unconscionable.

Misconception 5

"Vaccine-preventable diseases have been virtually eliminated from my country, so there is no need for my child to be vaccinated."

It's true that vaccination has enabled us to reduce most vaccine-preventable diseases to very low levels in many countries. However, some of them are still quite prevalent, even epidemic, in other parts of the world. Travelers can unknowingly bring these diseases into your country, and if you and your family were not protected by vaccinations, these diseases could quickly spread throughout the population, causing epidemics here. At the same time, the cases you currently have could very quickly become tens or hundreds of thousands of cases without the protection you get from vaccines.

We should still be vaccinated, then, for two reasons. The first is to protect our selves. Even if we think our chances of getting any of these diseases are small, the diseases still exist and can still infect anyone who is not protected. A few years ago, a child who had just entered school caught diphtheria and died. He was the only pupil not vaccinated in his class.

The second reason to get vaccinated is to protect those around us. There are a small number of people who cannot be vaccinated (because of severe allergies to vaccine components, for example), and a small percentage of people don't respond to vaccines. These people are susceptible to disease, and their only hope of protection is that people around them are immune and cannot pass disease along to them. A successful vaccination program, like a successful society, depends on the cooperation of every individual to ensure the good of all. We would think it irresponsible of a driver to ignore all traffic regulations on the presumption that other drivers will watch out for him or her. In the same way, we shouldn't rely on people around us to stop the spread of disease; we, too, must do what we can.

Misconception 6

"Giving a child multiple vaccinations for different diseases at the same time increases the risk of harmful side effects and can overload the immune system."

Children are exposed to many foreign antigens every day. Eating food introduces new bacteria into the body, and numerous bacteria live in the mouth and nose, exposing the immune system to still more antigens. An upper respiratory viral infection exposes a child to 4-10 antigens, and a case of "strep throat" to 25-50. According to Adverse Events Associated with Childhood Vaccines, a 1994 report from the Institute of Medicine, United States,

"In the face of these normal events, it seems unlikely that the number of separate antigens contained in childhood vaccines would represent an appreciable added burden on the immune system that would be immuno-suppressive." And, indeed, available scientific data show that simultaneous vaccination with multiple vaccines has no adverse effect on the normal childhood immune system.

A number of studies have been conducted to examine the effects of giving various combinations of vaccines simultaneously. These studies have shown that the recommended vaccines are as effective in combination as they are individually, and that such combinations carry no greater risk for adverse side effects. Research is under way to find ways to combine more antigens in a single vaccine injection (for example, MMR and chickenpox). This will provide all the advantages of the individual vaccines, but will require fewer shots.

There are two practical factors in favor of giving a child several vaccinations during the same visit. First, we want to immunize children as early as possible to give them protection during the vulnerable early months of their lives. This generally means giving inactivated vaccines beginning at 2 months and live vaccines at 12 months. The various vaccine doses thus tend to fall due at the same time. Second, giving several vaccinations at the same time will mean fewer office visits for vaccinations; this saves parents both time and money and may be less traumatic for the child.

Appendix III: Measles, Mumps, and Rubella Epidemiology[16,17]

	Causative Agent	Incubation Period	Mode of Transmission	Complications	Period of Communicability	Signs and Symptoms
Measles	Highly contagious virus that is a member of the Paramyvirus family, genus morbillivirus, and is closely related to the rinderpest and canine distemper virus.	8-12 days from exposure to onset of symptoms.	Spread airborne or by direct contact with small droplets from nose, throat, and mouth of a person in prodromal or early eruptive stage of disease.	Complications occur in 30% of cases. 1-3 deaths per 1000 cases. Permanent brain damage occurs in 1 per 1000 cases. Can lead to pneumonia, encephalitis, brain damage, ear infection, and seizures.	From 2-4 days before rash appears until 2-5 days after onset.	Symptoms begin with prodromal fever, coryza, cough, and conjunctivitis. Kopliks spots generally appear 2-4 days later. The characteristic rash begins 3-5 days later in front of and below the ears and on the side of the neck, as irregular macules that soon become maculopapular cutaneous rash, which spreads rapidly (within 24-48 hours) to the trunk. After 3-5 days, fever diminishes and the rash fades to a coppery-brown discoloration followed by desquamation.
Mumps	A moderately contagious virus that is a member of the paramyxovirus family.	12-25 days after exposure.	Spread by infected droplets or direct contact with material contaminated with infected saliva.	Parotitis occurs in 30% to 40% of cases. 1-3 deaths per 10,000 cases. Hearing loss in 1 per 20,000 cases. Orchitis (in post puberty males) 20-50% of cases. CNS; meningitis 15% of cases, encephalitis 2 per	From 1-6 days before the salivary glands swell.	Up to 20% of mumps infections are asymptomatic. However, typically mumps begins with chills, headache, anorexia, malaise, and fever, which last for approximately 12-24 hours before the salivary gland involvement is noted. Serious side effects are more common

				100,000.		in adults than children.
Rubella	A contagious virus classified as a toga virus that is closely related to group A arboviruses (such as Eastern and Western Equine Encephalitis).	12-23 days	Spread by airborne droplets or close contact with an infected individual.	Arthritis/Arthralgia occurs in up to 70% of adult women. Encephalitis occurs 1 per 5000 cases. Hemorrhagic manifestations occur 1 per 3000 cases. Up to 85% of infants infected in the first trimester of pregnancy will develop CRS.	From 1 week before onset of rash to 1 week after rash fades. Typically persons are “most” contagious when the rash is first erupting.	Symptoms are often mild. 30-50% of all cases may be subclinical or inapparent. Typically rubella begins with malaise, fever, headache, rhinitispostauricular and suboccipital lymphadeno-pathy with tender nodes. 1-2 days later a fine (pinpoint), pinkish macular rash begins to appear on the face and neck, spreading to the trunk and limbs. The rash lasts for approximately 1-3 days.

Appendix IV: Public Comment

The following statement was submitted to HTAC during the public comment period on this assessment. The workgroup and full Committee reviewed each statement and incorporated them into the report as the Committee deemed appropriate.

From: Harry Hull

To: Anil Kaul

Date: 05/30/01 10:19 AM

Subject: Re: MMR/Autism Report

Anil: Thanks for the opportunity to review this report. Overall, it is an excellent report, comprehensively reviewing the literature and agreeing with the scientific consensus that there is no link between autism and MMR vaccine. I thought that the section on misconceptions about immunization was also excellent and would help practitioners and parents to better understand some of the concerns that have been raised about immunization.

I would also note that the table on page 4 contains 2 errors. Mumps does not cause 1-3 deaths per 1000 cases. Mumps death is rare. Encephalitis occurs at a rate of 1-2 cases per 10,000. I am also not clear what complications occur in 50-60% of cases. I suggest that you redo this section.

In the same table under complications of rubella, I am unclear what is unusual and what occurs in up to 70% of adult women. Again, I suggest that you rewrite this part of the table.

You also might specifically mention encephalitis and pneumonia as complications of measles.

Best regards.

Harry Hull

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