# Medicine: Vaccination, Medicolegal Aspects

## Introduction

Vaccination is the administration of antigenic material (a vaccine) to produce immunity to a disease. Vaccination (from the Latin word *vacca* for cow) is traditionally thought to have been started by the British physician Edward Jenner (1749–1823), who observed that milkmaids never suffered from smallpox, and theorized that the pus in the blisters which milkmaids received from cowpox (a disease similar to smallpox, but much less virulent) must be protecting them from smallpox somehow. On May 14, 1796, he tested his hypothesis by inoculating James Phipps, the 8-year-old son of his gardener with material from the cowpox blisters of the hand of Sarah Nelmes, a milkmaid who had caught cowpox. Injection of variolous material later did not produce smallpox. However, there is documentary evidence of the inoculation of serous fluid by nomadic herders in Africa much earlier (sixteenth century) to protect their cattle against sheep pox, and it has even been asserted that human variolation was attempted in China or India even before then [1].

## Medicolegal Aspects

### *Vaccination and Religion*

There are religious arguments against vaccinations. One is that vaccines are made with foreign proteins (viruses and bacteria), which are potentially toxic. Injection of toxic chemicals and foreign proteins into the bloodstream is a violation of God's directive to keep the body (considered as temple) holy and free from impurities. Furthermore, many vaccines are produced in animal tissues. God warns not to mix the blood of man with that of animals. Finally since many vaccines are produced in aborted fetal tissue, by getting vaccinated, one supports the practice of abortion. These religious arguments have been advanced as an excuse against compulsory vaccination, compelling many legislatures to introduce exemption clauses in their compulsory vaccination statutes.

### *Compulsory Vaccination*

But there have been other arguments against compulsory vaccination. The so-called antivaccination lobby asserts that forcible immunization not only robs them of their natural immunity but also deprives them of fundamental and religious rights, which allow them to lead their life their own way. Contrary to this is the medical and state view that compulsory vaccination to all provides what has been called the "herd immunity", and it would ensure better health for all citizens [2–6]. As time passed, more and more objections have been advanced by antivaccinationists. The most common – unfortunately backed up by some spurious and now discredited research – is that the vaccines cause illnesses such as autism, attention disorders, and immune dysfunction [7].

One of the earliest cases regarding compulsory vaccination is *Jacobson v. Massachusetts, 197 U.S. 11 (1905)*. In 1901, a smallpox epidemic swept through the Northeast United States. In Cambridge, Massachusetts, the city government sought to subdue the epidemic by requiring all adults to receive smallpox inoculations. Failure to do so would result in a $5 fine. In 1902, Henning Jacobson refused to be vaccinated and to pay the fine. He argued that the vaccine law violated both the Massachusetts and US constitutions; that the treatment could not be imposed upon healthy citizens simply because they have the potential to contract the disease. The state courts, including the Massachusetts Supreme Judicial Court, rejected his claims. Jacobson appealed to the US Supreme Court. Outcome of this decision was vital; only eleven states had compulsory vaccine laws at this time. The decision could annul those laws down or, conversely, clear the way for dozens of other states to adopt similar laws. Writing for the 7–2 majority, Justice Harlan rejected Jacobson's arguments. He grounded the opinion in social contract theory (an implicit contract between the State and the individual, whereby the individual surrenders some liberties to State in return for protection) and state police power. He added that the "government is instituted for the common good, for the protection, safety, prosperity, and happiness of the people, and not for the profit, honor or private interests of any one man." The Court recognized a sphere of protected individual liberties, but insisted that the state had broad powers to encroach on that sphere when "the safety of the general public may demand".

Paradoxically, the decision only served to strengthen the antivaccination movement. Three years after the decision, the Anti-Vaccination League of America was founded in Philadelphia. A similar case came up 17 years after *Jacobson*. In *Zucht v. King 260 U.S. 174 (1922)*, the question was whether states may bar school enrollment for children who have not offered proof of immunization. Like many cities, San Antonio, Texas, had an ordinance requiring all students to present a certificate of vaccination before they could enroll in school. Texas student Rosalyn Zucht refused to be vaccinated; the city barred her from attending school, and she sued. Virtually on the same reasoning, as advanced in *Jacobson*, the Court rejected Zucht's claims. It was only after this decision that the antivaccination movements gradually declined.

The recent rise of antivaccinationist movements once again (as evidenced by several vaccine safety controversies) can be attributed to two factors; first the decline of deadly diseases to such a low level that safety factors of vaccinations and other minor grounds (e.g., religious and philosophical) rose into prominence (vaccinations thus becoming a victim of their own success!), and second, parents were eager to find a culprit for the spate of idiopathic illnesses such as autism that were cropping up in their children. In *Hanzel v. Arter, 625 F. Supp. 1259 (S.D. Ohio 1985)*, Stanley Hanzel, Jr. and Tisha Hanzel, the children of Plaintiffs Stanley and Sandy Hanzel, who were studying at the New Lebanon public schools, refused immunization on the basis of their belief in "chiropractic ethics", a body of thought which teaches that injection of foreign substances into the body is of no benefit and can only be harmful. Dr. Milton Arter, superintendent of the New Lebanon Board of Education, thought that their belief in chiropractic ethics did not constitute "good cause" for an exemption for the children under Ohio Rev.Code § 3313.671(A)(3), and that their children would have to be immunized in order that they be allowed to remain in the New Lebanon public schools. Ohio Rev.Code § 3313.671(A)(3), read:

> A pupil who presents a written statement of his parent or guardian in which the parent or guardian objects to the immunization for good cause, including religious convictions, is not required to be immunized.

Hanzels sued Arter claiming that their belief in chiropractic ethics was indeed a "good cause". Furthermore they alleged that mandatory immunization violated the constitutional right to privacy. The court ordered in favor of Arter, taking virtually the same reasoning that was taken 80 years back in *Jacobson*.

### *Vaccine Safety Controversies*

**Pertussis Vaccine and Brain Damage.** The interrelationship between pertussis vaccine and brain damage has a long history. Whole-cell pertussis vaccine was first used on a large scale by Madsen, during a 1925 epidemic in the Faroe Islands (whole-cell pertussis vaccine is the traditional "old" vaccine made by whole bacterial cell and its toxins). In 1933, he reported two cases of permanent brain injury in children, which could possibly be due to pertussis vaccine [8]. Both infants had received initial subcutaneous injections within 8 days of birth, leading Madsen to recommend against vaccination of infants under 1 month. Both infants exhibited cyanosis prior to death; one infant experienced convulsions. In 1948, Byers and Moll presented a watershed case series of adverse reactions to pertussis vaccine [9]. This report was crucial to practitioner recognition of the possibility that adverse risks could be associated with pertussis vaccination. Mainly to address the fears of the general public, acellular pertussis vaccine is being produced now. This is the so-called DTaP vaccine (**D**iptheria, **T**etanus, **a**cellular **P**ertussis vaccine).

The leading case relating to pertussis vaccine is a class action suit *Loveday v Renton and the Wellcome Foundation [1990] 1 Med LR 117* (commonly known as the pertussis vaccine litigation), in which about 200 brain-damaged children, the damage supposedly a result of diphtheria, pertussis, and tetanus (DPT) vaccine, sought compensation from manufacturers, doctors, and health authorities who employed them. The case was heard in the High Court of Justice in London, from early October 1987 until late February 1988. After a 61-day-hearing, High Court judgment was given to the effect that the judge was not satisfied on balance of probability that pertussis vaccine can cause permanent brain damage in young children.

**Vaccines, Asthma, and Allergy.** Vaccines have been implicated as a cause of the rising incidence of asthma and allergic disorders in developing countries [10]. Some studies have suggested that vaccines increase the risk of atopy. Atopy is an allergic

hypersensitivity affecting parts of the body not in direct contact with the allergen. Typical examples are topic eczema or atopic dermatitis. There have been some concerns among parents that vaccines – by disturbing immune mechanisms – may be responsible for atopy. These are only "beliefs" and no scientific studies support this. Scientific studies suggest that there is "no link" between vaccinations and atopy [11, 12].

Vaccines that have been implicated in the development of asthma and allergy are diphtheria, tetanus, whole-cell pertussis, oral polio, MMR (measles, mumps, and rubella), and the influenza vaccines. However, no such association has been scientifically proven.

**Hepatitis B and Multiple Sclerosis.** Concern about hepatitis B vaccination arose from France, which had a large-scale population hepatitis B vaccination program until recently [13]. Over one-third of the entire French population has been vaccinated against hepatitis B. A few recent case reports were made in France of multiple sclerosis (MS) or MS-like illness following hepatitis B vaccines [14]. Explanations provided for the development of MS are specious and circuitous and involve the so-called "theory of molecular mimicry". Some years ago, it was demonstrated that part of rabbit myelin is closely related to the "polymerase" protein of the hepatitis B virus. Thus, when the polymerase protein of the hepatitis B virus is injected to a rabbit, an inflammation can be observed in its brain. It was proposed that a similar mechanism in humans could produce MS. However, there is no such close relationship between hepatitis B polymerase and human myelin. Furthermore, the hepatitis B vaccine does not contain the polymerase protein from the hepatitis B virus. There is therefore no risk that such a mechanism could cause MS after hepatitis B vaccination [15, 16].

However, this did not deter people from claiming compensation and suing the manufacturers before the courts. They all attributed their disease to the hepatitis B vaccination. Surprisingly, in April 1997 and June 1998, a Tribunal in Nanterre (near Paris) ruled in favor of three patients who had claimed to be "victims" of hepatitis B vaccination. The Nanterre Tribunal held the vaccines to be liable for the plaintiffs' diseases and awarded provisional damages. What was surprising was that no scientific or medical experts were called upon and that the causal link upheld by the judges was not supported by any scientific studies or data. Pasteur-Mérieux and SmithKline Beecham, both manufacturers of the hepatitis B vaccine, lodged an appeal. On April 2, 1999, in the two cases involving the vaccine, the Court of Versailles overturned the judgments of the Nanterre Tribunal and appointed a panel of medical experts to address the question of the alleged causal link between hepatitis B vaccination and the multiple sclerosis of the two plaintiffs.

**Vaccines and Sudden Infant Death Syndrome.** There is an anecdotal belief that vaccines cause sudden infant death syndrome (SIDS). The belief came about because a moderate proportion of children who die of SIDS had recently been vaccinated. SIDS deaths occur during the age range when many vaccinations are given and thus one would expect vaccinations to precede SIDS simply by chance. Several well-designed studies have shown that immunization does not increase the risk of SIDS and may even lower the risk [17, 18].

**MMR Vaccine Controversy.** MMR vaccine is an immunization shot against **m**easles, **m**umps, and **r**ubella. First developed by Maurice Hilleman in the late 1960s, it is a mixture of three live attenuated viruses, administered via injection. The shot is generally administered to children around the age of 1 year, with a second dose before starting school (i.e., age 4/5). The second dose is not a booster; it is given mainly to vaccinate those who had missed the first dose or had primary vaccine failure [19].

Autism is first noted in children around the same time the first MMR shot is given. Many parents associated the two together and began believing that autism is caused by MMR. In April 1994, Richard Barr, their solicitor, succeeded in winning legal aid for the pursuit of a class action suit against Aventis Pasteur, SmithKline Beecham, and Merck, the major manufacturers of MMR under the UK's Consumer Protection Act 1987. Owing to the 10-year-limit on the period in which an action can be brought under the Consumer Protection Act, court proceedings were started before the medical research had concluded.

MMR controversy started in a real big way in 1998, with a paper by Andrew Wakefield, senior lecturer in experimental gastroenterology at the Royal Free Hospital School of Medicine, London, which asserted that autism indeed could be caused by MMR.

With this paper, and the label of a leading medical journal – *the Lancet* – the controversy acquired the status of reliable scientific research. Wakefield's theory was that live viruses administered together caused inflammatory bowel disease (IBD) in children, which gave rise to intestinal absorption disorders, which in turn led to neurological disorders, such as autism [20]. Quite predictably, the report created considerable concern among parents, who began refusing MMR vaccination to their children. This caused a steep rise in the incidence of measles, and probably a number of unnecessary deaths. A subsequent investigation by an investigative journalist Brian Deer revealed that Wakefield not only took a fat amount of sum for research from interested parties (Richard Barr, the lawyer of parents who asserted their children got autism from MMR vaccines), but fudged data at several levels to produce the "desired" results [21, 22]. Wakefield's name was later struck off the UK's General Medical Council register, and immediately prior to this, the paper was retracted by the editors of *Lancet*, where the paper was first published [23]. Detailed surveys have since proven that there is no demonstrated link between MMR and autism [24].

**Thiomersal Controversy.** Thiomersal, an organomercury compound ($C_9H_9HgNaO_2S$), is a well established antiseptic and antifungal agent, and has been used as a preservative in vaccines since 1930s. Once in the body, thiomersal breaks up into smaller constituents, one of which is ethyl mercury ($CH_3CH_2Hg$). There have been concerns that it leads to the development of autism and other brain development disorders in children. In May 1999, the US Food and Drug Administration (FDA) found that by 6 months of age, infants could receive as much as 75 μg of mercury from three doses of the diphtheria–tetanus–pertussis vaccine, 75 μg from three doses of the *Haemophilus influenzae* type b vaccine, and 37.5 μg from three doses of the hepatitis B vaccine – a total of 187.5 μg of mercury [25]. In mid-June 1999, FDA scientists held a meeting to discuss their findings. Representatives from the Centers for Disease Control and Prevention (CDC) and the American Academy of Pediatrics (AAP) were present. These organizations are principally responsible for making vaccine recommendations for US children. Several attendees left the meeting concerned that infants might be receiving too much of mercury from vaccines. Pressure to remove thiomersal-based vaccines grew so much that on July 9, 1999, after much wrangling, the CDC and AAP asked pharmaceutical companies to remove thiomersal from vaccines as quickly as possible. Meanwhile, the doctors were asked to delay the birth dose of hepatitis B vaccine in children who were not at risk for hepatitis [25].

A detailed and more careful analysis has revealed that the concerns have been largely unfounded [26]. Extrapolations of toxicity were made from inadvertent *methyl mercury* ingestions that occurred in the infamous Minamata Bay disaster [26]. However, thiomersal releases *ethyl mercury* (and not *methyl mercury*) in the body and that too in very tiny amounts. The pharmacokinetics of methyl mercury and ethyl mercury are quite different, and it may not be correct to extrapolate the toxicity profile of one from the other. Methyl mercury has a half-life of 1.5 months (meaning that it takes as long as 1.5 months for the body to off-load half of the methyl mercury load). Methyl mercury thus has a tendency to accumulate in the body tissues. Ethyl mercury, on the contrary, has a half-life of less than 1 week and is actively excreted through the intestine [27]. This effectively means that any ethyl mercury introduced in the body is more quickly eliminated than its counterpart methyl mercury. Thus, ethyl mercury has a lesser tendency to accumulate in the body, and thus is not a serious poisoning candidate. A number of systematic studies conducted to resolve the issue have found that early exposure to thiomersal is quite harmless [28]. Nevertheless, the alarm raised among the general public has caused great damage. Infants who needed hepatitis B vaccines, but were not administered due to thiomersal fear have died of hepatitis. More importantly it has sprouted a cottage industry of charlatans, who offer mercury-chelating agents to autistic children, in a vain attempt to treat them of "mercury poisoning". An estimated 10 000 autistic children in the United States receive superfluous mercury-chelating agents every year [7], which themselves may be quite toxic. The controversy also diverted attention and resources away from efforts to determine the true causes of autism.

### *Law related to Vaccination*

**Vaccine Damage Payments Act, 1979.** In 1979, Britain passed the Vaccine Damage Payments Act 1979, an attempt at "no-fault" compensation. The Act

provided for vaccine damage tribunals: a chairman (in practice, legally qualified) and two medical practitioners, who could award £10 000 (raised in 1985 to £20 000), to claimants who satisfied the tribunal "on the balance of probability" that the disablement resulted from vaccination. The tribunals' decisions are subject to review by the High Court [29].

**The National Childhood Vaccine Injury Act, 1986.** The National Childhood Vaccine Injury Act (NCVIA) of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34) was enacted in the United States to reduce the potential financial liability to vaccine makers due to vaccine injury claims. The legislation was aimed at ensuring a stable market supply, and to provide cost-effective arbitration for vaccine injury claims. The Act requires health care providers to report (i) any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine and (ii) any event listed in the Reportable Events Table that occurs within the specified time period after vaccination. The data are stored electronically by the CDC in the Vaccine Safety Datalink (VSD).

Under the NCVIA, the National Vaccine Injury Compensation Program (NVICP) was created in 1988 to provide a federal no-fault system for compensating vaccine-related injuries or death by establishing a claim procedure involving the United States Court of Federal Claims and special masters. It also created the Vaccine Adverse Event Reporting System (VAERS) (please see below).

**The Project Bioshield Act, 2004.** The Project Bioshield Act was an act passed by the US Congress in 2004 mainly as an aftermath of the 2001 terrorist attack. The Act calls for $5 billion for purchasing vaccines that would be used in the event of a bioterrorist attack. This is a 10-year program to acquire medical countermeasures to biological, chemical, radiological, and nuclear agents for civilian use.

### *Vaccination Trial Controversies*

Vaccination trials, especially of new disease, have always evoked social, political, economic, and ethical controversies. Human immunodeficiency virus (HIV) vaccine trials have evoked several controversies. A serious politicoeconomic controversy arose with the *RV 144* trial – a phase III HIV vaccine trial, one of the largest till date – that was conducted in Thailand from October 2003 till July 2006. A total of 16 402 Thai volunteers aged 18–30 participated, who received a vaccine made from the live-replicating canarypox vector ALVAC combined with gp120. A large number of scientists believed that since the gp120 component had been proved completely incapable of preventing or ameliorating HIV-1 infection, there was no rationale for carrying on this trial. The trial was thought to be a complete wastage of $119 million (to be spent on it). More serious objections were that the approval for such trials was taken improperly and that a failure of such a large trial would erode public and political confidence in the development of a successful HIV vaccine, making future funding more difficult [30].

More recently, an ethical controversy arose when tgAAC09, an HIV vaccine that uses an adeno-associated viral vector was used in India, even after it was well known that the vaccine did not elicit significant immune responses in similar trials in Europe [31]. The New York-based International AIDS Vaccine Initiative (IAVI), which sponsored the trial, claimed the trial was justified because "the safety and immunogenicity among Indian and European volunteers may be completely different" owing to ethnicity and genetic factors. The Indian Council of Medical Research (ICMR) asserted that the volunteers were fully informed about the European data and given the option to withdraw. The trial remains mired in controversy, with the exact intentions of sponsoring agencies unclear.

### *Vaccine Adverse Event Reporting System*

The Vaccine Adverse Event Reporting System (VAERS) is a US program established in 1990 for vaccine safety, comanaged by the CDC and the FDA. It is an outgrowth of the 1986 *National Childhood Vaccine Injury Act* (please see above). It is a postmarketing safety surveillance program, collecting information about adverse events (possible side effects) that occur after administration of vaccines. It is a passive reporting system to which anyone can report an event [32]. It acts as a kind of "early warning system" – a way for physicians and researchers to identify possible unforeseen reactions or side effects of vaccination for further study. Limitations include unverified reports,

underreporting, inconsistent data quality, and absence of an unvaccinated control group [33].

### *Vaccination Deaths*

Vaccinations are often administered under the garb of a genuine time-tested drug. In 2007 in Poland, about 350 homeless people died after a controversial medical trial for a vaccine to the H5N1 bird-flu virus. The victims were wrongly informed that it was an anti bird-flu drug and were given a paltry £1–2 to act as guinea pigs for the vaccine.

In 2008, four children died in Tamil Nadu, India, after receiving measles vaccination. The entire vaccination program was suspended and the entire batch of vaccines was recalled. The cause of death remains unknown to this day. The incident virtually repeated itself in August 2010, in Uttar Pradesh, India, when four infants all between 6 and 9 months of age died after they were vaccinated for measles. The cause of death was probably anaphylaxis. Minutes after they were given the measles vaccine, all four infants became breathless, began to sweat, and their pulse fell rapidly – all symptoms of anaphylactic shock. The vaccine was tested for sterility, abnormal toxicity, and identity, and nothing abnormal was found.

## Conclusions

Vaccination is a sensitive subject involving many dimensions besides just scientific and technical. This includes social, religious, political, legal, moral, and ethical dimensions. People are very sensitive when an issue affects their children, as is the case with vaccination. Media can affect public opinion very quickly and profoundly and any image created by media is hard to forget even if wrong. Thus, it should report vaccine-related events in a neutral way, and not demonize the vaccination programs without a genuine basis.

Vaccines, as with many medicines, will continue to feature in litigation.

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