

## ADULT VACCINATION GUIDE – MISCONCEPTIONS, SAFETY ISSUES, CONTROVERSIAL BELIEFS, AND SURVEILLANCE

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### ABSTRACT

As some life-threatening epidemics have disappeared, and certain infectious diseases are now being eliminated in Europe and North America, it is getting difficult to convince people of the need to vaccinate children against what is presently viewed as a minor risk. For the success of any vaccination programme, it is important for doctors to be well-informed about vaccination and be good sources of authoritative and scientifically justified advice. There are common misconceptions in popular literature about vaccination, safety concerns, and controversial beliefs which doctors should take note of. As doctors' attitudes have a major influence on their patients, doctors should be positive about vaccinations for children and adults.

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### INTRODUCTION

At a time when the Third World is gaining better access to immunization, under the impetus of WHO and its Expanded Programme on Immunization, launched in 1974, the acceptability of vaccination is increasingly being called into question in developed countries. In so far as some life-threatening epidemics have disappeared, and certain infectious diseases are now being eliminated in Europe and North America, it is getting difficult to convince people of the need to vaccinate children against what is presently viewed as a minor risk.

Vaccinations are not for children only. They are also important for adults, including the elderly. Some additional vaccinations may be motivated by special risks connected with occupational hazards, travel or some chronic ailments.

Vaccinations have been repeatedly demonstrated in both research trials and in the field to be effective medical interventions we have to prevent diseases. More than two million people died in 2002 of diseases preventable by widely used vaccines. It has been estimated that vaccinations currently save 3 million lives per year throughout the world while remaining one of the most cost effective health interventions. Also, serious adverse events following vaccinations are rare. But despite a very good record of effectiveness and safety, there are people who have reservations about vaccinations. Thus, doctors

need to know the arguments frequently raised by opponents of vaccination and be knowledgeable of scientific evidence so that they can advise their patients in making an informed choice about the benefits and risks of vaccinations. For the success of any vaccination programme, it is important for doctors to be well-informed about vaccination and be good sources of authoritative and scientifically justified advice. Doctors should also be positive about vaccinations because their attitudes have been found to be a major influence on their patients.

Knowledge on Vaccine Efficacy is also important.

### VACCINE EFFICACY

Vaccine efficacy is a measure of the level of protection against a disease in persons who have been vaccinated compared with the attack rate in persons who have not been vaccinated, being aware that no vaccine is 100% effective.

Before vaccines are made available, they are tested for safety and efficacy in clinical trials and afterwards, in mass trials. Furthermore, after introduction into vaccination schedules, there is continuing surveillance of efficacy and safety through trials and post marketing surveillance.

Because we are still a long way from having an "ideal vaccine", misconceptions, safety issues and controversies will always be around. An "ideal vaccine" may be defined as one which is highly antigenic, totally effective in single injection, produces no side effects and provides solid life-long immunity in 100% of the individuals vaccinated.

In the discussions to follow, it is inevitable that some of the material facts will have references to childhood vaccinations and diseases.

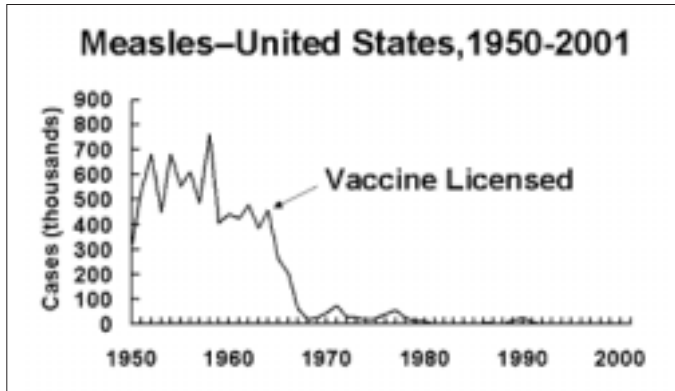
### MISCONCEPTIONS

There are six common misconceptions that appear in the popular literature on vaccination.

1. Diseases had already begun to disappear before vaccines were introduced, because of better hygiene and sanitation. It is accepted that improved socioeconomic conditions had an indirect impact on disease. The decline in communicable diseases is multifactorial, and living standards do play an important role. However, vaccination has also had a clear and significant impact. Better nutrition, development of antibiotics and higher standards of medical care also have increased survival rates among the sick. Taking measles as an example, the graph shows the reported incidence of measles from 1950 till 2000 in

United States. There were periodic peaks and valleys throughout the years, but the real permanent drop coincided with the licensing and wide use of measles vaccine beginning in 1963. Graphs for other vaccine-preventable diseases like Pertussis, Hib, Varicella, Hepatitis B show a similar pattern.

Figure 1



The experiences of several developed countries like Great Britain, Sweden, and Japan showed that when they cut back the use of pertussis vaccine because of fear about the vaccine, the effect was dramatic and immediate. Epidemics and deaths followed. There was also a major epidemic of diphtheria with death in the former Soviet Union from 1989 to 1994 following low primary immunization rates for children and the lack of booster vaccinations for adults.

**2. The majority of people who get disease have been vaccinated.**

This is an apparent paradox, in that as vaccination coverage increases, there are increasing proportions of cases of vaccine-preventable diseases in vaccinated children. This apparent paradox is explained by two factors. First, no vaccine is 100% effective. Second, where vaccinated people vastly outnumber those not vaccinated, there will be few un-vaccinated people. When these two factors are present together in an outbreak, those who have been vaccinated will outnumber those who have not, thus giving rise to more cases of vaccine-preventable diseases in the vaccinated.

**3. There are “hot lots” of vaccine that have been associated with more adverse events and deaths than others.**

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. All developed countries where vaccines are manufactured have natural regulatory and licensing bodies like the FDA in North America and The Australian Therapeutic Goods Administration (TGA). In addition, every vaccine lot is safety-tested by the manufacturer and the results of these tests are reviewed by FDA.

**4. Vaccines cause many harmful side effects, illnesses and even death**

Most vaccine adverse events are minor and temporary, such as a sore arm or mild fever. More serious adverse events occur rarely. As for vaccines causing death, it is hard to assess the risk statistically because so few deaths can plausibly be attributed to vaccines.

**5. Vaccine-preventable diseases have been virtually eliminated from developed countries, so there is no need for childhood vaccination in such countries.**

It is true that vaccination has enabled us to reduce most vaccine-preventable diseases to very low level in most developed countries like the United States. But there are some diseases quite prevalent and even epidemic in other parts of the world and travelers can unknowingly import these diseases causing epidemics if the home country was not protected by vaccinations. In this context, vaccination is important for two reasons : First, to protect ourselves and second, by getting vaccinated we protect those around us, especially those who, for various reasons, cannot be vaccinated and those who don't respond to vaccines.

**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.**

Available scientific data shows that simultaneous vaccination with multiple vaccines has no adverse effect on the normal childhood immune system. Numerous studies conducted to examine the effects of giving various combinations of vaccines simultaneously have shown that the recommended vaccines are as effective in combinations as they are individually, and that such combinations carry no greater risk for adverse side effects.

**SAFETY ISSUES**

Here, a major concern of opponents of vaccination is that they consider vaccines to cause harm, whether or not they prevent disease.

- κ The side effects of DTP include Brain Damage
- κ Vaccines cause Sudden Infant Death Syndrome (SIDS)
- κ Some vaccines may cause Mad Cow Disease
- κ MMR vaccine cause Inflammatory Bowel Disease and autism
- κ Hepatitis B vaccine causes multiple sclerosis (MS)
- κ Vaccines can cause diabetes
- κ Vaccines are contaminated with adventitious viruses
- κ The Rubella and Chicken-pox vaccines are cultured on cell lines of aborted fetuses
- κ Vaccines suppress the immune system
- κ Vaccines contain foreign proteins
- κ Vaccines viruses persist after vaccination

To discuss a few concerns :

### **Vaccines cause SIDS**

This belief came about because a moderate proportion of children who died of SIDS had been vaccinated before. On the surface, this seems to indicate that vaccination was the cause of death. However, this logic is faulty, as it confuses association with causality. Several studies have shown that vaccination does not increase the risk of SIDS and may even lower the risk.

### **Some vaccines may cause Mad Cow Disease**

In November 2000, an expert committee in Australia reviewed fully all vaccines that were “grown” in calf serum originally sourced from UK cattle and concluded that the risk of exposure to variant Creutzfeldt-Jakob Disease (vJCD) through vaccines is negligible. These findings follow a similar verdict from the American FDA.

### **MMR vaccine cause Inflammatory Bowel Disease (IBD) and Autism**

In 1993, a group of researchers led by Dr Wakefield at the Royal Free Hospital suggested an association between both the natural and vaccine type of measles virus and IBD. In 1998 researchers from the same group reported the occurrence of a new syndrome of an unusual type of IBD in association with autism.

Reviewers of these studies by expert groups around the world have found the suggested associations to be weak and the studies to have several flaws. In 1998, Sir Kenneth Calman, British Chief Medical Officer convened a meeting of the Medical Research Council and a group of national and international experts, including WHO to review the work of Wakefield and the Royal Free Hospital IBD study group. The meeting concluded that based on current evidence ‘there is no link between measles and measles vaccine with either Crohn’s Disease or autism!’

### **Vaccines cause Diabetes**

There is no evidence that vaccines cause diabetes. There have been a number of studies which have searched for links between diabetes and vaccinations and the only study suggesting a possible increase in risk was from Dr John B Classen. He found that if the first vaccination in children is performed after two months of age, there is an increased risk in diabetes. There were other researchers who have studied this issue and have not verified Dr Classen’s findings. This included a group from the highly respected international Cochrane Collaboration which reviewed all the available studies and did not find an increased risk of diabetes associated with vaccination. The National Institutes of Health in the USA have met and reviewed the evidence and concluded that there is no link between vaccines and diabetes.

### **Hepatitis B vaccine causes Multiple Sclerosis (MS)**

There is no evidence that hepatitis B vaccine causes MS.

Concern about hepatitis B vaccination arose from France which had a large scale population hepatitis B vaccination programme. A few recent case reports were made in France of MS or MS-like illness associated with hepatitis B vaccines.

When the French data were examined, however, the rate of MS in vaccinated people was not significantly different from the expected population rate. In addition, mass vaccination with hepatitis B vaccine in New Zealand, Taiwan and Alaska has not resulted in any serious adverse events or illnesses suggestive of MS. In the USA, surveillance of adverse events after hepatitis B vaccination has also not shown any clear association between hepatitis B vaccine and serious adverse events.

### **Vaccines are contaminated with adventitious viruses**

It has been said that vaccines are cultured on animal tissues and therefore contain many bacteria and viruses other than the ones they are supposed to immunize against. It is misleading and an exaggeration to state that vaccines are cultured on animal tissue and therefore contain many contaminants. Only viral vaccines are cultured in material derived from animal tissues. Bacterial vaccines are manufactured in cultures free of animal cells.

The viruses used in current viral vaccines are propagated in chicken eggs, primary cell cultures and continuous cell lines. These substrates are thoroughly screened for adventitious agents such as other viruses or bacteria.

Between 1955 and 1963 some batches of polio vaccines were inadvertently contaminated with monkey viruses called Simian Virus 40 (SV40) which has since been found to be capable of causing cancer in hamsters. An international workshop on SV40 viruses in USA in January 1997 concluded that there is no evidence of increased cancer risk in people who were given vaccines containing SV40.

There is no scientific evidence linking AIDS to polio vaccines. In addition, polio vaccines stored in the 1950s has been tested with the latest technology for the presence of HIV, the virus which causes AIDS, and no HIV had been found.

### **Additives in vaccines are toxic**

Additives in many vaccines are said to be ‘toxic’ e.g. formaldehyde, thiomersal and aluminum.

The newer generation vaccines e.g. recombinant Hepatitis B vaccine, Conjugated Hib vaccine, acellular pertussis vaccine are highly purified subunit components of the disease causing organism, and are virtually free of toxic component often associated with the whole organism e.g. bacterial endotoxin.

Formaldehyde is a chemical agent that is used in the manufacture of certain vaccines made from components of bacteria or viruses. For example, formaldehyde is used to detoxify the tetanus toxin protein produced during the manufacture of tetanus vaccine. The non-toxic protein which becomes the active ingredient of the vaccine is further purified

to remove contaminated and any excess (unreacted or unbound) formaldehyde.

The adjuvant in DTP vaccine (usually very small amounts of aluminum salt) improves the protective response to vaccination. Diphtheria and tetanus toxoid are weak immunogens and they are absorbed onto adjuvants to strengthen the immune response. The main functions of adjuvant is to keep antigens near the injection site and to activate antigen-presenting cells.

Preservative is added to some vaccines e.g. live measles vaccine contains trace amounts of neomycin, and polio vaccine is stabilized with sucrose or magnesium chloride. In killed and toxoid vaccines, thiomersal is usually used.

Thiomersal is a compound which contains 49.6% mercury and it has been used in very small amounts in vaccines since 1930s, as it prevents bacterial and fungal contamination. There is no scientific evidence that thiomersal in vaccines causes any adverse health effects in children. However, there is a possibility that low birth weight newborns receiving repeated doses of thiomersal containing vaccines may result in levels of mercury that are above the recommended guidelines. Accordingly, the monovalent Hepatitis B vaccine which contains 25 microgram of thiomersal per dose has since May 2000 being replaced by a thiomersal – free monovalent hepatitis B vaccine.

## CONTROVERSIAL BELIEFS

Alternative views on health and disease can create controversies in the minds of many people.

### 1. Rejection of evidence supporting immunization: Infectious diseases are not serious and are a normal part of growing up.

Parents may believe that the vaccine-preventable diseases of childhood do not cause serious illness and are a normal part of a child's growth. However, studies have shown that pertussis causes significant morbidity like post-tussive vomiting may lead to significant weight loss; neurological complications with seizures, cerebral hypoxia and cranial nerve abnormalities. Since whooping cough is not only highly infectious but also causes severe disease, the risks of complications or even death for each unimmunized child are high.

Measles is one of the most severe and infectious disease of childhood. In the 1990s, one in every 5-10,000 measles cases died from the acute effects of the disease, despite the best modern medical care. Measles is still a leading cause of death worldwide. Subacute Sclerosing Panencephalitis (SSPE) is a delayed response to wild measles infection with severe encephalopathy occurring years after wild measles infection and has a uniformly fatal outcome.

Similarly, severe morbidities can result from Haemophilus Influenza Type B (HIB) infection, polio and diphtheria including Hepatitis B.

## 2. Some alternative views of health and health care

### (a) *The germ theory of disease is false*

The germ theory of infectious disease is one of the bases of scientific medicine, which has had virtually universal support from, at least, the time of Pasteur and Koch's postulates in the late nineteenth century.

### (b) *Immunization is unnatural*

Vaccines provide stimulus to the immune system as infection does, but without disease. In this sense, vaccination is natural.

### (c) *Specific immunity is not important for protection from disease*

Vaccination is the only tested and proven means of protection against the vaccine- preventable diseases.

## 3. Homeopathic vaccines

There is a wide variation in the use of "homeopathic vaccines" by homeopathic practitioners. Also, few studies where 'homeopathic vaccines' have been subjected to scientific scrutiny are available. Homeopathic 'vaccination' offers no proven protection against infectious diseases. The UK Faculty of Homeopathy supports conventional vaccination and is not aware of any evidence supporting the use of 'homeopathic vaccination'.

## SURVEILLANCE AND REPORTING OF ADVERSE REACTIONS

Modern vaccines are safe and effective; however, adverse events have been reported after administration of all vaccines. These events range from frequent, minor, local reactions to extremely rare, severe, systemic illness, e.g. encephalopathy or Guillian Barre syndrome. Reporting adverse events, including serious events, is a key stimulus to developing studies to confirm or refute a causal association with vaccination.

Spontaneous, suspected adverse reactions are reported to the Health Services Authority (HSA) Singapore, using a prescribed form which can be downloaded at [http://www.hsa.gov.sg/docs/Annex\\_A\\_HAS\\_ADR\\_reportingform.pdf](http://www.hsa.gov.sg/docs/Annex_A_HAS_ADR_reportingform.pdf). Details on reporting requirements are given in a document issued by HSA. See reference 6.

## CONCLUSIONS

Modern vaccines provide high levels of protection against several diseases, consequent disability and death. Today vaccine-preventable diseases are still with us and continue to cause substantial distress, disability and even death.

Misconceptions, concerns about vaccine safety, and controversial beliefs reduce vaccine uptake by those who will benefit. We have a role to provide authoritative and scientifically justified advice. As doctors, attitudes are a major influence on their patients: doctors should be positive about vaccinations for both children and adults.

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#### LEARNING POINTS

- o Available scientific data shows that simultaneous vaccination with multiple vaccines has no adverse effect on the normal childhood immune system.
  - o Recommended vaccines are as effective in combinations as they are individually, and such combinations carry no greater risk for adverse side effects.
  - o Vaccination is the only tested and proven means of protection against the vaccine-preventable diseases.
  - o Misconceptions, concerns about vaccine safety, and controversial beliefs can reduce vaccine uptake by those who will benefit.
  - o Doctors have a role to provide authoritative and scientifically justified advice.
  - o Suspected adverse events advice are reported to the Health Sciences Authority (HSA) Singapore.
  - o Doctors should be positive about vaccinations for both children and adults.
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