Why do we Immunize Children?
- An approach to Parents who are Uncertain or Object.

Cameron N
Public Health Department, University of Stellenbosch.

Immunization against common childhood conditions is the public health endeavour that personally touches the most people in the world. The diseases being immunized against were very common, are very infectious, and have high rates of death and disability.

Following the eradication of small pox in 1978, the WHO's Expanded Programme on Immunization helped improve global coverage of routine childhood information to almost 80% by 1990. This has dramatically reduced the incidence of key childhood infectious diseases. In the 1990s the campaigns to eradicate polio and eliminate measles have further demonstrated the value of immunization. Together with this success, has almost inevitably come opposition. This article argues the case for immunization and outlines an approach to parents who are unsure about, or who object to immunization.

The case for immunization:

The Case for Immunization: Much less disease and many fewer deaths in the world!
Immunization prevents many million deaths each year both in children and in adults. Small pox has been eradicated. Polio occurs in very few countries and measles is now very rare in many countries. Whooping Cough, Diphtheria and Tetanus are rare where there is reasonable immunization coverage. However about one in four children are not immunized and WHO estimates about three million people still die from diseases which could have been prevented by immunization.

The Case for Immunization: Safety and Quality
All modern vaccines go through extensive testing during development and careful quality checks before being marketed. Before any lot or shipment of vaccine released in South Africa, the documentation is scrutinized and samples are tested by the National Vaccine Control Laboratory in Bloemfontein. Adverse Events Following Immunization (AEFIs) are reported to the Medicines Control Council and the Immunization Programme of the Department of Health for investigation.

The Case for Immunization: Local Outbreaks
Outbreaks tend to occur in groups of unvaccinated children. Paralytic cases of polio have occurred in north America and in the Netherlands in a religious group who refused immunization. The collapse of the Soviet Union in the early 1990s resulted in a breakdown of the health care system and was followed by there were 50,000 cases of diphtheria with 1,700 dying as a result. In the mid 1970s in the UK there were media reports that pertussis vaccine may cause brain damage and about 30 – 40% of parents then refused the vaccine. There were over 100 000 cases of whooping cough with 40 deaths reported before coverage went up again to over 90%. In Australia a similar scare in 1994 resulted in over 5000 cases of whooping cough before immunization coverage went up again.

The Case for Immunization: Personal Risk Reduction
Most people who have motor vehicle accident have brushed their teeth in the last 24 hours. Most people would see this as association as coincidental and not causal. Similarly, the first years of a child's life are the most vulnerable years to illness. During this time childhood vaccines are given and similarly most severe side effects and deaths linked to immunization, are coincidental.

We tend to accept that when drugs are given to sick people, a proportion will have even quite serious side effects and so doctors use them with caution. Vaccines, by contrast, are given to healthy children and public tolerance of adverse events is much lower.

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Local pain, swelling and redness</th>
<th>Fever &gt;38°C</th>
<th>Systemic manifestations</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>90%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Hib + Hep B</td>
<td>5 -15%</td>
<td>1 - 10%</td>
<td>-</td>
</tr>
<tr>
<td>DTP</td>
<td>~ 50%</td>
<td>~50%</td>
<td>~50%</td>
</tr>
<tr>
<td>Measles/MMR</td>
<td>~10%</td>
<td>5 - 15%</td>
<td>&lt;5% (incl rash)</td>
</tr>
<tr>
<td>Polio</td>
<td>-</td>
<td>&lt;1%</td>
<td>&lt;1%</td>
</tr>
</tbody>
</table>

Table 1. Vaccine related minor side effects
Table 2. Comparison of the risk from disease vs the risk from vaccination

<table>
<thead>
<tr>
<th>Disease risk</th>
<th>Vaccine risk</th>
</tr>
</thead>
</table>
| **Polio:** Paralysis: 1 in 100 cases  
Death following paralysis: 1 - 10 per 100 | Paralysis: 1 per 2 - 3 million doses |
| **Measles:** Pneumonia: 1 in 20  
Encephalitis: 1 in 2,000  
Death: 1 in 3,000 | Encephalitis / Severe allergic reaction: 1/ million  
Febrile seizures: 1/ 3,000  
Thrombocytopenia: 1/ 30,000  
Severe allergic reaction: 1/ 100,000 |
| **Diphtheria:** Death 1 in 20 | |
| **Tetanus:** Death 1 in 33 | |
| **Pertussis:** (Whooping Cough)  
Pneumonia: 1 in 8  
Encephalitis: 1 in 20  
Death: 1 in 200 | DTP:  
Persistent crying*: 1 in 100  
Seizures*: 1/ 1,750 to 1/ 12,500  
Hypo-tonic/Hypo-responsive Episodes (HHE)*: 1/ 100 to 1/ 33,000  
Anaphylaxis: 1 in 50,000  
Encephalopathy: 1 to 10/ million  
Death: *none proven  
* with full recovery |

Based on studies published in the scientific literature. See [www.who.int/immunization safety/en/](http://www.who.int/immunization safety/en/). When effects only occur rarely, it becomes more difficult to attribute cause. Note the risk of serious complications or death from one of these diseases is high is measured in percentages rather than hundreds of thousands of doses. The diseases tend to be more severe in adults.

Below are two tables, the first looking at the common side effects and the second comparing risks of more serious side effects with risks as a result of the disease in question.

Side-effects such swelling, redness and soreness of the arm and even slight fever are fairly common, but not serious and can be dealt with symptomatically. The risk of serious side effects due to immunization is far smaller than the risk of serious complications or death due to the disease itself as in table 2 below.

The Case for Immunization: Disease Eradication. This is achieved through high routine immunization coverage, good surveillance, mass campaigns and where necessary mopping up in high risk areas.

An approach to parents who are unsure about, or who object to immunization

Be positive and keep relationships open, by listening first, responding to concerns, providing good information, being friendly and efficient. Key points to note:

- There is no "perfect" vaccine that protects everyone who receives it and is entirely safe for everyone.
- Effective vaccines (i.e. vaccines inducing protective immunity) may produce some undesirable side effects which are mostly mild and clear up quickly.
- The majority of serious events thought to be related to the administration of a vaccine are not due to the vaccine itself, many are simply coincidental events, others may be due to human error.
- It is not possible to predict every individual who might have a mild or serious reaction to a vaccine, although there are a few contraindications to some vaccines. By following contraindications, the risk of serious adverse effects can be minimized.

Listen: One of the most effective interventions is just to listen and to hear the specific concerns of the parent sitting in front of you. People can have a variety of religious or philosophical objections or are concerned about the safety or efficacy of vaccines, or may believe that the diseases do not pose a serious health risk. It may help to reflect back briefly to ensure clear understanding.

Recognize Legitimate Parent Concerns: When discussing immunization it is essential that you should recognise that side effects and adverse events are associated with vaccines. Listening to mothers will help you understand the concerns are and find a variety of appropriate responses to different mothers.

Provide Context: When you speak, use short sentences and familiar words. Parents understandably often more concerned about the risk of immunization than the risk of not doing so. It maybe useful to compare risks associated with the vaccine and with the disease, (see table 1 & 2.)

Gently discuss Misinformation: Be informed also about the arguments so that you can respond to the misinformation and respond knowledgably. Provide additional reliable sources. (See table 3)

Build a logical case for immunisation:

a. Immunisation stimulates a natural process called immunity.
   b. Vaccines protect the individual child and prevent the spread of epidemics.
   c. Outbreaks occur in groups of unvaccinated children in countries where the diseases had become rare with resulting deaths and disability: (Diphtheria in Russia, Whooping Cough in the UK and Australia, Polio in Holland and Nigeria).
   d. There are very high international standards for manufacturing vaccines. Vaccines are extensively tested for safety, quality and efficacy by the manufacturers and by independent scientific.
Recognize that it is the Parent’s decision: Childhood immunization is not compulsory in South Africa. The role of the doctor or nurse is to help parents make a well-informed decision not to force the issue. Accept gracefully that the beliefs and ideas of others are often beyond our ability to change.

Make a clear recommendation: Be personally encouraging but leave no doubt as to your opinion and recommendation. If you are unsure, the parents will be as well. Give a clear message. For example: “Immunization is a good thing for your child and the community. You need to be sure that you have thought to the consequences for both should you decide not to have your child immunized.”

Responses to some concerns about vaccination (adapted from: www.who.int/immunization/safety/en/)

Below we respond to some of the concerns raised about vaccines and immunization programmes.

Most infectious diseases had already begun to disappear before vaccines were intro-dued, because of better hygiene, sanitation and nutrition. Serious outbreaks of other diseases tend to re-occur when immunization levels drop, even in well-developed countries. The introduction of Haemophilus influenzae type b (Hib) vaccine in recent years in countries such as the US has lead to the disease almost disappearing, this cannot be attributed to better hygiene or malnutrition.

In epidemics, many who get disease have been vaccinated. No vaccine gives 100% protection. If a high proportion of children in a school have been immunized and there is an outbreak of that disease, it is likely that a significant number of those who get disease will have been immunized, however the attack rate is likely to be far less in the immunized than the unimmunized children.

There are certain Hot Lots of vaccine that have been associated with more adverse events and deaths than others. This has been shown in practice to be very unlikely. (see also The Case for Immunization: Safety and Quality).

Vaccines cause many harmful side effects, illnesses, and even death - not to mention possible long-term effects we don’t even know about. Besides the many studies looking at the incidence of adverse events following immunization, there are well developed surveillance and reporting systems in place in many countries including South Africa, which help identify and investigate such events. The vast majority of AEFIs are found by expert independent review to be related to other causes and not the vaccine.

Vaccines and their safety: The National Network for Immunization Information, the Safe Injection Global Network, the Vaccine Adverse Event Reporting System, the WHO, the Immunization Action Coalition, the American Academy of Pediatrics, The CDC, and Immunization Action Coalition have all listed the incidence of adverse events following immunization, there are well developed surveillance and reporting systems in place in many countries including South Africa, which help identify and investigate such events. The vast majority of AEFIs are found by expert independent review to be related to other causes and not the vaccine.

Vaccine preventable diseases are now so rare in middle class homes, the risk associated with the vaccine is higher than the disease. Some parents rely on the high immunization rate in the community to protect their children. To what extent is this a valid argument? Outbreaks have re-occurred in communities where vaccination coverage has dropped due to publicity about side effects to vaccine. Travellers can bring these diseases into any country. Unimmunized adults travelling to other countries could have unexpected and expensive health problems, and often these diseases are more serious in adults than in children.

Giving a child multiple vaccinations at the same time overloads the immune system. The immune system is geared to handle multiple antigens at the same time. There is no evidence that introducing a number of antigens as vaccines leads to suppression of immunity. The evidence is that immunization boosts the immune systems and improves child survival and that the recommended vaccines are as effective in combination as they are individually, and in combination carry no greater risk for adverse side effects. Combining vaccines mean fewer injections, which is to everyone’s benefit.

Homeopathic vaccines are better and safer. Reported side effects may be very few; however, the evidence that they give effective protection is anecdotal and not scientifically verified.

Children need diseases like measles to develop into healthy adults. Again the evidence for this is lacking. Many children die during a measles epidemic.

In Thimerosal and MMR vaccine not linked to Autism and Attention Deficit Hyperactivity Disorder (ADHD)? Thimerosal is a mercury-based preservative used in the manufacturing process of vaccines and in certain multi-dose vials of vaccines in order to prevent the growth of bacteria and fungi and to stabilize the vaccine so that it remains safe and effective over time. Multi-dose vials of DTP in South Africa do contain thimerosal. The between vaccines containing thimerosal and best available science shows is no link autism or ADHD. A study published in 2003 reviewed the records for all children born in Denmark between 1990 and 1996 and compared the children immunized with thimerosal containing vaccines to those vaccinated with thimerosal-free vaccines and

Table 3. Some useful vaccine safety information websites:

<table>
<thead>
<tr>
<th>Website</th>
<th>URL</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO</td>
<td><a href="http://www.who.int/immunization/safety/en/">www.who.int/immunization/safety/en/</a></td>
</tr>
<tr>
<td>Immunization Action Coalition</td>
<td><a href="http://www.immunize.org">www.immunize.org</a></td>
</tr>
<tr>
<td>Institute for Vaccine Safety (JHU)</td>
<td><a href="http://www.vaccinesafety.edu">www.vaccinesafety.edu</a></td>
</tr>
<tr>
<td>American Academy of Pediatrics</td>
<td><a href="http://www.cispimmunize.org">www.cispimmunize.org</a></td>
</tr>
<tr>
<td>National Network for Immunization information</td>
<td><a href="http://www.immunizationinfo.org">www.immunizationinfo.org</a></td>
</tr>
<tr>
<td>Safe Injection Global Network</td>
<td><a href="http://www.injectionsafety.org">www.injectionsafety.org</a></td>
</tr>
<tr>
<td>The Vaccine Page</td>
<td><a href="http://www.vaccines.org">www.vaccines.org</a></td>
</tr>
<tr>
<td>Vaccine Adverse Event Reporting System</td>
<td><a href="http://www.vaers.org">www.vaers.org</a></td>
</tr>
<tr>
<td>BBC</td>
<td><a href="http://www.bbc.com">www.bbc.com</a> (useful especially for lay-audiences)</td>
</tr>
</tbody>
</table>

PNT May/Jun 2009 Vol. 13 No. 3
found that the risk of autism was similar in children regardless of the type of vaccine. In May 2004, the Institute of Medicine in the USA published an extensive review of the scientific literature that concluded that MMR vaccine and thimerosal-containing vaccines do not cause autism; that any links between these vaccines and autism are theoretical and that the causes for autism remain unknown.

Is there not a link between allergies and asthma and DTP or Hepatitis B vaccine; or between to auto immune diseases like Multiple Sclerosis and Hepatitis B vaccine; or between type I Diabetes Mellitus and BCG, Hib or MMR vaccine? Various theoretical immunological mechanisms have been proposed to try to explain such links, however several large well-conducted prospective and retrospective studies have shown no difference in children who received or did not receive the vaccines implicated.

Does SV40 in polio vaccine not cause cancer? SV40 is a monkey (simian) virus that infects several monkey species without making the animals sick. Kidney cells from infected monkeys were used in the production of polio vaccines before the discovery of SV40 in 1960. To date, there is no epidemiological evidence that shows people possibly exposed to the SV40 contaminated polio vaccine are at increased risk of developing the type of cancers that rodents developed after direct exposure to SV40.

**DTP vaccine has resulted in an increase in Sudden Infant Death Syndrome (SIDS).** As sudden infant death syndrome (SIDS) tends to occur in the months of life when DTP vaccine is given, it does happen that infants sometimes die within 24 hours of having received the vaccine. During the 1980s, several well-controlled studies found, that there was no difference in the incidence of SIDS in those babies given DTP vaccination and those who were not given DTP. In fact, in some of the studies, children who had recently received a DTP shot were less likely to die unexpectedly.

**What about AEFIs during mass campaigns?** During mass campaigns when millions of children are immunized in a short period of time there may appear to be an increase in AEFIs. See table 2. To the Media these seem to be clustered and raise questions about the quality of the vaccine. Health officials should be briefed to ensure that expert opinion is available at short notice to brief the media so that confidence or the health workers and the public are not undermined by a response that otherwise may be slow or inadequate. It is important that all immunization staff are able to immediately treat any anaphylactic reaction to measles vaccine. There is a strong case for immunization. And there will always be parents who are concerned about giving a healthy looking child a substance which interferes with the body’s immune system or about which there is controversy. And new objections are bound to come. And new objections are bound to come.

**Sometimes an AEFI is due to human error, including vaccine failure.**

**Storage and Preparation of vaccine**

- **Storage:** If liquid vaccine is stored against the cooling plate at the back of the fridge it may be frozen and becoming lumpy and ineffective.
- **Substitution:** If a drug such as a muscle relaxant or insulin or oxytocin inadvertently substituted for vaccine or diluent, death can occur rapidly.
- **Contamination:** If a dilluent/vaccine becomes contaminated an abscess can occur.
- **Preparation:** If an adsorbed vaccine such as DTP is not shaken properly and the aluminium adjuvant forms a sediment at the bottom of the vial and is injected a chemical abscess can occur.

**Dose and Administration**

- Too much or too little vaccine given in one dose.
- Improper site or route of administration.(subcutaneously instead of intra muscularly or vice versa)*
- Contraindications ignored. There are very few real contra indications to immunization. However very rarely children are allergic to one of the components in a particular vaccine. Previous anaphylactic episode following immunization is an absolute contra indication to re-immunization with that vaccine.
- Label on container not read properly.
- Prolonged use of reconstituted live vaccine (e.g the continued use of measles or BCG vaccine vial for more than 6 hours is associated with an increased risk of sepsis)
- Poor infection control. Transmission or bacterial or viral infection via unsterile needles or syringes is potentially the most easily overlooked and highest risk activity more especially, but not only, in a busy inadequately resourced health centre.

**Case study 1.** The last 2 children vaccinated against measles after a busy day at a rural clinic collapsed and died within 20 minutes. The nurses took the unusual step of incinerating all vials and injection materials.

**Expert opinion:** Measles vaccine diluent vials, and oxytocin and insulin ampoules, look similar and were stored on the same shelf in the clinic refrigerator. It is probable that oxytocin or insulin was accidentally used to reconstitute the measles vaccine.

**Case study 2:** Two symptomatic HIV-positive 8-year-olds received measles vaccine from different vaccination teams in different schools during a 1998 measles “catch-up” vaccination campaign. Both children had symptoms of rash and fever in <24 hours, which resolved. However, one child died 17 days later, the other 21 days later.

**Expert opinion:** Both children must have been incubating measles disease at the time of receiving vaccine, since viral replication due to vaccine could not occur in such a short time. Death in both cases was due to AIDS; receipt of vaccine was coincidental.

Both cases studies are summaries of true events, neither of which occurred in South Africa. In most countries, including South Africa, there is a AEFI reporting and investigation procedure aimed at helping us learn from mistakes.