

Getting Our Point Across

**Immunization Information Resources for Staff in
Ontario Health Units**



**Getting Our Point Across Working Group
January 2001**

A. Foreword

Getting Our Point Across, was the name of a workshop held in Burlington, Ontario on December 17, 1999 and co-sponsored by the Central West Health Units and the Public Health Branch, Ontario Ministry of Health and Long Term Care. The workshop was a starting point for the development of this resource.

Getting Our Point Across, the resource, has been developed to provide condensed, scientific information to the nursing and medical staff in the local Boards of Health. The information was written to help staff respond to inquiries especially about anti-vaccine allegations and to develop training programs and materials.

The goals are to:

- Make available annotated research material to enhance health department staff understanding of the vaccine issues and allegations.
- Provide nursing and medical staff in the health departments with relevant scientific information in a readily accessible format to answer questions about vaccines and current anti-vaccine allegations.
- Promote consistency in response to vaccine questions and concerns across the province.

In a survey in December 1999, specific information was collected about the types of issues facing staff. The general and specific allegations identified from the survey were researched using both standard information sources e.g., (Canadian Immunization Guide, immunization web sites e.g. Health Canada and the Centers for Disease Control) and by Medline searches.

The Getting Our Point Across Working Group included Vaccine-Preventable Diseases Program managers or their designates as well as individuals assigned to the Disease Control Service, Public Health Branch, Ontario Ministry of Health and Long-Term Care. The resource has been researched and written by Donna Mitchell, Ph.D., Health Promotion Consultant; Dr. Rose Bilotta, Community Medicine Resident and Lisa Demaline, Public Health Nurse. The Working Group who focus tested and reviewed the draft documents also included:

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A. FOREWORD	2
1. BACKGROUND.....	6
2. MAKING AN INFORMED CHOICE	10
3. IMMUNIZATIONS AND SCHOOL ATTENDANCE	16
B. GENERAL VACCINE ISSUES	
4. HOW VACCINES WORK.....	19
5. VACCINE SAFETY.....	21
6. VACCINE FAILURE	24
7. VACCINE PRODUCTION.....	25
8. VACCINE EFFICACY.....	27
9. OVERALL SUCCESS OF VACCINES	29
10. VACCINES AND ANAPHYLAXIS	30
11. BABIES NEED TO BE IMMUNIZED.....	31
12. BREASTFEEDING AND IMMUNIZATION.....	32
C. GENERAL ANTI-VACCINE MYTHS	
13. MYTH: VACCINES CAUSE LONG TERM HEALTH PROBLEMS.	33
15. MYTH: VACCINES HAVE DANGEROUS INGREDIENTS.....	37
16. MYTH: VACCINES ARE CONTAMINATED WITH BLOOD.....	40
17. MYTH: VACCINES CAUSE DIABETES.....	41
18. MYTH: VACCINES CAUSE CHRONIC FATIGUE SYNDROME.....	43
19. MYTH: VACCINES WEAKEN THE IMMUNE SYSTEM.....	44
20. MYTH: ALTERNATIVE MEDICINES PROVIDE BETTER AND SAFER PROTECTION THAN VACCINES.....	45
21. MYTH: THERE ARE GREATER RISKS FROM THE VACCINES THAN THE DISEASES.....	47
22. MYTHS: HEALTH UNITS AND GOVERNMENTS COVER UP RISKS AND GIVE BIASED, PRO- VACCINE INFORMATION	49
D. SPECIFIC VACCINE QUESTIONS	
23. MMR VACCINE AND AUTISM.....	51

24. MMR VACCINE AND INFLAMMATORY BOWEL DISEASE (IBD).....	53
25. CAN CHILDREN WITH EGG ALLERGIES HAVE VACCINES?	54
26. DO VACCINES CAUSE SEIZURES/BRAIN DAMAGE?	56
27. DO VACCINES CAUSE SUDDEN INFANT DEATH(SIDS)?	58
28. POLIO VACCINE AND CANCER.....	60
29. WHY DO CHILDREN NEED THE HEP B VACCINE?.....	63
30. DOES THE HEPATITIS B VACCINE CAUSE MULTIPLE SCLEROSIS?.....	65
31. IS HEP B VACCINE MADE FROM BLOOD PRODUCTS?	68
32. IS CHICKENPOX (VARICELLA) VACCINE RECOMMENDED?	69
33. DOES THE INFLUENZA VACCINE CAUSE THE FLU?	72
34. DOES THE FLU VACCINE CAUSE ALZHEIMER'S DISEASE?	74
35. DOES THE FLU VACCINE CAUSE GUILLAIN BARRE SYNDROME (GBS)?.....	76
E. OTHER RESOURCES FOR HEALTH UNIT STAFF	
36. COMMUNICATING RISK TO PARENTS.....	78
37. SUGGESTIONS FOR COMMUNICATING WITH THE ANTI-VACCINATION PARENT*	81
38. RECOMMENDED BOOKS	82
39. IMMUNIZATION WEB SITES.....	83
40. JUDGING THE SOURCE OF YOUR INFORMATION.....	87
41. INDIVIDUALS WHO ADVOCATE AGAINST IMMUNIZATION.....	89

VACCINE ARTICLES

F. GENERAL VACCINE INFORMATION

- Summary of Rules for Childhood Immunization
- Childhood Vaccinations-What Every Parent Should Know.
- Should You Vaccinate Your Child?
- How to Manage Parents Unsure about Immunization.

G. SPECIFIC VACCINE ARTICLES

HEP B

- Multiple sclerosis and the hepatitis B vaccine.
- School-based hepatitis B vaccination programme and adolescent multiple sclerosis.
- Expanded Programme on Immunization: Lack of evidence that hepatitis B vaccine causes multiple sclerosis.

HIB

- Association between type 1 diabetes and Haemophilus influenzae type b vaccination: birth cohort study.
MMR

- Ireland's Measles outbreak kills two.
- Recommendations for using MMR vaccine in children allergic to eggs.
- New research demolishes link between MMR vaccine and autism.
- Autism and measles, mumps, and rubella vaccine: no epidemiological evidence of a causal association.
- A case-control study of measles vaccination and inflammatory bowel disease.

PERTUSSIS

- Marked reduction in Febrile Seizures and Hypotonic-Hyporesponsive Episodes with Acellular Pertussis-Based Vaccines: Results of Canada-Wide Surveillance.
- Cumulative Incidence of Childhood-Onset IDDM is Unaffected by Pertussis Immunization.
- No evidence that vaccines cause insulin dependent diabetes mellitus.

POLIO

- No Link Found Between Contaminated Polio Vaccine and Cancer.
- Contamination of poliovirus vaccines with simian virus 40 (1955-1963) and subsequent cancer rates.
- Simian virus 40, poliovirus vaccines and human cancer: research progress versus media and public interests.

THIMEROSAL

- Thimerosal and Vaccine Public Information: Questions/Answers.
- Notice to Readers: Summary of the Joint Statement on Thimerosal in Vaccines.
- Thimerosal Hyperlinks.

INFLUENZA

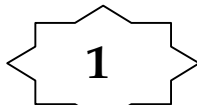
- Citation in Evidence-Based Medicine, September/October 1999: 140 - Effectiveness of influenza vaccine in health care professionals. A randomized control trial.
- Never Get the Flu Again

H. ANTI-VACCINE REBUTTALS AND ARTICLES

- Vaccine Myths from Vaccines.
- Health Consequences of Religious and Philosophical Exemptions From Immunization Laws-Individual and Societal Risk of Measles.
- Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story.
- Anti-immunisation scare: The inconvenient facts.
- Concerns about immunisation.
- Common Questions About Science and "Alternative" Health Methods.
- Physicians may have to "sell" benefits of immunization to skeptical parents.
- It's wise to immunize, regardless of what the Web says.

I. STORIES OF UNPROTECTED PEOPLE <http://www.immunize.org/stories.htm>

Story #2	Parent of child with HBV testifies about importance of hepatitis B vaccination
Story #4	Three fatal varicella cases in unvaccinated young women
Story #5	I awoke one morning unable to walk
Story #8	Five varicella deaths could have been prevented
Story #9	I was at no risk for ever having hepatitis B
Story #10	Pertussis claims the lives of two infants
Story #11	Measles outbreak associated with an unvaccinated population
Story #20	Infant dies of congenital rubella syndrome
Story #22	Infection control nurse urges parents to support US vaccine program
Story #23	Nick- a close call with whooping cough
Story #28	Polio victim entreats parents to say "yes" to vaccines
Story #35	Physician remembers the tragedies of vaccine-preventable disease



1. BACKGROUND

In Ontario, vaccine coverage rates are generally high. However public health staff and community physicians report growing opposition to immunization. One factor is the increasing number of individuals using the Internet to access information, especially health information. Easily accessible anti-vaccine sites make claims that are both sensational and frightening. Some parents call health unit staff to ask about these claims, but others make decisions based solely on the information available on the Internet.

This section includes a brief review of some of the vaccine preventable diseases that have infected and killed people for centuries. Some anti-vaccine issues and allegations received from the Ontario Health units are also reported.

Vaccine Preventable Diseases

Small pox: European explorers brought small pox with them on their voyages causing epidemics of the disease that killed millions of aboriginal people in the Americas. In 1796, an English country doctor named Edward Jenner observed that milkmaids rarely contracted smallpox. He hypothesized that the milkmaids were in some way protected from smallpox through their exposure to a less serious disease of cowpox. Jenner prepared a vaccine from the cowpox sores of milkmaids that provided protection or immunity to small pox. Over the next 200 years, mass immunization programs with the small pox vaccine have led to successful worldwide eradication by 1977. Small pox was declared eradicated in 1980.

Polio: Poliomyelitis, a disease of the nervous system, appears to be thousands of years old. People with polio-like withered limbs were found painted in the tombs from ancient Egypt. In the 1940s and 1950s, polio epidemics occurred throughout North America leaving many children and adults with paralysis, some depending on iron lungs to breathe. The advent of the polio vaccine has eliminated this serious disease in the Americas. However, polio still exists in parts of the world and the World Health Organization and its partners are currently working to stop the transmission of wild virus by the end of the year 2000 and certify eradication by the year 2005.

Pertussis: Pertussis vaccine has been part of the routine Ontario immunization for about 50 years. Pertussis affects all age groups yet is most serious for young babies. Whooping cough can cause brain damage and death in young babies. The whole cell pertussis vaccine, no longer used in Canada, was wrongly accused of being unsafe. In several countries, anti-vaccine groups successfully argued for cessation of pertussis immunization. This resulted in lower immunization coverage rates and increased disease and death.¹

In 1974, infant pertussis coverage in Japan was nearly 80%. There were few cases of pertussis and no deaths. Two infants died within 24 hrs of the Diphtheria, Pertussis, Tetanus (DPT) immunization and in response to alarmists, the Ministry of Health and Welfare eliminated the

¹ Gangarosa EJ et al. Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story. Lancet 1998; 351(9099): 356-361.

pertussis immunization program using the whole cell pertussis vaccine. Coverage rates in 1976 dropped to 10%. In 1979 there were more than 13,000 cases and 41 deaths from pertussis.¹

In 1989, East Germany achieved 95% coverage of DTP vaccine by requiring vaccination. This country had one to two cases of pertussis per 100,000 during 1980-1990. West Germany adopted a non-compulsory immunization policy and had low coverage of approximately 11% with an incidence of pertussis reported at 180 per 100,000, well over 100 times higher than in East Germany.²

Diphtheria: Routine immunization against diphtheria has been used in Canada since 1930. Before the vaccine 9,000 cases were reported in one year in Canada and diphtheria was a common cause of death in children between one and five years. With routine immunizations, the incidence has remained extremely low (1 reported case in 1999) but has not been eradicated.

During the political restructuring in the former USSR, immunization programs became less organized. Diphtheria cases in Russia jumped from 839 in 1989 to 50,000 cases in 1994.

**“Vaccines are among the very safest tools of modern medicine.
Serious side effects are very, very rare.”³**

Health Unit Reports of Anti-Vaccine Activity

In December 1999, a telephone survey was developed to assess the issues and needs facing the vaccine preventable disease (VPD) staff in the health units across Ontario. Interviews were conducted with VPD managers or their designates from all thirty-seven health units. The VPD managers identified supports that might help them better inform parents about the safety and effectiveness of immunizations.

Thirty health units (81%) reported the presence of individuals or groups in their region who are advocating against immunization. Most commonly, respondents reported that these individuals or groups raised questions and were vocal about serious adverse effects attributed to the vaccinations and usually stated that vaccinations weren't necessary.

Anti-immunization messages were usually given 'person to person' or in newspaper articles. Some individuals were receiving information at chiropractors' offices or in health food stores.

Myths commonly reported

VPD managers/staff reported that the most common myths were:

- that vaccines cause harmful side effects,
- that vaccines hurt the immune system and
- that vaccines aren't necessary since the diseases they protect against are gone or very rare.

² Gangarosa EJ et al. Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story. Lancet, 1998; 351(9099): 357.

³ Report of the Chief Medical Officer of Health, Immunization, The Next Steps. Queen's Printer for Ontario, 1995: 3.

See Table 1.

Table 1 General anti-vaccine messages *

<ul style="list-style-type: none"> • Vaccines cause serious adverse effects - cause serious irreparable harm. • Vaccines aren't safe (general message). • Vaccines aren't necessary. The diseases are gone. • Parents shouldn't put toxic/poisonous substances into their children. • Health Units and Government give biased, pro-vaccine information and cover up risks. • Vaccines weaken the immune system. • Natural medicines provide 'natural' protection. • There are greater risks from the vaccines than from having the illnesses. <p style="text-align: right;"><i>* in descending order of frequency of response</i></p>

Other specific **myths** were also reported:

- Flu vaccine causes the flu.
- Polio vaccine causes cancer.
- Pertussis vaccine causes brain damage.
- Kids with egg allergies can not have Measles, Mumps, Rubella (MMR) or Hepatitis B.
- Hepatitis B vaccine causes chronic fatigue or Multiple Sclerosis.
- Flu vaccine causes Alzheimer's.
- Childhood vaccines cause Sudden Infant Death (SIDS), diabetes, autism, hyperactivity, brain dysfunction, mental and muscular disabilities.
- Hepatitis B vaccine is made from blood products.

Although most VPD managers reported the presence of an anti-immunization group or individual, few felt that their impact was significant at this time. Eight health units reported that the anti-immunization effects were starting to be seen.

When asked about the future impact of the anti-immunization groups, nineteen VPD managers (51%) thought that the impact of anti-immunization groups would be greater in the future than at the present time. Nine (24%) felt the impact would be about the same as it is today, whereas 16% stated they were not sure. None felt the impact would be less than it is now.

Early Tracking Data of Philosophic/Religious Exemptions

From the Immunization Record Information System (IRIS) database, 3 birth cohorts were analyzed for number of philosophic/religious (P/R) exemptions at age 5, age 8 and age 17. The hypothesis is that if the anti-vaccine efforts were having an impact, the proportion of exemptions in a given age group would have increased over time. For example, more 5-year-olds today would have exemptions than the 8-year old cohort or the 17-year old cohort when they were 5 years old. The tracking was done using the diphtheria vaccine.

The preliminary results show that although the absolute numbers of exemptions are small (range 150-775 exemptions), the percentages differ significantly across the different cohorts (see Table 2).

There were more exemptions recorded in the cohort of children who were currently 5 years old than in the cohorts who were 5 years old in 1996/97 or those who were 5 years old in 1987/88.

At the age 5 data entry point:

- The current 5 year olds had 524 (0.4%) exemptions.
- The current 8 year olds with 526 (0.36%) exemptions.
- The current 17 year olds with 150 (0.11%) exemptions.

This increasing trend is statistically significant although there are several limitations in interpreting the data. The data is from cohorts who may differ in composition e.g., number of foreign born who may have a greater number of religious exemptions. The accuracy of IRIS tracking and data management is also a limitation. However, this trend will be investigated further.

	Size of cohort	# with P/R* exemption			% with P/R* exemption		
		At age 5	at age 8	at age 17	At age 5	at age 8	at age 17
5 year olds	129855	524			0.4		
8 year olds	144788	526	775		0.36	0.54	
17 year olds	131552	150	220	632	0.11	0.17	0.48

*P/R (Philosophic or religious exemption) *Source: IRIS live database, MOHLTC, 2000*

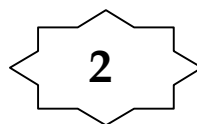
Summary

The major anti-immunization message is that vaccines are not safe. Efforts are made to attribute a list of serious long-term effects to vaccines including SIDS, autism, MS, cancer, learning disorders and violent behavior. Allegations link vaccines to illnesses that have poorly understood etiologies. Findings from single, non-reproducible studies or anecdotal reports are used to support the claims. At times, names of medical doctors and researchers are associated with the allegation, adding credibility. Anti-vaccine web based sites frequently share personal stories and pictures of children who reportedly have suffered as a result of immunization. These sites appeal to parents' desires to protect their children and keep them safe.

With the concerns being raised, it is essential that health professionals keep in mind the number of lives being saved by immunization.

"Immunization against infectious diseases is a cornerstone of public health - in the past, now and into the future."⁴

⁴ Report of the Chief Medical Officer of Health, Immunization, The Next Steps. Queen's Printer for Ontario, 1995: 17.



2. MAKING AN INFORMED CHOICE⁵

- The viruses and bacteria causing vaccine preventable diseases still exist with the exception of small pox, which is considered eradicated.
- Without vaccines, epidemics of vaccine preventable diseases would again occur, causing increased illness, disability and death.
- Vaccine preventable diseases can have serious long-term effects and even death.

Comparison of effects of diseases and vaccines⁶

Incidence Before Vaccination	Disease Incidence After Vaccination	Effects of Disease	Side Effects of Vaccine
<p>Polio Spread by feces and saliva. Incubation: 1-2 weeks. Infection may lead to fever, headache, nausea and vomiting, muscle weakness and paralysis.</p> <p>Range 2.5 - 28.3 /100,000. Epidemic years had up to 20,000 cases of paralytic disease.</p>	<p>Indigenous disease eradicated from the Americas. Still endemic in other parts of the world. In 1988 > 35,000 cases; in 1999 < 6,000 cases worldwide.</p>	<p>1% of infections have paralysis, but about 1 in 20 hospitalized patients die and 50% of survivors remain paralyzed for life.</p>	<p>IPV used in Canada so vaccine-associated polio, though very rare, is no longer a risk. Local discomfort or inflammation in 5% of recipients. – see side effects of DTaP vaccine below for combination use.</p>
<p>Diphtheria Spread by nasal droplets. Incubation: 2-5 days. Infection leads to severe pharyngitis and cervical adenopathy. Patient is infectious for up to 2 weeks.</p> <p>Highest in 1924 with 9,000 cases that year.</p>	<p>Now 2-5 reported cases per year, none reported in 1996.</p>	<p>Case fatality rate 5-10%. Toxin may lead to myocardial and neurologic complications.</p>	<p>DTaP vaccine – about 20% have local discomfort or inflammation, 5% have fever. A transient nodule may develop at the injection site, lasting a few weeks. Up to 70% at the 4-6 yr booster develop redness and swelling.</p>

⁵ Excellent reproduceable resources can be found at: www.immunize.org. See: What would happen if we stopped vaccinations? Part II, Needle Tips, Spring/summer 2000: 15-16.

⁶ Adapted from http://www.hc-sc.gc.ca/hpb/lcdc/publicat/immguide/comp_e.html

Disease Incidence Before Vaccination	Disease Incidence After Vaccination	Effects of Disease	Side effects of Vaccine
Pertussis			
Spread by cough and nasal droplets. Incubation: 7-10 days. Symptoms include runny nose and irritating cough, which may develop into chronic cough with characteristic whoop.			
Average 153 /100,000.	Average 10 /100,000.	About 1% case fatality in patients under 6 months, from pneumonia or fatal encephalopathy (usually hypoxic). Several deaths still occur every year, particularly in unimmunized infants.	See above – side effects of DTaP vaccine. Rate of reactions to acellular pertussis vaccine is less than with whole cell.
Hib			
Spread by nasal droplets. Incubation: 2-4 days. Presents as an acute illness with fever, vomiting, and lethargy (symptoms of meningitis) in 55-65%. In the remainder, it can also cause epiglottitis, pneumonia, bacteremia and other complications.			
Leading cause of bacterial meningitis in infancy. About 2,000 cases per year.	Only anecdotal cases now being reported, less than 60 cases per year since 1992.	Case fatality of meningitis is 5% (10-15% of survivors have permanent neurologic sequelae and 15-20% have deafness).	5% have discomfort or local inflammation, 2% have fever. Usually given in combination with DTaP (see above – side effects of DTaP vaccine).
Measles			
Spread by cough and nasal droplets. Incubation: 1-2 weeks. Symptoms include fever, sore throat, cough, runny nose, itchy eyes and a red rash that starts on the face and spreads to the rest of the body.			
Cyclic with increasing incidence every 2-3 years. About 300,000 to 400,000 cases per year estimated.	Recent outbreaks with 11,000 cases (1989) and 2,300 (1995). With 2 dose schedule, now less than 400 cases per year.	Complications such as bronchopneumonia and otitis media in about 10%. 1/1,000 encephalitis (case fatality 10%, permanent sequelae 25%). 1/25,000 develops SSPE.	5-10% have discomfort, local inflammation or fever with or without a non-infectious rash. 1 in 1 million recipients develop encephalitis. About 1 in 24,000 develop transient thrombocytopenia.
Mumps			
Spread by saliva. Incubation: 2-3 weeks. Symptoms include fever and parotitis.			
Highest in 1942 with 52,344 cases. Average incidence 136 /100,000.	Average incidence 2.35 /100,000, or about 500 cases annually.	1/ 200 children develops encephalitis. 20-30% of post-pubertal males develop orchitis, 5% of females develop oophoritis. Occasionally, mumps causes infertility or deafness.	Fever and a mild skin rash occasionally occurs. 1% of recipients may develop parotitis. 1 in 3 million recipients may develop aseptic meningitis.
Rubella			
Spread by nasal droplets. Incubation: 2-3 weeks. Symptoms include fever, headache, itchy eyes, cervical adenopathy and rash.			
Highest in 1936 with 69,401 cases. Average 149 /100,000.	Average of 8.5 /100,000. About 2,000 cases reported annually.	50% develop a rash and adenopathy; 50% of adolescents and adults have acute arthralgias or arthritis; 1/6,000 develops an encephalopathy. Infections in the first 10 weeks of pregnancy have an 85% risk of CRS.	About 10% have discomfort, local inflammation or fever. About 5% have swollen glands, stiff neck or joint pains. About 1% develop a noninfectious rash. Transient arthralgias or arthritis may occur, more in post-pubertal females.

Adapted from the Canadian Immunization Guide, Fifth Edition, 1998

Vaccines Past and Present

A look at the history of some vaccine preventable diseases highlights what could happen if we stopped immunizing.

DPT

Diphtheria

Symptoms: Disease involving primarily tonsils, pharynx, larynx, nose and other mucous membranes. Marked patch or patches of adherent grayish membrane with surrounding inflammation. May include moderately sore throat, with enlarged and tender cervical lymph nodes.⁷

Complications: Can cause death by suffocation. The diphtheria toxins can damage the heart. About 10% of people infected with diphtheria die.⁸

Prevaccine: In the 1920's about 1,000 deaths occurred each year in Canada, and before 1900 diphtheria was one of the main causes of death in children.

Today: Fewer than 5 cases were reported in Canada with no deaths.

N.B. With a decrease in diphtheria immunization in the former Soviet Union, diphtheria rose from 839 cases in 1989 to 50,000 in 1994 with 1,700 deaths occurring.⁸

Pertussis

Symptoms: Respiratory tract symptoms with initial catarrhal stage followed by irritating cough lasting for 1-2 months. Cough can be followed by characteristic crowing or high pitched inspiratory whoop.⁷ The prolonged coughing and vomiting spells can cause problems with eating, drinking and breathing.

Complications: Pneumonia, brain damage, seizures and developmental delays.

Prevaccine: Most deaths from pertussis (whooping cough) occurred in infants less than 12 months old.⁹

Today: new "acellular" pertussis vaccine was introduced in Canada in 1997. Preliminary results of a large Canadian study¹⁰ show substantial improvement in vaccine safety, indicated by 87% fewer febrile seizures and 75% less fainting post vaccine administration.

However vaccine coverage remains lower than desired (Ontario average coverage for 1997 was 80.3% with 1998 provincial incidence of 17 cases per 100,000.) New concerns have been raised about adults who received immunity to pertussis through the vaccine, but may now be susceptible to pertussis infection and risk passing this highly contagious virus to young children.

N.B. The "whole cell" vaccine used in Canada until 1997 caused side effects including fever, fussiness, crying, and drowsiness. Strong anti-vaccine reaction to the whole cell pertussis

⁷ Benenson, AS (Ed.) Control of Communicable Diseases Manual 16th Edition, APHA; 1995: 150; 347.

⁸ CIAP web site: www.ciap.cpha.ca/resource/keydis/page3.htm

⁹ Canadian Immunization Guide, 1998: 19.

¹⁰ Scheifele DW et al. Marked reduction in febrile seizures and hypotonic-hyporesponsive episodes with acellular pertussis-based vaccines: results of Canada-wide surveillance, 1993-1998. The Infectious Disease Society of America Conference, November 1999.

vaccine contributed to decreases in vaccine use followed by outbreaks and many related deaths in Sweden, Japan and the United Kingdom in the 1980's.¹¹

Tetanus:

Symptoms: Tetanus toxins block normal control of nerve reflexes in the spinal column causing painful muscular contractions primarily of the masseter and neck muscles, secondarily of trunk muscles. **Complications:** Even with treatment, a severe disease, with case fatality of 10-20%.

Prevaccine: Vaccine has been available since 1940's.

Today: Since 1982, fewer than 2 cases were reported per year in Canada.¹²

Polio:

Symptoms: Causes acute paralysis, disability, and death. Attacks cells in the spinal cord and brain stem. Arms and legs are most commonly involved.

Complications: When nerves are destroyed, muscles atrophy.

Prevaccine: In 1959 nearly 2,000 cases of paralytic polio in Canada (often children) with most left with lifelong disability.¹³

Today: Worldwide eradication is close, but 'wild' cases are still brought into Canada through travel. Most recent is an outbreak of poliomyelitis in the Dominican Republic and Haiti of an unusual derivative of the Sabin type 1 oral polio vaccine in areas of low vaccine coverage.

Haemophilus influenza Type b: (Hib)

Symptoms: Usually sudden fever, vomiting, lethargy and meningeal irritation, with bulging fontanelle in infants or stiff neck and back in older children. Progressive stupor or coma.¹⁴ Hib was the most common cause of bacterial meningitis and a leading cause of serious infections in young children until 1988.

Complications: Pneumonia and epiglottitis (swelling in the throat which effects the ability to breathe), as well as deafness, seizures, and developmental delays.

Prevaccine: About 2,000 cases occurred a year, many causing life threatening meningitis, and about 100 deaths per year.

Today: Hib vaccine was introduced in 1988 and there were only 3 cases in Ontario in 1999.

MMR

Measles:

Symptoms: Prodromal fever, conjunctivitis, coryza, cough and Koplik spots on the buccal mucosa with red blotchy rash on the third to seventh day. Highly contagious.¹⁴

Complications: Otitis media and bronchopneumonia in about 10% of reported cases. Measles encephalitis occurs approximately 1 of every 1,000 reported cases and may result in permanent brain damage. Prior measles infections are associated with subacute sclerosing panencephalitis (SSPE), a rare but fatal disease.¹⁵

¹¹ Gangarosa EJ et al. Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story. Lancet, 1998; 351(9099): 356-361.

¹² CIAP web site: www.ciap.cpha.ca/resource/keydis/page6.htm

¹³ Canadian Immunization Guide, 1998: 44.

¹⁴ Benenson, AS (Ed.) Control of Communicable Diseases Manual 16th Edition, APHA; 1995: 308; 293.

¹⁵ Canadian Immunization Guide, 1998: 118.

Prevaccine: Most Canadians were exposed to measles— about 80,000 cases a year or over 300,000 during an epidemic year. Measles were responsible for between 50-75 deaths each year in Canada.¹⁶

About 1 million children die each year from measles infection worldwide.¹⁷

Between 1989 and 1995 several large outbreaks occurred in children and young adults who had received 1 dose of measles vaccine. With a 90% efficacy rate, the single dose still allowed the circulation of the virus. In 1996-97 a two-dose measles vaccine schedule was implemented.

Today: In Ontario over 2,000 cases of measles were reported in 1995, but as a result of increased immunization, only 2 cases were reported in 1999.¹⁸

Mumps:

Symptoms: Fever, swelling and tenderness of one or more salivary glands, usually the parotid and sometimes the sublingual or submaxillary glands.¹⁹ Usually a mild disease.

Complications: Orchitis, usually unilateral occurs in 20-30% of postpubertal males and oophoritis in about 5% of postpubertal females. Sterility is an extremely rare sequel. About 10% of people infected with mumps can get meningitis. A small proportion (1-2 of 10,000) can get encephalitis, leading to permanent brain damage.^{19,20}

Today: Cases of mumps have decreased by 90%, and mumps encephalitis has virtually disappeared in countries with effective vaccination programs.²¹

Rubella (German Measles):

Symptoms: Usually a mild febrile illness with a diffuse punctate and maculopapular rash sometimes resembling measles or scarlet fever.¹⁹

Complications: Devastating effect on growing fetuses. Up to 90% of babies born to mothers who had rubella during their first trimester of pregnancy develops **congenital rubella syndrome (CRS)** which results in severe disabilities for the infant including heart defects, cataracts (on eyes), developmental delays and deafness.

Prevaccine: In the US, approximately 2000 babies were born with CRS during non-epidemic years²².

Today: Number of CRS babies ranges from 4-8 per year in Canada.

Hepatitis B Vaccine (HBV)

Hepatitis B:

Symptoms: About half of infected people develop a variety of symptoms including weakness, lack of appetite, aches and jaundice. Some recover completely.

¹⁶ Canadian Pediatric Society. Your Child's Best Shot; 1997: 64.

¹⁷ WHO, Vaccine and immunization information from gpv, global programme for vaccines and immunization Wednesday, July 20, 2000 (16:09) url: <http://www.who.int/vaccines-diseases/research/virus1.htm>

¹⁸ Varughese P. Current Status of Measles in Canada: Provisional Report (as of Dec 10, 1999), Update: Vaccine Preventable Diseases 7 (3) Dec 1999/January 2000.

¹⁹ Benenson, AS (Ed.) Control of Communicable Diseases Manual 16th Edition, APHA; 1995: 315; 405; 87.

²⁰ Canadian Pediatric Society. Your Child's Best Shot, 1997: 77.

²¹ CIAP web site: www.ciap.cpha.ca

²² Canadian Pediatric Society, Your Child's Best Shot, 1997: 86.

Complications: 90-95% of infants, 25-50% of children and 6-10% of adults develop chronic infection that can cause cirrhosis and death from liver failure after 15-30 years in 15-20% of those chronically infected.²³

Prevaccine: An estimated 20,000 new infections occurred in Canada each year.

Today: Universal vaccine programs are too new to know the impact on the rate of chronic infection.²¹

Varicella Vaccine

Chickenpox or Varicella:

Symptoms: Sudden onset of slight fever, mild constitutional symptoms and skin eruptions for 3-4 days that leave granular scabs. More abundant in covered areas of the body.¹⁹ Is usually a mild, highly contagious disease caused by the varicella zoster virus (VZV).

Complications: can be life threatening to immunocompromised children, term infants born to women who had onset of varicella rash within 4 days before delivery and among individuals 20 years of age or older. VZV has been linked to group A streptococcus infection. The latent virus can cause zoster or "shingles".

Vaccine is available but is not yet publicly funded.

Influenza vaccine

Influenza:

Symptoms: Abrupt onset of fever, sore throat, nonproductive cough, and extreme malaise lasting several days. More severe disease can result if the influenza virus invades the lungs (primary viral pneumonia) or if secondary bacterial pneumonia occurs.

Complications: High risk individuals (e.g. elderly, immunocompromised or those with chronic diseases such as diabetes, heart disease etc.) have a higher incidence of hospitalization and death from pneumonia. Cardiopulmonary or other chronic diseases may be exacerbated by influenza infection leading to hospitalization and death.

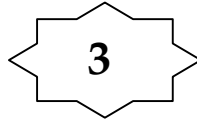
Postvaccine: The vaccine is 70-90% effective in healthy adults and vaccination of health care workers has been shown to reduce morbidity and mortality in residents of long-term care facilities. The influenza vaccine is 50-60% effective in preventing hospitalization and pneumonia and 85% effective in preventing death in elderly persons in nursing homes.^{24, 25, 26}

²³ Canadian Immunization Guide, 1998: 90.

²⁴ NACI. Statement on Influenza Vaccination for the 2000-2001 Season, CCDR, June 2000 (26):9.

²⁵ Carman WF et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial. Lancet Jan 8 2000; 355: 93-97.

²⁶ Potter JM et al. Influenza vaccination of health care workers in long-term-care hospitals reduces the mortality of elderly patients. Journal of Infectious Diseases 1997; 175: 1-6.



3. IMMUNIZATIONS AND SCHOOL ATTENDANCE

History

Vaccines are available for a number of diseases including measles, mumps, rubella, tetanus, diphtheria, poliomyelitis, pertussis and haemophilus influenza type b. In unvaccinated people, these diseases cause disability and death. The higher the number of unvaccinated people in the population, the greater the risk of exposure to these dangerous diseases.

The World Health Organization (WHO) declared global eradication of smallpox in May of 1980 due to successful vaccination. Since immunization is an effective health measure, it is important that parents ensure children are up to date with their immunizations or have thought very seriously about the risks of not immunizing.

Young children in group settings such as day cares or school are at increased risk of becoming infected with communicable diseases. In Ontario, the **Day Nurseries Act (DNA) of 1990** requires operators of licensed day nurseries to ensure that children, who are attending, are immunized as recommended by the local Medical Officer of Health (Section 33 (1) and Section 62 (3)). All children attending school in Ontario must meet one of the requirements set out in the **Immunization of School Pupils Act (IPSA) of 1990**.

REQUIREMENTS UNDER IMMUNIZATION OF SCHOOL PUPILS ACT (ISPA), 1990 (Section 3).

Parents of school pupils are responsible to provide documentation indicating that one of the following requirements has been met:

- i. *The child's immunizations are up to date according to the immunization schedule.*
 - A signed physician statement indicating that the pupil has completed the prescribed program of immunization is required. (Sect. 6.2.a.i)

OR

- ii. *Medical reasons exist for which immunization of their child is not recommended. (Statement of Medical Exemption - Form 1)*
 - A physician statement that the immunization is unnecessary by reason of past infection or laboratory evidence of immunity. (Sect.12.2.b.ii) Form 1 requires the physician to explain the contra-indications detrimental to health.

OR

- iii. *Due to reasons of religion or conscience, the parents have chosen not to have their child immunized. (Statement of Conscious or Religious Belief -- Form 2)*
 - Parents must provide a signed affidavit that immunization is against their conscience or religious belief and file this statement with the proper Medical Officer of Health (Sect. 3.3).
 - Persons authorized to sign affidavits, under the Commissioners for taking Affidavits Act (Revised 1990) include:

In Ontario: (Sect. 1.(1))

- * Member of the Assembly
- * Provincial judges or justices of the peace
- * Barristers and solicitors entitled to practice law in Ontario

Local municipality: (Sect. 1.(2))

- * Medical Officer of Health (area with population > 100,000)
- * Administrative heads (building standards, welfare, assessment or planning)
- * Clerks, deputy clerks and treasurers of local municipalities
- * Heads of municipal councils, reeves of towns, deputy reeves, members of city council.

What if a parent chooses not to immunize a child in school?

If a child is not appropriately immunized and has not provided documentation of meeting one of the three requirements under the Immunization of School Pupils Act of 1990, the Medical Officer of Health may require the school to suspend that child in the event of an outbreak, until the circumstances for making the order no longer exist. (IPSA, 1990, Section 6 & 9)

Parents who refuse to have their child immunized, and do not meet requirement ii or iii, are guilty of an offence and on conviction are liable to a fine to a maximum of \$1,000. (IPSA, 1990, Section 4)

If the child meets requirements ii or iii, parents should understand the future consequences:

- **HEALTH**

If exposed to the disease, the child is at increased risk of becoming very ill, which may result in disability or death. A population-based, retrospective cohort study of data from 1985 to 1992, in individuals aged 5 to 19 years, showed that non-immunized individuals were 35 times more likely to contract measles than those who were vaccinated.²⁷

- **SCHOOL**

If an outbreak or threat of outbreak of any of the vaccine preventable diseases exists, non-immune students may be excluded from school by an order written by the Medical Officer of Health. (Sect. 12.1.) The order remains in force until rescinded in writing by the Medical Officer of Health (Sect. 12.3), when he/she is satisfied that the outbreak or the immediate risk of the outbreak of the designated disease has ended (Sect. 12.4).

²⁷ Salmon D et al. Health Consequences of Religious and Philosophical Exemptions From Immunization Laws: Individual and Societal Risk of Measles. *Journal of the American Medical Association* July 1999; 282(1): 47-53.

REQUIREMENTS UNDER THE DAY NURSERIES ACT (1990, Section 33 (2))

If childhood immunization is refused:

- A parent must indicate in writing that they object to the immunization on the ground that it conflicts with the sincerely held convictions of the parent's religion or conscience.

OR

- A legally qualified medical practitioner gives medical reasons in writing to the operator as to why the child should not be immunized.

The Medical Officer of Health, under the Health Promotion and Protection Act (Section 22) can order the exclusion of a child from a day/nursery setting if an outbreak or threat of an outbreak exist.

Immunization Schedule

Recommended immunizations begin at 2 months of age to protect infants from illnesses that can be very serious for them. The following is the recommended schedule for children.

AGE	Pertussis	Diphtheria	Tetanus	Polio	HIB	Measles	Mumps	Rubella
2 months	✓	✓	✓	✓	✓			
4 months	✓	✓	✓	✓	✓			
6 months	✓	✓	✓	✓	✓			
12 months						✓	✓	✓
18 months	✓	✓	✓	✓	✓			
4-6 years	✓	✓	✓	✓		✓	✓	✓
14-16 years		✓	✓	✓				
Every 10 years		✓	✓					



4. HOW VACCINES WORK

- Vaccines work with a person's active immune system to create antibodies and memory cells that target the weakened or killed viruses or bacteria or their parts found in the vaccine.
- These modified viruses or bacteria are unable to cause the full disease but produce a faster immune response if the body should come in contact with the actual disease.
- Immunization works at two levels. It protects the individual who receives the vaccine from the specific disease and when large numbers of people are immunized produces a reduction of the incidence of the disease - a 'herd immunity'.²⁸

What is immunity?²⁹

- The immune system helps protect the body against infection by making disease fighting antibodies.
- The immune system consists of a non-specific system that includes macrophages, neutrophils and natural killer cells and a specific immune system with B lymphocytes, T lymphocytes, and antigen-presenting cells.
- The specific immune system takes several days or longer to respond to a germ invading for the first time but responds more quickly and powerfully the next time it recognizes the germ. This mechanism occurs by the immune system creating B and T memory cells.
- Some B lymphocytes become plasma cells that produce antibodies which attach to invading germs and mark them for destruction by other immune cells.
- Antibodies are specific. For example, the antibodies for pertussis will not protect against the rubella virus.
- Vaccines work with the immune system to alert the body to specific diseases.
- When a vaccine is given, the body makes antibodies to fight the weak, dead or partial germs contained in the vaccines. Also the body creates the memory to recognize and destroy the wild (and much more powerful) disease causing germs when they enter the body.
- The length of time the vaccine protects the body varies with different vaccines. This is why some vaccines are given more than once or require regular boosters to maintain protection.

Do mothers pass immunity to their babies?

- A second type of immunity is *passive immunity* such as when newborn babies receive some immunity from their mothers. Some antibodies are passed from the mother to the baby before birth and may last for the first year of life. The immunization schedule recommends that the

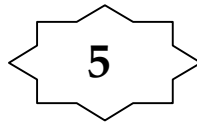
²⁸ Fox JP et al. Herd Immunity: Basic Concept and Relevance to Public Health Immunisation Practices. American Journal of Epidemiology 1971; 94 (3): 179-89.

²⁹ Humiston SG, Good C. Vaccinating your child, questions and answers for concerned parents. Peachtree Publishers, Atlanta; 2000: 17.

first measles vaccine should be given on or after the child's first birthday. This allows time for the maternal antibodies to decrease and not interfere with the baby's antibody production.³⁰

- For some diseases, immunity is not received from the mother. It is important to protect babies early in life against diseases such as diphtheria, pertussis, polio, tetanus and haemophilus b, because these diseases are very dangerous to non-immune babies. Vaccination is the best way to provide this protection.

³⁰ Recommendations of the Advisory Committee on Immunization Practices. Measles, mumps and rubella- vaccine use and strategies for elimination of measles, rubella and congenital rubella syndrome and control of mumps. MMWR, 22 May 1998 47RR-8); 1-57.



5. VACCINE SAFETY

Vaccine safety is extremely important and is taken very seriously because unlike other medications, vaccines are given to healthy children to prevent illness.

- The vaccines used in Ontario today are extremely safe, but may cause reactions with a small number of people.
- Most adverse events associated with vaccines are minor and transient, like a sore arm or fever.
- More serious adverse vaccine events like a hypotonic response or excessive crying are reported in:
 - 1 in 1000 - to 1 in a million doses.
 - Severe neurological events are so rare that rates can not be determined.³¹
- Vaccines are blamed for conditions that are poorly understood and are most common in the first year of life. *Example:* Sudden Infant Death (SIDS) happens most frequently in the first 6 months of life during the time babies receive 3 vaccinations. By chance alone, a child may die of SIDS following a vaccination.³¹ Research has shown no increased incidence of SIDS with vaccinated babies.^{32, 33}
- Vaccines are changed when safer ones are tested and found effective.
 - Example:* The old pertussis vaccine included in the DTP vaccine protected children but especially babies from the serious effects of whooping cough. About 50% of children had a low fever or soreness at the needle site. A small number had high fever, seizures and persistent crying.³⁴ In 1997 the improved acellular pertussis vaccine was recommended for use. These vaccines were effective in producing the immune response³⁵ while having significantly fewer reactions indicated by 87% fewer febrile seizures and 75% less fainting post vaccines.³⁶
- Many vaccines have been used for decades with no evidence of long-term adverse effects. Ongoing vaccine testing and monitoring, using advancing research techniques are continuing.³⁷

³¹ Canadian Immunization Guide, Health Canada, 1998: 39, 41.

³² Advisory Committee on Immunization Practices. Update: vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions Morbidity Mortality Weekly Report 1996; 45 (RR-12): 1-35.

³³ Griffin MR et al. Risk of Sudden Infant Death Syndrome after Immunization with the Diphtheria-Tetanus-Pertussis Vaccine. New England Medical Journal 1988; 319: 618-23.

³⁴ Offit PA, Bell LM. Vaccines: What every parent should know. IDG Books, NY, 1999: 37-8.

³⁵ Canadian Immunization Guide, Health Canada, 1998: 134.

³⁶ Scheifele DW et al. Marked Reduction in Febrile Seizures (FSz) and Hypotonic-Hyporesponsive Episodes (HHE) With Acellular Pertussis-Based Vaccines. Results of Canada-Wide Surveillance, 1993-1998. The Infectious Disease Society of America Conference, November 1999.

³⁷ Chen RT et al. Safety of Routine Childhood Vaccinations, An Epidemiological Review; Paediatric Drugs 2000 Jul-Aug; 2 (4): 273-290.

Vaccine testing and monitoring

- Vaccines go through a series of tests before they are approved for use. Before any vaccine is approved for use in Canada, it must be shown to be safe and effective in preventing the disease that it targets.³⁸
- The Bureau of Biologics of Health Canada regulates all vaccines for humans. The Bureau supervises and inspects the manufacturers of vaccines to ensure that all the requirements for safety, sterility and quality control are met.³⁸
- The Bureau establishes the tests to evaluate the safety of each batch of vaccine and both the manufacturer and the laboratory of the Bureau do most safety tests.
- All batches of vaccine must pass the safety and potency (ability of the vaccine to produce the immune response) tests before they are released.
- In Canada, Immunization Division of Health Canada coordinates postmarketing surveillance of vaccine adverse events. Physicians and public health nurses report adverse reactions occurring after vaccination to the local health department. These reports are investigated by the local Medical Officer of Health, then forwarded to the provincial ministry of health and then to Health Canada.³⁸
- IMPACT (Immunization Monitoring Program, Active) is a unique program to detect severe adverse events related to vaccination. Nurses at each of 11 children's hospitals across Canada review all admissions to hospital for illnesses that may be related to vaccination including seizures, encephalitis, encephalopathy and acute paralysis. Each year nurses screen more than 90,000 children admitted to these hospitals. Since 1990, when IMPACT first started, there have been no cases of encephalitis, encephalopathy or acute paralysis related to vaccines. Some seizures have been detected following vaccination.³⁸
- The Advisory Committee on Causality Assessment reviews all severe adverse events following vaccination. The group of medical experts meet for 4 days each year to review all serious cases to determine whether the adverse event was related, possibly related, unlikely to have been related or unrelated to the implicated vaccine.³⁸
- Monitoring of vaccine safety is an ongoing international process³⁹. Researchers in many countries⁴⁰ continually monitor vaccine safety and effectiveness through surveillance systems and research studies.

Comparisons of risk

- By choosing to avoid the minimal risks associated with vaccines, parents may place their children at the very real risks of catching the vaccine preventable diseases.
- The following chart shows the risks of serious side effects from the diseases and from the vaccines.

³⁸ Canadian Pediatric Society, Your Child's Best Shot, A parent's guide to vaccination, 1997: 8-10.

³⁹ Scholtz M, Duclos P. Immunization safety: a global priority. Bulletin of the World Health Organization, 2000; 78(2): 153-154.

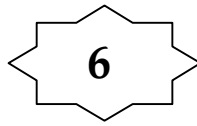
⁴⁰ See Chen RT, Hibbs B. Vaccine Safety: Current and Future Challenges, Pediatric Annals, July 1998;27 (7): 445-455 also at <http://www.cdc.gov/nip/vacsafe/research/peds.htm>

Risks from Diseases vs. Risks from Vaccines⁴¹

Risks of serious side effects from DISEASES	Risks of serious side effects from VACCINES
<p>Measles Pneumonia: 1 in 20 Encephalitis: 1 in 2,000 Death: 1 in 3,000</p> <p>Mumps Encephalitis: 1 in 300</p> <p>Rubella Congenital Rubella Syndrome: 1 in 4 (if woman becomes infected early in pregnancy)</p>	<p>MMR Encephalitis or severe allergic reaction: 1 in 1,000,000</p>
<p>Diphtheria Death: 1 in 20</p> <p>Tetanus Death: 3 in 100</p> <p>Pertussis Pneumonia: 1 in 8 Encephalitis: 1 in 20 Death: 1 in 200</p>	<p>DTP Continuous crying, then full recovery: 1 in 100</p> <p>Convulsions or shock, then full recovery: 1 in 1,750</p> <p>Acute encephalopathy: 0-10.5 in 1,000,000</p> <p>Death: None proven</p>

NOTE: Please see the index for listings of specific vaccine allegations.

⁴¹ National Immunization Program. Six Common Misconceptions about Vaccines and how to respond to them. CDC web site, www.cdc.gov/nip/publications/6mishome.htm

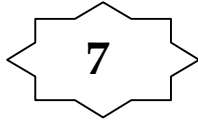


6. VACCINE FAILURE

- One claim made by anti vaccination groups is that *most* people who get vaccine preventable diseases have been vaccinated. **This statement is not correct.**
- No vaccine provides 100% immunity. Most have tested efficacy at about 90%.⁴² This means that for every 100 people who receive the vaccine, 90 will become protected from the disease.
- There are individual differences, but childhood vaccinations protect most children during an outbreak of the disease.
- Although immunized children can develop the infection, their risk is much reduced. A recent study of a measles outbreak in Quebec City showed that very few vaccinated children (9%) developed measles during an outbreak whereas all (100%) unvaccinated children developed measles. In terms of numbers, 41 or 66% of the children who developed measles were immunized. However, comparing groups of vaccinated and unvaccinated for measles, the attack rate for immunized children was 9%, compared to an attack rate of 100% for unimmunized children.⁴³
- Because of successful immunization programs, most children in Canada are vaccinated. During an outbreak, there may be a greater **number** of vaccinated children with the disease than the number of unvaccinated with the disease. It may appear that vaccinated children are not protected. However, because most children are vaccinated, even the small percentage that do not receive immunity from a vaccine may outnumber those who were never vaccinated.
- By increasing the number of children who are actually immunized, a community also decreases the opportunities for disease to be transmitted to those who did not become immune and for the small number who cannot be immunized for medical reasons.

⁴² Canadian Pediatric Society. Your Child's Best Shot, 1997: 121.

⁴³ De Serres G et al. Measles vaccine efficacy during an outbreak in a highly vaccinated population: incremental increase in protection with age at vaccination up to 18 months. *Epidemiol Infect* 1995;115:315-23.



7. VACCINE PRODUCTION

There are 2 main types of vaccines: live and inactivated.⁴⁴

- To make live vaccines, the specific virus or bacteria is grown in a controlled laboratory setting, then weakened for the vaccine. Inactivated vaccines consist of whole microbes that have been killed by heat or chemicals.
- Live vaccines are weakened so they will not cause the disease, but do produce the memory cells to recognize the wild disease if it enters the body at a later time and attack it.
- In some cases, the weakened virus in the vaccine may cause a mild case of the disease.
- Inactivated vaccines can not cause even mild cases of the disease but do create an immune response in the body. Because the response is small, inactivated vaccines usually require more than one shot (boosters).

How do vaccines work?⁴⁴

- Vaccines work by introducing a small amount of a disease that has been made safe to create a memory in the body's immune system. The immune system learns to recognize this disease without becoming ill. Later, if that same immune system comes in contact with the disease, it is prepared to fight it off quickly. By doing this, the body remains healthy *and* fights disease.
- Toxoids are a form of vaccines made by inactivating the toxins or poisons produced by the germs. Vaccines for diphtheria and tetanus work by helping the body fight off the harmful effects of the 'germs' poison.

Vaccine additives⁴⁴

- Vaccines may contain a number of additives to increase the safety or effectiveness of the vaccines.

Antibiotics:

- Neomycin may be added to prevent germs from growing in the vaccine culture.

Preservatives:

- Thimerosal is a preservative that helps prevent contamination of the vaccine. Thimerosal is made from mercury, which in large doses – many times more than is in vaccines, have been

⁴⁴ Humiston SG, Good C. Vaccinating your child, questions and answers for concerned parents. Peachtree Publishers, Atlanta; 2000: 18-21.

shown to cause developmental problems. Thimerosal is not contained in childhood vaccinations in Canada, except for the Hepatitis B Vaccine. It was present in children's vaccines in the U.S. until 1999.

- Formaldehyde is used to inactivate the polio vaccine virus and kill germs in other vaccine cultures.

Stabilizers

- Chemicals such as sulfites and monosodium glutamate (MSG) help maintain vaccine effectiveness despite heat, light etc.

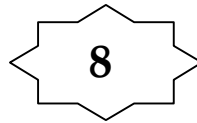
Adjuvants

- Aluminum gels or salts promote an antibody response in the body.

Vaccine monitoring⁴⁵

- The Bureau of Biologics of Health Canada supervises all vaccine production. Each factory is inspected and must meet strict standards; each batch of vaccine must be shown to be safe and effective through tests set out by the Bureau before it is sent out to the public.
- Canada is considered a world leader in “postmarketing surveillance” of adverse vaccine events. All adverse events (side effects) are to be reported to public health departments, who forward reports to provincial ministries of health, and then to the Immunization Division of the federal Laboratory Center for Disease Control at Health Canada. In Ontario, this reporting is required under the Health Protection and Promotion Act.
- There are approximately 4000 yearly reports for the approximately 4.5 million vaccine doses received by Canadians each year or one report per 100, 000 vaccine doses. Most reports are quite minor, such as a fever, or swelling at the infection site.
- The Immunization Division and the Canadian Paediatric Society also work together on an immunization monitoring program called IMPACT. This gathers information from admissions to children's hospitals considered to be related to immunization. They have found severe neurologic illness to be “extremely rare” after vaccinations. Serious adverse vaccine events have been found to occur in approximately one in one million doses of vaccine received. The majority of these result in complete recovery. Neurologic illness (associated with vaccination) is so rare that it cannot be accurately assessed; it is often much lower than that seen in individuals who have not been recently immunized.
- Yet another monitor of safety is the Advisory Committee on Causality Assessment. This group of experts meets two times a year, and does a case by case review of selected severe or unexpected adverse reactions that have been reported to Health Canada or IMPACT. The committee evaluates the likelihood that each case is related in some way to immunization and what steps should be taken as a result.
- In Ontario, all health departments are required to inspect offices and other facilities using vaccine to ensure appropriate storage of vaccine. These cold chain inspections include training about proper vaccine storage and handling.

⁴⁵ Canadian Pediatric Society. Your Child's Best Shot, 1997: 8.



8. VACCINE EFFICACY

- Vaccines are very effective at their jobs - so effective that most vaccine preventable diseases are now very rare.
- Some individuals do not develop immunity after being vaccinated. This happens infrequently and the proportion varies by vaccine.

Example: Approximately 90% who receive one dose of measles vaccine develop a response sufficient to protect them against the disease. However, the vaccine effectiveness is enhanced to nearly 100% with a second dose of measles vaccine.⁴⁶

Example: The influenza vaccine is also not 100% effective against the disease but is extremely effective in preventing **severe** disease and death in those who have been immunized.⁴⁷

- Vaccine research is ongoing and as new vaccines are tested and shown to be more effective they replace the older less effective ones.
- The protection from several vaccines decreases over time and requires “booster” doses of vaccine to maintain immunity.
- Effectiveness of vaccines is enhanced by herd immunity.

What is herd immunity?

As the proportion of immunized people in the population increases, the ability of the disease to spread decreases since fewer people will be vulnerable to the disease. These vulnerable, non-immune people will benefit from this situation since their chance of coming into contact with the disease will decrease if people who are immune due to immunization surround them. This is the concept of “herd immunity”.

Therefore, people who benefit from immunization programs include not only those who get protection from the vaccine but also:

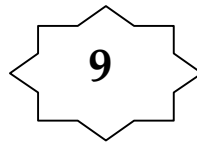
- The small number of people who cannot be immunized for medical reasons (serious medical conditions or severe allergies related to a vaccine component).

⁴⁶ Vitek CR et al. Increased protections during a measles outbreak of children vaccinated with a second dose of measles-mumps-rubella vaccine. *Pediatric Infectious Diseases Journal*. July 1999;18 (7): 620-3.

⁴⁷ National Advisory Committee on Immunization, Statement on Influenza Vaccination for the 2000-2001 Season. *Canada Communicable Disease Report*, June 2000 (26).

- Pregnant (non-immune) women and their unborn babies from rubella which can have devastating effects on the babies.
- The few people who do not have immunity after vaccination.

Each person represents a link in the protective immunization chain.



9. OVERALL SUCCESS OF VACCINES

Comparison of Maximum and Current Reported Morbidity of Vaccine Preventable Diseases in Canada⁴⁸

Vaccine-preventable Disease	Pre-vaccine	1997	1998
Poliomyelitis (polio)	20,000	0	0
Diphtheria	9,000	1	0
Pertussis	25,000	4,439	7,519
Tetanus (death)	40-50	0	0
Haemophilus influenza b (Hib)	2,000	60	50
Measles	300,000	572	12
Mumps	52,000	254	110
Rubella	69,000	4,007	69

⁴⁸ Pless R. Immunization Safety: the new challenge to vaccine-preventable disease control. Presentation to Getting Our Point Across, Central West Region, 1999.

10. VACCINES AND ANAPHYLAXIS

- Anaphylaxis has been associated with immunizations but is a very rare adverse event. Based on the last 5 years of complete national data, the annual rate of anaphylaxis ranges from 0.11 to 0.31 per 100,000 doses of vaccine distributed.⁴⁹ This means there may be between 1 and 3 cases of anaphylaxis with every 1,000,000 doses of vaccine distributed.
- Health care professionals who give vaccines are aware of the signs and symptoms of anaphylaxis, and have emergency supplies of drugs (i.e., adrenaline) to counteract these effects.
- Health professionals also assess each person prior to immunization for severe allergies and a history of previous reactions to immunization. For example, since Hepatitis B vaccine is grown in yeast cells, it might produce an allergic reaction in someone with an allergy to yeast.
- If a person is known to be allergic to a specific vaccine or component of a vaccine, they should not be immunized with that vaccine.

What is Anaphylaxis?

- Anaphylaxis is a sudden, serious, allergic reaction to a substance. Symptoms include, swelling of the mouth/throat, difficulty breathing, and significant changes in heart function. It can cause death if not treated quickly and appropriately.
- People with severe allergies may experience anaphylaxis when exposed to the substance although the reaction is not necessarily “anaphylactic”. For example a serious allergic reaction can include hives (a rash) and swelling but does not progress to the point of affecting breathing or heart function.

Are vaccines responsible for more allergies being diagnosed?

- Current data strongly suggests that vaccines are not responsible for the increased number of allergies being diagnosed.⁵⁰ Our immune systems are extremely complex and are exposed to thousands of foreign substances during our lifetime. Vaccines give a very small and highly controlled part of this exposure.
- Although there has indeed been an increase in the diagnosis of anaphylactic reactions, for example to peanuts, there is no scientific evidence linking this with vaccines.
- Research of autoimmune diseases and immunology is occurring in many countries at this time.⁵¹

⁴⁹ Canadian Immunization Guide, Fifth Edition, 1998: 9.

⁵⁰ Rose NR. Immunologic hazards associated with vaccination of humans. Journal of Autoimmunity Feb. 2000; 14(1):11-3.

⁵¹ Shoenfeld Y, Aron-Maor A. Vaccination and autoimmunity-'vaccinosis': a dangerous liaison? Journal of Autoimmunity Feb. 2000;14(1):1-10.

11. BABIES NEED TO BE IMMUNIZED

- Infants are most at risk for serious illness and death from diseases such as Hib, measles and pertussis. Highest death rates for childhood diseases such as pertussis occur in young infants and immunization protects babies at a time when they are most vulnerable. Babies need to be immunized according to the recommended schedule that begins in early infancy.⁵²
- On a daily basis, infants' immune systems interact with many "foreign substances" that exist in the environment. A case of strep throat exposes a child to between 25 and 50 foreign antigens.⁵³ The numbers of antigens in vaccines are carefully controlled in the manufacturing process and have been tested before being approved.
- There is no evidence that side effects from vaccines occur any more often in infants than other age groups.⁵²
- Some parents are concerned about giving vaccinations for different diseases at one time. Numerous studies have been done with combination vaccines. The studies show that the recommended vaccines (5-in-1 or DTaP-Hib, and MMR) cause no greater risk for adverse side effects and are as effective in combination as they are individually.⁵³
- Vaccines are changed when safer ones are tested and found effective. The old pertussis vaccine included in the DTP vaccine protected children but especially babies from the serious effects of whooping cough. About 50% of children had a low fever and soreness at the needle site. A small number had high fever, seizures and persistent crying.⁵⁴ In 1997 the improved acellular pertussis vaccine was recommended for use. These vaccines were as effective in producing the immune response⁵⁵ while having significantly fewer reactions indicated by 87% fewer febrile seizures and 75% less fainting post vaccines.⁵⁶
- The protection against haemophilus influenzae type b is improved in the 5-in-1 shot.⁵⁷
- It is recommended that premature babies be immunized with full doses of vaccines at the same chronological age and according to the same schedule as full term infants, regardless of birth weight, as long as their clinical condition is satisfactory.⁵⁵

⁵² Canadian Paediatric Society. Your Child's Best Shot, 1997.

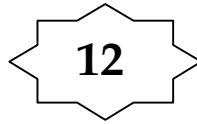
⁵³ LCDC web site URL: http://www.hc-sc.gc.ca/hpb/lcdc/publicat/immguide/comp_e.html

⁵⁴ Offit PA, Bell LM. Vaccines: What every parent should know. IDG Books, NY. 1999: 37-8.

⁵⁵ Canadian Immunization Guide, Health Canada, 1998: 134, 24.

⁵⁶ Scheifele DW et al. Marked Reduction in Febrile Seizures (FSz) and Hypotonic-Hyporesponsive Episodes (HHE) With Acellular Pertussis-Based Vaccines. Results of Canada-Wide Surveillance, 1993-1998. The Infectious Disease Society of America Conference, November 1999.

⁵⁷ IMPACT News, Spring 2000.



12. BREASTFEEDING AND IMMUNIZATION

- Although breast milk has numerous benefits to infants and children including overall health for the child, breast milk does not provide protection to a child against specific vaccine preventable diseases.
- Immunity in the form of antibodies from the mother is not passed on to the infant for diseases such as pertussis.
- Breastfeeding does not interfere with immunization of the infant with either live or killed vaccines. Infants who are breastfed should receive all the recommended vaccinations at the usual times.⁵⁸
- Pertussis (whooping cough) can affect a child's ability to breathe and is most serious for children under the age of one year. The immunization schedule recommends babies receive their first shot of pertussis at 2 months. Haemophilus influenza type b (Hib) is also most serious in infancy and early childhood and immunities come from vaccines.
- Immunity against measles can be passed from the mother to child prior to birth and can persist for about 1 year after birth. The immunization schedule recommends starting measles immunization at one year of age.
- Some research suggests that breastfeeding enhances the active immune response in the first year of life.^{59, 60, 61}
- Good nutrition at any age is important for immune function but good nutrition alone does not provide immunity against specific diseases. To build specific immunities against vaccine preventable diseases, infants must receive the specific vaccinations.
- Lactating mothers who have not received the recommended immunizations may be safely given rubella and other routinely used vaccines postpartum.⁵⁸

⁵⁸ Canadian Immunization Guide, 1998: 14.

⁵⁹ Hanson LA. Breastfeeding provides passive and likely long-lasting active immunity. *Annals Allergy Asthma Immunology* Dec 1998; 81 (6):523-33.

⁶⁰ Pabst HF et al. Differential modulation of the immune response by breast- or formula-feeding of infants. *Acta Paediatrica* Dec 1997;1986(12):129:1-7.

⁶¹ Pabst HF, Spady DW. Effect of breast-feeding on antibody response to conjugate vaccine. *Lancet* 1990 Aug 4;336 (8710):269-70.

13. MYTH: Vaccines cause long term health problems.

- The vaccines used in Ontario today are extremely safe. The risk of vaccines causing serious harm is very small. Even small risks are studied and newer and safer vaccines are used when available.
- Most adverse events associated with vaccines are minor and transient, like a sore arm or fever. More serious adverse vaccine events such as hypo responsiveness or excessive crying are reported in:

1 in 1000 - to 1 in a million doses.

 Severe neurological events are so rare that rates can not be determined.⁶²
- Ongoing vaccine testing and monitoring using advanced research techniques are continuing.⁶²
- Reactions to vaccines are monitored on an ongoing basis (postmarketing surveillance). A national committee of medical experts (The Advisory Committee on Causality Assessment) reviews all reports of severe reactions. Many vaccines have been used for decades with no evidence of long-term adverse effects.

Example:

- Vaccines are blamed for medical conditions that are poorly understood and are most common in the first year of life. Sudden Infant Death (SIDS) happens most frequently in the first 6 months of life during the time babies receive three vaccinations. By chance alone, a child may die of SIDS following a vaccination.⁶³ Research has shown no increased incidence of SIDS in vaccinated babies.^{64, 65} Other research has found a relationship between SIDS and sleeping position.⁶⁶ Subsequent studies have found that placing an infant on the back while sleeping significantly reduced the prevalence of SIDS.⁶⁷
- The old pertussis vaccine included in the DTP vaccine protected children but especially babies from the serious effects of whooping cough. Some parents reported that their children developed serious problems to this vaccine. Adverse vaccine event data indicated that about 50% of children had a low fever or soreness at the needle site. A small number had high

⁶² Canadian Immunization Guide, Health Canada, 1998: 41.

⁶³ Chen RT et al. Safety of Routine Childhood Vaccinations, An Epidemiological Review. Paediatric Drugs 2000 Jul-Aug; 2 (4): 273-290.

⁶⁴ Advisory Committee on Immunization Practices. Update: Vaccine Side Effects, Adverse Reactions, Contraindications, and Precautions. Morbidity Mortality Weekly Report 1996; 45 (RR-12): 1-35.

⁶⁵ Griffin MR et al. Risk of Sudden Infant Death Syndrome after Immunisation with the Diphtheria-Tetanus-Pertussis Vaccine. New England Medical Journal 1988; 319: 618-23.

⁶⁶ Mitchell EA et al. Results from the first year of the New Zealand cot death study. New Zealand Medical Journal 1991; 104 (906):71-6.

⁶⁷ Haslam RH. Smoking and Sleeping Position are only Pieces of the Puzzle Resulting in the Sudden Infant Death Syndrome. Pediatric Research 2000; 48: 715.

fever, seizures and persistent crying.⁶⁸ In 1997 the improved acellular pertussis vaccine was recommended for use since it was shown to be effective in producing the immune response⁶⁹ while having significantly fewer reactions indicated by 87% fewer febrile seizures and 75% less fainting post vaccines.⁷⁰

- Active research is initiated even when there is no strong data linking vaccines to a medical condition.
- The original allegation linking autism and MMR came from a case report study of 12 children (no control group) who had bowel disease and regressive developmental disorder.⁷¹ A panel was set up by the Medical Research Council of Britain to investigate this possible link. A second study, involving 500 children and reliable research methods found no such link supporting epidemiological research that shows no increase in autism when the MMR vaccine was introduced in 1988.⁷²

As a result of continued public concern about the allegation, the Centers for Disease Control (CDC) is currently initiating further studies.⁷³

See other myths in this binder.

⁶⁸ Offit PA, Bell LM. Vaccines: What every parent should know; IDG Books, NY, 1999: 37-8.

⁶⁹ Canadian Immunization Guide, Health Canada, 1998: 134.

⁷⁰ Scheifele DW et al. The Infectious Disease Society of America Conference, November 1999.

⁷¹ Wakefield AJ et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. Lancet, 1998, 351:637-641.

⁷² Taylor B et al. Autism and measles, mumps and rubella vaccine: no epidemiological evidence for a causal association. Lancet 1999, 353: 2026-2029.

⁷³ See: www.cdc.gov/nip/vacsafe/concerns/autism/autism-res-cdc.htm

14. MYTH: The diseases were disappearing before use of vaccines.

This statement is not true. Vaccines have significantly reduced disease. In the case of small pox, worldwide immunization resulted in the elimination of the disease.

- Better nutrition, 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.
- Dramatic drops in diseases such as measles occurred soon after vaccine licensure. Graphs for other vaccine-preventable diseases show a roughly similar pattern, demonstrating a significant drop in cases occurring after vaccine programs were implemented.⁷⁴
- Hib vaccine is a good example to show the direct drop in disease following the use of a vaccine. Before 1985, Haemophilus influenzae type b (Hib) was very common in Canada with 1,500 cases per year of Hib meningitis in children under 5 years of age. About 1 of every 300 children developed meningitis or severe Hib infections by age 5. With routine immunization the number of Hib infections have decreased by 98% (8 cases vs. 495).⁷⁵
- Strong anti-vaccine movements raised fears of side effects to pertussis leading to drops in vaccine use in several countries including Great Britain, Japan and Sweden. The effect:
 - 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.
 - Japan: experienced a drop in vaccination rates from 70% (393 cases and no deaths) in 1974 to rates of 20%-40% (13,000 cases and 41 deaths) in 1979.
 - 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 1985.⁷⁶
- With the addition of a second measles shot in 1996, the number of observed measles cases dropped significantly. Number of Ontario cases⁷⁷:

1995: over 2000	1999: 2
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- Polio, a highly infectious paralytic disease, has been eradicated from the Americas directly related to vaccine use. In 1959 there were 1,887 paralytic cases in Canada⁷⁸. The last

⁷⁴ Report of the Chief Medical Officer of Health. Immunization, The Next Steps. Queen's Printer for Ontario, 1995: 3.

⁷⁵ Canadian Immunization Awareness Web site: www.ciap.cpha.ca

⁷⁶ Gangarosa EJ et al. Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story. Lancet, 1998; 351(9099): 356-361.

⁷⁷ Reportable Disease Information System, Public Health Branch, Ontario Ministry of Health and Long-Term Care, 1999.

recorded case of wild polio virus in the Americas occurred in Peru in 1991. In the past few years, there have been no cases in Canada yet the wild poliovirus still exists in several parts of the world. With widespread travel, polio can be imported and polio immunization in Canada continues to be important. Intensive immunization programs are being conducted in countries where the wild poliovirus still exists, such as in Pakistan and parts of Africa.

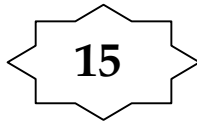
- Diphtheria was a serious disease with a 5-10% mortality rate. In 1924 there were 9,000 reported cases. Diphtheria vaccine was started in the 1930's. In Canada, very low rates of diphtheria occur with no deaths reported since 1983.⁷⁸
- A major epidemic of diphtheria occurred in the former Soviet Union in the early 90's, where low primary immunization rates for children and the lack of booster vaccinations for adults resulted in an increase from 839 cases in 1989 to nearly 50,000 cases and 1,700 deaths in 1994.⁷⁹
- If vaccine preventable diseases were disappearing without the vaccines, then chicken pox (varicella) would be disappearing today. That is not the case. Most children in Canada do get chicken pox as did their parents and grandparents. In countries using the varicella vaccine, the number of cases of chicken pox is decreasing.⁸⁰

Vaccines are extremely effective in reducing disease they are designed to prevent.

⁷⁸ Canadian Immunization Guide, 1998: 144, 72.

⁷⁹ Vitek CR, Wharton M. Diphtheria in the Former Soviet Union: Reemergence of a Pandemic Disease, Emerging Infectious Diseases, 1998; 4 (4). www.cdc.gov/ncidod/eid/vol4no4/vitek.htm

⁸⁰ Asano Y et al. Experience and reason: twenty-year follow-up of protective immunity of the Oka strain live varicella vaccine. Pediatrics 1994; (94): 524-526.



15. MYTH: Vaccines have dangerous ingredients

- Vaccines include different ingredients used in the manufacturing process and as preservatives. (Product inserts, which are distributed in every package of vaccine, discuss the content of individual vaccines.)
- Vaccines contain ingredients to preserve them, to increase their safety, or to make them more acceptable for use by the immune system. Ingredients are present in trace quantities that have been found to be safe during vaccine testing.
- The childhood vaccines used in Canada do not contain thimerosal with the exception of two hepatitis B products used for some infants in Canada (Engerix B from SmithKline Beecham and Recombivax from Merck Sharpe Dohme) and the influenza vaccine.⁸¹

All vaccines undergo extensive testing before clinical trials are done with humans. They are licensed for use only after their safety has been shown. Once in use, side effects or adverse events are monitored on an ongoing basis. There is no evidence of long-term harm caused by vaccines that are in current use.

A recent finding showed that some US children had mercury levels that exceeded the recommended guidelines of their Environmental Protection Agency. The vaccines used for young children in the United States contain thimerosal, a mercury-based preservative that has been used since the 1930's. A statement from the American Academy of Pediatrics recommends that "government agencies work rapidly toward reducing children's exposure to mercury from all sources."⁸²

The following ingredients may be in vaccines:

Thimerosal/Mercury

- Thimerosal is added to some vaccines in very small amounts to prevent bacterial and fungal contamination of the vaccine.
- In Canada, none of the routine childhood vaccines contains thimerosal but it is present in the Hepatitis B vaccine used for high-risk infants.
- In Ontario, Hepatitis B vaccine is routinely offered to grade seven students. Since these students have larger body sizes the level of mercury content in the vaccine is well within the acceptable level.⁸³

⁸¹ Laboratory Centre for Disease Control & Therapeutic Products Programme Thimerosal and Vaccine Public Information: Questions/Answers, Draft July 23, 1999.

⁸² American Academy of Pediatrics (US), Thimerosal in Vaccines – an Interim Report to Clinicians; July 15, 1999.

⁸³ Laboratory Centre for Disease Control & Therapeutic Products. Programme Thimerosal and Vaccine Public Information: Questions/Answers, Draft July 23, 1999.

- The tolerable daily intake (the daily intake of a substance from all sources during a person's entire lifetime which appears to be without appreciable risk to health on the basis of all known facts) is **0.71 micrograms (mcg) per kilogram body weight per day**.⁸³
- A 12 or 13 year old weighing between 34 and 45 kg (75 - 100 pounds) would have an estimated tolerable daily intake of 24.2 - 32 mcg. **The childhood influenza vaccine contains 12.5 mcg of mercury.**
- Thimerosal has been used since the 1930's with no evidence of safety concerns. The concerns expressed about thimerosal are based on its repeated use in childhood vaccines used in the U.S.

See Thimerosal articles in Section G including the table of vaccines with Thimerosal licensed in Canada.

See also: www.cdc.gov/epo/mmwr/preview/mmwrhtml/mm4927a5.htm

Aluminum

- Aluminum gels or salts of aluminum may be used as “adjuvants” in vaccines to help vaccines to work faster, increase their strength, or duration of response with the immune system.
- The amount of aluminum in each dose of vaccine is less than one milligram. This amount is not known to cause any harm to humans, and in fact, people take much higher amounts in many antacids without any serious problems.⁸⁴
- Aluminum, the most abundant metal on Earth, is found in soil, in water and in air. Its compounds are often used in food as additives, in drugs (e.g., antacids), in consumer products (e.g., cooking utensils and aluminum foil) and in the treatment of drinking water (e.g., coagulants).⁸⁵
- Historically, aluminum has been considered relatively non-toxic; healthy individuals can tolerate oral doses as high as 7 grams per day without experiencing harmful effects. The World Health Organization has estimated that individuals who regularly ingest aluminum-containing pharmaceuticals may have intakes as high as 5 grams per day.
- In recent years, the public and the media have become concerned about other possible adverse effects of aluminum on human health, including its role in Alzheimer's disease, Parkinson's disease and amyotrophic lateral sclerosis (Lou Gehrig's disease). In addition, questions have been raised about the potential risks to infants who drink baby formula containing aluminum.

Antibiotics

- Measles, mumps and rubella (MMR), as well as inactivated polio (IP) vaccines contain trace amounts (less than 0.000025 grams 0.25 mcg) of neomycin – an antibiotic.⁸⁶
- Neomycin is added during the manufacturing process to prevent bacterial contamination.

⁸⁴ Canadian Paediatric Society. Your Child's Best Shot; 1997:129.

⁸⁵ Health Canada. It's your health, Aluminum and Human Health, April 1999. <http://www.hc-sc.gc.ca/main/hc/web/ehp/ehd/catalogue/general/iyh/alhuman.htm>

⁸⁶ Laboratory Centre for Disease Control & Therapeutic Products. Programme Thimerosal and Vaccine Public Information: Questions/Answers, Draft July 23, 1999.

Formaldehyde

- In order to make vaccines safe, formaldehyde is used during vaccine production to kill or inactivate bacteria and viruses. Once the germ is killed the vaccines are purified to remove almost all of the formaldehyde.
- The DPaTP-Hib (5 in 1 or Pentacel) needle has less than 0.02% formaldehyde – less than 200 parts per million. This is several hundred times lower than the amount known to cause any human harm.⁸⁶

16. MYTH: Vaccines are contaminated with blood

- This is a myth. There are no animal or human blood cells in vaccines although there may be trace amounts of human serum albumin (HSA).⁸⁷
- Albumin is a protein in the plasma that helps transport medicines such as vaccines.
- During the production of vaccines, the viruses are grown in certain animal or human cells. Calf serum (part of blood) may be added to keep cells growing. These are used *during* vaccine production, but when the vaccine is purified all of the calf serum and all cells are removed. *Trace* amounts of some proteins (e.g. albumin) may remain, but not the cells themselves.
- Products used in the production of vaccines are from specific or “clean” herd or cell lines and are tested for known infectious agents.

Is the Hepatitis B vaccine made from blood products?

Since 1986, the hepatitis B vaccine has been produced synthetically in yeast cells. In the early 1980’s, the protein on the outer envelope of the virus was obtained from the plasma (the liquid part of blood) of chronic hepatitis B infected persons. Due to the public’s fear of acquiring other viruses from blood products, the safer alternative, using yeast cells, was developed.

Are vaccines contaminated with brain cells?

- There has also been concern raised over use of brain tissue in the production of vaccines and a theory that “mad cow disease” (spongiform encephalitis) might be contracted from vaccines.
- Rabies vaccines are used for the prevention of human rabies and have never been part of the routine immunization schedule. Rabies vaccine is the only vaccine in Canada that has contained animal brain cells. However these vaccines have not been used in Canada since 1985. The most frequent side effects to the current rabies vaccine include local pain and swelling and some mild systemic reactions such as head ache and nausea.⁸⁸
- The rabies vaccine currently used in Ontario does not contain animal cells and is more effective and has fewer side effects than the rabies vaccine used before 1985.

⁸⁷ Canadian Paediatric Society. Your Child’s Best Shot;1997: 130.

⁸⁸ Canadian Immunization Guide, 1998: 149-156.

17. MYTH: Vaccines cause diabetes

Well-controlled studies have found no basis for an association between diabetes and vaccination.^{89, 90}

The Allegation

Classen et al. gained media attention claiming that vaccines can both cause and protect against diabetes, depending on the timing of vaccinations. This conclusion was based on a review of Insulin Dependent Diabetes Mellitus (IDDM) rates in different countries with different vaccination policies.⁹¹ They proposed that additional doses of haemophilus influenzae b vaccine might increase IDDM risk. This study has been refuted since it did not account for the many other differences between these countries and their populations such as diet, genetic predisposition and environmental exposures.

Another study⁹² cannot be generalized to routine vaccines administered to children. They studied the onset of IDDM in laboratory rats using anthrax vaccine, which has never been routinely used in the Ontario population and, tuberculosis (BCG) vaccine, that is used very rarely in high risk groups only.

- An extensive scientific review by the Institute for Vaccine Safety Diabetes Workshop Panel evaluated the data linking diabetes and vaccination. The workshop participants were experts on the pathogenesis of diabetes, autoimmunity, epidemiology, biostatistics, vaccines and adverse events associated with vaccines. The review panel concluded that no vaccines have been shown to increase the risk of type 1 diabetes in humans.⁹³
- Current well-controlled studies have found no basis for an association between diabetes and vaccination.^{94, 89, 95}

⁸⁹ Karvonen M et al. Association between type 1 diabetes and Haemophilus influenza type b vaccination: birth cohort study. *British Medical Journal* 1999; 318: 1169-1172.

⁹⁰ Jefferson T, Demicheli V. No evidence that vaccines cause insulin dependent diabetes mellitus. *Journal of Epidemiology and Community Health* 1998; 52:674-5.

⁹¹ Classen JB, Classen D. The timing of pediatric immunization and the risk of insulin-dependent diabetes mellitus. *Infectious Diseases in Clinical Practice* 1997; 6:449-54.

⁹² Classen JB. The timing of immunization affects the development of diabetes in rodents. *Autoimmunity* 1996; 24: 137-45.

⁹³ The Institute for Vaccine Safety Diabetes Workshop Panel. Childhood immunizations and type 1 diabetes: Summary of an Institute for Vaccine Safety Workshop. *Pediatric Infectious Diseases Journal* 1999;18 (3): 217-222.

⁹⁴ DeStefano F et al. Hepatitis B and Hib Vaccines are not associated with increased risk of type 1 diabetes. Presentations to Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), Toronto, Canada, Sept. 2000.

⁹⁵ Jefferson, T Demicheli V. No evidence that vaccines cause insulin dependent diabetes mellitus. *Journal of Epidemiology and Community Health* 1998; 52:674-5.

Insulin Dependent Diabetes Mellitus

Insulin Dependent Diabetes Mellitus or Type 1 diabetes typically begins in childhood. Insulin is required for the body to use sugar for energy. There is a higher risk of developing IDDM if someone within a family has already developed it suggesting a genetic link.⁹⁶ Several genes are likely involved but the one most associated is located on chromosome 6.⁹⁷

Other factors may include environmental factors^{96,97} and exposure to certain illnesses early in life such as congenital rubella syndrome.⁹⁸

⁹⁶ LaPorte RE et al. Prevalence and incidence of insulin-dependent diabetes. In: Harris MI et al. (eds) Diabetes in America. 2nd ed. NIH Publications, Bethesda MD: 1997: 33-46.

⁹⁷ Atkinson MA Maclaren NK. The pathogenesis of insulin-dependent diabetes mellitus. New England Journal of Medicine 1994; 331:1428-36.

⁹⁸ McEvoy RC et al. Children at high risk for diabetes mellitus: New York studies of families with diabetes and of children with congenital rubella syndrome. Advances in Experimental Medical Biology 1988; 246: 221 -7.

18. MYTH: Vaccines cause Chronic Fatigue Syndrome

- Chronic Fatigue Syndrome (CFS) is a complex disorder and the cause of CFS is unknown. There is **no evidence that it is caused by vaccines**.
- The alleged link between hepatitis B vaccine and chronic fatigue syndrome first began in 1991.⁹⁹

What is CFS?

- Symptoms include extreme fatigue that does not improve with bed rest and worsen with physical or mental activity. People with CFS are usually forced to decrease many of their normal activities. There are other symptoms of CFS, which have been established to assist in the medical diagnosis of this syndrome.
- The cause(s) of CFS are unknown, although this has been, and continues to be investigated. A case control study by Mawle et al¹⁰⁰ has shown no increased risk of CFS with exposure to many infectious agents including hepatitis B, measles, rubella, and varicella zoster. This observation suggests that if the disease itself does not increase risk, the vaccine, which imitates the disease, should not either.

A new theory proposes the concept of multiple risk factors coming together on an individual basis to bring on this syndrome.¹⁰¹

- Patients with chronic fatigue syndrome and chronic hepatitis C were found to have deficiencies in serum acylcarnitine (p<0.001).¹⁰²
- A study involving 40 patients with acute viral hepatitis A or B, found that these patients were more likely to suffer from fatigue up to 30 months post-infection compared to their matched controls hospitalized for other infectious diseases.¹⁰³
- There is no scientific evidence linking CFS and vaccinations.

⁹⁹ Anonymous. Alleged link between hepatitis B vaccine and chronic fatigue syndrome. Canada Diseases Weekly Report. 1991;17(40):215-216.

¹⁰⁰ Mawle AC et al. The seroepidemiology of chronic fatigue syndrome: a case-control study. Clinical Infectious Diseases. 1995; 21: 1386-1389.

¹⁰¹ See Possible Causes of CFS at http://www.cdc.gov/ncidod/diseases/cfs/cfs_info3.htm

¹⁰² Kuratsune H et al. Low levels of serum acylcarnitine in chronic fatigue syndrome and chronic hepatitis C, but not in other diseases. International Journal of Molecular Medicine 1998;2(1):51-56.

¹⁰³ Berelowitz GJ et al. Post-hepatitis syndrome revisited. Journal of Viral Hepatitis 1995;2(3):133-138.

19. MYTH: Vaccines weaken the immune system

Giving a child multiple vaccinations for different diseases at the same time does not overload the immune system.

- Children are exposed to many germs every day. Vaccines contribute to a small, controlled proportion of any child's total exposure.
"One parent observed that in the span of a few hours a North American child may eat her own nasal discharge, kiss the dog on the lips, taste the handrail at the airport, and still be able to survive quite nicely. The immune system is remarkably robust."¹⁰⁴
- Bacteria live in the mouth and nose. An upper respiratory viral infection exposes a child to 4 - 10 antigens, and a case of "strep throat" to 25 - 50.¹⁰⁵
- 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.^{106, 107, 108}
- The question of a connection between vaccination and autoimmune illness (or phenomena) is surrounded by controversy. Although research data is lacking to prove causal relationships between vaccines and multiple sclerosis (MS) or between vaccination and autism, heated discussions continue.¹⁰⁹
- Numerous studies are currently underway.¹¹⁰

¹⁰⁴ Humiston SG, Good C. Vaccinating your child, questions and answers for concerned parents. Peachtree Publishers, Atlanta; 2000: 21.

¹⁰⁵ Halsey N. Testimony before the U.S. House of Representatives Committee on Government Reform, October 12, 1999.

¹⁰⁶ Eskola J et al. Combined vaccination of Haemophilus influenzae type b conjugate and diphtheria-tetanus-pertussis containing acellular pertussis. Lancet 1999; 354: 2063-2068.

¹⁰⁷ Dagan R et al. Safety and immunogenicity of a combined pentavalent diphtheria, tetanus, acellular pertussis pentavalent vaccine. Pediatric Infectious Diseases Journal 1997; 16: 1113-21.

¹⁰⁸ Mills E et al. Safety and immunogenicity of a combined five-component pertussis-diphtheria-tetanus-inactivated poliomyelitis-Haemophilus b conjugate vaccine administered to infants at two and four months of age. Vaccine 1998; 16: 576-85.

¹⁰⁹ Shoenfeld Y, Aron-Maor A. Vaccination and autoimmunity-'vaccinosis': a dangerous liaison? Journal of Autoimmunity 2000; 14 (1):1-10.

¹¹⁰ See: www.cdc.gov/nip/vacsafe/concerns/autism/autism-res-cdc.htm

20. MYTH: Alternative medicines provide better and safer protection than vaccines

There is no evidence that this is true. Vaccines are known to be approximately 90% effective and to significantly reduce the incidence of vaccine preventable diseases.

Natural medicines include a wide range of chemicals. Some natural medicines are extensively used in other countries and information is known about their safety and effectiveness.¹¹¹ Others are unknown.

Under current legislation¹¹², herbal remedies can be sold as a food or a drug. If sold as food, no claims can be made on the labels about the health effects. If health claims are made, the remedy is considered a drug and packagers must apply for a drug identification number (DIN).

In order to obtain a DIN, information must be provided about the manufacturer, brand name, medicinal ingredient(s), and strength of medicinal ingredient(s), pharmaceutical form, and route of administration. In addition, in keeping with the Food and Drugs Act, subsection 9(1), the Drugs Directorate requires the submission of sufficient data to evaluate the safety and efficacy of a drug for its intended use.

Once a DIN is issued, a post-market audit is done to assure compliance with good manufacturing practices and verification of data submitted to support the DIN. This audit process is currently being developed.

For remedies sold as food, no claims or suggested dosages may be mentioned. If health claims are made, it may be a violation of the Food and Drug Regulations, section C.01.04.

Despite the widespread belief that herbal products are safe because they are ‘natural’, adverse effects can occur with these products. Adverse effects include allergic reactions, nausea, vomiting and sedation.^{113, 114} There is also the risk of potential interactions between conventional and herbal medicines.^{115, 116} From another perspective, the use of herbal treatments may lead to postponing conventional treatment for serious or life threatening illnesses.¹¹⁷

¹¹¹ References on Allied and Complementary Medicine, see <http://library.dialog.com/bluesheets/html/b10164.html>

¹¹² See <http://www.hc-sc.gc.ca/hpb-dgpps/therapeut/>

¹¹³ Shaw D et al. Traditional remedies and food supplements. A 5-year toxicological study (1991-1995). *Drug Safety* 1997;17(5):342-56.

¹¹⁴ Ernst E, De Smet P. Risk associated with complementary therapies. In: Dukes M. (Editor), *Meyler's side effects of drugs*, Berlin: Elsevier Science B.V, 1996, 1427-54.

¹¹⁵ Miller LG. Herbal medicinals. Selected clinical considerations focusing on known or potential drug-herb interactions. *Archives of Internal Medicine* 1998;158: 2200-2211.

¹¹⁶ D'Arcy P. Adverse reactions and interactions with herbal medicines. Part 2- drug interactions. *Adverse Drug React Toxicology Review* 1993; 12(3): 147-62.

¹¹⁷ Kaegi E. Unconventional therapies for cancer: 1. Essiac. *Canadian Medical Association Journal* 1998; 158(7): 897-902.

The extent of the risks of herbal products remains largely speculative since there is little quality information about adverse effects of herbs or the interaction between herbs and conventional medicine. Further, the quality control of herbal products has not yet been standardized. Products labeled as the same herbal treatment may contain different components and some have been found to contain potentially toxic adulterants.^{118, 119}

At this time there are no herbal remedies licensed as vaccines.¹²⁰ Foods that are said to have medical properties and do not have a DIN should not be used.

The health food market is a fast growing industry in Canada and estimated to be worth more than \$1 billion with about 56% of Canadians reporting use of alternative or complementary treatments including herbs, minerals and vitamin supplements in the past six months.

“It’s a marketing environment and people with nice, flashy bottles and nice ads are believed unfortunately.”¹²¹ The concern is the lack of standardization in products including active ingredients as well as additives.

Claiming a product is natural is no assurance that it is safe. In Canada, an Office for Natural Health Products (ONHP)¹²² has been created to standardize labeling of these products. Consultation is occurring and a plan for standardization and safety is being developed at this time.

On the other hand, vaccines are carefully monitored and tested for precise ingredients, safety and efficacy. It is ironic that some individuals are highly critical of the known ingredients of vaccines but fail to question what they are consuming in unregulated herbal products.

¹¹⁸ Shaw D et al. Traditional remedies and food supplements. A 5-year toxicological study (1991-1995). *Drug Safety* 1997;17(5):342-56.

¹¹⁹ Keen R et al. Indian herbal remedies for diabetes as a cause of lead poisoning. *Postgraduate Medical Journal* 1994; 70:113-4.

¹²⁰ Personal communication, Michaline Ho, Office of Natural Health Products, Health Canada.

¹²¹ Salama S. The inside story on vitamins, *The Hamilton Spectator*, Sept 28, 2000, RH1

¹²² see URL: www.hc-sc.gc.ca/hpb/onhp/welcome_e.html

21. MYTH: There are greater risks from the vaccines than the diseases.

The following chart shows the risks of serious side effects from the diseases and from the vaccines. The risks from the vaccine preventable diseases far exceed the risks from immunization.

Risks from Diseases vs. Risks from Vaccines^{123, 124}

Risks of serious side effects from DISEASES	Risks of serious side effects from VACCINES
<p>Measles Pneumonia: 1 in 20 Encephalitis: 1 in 2,000 Death: 1 in 3,000</p> <p>Mumps Encephalitis: 1 in 300</p> <p>Rubella Congenital Rubella Syndrome: 1 in 4 (if woman becomes infected early in pregnancy)</p>	<p>MMR Encephalitis or severe allergic reaction: 1 in 1,000,000</p>
<p>Hib Case fatality of meningitis is 5% 10-15% of survivors have permanent neurologic sequelae 15-20% have deafness</p>	<p>Hib 5% have discomfort or local inflammation 2% have have fever.</p>

¹²³ CDC web site – Vaccine Safety – Myths URL: <http://www.cdc.gov/nip/publications/6mishome.htm>

¹²⁴ Canadian Immunization Guide, 1998, back cover.

Risks of serious side effects from DISEASES	Risks of serious side effects from VACCINES
<p>Hepatitis B Initial infection may be asymptomatic in up to 50% cases</p> <p>1-2% case fatality</p> <p>Risk of chronic carrier varies with age (infants 90-95% risk; children < 5 years 25-50%, adults 6-10%)</p> <p>Chronic carriers at increased risk for hepatic cirrhosis and cancer.¹²⁵</p>	<p>Hep B Mild transient soreness at injection site.</p> <p>Anaphylaxis very rare- 1 event per 600,000 vaccine doses distributed, based on the reports to Vaccine Adverse Event Reporting System (VAERS).¹²⁶</p> <p>Cases of rheumatoid arthritis and demyelinating diseases of the CNS reported rarely but no causative link has been identified.</p>
<p>Influenza In preschool and school aged children – hospitalization 100 per 100,000 and 500 per 100,000 for those with high risk conditions.</p> <p>Increased risk for death for individuals with chronic coronary or pulmonary illnesses.¹²⁷</p> <p>Deaths: approximately 500 to 1,500 per season in Canada.</p>	<p>Influenza vaccine Split virus vaccine – no increased frequency of fever or other systemic symptoms compared to placebo</p> <p>Whole-virus vaccine - Fever, malaise and myalgia may occur within 1 or 2 days after vaccination.</p> <p>Risk of GBS very small.</p>

See also Risks of not immunizing.

¹²⁵ Canadian Immunization Guide, 1998, 90.

¹²⁶ Centers for Disease Control and Prevention. Update: vaccine side effects, adverse reactions, contraindications, and precautions. Recommendations of the Advisory Committee on Immunization Practices. Morbidity and Mortality Weekly Report. Sept 6, 1996;45(RR-12):1-35.

¹²⁷ National Advisory Committee on Immunization. Statement on Influenza Vaccination for the 2000-2001 Season, Canada Communicable Disease Report, June 1, 2000.

22. MYTHS: Health Units and Governments cover up risks and give biased, pro-vaccine information

- The goal of public health departments is to help parents make informed choices about vaccines.
- Public health and governments are very concerned about the safety of all medicines. Vaccine safety is extremely important and is taken very seriously because unlike other medications, vaccines are given to healthy children to prevent illness.
- Health units and health ministries are pro-vaccine based on the best available research. The research shows that vaccines prevent disease and save lives. (See also Overall Success of Vaccines # 9.)
- Vaccine research is growing. Medical researchers around the world have access to medical conferences and journals to speak about and publish research either pro or against vaccines. Public health staff in Canada, the US and elsewhere continually monitor the research to learn about new vaccine trials, case reports of adverse events, and vaccine efficacy.

The Allegation

Many vaccines are publicly funded in order to promote high vaccine use. This has led some anti-vaccine groups to suggest that the governments who buy the vaccine are in partnership with pharmaceutical companies.

- Publicly funded vaccines have contributed to significant reduction of vaccine preventable diseases including the eradication of small pox and elimination of polio from Canada.
- Vaccines are tested and monitored at various stages to ensure safe products.
- Many vaccines have been used for decades with no evidence of long-term adverse effects. Ongoing vaccine testing and monitoring, using advancing research techniques are continuing.¹²⁸

Vaccine testing and monitoring

Governments take vaccine safety very seriously and have put a number of safe guards in place.

- Vaccines go through a series of tests before they are approved for use in Canada. Testing must show that vaccines are safe and effective in preventing the disease that it targets.¹²⁹
- The Bureau of Biologics of Health Canada regulates all vaccines for humans. The Bureau supervises and inspects the manufacturers of vaccines to ensure that all the requirements for safety, sterility and quality control are met.¹³⁰

¹²⁸ Chen RT et al. Safety of Routine Childhood Vaccinations, An Epidemiological Review; Paediatric Drugs 2000 Jul-Aug: 2 (4): 273-290.

¹²⁹ Canadian Pediatric Society. Your Child's Best Shot, A parent's guide to vaccination, 1997: 8.

- The Bureau establishes the tests to evaluate the safety of each batch of vaccine and both the manufacturer and the laboratory of the Bureau do most safety tests.
- All batches of vaccine must pass the safety and potency (ability of the vaccine to produce the immune response) tests before they are released.
- In Canada, Immunization Division of Health Canada coordinates postmarketing surveillance of vaccine adverse events. Physicians and public health nurses report adverse reactions occurring after vaccination to the local health department. These reports are investigated by the local Medical Officer of Health, then forwarded to the provincial ministry of health and then to Health Canada.¹³⁰
- IMPACT (Immunization Monitoring Program, Active) is a unique program to detect severe adverse events related to vaccination. Nurses at each of 11 children's hospitals across Canada review all admissions to hospital for illnesses that may be related to vaccination including seizures, encephalitis, encephalopathy and acute paralysis. Each year nurses screen more than 90,000 children admitted to these hospitals. Since 1990, when IMPACT first started, there have been no cases of encephalitis, encephalopathy or acute paralysis related to vaccines. Some seizures have been detected following vaccination.¹³⁰
- The Advisory Committee on Causality Assessment reviews all severe adverse events following vaccination. The group of medical experts meet for 4 days each year to review all serious cases to determine whether the adverse event was related, possibly related, unlikely to have been related or unrelated to the implicated vaccine.¹³⁰
- Monitoring of vaccine safety is an ongoing international process¹³¹. Researchers in many countries¹³² continually monitor vaccine safety and effectiveness through surveillance systems and research studies.

¹³⁰Canadian Pediatric Society, Your Child's Best Shot, A parent's guide to vaccination, 1997: 8-10.

¹³¹ Scholtz M, Duclos P. Immunization safety: a global priority. Bulletin of the World Health Organization, 2000, 78 (2): 153-154.

¹³² See Chen RT, Hibbs B. Vaccine Safety: Current and Future Challenges, Pediatric Annals, July 1998;27 (7): 445-455 also at <http://www.cdc.gov/nip/vacsafe/research/peds.htm>

23. MMR VACCINE AND AUTISM

Although the cause of autism is unknown, research to date strongly suggests that autism is **not** caused by the Measles, Mumps, Rubella (MMR) vaccine.^{133, 134, 135}

- Research with families of twins suggests that there is a strong genetic component with autism.^{136, 137}
- Parents may first notice symptoms of autism as the child begins to have difficulty or delays in speaking, which tends to occur about the age when the MMR vaccine is given. The temporal association does not mean that one causes the other.
- Research shows that autism is three to four times more common in boys than girls but MMR vaccination rates are the same.
- Epidemiological research shows no increase in autism when the MMR vaccine was introduced in 1988.¹³⁸
- Incidence data suggest that autism occurs in 1/1000 children whereas very large numbers of children have received the MMR vaccine

What is autism?

Autism is a chronic developmental disorder characterized by problems in social interaction, communication, and restrictive and repetitive interests and activities. Autism is most often identified in toddlers between 18 and 30 months of age when delays in speaking are observed.

The Allegation

In 1998 a small study reported an observation that children given the MMR vaccine were observed to have inflammation of their intestines that may have preceded the development of autism.¹³⁹

- This study involved 12 children with bowel disease and regressive developmental disorders and did not have a control group.

¹³³ Bower H. New research demolishes link between MMR vaccine and autism. *British Medical Journal* 1999; 318(7199):1643.

¹³⁴ DeStefano F et al. Autism and measles, mumps and rubella vaccine: No epidemiological evidence for a causal association. *Journal of Pediatrics* 2000; 136(1):125-6.

¹³⁵ DeStefano F et al. Negative association between MMR and autism. *Lancet* 1999; 353(9169):1987-8.

¹³⁶ Szatmari P et al. Genetics of autism: Overview and new directions. *Journal of Autism and Developmental Disorders* 1998; 28: 351-368.

¹³⁷ Spiker D. The role of genetics in autism. *Infants and Young Children* 1999; 12: 55-63.

¹³⁸ Taylor B et al. Autism and measles, mumps and rubella vaccine: no epidemiological evidence for a causal association. *Lancet* 1999; 353: 2026-2029.

¹³⁹ Wakefield AJ et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children. *Lancet* 1998; 351:637-641.

- In at least 4 of the 12 cases, the behavioral symptoms appeared before the bowel symptoms, suggesting no link to bowel disease or MMR vaccine as a trigger.
- The original study received a lot of media coverage even though the authors of this study admitted at the time that they had NOT proven a link.

A panel was set up by the Medical Research Council of Britain to investigate a possible link between MMR and autism. In a second study, the authors identified all 498 known cases of autism spectrum disorders (ASD) in children living in certain districts of London who were born in 1979 or later and correlated the cases to an independent vaccination registry. The authors found that:

- The number of ASD cases has been increasing since 1979, with no jump after the introduction of the MMR vaccine in 1988.
- Children who were vaccinated before 18 months of age were diagnosed with autism at ages similar to children who were vaccinated after 18 months of age, indicating that the vaccination did not result in earlier expression of ASD characteristics.
- The authors discovered that at age two, the MMR vaccination coverage among ASD cases was nearly identical to vaccination coverage of children in the same birth cohorts in the whole region, providing evidence of a lack of overall association between the ASD and the vaccination.
- The first diagnosis of autism or initial signs of behavioral regression were not more likely to occur within time periods following MMR vaccination than during other time periods. However, parental concern clustered at six months post-vaccination.¹⁴⁰

Other research in England¹⁴¹ examining any possible link between measles vaccine and neurologic events found no indication that the measles vaccine contributes to the development of long-term neurological damage, including educational and behavioral deficits. Another study compared autism prevalence rates in populations of children from two communities in Sweden (prior to 1982). The results indicated no difference in autism prevalence between children born after the introduction of the MMR vaccine in Sweden and those born before the vaccine was used.¹⁴²

However, due to public concern about the allegation, the Centers for Disease Control is currently conducting the following studies¹⁴³:

- A study on the prevalence of autism.
- A study to examine whether the timing of vaccines administered before age 2 differs in children with autism as compared with a control group.
- A study with the National Institutes of Health to evaluate whether vaccination is linked with developmental regression, which occurs in a subset of children with autism.
- A study to examine inflammatory bowel disease and MMR vaccination using the Vaccine Safety Datalink.

¹⁴⁰ Taylor B et al. Autism and measles, mumps and rubella vaccine: no epidemiological evidence for a causal association. *Lancet* 1999, 353: 2026-2029.

¹⁴¹ Miller D et al. Measles vaccination and neurological events. *Lancet* 1997;349: 730-31.

¹⁴² Gillberg C, Hejlskov H. MMR and autism. *Autism* 1998;2:423-4.

¹⁴³ See: www.cdc.gov/nip/vacsafe/concerns/autism/autism-mmr.htm

24. MMR VACCINE AND INFLAMMATORY BOWEL DISEASE (IBD)

In large well-controlled studies, there is no evidence of an association between the MMR vaccine and inflammatory bowel disease (IBD).

- In a fourteen year prospective study in Finland all adverse events following MMR were investigated.
- About 3 million vaccine doses were delivered, with 31 children developing gastrointestinal symptoms after vaccination (rate of 0.03 per 1000 doses). Diarrhea with vomiting was the most frequent symptom, usually subsiding in 1 week.
- The authors found no evidence of MMR causing a pervasive developmental disorder or inflammatory bowel disease.¹⁴⁴
- Children's hospital admissions for Crohn's disease did not increase following the introduction of the second dose of the MMR vaccine.¹⁴⁵
- Scientists continue to study this issue, as well as other theories about the cause(s) of IBD.¹⁴⁶

IBD

- Inflammatory Bowel Disease is fairly rare (3-20 new cases diagnosed per 100,000 people per year) and is usually diagnosed in individuals between 15 and 30 years of age.
- Ulcerative colitis and Crohn's disease are two common types of IBD. People with IBD have an inflamed digestive tract, which can result in bloody diarrhea, pain and weight loss.
- The cause(s) of IBD is not yet known, and may involve aspects of heredity, environmental causes, significant emotional events, infection, viruses and immune system problems.
- It has not been shown that measles, mumps or rubella infections can cause IBD.^{147, 148, 149}

For more information see also the Centers for Disease Control and Prevention, National Immunization Program Web site: www.cdc.gov/nip/vacsafe/concerns/IBD.htm

¹⁴⁴ Peltola H et al. No evidence for measles, mumps, and rubella vaccine-associated inflammatory bowel disease or autism in a 14-year prospective study. *Lancet* 1998; 351:1327. See www.vaccinesafety.edu/mmrandibd.htm

¹⁴⁵ Miller E, Waight P. Second immunisation has not affected incidence in England. *British Medical Journal* 1998; 316: 1745.

¹⁴⁶ Metcalf J. Is measles infection associated with Crohn's disease? *British Medical Journal* 1998; 316:166.

¹⁴⁷ Pebody RG et al. Measles, measles vaccination, and Crohn's disease. *British Medical Journal* 1998; 316:1745.

¹⁴⁸ Bedford H et al. Autism, inflammatory bowel disease, and MMR vaccine. *Lancet* 1998; 351(9106):907; discussion 908-9.

¹⁴⁹ Feeney M et al. A case-control study of measles vaccination and inflammatory bowel disease. *Lancet* 1997; 350(9080):764-6.

25. CAN CHILDREN WITH EGG ALLERGIES HAVE VACCINES?

- Yes. Allergy to eggs is NOT a contraindication to receiving MMR, Influenza or Hepatitis B vaccine. The only contraindication is an anaphylactic response to a previous dose of the specific vaccine.

MMR:

- The measles virus is grown in cultures of fibroblasts from chick embryos. The amount of the egg protein, ovalbumin, may vary in different MMR vaccines. Studies have found that the vaccine could contain none, picogram quantities, or 0.5-1nanogram (ng) of ovalbumin per 0.5ml dose.^{150,151,152} Note: 1 ng= one billionth gram. 1 picogram = one trillionth gram.
- The MMR vaccine contains very small amounts of ovalbumin, as well as neomycin and gelatin.
- Severe allergic reactions have been reported in children who are allergic to the gelatin, and have no allergy to egg.^{153, 154}
- A number of studies have confirmed that it is safe to administer the measles, mumps and rubella vaccine to egg-allergic children.^{155,156} A Danish study examined all allergic side-effects for 1987-1996, involving 1,200,000 MMR vaccinations. None had anaphylactic shock.¹⁵⁷ Anaphylaxis after measles vaccination is RARE.
- Another study investigated the use of measles vaccine in children with a history of egg protein hypersensitivity referred to a specialist immunization facility between 1987 and 1993. Out of 200 children, only one child had an anaphylactic reaction. Therefore, the proportion experiencing an anaphylactic reaction was 0.5% (95% CI 0.01-2.75%). The authors concluded that a history of egg protein allergy should no longer be regarded as a contraindication to vaccination.¹⁵⁸

¹⁵⁰ O'Brien TC et al. Quantitation of residual host protein in chicken embryo-derived vaccines by radial immunodiffusion. *Applied Microbiology* 1971;21:780-782.

¹⁵¹ Herman JJ et al. Allergic reactions to measles (rubeola) vaccine given in patients hypersensitive to egg protein. *Journal of Pediatrics* 1983;102:196-199.

¹⁵² Fasano et al. Egg hypersensitivity and adverse reactions to measles, mumps, and rubella vaccine. *Journal of Pediatrics* 1992;120:878-881.

¹⁵³ Sakaguchi M et al. IgE antibody to gelatin in children with immediate-type reactions to measles and mumps vaccines. *Journal of Allergy and Clinical Immunology* 1995;96:563-565.

¹⁵⁴ Kelso JM et al. Anaphylaxis to measles, mumps, and rubella vaccine mediated by IgE to gelatin. *Journal of Allergy and Clinical Immunology* 1983;91:867-872.

¹⁵⁵ Freigang B et al. Lack of adverse reactions to measles, mumps and rubella vaccine in egg-allergic children. *Annals of Allergy* 1994;73:486-488.

¹⁵⁶ James JM et al. Safe administration of measles vaccine to children allergic to eggs. *New England Journal of Medicine* 1995;332:1262-1266.

¹⁵⁷ Christensen M et al. MMR-vaccination of children allergic to eggs. *Ugeskr Laeger* March 1999;161(9):1270-1272.[Danish]

¹⁵⁸ Baxter DN. Measles immunization in children with a history of egg allergy. *Vaccine* 1996;14(2):131-134.

- A larger study involving 500 egg-allergic children who received the MMR vaccine reported NO anaphylactic reactions, and only five children had a minor rash within two hours of administration.¹⁵⁹
- Skin testing has not been found to be helpful in predicting which egg-allergic children might have an adverse reaction.¹⁵² Other authors have reported that an intradermal skin test utilizing 0.02ml of 1:1 dilution of the vaccine, resulting in a wheal greater than 5mm was found to be the most reliable in predicting a possible adverse reaction.¹⁶⁰
- Based on an analysis of the literature in Medline between 1966 to 1999, the evidence indicated that children with egg allergies could be given MMR.¹⁶¹ This recommendation was reviewed and endorsed by the Committee on Infection and Immunisation of the Royal College of Pediatrics and Child Health, and the British Society of Allergy and Clinical Immunology. The guidelines are in broad agreement with those of the American Academy of Pediatrics and the Canadian National Advisory Committee on Immunization.
- The British Medical Journal article provides an algorithm for administering MMR vaccine in children who are allergic to eggs.¹⁶¹ Vaccination should be done in the hospital if previous exposure to egg led to cardiorespiratory reactions (difficulty breathing, noisy breathing, stridor, hoarseness, cyanosis, change in consciousness, pallor or hypotension) or if the child has coexisting active, chronic asthma. Vaccination can be done in the office if the child experienced mild reactions after ingestion of egg (oral, gastrointestinal, localized or generalized urticaria). As with all vaccines, epinephrine should be available in case of an emergency.

Influenza Vaccine

- The influenza vaccine is an inactivated vaccine, which contains trace amounts of egg.

Ontario Ministry of Health Statement on Influenza Vaccination for 2000-2001:

- “Influenza vaccine should not be given to people who had an anaphylactic reaction to a previous dose, or with known ANAPHYLACTIC hypersensitivity to eggs manifested as hives, swelling of the mouth and throat, difficulty in breathing, hypotension or shock.”
- “Individuals with acute, febrile illness usually should not be vaccinated until their symptoms have abated.”

(Based on Canada Communicable Disease Report 1 June 1999 (25) An Advisory Committee Statement (ACS). National Advisory Committee on Immunization Statement on Influenza Vaccination, 2000-2001 Season)

¹⁵⁹ Herman JJ et al. Allergic reactions to measles (rubeola) vaccine given in patients hypersensitive to egg protein. *Journal of Pediatrics* 1983;102:196-199.

¹⁶⁰ Miller JR et al. The safety of egg-containing vaccines for egg-allergic patients. *Journal of Allergy and Clinical Immunology* 1983;71(6):568-573.

¹⁶¹ Khakoo GA, Lack G. Recommendations for using MMR vaccine in children allergic to eggs. *British Medical Journal* April 2000;320(1):929-932.

26. DO VACCINES CAUSE SEIZURES/BRAIN DAMAGE?

- Vaccines *can* cause fevers and in some children, a fever may cause what is known as a “febrile seizure.”
- Febrile seizures *do not* cause brain damage. The Institute of Medicine, in the United States, has reviewed many reports and research studies related to vaccines and seizures, and found that children who experienced febrile seizures did not experience long term problems.¹⁶²
- Children susceptible to febrile seizures may experience them with any situation that causes a high fever such as a cold.

What can be done to decrease the risk of fevers and febrile seizures?

- Since 1997, Canada has used a newer, “acellular” pertussis vaccine. It has been used in Japan for over 15 years and found to have far fewer side effects. A large Canadian study has just released preliminary results about the use of this vaccine in Canada. The findings include a decrease in febrile seizures by 87%, and a decrease in fainting by 75% (related to receiving pertussis vaccine).¹⁶³
- Parents can avoid many of the minor, passing side effects of vaccinations (such as fever, swelling of the injection site, fussiness) with the use of acetaminophen in the appropriate dose by weight for their child. A doctor or pharmacist can help parents decide this safe amount.

Allegation that vaccines cause brain damage

The pertussis vaccine has been claimed by anti-vaccine groups to cause brain damage. There are several facts that make it *extremely unlikely* that pertussis vaccine can cause permanent brain damage.

- The brain damage caused by the pertussis DISEASE occurs because of lack of oxygen and bleeding in the brain, caused by prolonged coughing spells. This coughing does not happen following pertussis vaccination.
- No mechanism has been found to show how the vaccine could damage the brain.

¹⁶² Institute of Medicine. Adverse Events Associated with Childhood Vaccines, 1994.

¹⁶³ Scheifele D et al. Marked reduction in febrile seizures and hypotonic-hyporesponsive episodes with acellular pertussis-based vaccines: results of Canada-wide surveillance, 1993-1998. The Infectious Disease Society of America Conference, November 1999.

- Several studies involving large numbers of children have found no patterns of brain abnormalities, acute brain illness (other than febrile seizures) or permanent brain damage, which could be linked to vaccine use.¹⁶⁴
- Problems with brain development often become noticeable only after the first few months of life, regardless of immunization. If the timing of vaccination, or a fever related to this coincides approximately with the time when symptoms begin to become noticeable, it is natural to question the vaccine. However, there is no evidence that the vaccine caused the illness.¹⁶⁵

¹⁶⁴ Canadian Paediatric Society, *Your Child's Best Shot*, 1997.

¹⁶⁵ Taylor B et al. Autism and measles, mumps and rubella vaccine: no epidemiological evidence for a causal association. *Lancet* 1999; 353: 2026-2029.

27. DO VACCINES CAUSE SUDDEN INFANT DEATH(SIDS)?

- There is no scientific evidence that the pertussis vaccine or any vaccine increases the risk or causes Sudden Infant Death (SIDS). The cause of SIDS is unknown at this time but does tend to occur about 2-4 months of age in babies who are vaccinated or not vaccinated. Recent evidence suggests that placing an infant on the back while sleeping significantly reduced the prevalence of SIDS.¹⁶⁶

The Allegation

- In 1985 Dr Viera Scheibner was testing her husband's infant breathing monitor called a "cotwatch" when she observed periods of 'stressed breathing' in babies following the DPT vaccination.
- She attempted to alert the medical and scientific community to her observation and was rebuffed. To share her views, she wrote the book, *Vaccination: One hundred years of orthodox research shows that vaccines represent a medical assault on the immune system.*¹⁶⁷

It is of interest to note that Dr. Scheibner is trained in micropalaeontology (the study of microscopic fossils) and has no medical training. Reviews of her book consistently note a limited understanding of vaccine research and scientific methodology.^{168, 169} For example, despite considerable research showing the efficacy of vaccines, Dr. Scheibner states:

"there is no evidence whatsoever that vaccines of any kind – but especially those against childhood diseases – are effective in preventing the infectious disease they are supposed to prevent." (p. 2)

To illustrate her lack of understanding about statistical analysis between two populations with different sized samples, the following quote is cited.

"So the vaccine seemed to provide some degree of protection; however, the numbers of vaccinated and unvaccinated are so different that any comparison is scientifically invalid." (p.15)

¹⁶⁶ Haslam RH. Smoking and Sleeping Position are only Pieces of the Puzzle Resulting in the Sudden Infant Death Syndrome. *Pediatric Research* 2000; 48: 715.

¹⁶⁷ Scheibner V. *Vaccination 100 years of orthodox research shows that vaccines represent a medical assault on the immune system.* Dr. V. Scheibner, Blackheath, 1993.

¹⁶⁸ Bassler S. Anti-immunisation scare; the inconvenient facts. *Australian Skeptics* 1999; 17(1)
<http://www.skeptics.com.au/journal/anti-immune.htm>

¹⁶⁹ Leask JA. Viera Scheibner Ph.D. prominent vaccination opponent. Paper in preparation, 2000.

- The peak time for SIDS is between two and four months of age which is also the recommended times for the first two doses of DTP.
- By chance, infants might die from SIDS about the time or soon following their immunization.
- Other researchers in the US and elsewhere have evaluated the possibility that DTP immunization can increase the risk for SIDS. None of the well-controlled studies demonstrated a difference in occurrence of SIDS in vaccinated and unvaccinated groups.^{170, 171, 172}

Do vaccines cause shaken baby syndrome?

Another allegation proposed by Dr. Scheibner is that shaken baby syndrome is in fact a result of vaccine damage.¹⁷³ There is no evidence to support this claim.

- CDC analyzed data from its ongoing Metropolitan Atlanta Developmental Disabilities Surveillance Program (MADDSP) for 1991, the most recent year for which complete data were available, to assess the prevalence and determine the specific etiology of postnatally acquired developmental disabilities. This analysis indicated that bacterial meningitis and child battering were the leading postnatal causes of developmental disabilities. Children with postnatally acquired developmental disabilities had a higher average number of disabilities than all other children with developmental disabilities.¹⁷⁴

¹⁷⁰ Jonville-Bera AP et al. *Fundamental Clinical Pharmacology* 1995; 9(3): 263-70.

¹⁷¹ Carvajal A et al. *Medicina Clinica (Barc)* 4 May 1996 ;106(17): 649-52.

¹⁷² Mitchell EA et al. *Archives of Diseases in Childhood* 1995 Dec 73(6): 498-501.

¹⁷³ Scheibner V. Shaken Baby Syndrome: the vaccination link. *Nexus magazine* 1998;5(5).

<http://www.nexusmagazine.com/shakenbaby.html>

¹⁷⁴ CDC. Postnatal Causes of Developmental Disabilities in Children Aged 3- 10 Years -- Atlanta, Georgia, 1991. *Morbidity and Mortality Weekly Review*, February 16, 1996; 45(06):130-134.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/00040247.htm>

28. POLIO VACCINE AND CANCER

SV40 and Polio Vaccine

- Simian virus 40 or SV40 is a virus that was first discovered in 1960 and belongs to a group of viruses (papovaviruses) that may cause some cancers in rodents. SV40 has also been found in rhesus monkeys and causes lesions to form in tissues of the brain, lung, kidney, lymph and spleen of immunocompromised monkeys.^{175, 176}
- Soon after its discovery in 1960, SV40 was identified in polio vaccine. In 1961, the virus was found to cause tumors in rodents. That same year the federal government required all polio vaccine to be free of SV40.
- Extensive testing of the polio vaccine was done to determine if it was contaminated with SV40.
- The inactivated polio vaccine used in Canada is produced from cells that have been studied for many years. They are tested repeatedly for contamination and SV40 is not present in current vaccines.¹⁷⁷
- SV40 has no relationship to HIV, the virus that causes AIDS in humans, or simian immunodeficiency virus (SIV), the virus that causes AIDS in monkeys.
- Some researchers identified SV40 virus in the cells of some rare human cancers^{178, 179} in individuals who had not receive the SV40 contaminated vaccine. This suggests that SV40 is circulating and not introduced solely in the vaccines. However, other scientists have not been able to validate these findings.

Who received SV40 contaminated polio vaccine?

- People receiving a polio shot between 1954 and 1963 may have had vaccine contaminated with SV40.

¹⁷⁵ Lednicky JA et al. Natural isolates of simian virus 40 from immunocompromised monkeys display extensive genetic heterogeneity: new implications for polyomavirus disease. *Journal of Virology* 1998; 72: 3980-3990.

¹⁷⁶ Newman JS et al. Identification of SV40 in brain, kidney and urine of healthy and SIV-infected rhesus monkeys. *Journal of Neurovirology* 1998; 4: 394-406.

¹⁷⁷ Canadian Pediatric Society, *Your Child's Best Shot*, 1997: 47.

¹⁷⁸ Butel JS, Lednicky JA. Cell and molecular biology of simian virus 40: Implications for human infections and disease. *Journal of National Cancer Institute* 1999; 91: 119-134.

¹⁷⁹ Carbone M et al. Simian virus 40, poliovaccines and human tumors: a review of recent developments. *Oncogene* 1997; 15: 1877-1888.

SV40 impact on health

- When SV40 was discovered in the early 1960s, researchers did not know if SV40 virus could negatively affect the health of people. Medical researchers are conducting follow-up to determine if individuals who received the polio vaccine with SV40 have had cancers that could be related to SV40.
- The Centers for Disease Control and Prevention is not aware of any person who has developed an illness as a result of receiving a polio vaccine that may have been contaminated with SV40.¹⁸⁰ It is hypothesized that the formalin used to inactivate the polio viruses would have helped to inactivate SV40. It is likely that in many contaminated batches, in which the initial concentrations of SV40 were not high, formalin may have inactivated most or all of the SV40 virus.¹⁸¹
- Many of the persons reported to have SV40 in their tumors were too young to have received vaccine containing SV40. Further, the DNA sequencing of the SV40 found in tumors is different from the DNA sequencing of laboratory SV40.¹⁸² This suggests that the SV40 being found in tumors is unrelated to the SV40 in polio vaccine during the 1950s through early 1960s.
- The only other vaccines found to contain SV40 were those given to protect young men from respiratory infections in army camps between 1955 and 1961.

What you need to know

- Data are reviewed on an ongoing basis in Canada through national consultation with experts in public health, immunology, paediatrics, and epidemiology to test if people who received SV40 containing polio vaccine might be at greater risk of developing certain cancers.
- The SV40 issue was discussed at a National Institute of Health (NIH) meeting in Bethesda, Maryland in early 1997. Review of the data presented at this meeting did not indicate that there was an excess risk of any of the common forms of cancer in those persons exposed to SV40 in polio vaccines between 1955 and 1963.¹⁸³
- International research about SV40 is continuing since evidence suggests that SV40 is transmitted among humans.¹⁸²
- Poliomyelitis is a contagious disease that most often affects non-immune children less than three years old. It can cause paralysis within hours of infection and has no known cure. Because of worldwide efforts to immunize all children, the World Health Organization has

¹⁸⁰ Centers for Disease Control, Simian Virus 40 (SV40) and Cancer, <http://www.cdc.gov/nip/vacsafe/concerns/Cancer/default.htm>.

¹⁸¹ Shah K, Nathanson N. Human Exposure to SV40: review and comment. *American Journal of Epidemiology* 1976; 103: 1-12.

¹⁸² Butel JS. Simian virus 40, poliovirus vaccines, and human cancer: research progress versus media and public interests. *World Health Organization* 2000; 78(2): 195-198.

¹⁸³ National Institutes for Health Workshop. Simian Virus 40 (SV40), a Possible Human Polyomavirus. *Emerging Infectious Diseases* 1997 April-June; 3(2): 245-247.

set the goal to stop the transmission of wild polio virus by the end of 2000 and to certify eradication by 2005. Until that time, immunization against polio will continue to be necessary.

- The use of polio vaccine has saved many children from death and lifelong disability. Vaccines made today are free of SV40 or similar viruses, and scientists continue to closely monitor these vaccines to maintain high levels of safety for everyone receiving them.

If someone had a polio vaccine in the late 1950s/early 1960s what should they do?

Since no specific disease risk has been established at this time, people do not need to be tested to see if they were exposed to the virus. Anyone experiencing health concerns should consult their health care provider.

29. WHY DO CHILDREN NEED THE HEP B VACCINE?

Some parents state that their children are not at risk for Hepatitis B since they are not ‘promiscuous’ or ‘drug users’.

- Hepatitis B is a virus that infects the liver causing an inflammation of the liver, cirrhosis (severe liver disease) and liver cancer.¹⁸⁴
- Hepatitis B is transmitted by blood and close personal contact, much like AIDS, but Hepatitis B is 50 to 100 times more infectious than AIDS.¹⁸⁵
- Worldwide, approximately 2,000 million people have been infected with the virus, and more than 350 million are chronic carriers of the virus. These chronic carriers are at high risk of death from cirrhosis of the liver and liver cancer, diseases that kill about one million persons each year.¹⁸⁵
- Originally the Hepatitis B vaccine was recommended only for intravenous drug users, health care workers, men who have sex with men, people living with someone infected with Hepatitis B and children born to mothers who are Hepatitis B positive. However, in the U.S., 30-40% of Hepatitis B infections occur in people not in a high risk group.^{184, 186}
- Although there are no national data on the prevalence of chronic Hepatitis B infection in Canada, it appears that fewer than 5% of residents have evidence of past illness.¹⁸⁷
- The recommendation (from NACI) is for universal immunization during childhood, and a pre-adolescent strategy is recommended as a cost-effective option.¹⁸⁷ Although the vaccine will not cure chronic carriers, it is 95% effective in preventing people from becoming carriers, and is the first vaccine against a major human cancer.¹⁸⁷
- Children’s immune response to Hepatitis B vaccine is better than in adults.¹⁸⁷

The following table outlines those persons in Ontario who are eligible for publicly funded Hepatitis B Vaccine.

The following groups receive publicly funded hepatitis B vaccine through the Public Health Branch program. Vaccine is ordered through local health departments.

¹⁸⁴ Offit PA, Bell LM. Vaccines: What every parent should know. Revised edition. IDG Books, NY, 1999:75,76.

¹⁸⁵ World Health Organization Hepatitis B Fact Sheet: <http://www.who.int/health-topics/hepatitis.htm>

¹⁸⁶ Hepatitis B virus: a comprehensive strategy for eliminating transmission in the United States through universal childhood vaccination. Recommendations of the Immunization Practices Advisory Committee (ACIP). Morbidity and Mortality Weekly Report November 22, 1991: 40.

¹⁸⁷ Health Canada, Canadian Immunization Guide, 1998: 90, 95.

Individuals eligible for Hepatitis B Vaccine at no cost

1. Infants born to carrier mothers - 2nd and 3rd dose only
2. Household and sexual contacts of chronic carriers
3. Household and sexual contacts of acute cases
4. Patients on renal dialysis and those with diseases requiring frequent receipt of blood products (e.g., haemophilia) - 2nd and 3rd dose only
5. Children and adults who are in the community awaiting liver transplants - 2nd and 3rd dose only
6. Intravenous drug users
7. Homosexual men and heterosexuals with multiple sex partners (mainly in STD clinics)
8. Those having needlestick injuries in a non health care setting
9. Hepatitis B School Immunization Program - Grade 7 Students
10. Children < 7 years old whose families have immigrated from countries of high prevalence for hepatitis B, and who may be exposed to HBV carriers through their extended families
11. Hepatitis C carriers.

MOHLTC September 1998

30. DOES THE HEPATITIS B VACCINE CAUSE MULTIPLE SCLEROSIS?

- No direct association has been found between the Hepatitis B (Hep B) vaccine and Multiple Sclerosis (MS).¹⁸⁸
- Hepatitis B is a very serious disease, and the Hep B Vaccine is highly effective in preventing the disease.
- In 1998, in the wake of enormous pressure from anti-vaccine groups, the French Ministry of Health announced a decision to suspend routine Hep B immunization of adolescents in French schools, while continuing the immunization of infants and high risk adults.
- Media reports highlighted two case reports suggesting a link between Hepatitis B vaccines and development or flare-up of demyelinating diseases such as multiple sclerosis (MS). Although generating considerable concern, these limited case reports have shown *no actual proof* linking MS and Hep B vaccines.^{189, 190}
- In France, a descriptive analysis of adverse event reports in those vaccinated with GenHevac B vaccine from 1989 to December 31, 1998 was undertaken.¹⁹¹ Of all those who received the vaccine, 187 cases were reported to have demyelinating disease (0.54 reports per 100,000 doses of GenHevac B distributed). The average age of onset was 31.7 years of age, with 73% female cases. The authors analyzed the time between the last dose of vaccine and the onset of disease, which ranged from 1 day to 5 years (median: 60 days). The authors concluded that their results and current available clinical and epidemiological data regarding multiple sclerosis, suggest that there is NO causal relationship between CNS demyelinating disease and vaccination with GenHevac B.
- The most plausible explanation of the observed temporal association between vaccination and multiple sclerosis is a coincidental association.¹⁹² Each year, out of 100,000 people in the general population, 2-5 individuals are diagnosed with multiple sclerosis.¹⁹³ When one

¹⁸⁸ Press Release WHO/67, 2 October 1998 www.who.int/vaccines-diseases/safety/hotspot/hepb.htm

¹⁸⁹ Renard JL et al. Acute transverse cervical myelitis following hepatitis B vaccination. Evolution of anti-HBs antibodies. Presse Medicale 1999 Jul 3-10;28 (24):1290-2.

¹⁹⁰ Tourbah A et al. Encephalitis after hepatitis B vaccination: recurrent disseminated encephalitis or MS? Neurology 1999 Jul 22;53(2):396-401.

¹⁹¹ Soubeyrand B et al. Central nervous system demyelinating disease following hepatitis B vaccination with GenHevac B. Review of ten years of spontaneous notifications (1989-1998). [French] Presse Medicale 2000;29(14):775-780.

¹⁹² Monteyne P, Andre PE. Is there a causal link between hepatitis B vaccination and multiple sclerosis? Vaccine 2000;18(19):1994-2001.

¹⁹³ Murray CJ, Lopez AD. Evidence-based health policy--lessons from the Global Burden of Disease Study. Science 1996 Nov 1;274(5288):740-3.

examines 100,000 people who received the Hep B vaccine, only 0.65 people are diagnosed with MS. *The incidence of MS is no higher amongst the vaccinated population than in the non-vaccinated population.*

- A recently published research letter from British Columbia described no evidence between Hepatitis B vaccination and developing MS in adolescence.¹⁹⁴ Studies in other countries have found no evidence of an association.¹⁹⁵
- In 1997, the World Health Organization and the European Viral Hepatitis Prevention Board, followed by the National Multiple Sclerosis Society, in 1998, concluded that no current evidence links hepatitis B vaccination and multiple sclerosis.¹⁹⁶
- There have been 550 million individuals immunized with Hepatitis B vaccines since 1982, with no increased rates of MS or flare-ups observed.¹⁹⁶
- In Italy, hepatitis B vaccination has been mandatory since 1991 for newborns, 12-year-old children, as well as high-risk groups.¹⁹⁵ In order to evaluate the risk/benefit strategy of hepatitis B vaccination, the authors study a hypothetical cohort of 100,000 newborns using a simulated model. In the cohort, one would expect 1,099 hepatitis B cases that would be prevented with vaccination. Even if we assume that the connection between multiple sclerosis and hepatitis B were true (highest odds ratio of 1.7), the excess of “life-time” multiple sclerosis incidence would be 0.3% for 12-year-old subjects, and 2.9% for adults. Therefore, benefits of vaccination outweigh the theoretical (and unproven) risk of possible multiple sclerosis.
- What would happen if we stopped vaccinating with hepatitis B? There are more than 2 billion persons who have been infected with hepatitis B virus worldwide. Out of these, 350 million are life-long carriers of the disease who can transmit the virus to others. Each year, one million of these people die from liver disease and liver cancer.¹⁹⁷

What is MS?

Multiple sclerosis (MS) is a central nervous system disease seen more often in women than men, and usually diagnosed in early to mid-adulthood. MS is a progressive, deteriorating disease with periods when symptoms are worse, and remissions when symptoms are much better. The immune system attacks and damages the fatty material (myelin) around nerves in the brain and spinal cord. Symptoms of MS vary between individuals, and are caused by the breakdown of myelin, which is part of nerve tissue. There is no known cure for MS.

What causes MS?

The cause of MS is not known. The most widely accepted theory is that MS occurs in patients with a genetic susceptibility, and that some environmental factor(s) triggers flare-ups. The

¹⁹⁴ Sadovnick A, Scheifele D. School-based hepatitis B vaccination programme and adolescent multiple sclerosis. *Lancet* 2000; 355, February 12:.

¹⁹⁵ Tosti ME *et al.* Multiple sclerosis and vaccination against hepatitis B: analysis of risk benefit profile. *Italian Journal of Gastroenterology & Hepatology* 1999 Jun-Jul;31(5):388-91.

¹⁹⁶ Humiston SG, Good C. Vaccinating your child, questions and answers for concerned parents. Peachtree Publishers, Atlanta; 2000: 40,69.

¹⁹⁷ www.cdc.gov/nip/publications/fs/gen/WhatIfStop.htm

genetic predisposition theory is supported by studies showing increased risk of MS in families of people with MS, as well as certain ethnic populations, such as northern Europeans. Many environmental and infective factors have been studied, but none have been found to trigger MS.

It is natural for people to look for causes when a serious illness occurs, but scientific research is the appropriate test of theories, not individual stories and conclusions drawn from them.

31. IS HEP B VACCINE MADE FROM BLOOD PRODUCTS?

No. Since 1986, the Hepatitis B vaccine has been produced in yeast cells.

In the early 1980s, the protein on the outer envelope of the virus was obtained from the plasma (the liquid part of blood) of chronic Hepatitis B infected persons. Due to the public's fear of acquiring other viruses from blood products, the safer alternative using yeast cells was developed.

32. IS CHICKENPOX (VARICELLA) VACCINE RECOMMENDED?

Varicella vaccine is recommended for primary vaccination of healthy children 12 months to 12 years who are susceptible to the disease.¹⁹⁸

However, the chickenpox vaccine is not presently one of the regularly scheduled or publicly funded vaccines for Ontario children. In Canada it was licensed for use in 1998¹⁹⁸ and is available for people through their physician. This vaccine has been used in Japan for over 20 years¹⁹⁹ and in the U.S. since 1995.²⁰⁰

What is Varicella?

- Varicella or chickenpox is a very common contagious disease, which most children catch by the time they reach adolescence.
- Spread is by contact with an infected person – a person is infectious as long as 5 days but usually 1-2 days before the rash appears until all lesions have crusted, usually about 5 days. Since the incubation period is 2-3 weeks, the susceptible individuals should be considered infectious 10-21 days following exposure.²⁰¹
- Usually the illness is considered mild - the average child will have 400 skin lesions (“pox”) and several days of discomfort including itchiness, and some pain. Specific complications occur in 5% to 10% of cases of varicella in otherwise healthy children.^{202, 203}
- The most common complications from varicella are bacterial infections of the skin and soft tissues in children and pneumonia in adults.¹⁹⁸
- Hospitalization rates for varicella vary but are in the range of 5.3-7.5 per 100,000 each year. Of those, 92.5% were children less than 15 years of age.²⁰⁴
- Although the varicella-related mortality rate among children generally is low, the highest morbidity rates occur during the first year of life and after the age of 15. Between 1987 and 1996 there were 1 to 16 deaths each year attributable to varicella with 26% being children less than 10.²⁰⁵ Among persons greater than or equal to 15 years of age, the risk for death

¹⁹⁸ National Advisory Committee on Immunization. Statement on Recommended Use of Varicella Virus Vaccine, Canada Communicable Disease Report. (25) 1 May, 1999.

<http://www.hc-sc.gc.ca/hpb/lcdc/publicat/ccdr/99vol25/25sup/acs1.html>

¹⁹⁹ Asano Y et al. Experience and reason: twenty-year follow-up of protective immunity of the Oka strain live varicella vaccine. *Pediatrics* 1994;94:524-526.

²⁰⁰ Recommendations for the use of live attenuated varicella vaccine. *Pediatrics* 1995; 95:791-796.

²⁰¹ National Immunization Program – Varicella clinical QA. <http://www.cdc.gov/nip/Q&A/clinqa/var.htm>

²⁰² Dunkle L et al. A controlled trial of acyclovir for chickenpox in normal children. *New England Journal of Medicine* 1991;325:1539-44.

²⁰³ Choo PW et al. The epidemiology of varicella and its complications. *Journal of Infectious Diseases* 1995;172:706-12.

²⁰⁴ Law BJ et al. Chickenpox in Manitoba: a population-based assessment using the Manitoba Health Services Commission Database. Poster presentation. 3rd National Immunization Conference, 6-9 December 1998, Calgary Alberta.

²⁰⁵ Health Statistics Division, Statistics Canada, unpublished data.

increases with age, from 2.7 per 100,000 among persons 15-19 years of age to 25.2 per 100,000 among persons 30-49 years of age (CDC, unpublished data).

- The chickenpox virus remains in the body after the infection, and can reappear later in life as shingles. This painful condition which can occur repeatedly, may take several weeks to heal and can cause posttherapeutic neuralgia.
- If a pregnant women becomes infected with chickenpox in the first half of the pregnancy the baby may suffer from congenital varicella syndrome. This syndrome can affect the growth of the fetus (low birth weight), scar the skin, and cause defects in bones, eyes and nervous system. The syndrome is seen in 0.5 to 2.0 percent of babies of mothers infected in the first half of their pregnancies, and is preventable.²⁰⁶

Who should be immunized?

- The National Committee on Immunization (NACI) recommends this vaccine for “healthy persons 12 months or more of age that are susceptible to the disease”.²⁰⁷
- The vaccine can be given at the same time as other childhood vaccinations, at a different site on the child.
- People 13 years and older will need two doses at least four weeks apart.

What should parents know about the vaccine?

- The chickenpox vaccine is a live, attenuated (weakened) vaccine with effectiveness of 95% against getting severe chickenpox for at least seven to ten years.^{208, 209} At this time no booster doses are recommended.
- Side effects of the vaccine are generally mild and may include pain and redness at the injection site. Less often, a fever or rash may happen.²¹⁰
- Vaccination is contraindicated for persons who have a history of anaphylactic reaction to any component of the vaccine, including gelatin. Varicella virus vaccine does not contain preservatives or egg protein -- substances that have caused hypersensitive reactions to other vaccines. Varicella virus vaccine should not be administered to persons who have a history of anaphylactic reaction to neomycin.²¹¹

Who should not get this vaccine?

The varicella vaccine is not recommended for:

- Those who may have hypersensitivity to any part of the vaccine, such as gelatin;
- People who are taking medication which suppresses their immune systems;
- Babies less than one year old;

²⁰⁶ Pastuszak AL et al. Outcome after maternal varicella infection in the first 20 weeks of pregnancy. *New England Journal of Medicine* 1994; 330: 901-905.

²⁰⁷ National Advisory Committee on Immunization. Statement on Recommended Use of Varicella Virus Vaccine, *Canada Communicable Disease Report*. 1 May 1999; 25. <http://www.hc-sc.gc.ca/hpb/lcdc/publicat/ccdr/99vol25/25sup/acs1.html>

²⁰⁸ Weibel RE et al. Live attenuated varicella virus vaccine: efficacy trial in healthy children. *New England Journal of Medicine* 1984; 310:1409-1415.

²⁰⁹ Plotkin SA. Varicella vaccine. *Pediatrics* 1996;97: 251-253.

²¹⁰ Weibel RE et al. Live attenuated varicella vaccine: efficacy trial in healthy children. *New England Journal of Medicine* 1984;310:1409-15.

²¹¹ See specific package insert.

- Pregnant women, or those planning to become pregnant within one month of getting vaccinated.

Does my child need this vaccine to attend school/daycare?

- The Immunization of School Pupils Act (RSO 1990) or the Day Nurseries Act (RSO 1990) does not presently require the varicella vaccine.
- It is not a publicly funded vaccine although some health benefits programs may cover part or all of this cost.

33. DOES THE INFLUENZA VACCINE CAUSE THE FLU?

NO. The influenza vaccine is made using “killed” viruses. This means that it can not cause the flu.

- At times, people may confuse symptoms of a cold with the flu.
- They may have been exposed to the flu and caught it prior to receiving their vaccination.
- They may have come in contact with some strain of influenza not included in the vaccine.

What is the “flu”?

Influenza or the flu is a very contagious viral infection of the respiratory tract. It is sometimes confused with the common cold, as well as gastrointestinal illnesses (“stomach flu”). Influenza is neither of these. The flu tends to have a sudden onset, and be more severe than a cold, and include these symptoms: stuffy nose, sore throat, cough, fever, headaches, general body aches and weakness. Influenza usually lasts for 5 to 10 days, but the cough and weakness may last up to 6 weeks. The flu can weaken the body’s ability to fight off other infections. See Table.²¹²

SYMPTOM	COMMON COLD	INFLUENZA
Fever	Rare	Often high; sudden onset: lasts 3-4 days
Headache	Rare	Frequently
Aches and pains	Slight	Usual; often quite severe
Weakness	Rare/Mild	Moderate to extreme; may last up to one month
Bed ridden	Rare	Frequently; may last up to 5-10 days
Sniffles	Common	Sometimes
Sneezing	Usual	Sometimes
Sore Throat	Common	Sometimes
Cough	Sometimes; Mild to moderate	Usual: Can become severe
Complications	Sinus or ear infection	Pneumonia Kidney Failure Heart Failure Can be life threatening

²¹² McQuigge M et al. Do you know the facts about the influenza vaccine? Press Release- Part 2, Bruce-Grey-Owen Sound Health Unit, 1999.

Most people who get influenza will not become seriously ill. However, the flu can also lead to serious complications such as pneumonia, bronchitis, kidney and heart failure, especially in people with other health concerns and older adults.

The flu is spread through contact with an infected person who coughs or sneezes. It is also spread by direct contact with things that have been contaminated with the virus such as unwashed hands, eating utensils, toys and clothes.

Why is a flu shot needed each year?

Each year the World Health Organization monitors the influenza viruses circulating and causing infections, and in turn recommends the vaccine components that will be most effective for the coming year. Because the viruses affecting people are changing, new vaccines are developed each year to fight them.²¹³

²¹³ National Advisory Committee on Immunization. An Advisory Committee Statement (ACS) Statement on Influenza Vaccination for the 1999-2000 season. Canada Communicable Disease Report, 1 June 1999 (25).

34. DOES THE FLU VACCINE CAUSE ALZHEIMER'S DISEASE?

There is no evidence that repeated flu shots cause Alzheimer's Disease (AD) although one physician has made this allegation.

- A physician verbally reported that individuals receiving the flu shot for five consecutive years were at increased risk for AD. This was attributed to the mercury and aluminum contained in the vaccine.²¹⁴

The Facts

- Influenza vaccines have never contained aluminum.
- The mercury found in the vaccine is from thimerosal, which is used as a preservative in the vaccine. The amount of exposure to mercury, as a result of receiving the vaccine, is considerably lower than the amount Health Canada considers as safe even when combined with everyday sources of mercury. Other sources of mercury are dental amalgam (a type of tooth filling) and fish consumption (fresh fish and canned tuna are examples).
- In Canada and the US, the influenza vaccines have 25 micrograms (mcg) of mercury in every 0.5 milliliter (ml) adult dose, and 12.5 mcg of mercury in every 0.25 (ml) infant dose. (Children under 9 years are advised to receive 2 doses in their first year of receiving the influenza vaccine.)
- The estimated (total) daily intake of mercury for Canadians is 7.7 mcg/day. The flu shot would bring the total intake of mercury to approximately 32.7 mcg - well below the tolerable daily intake for adult women and men (range of 42.6mcg-49.7mcg). Considering that the influenza immunization is repeated at the most annually, a single dose of influenza vaccine does not contribute significantly to mercury exposure in the recipient even on the day of injection.
- A recent study found no significant difference in brain mercury levels between subjects with Alzheimer's Disease and subjects who did not have Alzheimer's.²¹⁵
- The influenza vaccine is approximately 70% effective. It protects most who receive it from the flu or reduces the seriousness of the disease including complications such as pneumonia and kidney failure, associated with influenza.²¹⁶

²¹⁴ Fudenberg H. National Vaccine Information Center: First International Public Conference on Vaccination, September 1997.

²¹⁵ Saxe SR et al. Alzheimer's Disease, Dental Amalgam and Mercury. Journal of the American Dental Association 1999;130:191-199.

²¹⁶ Carman WF et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: A randomised controlled trial. Lancet Jan 8, 2000.

Facts about Mercury (Hg)*

- Mercury is a naturally occurring element - the estimated intake of Hg for the average Canadian is 7.7 micrograms/day. This is equivalent to an absorbed dose of 5.3 mcg/day.
- Fish consumption contributes to about 40% of absorbed dose.
- Dental amalgam accounts for about 42% of the absorbed dose.
- Other foods contribute about 3.4% of absorbed dose.
- Average tolerable daily intake (for woman estimated weight of 60kg – 42.6 mcg/day - for man estimated weight of 70kg – 49.7mcg/day (based on a tolerable daily intake** of 0.71 mcg /kg/day).

**Contaminant Profiles, Health Canada, 1998; 78-83.*

** “Tolerable daily intake: The daily intake of a substance from all sources during a person’s entire lifetime which appears to be without appreciable risk to health on the basis of all known facts.” *Laboratory Centre for Disease Control & Therapeutic Products Programme, Thimerosal and Vaccine Public Information: Questions/Answers, Draft July 23, 1999.*

35. DOES THE FLU VACCINE CAUSE GUILLAIN BARRE SYNDROME (GBS)?

There is a very small risk of a person developing GBS following an influenza vaccine. A conservative estimate is that the risk for GBS may be 1 to 2 cases per million persons vaccinated.

- Guillain-Barré Syndrome (GBS) is a rare disorder of the nervous system that causes temporary paralysis and loss of reflexes.
- The cause of GBS is unknown but a virus is suspected.
- GBS usually begins with muscle weakness usually in the legs then arms with most patients making a complete recovery.²¹⁷
- Although most patients recover, up to 6% die of complications.²¹⁸

Vaccines associated with GBS²¹⁹ include:

- Swine Flu vaccine (A/New Jersey) vaccine in 1976-1977
- Oral polio vaccine
- Tetanus toxoid

Data suggests that with the Swine Flu vaccine (1976-1977) the incidence of GBS following vaccine may have been as high as 10 cases per million vaccinated.²²⁰

A large study reviewed hospital discharge summaries from 4 states between September 1, 1992 and February 28, 1993 and September 1, 1993 and February 28, 1994 to identify patients with GBS. Comparison of GBS following vaccine and non-vaccine related cases showed some differences.²¹⁸

- Patients with vaccine associated GBS were less likely to have had a prior gastrointestinal illness, respiratory illness, Epstein-Barr virus infection, Cytomegalovirus infection or surgery (33% vs. 57%).
- The mean age of patients with vaccine associated GBS was older.
- The proportion requiring ventilation and the proportion that died were comparable.
- Among 4 million vaccine recipients under 45 years of age, there were no vaccine-associated cases of GBS.
- Onset of GBS following vaccine peaked in the second week after vaccination usually between day 9 and 12.²¹⁸

²¹⁷ Asbury AK, Cornblath DR. Assessment of current diagnostic criteria for Guillain-Barre syndrome. *Annals of Neurology* 1990; 27: S21-4.

²¹⁸ Lasky T et al. The Guillain-Barré syndrome and the 1992-1993 and 1993-1994 influenza vaccines. *New England Journal of Medicine* 1998;339:1797-802.

²¹⁹ Stratton KR et al. *Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality*. Washington, DC: National Academy Press, 1994: 464.

²²⁰ Prevention and control of influenza: recommendations of the Advisory Committee on Immunization Practices (ACIP). *Morbidity and Mortality Weekly Report*. 1998; 47 (RR-6): 1-26.

- Relative risk for GBS in a non-vaccinated population is 0.145 case per million persons per week or 0.87 case per million persons per six week period.
- The risk during the 6 weeks following vaccination was 0.61 case per million vaccinations.

36. COMMUNICATING RISK TO PARENTS

When a parent calls a health unit, it is an opportunity for staff to provide important health teaching. The intent is to promote an informed choice about immunization. Strong scientific research supports immunization as an effective health promotion strategy. Vaccines save lives, yet parents may have heard frightening stories about serious side effects or long term problems following immunization.

Parents need to understand the risks of vaccine preventable diseases and the risks of vaccines. The following passage is taken from the CDC web site.²²¹

1. Risk communication is a dynamic process in which many participate, and these individuals are influenced by a wide variety of circumstances, interests, and information needs. Effective risk communication depends on the providers' and recipients' understanding more than simply the risks and benefits; background experiences and values also influence the process.²²² Good risk communication recognizes a diversity of form and context needs in the general population.
2. Second, the goal that all parties share regarding vaccine risk communication should be informed decision-making. Consent for vaccination is truly 'informed' when the members of the public know the risks and benefits and make voluntary decisions.
3. Finally, there is often uncertainty about estimates of the risk associated with vaccination. Risk communication is more effective when this uncertainty is stated and when the risks are quantified as much as science permits. Trust is a key component of the exchange of information at every level, and overconfidence about risk estimates that are later shown to be incorrect contributes to a breakdown of trust among public health officials, vaccine manufacturers, and the public. Continued research to improve the understanding of vaccine risks is critical to maximizing mutual understanding and trust."²²³

Suggestions for speaking to parents concerned about immunization:

- Listen to the person's specific concerns. It is often more important for a person to trust the source of information, and feel that the source is sympathetic to their needs, than to hear about statistics and details.

²²¹ National Immunization Program. An overview of vaccine safety. <http://www.cdc.gov/nip/vacsafe/#Risk>

²²² Zeckhauser R. Coverage for catastrophic illness. *Public Policy* 1973; 21:149-72.

²²³ Institute of Medicine, Vaccine Safety Forum. Risk communication and vaccination: summary of a workshop. Washington, DC: National Academy Press, 1997.

- Know the information you are sharing or be clear if you do not know the answer. A guess has little value to a person and if you are perceived to be less than honest, your credibility will be lost. Once credibility is lost it may be impossible to regain it.
- Speak clearly and with compassion. Some people have heard of or experienced sick children following a vaccination. If it appears to be vaccine related problem ensure that an adverse vaccine reaction (AVR) report is completed. If it is a time limited problem, suggest strategies to help the child e.g. acetaminophen for fever.
- Ask if your message is clear. Use concrete examples to illustrate situations.
- Remain calm. Some parents may be upset or angry. Listen but base your response on current research. Do not agree that the vaccines might have caused a problem if most current research does not support this.
- Avoid using absolute risk numbers. Keep in mind that many people cannot understand what probability numbers represent.
- Remind parents that not immunizing carries real risk. This is often overlooked by parents trying to assure their children's well being. Perhaps also mention that risk is greater for some individuals who are unable to receive vaccinations. Others who are immunized can not pass the disease to them.

Although vaccines are very safe, they are not 100% safe. The risks of vaccines are often exaggerated. The following outline illustrates some of the factors that help us decide about risks.

Risks²²⁴ are generally more worrying (and less acceptable) if perceived:

- To be involuntary (e.g. mandated by policy or law) rather than voluntary;
- As inequitably distributed (some benefit while others suffer the consequences);
- As inescapable by taking personal precautions (there's nothing one can do to avoid the risks);
- To arise from the unfamiliar or novel source (a plane crash vs. a car crash);
- To result from man-made, rather than natural sources (risks from vaccines vs. risks from the diseases);
- To cause hidden and irreversible damage, e.g. through onset of illness many years after exposure;
- To pose some particular danger to small children or pregnant women or more generally, future generations;
- To threaten a form of death (or illness or injury) arousing particular dread (e.g., SIDS, autism, multiple sclerosis, Alzheimer's Disease to list a few);
- To damage identifiable rather than anonymous victims;
- To be poorly understood by science (e.g. the immune system is very complex and difficult to discuss easily. The etiology of diseases such as SIDS, autism, Alzheimer's are not known).

²²⁴ Bennett P, Calman K. Risk Communication and Public Health, Oxford University Press, 1999: 6.
<http://www.cdc.gov/nip/vacsafe/#Risk>

- As subject to contradictory statements from responsible sources (or even worse from the same source).

Many of these factors come into play in considering the risks of vaccines. The results of numerous, large sample, well controlled research studies have less impact than a personal experience with one child who suffered a side effect from a vaccine.

The source of information also is important. The message from a trusted health provider is usually taken more seriously than from an anonymous source.

The media may give equal coverage to the findings of a single case report and the findings from numerous well-controlled, peer-reviewed studies. This type of reporting may occur since media frequently seek out stories with:

- Questions of blame
- Alleged secrets and attempted cover ups
- Human interest through identifiable heroes, villains, dupes
- Links with existing high profile issues or personalities
- Conflict
- Signal value – the story as a portent of further ills
- Many people exposed to risk – even at low levels (perceived generalizability – you could be next)
- Strong visual impact - pictures of suffering
- Links to sex and/or crime.²²⁵

Several recent media reports have provided well-researched and balanced articles about immunization. See articles from Canadian Living and Readers Digest (sections F and G).

²²⁵ Bennett P, Calman K. Risk Communication and Public Health, Oxford University Press, 1999: 17.

37. SUGGESTIONS FOR COMMUNICATING WITH THE ANTI-VACCINATION PARENT*

- Listen to their concerns. Show that you really do care about the health and safety of their individual child.
- Admit that some old vaccines did cause problems, BUT WE DON'T USE THEM ANYMORE. Newer vaccines are used today (e.g. Oral polio could cause paralytic polio in 1 out of 3 million doses given, and is not longer used in Canada. Pertussis vaccine caused high fevers in some children but has been replaced by acellular pertussis vaccine).
- Vaccines are effective. Hib vaccine introduced in 1992 has virtually eliminated Hib meningitis that killed or injured hundreds of children each year in Ontario.
- When immunization is stopped before the disease is eradicated, it returns and children get sick from the disease. Between 1974 and 1995 pertussis vaccination rates declined in Britain and Japan.²²⁶ During this decline, there were 30-40 pertussis deaths each year in these countries. In Russia, when their immunization system stopped in 1994, deaths from diphtheria jumped from 0 to over 1700.²²⁷
- When claims are made that certain vaccines cause rare but terrible diseases, researchers independent from the vaccine manufacturers immediately investigate these claims. So far, claims have not been supported by research. (Vaccines do not cause autism, SIDS, chronic fatigue or MS.)
- Consider having parents sign a waiver stating that they are aware of your warning that denying their child routine vaccinations may result in death, brain damage, permanent disability or serious damage to their own unborn children. This could be added to Form 2. (Parents must have Form 2 signed if they chose to not have their children immunized due to religious beliefs or conscience. School Pupil's Act, 1990)

*Used with permission of Ross A. Pennie, MD, FRCPC
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 McMaster University, Hamilton, Ontario,
 2000

²²⁶ Gangarosa EJ et al. Impact of Anti-Vaccine Movements on Pertussis Control: The Untold Story. Lancet 1998; 351(9099): 357.

²²⁷ CIAP web site: www.ciap.cpha.ca/resource/keydis/page3.htm

38. RECOMMENDED BOOKS

The following books may be useful to people looking for further information about immunizations.

Canadian Immunization Guide, National Advisory Committee on Immunization, 1998.
Guide canadien d'immunisation, National Advisory Committee on Immunization, 1998.

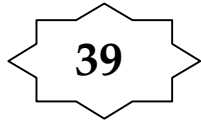
Your Child's Best Shot. The Canadian Paediatric Society. 1997.

Faire vacciner mon enfant, c'est important, Société canadienne de pédiatrie, 1997.

**Vaccines: What Every Parent Should Know*. Paul Offit and Louis Bell. IDG Books. 1999.

**Vaccinating your child, questions and answers for concerned parents*. Humiston, SG & C Good, Peachtree Publishers, 2000.

*(American).



39. IMMUNIZATION WEB SITES

CANADIAN SITES

Health Canada sites

<http://www.hc-sc.gc.ca/>

Health Canada Online-Main Site

<http://www.hc-sc.gc.ca/english/>

Health Canada Online

<http://www.hc-sc.gc.ca/main/lcdc/web/publicat/ccdr/>

Health Canada: Population and Public Health Branch

<http://www.hc-sc.gc.ca/hpb/lcdc/publicat/immguide/>

Health Canada: Population and Public Health Branch: Canadian Immunization Guide, 5th Edition, 1998

<http://www.hc-sc.gc.ca/hpb/lcdc/bid/di/>

Health Canada: Population and Public Health Branch: Division of Immunization

<http://www.hc-sc.gc.ca/hpb/lcdc/>

Health Canada: Laboratory Centre for Disease Control

<http://www.hc-sc.gc.ca/hppb/hpo>

Health Canada- health promotion online: Under the 10 Hottest Resources on HPO – check out The Canadian Guide to Clinical Preventive Health Care, Section 3, Immunization of Children and Adults.

www.canadian-health-network.ca

The Canadian Health Network has articles, reports and papers. A new section has been added on immunization - frequently asked questions, prepared by the Canadian Public Health Association.
English

http://www.canadian-health-network.ca/html/faq/chntopiccategory_13e.html

French

http://www.canadian-health-network.ca/html/faqf/chntopiccategory_13f.html

Canadian Public Health Association:

<http://www.immunize.cpha.ca/>

Canadian Immunization Awareness Program web site includes lists of resources, a Q and A section, and hot links to other immunization sites.

<http://www.influenza.cpha.ca/english/images/l-top.jpg>

Canadian Coalition for Influenza Immunization

<http://www.cpha.ca/International.Programs/IntP.home.html>

International Programs

Other Canadian Sites

www.cps.ca

Canadian Pediatric Society material includes information about vaccines and Q and A from the book, Your Child's Best Shot.

www.fightflu.com

The Lung Association site includes a Q/A and information about influenza and the flu vaccine.

<http://www.cihi.ca/>

Canadian Institute for Health Information

<http://www.cids.medical.org/>

The Canadian Infectious Disease Society

Ontario Ministry of Health

<http://www.gov.on.ca/health/>

Ontario Ministry of Health and Long-term Care

http://www.gov.on.ca/health/english/pub/pub_mn.html

Ontario Ministry of Health-Publications Online

U.S. IMMUNIZATION SITES**Centers for Disease Control**

<http://www.cdc.gov/>

The Centers for Disease Control main address.

<http://www.cdc.gov/od/nvpo/>

Centers for Disease Control and Prevention: National Vaccine program

<http://www.cdc.gov/nip/>

Centers for Disease Control and Prevention: National Immunization Program

www.cdc.gov/nip/vacsafe/

The Centers for Disease Control, (U.S.) has vaccine safety fact sheets and information about vaccine safety, hot topics, questions and concerns about vaccine side effects.

<http://www.cdc.gov/nip/vacsafe/concerns/autism/>

Centers for Disease Control and Prevention-Parent Concerns re Autism

<http://www.cdc.gov/nip/publications/pink/default.htm>

Centers for Disease Control and Prevention: Contents of the Pink Book

<http://www.cdc.gov/mmwr/>

Morbidity and Mortality Weekly Report

<http://www.cdc.gov/nip/news/vacsafe.htm>

Questions and Answers About Vaccine Safety

Immunization Action Coalition

<http://www.immunize.org/>

Immunization Action Coalition-Homepage. The Coalition publishes Needletips and Vaccinate Adults and has a search capability.

<http://www.immunize.org/news.d/cdc-resr.htm>

CDC Resources You Should Know About

www.immunize.org/stories/

Stories of people who have suffered or died from vaccine- preventable diseases.

<http://www.immunize.org/genr.d/vaxsafe.htm>

Immunization Action Coalition-Vaccine Safety

<http://www.immunize.org/vis/instr00.htm>

Immunization Action Coalition-Vaccine Information Statements

<http://www.immunize.org/catg.d/4037stop.htm>

What would happen if we stopped vaccinations?

<http://www.immunize.org/nslt.d/n17/rules1.htm>

Summary of rules for childhood immunization (US)

<http://www.immunize.org/catg.d/p2011b.pdf>

Summary of recommendations for adult immunizations (US)

Other sites

www.vaccinesafety.edu

Institute for Vaccine Safety is U. S. site, presents current issues about vaccines.

www.quackwatch.com/index.html

Quackwatch describes itself as a guide to health fraud, quackery and intelligent decisions.

www.idsociety.org

Infectious Diseases Society of America and home to the National (US) Network for Immunization Information produces Immunization News Briefs. To subscribe, visit this site.

www.vaccines.com

The Vaccine Page is a new site and provides timely vaccine news. The editors do not screen articles.

<http://www.immunizeseniors.org/website/index.htm>

100% Immunization Campaign: Immunization for seniors

<http://www.vaccine.org/>

Allied Vaccine Group (Bill and Melinda Gates)

<http://www.fedbuzz.com/vaccine/vacmain.html>

Health & Safety: FedBuzz Report

<http://www.infoinc.com/imnews2/regform.html>

Infectious Diseases Society of America

<http://www.immunofacts.com/>

The Immunization Gateway: Your Vaccine Fact-Finder

<http://www.slackinc.com/child/idc/idcbull.htm>

Infectious Diseases in Children

<http://www.niaid.nih.gov/>

National Institute of Allergy and Infectious Diseases: National Institutes of Health

<http://www.idsociety.org/NNii/toc.htm>

Infectious Diseases Society of America

<http://www.injectionsafety.org/html/background.html>

Safe Injection Global Network (SIGN)

<http://www.keepkidshealthy.com/pedipilot.html>

The Paediatric Pilot Page

<http://www.niaid.nih.gov/publications/vaccine.htm>

National Institute of Allergy and Infectious Diseases (NIAID)

<http://www.vaers.org/>

Vaccine Adverse Event Reporting System (VAERS)

<http://www.vaccinesafety.edu/>

The Institute for Vaccine Safety

<http://www.vaccinealliance.org/>

Global Alliance for Vaccines and Immunization (You can subscribe to a newsletter)

World Health Organization

<http://www.who.int/>

World Health Organization-Main Homepage

<http://www.who.int/vaccines/>

The World Health Organization's on Vaccines and Immunization

<http://www.who.int/bulletin/tableofcontents/vol.77no.12.html>

Bulletin of the World Health Organization

<http://www.who.int/emc/>

Communicable Disease Surveillance and Response

<http://oms2.b3e.jussieu.fr/flunet/>

Flu Net: Global Influenza Surveillance Network

Anti-Vaccine Sites

<http://www.909shot.com/>

National Vaccine Information Center. Positioned to help parents make informed choices by emphasizing the harmful effects of vaccines.

<http://www.vaccines.bizland.com>

People Advocating Vaccine Education (P.A.V.E.). Links to many other anti-vaccine sites.

<http://www.whale.to/vaccines.html>

Links to anti-vaccine sites.

<http://www.freedomofchoice.org>

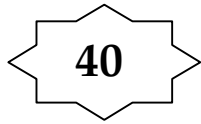
Antivaccine site emphasizing the risks of vaccines.

<http://thinktwice.com>

Site marketing anti-vaccine books by Neil Miller.

<http://aapsonline.org>

Association of American Physicians and Surgeons have anti-vaccine materials listed on their site.



40. JUDGING THE SOURCE OF YOUR INFORMATION

By early 2000, there were reportedly about 100,000 health related Internet sites. Some have university or journal sources and many are individual sites. The vast quantity of information requires a careful review of the source of information.

The following are guidelines:

Check the source of the information.

- Is the author or organization responsible for the document clearly stated?
- Is the author a professional or accredited authority on the subject? Does the author have specialist training in the area related to vaccines? (See following information sheet listing individuals who actively advocate against immunization.)
- If not an authority, does the author state why he/she is interested in this topic?
- If it is an organization sharing information, what is their reputation? What is their stand on issues?

What is the information?

- Is medical information clearly stated and explained?
- What type of evidence is used to share information? Personal stories carry emotional impact but a single case or individual collection of stories can not prove a cause and effect relationship. Scientific studies and research published in recognized peer reviewed journals are more likely to be controlled for biases or placebo effects.
- Partial quotations from known “leaders” may be out of context. Check the original source if in doubt.
- Is the information presented in a Canadian context? Health issues, especially immunizations differ between countries.
- Check the dates of references. Vaccine research and development as well as more sophisticated research has been occurring over the past few years. Research earlier than 1990 may be out of date. Some vaccines have changed and some of the older research findings do not apply to currently used vaccines.

What is the intent?

- Does the content encourage you to purchase a product available through the resource or on that web site?
- Is the author’s/organization’s interest clearly stated?
- Is strong emotional language used? Is imagery used to make vaccines sound scary?
- Does the information present more than one side of an issue? Does the source claim to provide a balanced view?
- Does the source state that health information is not health advice, or a substitute for visiting a health provider?

Internet Sites

- Be wary of sites that do not take responsibility for their own posted information.
- Be reminded that conspiracy theorists abound. Why would medical and other authorities go to such lengths to conspire against the children of the world?
- Ask yourself “Are the statements believable?” (Health Canada, 1998)
- In evaluating a web site, consider the three following questions: Who, What and Why.

WHO

- Medically trained and qualified professionals provide the medical or health advice unless a clear statement is given as to why another qualified person is giving this information.
- The information is given to support not replace the relationship that exists between the site visitor and his/her existing physician.
- The identity of the author(s) of the site is stated with contact addresses for visitors who seek more information.

WHAT

- The information is supported by clear references to source data. Date when page was last modified is clearly displayed.
- Any claims relating to the benefits/performance of a specific treatment, commercial product or service is supported by appropriate, balanced evidence.

WHY

- The support for this web-site is clearly stated including commercial and non-profit organizations contributing funding, services or materials including open disclosure of advertising policy and editorial policy.

41. INDIVIDUALS WHO ADVOCATE AGAINST IMMUNIZATION

Health professionals will encounter parents who have received information about immunization from a variety of sources. Not all of these sources are medical experts and some may present a clearly anti-immunization message. Health Unit staff may wish to compile local information in order to understand callers' perspectives, as well as the source of information.

At a conference in December 1999, Dr. Jim Campbell, of the Ontario College of Chiropractic, shared some of the following information about sources of anti-vaccine sentiment.²²⁸

Vera Scheibner PhD

- Often identified as retired principal research scientist.
- Assisted her husband in testing an infant breathing monitor, the cotwatch.
- Author of *Cotwatch*, and *Vaccination: One hundred years of orthodox research shows that vaccines represent a medical assault on the immune system*. Blackheath, NSW: Vera Scheibner, 1993.
- States that DPTP vaccinations cause SIDS, and that all vaccines have serious side effects, and are ineffective against infectious diseases.
- She is educated in micropalaeontology, the study of microscopic fossils.
- Awarded the 1997 Australian Skeptics Bent Spoon Award. This annual award committee states that she represents a serious threat to the health of Australian children though her high profile, unscientific, anti-immunization campaign.
- Recent article states that Shaken Baby Syndrome is actually vaccine damage.

Harris Coulter PhD

- Sociologist, history of medicine with interest in homeopathy.
- No medical background or training but quoted by anti-immunization groups as the “premier medical historian of our time”.
- Co-author: Coulter H & BL Fisher. *A Shot in the Dark*, Avery Publishing, second edition, 1991.
- H. Coulter *Vaccination, Social Violence and Criminality. Medical Assault on the American Brain*.

²²⁸ Dr. Jim Campbell, Getting our point across, December 1999.

Barbara Loe Fisher

- Co-author of *A Shot in the Dark*, Avery Publishing, second edition, 1991
- Lay president of the National Vaccine Information Center, and has a child who she claims is vaccine damaged. www.909shot.com
- Provides emotional testimony.

Neil Z Miller

- Author of books, *Vaccines are they really safe and effective? A Parent's Guide to Childhood Shots*. New Atlantean Press, 1999 and *Immunization Theory and Reality. Expose on Vaccination*, 1996 (discusses secret government data base and Gulf War syndrome).

Dr. Leonard Horowitz

- U.S. dentist with a Masters degree in health education/counselling psychology, Masters of Public Health degree in Behavioral Sciences/ Media Health Promotion from Harvard University.
- Conducts public seminars about emerging viruses, vaccinations and new auto-immune diseases. In these seminars he discusses "why vaccines are delivering epidemics like AIDS, cancer, chronic fatigue, Gulf War syndrome and a host of auto-immune diseases.... He states that AIDS and Ebola were man-made."²²⁹
- One of his books is entitled *Emerging Viruses: AIDS & Ebola-Nature, Accident or Intentional?* (self published)

Dr. Guylaine Lanctôt

- Physician who worked for nearly 20 years in phlebology (treatment of varicose veins). She no longer practices medicine.
- Authored book *The Medical Mafia, Here's the Key Inc.*, 1995.
- One table in the book lists a pot-pourri of complications from vaccinations gathered informally from patients and attendees at her seminars. This list is being circulated to prove the dangers of vaccines.
- Her statements are not supported with references.

Catherine Diodati MA

- Author of *Immunization: History, Ethics, Law and Health*, 1999.

There are several vocal Ontario chiropractors, known to advocate against immunization.

These are some familiar names.

Ogi Ressel

- Burlington. Chiropractor who advertises an anti-immunization message in Halton newspapers.

Robert Pike

²²⁹ Dynamic Seminars:Dr. L. Horowitz. Emerging Viruses, Vaccination and New Auto-immune Diseases, Promotional Materials for November 1999.

- Keswick. Publishes question and answer articles related to vaccine safety and efficacy in local newspaper.

Jeffrey Winchester

- Kitchener. Picketed meningitis immunization clinics during meningitis outbreak.
- Also displayed a sign in the community encouraging people not to vaccinate.

Katrina Kulhay

- Toronto. Promotes video “Vaccination the Hidden Truth. Should we Shoot First and Ask Questions Later?”

Based on a presentation given by Dr. Jim Campbell, 1999.