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Biomedical ethics: The ethical implications of mass immunization.

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BIOMEDICAL ETHICS: THE ETHICAL IMPLICATIONS OF MASS IMMUNIZATION

by

Catherine J.M. Diodati

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ABSTRACT

Mass immunization is distinct from other medical practices in that *healthy individuals* assume largely *unknown risks* with no goal of improving their *present* state of health. Vaccinees face the very real prospect of vaccine-related adverse effects, some permanently debilitating or even fatal, for a promise of future health protection even when no immediate or direct threat to health exists.

Mass immunization has always met with some measure of opposition. What is new about the current controversy is that many physicians, nurses, and medical researchers have articulated their own opposing viewpoints supported by factual evidence. Mass immunization presents a vital, and largely ignored, area of inquiry for biomedical ethics. Most immunization-specific literature focuses upon scientific research, immunization recommendations, and disease-related morbidity and mortality rates. Public health officials medically justify mass immunization but the question that is virtually left unanswered by existing literature is whether or not mass immunization is *ethically* justifiable.

The rationale in support of mass immunization is predominantly utilitarian: when a high percentage of a population is immune to disease then the chain of disease transmission is broken, thus creating a healthier society. The possibility remains, however, that the greatest good of society could be non-congruent with the greatest good of the individual. An ethical inquiry seems to be the appropriate venue to explore this apparent disparity because ethical principles, already accepted in other areas of health care, can serve as precedents for evaluating mass immunization. Specifically,

this Thesis will evaluate mass immunization using four well-established ethical principles: *respect for autonomy; non-maleficence; beneficence; and justice*. The discussion will focus primarily upon evaluating, rather than revising the current system. However, where appropriate, solutions will be suggested.

The ethical discussion will be grounded in findings from international scientific, medical, epidemiological, and legal documents. This thesis is primarily concerned with the ethical implications of mass immunization within a Canadian context. However, in that there is little Canadian literature available in this area, it is merely prudent to recognize the great contribution international literature will have in formulating a well-grounded argument.

DEDICATION

For my beautiful daughter Ashleigh,
who first taught me that serious vaccine reactions are not a myth.
Thank you for your patience and understanding.

For David,
whose continual support and love have sustained me through this long journey.

For my parents, Tony and Jennie Diodati,
and my sister and brothers, Pam, Tony and Hugh.

Thank you for your support, encouragement and love.

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I gratefully acknowledge the help, encouragement and guidance of my advisor, Dr. Dietmar Lage, and my Thesis Committee, Dr. Donna Foley, Dr. Mahesh Mehta, and Dr. Michael Dufresne. Dr. Lage believed in this work, and in my ability from the start. No one could ask for a more supportive, professional, and knowledgable advisor. I also owe Dr. Donna Foley a great debt of thanks for help and guidance that went well above the call of duty. I thank Dr. Mehta and Dr. Dufresne for sharing their expertise and good humour. I have been most fortunate to have had such an excellent Committee.

I would also like to make special mention of the contribution of J. Brian Taylor, paralegal, whose interest in this subject parallels my own. Brian's enthusiastic emails provided an integral opportunity to discuss the many aspects of immunization. Thanks go to Edda West for sharing her expertise and to the Ontario Chiropractic Association for allowing me to attend their Convention '96 so that I might attend Edda's seminars.

Many others have shared both their time and resources with me. Dr. Harold Buttram and the late Dr. Robert Mendelsohn provided me with the initial information I needed to pursue my research. They were also instrumental in saving my daughter's life. Without their courage and honesty many more children would count among the vaccine-damaged statistics. Thank you to Dr. George Zahrebelny for answering questions and for providing vaccine package inserts at my request.

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I would like to acknowledge special permission granted to utilize and publish materials in this Thesis. In particular, I would like to thank Dr. Viera Scheibner, New Atlantean Press, Princeton University Press, Human Life International, Laboratory Centre for Disease Control, and the Canada Communication Group. I would like to thank the Canadian Institute of Child Health for allowing me to use and adapt their survey. Thanks to all of the survey respondents who provided me with a current view of immunization policy and practice in Canada.

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE
INTRODUCTION

The practice of mass immunization presents a vital area of inquiry for biomedical ethics. While many medical issues have received significant consideration, mass immunization appears to have been largely neglected by modern biomedical ethicists. Ethical debate regarding mass immunization appears to be particularly scarce in the Canadian context. Much of the immunization-specific literature available focuses upon scientific research, international recommendations for immunization, as well as disease and vaccine-related morbidity and mortality rates. Public health officials generally rely on a medical rationale to justify mass immunization but the question that is left virtually unasked by existing literature is whether or not mass immunization is *ethically* justifiable. This Thesis has been undertaken with the express purpose of determining whether or not mass immunization is ethically justifiable in light of arguments presented by both proponents and opponents.

To this end, many aspects of immunization will be discussed. Within the Introduction, an historical and contextual analysis of immunization will be presented. Herd immunity, as the basis for the utilitarian rationale behind mass immunization, will be explored and the limitations, inherent to the utilitarian approach, will be discussed. In the following chapters, similarities and differences between natural and artificial

immunity will be compared, providing a necessary scientific foundation upon which the forthcoming ethical inquiries will be based. Specifically, this work will evaluate mass immunization using four well-established ethical principles: *respect for autonomy; non-maleficence; beneficence; and justice*. An ethical inquiry seems to be an appropriate venue because ethical principles, already accepted in other areas of health care, can serve as precedents for evaluating mass immunization. Finally, a summation and conclusion segment will be presented which will include a discussion of vaccines that are currently under development.

1. THE HISTORY OF VACCINES

For centuries, people have tried to find means to induce immunity prior to infection thereby escaping the potentially debilitating or fatal consequences of disease. Early therapeutic measures and "cures" often proved to be at least, if not more, detrimental to patients than the disease itself. Understandably, preventive medicine arose out of a genuine desire to halt infection from occurring in the first place.

Although the technological developments needed to understand the true nature of disease did not become available until the 16th century discovery of the compound microscope, ancient manuscripts demonstrate a very basic understanding of natural immunity. The Greek historian Thucydides (c. 460-400 BCE) noted that, during a plague that virtually wiped out one quarter of the Greek population, some people escaped infection despite exposure and others, who recovered from the plague, were

never again infected by the disease.[1] Thucydides and the ancients may not have been able to explain how immunity was acquired, but this very basic understanding of disease etiology is the foundation upon which the practice of immunization has been built: if an individual survives exposure to a disease, that individual would then be protected from subsequent infections of the same disease.

The notion that disease was caused by imperceptible particles had been postulated since ancient times but it wasn't until the 19th century that scientists had both the technology and the willingness to consider the parasitic (vs. humoral) theory of infection. Long before scientists could observe invasive organisms through microscopes, people attempted to acquire immunity through various modes of controlled exposure to diseases and poisons. Many early attempts to acquire immunity proved fruitless, if not downright lethal. For example, historical records indicate that people attempted to acquire immunity to dangerous diseases and substances through processes such as: drinking the blood of poisoned ducks, eating the livers of mad dogs as a rabies preventative, and inhaling powdered smallpox crusts.[2] The first attempt at inoculation appears to have come out of the Middle East where physicians inoculated individuals with a serum derived from smallpox lesions. This process, called

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[1]Carl Heintze, A Million Locks and Keys: The Story of Immunology (New York: Hawthorn Books, Inc., 1969), 68; Martin J. Gutnik, Immunology: From Pasteur to the Search for an AIDS Vaccine (New York: Venture Books, 1989), 11.

[2]K. Ranson et al., eds., Grolier Academic Encyclopedia (Danbury, CT: Grolier International Inc., 1991), 57; Martin J. Gutnik, Immunology: From Pasteur to the Search for an AIDS Vaccine (NY: Venture Books, 1989), 12.

variolation, was extremely unreliable: sometimes it would induce immunity and sometimes it would infect the recipient with smallpox.[3]

Many early attempts at artificially acquiring immunity were focused upon smallpox. The disease appeared to be largely endemic to Africa, Asia and the Middle East. It was imported into Europe by returning Crusaders, to the Americas by slave ships and to South America by the Spanish conquistadors.[4] The disease was at its peak during the eighteenth century, claiming approximately fifteen million lives every twenty-five years in Europe alone. It flourished largely due to the industrial revolution which brought droves of people into cities and towns, searching for sustainable employment, and forcing them to live in overcrowded slums without clean drinking water, adequate food or any proper means to dispose of waste and sewage.[5]

It was during this peak period that a physician named Edward Jenner (1749-1823) attempted to make the practice of acquiring immunity to smallpox more safe and effective. As a boy, Jenner himself had been subjected to a brutal method variolation, preceded by intermittent bleedings, starvation and purging, common in his day. As in Jenner's case, individuals would present themselves at an inoculation stable- the local apothecary's barn.[6] The apothecary would scratch the patients' arms with a knife and

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[3]Gutnik, 14.

[4]Allan Chase, Magic Shots: A Human and Scientific Account of the Long and Continuing Struggle to Eradicate Infectious Diseases by Vaccination (NY: William Morrow & Co., Inc., 1982), 48.

[5]Ibid., 53.

[6]Variolation was conducted under other circumstances where recipients were not isolated and were thus responsible for causing outbreaks of smallpox in the larger community.

cover the wounds with bandages smeared with the dried scabs of smallpox victims.[7] Those variolated were generally kept isolated in the barn for approximately 2-3 weeks, until fevers subsided and smallpox scabs dried and fell off, when they were no longer capable of transmitting the virus to others. These live smallpox virus inoculations were intended to produce a mild case of the disease, and permanent immunity upon recovery, but they were often responsible for fatalities, scarring, blindness, outbreaks of the disease, and donor-to-recipient[8] transmission of syphilis[9], hepatitis and tuberculosis.[10]

Although over 75% survived natural smallpox infection, there was no real cure for the disease and many so called "cures" of the day were poisonous, likely killing as many patients as the virus itself.[11] However, when a patient recovered, the "cure" was often lauded as the cause of recovery and, conversely, when the patient died, it is likely that the "cure" was not implicated. Neither proposed cures, nor variolation, provided truly safe means to address smallpox.

As an adult, Edward Jenner became interested in finding an alternate means to prevent smallpox. Local farmers, and patients of Jenner, were known to deliberately

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[7]Chase, 44.

[8]Since the smallpox matter used in variolation was derived from other humans, there existed great opportunity to infect the recipient with any number of diseases infecting the donor.

[9]In the United Kingdom alone, it was found that within the first year of compulsory immunization, "deaths from syphilis among infants under one year of age suddenly increased by one-half, and the increase [continued] steadily ever since." Annie Riley Hale, The Medical Voodoo (New York: Gotham House, 1935), 66.

[10]Chase, 44.

[11]Ibid., 50f.

infect themselves and their families with cowpox,[12] believing that recovery from this mild disease would protect them from infection with smallpox.[13] In 1796 Jenner formulated a vaccine derived from a milkmaid's cowpox sores and introduced this into the blood, via two cuts in the arm, of a young boy named James Phipps.[14] After six weeks had passed, Jenner introduced smallpox-infected serum into Phipps' blood: the boy did not contract smallpox.[15] Jenner tested his inoculation on many more people, with varying results.[16]

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[12]"Cowpox" appears to be similar to smallpox in that it also causes a pustular (pus-containing) rash. Cowpox, however, is caused by the *vaccinia* (pertaining to cows) *virus* whereas smallpox is caused by the *variola virus*. Kenneth N. Anderson et al., eds., Mosby's Medical, Nursing, and Allied Health Dictionary (St. Louis, MO: Mosby-Year Book, Inc., 1994), 406.

[13]Chase, 45.

[14]Arnold J. Levine, Viruses (New York: Scientific American Library, 1992), 58. It should be noted that many of Jenner's medical colleagues opposed his supposition that exposure to cowpox conferred immunity to smallpox. In fact, they had seen dairymaids who, after recovering from cowpox infections, became infected with smallpox. Cf. Neil Z. Miller, Immunization: Theory vs. Reality: Exposé on Vaccinations (Santa Fe, NM: New Atlantean Press, 1996), 24.

[15]Gutnik, 27.

[16]The risks associated with this vaccine are well recognized. Even James Phipps, Jenner's original vaccinee, as well as Jenner's own son died prematurely, at ages 20 and 21 respectively, of tuberculosis: "a condition that some researchers have linked to the smallpox vaccine." Phipps apparently was revaccinated 20 times and Jenner's son was vaccinated more than once. Cf. Neil Z. Miller, Vaccines: Are They Really Safe and Effective? (Santa Fe, NM: New Atlantean Press, 1993), 45f. The smallpox vaccine may actually have been responsible for a *rise* in smallpox related deaths. According to the Registrar-General's report, which commented on the ongoing results of the 1853 compulsion of vaccination in England and Wales, the vaccine "killed 14,000 infants a year and probably injured 140,000 a year." Even early evidence indicated that vaccination led to long-term immune malfunction, with vaccine recipients demonstrating a greater susceptibility to diphtheria, tuberculosis and cancer. Hale, 106, 113f.

In 1798 Jenner formulated a new vaccine, which combined horse-grease[17] and cowpox matter. He promoted the new vaccine as being superior to the initial cowpox vaccine which, he said, "had no protective virtue."[18] Jenner's new formula was met with public disgust and his experiments met with failure. Jenner once again promoted his initial cowpox vaccine. By 1807, he won the confidence of the Royal College of Physicians and the British Parliament and mass inoculation campaigns began.[19] Jenner's discovery eventually led to the end of variolation: some countries banned the practice immediately while others, notably England, waited for another few decades to phase out the practice.[20] Along with the international acceptance of Jenner's vaccine came the initiation of compulsory mass vaccination laws, with Bavaria leading the way in 1807.[21] At various intervals throughout the 1800s many nations adopted compulsory vaccination laws, often requiring all citizens to receive two doses of Jenner's vaccine.[22] The smallpox vaccine was widely used until 1979 when the World Health Organization declared smallpox to be eradicated world-wide.

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[17]"Horse grease" (seborrhoea) is a condition which used to be commonly found in the lower limbs of heavy cart-horses. Largely due to unhygienic stable conditions, the horses heels would become inflamed, denuded of hair, and they would exude an offensive-smelling greasy fluid. Grease was often confused with a similar affliction called "horse pox" which, incidently, was contracted either by contact with cowpox (eg. infected clothing, brushes, etc.), by inoculation (primarily) or by contact with a vaccinated human being. Dr. M. Horice Hayes, Veterinary Notes for Horse Owners: An Illustrated Manual of Horse Medicine and Horse Surgery (London: Stanley Paul & Co., Ltd., 1970), 179f, 125f.

[18]Miller, Exposé on Vaccinations, 24.

[19]Ibid., 25.

[20]Chase, 45.

[21]Ibid., 62.

[22]Ibid., 62ff.

Approximately one hundred years after Jenner began his experiments, Louis Pasteur addressed the problem of animal diseases, building upon Jenner's methods. Pasteur formulated vaccines to prevent chicken cholera, as well as sheep and bovine anthrax, derived from the isolation of specific bacteria.[23] Pasteur understood that "different microorganisms caused different diseases" but isolating the causative agents still proved problematic: microscopes were capable of revealing bacteria, but they were not yet capable of revealing viruses, which are much smaller.[24] Isolating causative agents allowed Pasteur to attenuate, or weaken, the bacteria so that they could be used in vaccines. Although Pasteur was unable to isolate the rabies virus, he believed that rabies was transmitted through saliva. He attenuated the undetectable virus by injecting saliva from the mouth of a rabid dog into a rabbit's spinal cord, which he later harvested and dried, to use as a base for his anti-rabies vaccine.[25]

In mid-July 1885 Pasteur was presented with a young boy, Joseph Meister, who had been bitten by a rabid dog. Although the vaccine was not intended for human use, Pasteur was convinced to treat Meister. With no known cure for rabies, the boy would certainly die anyway. Pasteur administered a series of injections, each more virulent than the last, over a ten-day period: Meister became the first person ever known to have survived after having been bitten by a rabid animal.[26]

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[23]Gutnik, 32-35.

[24]Ibid., 35f.

[25]Ibid., 36.

[26]Ibid., 39.

Pasteur's vaccine did not receive universal approval, in fact, many of his contemporaries claimed that the rabies vaccine killed as many people as it supposedly cured and that many of his so-called cures were contrived. Pasteur's critics noted that it was often the case that the same suspect animal had bitten more than one individual and that those who did not receive Pasteur's vaccine fared just as well, if not better, than those receiving the rabies vaccine: in some cases, the untreated animal survived whereas the treated patient died.[27]

Pasteur's contemporaries were beginning to uncover the mysteries of the immune system and of the pathogens responsible for various diseases. Elie Metchnikoff, for example, discovered phagocytes (cell eaters) in 1882.[28] At about the same time, Paul Erlich demonstrated that all female mammals pass immunity on to their offspring through their milk in a process called *passive acquired immunity*.[29] Erlich also began developing theories on serum immunity which later led to an understanding of antibodies. Scientists in various parts of Europe were conducting experiments that proved vital for vaccine development. In Paris, Émile Roux and Alexandre Yersin demonstrated that it was toxins, secreted by diphtheria bacilli, that caused the clinical manifestations (eg. lesions) of the disease.[30] Simultaneously, in Germany, Emil von Behring discovered that repeated non-lethal doses of diphtheria toxin, injected into

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[27]Cf. Walene James, Immunization: The Reality Behind the Myth (Westport, CT: Bergin & Garvey, 1995), 87f.

[28]Gutnik, 49.

[29]Gutnik, 55.

[30]Bernard Dixon, Beyond the Magic Bullet (New York: Harper & Row Publishers, Inc., 1978), 48.

laboratory animals, caused their serum to produce an agent capable of neutralizing the toxin.[31] Toxin-antitoxin preparations were soon used, with limited success, in treating diphtheria. These early preparations were crude and often resulted in vaccine-related intoxication (poisonings) and death, either due to the under-neutralization of the toxin or, quite simply, to the accidental administration of pure toxin.[32] Erlich began experimenting with quantities of toxins and antitoxins in order to determine standard measures to be used in disease prophylaxis.[33] Briefly, Erlich found that by injecting both the minimal lethal dose (MLD) of toxin, injected into a 250 gm. guinea-pig, with 100 times that amount of antitoxin, the animal would survive inoculation. He provided the formula for adequately neutralizing the diphtheria toxin. Erlich's methods are followed to this day.

By the early 1920s, the toxin-antitoxin preparations were being replaced by safer preparations called anatoxins or toxoids. Formalin (formaldehyde) was added to the diphtheria toxin, reducing its toxic properties, and enabling scientists to devise a simpler and safer vaccine. Similar methods were used to develop the tetanus toxoid vaccine which became available in 1933.[34] During the 1940s, the diphtheria toxoid

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[31]Edward A. Mortimer, "Diphtheria Toxoid," in Vaccines, ed. Stanley A. Plotkin and Edward A. Mortimer (Philadelphia: W. B. Saunders Company, 1994), 48.

[32]Cf. Sir Graham S. Wilson, The Hazards of Immunization (London, The Athelone Press, 1967), 19ff.

[33]Dixon, 49f.

[34]The tetanus toxoid vaccine is unique in that, unlike other vaccines, it is not intended to prevent a communicable disease.

was combined with the tetanus toxoid and pertussis vaccine to create the first combination vaccine, commonly referred to as the DPT vaccine.[35]

The ever increasing knowledge of how the immune system responds to pathogens led to many notable discoveries. In 1897 Almroth Wright introduced a killed typhoid vaccine for military use. In 1921 the BCG vaccine for tuberculosis was in use.[36] This particular vaccine was not readily adopted by all countries, however, because clinical trials left grave questions regarding its safety and efficacy.[37] Between 1920 and 1930 both diphtheria and tetanus toxoid vaccines had been improved and were introduced to the general public.[38] Canada adopted their use in the late 1930s. The 1930s also ushered in the use of safe antibiotics such as penicillin and sulfonamides: effective in the treatment of certain bacterial infections.[39] Advancements in the 1930s, of the processes used to attenuate and kill pathogens, resulted in what was finally considered by scientists to be a safe and efficient means of producing vaccines.[40] The yellow

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[35]Mortimer, "Diphtheria Toxoid," 50.

[36]Robert McHenry et al., eds., The New Encyclopaedia Britannica, 15th ed. (Chicago: Encyclopaedia Britannica, Inc., 1993), 23: 785.

[37]In what is termed the 1930 *Lübeck disaster*, 72 of 251 newborn infant recipients of the BCG vaccine died of tuberculosis, most of whom died 2-5 months after vaccination. In addition, 135 of the vaccinees suffered from clinical tuberculosis and the remaining "44 became tuberculin-positive but remained well." It is notable that there were another 161 infants born during the same period, in the same town, who were unvaccinated and remained completely unaffected by tuberculosis. An ensuing investigation concluded that the vaccine lot used had been contaminated but, interestingly enough, the vaccine itself was considered to be safe and effective. Similarly, of 280 children vaccinated in Pernik Bulgaria, 75 died and 111 had become seriously ill. The BCG vaccine has been implicated in a number of cases of post-vaccinal *erythema nodosum* (red, tender, subcutaneous nodules), *lymphadenitis* (inflammation/perforation of lymph glands), which primarily affects very young infants, *lupus vulgaris* (skin ulcerations), and *generalized tuberculosis*. Wilson, Hazards of Immunization, 66ff, 73, 240ff.

[38]McHenry et al., 23:784.

[39]Ibid., 784.

[40]Ibid., 785.

fever vaccine was among the first vaccines to be produced using the new methods and influenza vaccines followed about 15 years later.[41]

During the 1930s, numerous attempts were made to produce a safe and effective pertussis (whooping cough) vaccine but it wasn't until after WWII that scientists were able to test candidate vaccines reliably on laboratory mice, rather than on humans. Until very recently, only formalin-inactivated whole-cell pertussis vaccines were available but, because this vaccine often caused severe adverse reactions in a portion of vaccinees, researchers found it necessary to develop a safer, more refined, vaccine. The new *acellular* pertussis vaccine eliminates certain potentially non-immunogenic components which are believed to be related to many severe reactions.[42] However, the vaccine is, in fact, somewhat of a stab in the dark in that scientists still do not know which pertussis vaccine components may stimulate an appropriate immune response. Some clinical studies have determined that the acellular pertussis vaccine is more effective and causes fewer side effects than its whole-cell counterpart but the incidence of post-vaccinal "SIDS, near-SIDS, afebrile seizures, developmental delay, hospitalization and encephalopathy" appears to be virtually the same following the administration of either whole-cell or acellular pertussis vaccines.[43] This response has

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[41]Ibid., 785.

[42]It is believed that the endotoxin, a toxin which is contained within the bacterial cell walls, may be released into the body following immunization with the whole-cell vaccine, potentially crossing the blood-brain barrier and damaging brain tissue. The acellular vaccine should be free of this endotoxin. Cf. Charlotte Empey, "Landmark Malpractice Suit Has Far-Reaching Effects," Ontario Medical Review 56 no.7 (July 1989): 21.

[43]Gregory A. Poland, "Acellular Pertussis Vaccines: New Vaccines for an Old Disease," Lancet 347 no.8996 (27 January 1996): 210.

been interpreted to mean that these conditions are only temporally (coincidentally) related to vaccine administration rather than causally related.[44] In Japan, however, an acellular pertussis vaccine has been in use since 1981. This vaccine costs approximately $9 more per dose than the whole-cell vaccine but an 83% decline in minor reactions (e.g. fever and swelling) and a considerable decline in seizures, brain damage and fatalities have been noted since Japan adopted its use.[45] Despite Japanese experience, the whole-cell vaccine is still widely used.

Many scientific advances, which coincided with the long trek taken to create a safe and effective poliomyelitis vaccine, were to pave the way for the research and development of many subsequent vaccines. Poliomyelitis was identified as a viral disease (c. 1908) by Karl Landsteiner who induced poliomyelitis in monkeys using germ-free filtrates of dilutions of tissues from people with active cases of the disease."[46] The filters used by Landsteiner were fine enough that they could block the passage of bacteria; this indicated that a pathogen (i.e. a virus), much smaller than bacteria, was responsible for causing poliomyelitis.[47] Soon after, poliomyelitis was found to be a very common enteric (pertaining to the intestines) disease which is usually innocuous but, on rare occasions, may spread to the central nervous system and

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[44]Ibid.

[45]Andrea Rock, "The Lethal Dangers of the Billion-Dollar Vaccine Business," Money (December 1996): 152.

[46]Chase, 278.

[47]Electron microscopes, the first microscopes sensitive enough to allow scientists to view viruses, would not come into use for another three decades.

cause paralysis.[48] By 1910 investigations were under way to develop a vaccine against polio.

Paul Hienrich Römer apparently developed the first inactivated poliomyelitis vaccine in 1910. Early trials using heat-inactivated antigens proved unsuccessful: heat simply did not kill all of the viruses and Römer's test subjects (monkeys) contracted polio. Römer then tried to inactivate the virus with formaldehyde and when that proved to be equally inadequate he abandoned his work on polio vaccines.[49]

Finding a viable poliomyelitis vaccine proved to be a costly and frustrating venture. During the 1930's two vaccines, the Park-Brodie inactivated vaccine and the Kolmer live attenuated vaccines, promised to supply safe and effective prevention against poliomyelitis. By 1935, however, reports began to surface indicating that both vaccines were causing paralytic poliomyelitis in vaccinees.[50] By the end of the year, both vaccines had been withdrawn from use and remaining batches were destroyed.

During the 1930s scientists made an important discovery that would affect the future development of poliomyelitis vaccines: the disease could be caused by a variety of strains. A massive effort was initiated in 1949 to classify over 200 clinical strains of poliovirus isolated from patients all over the world. By 1951 82.1% of the isolates were designated as Type I poliomyelitis, 10.2% as Type II and 7.7% as Type III; the

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[48]Although their discovery was virtually ignored for nearly a generation by the scientific and medical communities, because continuing misconceptions still received favour, their conclusions were eventually accepted. Chase, 279f.

[49]Ibid., 294.

[50]Ibid., 280ff.

cost of the project was $1,370,000 US and the lives of 30,000 monkeys.[51] The cost of such experimentation was considered prohibitive and researchers sought alternate methods to propagate the virus. In 1949, John Enders, Frederic Robbins and Thomas Weller reported that they had successfully cultivated a poliomyelitis strain (Lansing) in cultures of human non-nervous system (e.g. fetal muscle and penile foreskin) tissues.[52] Shortly thereafter it was found that the poliovirus could be propagated in a variety of tissues from human and non-human primates. Monkey kidney tissues soon became the preferred host.[53] Huge supplies of expensive experimental monkeys were no longer necessary to propagate the virus since tissue cultures, which included appropriate nutrient mediums and antibiotics, served equally well.[54] This discovery greatly advanced the development and testing of vaccines henceforth.

A few promising vaccines appeared during the early 1950s[55] but by far and away the 1954 Salk inactivated (killed) poliomyelitis vaccine (IPV), and the 1960 Sabin (live) oral poliomyelitis vaccine (OPV), have been the most lauded vaccines (of any kind) ever to be introduced despite the fact that both vaccines historically have been

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[51]Ibid., 285, 295.

[52]Frederick C. Robbins, "Polio-Historical," in Vaccines, ed. Stanley A. Plotkin and Edward A. Mortimer (Philadelphia: W. B. Saunders Company, 1994), 138.

[53]Ibid.

[54]Live monkeys are still used by vaccine manufacturers, and the tests are duplicated by Health Canada, to test polio vaccines. Health Canada alone inoculates and then kills approximately 200-300 macaques per year in order to examine their spinal cords for signs of polio. Although an alternate method of testing exists, Health Canada has been reluctant to adopt it because it has not been approved by the World Health Organization. Stephen Leahy, "Life is Grim in Ottawa's Only Colony: No Primate Should Live in Conditions Polio-Test Monkeys Endure, Critics Say," The Toronto Star 10 September 1995, 8(F).

[55]Notably, one live poliomyelitis vaccine was created and tested by Hilary Koprowski. Koprowski's vaccine will be discussed in Chapter 3: Immunization and Non-Maleficence.

culpable in inducing the disease in vaccinees.[56] Since their introduction, the Salk and Sabin vaccines have been used *en masse* throughout the world and it is believed, by some health authorities, that these vaccines may eradicate poliomyelitis world-wide by the end of this century.[57]

A viable measles vaccine, another vaccine considered capable of eradicating its respective disease, followed closely behind the polio vaccines. It is interesting to note that historically measles often has been confused with smallpox. In fact, the earliest attempts made to prevent measles were by variolation. In 1758, Francis Home introduced a type of variolation using the blood of measles patients, since there was no pus exuded from the sores- as in the case of smallpox, and effectively infected a majority of his patients with, what he felt, was a milder form of the disease.[58] Measles variolation did not become common practice, however, because it had already been determined, from smallpox variolation, that the procedure also effectively transmitted syphilis, tuberculosis and a variety of other diseases.[59]

In 1911, Joseph Goldberger and John Anderson made two important discoveries. Firstly, filtration demonstrated that measles was a virus and, secondly, monkeys could be infected with measles, thus providing a suitable animal model for studying the

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[56]Details regarding the safety and efficacy of the Salk and Sabin vaccines will be discussed in forthcoming chapters.

[57]Many scientists reject the very notion of disease eradication. Although a disease may *appear* to be eradicated, it is believed that the pathogen either mutates, producing distinctive antigenic properties, or creates dormant sink populations which will become activated at some future point in time when conditions prove favourable.

[58]In one study it was found that 10 of 12 patients were infected by Home's variolation. Chase, 311.

[59]Ibid.

disease and for testing a vaccine.[60] The first experimental vaccine, which was cultivated in hatching eggs, was tested in 1940 on US military recruits but, due to severe reactions, it was quickly dropped.[61] By 1960, a live measles virus vaccine reached the testing stage and by 1963/4 both a live and an inactivated vaccine had been licensed. Within a few years, however, the inactivated vaccine was abandoned because it was found to provide very short-term immunity and because it placed vaccinees at a greater risk of atypical measles infection than did the live measles vaccine.[62]

At approximately the same time that the measles vaccines reached licensure, citizens in Europe and the United States were suffering from an enormous rubella epidemic. The epidemic provided a clear understanding of the connection between the disease and congenital birth defects (i.e. CRS: congenital rubella syndrome) and it sparked great interest among researchers to develop a rubella vaccine. By 1969/70 numerous vaccines were available but one, a European vaccine which utilized live virus cultivated in aborted fetal tissue, eventually won out over all other rubella vaccines. With the only possible exception of Japan, which uses vaccines cultivated in rabbit-kidney or quail-embryonic tissues, this appears to be the vaccine of choice

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[60]Ibid., 311f.

[61]Ibid., 312.

[62]Cf. Lauri E. Markowitz and Samuel L. Katz, "Measles Vaccine," in Vaccines, ed. Stanley A. Plotkin and Edward A. Mortimer (Philadelphia: W. B. Saunders Company, 1994), 232.

internationally.[63] In 1968, a mumps vaccine was licenced and, within a few years, the measles, mumps and rubella (MMR) combination vaccine came into use.[64]

Following this, researchers developed a variety of vaccines including: hepatitis A and B (1981)[65], pneumonococcal vaccine (1983), Hib (haemophilus influenza vaccine-1985), and the newest combination vaccine, called the Pentavalent Vaccine (1994), which adds Hib to the DPT-IPV combination formula. The search for new vaccines continues and researchers are trying to formulate vaccines for most of the diseases which afflict humanity.[66]

2. THE PROPER CONTEXT OF MASS IMMUNIZATION

Compulsory mass immunizations appear to have originated during the early 1800s. Laws were enacted in several jurisdictions to mandate that all individuals targeted for immunization must comply or face legal consequences. Today, immunization legislation varies widely depending upon national and regional policies.[67] The most common types of immunizations may be classified as either *routine* or *mass*

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[63]Stanley A. Plotkin, "Rubella Vaccine," in Vaccines, ed. Stanley A. Plotkin and Edward A. Mortimer (Philadelphia: W. B. Saunders Company, 1994), 310.

[64]Two combination vaccines, the measles-rubella and the rubella-mumps vaccines, preceded the MMR vaccine.

[65]The first hepatitis B vaccine utilized antigens derived from the plasma of human carriers and, since the introduction of the vaccine coincided with the introduction of the AIDS epidemic in North America, many people were reluctant to use this vaccine. This sparked the advent genetically engineered DNA vaccines. In this case, the hepatitis B surface antigen was cloned in yeast and in mammalian cells for use in vaccines. Cf. Susan L. Plotkin and Stanley A. Plotkin, "A Short History of Vaccination," in Vaccines, ed. Stanley A. Plotkin and Edward A. Mortimer (Philadelphia: W. B. Saunders Company, 1994), 7.

[66]New vaccines will be discussed in Chapter VII.

[67]Immunization policies and legislation will be discussed more thoroughly in forthcoming chapters.

immunizations.[68] It has become common practice to delineate these two types of immunization based upon why, where, and by whom, the vaccines are administered. *Routine immunizations* are those generally administered by one's usual health care provider (e.g. by the physician or nurse) at their office or usual health care facility, to target populations (e.g. children) by recommendation of public health departments, and with government approval and/or mandate. *Mass immunizations*, on the other hand, are considered to be those administered to target populations, usually by public health nurses, physicians or others specially trained for this purpose, outside of one's usual health care facility (e.g. schools). Mass immunization *campaigns* are generally mandated by public health and government officials to prevent or contain an epidemic and to quickly reduce the number of susceptibles within a population.

The difference between what is normally considered to be mass immunizations, as opposed to routine immunizations, is important. In mass campaigns vaccines are administered without the direct supervision of one's regular health care professional and without the benefit of one's medical records/history. Vaccinees generally are not screened, by the person(s) administering the vaccine, for allergies, contraindications and relevant family history matters, that might affect their response to the vaccine. In some cases, like the recent Ontario mass measles campaign, the vaccine may be developed specifically for the campaign, and may not be distributed to physicians, making it difficult to ascertain how helpful it would be for parents to consult their

[68]Special types of immunization, eg. passive artificial immunization and specific immunizations used for travellers, comprise their own distinct category and will receive minimal attention.

regular health care provider prior to providing consent. In general, more adverse events are expected to result from mass immunization campaigns due to discontinuity in health care and also due to potential problems associated with the rapid manufacture and distribution of large quantities of vaccine.

As important as the differences are between the two immunization categories, it would be a mistake to allow these differences to obscure their similarities. In fact, it is defensible to argue that most routine immunizations are, indeed, *mass immunizations* based upon three criteria: [1] the vaccines are administered to target populations (e.g. children at target ages); [2] the vaccines are administered *en masse*, ie. to a majority of the population, within a given country and/or internationally, despite the differences in setting or the timespan in which vaccines are administered; and [3] immunizations may be administered on either a voluntary or a mandatory (with or without allowable exemptions) basis.

Routine immunizations, not generally understood to be administered *en masse* include, for example, the DPT-P (diphtheria, pertussis, tetanus and polio) and Hib (haemophilus b) vaccines, administered in a series to children aged 2, 4, 6, 18 months and 4-6 years of age (DPT-P only), and the MMR (measles, mumps and rubella) vaccine administered to 12 month old children.[69] Since these vaccines are generally administered by one's regular health care professional (e.g. in a doctor's office or at a clinic-based well-baby visit), they are not usually understood to be "mass

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[69]The Td (tetanus and diphtheria toxoids) and influenza vaccines may also be considered amongst this group since the former are recommended for all 14-16 year olds and for all adults in ten-year boosters and the latter is recommended on a yearly basis for all adults over 65 years of age.

immunizations." It is my contention, however, that since all children of appropriate age are targeted for these immunizations, and that the vaccines are continually administered *en masse*, albeit on an individual basis, to these target populations, they can appropriately be referred to as mass immunizations. Where differences become important, the term "mass campaign" will be utilized to emphasize the special circumstances affecting immunization policy and procedure. The difference being, that the duration of a *campaign* is usually limited and that those persons administering the vaccine(s) are not typically one's usual health care professional, thus medical records and histories are not immediately available to them, and they are responsible for administering vaccines to many people in succession. All routinely administered childhood immunizations will be referred to as "mass immunizations" henceforth.

3. UTILITARIANISM AND HERD IMMUNITY

"Utilitarianism" and "herd immunity" are central correlative concepts in this discussion on mass immunization and, as such, the forthcoming ethical discussion will frequently refer back to these central concepts. "Utilitarianism" refers to the belief that the greater value (utility/usefulness) of a certain act or rule must be that which secures the greatest benefit for the greatest number.[70] Typically, utilitarians have equated this "benefit" with happiness and pleasure or, more specifically, with the absence or

[70]William L. Reese, Dictionary of Philosophy and Religion: Eastern and Western Thought (NJ: Humanities Press, 1980), 601.

avoidance of pain and suffering.[71] The greater utilitarian benefits profit not only the individual, but the whole or majority of the populace. The esteemed philosopher and utilitarian John Stuart Mill stated that the utilitarian ethic flows from an "internal sanction of duty" (i.e. conscience) whereby mature moral agents (those who have surpassed the "state of savage independence") become loath to act in any way that counters the best interests of society.[72] "The social state is at once so natural, so necessary, and so habitual to [humans], that...[we] never conceive[...ourselves] otherwise than as members of a body...."[73] According to Mill, mature individuals respond to an inner sense of social unity by desiring what is beneficial to the *whole of society* over and above that which is beneficial to particular individuals. The objective of law, too, is to secure the greatest benefit for the greatest number of people, even when it transgresses individual happiness. Although individual happiness is important in the utilitarian ethic, it is more expedient to create laws to which all individuals must submit in order to preserve utilitarian, versus individual, good.[74] Inflicting pain upon some individuals, therefore, may be justified if, in so doing, the majority benefit. To

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[71]Samuel Enoch Stumph, Philosophy: History and Problems (New York: McGraw-Hill Book Co., 1989), 365ff.

[72]John Stuart Mill, Utilitarianism ed. George Sher (Indianapolis: Hackett Publishing Co., 1988), 27ff.

[73]Ibid., 31.

[74]Expediency is closely linked to the utilitarian notion of *justice*. While it is understood that laws may indeed be unjust in particular circumstances, they are just if considered expedient in promoting the common good. Exactly what comprises the common good may be debatable. Mill suggests that true injustice occurs when individuals are deprived of personal property unless, of course, their actions have forfeited such rights; moral rights are taken or withheld; faith is broken (violating a promise); and, individuals are not treated impartially or equally. Still, even Mill would say that these injustices can be defended under certain circumstances. Cf. Ibid., 42ff.

be sure, the object of utilitarianism is not to purposely inflict pain on individuals, but if such pain accompanies the means to produce happiness for the majority then the means are considered to be justified by the end result.

The rationale behind mass immunization points unquestioningly to an utilitarian ethic. This is evidenced by the World Health Organization's correlation of compulsory immunization, which abrogates individual free choice, with the Utilitarian principle: *the greatest happiness of the greatest number.*[75]

> At the Thirteenth World Health Assembly it was stated: Vaccination is not simply a personal affair. Indeed, it is essentially a community matter, since the objective of most vaccination programmes is to produce a herd immunity.[76]

"Herd immunity" refers to "the level of disease resistance of a community or population."[77] Herd immunity is associated with mass immunization by virtue of the belief that if high percentages of a population or community are adequately immunized against certain diseases, virtually all persons will be protected from disease.[78] Herd immunity, then, is the utilitarian benefit produced by mass immunization.

By breaking the chain of disease transmission through mass immunization, the population should have fewer persons susceptible to disease and fewer persons capable of transmitting disease.[79] Unvaccinated persons should also benefit from mass

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[75]World Health Organization, Health Aspects of Human Rights (Geneva: World Health Organization, 1976), 42.

[76]Ibid., 43.

[77]Anderson et al., Mosby's Dictionary,732.

[78]George Dick, Immunisation (London: Update Publications, Ltd., 1978), 20.

[79]Albert Sabin, "Measles, Rubella, Poliomyelitis, and Influenza in the USA: Contrasts in Control by Vaccination," Advances in Vaccination against Virus Diseases. Edited by the Virus Department, Swiss Serum and Vaccine Institute, Bern. (Pratteln, Switzerland: Thür AG Offsetdruk, 1979); 30-53. Albert

immunization because, by increasing the number of immune persons within a society and thereby decreasing the number of susceptibles, "there is little likelihood that two nonimmune individuals will come into contact sufficiently to transmit the disease."[80]

> If the proportions of immunes within a population exceeds a certain figure, the organism [e.g. virus or bacteria] may be unable to maintain itself and dies out.[81]

In order to establish herd immunity, a certain threshold, or percentage, of vaccine coverage is necessary to break the chain of disease transmission. The most important variable in determining an appropriate threshold of vaccine coverage appears to be the basic reproductive rate (R_0) of the infection. "Basic reproductive rate" simply means "the average number of secondary cases produced by one primary case in a wholly susceptible population."[82] If the basic reproductive rate of infection is large, then the vaccine coverage needed to eliminate the infection will also be high.[83] For example, since the reproductive rate of measles is greater than that of rubella, it follows that the level of vaccine coverage, to produce herd immunity, will be greater for measles than for rubella.

Sabin M.D., Distinguished Research Professor of Biomedicine at The Medical University of South Carolina, was responsible for formulating the Oral Poliomyelitis Vaccine.

[80]Robert M. Veatch, "The Ethics of Promoting Herd Immunity," Family and Community Health 10 no.1 (May 1987) : 45.

[81]Ibid.

[82]Roy M. Anderson and Robert M. May, "Modern Vaccines: Immunisation and Herd Immunity," The Lancet 335 no. 8690 (17 March 1990): 641.

[83]Ibid.

TABLE 1

EPIDEMIOLOGICAL PROPERTIES OF INFECTIONS
TARGETED FOR ELIMINATION BY IMMUNIZATION

Infection	Average age of infection in years[84]	Rate of reproduction (R_0)	Herd immunity threshold (H) (percentages)
Diphtheria	11-14	14-18	80-85
Pertussis	4-5	14-17	92-95
Polio	12-15	5-7	80-85
Measles	4-5	15-17	88-95
Rubella	9-10	6-8	80-85
Mumps	6-7	10-15	84-86

Sources: Roy M. Anderson and Robert M. May, "Modern Vaccines: Immunisation and Herd Immunity," The Lancet 335 no. 8690 (17 March 1990): 642; Paul E.M. Fine, "Herd Immunity: History, Theory, Practice," Epidemiologic Reviews 15 no.2 (1993): 268.

The basic reproductive rate (R_0) depends on population density[85], social/behavioral factors affecting contact, average age of infection,[86] and on the demographics of a population.[87] When determining the herd immunity threshold (H), "defined as the

[84]These figures represent the average age of infection in developed countries before immunization.

[85]As population density increases so will the basic reproductive rate of infection, however, the increase may be disproportionate. Anderson and May state that "when population density doubles the prevalence of infection will usually increase *more than* two-fold". Anderson and May, 641 (emphasis added). Although Anderson and May discuss "population density" in general, Fine suggests that it may be more precise to consider only "the proportion of susceptibles" within a population when estimating the prevalence of infection. Vaccine coverage thresholds presented by Fine, however, do not differ significantly from those presented by Anderson and May. Cf. Paul E.M. Fine, "Herd Immunity: History, Theory, Practice," Epidemiologic Reviews 15 no.2 (1993): 268f.

[86]Children attending school, for example, will contact more potential susceptibles than a preschooler who is cared for daily in the home.

[87]Anderson and May, 641.

minimum proportion to be immunized in a population for elimination of infection", certain critical factors must be assessed. These factors include: appropriate ages for immunization[88], current incidence rates, and geographical region.[89] It is believed that immunization programs, which do not *continually* achieve threshold coverage, may actually facilitate the spread of disease to older, and more vulnerable, individuals.[90] On the other hand, recent evidence suggests that vaccine-induced herd immunity may have certain unfavourable effects on disease epidemiology.

Immunization against rubella presents an interesting example of both the utilitarian rationale behind mass immunization and of the sometimes perverse effects of inadequate immunity thresholds *and* of achieving targeted immunity thresholds but within the wrong herd population. Mass rubella immunization, perhaps one of the clearest examples of immunization for utilitarian purposes, is meant to offer protection, *not to the vaccine recipient* but, to fetuses in utero whose susceptible mothers may contact an infectious carrier. Although contact with the rubella virus does not always result in congenital rubella syndrome (CRS), the fetus of a non-immune mother who comes into contact with the virus during the first trimester of pregnancy may be at

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[88]Infants, still carrying maternal antibodies, and older persons, who are considered likely to have been in contact with certain diseases, may be excluded in immunization target thresholds. For example, "adults born before 1957 may be considered immune to measles" or mumps due to natural exposure. National Advisory Committee on Immunization, Canadian Immunization Guide Ottawa: Canada Communication Group Publishing, 1993) : 23.

[89]Anderson and May, 642; Fine, 287.

[90]Fine, 268, 287. In Chapter Four: Immunization and Beneficence, it will be demonstrated that, even amongst populations which have achieved herd immunity rates, the average age of natural infection has been increased.

risk.[91] For all other populations, "rubella is ...a benign disease that does not justify prevention by vaccination."[92]

To determine the herd immunity threshold for rubella immunization, health care professionals needed to consider whether it was more effective to inoculate young children (*reducing the risk of infection*) or whether to concentrate inoculations on adolescent girls prior to child bearing age (*decreasing the number of susceptibles*).[93] It appears to be the current practice in Canada[94], the United States, and the United Kingdom to immunize children soon after their first birthday[95] thus reducing the circulation of the wild virus among children.[96] This method for creating herd immunity has been described in the following way:

> [Mass childhood rubella immunization] programs ... designed to produce "herd immunity" [are] intended to prevent the spread of rubella to one "herd" - susceptible women of childbearing age - by creating a high level of immunity in another "herd" - young population groups.

Vaccinating children *en masse* against rubella is not justified by any significant health benefits accrued by the children themselves. Instead, inflicting some measure of pain

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[91]CRS can cause miscarriages, stillbirths, and a wide variety of abnormalities including: malformations, mental retardation, deafness, cataracts, glaucoma, encephalitis, congenital heart disease and diabetes.

[92]Jean H. Joncas, "Preventing the Congenital Rubella Syndrome by Vaccinating Women at Risk," Canadian Medical Association Journal 129 no.2 (15 July 1983): 110.

[93]Fine, 287.

[94]The *Canadian Immunization Guide* also recommends vaccination for "all female adolescents and women of childbearing age unless they have either laboratory evidence of detectable antibody or documented evidence of having received the vaccine." National Advisory Committee on Immunization, Canadian Immunization Guide, 110.

[95]Ibid.; Fine, 287.

[96]The United Kingdom adopted the strategy of immunizing adolescent girls only from 1971-1988. Similarly, the United States immunized women of childbearing age only from 1979-1982.

and risk of adverse events (e.g. arthritis) on this one target population has been justified by the greater utilitarian good proposed for another population.

It was determined that an 80-85% rubella vaccine threshold coverage is called for in order to induce herd immunity.[97] Theoretically, unless the number of immunes reach the targeted goal, either by contracting the disease naturally or by vaccination, a "proportion of women of reproductive age [remain] susceptible to the virus and the number of ...cases of congenital rubella syndrome actually increase[s]."[98] While this may be true for inadequate immunity rates, it appears that *adequate* vaccine-induced herd immunity rates may result in the same perverse consequences. In the United States, the number of CRS cases reported for 1969, the year the rubella vaccine was licenced, was 31; that number represents a nearly three-fold increase in cases reported for each of the three preceding years.[99] Certainly, as the above theory suggests, the initiation of rubella immunization, which would not reach herd immunity rates within the first year, could have resulted in an increase in CRS. Oddly enough, and perhaps unpredictably, the number of CRS cases did *not* decline in the following years *despite* widespread vaccination. In 1970 and 1971, CRS cases soared to 77 and 68, respectively. In fact, the number of CRS cases remained at very high levels (30-62 per

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[97]Cf. Table 1.

[98]Fine, 287.

[99]Rubella and CRS became nationally reportable in the US in 1966. In 1966, 1967 and 1968, 11, 10 and 14 CRS cases were reported, respectively. Figures have been derived from: Centers for Disease Control and Prevention, "Summary of Notifiable Diseases, United States, 1995. Morbidity and Mortality Weekly Report 44 no.53 (1995): 73-80. Statistics regarding rubella and CRS will largely be confined to the US experience since Canadian CRS figures, supplied by the Laboratory Centre for Disease Control, are available only from 1979 onwards and since vaccine strategies were not uniform throughout the country during the initial crucial years, it will be difficult to assess the efficacy of herd immunity strategies based upon Canadian experience.

year) for over a decade before they returned to the pre-vaccine rates.[100] Quite simply, this method of protecting one "herd" by creating immunity in another "herd" failed dismally.

Initially, the vaccine had "little or no impact on the number of [rubella] cases reported" but even when incidence rates fell into decline during the 1970s, there was no concurrent progressive decline in CRS until the early 1980s.[101] What actually happened is that rubella infections became less common in young children but appeared more frequently in older adolescents and adults which posed a *greater* health risk for women of reproductive age.[102] In 1980 Dr. Cherry, a member of the Advisory Committee on Immunization Practices, explained that "essentially we have controlled the disease in persons 14 years of age or younger but have given it a free hand in those 15 or older."[103] Contrast this with the fact that naturally occurring rubella epidemics, in the pre-vaccine era, "produced immunity in about 80% of the population

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[100]An exception occurred in 1991 when 41 cases of CRS were reported.

[101]Sabin, "Measles, Rubella, Poliomyelitis, and Influenza," 34. Sabin's assessment of the vaccine's inefficacy in preventing rubella among vaccinees would appear to be supported by a number of studies. For example, in Dr. Beverly Allan's 1973 study, she found an 80% attack rate of rubella among army recruits who had been vaccinated against the disease only 3-4 months prior. This example, and others demonstrating similar results, have been recorded in: Viera Scheibner, Vaccination: 100 Years of Orthodox Research Shows that Vaccines Represent a Medical Assault on the Immune System (Blackheath, Australia: By the author, 178 Govetts Leap Road, 1993), 111-121. Canadian experience seems to follow the American experience in that rubella cases increased during the first few years of vaccine use (no data was available on CRS for this period) and a significant decline in CRS began in 1981.

[102]Anderson and May, 642f. Immunization has also been culpable in raising the average age of infection for other common childhood diseases, for example, mumps and measles. Cf. Peter A. Briss et al., eds., "Sustained Transmission of Mumps in a Highly Vaccinated Population: Assessment of Primary Vaccine Failure and Waning Vaccine-Induced Immunity," The Journal of Infectious Diseases 169 (January 1994): 77-82; Health and Welfare Canada, "Measles in Canada - 1986," Canada Diseases Weekly Report 13 no. 6 (14 February 1987): 25.

[103]Scheibner, citing J.D. Cherry, 111.

by 20 years of age" and it becomes evident that, by targeting the wrong "herd", this immunization strategy produced the opposite results of those anticipated.[104] Furthermore, from 1970-1988, Britain adopted the strategy of immunizing only adolescent girls and susceptible women and, while this strategy did not decrease the number of rubella cases, CRS cases decreased, albeit slightly.[105] Similarly, from 1979-1982, the US adopted this same strategy and by 1981 there was a significant decline in CRS cases.[106] Even though the US returned to the childhood vaccination strategy, both rubella and CRS cases continued to decline, except for occasional divergences. It has been suggested, however, that the more recent decline in CRS may be attributed to other significant "hidden" factors such as a fall in the fertility rate and the more frequent use of therapeutic abortions.[107]

It seems fairly clear that even if herd immunity thresholds are reached, but they are not reached in the proper populations, the results are disastrous and contrary to the goals of the herd immunity theory. If only *susceptible* women of childbearing age were targeted for immunization against rubella, it is unlikely that the US would have

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[104]John S. Spika and Donald K. Clogg, "Rubella Vaccination: A Course Becomes Clear," Canadian Medical Association Journal 129 no.2 (15 July 1983): 106.

[105]Fine, 287; Scheibner, 121; Joncas, 110. It appears that Prince Edward Island and the Canadian prairie provinces initially adopted the British Strategy but all provinces now vaccinate infants at 12 months of age, except PEI where 15 month old infants are vaccinated against rubella. Cf. Joncas, 111; Nova Scotia Department of Health, Immunization Services (NS: Public Health Services, December 1993): 5.

[106]It should be noted that in 1979 a new, and more effective, rubella vaccine was introduced.

[107]In one study, it was theorized that, if therapeutic abortions were taken into account "...the result was a 10% increase in the incidence of CRS, and the real rate was probably much higher." Joncas, 111. Therapeutic abortions may be recommended to non-immune pregnant women who have come into contact with the rubella virus.

experienced such a dramatic increase in CRS cases.[108] Furthermore, this strategy would have conformed more closely to the utilitarian ethic in a variety of ways. The vaccine-related costs, pain and adverse events would have been less burdensome overall. If the naturally-acquired disease continued to produce immunity in 80% of the population, then only a small percentage would require immunization, fewer individuals would suffer discomfort, pain and adverse events from the vaccine and the costs associated with vaccination, and compensation for vaccine-induced injuries, would be greatly reduced. It seems fairly clear that if vaccine-derived herd immunity really is an utilitarian benefit, then the target populations must be appropriate or else the result is disastrous.

Limitations of Utilitarianism

Herd immunity as an utilitarian benefit has received much criticism. Theoretically, herd immunity should benefit societies both in lower disease incidence rates and in reduced disease-treatment costs. The possibility remains, however, that what is perceived to be the greatest good of society could be non-congruent with the greatest good of the individual. It must be understood, from the outset, that individual good *cannot* be separated legitimately from the good of society precisely because *society is nothing more than the congregation of individuals.* Guaranteeing utilitarian benefits,

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[108]Although an *increase* would have been unlikely, this does not suggest that immunization against rubella will prevent all CRS cases. In fact, numerous cases have been reported wherein adequately immunized women have given birth to infants with CRS. Cf. B. D. Das et al., "Congenital Rubella After Previous Maternal Immunity," Archives of Disease in Childhood 65 (1990): 545f; Christine Braun et al., "Congenital Rubella Syndrome Despite Repeated Vaccination of the Mother: A Coincidence of Vaccine Failure With Failure to Vaccinate," Acta Paediatrica 83 (1994):674ff.

therefore, must be considerate of the actual benefits received by individuals within their society. Therefore, if mass immunization can be defended as a true utilitarian benefit, it must be demonstrated that the practice indeed benefits individuals. For this reason, it is essential that individuals not only understand the collective good proposed by mass immunization, they must also understand the associated personal risks.

Vaccination has become such a routine part of health care that most individuals submit to this medical intervention without question. Many assume that since immunization has received such overwhelming support by trusted health authorities, for nearly a century, it *must* provide a safe and effective means of disease prevention. Although immunization has never been without its critics, there has been an increasing swell in the number of voices raising opposition to the mass use of vaccines.[109] Once thought to be inconsequential, these voices, including many within the medical community itself, are raising concerns that simply cannot be dismissed any longer.

Immunization is distinct from other medical practices in that *healthy individuals* assume largely *unknown risks* with no goal of improving their *present* state of health. Vaccine recipients face the very real prospect of vaccine-related adverse effects, some permanently debilitating or even fatal, for a promise of future health protection even when no immediate or direct threat to health exists. It is well known that when a larger number of vaccines are administered, a proportionately large number of adverse reactions tend to occur. Vaccines, therefore, can *cause* disease, disability and death in

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[109]Appendix A,Vaccine Awareness Groups and Resources, provides a list of some of the major groups and publishing companies that provide well-researched information on vaccines and associated adverse events.

some recipients who otherwise may have escaped natural infection or any associated serious consequences. In the interest of utilitarianism, then, proponents of mass immunization accept that a certain percentage of individuals will undoubtedly have to be sacrificed for the sake of herd immunity. Critics of mass immunization emphatically disagree. They maintain that the human sacrifice, which necessarily arises from mass immunization, cannot be justified by the utilitarian ethos.[110] Indeed, society cannot benefit from the unnecessary death or disability of even one of its members. The human cost, as well as associated health care, compensation and funeral expenses must be justified in order to accept mass immunization as a true utilitarian benefit.

In the forthcoming ethical discussion, mass immunization, as a utilitarian benefit, will be explored in a variety of ways. Specifically, mass immunization will be discussed in reference to the bioethical principles of: *non-maleficence, beneficence, respect for autonomy* and *justice*. Questions will be raised regarding the safety and efficacy of vaccines in order to determine whether or not mass immunization aligns with currently accepted ethical principles, as well as, the utilitarian ethic. A discussion of the potential effects of vaccine components and the historical efficacy of immunization will provide a firm basis upon which to assess immunization against the principles of non-maleficence and beneficence. Following this, the practice of immunization will be considered in relation to legal and ethical aspects of informed

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[110]Utilitarianism itself supports resistance to laws and/or policies that disadvantage a number of individuals within a society. Opponents to mass, and compulsory, immunization maintain that a significant number of individuals are disadvantaged by the practice, thereby violating the principle of utility.

consent, voluntary consent and compulsion to determine its adherence to the principle of respect for autonomy. The principle of justice will then provide a framework by which to assess who is ultimately responsibility for compensating individuals who have been injured by vaccines. In each case, correlations will be made between the respective ethical principle, the utilitarian ethic and current immunization policies and practices. The final chapter will provide a look toward the future of immunization and, following this, a summation of information and conclusions will be presented. Prior to the ethical discussion, however, selected scientific information will be discussed in order to provide a foundation for assessing the ethical implications of mass immunization.

CHAPTER TWO
NATURAL AND ARTIFICIAL IMMUNITY

Although knowledge of cellular and molecular immunity extends back as far as the late 19th century, and much information regarding the presence and action of bacteria and viruses predates that knowledge, many of the more intricate functions of the immune system were unknown prior to the 1960's.[111] In other words, much of what is presently known about immunology has been uncovered within the past thirty years and certainly, as time goes on, scientific research will uncover a great deal more. In the following pages a simplified discussion of the immune system, as it is currently understood, will be presented. In order to properly understand the underlying features of both naturally and artificially acquired immunity, it is important to have a basic understanding of how the immune system works.[112]

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[111]Gutnik, 14ff; Edward Edelson, The Immune System (NY: Chelsea Publishing House, 1989) , 15.

[112]Much of the information on natural immunity has been derived from: Kenneth N.Anderson et al., Mosby's Medical, Nursing, and Allied Health Dictionary; Robert S. Desowitz, The Thorn in the Starfish: The Immune System and How It Works (NY: W. W. Norton & Co. Inc., 1987); Edward Edelson, The Immune System (NY: Chelsea Publishing House, 1989) ; Martin J. Gutnik, Immunology: From Pasteur to the Search for an AIDS Vaccine (NY: Venture Books, 1989); Carl Heintze, A Million Locks and Keys: The Story of Immunology (New York: Hawthorn Books, Inc., 1969); Lennart Nillson, The Body Victorious (NY: Delacourt Press, 1987); and, Lydia Woods Schindler, Understanding the Immune System (United States Department of Health and Human Services Publications, National Institutes of Health, October 1991).

1. NATURAL IMMUNITY

The body is equipped with an amazing multi-level defence system capable of distinguishing cells it recognizes as *foreign* from cells it recognizes as *self*. The immune system is capable of producing an impressive arsenal of cells and antibodies[113] that seek to destroy foreign cells or organisms even before they have an opportunity to affect the body. Substances capable of eliciting an immune response are called *antigens*. Having encountered specific antigens, cells of the immune system are capable of "remembering" and responding quickly to the previously encountered foreign substances, effectively halting reinfection.

Why then does it seem possible for people to be infected more than once by the "same" disease? When a person "catches" a cold, say "for the third time this winter", he or she is not catching the same cold again and again. The antigens differ from one infection to the next. On occasion one may show signs of reinfection by the "same" antigen. Genetic mutation may account for such "reinfection". Although very similar, the antigen has actually been altered in such a way that the immune system does not recognize it as one previously encountered.

Another potential factor in apparent reinfection may be *incomplete immunity*. Incomplete immunity is generally considered to be anomalous to natural immunity; typically, when one recovers from a disease, the individual becomes permanently

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[113]An "antibody" is "an *immunoglobulin* (large protein molecule) produced by *lymphocytes* (small white blood cells produced in the lymph nodes, thymus, spleen, bone marrow and other clusters of tissue) in response to bacteria, viruses, or other *antigenic* (recognized as foreign) substances". Anderson et al., Mosby's Dictionary, 100; Schindler, 20.

immune to that disease. Alternately, it is believed that immunizations can induce immunity if a complete immunization series, including appropriate booster doses, has been administered. It appears however that immunization sometimes results in incomplete immunity. Immunity is considered to be incomplete if an individual becomes infected with a disease against which they have received adequate immunizations. Recent studies, for example, have demonstrated reinfection may occur, usually unaccompanied by typical manifestations of the disease, in persons who have previously demonstrated immunity.[114] In one study, for example, two women had demonstrated immunity to rubella prior to their pregnancies yet both women gave birth to infants suffering from congenital rubella syndrome.[115] Neither woman demonstrated typical manifestations of rubella infection throughout their pregnancies but, nonetheless, reinfection was clearly indicated by fetal damage and by sereological testing. Similarly, congenital rubella syndrome occurred in an infant whose mother had been vaccinated *three times* prior to conception.[116] Natural infection following immunization indicates incomplete immunity and is generally referred to as *vaccine failure*.[117]

Antigens may be derived from a diverse range of living and non-living matter and they may be viral, bacterial, fungal, plant or animal in nature. Viral antigens, for

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[114]Clinical diagnosis and/or serum tests indicating disease-specific antibodies generally serve as medically accepted confirmations of immunity.

[115]B. D. Das et al., 545-6.

[116]Christine Braun et al., 674-7.

[117]Other instances of incomplete immunity will be discussed in Chapter 4: Immunization and Beneficence.

example, may enter the body through the respiratory system, a blood transfusion, breaks in the skin or they may be ingested. Viruses are necessarily parasitic in nature; while they have the genetic material required for replication, viruses are devoid of the energy and raw materials necessary to accomplish it.[118] To overcome this, the viral genetic material enters the host-cell, redirecting the host's machinery and resources to its own replication. A solitary viral cell is capable of producing thousands of progeny, effectively killing its host-cell, and each of these progeny is capable of initiating another infectious cycle. Since one cycle may be completed in as little as twenty minutes, and since each of the progeny can repeat the cycle in other host-cells, it is estimated that 10^{73} progeny can be produced from one virus cell within twelve hours.[119]

Unlike viruses, bacterial antigens are capable of reproduction without the assistance of a host-cell but, like viruses, they can overwhelm the body within a short period of time if left unchecked. "If all the descendants survived, the initial cell would result in about 500,000 new cells after 6 hours".[120] Pathogenic (disease-producing) bacteria may attack cells directly and/or secrete toxins (poisonous waste products) which destroy everything around them.[121] Viral or bacterial pathogens multiply and spread throughout the body. During this *incubation period* (e.g. 10-14 days) the infected person exhibits no symptoms of infection. By the time symptoms finally do

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[118]Nillson, 88; Anderson et al., Mosby's Dictionary, 1652.

[119]Nillson, 88.

[120]K. Ranson et al., eds., Grolier Academic Encyclopedia (Danbury, CT: Grolier International Inc., 1991), 3: 16.

[121]Heintze, 71.

appear, the immune system is already engaged in a full-blown attack on the pathogens: various cells are immobilizing the antigens while others digest them and antibodies are already circulating throughout the bloodstream.[122] This rapid immune response protects the body from being overrun by antigens. It is often the case that the immune system disposes of antigens even before symptoms appear.

In some cases, apparently innocuous agents, such as ragweed pollen, dust, or animal hair, will be recognized as antigenic and the immune system's response, in this case, is known as an "allergy". The immune response to innocuous agents is considered somewhat misdirected because the body is reacting strongly to the allergen as though it were a toxic substance.

Another "misdirected" immune response, and one with far more serious implications, occurs when the immune system mistakenly identifies self-cells as non-self and elicits an attack, destroying self-cells, as in the case of autoimmune disease.[123] Some of the more well-known autoimmune diseases are: rheumatoid arthritis, multiple sclerosis, and type 1 diabetes mellitus (insulin dependant), to name a few.

Other "immune disorders may be caused by over- or under-activity of specific components of the immune system."[124] In the case of AIDS, the human immunodeficiency virus (HIV) kills helper T cells, essential elements in the overall immune response. HIV effectively disables the immune system "leaving the body

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[122]Terrence J. Bovill, "Vaccine Action," Health Consciousness 14 no. 3, (n.d.), 55.

[123]Schindler, 2.

[124]Edelson, 20.

vulnerable to a number of otherwise harmless microbes as well as to some kinds of cancer and other diseases."[125]

Under normal circumstances, however, the immune system is capable of a quick and effective response against antigens which have been introduced into the body. Once an antigen is detected, the immune response is activated: various cells and organs function interdependently, fighting infection, until the antigen no longer poses a threat to health.

The Immune System

Various organs throughout the body are integrally involved in the immune response.

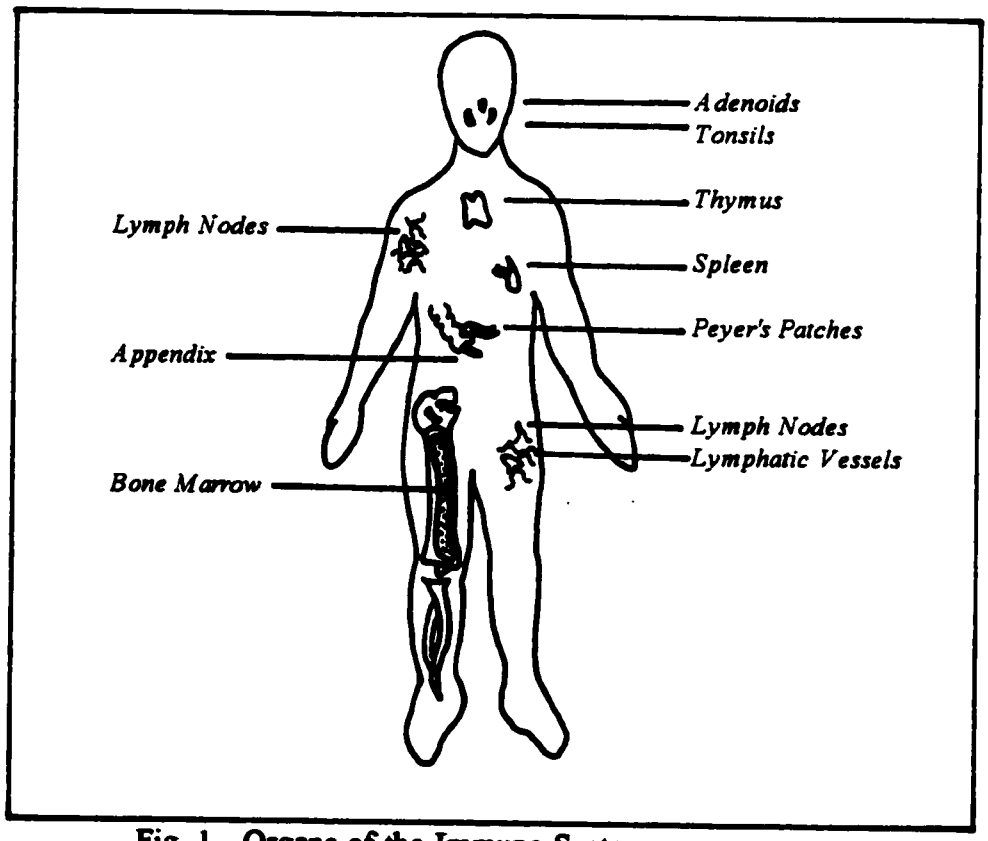

Fig. 1. Organs of the Immune System

[125]Ibid.

> Lymphoid organs include the bone marrow, thymus, lymph nodes, spleen, tonsils, adenoids, appendix, and clumps of lymphoid tissue in the small intestine called Peyer's patches. They... [effect] the growth, development, and the deployment of *lymphocytes*, the white cells that are key operatives of the immune system.[126]

The immune system is a remarkable network of cells and molecules with an innate regulatory system that ensures appropriate recognition, stimulation, induction, suppression, and memory functions.

Key Elements of the Immune System

Immune system cells originate as "stem cells" in the marrow of long bones. Some stem cells remain in the bone marrow (*B cells*) to develop and mature. When activated, B cells transform into antibody-secreting plasma cells. Other stem cells, *T cells*, "migrate to the thymus" where they "learn" to distinguish *self*-cells from *non-self* (antigenic) cells. Still others, large phagocytes ("cell-eaters"), either seed themselves within body tissues or circulate throughout the body awaiting the presence of antigens.[127] Each of these cells perform specific interrelated responses when presented with antigens.

The properly functioning immune system has an innate identification system. Each self-cell within the body has certain genetic molecular identity markers which allow all other self-cells to recognize it. Self-cells exist in what is referred to as *a state of self-tolerance*, whereby self-cells will not attack other self-cells. Antigens, on the other

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[126]Schindler, 3.

[127]Ibid., 3, 8.

hand, do not carry the same identity markers as self-cells. Characteristic shapes found on the surface of antigens, called *epitopes*, distinguish antigens as foreign or "non-self." This recognition of antigenic epitopes activates the immune response.

The Immune Response

Macrophages

Macrophages (i.e. large phagocytes) are generally the body's first line of defense. These large cell-eaters either become associated with certain organs (e.g. liver, or spleen) or they circulate throughout the body awaiting antigenic activity. When antigens are present, circulating macrophages localize at the infected site.

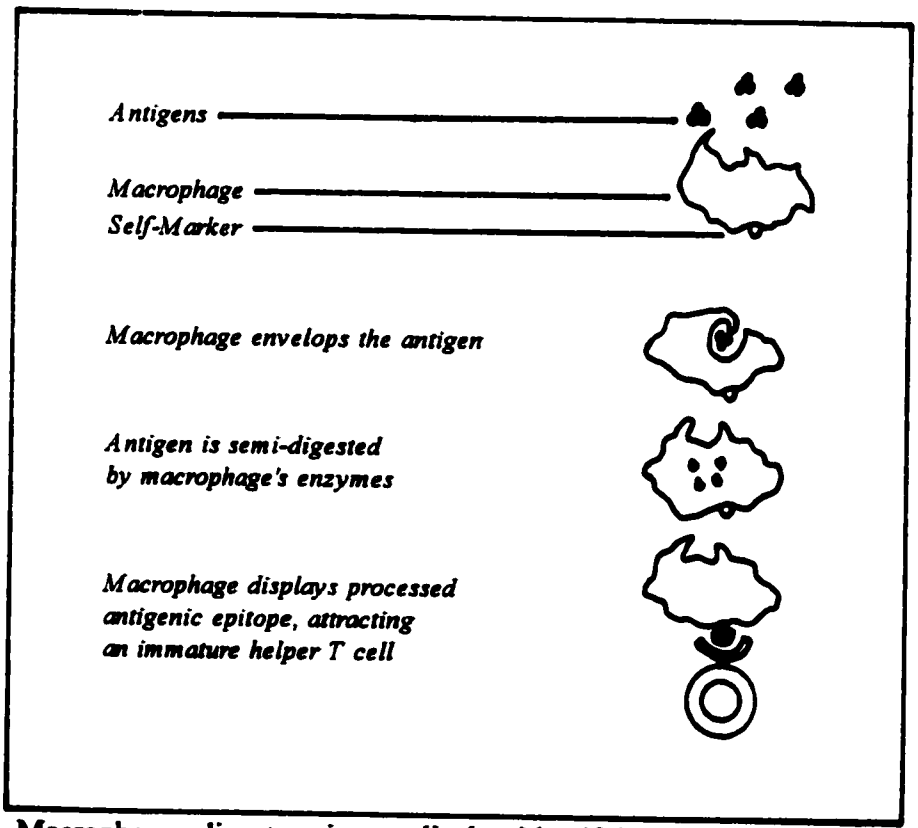

Fig. 2. Macrophages digest antigens, display identifying epitopes, and attract helper T cells.

A macrophage will envelop the antigen, break it down enzymatically (semi-digesting it with enzymes), and transport fragments of the digested material (epitopes) to its own cell-surface.[128] These processed epitope-containing fragments are displayed on the macrophage's surface enabling other immune cells to "read" what type of antigen is present and to respond appropriately. For example, these fragments will attract and activate another type of immune cell, *helper T cells.*

Helper T Cells

As the macrophage and the helper T cell approach each other they institute an "identity check" identifying each other's self-markers.

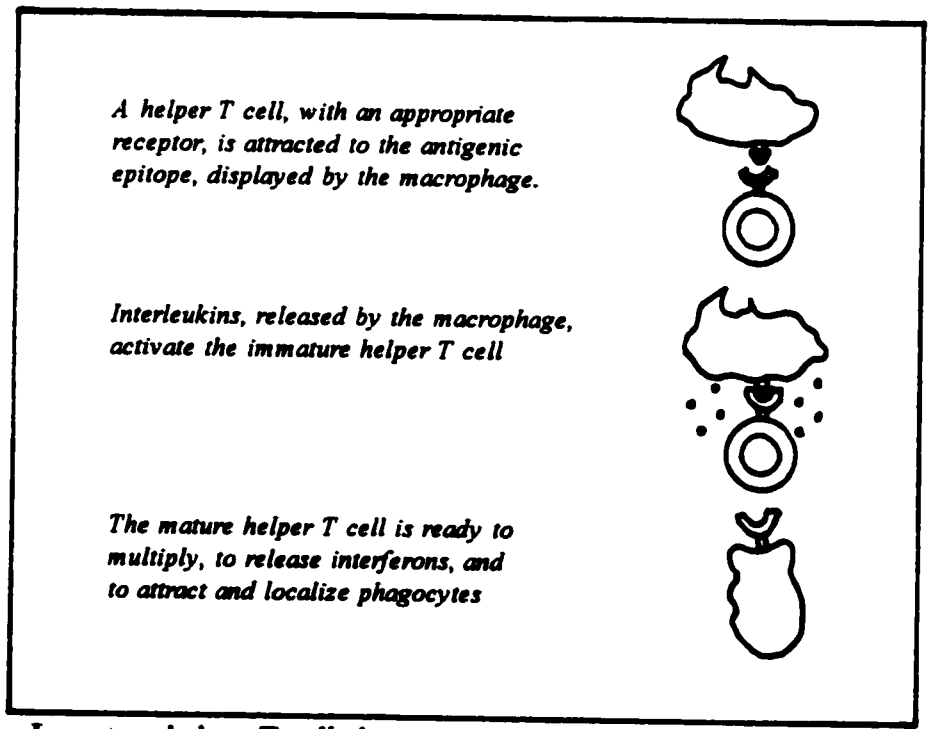

Fig. 3. Immature helper T cells become activated by interleukins released by antigenic-epitope displaying macrophages.

[128]Desowitz, 96.

This activity is tantamount to verifying each other's "password" to ensure that both cells are indeed allies. Since the helper T cell is unable to bind native antigens, it then attempts to attach its receptor to the displayed epitope. If the receptor[129] on the helper T cell binds to the antigenic epitope on the macrophage, the macrophage secretes regulatory molecules, *interleukins*, which cause the T cell to grow and divide and to produce various immune response molecules, including *interferons*.[130] Interferons[131], or more specifically "gamma interferons", do not kill viruses but they serve to alter surrounding cells "in such a way as to render them impervious to viral invasion."[132] The helper T cell also secretes chemical signal molecules, *lymphokines*, which attract more phagocytes to the infected site and localizes macrophages there.[133] The mature helper T cell also acts as a catalyst for killer (or cytotoxic) T cells and for certain B cells.

Killer T Cells

Receptors on an immature killer T cell, and those on an immature helper T cell, bind to different epitopes on a macrophage.

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[129]Different T cells have different antigen receptors.

[130]Interleukins induce fever, fatigue, sleep, the reproduction of T cells and activate T cells. Edelson, 48f.

[131]"Interferons" are natural proteins "formed when cells are exposed to a virus or other foreign particle of nucleic acid. It induces the production of translation inhibitory protein (TIP) in non-infected cells. TIP blocks translation of viral RNA, thus giving other cells protection against both the original and other viruses". Anderson et al., Mosby's Dictionary, 823.

[132]Desowitz, 93.

[133]There appears to be some question as to the number and type(s) of lymphokines: are there a variety of different types or is there one type capable of different functions? Ibid., 91.

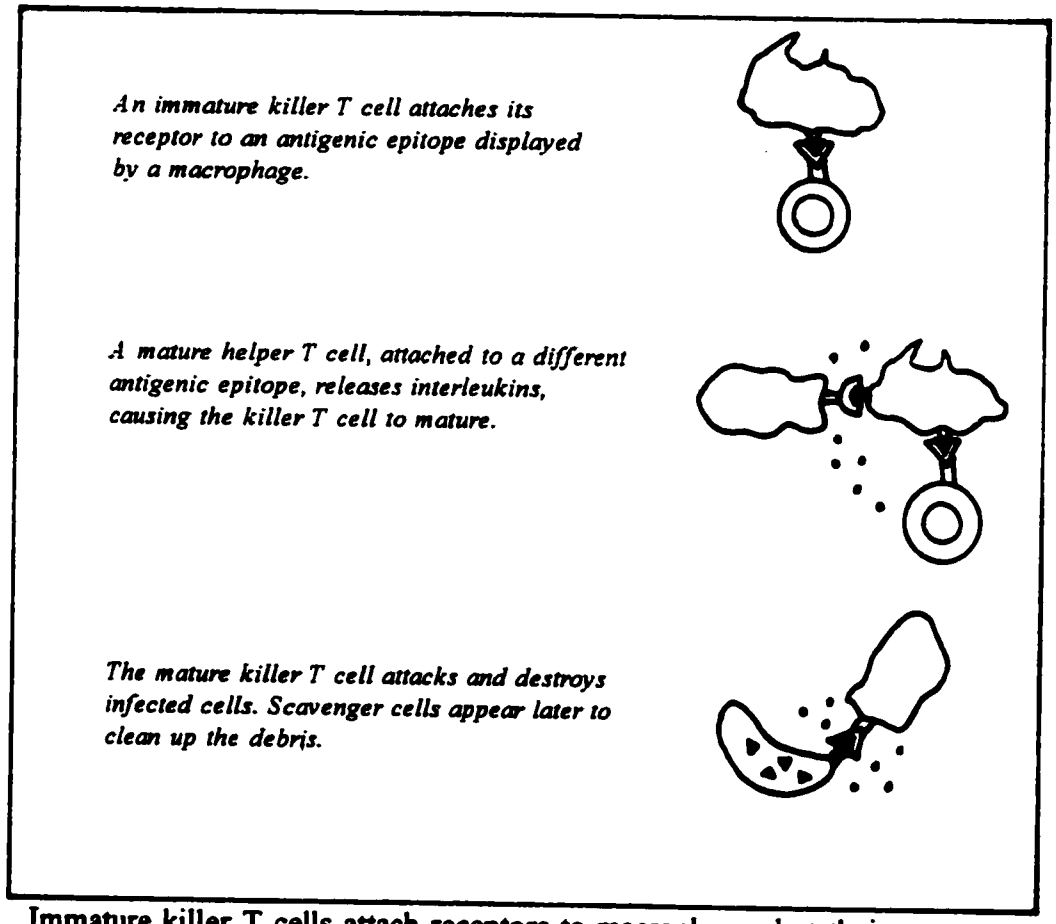

Fig. 4. Immature killer T cells attach receptors to macrophages but their maturation requires the assistance of interleukins released by helper T cells.

The interleukins, secreted in response to the helper T cell: macrophage interaction, promote maturation of the immature killer T cell. The resultant mature killer T cells have the potential to recognize, attack, and destroy infected cells by delivering a lethal burst of chemicals that produces holes in the target cell's membrane. This causes fluids to seep in and leak out of the target cell and leads to its rupture and death.

Activated killer T cells continue to destroy any infected cells they encounter until they receive chemical messages from *suppressor T cells*, effectively calling off the

attack.[134] Once suppression is signalled, many of the T cells will die off in three or four days. However, others will become dormant *memory cells* "preprogrammed" and ready for immediate attack should the antigen present itself again. Should the same antigen threaten invasion, these killer T cells can elicit an attack without having to wait for identification or activation from other cells.

B Cells

B cells differ from T cells in that they do have some receptors that interact directly with the native antigens. Like the macrophage, B cells can envelop and process an antigen and display antigenic epitopes on their cell surfaces. The displayed epitope attracts a mature helper T cell which, in turn, secretes interleukins. Interleukins secreted by helper T cells transform immature B cells into an "anti-body secreting plasma cells."[135]

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[134]Similarly, ***natural killer*** (NK) ***cells*** attack infected cells directly. NK cells, however, do not require the assistance of other cells to recognize foreign antigens. Schindler, 8.

[135]Ibid., 16.

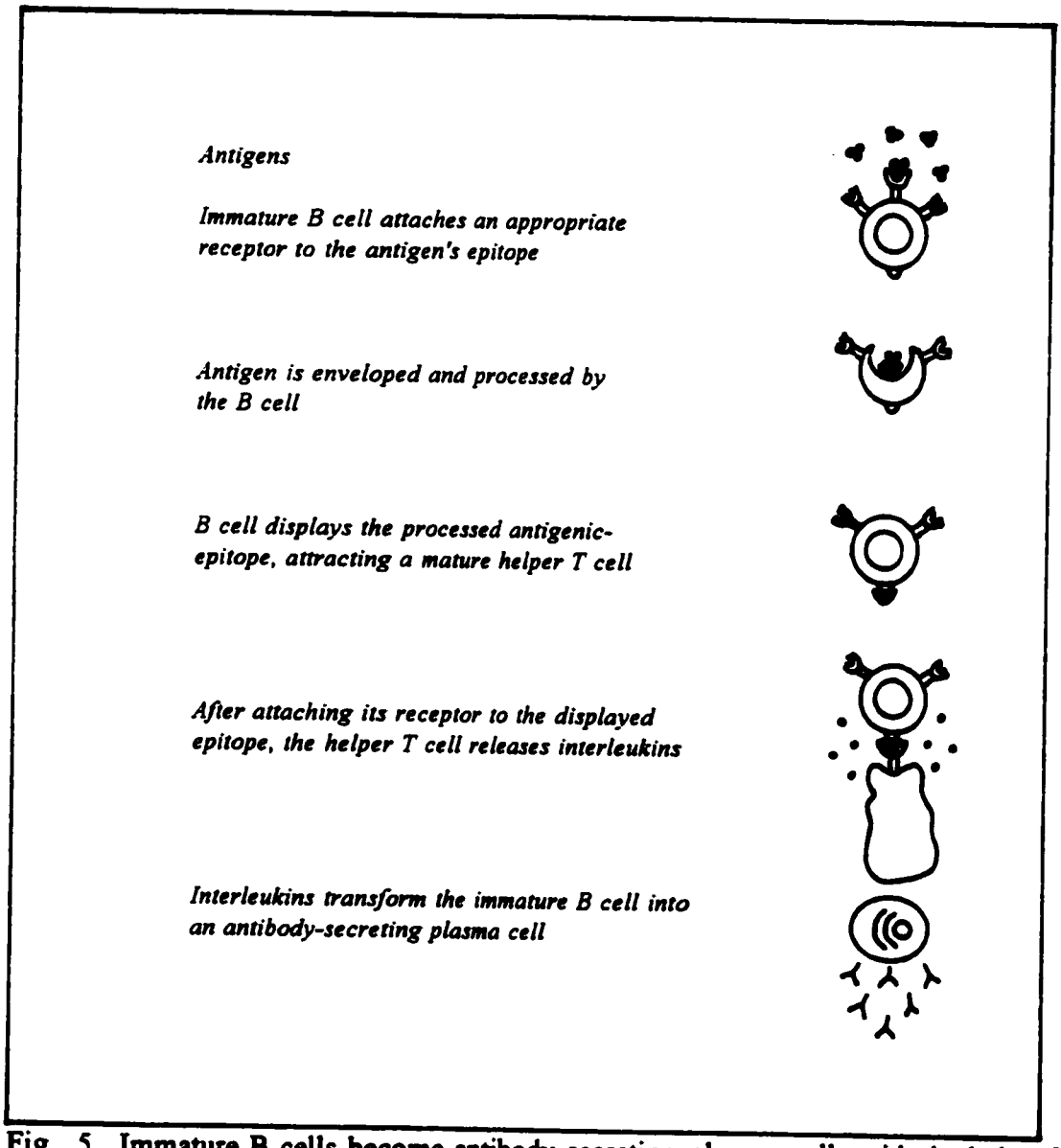

Fig. 5. Immature B cells become antibody-secreting plasma cells with the help of interleukins released by mature helper T cells.

The now mature B cell will produce many identical plasma cells (clones) and each plasma cell can produce millions of identical antibodies. The antibodies are specifically manufactured to respond to one specific antigen and no other.

Different specific antibodies are produced for every antigen. Considering the almost endless number of antigens that may be encountered, this ability is nothing less than amazing. The genetic material within the nucleus of each B cell underlies this ability. Although there is a finite number of genes contained within its DNA, the B cell, responding to lymphokines (a type of interleukin) secreted by helper T cells, "shuffles its antibody genes" to produce the appropriate antibody.[136] Once the genes are shuffled, the activated B cell changes into a plasma cell: "an antibody factory multiplying itself and secreting large amounts of the antibody."[137]

Antibodies

Antibodies take a variety of forms, each with specific functions, that are comprised of one or more "Y" shaped units.

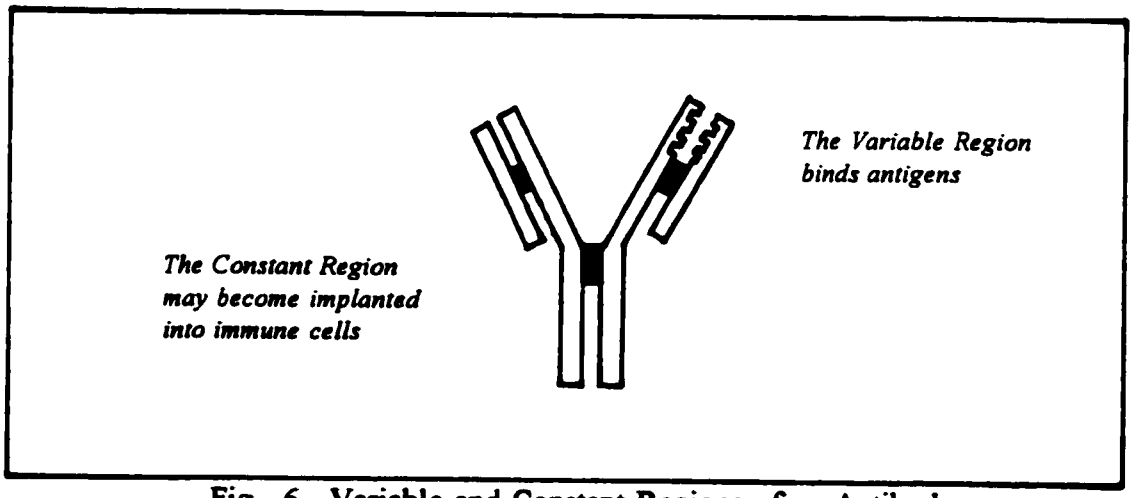

Fig. 6. Variable and Constant Regions of an Antibody.

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[136]Edelson, 31f.

[137]A similar shuffling of genes occurs in T cells, allowing them "to produce all the receptors needed to respond to an antigen". Ibid., 32.

The stem of the antibody, called the *constant region*, "serves to link the antibody to other participants in the immune defenses."[138] It is the constant region that adheres to other antibodies or to other immune cells which become activated when antigens become locked into the antibody's *variable region*.[139] The *variable region* comprises the tips of the Y's arms and varies from one type of antibody to another. The variable region is the site where the antibody forms a characteristic shape developed to enfold one specific antigen. Just as one key is ideally suited to open a lock, the antibody's variable region is designed to respond only to one antigen. Antibodies do not usually destroy antigens themselves, rather they attach themselves to antigenic epitopes. By attaching themselves to the antigen's epitopes, antibodies function as molecular "handcuffs", so to speak, restraining antigens until they can be destroyed. Specifically, antibodies can "disable bacteria from producing toxins, coat antigens for consumption by scavenger cells[140], and block viruses from entering body cells."[141]

Antibodies are of five distinct classes, called *immunoglobulins* (Ig), each with its own function. They are referred to as: IgG, IgA, IgM, IgD, and IgE. Immunoglobulins G, D, and E are single Y-shaped units, whereas IgA may have one, two or three attached Y-units, and IgM has five Y-shaped units attached together to form a cluster with a common centre. Antibodies may function on their own or they

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[138]Schindler, 6.

[139]Ibid., 20.

[140]"Scavenger cells" refer to any cells that can "engulf and destroy foreign material, dead tissues, or other cells." Ibid., 39.

[141]Michael A. Weiner, Maximum Immunity (Boston: Houghton Mifflin Company, 1986), 31.

may function in unison with other antibodies or cells. For example, an IgG may attack one epitope of a viral antigen while an IgM may attack another epitope of the same antigen. Alternately, an immunoglobulin may disable an antigen while an immune cell attacks and destroys the antigen.

Specific immunoglobulins tend to be found in certain areas of the body where they perform characteristic functions. For example, IgA are found in "body fluids (tears, saliva, respiratory, genitourinary, and gastrointestinal secretions) guarding body entrances."[142] IgG is the most common immunoglobulin, accounting for approximately 75% of all immunoglobulins in the blood, which coat antigens "speeding their uptake by other cells."[143] IgD, are often be found implanted into the membranes of B cells.[144] It is believed that IgD may regulate activation of the B cell and may have a role in allergic responses.[145] An IgE responds to allergens, by imbedding itself into a *mast cell* (a stationary cell, carrying chemical filled granules, found in tissues) or a *basophil* (circulating counterparts to mast cells), causing these cells to release chemicals that will attract other immune cells and cause local blood vessels to become leaky.[146] The released chemicals, called *mediators*, are responsible for reddening and swelling that accompany allergic reactions. Finally, IgM circulates throughout the bloodstream attacking antigens, particularly bacteria, and triggering an increased production of IgG.

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[142]Ibid., 34.

[143]Edelson, 36; Schindler, 6.

[144]Edelson, 37.

[145]Schindler, 7.

[146]Ibid., 20; Edelson, 26.

Antibodies, like other key elements in the immune response, make up a multi-levelled defense system capable of attacking pathogens where they enter the body (i.e. at the level of the skin, eyes, mouth, and the respiratory system) and at the deeper levels of blood, organs, and tissues. Each of these levels of immune system serve to weaken pathogens, to inhibit their reproduction, and to eventually eliminate their invasive threat. All together, the antibodies, T cells, B cells, phagocytes, monokines (ie. interleukins and interferons) and other cells and molecules work in a complementary fashion to protect the body. Each play an essential role in identifying antigens, relaying messages, and activating a complex and efficient immune response. One element of the immune system acts upon another, which in turn acts upon another, and so on. The immune response remains active until another type of cell, *suppressor T cells*, sends chemical messages indicating that the antigens have been defeated. At this point, the production of antibodies declines sharply but some of the killer T cells, like some activated (antibody-producing) B cells, will then "continue to circulate in the blood or 'hibernate' in a lymphoid organ... until they are again restimulated with the specific antigen."[147] The remaining activated cells are called ***memory cells*** because they "remember" the encountered antigen and they are poised to attack quickly and efficiently should the same antigen be encountered. When an antigen does present itself again, the ***memory cells*** effectively eliminate any chance of reinfection; natural immunity is thus conferred.

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[147]Desowitz, 100f.

2. ARTIFICIAL IMMUNITY

Whereas natural immunity results from recovery of a disease, artificial immunity is induced by the administration of manufactured, protein-based, formulae containing harvested antibodies or antigens. Artificially induced immunity, whether passive or active, is intended to protect the body from the more devastating effects of naturally acquired disease.[148] Methods of inducing artificial immunity are intended to imitate the body's natural response to infection. Passive immunization is employed *after exposure* to specific pathogens whereas active immunization is employed primarily as a *preventive* measure, administered *before exposure* to certain diseases, and secondarily to enhance antibody production post-exposure.

In the case of passive immunization, antibodies are harvested from a hyperimmune (convalescing) person or animal and administered either intravenously or by injection to another person to combat infection.[149] The administered immunoglobulin does not induce an immune response in the recipient; rather, it assists the body in fighting off an infection by increasing the number of antigen-specific antibodies. Passive immunization does not confer permanent immunity; its primary purpose is to enhance the immune response during an immediate health-threat.

Active immunity, on the other hand, induces an immune response by infecting the vaccinee with small amounts of antigens in order to expose the body gradually to

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[148]Passive and active vaccines to be discussed will primarily focus upon those used routinely in Canada. Vaccines used for travellers (e.g. cholera, plague, yellow fever, and typhoid) will receive minimal attention.

[149]Anderson et al., Mosby's Dictionary, 1424.

specific diseases. It is believed that by introducing small quantities of antigenic material into the body, at appropriate intervals, the immune system will gradually develop sufficient antigen-specific antibodies so as to protect the body from infection, should the antigen be encountered naturally. Active immunization, while longer-lasting than passive immunization, does not appear to confer permanent immunity. Health officials stress the importance of booster doses to ensure the maintenance of a sufficiently high level of immunity.[150] Active and passive immunizing agents may be administered simultaneously, as in the case of diphtheria, tetanus and rabies exposure, in an attempt to provide both immediate and long term immunity.[151] Theoretically speaking, while the passive immunizing agent supplies already primed antibodies, capable of responding directly to specific pathogens, the active immunization causes the body to produce its own antibodies on a grander scale.

Passive Artificial Immunity

Passive artificially-induced immunity imitates the natural transmission of passive immunity from a mother to her infant. During pregnancy, a fetus will receive maternal antibodies through the placenta and, when the infant is born, the nursing baby will receive antibodies through the mother's breast milk.[152] The artificial method imitates

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[150]Richard Schabas, Opportunities for Health: Immunization the Next Steps (Ottawa: Queen's Printer for Ontario, 1995), 2.

[151]National Advisory Committee on Immunization, Canadian Immunization Guide, 129; Connaught Medical Research Laboratories, Biological Products for Human Use, R. J. Wilson, ed., (Toronto: University of Toronto, 1957), 5.

[152]Anderson et al., Mosby's Dictionary, 1170. Cf. La Leche League International, The Womanly Art of Breastfeeding (Franklin Park, IL.: La Leche League International, 1981), 294ff.

this process by introducing an *antiserum*, i.e. "preformed antibodies derived from humans or animals", into a non-immune person by intramuscular injection or intravenously.[153] Passive immunization is generally recommended for non-immune, unimmunized, or immunosuppressed individuals when exposure to certain pathogens is suspected.[154] Passive immunizing agents are considered to provide short term benefits. They may, or may not, offer complete protection to the recipient but they have the potential to reduce the severity of the infection.[155] Passive immunizing agents must be used cautiously, however, because "hepatitis or hypersensitivity reactions can occur."[156] Passive immunizing agents are available in Canada for: measles, hepatitis A, B, and C[157], botulism, diphtheria, pertussis[158], rabies, tetanus, and varicella-zoster.

Preparation of Passive Immunizing Agents

Human Source

Immune globulins, derived from human sources, are obtained from pooled human plasma. Plasma is the watery, fluid portion of the lymph and the blood in which the

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[153]National Advisory Committee on Immunization, Canadian Immunization Guide, 129f.

[154]Ibid.

[155]Ibid.

[156]Anderson et al., Mosby's Dictionary, 1170, 106.

[157]Post-exposure management of hepatitis C through passive immunization is of unproven value since persons having antibodies to hepatitis C have been "specifically excluded from the donor pool." National Advisory Committee on Immunization, Canadian Immunization Guide, 132.

[158]According to the National Advisory Committee on Immunization, pertussis immune globulin "is of unproven value in infants and young children" and it is, therefore, not recommended. Similarly, hepatitis immunoglobulin is unlikely to affect those exposed to type C because current formulas specifically exclude donations from persons with antibodies to hepatitis C. Ibid., 132f.

leukocytes, erythrocytes, and platelets are suspended. Within a few hours after the blood has been collected, the plasma is removed from the whole blood by precipitation[159] with alcohol (e.g. ethanol) and by refrigerated centrifugation.[160] The product may be stabilized with amino acids (e.g. glycine) and it may contain thimerosal[161] (a mercury-based preservative), and sodium hydroxide or hydrochloric acid (to adjust pH levels).[162] The product is tested for antibody activity, the presence of micro-organisms, toxic substances, protein composition, and heat stability.[163] The final product contains 10%-18% proteins, high amounts of IgG and smaller amounts of IgA and IgM.[164] The solution is freeze-dried to remove the residual alcohol and to make the product more stable for storage and for transport.[165]

Animal Source

Animal-source antisera is usually derived from hyper-immunizing horses and harvesting their antibodies.[166] For example, a horse may be injected several times with a bacterial toxin and, when an adequate antibody titre (concentration) is determined,

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[159] "Precipitation" causes the settling of solids in a solution.

[160] Protein molecules are highly unstable, thus a precise temperature (-8° to 0° C) and specific ethanol concentrations must be maintained. The New Encyclopaedia Britannica, 15th ed. (Chicago: Encyclopaedia Britannica, Inc., 1980), 4: 193.

[161] Intravenously administered products do not necessarily contain preservatives. The New Encyclopaedia Britannica, 14: 193.

[162] The Physician's Desk Reference (Oradell, NJ: Medical Economics Co., 1996), 880.

[163] The New Encyclopaedia Britannica, 14: 193.

[164] National Advisory Committee on Immunization, Canadian Immunization Guide, 129.

[165] The New Encyclopaedia Britannica, 14: 193.

[166] National Advisory Committee on Immunization, Canadian Immunization Guide, 132.

the horse is bled from the jugular vein so that approximately 24 litres of serum are collected over 8 days.[167] After a period of rest (approximately 10 days) the entire procedure is repeated; this course may be repeated with one horse about four or five times and then the horse is "bled out under anaesthesia."[168] The antitoxin is then tested, diluted, filtered, refined by enzymatic or peptic digestion, and preservatives are added.[169] In Canada, equine-derived solutions are used for diphtheria and botulism antitoxins but they may be used "when[ever] human products are not available."[170] Human products are considered preferable, however, "because of the relatively high risk of serum sickness[171] following the use of animal products..."[172]

Active Artificial Immunity

Natural active immunity results from the body's response to infection: antigens elicit the production of antibodies and ultimately protect the body from subsequent infection by the same antigen. Active artificial immunity, induced by vaccines,

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[167]H. J. Parish, Antisera, Toxoids, Vaccines and Tuberculins in Prophylaxis and Treatment (Edinburgh: E. & S. Livingstone Ltd., 1958), 45.

[168]Ibid., 45; Connaught Medical Research Laboratories, 94.

[169]Parish, 46f; Connaught Medical Research Laboratories, 94.

[170]National Advisory Committee on Immunization, Canadian Immunization Guide 132.

[171]"Serum sickness" is caused by "an antibody reaction to an antigen in the donor." Within two to three weeks after the administration of an antiserum, the recipient may experience fever, skin rash, joint pain, swollen lymph nodes and an enlargement of the spleen. Anderson et al., Mosby's Dictionary, 1424.

[172]National Advisory Committee on Immunization, Canadian Immunization Guide, 132.

imitates natural immunity in that small amounts of live attenuated[173] or killed antigens are introduced into the body to induce the production of disease-specific antibodies which should protect the body from natural infection in the future.

Active vaccines are administered either intradermally (within the tissues of the skin), intramuscularly (within the muscles), subcutaneously (beneath the skin), or orally.[174] The frequency with which a vaccine should be administered depends greatly upon the type of vaccine, prevalence of disease in the recipient's environment, and the age, health condition, and allergies of the recipient.[175]

Preparation of Active Immunizing Agents

Vaccines used to induce active immunity are of three types: *virus vaccines*, *bacterial vaccines*, and *toxoids*. In each case, the living pathogen is harvested and encouraged to grow and reproduce (propagate) within an appropriate medium or host. Antigens, which constitute the most important element in the vaccine formula, may consist of "whole organisms or cells, organisms that have been broken apart or split by chemical treatment, or purified subunits from the whole organism."[176] The antigen, or

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[173]*Attenuation* of a disease organism means that the live antigen is weakened either by chemical or heat treatment or by "repeated passage through the cells of another species". Anderson et al., Mosby's Dictionary, 146.

[174]Ibid., 1626, 833f.

[175]See Appendix B for Canadian vaccination schedules and recommendations.

[176]V. A. Jegede, et al., eds., "Vaccine Technology," in Encyclopedia of Chemical Technology, 3rd ed. (New York: John Wiley & Sons, 1983), 23: 629.

its secreted toxins, are attenuated (heat or chemically treated) or killed, and combined with a series of chemicals to produce vaccines.

Micro-organisms found in *live* vaccines (e.g. attenuated virus vaccines) can replicate and induce an immune response but they are treated in such a way that their virulence, or disease-causing ability, is reduced.[177] Alternately, micro-organisms found in *killed*, or inactivated vaccines, should not be able to replicate in the vaccine recipient but they should still elicit an immune response. Each type of vaccine has its own unique method of preparation.

Toxoids

Diphtheria and tetanus vaccines are *toxoids*, meaning that they are derived from *toxins* secreted by bacteria, which have been treated with formaldehyde.[178] Formaldehyde is used to detoxify, or render the poisons harmless, which, if left untreated, would have a lethal effect on the recipient.[179] Diphtheria toxin, for example, is a powerful poison that becomes absorbed into the bloodstream and attacks various nerves, the kidneys, and the myocardium (muscle cells which form the bulk of the

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[177]Ibid., 628.

[178]Dixon, 48ff; National Advisory Committee on Immunization, Canadian Immunization Guide, 39, 115.

[179]Various experiments have been conducted, and accidents have been reported, which demonstrate the lethal effects of inadequately detoxified the diphtheria toxin. Toxin-rich solutions, which are completely free of bacilli, have proven to be just as lethal as the bacteria themselves when tested on laboratory animals. Similarly, a number of vaccine-related accidents, resulting in significant morbidity and mortality, have demonstrated that diphtheria *toxins* have been set free within properly prepared vaccines when they have been frozen for more than a few hours. Cf. Wilson, Hazards of Immunization, 19ff; Parish, 216.

heart wall).[180] Similarly, tetanus toxin is an extremely lethal substance; it is estimated that a mere 0.00025 gm. could kill a human being.[181]

When placed within a suitable medium, such as meat broth[182], the bacilli are stimulated into secreting toxins. The bacilli are filtered off, formaldehyde is added to the toxin-rich broth, and the mixture is incubated for two or three weeks.[183] Sometimes alum, or aluminum phosphate, is added to the toxoid since it causes the toxoid to be absorbed more slowly, encouraging the body to produce more antibodies over a longer period of time.[184]

Diphtheria and tetanus toxoids can be administered on their own but they are usually combined with other immunizing agents.[185] For example, the DPT-Polio (diphtheria, pertussis, tetanus, and polio) combined vaccines are routinely administered intramuscularly to children. Recently, the haemophilus influenza type b[186] (HIB) vaccine has been added to this combined preparation.

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[180]Parish, 43; Anderson et al., Mosby's Dictionary, 1035f.

[181]Parish, 54f.

[182]The broth may typically be derived from a combination of "dextrose, beef heart infusion, sodium chloride, and casein". Jamie Murphy, What Every Parent Should Know about Childhood Immunization (Boston, Earth Healing Products, 1993), 28.

[183]The New Encyclopaedia Britannica, 14: 193; Jegede et al.,630.

[184]National Advisory Committee on Immunization, Canadian Immunization Guide, 38.

[185]Specific indications regarding the acceptability and timing of administering different vaccines may be found in vaccine package inserts and in The Physician's Desk Reference.

[186]HIB bacteria is the major form of bacterial meningitis which primarily affects children under 5 years of age. HIB bacteria also affects respiration and can cause epiglottitis (hindering respiration), bacteremia (bacteria in the blood), cellulitis (a skin infection that can lead to tissue destruction), pneumonia, and septic (acute inflammatory) arthritis, as well. Cf. Introduction of Infant Haemophilus b Vaccine in Ontario: Information for Healthcare Providers, (pamphlet produced with the support of Lederle Laboratories, n.p., 1992), 1; National Advisory Committee on Immunization, Canadian Immunization Guide, 41; Anderson et al., Mosby's Dictionary, 562, 161, 286, 1421.

Bacterial Vaccines

In preparing bacterial vaccines, specific bacteria are first grown on an artificial medium such as nutrient agar (a red algae derivative) or casein (a colloidal protein in milk) plus minerals. The bacteria is then incubated, separated from the growth medium, and collected. A saline solution is added and the bacteria are killed either by heat or by germicidal agents and preservatives are added.[187] Chemicals commonly used as germicides/disinfectants and preservatives in vaccines are: phenol, thimerosal, 2-phenoxyethanol (an alcohol derivative), formaldehyde, and metallic salts.[188] Bacterial vaccines may also contain any of the following: polysaccharides, antibiotics (eg. neomycin, streptomycin, or polymyxin B), Tween 80 (a stabilizer), and adjuvants (antibody enhancing agents) such as aluminum hydroxide.[189] Pertussis, haemophilus influenza b, meningococcal, pertussis, pneumococcal, tuberculosis, typhoid, plague, and cholera bacterial vaccines are available in Canada.

Viral Vaccines

Viruses, used in the preparation of vaccines, typically will be harvested from infected fluids; for example, from the throat of an infected person. Since viruses require living cells for propagation, harvested antigens must first be grown on

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[187]The New Encyclopaedia Britannica, 14: 193.

[188]Elements of Biologicals (n.p.: Eli Lilly and Company, n.d.), 12.

[189]Vaccine package inserts list some of the ingredients found in vaccines. For more information Cf. The Physician's Desk Reference; Murphy, 25ff.

receptive host tissues.[190] Monkey kidney cells are used for propagating the three strains of polio virus used in Salk injectable inactivated (killed) and Sabin live oral poliomyelitis vaccines.[191] Human diploid cells provide the host tissue for rubella[192]. Chick embryos are used for measles, mumps, and yellow fever; eggs are used for influenza. Mouse brains are used for Japanese encephalitis and yeast is used for hepatitis.

Viruses may be inactivated (killed) with formaldehyde, as in the case of the Salk poliomyelitis vaccine, or the living virus may simply be weakened/attenuated (e.g. dried). Most virus vaccines are of the live, attenuated, type.

> [Cell cultures are generally grown in] the presence of a culture medium consisting of inorganic salts, amino acids, vitamins, dextrose, phenol red..., sodium bicarbonate..., antibiotics and [sometimes] calf serum.[193]

When incubation is complete, the mixture may be filtered or clarified, diluted, and stabilizers (e.g. hydrolyzed gelatin) and buffers may be added. Combination-type vaccines (e.g. MMR: measles, mumps, and rubella vaccines) are generally not mixed before this stage. The final vaccine may include a variety of chemicals such as:

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[190]For information regarding host tissues used in the production of viral vaccines refer to: The Physician's Desk Reference; National Advisory Committee on Immunization, Canadian Immunization Guide; and, vaccine package inserts.

[191]The Physician's Desk Reference, 845, 1176.

[192]Human diploid cell lines (WI-38) are cloned from fetal (3 month gestation) lung tissue. The cell line may require antibiotic-curing to destroy contaminants (e.g. bacterial). Special handling and precautions must be observed to avoid contamination. Human diploid cell lines require very complex media which including inorganic salts, amino acids, vitamins, glucose, phenol red (acid/pH indicator), and bovine fetal serum for growth and enrichment. American Type Culture Collection Product Sheet (Rockville, MD: n.p., 1995); Life Technologies, Gibco BRL Product Catalogue and Reference Guide (n.p.: Life Technologies, 1995-1996), 1-83.

[193]Jegede et al., 630ff.

alcohol (methanol, ethanol, or isopropyl), enzymes, phenol or thimerosal (as preservatives), formaldehyde, detergents, and organic solvents.[194] The final product may be used alone or in conjunction with other vaccines. Virus vaccines available in Canada include: rubella, poliomyelitis, measles, mumps, hepatitis B, influenza A and B, Japanese encephalitis, and yellow fever vaccines.

3. NATURAL AND ARTIFICIAL IMMUNITY

Vaccines are intended to prevent disease by eliciting an immune response, comparable to that conferred by natural immunity and recovery from infection. There are, however, significant differences between artificial and natural immunity. Primarily, the differences affect how the immune response is elicited; the degree of permanence of immunity; and, the safety and efficacy of methods used to acquire immunity. The majority of these differences will be discussed forthwith. However, the safety and efficacy of artificially acquired immunity will be addressed in the next two chapters.

Differences Affecting the Immune Response

When a disease is encountered naturally, the body reacts quickly by initiating an immune response at the point of entry as well as throughout the body where the various elements of the immune system become primed. Essentially, as the pathogens

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[194]Ibid., 630-633.

attempt to overtake the cells they are continually weakened and eliminated as they pass through a series of interdependent protective levels. In most cases, excluding tetanus and rabies among the "vaccine preventable diseases", the respiratory and gastrointestinal systems (secretory IgA systems) encounter the pathogens first. As soon as the body recognizes their presence, the immune response is initiated. This immediate response reduces the impact of infection, often eliminating disease even before symptoms become manifest.[195]

Vaccines, on the other hand, (with the exception of the oral polio vaccine) are injected directly into the body, *bypassing* many of the body's initial immune defences. This may be likened to a Trojan horse, wherein the "invaders" have been allowed to bypass the usual primary defensive mechanisms to initiate a "surprise attack," causing the defensive players to scramble into action. Unlike natural infection, which immediately functions to weaken the pathogen and simultaneously sends out chemical "messages" to activate other immune system elements, there is no opportunity to "prime" the immune system as a whole. In this way, vaccines do not elicit an immune response that can be considered comparable to natural immunity. In fact, the immune system is so hard pressed to respond to the internal "attack" that it compensates by utilizing far more immune cells than it normally would during natural infection.

The differences in immune response demands are particularly significant for infants and young children, whose immune systems will not be fully developed until about age

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[195]"In the case of natural infection, it has been estimated that the frequency of inapparent infections outnumber clinical illnesses by at least one hundred-fold," testifying to the efficacy and importance of the secretory/mucosal immune response. Harold E. Buttram and John Chriss Hoffman, Vaccinations and Immune Malfunction (Quakertown, PA: The Humanitarian Publishing Co., 1985), 22.

12. Theoretically speaking, during the course of a typical childhood infection (e.g. chickenpox), approximately 3-7% of the body's immune capacity (e.g. plasma cells or lymphocytes) are utilized in eliminating disease whereas the immune response to immunization could utilize approximately 30-70% of that same child's immune capacity.[196]

> It should be emphasized that, once an immune body (plasma cell or lymphocyte) becomes committed to a given antigen, it becomes incapable of responding to other antigens or challenges.[197]

For the infant, or young child, this means that an enormous percentage of his or her immune cells have been committed to the specific antigens introduced by the vaccine(s). The pathogens that are introduced through immunization are derived from 3-5 different viruses or bacteria and, unlike natural infection, multiple diseases are introduced into the body simultaneously. The immune system must recognize and act upon a variety of pathogens all at once. The long term potential consequences, of which, may be a greater susceptibility to infections, allergies, cancers and various mental and behavioural disorders because the maturing immune system has been overwhelmed.[198]

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[196]Ibid., 6.

[197]Ibid.

[198]It has been demonstrated, for example, that children who receive the pertussis vaccine are five times more likely to develop asthma than their unvaccinated counter-parts. Similarly, both ulcerative colitis and Crohn's disease appears to be more prevalent in individuals who have received the measles vaccine and, alternately, some intestinal illnesses (e.g. parasitic) appear less often in individuals who have recovered from natural measles infection. Ibid.; Harold E. Buttram and William G. Kracht, Current Childhood Vaccination Programs: Do Harmful Effects Outweigh the Benefits? (Quakertown, PA: Woodlands Healing Research Center, 1997), 2f; Cf., also, Harris L. Coulter, Vaccination, Social Violence, and Criminality: The Medical Assault on the American Brain (Berkeley, CA: North Atlantic Books, 1990).

In most cases, vaccination series are initiated when a child reaches two months of age, long before the immune system has matured. In the developed world, it is rare that infants and very young children would encounter the diseases against which they are vaccinated: most endemic childhood diseases tend to demonstrate a marked increase as children enter school and they are exposed to many other people. When they do encounter pathogens naturally, they have the advantage of a secretory immune response, which is by-passed during immunization. Recent studies have also indicated that natural infections actually assist the immune system to mature while vaccines tend to depress cellular (e.g. T cell) immunity. In one study, 11 healthy *adults* were found to have experienced a significant, albeit temporary, drop in *helper T cells;* in four of the subjects studied, "the T-helper cells dropped to levels seen in active AIDS patients."[199] Natural infections, on the other hand, appear to stimulate and strengthen the immune system.

Furthermore, it is extremely unlikely that such young children would normally meet with the challenges presented by toxic and carcinogenic (e.g. formaldehyde) vaccine components; these simply are not present during natural infection and they add an additional burden to the immune system.[200] It seems counter-productive to interfere with an immature immune system by unnecessarily challanging it with numerous pathogens and chemicals and, in so doing, threatening its normal development. The small amount of the immune bodies utilized during natural infection

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[199]Buttram and Kracht, 2.

[200]Vaccine components will be discussed more thoroughly in Chapter 3.

ensures that there are sufficient stores retained to respond to the various challanges presented throughout one's lifetime. The vast amounts of immune bodies utilized, because the many neutralizing levels of the immune system are bypassed, during vaccination have the potential to leave the body vulnerable and, ultimately, less capable of responding to future challanges. It is clearly unreasonable to expect that introducing disease and toxic chemicals into a body, and particularly into a body whose immune system is not completely developed, should result in improved health.

Degrees of Permanence

Both critics and proponents of immunization recognize that vaccines are indeed imperfect. A single dose of vaccine rarely, if ever, confers life-long immunity. Most vaccines are administered in a specified series, depending upon the type of vaccine and upon the recipient's age and locale, and usually booster doses are required to maintain sufficient immunity to prevent infection.[201] Although standard vaccine schedules have been recommended for the maintenance of adequate immunity for the general populace, "there is no way of knowing how long this partial or temporary immunity will last in any given individual."[202] If artificial immunity wanes during adolescence or adulthood, older individuals become susceptible to childhood diseases, when they present greater health risks. Even if the adult escapes infection, there remains yet

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[201]Schabas, Opportunities, 2.

[202]Richard Moskowitz, "Immunizations: The Other Side," in Vaccinations: The Rest of the Story ed. Peggy O'Mara (Santa Fe, NM: Mothering, 1996), 12.

another disadvantage to artificial immunity: individuals cannot confer passive immunity to their children. Natural immunity, on the other hand, provides permanent immunity and, as an added bonus, passive immunity can be passed onto one's progeny.

4. COMMENTS

Proponents of immunization warrant that the occasional inconvenience of (re)inoculation is more than compensated for by virtue of its safety and efficacy when compared to contracting diseases. To be sure, contracting disease naturally may incapacitate a person for a period of weeks and, since the infectious period of a disease may not be accompanied by symptoms, there remains the possibility of infecting many contacts. How well people tolerate disease depends largely upon the age and general health of the individual and upon available nutrition, sanitation and medical treatment. Vitamin supplimentation, for example, may mean the difference between an unremarkable recovery period and serious complications.[203] While one person recovers from a disease with no complications, another person may be left with disabilities, or die, from the same disease. Proponents warrant that the long-term benefits of artificial immunization, i.e. in preventing and historically eliminating disease, outweigh the risks associated with the vaccines themselves and far outweigh risks associated with naturally contracting vaccine-preventable diseases.

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[203]Vitamin A supplimentation, for example, has been demonstrated to reduce measles-associated complications. Similarly, vitamin supplimentation can indeed reduce adverse events associated with vaccination. Observations made on both humans and animals have shown that vitamin C supplimentation, prior to vaccination, significantly reduces post-vaccinal morbidity and mortality in vitamin deficient subjects. Buttram and Kracht, 3; Archie Kalokerinos, Every Second Child (New Canaan, CT: Keats Publishing, Inc., 1981), 122f, 140.

Opponents, on the other hand, dispute such claims by stating that artificial immunization not only endangers an otherwise healthy body, but they state that claims supporting the safety and efficacy of immunization are simply not supported by historical evidence. Such arguments may not be taken lightly and, for this reason, the following chapters will be dedicated to examining the opponents' arguments in view of available evidence and with respect to the four ethical principles commonly employed to evaluate medical policies and procedures. The scientific information included in this chapter will provide an important foundation for the ethical arguments that follow. Ethical inquiry, in this case, must be securely conjoined with both scientific and historical evidence in order to avoid purely emotive conclusions.

The safety of vaccines will be discussed in the forthcoming chapter entitled "Immunization and Non-Maleficence" since the principle itself requires that anticipated harm must be kept to an appropriate minimum in any medical intervention. In particular, the chapter will discuss whether potentially hazardous vaccine components can be justified in respect to the principle of non-maleficence.

Similarly, vaccine efficacy will be assessed in the fourth chapter entitled "Immunization and Beneficence." Since the principle of beneficence requires that a proportionate benefit must be anticipated from medical interventions, an historical analysis of the benefits of immunization will be considered. This chapter will consider whether vaccination has indeed reduced morbidity and mortality rates for the corresponding diseases and whether vaccines have demonstrated a propensity for protecting vaccinees from naturally acquiring disease.

Taken together, these three chapters should provide a substantial basis upon which to assess whether mass immunization offers general utilitarian and/or individual benefits. In light of the conclusions drawn from these chapters, immunization policies and procedures, as they apply to both individuals and societies, will be examined.

CHAPTER THREE
IMMUNIZATION AND NON-MALEFICENCE

Natural and artificial immunity differ significantly in function, i.e. how the immune system responds to challenges, and in the degree of permanence conferred. There remains yet another important difference to be considered. Although artificial immunity is meant to eliminate disease, thereby relieving vaccinees of the harmful effects of natural infection, vaccines themselves are comprised of hazardous elements which are capable of causing their own harmful effects. These hazardous elements, excluding the antigens of course, are not encountered with natural infection. Furthermore, the antigens found in vaccines have, at times, caused disease in vaccinees. One of the primary arguments presented by opponents to immunization is that toxic and pathogenic vaccine components have the ability to cause unnecessary harm, and sometimes death, in an otherwise healthy person. This argument is associated with the ethical principle of non-maleficence in that the potential harm caused by vaccines derives from the use of unsafe vaccine components and methods of preparation: both of which are officially sanctioned by governments, health care officials and international health organizations.

1. THE PRINCIPLE OF NON-MALEFICENCE

> *The principle of non-maleficence* has long been associated in medicine with the injunction *primum non nocere*: "Above all [or first] do no harm."[204]

On a very basic level, it is clear that this principle demands that medical personnel and scientific researchers refrain from purposely and unnecessarily injuring their patients or subjects. The issue becomes far more complex, however, when one attempts to define what "harm" entails and whether the inherent harm, associated with any medical intervention, can be justified by the proposed outcome.[205] Clearly, *undue* harm would be incurred if the risks associated with treatment were proportionally higher than those associated with the condition itself.[206] For example, it is well known that administering any drug during pregnancy presents a risk to the fetus. During the late 1950s, two anti-nausea medications, Thalidomide and Bendectine, were distributed to pregnant women.[207] Both of these drugs had the potential to cause limb reduction defects in the fetus. The good proposed by the drugs, i.e. to reduce nausea, simply

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[204]Tom L. Beauchamp, "The 'Four-Principles' Approach," in Principles of Health Care Ethics, ed. Raanan Gillon (Chinchester, England: John Wiley & Sons Ltd., 1995), 5.

[205]The principle of non-maleficence necessarily conjoins itself with the principle of beneficence. While the former requires the avoidance of undue harm, the latter requires that positive steps be taken to avoid harm *and* to do good. Each of these principles seem to imply the other and, for this reason, they cannot always be treated as separate, or competing, principles.

[206]Even when the principle of non-maleficence would be clearly violated, based upon proportional risks, this principle may be overruled by other competing principles. If, for example, a patient insists upon an unnecessarily risky procedure, then autonomy may well overrule non-maleficence. Similarly, if a procedure is considered to be a utilitarian benefit, individuals may be compelled to submit to the intervention despite the violation of non-maleficence. Both of these competing principles will be discussed more thoroughly in forthcoming chapters.

[207]In the case of Bendectin, which was still being distributed during the 1980s, the manufacturer falsified the results of animal safety tests, reporting that abnormalities had occurred in one of twenty-four rabbit kits. Seventeen years later, court inquiries revealed that abnormalities had actually occurred in one of every *eight* rabbit kits. Robert S. Mendelsohn, Male Practice: How Doctors Manipulate Women (Chicago: Contemporary Books, Inc., 1981), 138.

was not justified in view of the greater potential harm. Both drugs were still distributed even after their adverse effects were known, thereby violating the principle of non-maleficence.[208] A patient's health must not be unnecessarily endangered. The principle of non-maleficence requires that undue harm be avoided.

Although our health care professionals strive to maintain the principle of *non-maleficence*, meaning *do no harm*, this desirable principle cannot, and is not, observed at all times. Certain inherent risks exist with *any* medical intervention. If, theoretically, governments and health care professionals refused to allow the administration of any treatment or procedure that carried some element of risk, few medical interventions could be used. For example, if health care providers know that a patient will certainly die without a heart transplant, and also know that this patient will have a 30% survival rate if she or he does have the surgery, should health care professionals deny this patient the transplant because there is a 70% risk that this person will not survive the surgery?

A less dramatic example may be observed regarding pain control. The commonly used analgesic "acetaminophen" may be purchased, in low dosages (e.g. 325-500 mg) at any pharmacy without a prescription; higher doses, combined with other medications, are available by prescription. It is known that acetaminophen can be addictive and that "adult dosages exceeding 10-15 g can produce liver failure... and doses above 25 g can be fatal."[209] If the government and health care providers were to

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[208]Ibid., 136ff.

[209]Anderson et al., Mosby's Dictionary, 13.

refuse any treatment that carried some associated risk, then persons who suffer from chronic and extraordinary pain would be denied adequate doses of this analgesic. The point is that the possibility of causing injury cannot always be the only predetermination to action. Otherwise many health care practices would come to a grinding halt.

Such is the case with mass immunization practices. One cannot assume that since mass immunization is being practiced, it *must* be safe for all persons. On the contrary, there is ample documentation demonstrating that immunization has proven to be quite detrimental to certain individuals.[210] It would be imprudent, however, to think of our governments, physicians, or nurses as negligently administering toxins when they know that risks exist for a certain percentage of individuals. Supporters of mass immunization certainly are aware that risks exist for any immunized individual but it is held that the general good derived from mass immunization exceeds the inherent risk.[211]

Critics of immunization disagree. Many critics have asked whether it makes sense to inject foreign antigenic proteins and harmful chemicals into a *healthy* body in order to protect the body from a disease it may *never* contract anyway, particularly when no one understands the long term effects the vaccine components may have.[212] The

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[210]Cf., for example, Wilson, Hazards of Immunization. This book contains numerous examples of vaccine-accidents and complications. In his introduction, the author states that while most of the *larger* accidents have been reported in print, most accidents go unreported due to fears of compensation claims, of giving anti-vaccinationists a "weapon", or for other reasons. Ibid., 4f.

[211]Schabas, Opportunities, 3; World Health Organization, Health Aspects of Human Rights, 42-44.

[212]Cf. Robert S. Mendelsohn, How to Raise a Healthy Child...In Spite of Your Doctor (Chicago: Contemporary Books, Inc., 1984), 209ff; Miller, Vaccines?, 47ff.

potential for violating the principle of non-maleficence is great since the risks posed by immunizing agents may exceed the risks posed by natural infections. Such is the case with the rubella vaccine, as discussed previously. The disease is innocuous when contracted in childhood but the personal risks posed by the vaccine components, as well as their effect upon the disease's epidemiology, certainly outweigh those posed by the disease. Adverse reactions can occur with any vaccine: individuals may prove to be allergic to any vaccine component and/or they may incur a more serious (debilitating or fatal) reaction to the vaccine than they would have experienced they contracted the disease itself. Critics of immunization believe that vaccine components, either alone or in combination, have the ability to cause countless immediate and long term health risks.

Most vaccine components appear to be used in order to produce one of three effects: [1] foreign protein/antigens to induce an immune response, [2] various chemicals to attenuate, disinfect or kill the antigens, and [3] other chemicals are added to preserve the final solution. The effects any of the components may have on an individual, or even on a society, remain in question. In the short term, one may manifest a range of reactions from mild (e.g. fever and malaise) to severe (e.g. seizures, anaphylactic shock, paralysis, encephalitis and etc.) or even fatal.[213] Long term effects are more difficult to ascertain. Long term studies are lacking so it is

[213]National Advisory Committee on Immunization, Canadian Immunization Guide, 5; Cf. The Health Protection and Promotion Act, as amended by Bill 52, 1987.

difficult to determine which pathological changes are directly attributable to vaccines.[214] Critics of immunization have expressed concerns over a potential connection between toxic vaccine components and the rise in autoimmune diseases, cancer, AIDS, allergies, learning disorders, and violent behaviour.[215] The effects of some of the vaccine components are well known, and these will be described in due course, but what is not known conclusively is whether a bioaccumulation of specific components results in genetic mutations within the vaccinee and/or results in other presently unconfirmed adverse effects.

In the following sections of this chapter it will be demonstrated that vaccines contain hazardous components which pose an undue threat to the health of vaccine recipients. Specifically, many of the commonly used chemical vaccine components are known to be toxic and/or carcinogenic and they often *inhibit* the immune response more efficiently than they weaken antigens. Further, it will be demonstrated that chemicals used to attenuate or kill pathogens are inadequate. This pathogenic survival means that vaccinees actually risk infection from the fully virulent antigenic components remaining in the vaccine preparations. Moreover, vaccinees risk contamination from diseased host tissues. As mentioned in the previous chapter, vaccine preparation begins with the propagation of antigens, usually in human or animal host tissues. These host tissues can contain a myriad of their own distinct

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[214]Arnold S. Relman, "Immunization on Public Trial," New England Journal of Medicine 297 no. 5 (4 August 1977): 276.

[215]Cf. Buttram and Hoffman, Vaccinations and Immune Malfunction,9ff; Edda West, VARIANCE Newsletter (Summer 1994): 1f; Scheibner, 162ff, 255f; Miller, Vaccines?, 47ff; Coulter, xiv ff.

pathogens. Past experience has demonstrated that vaccinees can become infected by these extraneous, and often undetected, pathogens, leading not only to disease within the individual but, sometimes, introducing animal diseases into a new human reservoir. By virtue of the undue harm caused by the chemical and antigenic vaccine-components, the mass use of risky immunizing agents threatens the principle of non-maleficence.

2. VACCINE COMPONENTS

Chemical Components

Vaccine critics contend that the chemicals used to attenuate, kill, stabilize and preserve the pathogenic vaccine components may cause severe adverse reactions, causing undue harm to vaccinees.[216] In particular, the use of formaldehyde, thimerosal, aluminum phosphate, antibiotics, and phenol red appear to cause some measure of controversy because they have been proven to cause a variety of health problems. To be sure, the chemicals found in the final product appear in small quantities but their potential for harm may not be proportionally small. When entire populations are exposed to hazardous elements and, in particular, when children's immature immune systems are exposed, the potential for undue harm becomes enormous. Concerns also arise over the lack of information provided to vaccinees and to their parents or

[216]Cf. Murphy, 39ff.

guardians regarding toxicity levels in humans[217], possible adverse reactions attributed to combining the chemicals, the bioaccumulation of the chemicals administered with each successive immunization and the long term affects of these chemicals.[218] Many of the long term affects, resulting from the combination of chemicals and their bioaccumulation, simply are not known at this time. Long term vaccine-studies simply have not been executed for this purpose. In view of the lack of long term studies, one must ask whether there has been a sufficient effort made to "do no harm." A few of the chemical vaccine components, for which toxicity information is available, will be discussed.

Formaldehyde

Formaldehyde is of particular concern since it is a known carcinogen: a cancer causing agent.[219] Formaldehyde solutions are generally used as germicides and fungicides for plants, as insecticides, in the production of fabrics, explosives, but they are perhaps best known for their use in embalming fluids.[220] Formaldehyde is

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[217]Concerns arising over *informed* consent will be presented in Chapter Five: Immunization and Respect for Autonomy.

[218]Cf. Murphy, 39ff.

[219]Grace Ross Lewis, 1001 Chemicals in Everyday Products (New York: Van Nostrand Reinhold, 1994), 111; Robert E. Gosselin et al., eds., Clinical Toxicology of Commercial Products (Baltimore: Williams & Wilkins, 1984), III-198.

[220]Susan Budavari et al., eds., The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals (Rahway, NJ: Merck & Co., Inc.,1989), 662.

poisonous if ingested: it may cause tissue damage (e.g. lung damage), cellular mutations, vomiting and diarrhea.[221] Ingestion is also known to cause:

> severe stomach pain, hematemesis (vomiting of blood indicating upper gastrointestinal bleeding), hematuria (blood in the urine, usually a symptom of "renal diseases and disorders of the genitourinary system"), proteinuria (inordinate amounts of protein in the urine, generally associated with renal diseases), anuria (cessation, or below adequate, urine production), acidosis (overaccumulation of acids having various effects depending upon region affected), vertigo (dizziness), coma, and death.[222]

Formaldehyde has been known to cause skin irritation, corrosive damage to the stomach, and circulatory collapse.[223] Formaldehyde is considered to be incompatible with "strong oxidizers, strong alkalies, acids, phenols (also used in vaccine preparations), and urea."[224]

Formaldehyde, usually in its liquid form "formalin", is used in many vaccine preparations to inactivate the bacterial or viral antigens. It has been known for many years that formaldehyde is an inadequate disinfectant. The inadequacy of formaldehyde disinfectants is explained:

> The virus in the suspension may be partly clumped, and may be surrounded by gelatinous debris of protein material. This is hardened by the formaldehyde, so that the particles within are protected from its action. Inside the body, the coating is digested by enzymes and the virus particles are set free.[225]

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[221]Lewis, 111.

[222]Budavari et al., 662. Information in parentheses has been derived from: Anderson et al., Mosby's Dictionary, 719f, 1289, 107, 16, 1646.

[223]Gosselin et al., III-196f.

[224]Marshall Sittig, Handbook of Toxic and Hazardous Chemicals and Carcinogens (Park Ridge, NJ: Noyes Publications, 1985), 463.

[225]Wilson, citing M. V. Veldee, Hazards of Immunization, 46.

The fully virulent particles are now free to reproduce within the vaccinee, causing debilitating and even fatal effects.

That formaldehyde is inadequate in disinfecting vaccine preparations has been known for decades. In fact, its inadequacy was actually "*re*discovered" during various vaccine-related accidents during the 1950s.[226] Bacteriologists knew of its inadequacy for many years prior. Since formaldehyde *does not* have the ability to neutralize all antigens, and since it *does* have the ability to cause serious disability and death, there is no question that the continued use of this unreliable and hazardous substance clearly violates the principle of non-maleficence.

Phenol

Phenol is a highly poisonous, caustic substance derived from coal tar and used in the production of disinfectants, dyes, pharmaceuticals, plastics, germicides, and preservatives.[227] Exposure may result in systemic poisoning, weakness, sweating, headache, shock, excitement, kidney damage, convulsions, cardiac or kidney failure, and death.[228] Repeated exposure may also cause vomiting and mental disturbances.[229] Phenol is considered to be corrosive to the skin and it is known to be *protoplasmic*

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[226]The use of formalin in the polio vaccine, for example, allowed the polio virus to be set free in vaccinees and, since it does not kill all pathogens, it allowed a simian virus, SV40, to be introduced into humans. These incidents will be discussed in the forthcoming sections of this chapter. Wilson, Hazards of Immunization, 45f, 59, 287.

[227]Budavari et al., 1247; Sittig, 704; Robert H. Dreisbach, Handbook of Poisoning: Prevention, Diagnosis, and Treatment (Los Altos, CA: Lange Medical Publications, 1983), 402.

[228]Sittig, 705; Anderson et al., eds., Mosby's Dictionary, 1208.

[229]Sittig, 705.

poison: i.e. toxic to all cells.[230] Tests indicate that phenol actually *inhibits* phagocytic activity.[231]

The use of phenol in vaccine preparations introduces a poisonous and caustic substance into the body. Since it also inhibits phagocytic activity, it actually serves to *debilitate*, rather than stimulate, the immune response. Phagocytes serve as the body's first line of defense against antigenic activity: they engulf and digest antigens and they cause other elements of the immune system to become activated. Since vaccines are meant to *stimulate* an immune response, the use of *phagocyte-inhibiting* phenols contradicts the basic rationale for using vaccines. Furthermore, harm cannot possibly be avoided when it is understood that at the same time that pathogens are being introduced into the body, phenols are acting to inhibit an appropriate immune response.

Thimerosal

Thimerosal, also known as *merthiolate*, is a mercury derivative commonly used as a preservative in vaccines, serum, and gamma globulin (passive immunization). The role of thimerosal is to prevent any extraneous microorganisms from contaminating the vaccine. A variety of tests, however, have cast doubt upon the preservative since it appears to be non-selective in its action: it may render vaccine antigens impotent and it may leave harmful invading microorganisms undisturbed.[232] Furthermore, it has been

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[230]Dreisbach, 704; Gosselin et al., III-344.

[231]Murphy, 44f.

[232]Ibid., 42f.

demonstrated that thimerosal, like phenol, is considerably more toxic to white blood cells, particularly phagocytes, than it is to bacteria.[233]

It has been suggested that, since this form of mercury is poorly absorbed by the body, the chance of mercury poisoning is decreased in comparison with exposure to other forms of mercury.[234] However, there appears to be a cumulative effect to thimerosal: persons who have received successive treatments (eg. immunoglobulin serum preserved with thimerosal) show elevated mercury levels in their urine.[235] Even very tiny amounts of mercury are known to be cytotoxic and can be particularly destructive to brain, kidney and liver cells.[236] Ingested mercury has been associated with chromosome damage, depletion of zinc in the brain tissues, systemic poisoning, and genetic defects.[237] The effects of mercury are currently being examined, particularly regarding its use in dental amalgams (affecting autoimmune disease), and undoubtedly more information will soon be available.[238]

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[233]Ibid., 44ff.

[234]It is estimated, for example, that 2-4 times the amount of thimerosal is required to produce the same fatal reaction as inorganic mercury salts. Dreisbach, 263.

[235]Murphy, 46f; Cf. John D. Kirschman and Lavon J. Dunne, Nutrition Almanac (New York: McGraw-Hill Book Company, 1984), 81.

[236]It is interesting to note that the term "mad as a hatter" was coined in response to the pervasive severe mental illnesses commonly found amongst early British hat-makers who were in constant contact with mercury. In a variety of professions, workers have been found to suffer from memory loss, dementia, and some die as a direct result of their contact with mercury. It is well known that dentists, for example, suffer the highest rate of divorce and suicide when compared to other professional groups. H. Richard Casdorph and Morton Walker, Toxic Metal Syndrome (Garden City Park, NY: Avery Publishing Group, 1995), 132ff.

[237]Kirschman and Dunne, 81.

[238]Dental amalgams present a continual problem in that as one chews, "microscopic particles of the toxic agent float as a gas to [one's] brain[] to steadily set out conditions for dementia." Due to a variety of adverse health occurrences, the German government banned silver-mercury dental fillings in 1992. Casdorph and Walker, 133, 158f. Cf. also: Hal A. Huggins, It's All in Your Head: The Link Between

In light of evidence thus far available, it is clear that the bioaccumulation of thimerosal poses a serious health-risk. Like formaldehyde, thimerosal appears to be unreliable in protecting vaccines from contamination and, like phenol, thimerosal has a toxic effect upon white blood cells. The actual harm incurred by the use of thimerosal in vaccines may be currently inestimable but there is no doubt that harm indeed does occur. Once again, the principle of non-maleficence has been violated by the continued use of a known toxic substance in vaccine preparations.

Adjuvants

Aluminum salts[239] are used as *adjuvants*: they enhance antibody response by "trapping or pooling the vaccine antigen," causing a slow release of the antigen, "thereby stimulating the production of antibodies for longer periods of time."[240] Essentially, the adjuvant causes a prolonged exposure to smaller amounts of antigen, extending the duration and efficacy of the immunological response.[241]

Small quantities of aluminum salts in the blood can cause long term poisoning "characterized by motor paralysis and areas of local numbness, with fatty degeneration

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Mercury Amalgams and Illness (Garden City Park, NY: Avery Publishing Group, 1993).

[239]Aluminum salts are used in a wide variety of pharmaceuticals and other approved products (eg. antacids, buffered aspirin, antidiarrheals, douches and foods, etc.). Cf. Casdorph and Walker, 77ff.

[240]Murphy, 49.

[241]McHenry et al., 9:254.

of kidneys and liver."[242] Studies have indicated that aluminum salts, when present in the fluid surrounding the brain, can cause learning disabilities and dementia.[243] It is significant that behavioral disorders, attention deficit hyperactivity disorder, learning disabilities and autism have shown a marked increase, and are still increasing, in our children in recent decades.[244] Aluminum hydroxide gel, also a vaccine adjuvant, reduces blood phosphate, it appears to be carcinogenic and it can cause bone dissolution, and weak and aching muscles.[245] Aluminum salts and gels are considered to be corrosive to tissue.[246] These adjuvants have the ability to cause cerebral and neurological damage: apparently this is the cost of extending the immune response. The cost is too great and cannot be supported by the principle of non-maleficence.

Alcohols

Alcohols, such as ethanol, methanol, isopropyl, and 2 phenoxyethanol, are antiseptics used to "inhibit the growth and reproduction of microorganisms."[247] Alcohols are highly toxic and can cause a myriad of problems including: general malaise, blindness, acidosis (causing shallow respiration), hypoglycemia (low blood

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[242]Kirschman and Dunne, 65.

[243]Aluminum has been found in the brains of Alzheimer's patients. When trace amounts of aluminum have been applied to, or injected into, the fluid surrounding the brain, experimental animals have had seizures and have shown signs of dementia. Ibid.

[244]In the United States alone, there are approximately "2 million new cases of attention deficit each year" and autism has become epidemic, with the current number of cases reaching approximately 250,000. Buttram and Kracht, 1.

[245]Murphy,51; Kirschman and Dunne, 65.

[246]Lewis, 11.

[247]Anderson et al., Mosby's Dictionary, 106.

sugar), hyperlipidemia (e.g. elevated levels of fats, triglycerides, and cholesterol in the blood), central nervous system depression, gastrointestinal damage, coma and death.[248] Like the other chemicals used in vaccine production, alcohols counter the principle of non-maleficence because of their potential for serious harm.

Antigenic Components

Antigens are essentially proteins that are capable of causing disease and of eliciting an immune response. Bacterial and viral antigenic components comprise the central feature of any vaccine. Antigens used in vaccines should be treated in such a way that they lose their pathogenic (disease causing) ability while retaining the ability to elicit an immune response. Due to inadequate treatments, pathogens may survive to the final vaccine preparation. Furthermore, pathogens that infect vaccine host tissues may go undetected and/or survive treatment, thus contaminating the vaccines and causing different, and sometimes new, diseases in vaccinees. Pathogenic survival and contamination of vaccines by diseased host tissues place vaccinees, and sometimes their contacts, at undue risk of contracting disease. While this possibility remains, the principle of non-maleficence is seriously threatened.

[248]Dreisbach, 183-196.

Pathogenic Survival

Injection or oral administration of foreign proteins has the potential of causing disease in vaccinees and in their contacts.[249] Live virus vaccines appear to be more culpable in this regard because the virus actually replicates itself within the vaccinee imitating natural infection. Incidently, this is the reason why live virus vaccines are considered to produce a more efficient immune response with lower doses of antigen. The Sabin oral poliomyelitis vaccine (OPV) presents a striking example of a live virus vaccine that has been acknowledged as being capable both of causing the disease in vaccinees and in their contacts.[250]

Albert Sabin, founder of the vaccine, believes the live polio vaccine to be superior to the inactivated (Salk) poliovaccine because the OPV elicits an immune response in both recipients and in their contacts as well. He states:

> OPV is different from the other attenuated live virus vaccines in that it is given at the natural portal of entry [mouth] where *the vaccine strains multiply extensively and spread to unvaccinated persons in the family and the community*.[251]

Sabin also suggests that the OPV stands above other live virus vaccines since it is administered orally, emulating natural infection. OPV, like "wild" polioviruses, travels from the mouth, to the stomach and to the fecal excretions, where it again becomes a

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[249]Cf., for example, Wilson, Hazards of Immunization.

[250]William J. Curran, "Public Health and the Law: Public Warnings of the Risk in Oral Polio Vaccine," American Journal of Public Health 65 no.5 (May 1975): 501f; William J. Curran, "Public Health and the Law. Mass Immunization Programs: A Special Legal Area?," American Journal of Public Health 59 no.2 (February 1969): 137f; William E. Moore, "Duty to Warn Extended to Bystander in Close Contact with Polio Vaccinee," Mercer Law Review 24 (1977): 643-647; National Advisory Committee on Immunization, Canadian Immunization Guide, 96.

[251]Sabin, "Measles, Rubella, Poliomyelitis, and Influenza," 36 (emphasis added).

contagion for contacts.[252] It is well known that OPV, not only elicits an immune response but, can infect recipients and their contacts with the disease. Herein lies the crux of the critics argument: foreign antigens *do* retain the ability to cause disease in an otherwise healthy individual, thereby violating the principle of non-maleficence. To be sure, every precaution is taken to provide the safest product possible, but it remains a fact that between 1980 and 1993 all but one (imported) case of poliomyelitis in Canada were determined to be vaccine related.[253]

Killed viruses should provide a safer alternative to live vaccines. The antigens, while still capable of eliciting an immune response, cannot propagate themselves and, *theoretically*, they should not be able to cause disease. However, numerous vaccine-accidents have indicated that particles of antigenic material may escape detoxification: free antigenic particles in vaccines have been known to cause their own catastrophic epidemics.[254] In 1955, for example, vials of the Salk inactivated poliomyelitis vaccine (IPV) were distributed by Cutter Laboratories, causing 260 cases of poliomyelitis in

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[252]Fecal contamination may occur due to inadequate hand cleansing and, perhaps, due to flies. Flies may land on poliomyelitis contaminated feces and then on food. This appears to be a particular problem in areas where poor sanitation persists. Conversely, it is interesting to note that modern sanitation has been blamed for an increase in poliomyelitis cases. Apparently when individuals were regularly in contact with open sewers and privies they regularly came into contact with polioviruses. Contact during infancy, "when paralysis rarely occurs", meant that one gradually developed resistance to the disease. It appears possible, then, that elimination of this early contact caused a once mild disease to become far more virulent and debilitating. Cf. Scheibner, 163ff; Jane S. Smith, Patenting the Sun: Polio and the Salk Vaccine (New York: William Morrow and Co., Inc., 1990), 35f.

[253]National Advisory Committee on Immunization, Canadian Immunization Guide, 97.

[254]Cf. Wilson, Hazards of Immunization, 19ff.

vaccinees and their contacts. Inquiries revealed that the virus had not been completely inactivated by the formalin (formaldehyde solution).[255]

Although many tests are conducted to assure safety and efficacy prior to the release of any vaccine, it may be nearly impossible to isolate a few living organisms which have managed to survive to the final lot. This means that individuals can never be certain of whether they will be protected against a disease or become infected with disease from vaccines.[256] To be sure, modern vaccines do not usually cause the same diseases they are meant to prevent but it does occur. The oral poliomyelitis vaccine continues to be the main cause of the disease in the developed world. Proponents of vaccination maintain that the overall benefit of vaccines greatly outweighs the risks: the general populace remains healthy while a relatively small number of individuals become infected by vaccines. In general, people have come to accept proportional risks when they undergo treatments, the more serious the malady; the more serious the

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[255]Of the 260 reported cases, 192 were paralytic and 10 persons died: 5 vaccinees and 5 contacts. Ibid., 45f.

[256]New genetically engineered recombinant vaccines may present similar problems. These vaccines utilize one type of attenuated (weakened) antigen to house selected genetic material of another antigen. One such vaccine used the vaccinia virus from the conventional smallpox vaccine. Researchers inserted HIV genes into the vaccinia gene. When cells become infected with this recombinant virus, they tend to express the HIV epitope on their cell-surfaces. This new method is meant to stimulate both humoral (antibody) and cellular, particularly helper and killer T cell, responses. Theoretically, this method should elicit an immune response to the inserted antigen, which may otherwise go unrecognized as foreign by the immune system, by initiating an immune response to the outer antigen, which the immune system *will* recognize as non-self. When this vaccine was used on HIV positive patients, in an attempt to delay the progress of the disease, the result was that 3 of the 19 test subjects developed, and died from, vaccinia necrosis (severe skin lesions caused by the vaccinia virus). J.C. Guillaume et al., "Vaccinia From Recombinant Virus Expressing HIV Genes," Lancet 337 (27 April 1991): 1034f; Derek Baxby, "Safety of Recombinant Vaccinia Vaccines," Lancet 337 (13 April 1991): 913; Elizabeth L. Cooney et al., "Safety of and Immunological Responses to a Recombinant Vaccinia Virus Vaccine Expressing HIV Envelope Glycoprotein," Lancet 337 no. 8741 (9 March 1991): 567; John Crewdson, "Three Dead in AIDS Vaccine Test: Fatalities Went Unreported," Chicago Tribune, 14 April 1991, 1, 16f (1).

treatment. This presents a vastly different situation from the unproportional risks posed by preventive measures. Clearly, when disease is introduced into a healthy body by the use of a *preventive* agent, the harm is not justifiable. This is particularly true, and the injustice is amplified, when the disease, against which the vaccine is administered, does not pose an immediate and significant threat to the vaccinee.

Contamination of Vaccines by Diseased Host Tissues

Critics of immunization express concern over introducing foreign proteins into the human body due to the possibility of spreading disease from host tissues to vaccinees. Of particular concern are human and simian host tissues used in the production of rubella and polio vaccines, respectively. The use of human diploid tissue, harvested from an aborted fetus, caused considerable ethical and health- related concerns during the 1980s.[257] But, according to Dr. Neil Pearson of Connaught Laboratories, "the cell structure of the human fetus provides much greater certainty that vaccine recipients won't be infected with any animal viruses."[258] He went on to say:

> that with animal cell-based vaccines, there are viruses that cannot be identified and children would be injected with "a whole lot of micro-organisms that he or

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[257]Anti-abortionists were outraged that the compulsory rubella vaccine utilized aborted fetal tissue. Separate schools temporarily halted the use of the vaccine until a statement was issued from the Cardinal Carter Centre for Bioethics in Toronto approving use of the vaccine. Father Gallager, of the Centre for Bioethics, stated that any Catholics who refused the vaccine could *not* defend their case by citing official church doctrine. The ethical debate continued without complete resolution. A vaccine was later produced against rabies using aborted fetal tissue. Murray Campbell, "Anti-abortionists Fight Vaccine Made with Fetal Tissue," The Globe and Mail, 30 November 1984, 1f; "Church Approves Use of Measles Vaccine," Winnipeg Free Press, 4 December 1984, 11.

[258]"Vaccine From Fetus Slammed," Calgary Herald, 30 November 1984, 10(A).

she normally wouldn't come into contact with if they were living a normal life."[259]

Dr. Pearson appears to suggest that human fetal tissue provides a measure of safety regarding disease transmission, from host-tissue to vaccinee, that might not be afforded if the host tissue were derived from an animal source. To be sure, there are a number of diseases endemic to animals that, under normal circumstances, are not considered pathogenic for humans.[260] Still, the majority of vaccines use animal host tissues and/or cell growth media which include animal (usually bovine-fetal) serum.[261]

The viability of transmitting animal diseases to humans became apparent through scientific experimentation. By the 1960s, in fact, experiments identified over 40 simian viruses found in monkey kidney cell cultures: the same types used in polio vaccine production.[262] One of these viruses, the respiratory syncytial (RS) virus, was found to cause respiratory ailments in laboratory volunteers.[263] Subsequent serological studies established an etiologic relationship between the RS virus and respiratory infections in infants.[264] Further, by 1962 a variety of studies confirmed that the RS

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[259]Campbell, 1.

[260]In other words, the normal contact humans have with animals does not lead to cross-species contamination for certain diseases.

[261]Bovine serum appears to present particular health risks, especially when combined with the pertussis vaccine. In one study, conducted to determine the underlying pathology of pertussis vaccine-related encephalopathy, it was discovered that "BSA [(bovine serum albumin)], present in fetal and adult bovine sera, produced encephalopathy together with the pertussis vaccine" in laboratory mice. L. Steinman et al, "Murine Model for Pertussis Vaccine Encephalopathy: Linkage to H-2," Nature 299 (21 October 1982): 738-740.

[262]Scheibner, 152ff.

[263]Ibid., 153.

[264]Ibid., 153ff, 161.

virus, and other simian viruses, are resistant to heat and formaldehyde and therefore can survive usual measures implemented to kill the poliovirus for vaccines.[265] One such virus, SV40, was found to contaminate both the oral and inactivated poliomyelitis vaccines. Early experiments confirmed that SV40 caused cancer in lab animals and recent experiments have associated SV40 with rare forms of bone, brain, and lung cancers.[266] Clearly, simian viruses are able to contaminate humans with new, and highly virulent, diseases.

When a disease is endemic to a population, that population tends to develop antibodies to the disease and pass the antibodies on to their offspring. The population, as a whole, generally develops an adequate immune response to the disease. Monkeys, for example, may have developed an adequate immune response to a disease but, when that same disease is introduced to a virgin soil population (e.g. humans), that disease becomes far more virulent in its new host because there are no established immune defences to counter it.

In 1985, questions began to arise concerning a potential connection between the advent of HIV (human immunodeficiency virus) and the resilience of simian viruses, particularly SIV (simian immunodeficiency virus), in polio vaccines. SIV provides the closest correlate to AIDS-causing HIV and serologic tests discovered the SIV in rhesus, cynomolgus, and African green monkeys.[267] Kidney tissues from the African

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[265]Ibid., 160.

[266]Drs. John Bergsagel, Benjamin Sweet and Michele Carbone, "Virus SV40," interview by Trish Wood, The Fifth Estate (25 February 1997).

[267]Scheibner, 158.

green monkeys[268] are most often used as host tissues for the polio virus vaccine.[269] Either human or monkey cells could have been used but monkey cells were ultimately chosen because of their availability and because researchers feared that the use of human cells lines may facilitate the spread of cancer.[270]

It must be understood that HIV, and SIV for that matter, cannot be transmitted by casual contact the way that the RS virus can be transmitted: there must be some exchange of body fluids or tissues from an infected party into another non-immune party.[271] If some small portion of the tissues or blood from an infected African green monkey has made its way into the vaccine, the potential for contamination is inherent.[272] Exposure does not guarantee infection nor can it be assumed that every polio vaccine recipient has been exposed to SIV. But there is substantial evidence suggesting that the poliomyelitis vaccine may have introduced a disease, previously endemic to monkeys, into a new (human) host.

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[268]Prior to 1961, most vaccine researchers used kidney tissues from Asian rhesus macaques. They began using African green monkeys instead because it was believed that they would be free of SV40 commonly found in the rhesus macaques. Tom Curtis, "The Origin of AIDS: A Startling New Theory Attempts to Answer the Question 'Was it an Act of God or an Act of Man?'," Rolling Stone (19 March 1992): 59.

[269]Walter S. Kyle, "Simian Retroviruses, Poliovaccine, and the Origin of AIDS," The Lancet 339 no.8793 (7 March 1992): 600. It should be noted that Connaught Laboratories in Canada currently uses human diploid cells, human albumin and bovine serum for one of their IPVs and monkey kidney tissues for another.

[270]Curtis, "The Origin of AIDS," 56.

[271]Ministry of Health Ontario, Understanding AIDS and HIV Infection: Information for Hospitals and Health Professionals (n.p.: Queen's Printer for Ontario, 1988), 36, 13.

[272]SIV/HIV actually infects lymphocytes and macrophages which, despite preparation of the monkey kidney tissues (e.g. mincing), remain within these tissues.

There are currently two distinct populations which appear to be the hardest hit by the AIDS epidemic: equatorial Africans and North American homosexual men. While the HIV types differ between these two populations, the former primarily demonstrating HIV-2 and the latter HIV-1, both appear to be casually and temporally related to different poliomyelitis vaccines contaminated with SIV-infected monkey kidney tissues.

In 1957 the first-ever mass oral poliomyelitis vaccine campaign was initiated and, within a three year period, at least 325,000 inhabitants of equatorial Africa received the newly formulated Koprowski oral-spray polio vaccine.[273] Prior field trials for this vaccine consisted of twenty "mentally deficient volunteer" children from New York; other children, including infants born to institutionalized women in New Jersey; and 150 chimpanzees, and their caretakers, in the Belgian Congo.[274] In 1959, Albert Sabin reported in the *British Medical Journal* that he had discovered and "unidentified cell-killing virus" in Koprowski's vaccine.[275] That same year, the first known case of AIDS, later confirmed using a preserved plasma sample, appeared in Leopoldville, the Belgian Congo.[276] By 1962, several more cases of this strange and deadly disease appear in Zaire. As time progressed, more cases of HIV/AIDS emerged in areas corresponding to those targeted for the Koprowski mass vaccine campaign. In 1991, it was discovered that some SIV strains were virtually identical to the HIV-2 strains

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[273]Curtis, "The Origin of AIDS," 56.

[274]Ibid., 59.

[275]Ibid., 61.

[276]Ibid., 56.

plaguing Africans.[277] In fact, Robert Gallo, a preeminent AIDS researcher for the US federal government, stated that:

> the monkey virus *is* the human virus- there are monkey viruses as close to isolates of HIV-2 as HIV-2 isolates are to each other.[278]

It seems to be fairly clear that the Koprowski vaccine played an instrumental role in the introduction of HIV-2 into the African population. Since the vaccine was of a live-oral-spray type, any lesion within the vaccinees mouth would provide a prime portal of entry for SIV which might otherwise have been destroyed by the gastrointestinal system. Survival of the pathogen in the vaccine would have almost been guaranteed because any disinfectants that would have been strong enough to kill the SIV, had the virus been detected at the time, also would have rendered the poliomyelitis antigen impotent. Clearly, it is reasonable to assume a causal relationship between Koprowski's vaccine and the high concentration of HIV-2 positive individuals residing in the same regions of equatorial Africa.

Still, one looming question casts doubt over the theory that the poliomyelitis vaccine was the source of SIV/HIV contamination between monkeys and humans: why would the disease appear to strike male homosexuals in numbers that exceed all other North American populations?[279] In Africa, for example, there does not appear to be

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[277]Ibid., 61.

[278]It is interesting to note that Gallo finds the same similarity among STLV-1 (simian T-cell leukemia viruses) and their human counterpart HTLV-1. Ibid., 108.

[279]This discussion is in no way meant to comment on sexual orientation, rather it is presented as a viable explanation of inadvertent cross-contamination between vaccine host tissues and vaccinees. The gay male population was apparently singled out for treatment with an especially virulent poliomyelitis vaccine. Simultaneously, a simian virgin soil territory disease appeared amongst gay males.

one particular sector of the population singled out for infection. If the polio vaccine really was responsible for introducing a simian virus into a new human host, why would one sector of a particular population demonstrate greater susceptibility?

In 1992 a viable connection was made: in the late 1970s it became popular practice to treat homosexual men[280], infected with genital herpes, with oral poliomyelitis vaccines.[281] It appears that the series of treatments involved vaccines that were far more virulent than those used as polio preventives.[282] Since it has been established that polioviruses, administered in the oral vaccine, remain contagious in the feces, it seems logical to assume that penile-anal sexual contact may also provide a viable means of SIV/HIV infection/transmission between an individual treated for herpes with the poliovaccine and a healthy host. The incidence of herpes, as well as other ulcerative genital conditions, amongst sexual partners further facilitates the spread of HIV.[283]

It is not necessary to demonstrate that large numbers of homosexual men were treated for herpes with the polio vaccine during the 1970s in order to establish a causal link between the vaccine and the AIDS epidemic in North America. If one were to consider the number of sexual contacts made by one solitary bath house patron, who

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[280]It is speculated that homosexual males were specifically targeted for this experimental use of the poliomyelitis vaccine due to the vast spread of sexually transmitted diseases within this population, occurring simultaneously with the advent of public bath houses and sex clubs. The incidence of herpes, hepatitis B, enteric diseases and various other STDs grew at alarming rates. Cf., for example, Randy Shilts, And the Band Played On (New York: Penguin Books, 1988), 18ff.

[281]Kyle, 600-601; Scheibner, 156; Adolph Tager, "Preliminary Report on the Treatment of Recurrent Herpes Simplex with Poliomyelitis Vaccine (Sabin's)," Dermatologica 149 (1974): 253-255.

[282]Kyle, 601.

[283]Jad Adams, AIDS: The HIV Myth (New York: St. Martin's Press, 1989), 200.

happened to be infected with herpes and was treated with the polio vaccine, one could assume that many secondary infections could result. For example, the well known "patient zero", a young airline steward named Gaetan Dugas, boasted having had 2,500 sexual partners within a ten year period.[284] It is a virtual certainty that Dugas contracted herpes among the various assorted other sexually transmitted viruses from which he suffered. If Dugas, or any of his sexual partners, carried this monkey-turned-human virus, the secondary and tertiary cases could spread ad infinitum. Whether or not Dugas was indeed the index case for this disease (HIV/SIDS), as the popular theory holds, is irrelevant. Furthermore, it is not important to determine whether Dugas himself was treated for herpes with the polio vaccine because the treatment was indeed used and, due to the frequency of contacts made at public bath houses and sex clubs, contact with SIV/HIV became virtually inevitable. What is relevant is that the disease is temporally associated with the use of the extremely virulent poliomyelitis vaccine to treat herpes. The practice of using the poliovaccine to treat herpes apparently continues in some parts of the world, notably Africa, but its safety and efficacy remain questionable.[285] It is interesting to note that the World Health Organization currently cites sub-Saharan Africa as having "the highest concentration of [HIV] cases."[286]

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[284]Shilts, 83.

[285]B. D. Schoub, "Polio Vaccine for the Treatment of Recurrent Herpes Simplex Infections," South African Medical Journal 79 no. 10 (18 May 1991), 623.

[286]World Health Organization, "Update on AIDS," WHO Drug Information 9 no. 4 (1995), 196.

It should be noted that an early version of the hepatitis B vaccine also has been implicated in the spread of HIV. This early vaccine, available from 1970 to about the mid-1980s, used human plasma as its host. According to a variety of reports the donors, who provided plasma for use in the vaccine, were likely candidates for (undetected) HIV infection.[287] This vaccine does not explain the origin of SIV in the human population but it may have been responsible for further spreading of the disease.[288]

Disease does not erupt ex nihilo; there must be a source. In the case of SIV/HIV, a monkey disease suddenly crossed species. Since the polio vaccines contained undetected simian viruses, there appears to be little doubt that the contaminated vaccines provided the necessary means to introduce simian viruses into a new human population. Although cross-species contamination was certainly unintentional, there is no reason to assume that it was impossible. Exposing individuals even to the possibility of cross-species contamination demonstrates a general disregard for the principle of non-maleficence.

The polio vaccine may not provide the only example of host tissue:vaccinee contamination. In fact, current Swiss research has discovered the presence of an enzyme, *reverse transcriptase* (RT), within the chick embryo cells currently used as host tissues in the production of measles, mumps, yellow fever and (some) influenza

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[287] Cf. Miller, Vaccines?, 44; Scheibner, 3ff; Edda West, "Hepatitis: Shots Set for All Grade 7's," VARIANCE Newsletter (Summer 1994): 13f.

[288] Similarly, many Canadians now suffer from AIDS caused by contaminated blood purchased during the early 1980s from a San Francisco blood bank.

vaccines.[289] This discovery suggests the possibility that latent infections and genetic mutations may occur in individuals receiving these vaccines.

> RT activity is associated with the presence of retroviruses,[290] a class of viruses which can permanently alter the genes of the cells they infect.[291]

Through a process called *reverse transcription*, the RNA of retrovirus cells can utilize enzymes to create DNA.[292] Under normal circumstances, "it is the DNA that directs the manufacture of all new proteins and other cell parts, including RNA."[293] RT reverses this process.

> In this case, the viral RNA directs the manufacture of deadly foreign DNA, which [becomes integrated into the host DNA from where it] ...commands the cell's reproductive machinery to produce more viruses rather than healthy new cells.[294]

The resulting proviral DNA strand is not recognized by the immune system as a mutation and thus the immune system does not respond. The error is irreparable.

Once the viral genes are incorporated into the genetic material of the human host, the virus may remain latent (dormant) for an indeterminate period of time until it is

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[289]National Vaccine Information Center, "Animal Virus Enzyme Found in MMR Vaccine," The Vaccine Reaction 1 no.5 (Nov/Dec 1995), 1.

[290]In this case, it has been suggested that the detected retrovirus may be an avian leukosis virus which can cause a leykemia type illness. Ibid.

[291]Ibid.

[292]Louis Levine and Sharon Cosloy, "Virus," The 1995 Grolier Multimedia Encyclopedia Version 7.0.1 (Grolier Electronic Publishing, Inc., 1995).

[293]Leonard G. Horowitz, Emerging Viruses: AIDS & Ebola: Nature Accident or Intentional? (Rockport, MA: Tetrahedron, Inc., 1997), 66.

[294]Ibid.

activated.[295] The effective magnitude of vaccine-related RT will likely remain undiscovered for a good many years until, at least, long term studies are conducted in this area. In the meantime, the World Health Organization recommends the continued use of these vaccines.[296] Conversely, critics of immunization contend that the continued use of highly unpredictable pathogenic material in vaccines, utilized en masse, displays a general disregard for the principle of non-maleficence.

3. COMMENTS

The chemicals and antigens used in vaccines are introduced into the body in very small quantities. Proponents of immunization believe that exposure to such minute quantities of the vaccine components means that vaccine-associated risks are proportionately small. Critics of immunization disagree. It is difficult to allay the concerns of vaccine-critics with an assurance of minimal exposure because each person may have somewhat different reactions to vaccine components and the long-term and cumulative effects remain relatively unknown. Predetermination of hypersensitivity to vaccine components would certainly prove beneficial in reducing adverse events. It is, however, impossible to predict individual reactions to vaccine components prior to immunization: most vaccine components are simply not encountered in everyday life and, moreover, they are rarely encountered by infants prior to immunization. Still, this

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[295]The mechanisms which facilitate activation are currently under investigation. Carisa Cunningham, "AIDS," The 1995 Grolier Multimedia Encyclopedia Version 7.0.1 (Grolier Electronic Publishing, Inc., 1995).

[296]National Vaccine Information Center, "Animal Virus Enzyme Found in MMR Vaccine," 1.

does not absolve the vaccine manufacturers, governments (who may compel vaccination) and health officials of their responsibility to investigate the long term affects of vaccines on societies and to formulate simple and cost-effective hypersensitivity tests to determine potential allergies, prior to immunization. The fact that long term studies are notably absent, itself indicates a transgression of the principle of non-maleficence. How can vaccine manufacturers, governments and health officials maintain the principle of non-maleficence unless serious efforts are put forth to determine, and then reduce, the actual harm incurred?

Clinical trials attempt to determine both the safety of a vaccine, prior to public release, and to determine the vaccine's effectiveness in stimulating an immune response in humans.[297] The actual trials initially involve testing vaccines on laboratory animals. Tests done on laboratory animals present certain problems, however, since the results may not provide an accurate basis to evaluate human risk.[298] In fact, many substances that appeared to be safe in animal trials, and received government approval, were later found to be dangerous to humans.[299]

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[297]National Institutes of Allergy and Infectious Diseases, "Evolution of Vaccine Development," Neonatal Network 11 no.4 (June 1992): 45.

[298]Cf. "Animal Tests Unreliable in Assessing Chemical Risk," Medical Post 26 no.42 (27 November 1990): 51.

[299]For example, an antiviral drug, *fialuridine* appeared to be safe during animal trials but caused liver failure in 7 of 15 humans, 5 of whom died and the other two required liver transplants. Many other drugs that appeared safe for animals presented serious risks for humans. In one study, 198 new drugs, marketed between 1976 and 1985, were reviewed and it was found that 52% caused serious risks, leading to hospitalization, disability or death, and that these risks had not been predicted by animal *or* limited human trials. Neal D. Bernard and Stephen R. Kaufman, "Animal Research Is Wasteful and Misleading," Scientific American 276 no.2 (February 1997), 80-82.

If the animal trials do appear to be successful (i.e. safe and effective), the vaccine is then tested on a small number of human volunteers. The final stage of testing will generally involve larger groups of people who live in an area where the corresponding disease is considered to pose a threat. The ultimate effects of a vaccine may not become apparent until the vaccine has been released for use by the general public. In order to assess *all ultimate consequences* of a vaccine, clinical trials *should* include subjects from all age and race categories, including individuals with health conditions that may require special consideration, and the trials should be conducted "for five or even twenty years while withholding licensure."[300] Unfortunately such rigorous demands are not met.[301] Clinical trials "are seldom easy, are usually costly in time and effort, and sometimes are dangerous to patients."[302] Long term studies following the release of vaccines are rarely executed. While it would be technically feasible to execute long term studies, they are perhaps regarded as an "[un]wise use of public health resources" given the fact that few serious adverse events are currently acknowledged as causally related to vaccines.[303]

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[300]Relman, 276.

[301]To be fair, it should be noted that the pressures exerted by public demand may be another culpable factor in shortening the duration of clinical trials.

[302]J. P. Bull, "The Historical Development of Clinical Therapeutic Trials," Journal of Chronic Disease 10 no.3 (September 1959): 218.

[303]The reasons indicated for the lack of long term studies were, in fact, used by the Institute of Medicine when deciding not to initiate a US study to determine causal relations between the DPT vaccine and serious neurological outcomes following vaccination. Cf. MedWeb: Centers for Disease Control and Prevention, "DPT and Permanent Neurological Damage," DPT Vaccines: Scientific Reasons to Continue DPT Vaccination (9 March 1995).

It is clear, however, that the hazardous chemicals and antigens used in vaccines can cause undue risks to vaccinees. In most cases, it is the otherwise *healthy* individual who is exposed to risks from pathogenic survival, contaminated host tissues and toxic chemicals found in vaccines. In the developed world, many of the diseases, for which vaccines exist, are either no longer endemic or they do not present serious risks to most of the population. The proportion of risk associated with vaccines may well outweigh the risks associated with the diseases. Even if the proportion of risk were equal, or even somewhat less for the vaccine than for the disease, there can be no assurance that the person who suffers from vaccine reactions would be the same person to suffer serious complications from the disease, that is - *if* this person were to become infected in the first place. There is no guarantee that any person will contract any given disease but, with vaccination, it is guaranteed that all vaccinees will be exposed to toxic chemicals and to a variety of diseases. It is somewhat like a roulette game that never ends, individuals may find out if they are "winners", escaping natural infection and adverse events, or learn at some future time that they actually lost the game, perhaps in the form of long-term immune malfunction.

It is not necessary to demonstrate that the majority of the populace is adversely affected by vaccine preparations, it is quite sufficient to know that everyday of every year a small number of vaccinees incur transient illnesses, permanent disability, long-term immune malfunction and some die as a direct result of vaccines. The harm caused does not result from an unsuccessful treatment of an already contracted disease; the harm results from the introducing the body to unsafe chemicals and proteins

intended to prevent a disease which may never pose a serious threat. The mass use of vaccines, therefore, violates the principle of non-maleficence.

Still, as all ethicists understand, bioethical principles are often found to be in contention with one another. It would, therefore, be imprudent to condemn the use of vaccines based upon the violation of one sole principle. The violation of the principle of non-maleficence may be justified, at least partially, *if* it can be demonstrated that the mass use of vaccines not only complies with other bioethical principles but that the relevant principles, and the good derived from vaccines, supersede the principle of non-maleficence in this case.

In the forthcoming chapters, then, immunization will be evaluated in respect to other equally important bioethical principles. In the following chapter, the historical efficacy of immunization will be discussed in regard to the principle of beneficence which, since it demands proportionate good to accompany medical treatments, necessarily allies itself with the principle of non-maleficence. Historical evidence will be presented in order to ascertain whether vaccines have actually eliminated disease and whether they do indeed protect vaccinees against corresponding diseases. In other words, despite the potential ill effects, have vaccines demonstrated the ability to eliminate disease over time and in areas where a considerable portion of the population are adequately immunized? If vaccines have proven themselves in this way then the principle of non-maleficence may, in fact, be upheld despite the use of known toxins and unpredictable pathogens within vaccine formulae. If, on the other hand, historical evidence does not support the safety and efficacy of vaccines then the harm incurred

by the mass use of vaccines greatly outweighs their benefits and a second bioethical principle will have been compromised. Considered together, the two principles should provide an adequate means for evaluating the risks versus the benefits of the mass use of vaccines. Following this discussion, the principles of respect for autonomy and justice will be discussed in relation to immunization policies and procedures.

CHAPTER FOUR
IMMUNIZATION AND BENEFICENCE

Vaccines contain numerous known toxins, carcinogens and pathogens which continue to threaten the health of vaccine recipients. In the preceding chapter, it was concluded that the mass use of these hazardous immunizing agents violates the principle of non-maleficence. Although some harm may be expected to accompany any invasive medical treatment, immunizing agents can cause ***undue harm***: toxins, carcinogens and pathogens are being introduced into otherwise ***healthy*** bodies, and usually immature bodies, in order to prevent a disease which, generally, poses no immediate threat and may never pose any threat. Furthermore, it appears that the long term affects of the immunizing agents may be more deleterious to certain individuals than those posed by contracting a disease naturally.

The fact that harm does occur from the use of vaccines is not disputed. It is believed, however, that risks posed by the immunizing agents are justified by the overwhelming benefits incurred directly from their use: it is believed that immunizing agents are responsible for a general decline in the incidence of vaccine-preventable diseases and for a corresponding decline in morbidity and mortality rates associated with those diseases. To be sure, it would be imprudent to denounce any medical treatment based upon its lack of adherence to *one* ethical principle, particularly when

the practice promises to fulfil the demands of other important ethical principles. In other words, even though the mass use of risky immunizing agents violates the principle of non-maleficence, the violation *may* be justified *if* the benefits incurred outweigh the risks involved. This chapter will explore the benefits historically attributed to vaccines and, thus, will evaluate immunization in regard to another ethical principle: the principle of beneficence.

1. THE PRINCIPLE OF BENEFICENCE

> The principle of beneficence potentially demands more than the principle of non-maleficence because it requires positive steps to help others, not merely the omission of harm-causing activities.[304]

The principles of non-maleficence and beneficence are closely related and, to some extent, overlap each other. While the principle of non-maleficence demands that undue harm be avoided, the principle of beneficence demands positive action to prevent harm *and* to provide actual benefits. In the case of immunization, for example, the principle of beneficence requires that positive steps be taken to reduce the harm caused by immunizing agents *and* it requires that the benefit received from the use of harmful agents outweighs their risks.[305]

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[304]Beauchamp, "The 'Four-Principles' Approach," 5.

[305]Although the use of unsafe vaccine components continues, it is acknowledged that efforts are continually being made to improve the safety of vaccines. A thorough discussion of the actual steps being taken to avoid the use of toxins, carcinogens and active pathogens would necessarily require the investigation of specific strategies employed by vaccine developers. Due to competitive secrecy maintained by the various pharmaceutical manufacturers, it seems very unlikely that sufficient information could be attained. The discussion on immunization and beneficence, therefore, shall be limited to determining whether the steps taken to avoid disease through immunization have historically demonstrated that the benefits of immunization justify inherent risks.

Immunization has long been credited as one of the most positive steps ever taken to help humanity in our fight to prevent, and even overcome, certain debilitating and life-threatening diseases. Vaccines have been credited with the total eradication of smallpox and they are believed to be capable of eradicating poliomyelitis and measles by the end of this century.[306] Proponents of immunization believe eradication to be plausible because these diseases are considered endemic only to humans. Theoretically, since no other reservoir of these diseases are known to exist, elimination of the diseases, via immunization, *should* lead to eradication.[307] An important distinction should be made between the terms "elimination" and "eradication" which often are interchanged inappropriately. "Elimination" refers to either "regional eradication, or reduction of disease incidence to some tolerably low level, or else reduction of disease to zero without total removal of the infectious agent."[308] The use of the word "eradication", on the other hand, "implies the reduction of both infection and disease to zero."[309] Even if eradication is not feasible, vaccines are considered responsible, at the very least, for decreasing the incidence and severity of certain diseases.

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[306]Schabas, Opportunities, 2.

[307]Disease eradication is a highly contentious issue. Many scientists reject the viability of disease eradication maintaining, instead, that disease can be controlled at best. Apparently eradicated diseases do not disappear, rather, they may mutate, taking another form, and perhaps "reappearing" in their first form even hundreds of years later. These sink populations are latent pathogens/diseases which become active under suitable conditions.

[308]Fine, 265.

[309]Ibid.

The principle evidence used to substantiate vaccine efficacy is the decline in "vaccine-preventable diseases", as well as a correlative decline in disease-related cases of morbidity and mortality, prevalent within this past century. For example, paralytic poliomyelitis appears to have virtually disappeared in developed countries within decades of the vaccine's introduction and the more acute forms of measles, mumps and rubella have become less prevalent since the associated vaccines became available.[310] In fact, based upon the *apparent* (statistical) efficacy of immunization over time, it has been deemed an universal utilitarian good: a benefit to all people world-wide. The principle of beneficence regarding immunization, therefore, may be measured against immunization's utilitarian effects: the benefits derived from the mass use of vaccines *are* precisely the benefits obtained by the general populace in the form of disease prevention and lower incidences of disease-related morbidity and mortality over time.

2. VACCINE EFFICACY

The incidence of many once common debilitating and fatal diseases has dropped dramatically in the developed world. Proponents and opponents to immunization often disagree over exactly which factors have most affected this decline. Proponents of immunization claim that successful immunization programs are largely responsible for the reduction of disease-related morbidity and mortality. Opponents, on the other hand, claim that the reduction is largely due to the long term development of natural passive immunity and to improvements in nutrition, hygiene, sanitation and medical

[310]Moskowitz, "Immunizations: The Other Side," 12.

treatment.[311] They claim that a dramatic decline in disease incidence began long before the introduction of vaccines and, hence, the use of apparently favourable statistics, ie. those restricted solely to the vaccine-era to defend the utilitarian beneficence of immunization, are misleading. Critics maintain that the myth of vaccine efficacy has been used to mislead the public in order to gain compliance to mass immunization, to support mandatory immunization legislation over and against the best interests of individuals within a society, and to divert public attention away from the inherent harm associated with immunization.

From the outset, it must be acknowledged that it will be difficult to accurately delineate the health benefits accrued solely from vaccines as opposed to those accrued from general public health improvements precisely because both are temporally related. The advent of refrigeration, antibiotics, adequate sewage disposal, water filtration and the improved availability of qualified health care coincided with the mass use of vaccines. These basic public health advantages have contributed greatly to the decline in disease-related morbidity and mortality, particularly in the developed world. While, conversely, their absence in many parts of the developing world has meant that disadvantaged nations suffer terribly from disease, despite the presence of mass immunization strategies.

The impact of general public health improvements is inestimable, to be sure, but it may be possible to gain some insight into the utilitarian beneficence of immunization

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[311]It must be understood that proponents of immunization do not ignore the fact that improvements in nutrition, hygiene, sanitation and medical treatment have contributed to the decline in disease. Many, however, ***emphasize*** that immunization is ***primarily responsible*** for disease elimination or reduction.

by comparing disease patterns in the pre- versus post-vaccine eras. To this end, various international statistics will be utilized to determine the impact of immunization on disease incidence patterns. Undoubtedly one *should* expect to find a higher incidence of disease, and disease-related morbidity and mortality, prior to the vaccine era. It may, however, be difficult to determine conclusively whether vaccines, or other factors affecting general health, have been most effective in reducing disease and its resultant morbidity and mortality.

Inaccuracies Associated With Statistical Evidence

Prior to introducing statistical evidence, it is necessary to consider certain important elements that inevitably will affect statistical accuracy. Providing accurate statistics to evaluate vaccine efficacy may prove problematic for a variety of reasons. Lurking variables, i.e. "some other feature underlying the data that you may not realize is there", lies at the heart of the problem.[312] For example, since certain diseases may have become reportable only relatively recently (hindering a long-term view of disease patterns), and since vaccine use may not be uniform within a country at any given time, the discontinuity of data may not provide a coherent estimate of the efficacy of vaccines versus the efficacy of passive immunity and general health improvements. Indeed, the same raw data may support opposing conclusions: both of which are "technically honest and...accurate."[313]

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[312]Boyce Rensberger, "When Debate Involves Numbers, Beware the 'Lurking Variable'," Washington Post, 2 November 1992, 3(A).

[313]Ibid.

Many more lurking variables will undoubtedly prove problematic for an accurate assessment of historical vaccine efficacy. For example, it is often found that many cases of a disease will go unreported, particularly when medical attention is not sought or is unavailable or when a disease is misdiagnosed. Indeed, it is widely held that disease-related statistics grossly underestimate the actual incidence.

Furthermore, in a few cases at least, it appears that once the vaccines were introduced, incidence of the naturally occurring diseases were reclassified: either the disease was redefined (e.g. the required duration symptoms may be increased to support a diagnosis) and/or cases were reported under different names (e.g. due to more accurate diagnostic procedures or due to sheer ignorance of the possibility of vaccine failure). Reclassification *itself* immediately reduces incidence statistics and, ultimately, causes vaccines to appear to be more efficient than they really are. George Bernard Shaw, made the following statements regarding the reclassification of disease and its affect upon maintaining accurate statistics:

> During the last considerable epidemic at the turn of the century, I was a member of the Health Committee of London Borough Council, and I learned how the credit of vaccination is kept up statistically by diagnosing all the revaccinated cases (of smallpox) as pustular eczema, varioloid or what not--except smallpox."[314]

Presumably, diagnosticians found it difficult to believe that individuals remained susceptible to smallpox after vaccination. Reclassifying disease may have been the result of a genuine belief that the corresponding diseases cannot occur after immunization or, alternately, diseases may be reclassified because more efficient

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[314]James, 41; Hale, 123.

diagnostic procedures allow for the differentiation of similar diseases. Regardless of the reasons, disease-reclassification profoundly affects statistical accuracy and, thus, statistical anomalies are created, making it virtually impossible to evaluate *actual* vaccine efficacy. In other words, one cannot return to an earlier era to determine how many cases were misdiagnosed; misdiagnosed cases will continually taint statistics.

Perhaps one of the most important factors hampering a definitive determination of vaccine-efficacy is the fact that statistics have not uniformly differentiated the incidence of disease among three distinct groups of individuals: those who have been adequately immunized; those who are incompletely immunized; and those who are unimmunized. The distinction is significant because, *if* vaccines truly prevent disease, the two initial groups should demonstrate a lower, virtually non-existent, incidence of disease, including lower morbidity and mortality rates than the latter, unimmunized, group. Non-differentiation makes it impossible to assess the impact of vaccine failure. Furthermore, until recently, statistics did not differentiate individuals who contracted disease naturally from those who have contracted disease from the vaccines themselves or from proximate contact with a recent vaccinee. When statistics neglect such differences, false conclusions may be drawn regarding the true safety and efficacy of vaccines.

Such lurking variables will undoubtedly taint any findings derived from statistical evidence. However, an examination of the patterns of disease-incidence over a long period of time should provide *some* insight into the efficacy of vaccination as a utilitarian benefit. Particular emphasis will be placed upon the historical efficacy of

mumps, poliomyelitis and measles vaccines. The latter vaccines are particularly relevant at this time because the World Health Organization, along with international medical officials and governments, have instituted global eradication programs against poliomyelitis and measles. It is believed that both diseases can be eradicated by the year 2000 based upon two assumptions: poliomyelitis and measles are endemic only to humans and historical evidence appears to support the overwhelming efficacy of both vaccines in preventing disease incidence and associated morbidity and mortality.

Despite the fact that poliomyelitis and measles are believed to be endemic only to humans, there is currently insufficient evidence available to determine whether disease eradication itself is at all possible. Although smallpox appears to have been globally eradicated, it is impossible to predict whether or not the disease will reappear at some point in the future: either in its original, or in some mutated, form.[315] Statistical evidence will be confined, therefore, to the historical efficacy of vaccines in *reducing* the incidence of disease and disease-related morbidity and mortality.

3. STATISTICAL EVIDENCE AND VACCINE EFFICACY

The Measles Vaccine

Historically, measles has been a significant disease in terms of incidence and, prior to 1915, high measles-related deaths among children occurred. Comprehensive

[315]Reserves of the virus are held in storage at government disease control agencies in case it is again needed for study and/or vaccine production. Levine, 60.

statistical evidence from England and Wales demonstrates epidemiological patterns and changes in the mortality rate among children under 15 years of age.

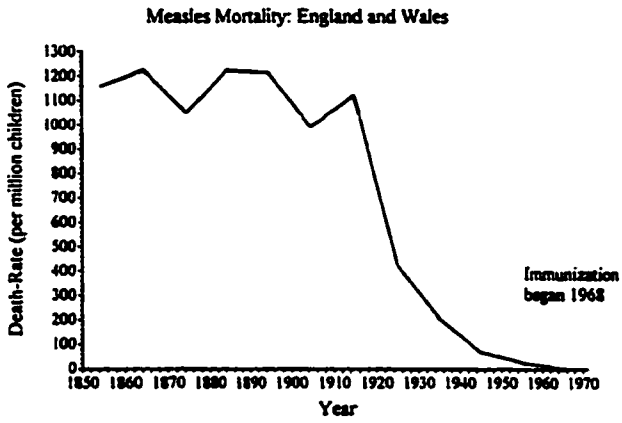

Figure 7a. Measles Mortality Rates of Children Under 15: England and Wales, 1855-1970.

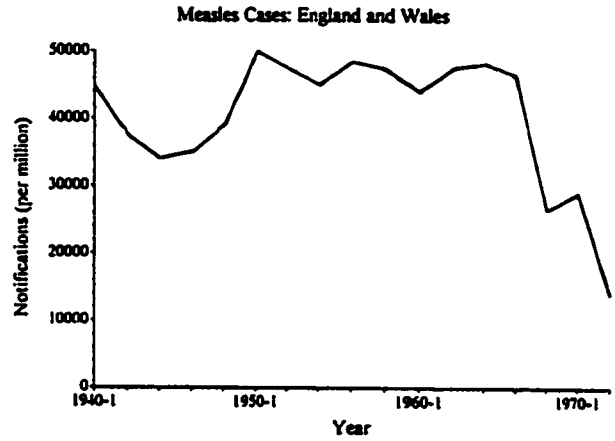

Figure 7b. Measles: Mean Annual Notification Rates of Children Under 15: England and Wales, 1940-1972.

Source: Thomas McKeown, The Role of Medicine: Dream Mirage or Nemesis? (Princeton, NJ: Princeton University Press, 1979), 105f. Reprinted by permission of Princeton University Press.

As illustrated by figure 7a, the measles death-rate fell into rapid decline from about 1915 onward: twenty years before adequate treatments for secondary infections became available and about fifty years before the introduction of the vaccine.[316] Since the disease only became nationally reportable in 1940, it is impossible to determine whether this decline was influenced by a simultaneous national decline in measles incidence. However, as figures 7a and 7b taken together indicate, measles incidence

[316]Thomas McKeown, The Role of Medicine: Dream, Mirage or Nemesis? (Princeton, NJ: Princeton University Press, 1979), 105f.

continued to peak and rescind while the death rate continued in a steady decline. It may be assumed then, that measles-related deaths declined irrespective of varying incidence rates. Two important factors may have been responsible for the decline in mortality: reduced family sizes and evolutionary selection.

It is known that during 1915-1935, there was a marked reduction in average family sizes, particularly amongst the poor. Smaller families meant that there was less opportunity for older (school-aged) siblings to transmit the disease to younger siblings, whose immature immune systems were no longer protected by maternal antibodies and, in whom, the disease proved most dangerous.[317] Furthermore, since measles deaths occurred twenty times more often among poorer children than their wealthier counterparts, a reduction in family size amongst poorer families would naturally result in decreased mortality rates.

Evolutionary selection most certainly played a part in the drastic decline in measles deaths amongst children as well. The theory of evolutionary selection explains that, as a matter of survival, all living things change and adapt, over time, in response to their environmental conditions. Changes occur "through the natural selection of variants produced through genetic mutations, hybridization, and inbreeding," which transform simple entities into more complex forms that are stronger and more prolific.[318] It is well known, for example, that a society's exposure to a disease *over time* often makes naturally contracting that disease safer. In other words,

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[317]A. H. Gale, Epidemic Diseases (Harmondsworth, Middlesex: Penguin Books, Ltd., 1959), 102.

[318]Anderson et al., Mosby' Dictionary, 582.

serious complications tend to be reduced with each successive generation infected. The reason is twofold, and demonstrates a certain symbiosis between the pathogen and its host:

> ...a lethal disease caused by a pathogen in a susceptible host tends to give way as less virulent [pathogens] and more resistant hosts emerge.[319]

The host becomes more resistant to the pathogen both through repeated exposures and as a result of passive immunity. The pathogen becomes weakened and/or mutated, ensuring the latter's own survival. If pathogens were capable of overtaking their hosts so efficiently that each host inevitably dies, then the success of the pathogen would also mean its own ultimate destruction. "Evolutionary selection, in the long run, tends to favour the survival of both a [pathogen] and its host."[320] This symbiosis can be noted in the case of measles, now known to be a common disease which rarely results in fatality. Currently, the vast majority of measles-related complications and deaths are found among those living in extreme poverty, as in developing nations, and among the immunocompromised whose immune systems have been weakened either by a pre-existing disease (e.g. HIV) or by an immunosuppressive agent (e.g. drugs used to prevent the rejection of a transplanted organ).

With the advent of the measles vaccine, one would expect that incidence rates would fall dramatically. Figure 7b *appears* to support this notion but it must be understood that the vaccine was not used nationally until 1968 and by the end of 1972

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[319]Max Essex And Phyllis J. Kanki, "The Origins of the AIDS Virus," Scientific American 259 no.4 (October 1988) : 64.

[320]Ibid.

less than one quarter of all children had been vaccinated. It is, therefore, difficult to determine the actual efficacy of the vaccine in reducing the total number of measles cases.[321] The same holds true for Canadian statistics.

Measles Cases In Canada: 1924-1995

Number of Cases by Year

Year	Number	Year	Number
1924	39216	1960	0
1925	22777	1961	0
1926	39429	1962	10185
1927	28150	1963	8535
1928	27733	1964	7860
1929	42132	1965	4100
1930	21606	1966	0
1931	25664	1967	0
1932	53508	1968	0
1933	13471	1969	11720
1934	29115	1970	25137
1935	83127	1971	7454
1936	55724	1972	3136
1937	57408	1973	10911
1938	26328	1974	11985
1939	44476	1975	13143
1940	45851	1976	9158
1941	81051	1977	8832
1942	26258	1978	5858
1943	60485	1979	22444
1944	55317	1980	13864
1945	26978	1981	2307
1946	67526	1982	1064
1947	39455	1983	934
1948	66004	1984	4078
1949	58511	1985	2816
1950	55653	1986	14941
1951	61370	1987	2385
1952	56178	1988	611
1953	57871	1989	11145
1954	36850	1990	1033
1955	56922	1991	6178
1956	53986	1992	2742
1957	49712	1993	203
1958	35531	1994	523
1959	9703	1995	2362

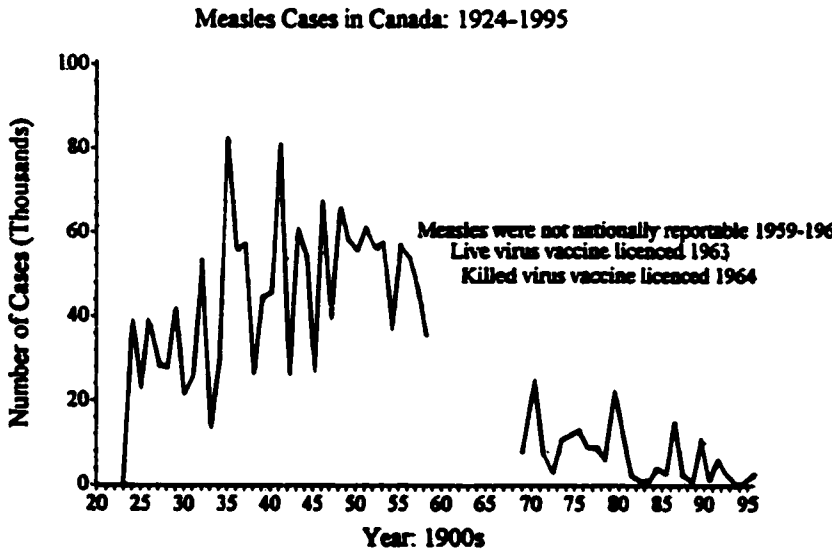

Figure 8. Measles Cases in Canada: 1924-1995. Source: Laboratory Centre for Disease Control, Health Canada. Reproduced with the permission of the Minister of Public Works and Government Services Canada, 1996.

[321]McKeown, 106.

According to statistics provided by the LCDC, measles was not nationally reportable from 1959-1968, important years immediately preceding and following vaccine licensure. From 1924 to the mid-1950s, except for obvious divergences in 1933, 1935 and 1941, the reported incidence of measles in Canada demonstrates the cyclical nature of measles epidemics peaking and rescinding within a relatively predictable range. Although the important pre- and post-vaccine statistics are unavailable, one can clearly see that, overall, measles became less common, but retained their cyclical nature, in the post-vaccine era. While one might assume that the vaccine caused the reduction in incidence rates, current research indicates that this assumption may be false. Measles cases now appear predominantly amongst the fully vaccinated. That vaccinees, rather than their unvaccinated counterparts, are at greater risk of contracting measles has been well established. The World Health Organization estimates that "the chances are about 15 times greater that measles will be contracted by those vaccinated for them than by those who are not."[322]

On January 6, 1990, Health and Welfare Canada published one of the most thorough surveillance reports thus far available.[323] While the study focused strictly on measles in Canada, it provides a good example of the type of information required to assess vaccine efficiency. Of particular interest are statistics indicating the immunization status of cases in Ontario and Alberta, 1988.[324]

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[322]Mendelsohn, How to Raise a Healthy Child, 216.

[323]Health and Welfare Canada, "Measles in Canada - 1988," Canada Diseases Weekly Report 16 no.1 (6 January 1990): 1-6.

[324]Ontario and Alberta were selected based upon the availability of data. Immunization status was not available for cases from all provinces.

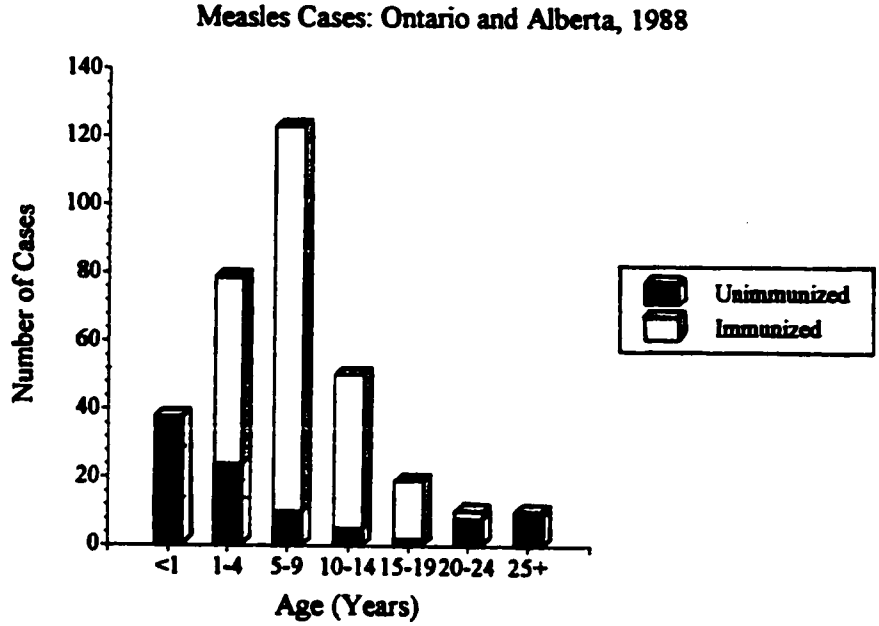

Figure 9. Measles Cases by Immunization Status: Ontario and Alberta, 1988. Source: Health and Welfare Canada, Canada Diseases Weekly Report 16 no.1 (6 January 1990). Reproduced with the permission of the Minister of Public Works and Government Services Canada, 1996.

Since the measles vaccine is not recommended for children under 1 year of age, it is not surprising to find that all cases within this category are unimmunized. Still, one must wonder why these children have not been protected by maternal antibodies? In the pre-vaccine era, "it was extremely rare for an infant to contract measles" but by 1993 over 25% of cases occur in infants <1 year of age.[325] It has been suggested that the growing number of infections among infants is the direct result of vaccination. Mothers who have not acquired *natural* immunity cannot passively immunize their babies and, therefore, immunization has put these infants at risk of infection by defeating natural passive immunity.

[325]Miller, Vaccines?, 27.

What is indeed surprising, however, is that the vast majority of measles cases occurred amongst *adequately immunized* individuals aged 1-19. If the vaccine truly provided immunity to the disease, vaccine recipients should rarely, if ever, contract the disease. That the vaccine does not seem to protect some individuals from the disease is not, in itself, a violation of the principle of beneficence because vaccine failure can be expected in a small percentage of individuals. That more vaccinees contract the disease than their unvaccinated counterparts, however, is quite another story.

Furthermore, the measles vaccine seems to have caused a precarious change in the disease's epidemiology. In the pre-vaccine era, the average age of infection was 4-5 years[326], but, as figure 10 indicates, the average age of infection has increased.

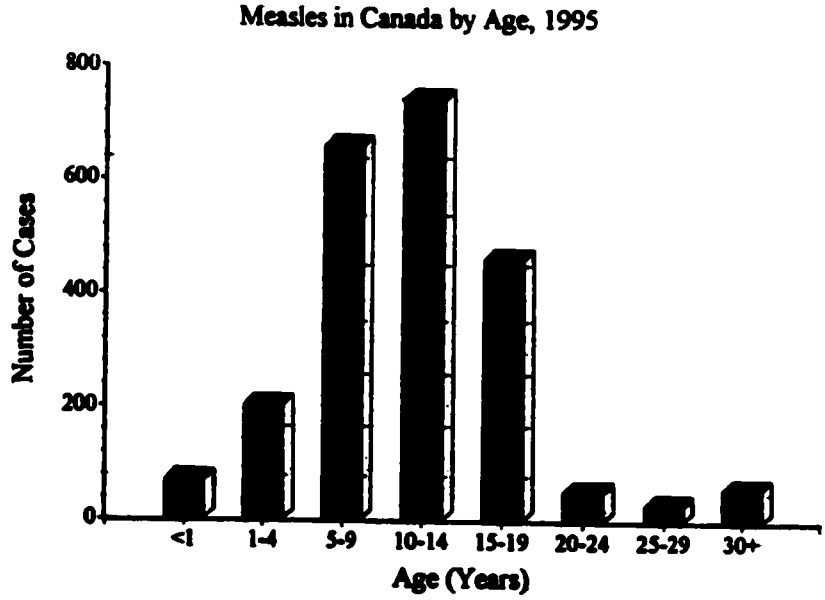

Figure 10. Measles by Age: Canada, 1995. Source: Paul Varughese, Division of Immunization, Bureau of Infectious Diseases, LCDC. "Measles in Canada, 1995 (As of December 27)," Measles Update 3 no.4 (November/December 1995), 7. Reproduced with the permission of the Minister of Public Works and Government Services Canada, 1996.

[326]Anderson and May, 641.

Of the 2,092 cases represented here, almost 90% had a documented history of measles vaccination; 91% of which had been immunized between 1980 and 1994.[327] The statistics from 1995 indicate that most measles infections occur amongst the 10-14 age group, followed closely by the 5-9 year olds and the 15-19 year olds.[328] It is known that typical childhood diseases appear to be more detrimental when they are contracted outside of the normal pediatric range.[329] It is highly significant, therefore, that the vaccine appears to be *raising* the average age of infection.

It has also been found that when measles appears in those "outside the pediatric range or in those previously immunized... or in the immunosuppressed" an atypical form of the disease may occur.[330] The following signs have been noted with atypical presentations of measles: the absence of Koplik spots, abnormal measles rash, persistent high fevers necessitating hospitalization, hypoxia (lack of oxygen at the cellular level affecting heart and respiratory functions and causing mental confusion),

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[327]Of the remaining cases, immunization status could not be determined for 4.5%, 3.9% were not eligible for immunization (they were either <1 year of age or were born before 1957), and the small remainder were exempt from immunization for medical or personal reasons. Paul Varughese, Division of Immunization, Bureau of Infectious Diseases, LCDC. "Measles in Canada, 1995 (As of December 27)," Measles Update 3 no.4 (November/December 1995), 7.

[328]Significant measles epidemics are occurring in secondary school, and in college/university, aged students. One striking example occurred in 1988 at a Colorado college where 98% of the students had documentation of adequate measles immunity. Of the 84 documented cases of measles, 70 (83%) had been vaccinated at 12 months of age or older, 5 (6%) had received the vaccine prior to their first birthday (a potential factor in vaccine failure), and only 9 (11%) had no documentation of vaccination. Bradley S. Hersh et al., eds., "A Measles Outbreak at a College with a Prematriculation Immunization Requirement," American Journal of Public Health 81 no.3 (March 1991): 360-4.

[329]Anderson and May, 642f.

[330]Kenneth H. Rand, Richard W. Emmons and Thomas C. Merigan, "Measles in Adults: An Unforeseen Consequence of Immunization?" Journal of the American Medical Association 236 no.9 (30 August 1976) : 1028-31.

and giant-cell pneumonia.[331] It is believed that the normal measles rash is "caused by a cell-mediated immune reaction which damages cells infected with measles virus."[332] The absence, or diminished presentation, of the rash "may imply that intracellular virus escapes neutralisation ...[perhaps] giv[ing] rise to the development of disease subsequently."[333] An atypical or absent rash during infection indicates that the immune response is only partially effective and that the virus may linger and become manifest in other ways at a later date. It is quite likely that this atypical presentation suggests viral mutation and the long term results are virtually unknown.[334]

The epidemiological changes noted in recent measles infections necessitated some form of redress. Interestingly enough, since the first dose of the measles vaccine appears to have failed in a certain number of recipients[335], the World Health Organization, in conjunction with UNICEF and government officials world-wide, have responded by calling for a second dose of the vaccine for older children and

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[331]Ibid., 1028ff; Anderson et al., Mosby's Dictionary, 780.

[332]Tove Rønne, "Measles Virus Infection Without Rash in Childhood is Related to Disease in Adult Life," The Lancet 1 no.8419 (5 January 1985): 1.

[333]Ibid.

[334]Perhaps the long term effects will resemble those observed when immune serum globulin (artificial passive immunity) has been administered post-exposure. In this case, the immune globulin "interferes with development of cytolytic [destruction of cells] reactions and enables intracellular measles virus to escape the acute infection." Missed measles rash, in this case, has been associated with various immunoreactive diseases (e.g. arthritis), sebaceous skin diseases (e.g. seborrhoeic dermatitis), degenerative diseases of the bone and cartilage (e.g. Scheuermann's disease, patellar chondromalacia) and certain tumours. Ibid., 1-4.

[335]The official reasons given to explain the vaccine failure are ambiguous and point to everything from interference of maternal antibodies (in vaccinees <15 months old) to improper storage and handling of the vaccine to less effective stabilizers used in vaccines manufactured prior to 1979. These reasons are debatable, however, in light of an analysis which demonstrates that attack rates among vaccinees did not differ significantly pre-1980 and post-1989. Cf. Hersh, et al., "Measles," 362; National Advisory Committee on Immunization, Canadian Immunization Guide, 72f.

adolescents.[336] It is hoped that a second dose of the vaccine will evoke an immune response in those persons who failed to seroconvert (i.e. to develop a positive antibody response) from the first vaccine.[337] Theoretically, the second dose *should* eliminate measles infections among older individuals. If, however, the current pattern obtains, it is entirely likely that the current mass measles re-inoculation program will again evidence a shift in the age people experience attacks without positively affecting incidence rates. Rather than conferring life-long immunity for vaccine recipients, mature adults may become the new target-host for the measles virus since permanent immunity will have been escaped by virtue of lack of exposure to the natural disease in childhood and by virtue of the fact that artificial immunity will have diminished by adulthood. The probable solution will be to call for yet another series of inoculations for adults.

Critics of the measles vaccine maintain that since the naturally occurring disease is generally mild in nature, "with rare serious complications and negligible fatality in normal children,"[338] it is preferable to acquire natural, and permanent, immunity that results from naturally contracting the disease. Furthermore, only natural immunity can

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[336]Initially, a single dose of the measles vaccine was believed to be capable of eradicating the disease by 1982. Edda West, "What if My Child Gets Measles?," VARIANCE Newsletter (Winter-Spring 1996): 5.

[337]Scientific evidence appears to cast doubt upon the beneficence of revaccination. It has been found that, with both measles and mumps vaccines, re-inoculation fails to produce any remarkable long-term increase in antibody titres. Cf. J. Deseda-Tous et al., eds., "Measles Revaccination Persistence and Degree of Antibody Titre by Type of Immune Response," American Journal of Diseases in Childhood 132 (1978): 287-90, as cited by: Briss et al., 81.

[338]Approximately 50% of measles-related fatalities are associated with serious chronic disease or disability. Scheibner, 83.

confer benefits to subsequent generations in the form of passive immunity.[339] Continuous re-inoculations will eventually eliminate passive immunity against measles from entire populations and the result will be devastating. The impact will resemble the introduction of a pathogen in a new host and, undoubtedly, we will again evidence high measles-mortality rates.

Proponents of mass measles immunizations often support their position by pointing to two particularly horrific results of infection: they maintain that "1 of every 1,000 cases" results in measles encephalitis, perhaps leading to permanent brain damage" and that death occurs approximately once in 3,000 cases.[340] These figures have been disputed by health care professionals. Many pediatricians believe that the 1/1000 encephalitis rate is grossly exaggerated.

> The incidence of 1/1,000 may be accurate for children who live in conditions of poverty and malnutrition[341], but in the middle- and upper-income brackets...the incidence of true encephalitis is probably more like 1/10,000 or 1/100,000.[342]

In other words, the figures may be accurate in some parts of the world but it is misleading to apply such figures universally and it is particularly misleading to apply them to developed nations.

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[339]Meg Edwards and Edda West, "The Measles Vaccine," VARIANCE Newsletter (Winter-Spring 1996) : 4.

[340]National Advisory Committee on Immunization, Canadian Immunization Guide, 70.

[341]Supplementation of vitamin A has been shown to reduce measles-related morbidity and mortality. Cf. American Academy of Pediatrics, "Measles," in 1994 Red Book: Report of the Committee on Infectious Diseases. 23rd ed., ed. Georges Peter (Elk Grove Village, IL: American Academy of Pediatrics, 1994), 310.

[342]Mendelsohn, How to Raise Healthy Child, 215.

Canadian critics of immunization found the 1/3,000 death rate, attributed to measles-related complications, equally exaggerated: their own review of government data indicated that the actual measles-associated death rate "is closer to 1 in 10,000 cases, which seems to be more in line with British and German experience."[343]

In light of the fact that vaccinees are at greater risk of infection, coupled with the evolution of atypical measles cases and the increase in the average age of infection, there is a strong suggestion that any interference with the natural progression of the disease will result in a variety of detrimental anomalies. Is artificial immunity causing one relatively benign disease to become something quite different, thereby creating entirely new, and perhaps more virulent, diseases among older hosts? Long term studies, *which are notably absent*, regarding the effects of active immunization must be employed if the answer to this question is to be known. Without such answers, it is understandable that critics should question whether revaccination, or even initial vaccination, is beneficent. Current data suggests that mass measles vaccination violates the principle of beneficence because the risks associated with the measles vaccine appear to outweigh the benefits, both in the short and long terms. The disease is innocuous in the developed world and not only do vaccinees succumb to infection in greater numbers than their unvaccinated counterparts, but infections are occurring amongst older persons, sometimes in an atypical and more severe manner, and in infants who do not receive passive immunity from their vaccinated mothers. All of

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[343]Vaccine Risk Information and Resource Group, "Editorial," VARIANCE Newsletter (Winter-Spring 1996) : 3.

these liabilities are the direct result of the measles vaccine. Despite the fact that proponents defend the vaccine by citing reduced incidence rates, the known liabilities are overwhelming and the future liabilities are presently incalculable. Furthermore, despite the fact that herd immunity thresholds are generally met, if not exceeded, epidemics continue to occur in 3-4 year cycles. There does not appear to be any substantial utilitarian benefit derived from the measles vaccine. Since the vaccine contains hazardous elements, and since its efficacy remains highly questionable, its continued use violates both the principle of non-maleficence and the principle of beneficence.

The Mumps Vaccine

The mumps vaccine is commonly administered in combination with the measles and rubella vaccines. Since the mumps vaccine appears to cause some of the same problems for beneficence as the measles vaccine, it will be discussed, albeit briefly, here.

Mumps has always been considered a relatively innocuous disease when experienced in childhood. In rare cases, mumps has been associated with viral meningitis, deafness (usually transient), orchitis (inflammation of the testes) and oophoritis (inflammation of the ovaries). Permanent sequelae are very rare. The vaccine was apparently created in order to protect adult males, i.e.- who did not

acquire immunity from the disease in childhood, from contracting the disease and to address the few cases of meningitis associated with the disease.[344]

Post-pubescent males, who contract mumps, run the risk of orchitis which may, on rare occasions, cause sterility. When orchitis does cause sterility, generally only one testicle is affected. Concerns regarding sterility are minimal especially when it is understood that "the sperm production capacity of the unaffected testicle could repopulate the world."[345] Since the introduction of the mumps vaccine, the incidence of mumps has apparently declined in pre-pubescent children, however, there appears to have been an increase in post-pubescent adolescents and adults.[346] The age-shift is, of course, significant in that post-pubescent adolescents and adults are at greater risk of complications than children.

In one study, whose findings appear to correlate well with other studies, not only was there an increase in the number of mumps cases following the introduction of mandatory mass mumps immunization, but the average age of infection was ≥ 15 years for 63 of the 68 cases reported.[347] This particular study focused upon a 1991 (January-June) outbreak, in Maury County Tennessee, among high school and junior high school

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[344]Many *vaccine-associated* cases of mumps (typical and atypical cases) and meningitis have been reported as well. Cf. Scheibner, 102ff.

[345]Mendelsohn, How to Raise a Healthy Child, 213f.

[346]Cf. Scheibner, 102ff; Bradley S. Hersh, et al, eds., "Mumps Outbreak in a Highly Vaccinated Population," The Journal of Pediatrics 119 no.2 (August 1991): 187.

[347]Briss et al, 77-82.

students.[348] Of the 68 cases investigated, 67 had been previously vaccinated against mumps and these were amongst a highly (98%) vaccinated school-population. It is interesting to note that prior to the 1988 school immunization requirement, mumps was relatively uncommon in this area. From 1971-1979, inclusively, only 85 mumps cases had been reported and there were no cases reported during the 1980s. A few years after the mandatory requirement came into effect, which increased immunization uptake to 99.6% in Maury County, there was a resurgence of mumps.[349] This counters the very foundation upon which mass immunization is supported: despite the fact that herd immunity thresholds were *exceeded*, disease incidence *increased*![350]

The mumps vaccine itself has been known to infect individuals with mumps, a fact that was demonstrated during the clinical trials, and it can cause meningitis in vaccine recipients.[351] Considering the innocuous nature of the disease itself, the apparent lack of safety and efficacy of this vaccine, and its ability to defer the disease to older hosts,

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[348]In order to test vaccine efficacy, thirty four volunteers were revaccinated, two of which (oddly enough) had contracted mumps during the outbreak and had submitted serum samples post-infection. Serum samples were taken prior to revaccination and of the 34 volunteers, 6 had high anti-mumps antibody titres, 25 had intermediate titres and 3 were seronegative (demonstrating no evidence of immunity). After 10 months, antibody titres were found to be similar to those measured immediately before revaccination. Revaccination did not improve protection against the disease for the majority of recipients, however, 2 of the 3 seronegative volunteers seroconverted after revaccination. Ibid., 80f.

[349]The increased incidence of mumps following mass vaccination, and the resultant increase in the average age of infection, have been documented by numerous researchers. Cf., for example, Scheibner, 105ff; Hersh et al, "Mumps," 187-193.

[350]It should be noted that the compulsory use of diphtheria toxoid was followed by significant increases in incidence rates. In France, for example, incidence increased by 30%, cases tripled in Switzerland, Hungary saw a 55% increase and cases in Germany "increased from 40,000 per year to 250,000," most of whom were immunized. In nearby Norway, which refused mass toxoid use, there were only 50 cases in 1943 while France had 47,000 cases. Cf. Trevor Gunn, Mass Immunization: A Point in Question (Ulverston, Cumbria: Cutting Edge Publications, 1992), 16; Miller, Vaccines?, 24.

[351]Scheibner, 102ff.

its continued use most assuredly counters the requirements of the principles of beneficence and non-maleficence.

The Poliomyelitis Vaccine

Poliomyelitis has never been a significant disease in terms of incidence rates, particularly when compared to other communicable diseases. It has been estimated that over 90% of persons exposed will remain asymptomatic, even under epidemic conditions, indicating that the naturally occurring polioviruses are not as virulent as one might suspect.[352] Further, polio-related fatalities are rare.

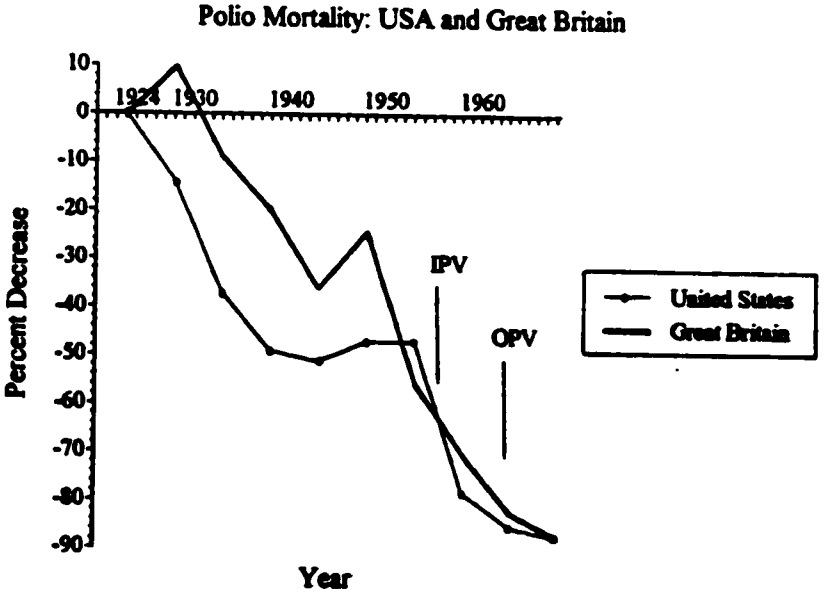

Figure 11. Decrease in Poliomyelitis Mortality Rates: The United States and Great Britain, 1923-1968. Source: Neil Z. Miller, Vaccines: Are They Really Safe and Effective? (Santa Fe, NM: New Atlantean Press, 1993), 19. Reproduced with the permission of New Atlantean Press.

[352]Miller, Vaccines?, 19.

Case fatality rates fell into decline during the first quarter of this century. As figure 10 indicates, there was a marked decline in the polio-related mortality long before the introduction of the vaccines.Since the poliomyelitis mortality rates declined significantly, prior to the introduction of the vaccines, it is clear that other factors are at work here. To be sure, general sanitary improvements initiated during the latter part of the 19th century must take some of the credit.[353] More importantly, however, was an evident change in the host-pathogen relationship. The incidence of the disease did not decrease even though the mortality rate declined steadily indicating that the pathogen, while remaining highly infectious, became less virulent in an increasingly more resistant host.[354] The significance of the disease remained in its ability to paralyse susceptible individuals.

Poliomyelitis vaccines were sought primarily to prevent paralytic cases. The Salk inactivated poliomyelitis vaccine (IPV) was first introduced in Canada in 1955 and was followed, in 1962, by the introduction of the Sabin (live) oral poliomyelitis vaccine (OPV). Poliomyelitis became a reportable disease in Canada in 1924. Statistics indicate that until the mid-1940s poliomyelitis generally struck approximately 200-2000

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[353]These same sanitary improvements may have been responsible for the upsurge of poliomyelitis during the 1940s-1950s. Although highly problematic in a variety of ways, open sewers and privies would have caused continual exposure to the disease, resulting in naturally acquired immunity. Once this form of exposure was eliminated, it follows that future generations would not be as resistant to the pathogen as their forebears. It is no surprise, then, that within a few generations of sanitary innovation, the incidence of poliomyelitis increased.

[354]In fact, available US statistics indicate that the total cases of poliomyelitis rose significantly in 1943 and remained high until 1953 but the mortality rate did not increase proportionally. A slight increase was noted but it did not approach previous figures even during peak incidence periods. Cf. Centers for Disease Control, "Summary of Notifiable Diseases, United States, 1989," Morbidity and Mortality Weekly Report 38 no.54 (1989): 53-58; Miller, Vaccines?, 18f.

people per year in Canada, with the cycle reaching its peak approximately every five years.

Poliomyelitis Cases In Canada: 1924-1995

Number of Cases by Year

Year	Number	Year	Number
1924	158	1960	909
1925	159	1961	188
1926	113	1962	88
1927	609	1963	122
1928	787	1964	19
1929	770	1965	3
1930	1027	1966	3
1931	1342	1967	2
1932	956	1968	0
1933	255	1969	2
1934	520	1970	2
1935	363	1971	6
1936	978	1972	2
1937	3905	1973	4
1938	577	1974	3
1939	359	1975	2
1940	192	1976	0
1941	1861	1977	2
1942	687	1978	6
1943	327	1979	3
1944	722	1980	0
1945	384	1981	0
1946	2527	1982	0
1947	2291	1983	0
1948	1168	1984	1
1949	2458	1985	1
1950	911	1986	0
1951	2568	1987	1
1952	2334	1988	3
1953	5384	1989	2
1954	1526	1990	0
1955	584	1991	0
1956	404	1992	1
1957	185	1993	0
1958	249	1994	0
1959	1887	1995	1

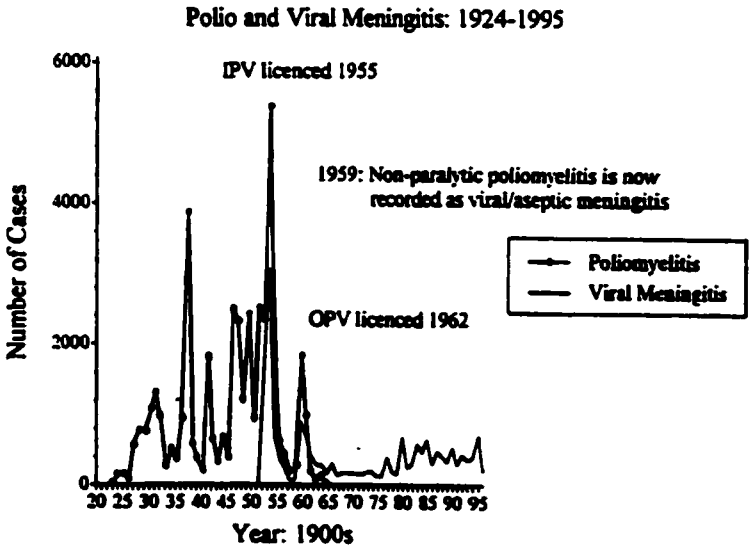

Figure 12. Poliomyelitis Cases in Canada: 1924-1995. Source: Laboratory Centre for Disease Control, Health Canada. Reproduced with the permission of the Minister of Public Works and Government Services Canada, 1996.

An inversion to this cycle occurred between 1946 and 1955, when incidence rates remained at their peak except for lows appearing every five years. Following this, the cycle reverted to its original pattern until about 1964 when the disease fell into decline.

It is important to note that the above Laboratory Centre for Disease Control (LCDC) figures reflect *all* (paralytic *and* non-paralytic) reported cases of poliomyelitis in Canada between 1924 and 1951. Paralytic cases were not distinguished from non-paralytic cases until a recommendation was made by the Dominion Council of Health in 1949. The LCDC figures provided from 1952 and onward represent this administrative change: recording only those cases adhering to the requirements for a diagnosis of *paralytic* poliomyelitis. In a report released in June of 1959, another administrative change was recommended by the Dominion Council of Health, further altering the way in which apparent cases of poliomyelitis would be reported. All non-paralytic cases of poliomyelitis were to be henceforth recorded as "meningitis, viral or aseptic", a disease which itself only became reportable in 1952.[355] These two administrative changes effectively reduced the apparent incidence of poliomyelitis. In particular, since the latter change is temporally correlative to the introduction of the polio vaccines, the vaccines *appear* to have been responsible for a reduction in poliomyelitis cases when it is entirely possible that the administrative changes are primarily responsible.

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[355]Dominion Bureau of Statistics, Poliomyelitis Trends, 1958 (Ottawa: The Queen's Printer and Controller of Stationary, 1959), 1.

The figures listed above are those currently used by the Laboratory Centre for Disease Control in Canada. It is important to note, however, that figures recorded earlier by the Dominion Bureau of Statistics (DBS) vary with the LCDC figures somewhat, particularly for the years between 1952 and 1956: the years immediately preceding and immediately following the introduction of IPV.

TABLE 2

DOMINION BUREAU OF STATISTICS: POLIOMYELITIS CASES, 1952-1956

Year	Total Cases	*Paralytic only*	Non-Paralytic
1952	4755	1442	3313
1953	8878	3691	5187
1954	2390	1163	1227
1955	1021	551	470
1956	600	368	232

Source: Dominion Bureau of Statistics, Poliomyelitis Trends, 1956 (Ottawa: The Queen's Printer and Controller of Stationary, 1957), 2f.

TABLE 3

LABORATORY CENTRE FOR DISEASE CONTROL: RECORDED CASES OF POLIOMYELITIS AND VIRAL MENINGITIS, 1952-1956

Year	*Paralytic Poliomyelitis*	Viral Meningitis
1952	2334	1922
1953	5384	3079
1954	1526	698
1955	584	375
1956	404	226

Source: Laboratory Centre for Disease Control, Health Canada.

If all figures were accurate, the pre-existing DBS figures (Table 2) for paralytic-only cases should correspond exactly to the LCDC's figures (Table 3) for paralytic poliomyelitis during the specified years.[356] Further, DBS non-paralytic cases should closely correspond with LCDC's figures for viral meningitis with, perhaps, more cases appearing under "viral meningitis" since diagnoses would not be restricted solely to the non-paralytic poliomyelitis reclassification. In neither case do the DBS and LCDC figures conform exactly. This is problematic in that the LCDC paralytic poliomyelitis figures, which are the official statistics used in Canada, are much higher than the DBS figures for the period immediately preceding the 1955 introduction of the inactivated polio vaccine. The figures from 1954 have been increased by 31.2% and the figures from 1953 and 1952 have been increased by 45.87% and 61.86%, respectively; the post-vaccine figures for 1955 (6%) and 1956 (10%) have been increased to a far lesser degree. What led to these changes in the LCDC figures is unknown but since the figures have only been significantly altered (increased) for the period preceding the 1955 introduction of IPV, the result is that the vaccine *appears* to have been far more effective in controlling paralytic poliomyelitis than it may actually have been.

In 1959, apparently the first year non-paralytic poliomyelitis was recorded as viral meningitis, viral meningitis statistics increased more than ten-fold. While 1959 was a peak year for poliomyelitis cases, and it would follow that non-paralytic/viral

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[356]Figures have been taken from the 1956 DBS report because this report appears to be the most recent which records all cases of poliomyelitis; subsequent reports exclude total case rates. It must be acknowledged that in the 1961 DBS Report, Poliomyelitis Trends, 1960, the figures for paralytic poliomyelitis have been adjusted. For the years including 1951-1957 the number of paralytic poliomyelitis cases were increased in the 1961 report. These increases still do not allow for a closer correspondence between the DBS and LCDC statistics except for the years 1955 and 1956.

meningitis cases would also be high, it is interesting to note that in the following years poliomyelitis cases dropped dramatically but "viral meningitis" cases remained in the hundreds, peaking every 3-5 years. The incidence cycle was *apparently broken* for poliomyelitis and, simultaneously, *initiated* for viral meningitis.

Due to the alterations made to the poliomyelitis figures in the period corresponding to the introduction of the vaccines, it is difficult to determine conclusively whether it was the vaccine or the manipulation of statistics that was most responsible for the apparent decline in poliomyelitis during the mid-1950s.[357] It is entirely likely that the disease simply reverted to its earlier incidence patterns and/or general passive immunity was facilitated by increased public exposure to the wild viruses. What is clear, however, is that by 1964 paralytic poliomyelitis was virtually eliminated in Canada.

Since the issue here is one of utilitarian beneficence, one might prefer to err on the side of caution and state that the vaccines did have a positive effect on reducing disease incidence.[358] This does not, however, support the vaccine's continued mass use in regions where the disease has been eliminated for decades. For three decades, in fact, poliomyelitis has been virtually eliminated in the developed world. Supporters of

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[357]The same holds true for US figures. After the live virus vaccine was introduced in the United States, "paralytic poliomyelitis" was redefined. Previously, the diagnosis could be made if a patient exhibited paralytic symptoms for 24 hours but, after the introduction of the vaccine, paralytic symptoms had to persist for at least 60 days. Furthermore, US cases of aseptic meningitis were distinguished from poliomyelitis after the vaccine was introduced. These major changes drastically reduced the number of poliomyelitis cases reported. Since they occurred simultaneously with the introduction of the vaccine, the statistics *appear* to support vaccine efficacy when, in fact, the reduction would have occurred whether the vaccine was available or not. Miller, Vaccines?, 21.

[358]Critics, however, claim that an equally dramatic decline was noted in countries where the vaccines were not used extensively. Mendelsohn, How to Raise a Healthy Child, 210.

mass immunization state that the primary reason for continuing the mass use of the poliomyelitis vaccines is to avoid a resurgence[359] of the disease.[360] This suggests that the polio vaccines are responsible for the elimination of the disease and for the decline in poliomyelitis-related morbidity and mortality. As noted earlier, however, the actual role the vaccines played in reducing poliomyelitis incidence and morbidity is unclear, yet plausible to some degree, but they clearly had nothing to do with the decline in mortality. The question that remains is whether or not the continued mass use of these toxic immunizing agents can be considered an utilitarian benefit when the disease presents virtually no risk at all?

Critics point out that the continued use of the poliovirus vaccines, particularly in countries where the disease is no longer endemic, is reminiscent of the reluctance to abandon the smallpox vaccine. In that case "smallpox vaccination remained as the *only source of smallpox-related deaths for three decades after the disease had disappeared.*"[361] This scenario has been repeated with the polio (OPV) vaccine.

The Canadian National Advisory Committee on Immunization acknowledges that since 1980, 9 of the 10 reported cases of poliomyelitis have been vaccine related: the 10th case (1988) was "caused by a strain imported from Pakistan" and was not transmitted to another person.[362] According to critics of mass immunization, such

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[359]It must be considered, however, that the vaccines themselves may have facilitated this possibility in that we now have entire nations devoid of natural passive immunity against polio.

[360]National Advisory Committee on Immunization, Canadian Immunization Guide, 96.

[361]Mendelsohn, How to Raise a Healthy Child, 211 (emphasis added).

[362]National Advisory Committee on Immunization, Canadian Immunization Guide, 96.

figures indicate that the risk of contracting paralytic poliomyelitis, in Canada and other developed nations, from the oral poliovirus vaccine far outweighs the risk of contracting the disease naturally. Since the Sabin oral poliomyelitis vaccine has been demonstrated to be the sole cause of poliomyelitis, barring the few imported cases, in much of the developed world, its continued use violates the principle of beneficence most grievously.[363] Furthermore, since it has been established that infected host tissues can transmit undetected pathogens via vaccines, the mass use of either polio vaccine violates both the principles of non-maleficence and beneficence.[364]

4. COMMENTS

In the previous chapter, it was determined that the mass use of harmful immunizing agents violates the principle of non-maleficence. The violation of one ethical principle, on its own, cannot be allowed to condemn any medical intervention. Competing bioethical principles must be balanced if any intervention is to be assessed fairly. Still, evidence indicates that mass immunization also violates the principle of beneficence.

Beneficence, in the case of mass immunization, is necessarily utilitarian in nature. That is, the benefits accrued from mass immunization are precisely the benefits experienced by entire societies. Mass immunization is widely held to be one of the

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[363]While the Salk IPV has not been known to cause polio since its initial use, there appears to remain some question regarding its ability to provide adequate protection against the disease. Cf. Mendelsohn, How to Raise a Healthy Child, 228f.

[364]Cf. Chapter Three: Immunization and Non-Maleficence: Antigenic Components: *Pathogenic Survival* and *Contamination of Vaccines by Diseased Host Tissues.*

greatest utilitarian health benefits to date due to its professed ability to eliminate many diseases and their resultant morbidity and mortality. Evidence indicates, however, that vaccines have had little effect upon mortality because disease-related mortality rates fell into decline long before vaccines were introduced.[365] Insofar as morbidity and mortality rates are concerned, it appears that general public health improvements, in combination with natural selection and cumulative passive immunity, account for the decline. There is no reason to believe that, in the absence of the vaccines, the morbidity and mortality rates would have increased except, of course, during limited and unusually high epidemic periods. Overall, the decrease could be expected to continue regardless of immunization.

The effect of mass immunization on incidence rates is more difficult to determine. In the case of poliomyelitis, incidence rates indeed appear to have declined significantly in the post-IPV/OPV era.[366] To be sure, an indeterminate percentage can be attributed solely to the disease's reclassification and to improved diagnostic procedures. Still, it must be recalled that, except for occasional epidemics, polio incidence rates were rather low prior to the late 1940s-early 1950s. This upward surge in incidence likely resulted from a reduction in general exposure to the disease. Sanitation improvements meant that individuals were no longer exposed to the disease through privies and open sewers. The gradual development of antibodies and conferring of passive immunity would necessarily decline, thus causing a more virulent

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[365]Declining mortality rates also were noted, long before vaccine introduction, for: diphtheria, tetanus, pertussis and tuberculosis. Cf. McKeown, 99-105.

[366]The utilitarian effect of earlier poliomyelitis vaccines have not been evaluated.

disease in a less resistant host. In time, increased exposure would naturally produce more resistant hosts, again decreasing incidence rates. Exactly how effective the poliomyelitis vaccine is/was in reducing incidence remains speculative: no absolute determination of utilitarian beneficence can be made using incidence rates exclusively.

The scales appear to be tipped, however, when it is understood that the poliovaccines are capable of infecting countless vaccinees with undetected pathogens lurking in contaminated host-tissues.[367] They are further tipped by OPV-induced poliomyelitis in vaccinees and their contacts. Certainly, it cannot be considered beneficent nor non-maleficent to expose vaccinees to these grave health risks, including the deleterious effects of the vaccine's chemical components, particularly when the disease now poses only negligible risks. Oddly enough, it appears that the only reason to continue mass immunization against poliomyelitis is to try to make up for the loss of passive immunity resulting from decades of vaccine use.

The measles and mumps vaccines present a somewhat different perspective on vaccine efficacy. Both vaccines have been responsible for raising the average age of infection, beyond the pediatric range, when the diseases become more dangerous.[368] This can hardly be understood as an utilitarian benefit, particularly when both diseases are relatively innocuous when contracted in childhood. It is known that vaccinees contract measles 15 times more often than their unvaccinated counterparts and we are

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[367]Cf. Chapter Three: Immunization and Non-Maleficence: Antigenic Components: Contamination of Vaccines by Diseased Host Tissues.

[368]The rubella vaccine also has raised the average age of infection beyond the pediatric range. Cf. Chapter One: Introduction: Utilitarianism and Herd Immunity.

witnessing atypical manifestations of the disease in vaccinees.[369] Further, the vaccine has facilitated infant infections because vaccinated mothers cannot confer maternal antibodies.

Although this chapter has primarily explored the utilitarian effects of mass immunization in relation to measles and poliomyelitis, many of the same observations can be found when examining other vaccines. It should be no surprise to find that all vaccines are capable of altering a disease's natural epidemiology, particularly regarding changes observed in the average age of infection and an overall reduction in natural passive immunity. All vaccines are capable of causing disease and death in vaccinees and some vaccines appear to render vaccinees more susceptible to disease. It is known that vaccines have provoked other diseases (e.g. meningitis, Guillain Barré Syndrome, arthritis, cancer, and etc.) in vaccinees. The individual and utilitarian costs are inestimable.

Since societies, by definition, are comprised of individuals, the over-all affect of mass immunization upon societies can never legitimately be separated from the affects experienced by individuals. It is apparently, and infelicitously, assumed that the utilitarian benefit rendered to societies outweighs the harm inflicted upon a percentage of individuals but, the harm cannot be defended especially since mass immunization creates at least as many problems as it hopes to resolve. It is very important, then,

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[369]In many cases, compulsory mass immunization precipitated epidemics of the very diseases the vaccines were designed to eliminate. Smallpox incidence and mortality rates soared when vaccination laws were enforced. Similarly, as mentioned earlier, mumps and diphtheria cases were greatly increased when the vaccines were mandated en mass. Cf. McKeown, 100; Miller, Vaccines?, 45.

that individuals understand the risks associated with immunization *before* consenting to the procedure.

In the following chapter, current immunization practice will be assessed in regard to the principle of respect for autonomy. Since individuals face numerous health risks in submitting to immunization, the ethical and legal aspects of informed consent, voluntary consent and compulsion, are highly relevant to this discussion. It is assumed that if the public is made aware of all of the risks associated with immunization, uptake will drop below herd immunity rates, leading to a resurgence of disease. Truly informed consent, therefore, may hinder mass immunization programs. Should compulsion, then, be defended in the interest of utility? If individuals are compelled to submit to immunization, either through legislation or a sentiment of utilitarian duty, should they be compensated for injuries incurred? Who is ultimately responsible to compensate injured individuals? These questions will be explored both in the following chapter and in Chapter VI: Immunization and Justice.

CHAPTER FIVE
IMMUNIZATION AND RESPECT FOR AUTONOMY

1. THE PRINCIPLE OF RESPECT FOR AUTONOMY

"Autonomy" means "self-government" whereas the bioethical principle *respect for autonomy* incorporates and surpasses the idea of self-government by inferring an obligation, on the part of others, to respect autonomous choices made by reasonable, competent, individuals.[371] "Respect", in this case, infers both an attitude and an act. As an attitude, "respect" means esteeming, although not necessarily agreeing with, another person's beliefs and choices as having inherent value.[372] As an act, "respect" means:

> refraining from interfering with, or attempting to interfere with the autonomous choices and actions of others, through subjugating them to controlling influence, usually coercion or manipulation of information.[373]

In other words, competent[374] individuals are *"entitled* to determine their own destiny,

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[371]James F. Childress, "The Place of Autonomy in Bioethics," Hastings Center Report 20 no.1 (January-February 1990) : 12f.

[372]Ibid., 13.

[373]Ibid.

[374]The presumption of competency is inherent to the principle of *respect for autonomy*. Autonomy may be violated if the patient is not competent (e.g. unconscious, incoherent, impaired by alcohol, drugs, injury or disability) so long as the action is taken in *his or her* best interests. According to Canadian law, all patients, including children, are presumed to be "legally competent to give consent to treatment ...[and are] capable of authorizing treatment" unless there is "adequate proof that the individual cannot exercise his or her thought processes to reach a treatment decision." An individual cannot be considered incompetent simply because he or she refuses a prescribed treatment or chooses an

with due regard to their considered evaluations and views of the world", without undue interference, and they are entitled to receive accurate information which will affect their decisions.[375] However, maintaining the principle of respect for autonomy may not be nearly as straightforward as this basic description implies.

The requisites of maintaining the principle of respect for autonomy are indeed complex and one cannot suppose that any strict set of rules will provide an adequate framework for assessing ethical choices or responses in all situations. The task of bioethics, however, must be to clarify the complexities of moral decision-making considering varied, and sometimes opposing, perspectives. Regarding the principle of respect for autonomy, it is imperative that the rights and responsibilities of the moral agent and of those involved in the decision-making process be clarified because they are inextricably interconnected.

The Proper Context of the Principle of Respect for Autonomy

The *principle of respect for autonomy* has received considerable criticism largely because it has been oversimplified and inappropriately perceived as subrogating (or

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alternate form of care. Children are not summarily dismissed as mentally incompetent regarding consent or refusal of treatment by virtue of the "mature minor" rule which considers the child's ability to understand "the nature and consequences of a treatment decision" rather than relying upon an "arbitrary distinction[] based on a child's proximity to the so-called 'age of majority'." Lorne E. Rozovsky and Fay A. Rozovsky, The Canadian Law and Consent to Treatment (Toronto: Butterworths, 1990), 4-7.

[375]Tom L. Beauchamp and LeRoy Walters, Contemporary Issues in Bioethics (Belmont, CA: Wadsworth Publishing, Inc., 1994), 23.

subordinating) other bioethical principles and values.[376] One oversimplification of this principle suggests that the autonomous choices of individuals supersede fair medical and social allocations; "patients appear to have the right to claim whatever resources they desire," or alternately to refuse tests and treatments, "regardless of the burden on the community."[377] Such a narrow focus on absolute autonomous rights appears to legitimate any frivolous, uninformed choice and to effectively undermine the genuine concerns of others who may be directly or indirectly affected. This inadequate conception places patient autonomy over and against concerns of the community, health care professionals, other patients and family members for it presumes that autonomous choice takes absolute precedence over other equally important principles, virtues and even rationality.

Certainly the autonomous choice of a competent individual marks a central issue for the principle of respect for autonomy but, clearly, it cannot be the only issue under consideration. The principle of *respect for autonomy* should be understood, not as "taking absolute priority over...other principles" but, "viewed as *prima facie* binding, competing equally with other *prima facie* principles in particular circumstances."[378]

The principle of *respect for autonomy* does not warrant patient anarchy since it does not overrule other bioethical principles. Indeed, a patient may choose to act irresponsibly, or have irresponsible demands, but their rights cannot be allowed to

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[376]Cf. James F. Childress and John C. Fletcher, "Respect for Autonomy," Hastings Center report 24 no.3 (May-June 1994) : 34f.

[377]Ibid., 35.

[378]Childress, 15.

infringe upon the rights of others. For example, a patient admitted to an emergency department, with a minor injury, will not receive treatment before another who is more seriously injured, despite their demands for immediate treatment. In this case it is evident that the principles of justice, specifically the just allocation of medical resources, and non-maleficence, the refusal of allowing harm to come to the more seriously injured patient through delay, take precedence over the principle of respect for autonomy. The primary focus of the principle is the obligation of others to recognize that competent individuals "must be accorded the right to have their own opinions and to act upon them (as long as those actions produce no moral violation)."[379] Autonomous decisions are undoubtedly influenced by a myriad of factors directly relevant to the individual. In respecting patient autonomy, on a very basic level, persons are in fact agreeing to respect and support an individual's efforts to negotiate amongst conflicting loyalties, values, risks and benefits in order to formulate decisions which will provide the greatest mental, emotional, and physical integrity, under the circumstances.

Respecting the autonomy of competent individuals necessarily means that individuals receive the most accurate and complete information available in order to provide informed consent. Individuals must be afforded the right to negotiate amongst alternative treatments and to refuse any treatment, as long as doing so does not immediately endanger another person.[380] In cases where medical treatment is

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[379]Beauchamp and Walters, 23.

[380]Isolation and treatment, for example, may be forced upon an individual when she or he is infected with a contagious disease that threatens to infect others.

compelled, it is up to the medical profession to prove that the threat is so great that it justifies the infringement of individual rights. *Informed* consent and *voluntary* consent comprise central issues relating to the principle of respect for autonomy. Each issue, therefore, will receive specific attention in its particular application to immunization.

2. INFORMED CONSENT

Consent to treatment is generally considered to take two forms: expressed and implied consent. An individual *expresses* consent either verbally or in writing. In some areas, for example in Ontario, Saskatchewan, New Brunswick, and Quebec, written consent is required by law before surgery can be performed. In most cases, however, verbal or implied consent is sufficient for most medical treatments. An individual may *imply* consent either by his or her "words, writing, or actions, or from the circumstances."[381] A patient may *imply* consent, for example, by presenting a bare arm for inoculation. Implied consent may also underlie expressed consent: when a patient signs a consent form for surgery, she or he also implies consent for the incision, suturing, and et cetera.[382] In Canada, legislation has been enacted to protect individuals from unwanted treatment. Merely touching another person without consent, whether injury is incurred or not, constitutes assault and battery and the offending party can be sued.[383] The consent to treatment rule may be overridden under three

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[381]Lorne E. Rozovsky, Canadian Hospital Law: A Practical Guide (Toronto: Canadian Hospital Association, 1974), 29.

[382]Ibid.

[383]Ibid, 28.

circumstances: where certain treatments are legally enforced, when the patient is unable to give consent *in an emergency situation*, or when a patient is determined to be incompetent.[384]

Consent to treatment must be *informed consent* to be considered legally valid. In order for an individual to make appropriate health care decisions, he or she must be availed of relevant information regarding "the nature, risks, benefits and reasonable alternatives of having or not having the proposed treatment" or procedure.[385] Informed consent requires that physicians, nurses, and other health care providers furnish adequate information to their patients, or to guardians of their patients, *prior* to treatment and in a manner that they can understand. Exceptions should be allowed only in case of emergency, *if* the patient is not considered competent at the time, *and if* delaying the treatment could seriously injure the patient.[386] Legislation regarding exactly what comprises informed consent varies and, to be sure, may be found inadequate when compared to ethical requirements for informed consent.

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[384]Lorne E. Rozovsky, The Canadian Patient's Book of Rights. (Toronto: Doubleday Canada Ltd., 1980), 32f.

[385]Ibid., 42. Cf. Appendix D for official Canadian policies regarding immunization and disclosure.

[386]Another notable exception occurs when full disclosure may actually hinder the efficacy of the treatment. For example, if a placebo is prescribed for a psychiatric patient, informing the patient that they are receiving a placebo will render the "treatment" useless. This *therapeutic licence* is reserved only for a few specific instances and cannot be used to support lack of disclosure based upon the possibility that full disclosure will upset the patient or cause the patient to refuse treatment. Ibid., 29f.

Legislation and Informed Consent

What exactly comprises "informed consent" under Canadian legislation? Unfortunately current legislation leaves the issue open to so much interpretation that both health care providers and patients are left to their own resources to answer this question. To be sure, "the consent process is more than the clerical act of obtaining a patient's signature."[387] The consent process refers to the actual dialogue between health care providers and their patients. According to decisions made in 1980 (i.e. *Hopp v. Lepp* and *Reibl v. Hughes*) by the Supreme Court of Canada, it was made clear that "patients need not receive information about all the known risks" associated with medical interventions but they must be apprised of "material and special risks."[388] The *material and special risks standard* means that individuals must be made aware of "probable risks and factors that have the potential for untoward consequences" which would "influence a person's decision regarding treatment."[389] This standard has been "interpreted to mean the prospect of serious injury, paralysis, or death."[390] The material and special risks standard does not clearly address exactly what caregivers should disclose and what legitimately can be omitted.[391] The caregiver must apprise

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[387]Lorne E. Rozovsky, "Consent to Treatment: Myths and Realities," Leadership in Health Services 2 no.4 (July/August 1993): 21.

[388]Ibid., 19.

[389]Ibid.

[390]Ibid.

[391]Certain things can legitimately be omitted if they are deemed to be common knowledge. For example, a physician does not need to warn patients about "the dangers of anaesthesia or the risks of infection" following surgery because these risks are possible with any surgical procedure and they are "matters which men of ordinary knowledge are presumed to appreciate." The physician is required to disclose information that is relevant to the patient's decision to consent to, or refuse, the particular

the patient of relevant information which could potentially affect or change his or her decision to consent to, or refuse, a proposed treatment.[392] The problem of deciding what is sufficient to disclose is made more difficult because assessments regarding the risks associated with certain procedures, and the frequency with which the risks become manifest, often differ from one study to the next. Furthermore, if serious risks are considered to be rare occurrences, they are likely to be considered as mere possibility and may not be disclosed.[393]

Canadian law addresses lack of disclosure in a peculiar way. If an undisclosed adverse event follows medical treatment, Canadian law does *not* consider whether the individual, by their own testimony or standards (the *subjective test*), would have refused treatment based upon full disclosure of all risks.[394] Rather, the law determines the validity of consent based upon an *objective test*:

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proposed treatment. *Reibl v. Hughes*, (1980) 2 S.C.R. 886, 894.

[392]*Reibl v. Hughes*, 899.

[393]Rozovsky, "Consent: Myths and Realities," 20. Although physicians are generally not required to apprise their patients of rare risks associated with treatments/procedures, according to *Hollis v. Birch* (1996), manufacturers must warn physicians of risks no matter how rare. In this case, *unexplained* breast implant ruptures were found to occur in less than 1/10th of 1% of units sold but this small number did not exonerate the manufacturer of its duty to warn of the potentiality. Derek J. Mullan and R. Glen Boswall, "Comments on *Hollis vs. Birch*," in Products Liability in Canada (Toronto: Insight Press, 1996), 348.

[394]This *subjective* standard has been rejected because it is believed that, *in retrospect*, no person would ever have permitted the treatment if they had been made aware of the risks that caused their injury. In this way, the subjective standard would "expos[e] the physician to the patient's hindsight and bitterness." This is seen as a "gross defect" inherent to the subjective standard which *should* be overcome by applying the *objective* (reasonable person) standard. The Chief Justice, in this case, did, however, note that the patient's particular circumstances may be relevant even to the objective standard. For example, Reibl could have postponed the surgery which debilitated him, for 1½ years, until he was eligible for a pension. A reasonable person, according to the Chief Justice, would have delayed this surgery in view of the particular circumstances. *Reibl v. Hughes*, 897ff.

> ...what the average, prudent person, the reasonable person in the patient's particular position would have agreed to or not agreed to, if all material and special risks of going ahead with the [procedure] or foregoing it were made known to him [or her].[395]

In essence, Canadian law has blinded itself to the individual's right to make autonomous informed choices because the court can determine that the harmed individual retrospectively would have accepted the treatment based upon the supposed informed consent of an (imaginary) "reasonable" person.[396] In other words, plaintiffs must demonstrate an impossibility: that the imaginary reasonable person would have refused treatment if he or she had been informed of all associated risks. The sad implication that follows is that patients who have suffered serious debilitating and fatal results from medical procedures will often be denied compensation based upon lack of disclosure or invalid (uninformed) consent.[397] The legal minimum standard for informed consent does not adequately protect individuals from ignorance of grave and unknown potential adverse events and it rarely allows for compensation when they do occur.

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[395]Rozovsky, "Consent: Myths and Realities," 20.

[396]Interestingly enough, the *subjective test* was applied in the Supreme Court case of *Hollis v. Dow Corning Corporation* (1995) where the manufacturer failed to provide adequate warnings to physicians, despite their knowledge "that several *Silastic* breast implants had ruptured for no apparent reason." Justice La Forest determined that, while the *objective test* should still be applied to causation issues affecting the doctor-patient relationship, the relationship between the manufacturer and the patient is radically different. The physician functions to protect the patient's health whereas the manufacturer exists to sell their product. In essence, the manufacturer has the advantage of accentuating the "product's value and de-emphasiz[ing] its risks" to the patient and it is this advantage, coupled with the manufacturer's "advantage in information and resources", that justified the court's decision to utilize the *subjective test*. It will be interesting to observe the impact this case will have on future litigation. Eugene Meehan, "An Overview of *Hollis v. Dow Corning Corp*," in Products Liability in Canada (Toronto: Insight Press, 1996), 66ff.

[397]The issue of compensation regarding vaccine-associated adverse events will be discussed in Chapter VI: Immunization and Justice.

Ethical Requirements for Informed Consent

Typically, individuals rely upon the guidance of their health care provider in making medical decisions. Some individuals, in fact, prefer to be told which medical options to accept so they are not burdened with having to educate themselves. They prefer the parentalistic model of health care in which they play an entirely passive role. Medical language has become so minimally accessible to most individuals that it frequently supports patient passivity and ignorance. Still, unless a patient *specifically* chooses the parentalistic option, it should be assumed that full disclosure and dialogue are necessary. Furthermore, disclosure should be the responsibility of the specific health care provider responsible for administering any proposed treatment and should be considerate of the patient's history and values. Health care providers should make themselves aware of their patient's concerns, they should be available to answer any questions patients may have, and they should *not* proceed with any procedure if they detect hesitation and until all areas of uncertainty are addressed.

Immunization and Informed Consent

Mass immunization, and particularly mass campaigns, appear to be one of the last strongholds of parentalistic medicine and, often, truly *informed* consent may be lacking. Mass immunizations have received such tremendous support from international health agencies, governments and media campaigns, that they no longer *appear* to be interventions that require significant dialogue between health care

providers and patients. In fact, many individuals unquestioningly accept mass immunization as a "right of passage." Such general complacency indicates that the public is unaware of the potential serious adverse effects that vaccines and their components may have. Uninformed (invalid) consent is often the result. According to both ethics and law, the onus rests upon the expert to disclose pertinent information and not upon the patient to ask the appropriate questions. However, as past Canadian trials attest, even if a doctor fails to properly advise his or her patient of risks associated with a procedure, injured parties rarely win lawsuits.[398] In practice, then, since there are few repercussions for inadequate disclosure, patients must still ask about the benefits, risks and alternatives in order to receive adequate information for providing informed consent. The underlying, and infelicitous assumption, here is that the patient *already* knows enough about the procedure to be able to ask the appropriate questions.

The disclosure process may be further frustrated by limitations set forth by the Canadian Health Protection Branch on drug manufacturers. Drug manufacturers are required to disclose even slight risks about their products to physicians but the Health Protection Branch may limit or prohibit the risks included in warnings.[399] The logic behind this is that if there are too many warnings issued, the busy consumer, the doctor in this case, will be "inundated with written material" and "may disregard all...[warnings], including the critical ones."[400] Essentially, even the administering

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[398]Rozovsky, Canadian Patient's Book of Rights, 31-34.

[399]Mullan and Boswall, 348f.

[400]Ibid., 349.

physician may not be availed of all pertinent information to pass on to his or her patient.

The parentalistic posture adopted by international government and health care authorities has laid the foundation for mass uninformed consent to immunization. In fact, there does not appear to be any other medical intervention that is promoted indiscriminately *en masse* and without due regard for autonomous choices derived from normal doctor-patient dialogue. The public is continually bombarded with reminders to immunize at the doctor's office, the health care clinic, in medical pamphlets, at school, on television and in the newspapers. What is consistently lacking, in the content of these reminders, is thorough information regarding the more serious vaccine-related risks.[401] The public is provided with more information on package inserts when they purchase non-prescription drugs then they are when submitting to immunization.

Mass immunization campaigns are particularly culpable in this regard. During mass immunization campaigns vaccinees rarely, if ever, have the opportunity to consult with the individual administering the vaccine prior to vaccination. This means that individual and family medical histories are neglected by the administering health care worker and dialogue with the patient, at the time of immunization, is minimal at best. Patients who are lined up in mass campaigns are not asked whether they or family members have experienced adverse reactions to vaccines in the past.[402] The signed

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[401]Excluding television advertisements, minor vaccine reactions, eg. fever and tenderness at the injection site, are usually disclosed.

[402]Recently, the second of three hepatitis immunizations were administered to grade seven students at Windsor, Ontario schools. An individual, who was present at one school during the inoculations, mentioned that, as a group, the children were asked whether they were in the hospital recently (since the

consent form is accepted as being *informed* consent and it remains the sole responsibility of the patient, and/or their guardians, to determine whether immunization is advisable. Even when information pamphlets are distributed prior to immunization, individuals are neither provided with a complete list of vaccine components nor with information explaining their toxicity or potential long-term affects.

In the case of the recent mass measles vaccination campaign of school children in Ontario, information leaflets, which included consent forms, were distributed to children by their teachers. The leaflet provided brief information regarding recent outbreaks, adverse events associated with measles, the need to introduce a second measles immunization (due to vaccine failure in 5-10% of previously immunized individuals), mild vaccine reactions (rash, malaise and fever), general contraindications to the vaccine[403] and the safety of the vaccine.[404] The leaflet also mentioned that the vaccine would not be made available to personal physicians and that the second dose of this vaccine is mandatory for children to attend school unless parents obtain an

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last vaccine), whether any were ill beyond a cold and whether any were pregnant. No specific questions were asked about reactions to the last vaccine and dialogue between the public health nurses and individual vaccinees were minimal to non-existent. Students were not even given advance notice of the date for the second immunization; they were simply called to the gym for the inoculation.

[403]The contraindications listed were: fever or illness more serious than a cold; a disease which lowers the body's ability to fight infection; taking medication which lowers the body's ability to fight infection; a severe allergy to eggs; and, allergy to neomycin.

[404]It is interesting to note that the leaflet states that "the red measles vaccine has been used in Canada for over 25 years." However, an informal inquiry with the Windsor and Essex County Health Unit revealed that the vaccine was developed by Connaught Laboratories specifically for use in the measles mass immunization campaign.

exemption form.[405] Telephone numbers for the local health unit and the Ministry of Health were provided separately to the students.

The manner in which information was distributed to the vaccinees and their parents, and in which consent was obtained, is ethically problematic for a variety of reasons. The information was provided through teachers who, although admirable in their duties, are not health care professionals and, therefore, are incapable of addressing health care concerns. Oddly enough, however, it appeared that some pressure was exerted upon educators to gain compliance. This became evident as students returned home with the misdirected notions that they would lose their opportunity for education and, in fact, *die* if they did not receive this vaccine.[406] Something quite perverse occurred here; the usual boundaries that exist between education and private health care were breached as educators became instruments to promote specific health care decisions. Teachers are trusted authority figures and the government's use of teachers to promote immunization is nothing less than a coercive measure effectively decreasing the voluntariness of consent.[407] So too, by administering vaccines at school, thereby removing the procedure from a normal health care setting, immunization no longer *appears* to be an invasive medical intervention.

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[405]Ontario Ministry of Health, Help Wipe Out Red Measles (Ottawa: Queen's Printer for Ontario, 1995).

[406]During the British mass measles campaign, called Operation Safeguard, parents and children were also led to believe that children would die if they contracted measles. Alison Whyte, "Immunisation: Adverse Reactions," Health Visitor 68 no.7 (July 1995): 270.

[407]The horrendous position in which teachers have been placed could indeed have personal legal repercussions. Their influence may be construed as coercion and/or as providing medical advise without having the necessary qualifications to do so.

Medical decisions should neither be encouraged nor discouraged at the hands of educators. The proper realm for medical decision making necessarily incorporates open dialogue between a patient and his or her physician, or regular health care provider, and in an environment that is conducive to meeting the needs of individual patients.

During mass immunization campaigns, the person administering the vaccine, usually a public health nurse, is absent until the day appointed for the immunization clinic. Even when the PHN is present, he or she does not have the opportunity to consult with each vaccinee, parent or guardian in order to assess family and medical histories, the vaccinee's current health status or question the vaccinee about prior vaccine-reactions to determine the appropriateness of immunization for each recipient. The assembly-line nature of mass immunizations precludes individual attention: the essential factor underlying informed consent.[408] Furthermore, in this scenario, the family physician, who is most familiar with the particular individual, is excluded. There is no way to determine whether individuals have received adequate information, and understood the information supplied, and whether they have doubts about the procedure. Neither a signed form, nor verbal or implied consent, should be interpreted

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[408]The British "Operation Safeguard" mass measles immunization campaign, conducted during the latter part of 1994, assigned school nurses to inoculate 150 children per day. In an 8 hour work day, that means each nurse inoculates *one child every 3.2 minutes*. To be sure these numbers appear to be extraordinary and, presumably, they do not necessarily reflect the typical number of inoculations administered daily by each health care provider during all mass immunization campaigns. Nonetheless, when health care professionals are charged with a vast number of patients each day, they simply do not have the time to consult with individual patients, review medical histories, and assess whether vaccination is indicated or contraindicated in each case presented. Cf. Yvonne Roberts, "A Shot in the Dark," London Times Magazine, 17 December 1995, 17.

to mean that individuals are adequately informed of vaccine-related risks. Mass immunization campaigns transgress the principle of respect for autonomy in that the *process* of informed consent has been reduced to obtaining a signature verifying consent to treatment only.

It should be noted that information leaflets also did not make mention of the more serious adverse events associated with the vaccine. According to Connaught Laboratories' *Measles Virus Vaccine, Live, Attenuated (Dried)* package insert, it is also possible for vaccinees to experience high fevers, convulsions, potentially fatal allergic reactions, encephalitis, encephalopathy and subacute sclerosing panencephalitis. The information leaflets neglected to disclose this information and merely stated that "serious side effects are rare."[409] Furthermore, no mention was made regarding the possibility of atypical measles, and the increase in the average age of infection, associated with the measles vaccine and that the incidence of measles appears to be higher among immunized individuals.[410]

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[409]This lack of disclosure seems to counter provisions set out in the Ontario *Health Protection and Promotion Act* (May 1996), Section 38, Articles 1-2 indicating that, if consent has been given in accord with the *Health Care Consent Act 1996*, the physician or person authorized to administer the immunizing agent "shall cause the person who has given consent to be informed of the importance of reporting to a physician forthwith any reaction that might be a reportable event." Reportable events include: persistent crying or screaming, anaphylaxis or anaphylactic shock within 48 hours of immunization, shock-like collapse, high fever or convulsions within 3 days, arthritis within 42 days, generalized urticaria, residual seizure disorder, encephalopathy, encephalitis, or any significant occurrence within 15 days or death at any time following the aforementioned symptoms. In this regard, the consent form supplied by the Ontario Ministry of Health stated: "if your child has a high fever, convulsions or any other serious symptom after the vaccine, call your doctor." In comparing this with the adverse events listed on Connaught's package insert, there are a significant number of "reportable events" that have not been disclosed despite the fact that the person giving consent must report these reactions to their physician.

[410]For more information on epidemiological changes associated with the measles vaccine, see Chapter Four: Immunization and Beneficence: Historical Evidence: Measles.

While mass campaigns are particularly culpable regarding consent based upon inadequate disclosure, it should be understood that the same situation frequently arises during routine-mass immunizations. While routine-mass immunizations have the advantage of administration by one's usual health care professional, it is generally known that vaccinees and their parents or guardians are often provided with little information regarding the safety and efficacy of vaccines and their components. Vaccine package inserts contain a great deal of important information but they are rarely, if ever, offered to the patient.[411] More often than not, when vaccinees are provided with information prior to vaccination, the information has been produced by the vaccine manufacturers and underplays adverse events associated with vaccines. One will frequently find that available vaccine literature discusses the dangers of naturally acquiring the disease in question, supported by morbidity and mortality statistics, but vaccine-associated morbidity and mortality statistics are generally absent...as though they do not exist. Furthermore, one will rarely, if ever, find statistics indicating vaccine failure (how many vaccinees typically contract the disease despite adequate immunizations), how many individuals contract the disease *from the vaccine* and how vaccines have affected society overall (e.g. atypical and more severe manifestations of a disease appearing in older persons). Generally speaking, accurate

[411]Each vaccine vial comes with a package insert listing ingredients, warnings, contraindications, adverse events, and etc. (Similar information can be found at any library in the Physician's Desk Reference.) Although the inserts may require some further clarification, the patient will have the information they need to ask important questions. Patients should be informed of the vaccine package insert's existence and be able to request a copy from their physician or health care worker long before the immunization is to be administered.

and thorough information is unreasonably difficult to obtain. Due to this incredible general lack of disclosure, truly *informed* consent is not remotely possible.

That severe vaccine related adverse events occur is not disputed by health authorities or by vaccine manufacturers. Potential severe and fatal reactions to vaccines should not be hidden from vaccinees and/or their parents or guardians. Michael Corr, head of the Immunisation Project, Health Education Authority in England, appears to be leading vaccine literature to new levels of honesty. Corr recognizes that currently available literature is inadequate and that parents have a right to make informed decisions. Corr states that:

> The main issue of my work is that people have a right to know what the side effects of immunisation are likely to be. ...When the public become aware of any attempt by government or health professionals to "cover up" any sort of story, this only can have the effect of undermining the strength of our messages and the valuable relationship we have built up with parents. A cover up could threaten the whole programme.[412]

Corr is currently revising vaccine literature which will be translated into 22 languages and will be made available on tape and in braille.[413] Currently, the British Health Education Authority provides vaccine literature to health visitors to be given to mothers at their child's 10 day birth visit.[414] The efforts of Corr and the Health Education Authority appear to be moving toward a more ethical approach to the disclosure and consent problems that plague current immunization policies and practices. Certainly, information leaflets cannot provide the sole means of information

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[412]Michael Corr, London, England, email correspondence to author, 19 August 1996.

[413]Alison Whyte, citing Michael Corr, 270.

[414]Michael Corr, London, England, email correspondence to author, 19 August 1996.

for those affected by immunization decisions, but adequate and thorough printed information may well provide an essential step toward improving the consent process.

Sufficient immunization protocols also should be in place to determine, inasmuch as it is possible, whether particular vaccines should be administered to, deferred for, or omitted for all individuals.[415] Those who administer the vaccines should retain written verification confirming that information regarding risks, associated with *both* the diseases and vaccines, have been provided to vaccinees, and/or their parents or guardians, in a language and a manner that they can understand. Those administering the vaccines should document whether all questions have been addressed and that the information provided was understood. Screening histories should be taken and the individuals should be informed of appropriate procedures should adverse events occur. Furthermore, allergy tests should be made available prior to immunization to test for sensitivity. The cost of immunization might increase but the additional time and money would be well spent if even one child was spared from an untimely and preventable death or from a lifetime of disability.

3. VOLUNTARY CONSENT

Closely associated with the right to informed consent is the right to *voluntary* consent. For consent to be considered voluntary, patients cannot be compelled or coerced into providing consent and consent cannot be obtained through fraud or

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[415]The New Brunswick Immunization Protocol Form, used by public health nurses, appears to be one of the more thorough immunization protocols available. Cf. Appendix C.

misrepresentation. Just as the withholding of information invalidates consent, so too does compulsion or coercion exerted by an external force (e.g. legislation). Individuals must be able to choose among alternate treatments and/or to refuse treatment as long as their choice does not immediately endanger another individual.

One of the most important aspects of voluntary consent is conscientious objection. *Conscientious objection* means that individuals retain the right to refuse any proposed medical treatment. Individuals retain the right of conscientious objection in *most* areas of healthcare. Government officials, however, may enact legislation compelling individuals to submit to certain types of treatment thereby nullifying voluntary consent. Autonomy and consent are invalidated, under such circumstances, because the repercussions associated with refusal are likely to be so grave that they obscure the personal risks associated with compliance and ordinary individuals would find it extremely difficult to resist.[416]

Like military conscription during times of war, if it can be demonstrated that there is a clear and present danger, individuals may lose their right to conscientious objection. For example, each Canadian province and territory mandates the compulsory treatment of communicable diseases in order to protect others from disease transmission.[417] Since the infected person presents a clear and present danger to society, the society's right to be protected from the disease supersedes the individual's right to refuse treatment.

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[416]Dietmar Lage, Subject to Consent: The Ethics of Human Subjects Research in Canada (Winnipeg: Wuerz Publishing Ltd., 1997), 92.

[417]Lorne E. Rozovsky, Canadian Patient's Book of Rights, 32.

Compulsory immunization has often been viewed in the same light as the mandatory treatment of communicable diseases; both are viewed as necessary measures in the war against disease. Vital differences exist, however, between the two methods intended to prevent disease transmission, which support opposing perspectives regarding compulsion and conscientious objection.

In the case of immunization, used as a means to prevent disease transmission, the vaccinee has not yet, and may never be, infected with the disease(s) in question. There is no clear and present danger to society, as in the case of the already infected person, that would justify the infringement of individual rights. Immunization does not prevent the spread of disease from an *infected* individual to a non-immune individual in the way therapeutic disease treatments should. Rather, immunization is intended to prevent disease transmission by preventing primary infection and thereby reducing the number of associated secondary infections. Compulsory immunization is generally found to be supported by two utilitarian arguments: [1] unvaccinated persons present a health-risk to others because they remain vulnerable to disease and contribute to disease transmission and [2] unvaccinated persons burden society with high disease-treatment costs which could be avoided by relatively inexpensive immunizations. Immunization may be compelled through legislation, therefore, for the sake of proposed utilitarian benefits.

Compulsory immunization legislation is addressed specifically to those persons who would not submit to immunization otherwise. For example, it is widely held that if a significant number of individuals were to refuse immunization "a large reservoir of

unvaccinated persons could contribute to epidemic outbreaks that might involve vaccinated individuals as well."[418] Epidemic outbreaks burden individuals and societies in a myriad of ways. Besides the obvious health risks, the financial burdens are great. Health care resources are stretched to their limits by costly disease treatments and hospital stays and numerous work days are lost to care for the infected person(s). The medical and financial arguments used in support of compulsory mass immunization warrant that it is the responsibility of all individuals to submit to immunization in order to protect not only themselves from infection but to do their part in protecting society as a whole from disease transmission and from the high costs of disease treatment. As convincing as these arguments sound, they do not adequately defend the revocation of conscientious objection inherent with compulsory immunization.

The first argument, presented in support of compulsory immunization, presupposes both the vulnerability of unvaccinated persons to disease and the general invulnerability of vaccinated persons to disease. In other words, unvaccinated people, *unlike their vaccinated counterparts*, are considered to pose a health-threat to the general populace because they remain susceptible to disease and contribute to disease transmission. Vaccinated persons, on the other hand, apparently are presumed to remain invulnerable to disease, and to be incapable of transmitting disease, *unless* a sufficient number of susceptible people become infected. According to this logic, unvaccinated individuals are not only the cause of disease amongst themselves but, in

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[418]Richard Moskowitz, "Unvaccinated Children," in Vaccinations: The Rest of the Story, ed. Peggy O'Mara (Santa Fe, NM: Mothering, 1996), 25.

sufficient numbers, cause disease amongst the fully vaccinated. The logic here is flawed. *If* individuals are truly protected from disease by immunization then only unvaccinated persons would remain vulnerable.

> If the vaccines conferred a true immunity, as natural illnesses do, then the unvaccinated people would pose a risk only to themselves.[419]

Unvaccinated persons could not infect any person who is truly immune to a disease. If an unvaccinated individual transmits disease to a vaccinated individual then the vaccine has failed to produce immunity. As demonstrated in previous chapters, adequately immunized persons do, in fact, succumb to the very diseases against which they have been vaccinated. In some cases, measles for example, vaccinated persons comprise the majority of cases in recent epidemics. Immunization also appears to be responsible for instigating antigenic mutations, thus rendering current vaccines ineffectual, and for deferring some childhood diseases to older age groups where the diseases become more severe. How then can compulsory immunization be supported as a means of protecting vaccinated individuals from infection?

It may be argued that even if the unvaccinated only pose a threat to themselves, the expense of disease-treatment burdens the health care system and resources on a far grander scale than preventive measures. This argument would hold greater weight if it could be proven that *only* unimmunized persons became infected with "vaccine-preventable" diseases. As indicated in earlier chapters, this is simply not the case. Moreover, the vaccines themselves are capable of causing disease, disability and death

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[419]Ibid.

in vaccinees. To be sure, the human cost is immeasurable and the loss of even one life, sacrificed through death or disability, defrauds compulsory immunization as a benefit to society. Financially speaking, the cost may actually exceed any supposed savings believed to be gained through immunization.

In order to accurately assess the cost-benefit ratio of mass immunization, certain variables, which are *not* readily available, must be taken into account. On a very basic level, it must be understood that if a disease is not, or is no longer, endemic, vaccination against the disease could only be considered a cost-deficit. The smallpox vaccine, for example, was continued in North America for decades after the disease presented no threat thus there was no cost-benefit accrued by its continued use. Even in areas where a disease may remain endemic, it is only those persons who would have become infected, had they *not* been immunized and then *required treatment*, who would provide cost-benefit figures.[420]

Considering that mass immunizations must be administered to entire targeted populations, and generally require numerous booster doses, the expenditure associated with mass immunization may well outweigh the costs of treating the relatively few who would require acute care following natural infection.[421] For example, the Ontario government spent approximately $4.5 million between February 1 and June 15, 1996 to

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[420]If an individual escapes infection directly as a result of immunization, versus due to lack of exposure, then immunization can be said to have provided a cost benefit, particularly *if* that person would have required acute care as a result of natural infection.

[421]Cf. Louise B. Russell, "Is Prevention Better Than Cure?," in Studies in Social Economics (Washington: The Brookings Institution, 1986), 10ff.

provide a *second* measles inoculation to 2 million school-aged children.[422] The program was introduced because it was estimated that 5% of the vaccine recipients remained susceptible to measles after one dose; 95%, therefore, were considered to be adequately protected by the first immunization.[423] It was estimated that the second inoculation would raise this figure to 97%. Economically speaking, the province paid $4.5 million to increase herd immunity thresholds by 2%. Interestingly enough, the National Advisory Committee on Immunization recommended *against* the costly second inoculation in 1990 because they felt that it would have "little impact on potential school outbreaks for many years" and because there was little evidence to suggest that those who failed to seroconvert after the first vaccine, would do so after the second.[424] The proposed 2% increase in herd immunity may well be overly optimistic. Even if it is not, the number of individuals requiring acute care would not be significantly altered and it is doubtful whether the $4.5 million spent could be justified.

One must also differentiate treatment costs for those who are unvaccinated and for those who are vaccinated. It could not be said that immunization reduces health care costs, based upon treatment figures, unless it can clearly be demonstrated that both the

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[422]For the same number of children, the initial vaccine, in the form of the MMR, would have cost the government approximately $16 million at 1995 prices. Cf. Richard Schabas, "Measles Elimination: Time to Catch-Up," Measles Update 3 no.3 (August/September 1995): 2.

[423]The Canadian Immunization Guide estimates the vaccine failure rate at 1% to 5%, but the Ontario consent forms stated that the failure rate was between 5% to 10%, therefore the median of 5% has been adopted here.

[424]National Advisory Committee on Immunization, "Statement on Recommended Use of Measles Vaccine in Canada," Canada Diseases Weekly Report 16 no.2 (January 1990): 9.

cost of vaccine administration plus the cost of treating infected *vaccinated* persons is much less than the costs of treating unvaccinated infected persons: both groups succumb to natural infection *despite* immunization. Furthermore, the cost of treating and compensating individuals suffering from vaccine-related adverse effects, including costs associated with fatalities, must be factored in to the equation. What is the cost of hospitalization or institutionalization, for example, for those who have been vaccine-damaged compared to those who have been permanently injured by natural infection, differentiating the latter, of course, between vaccinated vs. unvaccinated persons? How many days have been lost from school or work because of vaccine reactions vs. natural infection? Many such variables underlie an accurate assessment of the true financial picture. In the absence of reliable statistics, it cannot be assumed that mass immunization provides a utilitarian financial benefit. Arguments to the contrary are presently unsubstantiated and should not be allowed to influence legislation regarding compulsory immunization. Compulsory immunization legislation, however, does exist in many countries.

In Canada, each province and territory reserves the right to enforce preventive measures, for example mass immunization, as they so choose and they may amend legislation at any time.[425] Based upon survey results and follow-up telephone consultations, it appears that compulsory immunization legislation exists in Canada for: Manitoba (measles), New Brunswick (diphtheria, tetanus, polio, measles, mumps and

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[425]Dr. Paul Varughese, Head of Surveillance Technology Supply for the Division of Immunization, Bureau of Infectious Diseases, at the Laboratory Centre for Disease Control, Health Canada, telephone interview conducted by author, 29 January 1996.

rubella), Ontario[426] (all child immunizations) and National Defence[427,428] Excluding National Defence, written exemptions are permitted for medical reasons and for reasons of conscience or religious belief.[429] Where compulsion is the rule, the existence of some form of exemption is vital for the good of individuals and for society. In particular, exemptions based upon conscientious objection must be maintained because, as many families have found, health care providers may not acknowledge certain reactions as being causally related to vaccines. In these cases, vaccinees and their parents must have the right to refuse immunization by some valid

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[426]In their survey response, the Ontario Ministry of Health, Public Health Branch, indicated that *no* vaccines are mandatory based upon the existence of valid exemptions. The mandatory status of immunization in Ontario herein has been determined by information set forth in the Immunization of School Pupil's Act Chapter 1.1. In particular, immunizations are required for all school pupils unless a physician provides a medical exemption or unless parents obtain a Statement of Conscience or Religious Belief Affidavit. Every person who fails to immunize their child/ward, *or* to provide the necessary exemption form to the Medical Officer of Health, "is guilty of an offence and on conviction is liable to a fine of not more than $1000." Furthermore, the MOH may have the pupil suspended from school. Government of Ontario, Immunization of School Pupil's Act (Office Consolidation) (Ottawa: Queen's Printer for Ontario, September 1994), 2f.

[427]National Defence mandates immunization against diphtheria, polio and tetanus for all adults; hepatitis A for Canadian Armed Forces members deployed to theatre scenes for more than 6 months; and yellow fever and ISG malaria upon deployment. In the completed survey, National Defence did not indicate that any exemptions were permitted.

[428]Certain professions and institutions may require immunization but these are not mandated by provincial law.

[429]In the United States, excluding Alaska where vaccinations do not appear to be mandatory, most states, except Mississippi and West Virginia, allow individuals some form of exemption other than a medical exemption. In some cases, where religious, rather than conscientious, exemptions exist, individuals must prove that they are members/adherents of a recognized church whose teachings are opposed to immunization. The states which require such proof are: Arkansas, Hawaii, Iowa, Kansas, Nebraska, Oregon, South Carolina, South Dakota and Texas. Recent Federal Court decisions, however, have expanded exemption rights so that individuals who have personal religious beliefs against immunizations, but are not necessarily members of an organized religion or of a church that opposes immunization, may claim a religious exemption. James R. Filenbaum, a Suffern, New York lawyer, has been successful in obtaining a number of such exemptions but the process must be handled in court. Neil Z. Miller, Vaccine Exemptions: A State-by-State Summary of Legal Exemptions to "Mandatory" Vaccine Laws (Santa Fe, NM: New Atlantean Press, 1995), 15f; Anonymous, "Inoculation Exemption Rights Expanded," Health Science (September/October 1997): 7.

means other than by medical exemption. Furthermore, since long term effects are not well documented, mandating vaccines, without exemption, would demonstrate gross negligence on the part of lawmakers and a general disregard for the health of their citizens. Vaccines undeniably contain hazardous components, and as such, should not be forced upon unconsenting individuals.

Critics of compulsory immunization assert that no vaccine should ever be mandated. To be sure, vaccines provide temporary immunity to a portion of the population and they tend to cause numerous adverse effects, including disability and death, disease mutation and they can increase the average age of infection. That vaccines are *known* to sacrifice a certain percentage of lives every year, *should* stand as reason enough to avoid compelling immunization. Furthermore, where immunization is compelled, there always remains the chance that exemptions will be rescinded, ultimately endangering many lives.[430] The very fact that individuals are required to obtain legal exemption forms (e.g. "affidavits"), that is - *if* they are aware of this option, seems to be coercive in itself.[431] In no other case does refusal of a medical intervention require a legal form or written statements, without which,

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[430]In one case, state exemptions were so much rescinded as they were ignored. When a California woman brought her child to the hospital for a minor mishap, the medical personnel, upon learning that the child was not "up-to-date" on her immunizations, stated that they would not release the child until the immunizations were administered. When the mother refused, they reported her to Social Services claiming child abuse. Despite the fact that California allows for exemptions based upon personal convictions, the State Attorney General sought to prosecute the mother. Miller, Exposé on Vaccinations, 85.

[431]In Canada, it appears that only New Brunswick and Ontario require specific exemption forms. The Ontario form also requires the signature of a Commissioner of Oath. Manitoba requires that parents or guardians submit written statements of refusal to the Medical Officer of Health. The Yukon Territories requires a written statement of refusal but, in this case, the statement is to be kept with the patient's medical records as a means to avoid unwanted immunizations.

individuals can be heavily fined and suspended from school. The inherent threat of fines, and exclusion from school, places dissenters in an awkward pseudo-criminal position.[432] Further, the *right* to education is used as a *reward*[433] for compliance and by withholding this "reward," the individual's future subsistence is threatened.[434] It may simply be easier and less frightening for individuals to comply with immunization requirements thereby foregoing their right to *voluntary* consent. Compulsion is a powerful tool for gaining compliance, even when exemptions exist, because many people will submit to immunization without being adequately informed of potential risks or they may disregard potential risks because the risks associated with refusal appear to be more immediate and tangible. Many believe that if government and health authorities mandate vaccines, then vaccines are truly safe and effective for *all*

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[432]The situation appears to be far worse in the US than it is in Canada. Many reports have surfaced indicating that US citizens have had their children removed from their homes by police and state social workers and have had vaccines forced upon them. US welfare recipients have been threatened with financial ruin if they refuse immunizations. In some cases, education and necessary medical attention have been threatened in order to gain compliance to immunization. Cf. National Vaccine Information Center, "Vaccine Police Force Mother to Vaccinate Her Child," The Vaccine Reaction 1 no.5 (November/December 1995): 6; Neil Z. Miller, Immunizations: The People Speak! (Santa Fe, NM: New Atlantean Press, 1996), 49f; Idem, Exposé on Vaccinations, 85-87.

[433]Recently, the *Immunisation Awareness Society* of New Zealand reported on a different type of "reward" offered for immunization compliance. Children, and their families, were offered a variety of "incentives" to be won, ranging from popsicles, dolls, bicycles, and electronic PlayStations, to video recorders, microwave ovens and stereo radio cassette recorders, for compliance to meningococcal meningitis, measles, MMR and Td-polio campaigns. Apparently, this strategy worked. In one region, where the Td-polio/MMR campaigns were executed, compliance "skyrocketed from 46% to over 80%" indicating that individuals will indeed succumb to medical interventions if the reward is hard to resist. Offering incentives (bribery) for submission to medical interventions is coercive and unethical. If there is a "reward" to be derived from an intervention, the reward *should* be improved health and the decision to submit *should* be based upon informed and voluntary consent, not upon material rewards. Immunisation Awareness Society, "Scaremongering, Bribery and Compliance," IAS Newsletter 9 no.4 (May-July 1997): 21.

[434]Cf. Lage, 92.

people.[435] This is simply not true and the promised rewards for compliance, coupled with the threats for non-compliance, are coercive measures which threaten informed and voluntary consent.

4. COMMENTS

The principle of *respect for autonomy* requires that autonomous choices, made by reasonable, competent individuals, should be respected. Choices may not be considered autonomous if they are influenced by coercive means or by the manipulation of information. Furthermore, the principle of *respect for autonomy* maintains that consent is only valid when individuals are adequately apprised of both the risks and the benefits associated with any medical intervention. Mass immunization, and particularly mass immunization campaigns, violate the principle of *respect for autonomy* in a myriad of ways.

In order for a reasonable, competent individual to make an autonomous choice and to give informed consent, she or he should be made aware of the risks that are known to be associated with any medical intervention. Canadian legislation regarding disclosure and the minimum legal standards for informed consent are inadequate in that many vaccine associated risks need not be disclosed to the public. An exhaustive

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[435]It should not be forgotten that vaccines are a multi-billion dollar business. Manufacturers, who receive the greatest financial benefit from the sale of vaccines, are instrumental in developing government immunization policies. Governments benefit from vaccine sales through taxes. In some cases, notably in the UK, doctors receive a financial bonus if they achieve 70%-90% vaccine coverage among their patients. One wonders whether voluntary consent is at all possible when those who are recommending, and/or mandating, immunization stand to profit from it. Susan Curtis, "Jabs in the Dark?" Here's Health (January 1995): 26; Anonymous, "Health Professionals Comments," The Informed Parent 18 (Spring 1997): 2; The Informed Parent Group, Shouldn't The After-Effects of Childhood Vaccination be Discussed Before? (Harrow, Middlesex, UK: The Informed Parent, n.d.), 3.

review of Canadian and international public vaccine literature demonstrated that risks associated with immunization are minimized. Vaccine components, and their known toxicity, are notably absent from publicly distributed vaccine information pamphlets. Surely disclosure of the facts that vaccines contain known carcinogens, have the potential to inhibit immune function, cause disease, disability and death, raise the average age of infection and fail to produce immunity in a percentage of vaccinees, comprise material risks that a reasonable person requires in order to make an informed decision to consent to, or refuse, immunization. However, unless individuals are *already* aware that vaccines can cause significant harm, and *then* endeavour to learn medical terminology, acquire vaccine package inserts, and do exhaustive research, they cannot hope to make an autonomous choice or to provide truly informed consent to immunization. The onus *should* be upon the expert to disclose adequate information and *not* on the patients who cannot possibly ask appropriate questions if they do not know what can or should be asked.

Compulsory mass immunization renders informed and voluntary consent irrelevant. In this medico-legal parentalistic alliance, individual rights are usurped in that persons are forced to submit to the indiscriminate administration of toxic vaccine components. One might argue that, since allowable exemptions exist in most places supporting compulsory immunization, no one is really forced to submit to immunization. This argument loses its strength, however, since many individuals will submit to immunization based upon inadequate information, upon the overwhelming support of medical and government officials, and upon the threats of expulsion or fines for

inadequately immunized pupils. The strength of such official support, combined with public ignorance, lead many to believe that immunization *must* be safe and effective. Compulsory immunization induces a sense of duty; individuals feel obliged to submit. Submission may be further guaranteed by legal punishment for refusal. The current practice of compulsory immunization represents a clear case of both the manipulation of information and official coercion to obtain consent thereby violating the principle of respect for autonomy.

Mass immunization campaigns amplify this violation of the principle of respect for autonomy in that this medical intervention is removed from the normal circumstance existing in all other areas of health care. Participation in mass immunization campaigns is almost always compulsory and vaccine administration rarely will be carried out by an individual's usual health care professional. The normal opportunity for doctor-patient consultation becomes impeded and the consent process is reduced to the acquisition of a signature. The health care workers administering the immunization, during a mass campaign, have neither the time nor the information (e.g. patient medical history files), to provide adequate assessments on a case by case basis. Since they cannot be expected to provide this personal attention, attention that necessarily accompanies all other medical interventions, mass immunization campaigns transgress the principle of respect for autonomy.

Autonomous choice, based upon adequate dialogue between the patient and the physician, has been flouted in favour of the *herd* approach to immunity. Indeed, mass immunization campaigns not only strive to create herd immunity but, in the process,

create herd medicine. *Herd medicine*, ie. prescribing, mandating, and administering any medical intervention to entire targeted populations, cannot hope but to violate all biomedical ethical principles.[436] Under no circumstances, including immunization, can compulsion to medical treatment be considered advantageous for all persons. It has been well established that various individuals will respond differently to both preventive and therapeutic interventions; mass immunization campaigns neglect this fact. Such negligence cannot be supported by the bioethical principles of respect for autonomy, non-maleficence, beneficence or justice.

Mass immunization, and particularly mass immunization campaigns, expose entire societies to potential health risks without their *informed* consent. Since mass immunization is promoted as being an utilitarian good, and participation as the individual's responsibility to society, then justice would dictate that harmed individuals should receive due compensation. As mentioned earlier, however, compensation may be denied. This is particularly true for vaccine-injured Canadians because, unlike some other countries, claims are still addressed by the judicial system. The judicial system requires plaintiffs to demonstrate fault in order to receive compensation. Unless obvious negligence is involved, fault cannot be demonstrated. Plaintiffs must also definitively prove that the vaccine can cause the type injury in question and that it indeed caused the individual's injury. This enormous task is confounded by the sheer lack of adequate studies assessing adverse reactions and by the scientific community's

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[436]The only possible exception to this would be *if* an entire population became infected with a communicable disease. Mandatory treatment, in this case, would not violate ethical principles. Still, even in this case, all efforts should be made to determine the safety of treatment for individuals (e.g. consider known allergies and provide alternate treatments where necessary).

inability to agree upon methodological adequacy. The unjust result is that injured parties must bear the financial burdens on their own. In the following chapter, *Immunization and Justice*, medical, ethical and legal considerations regarding compensation will be discussed and a Canadian compensation scheme will be proposed.

CHAPTER SIX
IMMUNIZATION AND JUSTICE

1. THE PRINCIPLE OF JUSTICE

The term "justice" comes from the latin root "jus", meaning "right" or "law." Most current definitions of "justice" essentially incorporate the notions of equality and social cooperation in accord with "currently accepted ethical law or as decreed by legal authority."[437] Whether as a right or as a law, *justice* implies obligation. As a right, justice means that individuals should be accorded that which is fair, due, or owed.

> Any denial of a good, service, or piece of information to which a person has a right or entitlement based in justice is an injustice. It is also an injustice to place an undue burden on the exercise of a right: for example, to make a piece of information owed to a person unreasonably difficult to obtain.[438]

In terms of justice as law, citizens have an obligation to obey the laws set within their society and, in turn, justice requires that individuals receive fair treatment, whether reward, burden, or punishment, impartially. Equity appears to be the central issue for determining what is just and, therefore, stands as the central issue in the bioethical *principle of justice*.

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[437]Donald O. Bolander et al. eds., New Webster's Dictionary and Thesaurus of the English Language (NY: Lexicon Publications, Inc., 1991), 532.

[438]Beauchamp and Walters, 26.

Although there are a number of contextually relevant principles of justice, each share a similar premise: that is,

> like cases should be treated alike, or to use the language of equality, equals ought to be treated equally and unequals unequally.[439]

In terms of *distributive justice*, for example, which calls for the equitable distribution of social resources and burdens, an *equal* share of resources for all may, in fact, prove *inequitable*. That is, those persons with a greater need may be disadvantaged while others may not need or even want what they are given.[440]

> (D)ifferences in treatment on grounds of special need may be construed as attempts to restore inequalities due to natural or extraneous causes. This would account for the justice of giving special attention to people - for example, those who are disabled [physically] or mentally... - who are, for no fault of their own, at a disadvantage with respect to others.[441]

It is easy to see how an *equal* distribution of health care dollars could be unfair. An individual who is seriously ill would require, but not get, more than a healthy individual, while the healthy individual would neither need nor want their full allotment. On the other hand, an *equitable* distribution of health care dollars would mean that those with the greatest need would be allotted more health care dollars than the healthy individual.

Equity must also be considerate of burdens. Justice implies that each person must bear a certain share of the public burdens but not to the extent that the burdens would

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[439]Ibid.

[440]Bernard Hoose, "Theology and the Four Principles: A Roman Catholic View II," in Principles of Health Care Ethics ed. Raanan Gillon (Chinchester, England: John Wiley & Sons Ltd., 1994), 50.

[441]William K. Frankena, "Social Justice," in Moral Problems in Medicine ed. Samuel Gorovitz, et al. (Engelwood Cliffs, NJ: Prentice-Hall, Inc., 1983), 506.

injure and impoverish some while having minimal effect upon others. An *equitable* share of the burdens implies a consideration for the individual's capacity to shoulder the burdens. Income taxes, for example, are a public burden and everyone with the same income is expected to pay the same amount in taxes. However, some people, through no fault of their own, have additional financial burdens such as caring for an invalid child. As a society, we recognize that such additional personal burdens warrant special consideration and, in so doing, we reduce the *public burden* (income taxes remitted) for these individuals. By considering individual capabilities we are insuring that the distribution of public burdens is fair. The distribution of burdens, as well as benefits, must be *equitable* to preserve utilitarian justice.

As mentioned previously, "society" is not an extant entity on its own. A society is nothing more than a collective of individuals. Utilitarian justice, therefore, must be considerate of the aggregate benefits and burdens allotted to individuals within their society. When an individual is injured, for example, while undertaking some measure for the public good, it would seem just that the same society which benefits from this person's action(s) also assumes responsibility for extraordinary burdens incurred. A fire-fighter who is injured while combatting a fire should receive some financial assistance from the society that has benefited from his or her actions. The injury represents an extraordinary burden, incurred while he or she was executing an action for the public good, and the just society should assume responsibility in balancing the inequity insofar as it is possible. Obviously, the injury cannot be undone, but the

society can make sure that she or he is not impoverished because of it. Justice requires the balancing of benefits and burdens.

2. IMMUNIZATION AND JUSTICE

While it certainly seems just that everyone should receive equal access to health care, including preventive medicine, equal access does not necessarily imply an equal distribution of benefits and burdens. On occasion the burden placed upon certain individuals exceeds the burden normally shared by the public. Like the fire-fighter, most individuals submit to immunization for the public good.[442] In the case of serious vaccine-injury, the damages are often irreversible. When certain individuals are required to bear extraordinary burdens, through no fault of their own and for the benefit of the general populace, justice would require an attempt to re-establish equity insofar as this is possible. At a minimum, re-establishing equity should involve some form of financial compensation that will cover medical, educational, and other care expenses, wage loss, and some compensation for pain and suffering. The balance of benefits to burdens can never be adequately re-established when individuals are made to suffer a lifetime of disability, or the untimely loss of a loved one, but providing compensation for vaccine-injured families may allow them a more equitable chance at a decent life then would otherwise be afforded if they had to bear the burdens by themselves.

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[442]Although part of the reason for immunization may be to avoid disease in one's self, immunization is promoted internationally to induce herd immunity, ie.- to protect the general populace from epidemics. Cf. Chapter One: Introduction: Utilitarianism and Herd Immunity.

When an individual does suffer permanent adverse reactions from immunization, who should bear the responsibility of compensation: vaccine manufacturers; health care providers administering the vaccines; society; or the individuals themselves? The answer is not at all clear. Many conflicting arguments, supporting the various perspectives, have often caused injured individuals to be left uncompensated or to lose what resources they do have in extended legal battles.

In some cases, particularly when negligence can be proven, it is easier to assign responsibility. For example, in 1975 DPT Lot 1182, manufactured by the state of Michigan, passed the manufacturer's safety and toxicity tests but was subsequently found to be a "hot lot" in FDA tests.[443] Lot 1182 was found to be three times more virulent than allowed by law and the FDA refused to allow Michigan to distribute the vaccine elsewhere. The 400,000 doses of the vaccine were not destroyed as they should have been, rather,

> Michigan health officials decided to see just how reactive it was by testing it on several hundred children in Ingham County.[444]

At least three of the children were left with seizures, paralysis, and brain damage. Clearly the Michigan Department of Health was negligent in their careless disregard for the health and safety of the Ingham County children.[445]

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[443]"Hot lots" are excessively virulent batches of vaccine which are considered to be more pathogenic and reactogenic than standard vaccine formulae. Harris L. Coulter and Barbara Loe Fisher, DPT: A Shot in the Dark (Garden City Park, NY: Avery Publishing Group, 1991), 176f.

[444]Ibid., 176.

[445]The negligent conduct of the Michigan Department of Health is clear, however, when parents sued the Michigan Department of Health for "potentially lethal misconduct" showing "callous disregard for human life", the court saw fit to dismiss the case due to "sovereign immunity", granted when

Similarly, the 1976 swine influenza mass immunization campaign demonstrated careless disregard for health and safety, but on a far grander scale. Millions of people were immunized with a vaccine that was developed and distributed before adequate tests were performed. Even when evidence indicated that the vaccine was unsafe, and unnecessary, the immunization campaign was still advanced. The results were disastrous.

After diagnosing swine influenza in four Fort Dix recruits in January of 1976, the US government spearheaded a mass immunization campaign.[446] This influenza strain contained an H1 antigen similar to that of the deadly 1918 Spanish influenza and health officials feared another pandemic (widespread/universal) infection.[447] Government and health officials responded quickly and by August 6th a vaccine had been formulated and mass-manufactured.[448] Administration of the vaccine was delayed, however, because the insurance underwriters of the manufacturing companies refused to provide liability insurance.[449] Concerns revolved around a prior court

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"claims aris[e] from services that only the government can provide." Ibid., 177.

[446]K. Ranson et al., eds. Grolier Academic Encyclopedia (Danbury, CT.: Grolier International Inc., 1991), 172. Cf. Gerald Ford, Public Papers of the Presidents of the United States (Washington, DC: The Office of the Federal Register National Archives and Records Service, General Services Administration, 1979), 257, 258, 280, 341, 342, 685, 688, 715. (Please note: citations refer to the sequential numbers assigned to the Presidential Papers and not pagination).

[447]Ford, 341, 342, 688.

[448]Ibid., 718.

[449]Richard Gaskins, "Equity in Compensation: The Case of Swine Flu," The Hastings Center Report 10 no.1 (February 1980): 5f.

ruling[450] imposing "strict liability" upon vaccine manufacturers to warn the public directly of vaccine-related risks in mass immunization campaigns.[451]

> Swine flu vaccine was newly developed; it had no established record of adverse events on which to base estimates of injury, nor enough clinical testing to guarantee that warnings could be made adequate for legal purposes. The vaccine was to be distributed on a national scale with unprecedented speed, through state and local health departments over which manufacturers had no control.[452]

The United States Government itself, in an attempt to hasten the inoculation program, assumed liability protection[453] on behalf of "those who manufacture, distribute, and administer" the vaccine in exchange for profits afforded from the vaccine.[454] The government, having assumed strict liability, issued warnings of vaccine-related adverse events. On the consent forms[455], issued at the start of the immunization program, only "children under a certain age, persons allergic to eggs, and persons with a fever or who had received another vaccine within fourteen days" were warned to take precautions.[456] Individuals were also informed that:

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[450]Cf. *Davis v. Wyeth Laboratories, Inc. and American Home Products Corporation*, No. 20, 995, United States Court of Appeals for the Ninth Circuit.

[451]Strict liability does not apply to routine vaccinations because it is assumed that patients will be informed of possible adverse events from their physicians. Gaskins, 5.

[452]Ibid., 6.

[453]This liability coverage did not include protection in the case of negligence.

[454]Ford, 723; Gaskins, 6.

[455]The consent forms were amended in early January 1977 to state that there was a remote risk (1 in 105,000) of developing Guillain-Barré Syndrome resulting in more remote chance (1 in 2 million) of death. Gaskins, 7; Arnold W. Reitz, "Federal Compensation for Vaccination Induced Injuries," Boston College Environmental Affairs Law Review 13 (1986): 180.

[456]Gaskins, 7.

> As with any vaccine or drug, the possibility of severe or potentially fatal reaction exists. However, flu vaccine has rarely been associated with severe or fatal reactions.[457]

By October 1st inoculations had commenced and by October 11th "three people over the age of 70, with diagnosed cardiac problems, died shortly after receiving swine flu shots."[458] The CDC responded to the deaths by stating that 10 to 12 deaths per 100,000 are to be expected daily among persons aged 70-74. "Thus, elderly people dying the day after vaccination is to be expected."[459]

By October 14th, more than a dozen vaccine-related deaths had been recorded.[460] On October 14th, President Ford and his family were televised receiving their swine influenza immunizations and the public immunization campaign continued despite the reported deaths.[461] Soon a second adverse reaction presented itself: fifty-four vaccine-related cases of Guillain-Barré Syndrome[462] were reported.[463] By December 16th the U.S. government, conceding to both the presence of adverse events and to the *lack of* pandemic infection, called for a "one month suspension of the immunization program"

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[457]Ibid.

[458]Reitz, 179.

[459]Ibid.

[460]Levine, 175.

[461]Reitz, 179; Levine, 175.

[462]Guillain Barré Syndrome: "an idiopathic (cause unknown), peripheral polyneuritis (extremely painful disorder involving several nerves simultaneously) occurring between 1 and 3 weeks after a mild episode of fever associated with a viral infection or with immunization." Anderson et al., Mosby's Dictionary, 679, 785, 1061, 1245.

[463]Levine, 175.

after more than 40 million persons had received the vaccine.[464] The swine flu mass-immunization campaign was officially ended by March 1977.

US government and medical officials promoted a vaccine that was never properly tested and they continued to support its use even after they were aware of its dangers *and* in the absence of pandemic infection. The US government did assume responsibility in compensating some of the swine flu vaccine victims, however, since compensation was based upon the timing of the onset of symptoms, many individuals were denied compensation.[465] A 1979 report from the US Public Health Service Claims Officer confirms that nearly 3,700 claims had been filed by December 1978.[466] The claims were largely personal injury claims, with "over 1,000 claims... based on Guillain-Barré Syndrome" and 304 death claims.[467]

These figures refer only to claims filed in the US. The vaccine was used simultaneously in Canada but fewer claims would be allowed. Canadian law has no mandate for manufacturers to "warrant the fitness of the product" so it would be virtually impossible for Canadians to receive compensation based upon the administration of a faulty product. Only in the case where the actual administration of

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[464]Ibid.; Reitz, 179.

[465]For example, compensation claims for Guillain-Barrè Syndrome, resulting from the Swine Influenza vaccine, would be considered *only* if the diagnosis of GBS had been made within 6 weeks of vaccination. On this basis, over 2,813 claims were denied compensation. Cf. Tom Christoffel and Stephen P. Teret, "Epidemiology and the Law: Courts and Confidence Intervals," American Journal of Public Health 81 no.12 (December 1991): 1661-1666.

[466]Lorne E. Rozovsky, "The Legalities of the Swine Influenza Inoculation Program," Canadian Journal of Public Health 67 (September/October 1976): 378-380; Gaskins, 5.

[467]Gaskins, 5, 8.

the vaccine was deemed negligent, that is - due to the lack of "reasonable and prudent care on behalf of those administering the service," would claims be considered viable.

Injuries are not always the result of improperly tested vaccines, or of negligently released "hot lots." Any vaccine can leave the laboratory in prime condition but improper handling and temperature fluctuations can cause vaccines to become unstable and toxic.[468] Furthermore, even properly prepared, transported, stored, and administered vaccines are capable of causing adverse reactions, permanent injury and death. In most cases, negligence cannot be determined and, therefore, it is not clear who is responsible for re-establishing equity through compensation.

The fact that vaccine related-injuries do occur, as a result of approved vaccines distributed for general use, is undisputed.[469] The Bureau of Communicable Disease Epidemiology at the Laboratory Centre for Disease Control in Ottawa is responsible for the surveillance and investigation of vaccine-associated injuries.[470] Governments of other countries provide similar surveillance means.[471] Connaught Laboratories, SmithKline Beecham, and Merck, Sharp, and Dohme, vaccine manufacturers in

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[468]Wilson, Hazards of Immunization, 287.

[469]In Canada adverse events are published in an annual report entitled Canada Communicable Disease Report. Morbidity and Mortality Weekly provides data on adverse events as well.

[470]National Advisory Committee on Immunization, Canadian Immunization Guide., 5. This informative guide, published by the Canadian Federal Government, provides information regarding incidence of disease, recommendations for vaccine use, contraindications, anticipated adverse reactions, information regarding procedures for reporting adverse events, and recommendations regarding outbreak control.

[471]In the United States, the Atlanta Center for Disease Control provides surveillance. (See also- The National Childhood Vaccine Injury Act of 1986, Public Law 99-660).

Canada, also provide internal surveillance through the offices of their Medical Directors.[472]

That vaccine-related adverse events do occur is not, in itself, enough evidence to assign responsibility. The fact of the matter is that adverse events can be accounted for in a myriad of ways. Causative factors can include: hidden allergies or undiagnosed illness in the vaccine recipient,[473] improper storage and handling of vaccines,[474] contaminated batches of vaccine,[475] and proximate contact with a recent vaccine recipient.[476] Assigning responsibility for compensation often presents formidable problems and these problems are exacerbated when injuries are not immediately diagnosable.[477]

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[472]Information regarding reporting adverse events directly to the vaccine manufacturers is listed on vaccine package inserts and may also be found in the Physicians Desk Reference which lists pertinent information on all currently available vaccines.

[473]All vaccine package inserts list a variety of illnesses and allergies that contraindicate specific vaccine use.

[474]Cf. Schabas, Opportunities, 11.

[475]Many incidents have occurred where contaminated vaccine batches have gone undiscovered until after the vaccine was administered to the public. One such example of contamination occurred when simian retroviruses, SV1 to SV40, went undetected in polio vaccines resulting in a myriad of new diseases, mainly respiratory in nature, being introduced into human recipients. Cf. Scheibner, 152ff.

[476]An example of proximate contact with a vaccine recipient causing adverse reactions has been proven many times with the Sabin Oral Poliomyelitis Vaccine. Sabin himself states that since the live virus remains active in vaccine recipients, for a period of one to two weeks in the throat and for about two months in the feces*, contact with vaccine recipients will have some immunological effect upon vaccinee contacts. In 1974 the US Circuit Court of Appeals (*Reyes v. Wyeth Laboratories*) found that the Sabin OPV can produce cases of paralytic poliomyelitis in bystanders of recent vaccinees; this precedent setting case has allowed compensation for injured bystanders in the US. Cf. Sabin, "Measles, Rubella, Poliomyelitis, and Influenza," 36; American Academy of Pediatrics, "Poliovirus Infections," in 1994 Red Book: Report of the Committee on Infectious Diseases 23rd ed., ed. Georges Peter (Elk Grove Village, IL: American Academy of Pediatrics, 1994), 380; William J. Curran, "Public Warnings," 501-502; Moore, "Duty to Warn," 643-647.

[477]The diagnosis for GBS, caused by the swine influenza vaccine, marks one such example.

Assigning responsibility for vaccine-related injuries/death is one concern of "Tort Law." Tort law addresses compensation due to persons who are wronged, either intentionally or unintentionally, "through failure to exercise the care that could be expected of a prudent person."[478] Compensation for vaccine related injuries fall under the jurisdiction of tort, or toxic-tort, law. When it comes to the matter of compensation for vaccine-related injuries/death, the procedural and jurisdictional differences between provinces, states, and countries become important.[479] For example, the US has mandated "strict liability" legislation, placing the burden of proof (re: safety) upon vaccine manufacturers, and allowing for compensation for vaccine-related injuries.

It is incorrectly assumed that the same holds true for Canada. "Strict liability for a defective product under an implied warranty does not exist" in Canada.[480] Apparently the reason for Canada's hesitancy in adopting strict liability legislation, is the fear of "beleaguer[ing] Canadian courts...with a sudden growth of litigation in the products liability area."[481] In Canada, it is presently impossible to receive compensation for a vaccine-related injury unless the claimant can "prove that the producer of the product [or the person administering the vaccine] was negligent, that is- did not live up to the

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[478]Christoffel and Teret, 1661f.

[479]World Health Organization, Health Aspects of Human Rights, 43.

[480]Rozovsky, "Legalities of the Swine Influenza Program," 379; Rodney L. Hayley, "A Breath of Fresh Air: The *Privest* Decision on Asbestos in Buildings," in Products Liability in Canada (Toronto: Insight Press, 1996): 21f.

[481]It has been suggested that US courts are "retreating from the pure concept of strict liability" due to a great increase of such cases. Hayley, "A Breath of Fresh Air," 22.

average, reasonable and prudent standard of care."[482] Although vaccine manufacturers must warrant that they have lived up to a reasonable, prudent standard of care, they are not required to "warrant the fitness of the product."[483] Further, vaccines are not considered to be defective simply because they are, like many pharmaceuticals and biologicals, inherently dangerous.[484] In Canada, the burden of proof rests with the *plaintiff* who must prove negligence in the production and/or administration of the vaccine. The plaintiff must be able to *prove* that the vaccine caused the adverse event in question and that no other potentialities could have caused the event. The burden placed upon the plaintiff, to definitively demonstrate causation and fault, is formidable and generally results in no compensation.[485] Furthermore, due to the reasonable person and material and special risks standards, Canadians cannot receive compensation even when they have *not* been informed of potential adverse events associated with immunization.[486]

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[482]Rozovsky, "Legalities of the Swine Influenza Program," 379.

[483]Ibid.

[484]A vaccine that was contaminated by a foreign substance would, of course, be considered defective. S.M. Waddams, Products Liability (Toronto: Carswell Thomson Professional Publishing, 1993), 41f.

[485]Cf. P.G. *du Québec v. Lapierre*. (1985) 1 S.C.R. 241; *Rothwell v. Raes*. (1990) 79 D.L.R. (4th) 280 (Ont. C.A.).

[486]In the previous chapter, it was noted that limited, biased, and somewhat arbitrary, disclosure, regarding vaccine-related risks, is common practice. It would seem that if there is a chance, however remote, that a serious adverse event could occur, individuals *should* have a right to that information. It should not be unreasonably difficult to obtain. In other words, before submitting to immunizations, individuals should have relevant information, in plain language, available. As it stands now, one must endeavour to learn complex medical terminology and spend countless hours, days and weeks (at a minimum) researching vaccine components and the risks they pose. The extraordinary difficulty in obtaining adequate information is indeed unjust.

The well-known Patrick Rothwell case illustrates just how prohibitive Canadian legislation stands regarding compensation for vaccine-injured persons. On January 17, 1979 Donna Rothwell gave birth to twins: Patrick, who was assessed as normal[487], and another male, who was "stillborn and macerated as a result of torsion of the umbilical cord[488], with no evidence of congenital anomalies."[489] Patrick initially displayed "jitteriness" and intermittent cyanosis (a blue discoloration of skin and mucous membranes) but consulting physicians found no underlying pathology and considered Patrick to be well.[490] In the following months, Patrick appeared to be developing normally.

During the first half of 1979, Patrick was given his first three doses of the DPT-P vaccine. After the first, and more pointedly after the third vaccination[491], Patrick

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[487]Patrick was born at 38 weeks of gestation, normal for a twin, and his Apgar scores were within normal ranges. While Patrick and his mother were released from hospital a few days later than expected, this had nothing to do with Patrick's condition. He was considered to be normal at discharge. *Rothwell v. Raes*, (1988) 54 D.L.R. (4th) 286 (Ont. H.C. 1988).

[488]Prolonged exposure to amniotic fluid may cause maceration (a softening/breaking down of skin) in post-term or dead fetuses. In this case, it appears that the infant died as a result of a twisted umbilical cord which would effectively eliminate the passage of nutrients and oxygen to the fetus from the placenta and block the fetus' only means to eliminate waste. Cf. Anderson et al., Mosby's Dictionary, 941, 1225, 1566, 1611.

[489]Christopher J. Morgan and Thomas B. Anderson, "Rothwell v. Raes: The DPTP Controversy," Canadian Doctor 54 no. 9 (December 1989): 5; Cf., also, autopsy findings in: *Rothwell v. Raes*, (1988), 284.

[490]The counsel for the defence claimed that Patrick's jitteriness and pallor at birth were indicative of neurological damage that did not become apparent until his future development revealed anomalies. They maintained that Patrick suffered from prenatal periventricular leukomalacia (PVL), ie.- damage caused by a reduction or elimination of oxygen to the brain, for an extended period, in utero. Theoretically, since the twins were monozygotic (identical), *and* shared one placenta, the chances for PVL were increased. Judge Osler *did not*, however, believe the PVL theory in Patrick's case because there had been no case of PVL in an infant that did not present obvious, and far more serious, neurological deficits at birth. *Rothwell v. Raes*, (1988), 284ff, 315ff, 335.

[491]Patrick's second vaccine was followed by typical reactions: slight fever, crankiness and the injection site was tender and swollen.

cried[492] inconsolably for long periods of time.[493] Most significantly, after the third immunization, Patrick exhibited signs of developmental anomalies indicative of brain damage. Previously, Patrick was known to be a happy, playful and responsive baby who could pick up small objects, roll from his back to his stomach, lift his head and shoulders and react to surrounding stimuli. After the third immunization, Patrick "became lethargic, resisted stimulation"; he became increasingly cranky, stopped responding to external stimuli and began having seizures.[494]

Numerous physicians and neurologists were consulted and they concluded that:

> ...on the basis of the investigations and the history of the parents, the possible diagnosis was post-pertussis encephalitis.[495]

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[492]After the third vaccine, Patrick was screaming as well as crying.

[493]At the time of trial one physician noted that the Advisory Committee on Immunization Practices (ACIP) considered, inconsolable crying/screaming, lasting 3 or more hours, within 48 hours of immunization as a serious reaction to the vaccine. Connaught Laboratories' "DPT Polio Absorbed" vaccine package insert states this to be a contraindication to further immunization. Strangely enough, both the current Canadian Immunization Guide and the current Red Book fail to acknowledge the significance of this reaction. In a Manitoba case currently awaiting trial, a previously healthy 18 month old, Sara Dignazio, received a fourth dose of DPT on the advise of her physician, despite prior screaming episodes following immunization. After the fourth shot, Sara suffered demyleniating encephalitis, she no longer speaks, she doesn't appear to know what to do with her toys and she appears to be in "unspeakable pain." Cf. *Rothwell v. Raes*, (1988), 311; National Advisory Committee on Immunization, Canadian Immunization Guide 3, 89; American Academy of Pediatrics, "Pertussis," in 1994 Red Book: Report of the Committee on Infectious Diseases, 23rd ed. (Elk Village, IL: American Academy of Pediatrics, 1994), 363; Catherine Mitchell, "Shots' Risks in Shadows: Parents' Suit Fuels Vaccination Debate," Winnipeg Free Press 8 December 1995, 3(A).

[494]*Rothwell v. Raes*, (1988), 296ff.

[495]Morgan and Anderson, 32. It should be noted that while some of the expert witnesses continued to support this diagnosis, the physician who originally made the diagnosis apparently changed his mind based upon an error in Patrick's medical charts and based upon the prevalent (and recently altered) opinion on pertussis vaccine encephalopathy within the medical community at the time of the trial. Although the signed report indicated that Patrick's condition possibly resulted from the vaccine, the physician actually could "not remember whether or not he read the report before he signed it." *Rothwell v. Raes*, (1988), 301ff.

Post-pertussis encephalitis is believed to result from the pertussis element of the DPTP vaccine which causes encephalopathy (abnormalities in the structure or function of brain tissues), seizures, and severe brain damage.[496] Patrick Rothwell was left blind[497], nearly deaf, "unable to walk, talk or feed himself, and [he was] trapped at the developmental level of a seven-month-old with a life expectancy of no more than 30 years."[498] Patrick requires long-term institutional care.[499]

The Rothwells filed lawsuits based upon the negligence of the physicians, of the manufacturer, and of the Ontario government. The suit alleged negligence by the doctors for administering the vaccine and for failing to warn the parents of the associated material risks.[500] Connaught Laboratories was alleged to be negligent for manufacturing a vaccine which they should have known was inherently dangerous and

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[496]Mouse tests have shown that bovine serum albumin (BSA), commonly used as a cell growth medium for vaccines, in combination with the pertussis vaccine can cause encephalopathy. Almost all babies will have some level of sensitization to BSA since they are exposed to cow's milk either directly or through their mother's breast milk. Children who are allergic to cow's milk appear to be especially vulnerable to pertussis vaccine-induced encephalopathy. Steinman et al., 738-40; Coulter and Fisher, 126-129.

[497]An EEG revealed slow and sharp wave activity, "indicative of seizure disorder" stemming "from the occipital [(back)] part of the brain ...which is concerned with vision and the interpretation of vision." Examinations confirmed that there was nothing abnormal in or about Patrick's eyes themselves. *Rothwell v. Raes*, (1988), 300f.

[498]Thomas Claridge, "Parents Lose Vaccine-Risk Appeal: Court Upholds Ruling that the Whooping Cough Shot Didn't Cause Child's Brain Damage," The Globe and Mail, 15 December 1990, 8 (A).

[499]Allan Hutchinson, "Shouldn't We Help the Victims When Vaccines Go Wrong?" Globe and Mail 27 August 1992, 8(A).

[500]Morgan and Anderson, 5. Evidence indicated that the parents were informed only of potential minor reactions, for example, fever, irritability and tenderness at the injection site. Prior to Patrick's third injection, he suffered from a throat infection and was given antibiotics. The attending physician warned Donna Rothwell not to have the third vaccine administered until the medication was finished and the infection was cleared. Although this doctor sent this information to the Rothwell's physician, and although Donna herself asked her physician to examine Patrick's throat prior to the injection, Dr. Raes denied knowledge of Donna's request or of the other physician's report. *Rothwell v. Raes*, (1988), 196, 293ff.

for failing to provide the medical community with adequate information regarding proper administration and potential associated dangers.[501] Finally, the Ontario government[502], a major shareholder of Connaught Laboratories at the time, was sued for negligently recommending and distributing the dangerous vaccine.[503]

The vaccine manufacturer alone was found to be negligent for failing to adequately warn physicians about the possibility of vaccine-related "encephalopathy and grave brain damage."[504] They were not found negligent in their design or manufacture of the vaccine because they were utilizing current standards. The judge stated that while the product was "by 1980s standards a crude and unsatisfactory biological product", and that the safety test, specifically the "mouse toxicity test," was likewise "crude" and produced "no satisfactory correlation" of toxicity from mice to humans, the manufacturer was not negligent in its methods.[505] Further, although the acellular vaccine was available in Japan, Connaught could not be considered negligent in

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[501]Morgan and Anderson, 5.

[502]The role of the Ontario Ministry of Health was actually confined to the funding and distribution of vaccines and, in this capacity, it was not found negligent in its duties. All provinces had deferred the regulation and licensing of vaccines to the federal government. Further, since Alberta was the only province to have instituted a formal monitoring system on adverse events prior to 1987, Ontario's practice of passively reporting "important or interesting" adverse reactions to the federal government was well within established practice. Similarly, since no other provinces at that time issued warnings of serious vaccine reactions, and since health authorities felt that risks from the disease were greater than risks from the vaccine, no negligence was found in their duty to warn. *Rothwell v. Raes*, (1988), 196, 343ff. For information regarding current Canadian policy on issuing warnings and monitoring adverse events, see Appendixes D and E.

[503]Morgan and Anderson, 32; Edda West, "Vaccinations: An Overview," VARIANCE Newsletter (Summer 1994): 8.

[504]Although Connaught was found to be negligent in its duty to warn physicians of these potential adverse events, ***which they had been aware of for a number of years***, no judgement against the company was issued because a causal relationship between the vaccine and encephalopathy had not been established during the trial. *Rothwell v. Raes*, (1988), 196.

[505]Ibid., 342f.

continuing to manufacture the whole-cell vaccine because the former had neither been thoroughly tested nor confirmed as being superior to the latter.[506]

Since the lawsuit involved the government, the case was presented before a judge alone; trial by jury is prohibited if the government is named in a lawsuit.[507] At the end of the 74 day trial, Justice John Osler dismissed the case. The defence "convinced the judge that the plaintiff must prove cause and effect, and that the injury was caused by negligence."[508] Essentially, the court demanded that the Rothwells prove general causation between the pertussis vaccine and brain damage, before entertaining Patrick's injuries, and prove negligence on the part of the doctors, the manufacturer and the province, regarding the actual administration of the vaccine and failure to issue warnings of potential adverse events.

Causation could not be proven definitively. This is largely due to the fact that the probability of causation is based upon limited, conflicting and often biased, scientific studies.[509] Most existing studies which evaluate probability and incidence of vaccine-

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[506]The endotoxin, ie. the toxin which is contained within the bacterial cell walls and released into the body when the bacterium dies, has apparently been removed in the acellular vaccine. Anderson et al., Mosby's Dictionary, 552. Cf, also, Chapter One: Introduction: The History of Vaccines.

[507]West, "Vaccinations: An Overview," 8. It has been suggested, based upon US experience, that trials by jury tend to produce more favourable results for drug-injured plaintiffs. Furthermore, it must be acknowledged that a judge is employed by the state, the same state named in the lawsuit, perhaps creating an inherent conflict of interest. Cf. Empey, 19.

[508]Empey, 21.

[509]It should be noted that many of the studies, which claim that the pertussis vaccine cannot cause brain damage, have been undertaken by researchers who received their funding from vaccine manufacturers or have otherwise vested interests in exonerating the vaccine. Cf. Coulter and Fisher, 183f.

related adverse events have been found to demonstrate methodological flaws.[510] Perhaps the most damning flaw stems from the focus of the vast majority of studies which is to explore the extent to which adverse events are *over-estimated*: a serious bias which inevitably influences the study-outcomes.[511] Ultimately, the results were deemed to be inconclusive and causality could not be established.[512]

Since valid and unbiased scientific data is lacking, plaintiffs cannot possibly demonstrate causation in a manner that would be acceptable to Canadian courts.[513] Citing other cases of previously normal children who have suffered vaccine-related adverse events are considered to be merely anecdotal and they do not fulfil the legal requirements for "proof" of causation. Furthermore, since the court system operates on assigning fault, compensation cannot be offered on the basis of negligence when approved vaccines are administered according to federal recommendations, even when the result is disastrous.

Clearly, compensation for vaccine injuries has been based upon impossibilities and no Canadian will ever receive just compensation for vaccine injuries, incurred because

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[510]Paul E.M. Fine and Robert T. Chen, "Confounding in Studies of Adverse Reactions to Vaccines," American Journal of Epidemiology 136 no.2 (15 July 1992): 121-135.

[511]Ibid., 133.

[512]Justice Osler stated that a long term, randomized, prospective controlled trial would provide the most reliable results. An adequate study would require an enormous cohort to be observed over a long period. Osler also stated that "no study of this variety had been undertaken." *Rothwell v. Raes*, (1988), 195.

[513]It is quite often the case that reports of a vaccine's inefficacy or associated dangers will surface only after a "new and improved" vaccine has been developed to replace a prior version. Such is the case with the pertussis vaccines. The whole cell pertussis vaccine was recently replaced by an acellular vaccine. Before the new vaccine hit the market, many health officials denied that the vaccine could cause permanent brain damage. Once the new vaccine was released, the public was informed that the new vaccine, unlike its predecessor, will not cause brain damage.

they acted for the utilitarian good, unless the requirements are changed. Justice Osler himself recognized the inherent injustices within the legal system that serve to increase the costs to the plaintiffs while refusing compensation.[514]

The costs incurred by the Rothwells, and by other victims of vaccine injury, through court proceedings and through the daily care of the injured party are formidable.[515] Justice Osler, although distressed at his inability to award compensation to the Rothwells under current legislation, recognized the need for legislative reform which would prove more favourable to those suffering from vaccine-induced injuries:

> Surely it would be worthwhile for our society to agree to a certain adequate, though not lavish, standard of compensation upon proof of prior good health, the administration of vaccine and catastrophic damage within a limited period of time.[516]

Justice Osler acknowledged that the judicial system is not the proper avenue for addressing vaccine injury claims. Instead, he suggested that it would be more appropriate to implement schemes of no-fault compensation, governed by a tribunal, for people who suffer from serious adverse events which are temporally associated with immunization.[517]

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[514]In another case, 5 year old Nathalie Lapierre suffered (measles) vaccine-related acute viral encephalitis which left her permanently, and almost totally, disabled. The Québec Superior Court awarded the Lapierre's $385,000, with interest and costs, to be paid by the Government of Québec but the case was lost on appeal. There was no dispute over the fact that Nathalie was injured by the vaccine but the original judgement was reversed "on the ground that Québec civil law does not recognize no-fault liability." *P.G. du Québec v. Lapierre*, 241.

[515]Justice Osler estimated that the legal costs of the Rothwell lawsuit exceeded $1,000,000. *Rothwell v. Raes*, (1988), 354.

[516]Ibid., 353ff.

[517]Ibid., 354f.

According to Dr. Paul Varughese, of the Laboratory Centre for Disease Control Canada, there are still no federal provisions for compensation in Canada.[518] Dr. Varughese noted that the issue of federal compensation had been discussed but that it was "quietly dismissed" with no legislation resulting. Results of a recent survey of Canadian provinces and territories indicate that none have either policies or legislation in place to address compensation for vaccine-induced injuries and none have immediate plans to develop compensation schemes.[519] Apparently Justice Osler's recommendations, and the pleas of many Canadian citizens[520], have been completely ignored by the federal and provincial governments. The only recourse available to vaccine-injured parties is through the court system.

In Canada, it seems that far more attention is payed to national vaccine uptake (coverage rates) than to adverse event reporting. Uptake figures, resulting from a February 1995 LCDC survey and provided to WHO, demonstrated Canadian immunization coverage to exceed herd immunity levels: DPT3 (3 doses by age 2) reached 94.1%, Polio3 (87.4%) and single dose measles vaccine (96.2%).[521] Sadly, although such accurate coverage figures are readily available, the same does not hold

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[518]Telephone Interview conducted on January 29, 1996. Dr. Paul Varughese is the Head of Surveillance Technology Supply for the Division of Immunization, Bureau of Infectious Diseases, at the Laboratory Centre for Disease Control, Health Canada.

[519]Cf. Appendix F. Only Saskatchewan and Québec failed to reply to the survey. According to *P.G. du Québec v. Lapierre*, 241, however, Québec does not compensate vaccine injured persons. It should be noted that First Nations & Innuit Health indicated that they had no policy or legislation for compensation; National Defence did not reply to this question.

[520]At the time of the Rothwell case, the first of its kind to come to court in Canada, there were no less than 40 similar Canadian actions waiting in the wings. Empey, 21.

[521]Telephone Interview with Dr. Paul Varughese conducted on January 29, 1996.

true for adverse event figures. In Canada, adverse event reporting is voluntary unless provincial mandates exist.[522] While adverse events *should* be reported to the local public health unit who then forwards the report to the provincial health department, who should then report to the LCDC, no federal mandate exists requiring reporting.[523] It is no great surprise, then, that under-reporting would result. The utilitarian injustice resulting from under-reporting is public ignorance regarding the ability of vaccines to permanently injure or to kill vaccinees. Moreover, this ignorance extends itself into the Canadian courtroom, denying injured parties compensation, because the myth of vaccine safety has been carefully implanted.

Unlike Canada, a number of other countries have adopted special legislation to compensate vaccination victims. For example, France, the United Kingdom[524], Japan,

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[522]Telephone Interview with Dr. Paul Varughese conducted on January 29, 1996. It should be noted that, according to the *Ontario Health Protection and Promotion Act* 1996 H.7, s. 38 (3), "a physician or person registered under Part IV (nursing) or VI (pharmacy) of the *Health Disciplines Act* who, while providing professional services to a person, recognizes the presence of a reportable event *and forms the opinion* that it may be related to the administration of an immunizing agent shall, within seven days..." report the event to the medical officer of health (emphasis added). The problem with the obligation to report adverse effects, is that discretionary power is left in the hands of the physician. In one case, a previously alert and healthy 6 month old girl fell unconscious for an entire week after receiving her third DPT-P immunization. Immediately after immunization, she became extremely sleepy and over the next 24 hours, when she would arouse slightly, she would make high-pitched shrieks. Other than that, the child remained unresponsive for the following 7 days. On reporting this to her physician, the mother was informed that neither the shrieks nor the change in consciousness could be vaccine-related. Since this physician was of the opinion that such reactions could not be vaccine-related, he did not submit an adverse event report to the authorities.

[523]The LCDC's Bureau of Communicable Disease Epidemiology has operated a computerized Vaccine-Associated Adverse Events (VAAE) database since 1987. They are responsible for "post marketing surveillance of adverse events temporally associated with immunizing agents." National Advisory Committee on Immunization, Canadian Immunization Guide, 5.

[524]The United Kingdom's *Vaccine Damage Payments Act* came into force on March 22, 1979, six years after the Association for Vaccine Damaged Children launched a campaign to persuade the government to set up a compensation scheme. The Act was passed but it received criticism within Parliament. The £10,000 cap on awards was criticized as being too small and the 80% disability requirement for compensation was seen as arbitrary and rigid. Furthermore, no provisions were made

the Federal Republic of Germany, Denmark, New Zealand and the United States have each acknowledged a social responsibility to compensate injured parties.[525]

In France "*before the unavoidable nature of this risk* [vaccine injuries and mortality] *was established*" the courts handled vaccine injury cases much like we do in Canada: hearing "...actions in liability within the classical framework."[526] By the 1960s, however, a small group of administrative tribunals initiated a broader venue for compensation, applicable to those cases of vaccine-injury where fault could not be established. It was noted that:

> If in the public interest an additional sacrifice is imposed on someone, which falls on him by chance, there is a deliberate breach of equality which should apply between citizens with respect to public burdens, and that equality must be re-established by means of a compensatory payment.[527]

In other words, when a person submits to immunization for the utilitarian benefit, it is then the society's responsibility to compensate unduly injured parties since the utilitarian ethic requires the equal distribution of burdens as well as benefits. Compensation is society's attempt to recognize the injustice done to the injured person in the interest of the community at large and to assume the just utilitarian obligation to equalize the burdens insofar as this is possible.

> ...The case for state responsibility seems unusually compelling when an individual -and a healthy individual at that- is encouraged to participate, *in the*

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for vaccine-related deaths occurring before the scheme was announced or for those who were injured by vaccines prior to July 5, 1948. Cf. Peter Allsop, ed. "Vaccine Damage Payments Act 1979," Current Law Statutes Annotated 1979 (London: Sweet and Maxwell Ltd., 1980), 17-17/13.

[525]*P.G. du Québec v. Lapierre*, 241.

[526]Ibid., 267, emphasis added.

[527]Ibid., 268.

> *interests of the community at large*, in treatment involving a known, albeit statistically slight, risk.[528]

Herein lies the specific justification for compensating vaccine-induced injuries that is not present even in most other types of medical litigation: the injury results, *not* as a result from preventing or curing one's *own* illness but, from an attempt to prevent illness in the general population. The obligation of society to compensate injured individuals should be proportional to the obligation (legal or implied) of individuals to submit to immunization in the interests of their society.

In 1986 the US Congress instituted the *National Childhood Vaccine Injury Act* which allows vaccine injured individuals to file compensation claims, with a special master appointed by the Court of Federal Claims, against the Secretary of the US Department of Health and Human Services (DHHS).[529] Rather than having to establish fault, as would have been the case with a traditional court case, claimants could establish causation based upon the type of injury and the time period of the first symptom's onset, as found in the National Vaccine Injury Compensation Program's (NVICP) Vaccine Injury Table.

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[528]Harvey Teff, "Compensating Vaccine-Damaged Children," New Law Journal 127 no.5819 (15 September 1977): 905.

[529]It should be noted that claimants cannot sue the manufacturer, or anyone involved in administering the vaccine, until the DHHS claim has been settled. If compensation has been received from a civil suit, claimants are ineligible for compensation under the Act. If compensation is accepted under the Act, claimants can never sue the manufacturer. The latter requirement has been imposed to protect the vaccine market because, after many costly lawsuits, a number of companies withdrew from vaccine production. Those companies who continued to produce the DTP vaccine raised their prices, from 19¢/dose in 1980 to almost $15.00/dose in 1989, in an attempt to, at least partially, address compensation paid out from vaccine liability suits. Ellen Wright Clayton and Gerald B. Hickson, "Compensation Under the National Childhood Vaccine Injury Act," Journal of Pediatrics 116 no.4 (April 1990): 509f; Marlene K. Tandy, "Federal Circuit Review of Vaccine Compensation Cases Under the National Vaccine Injury Act: 1990-1995," The Federal Circuit Bar Journal 5 no.1 (Spring 1995): 29, 31.

TABLE 4

NVICP VACCINE INJURY TABLE, 1989: SELECTED ENTRIES[530]

Type of Vaccine	Illness, disability, injury, or condition covered	Time period for first symptom of onset or significant aggravation after vaccine
DTP, pertussis, DTP/polio combination; or any other vaccine containing whole cell pertussis bacteria, or specific pertussis antigen(s)	Anaphylaxis or anaphylactic shock	25 hours
	Encephalopathy (or encephalitis)	3 days
	Shock-like collapse or hypotonic- or hyporesponsive collapse	3 days
	Residual seizure disorder[531]	3 days
	Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above that arose within the time period prescribed	Not applicable

Source: Edward W. Brink and Alan R. Hinman, "The Vaccine Injury Compensation Act: The New Law and You," Contemporary Pediatrics 6 (July 1989): 30.

According to the 1989 Vaccine Table, if, for example, a child suffered encephalopathy within 3 days of immunization, the parents would be responsible for showing that the injury occurred, the extent of damages, and that there was not "a preponderance of evidence that the illness...[was] due to factors unrelated to the administration of the vaccine."[532] They would not have to prove that the vaccine could cause encephalopathy. However, if the initial symptoms occurred later than the time period

[530]The Vaccine Table also includes requirements for injuries caused by other vaccines.

[531]In order to claim residual seizure disorder, the individual could not have suffered seizures/convulsions, unaccompanied by a fever of less than 102°F, prior to the seizure which followed vaccine administration. The initial seizure or convulsion must have occurred within 3 days of vaccine administration, followed by two or more within one year of vaccine administration and were accompanied by a fever of less than 102°F or were afebrile.

[532]Clayton and Hickson, 510.

allotted, or if the injury is not included in the Table, claimants must then prove that the vaccine caused the injury.[533] In either case, the DHHS retains the right to oppose all claims.[534]

The NVICP requires less proof than would be required in traditional court cases, increasing the chances of compensation, but the awards are much smaller.[535] Still, whether or not claimants receive compensation, they may still recover attorney fees as long as their claim "was brought in good faith and there was a reasonable basis for the claim."[536] As of the Spring of 1995, over $500 million in compensation has been awarded under the Act.[537]

The NVICP has undergone a number of changes since its inception, the most recent of which threatens the integrity of the entire program. In February of 1995, Donna E. Shalala, Secretary of the DHHS, "published final rules in the Federal Register (Vol. 60, No. 26- Wednesday, Feb. 8, 1995) that effectively destroy the integrity of the National Childhood Vaccine Injury Act of 1986."[538] Effective March 10, 1995, recognized DPT related adverse events were reduced to anaphylaxis

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[533]Ibid.

[534]The DHHS has been criticized recently for their vehemence in fighting claims and effectively dragging out the cases for so long that "few lawyers will represent [claimants] in the compensation program because legal costs are too high. National Vaccine Information Center, "Shalala Takes Away Compensation for DPT Injured Children," The Vaccine Reaction, 1 no.1 (March 1995): 2.

[535]The NVICP has been criticized for offering inadequate awards which are too low to cover medical and care-related expenditures but high enough that claimants would lose public assistance if they accept the award. Ibid.

[536]Clayton and Hickson, 510.

[537]National Vaccine Information Center, "Shalala Takes Away Compensation," 2.

[538]Ibid., 1.

occurring within 4 hours of vaccination and encephalopathy/encephalitis occurring within 72 hours of vaccination.[539] Other, previously recognized, adverse events including "high pitched screaming, collapse/shock, bulging fontanelle or seizures within 72 hours of a DPT vaccination... [which can cause] permanent neurological damage, including residual seizure disorder..." will no longer be compensable.[540]

> One lawyer who represents vaccine injured children in the US Court of Claims, commented, "What you have now can be compared to a federal program that will compensate anyone who is in a plane crash in a snowstorm within 10 miles of Tahiti. Nobody will ever qualify."[541]

It seems fairly clear that the Department of Health and Human Services, in conjunction with the Center for Disease Control and the Food and Drug Administration, are taking steps to weaken the US compensation program. In terms of justice, this will mean that individuals who *should* be eligible for compensation will be denied and that the public will be misled regarding the frequency of serious adverse events: fewer compensation awards will undoubtedly make serious adverse events look like a thing of the past. Furthermore, fewer compensation claims will mean that there will be less pressure on vaccine manufacturers to develop safer products. The inordinate burdens placed upon individuals will not decrease, only compensation will decrease. Obviously, the current US program should not be used exclusively as a model for a Canadian compensation program.

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[539]Ibid.

[540]Ibid.

[541]Ibid.

3. COMMENTS

Since Canada does not recognize "strict liability," and since individuals administering vaccines are rarely found to be negligent in the execution of their duties, current Canadian law does not have an appropriate mechanism in place to compensate vaccine victims. Insofar as the current practice of immunization in Canada is concerned, there remains no equitable distribution of the public burdens and, therefore, the principle of justice is violated.

On November 26, 1997, no-fault compensation was recommended by Ontario's Justice Horace Krever for individuals who have contracted, or will contract, AIDS or hepatitis C from tainted blood products.[542] Krever's four-year investigation revealed that the federal and provincial government, the Red Cross, and Connaught Laboratories were aware, at least as early as 1985, that AIDS-contaminated blood had been distributed in Ontario between 1983 and 1984. Negligence was found on a number of counts: no effort was made to recall the tainted blood; individuals were not informed of the possibility of infection which resulted in secondary infections; the screening of blood donors was knowingly inadequate; the implementation of five-dollar (AIDS) blood-screening kits was delayed for seven months while the Red Cross and provinces quibbled over who should foot the bill; it took an entire year, after it was known that

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[542]Unfortunately, at present, Health Minister Allan Rock has deemed the recommended compensation to be applicable to *future* cases only. Cf. Mark Kennedy, "Feds Apologize for Tainted Blood: Ottawa to Discuss Compensation with Provinces," Windsor Star, 27 November 1997, 1-2(A); André Picard, "New Council to Pilot Blood Report: Krever Expected to Recommend No-Fault Compensation for Future Victims of Tainted Blood," Globe and Mail, 26 November, 1997, 1(A), 5(A); Daniel Girard, "Krever Inquiry: Ottawa Got Blood Tainted by HIV," Ottawa Citizen 11 April 1995, 1(A).

high levels of heat would kill the AIDS virus in blood, for safer products to become available; and, a hepatitis C screening test, available since 1986, was never purchased due to the cost.[543] Although negligence was found, Krever clearly stated that *society* has an obligation to compensate those individuals who have been injured, through no fault of their own, by tainted biologicals.[544] Clearly, this obligation should be extended to include vaccine-injured individuals, particularly since their injuries result from actions intended to protect society as a whole.

It would be advisable to implement a no-fault system of compensation for vaccine-injured Canadians outside the normal court system, which invariably rules on determinations of fault. In order to implement a fair compensation scheme for Canadians, certain changes must be made to immunization policies and procedures and to legislation. To begin with, more stringent laws are required to protect potential vaccinees from unforeseen adverse events. No vaccine should ever be administered unless vaccinees or their guardians are provided with a complete list of risks and contraindications, in understandable language, long before the vaccine is administered. This will allow for further research and/or doctor-patient dialogue and it should help in

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[543]It is expected that, among Krever's recommendations for various changes to the administrative and safety procedures, more adequate screening and testing procedures should be implemented and an efficient method to track, and inform, infected blood-recipients should be set in place. Although, right on the heels of Krever's recommendations, reports are emerging that describe how the Canadian Blood Agency is disposing of a tracking system, which apparently "is not year-2000 compatible", that matches the blood donor with the recipient, and replacing it with a system that will track blood only to hospitals where it has been sent. The hospitals will then be responsible for implementing their own, more specific, tracking system. (Many computer software programs were not designed to adapt to the new millennia and simply will not recognize "2000" as a year.) André Picard, "Blood Agency Drops $60-Million System: Experiment to Track Donations 'Vein-to-vein' Failed, More Limited Software Planned," Globe and Mail, 26 November 1997, 5(A).

[544]Criminal charges may still be laid.

reducing adverse events since there will be more time to determine the advisability of the procedure.

Adverse event reporting should be mandated as well. In both Canada and the US, the list of officially recognized contraindications appears to vary from time to time, and they seem to vary with those outlined on the manufacturer's package inserts. Mandatory adverse event reporting, including long term follow-up, should provide more accurate lists. Further, since the timing of the onset of symptoms appears to play an important role in compensation claims, mandatory adverse event reporting would provide an accurate, although not stringent, assessment of causation. Long term follow-up is essential in order to determine long term immune malfunction and latent infections associated with immunization.

Although more stringent disclosure policies and mandatory adverse event reporting will reap enormous health benefits for the general populace, they should not defer the implementation of a compensation scheme. It may take years before such changes provide benefits, and the benefits are guaranteed, but, in the meantime, many families are in need of compensation. To be sure, a compensation scheme should be set up *outside* of the Canadian court system. Clearly, the current system is failing to equalize the burdens inflicted upon vaccine-injured persons.

Existing international vaccine-injury compensation schemes, or similar schemes, utilized in other areas of compensation in Canada, could provide an adequate framework for implimenting a Canadian compensation scheme. The scheme could, perhaps, be modelled after the Ontario Criminal Injuries Compensation system which

requires applicants to prove, on the balance of probabilities, that she or he was a victim of crime. This process could easily be adapted to vaccine-compensation cases.[545] Applicants/claimants would not have to prove that the vaccine causes injury, which is the impossible task required in Canadian courts today, but they would have to demonstrate prior good health and serious injury or death following immunization. The following suggestions, based upon the Ontario Criminal Injuries Compensation[546], might serve as an initial model upon which to base a Canadian vaccine injuries compensation scheme.

> [1] The Vaccine Injuries Compensation would provide compensation to those persons directly affected by a serious injury or death resulting from approved or experimental vaccines. Both existing and future cases will be compensable.
>
> [2] The injured person, or those persons financially responsible for the injured person, will qualify for compensation. In the case of death, dependants will qualify for compensation.
>
> [3] The adverse event should first be reported to the physician who must then report the incident to the local Medical Officer of Health and the Laboratory Center for Disease Control. The LCDC must then retain adequate records of all adverse events which should be available to the public, in annual reports, while retaining patient anonymity. Individuals can then contact the Compensation Board for inquiries and to receive an application form.
>
> [4] The application form should be submitted within 3 years[547] of the onset of symptoms (e.g. acute neurological symptoms, paralysis, and etc.) and/or the diagnosis of injury. This will not preclude latent infection or long term immune malfunction. Only after mandatory adverse event reporting has

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[545]To be sure, if the vaccine-related injury or death results from negligence, the case must be brought before the courts. The compensation scheme would still be applicable to such cases if the negligence suit is dismissed or if the award is insufficient to cover the plaintiff's needs.

[546]Suggestions are based upon The Criminal Injuries Compensation Board's Guide to Applicants (Toronto: Criminal Injuries Compensation Board, n.d.).

[547]The suggestion for a three-year limit on applications is purely arbitrary and merely represents an inexact average between the UK (6 years) and US (1 year) intervals.

produced adequate temporal:causation assessments, will the timing of the onset of symptoms be limited.[548] Once limitations have been imposed, it will still be possible to have applications assessed to determine extenuating circumstances; the viability of a hearing will be made based upon the application.

[5] Applicants need not retain legal counsel but are welcome to do so. Moderate compensation for legal expenses and disbursements will be awarded, regardless of outcome, providing the claim was made in good faith.[549]

[6] Compensation could include:

(a) Actual and reasonable expenses incurred as a result of the injury or death; such as, medical and therapeutic expenses, prescriptions, prosthetic devices, funeral expenses, etc. Personal expenses (e.g. clothing) are not compensable.
(b) Net salary or wages lost due to the injury/death or due to the necessary care of the injured person.
(c) Monetary loss incurred by dependants as a result of injury or death.
(d) Pain and suffering for injuries sustained.
(e) Other monetary expenses including: expenses to attend the hearing and obtain documents, interpreter and witness fees. Benefits received from other sources will not be duplicated in an award.

[7] Prior to the hearing, the applicant or counsel must provide necessary documentation to support the claim. Proof of prior good health, immunization and subsequent injury (e.g. medical reports), proof of expenses and lost earnings will be required. The question of whether the injury was caused by the vaccine will be based upon the balance of probability.[550]

[8] Initially the application will be assessed to determine whether the claim falls within the terms of legislation. Negligence cases may still be addressed by the Canadian Court system but do not necessarily preclude compensation from the Board if the Court award is insubstantial or if the case is dismissed. After all

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[548]In the meantime, it would perhaps be prudent to survey international tables to determine presumptive causation. Some initial standard must be set in order to handle cases efficiently and expediently, when possible. A final table need not be established until the mandatory adverse event reporting provides sufficient data.

[549]The majority of the award is intended to go to the injured person(s) and not to legal fees. Legal fees would be greatly reduced, in comparison to court cases, in that the hearing should typically last only one day.

[550]Individuals do not have to prove that the vaccine can cause particular injuries, as the courts require, but they must show that the injury did not occur prior to vaccination. In other words, if a child had no clinically obvious and related abnormality prior to immunization, the balance of probability would suggest that the injury resulted from the vaccine.

of the necessary documentation has been submitted to the Board, a hearing will be scheduled. The hearing will be conducted by members of the board and a timely response will be provided to the applicant. The board will provide a written statement, explaining grounds, if the claim is disallowed.

[9] An applicant can appeal the Board's decision. Appeals will be reviewed by a 3-member tribunal. In the event of new and significant evidence, a disallowed claim may be reviewed at any time.

Obviously such a program would require significant funds to provide adequate compensation for all of the cases judged favourably. A significant portion of the finds required would likely come from tax revenues but a fairly large portion should be recoverable from the vaccine manufacturers themselves. This sort of program could free up a significant amount of money since the vaccine manufacturers would avoid enormous litigation costs. A percentage of the profits from each vaccine could be collected as a surtax that would be applied directly to the program. As an incentive to provide the safest product possible, the surtax could be variable, to be determined on a yearly basis, depending upon the number of claims awarded and depending upon the percentage of cases that arise from the particular manufacturer's vaccines.[551] Undoubtedly, this would have the added advantage of encouraging manufacturers to discover and provide the safest products possible.

Ideally, immunization should protect individuals from disease, confer long-lasting immunity and protect contacts from disease, without imposing serious risks to the

[551]This would provide some protection to a manufacturer whose vaccine causes fewer adverse events than their competitor. If a particular vaccine is found to cause an extraordinary number of adverse events, the manufacturer should be responsible for a larger percentage of the funds required for compensation, otherwise there will be little incentive to produce safer vaccines.

health of the vaccinee.[552] This idyllic situation does not exist. That serious vaccine related-adverse events do occur is not disputed. It seems reasonable to assume that if individuals are unduly burdened as a result of immunization, an act performed for the utilitarian good, a just society should attempt to balance the inequity by providing compensation.

The initiation of a mandatory adverse event reporting system and of a compensation scheme should have positive effects upon issues previously discussed. They should provide a better understanding of the harm versus the benefits incurred by vaccines, based upon the experience of the whole of society versus the limited experience of clinical trial participants, and this information could be used to guide vaccine production and recommendations. If a particular vaccine is demonstrated to be ineffective and/or to cause serious reactions, the manufacturer could be directed to make changes to the vaccine and, until a more efficient and safe product is produced, health officials could and should alter their recommendations. Furthermore, both health care workers and the general public will benefit from a more accurate assessment of vaccine-related risks and benefits, facilitating a more informed and voluntary consent process. Finally, mandatory adverse event reporting, coupled with a no-fault compensation scheme, will equalize the benefits and the burdens shared by a truly just society.

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[552]Cf. National Advisory Committee on Immunization, Canadian Immunization Guide, 1.

CHAPTER VII
ADDITIONAL CONSIDERATIONS, SUMMATION AND CONCLUSIONS

1. ADDITIONAL CONSIDERATIONS

Technological ability appears to be one of the major forces shaping the new vaccine frontier. As we become more technologically advanced, we appear to be becoming less tolerant of our inability to control disease, including minor uneventful diseases, and we look to science to solve life's inconveniences, along with our more serious ailments, quickly and cheaply. The future of vaccine development concerns everything from the profound to the absurd to the downright dangerous. In the realm of the profound, researchers are developing vaccines that will augment antibody and/or T cell responses against pathogens (e.g. cancer and HIV/AIDS) that the body has difficulty recognizing and, against which, has difficulty in eliciting an effective immune response. These *therapeutic* vaccines seem to fall into a new category that lies somewhere between passive and active vaccines. They are not preventives, although preventives have been attempted, instead they are meant to treat individuals

with existing infections. They may well provide a somewhat less toxic alternative to current treatments.[553]

In the realm of the absurd, researchers are continuing to develop vaccines for completely innocuous diseases such as chicken pox. The absurdity of this type of research, aside from wasted resources, lies in the fact that the vaccine will assuredly disable and kill vaccinees, raise the average age of infection and defeat passive immunity - all to prevent a disease that presents no health risk.

In the realm of the downright dangerous are *preventive* HIV vaccines, edible vaccines (which share the absurd category, as well) and contraceptive vaccines. Each of these three vaccines, in one form or another, have reached the testing stage, either on humans or in animals. The future prospects, which will be discussed forthwith, have frightening health and ethical implications.

Modern technological ability will affect immunization in another potentially threatening way: immunization tracking systems and "smart cards" will provide a means, not only to maintain accurate immunization and recall records for which they are designed but, to oversee and influence personal health care decisions. In other words, private medical information may become accessible to both private and public sector interests breaching patient privacy. Furthermore, vital services may be denied to individuals on a variety of levels if they refuse immunizations. This has already

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[553]The typical treatments used for cancer and HIV/AIDS patients are extremely toxic. At some future point, surely it will be acknowledged that our current treatments are rather barbaric but they are the best that conventional medicine has to offer at the moment. The new vaccines may be a step toward replacing the highly toxic treatments currently used but they cannot be the final step because they too will contain toxic and pathogenic elements.

occurred in some areas. In the following section, ethical implications concerning the new vaccine frontier, followed by immunization tracking systems and smart cards, will be discussed. A general summation, of material presented throughout this study, and conclusions will then be presented.

The New Vaccine Frontier

Contraceptive Vaccines

Immunological approaches to fertility control, in the form of contraceptive vaccines, marks one of the new frontiers in vaccine research. This new approach was precipitated by scientific discoveries, made during the 1960s, which unveiled the complex interactions between the immune and reproductive systems.[554] For over 20 years, many attempts have been made to interfere with fertilization or to "immunoneutraliz[e]" the reproductive process "by inducing antibodies against oocytes [incompletely developed ovum/egg], ...spermatozoa," hormones essential to reproduction and placental antigens.[555] One formulation which appears to hold particular promise, and has already been tested upon a number of individuals, is an anti-hCG contraceptive vaccine combined with either a tetanus toxoid or a diphtheria toxoid.

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[554]Camille Charney, "History of Research and Development of the Anti-Fertility Vaccine: The Filipino Assault" [draft] (Ottawa: Human Life International, forthcoming), 3.

[555]D. W. Hahn, J. L. McGuire, and Gabriel Bialy, "Contraceptives," in Encyclopedia of Chemical Technology, 4th ed., vol.7 (New York: John Wiley & Sons, 1993), 243.

In early pregnancy, the hCG (human chorionic gonadotrophin) hormone is secreted by the placenta effectively "preparing the uterus to accept the fetus immunologically" and forestalling menstruation.[556] HCG is necessary to sustain pregnancy. Normally, the body would not create hCG-specific antibodies because hCG is a substance that would be identified as *self* by the immune system. "Linkage to a [tetanus or diphtheria] carrier was done to overcome the immunological tolerance to hCG."[557] Carriers capable of evoking an immune response, such as the tetanus or diphtheria toxoids, are combined with hCG causing the body to elicit an immune response against the combined molecule. Two types of antibodies are then produced: one against the tetanus or diphtheria bacteria and another against the hCG hormone. HCG-specific antibodies induced by the vaccine decrease the level of hCG to the extent that a pregnancy cannot be maintained by the body. Pregnancy is not prevented, rather, it is aborted.

Contraceptive vaccines promise to provide an inexpensive, reversible, long term method of birth control, that will eliminate user failure (i.e. unplanned pregnancy resulting from inadequate or improperly used contraceptives). Many ethical questions have arisen about the use of the anti-hCG vaccine. Certainly the abortion of viable pregnancies cause grave concerns for religious and pro-life adherents; this fact is

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[556]Anderson et al., Mosby's Dictionary, 326, 684.

[557]James A. Miller, citing a paper delivered at the 4th International Congress of Reproductive Immunology (Keil, West Germany, 26-29 July 1989), Are New Vaccines Laced with Birth Control Drugs? (originally published in HLI Reports, Human Life International, Gaithersburg, Maryland; June/July 1995, Vol.13 no.8) New Atlantean News. (Cf. http://www.new-atlantean.com/global/birthcom.html)

undisputable. There are, however, less obvious ethical concerns associated with this vaccine that require investigation. In particular, the risks associated with this vaccine may well outweigh any proposed benefit: the safety and efficacy of the vaccine has not been satisfactorily demonstrated and, as a sole means of birth control, the vaccine simply cannot prevent sexually transmitted diseases. Furthermore, this vaccine can be, and has been, used as a means of population control, without the informed consent of vaccinees.

The efficacy of the anti-hCG vaccine as a contraceptive must be called into question. The vaccine "produces antibodies to hCG six-to-eight weeks after vaccination" but the number of detectable antibodies appear to decrease significantly within six months.[558] Multiple boosters are often required in order to ensure prolonged contraception in some individuals. As with any vaccine, artificially induced antibody response varies among individuals. Conception during the initial or waning periods may occur and the results are likely to prove disastrous. If a child is conceived during the initial period, spontaneous abortion is virtually guaranteed. If, on the other hand, conception occurs during the waning period, abortion or congenital abnormalities may result and/or a child may be born into a family where she or he is not welcome.

The fact that the effects of the anti-hCG vaccine presently appear to be reversible does not eliminate the potential for the permanent destruction of hCG-tolerance in some individuals, thereby eliminating any future chance for viable pregnancies. The anti-hCG vaccine is designed to elicit an immune response *against* one of the body's

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[558]Jegede et al., 635.

natural elements. It causes the immune system to identify the hCG hormone as foreign and to attack itself. This action essentially imitates auto-immune diseases. Based upon experience with currently identified auto-immune diseases, it seems fairly clear that once the state of self-tolerance has been quelled there is a minimal chance of reversal. To be sure, not all recipients of the hCG vaccine will be prone to such an auto-immune response, but the possibility remains viable and there is no way to determine an individual's susceptibility at this point in time.

The anti-hCG vaccine presents another health risk, not inherent to the vaccine preparation itself but, in its use as a sole means of contraception. Conception no longer stands as the sole concern of partners engaging in sexual activity; sexually transmitted diseases must rise to the forefront of such concerns. It is without a doubt that the vaccine cannot prevent the spread of HIV or any other sexually transmitted disease. The concern that arises with the vaccine, that may well be peculiar to this form of contraception, is the purported efficacy of this method. With other forms of birth control it is generally understood that there always remains a possibility of conception: manufacturers generally alert users that they should utilize more than one form of contraception. For example, condoms are often recommended in tandem with artificial hormone supplements. One wonders, however, whether the added protection will be neglected if people become over-confident with the vaccine's efficacy? Certainly, if the contraceptive vaccine is made available to the general public, some form of caution must be expressed clarifying the need for protection against sexually transmitted diseases.

One of the most important ethical considerations to arise with the introduction of anti-hCG contraceptive vaccines, which utilizes diphtheria and/or tetanus toxoid carriers, is the potential for the vaccine's unethical use. Because the vaccine promises to provide an inexpensive means of population control, and because the contraceptive components can be hidden in vaccines typically used en masse, the vaccine could be administered to countless unsuspecting and non-consenting women. To be sure, population control has become an important issue in recent years, especially in areas where natural resources are insufficient to support huge populations. Indeed efforts should be made to educate and assist persons with contraceptive methods but ethical problems arise when birth control is taken out of the hands of the individuals concerned. This concern is hardly as speculative as it sounds. HCG vaccine trials have already been initiated amongst uninformed and non-consenting women in the Philippines, Mexico and Nicaragua.[559]

Consider, for example, the World Health Organization's recent strategies to eliminate neonatal tetanus world-wide. Neonatal tetanus appears to present the greatest problem in developing countries due to unsanitary birthing conditions, attendants who do not adequately wash their hands, and to unhygienic birthing practices, found among

[559]It should be noted that a number of other clinical trials were conducted using this vaccine. In India, for example, a number of clinical trials were carried out amongst women apparently informed that the vaccine was contraceptive in nature. In two note-worthy trials, it was found that 2 of 6 women became pregnant (1974-1976 trial) and that 26 of 88 women became pregnant (1976-1978 trials) during the vaccine's waning period. In the latter case, only 4 of the women carried their pregnancies to term and delivered normal babies. Cf. Charney, Appendix I.

some cultures, which include applying animal dung to the umbilical stump.[560] In 1991, the World Health Organization released their plan to "eliminate neonatal tetanus by 1995."[561] The plan included immunizing every woman of child-bearing age, regardless of whether she was pregnant or not, with five doses of the tetanus toxoid (TT) over a period of 2½ years.[562] These recommendations vary greatly with those considered adequate in other countries. In Canada and the United States, for example, tetanus immunizations are recommended only once per decade for all (male and female) previously immunized adults and preceded by three-doses administered in one year for all unimmunized adults.[563] Both Canadian and US authorities recommend only two doses for previously unimmunized pregnant women.[564] The WHO program, however, recommends the following tetanus toxoid immunization schedule for women of childbearing age living in regions where neonatal tetanus presents significant problems:

TT-1 at first contact
TT-2 at least 4 weeks after TT-1
TT-3 at least 6 months after TT-2
TT-4 at least 1 year after TT-3
TT-5 at least 1 year after TT-4

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[560]Steven G. F. Wassilak, Walter A. Orenstein and Roland W. Sutter, "Tetanus Toxoid," in Vaccines, ed. Stanley A. Plotkin and Edward A. Mortimer (Philadelphia: W. B. Saunders Company, 1994, 66.

[561]The Expanded Programme on Immunization actually began in 1974. In 1991, however, it was found that immunization coverage against neonatal tetanus remained unsatisfactory (33% uptake) and a particular plan was considered to address under-immunized populations. World Health Organization, "Prevent 565,000 Children from Dying of Neonatal Tetanus Every Year," Expanded Programme on Immunization (Geneva, World Health Organization, 1991), 1.

[562]Ibid., 3f.

[563]National Advisory Committee on Immunization, Canadian Immunization Guide, 116; American Academy of Pediatrics, 1994 Red Book, 24.

[564]National Advisory Committee on Immunization, Canadian Immunization Guide, 118; American Academy of Pediatrics, 1994 Red Book, 42.

These recommendations were not followed during WHO's tetanus vaccination campaign in Mexico, the Philippines, and Nicaragua: women were injected with the first three doses of tetanus toxoid within a three month period, which were soon followed by the two latter doses.[565] To make matters worse, the women were injected with the anti-hCG/tetanus toxoid compound vaccine without their knowledge or consent.[566]

The Philippine Medical Association conducted tests on the vaccine and found that 20% of the samples tested positive for hCG.[567] It is interesting to note that Filipino Senator Francisco Tatad stated that, although the highest incidence of tetanus is amongst men, the vaccine campaign in question targeted only young girls and women of childbearing age. Tatad also noted that, following this vaccination campaign, "there was an avalanche of reports of excessive swelling of injection sites together with *unusually high numbers of miscarriages among pregnant women*."[568] Tetanus toxoid boosters are known to cause local and systemic reactions if they are administered more frequently than in ten year intervals so it is not surprising that the tetanus component, all on its own, could account for the swelling at the injection site.[569] Conversely,

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[565]It was reported that health officials "started vaccinating teenagers without their consent and were even going house to house." National Vaccine Information Center, The Vaccine Reaction ed. Barbara Loe Fisher (Vienna, VA: National Vaccine Information Center, July 1995), 2.

[566]Ibid., citing James Miller of *Human Life International*, 1.

[567]Twenty two of the vaccines were manufactured by Connaught Laboratories and twenty two were manufactured by Intervax Biologicals, both Toronto, Ontario firms. Tests confirmed that the vaccines used in Mexico and Nicaragua also contained hCG tied to a tetanus toxoid carrier. Human Life International, Press Release, 31 October 1996; Miller, Are New Vaccines Laced with Birth Control Drugs?.

[568]Human Life International, Press Release, 31 October 1996 (emphasis added).

[569]National Advisory Committee on Immunization, Canadian Immunization Guide, 116.

tetanus toxoid is *not* known to be teratogenic (adversely affecting prenatal development) thus it cannot account for the increase in miscarriages; obviously the anti-hCG component is responsible.

"When the first reports surfaced in the Philippines, World Health Organization and Philippine health officials categorically denied that the vaccine contained hCG."[570] Independent studies, however, demonstrated that vaccine vials indeed contained hCG and subsequent investigation revealed that 27 out of the 30 women tested were found to have "high levels of hCG antibodies.[571] The incidence of high levels of anti-hCG antibodies is highly significant because they simply cannot be attributed to any other factor but the administration of hCG coupled with an antigen intended to evoke an immune response. Confronted with this evidence, WHO then claimed that there were only tiny amounts of hCG in the vaccine; that "hCG is part of the vaccine manufacturing process"; and they suggested that the tests designed to detect hCG are faulty and often produce "false positives."[572] This explanation was not convincing.

The anti-hCG/tetanus toxoid vaccine clinical trials conducted by WHO and the implicated vaccine manufacturers breached numerous internationally recognized ethical standards.[573] The use of this vaccine on uninformed and unconsenting women stands in direct violation of the 1947 Nuremberg Code which stresses the voluntary consent of human subjects. The 1964 Declaration of Helsinki states that "concern for the

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[570]National Vaccine Information Center, citing James Miller, 1.

[571]Ibid.

[572]Ibid.

[573]Cf. Charney, 25.

interests of the subject must always prevail over the interests of science and society" and that potential benefits must outweigh adverse effects to the subject. Most notable, however, is the evident violation of the unanimously passed resolution from the 1968 United Nations Human Rights Conference which states:

> Couples have the right to decide freely and responsibly on the number and spacing of their children and a right to adequate education and information in this respect.[574]

The principles of *respect for autonomy*, *beneficence* and *non-maleficence* have unquestionably been violated. Vaccinees were never informed of the hCG component and therefore neither informed nor voluntary consent was obtained. Vaccinees were never informed that they were being used as experimental subjects nor were they made aware of potential short term and long term risks associated with the new vaccine. This vaccine has the potential to terminate viable pregnancies and to abort future pregnancies for at least six months after administration of the vaccine. The harm from this vaccine may endure over even longer periods of time, perhaps even a lifetime; the effects are virtually inestimable at this time. Furthermore, since those responsible for the vaccine trials refuse to admit culpability, there remains no chance for justice for those adversely affected by the vaccine.

Clearly, this particular vaccine presents enormous opportunities for abuse. If contraceptive vaccine trials can be conducted without the informed consent of the vaccinees, the vaccine presents a viable threat to individuals inhabiting areas where government and health officials are willing to employ radical means to ensure

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[574]Ibid.

population control. It is well known that, in certain areas of the world, foreign aid is dependant upon birthrate reductions and that sterilizations and abortions have been forced upon numerous individuals.[575] The anti-hCG vaccine could provide a valuable vehicle to unethical authorities in guaranteeing compliance to birthrate reduction because the vaccine can be integrated into any compulsory vaccination program without the vaccinee's knowledge. It is interesting to note that this vaccine was designed primarily for use on poor women from Latin American, Caribbean, Asian, African and Pacific countries.[576] The anti-hCG vaccine relegates pregnancy, particularly among impoverished women, into the realm of disease: a disease that can be prevented. Among the other ethical abuses already discussed, one must therefore add social and racial genocide based upon economic status.

Edible Vaccines

Amongst the assortment of new vaccines currently under development, a new vaccine-*type* has arisen from a concept that previously could only be considered a science-fiction novelty: the edible vaccine. "Researchers in the United States are growing potatoes genetically engineered to contain edible vaccines."[577] According to the WHO/UNICEF release, "key genes are inserted into edible plants where they replicate - producing vaccines at a fraction of the cost" of other vaccine-types.

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[575]Ibid., 27; Cf. Horowitz, 163-180.

[576]Charney, 29.

[577]Sheila Davey, State of the World's Vaccines and Immunization (Geneva: World Health Organization), 117.

> Genetically altered food means scientists are moving genes between species- from a [pathogen (e.g. viruses and bacteria)] to a plant and from an animal to a plant - and we are eating the end result.[578]

Although it is current practice to insert plant or animal derived DNA into genetically altered foods, the possibility remains that *synthetic* DNA will be utilized which will undoubtedly "contain bits of genetic code never occurring before in any species."[579] The long term results, of which, are virtually unknown.

Phase I studies have been conducted using cholera/enterotoxic E. coli-altered potatoes on mice; the results indicated that the mice were indeed successfully immunized.[580] Similar studies were conducted using hepatitis B, resulting in what appeared to be a "priming" effect: the mice demonstrated stronger immune responses to "low level immunization with commercial hepatitis B vaccine."[581] Further studies are planned to determine the feasibility of using genetically engineered bananas for hepatitis B, and other vaccines, in an effort to provide cost-effective vaccines for developing countries. Potatoes and soya (to be processed into soya milk) are two other candidates under consideration for genetically engineered edible vaccines.

WHO/UNICEF recognizes that edible vaccines will present certain problems. Questions arise as to whether the new products should be regulated as food or as biologicals and whether it is possible to control, and maintain, consistent dosages?

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[578]Leslie Gillett, "Genetic Alterations Change What You Eat," The Windsor Star, 15 February 1997, 16(D).

[579]Paul B. Thompson, "Food Biotechnology's Challenge to Cultural Integrity and Individual Consent," Hastings Center Report 27 no.4 (July/August 1997): 35.

[580]Davey, 117.

[581]Ibid.

How will the dosages be measured? Is it possible to prevent over-dose? Will policies, procedures, and pricing be the same for developing versus developed nations? One question will remain central to the development and use of edible vaccines: will the general public *ever* accept edible vaccines?

The introduction of edible vaccines marks but one aspect of an unfortunate era when scientific research is continually misused to contaminate the world's food supply. The edible vaccine follows in the footsteps of a series of food products that have been genetically altered, that is- contaminated, with toxic insecticides, antibiotics and hormones. While the product output may have increased by such measures, the cost to general public health and to the integrity of the environment have not been adequately measured.

In Canada there are currently 13 unmarked genetically engineered food products on the market: no legislation exists that would require these products to be clearly labelled as genetically altered.[582] In the US, there are no less than 500 genetically altered foods awaiting approval.[583] It is already known that genetically altered foods can have deleterious effects on the health of persons who ingest them. In one case alone, 37 US citizens were killed, and thousands of others were left permanently disabled, as a result of contaminants derived from genetically engineered bacteria used to produce tryptophan (a food supplement).[584] The transferred genes (proteins) also retain their ability to provoke allergic reactions, even in their less visible state. There can be no

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[582]Gillett, 16(D).

[583]Ibid.

[584]Ibid.

accurate way of predicting the full range of long term affects of edible vaccines. It is entirely likely that they will prove to be no more safe or effective than current vaccines; they will simply be cheaper and they will allow for the enforced vaccination of any herd populace targeted.

The environmental cost of genetically altered foods presents a less obvious, but no less serious, health risk. Cilombo St. Michael, a health activist and researcher, states:

> This is because modified organisms, once introduced into the food chain, can never be recalled from the environment, and will have unlimited and totally unpredictable effects on our health and ecosystems.[585]

In other words, the genetically altered foods used to produce vaccines will have *permanent* effects on our health and environment. We delude ourselves if we believe that we can simply eliminate the pathogens from our food supplies at some future date. The pathogens, and any chemicals used in the production of the vaccines, will enter not only the specified plants, they will also be absorbed into the soil and ground waters, passing on modified genetic information to new generations of vegetation, animals and humans and they will create an unbreakable cycle of contamination and genetic mutation. It is simply impossible to introduce pathogens and poisons into the environment and expect health improvements to result.

The use of genetically altered foods to produce edible vaccines presents a myriad of ethical problems. Edible vaccines have the potential to pollute the otherwise healthy bodies of unsuspecting consumers. They transgress the principles of respect for autonomy on a number of counts. Scientists and governments could decide to treat all

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[585]Ibid.

consumers as patients in need of medical treatment; patient-physician consultation becomes irrelevant, as does informed and voluntary consent. Consumers are currently not informed that they are purchasing genetically altered foods. Many scientists, and the food industry, oppose mandatory labelling because they understand that the informed public will resist buying these products due to what "experts" believe are spurious safety concerns.[586] Can we expect this to change when our food is altered to induce herd immunity? Based upon the evident coercion and compulsion tactics employed in current immunization practices, there seems to be little hope for either informed or voluntary consent if edible vaccines are allowed to reach the market. Respect for autonomy must be preserved by practical measures, including labelling and the availability alternate food choices.

The principles of non-maleficence and beneficence are clearly violated by edible vaccines due to the irretractable contamination of individual health and of the environment. Undue harm cannot be avoided when a populace is vaccinated *en masse* and when the soil becomes irreparably damaged. The promise to do some good seems quite limited to the dollars and cents saved by a cheaper method of vaccine production. There is no way to assure that the mass vaccination of consumers and the modification of the land will, in any way, *improve* health over the long term.

Based upon evidence of compensatory irresponsibility, it is very likely that the principle of justice will fare no better. Compensation for those adversely affected by edible vaccines will become an even more complex issue, involving also farmers,

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[586]Thompson, 38.

grocers, and countless others. The Canadian government has yet to see their way clear to assigning financial responsibility to those involved now; how much more of a problem will this become when responsibility can be shifted amongst a larger group of players? So too, who will compensate the farmers who are left with contaminated fields? Will the fact that the land becomes unsafe actually cause restrictions on its use or will the governments turn a blind eye to the whole affair? The introduction of edible vaccines stands out as one of the more all-encompassing violations of ethical principles known to date: it is an idea that should not be allowed to reach fruition.

Chickenpox Vaccine

The new chickenpox vaccine, oddly enough, is meant to prevent a disease that is relatively innocuous when contracted during childhood except, of course, for those few individuals who have impaired immune systems (e.g. leukaemic children). Like the rubella vaccine, this one is cultured on lung tissue of aborted fetuses. At present, the chickenpox vaccine is very expensive to produce[587] and difficult to store.[588] In the US, marketing of the vaccine, which began in 1995, was delayed due to concerns regarding

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[587]Interestingly enough, Merck Laboratories, the manufacturers of the chickenpox vaccine for North America, conducted a cost-benefit evaluation and found that the vaccine provided no real cost-advantage from medical and health care perspectives. The vaccine is estimated to cost US$39 per dose *wholesale*, while individuals, in the US may pay between $60 to $100 per dose. The only cost-benefit would be for parents who might otherwise lose wages to stay home to care for their sick child. It has been estimated that the $400 million would be saved in lost wages, in the US alone but, as impressive as this sounds, the savings would actually amount to about $2 per American. Cf. Kristine M. Severyn, "Is Chickenpox Vaccine a Good Idea?" Dayton Daily News, 3 June 1995, A13; Stanley A. Plotkin, "Questions About Varicella Vaccine," Pediatrics 98 no.6 (6 December 1996): 1226; Peter L. Hurst, "Questions About Varicella Vaccine," Pediatrics 98 no.6 (6 December 1996): 1225f; Arthur Lavin, "Varicella-Zoster Vaccination for Health Care Workers," The Lancet 343 no.8909 (28 May 1994): 1363.

[588]Schabas, Opportunities, 15.

the vaccine's safety and efficacy. Essentially, the injection of this live mutant strain of herpes virus, into millions of children, has the potential to cause herpes zoster (shingles), or to delay the onset of the natural infection until adulthood, where the disease becomes quite dangerous.[589] The long term risks are presently inestimable.

> As is well known, herpes viral DNA insinuates itself into the human genome[590] for the lifetime of a host. Presumably, the same would be true of a varicella virus altered for immunisation purposes. [591]

In other words, once the varicella virus has been injected into the body there remains the chance that the latent virus will become activated at some future time as herpes zoster (shingles).

Prior to the 1995 licensure of the varicella vaccine in the US, it had already been established that herpes zoster can indeed result from the vaccine. In 1987, for example, two normal children, both vaccinated in July of 1983, developed fevers and painful-itchy lesions that were confirmed as zoster.[592] Previous Japanese experience confirmed cases of vaccine-related zoster amongst leukaemic children (primarily) and among normal children.[593] Post-vaccinal zoster *appears* to be milder than that following natural infection, however, one must wonder whether individuals, who would

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[589]Severyn, A13; Lavin, 1363.

[590]"Genome" refers to "the complete set of genes in the chromosomes of each cell of a particular living organism," Anderson et al., Mosby's Dictionary, 665.

[591]Lavin, 1363.

[592]Stanley A. Plotkin et al, eds., "Zoster in Normal Children After Varicella Vaccine," The Journal of Infectious Diseases 159 no.5 (May 1989): 1000.

[593]Ibid.

never have developed zoster otherwise, would take comfort in the fact that they must endure "mild" episodes of vaccine-induced zoster.

That vaccines can increase the average age of infection, has been clearly established with the measles and mumps vaccines. The chickenpox vaccine appears to be yet another means to prevent innocuous diseases in childhood only to defer them to adulthood. Considering the fact that chickenpox is relatively harmless, it seems imprudent, if not downright unethical, to inject healthy bodies with yet another set of antigens and chemicals that will predictably result in a greater number of adult infections and fatalities and burden countless people with herpes zoster. The chickenpox vaccine stands as yet another example of techno-scientific hubris overruling prudence and utility.

Cancer Vaccines

While there is still much to learn about cancer, it is known that "cancers arise because DNA in the cell of some particular tissue is altered by a chemical or physical influence called a carcinogen" and the involved cell appears to replicate uncontrollably.[594] In a process called *metastasis*, these new cells enter the blood

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[594]Certain proteins have recently been discovered which may provide important clues in the understanding and treatment of cancers. One protein called *thioredoxin*, which stimulates cell growth, "has been found to be elevated in many cancers." Another protein called *P-glycoprotein (p170)*, which is found in normal cells, but is "upregulated" in cancerous cells, appears to have an effect upon whether or not chemotherapy will be successful. Some cancers are resistant to chemotherapy and tests indicate the presence of *p170*, or similar proteins, may be the cause. This is precisely the case with retinoblastoma (a rare eye-tumour found in newborns and young children. Previously, retinoblastoma could only be treated surgically (leaving some children blind) or by radiation (which left more than one third of the children with secondary tumours), but the discovery of *p170* has led to the discovery of a new treatment: an immunosuppressant, *cyclosporin*, which overcomes the drug-resistance

vessels and, although most will be destroyed en route, some may implant themselves in other tissues.[595] Cancer cells appear to be able to elude the mechanisms that normally initiate an immune response and they somehow inhibit apoptosis- the process by which the immune cells kill infected cells. Many types of cancer have been associated with exposure to carcinogenic chemicals, cigarette smoke, ionizing radiation (e.g. x-rays) and ultraviolet rays.[596] The high incidence of malignant tumours found in organ recipients after immunosuppressive therapy indicates a strong link between immunodeficiency and cancer.[597] Other types of cancer have been associated with infectious agents.[598] In the latter case, except with the possible exception of HIV and Epstein-Barr, viral links to cancer have been difficult to establish in humans. In animal tests, it has been found that many viruses induce malignant tumours but, even

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(chemotherapy-resistance) caused by *p170*. In newly diagnosed cases, long term cure has reached 94% with this treatment and in other cases, that previously did not respond to chemotherapy, there has been an approximate cure rate of 60%. It is believed that other, similar, proteins may account for the continued resistance in those who still do not respond to the treatment. Multi-drug resistant proteins have been found in many other forms of cancer including "rhabdomyosarcoma [most frequently in the head and neck but can occur in many areas], osteogenic sarcoma [bone], Ewing's sarcoma [bone marrow], leukemia, lymphoma, myeloma [bone marrow/ many sites] and breast cancer." Canadian Cancer Society, "Cancer Research Across Canada: What's Happening," Progress Against Cancer 51 no.1 (April 1997): 9f; Anderson et al., Mosby's Dictionary, 1366, 1130, 582, 1033.

[595]The cells may be destroyed by something as simple as trauma induced by blood circulation or as complex as an immune response mounted against the original tumour. Sherwin B. Nuland, The Wisdom of the Body (NY: Alfred A. Knopf, Inc., 1997), 49.

[596]Genetic susceptibility to cancer also may be suggested by the frequency of tumours found within some families.

[597]Anderson et al., Mosby's Dictionary, 247.

[598]It is estimated that between 15 to 20 percent of cancers are viral in origin. These include: "cervical, liver, nasopharyngeal (nose and throat), Burkitt's lymphoma [(which may be found in the jaw or abdomen)] and kaposi sarcoma (AIDS related). Canadian Cancer Society, 10.

then, the virus particles may not necessarily be found within the tumours themselves.[599] Still, it is the virus-induced cancers that provide the most likely candidates for vaccine research because the antigen:immune system response is better understood and because the more cost-effective virus vaccines are easier to produce and administer.[600] The bad news here is that since viral cancers are rather limited in the developed world, as opposed to Africa and Asia where virus induced cancers comprise 40-50% of cancer mortalities, the vaccines may be too expensive for those who need them most.[601]

The quest for an efficient cancer vaccine has met with many challenges. Foremost among the challenges faced by researchers are the facts that even one single type of tumour can present many different antigens, some do not appear to present identifiable antigens, and that humoral (antibody) based immunity appears to be effective only in *detecting* tumour antigens but ineffective in *preventing* the formation of cancer.[602] In mouse tests, for example, it has been demonstrated that passive immunity against

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[599]For example, when the first IPV was tested in hamsters there appeared to be no untoward effects. However, within 130-327 days post-inoculation, 42 of the 151 hamsters tested developed tumours. Already thousands of people had received the vaccine. No virus was detected in the tumours but their serum contained antibodies that detected tumour antigens. Scientists then used the antibodies to detect the virus (SV40) in the primary monkey-kidney cell cultures used as the host tissue in poliomyelitis vaccine production. Levine Viruses, 91.

[600]John S. Cole and Jack Gruber, "Progress and Prospects for Human Cancer Vaccines," Journal of the National Cancer Institute 84 no.1 (1 January 1992): 21.

[601]Ibid. Vaccines, vitamins and therapeutics which may be easily affordable to the developed world are often too expensive for developing nations. Despite the efforts of UNICEF, who have managed to reduce some prices through agreements with manufacturers, necessary donor funding has been difficult to attain. The effect has been two-fold: manufacturers tend to abandon the development of drugs and biologicals that would be too expensive for poorer markets and, even if they are made available, the drugs and biologicals rarely reach the poorer nations who need them the most. Cf. Davey, 6-10.

[602]Cole and Gruber, 20; Levine, 89f; Alan N. Houghton, "On Course for a Cancer Vaccine," Lancet 345 no.8962 (3 June 1995): 1385.

cancer can be conferred only by the cells, versus the serum (typically used in passive immunizations), fractionated from the blood of another immune mouse.

There is an inherent implication here that any proposed *preventive* (active) vaccine against cancer may be utterly useless.[603] By their very nature, both passive and active immunizations are intended to elicit an antibody response. Active (preventive) immunizations are meant to induce the production of antigen-specific antibodies, thereby causing a rapid and effective immune response, should the antigen be encountered naturally. Passive immunization, on the other hand, utilizes pre-formed antibodies to boost an individual's immune response after exposure to an antigen. The fact that there are numerous types of antigens[604] associated with cancer, some not recognized by the body as being *non-self*, means that the quest for a cancer vaccine presents complexities not encountered in other areas of vaccine research. Scientists have struggled with the enormous task of creating a vaccine, i.e. mimicking the natural immune response, for an antigen that often appears to go unrecognised (as *non-self*) by the immune system.[605]

Some of the vaccines currently under development are not intended to prevent cancer but to reduce the chances of recurrence after surgery and chemotherapy and/or

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[603]Preventive vaccines, while not discussed here, are under development. Primarily they appear to address viruses that are know to cause cancer in certain individuals. It is believed that, if chronic carries states (eg. as with hepatitis B and C) can be avoided through preventive vaccines, associated cancers will be avoided. Still, since vaccines introduce carcinogenic chemicals and animal viruses into vaccinees, some question remains as to whether preventive vaccines will cause cancer in vaccinees, who otherwise would have been cancer-free, or whether they will merely result in a "trade off" of one type of cancer for another?

[604]It has been said that "cancer isn't just one disease, it's several hundred..." Canadian Cancer Society, citing Dr. Grant McFadden, 11.

[605]Houghton, 1384.

to cause a regression of tumours.[606] These new genetically engineered, custom-made, vaccines are prepared from the individual's own biopsied tumour. The cells are propagated in a tissue culture fluid and are then genetically engineered (e.g. inserted into an antigen that *will* be recognized as *non-self*) to elicit an immune response when injected back into the individual's body.[607] This genetic manipulation alters the cancer cells in such a way as to allow the immune system to better recognize them as *non-self*, thereby eliciting an effective immune response.

While all vaccines contain toxic chemicals, this particular vaccine may provide a less toxic alternative to existing cancer treatments. Since pathogens are derived from the individual's own tumour, the vaccine should provide an appropriate treatment.

HIV Vaccines

HIV/AIDS has often been referred to as a plague, an anomaly in the minds of most people, which could hardly have been imagined in this modern era which boasts of so many scientific and medical advances. Yet, despite all of the modern advances, HIV/AIDS currently defies all efforts to cure the deadly disease.[608] Since no cure

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[606]Stanford University Medical Center, "A Cancer Vaccine? Yes, But It Won't Prevent You From Getting Cancer," Healthline (February 1993): 5.

[607]Ibid.; Jennifer Ditchburn, "Tumour-Fighting Vaccine Provides Cancer Patients Glimmer of Hope," Windsor Star, 12 April 1997, 13(A).

[608]This statement requires some qualification in that certain antiretroviral drugs (e.g.zidovudine) may prevent fetal infection in two-thirds of the infants born HIV positive. Still, there appears to be a remarkably low incidence of HIV infection in full term infants born to HIV positive mothers. Infection is evident in only 25% of such infants indicating that there is a high level seroconversion (positive to negative) occurring despite the fact that the fetal immune system is quite immature. World Health Organization, "Update on AIDS," 202.

exists, efforts to prevent infection have assumed a primary role. The search for an AIDS vaccine has been riddled with obstacles. Many attempts have been made but most have been abandoned due to the continual mutations of the disease which render the vaccines useless from the outset. Another obstacle, which delays AIDS vaccine research, is the lack of a suitable animal model for testing the vaccines and for studying immune responses to the disease.[609] It is known that the pathogenesis of the disease differs from other infections, but the pathogenic process is not well understood.[610] Complicating vaccine research even further is the fact that no one really knows what elements of the immune system can actually elicit an effective immune response.[611] Since vaccines are generally designed to imitate the natural immune response to an infection, this current lack of knowledge is highly significant.

Passive immunization has been attempted but the results appear to be useless at best and disastrous at worst. Passive immunity has been achieved in chimps but *only* if administered *immediately* before or *immediately* after challenge with intravenous HIV infection. No protection was noted if the challenge was initiated as early as one

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[609]Davey, 8.

[610]World Health Organization, "Update on AIDS, 202; Christine Grady, The Search for an AIDS Vaccine: Ethical Issues in Development and Testing of a Preventive HIV Vaccine (Bloomington: Indiana University Press, 1995), 87f.

[611]The HIV virus can invade the central nervous system but its primary targets seem to be macrophages and T4 (helper T) cells. Oddly enough, infected macrophages may actually "carry HIV to T4 cells during routine interactions of the two cell types." At the very least, an effective HIV vaccine would have to prevent the virus from infecting both macrophages and T cells. This problem is exacerbated because once the retroviral genes are inserted into a cell, the virus does not necessarily begin to replicate immediately. It may remain dormant and invisible to the immune system. It is difficult, then, to determine exactly which element(s) of the immune system should be stimulated to elicit an effective immune response. Thomas J. Matthews and Dani P. Bolognesi, "AIDS Vaccines," Scientific American 259 no.4 (October 1988): 122.

hour after passive immunization and no protection was afforded to chimps who were challenged by intravaginal infection. In some cases, passive immunization appeared to *enhance* infection.[612] This indicates that, unlike other vaccines, inducing antibodies cannot be the goal of HIV vaccine development. Even killer T cells have been shown to have limited efficacy against this continually mutating intracellular virus, which may not express identifiable antigens on cell surfaces.[613]

A variety of candidate active immunizations have been developed and tested. Unlike other areas of vaccine development and testing, the protocol for HIV vaccine testing has changed: both animal and human trials have occurred *simultaneously*. Since no appropriate animal model can reliably assess vaccine safety and efficacy in humans, human trials have been initiated without predeterminations of vaccine safety and efficacy. *Live attenuated virus vaccines* seem to have been ruled out for HIV vaccine development due to the potential for the virus to revert to its *wild* virulent form and due to the possibility of carcinogenesis.[614] *Inactivated (killed) whole virus vaccines* have been attempted but previous studies with other inactivated retroviral vaccines have indicated that viral enhancement, or more severe clinical manifestations of the disease, have resulted. Still, inactivated HIV vaccines have been used on HIV positive patients in an attempt to slow the progression of the disease, and to inhibit opportunistic infections, by boosting the immune response.[615]

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[612]Grady, 97f.

[613]Ibid., 89.

[614]Ibid., 90.

[615]Ibid., 90f.

Two other types of HIV vaccines are currently under development: subunit and recombinant vaccines. *Subunit vaccines* use one component of the antigen (in this case, the envelope)[616] which should induce and immune response without causing the disease in vaccinees. Subunit vaccines are not as immunogenic as other whole cell vaccines and may not elicit an effective immune response. The subunits themselves may not be detected by the immune system and often must be combined with some other immunogenic element, such as an adjuvant which acts as an antigen and/or causes inflammation.[617] Trials have indicated that the HIV-neutralizing antibodies induced by subunit HIV vaccines last only for a few months, therefore, multiple boosters would be required. Furthermore, subunit vaccines may cause immunodeficiency, autoimmunity or immunotoxicity (inhibition of T cells) in vaccinees.[618]

Recombinant, or hybrid, vaccines insert HIV genetic material into other live viruses (e.g. vaccinia, herpes, adenoviruses) which should elicit an immune response to both viruses at the same time. Recombinant HIV vaccines have certain advantages over other HIV vaccines in that they are relatively inexpensive, stable, have a long shelf life, can be adapted to several different antigens, elicit both humoral and cellular

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[616]The "envelope" is the outermost protein, i.e. *glycoproteins*, of the virus. These glycoproteins bind the virus with certain receptors on the cell membranes facilitating the internalization of viral RNA. Glycoproteins are thought to be important because they have been found on both the virus and on infected cells. It is believed that this is also the element most responsible for mutations, and for confounding the immune system, because they seem to be able to alter their amino acid sequences, causing continual changes. Cf. Matthews and Bolognesi, 122.

[617]Ibid.

[618]Grady, 91f.

immune responses and, depending upon the antigens used, may be administered orally.[619] Still, there is some measure of guess work involved when attenuating the viruses and there is a potential for severe reactions to the viruses used, for both vaccinees and their contacts.[620]

Recombinant vaccines have been used in human trials and these trials provide a good background for an ethical discussion on the testing of HIV vaccines. In one instance, the vaccine was used *therapeutically* on HIV positive patients to enhance their immune response. In another instance, the vaccine was used as a *preventive* on HIV negative children to evoke artificial immunity. Both trials were initiated by French researcher Dr. Daniel Zagury.[621]

In March of 1989, Zagury's medical team initiated experimental vaccine therapy on HIV positive volunteers at Saint Antoine Hospital in Paris. The volunteers had been told that the treatment would either improve their condition or it would do nothing; there was apparently no mention of potential risks.[622] The antigenic component of the vaccine was comprised of three strains of HIV DNA inserted into vaccinia viruses[623], supplied by Robert Gallo through the National Institutes of Health (NIH), and treated

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[619]Oral administration may induce mucosal immunity which does not occur with injected immunizing agents.

[620]Grady, 92f.

[621]It should be noted that Zagury's trials extended beyond the two to be discussed here but these two examples should provide an adequate background for the ethical discussion. For more information on the other trials conducted by Dr. Zagury see: Thomas A. Nairn, "The Use of Zairian Children in HIV Vaccine Experimentation: A Cross-Cultural Study in Medical Ethics," The Annual of the Society of Christian Ethics (1993): 223-243.

[622]John Crewdson, "He Said He Was Doing It for a Good Cause," Chicago Tribune, 14 April 1991, 17 (1).

[623]Vaccinia (cowpox) viruses were used in the smallpox vaccine.

with formaldehyde.[624] The experiment had been approved by French and US authorities but only for HIV positive patients who had no chance of survival beyond one year and who were too ill to benefit from treatment with AZT.[625] The French National Committee on Medical Ethics gave its approval with the condition that they be apprised of results on a case-by-case basis. Approval from the NIH's Office for Protection from Research Risks (OPRR), which would be necessary for the international Zagury-Gallo collaboration, was never sought.[626] None of the authorities were informed that one of the vaccinia virus strains used had never been tested for safety in humans.[627]

Prior to this experiment it was known that the vaccinia virus is dangerous for immunocompromised or malnourished patients. Zagury felt that formaldehyde would effectively neutralize the virus and cause no untoward effects. This mistake has been made again and again by vaccine researchers who fail to learn from past experience. In fact, the formaldehyde did not inactivate the virus sufficiently and three of the volunteers developed necrotizing vaccinia: skin and tissue deterioration caused by the vaccinia virus. The first patient died on March 5th, 1990, followed closely by the

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[624]John Crewdson, "3 Dead in AIDS Vaccine Tests: Fatalities Went Unreported," Chicago Tribune, 14 April 1991, 17 (1).

[625]AZT, also called Zidovudine or Retrovir, is an HIV virus inhibiter.

[626]John Crewdson, "3 Dead," 16 (1).

[627]In fact, even NIH researcher Bernard Moss, who prepared the recombinant virus for Zagury, believed that the virus was to be used in monkeys, not in humans. John Crewdson, "AIDS Vaccine Banned After 3 Die," Chicago Tribune, 16 June 1991, 10 (1); John Crewdson, "Secret AIDS Tests on African Kids Detailed," Chicago Tribune 17 July 1991, 11 (1).

second on July 6th, and the third on October 1st.[628] The deaths were not reported to the proper authorities. Instead, the Zagury team published an article in The Lancet, on July 21, 1990, stating that there had been no deaths, no complications and no discomfort associated with the vaccine.[629] In fact, Zagury and his associates continued to report that the vaccine was safe and effective despite the fact that the level of AIDS virus did not decline in any of the surviving vaccinees.[630]

Three months after the first volunteer died, the experiment was expanded to include more volunteers.[631] In December, Paris dermatologist Jean-Claude Guillaume, who had attended two of the three patients with necrotic lesions, contacted Zagury's team when he realized that the deaths were vaccine related. Guillaume had tested reserved skin samples and found evidence of vaccinia infection.[632] Zagury did not seem to be influenced by Guillaume's request to change their protocol.

In February of 1991, the NIH halted the experiment due to a number of ethical violations. Among other things, over half of the volunteers were being treated with AZT and many did not fulfil the limited-survival criteria.[633] The French government

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[628]Crewdson, "3 Dead in AIDS Vaccine Tests," 16 (1); J. C. Guillaume et al., "Vaccine Nécrotique Après Immunothérapie Chez Deux Malades Attients de SIDA," Annales de Dermatologie et de Venereologie 119 (18-21 Mars 1992): 861.

[629]Crewdson, "3 Dead," 16 (1).

[630]Ibid.," 17 (1).

[631]Ibid., 1 (1).

[632]Crewdson, "Dermatologist Was Correct: Paris Professor Linked Deaths to AIDS Experiment, Chicago Tribune 14 April 1991, 16 (1); J. C. Guillaume et al., "Vaccinia From Recombinant Virus Expressing HIV Genes," Lancet 337 (27 April 1991): 1034f.

[633]Many of the volunteers had not developed full blown AIDS. From available information, the first two men who died had been well enough to expect to be able to continue working for an indefinite period. Crewdson, "3 Dead," 16 (1); Idem, "He Said He Was Doing It for a Good Cause," 17 (1);

investigated, and cleared, Zagury of allegations that he had conducted unethical research on humans subjects.[634] The government did not investigate Zagury's earlier vaccine trials.

Zagury's vaccine trial neglected to follow proper protocols for experimentation on human subjects. Only some of the appropriate authorities were contacted for approval and, even when they were, their conditions were ignored. The risky study was to be restricted to individuals who had no more than one year's life expectancy and who could not be treated with AZT. Had the vaccine demonstrated some improvement in the condition of these patients, the study *then* could have been extended to other HIV positive patients. As it was, this experiment caused undue harm to the three men who died prematurely.

Volunteers were not informed of the possibility of any risks. They were led to believe that the worst outcome would be no change to their present condition. In fact, no benefit was accrued by any of the volunteers. The authorities who might have been able to protect the volunteers were no better informed than the volunteers themselves. The team continually professed the safety and efficacy of the vaccine. Vital information was suppressed and the study was expanded despite the deaths. There was an apparent careless disregard for the lives of the volunteers. Obviously this study violated the principles of respect for autonomy, non-maleficence and beneficence.

Alexander Dorozynski, "French AIDS Researcher Cleared," Science 252 no.5003 (12 April 1991): 203.

[634]Dorozynski, 203.

Prior to this, Zagury tested the vaccine for its preventive virtues. In July of 1986, Zagury inoculated 22 HIV *negative* children from Zaire, ranging from 22 months-18 years old, and he did so without any government approval.[635] Zagury contends that, while he initially did not intend to test the vaccine on children, he was persuaded to do so for compassionate reasons. Later, when replying to allegations of unethical behaviour, Zagury told the OPRR:

> I should stress that in our action we profited by compassionately allowing for the participation of the children. Their fathers had died of AIDS; and their mothers, wasting away because of the same disease, begged us to do something for their children. This inoculation, evidently good, did not bring them either clinical or human harm. All of the children came through the experiment well. Rather than harm, our action proved to be a source of comfort and hope for their families.[636]

When the NIH investigated, Zagury denied that he used any children in his experiment. Later he said that only nine children had been vaccinated. Sometime later, he admitted to inoculating eighteen children. Zagury told the NIH that the children were being "monitored and remain healthy" but he refused to allow the NIH investigators access to his records. When asked to produce signed consent forms, Zagury was unable to do so.[637]

It must be understood that the children would not become infected with HIV through normal contact with their infected mothers and were at no greater risk of becoming infected than anyone else in the region. One must wonder whether the

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[635]Crewdson, "Secret AIDS Tests," 1 (1), 11 (1); Grady, 102; Constance Holden, ed., "Zagury Probe Concluded," Science 260 no.5109 (7 May 1993): 757.

[636]Nairn, 225f.

[637]Crewdson, "Secret AIDS Tests," 11 (1).

mothers, who "begged" Zagury for "comfort and hope," really understood this before providing consent. Was the consent truly informed, and could it be considered voluntary, if indeed the mothers were led to believe that this vaccine was the only source of hope for their children's survival? To be sure, since this was a Phase I trial, Zagury could not legitimately promise that the children would benefit from the vaccine and, most assuredly, they would be exposed to undetermined risks.

> Phase I research, *ipso facto*, exposes experimental subjects to risk, with any direct benefit to a seronegative person being accidental.[638]

Interestingly enough, in published reports of the experiment, Zagury failed to mention that the experimental subjects "were children or how they were recruited."[639] Two scientists involved in the experiment stated that "to their knowledge none of the mothers had AIDS" so there is some question remaining as to who begged who for permission to allow the children's participation.[640] Further, in an interview conducted in 1990, Zagury himself stated that "there were maybe some children" used in the experiment and this was done because "the immune system [in children] is the best."[641] The inherent contradictions in Zagury's statements cast doubt upon the humanitarian motive for involving children in this Phase I study. It seems more likely that the interests of the scientific investigator, to further scientific knowledge with the hope of

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[638]Nairn, 241.

[639]Grady, 102.

[640]Crewdson, "Secret AIDS Tests," 11 (1).

[641]Ibid.

producing the first successful HIV vaccine, superseded the interests of the physician, which are to benefit the patient.

This experiment violated basic experimental protocols and ethics. As with the experiment at Saint Antoine Hospital, Zagury hid vital information from authorities. He apparently gained consent through questionable means thereby flouting the requirements for informed and voluntary consent. Further, he needlessly endangered his "volunteers" while knowing that they may not accrue any benefits from the intervention. HIV preventive vaccine trials should never precede therapeutic trials. Therapeutic trials can determine vaccine efficacy and they will not expose healthy individuals to accidental HIV infection or carcinogenesis.

There is no question that HIV vaccine trials will be risky. The disease is so unpredictable that any HIV vaccine will likely prove to be equally unpredictable, endangering many lives before workable products are discovered. Since there is no appropriate animal model in which to study the disease, or in which to correlate the effects of the vaccine in humans, Phase I human experimentation will continue. The lack of informed and voluntary consent inherent to Zagury's experiments reveal the concern of researchers to attract volunteers at any cost. To be sure, many researchers would be appalled at the ethical violations and would be loath to repeat them, but the potential for ethical abuse has been established.

The epidemiology of HIV seems to be in a class by itself and there is so much left undiscovered. While other vaccines were pursued before the diseases were well understood, HIV vaccine research requires a different strategy. With normal childhood

diseases, recovery is expected to follow natural infection. If the vaccine inadvertently caused the disease, the vaccinee, too, could reasonably be expected to recover. This is not the case with inadvertent HIV infection or with vaccinia infection in immunocompromised or malnourished patients. Furthermore, due to the nature of HIV and to the many unknown variables concerning cell mutations, vaccine-induced carcinogenesis remains a viable possibility. Non-maleficence and beneficence cannot be guaranteed.

Does this mean that HIV vaccine research should be abandoned? To admit that would be to admit that scientific research and ethical behaviour are diametrically opposed. This simply cannot be true. Still, good intentions may be blinded by the drive for advancement, therefore, certain limitations must be imposed on HIV vaccine studies to ensure ethical behaviour. HIV vaccines should be restricted to therapeutic use only. Preventive vaccines have historically been shown to cause as many, if not more, problems than they hope to solve. A preventive HIV vaccine, like other vaccines, may suppress infection but it will not stop infection. As mentioned earlier, all vaccines have the ability to suppress the immune system and this ability may be particularly dangerous when HIV is also present in the vaccine. There is so little known about the disease and about the potential effects of the vaccine that it seems foolhardy, at best, to focus on a preventive HIV vaccine.

Even if appropriate scientific and ethical parameters could be predetermined and maintained for a preventive HIV vaccine trial, there are still unresolved issues to be addressed. Experimental subjects must often rely upon their own health insurance to

cover treatments for adverse effects but many insurers will not cover expenses incurred from experimental procedures.[642] In the case of an HIV/AIDS vaccine, this reluctance may be heightened. For HIV negative volunteers, a "successful" preventive vaccine will produce positive HIV test results (showing the presence of HIV antibodies) and one cannot help but wonder whether insurance companies will refuse coverage for such individuals. Further, who will compensate injured parties and their partners should volunteers succumb to AIDS? Will anyone take responsibility for wage loss due to disease and disability or due to pure and simple prejudice? The problems associated with preventive HIV vaccines are formidable.

The more appropriate avenue of research and trials would follow the example of cancer vaccine research: therapeutic versus preventive vaccines. Trials should be closely observed by external bodies. Since the risks involved with HIV vaccine experimentation are so great, greater involvement of authoritative ethical committees is warranted. Passive involvement will not provide adequate protection for experimental subjects. Had the approval conditions been observed in the Saint Antoine study, it might be assumed that the proportion of good could have outweighed the harm.

Immunization Tracking Systems and Smart Cards

Technological advances affecting immunization are not restricted to the development of new biologicals. Immunization tracking systems and "smart cards"

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[642]Robert E. Stein, "Insurance and Liability Issues in the Development of an HIV Vaccine," Food, Drug, Cosmetic and Medical Device Law Digest 10 (April 1993): 80.

will have important implications for patient privacy and confidentiality. Immunization tracking systems will provide electronic monitoring of immunization status. When an individual enters clinic, for example, attending health care workers can access his or her immunization records to determine whether immunization is appropriate. The tracking system will also allow regular health care workers to provide timely reminders for due immunizations. The tracking system will replace personal immunization records which may be lost and they will provide easy access to health care providers, no matter how often individuals move or change providers.

In Canada, many provinces have some form of provincial or agency tracking however only New Brunswick (HNIC[643]), Manitoba (MIMS[644]) and Nova Scotia (MSI[645]) indicate that they have automated databases currently in use or under development.[646] At present there are no plans to institute a national central registry in Canada. In the United States, however, it appears that a national central registry may be available in the near future.[647] To date, many states are currently using or creating

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[643]New Brunswick's HNIC database is currently incomplete since physicians do not yet have access to the system.

[644]Manitoba's Immunization Monitoring System (MIMS) came into use on January 1, 1988. The immunization status of children born on or after the start-up date will have MIMS records; some children born as early as January 1, 1980 may also have MIMS records.

[645]Nova Scotia's MSI database is currently under development using a new physician database.

[646]Immunization Policy Survey conducted May 1996.

[647]The nation-wide tracking system has been proposed (Cf. *Comprehensive Child Immunization Act of 1993*) as part of the Clinton administration's $1 billion program to vaccinate all US children. The national registry has not been implemented to date. Miller, Immunizations: The People Speak!, 42.

programs that will make such information available to medical personnel, schools, public health departments and the Center for Communicable Diseases.[648]

Concerns relating to the ethical use of immunization tracking systems apply primarily to protection, disclosure and use of the information collected. Ideally, tracking systems should not be accessible to anyone other than attending health care workers and their patients. But, as previous experience has shown, whenever electronic delivery systems are developed, a myriad of "need-to-know" claims arise and the information is shared between a variety of governmental agencies and programs.[649] Furthermore, as Canada moves toward the privatization of many government programs, the private sector, for which no privacy regulations exist[650], may gain access to private medical records. Insurance companies, for example, could access this information and raise premiums for unvaccinated individuals. As the Canadian public health insurance systems are being restructured, private carriers become a real possibility as do the prejudicial effects of more easily accessible medical records.

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[648]The following US states currently have immunization tracking systems in use (those known to be under development will be indicated by an asterisk): Arkansas, Arizona, California, Colorado, District of Columbia, Georgia, Indiana, Illinois*, Indiana, Iowa, Maryland, Massachusetts, Michigan*, Minnesota, Mississippi, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Virginia, Washington and Wisconsin. Other states may have systems under development or in use. Data collected by: Stuart T. Weinberg "Immunization Tracking Systems by Region," updated 24 September 1994. Cf. http://www.he.net/~dvk/imms/tracking.htm

[649]Bruce Phillips, Annual Report: Privacy Commissioner 1995-96 (Ottawa: Canada Communications Group, 1996). The Ontario Ministry of Health, for example, has already announced its desire to integrate its databases with those of the Ministry of Social Services. Ronald H. Smukler, "Ontario's Health Number: A Threat to Privacy and a Solution," Canadian Medical Association Journal 145 no.12 (15 December 1991): 1567.

[650]Only Québec has extended privacy legislation to the private sector.

Medical policing also could result from the tracking systems. It has already been demonstrated that schools, social service agencies, and police have become involved in punishing individuals for refusing immunization. If this information becomes more widely available, then the opportunities for coercion and abuse are expanded. In the US, for example, social rights have been linked with compliance to immunization and participation with immunization tracking systems. Illinois is currently trying to pass a legislative bill allowing immunization records to be used and shared without parental consent.[651] Public state clinics, interestingly enough, provide *both* consent forms and food coupons and they find that individuals "gladly sign consent for [tracking system participation]."[652] The unethical linking of social rights and immunization has been established already. How much easier will it become to deny these rights when private medical information becomes accessible to more agencies?

Furthermore, as many hackers have shown, electronic databases simply are not secure.[653] Unauthorized access and use of the databases seems inevitable. "Smart cards," on the other hand, could *enhance* privacy *if* proper legislation is enacted prior to implimentation. The proposed multi-purpose smart cards are small plastic cards containing microchips capable of storing, retrieving and processing vast amounts of

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[651]Susan Bray, Project Manager, Illinois Statewide Immunization Information System, email inquiry, 19 January 1997.

[652]If consent is attained, the information may be shared with other agencies otherwise the recorded information is restricted to the physician and for statistical use. Ibid.

[653]In a 1994-5 evaluation of the US Department of Defence's information systems, it was found that 88% of the 12,000 defence systems targeted were successfully breached and only 4% of the breaches were detected. Brian Foran, "Information Warfare: Attacks on Personal Information," Address to the 8th Annual Canadian Computer Security Symposium: Business and Security in an Electronic World, Ottawa, Ontario, 2 May 1996.

personal information which would be used to replace driver's licences, health cards (including all medical records), other government identification cards (eg. hunting licences) and, in some cases, may act as debit cards for welfare recipients.[654]

The smart card, like the immunization tracking system, is expected to increase efficiency in record keeping, make personal information more easily accessible and reduce expenditures. It also could allow for the surveillance of card-user activities.[655] There is no doubt that the private sector will become integrally involved in the development and use of the smart card.

> In other words... private sector providers, as components of the government delivery systems, could become repositories of vast databases on Canadians.[656]

The potential for such wide-spread use of vast amounts of sensitive information simply escalates opportunities for leaks and other improper uses of personal data. Smart cards have the potential to act as complete personal dossiers disclosing a lifetime of information to a myriad of strangers and, in the worst case scenario, to act as national identity cards "which petty bureaucrats and police can demand at will."[657] Enormous amounts of personal information will be made accessible through a single point of

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[654]Bruce Phillips, Privacy Framework for Smart Card Applications: A Discussion Paper (Ottawa: Privacy Commissioner of Canada, 1996); Idem, Annual Report: 1995-96, 6f.

[655]Cf. The Privacy Committee of New South Wales, Smart Cards: Big Brother's Little Helpers (Sydney: Privacy Committee of New South Wales, 1995): 35; Tom Wright, Smart Cards (Toronto: Office of the Information and Privacy Commissioner of Ontario, 1993), 26.

[656]Brian Foran, "Privacy in the Electronic World," Address to Access and Privacy: Meeting the Challenges of Change, Toronto, 26 September 1996.

[657]Phillips, Privacy Framework for Smart Card Applications.";Foran, "Privacy in the Electronic World."

entry, "effectively transferring power from individuals to the government": the smart card could prove to be "the ultimate tool of state control."[658]

On the other hand, if proper privacy legislation is enacted *prior* to the development and use of smart cards, they may actually enhance personal privacy in a way not guaranteed by immunization tracking systems: they may allow card users more control over who is allowed to access their personal information and over the type of information retained in their files.[659] Still, it must not be forgotten that, unless stringent and enforceable regulations are implemented, both tracking systems and smart cards could be used as yet another tool to weed out immunization dissenters and to coerce compliance through both public and private sector interests. The challenge for our governments and health care professionals is to develop and implement ethical protocols prior to their widespread use.

2. SUMMATION AND CONCLUSIONS

In this study immunization has been assessed in regard to the bioethical principles of: non-maleficence, beneficence, respect for autonomy and justice. These particular principles have been chosen because of their common application in other areas of medicine. In any discussion involving bioethical principles, it must be acknowledged that no single principle overrules all other principles. Ethical determinations are made

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[658]Barrie McKenna, citing Bruce Phillips, "Your Life on a Chip," The Globe and Mail, 23 November 1995, 7(B).

[659]The Privacy Commissioner of Canada has proposed certain guidelines which should be considered *prior* to the development or implementation of these systems. Cf. Phillips, Annual Report: 1995-96 6ff; Idem, "Privacy Framework for Smart Card Applications."

by balancing and countervailing competing claims of the different principles. For example, a particular medical intervention may be found to violate one principle (e.g. non-maleficence) but may be vindicated by its adherence to other competing principles (e.g. beneficence). Mass immunization policies and practices have been examined in regard to their adherence to the four principles alone and in conjunction with each other. The result demonstrates that current mass immunization policies and practices violate all four commonly accepted bioethical principles in a variety of ways and, from its inception, the threat of physiological and ethical violations associated with mass immunizations were inherent.

To be sure, Jenner's cowpox vaccine, the first in a long line of mass immunizing agents, was far more safe than the prior practice of variolation. Still, despite the known fact that Jenner's vaccine was responsible for a rise in smallpox, and made vaccinees more susceptible to tuberculosis, diphtheria and cancer, mass immunization was forced upon individuals internationally. In this case, and in the case of many other vaccines, it appears that when disease incidence and related morbidity and mortality decline, vaccines are lauded as the cause but, when incidence, morbidity and mortality increase, or secondary infections result, vaccines rarely, if ever, are implicated. Over time, mass immunization has become such a routine part of health care that most individuals have lost the sense that this is indeed an invasive and dangerous endeavour. It is commonly believed that artificial immunity is a superior replacement for naturally acquired immunity.

Prior to the ethical discussion, natural and artificial immunity were examined. While both types elicit immune responses, they do so differently. With natural immunity, a pathogen must successfully evade a series of immune defences if it is to cause disease. The pathogen is continually weakened by the multi-levelled immune system and, therefore, its impact is proportionally weakened. Recovery from a disease results in permanent immunity and has the added advantage of conferring passive immunity to future generations. Artificial immunity, on the other hand, by-passes the secretory immune defences and sends pathogens deeper into the body, effecting a "surprise attack," and utilizing a greater portion of the immune cells than during natural infection. Artificial immunity is temporary and it cannot provide passive immunization to subsequent generations. When artificial immunity wanes, older individuals become susceptible to diseases that *would* have been innocuous during childhood but cause serious health risks in adulthood. Furthermore, as new generations are born without the advantage of passive immunity, younger and younger children succumb to diseases they, otherwise, would have been protected against. The decline in passive immunity also interrupts the process of evolutionary selection so much so that a previously weakened pathogen may become more virulent in an effectively "new" host whose immune system has not been primed naturally. Artificial immunity carries the further disadvantage of introducing toxic chemicals and extraneous pathogens into an otherwise healthy body. From a purely scientific position, natural immunity is far superior to artificial immunity.

From an ethical stance, artificial immunity, induced by mass vaccination, creates a series of serious problems. Introducing toxic and carcinogenic chemicals *en masse* has the potential for long term immune malfunction. In a few cases, these chemicals are more toxic to immune cells than they are to pathogens. They can actually *suppress* the immune system which is contradictory to the very goal of vaccination and in violation of the principle of non-maleficence. Vaccines contain numerous detected *and undetected* pathogens. Vaccines have been found to infect vaccinees, not only with the diseases they were designed to prevent but, with other pathogens within the host tissues that escaped neutralization during the manufacturing process. Barring a few imported cases, the oral poliomyelitis vaccine, for example, remains the sole cause of this paralytic disease in many developed countries. Recent discoveries have also implicated poliovaccines with cancer, respiratory diseases and HIV/AIDS. If this were an isolated example, one might consider this to be a forgivable error, but it is not isolated, rather the effects of pathogenic survival in vaccines have been ignored. The promotion of the measles, mumps and yellow fever vaccines, *despite the potential for retrovirus-infected host-tissues to cause reverse transcription*, merely illustrates yet another violation of the principle of non-maleficence. Vaccines are promoted continually despite their ability to injure and kill a certain percentage of vaccinees. The long term effects are virtually undiscovered as yet but one can hardly expect healthy future generations if we continue to disable present generations with hazardous chemicals and pathogens.

The principle of non-maleficence was found to be violated by the use of risky immunizing agents. Still, since mass immunization is employed for the utilitarian benefits promised, the practice may have been vindicated if the benefits received outweighed the potential risks involved. This was hardly the case, however, since the few benefits, ie. reducing the incidence of many diseases, were attained at a greater cost.

In some cases, it is not even clear that vaccines, rather than administrative changes or the manipulation of statistics, were responsible for the decline in incidence rates. Morbidity and mortality rates associated with many "vaccine preventable" diseases fell into decline long before the vaccines became available. It is true that the incidence of many diseases appear to have declined when vaccines became available but it is also true that many vaccines have caused the average age of infection to increase, thereby creating a greater threat to older persons. It is also true that the vaccines have caused atypical, and serious, forms of previously innocuous diseases to appear. In some cases, notably the measles and mumps vaccines, vaccinees become infected with the natural disease more often than their unvaccinated counterparts. Artificially immunizing entire nations obviously has a cost and that cost must be factored in when assessing the benefits. One simply cannot surmise that mass immunization is an utilitarian benefit based upon lowered incidence rates. One must weigh the benefits of mass immunization against the actual harm caused by the disease, against the prevalence of the disease, and against the adverse effects to individuals and to entire societies caused by mass immunization. Mass immunization has detrimentally altered disease

epidemiology and it has interfered with natural passive immunity. Since the benefits appear to be overshadowed by the risks, mass immunization violates the principle of beneficence as well as violating the principle of non-maleficence.

Since the benefits of mass immunization primarily seem to be reduced incidence rates, and the associated risks incurred by individuals and societies alike appear to be great, individuals *should* be apprised of potential risks before providing *informed* and *voluntary* consent. The principle of respect for autonomy requires that individuals are provided with adequate information, eg. any significant information that may alter their consent decision, and they must be allowed to choose among alternatives without coercion. Herein lies, perhaps, one of the most serious ethical violations wrought by mass immunization.

Whether overt or covert, individuals are continually coerced into submitting to immunization without being fully informed of potential risks. Where legislation mandates immunizations, the principle of respect for autonomy is entirely flouted. In other situations, the principle does not fare much better because enormous pressure to immunize is exerted in advertisements, at school and in hospitals. It has been shown that even where exemptions exist, individuals have been pressured from health care workers, schools, police, and social service agencies to submit to unwanted immunizations. Some regions have even taken to bribing physicians and/or patients to submit to this medical intervention. Perhaps the worst violation against voluntary consent is the restriction of basic civil rights and services for the unimmunized. Certainly there can be no ethical defence for denying the right to education for

unimmunized individuals *except* during an epidemic and only for the epidemic's duration. The current practice of removing immunizations from typical health care settings, and putting teachers in the position of advising health care decisions, is coercive. Immunization then ceases to appear worthy of the regular doctor-patient dialogue that is required for all other interventions and the right to education is threatened for non-compliance. Voluntary consent becomes virtually impossible.

Similarly, informed consent is not remotely possible and this is particularly true for mass immunization campaigns. During routine mass immunizations, individuals at least have the opportunity to consult with their regular health care worker about the appropriateness of the procedure. Still, even in this scenario, it appears to be the case that individuals are not adequately informed of the risks prior to immunization. The information they are given is generally supplied *by the manufacturer*, who stands to gain financially by vaccine revenues, and they minimize the risks. During mass campaigns this problem is amplified. There is no opportunity to consult with the person administering the vaccine in advance and information provided to vaccinees is generally insufficient for the purposes of making an informed choice. These are serious violations of the principle of respect for autonomy.

Honesty and non-coercion would surely provide better results for mass immunization. If people understood the risks, and could submit to, or refuse, immunization without coercion, serious adverse events would very likely be reduced. With the proper information, individuals would be in a better position to determine the appropriateness of immunization based upon individual circumstances.

Since individuals submit to mass immunization for the utilitarian benefits promised, it stands to reason that when an individual suffers serious adverse events there should be some form of compensation. The principle of justice demands that both public benefits and burdens be distributed fairly. In Canada, the principle of justice is violated because public burdens, in this case, are not distributed fairly. Vaccine-injured Canadians are generally left to their own resources to provide for the extraordinary costs associated with vaccine injuries. Only on rare occasions when negligence can be proven can individuals expect any measure of financial compensation.

In most cases, however, no compensation is awarded. This is because vaccine injury cases are *still* handled by the justice system which, by its very nature, requires proof of causation and negligence. The vast majority of vaccine injuries result from approved vaccines that are administered according to regulations. There is no opportunity, therefore, for compensation claims to succeed in Canadian courts. The compensation process is further obstructed by the horrendous lack of non-biased studies on vaccine-associated adverse events and the voluntary nature of Canadian adverse event reporting. Injured individuals should not need to be in possession of scientific data to support their case. Nor should they be penalized because the experts have failed to provide definitive findings. Information on adverse events is unreasonably difficult to obtain. Denying compensation for vaccine induced injuries creates an imbalance in the distribution of public burdens which, most assuredly, is in violation of the principle of justice. The only solution appears to be mandatory

adverse event reporting coupled with a no-fault compensation scheme, as found in a number of other countries.

Current mass immunization policies and practices violate the bioethical principles of *non-maleficence, beneficence, respect for autonomy* and *justice*. In most bioethical discussions, one generally finds that the violations are not unilateral, as they are here. One expects to find that competing claims made by different ethical principles require balancing to accurately assess any particular issue. This study was undertaken with that goal in mind. As the study developed, however, it became increasingly clear that the violations inherent to the current practice of mass immunization affected all four of the bioethical principles discussed. In no case did the competing claims of one principle contest the claims of another. None of these bioethical principles, which are commonly observed in all other areas of medicine, have been observed in mass immunization. It must be concluded, then, that currently accepted mass immunization policies and practices are ethically indefensible.

APPENDIX A
VACCINE AWARENESS GROUPS AND RESOURCES

Canada:

Vaccine Risk Awareness Network
P.O. Box 169
Winlaw, BC V0G 2J0
(250) 355-2525
(416) 280-6035 (5 minute message & answering machine)
email: eddawest@netidea.com

The Vaccine Risk Awareness Network, formerly known as Vaccine Risk Information & Alternatives Resource Group (VARIANCE), publishes a quarterly newsletter entitled VRAN News. VRAN incorporates specifically Canadian, and international, materials in their newsletter.

United States:

The National Vaccine Information Center
512 W. Maple Avenue, #206
Vienna, VA 22180
(703) 938-DPT3
(703) 938-5768 (Fax)
website: http://www.909shot.com
email: info@909shot.com

The National Vaccine Information Center is operated by *Dissatisfied Parents Together* and publishes a bi-monthly newsletter entitled The Vaccine Reaction. They also regularly provide information on vaccine "hot lots" which are found to be extraordinarily reactogenic.

New Atlantean Press
P.O. Box 9638
Santa Fe, New Mexico 87504
(505) 983-1856
website: http://www.new-atlantean.com/global
email: global@new-atlantean.com

New Atlantean Press offers a comprehensive selection of well researched vaccine-related materials. A number of their books were often found to be recommended by independent vaccine awareness groups.

Ohio Parents For Vaccine Safety
251 West Ridgeway Drive
Dayton, OH 45459
(937) 435-4750

England:

The Informed Parent
19 Woodlands Road
Harrow, Middlesex, England
HA1 2RT
Tel/Fax 0181 861 1022

The Informed Parent publishes a quarterly newsletter incorporating international findings on vaccines.

Australia and New Zealand

Health Care Reform Group
P.O. Box 421
Glebe, New South Wales 2037
Australia

Immunization Awareness Society
P.O. Box 56-048
Dominion Road
Auckland, New Zealand
Phone 0-9-303-0187
Fax 0-9-424-4144
Website: http://www.netlink.co.nz/~ias.htm

The Immunization Awareness Society publishes a quarterly newsletter incorporating both national and international information relating to medical and legal concerns associated with immunization. IAS provides extensive, well-researched, information to promote public education, as well as, informed and voluntary consent.

Belgium:

The International Vaccination Newsletter
Krekenstraat 4, B-3600, Genk,
Belgium
(Attn: Dr. Kris Gaublomme)

The International Vaccination Newsletter is published quarterly. The newsletter contains both international findings on vaccines and interviews with well respected vaccine researchers. This newsletter provides one of the most complete lists of international vaccine awareness resource groups available.

Throughout the world, many vaccine awareness and resource groups have been initiated by physicians, practitioners of alternative and natural medicine, parents, whose children have been adversely affected by vaccines, and individuals who have become aware of the risks associated with vaccines. Primarily, these groups are concerned with providing information so that individuals are adequately equipped to make informed decisions about immunization. Clearly, most information available to the general public is limited to the benefits proposed by immunization. Vaccine awareness groups try to balance the information by providing an alternate perspective to the biased materials generally received by the public.

Most groups will publish a newsletter, some have developed websites, and all try to lend support to individuals whether they decide to immunize or not. Their scope is quite broad. Generally, in the newsletters one will be able to access both medical and legal aspects of immunization, international and personal experiences with certain vaccines, proposals for new vaccines and information about which vaccines tend to be the most reactogenic. A thorough examination of the above materials has indicated that the newsletters are very well researched. Some provide more specific documentation than others but the information provided was easily verified. Group representatives gladly shared their resources upon request.

It is important to note that these groups acknowledge vaccine induced injuries, providing both support and assistance to individuals who, otherwise, may have their concerns dismissed. Since vaccine reactions are often ignored, for a variety of reasons, vaccine awareness groups provide a vital service. Equally important is their demand for ethical reforms to immunization policies and procedures. Many groups which, incidentally, are non-profit organizations employing volunteers, have entered the political arena to initiate necessary changes to immunization policies and procedures. While each group's mandate may differ somewhat from the others, all appear to promote informed and voluntary consent and the acknowledgement, and compensation, of vaccine induced injuries. Most have actively challenged legislation or policies that inhibit the voluntariness of consent. Similarly, while challenging medical authorities to

provide more thorough information on contraindications and adverse events, these groups have taken the initiative to provide such information to the public. Many have been effective in challenging mandatory vaccination laws and in influencing governments to initiate compensation schemes for vaccine-injured individuals. Their efforts clearly indicate a sincere attempt to make immunization policies and practices conform to ethical standards.

APPENDIX B
CANADIAN VACCINE SCHEDULES AND RECOMMENDATIONS

IMMUNIZATION SCHEDULE FOR INFANTS AND CHILDREN: FEDERAL RECOMMENDATIONS

Age at Vaccination	DPT	Polio	Hib	MMR	Td*
2 months	X	X	X		
4 months	X	X	X		
6 months	X	X**	X		
12 months				X	
18 months	X	X	X		
4-6 years	X	X			
14-16 years		X**			X

* Td (tetanus and diphtheria toxoid), a combined absorbed "adult type" preparation for use in persons ≥ 7 years of age, contains less diphtheria toxoid than preparations given to younger children and is less likely to cause reactions in older persons. Repeat every 10 years throughout life. ** Omit this dose if OPV is used exclusively.

Source: National Advisory Committee on Immunization, Canadian Immunization Guide, 21. Reproduced with the permission of the Minister of Public Works and Government Services Canada, 1996.

PROVINCIAL/TERRITORIAL VACCINATION SCHEDULES

Province/ Territory	"Penta"	DPT	DPTP	OPV	Hib	MMR	Td	Hep B
Alberta	2, 4, 6, 18 months		4-6 years			12 mos. 4-6 years	14-16 years	Grade 5 (3 doses)
British Columbia	2, 4, 6, 18 months		4-6 years*			12 mos.* (MR: 19mo - 19yrs)		
Manitoba		2, 4, 6, 18 months 4-5 yrs.		2, 4, 18 months 4-6 yrs.	2, 4, 6, 18 months*	12 mos. (measles: 5 yrs. & grades 1-6)		
New Brunswick	2, 4, 6, 18 months		4-6 yrs. 14-16yrs[660]			12 mos.		≤ 12 hrs. 2, 12 mo.
New-foundland	2, 4, 6, 18 months*		4-6 yrs.*			12 mos.*		
North West Territories	2, 4, 6, 18 months		4-6 yrs.			12 mos. ≥ 18 mos.	14-16 yrs (Td polio)	birth[661], 1 & 6 mos.
Nova Scotia*	2, 4, 6, 18 months		4-6 yrs.			12 mos.		
Ontario	2, 4, 6, 18 months		4-6 yrs.			12 mos. 4-6 yrs.	14-16 yrs (Td polio)	Grade 7 (3 doses)
Prince Edward Island		18 mos.* 4-6 yrs.*	2, 4, 6, mos.*	18 mos.* 4-6 yrs.*	2, 4, 6, 18 months*	15 mos.* (measles: grades 1-12)		
Québec*		2, 4, 6, 18 months 4-6 yrs.		2, 4, 18 months 4-6 yrs.	2, 4, 6, 18 months	12 mos.		
Saskat-chewan*		2, 4, 6, 18 months 4-6 yrs.		2, 4, 18 months 4-6 yrs.	2, 4, 6, 18 months	12 mos.		
Yukon Territories			2, 4, 6, 18 months 4-6 yrs		2, 4, 6, 18 months	12 & 18 months	Grade 9 (Td polio)	Grade 4 (3 doses)

Source: Immunization Policy Survey conducted May 1996.

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[660]A polio booster is recommended for 14-16 year olds if all previous doses were given by injection (i.e. IPV vs. OPV).

[661]North West Territories also recommend the BCG vaccine, at birth, for all infants from communities with a history of TB outbreaks especially if there is a history of TB within the family.

Based upon the information supplied, and information supplemented[662], a few provincial/ territorial variations were found amongst specific vaccine schedules. It appears that OPV is routinely recommended in Manitoba, Prince Edward Island, Québec and Saskatchewan whereas other provinces routinely use IPV, presumably due to adverse-reactions associated with OPV and perhaps also due to the new Pentavalent vaccine which incorporates DPT-P and Hib into one injection.

Five respondents, Alberta, New Brunswick, North West Territories, Ontario and Yukon Territories, indicated the use of hepatitis B vaccine for infants and/or school aged children. While Canada is still considered to be "an area of low endemicity for hepatitis B, since fewer than 5% of residents are anti-HBs positive and fewer than 0.5% are HBsAg positive," cases of acute hepatitis B have increased more than twofold from 1980 to 1990.[663] The incidence appears to be relatively low in children, only 3% of all cases have been reported in children ≤ 15 years of age, and relatively high in 30-59 year olds: incidence rates appear to be twice as high in males vs. females and may depend largely upon occupation, geographical region and ethnicity.[664] Hepatitis B incidence rates begin to climb at the 15-19 year-old age group and it is believed that this climb is due to sexual activity and injection drug use.[665] Only the North West Territories indicated using the BCG vaccine at birth for infants considered at high risk of contracting tuberculosis.

A second dose of measles/ MR/MMR preparations have been initiated in 7 of the 12 provinces largely due to measles vaccine failure, estimated to occur in

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[662]Information denoted with an asterisk was unavailable through survey responses alone. No responses were received from either Québec or Saskatchewan. Supplemental information may contain errors due to schedule changes made since 1994. Supplemental information was derived from: Nova Scotia Department of Health, Immunization Services (NS: Public Health Services, December 1993), 5.

[663]National Advisory Committee on Immunization, Canadian Immunization Guide, 46.

[664]Ibid., 47f.

[665]Ibid., 47.

approximately 1%-5% of single-dose vaccinees.[666] In 6 of the 7 provinces, mass immunization programs were operative at the time of the survey. This information follows. Other than these few provincial/territorial variations, most vaccine schedules appeared to follow relatively uniform recommendations.

PROVINCIAL MASS IMMUNIZATION PROGRAMS

Provence/Territory	Vaccine	Specified Target Groups
British Columbia	measles/rubella	(19 mos. - 19 yrs.)
Manitoba	measles	(5yr olds; grades 1-6)
North West Territories	measles/rubella	
Ontario	measles	(junior kindergarten - OAC)
Prince Edward Island	measles	(grades 1-12)
Yukon Territories	measles	

Source: Immunization Policy Survey conducted May 1996.

National Defence indicated that mass immunization programs were in progress. Although the specific immunizations were not specified, it may be assumed that, since vaccines are mandatory for the Canadian Armed Forces, all vaccines may be included in the "mass immunization program" category.[667] Seven of twelve respondents indicated that mass immunization programs are currently in effect. Six respondents indicated that the mass campaign involved measles immunizations, two of which use measles-rubella combination vaccines.

It is interesting to note that none of the respondents included hepatitis B vaccines which are administered to school children in grades 4 (Yukon Territories), 5 (Alberta) and 7 (Ontario) as being "mass" immunization campaigns. It would seem apparent that

[666]Since 1989 the incidence of measles has increased significantly in both Canada and the United States where single-dose measles immunization rates appeared adequate to produce herd immunity. In 1989 (USA) and 1992 (Canada) recommendations were made to incorporate a second dose of measles vaccine for children and/or youths in an attempt to eliminate measles in the Americas. Ibid, 71.

[667]When asked which vaccines are considered mandatory for the Canadian armed forces, National Defence relied that diphtheria, tetanus (adults), polio (adults and health care workers), hepatitis A (CAF deployed to theatre scenes for >6 months), yellow fever and ISG malaria (CAF member deployment) were mandatory.

the designation "mass immunization programs" should include any immunization targeted for any specific group *en masse* which is not administered by one's regularly attending physician or health care worker. Similarly, the grade 9 Td polio vaccine administered in the Yukon Territories may also be considered a "mass immunization program."

APPENDIX C
THE NEW BRUNSWICK IMMUNIZATION PROTOCOL FORM

✧

Name of Vaccinee
Nom du vacciné _____ Date of Birth
Date de naissance _____

Checklist for informed consent	Date of Vaccine Y / M / D						Date du vaccin A / M / J	Liste de contrôle
1. Communication has occured in language the vaccinee or person authorizing the procedure can understand.							1. La communication s'est faite dans un langage que le vacciné ou la personne qui autorise la procédure peut comprendre.	
2. The vaccinee/legal parent/legal guardian is capable of comprehending and giving consent.							2. Le vacciné, ou le parent, ou le tuteur légal est capable de comprendre et de donner son autorisation.	
3. The vaccinee/legal parent/legal guardian has received verbal information and printed material pertaining to the particular immunizations prior to administration. This information included: — The nature and purpose of the vaccine — Risks and benefits — Risks associated with not having the vaccine — That it is the responsibility of the vaccinee /legal parent /legal guardian to keep the personal immunization records up-to-date and easily accessible.							3. Le futur vacciné, ou le parent, ou le tuteur légal a reçu les informations verbales et de la documentation écrite sur les vaccins avant que ceux-ci soient administrés. Les informations susmentionnées comprenaient: — la nature et le but du vaccin; — les risques et les avantages du vaccin; — les risques qu'il y a à ne pas recevoir le vaccin; — la responsabilité qui incombe au vacciné, ou au parent, ou au tuteur légal de garder le dossier de vaccination à jour et facile d'accès.	
4. Any questions have been answered and the vaccinee/legal parent/legal guardian indicated that the information was understood.							4. Aucune question n'est restée sans réponse et le vacciné, ou le parent, ou le tuteur légal a démontré qu'il avait compris toutes les informations reçues.	
5. The vaccinee/legal parent/legal guardian has understood that immunization records will not be treated as confidential unless otherwise requested.							5. Le vacciné, ou le parent, ou le tuteur légal a compris que les dossiers de vaccination ne sont pas confidentiels à moins qu'une demande spécifique soit faite en ce cas.	
6. A screening history was obtained, using the Screening Guide for Immunization (page 20).							6. Les antécédents médicaux furent obtenus à l'aide du Guide de dépistage aux fins de la vaccination (page 20).	
7. Vaccines and biologicals were given according to the recommendations of the Department of Health and Community Services.							7. L'administration des vaccins et des produits biologiques s'est effectuée conformément aux recommandations du ministère de la Santé et des Services communautaires.	
8. The vaccinee was asked to remain for the recommended observation period following administration.							8. Après l'administration du vaccin, il a été demandé au vacciné de demeurer sur place pendant la période d'observation recommandée.	
9. Documentation occured immediately following administration.							9. Le dossier a été complété immédiatement après l'administration du vaccin.	
10. The vaccinee/legal parent/legal guardian was advised to notify the health office if the vaccinee has needed medical attention within 2 weeks following immunization.							10. Le vacciné, ou le parent, ou le tuteur légal a été avisé qu'il devait informer le bureau de santé publique si une consultation médicale s'avérait nécessaire dans les deux semaines suivant la vaccination.	
11. The necessary reporting and recording of adverse event, reaction to injection, etc., has occurred.							11. Les réactions défavorables, une réaction à l'injection, etc., ont été signalées et inscrites au dossiers du vacciné.	
Signature of Public Health Nurse ⇨							⇦ Signature de l'infirmière hygiéniste	

Source: Public Health & Medical Support Services, Health & Community Services, New Brunswick, 1996. Reprinted with permission.

APPENDIX D
CANADIAN POLICIES REGARDING ADVERSE EVENT WARNINGS

THE EXISTENCE OF REQUIREMENTS FOR SPECIFIC DISCLOSURE OF CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS ASSOCIATED WITH IMMUNIZATION, AND OF RISKS ASSOCIATED WITH THE DISEASES TO BE PREVENTED, PRIOR TO IMMUNIZATION

Survey Respondent	Requirements Exist	Details Included:
Alberta	X	prior to any immunization regardless of vaccinee's age
British Columbia	X	
Manitoba	X	verbal disclosure; forms may soon be available
New Brunswick	X	required since at least 1986
Newfoundland	X	
North West Territories	X	
Nova Scotia	X	
Ontario	X	since 1986; under common law previously
Prince Edward Island	X	only required for immunizations, not diseases
Yukon Territories	X	
National Defence	X	since 1990; updated written information is provided

Source: Immunization Policy Survey conducted May 1996.

All respondents indicated that specific disclosure is required regarding contraindications and vaccine-associated adverse events. All but one respondent, ie. Prince Edward Island, indicated that disclosure is required for risks associated with acquiring the disease naturally. From information provided, however, it appears that only New Brunswick Public Health requires written documentation, from the person administering the vaccine, affirming that specific contraindications, risks and benefits have been *discussed with*, and *understood by*, vaccinees or by the person authorizing consent.[668] In other cases, for example on written consent forms, a statement such as, "I have read and understand the information provided and have had questions answered to my satisfaction", may appear next to the parent's, guardian's or vaccinee's signature.

[668]Cf. Appendix C: The New Brunswick Immunization Protocol Form.

INDIVIDUALS RESPONSIBLE FOR CONVEYING CONTRAINDICATIONS OR POSSIBLE ADVERSE EFFECTS ASSOCIATED WITH SPECIFIC VACCINES IN BOTH ROUTINE AND MASS IMMUNIZATION PROGRAMS

Respondent	Routine Immunization	Mass Immunization
Alberta[669]	public health nurse	physician/nurse
British Columbia	physician/nurse	physician/nurse
Manitoba	physician/nurse	physician/nurse
		local health unit
New Brunswick	physician/nurse	physician/nurse
Newfoundland	physician/nurse	physician/nurse
North West Territories	nurse	nurse
Nova Scotia	physician/nurse	physician/nurse
Ontario	physician/nurse	local health unit: administering nurse
Prince Edward Island	physician/nurse	physician/nurse
Yukon Territories	local health units: nurse	local health units: nurse
First Nations & Inuit Health	physician/nurse	physician/nurse
National Defence	nurse	nurse

Source: Immunization Policy Survey conducted May 1996.

Responsibility for conveying information regarding contraindications or vaccine associated adverse events lies primarily with the person administering the vaccine. Mass campaigns, however, generally preclude individualized attention. Local health units generally provide the contraindication/adverse event information on consent forms. Under these circumstances, it is apparently up to the individual to call local health units to address concerns or to obtain further information. It remains questionable whether questions and concerns regarding contraindications and adverse events can be properly addressed during mass campaigns when those administering the vaccines must fulfil large quotas daily and when parents/guardians may be absent during the actual immunization. It seems appropriate, then, to recommend that parents

[669]Alberta made the following observation: "Primary responsibility is with the nurse/physician administering the vaccine, however, responsibilities also lie with the manufacturer, provincial health department & health units. Such responsibilities are filled by the production of supporting documents, pamphlets & consultation services to the public health nurse, physician & general public."

inform themselves of contraindications and vaccine associated adverse events and consult their family physician or health care worker prior to any immunization, particularly in mass immunization campaigns.[670]

THE AVAILABILITY OF CIRCULATED MATERIAL, FOR PUBLIC ACCESS, REGARDING BOTH DISEASE RELATED RISKS AND RISKS THAT MAY BE ASSOCIATED WITH VACCINES

Respondent	Materials are circulated	Since:
Alberta	X	(updated with each new vaccine)
British Columbia	X	
Manitoba	X	
New Brunswick	X	1989
Newfoundland	X	
North West Territories	X	1989
Nova Scotia	X	
Ontario	X	1970s
Prince Edward Island	X	(re: vaccines only)
Yukon Territories	X	
First Nations & Inuit Health	X	(variable in each region at any specific time)
National Defence	X	

Source: Immunization Policy Survey conducted May 1996.

Printed materials supplied by respondents largely consisted of pamphlets published by vaccine manufacturers and fact sheets or pamphlets published by provincial health ministries. In most cases it was difficult to determine how efficiently the printed materials were delivered to the vaccinees, or to persons authorizing consent, prior to immunization. Manitoba Health, however, includes fact sheets when sending out their immunization reminder/consent form. The New Brunswick *Immunization Protocol* form requires that printed material be supplied prior to immunization and requires that public health nurses determine that the information is understood by the vaccinee/person authorizing consent.

[670]Information regarding contraindications and acknowledged adverse events may be found on vaccine package inserts. This information is also available, often in a more detailed form, in The Physician's Desk Reference, available at public libraries.

Ministry published fact sheets or pamphlets usually include general information regarding: immunization schedules, disease-associated risks, mild-moderate vaccine reactions, which reactions should be reported to a health care provider and recommendations to reduce fever and comfort the vaccinee. Specific information regarding contraindications to immunization appeared in most ministry-published fact sheets/pamphlets. A varied list of serious vaccine-related adverse reactions were found on *some* of the information sheets/pamphlets.[671] The possibility of neurological damage or death following immunization was rarely mentioned. While many of the ministry published materials were found to provide similar information, New Brunswick provided a somewhat more extensive list of contraindications and adverse events.

Some discrepancies were found between contraindications and adverse events listed by the various health ministries. One information sheet, *OPV Vaccine for Poliomyelitis*, supplied by Manitoba Health stated that "no early reactions or side effects have been associated with this vaccine." Conversely, The Alberta Health pamphlet stated that "the oral polio vaccine caused paralysis...(one in several million doses)...in [vaccinees or in their close contacts]."[672] Similarly, Connaught Laboratories, the manufacturer of OPV, informs health care providers that "the routine use of IPV eliminates the risk of paralytic poliomyelitis related to the use of OPV."[673] Such discrepancies could adversely affect vaccinees and those persons administering vaccines; both preventable adverse events and lawsuits could result from lack of disclosure.

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[671]Serious vaccine reactions included: convulsions, abnormal crying lasting more than three hours, fever exceeding 40° C/104°F, shock, allergic reactions (hives or respiratory difficulties),facial swelling and excessive drowsiness.

[672]This pamphlet, published September 1995 by Alberta Health, is entitled: "If Your Child Needs Any of These Vaccines: DPTP, DT, Polio, Hib, Here is Important Information You Should Know." Alberta used OPV until 1994.

[673]Connaught Laboratories, Information for the Health Care Provider: Introduction of Enhanced inactivated Polio Vaccine (IPV or Enhanced Salk Polio Vaccine) in Ontario (Willowdale, ON: Connaught Laboratories Ltd., n.d.), 1.

APPENDIX E
ADVERSE EVENT MONITORING IN CANADA

PERSONS RESPONSIBLE FOR REPORTING VACCINE-RELATED ADVERSE EVENTS TO AUTHORITIES

Respondent	Report to be made by:
Alberta	Public health nurse or physician administering immunization
British Columbia	Anyone with knowledge of the event
Manitoba	Nurse/physician administering the vaccine
New Brunswick	Physicians and nurses
Newfoundland	Individual administering vaccine or person receiving the history of the event
North West Territories	Nurse administering the vaccine
Nova Scotia	"Person with information"
Ontario	Health care provider who administered immunization
Prince Edward Island	Public health nurse
Yukon Territories	Nurse administering vaccine
First Nations & Inuit Health	Nurses for Medical Services Branch-administered vaccines
National Defence	(no reply)

Source: Immunization Policy Survey conducted May 1996.

Adverse event reporting is voluntary in Canada. Persons who administer the vaccines are primarily responsible for reporting adverse events but the report may be made by anyone with knowledge of the event. Some adverse events, including, but not limited to, anaphylaxis, severe shock, Guillain-Barré Syndrome and paralysis require diagnosis by a physician. Adverse events must have a temporal association with vaccine administration and must not be attributable to a pre-existing condition.

DESTINATION OF ORIGINAL ADVERSE EVENT REPORT

Respondent	Health Unit	Ministry of Health	LCDC[674]	Vaccine Manufacturer
Alberta		X		
British Columbia	X			
Manitoba	X	X	X	
New Brunswick	X	X		
Newfoundland	X	X	X	X
North West Territories		X		
Nova Scotia	X			
Ontario	X (MOH)			
Prince Edward Island			X	
Yukon Territories	X		X	
First Nations & Inuit Health			X	
National Defence	X (Health Prevention & Promotion Division)			

Source: Immunization Policy Survey conducted May 1996.

Typically, health care providers forward adverse event reports to local health units. The local health unit will then forward the report to provincial and territorial ministries. The reports are then sent to the LCDC's Bureau of Immunization. Adverse events are recorded on the LCDC's Vaccine Associated Adverse Events (VAAE) database for subsequent analysis. External advisory committees will investigate all serious and unusual adverse events.[675]

[674]LCDC: Laboratory Centre for Disease Control.

[675]Canadian Pharmaceutical Association, Compendium of Pharmaceuticals and Specialities 32nd ed. (Ottawa: Canadian Pharmaceutical Association, 1997), L8.

INDIVIDUAL OR AGENCY RESPONSIBLE FOR FOLLOW-UP AND INVESTIGATION OF REPORTED ADVERSE EVENTS

Alberta	Alberta Health & MOH where event occurred
British Columbia	BC Centre for Disease Control
Manitoba	LCDC; Provincial Department of Health; local MOH
New Brunswick	LCDC
Newfoundland	Nurse; Health Unit
North West Territories	Health Protection Unit, Dept. of Health & Social Services
Nova Scotia	Public Health, MOH
Ontario	Local Health Unit
Prince Edward Island	Public Health Nurse; Chief Health Officer (if necessary)
Yukon Territories	LCDC; MOH
First Nations & Inuit Health	LCDC (depending on nature of event) & Vaccine Manufacturer. If serious: Regional Medical Officer locally.
National Defence	Preventive Medicine Department

Source: Immunization Policy Survey conducted May 1996.

APPENDIX F
COMPENSATION FOR VACCINE-RELATED INJURIES IN CANADA

SPECIFIC LEGISLATION OR POLICIES REGARDING VACCINE INJURIES

Respondent	None exist	Intentions to develop plan in the near future?
Alberta	X	No
British Columbia	X	No
Manitoba	X	No
New Brunswick	X	
Newfoundland	X	
North West Territories	X	
Nova Scotia	X	
Ontario	X	No
Prince Edward Island	X	
Yukon Territories	X	
First Nations & Inuit Health	X	
National Defence	(no reply)	

Source: Immunization Policy Survey conducted May 1996.

No legislation or policies currently exist on a either a provincial or national level to compensate persons who are injured by vaccines.

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