The rationale for vaccines and potential inadvertent consequences including autism, AIDS and other epidemics

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Abstract

Humans and animals can be protected from epidemic infectious diseases by prior intentional stimulation of the immune system. This process is called immunization and has been hailed as the all time greatest contribution of science to human health. Such enthusiastic endorsements, together with compulsory legislation, have helped ensure widespread public acceptance and compliance with immunization programs. Dissenting or cautionary views on potential risks of certain vaccines have been largely ignored. The vaccine industry now has annual sales in excess of $6 billion with significant liability should adverse effects be proven. Society is facing alarming increases in various types of brain damaging and other illnesses consistent with an infectious process. A role for vaccine-derived "stealth-adapted" viruses in these illnesses, as well as in the emergence of the AIDS virus has been proposed. Such issues should be addressed by full disclosure and open participation of the public and independent researchers.
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1. Introduction

A primary function of the immune system is to provide long term protection against many types of infectious agents. Typically, the immune system responds to an initial exposure to a particular type of virus, bacterium or fungus, with a heightened capacity to subsequently respond to any further exposures to the same microorganism. With some types of microorganisms, the initial exposure will manifest as a time limited primary disease. This is seen, for example, with childhood exposure to common viral illnesses including measles and chicken-pox. Once an individual has contracted measles, he or she is essentially immune from any further episodes of measles.

Epidemics of infectious illnesses have historically taken an enormous toll on mankind. Common examples include plague, smallpox and syphilis during the middle ages; polio, influenza and tuberculosis during the early 20th century; and currently AIDS and hepatitis A, B and C. Explorations of remote areas of the world were severely hindered by diseases such as yellow fever and malaria.

Man has learned to cope with some of these illnesses by harnessing the power of the immune response. Although the mechanism was not understood at the time, Dr. Edward Jenner was able to prevent primary disfiguring infection with smallpox virus by intentional infection with a related virus, termed vaccinia that was infecting cows (vacca in Latin). The process was referred to as vaccination, and from 1796 began to replace the widespread custom of trying to limit the severity of primary infection using minimal exposure to pus collected from a smallpox skin blister.

The concept of germs causing infectious illnesses was jointly developed by Dr. Robert Koch and Louis Pasteur in the 1880's. While Koch failed in his attempts to develop a tuberculosis vaccine, Pasteur was successful with the development of a rabies vaccine. Essentially, he was able to grow the rabies virus in rabbits and to inject dried spinal cord material into patients exposed to the bite of a rabid animal.

Infectious agents responsible for such serious viral illnesses as polio, influenza and yellow fever were discovered in the early 20th century by Drs. Landsteiner, Shope, and Walter Reed respectively. Bacteria responsible for diphtheria, tetanus, pneumonia and whooping cough (pertussis) were also identified. Unlike viruses, bacteria could be readily cultured away from living cells. Viruses had to be transmitted between living animals. Fortunately, fertile chicken eggs could be used to propagate influenza and yellow fever viruses. In 1948, Dr. John Enders developed the first animal-free tissue culture method to grow polio virus. With each successfully grown microbe, efforts were made to develop material that could be used to immunize individuals (or animals) against challenge with the same disease causing microbe.

The immune system was also becoming better understood. The issue of whether protection was being provided by soluble factors (antibodies) or cells was addressed in the early 1900's without a clear consensus. Foreign material, referred to as an antigen, was initially thought to "instruct" certain cells to make antibodies that selectively bound to and neutralized the antigen. In 1957 MacFarlane Burnet postulated that the body was pre-equipped with cells that collectively could recognize all foreign antigens but that individual immune cells, identified as comprising lymphocytes and plasma cells, were responsive to only one particular antigen. Selective outgrowth of antigen-specific responding cells explained the heightened antibody and cellular reactivity to subsequent exposure to the same antigen. The levels of antibody reactivity correlated with the levels of resistance to many infectious diseases providing a ready assay to determine efficacy of various immunization protocols.

Killed bacteria and bacteria-derived products provided the mainstay for bacteria immunization programs. Infusion of serum antibodies collected from immunized animals could also be used to provide passive immune protection of patients in the

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early stage of bacterial illnesses. Modified toxins (toxoids) produced by diphtheria and tetanus bacteria were relatively easy targets for vaccination. Crude extracts and more purified subcomponent vaccines are available for pertussis, cholera, typhoid, meningococcus, pneumococcus, hemophilus influenza and a tuberculosis related bacteria (BCG).

Formalin killed egg-grown influenza viruses were successfully developed into clinical vaccines. The transfer of the yellow fever virus from monkeys to mice was shown by Dr. Max Theiler to significantly reduce its capacity to induce disease in humans. This led to the production in fertile eggs of a live yellow fever vaccine that is still in use today. Experience with influenza and yellow fever vaccines provided contrasting models of how to best develop a polio vaccine once it was successfully cultured. Dr. Jonas Salk used formalin to inactivate disease causing polio virus. Drs. Albert Sabin and Hilary Koprowski independently tried to reduce the virulence of polio viruses by extensive tissue culturing. Dr. Sabin was more successful in isolating weakened strains that were still able to induce a protective antibody response. His vaccine replaced that of Dr. Salk in the early 1960's, although in the United States, the use of inactivated polio vaccine was again mandated in 2000.

The introduction of polio immunization was followed by successful efforts to develop live vaccines against measles, mumps and rubella (MMR) viruses and more recently varicella zoster virus. Inactivated and more recently genetically synthesized hepatitis A and B antigenic materials have become available for vaccines. Experimental programs are underway to produce vaccines against many other viruses including herpes simplex viruses, cytomegalovirus, Epstein-Barr virus, human papillomavirus, rotavirus, Japanese B encephalitis virus and human immunodeficiency virus (HIV).

Numerous infectious agents have also been rendered as vaccines for animal use. Prominent examples include Newcastle disease virus in poultry, canine distemper virus in dogs, feline leukemia virus in cats and brucella bacteria in cattle.

2. Efficacy of Vaccines

The global eradication of smallpox has been attributed to vaccination and has served as a model for other illnesses, including polio. Common childhood infections with measles, mumps and rubella are less frequent in developed countries compared to the developing world. While some of this reduction can be traced to vaccine use, improved sanitation and nutrition were probably more important variables. Influenza mortality among the elderly and infirm is reduced in immunized populations. Because influenza virus can undergo antigenic changes, it is necessary to provide a vaccine that contains the virus responsible for an ongoing outbreak. The detection of a new influenza virus triggers a rapid response for vaccine production in time to provide protection to those not yet exposed to the current strain of influenza. Diphtheria and tetanus are rarely seen today and essentially only in individuals who have not been immunized. Mortality for meningococcus and pneumonia is reduced for those strains for which vaccines have been produced. Similar success stories apply to vaccinated livestock and domestic pets.

Lifelong protection against many infectious diseases is clearly achievable by vaccination. Moreover, the world remains at risk for newly emerging infectious agents, including common viruses with drastically altered antigens. Advances in biotechnology are likely to streamline vaccine manufacturing. Specifically, recombinant DNA technology is allowing the production in bacteria of structurally well defined antigens of viral, bacterial, fungal and parasitic microorganisms. A greater understanding of the immune system should also enable more directed approaches at eliciting the type of immunity that is most appropriate for a given type of infection. Effective vaccines are not yet available for several major illnesses, including tuberculosis, malaria and AIDS. A potential difficulty in the development and use of such vaccines is the growing reluctance of the public to accept the Government's blanket assurance that vaccines are safe and effective.

3. Adverse Effects of Vaccines

The use of vaccines has been justified as an important Public Health measure to stem the occurrence of epidemic illnesses. To be effective, it has commonly been argued that universal compliance with immunization programs is necessary. Frivolous concerns such as sprouting cow horns from taking vaccinia virus were aggressively countered by common sense. More serious concerns have periodically arisen and afforded less than stellar attention by Public Health authorities. The reluctance is explained in part by a protective reaction of those responsible for apparent oversights and by the considerable exposure of Industry to potential litigation. Historical examples include the probable transmission of syphilis and tetanus as inadvertent contaminants of vaccinia vaccine lots; the transmission of bovine leukemia virus to cattle herds because of contaminated experimental babesia vaccines; and an outbreak of Venezuela equine infectious virus in horses that was due to a contaminated vaccine.

Field testing of vaccines with live viral challenge can potentially explain the out-of-season cases of polio that occurred in the early 1950's in the United States. Actual polio cases developed among some of those receiving initial lots of Dr. Salk's vaccine because of inadequately assessed inactivation protocols. Simian virus 40 (SV-40) was a common contaminant of both live and killed polio vaccines produced in the freshly grown cells from the kidneys of rhesus monkeys. A switch was made to African green monkeys for further production of polio vaccine without the recall of known contaminated vaccine lots. Concerns about using fresh tissues from African green monkeys arose during the 1960's but simple suggestions such as using serum antibodies from the monkeys to test for possible contaminating viruses were disregarded.

In 1972 a joint Government-Industry study showed that kidney cell cultures from all eleven African green monkeys tested were contaminated with simian cytomegalovirus. Only 4 of the 11 isolates were detectable using the then mandated screening test. The Industry's contingency plan essentially concluded that the Bureau of Biologics would be unwilling to take the current product off the market in favor of a competing vaccine being produced in England from an established human cell line. African green monkeys continued to be used even after the Director

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of the Bureau of Biologics was informed in 1977 that licensed polio vaccines contained foreign DNA that was not of monkey cell origin. Of 8 vaccines lots from around this period that were recently tested in-house by the FDA Office of Vaccine Safety, 3 have DNA of simian cytomegalovirus. In a related study, British authorities reported that 32 of 34 polio vaccine lots from one manufacturer alone were contaminated with monkey cytomegalovirus DNA. FDA and British officials state they are unable to culture replicating cytomegalovirus from these vaccines. FDA was unwilling to provide samples of the vaccines for independent testing, ostensibly because of proprietary restrictions imposed by industry. This issue is important for at least two reasons: First, I have reported the definitive isolation of simian cytomegalovirus-derived cell damaging viruses from two patients with brain damaging illnesses, and as yet uncharacterized viruses from numerous additional patients with illnesses ranging from autism and learning disorders in children, chronic fatigue syndrome and fibromyalgia in adults, and various cancers and neurodegenerative illnesses in the elderly. The viruses were termed stealth because they were essentially not being recognized by the cellular immune system. Based on available DNA sequence data, it appears that the lack of effective immune recognition is due to the loss of the few major critical antigens that are targeted by the majority of virus reactive lymphocytes. Parents of stealth virus positive children have occasionally reported exacerbation of symptoms following vaccination. Vaccine viruses can promote the growth of certain stealth viruses in cultures. Furthermore, non-specific stimulation of the immune response could potentially trigger an anti-viral response directed at a few minor antigens retained by the stealth-adapted virus. Arguably, potential vaccine recipients should be screened for stealth virus infection prior to receiving the vaccine.

Cytomegalovirus, whether from African green or rhesus monkey, has multiple copies of the genes that promote cell entry of HIV and its precursor, the simian immunodeficiency virus (SIV) of chimpanzee. Cytomegalovirus contaminated experimental polio vaccines were used in chimpanzees in Central Africa. It is quite reasonable, therefore, that the use of experimental polio vaccine in Africa led to the conversion of SIV to HIV. Chimpanzees from Africa were also used to experiment with hepatitis B vaccine, again suggesting a possible link of vaccines with the spread of HIV in the United States. Requests to CDC to test stored human sera collected from polio vaccine immunized African children or hepatitis B immunized United States citizens have been ignored.

4. Political and Economic Considerations

These and other politically sensitive issues are seemingly not being addressed by our Public Health agencies. Undoubtedly, there is a reluctance of those in control to challenge the past performance of those entrusted with ensuring the Nation's health. The Pharmaceutical Industry also maintains a privileged position within our society. Not only does its financial strength curry support from Government, but it is likely to be heavily relied upon in the case of biological warfare. Unfortunately, the primary motivation of this industry appears to have shifted from global Public Health concerns to simple profit motivation. An enormous price differential exists between charges for pediatric vaccines in Westernized countries compared to the developing world. Part of this differential is attributed to refinements in vaccine production, for example use of more purified bacteria products, or the use of inactivated versus live but weakened polio virus. Still the differences are staggering, for example US$0.07 versus US$10.65 for diphtheria-tetanus-pertussis (DTP) vaccine and US$0.10 versus US$8.25 for polio vaccine. Far more money is to be made vaccinating children from affluent countries, as well as international travelers from these countries, than addressing the world's health needs. The multinational Pharmaceutical Industry has essentially withdrawn from servicing the developing world leaving this responsibility and low profit margin to a Developing Country Vaccine Manufacturers Network with facilities in countries such as India, Iran and Thailand.

The public is justifiably skeptical of the willingness of Government officials to request a full accounting of past and present vaccine manufacturing practices. Compulsory polio vaccination was legislated in the late 1950's to help reduce stockpiles of relatively ineffective lots of inactivated polio vaccines. Collusion between Government and vaccine producers may have occurred in the development and testing of agents of biological warfare. Intentional feeding of mentally retarded children with hepatitis B virus contaminated feces was justified as being necessary to protect other children. Possible responsibility for diseases such as AIDS, autism, sudden infant death syndrome, chronic fatigue syndrome and mental illnesses is vehemently denied and those making such suggestions attacked. To a large measure, vaccine and vaccine-related research have become money-driven endeavors with emphasis on perception rather than reality. This unfortunate trend needs to be addressed with forthright discussions that involve both the public and independent researchers.

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