WHO/MSD/MDP/00.10
English
Distr.: General

BEHAVIOURAL SCIENCE LEARNING MODULES

BEHAVIOURAL FACTORS IN IMMUNIZATION

DEPARTMENT OF MENTAL HEALTH
AND SUBSTANCE DEPENDENCE

WORLD HEALTH ORGANIZATION
GENEVA

BEHAVIOURAL FACTORS IN IMMUNIZATION

Preface

As in many areas of health care, behavioural factors play an important, sometimes crucial role in the successful implementation of immunization programmes. Effective immunization is one of the most cost-effective methods for decreasing mortality, morbidity, disability and the overall burden of disease, hence any intervention to make these programmes more effective is a public health priority. The present document is intended to provide some background information in this area and also to suggest some behavioural strategies towards effective immunization within communities.

Behavioural Factors in Immunization is a part of the Behavioural Science Learning Modules series of the World Health Organization (WHO). The Immunization module is a collaboration between WHO and the International Union of Psychological Science (IUPsyS) initiated by the Working Relationship established between them.

Development of the Immunization Module was produced through the auspices of the IUPsyS under the coordination of its Secretary-General and liaison to WHO, Professor Pierre Ritchie (University of Ottawa, Canada) and the IUPsyS Behavioural Science Modules Work Group chaired by Professor Robert M. Martin (University of Manitoba, Canada). The primary resource person for the module on Behavioural Factors in Immunization was Professor John Carr (University of Washington Medical Center, USA) with assistance from Dr John Clements (Medical Officer, VAB, Expanded Programme on Immunization, WHO, Geneva).

The contribution of colleagues from Brazil, Egypt, Italy, Kenya, Malaysia, Mexico, Palestine, Thailand, and Turkey who participated in the field review is gratefully acknowledged.

We would also like to gratefully acknowledge Ms Lauren S. Greenfield, BSN, RN, for granting us permission to reproduce the booklet *Plain Talk about Childhood Immunizations,* published by Public Health-Seattle & King County (2000) as Appendix B of the present document.

Behavioural Factors in Immunization was supported by grants from UNESCO via the International Social Science Council and the Canadian Register of Health
Service Providers in Psychology. WHO printed this module with financial support from the WHO Expanded Programme on Immunization (EPI) while IUPsyS and WHO share responsibility for its dissemination.

It is hoped that this document will be found useful by health care professionals responsible for immunization within governmental, as well as non-governmental organizations. We would be pleased to receive any feedback on the usefulness of this document and suggestions to make it better. These may be sent to the undersigned.

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BEHAVIOURAL FACTORS IN IMMUNIZATION

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I. Basic information about immunization

A major goal for the World Health Organization is the global control of certain infectious diseases (Jakarta Declaration, WHO, 1997). The risk of epidemic outbreaks of these diseases is related to many factors including population mobility, changes in human behaviour, social organization, climate, agricultural practices, and medical and public health practices. The main strategies for the prevention of infection are: (1) to eliminate or diminish the amount of infecting microorganism from circulation; (2) to enhance the host immune response; (3) to treat the infected host. Of these, the first and second together have the greatest impact since they protect the individual and control the spread of disease. Both goals can be achieved through active immunization.

A. Active immunization

Active immunization involves challenging the human immune system with a vaccine composed of modified pathogens. Since the immune system has a long-lasting memory for a wide range of specific infecting agents, vaccination provides the individual with long-term protection against a particular disease. Active immunization not only provides the individual with immune protection, but also reduces the circulation of the infecting agent in the population, thereby protecting unvaccinated individuals as well. This phenomenon, called **herd immunity**, operates in the target population once adequate rates of immunization are achieved, resulting in a drop in the incidence of the disease. However, once the incidence of a disease is significantly reduced, there is a danger individuals will no longer feel the need to get immunized, and rates of vaccination will fall. If the pathogen is still circulating and herd immunity is lost, there is the risk of a rise in the incidence of new infections. Thus, it is important that health professionals and the public be well educated about the importance of continuing immunization to prevent the re-emergence of infections.

B. Passive immunization

Passive immunization involves the transfer of antibodies generated by one individual to another individual in an attempt to prevent or attenuate an anticipated infection. The method is less effective and shorter lived than active immunization but it has the advantage of being more immediately effective. This is an important strategy in the use of antibody preparations for prophylaxis against/or treatment of tetanus, rabies, varicella and hepatitis A and B. Pooled human serum immune globulins contain a wide variety of IgG antibodies against different agents. The increasing availability of injectable immunoglobulin preparations which can be safely administered in high doses has broadened the use of this treatment. Individuals with congenital immuno-deficiencies treated with a regular infusion of immune globulin experience a reduced number of infections. However, passive immunization is not without difficulties. It may interfere with the immune response to some antigens like measles vaccine, but can be used effectively in combination with active immunization against such diseases as rabies and hepatitis B.

C. Vaccines

Live vaccines, derived from modified strains of the causative organism, may replicate and induce an immune response in the host. They have sufficient characteristics of the original pathogen to activate the

immune system of the recipient and cause long-lasting immunity. They rarely cause significant illness unless there are pre-existing immune defects in the host. "Killed" or inactivated vaccines trigger the immune system through antigens that are common to the original pathogen but which do not replicate. These vaccines require relatively large doses to trigger an effective immune response, and the protection may not be as long-lasting. While there is no risk of vaccine-induced infection, there may be a risk of a mild, modified form of the disease.

Vaccines can occasionally induce allergic reactions, ranging from mild to severe anaphylactic responses. Adverse responses may be due to components of the vaccine, e.g., residuals of materials used in the preparation of the vaccines, preservatives, etc. Specific recommendations with regard to allergic reactions are provided by the producers of each vaccine and should be consulted. Excessive interpretation of contraindications (e.g., non-febrile mild acute illnesses, or mild illnesses with temperature elevations of 101^{o}F or less) results in reduced uptake of vaccine. While severe illness should be viewed as contra-indicative of immunization, mild acute illness with or without low grade fever, current microbial therapy and the convalescent phase of an illness are not reasons to avoid or delay vaccination.

The effectiveness of a vaccine programme largely depends on (1) the proportion of susceptible individuals who have access to immunization services, (2) the vaccine failure rate (i.e., the proportion of individuals properly vaccinated but who fail to develop a protective response, (3) the vaccine efficacy (i.e., the proportion of individuals who may be expected to develop a protective response to the vaccine under optimal field conditions –never 100%), (4) effective procedures for preserving the vaccine at optimal temperature during transit, (5) the training of vaccinators to ensure proper administration of the vaccine, (6) the attitude of the vaccination staff, (7) the knowledge and attitudes of the population, and (8) the proportion of the population willing to submit to the vaccination schedule.

II. Assessment of risks in target groups

The risk of infection is never uniformly spread throughout a population, i.e., individuals in the population do not all have an equal chance of acquiring the infection. If the individuals most at risk can be identified, immunization activities can be focused on them. Target groups can be defined by age (e.g., influenza in the elderly), gender (e.g., rubella/females), location, environment (e.g., weather, climate, geography, natural disasters, etc.), sanitation (e.g., food preparation, clean water, waste disposal), and socio-demographic characteristics (e.g., social unrest, population migration).

A. Universal immunization

Certain diseases may require universal immunization of a population to control. Such efforts usually target infants in the first year of life so that immunity is completed as early as possible before the risk of infection, (e.g., diphtheria-pertussis-tetanus, polio). Others may require immunization of only selected high risk groups (e.g., at risk elderly for pneumococcus). In some cases the target group may not be the group the vaccine is designed to protect (e.g., rubella vaccination of all children and females of child bearing age in order to protect the fetus).

Since there are regional differences in infection rates and severity of every disease, the choice of vaccine and dosage regimen will vary with the local epidemiology of the disease, specific target population, and health system. The effectiveness of the delivery system can also vary with different vaccines, vaccine efficacy, and organization of the local health care service organization. Care must be taken to insure the balance of risks and benefits where cost constraints or logistical limitations make continuous universal immunization impossible.

B. High risk groups

Most universal immunization programmes target pediatric populations so as to maximize protection before the peak age of incidence of the disease, and since children are generally more readily accessible. Immunization of adults is often neglected because of the difficulty in getting the necessary acceptance (e.g., in cases requiring multiple vaccinations), the increased mobility of adults, and the supposition, not always accurate, that adults were immunized as children. However, under certain conditions immunization of adults is desirable and important, e.g., travellers, visitors, students, immigrants, refugees, or certain occupations where individuals may be brought into contact with potentially infectious environmental conditions (construction workers), or

at-risk populations (health care workers). Immunization of travellers provides an opportunity to ensure that routine immunization has been carried out. Other at-risk adult populations may include subgroups especially vulnerable to selected infectious diseases, e.g., influenza among the elderly.

Not all individuals are equally at risk from any given target disease. Women resorting to unsafe birthing practices put their infants at risk from neonatal tetanus. Such women are especially targeted to receive tetanus toxoid before giving birth. The actual location of such women is generally easy to identify in a given country. Thus special targeted campaigns may be carried out to vaccinate them. High risk groups may be identified because of where they live (e.g., in an urban slum – at risk of measles), gender (young women and congenital rubella syndrome), age (the elderly and influenza), occupation (health care workers and TB), migrants or refugees (measles), travellers (yellow fever).

C. Pregnancy

In general, the administration of vaccines should be avoided during pregnancy, or at least delayed until the second or third trimester in order to avoid potential teratagenic effects of the vaccine on the fetus and, in the case of live vaccines, possible congenital infection. Exceptions include diphtheria and tetanus vaccines which are considered to be safe in pregnancy. Yellow fever vaccine is a special case and exceptionally may be given to pregnant women if it is considered they are at high risk of the disease. Similarly, in the case of influenza, the risk of severe disease, especially after the second trimester, may be considered greater than the theoretical risk to the fetus of the inactivated virus. This is only applicable to US females at high risk.

Rubella vaccine is contraindicated in pregnancy since transplacental transmission of the vaccine virus to the fetus has been observed. However, congenital rubella syndrome (CRS) has not been reported in infants born to women inadvertently vaccinated in pregnancy. Therefore, such vaccination is not, *a priori*, an indication that CRS will result.

D. Immune deficiency

Patients with immune deficiency are especially at risk for severe infections since they are often unable to mount an adequate immune system response. Such patients include medically immuno-suppressed patients (e.g., as part of cancer treatments), or persons infected with HIV. With the exception of BCG in symptomatic individuals and yellow fever vaccine, WHO recommends that the standard childhood vaccines should all be given to HIV-infected infants as they are safe and reasonably effective, and the risk of each target disease is very much greater than the risk of using the vaccine. Some industrialized countries recommend the use of killed vaccines instead of the live viral vaccines in both congenital and acquired immune deficiency disorders.

III. Communication – the key to behaviour change

Immunization is an important form of primary prevention which protects the individual and the wider population by impeding the spread of infectious disease. However, immunization programmes may be less effective because eligible individuals chose not to complete vaccination schedules for various reasons. These include ignorance of the benefits and risks of immunization as well as a misunderstanding of the consequences of non-participation. Standards for Pediatric Immunization Practices are available and provide useful information for family and community education. However, care should be taken to insure that the information is presented to the public in the language(s), educational levels and cultural styles appropriate to the target population. It is essential that health care professionals communicate with members of target groups in terms that are readily understood, translating technical concepts into common language, transmitting essential information, addressing local concerns, allaying fears and demonstrating respect for local customs and practices.

A. Barriers

(1) *Knowledge*. A significant barrier to immunization may be the family's lack of knowledge or inaccurate perception about the importance of vaccines and the seriousness of the diseases prevented by the vaccines. For example, in the U.S. a 1993 poll showed that 47% of parents of children under five did not know that polio was contagious, 36% did not know that measles could be fatal, and 44% did not know that H. influenza type b was the leading cause of potentially fatal childhood meningitis. (Kimmel, et al., 1996).

Poor perception of the threat and potential severity of the disease may be influenced by local or culturally-based beliefs and a relative lack of medical knowledge leading individuals to assume the disease to be harmless, rare, minimally contagious, a "normal" part of childhood, or that individuals are resistant based on past exposure.
Expectant parents generally do not seek maternal immunization, thus avoiding the threat of damaging the foetus with vaccine. Tetanus toxoid is an exception and, when indicated, can be given safely in pregnancy. Parents may be fearful of vaccination effects on the young child, trying to balance their fear of committing harm against their fear of omitting care. Parents also worry about the potential side effects of vaccines and the number of injections their child will receive in a single visit. One study has shown that 67% of parents interviewed expressed concern over potentially dangerous side effects and that such concerns are often fostered by media reports. These concerns may be fueled by fears of the very concept of immunization and require a well planned and carefully carried out programme of public information to explain why immunization is needed and how it works, explaining the relative risk of damage by vaccines (extremely low) versus the risk from vaccine-preventable diseases (very high).

Religious and philosophical objections of parents to immunization are far more complex issues. Since religious groups tend to be clustered in geographic locations, these can pose a potential risk for outbreaks of a disease. Health care professionals need to familiarize themselves with relevant laws and local customs regarding this issue. Some countries may permit exemptions from immunization on religious and philosophical grounds. Some may permit the intervention of health care professionals in situations where a patient's life, especially that of a child, may be in danger. Even when religion appears to be a barrier, sensitive handling of the issue can often result in acceptance of vaccination.

(2) *Environmental and logistical barriers*. Such barriers may include climate, geography or limited accessibility to health care due to poor roads, a failure of the Ministry of Health to provide them, inadequate public transportation, inconvenient office hours, inaccessible locations, or long waiting lines. Access to immunization is influenced by the nature of the health care facility and service available. Public health clinics with large numbers of walk-in acute care cases may be more likely to overlook immunization needs than general practitioners with whom the family or patient has an established relationship.

(3) *Socio-economic status.* This affects availability of, or access to, health care by creating conflicting priorities for working families that must meet daily survival needs. Families that live in deprived socio-economic (SES) areas may have less access to, and are less likely to pursue immunization. Immunization rates can also vary among different ethnic groups. For example, some South Asians in the U.K. were at higher risk for rubella because they did not seek or accept immunization due to a lack of information about the disease and its teratogenic effects. Within this group, the symptoms of rubella were often confused with other diseases which were perceived as not severe or a threat to health. As a result, immunization for rubella was not seen as being important within this ethnic group.

(4) *Birth order and size of family*. The higher the number of offspring in a family, the greater the probability that the youngest will not be vaccinated. In fact, as a family increases in number, successive children are less likely to be vaccinated as the increasing family responsibilities demand more and more time and detract from health care decisions. Single parent families are especially at risk since the increased demands of family support and maintenance may impede health care decisions for the single parent who has no partner with whom to share responsibility.

While parents and health care professionals may be reluctant to administer multiple vaccines in a single visit, such a strategy is more convenient for families, and significantly increases the probability that the immunization programme will be completed for that family member. Families generally respond to an explanation that the patient's welfare is more properly served by comprehensive immunization than it is by a strategy aimed at minimizing the baby's and parents' discomfort!

(5) *Family mobility*. Families who live in temporary housing, or who migrate between jobs are especially at risk of failing to complete immunization schedules. Moving to a new area immediately after birth raises the probability that a child will not be immunized or that vaccination will not be completed. Individuals with no prior history of contact with the health care system, or families with no previous experience with vaccinations, are unlikely to have relevant knowledge of the need for immunization, nor do they pursue it.

(6) *Social and political instability*. Immunization programmes have been found to be vulnerable to disruptions of several kinds including high local rates of crime, political instability, sudden regime changes, withdrawal of donor aid and civil war.

(7) *Health staff's attitudes*. A programme can be seriously damaged by the poor interaction between staff and clients. In some cases, staff have been observed to be rude. Even when correct information was provided, the manner in which it was delivered was not conducive to parents' returning to complete immunization for their children. This kind of situation is obviously undesirable, but the reasons for such behaviour may be complex, not always directly within the control of the health worker, and require considerable effort to correct.

(8) *Financial*. The high cost of immunization to the consumer is likely to be a major barrier. Ways of lowering the cost include the provision of private or public health insurance coverage, government or publicly sponsored programmes, collaborative efforts by employers and government, public foundations and government, international/national/regional collaboration, pharmaceutical / government collaborations, etc. The benefits that accrue to employers from such collaborative efforts include reduced manpower losses due to sick leave, public relations benefits, free advertising, institutional good will, tax benefits, etc. Benefits to government include shared costs and the utilization of commercial infrastructures for implementation.

(9) *Legal considerations.* The success of immunization programmes can lead to the perception and expectation that these programmes are infallible. However, as has been shown, although serious adverse effects are rare, it is not yet possible to remove all risk. As a result, in industrialized countries there is a growing number of lawsuits for alleged vaccine-induced damage, especially in instances where immunization has been legally required. These potential threats of legal action can serve as significant disincentives to governments, agencies, pharmaceutical companies, and health care professionals to provide immunization. A significant diminution of immunization programmes as a result could prove to have disastrous consequences. Therefore, governments, institutions, and individual health care providers must ensure that patients are thoroughly informed of the risks involved, and of the potential for adverse effects. One recommended solution is the institution of a no-fault compensation agreement for vaccine related injuries. Several European countries have established no fault compensation agreements for vaccine related injuries. However, to ensure that compensation is paid only on genuine, scientifically accepted circumstances, a rigorous system of medical peer review is required. A skilled lawyer might convince a court that compensation is due for an event temporally associated with administration of vaccine, but which may have no causal association. Awarding damages in such a case may appear compassionate, but is actually against the public interest and unnecessarily damages a vaccine's reputation.

IV. Patient education

The effectiveness of information provided to the public depends upon the quantity of information provided, the clarity of the information and the source of the information. Information needs to be presented in a form that is readily understood by the lay public. It must be relevant and accurate regarding the disease and its potential risks with and without vaccine, the effectiveness and any contraindications or associated risks of the vaccine, and the procedures required for successful completion of the immunization programme. The information should come from authoritative sources such as community leaders, popular figures (e.g. football stars), religious leaders, and health professionals.

Since family and friends are important sources of health care information, efforts should be made to inform communities and educate families, even though some members may not be part of the target population. Educational efforts should be focused on parents and families who may not be motivated to obtain timely vaccinations, e.g., low educational level of either parent, large family size, low SES, minority, high use of public clinics, young parental age, single parent status, lack of prenatal care, and a late start with immunization.

Mass media campaigns have been shown to be highly effective in obtaining the acceptance of the public. Using such techniques, in excess of 99% of target group has been reached during the Polio Eradication Initiative of the 1990s. If not designed properly, however, mass media programmes run the risk of being overshadowed by the diffuse distractions of all media, and may tend to be ignored or dismissed in their association with commercial advertising.

Educational programmes in schools may have limited influence if messages brought home by children try to influence parents who are already over-burdened, and distracted. Nonetheless, some interesting examples of school aged children acting as family educators (e.g., Indonesia) indicate this strategy deserves further attention.

Successful public education programmes require a high community participation in the education effort. Radio, TV, and print media should feature concise, easily understood public service announcements using (a) national public figures who have reputations for sincerity and credibility; (b) well-known and authoritative local representatives of the target population; and (c) typical or representative members of the target population (i.e., the couple next door, the family down the street, etc.), with whom the members of the target population can identify.

V. Changing health behaviours

Ultimately, health education attempts to provoke a behavior change (in this case, taking children to be vaccinated) by appealing to an assessment of risk. In other words, the public needs to come to an understanding of the balance of risk of disease compared with the risk of getting immunized. At times of high risk such as during an epidemic of meningitis, the demand for vaccine is extremely high, reflecting the perceived high risk of disease and low risk of immunization. At other times when no disease is evident but the vaccine is known to have side effects, the reverse occurs and coverage falls. Health education's difficult task is to maintain coverage by reminding the public of the real possibility of a resurgence of the disease if coverage is not maintained while at the same time reassuring them of the low risk of immunization.

To ensure the appropriate message is delivered through the right medium, it is essential to understand where the public looks for decision-making information regarding vaccines. Unfortunately this information is not always at hand for national programme managers.

Risk communication science tells us what influences a person's view of risk, as well as what types of communications better inform or change behaviour. Relevant factors include a recipient's educational level, life experiences, beliefs, attitudes and values, while some base decisions on vaccine risk, according to how they perceive the risk of disease, the ability to control those risks and the preference for one type of risk over another. A recent Gallup poll was conducted of 500 people in each of six European countries. The poll revealed the principal motivation for getting vaccinated was fear of the disease (46%). Negative effects mentioned by anti-vaccination groups, such as the impact on the immune system, were quoted only rarely (5%) as motivational. Not surprisingly, trust is a key component of information exchange at every level.

The most critical issue is providing mechanisms by which families come in contact with the health care system. In countries where universal health care is provided, such contacts are built into the system. However, in countries or regions where health care is less accessible, other mechanisms for contact must be found. Almost all societies have key points of contact between the individual/family and institutions of the state where examinations for infectious diseases and immunization services can be initiated, e.g., kindergarten or school enrollment, applications for marriage, foreign travel, pubic sector employment, military service, government business, health care, education, etc. Such points of contact offer opportunities to check health records to determine if the individual or family is a candidate for an immunization programme.

A clear, positive effect on coverage rates was found in cases where a cadre of frontline health workers was rooted in the community, in direct and intensive contact with parents and children, as well as having a direct relationship to the government health services. Such community-level workers prove to have a powerful positive effect, increasing immunization coverage and avoiding dropouts. One of the activities of such front line health workers could be the monitoring of births as well as children's vaccination status. This would link locally-maintained records of vital events with the immunization register at health centres, and ensure an accurate basis for assessing coverage.

Once initiated, systems for maintaining contact to ensure follow through must be in place, especially if

the immunization programme requires periodic re-vaccination. Reminder systems utilizing communication systems (e.g., radio, TV, telephone, mail, e-mail), where available, should be used. Where not available, innovative use of available and traditional means of communication should be

explored (e.g., travelling news carriers, or announcements at celebrations, holidays, clan gatherings, sporting events, etc.). In all cases, the creative use of incentives for participation should be encouraged.

Studies indicate that workers' lack of technical competence and interpersonal skills is related to a deficiency in training and supervision, and to their often difficult working conditions. Good supervision is absolutely necessary for effective health care delivery, but studies show that where it exists at all, it is often carried out in a disciplinary and punitive manner. Unfortunately, the natural response to punitive supervision is a falsification of records and the suppression of negative data to avoid appearing a "poor" vaccinator. Therefore, supervision should be instituted if absent, and the incentive system should serve to strengthen a more supportive style of supervision which should focus on accurate reporting and improved performance at all levels.

VI. Adherence

The ideal system for maintaining high coverage would be based on educated choices. In reality, the most effective strategies for adherence involve using public systems that require individuals to have periodic contact with agencies where immunization can be monitored and administered, e.g., in connection with voting, applications for licenses or documents, registration for various purposes, etc. Incentives in the form of food, festivals, entertainment, compensations, tax benefits, etc., have also been used effectively in certain culture-specific situations. Penalties for non-compliance are not encouraged as they can result in the active avoidance of the intended goal. The general philosophy should be an understanding that immunization is beneficial to the individual and is associated with other benefits (such as improved survival/health), not punishment.

Strengthening of information, education and communication activities and using local-level and culturally acceptable institutions will enhance informed and willing public participation. Considering the need for long-term sustainability of immunization programmes, information flow to clients about the balance of benefits and risks of vaccines must be provided to permit informed decisions.

Knowledge of how to encourage behaviour change is needed to help service providers alter their attitudes from a paternalistic model of communication to a more open style of interaction, recognizing that there may be a range of valid points of view. The communication model is currently shifting from the more traditional approach of simple advocacy (persuade the parents to follow expert advice) to providing information required to make effective decisions and encouraging a decision-making partnership.

All levels of health staff involved in immunization must be concerned about and encouraged to become involved in the area of communication. They should realize that their own attitudes, uncertainties, and behaviour communicate to parents and may be a cause for parents refusing vaccines for their children.

VII. Evaluation

A. Effectiveness of immunization programmes

Effectiveness of well coordinated and well supported public and private health efforts is evidenced in Table 1. The increasing cost of health care in industrialized nations and the limited resources available in developing nations requires a rigorous assessment of the cost benefits of all medical interventions. In all analyses to date, effective immunization programmes have been shown to be more cost effective than most other preventive health strategies, and far less expensive than the cost of treating the infectious diseases after they are established.

Vaccination programmes require continuous and rigorous monitoring and record keeping to insure the quality and purity of the vaccine, and adequate coverage of the target population. An individual's immunization status should be reviewed at each opportunity, i.e., whenever that person comes into contact with a health care professional. Records should be consulted where available and if not available, a careful review of the health condition conducted, including a complete physical examination, observation of the general state of health, questioning the family members about the individual's condition, possible exposure to infectious diseases, contraindications to immunization, and other precautions.

Table 1. Comparison of maximum and 1986 morbidity of vaccine-preventable diseases in the U.S.

Disease	Maximum cases (year)	1986	% Change
Diphtheria	206,939 (1921)	0	100.00
Measles	894,134 (1941)	6282	99.30
Mumps *	152,209 (1968)	7790	94.88
Pertussis	265,269 (1934)	4195	98.42
Polio (paralytic)	21,269 (1952)	3	99.99
Rubella †	57,686 (1969)	551	99.05
Congenital rubella Syndrome	20,000 (1964-5)	14	99.93
Tetanus ‡	608 (1948)	64	89.35

* First reportable in 1968.
† First reportable in 1966.
‡ First reportable in 1947.
SOURCE: Finn & Plotkin (1991)

VIII. Teaching strategies

The principles outlined in this teaching module are best presented within the context of an interactive workshop conducted by a specialist in behavioural medicine. The workshop can be divided into discussion/exercise sessions which cover topics discussed in the text of the teaching module. Workshop leaders should use local health problems as teaching examples whenever possible.

Session A

Section I. Basic Information About Immunization (Page 1) – The workshop leader should review and encourage discussion about basic principles and mechanisms of immunization, drawing upon clinical examples relevant to local diseases, health conditions, health practices and beliefs.

Section II. Assessment of Risks in Target Groups (Page 3) – After reviewing the basic material in this section, the workshop leader can break the overall group into small groups of 3-4 people. Each small group is then instructed to define local immunization problems in terms of "at risk groups" and diseases. All groups then report back to the main group and discuss the consensus (or lack thereof).

End this general session with a discussion of "immune deficiency" and its implications, discussing local clinical examples and target groups.

Session B

Section III. Communication: The Key to Behaviour Change (Page 6) – The workshop leader conducts a review of module material on the principles of successful communication with target populations.

The group leader then asks the group to break up into dyads and consider a local infectious disease problem. One member of each dyad takes the role of a health care professional (HCP), the other takes the role of a lay person (LP) who is a member of a target population that is to be immunized against the disease. The HCP must then attempt to inform and explain the need for immunization to the LP, calling upon all the principles previously discussed. The LP should ask questions, seek clarifications and explanations, reflect fears and concerns typical of the local target population. The members of the dyad then switch roles and repeat the exercise. The total group then reconvenes and discusses the issues, insights and difficulties that were raised.

The workshop leader divides the group into small groups of 3-4 persons. Each small group is asked to discuss the barriers to the acceptance of immunization among local target populations and how each barrier might be addressed. The small groups then report

back to the group as a whole and discuss insights, issues and problems. The overall group is encouraged to especially consider the impact of staff/client interaction and the factors (respect, politeness, and civility) that can effect the outcome of this relationship.

Session C

Section IV. Patient Education (Page 10) – The workshop leader presents the basic principles and gives several relevant examples of successful patient education programmemes, encouraging a discussion of methods for disseminating public information about immunization, and compiling a list of potential local sources (e.g., authoritative, popular, professional, typical, etc.).

The group then divides into small groups of 3-4 persons and each group is given the task of designing a public information programme for a local disease and local target population, identifying specific information issues, media, sources, means of distribution, etc.

Session D

Section V. Changing Health Behaviours (Page 11) – Consider a local infectious disease problem. Discuss the behavioural principles required to not only encourage people to seek immunization but also to sustain or maintain the immunization programme over time, that is, continue to get immunized, booster shots, etc. What messages, sources, frequency of repetition, and mechanisms for continuing contact should be considered?

The group divides into small groups of 3-4. Each group is required to design a programme for immunization maintenance for a disease and target population specific to the local region. Each group is encouraged to focus on establishing a mechanism for maintaining continuing contact between the target population and the local health care system, and identifying personnel at each level of the system from "front line" to higher government levels. The total group then reconvenes and each small group reports on its project discussing insights, consensus observations and problems.

Session E

Sections VI-VII. Adherence and Evaluation (Pages 13-14) – The workshop leader leads a discussion on the behavioural principles involved in sustaining adherence to immunization and maintaining continued contact with the target populations. Discuss how this translates into practical application, i.e., mechanisms of reinforcement, reward, record keeping systems, continuing education, feedback, the concept of information as reinforcing, etc.

The group divides into 3-4 person subgroups and each subgroup is assigned the task of devising a system for tracking and evaluating the success of an immunization programme, defining who reports what, where, when, and to whom and how the data is to be analyzed (what do you do with it?).

Session F

Wrap up and summarization. The workshop leader conducts a discussion session where the entire group contributes to a summarization of the workshop findings, outlining the conclusions provided by the group on a large flipchart/blackboard, etc. The review should focus upon what has been learned, including the insights, pitfalls, barriers, problems and solutions identified. Results are edited and subsequently distributed to participants.

IX. References

Finn, A. & Plotkin, S. (1991). Immunization. In Wilson, J., Braunwald, E., Isselbacher, K., Petersdorf, R., Martin, J., Fauci, A. and Root, R. (Eds.). Harrison's Principles of Internal Medicine, 12th Edition. New York: McGraw-Hill, 472-478.

Heggenhougen, K. & Clements J. (1987). Acceptability of childhood immunization – social science perspectives. A review and annotated bibliography. Evaluation and Planning Center for Health Care Publications No. 14. London School of Hygiene and Tropical Medicine.

Kimmel, S., Madlon-Kay, D., Burns, I. and Admire, J. (1996). Breaking the barriers to childhood immunization. American Family Physician. 53 (5): 1648-1656.

Santoli, J., Szilagy, P., and Rodewald, L. (1998). Barriers to immunization and missed opportunities. Pediatric Annals. 27 (6): 366-374.

Streefland, P., Chowdhury, A., and Ramos-Jiminez, P. (1999). Patterns of vaccination acceptance. Social Science & Medicine. 49: 1705-1716.

Stygall, J. (1997a). Epidemics. In Baum, A., Newman, S., Winman, J., West, R. & McManus, C. (Eds). Cambridge Handbook of Psychology, Health and Medicine. Cambridge: Cambridge University Press. 456-457.

Stygall, J. (1997b). Malaria. In Baum, A., et al., (Eds). Cambridge Handbook of Psychology, Health and Medicine. Cambridge: Cambridge University Press 509-511.

Timberlake, N. (1997a). Rubella. In Baum, A., et al., (Eds). Cambridge Handbook of Psychology, Health and Medicine. Cambridge: Cambridge university Press, 581-582.

Timberlake, N. (1997b). Tetanus. In Baum, A., et al., (Eds). Cambridge Handbook of Psychology, Health and Medicine. Cambridge: Cambridge university Press, 603-604.

World Health Organization Scientific Advisory Group of Experts (1998). The Children's Vaccine Initiative (CVI) and WHO's global programmeme for vaccines and immunization (GPV). Weekly Epidemiological Record. 73 (37): 281-288.

World Health Organization (1997). The Jakarta Declaration

Appendix A

Vaccines used in the National Immunization Programmes in different countries

(Source: Immunization policy. WHO/EPI/GEN/95.03 rev. 1)

The target diseases

The EPI recommends that all countries immunize against poliomyelitis, diphtheria, pertussis, tetanus and measles, and that countries with a high incidence of tuberculosis (TB) infection should immunize against TB. Hepatitis B vaccine should be integrated into national immunization programmemes in all countries by 1997. Immunization against yellow fever is recommended in endemic countries. Table 1 summarizes the information on the EPI target disease which is most relevant to the design of control programmes.

Tuberculosis, caused by Mycobacterium tuberculosis (M. tuberculosis), caused an estimated 2.6 million deaths worldwide in 1990. The pandemic of HIV infection and an increase in multi-drug-resistant tuberculosis bacteria have profoundly worsened the public health burden of tuberculosis.

Diphtheria is a bacterial infection caused by Corynebacterium diphtheriae (C. diphtheriae), transmitted person to person through close physical and respiratory contact. Like other respiratory infections, transmission is increased in overcrowded and poor socio-economic conditions. In temperate climates, prior to vaccination, respiratory diphtheria commonly affected preschool and school-age children, and deaths occurred from exotoxin-induced damage to other organs. Large epidemics occurred in Europe during and after the second world war, with an estimated one million cases and 50,000 deaths in 1943. Nasal diphtheria may be mild and chronic carriage of the organism frequently occurs; asymptomatic infections are common. A cutaneous form of diphtheria is common in tropical countries, and may be important in transmission. Recently, large epidemics have occurred in Russia and the Ukraine.

Tetanus is caused by the action of a potent neurotoxin produced during the growth of the anaerobic bacterium, Clostridium tetani (Cl. tetani), in necrosed tissues such as occur in dirty wounds, or the umbilical cord if delivery has not been clean. Tetanus has an environmental reservoir, and is not a transmissible disease. In developed countries, it affects mainly elderly persons, because younger age groups have been immunized. In developing countries, neonatal tetanus is an important cause of infant mortality. Maternal tetanus can occur by postpartum contamination of the uterus. In addition to vaccination, improving delivery care and the care of wounds are important interventions to reduce tetanus.

Pertussis (whooping cough) is a bacterial respiratory infection caused by Bordetella pertussis (B. pertussis). It causes a severe cough of several weeks duration, with a characteristic whoop, often with cyanosis and vomiting. In young infants the cough may be absent and disease may manifest with spells of apnoea. Many of the symptoms are thought to be caused by toxins released by B. pertussis, in particular the pertussis toxin (PT; also known as lymphocyte promoting factor, LPF).

Poliomyelitis is an acute viral infection spread via the faecal-oral route, thus transmission is higher in areas of poor sanitation. Where sanitation is good, pharyngeal spread becomes more important. The majority of wild poliovirus infections are asymptomatic, the risk of paralysis is approximately 1 in 200 infections among infants <1 year old, and 1 in 100 infections among children aged 1-14 years. Factors increasing the likelihood of paralysis include the administration of injections or tonsillectomy during the incubation period of poliovirus infection, pregnancy, stress and trauma.

Measles is an acute viral infection that is transmitted by close respiratory contact, and may also spread via aerosolized droplets. Most deaths occur through secondary infections of the respiratory and/or gastrointestinal tract.

Yellow fever is a viral haemorrhagic fever that causes an estimated 30,000 deaths each year. In the forest pattern of yellow fever, the most common in the Americas, the main host is the monkey, and man is an accidental host. In the urban pattern, man is the host and the virus is transmitted via Aedes aegypti mosquitoes from person to person. The mosquito vector breeds in small stagnant water collections and hence transmission is facilitated by poor

environmental hygiene. Thirty-three countries in

Africa are considered at risk of yellow fever.

Acute **hepatitis B** is caused by the hepatitis B virus (HBV). Three of the antigens of the HBV are crucial in sero-epidemiology. These are the hepatitis B surface antigen (HBsAg) which is part of the coat of the virus, the core antigen (HBcAg), and the e antigen, a product of the breakdown of the core antigen which indicates high infectivity (HBeAg). Acute infection may be subclinical, especially in infants and young children, or may present with malaise, nausea and jaundice. The main public health consequences of HBV infection are the chronic liver disease and liver cancer that arise in carriers of the HBV virus, who are identifiable through detection of HBsAg. The younger the age at infection, the higher the chance of becoming a carrier; as many as 95% of infected infants, but only around 10% of adults, become long term carriers. In developing countries, the main route of transmission is perinatally (vertical transmission) from a carrier mother to her baby, which is more likely if the mother is positive for HBVe antigen, and "horizontal" transmission between young children. In industrialized countries, the main routes of transmission are sexual intercourse (which also plays a role in central and east Africa and much of Asia), blood to blood contact (e.g. transfusion, needle sharing among intravenous drug users, as well as mother to baby).

Vaccine preparations available

Bacterial vaccines include Bacilli Calmette Guerin BCG that contains live attenuated Mycobacterium bovis M. bovis), and pertussis vaccine that contains killed pertussis bacteria. Vaccines against diphtheria and tetanus are toxoids (detoxified bacterial toxins). Viral vaccines include measles, yellow fever and oral polio vaccine which are all live attenuated viruses. Hepatitis B vaccines are produced from the surface antigen. Some vaccines are available in a fluid form, ready for use, while others are in a freeze-dried (lyophilized) form that must be reconstituted with cool diluent prior to administration. Detailed information on the immunological basis for the use of these vaccines is provided in the EPI series of modules on the Immunological Basis for Immunization.

BCG. Although BCG is the most widely used vaccine in the world (85% of infants received a dose of BCG in 1993), estimates of efficacy vary widely and there are no reliable immunological markers of protection against tuberculosis. Clinical efficacy in preventing pulmonary TB has ranged from zero protection in the southern United States and in South India/Chingleput, to approximately 80% in the UK. There is no consensus on the reasons for this variation. Efficacy does not depend on BCG strain or manufacturer. Some studies suggest that efficacy is reduced if there has been prior sensitization by environmental mycobacteria, but the evidence is not consistent. The degree of protection has not correlated with the degree of tuberculin test sensitivity induced by immunization, nor with BCG scar size. Data showing that BCG protects against tuberculous meningitis and against miliary tuberculosis (estimated 75-86% protection) have led to a hypothesis that BCG protects against bloodborne dissemination of the bacteria, but does not limit the growth of localized foci that occurs in pulmonary TB. BCG also protects against leprosy, although the estimated efficacy has varied from 20% in Burma to 80% in Uganda. Because efficacy against pulmonary tuberculosis is doubtful, the mainstay of the tuberculosis control programme is case-finding and treatment. BCG immunization at birth, however, will reduce the morbidity and mortality from tuberculosis among children.

Diphtheria toxoid. Diphtheria toxoid is a formaldehyde-inactivated preparation of diphtheria toxin, adsorbed onto aluminium salts to increase its antigenicity. This toxoid protects against the action of the toxin. Immunized persons can be infected by toxin-producing strains of diphtheria, but the systemic manifestations of diphtheria do not occur. Although the public health burden of diphtheria has been low in most developing countries, because most children acquired immunity through subclinical or cutaneous infection, recent outbreaks of diphtheria have been observed in Algeria, China, Jordan, Lesotho, Sudan, and Yemen Arab Republic, showing the importance of immunizing children in all countries. Diphtheria outbreaks in adults in Europe show the need to maintain immunity against the disease throughout life (see section 5). There are no data from randomized controlled trials of the clinical efficacy of diphtheria toxoid, but outbreak investigations have shown efficacies of over 87%.

Diphtheria toxoid is almost always administered together with tetanus toxoid and pertussis vaccine as part of DPT vaccine in the primary vaccination series. It is also available as a component of other combined vaccines, or as a monovalent vaccine. DPT vaccine contains 10-20 Lf per dose of diphtheria toxoid, and the potency of diphtheria toxoid is at least 30 IU per dose. A combined diphtheria-tetanus vaccine exists

in two forms: DT, with 10 – 30 Lf per dose, intended for children 7 years of age or younger, and Td, which has a reduced amount of diphtheria toxoid (2 to 5 Lf per dose) for use in older children and adults because of hyperactivity to diphtheria toxoid in persons already sensitized to the antigen. DT is used for children who have contraindications to pertussis vaccine, and Td is used in countries that recommend booster doses of these toxoids throughout life.

Tetanus toxoid. Tetanus toxoid (TT) is a formaldehyde-inactivated preparation of tetanus toxin, adsorbed onto aluminium salts to increase its antigenicity. TT is stable and can withstand exposure to room temperature for months and to 37° C for a few weeks without a significant loss of potency. TT induces the formation of specific antitoxins, which neutralize the toxin. Antitoxin which passes to the foetus across the placenta following active immunization of the mother prevents neonatal tetanus. In general, a tetanus antitoxin level of 0.01 IU/ml serum, as determined by *in vivo* assays such as the neutralization assay, is considered the minimum protective level. The corresponding level of antibody measured by other assays may be higher, and usually 0.1 IU/ml of antibody measured by *in vitro* assays such as ELISA or passive haemagglutination is considered a safe estimation. TT is a highly effective vaccine, although as with all vaccines, some cases of disease occur in immunized individuals. In most studies, the efficacy of two doses of TT during pregnancy in preventing Nt has ranged from 80-100%.

Pertussis vaccine. Two types of pertussis vaccine are available: whole cell vaccines, which contain whole pertussis bacteria killed by chemicals or heat, and acellular vaccines, which have been introduced recently in some industrialized countries. Whole cell vaccines are effective in preventing serious illness, but they do not protect completely against infection with the organism. Efficacy and antibody levels wane with time after vaccination. The protective level of antibodies against pertussis is not known. The degree of protection against disease has varied widely in different studies, partly because of methodological differences, and there have been very few studies in developing countries. Nonetheless, the importance of pertussis vaccination is demonstrated by the decline in reported incidence in industrialized and developing countries with well established immunization programmes, and the rebound in incidence and recurrence of epidemics that occurred in countries such as Sweden, the UK and Japan when vaccination uptake fell. Whole cell vaccine causes frequent local reactions and fever. Rarely, it may cause neurological reactions.

Acellular pertussis vaccines contain isolated and purified immunogenic pertussis antigens. Usually they include pertussis toxoid (pertussis toxin treated to destroy its toxicity), filamentous haemagglutinin, agglutinogens and outer membrane protein. Local reactions are much less common following acellular than whole cell pertussis vaccine. The frequency of more serious neurological events in young children has not been determined. Acellular pertussis vaccines have been used routinely in Japan since 1981 in children above two years of age and in December 1991 were licensed in the USA for booster doses of DPT in children aged 15 months through 5 years. Several clinical trials are now in progress to compare the efficacy of primary immunization of infants with DPT acellular and whole cell pertussis vaccines. Meanwhile, the widespread use of DPT vaccine containing the whole cell pertussis component remains the cornerstone of pertussis control.

Poliomyelitis vaccines. There are two types of vaccine against poliomyelitis: oral and injectable. Oral poliomyelitis vaccine (OPV) is composed of the three types of attenuated polioviruses (1, 2 and 3). Because of its low cost, ease of administration, superiority in conferring intestinal immunity, and the potential to infect household and community contacts secondarily, the EPI recommends trivalent OPV as the vaccine of choice for eradication of poliomyelitis.

In industrialized countries, seroconversion rates after 3 doses of OPV have been demonstrated to be high (>90%) to all 3 types of virus. Seroconversion rates have been lower in developing countries, however: 73% (range 36% to 99%) for type 1, 90% (range 71% to 100%) for type 2, and 70% (range 40% to 99%) for type 3. The efficacy of 3 doses of OPV in preventing paralytic polio in developing countries ranges from 72% to 98% when the cold chain is properly maintained. Factors that reduce the immune response in developing countries (other than cold chain problems) include interference from other enteroviruses (that may be related to seasonal differences in response), and interference between the three vaccine viruses (that may be related to the relative doses of each virus type in the vaccine formulation). In many developing countries, routine immunization alone may not be sufficient to stop transmission of wild poliovirus, and supplementary immunization activities are recommended.

Concern over low seroconversion after 3 doses of OPV led to a revival of interest in inactivated polio vaccine (IPV) in some countries, either as the sole vaccine against polio or in schedules combined with OPV. An improved IPV (e-IPV, enhanced potency vaccine) has been developed and used in several European countries. A schedule of two doses of combined IPV/DPT has been used in Africa and Israel, with high sero-conversion rates to polio. However, pertussis agglutinin level waned faster in a two-dose schedule group than in a three-dose group. Although IPV suppresses pharyngeal excretion of wild poliovirus, this vaccine has only limited effects on intestinal excretion of poliovirus. The ability of IPV to eradicate poliovirus in developing countries, where faecal-oral transmission predominates, is doubtful.

Measles vaccine. Measles vaccines are live, further attenuated virus preparations derived from various measles virus strains isolated in the 1950s. Standard titre vaccines contain about but not less than 3 log 10 (i.e., 1000) infectious units per dose; higher potency vaccines do not increase sero-response when administered to children aged 9 months or above. In developing countries, sero-response rates and clinical efficacy have usually exceeded 85%.

Yellow fever vaccine. Freeze-dried yellow fever vaccine contains the live attenuated 17D virus strain. It is highly immunogenic, over 92% of immunized children developing neutralizing antibodies that persist for at least 10 years and often 30 years or more. In 1990, the EPI Global Advisory Group recommended that all countries at risk of yellow fever should incorporate the vaccine into their EPI schedules on a routine basis. The vaccine is recommended for use from 6 months of age and is most easily integrated into the EPI by administering it at the same time as measles vaccine (usually 9 months). As of 1992, 16 of 33 countries at risk in Africa included yellow fever vaccine routinely in their immunization programmes.

Hepatitis B vaccine. Two types of hepatitis B vaccine containing HBsAg are available: plasma-derived vaccine and recombinant vaccine. Both vaccines are safe and immunogenic even when administered at birth (maternal anti-HBsAg antibody does not interfere with the response to the vaccine), and highly efficacious. Over 90% of susceptible children develop a protective antibody response (over 10 mlU/ml) following three doses of vaccine, and the efficacy of the vaccine in preventing chronic carriage in most cohorts of children studied for more than 10 years exceeds 90%.

Infants of HBsAg-positive carrier mothers respond less well to the vaccine since it is often delivered after infection has occurred. The vaccine efficacy in preventing chronic HBV carriage in these infants ranges from 75% to 95%. Addition of one dose of hepatitis B immune globulin (HBIG) at birth to the vaccine schedule may improve efficacy somewhat, but use of HBIG is not feasible in most developing countries.

Administration of vaccines

Vaccines containing aluminium adjuvants (DPT, DT, TT, Td and hepatitis B vaccine) should be injected intramuscularly. Some Scandinavian and Eastern Europe countries practice deep subcutaneous injections of aluminium-adjuvanted vaccines, claiming a low rate of local reactions. The preferred site for intramuscular injection in infants and young children is the anterolateral aspect of the upper thigh since it provides the largest muscular mass. In older children, the deltoid muscle has achieved sufficient size to offer a convenient site for intramuscular injection. Similarly, in adult women, the deltoid is recommended for routine intramuscular administration of TT.

The buttock should not be used routinely as an immunization site for infants, children, or adults because of risk of injury to the sciatic nerve. Since the depth of gluteal fat in adult women is usually more than 3.5 cm, which is typically the length of the injection needle, injecting vaccines into the buttock may result in depositing the vaccine in the deep gluteal fat tissue. Gluteal administration of hepatitis B and rabies vaccine in adults has been associated with an impaired immune response possibly because of inadvertent deposition into, and poor adsorption of the vaccine from, fatty tissue.

Since hepatitis B vaccine is still expensive, some authors advocate the intradermal injection of a reduced dose of this vaccine. The adequacy and reliability of this practice has not been clearly established, and the EPI does not recommend this route. The immune response following a lower dose, especially of recombinant hepatitis B vaccine, may be reduced.

Basic immunization schedules and strategies

Routine immunization of infants. Recommendations for the age at which vaccines are administered are influenced by several factors:

- age-specific risks of disease
- age-specific immunological response to vaccines
- potential interference with the immune response by passively transferred maternal antibody
- age-specific risks of vaccine-associated complications
- programmatic feasibility

In general, vaccines are recommended for the youngest age group at risk for developing the disease whose members are known to develop an adequate antibody response to immunization without adverse effects from the vaccine. In addition to the need to protect infants before they encounter the wild disease-causing agents, administering vaccines early in life makes it easier to achieve high immunization coverage. Table 1 shows the immunization schedule recommended by the EPI for developing countries.

Table 1. The immunization schedule for infants recommended by the WHO Expanded Programme on Immunization

Age	Vaccines	Hepatitis B vaccine**	
		Scheme A	Scheme B
Birth	BCG, OPV 0	HB 1	
6 weeks	DPT 1, OPV 1	HB 2	HB 1
10 weeks	DPT 2, OPV 2		HB 2
14 weeks	DPT 3, OPV 3	HB 3	HB 3
9 months	Measles, Yellow fever*		

* in countries where yellow fever poses a risk.

** Scheme A is recommended in countries where perinatal transmission of hepatitis B virus is frequent (e.g., South East Asia). Scheme B may be used in countries where perinatal transmission is less frequent (e.g., sub-Saharan Africa).

The schedule calls for all children to receive one dose of BCG vaccine, 3 doses of DPT vaccine, 4 doses of OPV, and one dose of measles vaccine before the first birthday. In countries with HBsAg carriage rates of 2% or more, universal infant immunization with HB vaccine is recommended. Countries with a lower HBV prevalence may consider immunization of all adolescents as an addition or alternative to infant immunization. The rationale for this schedule is discussed below, and where relevant, reference is made to the variation in schedules in industrialized countries.

Age at initiating vaccination. The response to vaccines may be affected by maternal antibody transferred *in utero* to the foetus, and by the maturity of the immune response. Although immaturity of the immune system reduces the response to some polysaccharide vaccines (see section 8), young infants respond adequately to the EPI vaccines. Furthermore, babies born prematurely respond adequately to the EPI vaccines without any increase in side effects. Immunization of preterm infants should begin at the same chronological age recommended for term infants.

Because BCG is thought to be most effective in preventing tuberculous meningitis and disseminated disease in infants and young children, the EPI Global Advisory Group recommended in 1990 that BCG should continue to be given as soon after birth as possible in all populations at high risk of tuberculosis infection. However, further research is needed on the long-term effectiveness of BCG given in infancy. In some countries where the risk of tuberculosis infection is low, BCG vaccine is administered to school-age children. In England and Wales, for example, BCG vaccine is offered to tuberculin-negative school children at 10-13 years and appears to provide more than 70% protection against tuberculosis for at least 10 years. Many countries of central and eastern Europe administer BCG at birth and give additional doses to tuberculin-negative children at later ages (see section 5); there is not

evidence that multiple doses provide increased levels of protection.

Maternal antibody against most of the other EPI diseases is transferred to the foetus. Administration of DPT vaccine before one month of age results in a suboptimal response, but the first dose of DPT can be given effectively after four weeks of age.

Antibodies to polioviruses are transmitted transplacentally. Nonetheless, among neonates who receive a dose of OPV, 70 – 100% will develop local immunity in the intestinal tract and 30 – 50% will develop serum antibodies to one or more poliovirus types. Most infants excrete the virus for less than four weeks; therefore, the administration of a single dose of OPV at birth or as late as two weeks after birth should not interfere with the dose of OPV recommended at 6 weeks of age. Administration of an additional dose of OPV at birth leads to higher seroconversion rates at a younger age than occur with a 3-dose. An additional reason for providing OPV at birth and completing the DPT/OPV series early is that older children have a higher risk of injection-associated poliomyelitis (paralysis that is provoked by the administration of injections, including DPT vaccine, while a child is in the incubation period of poliovirus infection.

Persistent maternal antibody is a major factor determining the age for measles immunization. At age 9 months, 10 percent or more of infants in many countries still have levels of maternal antibody that interfere with the response to immunization. Delaying immunization would increase the rate of seroconversion, but would result in unacceptably high levels of morbidity and mortality prior to immunization in most developing countries.

From data on the age-specific incidence of measles and age-specific sero-conversion rates to measles vaccine in developing countries, immunization at age 8-9 months was predicted to lead to sero-conversion in at least 85% of infants and to prevent most of the cases and deaths. The EPI recommends immunization at age 9 months in routine immunization programmes in developing countries. In situations where there is a particularly high risk of mortality among children under age 9 months, such as refugee camps, hospitalized infants and HIV-infected infants, two doses of standard titre measles vaccine are recommended at 6 and 9 months of age. In industrialized countries, the risk of measles in young children is much lower, and measles vaccine is administered at 12-15 months of age, when virtually all children have lost maternal antibody and an optimal immune response is achieved.

For yellow fever, the age at administration has been determined by age-dependent rates of adverse events and by programmatic feasibility. Yellow fever is not recommended for use prior to 6 months of age because, although neurological reactions are extremely rare, 14 of 18 cases of encephalitis that have been temporarily associated with the vaccine (following over 200 million vaccine doses delivered since 1945) were reported in children immunized at 4 months of age or younger.

The age for beginning hepatitis B immunization depends on the proportion of infections that are acquired perinatally. In South-East Asia, where perinatal infection is common, it is important to administer the first dose as soon as possible after birth. The second dose is administered with DPT-1 and the third dose with DPT-3. In much of Africa, perinatal infection is less common, thus immunization can begin later. Programmatically, it is easiest if the three doses are administered at the same time as the three doses of DPT. A combined preparation of DPT and hepatitis B vaccine is likely to be available in the next 1-2 years, which will facilitate the administration of the vaccine, though countries with a high proportion of perinatal infection may still need to give monovalent HBV at birth even after the introduction of the combined vaccine.

Hepatitis B vaccine should be integrated into national immunization programmes in all countries with a hepatitis B carrier prevalence (HBsAg) of 8% or greater by 1995 and in all countries by 1997. Target groups and strategies may vary with the local epidemiology of the disease. When carrier prevalence is 2% or greater, the most effective strategy is incorporation in the routine infant immunization schedules. Countries with lower prevalence may consider immunization of adolescents as an addition or alternative to infant immunization.

Appendix B: An example of public service information about immunization

Plain Talk about Childhood Immunizations

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Check with your doctor, nurse or clinic if you have questions or concerns about immunizations. If you need help finding health care for your child, call Healthy Mothers, Healthy Babies at 1-800-322-2588 (voice) or 1-800-833-6388 (tty). Services are available in many languages.

The website address for this booklet is:
http://www.metrokc.gov/health/immunization/childimmunity.htm

A Message to Parents

Thank you for your interest in finding out more information about immunizations. As parents, we are asked to make many important decisions concerning our children. Some of the most difficult decisions can be in regard to their health care. To have your child immunized is one of these decisions. We all want to make the right choices and do what is best for our children. As a community, we also need to protect the public's health. We recommend that you have your child immunized, but ultimately the decision is yours.

We designed this site in response to requests by parents, health care professionals, school nurses, child care providers and others to:

- provide more information about immunizations and vaccine-preventable diseases, much in the same way you look for information on car seats, bicycle helmets, and age-appropriate toys;
- balance the benefits and risks of immunization and assist you in making an informed decision;
- clarify inaccuracies or misinformation about immunizations and vaccine-preventable diseases.

We have arranged the information so you can read each section independently. We use a question and answer format in many areas, but may not have included all the answers you need. We encourage you to discuss these issues with a health care professional or your local health department.

The Facts About Vaccine-Preventable Diseases

DIPHTHERIA, TETANUS & PERTUSSIS

Diphtheria, easily spread through coughing or sneezing, can cause paralysis, breathing and heart problems, and death.

Tetanus (Lockjaw) occurs when a tetanus germ enters a cut or wound. It can cause muscle spasms, breathing and heart problems, and death.

Pertussis (Whooping Cough), spread through coughing or sneezing, causes very long spells of coughing that make it hard for a child to eat, drink, or even breathe. Pertussis can cause lung problems, seizures, brain damage and death.

HEPATITIS B

Hepatitis B is an infection of the liver. It can be passed from an infected mother to her newborn during childbirth and from one person to another through blood or body fluids or by intimate contact. The hepatitis B virus can cause liver damage, liver cancer and death. It is second only to tobacco in causing human cancer.

HAEMOPHILUS INFLUENZAE TYPE B

Hib disease can cause meningitis (inflammation of the brain), infections of the joints, skin and blood, brain damage, and death. It is most serious in infants under one year of age.

MEASLES, MUMPS & RUBELLA

Measles, mumps and rubella spread from person to person very easily, through coughing, sneezing, or just talking.

Measles causes a high fever, rash, and cold-like symptoms. It can lead to hearing loss, pneumonia, brain damage, and even death. Measles spreads so easily that a child who has not been immunized will most likely get the disease if exposed to it. In fact, the measles virus can remain in the air (and be contagious) for up to 2 hours after a person with the disease as left the room.

Mumps can cause headache, fever, swelling of the glands of the jaw and neck, and swelling of the testicles in adolescents and adults. It can lead to hearing loss, meningitis (inflammation of the brain and spinal cord) and brain damage.

Rubella (German Measles) causes a slight fever and a rash on the face and neck. Pregnant women who get rubella can lose their babies, or have babies with severe birth defects (known as congenital rubella syndrome).

POLIO

Polio causes fever and may progress to meningitis and/or lifelong paralysis. Polio can be fatal. Persons infected with the polio virus shed the virus in th stool and can transmit the virus to others.

VARICELLA

Varicella (chickenpox) is a very contagious disease causing rash and fever. It is spread by coughing and sneezing or direct contact with drainage from the rash. Among children, a common complication is bacterial infection of the skin lesions. Varicella can lead to serious complications such as inflammation of the brain and pneumonia, and rarely "flesh-eating" bacterial infection or death. Varicella is more serious in adults and persons with impaired immune systems. If a woman has this disease while pregnant, it can cause birth defects and infant death.

HEPATITIS A

Hepatitis A is a liver disease caused by the hepatitis A virus. It is shed in the stool of infected persons. It is usually spread by close personal contact and sometimes by eating food or drinking water containing the virus. A person with hepatitis A can easily pass the disease to others within the same household.

INFLUENZA

Influenza is a contagious viral disease that may cause a sudden onset of fever, chills, muscle aches, cough, sore throat, headache, and may lead to severe pneumonia. Flu is spread through sneezing, coughing or direct contact with the infected individual. Children and family members with certain long-term health problems, such as asthma or diabetes are especially at risk for serious complications from the flu. Such complications include pneumonia, dehydration, meningitis, and even death. Influenza is a major cause of death among elderly persons.

PNEUMOCOCCAL DISEASE

Pneumococcal disease is a bacterial infection which is a leading cause of severe illness in young children and adults who have certain long-term health problems, such as: diabetes, heart or lung diseases, or conditions that lower the body's resistance to infection (e.g. leukemia, kidney failure). The disease is spread through sneezing, coughing, or direct oral contact with an infected individual. Pneumococcal disease can lead to serious infections of the lungs (pneumonia), the blood, and the covering of the brain (meningitis).

Immunizations Save Lives

Immunization is one of the greatest medical success stories in human history and has saved millions of lives in the 20th century.

Many serious childhood diseases are preventable by using vaccines routinely recommended for children. Since the introduction of these vaccines, rates of diseases such as polio, measles, mumps, rubella, diphtheria, pertussis (whooping cough), and meningitis caused by *haemophilus influenzae* type B have declined by 95 to 100%.

Prior to immunization, hundreds of thousands of children were infected and thousands died in the U.S. each year from these diseases. In under-immunized populations of the world, 600,000 children die each year from pertussis (whooping cough).

Without immunizations, the diseases we are now protected from will return to sicken and even kill many infants and children. Many of the children who survive could suffer from chronic health problems for the rest of their lives.

Immunizations Prevent the Spread of Disease

Diseases spread through communities by infecting unimmunized people as well as the small percentage of people for whom immunizations do not work. Individuals who are unimmunized increase the risk that they, and others in their community, will get the diseases vaccines can prevent. For some highly contagious diseases, such as measles, even a small number of unimmunized or underimmunized people can lead to an outbreak.

The biggest cause of the 1989-1991 measles epidemic in the U.S. was failure to vaccinate children between 12-18 months of age on time. This measles epidemic was responsible for 55,000 cases and more than 120 deaths. Nearly half of those deaths were in children under age 5, most of whom had not been immunized.

Eleven cases of measles in 1995 in Whatcom County, WA started when an unimmunized college student returned from an out-of-state visit.

In 1998, all of the cases of measles in the U.S. came from other countries. Dangerous infectious diseases largely under control in the U.S. are only a plane ride away, so we must all remain protected by being immunized.

Immunizations are Safe

Immunizations are extremely safe and getting safer and more effective all the time as a result of medical research and ongoing review by doctors, researchers, and public health officials. Immunizations are given to keep healthy people well, so they are held to the highest safety standards.

The number of recommended immunizations has increased because we are now able to safely protect children from more serious diseases than ever before.

Immunizations Save Money

Every dollar spent on vaccine saves seven dollars in medical costs and 25 dollars in overall costs related to vaccine-preventable diseases.

The estimated direct medical cost of the 1989-1991 measles outbreak in the U.S. was over $150 million. This does not include the indirect costs to the family, such as lost days of work, school and child care. Current estimates of direct medical costs and indirect (work loss) costs of hepatitis B related liver disease exceed $500 million annually.

Immunizations Are Strong Protection

Immunization is the single most important way parents can protect their children against serious diseases. Children who have not been immunized are at far greater risk of becoming infected with serious diseases. For example, a recent study showed that children who had not received the measles vaccine were 35 times more likely to get the disease.

Immunizations work by naturally using the power of the body's own immune system to battle against diseases.

There are no effective alternatives to immunization for protection against serious and sometimes deadly infectious diseases. While breastfeeding can help to prevent some diseases among babies, it is not effective in preventing the serious diseases that immunizations do.

And, Did You Know...

- With the increase in international travel and foreign adoption, serious vaccine-preventable diseases are literally only a plane ride away.
- Even if a disease is not currently present in a community, the bacteria and viruses that cause it have not gone away. Disease outbreaks can and do occur in communities that are not protected by immunization.
- Vaccines are free at most clinics in Washington State, paid for with public funds. (You may be charged a small administrative fee).
- An average of 81% of children in Washington State are immunized by the age of two; but in some areas, the rate is as low as 57%.

- Many of the diseases that vaccines prevent cannot be effectively treated or cured.

- Infants are often more vulnerable to disease because their immune systems cannot easily fight off disease bacteria or virus. Often, the effects of disease are more serious in infants than in older children.

The Immune System and How Vaccines Work

The immune system is the defense mechanism in each person that helps the body fight disease. Medical science has found an effective way to help the immune system fight disease through the use of vaccines.

- When you get an infection, your body reacts by producing substances called antibodies. These antibodies fight the invading germ (antigen) or disease and help you get over the illness. The antibodies usually stay in your system, even after the disease is gone, and protect you from getting the same disease again. This is called immunity.

- Newborn babies often have immunity to some diseases because they have antibodies from their mothers (known as maternal antibodies). But this immunity is only temporary.

- We can keep children immune to many diseases, even after they lose their mothers' antibodies, by immunizing them. The germs (virus, bacteria) that cause disease are weakened and then used to make the vaccines. These vaccines can be given to children as shots or as drops to be swallowed.

- Vaccines make the body think it is being invaded by a specific disease, and the body reacts by producing antibodies. Then, if the child is exposed to the disease in the future, he or she is protected.

- Some vaccines consist of weakened disease virus. These vaccines (measles vaccine, for example) are extremely effective. Some vaccines are "inactivated" (killed), and require multiple doses to build up the immune response (for example, IPV, inactivated polio vaccine). Some inactivated vaccines require booster doses throughout life.

QUESTION: Do vaccines decrease the immune system's natural ability to fight disease?

ANSWER: No. A vaccine produces an immune response that is very specific to the organism or antigen which produced it. For example, the antibodies produced in response to measles virus have no effect on the body's ability to respond to another illness, such as pertussis.

"The immune system is constantly working to protect us from bacteria and viruses in our environment", states Dr. Jeff Duchin, Public Health - Seattle & King County. "Immunizations strengthen our immune defenses against a specific infection. Immunizations do not interfere with our ability to fight off other infections that we are not immunized against."

QUESTION: I heard that the less you "bombard" the immune system at one time, the better, so you would not give several vaccines on the same day. Is this true?

ANSWER: No. A child's body is not harmed by receiving more than one childhood immunization at the same time. While there is clearly much more to learn about the immune system, some things we do know. Scientific data show that giving a child several vaccines at the same time has no adverse effect on a normal immune system.

According to William Atkinson, MD, U.S. Centers for Disease Control, "The immune system is an extremely capable system. It can manage and respond to literally millions of antigens (foreign substances) at the same time. Take for example, walking outside on a spring day with flowers and trees in bloom. Through your mouth, nose and lungs, your immune system will constantly respond to multiple antigens (like pollen and dust) as it does its work in your bloodstream. In the same way, in daily interactions, you may be exposed to multiple cold viruses and your body will respond successfully. But some infections can cause severe illness and death even in persons with healthy immune systems. We can help the immune system ward off the serious infectious diseases that immunizations can prevent."

QUESTION: Is the method of injecting vaccines harmful for the body?

ANSWER: No. Injecting the vaccines is a safe method that has been used for decades. Just as injecting infection-fighting antibiotics for illness is okay, so it is for giving vaccines. Vaccines are not injected directly into the bloodstream. In addition, the syringe and needle used for an immunization are sterile and are only used once and then thrown away, so there is no possibility for the spread of infection by getting immunized.
Some vaccines are given by mouth, while others, which may soon be available, are given in other ways (such as by being sprayed into the nose). The method used to administer vaccine, whether it be by injection or other route, is thoroughly tested for safety and effectiveness before it is used in the general population.

QUESTION: I have heard that some people get diseases that they have been vaccinated against. How could this be true?

ANSWER: Modern vaccines are extremely effective, but are not perfect. For example, a vaccine that is 90% effective means that one in every ten people who is vaccinated is not actually protected from the disease. Should disease affect such a community, those that are unprotected are likely to be infected -- which includes those who were not vaccinated and the 10% of people who were vaccinated but in whom the vaccine didn't work. Because most diseases that vaccines prevent are transmitted from person-to-person, the more people in a community who are immunized, the less the likelihood that disease will be transmitted and "find" the few that are unprotected.
Most vaccines require more than one dose to reach maximum immunity. Some, like tetanus and diphtheria, require booster doses throughout life to continue the immunity.

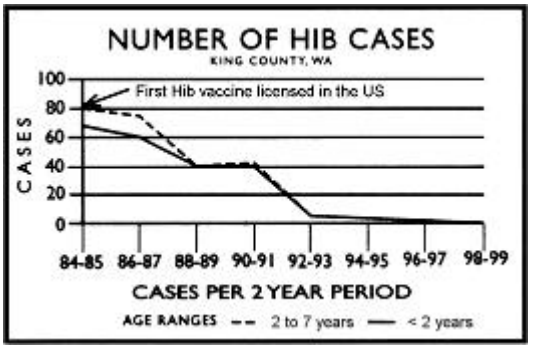
QUESTION: I heard that because of better hygiene and sanitation, vaccine-preventable diseases began to disappear before vaccines were introduced. Is this true?

ANSWER: Yes; many infectious diseases became less common as living conditions and hygiene improved, however they remained as serious threats due to periodic outbreaks in vulnerable populations. Combating diseases often takes a combined approach. Several factors have helped the work of vaccines including:

- Better nutrition
- Less crowded living conditions and better sanitation
- More effective antibiotics and other treatments

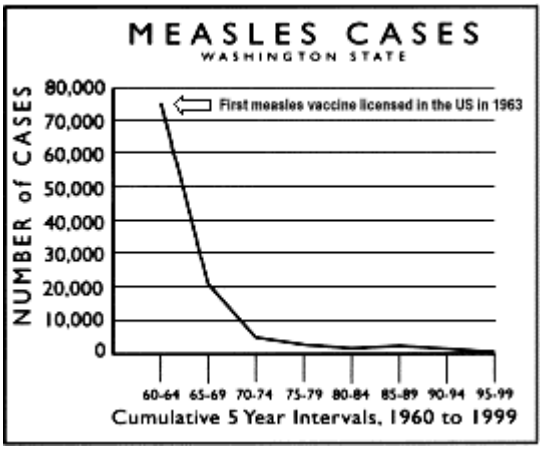
In spite of these advances, vaccine-preventable disease outbreaks still occur, because of lack of immunization or incomplete immunization. Diseases like measles and pertussis are highly contagious, regardless of hygiene and living conditions.

> ***Dr. Jeff Duchin, Public Health - Seattle & King County, states, "Immunizations have led to a dramatic decrease in serious childhood infections, such Hib disease, that could not have been accomplished through improvement in sanitary conditions alone."***



The incidence of measles, pertussis, Haemophilus influenzae type b (Hib) and other vaccine-preventable diseases has decreased dramatically, directly due to immunizations. The Hib vaccine was directly responsible for decreasing the incidence of Hib disease and Hib meningitis. Once the leading cause of death among young children, Hib disease has dropped more than 95% in the last five years (see Hib graph above). Sanitation is not that much better now than in the early 1990s; clearly, sanitation alone cannot account for the dramatic drop in Hib disease.

The graph below illustrates the decline in measles cases in Washington State since measles vaccine became available.



To Wait or Not to Wait

Parents frequently ask why immunizations are given so early in life. You may wonder if you can wait until your child is entering school to get the required immunizations. You may also wonder about the risk if your child does not receive all recommended immunizations.

QUESTION: Is it okay to wait until my child is getting ready to start school to get all his or her immunizations?

ANSWER: No. Waiting until kindergarten, or even until after the first birthday, to have your child immunized can put him/her at unnecessary risk of getting serious diseases. Maternal antibodies fade during the first year, when the child is also more frequently exposed to other children and adults who may be infected with these diseases. Many vaccine-preventable diseases are more severe and pose the greatest risk for complications in infants and very young children. For example:

- Infants who are 6-7 months old are at the peak age to get Hib disease.
- Of the 6 individuals hospitalized because of pertussis in King County in 1998, all were younger than 6 months, and one death occurred.
- During the 1990 measles epidemic, 49% of the 352 cases in Washington State were in children younger than four years of age. The majority of these children could have received measles vaccine at 15 months of age, but did not. Now, children routinely get measles vaccine as early as 12 months (and sometimes as early as six months in outbreak situations).

QUESTION: Can my child catch up if he or she is behind in immunizations?

ANSWER: Yes, but it is best to stay as close as possible to the recommended schedule.

An interruption in the schedule **does not** require a child to start the series over for any vaccines. However, until the entire vaccine series is received, the individual will not have the maximum protection against the disease. If a child is behind on the immunization schedule, a catch-up schedule can be determined by the child's doctor, nurse or clinic.

QUESTION: Are immunizations okay even if my child has a minor illness?

ANSWER: Yes. Immunizations can be given and should be requested during any visit to your doctor or nurse, even if your child has a minor illness, such as mild fever, a cold, diarrhea, or is taking antibiotics. The vaccine will still be effective. It will not make your child sicker. Receiving all immunizations when they are due is an important way to complete each vaccine series on time and avoid extra visits.

QUESTION: Are there times that vaccines should NOT be given?

ANSWER: Yes, sometimes there are medical reasons for not giving a vaccine or for delaying it. These are referred to as "contraindications" and "precautions". In general, a child should not receive an immunization if he or she:

- Has a medical condition that could be made more severe or even life threatening if the vaccine were given. Example: A child has a severe allergy to a vaccine component (e.g. neomycin, gelatin) that would cause a serious reaction, such as difficulty breathing, low blood pressure or shock, if the vaccine were given.

- Has a medical condition, which could reduce the ability of the vaccine to produce the desired immunity (such as severe illness). Example: A child has recently received blood products (such as immune globulin, or a blood transfusion), and the antibodies in the blood could damage a live vaccine, such as a measles vaccine.

In most instances, vaccines may be given if a child is breastfed, has an ear infection, is taking antibiotics, has mild diarrhea or has milk allergy.

Check with your health care provider if you have specific questions regarding these or other circumstances.

Questions and Answers about Specific Vaccines

(see also "Compare the Risks" section)

HEPATITIS B

QUESTION: I know that most people who get hepatitis B are adults. Why is it recommended that the hepatitis B vaccine series be given to infants?

ANSWER: In 1991, national immunization recommendations changed to recommend the routine immunization of **all infants** against hepatitis B because it is impossible to predict who will be exposed to hepatitis B in the future. Approximately 30% of those who become infected with hepatitis B do not have a known risk factor. In addition:

- The earlier in life a child is exposed to the disease, the more likely he/she will be come a chronic (lifelong) carrier. Adding hepatitis B to the already established immunization schedule helps us reach more people before they become chronic carriers.
- Hepatitis B virus infects 200,000 Americans annually; thousands of the victims are adolescents and young adults. There is no specific treatment for acute hepatitis B. The virus can cause liver damage, liver cancer and death. In the US, more than 1.25 million people are chronically infected and at least one-third of those were infected as infants or children.

- Unfortunately, vaccinating just high-risk individuals against hepatitis B has not proven to be an effective method for decreasing the incidence of this disease.

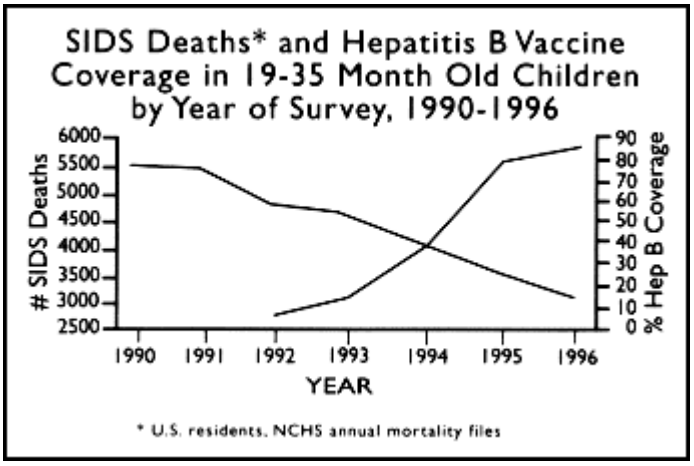
QUESTION: Does hepatitis B vaccine cause multiple sclerosis (MS) or SIDS (Sudden Infant Death Syndrome)?

ANSWER: No. Analyses by the World Health Organization, U.S. Institute of Medicine and the Medical Advisory Board of the National Multiple Sclerosis Society conclude that there is no evidence that the hepatitis B vaccine causes MS or other neurological diseases.

MS is an autoimmune disorder in which a person's antibodies attack the body's own myelin (a sheath that covers the nerves). MS is a life-long illness which fluctuates through periods of exacerbation (symptoms worsen) and remission (symptoms subside). The cause of MS is unknown, but the most widely held belief among medical experts is that patients are genetically at risk for the disease and some environmental factors can "trigger" disease exacerbation.

There is no evidence that hepatitis B vaccine increases the rate of MS in otherwise healthy individuals. In addition, a study by the French National Drug Surveillance Committee revealed that recipients of over 60 million doses of hepatitis B vaccine given between 1989-1997 were less likely to have neurological disease, including MS, than the general population. Hundreds of millions of persons worldwide have been immunized with the hepatitis B vaccine without developing MS or any other autoimmune disease. The National Multiple Sclerosis Society supports the wide and general use of hepatitis B vaccine.

There have been reports of exacerbations of MS following immunization in persons who already have MS. Although these cases may be purely coincidental, carefully controlled studies are currently underway to determine the nature of these reports.
Since 1991, infants have been receiving hepatitis B vaccine starting as early as the first day of life. If SIDS were somehow related to hepatitis B vaccination, we would expect to see an increase in SIDS deaths since 1991. However, this is not the case. In fact, there has been a steady decrease in the numbers of newborn deaths as the number of hepatitis B vaccinations have increased (see graph below).
Almost all infants are vaccinated during the first year of life. Because vaccines are usually given at ages 2, 4 and 6 months, there is a measurable chance of any event or death occurring within 24 hours of vaccination by coincidence alone. It is similar to saying that eating bread causes car crashes, because most car drivers who are in accidents could probably be shown to have eaten bread within the past 24 hours.
The Institute of Medicine reports: "All controlled studies that have compared immunized versus non-immunized children have found either no association...or a decrease risk...of SIDS among immunized children."



DIPHTHERIA, TETANUS and PERTUSSIS

DTaP vaccine protects against diphtheria, tetanus and pertussis (whooping cough). Of these diseases, pertussis (also know as the "100-day cough") currently poses the most serious threat to infants and children in the United States. Complications of pertussis in infants include pneumonia, convulsions, and in some cases brain damage or death.
In 1995, there was a large increase in the number of pertussis cases in Washington State. **In 1999, there were over 400 confirmed cases reported in King County, the most in 34 years. In 1998, 100% (five) of infants under 12 months of age with reported cases of pertussis were hospitalized, with one death.**

Of additional concern to Washington residents is the major epidemic of diphtheria which has been in progress in the former Soviet Union since 1990. The decline in the former Soviet Union's diphtheria vaccination rates has resulted in an increase from 839 cases in 1989 to nearly 50,000 cases and 1,500 deaths from diphtheria in 1995, the last year for which we have confirmed statistics. This poses a serious concern of importing cases of diphtheria in to the United States.

QUESTION: What is the difference between the old "whole-cell" DTP vaccine and the new acellular DTaP vaccine?

ANSWER: The new vaccines for pertussis, available since 1997, are known as "acellular" vaccines. They contain only the specific parts of the pertussis bacteria thought to be important for immunity. These differ from the old "whole-cell" vaccines that contain whole, killed pertussis organisms. "Whole-cell" vaccines are associated with a higher frequency of local reactions (e.g. redness, swelling, pain at the injection site) and fever. The CDC, American Academy of Pediatrics and American Academy of Family Physicians recommend that all doses of pertussis vaccine be acellular.

- In the clinical trials of Italy and Sweden, the acellular pertussis vaccines had fewer side effects than the whole-cell pertussis vaccine.

QUESTION: What are the side effects of the DTaP vaccine?

ANSWER: Most children who receive the DTaP vaccine will have no adverse reactions or experience only minor discomfort. This is a major advantage over the formerly used whole-cell DTP vaccine, which was associated with a higher frequency of adverse reactions. The most common reactions are soreness, swelling, and redness at the site of the injection, low fever, fussiness, drowsiness, or loss of appetite. Usually these reactions last from one to two days.
Serious reactions are reported rarely with the acellular pertussis vaccine.

QUESTION: How effective is the DTaP vaccine and is it worth getting?

ANSWER: A full serious of shots protects approximately 80 children out of 100 from getting severe pertussis (similar to the old whole-cell DTP vaccine). Approximately 95 out of 100 children will be protected from diphtheria, and virtually 100% of children will be protected from tetanus after the full DTaP series is given. Even children vaccinated with DTaP who do become ill with pertussis almost always have a milder illness than if they had not been vaccinated. A full series of four DTaP shots by age 18 months is recommended.

- Children, especially young infants, who catch pertussis, are often critically ill.
- Insufficiently immunized children contribute to higher rates of pertussis disease in some communities.
- Most individuals who have had a full series of DTaP or DTP vaccine are protected from diphtheria, tetanus and severe pertussis for many years.
- Because it is so contagious, the possibility of a child getting severe pertussis when exposed is far greater than the chances of experiencing a severe adverse reaction from the vaccine.

MEASLES, MUMPS and RUBELLA

QUESTION: Is there any evidence to indicate an association between the MMR vaccine and autism?

ANSWER: No. There is no evidence to suggest that the MMR vaccine will increase the risk of developing autism or any other behavioral disorder. Experts agree that autism is most likely a genetic disorder that occurs before birth*. A working group organized by the National Institutes of Health in 1995 reached a consensus that autism is genetic condition.

Typically, symptoms of autism first appear in children from 18-30 months of age. MMR vaccine is usually given to children 12 to 15 months of age. Although autism may be detected during the weeks or months following MMR vaccination, this does not necessarily mean that the disorder was caused by the vaccine. According to the published results of a large study (Lancet, June 1999), *there is no association between MMR vaccine and autism*.

*Priven J, The Biological Basis of Autism, Current Opinion in Neurobiology, 1997, 7:708-12 Rodier PM, Hyman SL. Early environmental factors in autism. MRDD Research Reviews 1998;4:121-128.

POLIO

QUESTION: Are there two different types of polio vaccines?

ANSWER: Yes. They are live, oral polio vaccine (OPV) and inactivated polio vaccine (IPV). OPV was the vaccine of choice of routine immunization of most children in the United States since 1963. **The year 2000 Childhood Immunization Schedule recommends the use of IPV alone for routine childhood polio vaccination.**
In 1998, a "sequential" polio vaccine schedule was recommended, meaning that the first two doses of polio vaccine were IPV, followed by two doses of OPV. The sequential schedule was used to reduce the risk of vaccine-associated paralytic polio (VAPP) which is caused *only by the oral vaccine*. VAPP is most likely to occur in persons with serious immune system disease or the with first dose of vaccine. Five to 10 cases of VAPP were reported in the US each year prior to the use of the sequential schedule. This represented one case per 2.5 million doses of OPV.
Although the sequential schedule reduced the number of cases of VAPP in 1998-99, it did not eliminate VAPP entirely. **An all-IPV schedule will eliminate the risk of VAPP. IPV cannot cause polio because it does not contain live polio virus.**

QUESTION: Is it still worth being immunized against polio?

ANSWER: Yes! Although wild polio disease has been eliminated from the United States since 1979 and the Western Hemisphere since 1991, it still exists elsewhere in the world. When the virus is eliminated worldwide, we will be able to stop using polio vaccine. However, as long as polio exists in the world, our children need protection. If children are not immunized, the disease could spread quite rapidly.

CHICKENPOX

QUESTION: Chickenpox (varicella) isn't a very serious disease. Why vaccinate?

ANSWER: Complications from varicella disease, such as pneumonia and encephalitis, "flesh-eating" bacterial infection and death can occur in children and adults. Vaccinating against the illness during childhood will help reduce the incidence of the disease (and related complications) in later years. Varicella vaccine also reduces the risk of "shingles", a painful nerve and skin disease caused by reactivation of the varicella virus.
The virus (chickenpox) vaccine was approved by the FDA in March 1995 and is recommended for:

- Children 12 months of age and older who have not had the chickenpox
- Individuals over age one year (who have not had chickenpox) who will have close contact with persons at high risk for serious complications from the disease (such as those with weakened immune systems)
- Adolescents 11 to 12 years of age who have not been previously vaccinated and have not had the disease
- Adults at high risk of exposure to chickenpox (who have no prior history of having the disease) such as health care workers and teachers

QUESTION: Does immunity from the varicella vaccine last?

ANSWER: Available data indicate that protection from varicella vaccine should last for at least 20 years. Experience with other live viral vaccines (like measles, mumps and rubella vaccine) has shown that post-vaccination immunity remains high throughout life. Studies are ongoing to determine how long protection from varicella vaccine lasts and whether booster doses may be needed in the future. Even if an immunized individual develops

chickenpox after being exposed to the disease, the illness will be much milder than if the person had never been vaccinated.

PNEUMOCOCCAL DISEASE

QUESTION: What is pneumococcus? Is there a pneumococcal vaccine for children?

ANSWER: Pneumococcus is a bacteria that is the most common cause of pneumonia, meningitis, sepsis (bloodstream infection causing shock), sinusitis, and ear infection in children under two years of age.
Unfortunately, the pneumococcal vaccine which has been used in the United States since 1983 is not recommended for children under two years of age because it is ineffective in this age group. A new pneumococcal vaccine which can be used in children under two years of age will probably be available during 2000.

The Adolescent Visit: Shots Aren't Just Kids' Stuff

Although infant and child immunization programs in the United States have greatly decreased the occurrence of many childhood infections, vaccine-preventable diseases such as hepatitis A and B, measles and rubella continue to affect adolescents and young adults.

In order to protect adolescents and young adults from these serious vaccine-preventable diseases, the ACIP, AAP and AAFP all strongly recommend an **adolescent health visit** at 11 to 12 years of age. This visit will enable parents and their health care providers to discuss the recommended vaccines and decide which immunizations their child needs. An adolescent health visit, of which immunizations are a part, also helps to affirm that child's lifelong commitment to good health.

QUESTION: Which vaccines are recommended for my adolescent?

ANSWER: The recommended vaccines for adolescents are hepatitis B, MMR, tetanus/diphtheria, and possibly varicella (chickenpox). Contact your doctor, nurse or clinic for information about scheduling your adolescent for these vaccinations.

Immunizations Recommended for Adolescents

- **Hepatitis B**
- **MMR** (measles/mumps/rubella) 2nd dose (if not previously given)
- **Td** (Tetanus/diphtheria) booster
- **Varicella** (if no prior immunization or history of the disease)

- **Hepatitis A** (for certain adolescents at high risk)

Legal Requirements and Considerations

QUESTION: What are the legal requirements for immunizing children?

ANSWER: Federal law requires that before immunizations are given, parents or guardians must have:

1. Information in writing (Vaccine Information Statements) about the risks and benefits of vaccination, and;

2. An opportunity to ask questions and obtain additional information about vaccinations from their health care provider.

The legal requirements for childhood immunizations vary from state to state. In Washington State, the requirements are defined in the Washington State Immunization Law (RCW28A.210).

The law requires parents or guardians to give their child care program or school a completed Certificate of Immunization Status (CIS) form for each child before attending. CIS forms are available from child care facilities, schools and health departments. Parents or guardians are encouraged to keep records of immunizations to validate the CIS document.

To legally attend child care or school, children must either:

- Be fully immunized for their age or
- Be in the process of catching up on late immunizations or
- Have a signed exemption from vaccination for medical, religious or personal reasons on the CIS form.

If a family signs a certificate of exemption, a child who is not fully immunized may be excluded from attending child care or school when cases of certain vaccine-preventable diseases occur or during outbreaks of vaccine-preventable diseases.
Completion and signing of the CIS form is the parent's or guardian's responsibility.
Maintenance of immunization records is a lifelong responsibility.
If a child transfers from a child care or school, that facility is required to provide you with the completed CIS form to give to a new child care program or school.

Vaccine Safety

Often parents have concerns about vaccine safety. In licensing vaccines, the U.S. Food and Drug Administration (FDA) has developed scientific criteria for approving vaccines and for monitoring side effects once approval has been given.

Approval of Vaccines

The approval process for a biological product such as a vaccine is based on federal regulations and involves clinical trials in three phases.

- **Phase One:** Studies concerned primarily with learning more about the safety of the product with a few study volunteers.

- **Phase Two:** Studies are usually longer and involve more study volunteers, designed to demonstrate the ability of a vaccine to induce the production of antibodies, as well as to further evaluate side effects and risks.

- **Phase Three:** Studies involving a very large number of study volunteers for longer time. They provide verification that a vaccine is effective in preventing a particular disease as well as information on risks vs. benefits. Clinical trials have been ongoing for years before a vaccine is ever licensed.

After completing the three phases, the manufacturer submits the safety and effectiveness data to FDA in an application for licensure to sell the product. FDA has the responsibility to review the clinical studies data, the facilities to be used and the methods to be used in the manufacture of the product for safety and effectiveness. On average, it takes over five years from the time of application for licensure until FDA approval of a product.

Monitoring Vaccine Safety

After a product is approved for sale, FDA continues to monitor vaccine safety and effectiveness by various means, including on-site inspection of the manufacturing facility. The U.S. FDA staff reviews manufacturers' testing of vaccines for their safety, potency, and purity. As a protective measure, the U.S. FDA staff may repeat some of the tests themselves.

There is also a national system operated by the FDA and CDC for reporting any possible adverse reactions following immunizations. This system is called the Vaccine Adverse Events Reporting System (VAERS). The system receives reports from healthcare providers, patients, parents or anyone who witnessed or even just heard of a possible adverse reaction that occurred after the receipt of any vaccine. Since 1988, health care providers who give vaccines and vaccine manufacturers are *required by law* to report certain serious adverse events.

Other notable features of the vaccine monitoring system are:

- A VAERS report does not mean the vaccine caused the adverse event. It only means the vaccination preceded the adverse event. VAERS is intended to look for trends and pinpoint the need to investigate further.
- After vaccine lot release, the FDA conducts reviews of the weekly VAERS reports.
- If VAERS is to work, the public should report any serious adverse event following any vaccine given. Report forms may be obtained by calling (800) 822-7967.

QUESTION: Are there certain vaccine lots that have been associated with more adverse events than other lots?

ANSWER: To date, no vaccine lot in the modern era has been found to be unsafe.

Vaccine lots are monitored by the VAERS reporting system (see previous section). Occasionally, people have interpreted the VAERS information incorrectly leading to unsubstantiated media reports about "unsafe lots" of vaccine. VAERS accepts **all** reports of **any** adverse event that has occurred following vaccination. Larger lots (i.e. one million doses) are likely to receive more adverse event reports than smaller lots (i.e. 10,000 doses). The fact that there are more reports for particular lot does not mean that the lot is unsafe, or that the vaccine caused the event.

The FDA has the legal authority to immediately recall a vaccine lot if the number of reports indicate that it may be unsafe, requiring further investigation. There is no benefit to either the FDA or the vaccine manufacturer in allowing unsafe vaccines to remain on the market.

QUESTION: Do vaccines cause chronic disease, such as diabetes, Chrohn's disease, and cancer?

ANSWER: After decades of vaccine use in the United States, available research shows no reliable evidence proving that vaccines cause chronic illness. Vaccine safety research, including research into theories linking vaccines to chronic diseases, is being conducted on a regular basis in the United States and overseas to assure that the public is receiving the safest possible vaccines.
Occasionally, researchers have published articles about their studies supporting theories about vaccine and chronic illness; however, when other researchers attempt to duplicate their results (the test of good research), they often cannot. Medical conclusions about vaccine safety and the causes of disease must be judged on the quality of the scientific research and evidence.
Because no vaccine is without risk, when medical and public health professionals recommend vaccines for infants and children, they must balance the scientific evidence of

benefits, costs, and risks. This balance changes as diseases are controlled or eliminated. For example, thanks to the smallpox vaccine, smallpox has been eliminated worldwide. Thus, the risk of adverse reactions from the vaccine now outweigh the risk of getting smallpox. Therefore, smallpox vaccine is no longer recommended for use in the general population.

QUESTION: How do we know VAERS works?

ANSWER: VAERS is an effective system for monitoring vaccine safety. Shortly after rotavirus* vaccine became available in 1999, cases of bowel obstruction among some infants who had received the vaccine were reported to VAERS. Although these reports did not provide sufficient evidence to determine if there was a relationship between the vaccine and the bowel disorder, the CDC recommended that use of the rotavirus vaccine be suspended pending further evaluation. The CDC's actions were a direct result of the data obtained through VAERS.

In October 1999, the ACIP recommended that rotavirus vaccine no longer be used because of the strong association between the bowel disorder and the vaccine. Medical experts agree that continued research is needed to clarify the relationship between the bowel disorder and the vaccine.

*Rotavirus is the most common cause of serious diarrhea in infants and young children in the United States.

Compare the Risks: Disease vs. Immunization

Risk of Disease and Serious Complications	Risk of Serious Reaction From Being Immunized
Haemophilus influenzae type B (Hib):	**Hib Vaccine:**
Hib disease ■ Before Hib vaccine, 1 in 200 children developed meningitis or other invasive Hib disease by age five. ■ Before vaccine, Hib was the leading cause of bacterial meningitis. ■ 60% of cases occur in children younger than one year. ■ Death: 1 in 20 children with invasive Hib disease. ■ Neurologic damage: up to 45 in 100 children with invasive Hib disease.	No known association between Hib vaccine and serious adverse events.
Polio:	**Inactivated Polio Vaccine:**
38,000 cases per year prior to vaccine; including 21,000 cases with paralysis. 58,000 cases in 1952. During 1970s, several outbreaks in the U.S. in non-immunized populations, none in U.S. since 1979. ■ *Permanent paralysis*: 1 in 100 ■ *Death*: 1 in 20 children and 1 in 4 adults with paralytic polio.	No known associations between IPV and serious adverse events. **Oral Polio Vaccine:** Permanent paralysis: 1 in 2.5 million doses

Measles:

Prior to the introduction of vaccine, 400,000 reported cases per year.
In 1989-91 epidemic: 55,622 cases due to large number unimmunized children, 45% less than 5 years old; 20% hospitalized, 123 deaths.

- *Pneumonia*: 1 in 20
- *Encephalitis* (brain fever): 1 in 2,000
- *Thrombocytopenia*: 1 in 6,000
- *Death*: 1 in 3,000

Mumps:

Cases: 200,000 per year before vaccine became available, currently 3,000-5,000 per year

- *Encephalitis*: 1 in 300
- *Testicular swelling*: 1 in 5 adults
- *Deafness*: 1 in 20,000
- *Death*: 1 in 3,000 to 1 in 10,000

MMR Vaccine:

Thrombocytopenia (bleeding tendency from temporary decrease in blood platelets): 1 in 30,000

MMR Vaccine - Measles:

Severe allergic reaction: less than 1 in 1,000,000

MMR Vaccine - Mumps:

Severe allergic reaction: less than 1 in 1,000,000

Rubella:

1.2 million cases in 1964-65, including 2,100 infant deaths, 11,250 abortions, and 20,000 cases of nervous system disorders.

- *Arthritis* (usually temporary): 7 in 10 adults
- *Thrombocytopenia*: 1 in 3,000.
- *Congential Rubella Syndrome* (deafness, cataracts, mental retardation) in 1 in 4 infants if women infected in early pregnancy.

MMR Vaccine – Rubella:

Arthritis (usually temporary): Up to 1 in 4, usually teenage or adult women.
Severe allergic reactions: less than 1 in 1,000,000

Diphtheria:

Prior to vaccine, 200,000 cases and 15,000 deaths in U.S. each year. Outbreak in Washington State during 1970s; 40 cases in U.S. 1980-93. With decreased immunizations, 50,000 cases in the former Soviet Union in 1995.

- *Death*: 1 in 10

DTaP Vaccine – Diphtheria:

No known association between diphtheria vaccine and serious adverse events.

Tetanus:

Prior to vaccine, 600 cases and 180 deaths per year in U.S. Currently, 50-100 cases per year, greater than 500,000 deaths per year worldwide.

- *Death*: 1 in 3

DTaP Vaccine – Tetanus:

- Severe neuritis (inflammation of the nerves): 1 in 100,000
- Severe allergic reaction: 1 in 1 million

Pertussis:

(Whooping Cough): Prior to vaccine, 200,000 cases and 8,000 deaths per year in U.S. Over 400 confirmed cases in King County, WA in 1999. 69% of all U.S. cases less than 5 years old, and almost half of these were younger than 12 months old. Many infants hospitalized:

- *Pneumonia*: 1 in 8
- *Convulsions/seizures*: 1 in 100
- *Death*: 1 in 500

DTaP Vaccine - Pertussis:

- Fever greater than 104ºF: Fewer than 3 cases in 1,000 doses
- Prolonged crying for 3 hours or more: 2 or fewer cases in 100,000 doses
- Seizure within 48 hours of vaccinations: 4 or fewer cases in 10,000 doses
- NOTE: The Institute of Medicine concluded that there is no evidence that pertussis vaccine causes SIDS (Sudden Infant Death Syndrome)

Hepatitis B:

Estimated number of persons infected each year in U.S.: 200,000 – 300,000. Nine of 10 infants infected at birth will become lifelong carriers of the disease, and one out of four of these infants will ultimately die of liver failure.

- *Hospitalizations per year*: 15,000
- *Deaths*: 5,900

Hepatitis B Vaccine:

Severe allergic reaction: 1 in 600,000

Varicella:	Varicella Vaccine:
50-100 deaths per year in the U.S., mostly in healthy children and adults. Hospitalization: 3 in 1,000 cases. Nine out of 10 people in a household who have not had chickenpox already will catch the virus if exposed to an infected household member. Disease is more severe and complications more frequent in adolescents and adults, and in those with weakened immune systems. Complications include: ■ Bacterial infection of skin lesions and scarring ■ Pneumonia ■ Reactivation of varicella virus as Herpes Zoster (shingles) in later life	Seizure caused by fever: less than 1 in 1,000 Pneumonia very rare.

News Stories

Miss America's Hearing Loss

Heather Whitestone McCallum, Miss America 1995, is deaf. Ms. McCallum had an infection with high fever in 1974, when she was 18 months old. A media item reported that an immunization had caused the fever and subsequent deafness, but this was a false report.

The real cause of her illness, according to her pediatrician, was *Haemophilus influenzae* b (Hib) infection. She was treated with Gentamicin, one of the powerful antibiotic drugs used for this life-threatening infection. Unfortunately, hearing loss is one of the possible side effects of Gentamicin, particularly in infants. Deafness is also a common result of Hib meningitis infection.

Had Ms. McCallum been born after 1985, she could have been immunized against the Hib infection and her disability prevented. Hib infections have been reduced by 90% since the vaccine was made available in 1985.

Measles Outbreak in Washington State

Western Washington University

Western Washington University experienced a measles outbreak in February 1995. With 11 confirmed cases, MMR shots were given to over 9,000 students, faculty and staff to provide protection from the disease and its potential complications.
The first case was exposed to measles while vacationing in California. The student returned to campus, became ill, and the exposed others.

Classes and events were canceled to halt the spread of the disease. Students had to show proof of measles immunization in order to attend classes and campus events. Those who chose not to be immunized were not allowed back into classes and campus activities until two weeks after the onset of rash in the last diagnosed case of measles. With quick action, the measles outbreak was controlled.

Clark County

Clark County in southwestern Washington experienced a measles outbreak beginning in March, 1996. The outbreak began when an exchange student, who was infected while overseas, returned to Clark County. Over 30 measles cases were confirmed, eight of whom were children under age three years. Six of the children had never been immunized against measles. This is yet another example of how vulnerable an unimmunized population is, especially during a disease outbreak.

A Mother and Child with Pertussis

A resident of Snohomish County, Mary, has three sons. She got pertussis (whooping cough) a week before the birth of her second child. She caught it from her oldest son's friend, who visited one day with racking coughs.

After recognizing the telltale whoop in the cough, Mary discussed the issue with a the friend's mother, who indicated she did not believe in immunizations.
Mary was seriously ill for six months and passed the disease on to her newborn son, who was hospitalized with pertussis at one week of age. (The child who originally infected Mary was also seen in the emergency room for pertussis-related seizures).
"My baby would cough 40 to 50 times in a row until he turned blue and threw up", Mary said. "I quite literally did not let go of him for the first six to nine months because I was afraid he was going to die."

The first five years of his life have been full of bouts of infections and an uncontrollable cough. Many people who had been exposed to Mary and her son had to be treated with antibiotics, because of their increased susceptibility to pertussis -- especially young children and those over 60.

The out-of-pocket cost to the family was extraordinary, even though both parents had excellent health insurance coverage. The community cost included many hours of investigation of contacts and the cost of the needed antibiotics..and this was a healthy pregnancy.

Source List

- Atkinson, Wm.; Gantt, J.; Mayfield, M.; Furphy, L. **Epidemiology and Prevention of Vaccine-Preventable Diseases**. (The Pink Book) U.S. Department of Health and Human Services, January 1999, 5th Edition.
- "CDC officials help physicians answer DTP safety questions", American Academy of Pediatrics News, March 1995, pg. 9-10.
- "Decline in Haemophilus influenzae Type b Meningitis-Seattle-King County, Washington", 1984-89, **MMWR**, vol. 39, no. 50, December 21, 1990.
- **Epi-Log**, Public Health - Seattle & King County, vol. 2, no. 4.
- Evans, Alfred S. **Viral Infections of Humans**, Third Edtion. Plenum Publishing Company, New York, NY, 1989.
- Evans, Alfred S. and Brachman, Philip S. **Bacterial Infections in Humans**, Second Edition. Plenum Publishing Company, New York, NY, 1991.
- **1997 Red Book, Report of the Committee on Infectious Diseases**, American Academy of Pediatrics. (Next edition expected in March 2000).
- Margolis, Harold, M.D. "The Road Ahead-Future Policy for the Elimination of Hepatitis B Transmission in the United States", 24th National Immunization Conference Proceedings, May 21-25, 1990.
- Offit, Paul A., MD and Bell, Louis A., MD **What Every Parent Should Know About Vaccines**, Macmillan Publishing Company, New York, NY, 1998.
- Plotkin, Stanley A., MD and Orenstein, Walter Pl, MD **Vaccines, Third Edition** W.B. Saunders Company, Philadelphia, PA, 1999.
- "Research Strategies for Assessing Adverse Events Associated with Vaccines: A Workshop Summary", Institute of Medicine, National Academy Press, 1994.
- Rivara, Frederick P., MD, MPH., "Epidemiology & Prevention of Pediatric Traumatic Brain Injury", **Pediatric Annals** 23:1, January 1994.
- Sanford, Jay P., "Tetanus-Forgotten But Not Gone", **The New England Journal of Medicine**, vol 332, no.12, p. 812-813.
- "Six Common Misconceptions about Vaccination (and how to respond to them)". U.S. Centers for Disease Control and Prevention, January 1996.

- "Standards for Pediatric Immunization Practices", **Journal of American Medical Association**, April 14, 1993.

- **"What Parents Need to Know About Vaccination And Childhood Disease: Guidelines For Parents"**. American Academy of Pediatrics, 1994.

Other Sources of Information

Further information about the FDA's responsibility in drug development is provided in the publication, *FDA Consumer*. This yearly magazine is available through the Government Printing Office, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250-7954.

Healthy Mothers, Healthy Babies Coalition of Washington, Hotline: 1-800-322-2588; services available in many languages.

Parents Guide to Childhood Immunization, Department of Health and Human Services, National Immunization Program, Atlanta, GA 30333.
Public Health - Seattle & King County (206) 296-4774 or www.metrokc.gov/health.
Snohomish Health District, (425) 339-5220 or (425) 775-3522 or www.snohd.org.
Vaccine Information Statements, available form most clinics and from the U.S. Centers for Disease Control and Prevention (CDC).
Washington State Department of Health Immunization Program (360) 236-3595 or www.doh.wa.gov.

Websites

- American Academy of Pediatrics: www.aap.org/family/parents/vaccine.htm
- Bill and Melinda Gates Children's Vaccine Program: www.ChildrensVaccine.org
- FDA (vaccine safety and regulations): www.fda.gov/cber
- Immunization Action Coalition, (651) 647-9009 or: www.immunize.org
- National Network for Immunization Information: www.immunizationinfo.org
- U.S. Centers for Disease Control and Prevention, National Immunization Program (800) 232-2522 (CDC Public Inquiries) or: www.cdc.gov/nip/

Dictionary

AAFP	American Academy of Family Physicians
AAP	American Academy of Pediatrics
ACIP	Advisory Committee on Immunization Practices (Federal vaccine advisory committee to CDC/NIP)
CDC/NIP	US Centers for Disease Control and Prevention/National Immunization Program
CIS	Certificate of Immunization Status
DTaP	Diphtheria, Tetanus, and acellular Pertussis vaccine
FDA	US Food and Drug Administration
Hep B	Hepatitis B
Hib	*Haemophilus influenzae* type b
IPV	Inactivated Polio Vaccine
MMR	Measles, Mumps, and Rubella vaccine
OPV	Oral Polio vaccine
VAERS	Vaccine Adverse Event Reporting System
Var	Varicella (chickenpox) vaccine
VIS	Vaccine Information Statement

Acknowledgments

This booklet was developed by Public Health - Seattle & King County and Snohomish Health District. We would also like to acknowledge receiving assistance from the following public and private agencies:

- Children's Hospital and Regional Medical Center
- Healthy Mothers, Healthy Babies Coalition of Washington
- Immunization Action Coalition of Washington
- Junior League of Seattle
- National Network for Immunization Information
- Rotary International
- State of Alaska Immunization Program
- U.S. Centers for Disease Control and Prevention
- Washington State Department of Health
- Whatcom County Health & Human Services