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## **An Investigation of the Immunization Practices of a Small Town Private Pediatric Group**

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**An Investigation of the Immunization Practices of a Small Town  
Private Provider Pediatric Group**

by

**Lloyd A. Taylor**

**A University Honors Department Senior Project and a  
College Scholars Department Senior Project**

**University of Tennessee, Knoxville**

**December 1995**

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**Investigation of the Immunization Practices of a Small Town  
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**I. Abstract**

Recent epidemics of vaccine-preventable childhood diseases among preschool children in the United States have brought the nation's immunization practices under scrutiny. Undervaccination of preschool children has led to current epidemics of measles and increases in the number of children who have acquired pertussis<sup>1</sup> both of which have the greatest complications when disease occurs early in life (appendix B).

Current trends in the research of immunization administration focus primarily on the delivery of vaccinations. Many scientists and doctors have hypothesized on solutions to the problems surrounding immunizations, searching for more effective ways of delivery. Issues of cost of vaccine and missed opportunities are currently prevalent in discourse about immunizations.

The purpose of this project was to investigate the immunization practices in a small town private provider pediatric group (PPPG), to assess problems that might diminish efficiency and accuracy of the administration of vaccinations in the practice, to propose possible solutions to those problems, and to hypothesize on a national solution to the enigma surrounding immunizations.

## II. Introduction

Much has changed since 1796 when Edward Jenner first inoculated James Phipps with cowpox and subsequently began the practice of immunization. Contemporary milestones have included the licensure of the first recombinant vaccine (Hepatitis B), the last indigenous case of smallpox in 1977, the final wild-virus polio case in the Western Hemisphere in 1991, and the elimination of polio in the Americas. <sup>2</sup>

Science's ability to manipulate the human body's immune system, to train it, has become one of the greatest, and perhaps one of the most taken for granted preventive health techniques. The development and use of vaccines have made major contributions to the health of our nation's children throughout this century. <sup>3</sup> Immunizations are now available to protect children against a host of diseases that were less than a generation ago significant causes of suffering and death. <sup>4</sup> Effectively immunizing all children is a fundamental goal of our country's health care system. <sup>5</sup> However, the system of delivering vaccines has not progressed as effectively as the technology of vaccine development. <sup>6</sup> Recent government proposals, including the Comprehensive Child Immunization Initiative advanced by President Clinton address this issue, focusing on the low levels of immunization among America's preschoolers, especially those age 0 to 2 years. Previous studies have identified a "toddler gap", in which the percentage of children who are up-to-date on vaccinations falls between the first

and second years of life.<sup>7</sup> Most of the protection gained from the battery of immunizations currently recommended by the Centers for Disease Control and Prevention in Atlanta (appendix E) "should be received by two years of age".<sup>8</sup> Immunization of preschool children is intended to provide protection to the group most vulnerable to the diseases. Approximately 80% of the recommended childhood immunizations should be received by 2 years of age.<sup>9</sup> Studies reported in both the "Journal of the American Medical Association" and the "Morbidity and Mortality Weekly Report" (MMWR) indicate, however, that currently only forty to fifty percent of the nation's preschoolers have received the recommended battery of protection.<sup>10 11</sup> In 1993, "an estimated 500,000 U.S. children aged 19-35 months lack[ed] at least three doses of DTP; 1 million need[ed] one or more doses of polio vaccine, and 750,000 need[ed] one or more doses of MMR."<sup>12</sup> Only 60% of a random sample of children conducted in two states were fully up-to-date by their second birthday according to one study.<sup>13</sup> Also, another study by Mustin et. al., found that successful completion of the recommended primary vaccine series in the first 7 months of life was only 46% in white infants and 34% in black infants, **even though** 82% of the white infants and 75% of the black infants had an adequate number of well-child visits.<sup>14</sup> These depressed levels have not been without ramifications. On-time initiation of immunization is especially important in the prevention of Pertussis (whooping cough), which has its highest morbidity in the first year of life.<sup>15</sup>

In 1993, according to the Centers for Disease Control and Prevention, the number of cases of pertussis reported was the highest of any year since 1967, and 36% of those cases occurred in a patient population 6 months of age or younger.<sup>16</sup> Similarly, the principal cause for the measles epidemic (1989-1990) was failure to provide vaccine to children at the recommended age. Thus, those most vulnerable to this disease remained highly susceptible and highly contagious.<sup>17</sup> From 1989-1990, over 28,000 cases of measles were reported in the United States, and there were 132 related deaths. In 1989 alone, more than 18,000 cases were reported and 41 deaths occurred- the largest number of deaths from measles to occur in the United States in over two decades.<sup>18</sup>

Gaining insight into these obvious shortcomings in the immunization policies of our health care providers and some of the reasons for these deficits in care was one focus of this investigation. Data was obtained through a review of the literature, through discussions with Dr. William Cook, Jr., M.D., on the topic of immunizations, and through sampling a statistically relevant number of active two-year old patients in a PPPG to determine the degree to which they were up-to-date. Current levels of immunization were assessed and possible factors influencing the administration of vaccine were investigated. Finally, a hypothesis was formed describing one method that might be implemented to create both a national tracking system for childhood immunizations **and** reduce cost of vaccine.

### III. Materials and Methods

For the purposes of this study the investigator used the Clinical Assessment Software Application Program (CASA) developed by the National Immunization Programs of the Center for Disease Control and Prevention in Atlanta. The program, which is readily available through the Bureau of Immunizations, Commonwealth of Virginia, determined the number of charts to be reviewed and the starting and ending points for review. (appendix D). Subjects were selected who were born between 12-20-91 and 12-18-92 and were also active patients of the PPPG in Radford, Virginia. The said practice is located in a prosperous area of the Blue Ridge Mountains of Virginia and serves patients from both the immediate area and from as far away as sixty miles. All six physicians, whose ages range from 36 to 58, are board certified by the American Board of Pediatrics. The practice is accustomed to providing a full range of general pediatric medical care for its patients, and is adjacent to the local hospital, Radford Community, which has 150 beds. Although two major universities are located within twenty miles of the practice, the environment is basically that of a small town (population approximately 16,000). The area has a number of large industries including an army arsenal, a heavy truck assembly plant, a foundry, a bearing manufacturing facility, and a plant producing high tech motors. Local schools rank well above the average on statewide achievement test and many of the students go on to college. The practice is currently open to new patients and



provides services to those on Medicaid. Immunization policies include administration of vaccination primarily during well-child visits. The immunization schedule followed by the practice mirrors the recommendations of the American Board of Pediatrics (appendix e). By the age of two, it is anticipated that four DTP (Diphtheria, Tetanus, and Pertussis Vaccine), three OPV (Oral Polio Vaccine), one MMR (Measles, Mumps, and Rubella Vaccine), and four HIB (Haemophilus Influenza B Vaccine) vaccinations shall have been administered. For the purposes of this study, this is considered up-to-date. Administration of the HEP B vaccine became standard procedure for the practice in 1993. Subsequently, patients selected for this study may not have been vaccinated with HEP B. Although the vaccination levels of HEP B were not specifically addressed by this investigation, any conclusions that are drawn concerning the vaccinations investigated can be assumed to be pertinent to HEP B as well. At the time of the study, the practice did not have a system in place to notify patients who were not up-to-date or who missed appointments. Also, the practice had no method in place for obtaining vaccination information from the local county health department, to which it refers a large number of its patients for immunization services.

Of the nine hundred and seventy one patients who were born between 12-20-91 and 12-18-92, one hundred and ninety charts were reviewed. This number was deemed statistically relevant by the CASA after the site data (collected at the PPPG) was entered into

the program in a manner similar to the example in appendix D. In order to obtain a random sample, a computer printout of active patients born between 12-20-91 and 12-18-92 was generated. The investigator, under the direction of the CASA, began sampling with the fourth patient on the computer generated list and then every fifth patient's chart was reviewed. The charts were reviewed over a period of two weeks. Information was gathered that included the patient's last name, birth date, medicaid status, and the dates of administration for each of the vaccinations in the recommended battery. After the initial review those patient's whose records were incomplete were reviewed a second time in attempts to obtain more immunization information. The missing information was obtained in all cases possible. Acquisition of this data was accomplished via telephone. Calls were placed to patients' guardians, local and state health departments, and to other pediatricians and/or family physicians in the surrounding area.

Finally, the data were analyzed to ascertain the degree of successful execution of vaccination, to assess problems that might diminish efficiency and accuracy of the administration of vaccinations in the practice, to propose possible solutions to those problems, and to hypothesize on the implications that any conclusions drawn might have on similar practices in America.

#### IV. Results and Recommendations

This study was designed to investigate the immunization practices of a PPPG. One hundred and ninety charts were reviewed. Of those one hundred and ninety patient charts, one hundred and ten were fully up-to-date. Recall that up-to-date for the purposes of this study indicates that the patient has completed four DTP, three OPV, one MMR, and four HIB vaccinations by age two. The remaining eighty patients were subjected to a second review and missing information was obtained in all cases possible. Acquisition of this information was accomplished via telephone leading to the discovery of an additional thirteen patients subject to this study who were also up-to-date. The remaining sixty seven patients whose records were incomplete had either transferred out of the practice, seventeen, had returned only for the two week newborn check-up, five, had visited the office only during illness, fourteen, were referred to the local health department, twelve, or were lacking information and were untraceable, nineteen. The PPPG thus had an above average efficiency for administration of immunizations (64.7 %) when compared with national levels of efficiency (60.0 % according to the study by Bobo, et al.). The immunization information, however, was not readily accessible. The lack of accessibility of the information led to incomplete records and poor data recovery during the initial review of charts, causing the practice to appear that it was not doing as well as it really was. The obvious deficiencies in the exchange of immunization

information between providers, particularly between the PPPG and the local health department, became a focus of this study.

Incomplete vaccination information in the charts of private providers is a direct result of referral. Approximately half of U.S. children receive their immunizations from private physicians; the other half receive their immunizations in the public sector, but many of these obtain their well-child care from private physicians.<sup>19 20</sup> Parents utilize these health departments for numerous reasons. Primarily, those who cannot afford immunization are more likely to express a preference to take their child to the health department.<sup>21</sup> Pediatricians often will refer patients to these departments when parents indicate financial hardships.<sup>22</sup> The cost of completion of the recommended series of vaccinations in a private sector setting is approximately \$324.00. The cost for the same series in the public sector is \$122.00. Patients may be responsible for all of the cost, none of the cost, or a percentage of the cost.<sup>23</sup>

In a "best case scenario", referral of this nature would not be problematic. Parents would take their children to the health departments and the necessary immunizations would be given. Then the parents would return to the pediatrician's office with the immunization information and charts would be updated. This, however, is often not the case. Parents whose children are seen at the pediatrician's office and are referred may never go to the health departments to acquire vaccination. Often, even if they do

go, the information is never shared with the pediatrician's office. This type of patient population can serve as fuel for problems similar to the recent measles and pertussis epidemics. The possibility that referral reduces the likelihood that a child will receive immunizations is troubling.<sup>24</sup> Each time a child leaves his/her physician's office without receiving needed vaccines, primary care is fragmented and an opportunity to immunize is missed.<sup>25</sup> The study by Mustin et al (see footnote 15) addresses this issue when it sites that at seven months of life "only 46% of white infants and 34% of black infants" had completed the recommended series of vaccinations "even though 82% of white infants and 75% of black infants had an adequate number of well-child visits." The American Academy of Pediatrics believes that medical care of infants, children, and adolescents should be accessible, continuous and comprehensive.<sup>26</sup> Referral due to cost has lead to incomplete medical records in the offices of the primary provider on both a national level and in the PPPG reviewed by this study and "the results confirm the importance of physicians' concerns over the cost of vaccines to their patients as the most important factor leading to referrals."<sup>27</sup>

Currently, the nations' direction regarding immunizations is focused on creating a national tracking system specifically designed to allow health care providers the ability to obtain and to give childhood immunization information freely. Theoretically, such a system would allow any health care provider (HCP) to access

a national data base. The HCP could enter vaccination information on a specific patient and also obtain information. This would give HPCs the capability to insure that all of their patients immunizations were fully up-to-date, regardless of where the vaccinations were given. This idea has not been pursued with much vigor recently because of beliefs that "computerized tracking systems are likely to require large investments in new equipment and training and considerable behavioral changes among private health-care providers and the public at large."<sup>28</sup> Devoid of a national tracking system, efforts must be made within each practice to better facilitate exchange and recording of immunization information. Although there are many methods by which this type of reorganization might occur, the following are the recommendations of this investigator to the PPPG which was the focus of this investigation. This recommended course of action is specifically targeted for this practice although it may be applicable in part or whole to other organizations who are trying to better facilitate the handling of vaccination information devoid of a national tracking system.

### V. Recommended Course of Action

1. WHO: All children born after 12-31-95 should be subject to the new procedures.
2. EDUCATION: At the time of the first visit with a patient (i.e. the creation of a patient chart) parents should be informed about the necessity of timely vaccinations. Inadequate maternal education regarding vaccinations has been shown to be related to delayed immunizations.
3. WRITTEN: During visits, when vaccinations are given, the subsequent shot information should be written in an area provided for at the front of the chart and initialed by the nurse administrator.
4. VISUAL: Once a vaccination is given, or information is obtained regarding administration at another health care center, a colored sticker should be placed on the cover of each chart and the date the immunization was given should be written in the center of the sticker. The colored stickers would provide an immediate visual cue of the patient's vaccination history allowing the parents, the nurse, and the physician to immediately assess the needs of the patient. The colors could be similar to those in table A.

**TABLE A**

VACCINE	DTP	MMR	OPV	HIB	HEB
COLOR	RED	GREEN	BLUE	ORANGE	YELLOW

It should be noted here that the placement of the sticker might be an exciting event for the child.

5. REFERRALS: Those patients who choose to have their immunizations administered in the public sector, but will continue to see the pediatrician for sick-visits should be given the first battery of immunizations. Their chart should be placed in an atypical colored folder and they should be asked to sign a postcard similar to the one below.

I give Child-Adolescent Health Associates of the New River Valley permission to notify the health department of my choice to obtain my child's immunizations there. Furthermore, I give both the health department and Child-Adolescent Associates permission to exchange that immunization information.

NAME: (please print) \_\_\_\_\_

SIGNED: \_\_\_\_\_

6. HEALTH DEPARTMENTS: The local health departments should keep a list of patient's primary care providers and should record any vaccinations given to a child on that list.
7. FOLLOW-UP: At the conclusion of each week, one nurse should be assigned the task of phoning the local health departments and updating the office charts with new vaccination information.

Implementation of such a procedure could allow the PPPG to have more accurate immunization information in the near future. This type of organization could lead to better centralization of



vaccination information even in the absence of a national tracking system. Possible increases in the number of children who are fully up-to-date and decreases in the number of those who receive duplicate vaccinations might also occur. Organization of this type, nonetheless, would only be a compromise solution to the current issues surrounding immunizations. Many relevant issues would not be addressed. For example, the central problem of referrals due to cost, which has led to the deficiencies in the immunization information found within many of the charts of the primary care providers would still prevail. Also, although the aforementioned recommendations would allow for exchange of information on a local level, they might not allow for exchange of the information on a regionally or national level. Thus, although enhanced exchange of information must currently begin at the local level, real advances in the solutions to national immunization issues will not occur until a program is initiated on a national level through a tracking system that also reduces cost of vaccine.

#### **VI. Point of Departure: The Ideal Solution**

The solution to the problems surrounding immunization administration may be simple, although a few assumptions have to be made. It must be assumed that any physician who wished to participate would have access to a computer with a modem. It must also be assumed that political bipartisanship would be achieved regarding this issue. With these assumptions made, let's look at a solution.

The federal government would have to shoulder the responsibility for initial acquisition of all vaccine from the drug companies. The drug companies would readily accept this idea because they could sell in bulk and would acquire government contracts. Currently the federal government accounts for much of the vaccine sold in the United States. As previously mentioned, it sells vaccine to health departments at a reduced price. In this model, the federal government would sell a specific amount of the purchased vaccine to any doctor who would administrate it. The government would sell it to all health care providers at the same reduced price (appendix C). The doctor could thus purchase a specific amount of the vaccine at a reduced rate and immunize children a price comparable to those incurred at health departments. This would solve the issue of missed opportunities due to cost.

The solution to the tracking problem could easily be related to the solution to the missed opportunities. The doctor would acquire a specific amount of vaccine at the reduced price. The amount of vaccine purchased by the doctor would be recorded. After each immunization given using government acquired vaccine, the health care provider, in this specific case the doctor, would be required to report it to the federal government agency in charge of immunization records and vaccine information. This agency could be the social security department. Currently, the social security department has access to the social security numbers of all of our

citizens. The network already exists on the local and state levels. Thus, in theory, all children born in this country have their own social security number soon after birth. In practice, a large percentage of the newborn population are assigned social security numbers early in life because these numbers are necessary if the parent(s) wish to claim their children as dependents on income tax forms. As a result, the Social Security Department already has all of the tracking capabilities in place. The report from the health care providers' office could be made electronically to the regional social security department. The report would contain the social security number of the child who received the vaccination, the date the vaccination was given, who gave it to the child, and the type of vaccination that was given.

When the health care provider wished to reorder vaccine, the only vaccine that would be replaced at the reduced price would be that which was given **and reported** to the social security department. Any vaccine that was used and not reported would be sold at a higher price. Therefore, by controlling the entire supply of vaccine, by holding health care providers accountable for a specific amount of vaccine, and by charging health care providers higher prices when they failed to report immunizations given, the federal government would be capable of tracking the immunization histories of our young and hopefully assure that those children who were underimmunized would be found and immunized.

The political issues surrounding the need for solutions to

immunization problems of our nation are few. Most agree that something must be done. However, the resolution is not such a comfortable topic. The scope of the social security department, patient's privacy, purchasing and distribution of vaccine, and the new roles of health departments and drug companies are prevalent issues that would have to be addressed even in the simplistic model proposed by this investigator. Most of these types of issues make politicians uncomfortable. However, if no real efforts are taken to increase the effectiveness of immunization administration, our children are the ones who will ultimately suffer.

**VIII. Acknowledgements:**

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**IX. Appendices**

Appendix A: Disease Pathogenesis of Vaccine-Preventable Diseases

Appendix B: Pertussis and Measles Tables of Interest

Appendix C: Vaccine Prices (in dollars) in the United States

Appendix D: CASA- Clinic Assessment Software Application

Appendix E: Recommended Childhood Immunization Schedule USA- 1995

All of the information contained within the appendices unless otherwise indicated, was taken from the following source:

Centers for Disease Control and Prevention. Epidemiology & Prevention of Vaccine-Preventable Diseases. Atlanta : CDC Printing Office, 1995.



**Appendix A: Disease Pathogenesis of Vaccine Preventable Diseases:**

1. Diphtheria
2. Tetanus
3. Pertussis
4. Measles
5. Mumps
6. Rubella
7. Haemophilus Influenza
8. Poliomyelitis

**1. Diphtheria:****Complications:**

Most complications of diphtheria and deaths are attributable to the effects of the toxin. The severity of the disease and complications is generally related to the extent of local disease. The toxin, when absorbed, affects organs and tissues distant from the site of invasion. The most frequent complications of diphtheria are:

**Myocarditis:**

Abnormal cardiac rhythms can occur early in the course of the illness or weeks later, and can lead to heart failure. If myocarditis occurs early, it is often fatal.

**Neuritis:**

This complication usually affects motor nerves and usually clears completely. Paralysis of the soft palate is most frequent during the third week of illness. Eye muscles, limbs, and diaphragm paralysis can occur after the fifth week. Secondary pneumonia and respiratory failure may result from diaphragmatic paralysis.

Other complications include otitis media and respiratory insufficiency due to airway obstruction, especially in infants.

**Death:**

The case-fatality rate for diphtheria is 5%-10%, with higher death rates (up to 20%) in persons <5 and >40 years of age. The case-fatality rate for diphtheria has changed in the last 50 years.

## 2. Tetanus:

### **Complications:**

**Laryngospasm** (spasm of the vocal cords) and/or spasm of the muscles of respiration leading to interference with breathing.

Fractures in the spine or long bones are a result of sustained contractions and convulsions.

**Hyperactivity of the autonomic nervous system** may lead to hypertension and/or an abnormal heart rhythm.

**Comas** may also occur in association with tetanus.

Secondary infections, may include **sepsis, indwelling catheters, hospital acquired pneumonia, and decubitus ulcers.**

**Pulmonary embolism** is particularly a problem in drug addicts and elderly patients.

**Aspiration pneumonia** is a common late complication of tetanus, found in 50%-70% of autopsied cases.

### **Death:**

Approximately 30% of reported cases are fatal. In the United States, most deaths occur in persons >50 years of age. In about 20% of tetanus deaths, no obvious pathology is identified and death is attributable to the direct effects of tetanus toxin. The course usually lasts several weeks, with gradual decline over time.

### 3. Pertussis

#### **Complications:**

Young infants are at the highest risk for acquiring pertussis and pertussis-associated complications. The most common complication and the cause of most deaths is secondary bacterial pneumonia. Data for 1989-1991 indicate that pneumonia occurred among 12% of all reported pertussis cases and among 16% of infants <6 months of age.

Neurological complications such as **seizures** and **encephalopathy** (a diffuse disorder of the brain) may occur as a result of **hypoxia** (reduction of oxygen supply) from coughing, or possibly from the toxin. Neurological complications of pertussis are more common among infants.

Other less serious complications include **otitis media**, **anorexia**, and **dehydration**. Complications resulting from pressure effects of severe paroxysms include **pneumothorax**, **epistaxis**, **subdural hematomas**, **hernias**, and **rectal prolapse**.

In the United States from 1989 through 1991, 41% of all reported pertussis cases were hospitalized, including 69% of infants. From 1989 through 1991, 20 deaths due to pertussis (case-fatality rate=0.2%) were reported. The case-fatality rate was highest in infants younger than 6 months of age (0.2%) and generally decreased with increasing age.

#### **4. Measles:**

##### **Complications:**

Approximately 30% of reported measles cases have one or more complications. Complications of measles are more common among children <5 and adults >20 years of age.

##### **Diarrhea:**

From 1985 through 1992, diarrhea was reported in 8% of reported cases, making this the most commonly reported complication of measles.

##### **Otitis Media:**

Otitis media is reported in 7% of reported cases, and occurs almost exclusively in child.

##### **Pneumonia:**

Pneumonia (6% of the reported cases) may be viral or superimposed bacterial, and is the most common cause of death.

##### **Encephalitis:**

Acute encephalitis is reported in approximately 0.1% of the reported cases. Onset generally occurs 6 days after rash onset (range 1-15 days), and is characterized by fever, headache, vomiting, stiff neck, meningeal irritation, drowsiness, convulsions, and coma. Cerebrospinal fluid shows pleocytosis and elevated protein. Case fatality rate is approximately 15%. Some form of residual neurological damage occurs in as many as 25%.

**Measles continued:**

**Seizures:**

Seizures (with or without fever) are reported in 0.6% to 0.7% of reported cases.

**Subacute sclerosing panencephalitis (SSPE):**

Subacute sclerosing panencephalitis (SSPE) is a rare degenerative central nervous system disease believed to be due to persistent measles virus infection of the brain. Average onset occurs 7 years after measles (range 1 month to 27 years), and occurs in five to ten cases per million reported measles cases. The onset is insidious, with progressive deterioration of behavior and intellect, followed by **ataxia** (awkwardness), **myoclonic seizures**, and eventually death.

**Measles during pregnancy:**

Measles during pregnancy results in a higher risk of prematurity and spontaneous abortion. Birth defects (with no definable pattern of malformation) have been reported rarely, without confirmation that measles was the cause.

**Death:**

Death from measles has been reported in approximately 1-2 per 1,000 reported cases in the United States in recent years. As with other complications of measles, the risk of death is higher in young children and adults. **Pneumonia** accounts for about 60% of the deaths. The most common causes of death are **pneumonia** in children and **acute encephalitis** in adults.

## 5. Mumps:

### Complications:

**Central nervous system (CNS) involvement** in the form of **aseptic meningitis** (inflammatory cells in cerebrospinal fluid) is common, occurring asymptotically in 50%-60% of patients. **Symptomatic meningitis** (headaches, stiff neck) occurs in up to 15% of patients and resolves without sequelae in 3-10 days. Adults are at higher risk for this complication than children, and boys are more commonly affected than girls (3:1 ratio). **Parotitis** may be absent in up to 50% of such patients. **Encephalitis** is rare (<0.2/1,000) and permanent sequelae or death is uncommon.

**Orchitis (testicular inflammation)** is the most common complication in postpubertal males. It occurs in up to 20%-50% of postpubertal males, usually after parotitis, but may precede it, begin simultaneously, or occur alone. It is bilateral in up to 30% of affected males. There is usually abrupt onset of testicular swelling, tenderness, nausea, vomiting, and fever. Pain and swelling subside in 1 week but tenderness may last for weeks. Approximately 50% of patients with orchitis have some degree of testicular atrophy, but sterility is rare.

**Deafness** caused by mumps is one of the leading causes of acquired sensorineural deafness in childhood. The estimated incidence is approximately 1 per 20,000 reported cases of mumps. Hearing loss is unilateral in approximately 80% of the cases and may be associated with vestibular reactions. Onset is usually

**Mumps continued:**

sudden and results in permanent hearing impairment.

**Oophoritis (ovarian inflammation)** occurs in 5% of postpubertal females. It may mimic appendicitis. There is no relation to impaired fertility. **Pancreatitis** is infrequent, but occasionally occurs without **parotitis**; the **hyperglycemia** is transient and reversible. While some single instances of **diabetes mellitus** have been reported, a causal relationship has yet to be conclusively demonstrated.

There is good evidence to support **intrauterine infection** with mumps as a cause of **endocardial fibroelastosis** or other congenital malformations. Increased fetal wastage, however, has been reported in pregnancies complicated by mumps.

In some young adults, particularly males, **monarticular arthritis, migratory polyarthritis, or arthralgia** occurs at about 2 weeks after onset; usually the larger joints are affected. Symptoms last from days to up to 3 months, but resolution is spontaneous and complete. Joint damage has not been reported.

**Viruria** is common in mumps infections. This may be accomplished by abnormal renal function tests and rarely by **nephritis**, which has sometimes been fatal.

**Deaths** from mumps are infrequent; 1-3.4 deaths per 10,000 reported cases in recent years.



**6. Rubella:**

**Complications:**

Arthritis or arthralgia may occur in up to 70% of adult women who contract rubella, but is rare in children or adult males. Fingers, wrists, and knees tend to be affected. Joint symptoms tend to occur about the same time or shortly after the appearance of the rash and may last for up to 1 month; chronic arthritis is rare.

Encephalitis occurs in one in 5,000 cases, more frequently in adults (especially in females) than in children. Mortality estimates vary from 0 to 50%.

Hemorrhagic manifestations occur with an approximate incidence of 1 per 3,000 cases, occurring more often in children than adults. These manifestations may be secondary to low platelet and vascular damage, with thrombocytopenic purpura being the most common manifestation. Gastrointestinal, cerebral, or intrarenal hemorrhage may occur. Effects may last from days to months, and most patients recover.

Additional complications include orchitis, neuritis, and a rare late syndrome of progressive panencephalitis.

## 7. Haemophilus Influenza:

### **Complications:**

Invasive disease caused by H. influenzae type b can affect many organ systems. The most common types of invasive disease are **meningitis, epiglottitis, pneumonia, arthritis, and cellulitis.**

**Meningitis** is infection of the membranes covering the brain and is the most common clinical manifestation of Hib disease, accounting for 50%-65% of cases. Hallmarks of Hib meningitis are fever, decreased mental status, and stiff neck. The mortality rate is 2%-5%, despite appropriate antimicrobial therapy. Neurologic sequelae occur in 15%-30% of survivors.

**Epiglottitis** is an infection and swelling of the epiglottis, the tissue in the throat that covers and protects the larynx during swallowing. Epiglottitis is an infection and swelling of this tissue, causing life-threatening airway obstruction.

**Septic arthritis** (joint infection), **cellulitis** (rapid progressing skin lesions which usually involve the face, head, or neck), and **pneumonia** are common manifestations of invasive disease.

**Osteomyelitis** (bone infection), **pericarditis** (infection of the sac covering the heart), are less common forms of invasive disease.

**Otitis media** and **acute bronchitis** due to H. influenzae are generally caused by nontypable strains. Hib strains account for only 5%-10% of the H. influenzae causing **otitis media.**

## **8. Poliomyelitis:**

### **Complications:**

The response to poliovirus is highly variable and has been categorized based on the severity of clinical presentation.

### **Inapparent infection without symptoms:**

Up to 95% of all polio infections are inapparent or subclinical. Estimates of the ratio of inapparent to paralytic illness vary from 50:1 to 1,000:1 (usually 200:1). Infected persons without symptoms shed the virus in the stool, and are able to transmit virus to others.

### **Minor illness (abortive poliomyelitis):**

Approximately 5% (4%-8%) of polio infections consist of a nonspecific illness without clinical or laboratory evidence of central nervous system invasion and are characterized by complete recovery in less than a week. Three syndromes observed with this form of poliovirus infection are upper respiratory tract infection (sore throat and fever), gastrointestinal disturbances (nausea, vomiting, abdominal pain, constipation, or, rarely, diarrhea), and influenza-like illness. These syndromes are indistinguishable from other viral illnesses.

### **Nonparalytic poliomyelitis:**

Nonparalytic aseptic meningitis (symptoms of stiffness of the neck, back, and/or legs) usually followed several days after a prodrome similar to that of minor illness occur in 1%-2% of polio

**Poliomyelitis continued:**

infections. Increased or abnormal sensations can also occur. Typically these symptoms will last from 2 to 10 days followed by complete recovery.

**Paralytic poliomyelitis:**

Less than 2% of all polio infections result in a flaccid paralysis (usually less than 1%). Paralytic symptoms generally begin 1 to 10 days after prodromal symptoms and progress for 2 to 3 days. Generally, no further paralysis occurs after the temperature returns to normal. The prodrome may be biphasic, especially in children, initial minor symptoms separated by a 1- to 7-day period from more major symptoms. Other prodromal signs and symptoms can include a loss of superficial reflexes, initially increased deep tendon reflexes and severe muscle aches and spasms in the limbs or back. The illness progresses to flaccid paralysis with diminished deep tendon reflexes which reaches a plateau without change for days to weeks and is usually asymmetrical.

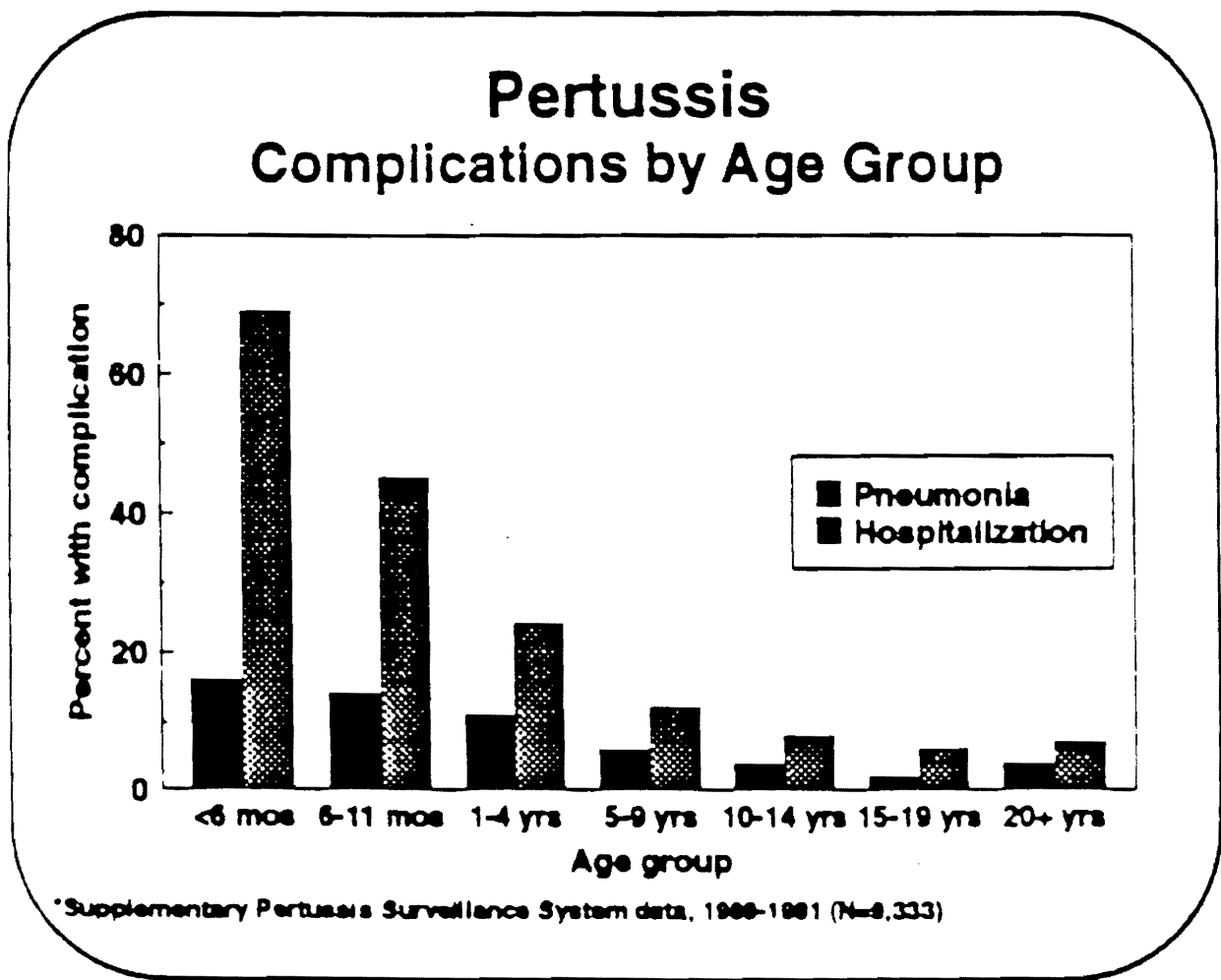
Many persons with paralytic poliomyelitis recover completely and, in most, muscle function returns to some degree. Patients with weakness or paralysis 12 months after onset will usually be left with permanent residua.

The death-to-case ratio for paralytic polio is generally 2%-5% in children and up to 15%-30% in adults (depending on age). It increases to 25%-75% with bulbar involvement. Bulbar polio accounts for 2% of the cases.

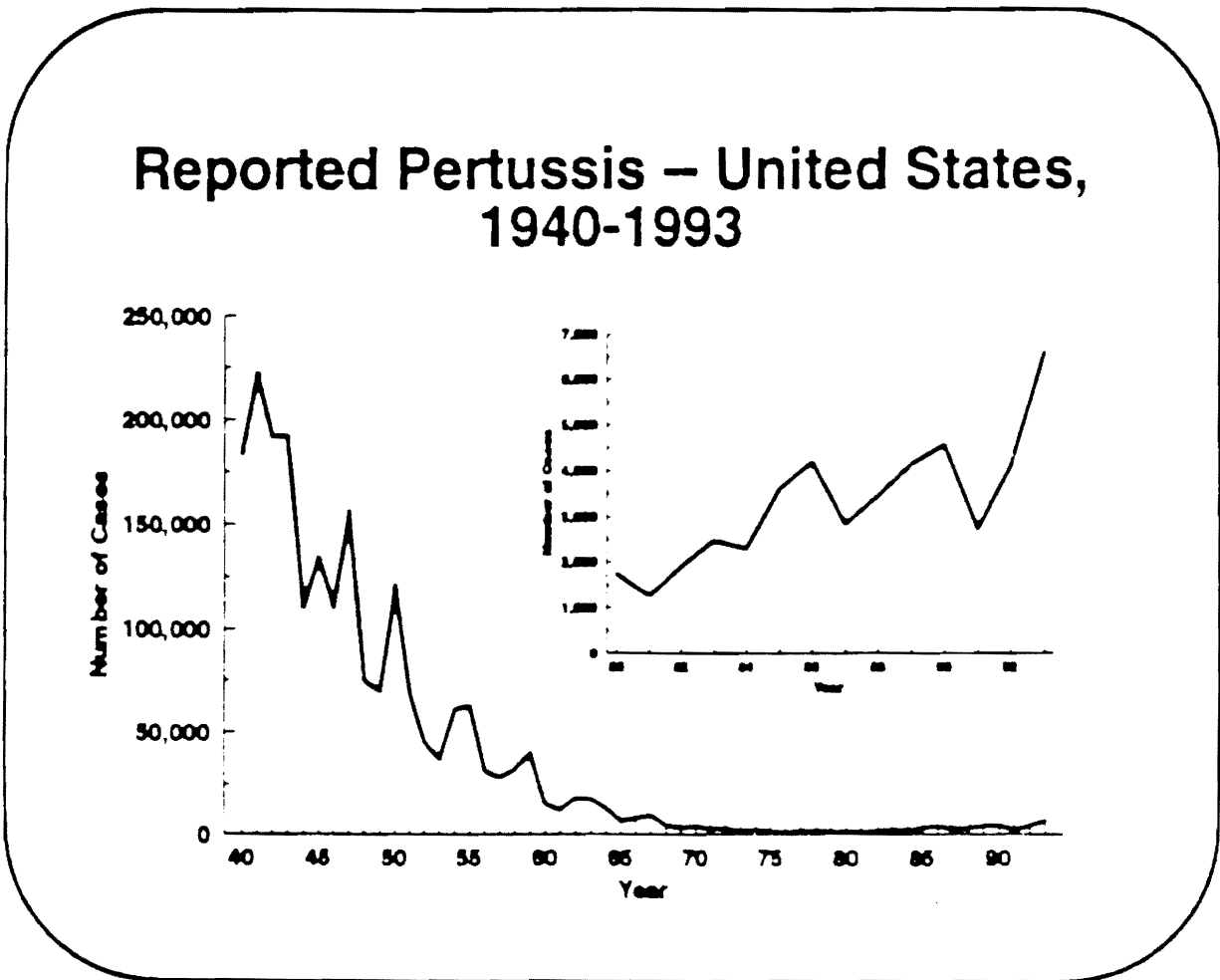
Appendix B: Pertussis and Measles Tables of Interest

1. Pertussis Complications by Age Group
2. Reported Pertussis- United States, 1940-1993
3. Reported Measles- United States, 1950-1993

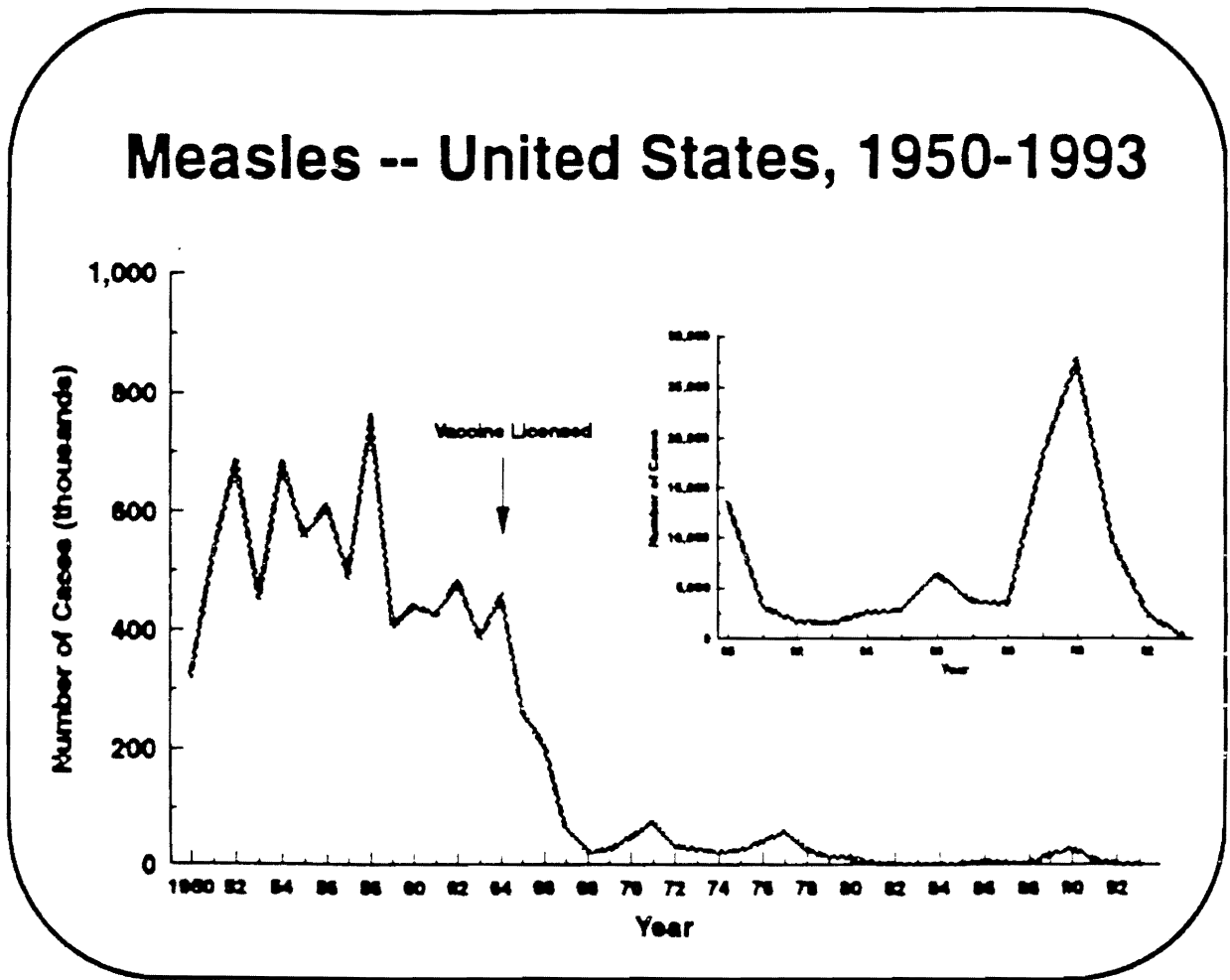
1. Pertussis Complications by Age Group:



2. Reported Pertussis- United States, 1940-1993:



3. Reported Measles-United States, 1950-1993:





Appendix C: Vaccine Prices (in dollars) in the United States

1. Vaccine Prices from 1977-February 1993
2. Federal Contract Prices for Vaccines in "Current" Dollars
3. Private Catalog Prices for Vaccines in "Current" Dollars

All of the information in Appendix C was taken from the following source:

Institute of Medicine. Division of International Health. The Children's Vaccine Initiative : Achieving the Vision. Eds. Violaine S. Mitchell, Nalini M. Philipose, and Jay P. Sanford. Washington, D.C. : National Academy Press, 1993.

1. Vaccine Prices from 1977-February 1993:Vaccine Prices (in dollars) in the United States  
1977-February 1993

DTP		OPV		MMR		Hib-CV	
CP	FC	CP	FC	CP	FC	CP	FC
0.19	0.15 <sup>a</sup>	1.00	0.30	6.01	2.42	NA	NA
0.22	0.15 <sup>a</sup>	1.15	0.31	6.16	2.35	NA	NA
0.25	0.15 <sup>a</sup>	1.27	0.33	6.81	2.62	NA	NA
0.30	0.15 <sup>a</sup>	1.60	0.35	7.24	2.71	NA	NA
0.33	0.15 <sup>a</sup>	2.10	0.40	9.32	3.12	NA	NA
0.37	0.15 <sup>a</sup>	2.75	0.48	10.44	4.02	NA	NA
0.45	0.42 <sup>a</sup>	3.56	0.58	11.30	4.70	NA	NA
0.99	0.65 <sup>a</sup>	4.60	0.73	12.08	5.40	NA	NA
2.80	2.21	6.15	0.80	13.53	6.85	NA	NA
11.40	3.01	8.67	1.56	15.15	8.47	NA	NA
8.92	7.69	8.07	1.36	17.88	10.67	NA	NA
11.03	8.46 <sup>b</sup>	8.07	1.36	24.11	16.18	13.75	11.00
10.65	7.96	9.45	1.92	24.11	16.18	13.75	6.00
10.65	6.91	9.74	1.92	24.07	14.71	14.55	5.20
9.97	6.25	9.45	2.00	25.29	15.33	14.55	5.16 <sup>c</sup>
9.97	6.25	9.91	2.09	25.29	15.30	14.55	5.16 <sup>c</sup>
10.04	5.99	10.43	2.16	25.29	15.33	15.13	5.37

Note: CP, Catalog Price; FC, Federal contract Price; NA, vaccine not licensed. Prices listed beginning with 1977.

2. Federal Contract Prices for Vaccine in "Current" Dollars:

## Federal Contract Prices for Vaccines in "Current" Dollars

Year	Price of OPV (\$)	PI	Price of MMR (\$)	PI	Price of DTP (\$)	Price Indices	
						CPI	PPPI
1977	0.30	51	2.42	51	0.15	61	59
1978	0.31	54	2.35	50	0.15	65	62
1979	0.33	57	2.62	56	0.15	73	67
1980	0.35	61	2.71	58	0.15	82	73
1981	0.40	68	3.12	66	0.15	91	81
1982	0.48	82	4.02	86	0.15	97	90
1983	0.58	100	4.70	100	0.42	100	100
1984	0.73	125	5.40	115	0.65	104	109
1985	0.80	138	6.85	146	2.21	108	119
1986	1.56	268	8.47	180	3.01	110	130
1987	1.36	234	10.67	227	7.69	114	141
1988	1.07	184	11.74	250	3.90	118	152
1989	1.63	280	11.74	250	3.40	124	166
1990	1.63	280	10.27	219	2.35	131	181
1991	1.71	294	10.89	232	1.70	136	196
1992	1.80	310	10.89	232	1.70	140	208

Note: Prices are indexed at a base year of 1993. PI, price index. Prices exclude the excise taxes for the Vaccine Injury Compensation Program that were in effect from 1988 to January 1993.

3. Private Catalog Prices for Vaccine in "Current" Dollars:

## Private Catalog Prices for Vaccines in "Current" Dollars

Year	Price of OPV (\$)	PI	Price of MMR (\$)	PI	Price of DTP (\$)	Price Indices	
						CPI	PPPI
1977	1.00	28	6.01	53	0.19	61	59
1978	1.15	32	6.16	55	0.22	65	62
1979	1.27	36	6.81	60	0.25	73	67
1980	1.60	45	7.24	64	0.30	82	73
1981	2.10	59	9.32	82	0.33	91	81
1982	2.75	77	10.44	92	0.37	97	90
1983	3.56	100	11.30	100	0.45	100	100
1984	4.60	129	12.08	107	0.99	104	109
1985	6.15	173	13.53	120	2.80	108	119
1986	8.67	244	15.15	134	11.40	110	130
1987	8.07	227	17.88	158	8.92	114	141
1988	7.78	219	19.67	174	6.47	118	152
1989	9.16	257	19.67	174	6.09	124	166
1990	9.45	265	19.63	174	6.09	131	181
1991	9.16	257	20.85	185	5.41	136	196
1992	9.62	270	20.85	185	5.41	140	208

Note: Prices are indexed at a base year of 1993. PI, price index. Prices exclude the excise taxes for the Vaccine Injury Compensation Program that were in effect from 1988 to January 1993.

Appendix D: An Example of the CASA Software Program

1. An example of Clinic Site Information Form
2. An example of the Sample Size Determination Process
3. An example of the Data Record Input Form

# Welcome to CASA

Clinic Assessment Software Application  
Version 3.0a

F1 = Help

Clinic Assessment Software Application (CASA)

- (1) Clinic Identification
- (2) Select Sample Size
- (3) Immunization Histories
- (4) Reports
- (5) Utilities
- (6) Maintenance
- EXit

Created by the National Immunization Program, CDC

1. An example of Clinic Site Information Form:

F1 = Help    PgUp = Top of Form    PgDn = Menu Bar

==== Clinic Site Information Form =====

Clinic Review Date:    /    /

Common Review Date:    /    /

Beginning Assessment Month:  
                          24

Ending Assessment Month:  
                          35

Clinic Type:

Site Name:

Reviewer Initials:

City:

State:

Zip:

00000-0000

Assessment  
Size:            0

Are You Going to Sample and Input Records From More  
Than ONE Filing System for this Clinic Site?  
(Press F1 for further explanation)

-----  
<F2/Select Sample Size> <Esc/EXit>

2. An example of the Sample Size Determination Process:

You are in the Sample Size Determination Process

Are the Immunization Records for this Practice Computerized? NO

Press the Space Bar to Alternate between YES or No

You are in the Sample Size Determination Process

Are there Fewer than 200 Two-Year-Olds in this Practice? NO

Press the Space Bar to Alternate between YES or NO



Sample Size Determination Process continued:

You are in the Sample Size Determination Process

Are the Files Organized by "Active" and "Inactive" Status:NO

Press the Space Bar to Alternate Between YES or NO

"Active" is Defined as All Children between 19 and 35  
Months of Age Who Have Ever Been Immunized in This Practice.

"Inactive" is Defined as Children Who Fall Outside of the  
Age Range or who have Moved or Gone Elsewhere for Treatment.

Are the Files Oriented by Individual or Grouped by Family? INDIVIDUAL

Press the Space bar to Alternate between INDIVIDUAL or FAMILY

Sample Size Determination Process continued:

You are in the Sample Size Determination Process

Are the Files Organized by "Active" and "Inactive" Status:NO

What are the Total Number of Files for the Clinic: 825

This Clinic Does not File its "Actives" Separately

"Active" is Defined as All Children between 19 and 35 Months of Age Who Have Ever Been Immunized in This Practice.  
"Inactive" is Defined as Children Who Fall Outside of the Age Range or who have Moved or Gone Elsewhere for Treatment.

You are in the Sample Size Determination Process

Do you have an Estimated Percentage of "Inactives" for this Clinic: YES

Press the Space Bar to Alternate Between YES or NO

An Estimate of the Percentage of "Inactive" Children is Necessary to Ascertain an Accurate Sample Size. If you do not have a Percent Figure then we will Provide you with an Estimation Tool.

"Active" is Defined as All Children between 19 and 35 Months of Age who have ever been Immunized in this Practice.  
"Inactive" is Defined as Children who Fall Outside of the Age Range or who have Moved or Gone Elsewhere for Treatment.

Sample Size Determination Process continued:

You are in the Sample Size Determination Process

Do You Have an Estimated Percentage of Missing Immunization Records: NO

Press the Space Bar to Alternate Between YES or NO

An Estimate of the Percentage of Children Missing Their Immunization Record is Necessary to Assure an Accurate Sample Size Count.

"Missing" is Defined as either Lacking an Immunization Record or Having the Immunization Record Missplaced in some Manner.

Press any key to continue ...

A Printout is Being Assembled  
That are to be Used to Select the Files to Review.

Working.....

The Following Information is Provided for this Clinic:

The Required Sample Size to be Reviewed is: 163

The Actual Sample Size to be Reviewed is: 165

The Starting Record Point is: 5

The Sampling Interval is: 5

3. An example of the Data Record Input Form:

F1 = Help      PgUp = Top of Form      PgDn = Menu Bar      DnArrow = Next Row

Demonstration Dataset Shot Record Input Form					
Record Number: 142			Review Date: 02/09/94		
Last Name:		DOB: / /			
File Origin: A					
Medicaid:					
Last Visit Date:		/ /			
Moved/Gone Elsewhere: N		If Moved, Date: / /			
	1	2	3	4	5
DTP:	/ /	/ /	/ /	/ /	/ /
OPV:	/ /	/ /	/ /	/ /	/ /
HIB:	/ /	/ /	/ /	/ /	
MMR:	/ /	/ /			
Me:	/ /	Mu: / /	Ru: / /	MR: / /	
HEPB:	/ /	/ /	/ /		
DT:	/ /	/ /	/ /	/ /	/ /
IPV:	/ /	/ /	/ /	/ /	/ /
Td:	/ /	/ /	/ /		
< F2/Prior >   < F3/Next >   < F4/Add Another >   < Esc/EXit >					

Valid Birthdates are Between 01/01/91 and 06/01/92

The Last Name/Unique ID is a Mandatory-Data-Entry Field

Appendix E: Recommended Childhood Immunization Schedule USA- 1995

# Recommended Childhood Immunization Schedule United States - 1995

Vaccines are listed under the routinely recommended ages. Shaded bars indicate range of acceptable ages for vaccination.

Age Vaccine	Birth	2 mos	4 mos	6 mos	12 <sup>5</sup> mos	15 mos	18 mos	4 - 6 yrs	11-12 yrs	14-16 yrs
Hepatitis B <sup>1</sup>	HB-1	HB-2		HB-3						
Diphtheria, Tetanus, Pertussis <sup>2</sup>		DTP	DTP	DTP	DTP or DTaP at 15+ m			DTP or DTaP	Td	
<i>H. influenzae</i> type b <sup>3</sup>		Hib	Hib	Hib	Hib					
Polio		OPV	OPV	OPV				OPV		
Measles, Mumps, Rubella <sup>4</sup>					MMR			MMR or	MMR	

<sup>1</sup> All pregnant women should be screened for HBsAg in an early prenatal visit; infants born to HBsAg-positive mothers should receive immunoprophylaxis for hepatitis B with 0.5 ml Hepatitis B Immune Globulin (HBIG) within 12 hours of birth, and 0.5 ml of either Merck Sharpe & Dohme vaccine (Recombivax HB) or of SmithKline Beecham vaccine (Engerix-B) at a separate site. In these infants, the second dose of vaccine is recommended at 1 month of age and the third dose at 6 months of age. For infants of HBsAg-negative mothers, the second dose of Hepatitis B vaccine may be administered between 1 and 4 months of age, provided at least one month has elapsed since receipt of the first dose. The third dose is recommended between 6 and 15 months of age.

<sup>2</sup> The fourth dose of DTP may be administered as early as 12 months of age, provided at least 6 months have elapsed since DTP3. Combined DTP-Hib products may be used when these two vaccines are to be administered simultaneously. DTaP (diphtheria and tetanus toxoids and acellular pertussis vaccine) is licensed for use for the 4th and/or 5th dose of DTP vaccine in children 15 months of age or older and may be preferred for these doses in children in this age group.

<sup>3</sup> Three *H. influenzae* type b conjugate vaccines are available for use in infants: HibOC [HibTITER] (Lederle Praxis); PRP-T [ActHIB; OmniHIB] (Pasteur Mérieux, distributed by SmithKline Beecham; Connaught); and PRP-OMP [PedvaxHIB] (Merck Sharp & Dohme). Children who have received PRP-OMP at 2 and 4 months of age do not require a dose at 6 months of age. After the primary infant Hib conjugate vaccine series is completed, any licensed Hib conjugate vaccine may be used as a booster dose at age 12-15 months.

<sup>4</sup> The second dose of MMR vaccine should be administered EITHER at 4-6 years of age OR at 11-12 years of age.

<sup>5</sup> Vaccines recommended in the second year of life (12-15 months of age) may be given at either one or two visits.

Approved by the Advisory Committee on Immunization Practices (ACIP), the Committee on Infectious Diseases (CID), American Academy of Pediatrics (AAP), the AAP Executive Board, and the Commission on Public Health and Scientific Affairs (CoPHSA), American Academy of Family Physicians (AAFP)