

**RESOLUTION OF THE
WHITE MOUNTAIN APACHE TRIBE OF THE
FORT APACHE INDIAN RESERVATION**

- WHEREAS,** members of the Tribal Council of the White Mountain Apache Tribe are duly elected representatives of the people of their respective districts and among the many issues of concern to the Council are the health and well-being of its Tribal members; and
- WHEREAS,** the Tribal Council supports carefully designed research projects to evaluate health problems which exist in the population and to develop appropriate interventions which seek to decrease or alleviate these problems; and
- WHEREAS,** many members of the Apache Tribe become sick with the “flu” every year, especially during the winter months, and those who become sick the most are the elderly, the chronically ill, and infants and young children; and
- WHEREAS,** although flu vaccines are available for adults to protect them from the flu, there is no licensed flu vaccine for infants and young children; and
- WHEREAS,** infants who become sick with the flu often experience more severe illness and hospitalizations due to flu-like illnesses than adults who are otherwise healthy; and
- WHEREAS,** the vaccination of expectant mothers during their 2nd or 3rd trimester of pregnancy with the flu vaccine causes a certain amount of maternal antibodies against the flu to be passed to their infants, but data and information are not adequate to reliably conclude that infants can be protected from the flu by antibodies which come from their mother; and
- WHEREAS,** the purpose of the proposed study is to find out how much infants benefit from influenza vaccine given to their mothers prior to their birth, and to find out how severe the problem of influenza illness is among Apache and Navajo children; and
- WHEREAS,** this is an observational study which means that pregnant mothers who enroll in this study will already to be vaccinated with the flu vaccine during their prenatal visits, and only one blood specimen will be taken from the mother, in addition to one umbilical cord blood specimen, and 2 blood specimens taken from infants; and
- WHEREAS,** infants in this study will be monitored for clinic visits and hospitalizations for flu-like illnesses until 6 months of age or until the end of the flu season, whichever comes first, and this study will be conducted for only three consecutive winters; and
- WHEREAS,** all participants must sign an informed consent and are assured that their participation

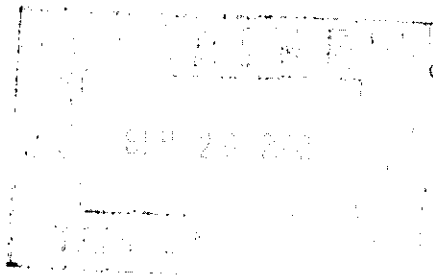
in this study is totally voluntary; and

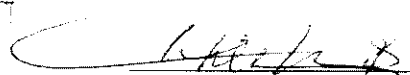
WHEREAS, for more than 22 years, the Johns Hopkins University has conducted research projects on the White Mountain Apache Reservation to reduce high rates of haemophilus, pneumococcal, hepatitis, and diarrheal infections in Apache babies and young children, and, as a result, many diseases in babies have been prevented and many lives saved.

BE IT RESOLVED by the Tribal Council of the White Mountain Apache Tribe that it hereby supports and approves the proposed John Hopkins University research project on the Fort Apache Indian Reservation to determine the extent to which infants benefit from maternal influenza immunization.

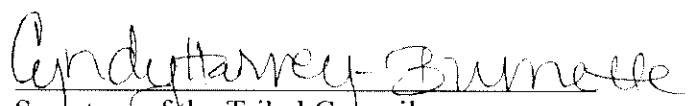
BE IT FURTHER RESOLVED by the Tribal Council of the White Mountain Apache Tribe that Johns Hopkins University and all other entities and personnel involved in the course of this study shall hold all personal data and information of any nature gathered on the test subjects in the strictest confidence.

The foregoing resolution was on August 21, 2002 duly adopted by a vote of FIVE for and ZERO against by the Tribal Council of the White Mountain Apache Tribe, pursuant to authority vested in it by Article IV, Section 1 (a), (s), (t), and (u) of the Constitution of the Tribe, ratified by the Tribe September 30, 1993, and approved by the Secretary of the Interior on November 12, 1993, pursuant to Section 16 of the Act of June 18, 1934 (48 Stat. 984).





Chairman of the Tribal Council



Secretary of the Tribal Council

MATERNAL INFLUENZA IMMUNIZATION STUDY

The Johns Hopkins Programs: White Mountain Apache and Navajo Reservations

Introduction.

The primary purpose of this study is to evaluate the benefit infants receive after their mothers have been vaccinated with the influenza (flu) vaccine while still pregnant. It is recommended that pregnant women receive the influenza vaccine to be protected against influenza illness (the "flu") and to prevent maternal complications. Thus far, very little information has been collected to determine the extent to which infants might benefit from maternal influenza immunization.

Background and Rationale.

Epidemics of the flu occur almost every year in the U.S. during cold months of the year. Adults can experience much illness, discomfort, and malaise. Adults who are otherwise healthy usually get over the illness with no complications. Older adults and those with chronic medical problems sometimes experience more severe illness.

The flu is particularly harsh on children. Children have higher rates of hospitalization due to the flu than adults. Infants less than 6 months old have the highest rates of hospitalizations for acute cardiopulmonary illnesses. For adults, flu vaccines are the best way to prevent getting sick with the flu. Flu vaccines, however, are not licensed for infants less than 6 months of age.

For about 10 years, it has been recommended that all women in their 2nd and 3rd trimesters of pregnancy be given the influenza vaccine. Receiving the flu vaccine prevents pregnancy complications caused by the flu infection and also prevents hospitalization due to the illness. A number of previous small scale evaluations have shown that infants born to mothers who were vaccinated during pregnancy benefited by having higher levels of antibodies against the flu. Thus far, there has never been any evaluation of the extent to which infants benefit from protection against the flu when their mothers were given the flu vaccine during their pregnancy.

On the Navajo and Apache reservations, the percentages of pregnant mothers who receive the flu vaccine are not known. Influenza immunization of pregnant women often occurs at the discretion of obstetricians; many obstetricians vaccinate pregnant women who anticipate given birth just prior to and during the cold months of the year.

Antibodies are substances made by the body to protect the person from infectious diseases. Immunizations ("shots") that babies receive at well-baby clinics (for example, DPT, hepatitis, and Hib) cause the babies to make antibodies against diphtheria and pertussis illness, tetanus, hepatitis, and haemophilus disease.

Immunizing pregnant women is not new. In many areas of the world, for example, very

small infants die because of tetanus infection. It was found that the best way to prevent tetanus in very small infants and to prevent deaths was to vaccinate mothers with the tetanus vaccine before giving birth to the baby. The mother responds to the vaccine by making antibodies against tetanus and passing the antibodies to the baby while still carrying the baby in her womb. This procedure, which is safe, has saved the lives of many infants.

Procedures.

The purpose of the study is to find out how much infants benefit from the vaccination of their mothers with the influenza vaccine before giving birth to their infants. A second purpose is to determine how severe the problem of influenza disease is among Navajo and Apache infants. A third purpose is to determine the percentage of pregnant women who receive the flu vaccine. This is basically an observational study. Study results will come from analyses of information and data gathered from data collection forms, blood specimens, and medical chart reviews.

This study will take place on the Navajo and White Mountain Apache reservations. Women and their infants who are seen at the University of Louisville Hospital, Kentucky, will also take part. In addition, this study will take place only during the "flu seasons" which are the cold months of the year. Three consecutive flu seasons will be the duration of this study, and it's anticipated that a total of 500 infants will be enrolled each flu season. Thus, about 1500 total mother-infant pairs will be enrolled.

When mothers who are expecting are about 36 weeks pregnant, trained study personnel will speak with the mothers about this study and about taking part in it. If interested in the study, an informed consent will be administered which explains the study in detail. All participants of this study are required to give their written consent. After consenting, a small amount (about 1 tablespoon) of blood will be obtained from the mother to test for antibodies against the flu.

Right after delivery of the baby, a small sample of blood will be obtained from the umbilical cord that is still attached to the placenta. Collection of umbilical cord blood is done at all deliveries to determine the blood type of the newborn. We will test the cord blood for antibodies against the flu; these antibodies were made by the mother. Blood samples will be collected two additional times: 1. at 2-3 months of age, and, 2. at 6 months of age or at the end of the flu season, whichever comes first. These two samples will be tested to see if amounts of antibodies have changed.

For several months after the baby has been born, the child will be monitored for all clinic visits and hospitalizations because of flu-like illnesses. If a diagnosis is made for a "flu-like" illness, a sample of material from the far back of the nose (NP, nasopharyngeal specimen) will be collected and tested for RSV (respiratory syncytial virus). This information will be only to help the child's doctor make a more define diagnosis of the illness.

Risks.

The risks involved in this study are minimal. Maternal immunization is a standard practice in many areas of the world. For about the past 10 years, the recommendation to give the influenza vaccine to women during their 2nd and 3rd trimesters of pregnancy has been in place. Flu vaccine is not given to anyone who has allergy to eggs or egg products. Only pregnant women who have received the flue vaccine will be enrolled in this study. Flu vaccine will have already been given to pregnant women during one of their prenatal visits. Johns Hopkins personnel will not administer the flu vaccine, but will only enroll those who have previously been vaccinated. In previous smalls scale studies in which pregnant mothers were administered influenza vaccine, no known evidence of adverse effects were experienced by their infants.

Benefits.

Since this study is only observational, no direct benefit will come to woman and their infants as a result of their participation in this study. However, since no large body of data currently exists to reliably determine the extent to which infants may be protected from influenza illness, favorable results derived from their participation in this study may benefit infants born in the future if maternal influenza immunization is adopted as a result of this study and becomes standard practice.

Confidentiality.

Information and data obtained from the participation of all infants and mothers in this study will treated with strict confidence. Hard data will be stored in locked file cabinets with only study personnel having access to these records. Data and information collected from all participants will also be store in computer files. For all data sets, each participant will be assigned a unique coded study umber, and only study personnel will have access to the breakout of the code. Analyses of data will be in aggregate to prevent identification of any participant. Publications resulting from this study will not identify any individual by name or location of residence.