

**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 many issues of concern to the Council are the health and well-being of its Tribal members; and
- WHEREAS,** members of the Tribal Council of the White Mountain Apache Tribe support carefully designed research projects which aim to raise the level of health of all residents of the Reservation; and
- WHEREAS,** much has been accomplished to prevent and/or cure many infectious diseases in the Apache population, but certain diseases continue to affect different segments of the population, especially those at most risk; and
- WHEREAS,** diseases caused by the pneumococcus bacteria (*Streptococcus pneumoniae*) affect Apaches of all ages and different segments of the population, especially babies, the elderly, alcoholics, diabetics, and those who have chronic diseases (heart, lung, and kidney diseases); and
- WHEREAS,** the pneumococcus bacteria live only in humans in the far back of the nose (nasopharynx, NP) and cause diseases such as pneumonia, meningitis, blood infections, ear infections, and others, and the problem of pneumococcus diseases in Apaches is 5 times worse than in the general population of the U.S.; and
- WHEREAS,** there are over 90 different types of pneumococcus, and about 30 types cause most of the diseases, but only two vaccines are available to protect people against pneumococcal disease: Prevnar for babies, and Pneumovax for persons older than 2 years old, but both of these vaccines do not protect against all types of pneumococcus; and
- WHEREAS,** in order to learn more about the different types of pneumococcus, and how these vaccines affect these different types, and which types of pneumococcus cause diseases the most, and about what needs to be done to offer people more protection from diseases, it is necessary to collect pneumococcal bacteria from People, and these are the purposes of the Long-term study among Apache families, and stated differently, the ultimate purpose of this study is to bring down the high rates of pneumococcal diseases among Apaches; and
- WHEREAS,** pneumococcus bacteria are spread from person-to-person like a cold such as by coughing and sneezing on one another, and much disease begins to get spread within families, and this is the reason that this research project will enroll families into this study; and
- WHEREAS,** about total 200 families from the Apache and Navajo reservations will be enrolled in this voluntary study, and the length of time of each family's participation in one

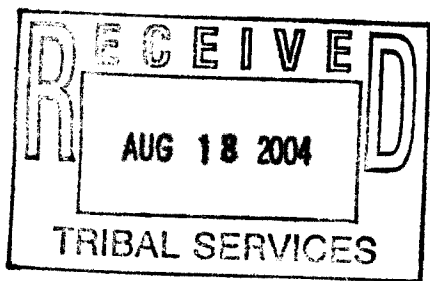
year, and this study will last 4 years, and informed consent will be administered that will explain the study in detail, participants will be allowed to withdraw at any time without any penalty; and

WHEREAS, procedures will include the collection about every other month of pneumococcus (7 times) from the nasopharynx (NP) of each enrollee along with the collection of saliva (7 times) and blood (2 times, at the beginning and end of that person's participation), and these specimens will be analyzed in the laboratory for types of pneumococcus, antibody levels in the blood; and

WHEREAS, a questionnaire will be administered to each enrollee and reviews will be made of the person's medical chart to check on clinic/hospital visits for pneumococcal diseases, and all precautions will be taken to maintain the highest levels of Confidentiality of everyone enrolled in this study.

BE IT RESOLVED by the Tribal Council of the White Mountain Apache Tribe that approval is hereby given to the Johns Hopkins University Center for American Indian Health to conduct the proposed research study entitled "Long-term NP Study among Apache and Navajo Families."

The foregoing resolution was on AUGUST 5, 2004 duly adopted by a vote of EIGHT 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

ACTING 
Secretary of the Tribal Council

LONG-TERM NP STUDY AMONG APACHE AND NAVAJO FAMILIES

The Johns Hopkins Program

INTRODUCTION

The overall purpose of this study is to reduce the severity of pneumococcal diseases in White Mountain Apache and Navajo families and communities. Pneumococcal bacteria are responsible for serious diseases such as meningitis, pneumonia, infections of the blood, ear infections, and others. Pneumococci live only in humans in the far back of the nose (nasopharynx, NP). This study is to learn more about how pneumococcal vaccination affects the bacteria that live in the nasopharynx.

BACKGROUND INFORMATION

In the White Mountain Apache and Navajo populations, rates of diseases caused by pneumococci have previously been found to be higher than in the general population of the U.S. (156/100,000 vs. 9/100,000). Infants and the elderly have high rates of diseases along with other at-risk groups such as alcoholics, those with diabetes, and those with chronic diseases (heart, lung, and kidney diseases).

There are over 90 different types of pneumococcus bacteria. Less than 30 types are responsible for almost all pneumococcal diseases. Pneumococcal bacteria live (are colonized) only in humans—in the far back of the nose (nasopharynx, NP) and mouth (oropharynx). The bacteria is transmitted from person to person like a “cold”, by coughing, sneezing, and otherwise coming into contact with material that comes from the nasopharynx and oropharynx of an infected person. Diseases caused by pneumococcus include meningitis, pneumonia, infections of the blood, ear infections, and others. Serious diseases require hospitalization. Death often results from serious infections.

For more than 20 years, a licensed vaccine (e.g. Pneumovax-23[®]) has been available to prevent pneumococcal diseases in adults. This vaccine, which does not work in very young babies, is made from components of 23 different pneumococcal types, and is supposed to protect individuals from diseases caused by these 23 types. However, it's been recently learned that the vaccine is not totally effective. Pneumovax-23[®] continues to be given, though, because there is no other “adult” pneumococcal vaccine.

From 1997 to 2000, the Johns Hopkins Programs conducted a study among Apache and Navajo infants that found a 7-valent pneumococcal conjugate vaccine (PnC7, Prevnar[®]) to be effective in preventing pneumococcal diseases in infants. This vaccine is made from components of 7 pneumococcal serotypes. Prevnar[®] became licensed and was included among vaccines which are now regularly given as well-baby shots. This vaccine works well to prevent diseases caused by the 7 pneumococcal types. However, it's being noticed that other types of pneumococcus continue to cause diseases in infants.

During the time the PnC7 vaccine was being evaluated, another study was being conducted to see what happens to pneumococcal bacteria living (colonized) in the nasopharynx (NP, the far back of the nose) of babies who received the PnC7 vaccine. Did the vaccine stop the bacteria from living in the NP? or did nothing happen to the bacteria? The answer to these questions was found by getting a small sample of material in the NP using a small swab that looks

like a “Q-tip”, and seeing if pneumococcus was contained in that material. What was learned was that, in babies who received all their pneumococcal vaccinations (a total of 4 shots), there was very little or no pneumococcus colonized in the NP. Also, when material was obtained from the NP of other family members in the home, they also had decreased amounts of pneumococcus colonizing the NP. This phenomenon is called “herd immunity” or “indirect immunity”. Thus, if a baby in a family is fully vaccinated with the pneumococcal vaccine and is protected from pneumococcal diseases, it’s possible for the baby to also protect others in the household who never received the pneumococcal vaccine.

Basically, the purpose of this study is to, on a long-term basis, gather additional information regarding the phenomenon of indirect immunity conferred between and among different household members. This will include collecting information also on the extent of colonization of the NP with vaccine-type and non-vaccine type pneumococcus. From this information, more will be learned about herd immunity, which is little understood among scientists. Also, the effect of routine, community pneumococcal vaccination on disease prevention will be determined. Information may also be obtained about the connection between pneumococcal colonization and getting sick with pneumococcal disease. Altogether, information may be obtained about how the high rates of pneumococcal diseases might be reduced in the Apache and Navajo populations.

METHODS AND PROCEDURES

About 200 families, with at least one child less than 8 years of age, will be enrolled into this study after they’ve had the study explained to them and after they have been administered and have signed the informed consent. A typical enrolled family will consist of 5 household members, but each family must have at least 2 members and may have more than 5. Children more than 6 years old will be asked to give their assent to participate in the study. The total duration of this study is 4 years.

The table below summarizes the activities to be accomplished by each enrollee of this study. This table will be carefully and totally explained to enrollees at the time of their enrollment.

Table. Timeline of Activities for Each Enrollee in the Long-term NP Study

Activity	Mo. 0	Mo. 2	Mo. 4	Mo. 6	Mo. 8	Mo. 10	Mo. 12
Consent	X						
Questionnaire	X	X	X	X	X	X	X
NP Sample	X	X	X	X	X	X	X
Saliva	X	X	X	X	X	X	X
Serum	X						X

No other activities, except those listed above along with laboratory analyses of specimens and record-keeping, will be performed in this study. Study personnel will not administer any vaccinations. Laboratory analyses will consist of identifying pneumococcal organisms by culture, serotyping the pneumococcal bacteria, and determining levels of serotype-specific anti-pneumococcal antibodies.

These specimens have been collected in the past for other studies, thus all Johns Hopkins personnel have had extensive training and experience in their collection.

RISKS AND BENEFITS

Collecting NP samples requires the insertion of a small swab that looks like a “Q-tip” into one of the openings of the nose. It is inserted as far back as possible so that the end of the swab barely touches the back wall of the nasopharynx. This procedure is performed quickly and with one single motion. Some discomfort may be felt, but is of slight duration. Rarely does this procedure result in any bleeding. Johns Hopkins personnel have had much experience in performing this procedure in people of all ages, infants through elderly individuals.

About 3-5 cc of blood (about a tablespoon) will be collected two times during the 12-month period of each enrollee’s participation in this study. Collecting specimens is a common procedure performed by Johns Hopkins personnel; thus, the staff has had much experience performing this procedure. However, risks include continued bleeding after blood has been collected, some bruising of the area where blood was taken, and possible infection if the procedure was not entirely sterile.

With regard to the questionnaire, there may be inadvertent disclosure of confidential information contained in the questionnaire. This is minimized by the assignment of a unique study number to each enrollee which is used on the questionnaire; the names of enrollees are not used.

Enrollees will not personally benefit from their participation in this study. However, information gathered and analyzed from their participation may lead to the development of interventions that can be used to prevent or reduce the high rates of pneumococcal disease in future generations of the Apache population.

CONFIDENTIALITY

The confidentiality of participants of this study is of utmost priority. Johns Hopkins personnel have all received training with regard to purpose, concepts, and practice of confidentiality. Each study person has been required to study for and pass a test related to confidentiality of research subjects. Steps to ensure confidentiality include, but are not limited to: the assignment of a unique study number to each study participant to use in place of the person’s name; using a locked file to store paper copies containing information about that person’s participation in the study; storing information about the participant in the computer with access gained only by study personnel.



*White Mountain Apache
Division of Health Programs*

Donna Vigil, Executive Director

June 28, 2004

**Raymond Reid, MD
Johns Hopkins Programs
P O Box 1240
Whiteriver, AZ 85941**

RE: Preventing Pnenumococcal Disease in Apache Children Research

Dear Dr. Reid:

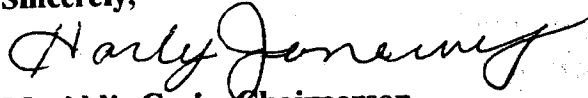
Many among our people on the White Mountain Apache Reservation have become severely ill because of infections due to pneumococci, especially infants, the elderly, and at-risk results adults. We appreciate past work that Johns Hopkins performed on this reservation using a candidate pneu-mococcal vaccine to bring down the once-high rates of disease in infants.

Because the Prevnar pneumococcal vaccine is relatively new, we understand the need for finding out relatively new, we understand the need for finding out more about the vaccine and its effects on the pneumococcal bacteria, including its colonization in the nasopharyaanx (NP); and on those who received the vaccine, and the potential for "indirect immunity" for people in the community.

We are quite pleased that Prevnar appears to work the way it's supposed to, and that many infants are being protected. We're also pleased to learn that the vaccine is safe. Knowing, however, that there are still many adults on this reservation who are continuing to get sick with pneumococcal disease, we support the proposed "long-term NP study" in which today's study participants may help find answers to how tribal members in the future may be protected from disease. We also support the study schedule in which each of 200 families will enrolled for a duration of 12 months, and that the study will last four years.

We look forward to hearing updated reports about this study, and to find learn about the final results.

Sincerely,

A handwritten signature in cursive script, appearing to read "Mariddie Craig".

**Mariddie Craig, Chairperson
Health Board Member**