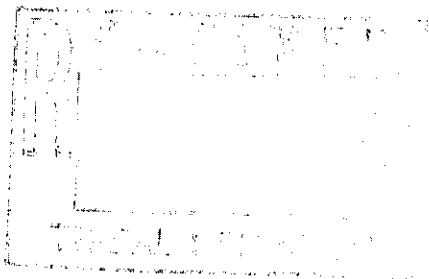


**RESOLUTION OF THE  
WHITE MOUNTAIN APACHE TRIBE OF THE  
FORT APACHE INDIAN RESERVATION**

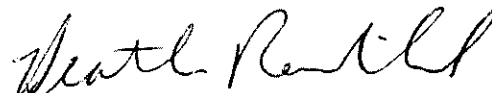
- WHEREAS**, members of the Tribal Council of the White Mountain Apache Tribe are duly elected representatives of the people of their respective districts; and among the many issues of concern to the Council are the health and well-being of its Tribal members; and
- WHEREAS**, the Tribal Council supports carefully designed research projects which aim to raise the level of health of all residents of the Service Unit; and
- WHEREAS**, studies have been determined that 10%-50% of people throughout the U.S. are infected with the *Helicobacter pylori* bacteria which lives in the stomach and duodenum (first part of the small intestine), and the infection often begins during infancy; and
- WHEREAS**, *H.pylori* can sometimes cause diarrhea, but usually lives many years in the stomach and duodenum without causing problems; and
- WHEREAS**, *H.pylori* infection is curable using antibiotics; and
- WHEREAS**, recently, it has been learned that long-term infection with *H.pylori* can often result in adults having ulcers of the stomach and duodenum, and ulcers can become cancers, which sometimes are fatal; and
- WHEREAS**, no study has been done to find out how severe the problem of *H.pylori* infection is in infants and toddlers on the Apache and Navajo population; and
- WHEREAS**, if infection rates are found to be high in babies, a simple method could be used to bring down these high rates to cure the infection, to prevent ulcers in adults, and to prevent the occurrence of cancers which once started out as *H.pylori* infections in babies; and
- WHEREAS**, representatives from Johns Hopkins University have proposed a study of 200 total babies from the Apache and Navajo reservations who would be voluntarily enrolled in the study only after written informed consent is obtained to better understand this disease.
- BE IT RESOLVED** by the Tribal Council of the White Mountain Apache Tribe that it hereby approves the research project within Tribal lands to determine the epidemiology of *Helicobacter pylori* infections among Apache infants and young children to be conducted by the Johns Hopkins University.

Resolution No. 11-2001-300

The foregoing resolution was on November 15, 2001 duly adopted by a vote of NINE 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), (b), (j), (k), (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

**Epidemiologic Study of the Prevalence of *Helicobacter pylori* Infection  
in White Mountain Apache and Navajo Infants and Toddlers**  
The Johns Hopkins Programs: Whiteriver & Navajo

Introduction and Purpose.

*Helicobacter pylori* is a bacteria that has been known to inhabit the gastrointestinal tract (stomach and intestines). It sometimes causes diarrhea, but, for the most part, the bacteria causes no illness. Many infants and toddlers become infected with *H. pylori*. Within the past decade, *H. pylori* has been linked to the occurrence of stomach and duodenal ulcers in adults.

The purpose of this study is to determine the extent to which White Mountain Apache and Navajo infants and toddlers are infected with the *H. pylori* bacteria. From this study, data will be collected and analyzed for the purpose of developing methods, if needed, to minimize the severity of the disease problem.

Background Information.

*Helicobacter pylori* is a bacteria that is often acquired during infancy by person-to-person spread. *H. pylori* infection is more prevalent in populations with high rates of other infectious diseases. For the most part, the bacteria live in the stomach and intestinal linings without causing problems. Rarely, *H. pylori* is suspected to cause diarrhea and malnutrition in infants, especially if diarrhea is persistent.

After a person becomes infected by *H. pylori*, the bacteria can remain inside the individual throughout the lifetime of that person if no medical therapy is given. If the person becomes infected as an infant, usually no clinical problem occurs during the younger ages. It isn't until the person becomes an adult and has chronically been infected with the bacteria that problems begin to occur. Based on studies in the U.S., between 10% to 50% of all persons are infected with *H. pylori*. Rate of infection in a population is inversely related to socioeconomic status.

During the past decade, a number of studies has linked long-term *H. pylori* infection with the occurrence in adults of ulcers of the stomach and duodenum (first part of the small intestine). These ulcers often develop into stomach cancers (gastric adenocarcinomas); results can be fatal.

With the recent understanding of the causes of stomach and duodenal ulcers, many ulcers are now treated with antibiotics, instead of the traditional way of using antacids and surgery when needed.

One of the possible aims of this study is to suggest interventions if high incidence rates of *H. pylori* infection are present among infants and toddlers. Interventions at an early age would prevent the occurrence of stomach and duodenal ulcers caused by *H. pylori*. It also would prevent the development of gastric adenocarcinomas.

Procedures.

This study is to determine the prevalence of infection among infants and toddlers by *H. pylori*. The only specimens that will be collected will be one stool sample and one blood sample. Additional data and information will be collected by the review of medical charts. No medications or vaccinations will be administered.

Well infants and toddlers age 0 to 23 months will be enrolled after parents or legal guardians have been administered and have signed the informed consent. At the time of enrollment or soon thereafter, a diaper containing stool will be obtained. Also, a 3 cc venous blood sample will be obtained. The medical record of the infant or toddler will be reviewed to collect demographic information, record of medications taken the past 90 days, illnesses since the day of birth, growth parameters, and other confounding variables such as history of breast feeding.

Stool will be tested for the presence of *H. pylori* antigen, and for the presence of occult blood. The blood sample will be tested for antibodies against *H. pylori*. Testing will occur in Johns Hopkins laboratories. When these procedures are completed, the infants's participation in this study is completed. Parents/guardians of participating infants will receive a package of diapers.

Only three sites will take part in this study: Whiteriver (Apache), Gallup and Shiprock. Only 200 total infants will be recruited from among the three sites. Participation in this study is totally voluntary. Signed informed consent will be obtained from the parents/legal guardians of each participant. Withdrawal from this study is also voluntary, and no penalty will levied against those who withdraw.

### Risks.

The risks related to taking part in this study are small. No medicines or vaccines will be given. Two types of specimens will be obtained from the participant. A 3 cc (about 1 teaspoon full) sample of blood will be taken from the back of the hand using a small needle and syringe. There is the small chance that bleeding will be prolonged, but bleeding usually stops with continued gentle pressure. There are no risks in obtaining a stool sample, since the sample will be obtained from stool in the diaper.

The medical charts of participants will be reviewed for clinical information such as the types of medications used by the participant within the past 90 days, the types of illnesses the participant has experienced since birth, and breast feeding history. There is the risk of accidental exposure of personal and/or clinical information obtained from the charts.

### Confidentiality.

All information pertaining to the infant and parents will be kept confidential. A unique study number will be used to identify the participant when recording medical and personal information on data collection forms. The study identification number will not link the information obtained to any specific participant. Information and data recorded on forms will be stored in locked file cabinets. Only study personnel will have access to files and computer-stored information pertaining to participants and their parents/guardians. All Johns Hopkins personnel have been trained and certified on the importance of confidentiality and on correct procedures for handling confidential information.