

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

- WHEREAS, Dr. Marc Traeger, M.D. of the Indian Health Services has come before the Tribal Council this date with a request for Tribal Council approval to conduct a study on the Fort Apache Indian Reservation to determine the prevalence of *Helicobacter pylori* in the White Mountain Apache Tribe; and
- WHEREAS, *Helicobacter pylori* (*H.pylori*) is a known etiologic factor leading to the development of chronic gastritis and peptic ulcer disease and gastric lymphoma and gastric carcinoma have also been associated *H.pylori*(1); and
- WHEREAS, *H.pylori* is a gram-negative bacterium known to cause gastritis and duodenal ulcer disease and is usually acquired at an early age and children who are affected early in life can become chronic carriers and are at risk for the development of chronic gastritis and duodenal ulcers; and
- WHEREAS, the materials and methods and selection criteria for the *H. pylori* study proposed by Dr. Traeger and other medical investigators has been distributed to the Tribal Council and discussed; and
- WHEREAS, the Tribal Council has been assured that there is no foreseeable risk for participation in the study by individual tribal members and that there may be benefits to individual tribal members if the *H. pylori* bacterium is discovered in their blood serum; and
- WHEREAS, the testing of blood serum will be performed only after informed consent and test results will be known only to investigators and to the subject's primary care provider and no names or other personal identifying factors will be revealed in the event the research project is submitted for publication; further, that consent will be administered by White River Hospital personnel.
- BE IT RESOLVED by the Tribal Council of the White Mountain Apache Tribe that based on the foregoing reasons, it hereby grants approval to medical investigators Mark Traeger, M.D. and other persons listed in the proposal paper to conduct a medical investigation as to the prevalence of *Helicobacter pylori* in the White Mountain Apache Tribe pursuant to the guidelines set forth in the attached proposal which is incorporated by reference herein.

Resolution No. 08-97-216

The foregoing resolution was on August 6, 1997, duly adopted by a vote of seven 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),(i),(s),(t) and (u) of the Constitution of the Tribe, ratified by the Tribe September 30, 1993, and approved by the Secretary of Interior on November 12, 1993, pursuant to Section 16 of the Act of June 18, 1934 (48 Stat. 984).

  
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Chairman of the Tribal Council

  
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Secretary of the Tribal Council

**Title:** The Prevalence of Helicobacter pylori in Native Americans

**Investigators:**

Marc Traeger, M.D., A. Steven McIntosh, M.D., Phillip E. Jaffe, M.D., Francisco C. Ramirez, M.D., FACP, University Medical Center, Tucson, AZ, White River Indian Hospital, White River, AZ, Carl T. Hayden VA Medical Center, Phoenix, AZ.

**Setting:**

White River Indian Hospital, White River, AZ.

**Expected Duration:**

2-3 months or until 150 consecutive specimens are collected.

**Purpose:**

To determine the prevalence of Helicobacter pylori in the White Mountain Apache Tribe.

**Background:**

Helicobacter pylori (H. pylori) is a known etiologic factor leading to the development of chronic gastritis and peptic ulcer disease. Gastric lymphoma and gastric carcinoma have also been associated with H. pylori(1). The epidemiology of H. pylori infection reveals that prevalence increases with age and is associated with striking differences between ethnic groups and socioeconomic status (2). In the United States, the prevalence of H. pylori is well established in adult Blacks, Hispanics and Whites 66%, 65%, and 26%, respectively (2). In all adults over the age of 50, more than 50% of the population have serologic evidence of infection.

In childhood, H. pylori infection is rare before the age of five in the United States. In France, 3.5% of children are infected in the first decade of life. In contrast, in Algeria and the Ivory Coast, 45% and 55% respectively of children are affected in the first decade of life (3). In Arkansas, Fiedorek showed the serologic evidence of H. pylori in children to be 31%. In this population the frequency of infection in African-American children was 50%, in comparisons to white children, 25% (4).

Unpublished data from the Phoenix Indian Medical Center investigating Pima Indians have recently shown Native Americans to have a higher than expected prevalence of *Helicobacter pylori* (6). This epidemiologic study used *H. pylori* qualitative serum antibody testing of 140 patients. There were 95 adults (68%) and 45 (32%) children. The serum antibody positivity was 84% in adults and 64% in children.

Pima Indians are only a subset of Native Americans and therefore do not represent all Native Americans. Consequently, it is imperative to verify these results and investigate further into why do Native Americans have a high prevalence of *H. pylori*. Person to person transmission, and poor sanitary conditions are the suspected mode of disease spread, but the actual route of transmission has yet to be defined.

#### **Hypothesis:**

The prevalence of *H. pylori* infection in the White Mountain Apache Tribe is greater than or at least 80%.

#### **Rationale:**

*Helicobacter pylori* is a gram-negative bacterium known to cause gastritis and duodenal ulcer disease. This bacterium is usually acquired at an early age; it is suspected (but not proven) to be transmitted from an adult or other family member. Children who are affected early in life can become chronic carriers and are at risk for the development of chronic gastritis and duodenal ulcers. The risk for gastric carcinoma later in life is unclear but thought to be elevated. In adult Native Americans, the rate of gastric carcinoma was found to be three times the rate of the general U. S. population (5). In Native Americans adults there is a high prevalence of *H. pylori* infection in patients with gastric cancer. Eradication of *H. pylori* from the gastric mucosa is associated with a healing of gastritis and ulcers in both children and adults. The relationship between the prevalence of *H. pylori* in Native American adults and children and their risk for the potential development of gastric cancer remains unknown. It is hypothesized that eradication or avoidance of *H. pylori* in childhood will prevent or decrease the development of gastritis, ulcers, and prohibit the potential development of gastric lymphoma or carcinoma later in life.

## Materials and Methods:

### a) Selection criteria:

Blood serum will be obtained from 150 consecutive Native Americans seen at the White River Indian Hospital inpatient wards, outpatient clinic, or emergency department after informed consent. Blood serum will only be taken from leftover blood specimens drawn for other purposes at the request of the Indian Health Service physician. No patient will be asked to give blood solely for the purpose of this study. There will be no monetary reimbursement for participation in this study nor is there any foreseeable risk for participation. The participants may benefit from this study by determining if they are infected with *Helicobacter pylori* which will allow their primary care doctor to treat them if indicated.

### b) Exclusion criteria:

No blood serum will be taken from any blood specimens with preservatives or anticoagulation material (e.g. CBC, PT, PTT, blood gas).

### c) Procedure:

Approximately 1 cc of blood serum will be transferred from any red top or yellow top blood specimen used for evaluation of blood chemistries. Once the serum is obtained it will be transferred into a plastic vial and kept frozen at  $-4^{\circ}\text{F}$  ( $-20^{\circ}\text{C}$ ) in a freezer at the White River Indian Hospital. Each sample will be labeled with date and medical record number of the patient whose blood was drawn. The lab will then dispose of the excess blood according to hospital protocol. After 150 samples have been collected, Dr. McIntosh will come to the White River Indian Hospital and perform the FlexSure *Helicobacter pylori* serum antibody test on the collected samples. The FlexSure test requires approximately one drop of serum to be added to a test strip that detects human antibodies to *H. pylori*. A positive or negative test result occurs in 4 minutes. Any remaining serum will be disposed of according to hospital protocol. In the symptomatic patient, the relative sensitivity is 93% and relative specificity is 90%.

## **Materials and Methods:**

### d) Sample size:

150 blood serum specimens. Target population age range 5 to 85 years old.

### e) Study design & analysis:

Prospective prevalence study. The prevalence rate will be calculated by dividing the number of positive tests by the total number of samples. Records will be reviewed maintaining confidentiality to determine demographic characteristics of age, sex, tribe and primary care provider.

### f) Consent & confidentiality:

Testing of blood serum will be performed only after informed consent. Test results will be known only to investigators and to the subjects primary care provider. No names or other personal identifying factors will be revealed in the event this research project is submitted for publication. The consent will be administered by Whiteriver Hospital personnel.

### g) Positive tests results & benefit for Native Americans

Any positive test result will given to the patient's primary care provider. This information can then be used to clinically correlate any symptoms that may suggest *Helicobacter pylori* infection and warrant treatment with antibiotics. Eradication of *Helicobacter pylori* can potentially prevent the development of or treat existing gastritis or ulcers in childhood, and possibly prevent gastric lymphoma or carcinoma in adulthood.

### h) Funding

The FlexSure test costs \$20 per test. The test kits will be purchased with research money by Dr. Francisco C Ramirez, Chief of Gastroenterology, Carl T. Hayden VA medical Center, Phoenix, Arizona. There will be no cost to any participants or to the White River Indian Hospital.

## REFERENCES

1. *Textbook of Gastroenterology*, second edition, edited by Tadataka Yamada. "Helicobacter pylori and Ulcer Disease" Ch. 61;1350-1358. JB Lippincott Company, Philadelphia, 1995.
2. Malaty HM; Evans DG; Evans DJ; Graham DY  
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Gastroenterology 1992 Sep;103:813-816
3. Megraud F, Brassens-Rabbe MP, Denis F, et. al: Seroepidemiology of Camphylobacter pylori infection in various populations. J Clin Microbiol 1989;27:1870-73.
4. Fiedorek SC, Malaty HM, Evans DL, et. al: Factors influencing the epidemiology of Helicobacter pylori infection in children. Pediatrics 1991;88;578-82.
5. Sievers ML  
Unusual Comparative frequency of gastric carcinoma, pernicious anemia, and peptic ulcer in Native Americans.  
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Unpublished data. Abstract submitted to American Gastroenterological Association annual meeting May 11 - 14, 1997.