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Texas Long Term Care Institute Research Award Application (REVISION 1: 8/20/2010)

TITLE: Prevalence of *Helicobacter pylori* in Residents of Long Term Care Facilities in Central Texas.

ABSTRACT: In 1983, the discovery of the bacteria *Helicobacter pylori* that thrives in the harsh, acidic environment of the human stomach opened the door for a new understanding of common gastroduodenal disorders [1]. *H. pylori* infection has been associated with gastric or duodenal ulcer disease, gastric lymphoma and carcinoma, dyspepsia, and esophageal reflux disease [2, 3, 4, 5]. Infection rates in some studies have shown to be as high as 70% in the elderly [6]. The infection rate in Central Texas is unknown. For this project, two long term care facilities will be selected in Central Texas. A stool sample will be collected from 20 residents at each facility and will be tested for *H.* *pylori* antigen to assess the infection rate.

DESCRIPTION OF PROPOSED STUDY

INTRODUCTION: *Helicobacter pylori* is a gram negative bacteria that survives in the highly acidic environment of the stomach. It survives by burrowing into the mucous layer and producing an enzyme, urease, [7] that neutralizes stomach acid around the bacteria. *H. pylori* is suspected to be a contributing factor in the development of gastritis, ulcers, gastric lymphoma and carcinoma, and esophageal reflux disease. Once identified, the infection can be successfully treated with a specific regimen of antibiotics and proton pump inhibitors like omeprazole [8].

Persons with advanced age living in long term care facilities may be particularly susceptible to infection. It is well documented that the immune system loses some functionality as a person ages. It is also known that living in proximity to others and being touched and assisted by numerous healthcare workers can spread infections quickly in healthcare facilities or long term care environments. Advanced age and inadvertent spread of the bacteria in the facility may contribute to a very high infection rate among the elderly residing in long term care facilities. By identifying geographical areas that have high rates of infection, alert physicians can perhaps more quickly administer antibiotics to those residents that begin to show the first symptoms of gastritis. This would reduce the rate of morbidity of gastroduodenal pathology. Areas with high rates of infection might also benefit by educating the facility staff about proper hand washing, disinfection, and other activities that can help reduce the infection rate. The purpose of this study is to determine if rates of infection in the elderly residing in long term care facilities Central Texas are as high as they are in other geographical areas.

METHODOLOGY: An application to the Texas State University Institutional Review Board will be submitted. Names of residents will not be used in the study. No invasive procedures will be involved as the specimen of choice for identifying a current infection is a small fecal (stool) sample. Two long term care facilities in Central Texas that have at least 20 residents will be chosen to participate. Consent forms will be obtained from residents. Unique identifying numbers will be assigned to residents in the nursing home who choose to participate. With management’s approval, the staff of the long term care facility will be instructed on how to collect the specimens. Specimen cups and protective gloves will be provided to the facilities by the principle investigator. One sample will be collected for each resident for a total of 40 samples, 20 from each facility. Each resident’s specimen will be labeled only with the corresponding unique identifying number. The specimens will be picked up by a representative of Texas State University and will be transported to the Clinical Laboratory Science (CLS) Program laboratory for analysis. Everything needed for analysis is available at our laboratory. The samples will be tested using Meridian’s *Helicobacter Pylori* Antigen Detection Test Kit from Meridian Bioscience, Inc., Cincinnati, Ohio. Students from the CLS program will assist the principle investigator in performing some of the laboratory testing of the specimens. The principle investigator will supervise and direct all activities associated with this project. All laboratory safety procedures and universal precautions will be followed to include the use of personal protective equipment.

IMPORTANCE OF THE PROJECT: This project will help identify infection rates in long term care facilities in Central Texas. If the infection rate is as high as that found in other areas, this can alert local physicians to closely watch for the first signs of gastric pathology, identify the infected individuals and treat them sooner. This award will also provide a small scholarship and valuable experience for CLS students and will lead to a publication in a clinical laboratory science journal such as the Journal of Clinical Laboratory Science or a journal associated with long term care. Determining the infection rate of *H. pylori* in Central Texas is a clinical laboratory science issue and is of great interest to the profession.

FOLLOW-UP: For those specimens that are found to be positive for *H. pylori*, a report will be sent to the management of the long term care facility that identifies the positive samples by the unique specimen number. The facility will have the names and unique specimen numbers of the residents and can identify those individuals that may be infected. It will be recommended to management that residents that show a positive test through this surveillance study be retested by a clinical laboratory that has a current certificate issued in accordance with the Clinical Laboratory Improvements Amendment (CLIA) of 1988. The clinical training laboratory at Texas State University cannot be certified by CLIA to perform actual patient testing but the laboratory can be involved in biomedical research. Treatment for residents suspected of carrying *H. pylori* will be the responsibility of the Medical Director of the long term care facility.

BUDGET:

Travel 6 trips to collect samples 80 miles X 6 = 480 mi @ 0.50/mi = $240.00

Meridian *Helicobacter pylori* Antigen Assay Kit $1,584.00 X 2 = $3,168.00

Specimen cups with lids 1 case @ $26.74 = $26.74

Non-sterile gloves 5 boxes @ $20.00 = $100.00

Student Scholarships (2 students @ $400 ea) = $800.00

Office Supplies = $200.00

TOTAL PROJECTED COST = $4,534.74

REFERENCES:

1. Warren JR, Marshall BJ. Unidentified curved bacilli on gastric epithelium in active chronic gastritis. Lancet 1983; 2:1273-5.

2. Wyatt JI, Shallcross TM, Crabtree JE, et al*.* *Helicobacter pylori*, gastritis, and peptic ulceration in the elderly. J of Clin Pathol 1992; 45:1070-4.

3. Delchier JC, Ebert M, Malfertheiner P. *Helicobacter pylori* in gastric lymphoma and carcinoma. Curr Opin Gastroenterol 1998; 14 S41-5.

4. Parsonnet J, Freidman GD, Vandersteen SP et al. *Helicobacter pylori* infection and risk of gastric cancer. N Engl J Med 1991; 325:1127-31.

5. Liston R, Pitt MA, Baneryee AK. Reflux esophagitis and *Heliobacter pylori* infection in elderly patients. Postgrad Med J 1996; 72:221-3.

6. Pilotto A. *Helicobacter pylori* infection in the elderly. Gastrointestinal Clin N Am 1990. 19:273-92.

7. Joklik WK, Willett HP, Amos, DB et al. Zinsser Microbiology, 20th Edition, Appleton & Lange, 1992. p 680.

8. Pilotto A, Di Mario F, Battaglia G et al. The efficacy of two doses of omeprazole for short and long term peptic ulcer treatment in the elderly. Clin Ther 1994; 16:935-40.

VITAE:

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Educational Background

MS, 1994, University of Arkansas for Medical Sciences, Major:Microbiology/Immunology Thesis: Immunity to reinfection and immunization of male guinea pigs against urethral infection with the agent of guinea pig inclusion conjunctivitis. *Sexually Transmitted Diseases*: 1996 Mar-Apr (2): 145-50

BSMT, 1979, Missouri Southern State College, Bachelors in Medical Technology

BS, 1975, Missouri Southern State College, Bachelors in Biology

Teaching

Assistant Professor in Clinical Laboratory Science Program, Texas State University, 2008 to present

Adjunct Professor for Nebraska School of Medicine, Clinical Laboratory Instructor for Interservice Physician Assistant Program at Ft. Sam Houston, TX, 1998-2000

Adjunct Professor for Nebraska School of Medicine, Clinical Microbiology Instructor for U.S. Air Force Physician Assistant Program, Sheppard AFB, TX, 1996-1998

Publications

Immunity to reinfection and immunization of male guinea pigs against urethral infection with the agent of guinea pig inclusion conjunctivitis. *Sexually Transmitted Diseases*: 1996 Mar-Apr (2): 145-50

Textbook chapter on clinical laboratory functions: *Hospitals, What They are and How* *They Work*, fourth edition, Jones and Bartlett: to be published in the latter part of 2010.

Funded Grants and Contracts

PI, Texas State University, Application for One-Time Research Support for the Associate Vice President for Research, qPCR support for Methacillin Resistant Staphlococcus Aureus, amount $32,000