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Helicobacter pylori: Findings in a Native American Population

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Introduction

Two decades after the association between *Helicobacter pylori* infection and peptic ulcer disease was shown in 1983,¹ it can still be regarded as one of the most important advances in gastroenterology. The introduction of the fiberoptic endoscope at around the same time²⁻⁶ underscored the dramatic change in the state of the art in the diagnosis and treatment of dyspepsia, peptic ulcer, and other upper gastrointestinal (GI) pathologies. Most recently, the description of the *H. pylori* genome in 1997 (1.67 million base pairs coding for approximately 1500 proteins) has offered an important insight into this gram negative microaerophilic organism.⁷ Analysis of the genetic data confirmed epidemiological evidence⁸ that *H. pylori* lives mostly in the human stomach with direct person to person transmission and little or no zoonotic transmission, and that iron scavenging is crucial in the survival of *H. pylori* in the stomach mucosa.

Given the variable clinical course of the *H. pylori* infection, which can lead to gastritis, duodenal or gastric ulcers, gastric cancer, or lymphoma, identification of and treatment for this pathogen are important issues for any clinician.⁴ Among the multiple diagnostic tests available for *H. pylori* detection in a symptomatic patient,⁹⁻¹⁴ esophagogastroduodenoscopy (EGD) has the distinction of being the only one that allows direct examination of the upper GI tract and is recommended for patients presenting with associated anemia, gastrointestinal bleeding, or weight loss, especially for patients older than 50 years.²

Navajo Native Americans form a unique ethnic group among the approximately 500 tribes and 310 reservations recorded in the United States in the most recent census. Navajo Nation is the home for about 300,000 Navajo members, forming the largest Native American tribe, on the largest reservation in the US that covers 25,000 square miles in Northern Arizona, New Mexico and Southern Utah.¹⁵ The patients served by Sage Memorial Hospital belong to a Native American community of about 15,000 spread over an area of 1,500 square miles in Apache County, Arizona in a rural, isolated setting.¹⁶

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We have conducted a retrospective study of patients who received care at the community hospital during a 38 month timeframe for symptoms suggesting upper GI pathology and who were assessed for *H. pylori* infection by one or more of three methods: serologic testing, EGD with biopsy followed by a rapid urease test (RUT), and/or biopsy with histological examination. The study has been approved by the Navajo Nation Human Research Review Board (NNHRRB).

Materials and Methods

All patients were referred for EGD by a primary care physician and had the procedure performed at the community hospital by a single physician (SHA); all upper endoscopies successfully performed at this location by this operator were included in this study. To ensure that all endoscopies were considered, the Operating Room Procedure Log Book was searched for all EGDs performed by this operator. After the patients were tabulated using MS Excel, an electronic search was performed using Meditech (which incorporates all patient files in electronic format) for patients who had EGDs performed by the same operator in that timeframe; no other patients were found. Patient records both in paper form (medical charts) and electronic format were then searched for all the information pertinent to the patients' care.

All patients had a signed informed consent form in the chart for EGD with biopsy and the physician doing the endoscopy evaluated them with a history and physical examination. During history taking, special attention was paid to abdominal symptoms; use of nonsteroidal anti-inflammatory drugs (NSAIDs), H₂ blockers, proton pump inhibitors, antacids; and home water supply. If not already done, blood was drawn to detect *H. pylori* antibody.

Patients fasted for at least eight hours prior to the procedure, and standard preparations were given to each. Conscious sedation was attained with 1 - 3 mg of midazolam, and the oropharynx was anesthetized with lidocaine spray.

During endoscopy, biopsies were taken from the gastric mucosa in 118 EGDs; some were tested bedside and the rest were sent for histological examination. Suspicious lesions had multiple biopsies. Biopsy specimens were tested with a Rapid Urease Test (Pyloritek, BARD, Billerica, MA) and the results were checked at one hour. Histological examination of specimens was performed by sending the harvested tissue to the Pathology Lab of Tricore in Albuquerque, New Mexico. The specimen was stained with Giemsa's stain to detect *H. pylori*, and the result was a qualitative determination (positive vs. negative) by a certified Pathologist.

Although the histological grading proposed by the Sydney system offers a more elaborate evaluation of the *H. pylori* infection, a recent study that compared this grading system with the number of *H. pylori* genomes obtained by PCR¹⁴ concluded that a positive/negative histopathology result is as useful as the four grades of infection proposed by the Sydney system. The serology testing was also expressed as a

qualitative result (positive vs. negative) after a quantitative determination of plasma antibodies to *H. pylori*. If any of the above three tests was positive, the patient was considered positive for *H. pylori*.

The resulting data were then analyzed using MS Excel for descriptive statistics and SPSS for inferential statistics.

Results

A total of 154 consecutive EGDs were successfully performed during a 38-month timeframe (08/2000 - 10/2003) by a single physician (SHA). The total number of patients examined was 145.

Demographics. Ninety-two patients were female (63.44%), and 53 patients (36.55%) were male; the age range was between 15 and 95 years. The average age for the females was 50.14 +/- 17.62 years and for males was 54.4 +/- 14.96 years.

Clinical Findings. Patients' history and physical examination findings are displayed in Table 1, summarizing the number and frequency of symptoms in patients undergoing the procedure. Epigastric pain is the most common complaint, followed by heartburn. More than half of patients reported using NSAIDs regularly. Patients' intake of medication relevant to the diagnosis was recorded based on the patient history taken by the physician prior to the endoscopy and previous medical chart data, and it was considered positive if the patient was on a given medication daily for at least two weeks and within six months prior to the endoscopy.

Table 1. Patients' history and physical exam

	Epig. Pain	Heartburn	Emesis	Hemet-emesis	EtOH	NSAID	H2 blocker and/or PPI	Antacids	Guaiac
Yes	134	78	66	14	42	79	97	28	29
% Total, n=145	92.41	53.79	45.51	9.65	28.96	54.48	66.89	19.31	20

Testing for H. pylori. Testing by using one or more of the three tests described above was performed in 131 of the 145 patients (90.34%). Of these, 95 (72.51%) were positive, with the remaining 36 (29.92%) testing negative for *H. pylori*. Three additional patients had positive serology results for *H. pylori* and another four had negative serologic tests, but these blood tests were performed more than six months after the EGDs (for the positive tests) or more than six months prior to the EGDs (for the negative results); these were all excluded from the analysis. We have found that 67 of 90 serology tests were positive for *H. pylori* (74.44%); 23 of 45 RUTs (51.11%) were positive; and 42 of 109 histology tests (38.53%) were positive. Of the 30 patients who had all three tests, IgG, RUT and histology, 13 were concordant (43.33%).

EGD notes. Of the 154 endoscopies, in 137 (88.96%) there were abnormal (positive) findings as documented in the procedure note by the physician. There was one histologically confirmed Barrett's esophagus, one case with esophageal acanthosis, one patient had an ulcerated polypoid mass in the esophagus, four patients had esophageal varices, of which one was bleeding, and there was one esophageal pseudodiverticulum (lower esophagus). The gastric pathology included two patients with fundic polyps, of which was one ulcerated but benign, four patients with gastric mucosal atrophy, and one patient with hemochromatosis. One patient was diagnosed with *in situ* gastric neoplasm on histopathology; another had previously diagnosed gastric adenocarcinoma for which he had had a partial resection more than ten years prior to EGD. Table 2 summarizes the endoscopic findings.

Table 2. Findings on EGD

	Esophagitis	Hiatal Hernia	Gastritis	Erosions	Gastric Ulcer	Duodenitis	Duodenal Ulcer
Yes (n =)	46	34	86	14	10	20	18
% Total	30.46%	22.51%	56.95%	9.27%	6.62%	13.24%	11.92%

Histology. Of the 109 pathology examinations, a total of 83 (76.14%) showed active inflammation of the gastric mucosa (corpus or antrum): 26 mild, 35 moderate and 22 severe. Additionally, 16 reports (14.67%) diagnosed chronic, inactive inflammation. Intestinal metaplasia was detected in 13 of the 109 histologic examinations performed (11.92%); 9 of the 13 patients (69.23%) with intestinal metaplasia tested positive for presence of *H. pylori* using one or more of the three tests used above. Another three patients had lymphoid hyperplasia without intestinal metaplasia on the histology exam.

Laboratory findings. The mean hematocrit (Hct) for females was 38.25 +/- 6.98 %; for males, 41.46 +/- 6.81 %; both in normal range. Anemia, defined as Hct below 37% in females and below 40% in males was found in 44/145 patients (30.34%). Blood groups of the patients with anemia are documented in Table 3. In the same patient subset there was

Table 3. Patients with anemia

	Hct. Range (anemia)	Anemia, pt number	Blood type O / Rh + pt number	Blood type O / Rh - pt number:	A / + pt number
Female	16.5 – 36.6%	28	14	1	1
Male	25.3 – 39.5%	16	10	1	2

not a statistically significant higher number of *H. pylori* positive patients (23/44 or 52.27%) than *H. pylori* negative patients (12/44 or 27.27%); $\chi^2 = 3.45$; $p = 0.063$.

An interesting fact was that most patients tested (as part of the chemistry profile ordered in some patients before the EGD for various reasons) had elevated globulins and low albumin, with a subsequent low albumin/globulin ratio (see Table 4). For the 120 patients tested for plasma albumin and globulins, the average was 3.52 +/- 0.46 for albumin, 95% CI = 0.003; min 2.0, max 4.40. For globulins, the average was 3.99 +/- 0.47, 95% CI = 0.003; min 2.90, max 5.70. Of the 120 patients tested for albumin, 77 (64.2%) were below normal (<3.8 g/dL). For globulins, 111 patients (92.50%) were above the normal limit (>3.3 g/dL); 104 were at 3.5 g/dL or above (86.6%). The albumin/globulin ratio was < 1 in 90 patients, and only 8 patients (6.7%) were in normal range (>1.1).

Table 4. Albumin and Globulins

	Albumin < 3.8 g/dl	Globulin > 3.3 g/dL	Globulin ≥ 3.5 g/dl	Albumin/Globulin ratio	
				<1.1	>1.1
Female (n = 74)	48 (64.9%)	67 (90.5%)	61 (82.4%)	68	6
Male (n = 46)	29 (63%)	44 (95.6%)	43 (93.5%)	44	2
Total = 120	77 (64.2%)	111 (92.5%)	104 (86.6%)	112 (93.3%)	8 (6.7%)

Discussion

H. pylori infection has rarely been studied in ethnic groups in North America. Parkinson et al¹⁷ showed that *H. pylori* infection is associated with low ferritin levels in an Alaska Native population. Bernstein et al¹⁸ published results from testing a Canadian Indian population and found that the *H. pylori* seroprevalence was 95%. In another ethnic study, Fennerty et al¹⁹ observed that *H. pylori* was significantly associated with intestinal metaplasia in Hispanics in the Southwestern United States; while Perez-Perez showed that more than 80% of Whiteriver Apache mothers were *H. pylori* seropositive, and 20% of the childhood infections were transient.²⁰

With the prevalence of *H. pylori* infection being strongly correlated with the socioeconomic environment³ and given that the local conditions have been compared to those of a third-world country,¹⁵ *H. pylori* might be expected to be found in 80% or more of the community members. The 72% rate found in this study may reflect the fact that some patients undergoing endoscopy have had treatment with histamine receptor blockers and proton pump inhibitors or in some cases antibiotics unrelated to dyspepsia in the weeks and months prior to endoscopy.

Regarding epidemiology, we have found no correlation between the presence of *H. pylori* and the presence of running water in the home. One possibility may be the contamination of some water distribution systems themselves, which may harbor *H. pylori* in the biofilms covering the pipes, especially those made of cast iron, as was shown in Scotland and Peru.^{21,22} Another study has shown that *H. pylori* is more resistant than *E. coli* to commonly used water disinfectants (chlorine, ozone); only monochloramine was found to be effective against *H. pylori*.²³

The lack of association between *H. pylori* positivity and blood group O, or *H. pylori* and anemia is in concordance with previous studies,^{24,25} although a recent study in Brazil found an association between blood group O and *H. pylori* positivity.²⁶ We have found that patients with anemia are more likely to have blood group O but overall the mean hematocrit of patients with blood group O (34.17%) stopped short of being statistically different than that of patients of blood group A (mean Hct = 40.10%), $p = 0.063$. Considering that *H. pylori* was shown to be associated with low levels of ferritin in various populations,^{27,28} and with iron deficiency anemia refractory to iron therapy,²⁹ it may be of interest to explore the association between patients with both anemia and blood group O and active *H. pylori* infection (as given by histology, RUT or urea breath test) in an epidemiological study of adequate power, for it is possible that virulence factors harbored by *H. pylori* may predispose patients with blood group O to anemia.

The World Health Organization and the International Agency for Research on Cancer officially confirmed the role of *H. pylori* infection in gastric cancers in 1994 and classified *H. pylori* as a definite carcinogen for its association with gastric adenocarcinoma and mucosa-associated lymphoid tissue lymphoma of the stomach (MALT lymphoma).³⁰ Recent studies showed that *H. pylori* was present in 98% of specimens taken from gastric cancers, by immunohistology³¹; that gastric cancer develops only in patients infected with *H. pylori* but not in uninfected person³⁰; that gastric cancer did not develop in any patients who received eradication therapy early in follow up³⁰; and that eradication of *H. pylori* alone induces regression of gastric MALT lymphoma in 70 to 80 percent of cases.^{32,33}

For the patients included in our study, about 12 % were found to have intestinal metaplasia, and one patient was diagnosed with *in situ* adenocarcinoma. These findings re-emphasize that endoscopy with histology cannot be replaced by other tests (serology, immunoblotting, urea breath test, rapid urease test) in detecting the most serious pathology related to *H. pylori*: neoplastic and preneoplastic lesions, which are found most frequently in patients older than 50.

Finally, the finding of elevated globulins and low albumin in a majority of patients with upper GI symptoms (who subsequently had endoscopy) is probably not specific for this pathology, but rather a characteristic of the whole community and a reflection of poor nutritional status and inadequate hygiene conditions. Further studies will be undertaken to try to define the extent and direction of this problem.

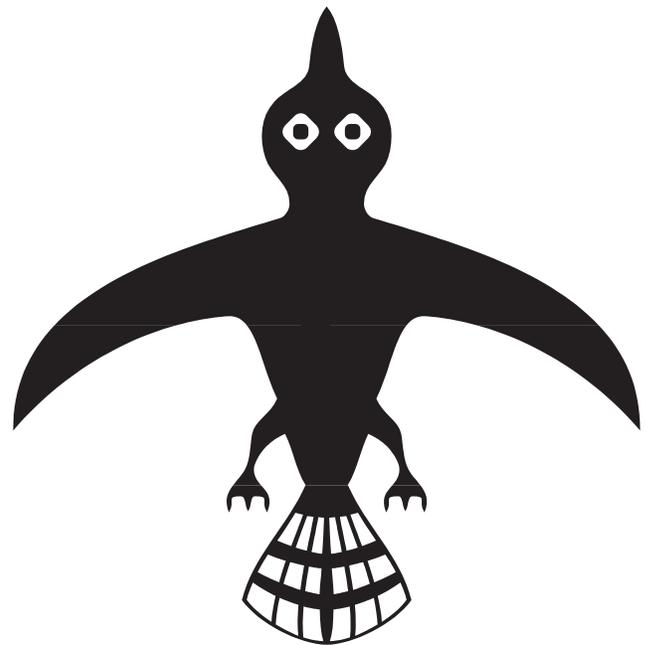
Conclusion

In the United States, there has been a decline in *H. pylori* infections as improvements in hygiene and economic conditions have interfered with the transmission cycle of the organism.⁴ However, as the data from the literature and this study show, in certain ethnic groups with high poverty rates, *Helicobacter pylori* infection is a pervasive problem that needs to be considered in a variety of gastrointestinal, hematological, and oncological pathologies. From a practical standpoint, *Helicobacter pylori* infection should be considered by the primary care provider practicing in an underserved area whenever symptoms of dyspepsia, anemia refractory to iron therapy, or weight loss in a patient over 50 are present.

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Implementing a Quality Improvement Initiative for Asthma Management in a Tribal Clinic

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Introduction

The prevalence of asthma has been increasing since the 1980s for all ages and ethnic groups.¹ In 2001, 6.9% of US adults and 8.7% of children had current asthma.² According to the 1999 National Health Interview Survey, 16.2% of American Indian/Alaska Native adults had ever been told by a doctor or health professional that they had asthma.³ Higher prevalence rates have also been reported for American Indian children: 12.3% for the Jemez Pueblo and 15.5% for the Assiniboine and Sioux Tribe.⁴ The financial burdens of asthma care have also been increasing.⁵ Asthma, along with diabetes and heart disease, were identified as high frequency and high cost conditions for Wisconsin tribal communities.⁶

Results of a records review at Spirit Lake for youth with asthma indicated a lack of adherence to National Asthma Education and Prevention Program (NAEPP) guidelines, and the authors recommended stronger asthma management strategies.⁷ Research indicates that evidence-based approaches to managing asthma can reduce costs, increase the quality of care, and improve patient outcomes.⁸ The quality of asthma care is dependent on the following provider-patient interactions: establishing the correct diagnosis, selecting appropriate treatment, instructing the patient in management techniques, and developing a partnership to promote adherence to the treatment plan. The outcome of treatment is then dependent on the adherence of the patient to those specific recommendations.

Development and implementation of a clinical care protocol for asthma was part of a continuous quality improvement (CQI) project that also included implementing best-practice protocols for diabetes and cardiovascular disease. The project was designed to improve patient care and outcomes, reduce the overall disease burden and costs, and promote structural changes to improve continuity of care. Overall project objectives were to: 1) Develop and implement a structure for CQI at a tribal clinic,

2) Review and adopt established clinical care protocols for selected chronic conditions, 3) Provide training and technical assistance to tribal clinicians and staff persons, 4) Educate and support patients in a high-risk population to manage their illnesses, and 5) Evaluate the tribe's CQI process and its impact on patient care.

The Evidence-Based Clinical Management of Patients with Chronic Conditions Project, supported by a grant from The Robert Wood Johnson Foundation (RWJF), was a partnership between Peter Christensen Health Center (PCHC) of the Lac du Flambeau Band of Lake Superior Chippewa and the University of Wisconsin (UW) Medical School. Peter Christensen Health Center is located in northern Wisconsin on the 144 square mile Lac du Flambeau Reservation. The clinic serves 5,500 Native American patients, provided over 28,000 ambulatory visits in FY 2002, and offers laboratory, radiology, pharmacy, public health, nutrition, and dental services. The medical staff includes two physicians, a physician assistant, a nurse practitioner, a dentist, and visiting podiatrists.

This article focuses on asthma management and includes specific objectives and action steps for developing the program, a flow chart for asthma assessment and treatment, development and use of the asthma register, aspects of staff training, information about patient education, and enhancements to pharmacy services. Results of the process evaluation identify program outcomes, as well as challenges. The authors encourage the replication of this best-practice protocol for asthma management in other tribal clinic settings.

Asthma Program Development

The goals of asthma management are to prevent chronic symptoms and exacerbations, maintain normal activity and normal or near-normal lung function, avoid missing school or work, and eliminate sleep disruption. These goals were not being met due to poor adherence by providers not following the NAEPP Expert Panel Report Guidelines,^{9,10} combined with poor adherence by patients not following their individually-tailored asthma action plans. Patient-provider communication is crucial in addressing poor adherence.

The CQI coordinator, also a registered respiratory therapist, began the asthma program by developing an Asthma Plan and Asthma Advisory Committee. The committee members included the CQI coordinator, physician, chief pharmacist, nurse practitioner, nursing support staff, lab supervisor, community health nurse, and dietician; also

included were the tribal elementary school nurse, and ad hoc members from the respiratory therapy and emergency departments at the off-reservation medical center. The committee met monthly to review NAEPP evidence-based guidelines, participate in educational sessions, assist in the development of asthma program policies and procedures, recommend action plans, and provide follow-up on implementation. The Asthma Plan outlined the program with the following goals, objectives, and action steps. The worksheet also included required resources, performance measures, and persons responsible for each objective.

Goal: Initiate the use of evidence-based, best practice asthma guidelines for the diagnosis and management of asthma by PCHC health care providers in order to optimize the quality of life and decrease health care costs for individuals with asthma.

Objective 1: Build capacity for the routine assessment and diagnosis of asthma.

1. Design and implement a standardized, evidence-based asthma initial assessment tool.
2. Design an asthma health summary sheet in the Resource and Patient Management System (RPMS).
3. Have patients return for follow-up office visits, especially when newly diagnosed.
4. Use an evidence-based patient self-assessment form for follow-up visits. This will be used as an aid in setting priorities and goals in patient's asthma action plan.
5. Utilize nurses, pharmacists, and/or other appropriate staff to assist with patient education, reinforcement, peak flow meter, spacer and metered-dose inhaler technique, and understanding of medications.
6. Conduct routine chart audits.
7. Track ER and hospital admission utilization at the off-reservation community hospital.

Objective 2: All individuals with asthma will have an asthma action plan in the medical record and, if applicable in school, to achieve asthma control as reflected in improved functional status and quality of life.

1. Design and complete an asthma action plan to include a school plan, with the patient and/or family member(s) for every individual diagnosed with asthma within the first two office visits.
2. Give the patient/family additional copies of the action plan to distribute to general care providers.

3. Follow-up at each visit: review patient adherence to the asthma action plan and agreed upon goals, and revise as needed.
4. Conduct intermittent medical records audits to ensure compliance with use of asthma action plans.

Objective 3: Build Information Systems (IS) capacity between local health care organizations so that a process for timely communication across the continuum between health care providers exists for relaying data that will improve asthma care.

1. Use automated pharmacy data to assist in identifying the prescribing and dispensing patterns for patient and physician populations.
2. Use IS systems to identify at-risk patients as patient appointments are made.
3. Use IS systems to notify primary care providers of ER, urgent care, and hospital admits.
4. Use IS to access specific patient asthma assessment tools and action plans across patient care settings.
5. Use IS to collect data to monitor health care systems performance measures related to asthma care.

Asthma Assessment and Treatment

The CQI coordinator conferred with the UW physician consultant to develop a protocol and set of documentation tools for asthma patient care. The process for assessment and treatment is described in a flow chart, beginning with a primary

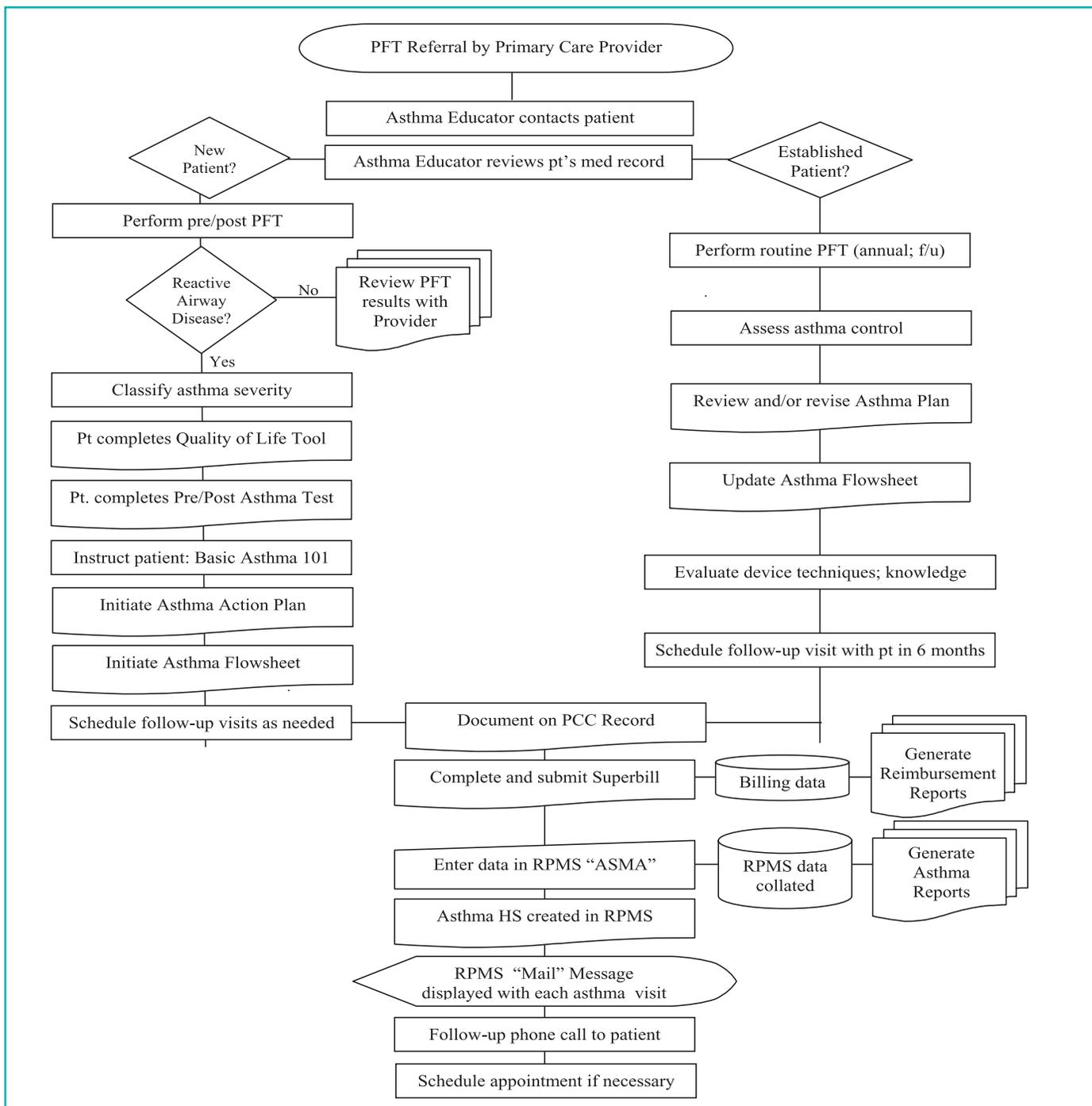


care provider's referral for a pulmonary function test. (See Figure 1, PCHC Asthma Management Algorithm).

Utilizing RWJF funds, the clinic purchased a spirometry unit, and the CQI coordinator/ respiratory therapist began performing pulmonary function tests (PFT). Prior to the availability of an in-clinic spirometry unit, patients were referred off-reservation to the community hospital 12 miles

away. The vast majority of referred patients did not present to the hospital for their ordered pulmonary function testing. The patients who kept their hospital appointments were expected to return to the tribal clinic for a follow-up appointment with their primary care provider. Time and space constraints made it difficult at best for the provider to offer optimal asthma education. Being able to conduct

Figure 1. Peter Christensen Health Center Asthma Management Algorithm



PFTs on site facilitates immediate follow-up because the CQI coordinator reviews the PFT results with the provider and assists in creating an asthma action plan, inclusive of appropriate medications. Routine pulmonary function testing is recommended as part of the assessment and monitoring of acute asthma. In addition, peak flow monitors are supplied for patients in order to optimize self-management, and spacers are dispensed to adults and children to augment metered-dose inhaler (MDI) medication delivery.

An Asthma Flow Sheet was developed for the provider to document information at each visit including encounter type, ratings of asthma severity, lung function, triggers, asthma plan, smoking history, health care utilization, functional status, and patient education. On the back of the flow sheet is an Asthma Action Plan that presents a stepwise approach for providers to use in managing asthma, with guidelines for classifying severity and medication requirements. There are different guidelines for adults and children older than five years of age (on a green form) and for infants and young children under five years of age (on a pink form). The Asthma Flow Sheet and Asthma Action Plan documentation tools are included in the patient's medical record.

An Asthma Treatment Plan is given to patients after reviewing information about triggers, rescue medication guidelines based on personal best peak flows (green, yellow, and red zones), and asthma control goals. At the provider's discretion, the Asthma Treatment Plan includes a statement signed by the provider that allows children to carry and use their medications at school, according to Wisconsin Statute 119.291, the Student Inhaler Law, which allows students with asthma to possess and use metered dose and dry powder inhalers with written permission.

Asthma Register Development

The CQI Coordinator developed a chart audit tool and reviewed 243 medical records of patients who had codes for asthma as an active problem or the purpose of a visit. The audit included a utilization review for two years of hospital/ER data on patients with the ICD-9-CM code of 493.0 for asthma. Eighty charts were flagged with a yellow sticker to indicate the need for screening and the patients were included in the asthma registry. When these patients had a clinic appointment, including visits for unrelated problems, the CQI Coordinator met with them to conduct pulmonary function screening.

Experience with the asthma care protocol, chart audit, and local registry enabled PCHC to participate as one of ten sites in the IHS RPMS Beta Test Site Project. The RPMS Asthma Register System, implemented in March 2003, is comprised of a register with patient management forms and reports, a mnemonic for PCC data entry for the asthma-related items on the PCC form, a health summary supplement, and maintenance reminders for the asthma health summary.¹¹ In addition to

generating a master list of asthma patients in the register, reports can identify patients who need follow-up appointments, asthma management plans, medication reviews, peak flow maneuvers, and severity classifications. The system can also generate asthma action plans and asthma daily self-management plans for patient education. The RPMS Health Summary for each asthmatic patient shows the last asthma visit date, peak flow zones, severity classification, management plan date, triggers, tobacco use, lung function data, number of reliever fills in the last 12 months, and date of each type of asthma patient education.

Training for Clinicians and Staff

The project sponsored an Evidence-Based Medicine Conference in May 2002 that was attended by all PCHC employees. Ongoing training for clinicians and staff was provided through two education meetings per month that addressed asthma, diabetes, or cardiovascular disease. At least six meetings focused exclusively on asthma and featured one to three hour presentations by the Medical School consultants, CQI coordinator, and pharmacist. Topics included Asthma 101, NAEPP Guidelines, Pharmacotherapy and Asthma Management, Tools of the Trade, Asthma in America: A Landmark Survey, Asthma Case Presentations, Documentation Forms, and Use of RPMS. In addition, the CQI coordinator conferred with providers regarding individual patients, and the Medical School consultants were available for discussions as needed.

Patient Education

Patient education includes information from the providers, one-on-one sessions with the CQI coordinator/respiratory therapist, explanations and demonstrations of medication use from the pharmacists, and videotapes about asthma in the clinic waiting room. Patient education materials include self-assessments, worksheets, and handouts. Assessments include the Mini Asthma Quality of Life Questionnaire and a survey for parents/caregivers who are living with a child asthma patient. The Asthma Treatment Plan has Asthma Control Goals on the back and patients also receive My Asthma Symptoms and Peak Flow Diary. An Asthma Pre/Post Test accompanies handouts that include the Asthma Fact Sheet, How To Stay Away From Things That Make Your Asthma Worse, and Your Metered-Dose Inhaler: How To Use It. Patients also complete an Evaluation of Asthma Education survey. The CQI coordinator helps children learn to identify their asthma triggers through the use of educational videotapes, along with a worksheet for them to write about how they feel. In addition to individual patient education for children at the clinic, the CQI coordinator conducted an asthma self-assessment survey at the local elementary school, and provided instruction for Head Start teachers and children.

Pharmacy Services

Improvements in medication management for asthma patients were accomplished with several enhancements in pharmacy services. The grant supported hiring a second pharmacist who helped considerably with the heavy pharmacy workload. As a result, the pharmacists have more time to deliver patient education, hand out information, reiterate the providers' instructions, and follow-up with patients. Ideally, the pharmacists were to meet with patients in the exam rooms, immediately after the providers, but the small facility does not have enough exam rooms to allow this approach. When patients come to pick up their medications, the pharmacists ask about their needs to determine whether they are using medications out of habit or for rescue. If a change to a higher strength is indicated, the pharmacists send the patients back to the provider.

Medication adjustments are also made as a result of the pulmonary function tests. Use of baseline PFT values, along with a trial of medication and observation, assists in diagnosing patients with asthma or other respiratory conditions. In addition, better medication management is related to a greater number of prescriptions for the inhaled long-acting beta agonist/corticosteroid medication utilizing the breath-activated delivery system. Other enhancements to pharmacy services include using QI reports based on medication refills and other data, and the asthma health summary that lists the asthma medications separately from all other medications. In addition, arrangements were made with pharmaceutical representatives to provide current information at the monthly staff education meetings.

Program Evaluation

In addition to the ongoing "Plan-Do-Check-Act" model¹² that is part of CQI, a researcher from the Medical School collaborated with PCHC on a more formal evaluation of the project. A process evaluation plan and evaluation questions were developed to describe progress toward goals and objectives, program successes and challenges, and lessons learned. Methods included a staff survey, site visit interviews with staff and consultants, and reviews of program documents.

Program Outcomes

The project built upon the existing strengths and assets at PCHC and further developed synergistic relationships with the Medical School, the local hospital and clinics, and other community agencies. The grant supported the acquisition of additional medical and ancillary staff, including a second pharmacist who helped considerably with the heavy workload in the clinic's pharmacy. The new CQI coordinator contributed to the project's success by being committed, dynamic, easy-going, positive, and well-organized. Under her guidance, the project brought CQI to the clinic and helped staff to work together more as a team, while prior to the grant, QI had not been discussed and was not done. The involvement in a partnership with the Medical School consultants helped

improve provider and community perceptions of the clinic and furnished valuable training for providers and staff. Especially in a rural setting, bringing in consultants and sending staff to conferences was important to help prevent isolation and assure that everyone received consistent information. The project increased PCHC employees' understanding of asthma (as well as diabetes and cardiovascular disease) and led to expanded skills and proficiencies. The project's accomplishments illustrate the high level of commitment of staff, consultants, and tribal leadership and their dedication to improving the overall health of the community.

Care for asthma patients was expanded with the asthma flow sheets, treatment plans, RPMS Asthma Register System, on-site pulmonary function tests, more prescriptions for the combined beta agonist/corticosteroid diskus, and one-on-one patient education. For example, an obese Native American adult experienced nightly sleep interruptions, could not tolerate any exercise, and was using a "rescue" inhaler approximately 20 times per day. After undergoing a PFT and appropriately rating the severity of asthma, answering the assessment questions, developing an asthma action plan, and being prescribed the most appropriate medication, this patient gained control of the asthma, was able to sleep uninterrupted and exercise, lost 35 pounds, and is still doing well.

Program Challenges

The biggest challenges for the project were the lack of space in the facility and the shortage of clinicians, given the number of patients served. The brief duration of the project limited what could be accomplished, even when the original 18 month grant was extended to 30 months. A busy clinic environment and a system driven by symptoms did not allow for the substantial amount of staff time and energy required to support change. In addition, inadequate technological systems presented challenges. Underutilization of RPMS and incomplete documentation of patient care were identified as areas for improvement. Not all providers used the asthma flow sheets and RPMS asthma patient care summary. Better communication between health care facilities was also recognized as a need. Gaining tribal council support was imperative for the paradigm shift from "business as usual" to the adoption of evidence-based medicine protocols. Moreover, lack of patient compliance, a high "no show" rate, and patients who needed to take more responsibility for their health were also challenging issues. Other tribal clinics that wish to replicate this project model should keep in mind these challenges, as well as the understanding that what works in one tribal clinic may not work in another setting.

Considerations

There are additional anticipated project impacts that are not measurable at this time. On-site pulmonary function tests, rather than referral to off-reservation providers, are expected to result in better patient compliance, more consistent provider

follow-up, increased clinic revenue, and decreased contract health costs. Staff reported that provider satisfaction was enhanced by having the on-site PFTs, protocols for standards of care, consultant inservices, and availability of the CQI coordinator as a resource. Continuity of care within PCHC reportedly improved as a result of the asthma protocol. Overall, improved management of asthma patients is expected to result in long-term outcomes of improved health status, reduced morbidity and mortality, and decreased hospital and ER expenditures.

Summary

The QI initiative for asthma management considerably expanded clinic services. Based on best practice guidelines, the project established a protocol for patient care, developed an asthma flow sheet and treatment plan, conducted training for clinicians and staff, identified patients in need of screening, provided pulmonary function tests, delivered patient education, improved medication management, and implemented the RPMS asthma register system. These accomplishments were facilitated by the partnership with the Medical School and the overall CQI process that was being implemented. The project faced challenges of space limitations, lack of staff time, inadequate technological systems, gaining tribal council support, and patient compliance issues. Nevertheless, project outcomes illustrate the potential for improved health status and decreased hospital and ER expenditures for patients with asthma.

Further Information

For more information about the clinical care protocol for asthma and the CQI process, contact Beverly Hart, RRT, Clinic Manager, Steele Memorial Clinic, 805 Main Street, Salmon, Idaho 83467; telephone (208) 756-6212; or e-mail bev.hart@steelemh.org.

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Practice-Based Research Networks in the Indian Health Service

Joan MacEachen, MD, MPH, Medical Director, Southern Ute Health Center, Ignacio, Colorado; and Charles Q. North, MD, MS, Medical Director, Albuquerque Service Unit, Albuquerque, NM and Chief Clinical Consultant for Family Medicine, IHS

If you are interested in clinical research, but you don't think you have the time or expertise required, you might consider joining a practice-based research network (PBRN). You may have heard of these networks from your residency program, from coworkers, or from reading the medical literature, and wonder what the experience would be like for you.

Advantages

Participating in research keeps you on the forefront of medical advancement. A research network allows you to discuss your research ideas on a broad level with other primary care clinicians including family physicians, internists, and pediatricians. Nurse practitioners and physician assistants are welcome also, if they work in the same settings. The network provides research expertise and funding to develop and carry out your study. Or you can participate in collecting and analyzing study data from other researchers' studies.

Practice-based networks unite research and practice by evaluating how clinicians handle common problems that present in our offices. They are an important means to evaluate the natural course of our patients' concerns and illnesses. They keep us directly linked with state-of-the-art academic findings. Often, when individual approaches are too limiting, collaboration offers expanded knowledge, perspective, energy, opportunities, and fun.

Another advantage of participation in PBRNs is that it gives you the opportunity to test new practice tools like hand held computers and coronary risk calculators. They also help in improving the quality of care you provide to your patients. Because staff members are integrally involved in many of these research projects, they also feel as if they are part of describing and promoting what we do in our practices. Our patients, too, show an interest in the results of the research done in our practices.

Importance of Practice-Based Research

Most research is performed in universities and medical centers, although only a small fraction of health care is delivered in this setting. Furthermore, most research funding is provided by drug companies and government grants, and

thus is aimed in directions that may or may not be applicable to our patient population. Practice-based research has arisen in response to the need for evaluation and expansion of the care provided by primary care physicians.

One example of applied practice-based research that has changed the way we practice medicine came from the ASPN (Ambulatory Sentinel Practice Network), which published an article on the care of patients experiencing spontaneous abortions.¹ Their research showed that 40% of miscarriages were managed entirely at home or in the office, and that the greatest morbidity was not due to infections or hemorrhage, but to psychological distress. These findings enabled the change in practice from a surgical to expectant management, with an emphasis on psychological support.

Following the Institute of Medicine's report on the numbers of errors occurring in medical practice, the federal government has funded large grants supporting practice-based research on medical errors in primary care. The Agency for Health Research and Quality (AHRQ) funded 19 new research networks after the report, including RIOS (Research Involving Outpatient Settings) Net in New Mexico, to which many Indian health practitioners belong. RIOS Net was just awarded an NIH grant to pool resources with two other networks in Colorado and Georgia as part of a national effort to build primary care research infrastructure to power studies that rapidly move research findings into practice.

Over 230 clinicians in underserved communities are members now, including about a third each from Community Health Centers, University of New Mexico community-based practices, and Indian health sites in the Albuquerque and Navajo Areas. Retired IHS family physicians Bill Freeman² and Paul Nutting³ have been instrumental in the development of and the establishment of the research agenda of ASPN, so the IHS has a long tradition of supporting the movement as a natural extension of the concept of community oriented primary care. Robert L. Williams, formerly Clinical Director at Crownpoint Service Unit and IHS National Clinician of the Year, is the director of the RIOS Net.

Types of Research Networks

You can participate in various networks depending on your specialty, interests, and location. For pediatricians, there is Pediatric Research in Office Settings (PROS).⁴ The best way to get information about PROS is to go to the PROS website at <http://www.aap.org/pros/>. You can click on a variety of the

areas (e.g., “About PROS,” or “Bibliography”) to get a good overview. It is even possible to download the forms needed to sign up by clicking on “How to Join PROS.”

There are also many regional primary care research networks, and some of these are based in family practice residencies. The Federation of Practice-Based Research Networks, established in 1997, keeps an inventory of American and international research networks. For those of us in Indian country who are isolated from regional networks, there is the American Academy of Family Physicians National Network for Family Practice and Primary Care Research. To get more information about regional networks or to learn how to join the AAFP’s network, contact Tom Stewart, Research Network Coordinator, AAFP National Network for Family Practice and Primary Care Research, by e-mail at tstewart@aafp.org, or by phone at (800) 376-5463. RIOS Net has a website at <http://hsc.unm.edu/rios>, or you may call Laura Day at (505) 272-4656 to receive membership information.

Experiences of Indian Health Practitioners in Practice-Based Research

One IHS pediatrician participated in a recent pilot PROS study entitled, “Healthy Lifestyles.” In an effort to stem childhood obesity, primary care clinicians and nutritionists utilized motivational interviewing to help influence parents of nearly obese children between 3 and 7 years old. He reports that watching the “real” study proceed over the next year or two will be interesting.⁵

A second venue that has been involved in practice-based research is the Southern Ute Health Clinic. This is a two-physician outpatient clinic, located five hours from the closest regional medical center. It has participated in practice-based research since 1997, when we became involved in several simple card studies for the ASPN network.

An early study evaluated the care of the secondary patient. For this study each provider reported all occurrences of care for a secondary patient – from advice, to providing a prescription, assessment or explanation of symptoms, follow-up of a previous episode of care, making or authorizing a referral, or general discussion of a health condition. It included 170 clinicians from 50 practice sites. This study resulted in an article⁶ that reported that primary care physicians provide care to a secondary patient during 6% of office visits. This care averaged five minutes and substituted for an office visit, but 95% of the time, no reimbursement was generated. Care to secondary patients may, however, facilitate access to care.

A second study in which this clinic was involved relied chiefly on our CHS clerk. It looked at the referral patterns of family practice physicians. This study included 141 family physicians in 87 offices in 31 sites. The article⁷ that resulted from this study revealed that one in twenty office visits results in a referral. Thirteen percent of referrals are patient-generated. The reason for the referral was chiefly for advice.

Most family physicians choose particular specialists for their referrals and rely for the most part on their personal knowledge of the specialist in making their choice. Surgical specialists represented 45% of the referrals.

When ASPN was transformed into the AAFP National Network for Primary Care, we again participated in a number of research projects, two of which involved patient safety. The first study looked at what physicians reported as errors in their practices. For this study, an error was defined as “anything that happened in your own practice that should not have happened, that was not anticipated, and that makes you say ‘*that should not happen in my practice, and I don’t want it to happen again.*’” Fifty-four physicians, equally distributed throughout the country, participated in this study. The resulting taxonomy of errors was published in *Quality Health Care*.⁸ Most of the reported errors reflected system dysfunction, and one-half resulted in adverse consequences. Eighty-six percent of the errors were classified as process errors, and 14% as clinical errors. Of the process errors, about one-third were due to office administration and, of these, 40% were due to misfiles.

The second patient safety study that our clinic participated in involved staff and patient error reports as well as physician reports. This was a pilot study to evaluate a web-based family practice error reporting system. It also compared error reports from patients and staff with those reported by the physicians themselves. The results of this study are still being processed, but the preliminary conclusions are that family physicians and their staff will report errors, and that the types of errors reported by staff and physicians are similar. Again the most common error is secondary to medical records. Additionally, it was concluded that the methods used for soliciting reports from patients were not adequate.

Teamwork and Institutional Review Boards

As you can imagine, it did take a bit of effort to engage the cooperation of all the staff to learn how to report errors and take the extra time to complete the reports. Most of the study organizers appreciate this and include incentives in their grant applications. In this case we received enough money to have a picnic and to support the coffee and birthday fund for quite some time.

A second challenge that must be met is the training of a study coordinator, generally a nurse or office manager, to assist with some of the studies. This requires time that is generally not reimbursed by the IHS or tribe. Again, most study organizers figure in a stipend for the study coordinator for each office site. There is a required web-based training in patient protection during investigations. There is also an annual Convocation of Practice-Based Research, which has included a day of training for study coordinators. The recent Convocation, held at Cheyenne Mountain in Colorado from March 2 - 6, 2005, included a daylong session in research skills training. Information about this can be requested from Thomas Stewart,

AAFP Research Network Coordinator at (800) 274-2237, ext 3172, or by e-mail at tstewart@aafp.org.

An additional hoop that must be jumped through is to obtain approval from your local Investigational Review Board for each study that you participate in. This has been changing in Indian health and may need to be addressed on a regional basis.

Conclusions

As Socrates would agree, we shouldn't practice medicine the way we've always done it just because that's what our more senior residents taught us. Those of us on the front line should take advantage of any opportunity we have to examine how we care for our patients. Joining a practice-based research network gives us a valuable way to improve the quality of care and to shape the future of medicine.⁹

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The 10th Annual Elders Issue

The May 2005 issue of THE IHS PROVIDER, to be published on the occasion of National Older Americans Month, will be the tenth annual issue dedicated to our elders. Indian Health Service, tribal, and Urban Program professionals are encouraged to submit articles for this issue on elders and their

health and health care. We are also interested in articles written by Indian elders themselves giving their perspective on health and health care issues. Inquiries or submissions can be addressed to the attention of the editor at the address on the back page of this issue.

A New, Quick and Easy Way to Find “Best” Clinical Articles: PubMed Clinical Queries

Diane Cooper, Biomedical Librarian/Informationist, Health Services Research Library, National Institutes of Health Library, Bethesda, Maryland

Is searching for clinical information on the Internet usually a matter of either too much or too little for you? With the increasing accumulation of clinical articles, it's easy to get overwhelmed with too many citations. At other times, nothing good seems to show up. If that describes you, a new program is just for you. To quickly find clinically relevant citations on etiology, diagnosis, therapy, or prognosis, try *PubMed Clinical Queries*. Developed by the National Library of Medicine, it's for busy clinicians who need a quick way to find original clinical studies to support clinical decision making.

PubMed Clinical Queries is a search program that accesses MEDLINE using the PubMed interface. MEDLINE already is easy to search by typing a subject into the search box. The benefit of using *PubMed Clinical Queries* is that it filters your search retrieval to a smaller set of citations that meet evidence-based standards. It uses preset search terms automatically for the subject you want to search. There are two types of searches you can perform: “Search by Clinical Study Category” or “Find Systematic Reviews.”

What is “Search by Clinical Study Category”?

It's a specialized interface that will find citations for reliable clinical studies in four study categories: etiology, diagnosis, therapy, or prognosis. You can choose whether you want your search to be “broad, sensitive” or “narrow, specific.”

Broad, Sensitive filtering will find mostly relevant articles. Less relevant articles will also be included, giving you a greater total number of articles for your query when you want to browse the literature.

Narrow, Specific filtering will retrieve the articles most relevant to your query, and will therefore limit the total number of articles found. Choose this option to refine your search to only the most relevant articles. Then the pre-set research methodology filters will quickly locate the relevant literature.

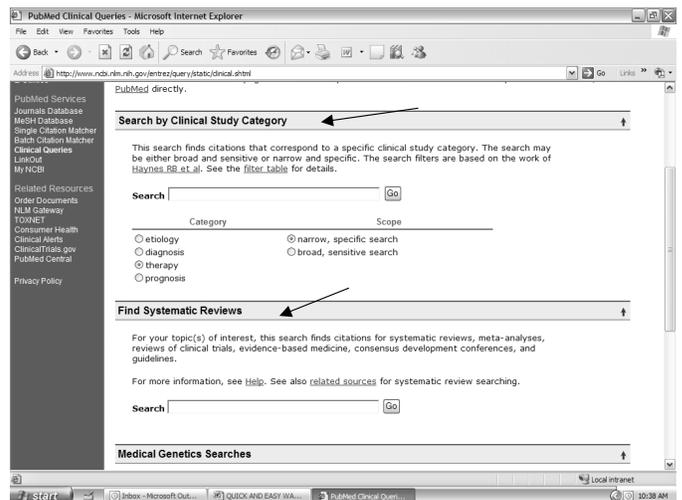
What is “Find Systematic Reviews”?

Using this interface will find reviews that identify, select, appraise, and analyze data from studies. They may also incorporate meta-analysis studies.

How to Find and Use *PubMed Clinical Queries*

1. Go to PubMed at www.pubmed.gov
2. Scan down the left side panel and click on Clinical Queries
3. You are presented with the two search options: Search by Clinical Study Category or Find Systematic Reviews
4. Choose the one you want and type in the box your subject, then click “Go”
5. Limit your retrieval further by clicking on Limits on the menu bar (above “Display”) that will show up with your first set of results
6. Limit by years or subsets if you wish (e.g., limit to clinical core journals)

Try it!



This is a page for sharing “what works” as seen in the published literature, as well as what is being done at sites that care for American Indian/Alaskan Native children. If you have any suggestions, comments, or questions please contact Steve Holve, MD, Chief Clinical Consultant in Pediatrics at sholve@tcimc.ihs.gov.

IHS Child Health Notes

Quote of the month

“The first step to wisdom is getting things by their right names.”

Chinese Proverb

Articles of Interest

Diagnosis and management of acute otitis media: clinical practice guideline of the American Academy of Pediatrics and American Academy of Family Physicians. *Pediatrics*. 113;5:May 2004:1451-1465. www.aap.org/policy/aomfinal.pdf.

Editorial Comment

The key to management of acute otitis media (AOM) is accurate diagnosis. Numerous studies show that at least 50% of the diagnoses of AOM are incorrect. The most common error is mistaking otitis media with effusion, which is sterile, for AOM that is an acute infection. The driving force behind this guideline is an effort to decrease the prescription of unneeded antibiotics by making diagnostic criteria more explicit and stringent.

The study acknowledges that history alone is not sufficient. A complaint of fever, crying, and earache is present in infants with AOM but also up to 70% of infants who only have a URI. An accurate diagnosis of AOM requires:

1. Acute onset of symptoms in the past 48 hours
2. Presence of middle ear effusion as confirmed by bulging or limited mobility of the eardrum
3. Signs or symptoms of middle ear inflammation such as erythema of the eardrum or distinct otalgia

The recommendations also addressed treatment suggestions. This portion of the guideline received a lot of attention in the medical and lay press because it was the first U.S. policy guideline to give the option of withholding antibiotic treatment for AOM. The committee endorsed the option to withhold initial antibiotic treatment in well appearing children over two years of age. This was based on the observation that the vast majority of AOM will improve spontaneously in 48 hours and the risk of invasive disease approaches zero in this age group. Each practitioner will have to make his/her own decision on treatment, but everyone who treats children should read this practice guideline.

Recent literature on American Indian/Alaskan Native Health

This isn't literature, but it is from a library.

The National Library of Medicine has a series of on-line exhibitions on the history of medicine. The exhibits rotate every 3 to 4 months, and past exhibits are stored in on-line archives that are immediately accessible. The exhibits are terrific and cover a wide array of subjects from Islamic medicine, to the history of the cesarean section, to scientific biographies. Visit the site at <http://www.nlm.nih.gov/exhibition/exhibition.html>.

The reason I found this site is the 1994 on-line exhibit “*If You Knew the Conditions*” . . . *Healthcare to Native Americans*. The exhibit has text and pictures that cover AI/AN health issues from the 19th century to the present. It helps to put present day issues in the proper historical context. The recurrent theme of neglect and lack of funds for Indian health is a reminder that “the more things change, the more they remain the same.” I recommend a visit.

Lastly, there is a History of Medicine homepage that can direct you to an archive of original texts and photos about medicine. The site is <http://www.nlm.nih.gov/hmd/>.





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THE IHS PRIMARY CARE PROVIDER



A journal for health professionals working with American Indians and Alaska Natives

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