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The Telephone Triage Nurse: An Essential Position at the Jicarilla Service Unit

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Telephone Triage

The American Academy for Ambulatory Care Nursing defines telephone triage as "An interactive process between nurse and client that occurs over the telephone and involves identifying the nature and urgency of client health care needs and determining appropriate disposition." More specifically, telephone triage is an encounter with a patient/client in which a specially trained, experienced nurse, utilizing clinical judgment and the nursing process, is guided by medically approved decision support tools (protocols) to determine the urgency of the patient's problem, and to direct the patient to the appropriate level of care.

Telephone triage is an essential element of patient care delivery, and is designed primarily to facilitate access to care and to provide consultation and assistance to patients and their families. The primary purpose of telephone triage is to assure patient safety and improve quality of care. Telephone triage is an interdependent nursing activity that is performed by a Registered Nurse in collaboration with a licensed physician or nurse practitioner.

Telephone Triage Nursing at the Jicarilla Service Unit

The Jicarilla Service Unit in northern New Mexico has had a telephone triage nurse (TTN) since mid-2003. It is a full time position, handling approximately 40 - 60 calls each day. If the triage nurse is already on the line and cannot answer the call, a very detailed and informed recording directs the caller to leave a message, or to hang up and dial 911 if it is a life threatening emergency. Messages are returned as quickly as possible, usually in less than 15 minutes. On occasion, it may take up to 60 minutes, depending on the call volume that day. Calls after clinic hours are returned the following day.

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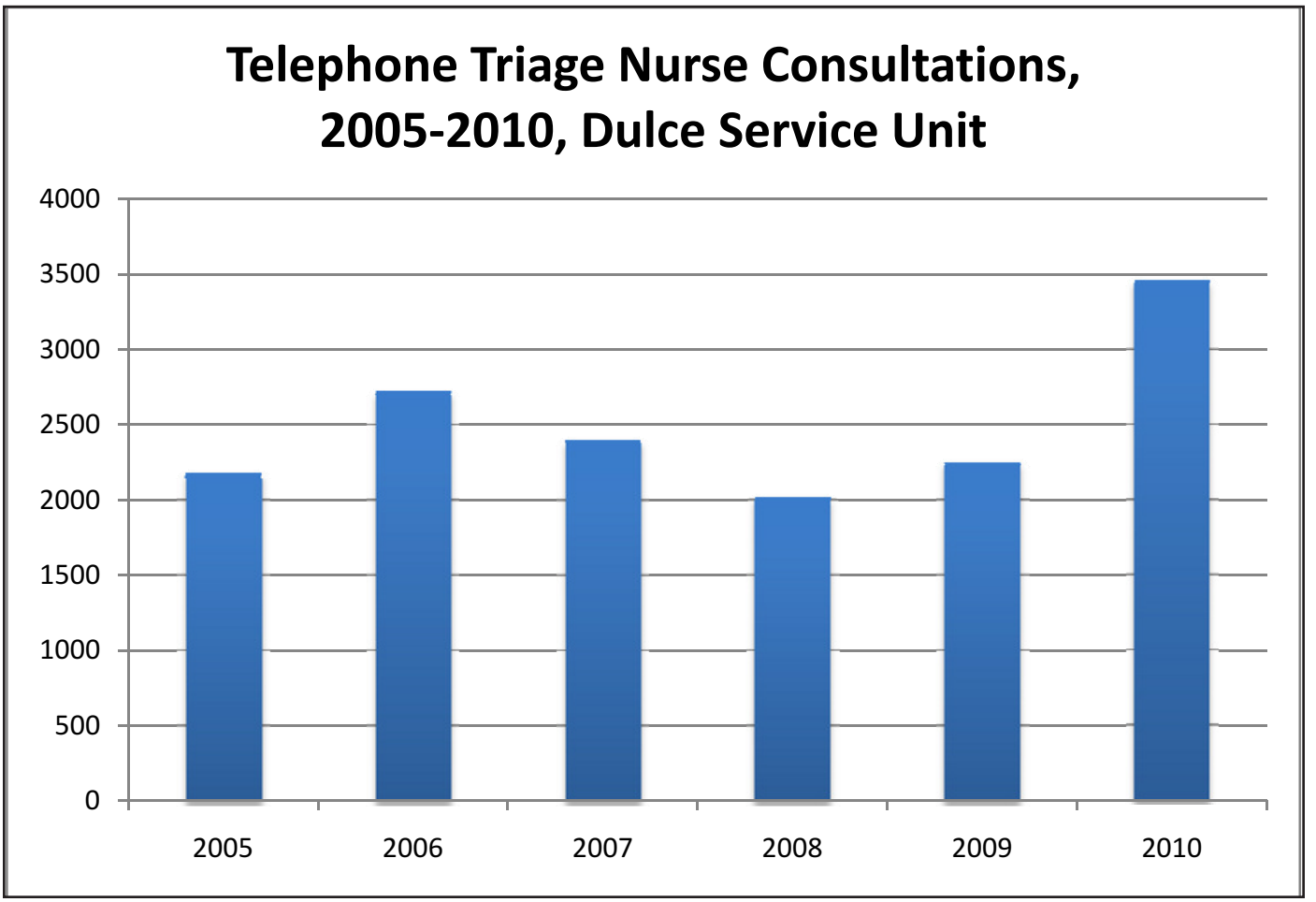
The TTN has full access to the patient's Electronic Health Record (EHR) and has several options to use based on his or her assessment of the caller:

- Schedule a routine appointment
- Schedule an acute care appointment
- Notify Emergency Care/EMS
- Coordinate and collaborate with the Jicarilla Behavioral Health or School-Based Health Program on psychosocial issues. The TTN is also a resource for patients to provide direction and immediate follow-up for issues such as depression/suicide, domestic violence, or any other behavioral health concerns
- Provide home care information/advice. An acute care physician always reviews and initials a home advice encounter
- Transfer callers to other departments (e.g., a referral question can be better answered by the Contract Health Clerk)
- Consult with acute care physician or patient's primary care provider for assistance in determining patient disposition
- Special situations: pregnancy tests/UTIs/frequent routine labs -- when a patient requires only one of the standing orders procedures, the TTN can enter a note in EHR, order laboratory tests, and instruct the patient to come to the clinic. The patient registers upon arrival and goes directly to the lab for the ordered procedure. The patient will then have a face-to-face encounter with the TTN for vital signs and be requested to wait in the waiting room for results or call back for results. The TTN will provide the patient with laboratory results once reviewed by a provider. If medication is needed, the provider will at that time place the order in EHR and the TTN will notify the patient of the need to go to pharmacy.

Outcomes

The program was started in mid 2003. It took time to gain acceptance of the community, but once all the nursing staff obtained the proper training and had all legal aspects of telephone triage in place, the telephone consultations increased quickly, and have averaged well over 2,000 per year among an

Figure 1. Telephone Triage Nurse Consultations, 2005 – 2010, Dulce Service Unit



active clinical population of 3,567 persons. In 2010, telephone consultations increased to over 3,000, mainly due to community concerns about H1N1 (see Figure 1). Over the last five years, most patients (66%) were female. By age, 33% were under 19 years of age, 48% 19 - 49 years, and 19% were 50+ years old.

The percentage of calls/visits that did not require an in-person appointment averaged over 25%. The nursing staff feel confident that telephone triage has reduced the number of unnecessary appointments and walk-in visits, due to the home care advice given and also the lab appointments that are handled by the TTN that do not require a provider visit.

Although a TTN phone consultation in and of itself is not a chargeable visit, the decrease in unnecessary provider visits has left more open appointment slots for those patients really needing to be seen. It has also helped educate the community on health care issues that can be treated at home and that do not require a visit to the clinic.

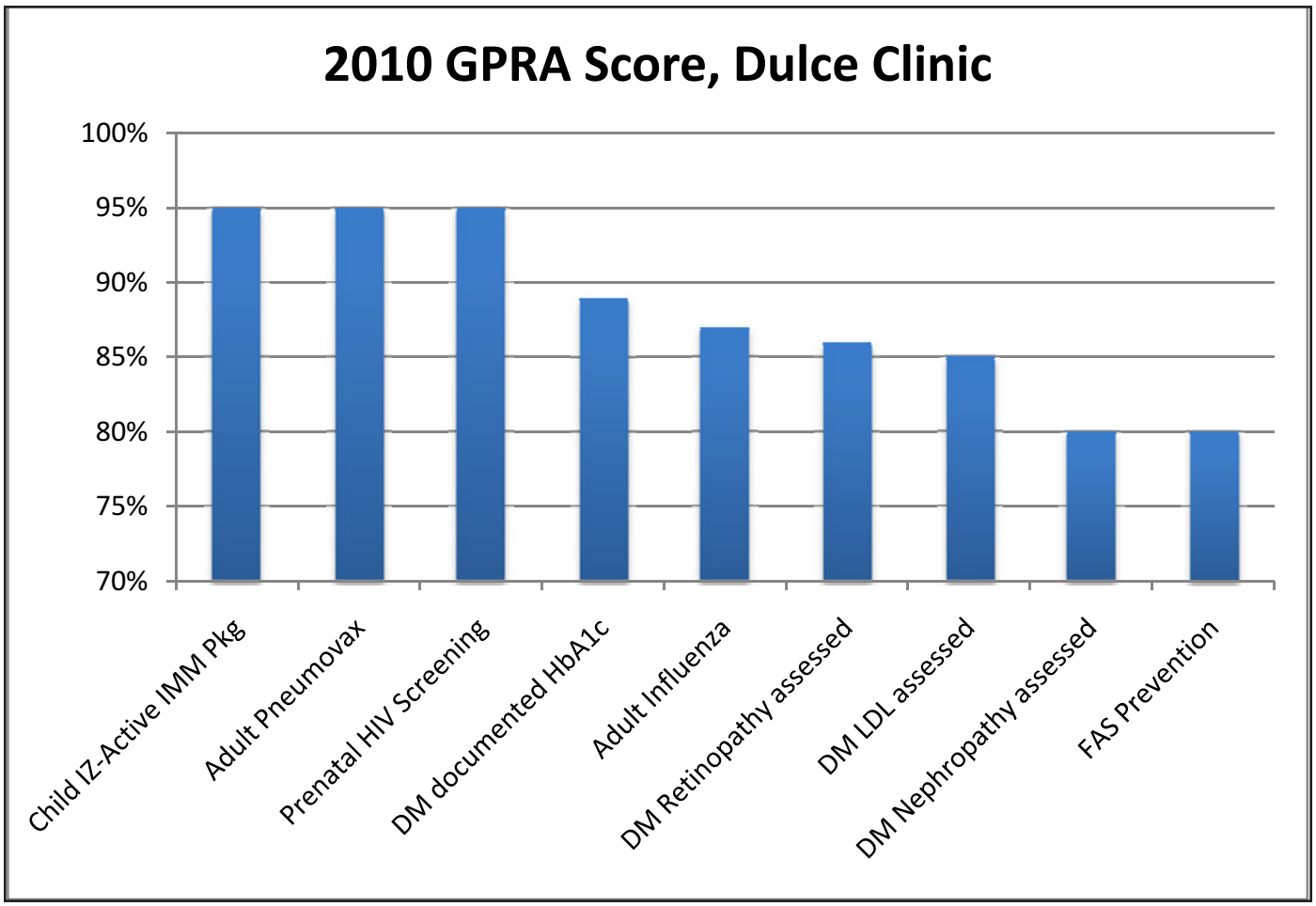
The TTN can provide a very private encounter that has helped some patients be more acceptable to STD screening and treatment for self and partner, since they do not have to call for an appointment or give information as to why they need to be seen.

If the TTN has triaged the patient and determined that the patient does not need to see a provider, then this is an opportunity for the TTN to inform the patient of needed upcoming/overdue screenings, immunizations, or routine appointments. Many of Dulce's GPRA scores are excellent, attributable in part to the TTN. Nine 2010 GPRA measures were 80% or higher at Dulce (see Figure 2).

The TTN Position is Highly Regarded by Community and Providers

The TTN is a well-respected position in Dulce. For the community, it provides a well-known and trusted point of contact. For persons who are unsure whether to come to the clinic, the TTN provides guidance, education, and assurance. For patients with a sensitive purpose of visit such as an issue around reproductive health, the TTN provides a confidential route to lab testing and follow up. Patient concerns pertaining to sexually transmitted disease symptoms, testing, and follow up are well suited to the TTN model.

Figure 2. 2010 GPRA Scores, Dulce Service Unit



Dulce is a small, rural community. Having TTNs who know the people of the community helps the service gain acceptance and trust. TTNs are rare in the Indian Health Service, but may be of great value to many service units. Special trainings, reference books, and protocols are available for TTNs. For further information, readers are encouraged to contact Gaylia Pride, RN, Director of Nursing (575) 759-7229; Nancy Watts, RN, TTN (575) 759-7248; or Reyna Garcia, RN, part-time TTN (575) 759-7248.

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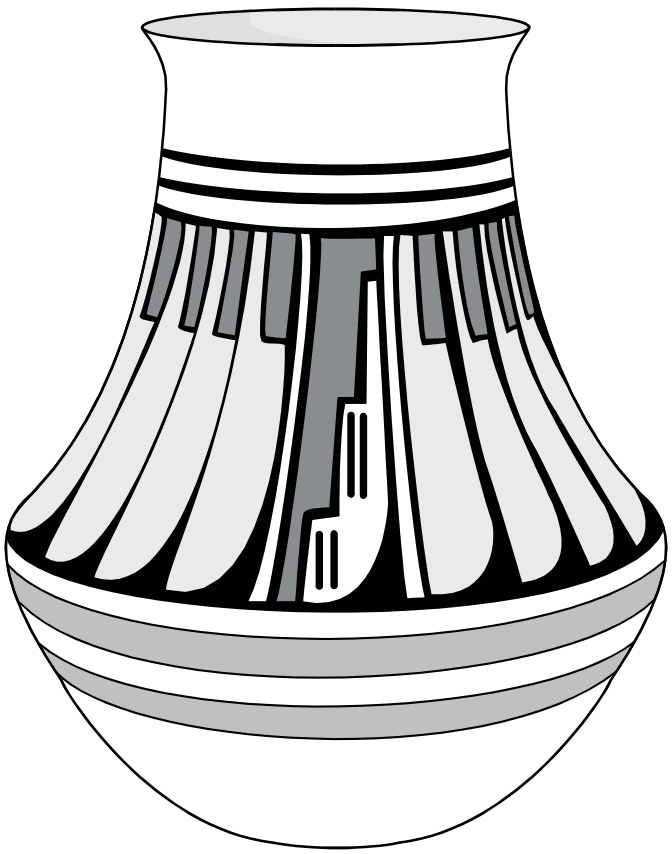
Other TTN procedures to note:

- TTNs limit return call attempts to three.
- A third party call will be accepted only in emergencies or for patients under 18 years of age
- If a caller will not disclose their name, the TTN is under no obligation to triage or give home care information
- Patients who received home care instructions are called back to assure improvement or offered an appointment in 48 - 72 hours
- TTN responsibilities supersede clinical care responsibilities except in emergencies



Implementation of a Mandatory Employee Influenza Vaccination Program in a Rural Tribal Health Care Facility

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Abstract

During the 2009 influenza A (H1N1) pandemic, 426 H1N1 deaths were reported in 12 states that represent more than 50% of the American Indian (AI) and Alaska Native (AN) population. In Arizona, where AIs comprise only 4.9% of the total population, they accounted for 18% of all confirmed H1N1 hospitalizations and 20% of all confirmed H1N1 deaths. The AI hospitalization rate for confirmed H1N1 in Arizona is 14.4 per 100,000; the rate for non-AI persons in Arizona is 3.9 per 100,000, making the AI hospitalization rate 3.7 times higher than the non-AI rate. Despite documentation in the literature that health care personnel (HCP) are responsible for nosocomial transmission of influenza and the recommendations for universal immunization of HCP from national advisory committees, HCP continue to have unacceptably low vaccination rates. Despite an aggressive employee influenza vaccination program, the Tuba City Regional Health Care Corporation (TCRHCC), has never exceeded 89% for vaccinated employees. In 2010, TCRHCC adopted a mandatory influenza vaccination policy for all employees.

Lewin's 3-stage model of change was selected as the framework for the process change. A force field analysis showed that the positive driving forces of patient safety, improved outcomes, decreased staff illness, decreased absenteeism, and community health benefits outweighed the resisting factors of fear, misunderstanding, and misconception. Resistance to change was managed by restructuring policy to direct behavior change. As the patient advocate, the Infection Prevention/Employee Health (IP/EH) Advanced Practice Nurse (APN) was in a unique position to influence health policy and implement evidence-based practice changes. Understanding the issues, the challenges, and the stakeholders, the IP/EH APN utilized Lewin's framework to implement institution-wide changes that increased the influenza vaccination rate from 89% to 97% within one month of policy implementation.

Introduction

Influenza is a viral infection that primarily infects the nose, throat, bronchi, and occasionally the lungs. The virus is efficiently transmitted person-to-person by droplets and secretions from coughing, sneezing, and by self-innoculation of mucosal surfaces from hand contamination. Influenza illness is often characterized by the sudden onset of a high fever, coughing, sneezing, sore throat, and body aches. Seasonal influenza occurs annually, while pandemics occur when there is a global influenza outbreak as the result of a new strain of influenza.[1] Vaccine is available for seasonal influenza but no vaccine readily exists at the start of a pandemic. Influenza and pneumonia were the eighth leading cause of death in the US in 2006, with an estimated 56,326 deaths attributed.[2] The mortality rate for influenza alone is estimated to be approximately 36,000 annually with mortality highest among the very young, very old, and chronically ill. Using data from four different studies, King, et al,[3] estimated that there are 200 million days of restricted activity, 75 million days of absenteeism, 22 million health care visits, and 110,000 hospitalizations annually as the result of infection with influenza.

In 2009, pandemic influenza A (H1N1) virus spread rapidly across the US, eventually infecting an estimated 43 to 89 million people between April 2009 and April 2010. Related hospitalizations were estimated to be 195,000 to 403,000, with an death toll of 8,870 to 18,300.[4] The burden of disease among American Indians and Alaska Natives (AI/AN) was estimated to be four times higher than in non-natives. During the period April 15 to November 15, 2009, data showed a disproportionate number of H1N1 influenza deaths among AI/AN populations in a 12-state cohort representing 50% of the AI/AN population. A total of 426 deaths from influenza A (H1N1) was reported by the 12-state cohort (AL, AK, AZ, MI, NM, ND, OK, OR, UT, WA, WY) with forty-two deaths (9.9%) occurring among AI/AN's leading to a population mortality rate of 3.7/100,000. This rate is more than four times higher than the 0.9/100,000 mortality rate for all other racial/ethnic populations. The majority of the AI/AN deaths occurred in Arizona (16) and New Mexico (8).[5]

Historically AI/AN have suffered disproportionately from influenza. During the 1918 pandemic, the mortality rate for AI in Arizona was 11.3%, New Mexico 11.3% and Utah 15.9%.[6]

During the influenza A (H1N1) pandemic, between April and November 2009, disparity continued to exist between AI/AN and all other racial ethnic groups. In Arizona, where AI comprise 4.9% of the population, 18% of all confirmed H1N1 hospitalizations and 20% of all confirmed H1N1 deaths occurred in AI. The AI hospitalization rate for confirmed 2009 H1N1 in Arizona is 14.4 per 100,000; the rate for non-AI persons in Arizona is 3.9 per 100,000, making the AI hospitalization rate 3.7 times higher than the non-AI rate.[5] AI/AN experienced the highest mortality at a rate four times greater than other racial/ethnic groups. The number of deaths among AI/AN in Arizona and New Mexico were 16 and 8 respectively.[8]

Tuba City Regional Health Care Corporation (TCRHCC), the largest employer in the area, is a licensed 72-bed tribal facility serving more than 35,000 AI/ANs located on the Navajo Nation in northeastern Arizona. The facility employs an average of 1076 health care personnel (HCP). HCP is defined as all workers: facility-paid, volunteer, student, resident, or Navajo Nation employees. The outpatient department, consisting of more than 20 specialty clinics, averages approximately 180,000 outpatient visits per year. The majority of HCPs are AIs with close ties to the community and extensive clan relationships. While a small percentage of employees commute long distances, the majority of professionals, including non-Natives, live in government provided housing. Due to the closeness of the community, both groups have increased opportunities for exposure and transmission.

Background

As previously mentioned, AIs in Arizona suffered disproportionally from infection with H1N1. The first case of H1N1 in Tuba City was diagnosed in May 2009. The staff of TCRHCC experienced a high incidence of employee absenteeism between May 2009 and February 2010. Four employees were hospitalized with H1N1, including one who required admission to an intensive care unit. Lost work time for the four employees averaged 10 days with a range of 5 to 20 days. Numerous HCPs were infected with influenza A and presumably influenza A (H1N1) (Farrell, unpublished data).

Nosocomial transmission. Nosocomial transmission of respiratory disease in hospitals and long-term care facilities has been well documented in the literature. During the 2003 severe acute respiratory syndrome (SARS) outbreak in Canada, more than 70% of the affected HCWs did not use personal protective equipment (PPE) while providing direct patient care.[8] A survey of 133 on-duty nurses at the Prince of Wales Hospital in Hong Kong found that 23% developed an influenza-like illness (ILI) during peak influenza season. Independent risk factors included suboptimal adherence to droplet precautions (masking) and failure to receive influenza vaccination.[9] Unvaccinated HCWs and children hospitalized with community-acquired influenza were identified as the major source of nosocomial influenza among pediatric patients.[10] A study of 1,520 patients in 75 United Kingdom National Health Service Hospitals identified 30 patients with noscomial H1N1 infection. Although they were unable to determine where and from whom the patients acquired influenza (e.g., visitor vs. HCP), the death rate was 27%.[11] Berg, et al[25] reported on an outbreak of nosocomial influenza in 13 out of 22 hospitalized patients suffering from emphysema and concluded that HCW staff was the probable source of infection. A HCW was also suspected as the source of an outbreak of influenza in a neonatal intensive care unit in 2000 where one death occurred among 19 infected infants.[13] A randomized trial of influenza vaccination in nursing home staff found a strong correlation between staff vaccination uptake and the all-cause mortality rates of residents. The results showed that vaccination of staff reduced the incidence of ILI in the residents and led to a decrease in staff absenteeism.[14]

HCP Influenza Vaccination. Studies focusing on the rates of HCP influenza vaccination have found that despite recommendations, the rate of vaccination remains low. Estimates from the CDC place HCP influenza vaccination rates at 40 to 50%.[15] Other studies estimate a seasonal vaccination rate of 61.9% and an H1N1 vaccination rate of 34.7% during the 2009 – 2010 influenza season.[16] It is also a known fact that HCP go to work ill where they can unknowingly shed virus and transmit infection. A study conducted in Glasgow following the 1993 - 4 influenza epidemic found that 23% of 120 unvaccinated HCP had serological evidence of influenza infection. Of the 120 HCP, 59% could not recall having influenza and 28% could not recall having any type of respiratory infection.[17] Considering that they were asymptomatic, it is likely they engaged in direct patient care. Another study found that 50% of HCP who reported an influenza-like illness (ILI) during the 2004 - 2005 flu season continued to work and have patient contact while ill.[18] In a random sampling of 1,000 inpatient nurses at the Mayo Clinic, a study found that the majority of the registered nurses (RNs) reported going to work when ill with ILI.[19] A more recent anonymous survey conducted in an urban academic setting to assess resident physicians' attitudes and behavior during the 2009 H1N1 influenza season found that 62% of residents and 9% of medical students who reported having an ILI continued to work or go to school despite being ill.[20]

Several studies have attempted to identify characteristics among HCWs who refuse influenza vaccination. A nationwide survey of HCPs in Northern Greece identified two main reasons for refusing vaccination: 43.2% felt they were not at risk and 33.4% feared adverse side effects.[21] A cross-sectional study done at the Bronx-Lebanon Hospital Center (Bronx, NY) found that the decision to be vaccinated is influenced by both personal and systemic factors. Nurses who were not vaccinated (45.4%) had ill-founded beliefs about the safety and effectiveness of the vaccine. They believed they were not at risk of becoming ill and were afraid of getting sick from the

vaccine.[22] After implementation of a mandatory influenza vaccination program at the National Institute of Health (NIH) in 2008, a survey was conducted to identify reasons for declination of vaccination. Of the 2,754 employees, 294 (10.6%) formally declined vaccination. The most frequent reasons cited were concerns about side effects (39.1%); a belief they were not at risk (20.7%); vaccine was not effective (17.7%); and a belief that it was harmful (11.6%). Additionally, 11.6% of the staff declining indicated they thought they could get influenza from the vaccine.[23]

Regional Vaccination Rates. Despite the documented benefits for both patients and workers, the HCP vaccination rate falls below the Health and Human Service (HHS) Healthy People goal of 60% for 2010. Future goals are 70% for 2015 and 90% for 2020.[24] Navajo Area Indian Health Service (NAIHS), which includes eight Indian Health and tribal facilities, reported that 80% of HCP received seasonal influenza vaccination and 66% received H1N1 vaccination during the 2009 - 2010 influenza season.[25] TCRHCC, also included in the NAIHS numbers, fared better than most regional and Navajo Nation facilities with vaccination rates of 78%, 83% and 89% respectively for the years 2007 - 2009. Rates for H1N1 vaccination, however, were lower with 50%. Reasons cited for declination ranged from vaccine shortage to fear of side effects.

The Need for Change. TCRHCC employs an aggressive HCP influenza vaccination program utilizing mobile vaccination carts, convenient hours, incentives, and declination forms. Despite the 89% vaccination rate for seasonal influenza, the Epidemiological Response Team (ERT) felt that 89% was not sufficient when it came to protecting patients and that the goal must be 100%. In February 2010, the ERT members reviewed an article highlighting the success of Virginia Mason Medical Center, Hospital Corporation of America, and the Children's Hospital of Philadelphia in mandating vaccination for HCP.[26] Historical vaccination data, disease burden, and facts about the benefits of influenza vaccination were given to the ERT members to review. The members were asked to entertain the idea of mandatory vaccination and be prepared to discuss and make a decision at the May 2010 meeting. At that meeting, the ERT members voted unanimously to propose a mandatory influenza vaccination program for all employees. Those employees who chose to decline vaccination on the grounds of a medical contraindication or religious reasons would be required to wear a mask covering their nose and mouth during influenza season November 1 through March 31.

Methods

The ERT appointed the IC/EH nurse to act as project manager and established a target date of full compliance for November 1. As part of the strategic plan, Lewin's 3-step change theory was selected as the framework to implement the change management process. Lewin, a social scientist, viewed behavior as the dynamic balance of driving and restraining forces. The driving forces push employees into the desired direction while restraining forces oppose change.[27] The first step was to identify forces that would facilitate or impede the proposed change. Driving forces included supporting literature, improved patient outcomes, decreased staff illness and absenteeism, patient and community safety, and decreased health care costs. Restraining forces included fear of side effects, false belief of not being at risk for illness, lack of confidence in the vaccine, inconvenient administrations times, and the belief that vaccination policies are coercive and violate the right to choose. The masking mandate was anticipated to be the most controversial and most difficult to enforce. To support this, the IC/EH nurse conducted a literature review to gather supporting evidence before proceeding on to the next phase. Poalillo[31] reported that the H1N1 virus may have an asymptomatic carrier rate as high as 9%, while Carlson[32] found that asymptomatic influenza infection may account for up to 66% of all influenza cases.

With the consensus of the ERT, that mandatory influenza vaccination should become a part of the culture of the facility and thus a condition of employment, the ERT needed to secure the buy-in of senior leaders. Supporting literature, including the position statements of national committees; the Advisory Committee on Immunization Practices (ACIP), Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA)[30] was presented to the Nurse Executive Council (NEC). The NEC, a committee of approximately 22 supervisory clinical nurses including the IP/EH nurse, the Assistant Chief Nurse and the Director of Nursing, has oversight over the largest group of hospital employees. The NEC unanimously supported both the vaccination and masking requirements. The policy was then presented to the Medical Executive Committee (MEC) where some resistance was expressed by those who were opposed to any influenza vaccination and those who argued that masking would not be enforceable. Despite objections, the policy passed with a majority vote. The policy was then presented to the Senior Leadership Committee (SLC) where opposition to masking was voiced but the policy was approved. On September 1, 2010, the Mandatory Influenza Vaccination for Employees policy was signed by the President of the Hospital Board of Directors.

Immediately, the IP/EH nurse began to communicate the policy changes to the staff via e-mail, flyers, and departmental meetings. Excerpts from literature demonstrating that AIs have a four times higher death rate from H1N1 and articles about HCP vaccination rates were distributed. The target date for 100% compliance was set for November 1, 2010, the date on which all employees who declined vaccination would be required to mask while on duty. An employee mass vaccination was conducted on October 7, 2010 in the hospital cafeteria. Subway $5 gift cards were given to employees receiving vaccination. Between the hours of 7:30 am and 11:30 am, over 400 employees, including SLC members, presented for

vaccination. The team returned that evening from 6 pm to 8 pm to vaccinate an additional 122 employees. Following the mass vaccination day, the IP/EH nurse utilized the mobile cart system and one-on-one appointments to reach the majority of the remaining employees. Some employees elected to receive their flu shot in the immunization clinic or through a private provider and were required to provide proof of vaccination. Any employee who declined vaccination was required to sign a declination form and acknowledge that they would be required to wear a mask while on duty. By the target date, 97% (1048) of employees had been vaccinated, 2% (26) had declined vaccination, and 1% (2) had been listed as unaccounted for due to extended medical leave status.

Sustaining the change. Change is not always comfortable and acceptance may not come quickly for everyone. Change brings about a new equilibrium that requires stabilization through the development and reinforcement of institutional policies and procedures. The mandatory influenza policy has been embraced as part of the culture and mission of TCRHCC. Feedback on vaccination rates was communicated regularly to the staff through e-mails and flyers. To avoid any unexpected surprises, all potential and new hires are informed of the policy prior to the offer of a position. Departmental managers are responsible for enforcement of the mask requirement and have done an excellent job in monitoring compliance. With only 26 refusals, non-compliance was relatively easy to observe and corrected on the spot. Any refusal to comply with the hospital policy placed the employee into a progressive disciplinary process.

Discussion

One of the major obstacles was the opposition of the key medical providers. As leaders, medical officers are expected to support the mission and values of the organization. Ottenberg, et al[31] cited the American Medical Association's (AMA) recently published statement, *"physicians have the obligation to accept immunization absent a recognized medical, religious, or philosophical reason to not be immunized and accept a decision of the medical staff leadership of health care institutions, or other appropriate authority to adjust practice activities if not immunized. It reasonable to require a physician who declined vaccination, to wear a mask or refrain from direct patient contact"* in their commentary discussing the legal and ethical issues of mandatory vaccination. The AMA's position on mandatory vaccination and practice changes is another driving force that supports the program's objectives.[32] Also encountered were several employees who had histories of allergies and/or adverse reactions who insisted on receiving influenza vaccination instead of masking. Successful vaccine uptake was obtained in the immunization clinic under the supervision of a medical provider for all but one employee. In addition to the Subway card incentive, pizza parties were provided for six departments reaching 100% compliance on the first day of the campaign. Feedback to employees is a crucial component of any successful program, and thus vaccination rates were made available to all staff. Department supervisors in turn provided additional recognition to their department, further supporting and recognizing the success of the program.

Conclusion

Identifying the need for change and creating an atmosphere where change will be accepted is a tall order in any work environment as many staff exhibit reluctance to leave their comfort zone. With a wide range of skill and knowledge, the APN is the ideal agent to influence change. Using Lewins's framework, the IP/EH APN was successful in identifying the need for change, implementing an action plan, and establishing a state of equilibrium that will assist in sustaining the change. Through a summary of the literature, the IP/EH APN was able to overcome resistance by providing evidence-based research supporting the claim that influenza vaccination is the simplest, safest and most effective tool in protecting patients from noscomial transmission of influenza. As with any other successful program, the tendency to become complacent is a part of human nature. To continue to have a successful program, there must be a continuing staff education program, monitoring of vaccination rates, feedback, and re-evaluation.

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FDA REMS: Implications and Considerations for the Indian Health Service

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In recent years, the United States Food and Drug Administration (FDA) implemented measures to ensure that medications are appropriately prescribed while providing patients and providers an understanding and assurance of the drug's benefits and risks. This paper discusses relevant information for health care providers concerning the FDA risk evaluation and mitigation strategies (REMS).

Background[1-2]

The FDA is an agency under the Department of Health and Human Services (DHHS). Over the years, many different amendments and laws were enacted that led to the present FDA. The Federal Food, Drug, and Cosmetic Act (FDCA) of 1938 contained several key provisions, including safety requirements for new medications. The Durham-Humphrey Amendment of 1951 defined types of medication that required medical supervision and thus, limited the sale of these products by prescription only from a licensed practitioner. The Kefauver-Harris Drug Amendments of 1962 provided requirements for manufacturers to prove effectiveness of products and strengthened safety requirements. In 1970, the FDA required a package insert to be included with oral contraceptives that discussed risks and benefits of use. In September 2007, the FDCA was amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA). These amendments granted new authority to the FDA. One such authority was the ability to require manufacturers of new or existing drug or biologic products to develop and comply with REMS.

What are REMS?

As the name implies, REMS are safeguard actions, developed by a drug sponsor, approved by FDA, whose goal is to ensure safe use of a product by patients. Prior to FDAAA, Risk Minimization Action Plans (RiskMAPs) were used to minimize risks for new drug products and many were "grandfathered" to become REMS at the time FDAAA was enacted.[3-5] After FDAAA, the FDA was granted expanded ability to regulate post market drug safety.[1] One avenue to improve drug safety was via the REMS requirements. REMS are specific to a drug product and individually tailored to help mitigate a potential safety issue. This risk management plan uses minimization strategies that go beyond what the product label contains. The FDA may require a drug sponsor to develop REMS:

- Before drug approval, if the FDA determines a REMS is necessary to ensure the benefit of a drug coming to market outweighs the risk associated with its use
- After approval, if the FDA identifies new safety information and determines a REMS is necessary to ensure the benefit of a drug remaining on the market outweighs the risk associated with its use

REMS requirements vary depending on drug product and the safety risk associated with the use of the product. There are different types of requirements that the FDA may impose for a particular drug product, and may include multiple requirements. These include:

- A Medication Guide or patient package insert (PPI)
- A Communication Plan for health care providers
- Elements to Assure Safe Use (ETASU)
- An Implementation System

Each of these will be discussed individually.

Medication Guide[5-7]

Prior to the draft guidance for Medication Guides, this was the most frequently employed requirement associated with REMS. This type of REMS is geared toward education of patients through the dispensation of FDA approved patient-friendly labeling. With this requirement, the FDA requires that a Medication Guide be issued at the dispensation of the prescribed medication or biologic. The FDA may require a Medication Guide if:

- patient labeling could help prevent serious adverse events
- a serious side effect is known that could affect the patient's decision to use or continue use of the drug
- patient adherence to directions is crucial for product effectiveness

The manufacturer is responsible for ensuring Medication Guides are available to be dispensed to the patient by health care providers. There is a draft guidance that is under public review that modifies the requirements for Medication Guide dispensation in certain settings and should further clarify dispensing requirements (Table 1). Additionally, this draft guidance modifies the requirement of Medication Guides as a part of REMS and "in most cases, FDA expects to include a Medication Guide in a REMS only when the REMS includes elements to assure safe use."[5]

Table 1. Draft Medication Guide Enforcement Discretion Policy[5]

Setting	Patient or Patient's Agent Requests Medication Guide	Medication Guide Distributed Each Time Drug Dispensed	Medication Guide Distributed At Time of First Dispensing	Medication Guide Distributed When Medication Guide Materially Changed
Inpatient	Must dispense Medication Guide	FDA intends to exercise enforcement discretion; Medication Guide need not be dispensed	FDA intends to exercise enforcement discretion; Medication Guide need not be dispensed	FDA intends to exercise enforcement discretion; Medication Guide need not be dispensed
Outpatient when dispensed to health care professional for administration to patient (e.g., clinic, infusion center)	Must dispense Medication Guide	FDA intends to exercise enforcement discretion; Medication Guide need not be dispensed	Must dispense Medication Guide	Must dispense Medication Guide
Outpatient when dispensed directly to patient or caregiver (e.g., retail pharmacy, hospital ambulatory pharmacy)	Must dispense Medication Guide	Must dispense Medication Guide	Must dispense Medication Guide	Must dispense Medication Guide

Note: When a drug is subject to a REMS that includes specific requirements for the review of a Medication Guide (possibly in conjunction with distribution), FDA does not intend to exercise enforcement discretion regarding those specific requirements set forth in the REMS (e.g., when health care providers are required to review the Medication Guide with patients before patients are enrolled in a REMS program as an element to assure safe use).

Communication Plan

The FDA may require a manufacturer of a drug or biologic to submit a communication plan as part of REMS requirements. These are approved materials, targeted at health care providers, to provide information about serious risk(s) associated with a drug or biologic, and may include information on implementing the REMS. The communication plan may include sending letters to health care providers, disseminating information to health care providers through professional societies, and specific information about REMS elements, such as monitoring parameters, protocols, or laboratory testing requirements.[7]

Elements to Assure Safe Use (ETASU)/Implementation System

A less frequently employed option under REMS is the use of ETASU. These are specifically required items, intended to provide safe access to certain drugs with known serious safety concerns listed in the approved labeling of a drug or biologic. These requirements may include:[7]

- Requiring specific training, experience, or certification for health care providers who prescribe the drug
- Requiring pharmacies, practitioners, or health care settings that dispense the drug to be specially certified
- Requiring the drug to dispensed only in certain health care settings, such as hospitals
- Requiring the drug to be dispensed only to patients with evidence or other documentation of certain safe-use conditions such as laboratory tests
- Requiring specific monitoring for patients using the drug
- Requiring enrollment of patients using the drug into a specific registry

For example, Oxycontin® (oxycodone HCL controlled-release) tablets, an opioid agonist, has REMS requirements associated with its use. The goals are to inform patients and health care professionals about the potential for abuse, misuse, overdose, and addiction, as well as the safe use of this product. The REMS requirements include the dispensation of a Medication Guide with each prescription. Each bottle will have one copy of the full prescribing information, two copies of the approved Medication Guide, and will include a prominent statement on the container packaging instructing, "authorized dispensers to provide a Medication Guide."[8-9]

ETASU elements are also required for this product and include a training requirement, a "Dear Healthcare Professional" letter to be mailed to prescribers and a requirement for the manufacturer to maintain a list of all prescribers who completed the training. Additionally, prescribers will be re-trained every two years as part of this REMS.[9] It should be noted that the FDA and members of the pharmaceutical industry are working to implement a single shared system REMS for long-acting and extended release opioids; therefore, please continue to watch for more information regarding opioid REMS.[10]

An implementation system may also be required when ETASU that require certification of pharmacies and hospitals, that limit the use to certain health care settings, or that require documentation of safe use conditions are part of the REMS. With this type of requirement, the drug sponsor must take reasonable steps to monitor and evaluate the implementation by health care providers, pharmacists and other parties in the health care system responsible for implementing the elements. The applicant must work to improve the implementation of these elements. Drug distribution may be affected by REMS; therefore the certification of the wholesaler and/or distributor may be required under the implementation system.

The erythropoiesis stimulating agents (ESA; Epogen®, Procrit®: epoetin alfa; Aranesp®: darbepoetin alfa) provide a good example of a class that has each of the REMS elements when they are used for the treatment of cancer related anemia. A Medication Guide must be given with each dispensation of the product. This must be provided as long as treatment continues and should follow the requirements set forth in the REMS for distribution of Medication Guides.[5] A health care professional communication was sent to nephrology professional societies, large dialysis organizations, nephrology group purchasing organizations, oncologists, hematologists, Directors of Pharmacy for hospitals, and other health care providers who may prescribe these products for patients with cancer. These agents have ETASU requirements for use in cancer related illness, via the ESA APPRISE Oncology Program. For providers who prescribe and dispense ESAs in private practice and in hospital-based settings, this includes certification, training (initial, then every three years) and attestation to their review of the APPRISE program requirements (not inclusive). Hospitals that dispense ESAs for treating patients with cancer must be certified as part of the APPRISE program. The manufacturer will assure that these products will be dispensed with documentation of safe-use conditions. Finally, an implementation system has been approved for these products. The manufacturer will monitor compliance with the ESA APPRISE Oncology Program via audits of private clinics and random sampling of hospitals. The manufacturer will ensure that these products are not distributed to facilities (hospital, private clinic, etc.) unless they are certified.

Enforcement of REMS

Elements associated with REMS are enforceable. FDAAA gave the FDA the authority to enforce drug sponsor compliance with REMS requirements and can deem a drug misbranded and potentially impose civil penalties for non-compliance. These enforcement actions can range from warning letters, injunctions, or monetary civil penalties of up to $10 million.[11] If a dispute arises between a drug sponsor and the FDA regarding a post approval REMS requirement, the FDA Drug Safety and Oversight Board (DSB) may review the dispute.[12] The IHS is a voting member of this board.[12-13] The FDA enforcement of REMS speaks only to the drug sponsor; however, failure of providers and/or facilities to comply with REMS requirements could contribute to civil liability being assessed on the sponsor or cause the drug to be misbranded.[14]

FDA responsibilities with REMS

After the manufacturer has submitted the REMS, it is the responsibility of the FDA to review the submission, provide comments to the sponsor, and approve the REMS. Additionally, through a Drug Safety and Risk Management (DSaRM) Advisory Committee meeting, the FDA must at least annually assess whether one or more ETASU REMS is meeting its intent of assuring safe use of a drug and is not unduly burdensome to patient access and the health care system. The FDA also assesses whether the manufacturer has appropriately assessed whether the REMS is meeting its goals and must provide the feedback in prescribed fashion.[1]

Current REMS

The FDA periodically updates the list of medications with FDA-approved REMS. Since January 4, 2010, the list has grown from 100 listings to 183.[14-16] The majority of the approved REMS only require a Medication Guide as the required element of the REMS (123). A communication plan is required of 49 of the approved REMS, while ETASU are required of 22.[15] (See Figure 1.)

Implications for IHS

The IHS National Pharmacy and Therapeutics Committee (NPTC) is responsible for increasing access to highly effective medications through formulary management, providing educational pieces for clinicians, and for maintaining the IHS National Core Formulary (NCF). At the time of this writing, the IHS NCF includes eight products that have REMS. Each of these eight included a Medication Guide as part of the REMS, two agents required a communication plan and none have ETASU. These agents were: alendronate, buproprion, clonazepam, clopidogrel, fluticasone/salmeterol, gabapentin, lopinovir/ritonavir, and salmeterol.[17] The NPTC includes a discussion, during the clinical presentation, of REMS when considering products for potential inclusion to the NCF.

Figure 1. Current FDA REMS (March 25, 2011)[16]

- 183 approved REMS
- 180 include a Medication Guide
- 123 include only a Medication Guide
- 49 include a communication plan
- 22 include ETASU
- 18 include implementation systems

Additionally, the NPTC includes a REMS section in each clinical drug monographs.

The IHS Pharmacy Specialty Group (PSG) discussed REMS in a recent meeting. This group is responsible for information resource management and technology, and serves as a central system to coordinate issues related to the pharmacy computer software.[18] They are working to develop methods to improve the identification of REMS drugs, dispensation of Medication Guides and documentation of REMS elements. Additionally, they are looking to develop "best practices" that may include the use of automation prompts, EHR reminders, electronic signature pads and focused patient education codes. More information should be forthcoming.

Facilities should begin looking at their system and identifying opportunities for REMS implementation. Considerations should be put in place for flagging of REMS agents, dispensation of Medication Guides, and documentation of REMS compliance. Implementing local policies and procedures for REMS should be considered. Area and local Pharmacy and Therapeutics committees should include discussions about REMS when considering new additions to formularies. Additionally, if medications with ETASU are used, facilities should assure compliance with the specific criteria.

Relevant Acronyms

FDA	Food and Drug Administration
REMS	Risk evaluation and mitigation strategies
DHHS	Department of Health and Human Services
FDCA	Federal Food, Drug, and Cosmetic Act of 1938
FDAAA	Food and Drug Administration Amendments Act of 2007
RiskMAPS	Risk minimization action plans
PPI	Patient Package Insert
ETASU	Elements to assure safe use
ESA	Eythropoiesis stimulating agents
NPTC	IHS National Pharmacy and Therapeutics Committee
NCF	IHS National Core Formulary
PSG	IHS Pharmacy Specialty Group
APPRISE	Assisting Providers and cancer Patients with Risk information for the Safe use of ESAs

Closing

The FDA REMS are currently in a period of change with the recent Draft Medication Guide Guidance.[5] The requirements and application of this information is an important piece for IHS health care providers to understand. Health care professionals provide critical roles in assuring safe and appropriate use of medications. REMS elements and requirements should be implemented into the IHS medication use process. Implementation should be carefully thought out to assure the appropriate use of these medications in a fashion that does not serve as a burden for the provider.

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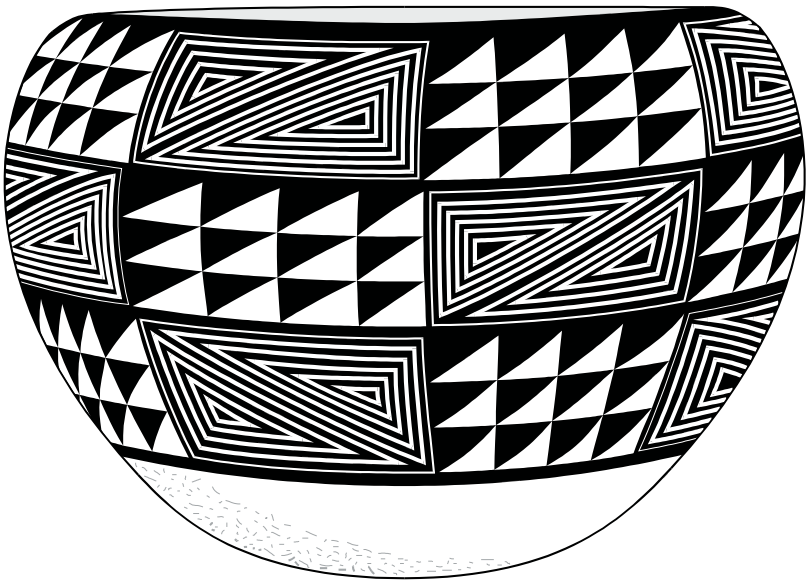


This is a page for sharing "what works" as seen in the published literature, as well as what is being done at sites that care for American Indian/Alaskan Native children. If you have any suggestions, comments, or questions, please contact Steve Holve, MD, Chief Clinical Consultant in Pediatrics at sholve@tcimc.ihs.gov.

IHS Child Health Notes

Quote of the month

"Men never do evil so completely and cheerfully as when they do it for religious conviction."

--Pascal

Articles of Interest

Association between sexually transmitted diseases and young adults' self-reported abstinence. *Pediatrics*. 2011 Feb;127(2):208-13. Epub 2011 Jan 3.

Investigators examined the accuracy of self reported sexual behavior in a national sample of over 14,000 young adults (mean age 22 years) who underwent urine testing for *Chlamydia trachomatis*, *Neiserria gonorrhea*, and *Trichomonas vaginalis*. Interviews on sexual behavior were done via an audio computer self interview completed at home. Six percent of the subjects tested positive for at least one sexually transmitted infection; surprisingly nearly 11% of infected participants reported having abstained from sexual intercourse in the previous 12 months.

Editorial Comment

Obtaining a complete and accurate history is felt to be crucial in the practice of good clinical medicine. It is equally clear that many adolescents and adults may not feel comfortable disclosing sensitive information about sexual practices. There are potential explanations that could account for the 10% discrepant results between sexually transmitted infections and sexual behavior such as latent chlamydial infection in some women. However, given these results, some might argue that routine screening for sexually transmitted infections should be done regardless of clinical history.

Infectious Disease Updates.
Rosalyn Singleton, MD, MPH
Meningococcal vaccine: Two vaccines, two doses, now for under two years

The myriad of new recommendations and vaccines for meningococcal disease can make one dizzy. First, some quick disease facts: meningococcal disease is a rare, devastating infection presenting primarily as meningococcemia or meningitis. The incidence in the US is about 0.2 – 4 per 100,000, with peaks in infancy and age 16 - 21 years, and a case fatality rate of 10 - 25%. Meningococcal conjugate quadrivalent vaccines (Menactra® and Menveo®) routine recommendations were recently changed from one dose in adolescents to "routine vaccination of adolescents (preferably at 11 - 12 years) with a booster dose at 16 years." The recommendations for high risk persons (e.g., asplenia, terminal complement disorder, etc.) aged 2 - 54 years have also been changed to a two-dose primary series. Why the change? The goal of the adolescent meningococcal dose was to protect persons 16 - 21 at the peak of disease; however, recent immunogenicity studies have shown that the vaccine may not provide protection for five years. Since meningococcal disease is rare and the vaccine is expensive, the extra dose was a contentious issue, with an Advisory Committee on Immunization Practice (ACIP) vote of 5 to 4.

There's more to come on meningococcal vaccines. Menactra® was just licensed down to nine months of age and Menveo® may be looking for licensure in infants. Also, a MenC/Hib vaccine is close to licensure for infants. With an already busy childhood vaccine schedule and high cost for a small number of cases, the routine use of meningococcal vaccine in infants will be a subject of intense debate.

Recent literature on American Indian/Alaskan Native Health
Jeff Powell, MD, MPH

First Steps for Mommy and Me: A pilot intervention to improve nutrition and physical activity behaviors of postpartum mothers and their infants. Taveras E, Blackburn K, Gillman M, et al. *Maternal and Child Health Journal*, October 19, 2010

This month's focus is a small pilot intervention, "Mommy and Me," a primary prevention approach to healthy behavior change among new mothers and their young infants. This review is a change of approach from past reviews, in that the study subjects are neither American Indian nor Alaska Native. I chose this small pilot, however, because it seems useful in the context of the focus on health promotion and disease prevention in Indian Country. What I find striking about this pilot is the simplicity and focus of the intervention, targeting the wellness of the mother/infant unit, not just mother or just the infant. In addition, the use of health educator implemented

motivational interviewing and primary pediatrician brief negotiation offers intriguing use of resources that may be adaptable to American Indian communities.

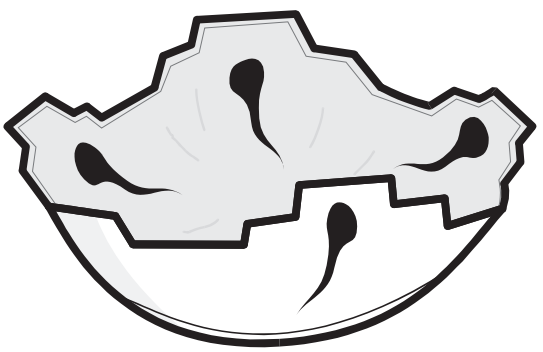
The article summarizes the intervention and findings implemented by Harvard Medical School and Harvard Pilgrim Health Care Institute. In summary, the study team developed and implemented a coordinated behavior change curriculum, enrolling 84 mothers/infant pairs (60 intervention pairs, 24 control "usual care" pairs). The study was prospective, non-randomized, controlled, and non-blinded. The intervention pairs of mothers and infants were enrolled from two primary care practices, and the control pairs were enrolled from a separate individual pediatric practice. These pairs were followed from just after birth through six months of age.

The study focused on "healthful diet/infant feeding," television viewing, sleep measures, and mothers' physical activity. The intervention designed to impact these targets is elegant in design and in use of professional resources. The study team engaged primary care pediatric practices and utilized primary care pediatric providers and health educators. To support these personnel, education materials were provided to the intervention practices. The education was carried out using pediatric provider brief negotiation (a truncated version of motivational interviewing that is well-suited to clinic time constraints), and health educator motivational interviewing. The brief negotiation was carried out during already scheduled infant well child visits. The motivational interviewing was implemented using a series of between visit health educator telephone calls lasting 15 to 20 minutes. In addition to the phone calls, supportive group teaching sessions were conducted by the pediatric providers of the intervention practices.

In addition to the modest numbers enrolled, the main limitations of this pilot are the short, six-month, intervention time, and the demographics of the enrolled mother/infant pairs. The pilot was carried out in a high socioeconomic status, well educated, and older mother demographic. This obviously limits the generalizability of this pilot program. Even so, I feel that this study holds promise for the "real world" because the intervention seems feasible in a non-research environment. So while the patient population for this particular pilot limits the study usefulness, the nature of the intervention itself increases the study usefulness.

Of course, the big question is, What about study effectiveness? In broad terms, the study looked at three types of results: mother and infant behavioral measures (based on evidence-based measurement tools); anthropometric outcomes (measurement of BMI, height for weight Z scores, etc.); and process outcomes (program acceptability and feasibility measures). Statistically significant outcomes included improved timing of introduction of solid foods, and improved sleep measures in the intervention infants. In addition, there was an important trend towards fewer very overweight (highest quartile of weight for length Z score) infants in the intervention group, though this finding was not statistically significant (22% of intervention infants versus 42% of control group infants were in the heaviest quartile, $P = 0.06$). Maternal behavior itself did not change with participation. In terms of program acceptance, the bottom line appears to be that mothers liked the program, would recommend it to a friend, and that primary care pediatric providers felt that the training and educational materials were very useful to their practice.

While the "Mommy and Me" intervention lacks generalizability based upon intervention population, it is exciting research in pediatric prevention. First, it appears to be a relatively non-resource intensive, realistic program amenable to broad implementation. Second, the intervention period in this pilot is very short – to have any positive outcomes in such a brief, six-month intervention is impressive. Finally, this program strikes me as compatible with the practice environments of AI/AN-serving clinics. In our local system, for example, we have robust teams of health educators, providers already familiar with brief negotiation and motivational interviewing, and access to motivational interviewing training. In addition, a holistic approach to community and to health care over the lifespan offers opportunities to expand these approaches to include multiple children within a family, and to integrate with prenatal and even pre-conception care.



April's issue of *The IHS Provider* recognized Sexually Transmitted Disease (STD) Awareness Month and, to raise awareness of the impact of STDs on the health of Native communities, the IHS National STD Program and its partners brought together a number of articles related to that topic. This month we publish three additional articles that did not make it into that issue, but which are equally important. Again, we are grateful to Scott Tulloch, BS, Program Manager, IHS National STD Program (CDC assignee), Albuquerque, New Mexico; Lori de Ravello, MPH, Public Health Advisor, IHS National STD Program (CDC assignee), Albuquerque; and Melanie Taylor, MD, IHS National STD Program (CDC assignee), Phoenix, Arizona for their devotion to this important problem and their work to get the word out in *The Provider.*

National Chlamydia Coalition Mini-Grant: Increasing Chlamydia Screening and Follow-Up in IHS, Tribal and Urban Indian Health Programs

Wendy Nakatsukasa-Ono, MPH, Program Director, Center for Health Training, Seattle, Washington

In 2010, the National Chlamydia Coalition (NCC) awarded a "mini-grant" to the Center for Health Training to develop a model protocol and decision tool/flowchart to guide standard delivery of STD care to AI/AN at risk for chlamydia and other STDs. This effort was undertaken in partnership with the Alaska Native Tribal Health Consortium, IHS National STD Program, JSI Research & Training Institute, Region VIII Infertility Prevention Project, Northwest Portland Area Indian Health Board, and the Phoenix Indian Medical Center.

Consistent with the NCC grants program, the goal of the project is to increase chlamydia screening and follow-up care among AI/AN. Project objectives include:

- Increase IHS, tribal and urban (I/T/U) Indian health programs' awareness of the importance of *Chlamydia trachomatis* (CT) screening for AI/AN, particularly adolescents and young women ages 15 - 24
- Increase I/T/U health programs' capacity to provide CT screening and follow-up care

To-date, the partners have developed:

- A sample policy for syphilis, chlamydia, gonorrhea, and HIV screening and patient and partner management within IHS and tribal health care
- Sample protocols and standing orders for STD and HIV screening and epidemiologic STD treatment
- STD screening recommendations chart
- Sexual risk assessment charting form
- Expedited partner therapy considerations and materials for patients and their partners

The partners have completed baseline clinic capacity assessments with a number of sites to: 1) document the existence and/or status of policy, protocols and standing orders, and other documents; 2) pilot the materials; and 3) assess organizational intention to use the documents developed by the project. All materials are scheduled to be completed in May 2011, and the partners will then disseminate these materials electronically through their national and regional networks.

For copies of the completed materials and/or more information, please contact Wendy Nakatsukasa-Ono, MPH, Program Director, Center for Health Training, telephone (206) 447-9538; e-mail *wono@jba-cht.com*.

Native STAND (Students Together Against Negative Decisions): Evaluating a School-based Sexual Risk Reduction Intervention

Carol Grimes, MPH, Program Evaluator, Northwest Portland Area Indian Health Board, Portland, Oregon

Compared to other US teens, American Indian and Alaska Native (AI/AN) youth experience significant sexual health disparities, including high teen birth rates and sexually transmitted illnesses (STIs). After experiencing more than a decade of decline, the teen birth rate increased 12% among AI/AN between 2005 and 2007 -- more than that of any other racial or ethnic population.[1] In 2009, young people (age 15 - 24) accounted for 67% of all chlamydia cases and 56% of all gonorrhea cases among AI/AN of all ages.[2] Many factors contribute to these disparities, including poverty, stigma, insufficient and inaccessible health services, and persistent social norms that support substance abuse and sexual violence.[3]

Native STAND Curriculum

Native STAND is a 29-session peer educator curriculum that covers a range of sexual and reproductive health topics, including communication and peer education skills. It is based on an intervention that was designed and evaluated among rural youth in the southern US and found to effectively increase condom self efficacy, HIV risk behavior knowledge, frequency of conversations with peers about birth control and STDs, and consistent condom use among participating students. In 2008, the curriculum was adapted for use among AI/AN youth by a multi-disciplinary workgroup of partners working with AI/AN and topical experts; activities were pilot tested with small groups of youth from the target audience.

Native STAND Evaluation

A mixed-methods study was conducted to evaluate the Native STAND curriculum in 2010. To more fully evaluate the adapted curriculum in Indian Country, 80 students attending four Bureau of Indian Education (BIE) boarding schools were selected by fellow students to be trained as peer educators using the Native STAND curriculum. The curriculum was delivered in 1½ hour classes by two or three adult staff at each school, each of whom had been trained to facilitate the Native STAND curriculum. A comprehensive pre- and post-computer-assisted self interview (CASI) survey was administered to participating students to assess changes in knowledge, attitudes, intentions, behaviors, and skills over time. At the end of the program, a series of focus groups and key informant interviews were also carried out with separate groups of students, facilitators, and school staff not directly involved in the program to identify programmatic strengths and weaknesses and to inform final program revisions.

Quantitative Evaluation Methods—Pre- and Post-Survey

To assess changes in student knowledge, attitudes, beliefs, intentions, behaviors, and skills, Native STAND students completed a CASI survey at the beginning of the program and again at its completion. The survey was administered using a web-based form, and was made up of 20 multi-item measures. Topics included Native self-identity, perceived life chances, sexual behavior history, STD/HIV prevention knowledge, condom use self-efficacy, and partner communication. The survey questions were drawn and adapted from several existing questionnaires that have been implemented and validated in other settings. To verify comprehension, the tool was first pilot tested with 15 intertribal AI/AN youth attending an adolescent reproductive health training. Statistical analyses included response frequencies by gender, mean scores with standard deviations by item and composite measure index, and t-tests to examine differences pre- and post-intervention.

Qualitative Methods—Focus Groups and Interviews

Focus groups and interviews were conducted at each participating school approximately one to two weeks after completing the curriculum. In order to capture the full scope of possible responses, four different moderator guides were developed: a youth participant focus group guide, a staff and faculty focus group guide, a school administrator interview guide, and a Native STAND facilitator interview guide. With permission, discussions were taped using an audio recording device and/or detailed notes were taken by a designated notetaker. For analysis, a coding scheme with unique codes was developed by project evaluators and all transcripts and notes were read twice and coded. Qualitative data were then separated and reassembled by site (School #1, School #2, etc) and focus group/interview type (student, facilitator, administrator, etc) to examine outcomes by subset.

Evaluation Results

The Native STAND program effectively educated and empowered AI/AN high school students at four BIE boarding schools to help their peers address sensitive adolescent health issues and concerns, including healthy relationships, sexual health, violence, and drug and alcohol use. After participating in the 29-session curriculum, students demonstrated significant improvements in knowledge of STD/HIV prevention, reproductive health, and healthy relationships. Youth at all four sites reported providing one-on-one counseling and referrals to their peers post intervention. Adult facilitators learned how to better communicate and teach about sensitive topics, and the program was well received by school staff and administrators, who recognized that the program addressed critical gaps in sexual health education on campus.

The impacts of Native STAND are just beginning to take root and should continue to grow as new students are trained and past graduates take on their new roles as student peer educators. The energy and enthusiasm of the first group of students sparked interest among other students to participate the following year. More systematic changes in social norms and behavior can be expected after the "diffusion of innovation" moves throughout the school community. Ideally, future studies will continue to evaluate the program to see how peer educators take what they learned and apply it at their individual schools.

For more information about Native STAND, contact: Dana Cropper-Williams, National Coalition of STD Directors, by e-mail at *dcropper@ncsddc.org*; telephone (202) 842-4660. The Native STAND website will be going live shortly. Visit *www.nativestand.com* and check back often for updates.

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1. Hamilton BE, Martin JA, Ventura SJ. Births: Preliminary data for 2009. National Vital Statistics Reports, 2010;59(3). Hyattsville, MD: National Center for Health Statistics.
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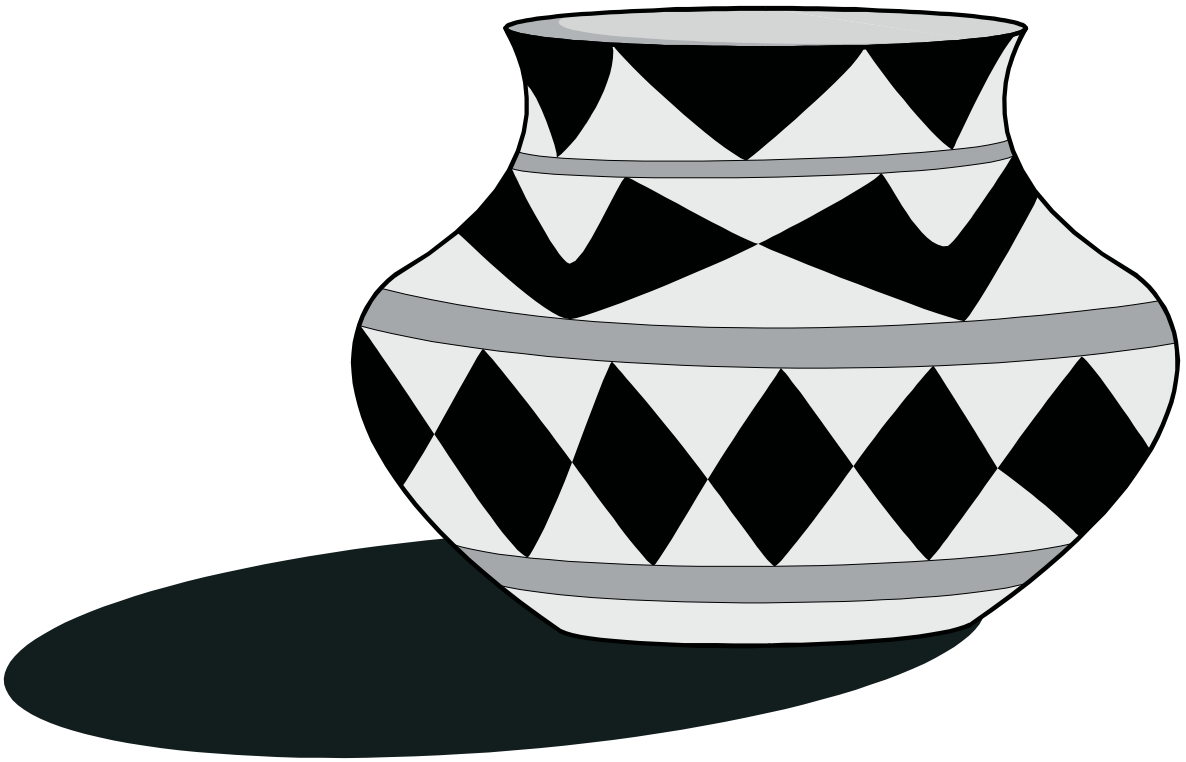
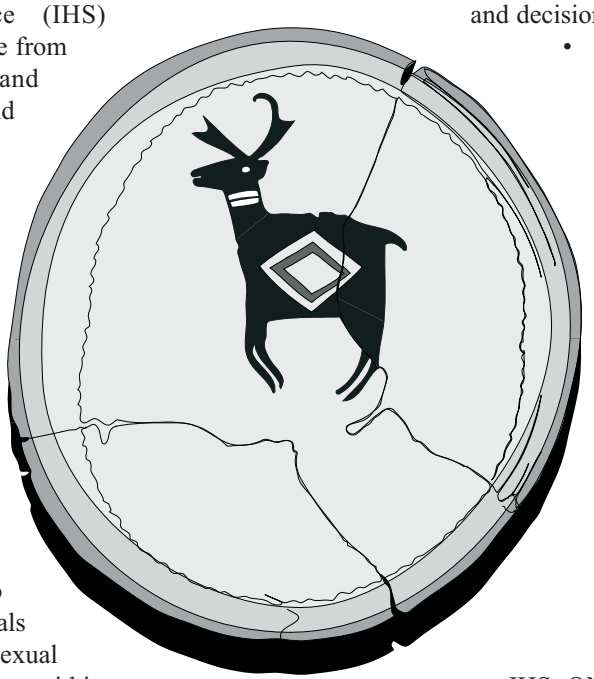


HIV/STD Tribal Advocacy Kit and Policy Guide for AI/AN Tribal Leaders

Colbie Caughlan, MPH, Project Coordinator, Northwest Portland Area Indian Health Board, Portland, Oregon

Tribal leaders and decision makers play a significant role in the health and wellbeing of tribal members. Their opinions are heard and respected. Their actions can influence others, and the tribal policies they create shape the lives of future generations. Because the decisions tribal leaders make can have such a long-lasting impact, health professionals and policy advocates must strive to communicate with tribal decision makers about the important health challenges within their communities.

The Indian Health Service (IHS) HIV/AIDS Program, with assistance from the Office of Minority Health and Resource Center (OMHRC) and Project Red Talon (PRT) of the Northwest Portland Area Indian Health Board (NPAIHB), designed the AI/AN Tribal HIV/STD Advocacy Kit and Policy Guide to specifically help tribal health advocates inform decision makers about the impact of STDs, HIV/AIDS, and unintended pregnancy on tribal health and the importance of implementing comprehensive prevention activities within their communities. The kit was also developed to aid health professionals and policy advocates in advancing sexual health program and policy initiatives within tribal communities.



To effectively address teen pregnancy and STDs, including HIV, it is imperative that community members overcome their discomfort and begin to take the steps necessary to protect future generations. Many tribal communities and health clinics do not have policies in place that address prevention, testing, and the treatment of HIV and other STDs. This is where tribal health leaders can step in and advocate to address gaps in sexual health programs and policies. Tribal leaders are an important resource for encouraging healthy community discussion and outreach on sexual health topics, in addition to shaping the programs and policies that protect their community's health.

The AI/AN Tribal HIV/STD Advocacy Kit will be available in April 2011 to all tribal communities that would like to gain support for policy implementation and other programmatic changes that can help prevent the spread of HIV and other STDs, reduce rates of unintended pregnancies, and address other issues important to sexual health. Health advocates can use "talking points" from the kit, provide kits for each Tribal Council member, and present the information included in the kit to their Tribal Council.

The kit includes information for tribal health advocates and decision-makers regarding:

- Facts and figures on the importance of addressing sexual health in our communities
- Tools for assessing community readiness to implement a sexual health program
  - Information on the policy change process and sample policy and resolution templates
  - Case studies of effective models for change in tribal communities
- Resources to strengthen community sexual health activities and policies
- Additional information and resources on a USB drive that accompanies each printed kit

IHS, OMHRC, and PRT -- all partners in the creation of the kit -- will promote this resource to tribal communities within their networks; however, printed kits can be requested by contacting the IHS HIV/AIDS Program at (301) 443-4644 or by e-mail at *lisa.neel@ihs.gov*. In addition, the kit will be available for download from several websites including:

- IHS HIV/AIDS Program: *www.ihs.gov/MedicalPrograms/HIVAIDS*
- OMHRC: *www.minorityhealth.hhs.gov*
- PRT: *www.npaihb.org/epicenter/project/project_red_talon*

Community Transformation Grants Are Coming Soon…

The Affordable Care Act includes funding to support new Community Transformation Grants (CTGs) for purposes of implementation, evaluation, and dissemination of evidence-based community preventive health activities. This grant program is designed to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence-base of effective prevention programming.

Who is Eligible?

- Indian tribes or tribal organization
- State and local governmental agencies
- Territories
- National networks of community based organizations
- State and local non-profit organizations

What Type of Activities Will Be Funded?

Applicants must devise a plan that lays out changes in policies, programs, environment, and infrastructure to promote healthy living and reduce disparities. Specific activities suggest providing sustained investments to

- Reduce tobacco use
- Reduce obesity (BMI
- Increase physical activity
- Increase healthy nutrition (such as consumption of fruits and vegetables, increases in low-fat milk consumption, and reductions in salt consumption)
- Reduce the severity and impact of chronic diseases and associated risk factors

Activities within the plan may focus on (but are not limited to):

- Creating healthier school environments, including increasing healthy food options, physical activity opportunities, promotion of healthy lifestyle, emotional wellness, and prevention curricula, and activities to prevent chronic diseases
- Creating the infrastructure to support active living and access to nutritious foods in a safe environment
- Developing and promoting programs targeting a variety of age levels to increase access to nutrition, physical activity and smoking cessation, improve social and emotional wellness, enhance safety in a community, or address any other chronic disease priority area identified by the grantee
- Assessing and implementing worksite wellness programming and incentives
- Working to highlight healthy options at restaurants and other food venues
- Prioritizing strategies to reduce racial and ethnic disparities, including social, economic, and geographic determinants of health
- Addressing special populations needs, including all age groups and individuals with disabilities, and individuals in urban, rural, and frontier areas

How Will National Organizations Be Involved in CTGs Program?

National organizations will be funded to provide training and technical assistance to funded communities to effectively plan, develop, implement, and evaluate community-based interventions to reduce the risk factors that influence the burden of chronic disease and associated risk factors in communities.

How Much Money is Available?

The Centers for Disease Control and Prevention's (CDC) Fiscal Year 2012 request of $221,061,000 from the Affordable Care Act Prevention and Public Health Fund will support CTGs.

Who Oversees the CTGs?

The CDC will award the grants, help develop community transformation plans, and provide training on effective strategies for the prevention and control of chronic disease and the link between physical, emotional, and social well-being.

How Will CTGs be Evaluated?

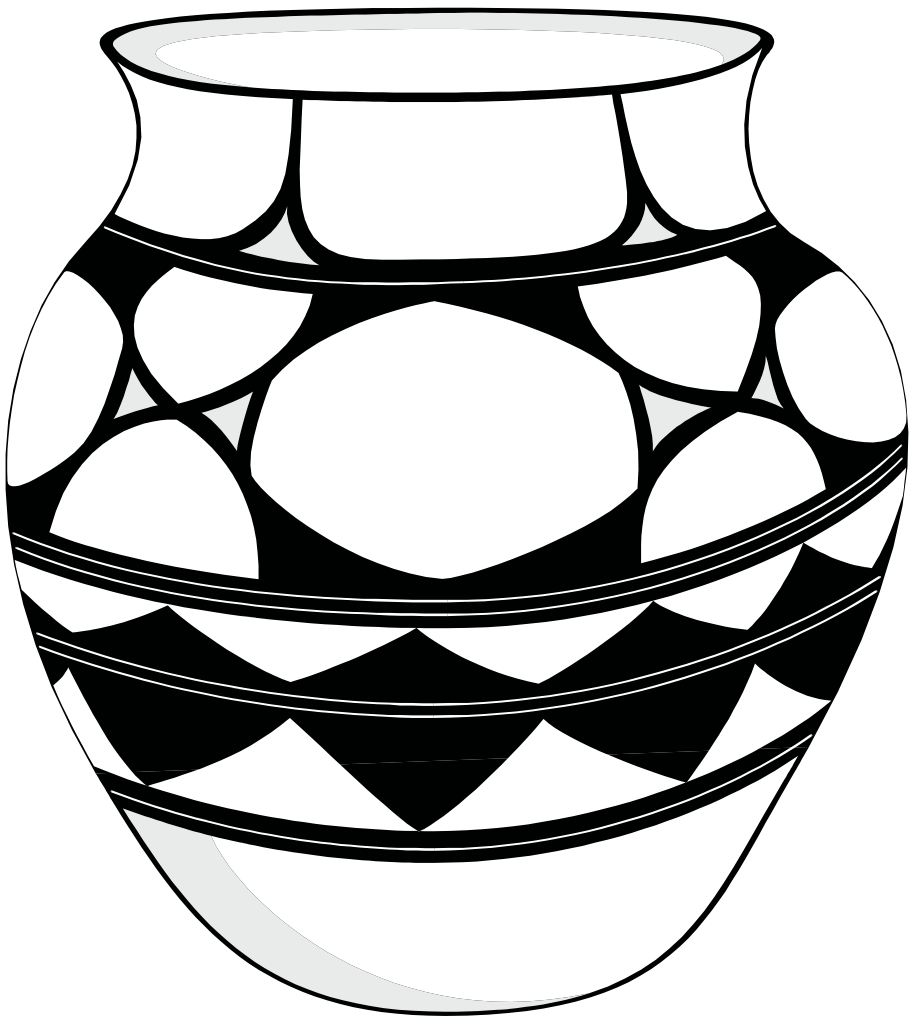
In general, funded programs will conduct activities to measure changes in the prevalence of chronic disease risk factors among community members participating in preventive health activities. In addition, the CDC will help devise a structure for evaluating programs.

Why Are CTGs Important?

Awarding CTGs will allow communities to focus on advancing state, local, tribal, and territorial policies and systems to reduce the leading causes of death, associated risk factors, and health disparities.

Where Can I Obtain More Information?

During 2011, CDC will announce the Funding Opportunity Announcement for the CTGs on www.grants.gov. For more details about CTGs, please see section 4201 of the Patient Protection and Affordable Care Act. For more information about the Affordable Care Act and Public Health Fund, visit *www.healthcare.gov*. Additional information will not be available until the Funding Opportunity Announcement is announced on *www.grants.gov*.



MAYO CLINIC

The Mayo Clinic and the Indian Health Service proudly announce

Save the Date!

"Intensive Case-Based Training in Palliative Care"

October 17-20, 2011
Rochester, Minnesota

This evolving and innovative program will include hands-on training using palliative care scenarios with live actors in the state-of-the-art Mayo Clinic Simulation Center, clinical rounds with Mayo Clinic staff in palliative care, pain management, and other teams, real-life case studies, and the opportunity to tailor training in specific areas of palliative care to meet your team or individual needs. The course is designed for those who wish to further their skills in clinical practice and program development in palliative care for their communities.

Participants: We can accept a total of 24 participants in teams of 2-4 individuals from an IHS, Tribal or Urban Indian Health program. Send the team that will be building or furthering your palliative care program. The most common teams include a physician, PA or NP, a nurse, and a social worker. Other members of a team could be a pharmacist, administrator, public health nurse, or CHR. More than one team may come from an Area.

Prerequisites: This is an intensive course, designed to build on existing knowledge and experience in providing palliative care. Applicants should have attended a previous EPEC-O for Indian Health training or have comparable experience in palliative care. EPEC-O for Indian Health training is available this year in a multiple-session palliative care track at the *Advances in Indian Health* conference in Albuquerque, NM, May 3-6, 2011. We will consider individuals or teams without those prerequisites on an individual basis.

Cost: The course itself is at no cost to the participant/team. Travel and per diem is the responsibility of the IHS, Tribal or Urban Indian health program. This remains an outstanding opportunity to receive world-class training in palliative care at relatively little cost. Travel dates will be Oct 16 & 21.

The deadline for applications is July 1, 2011. Applications will be accepted on a first-apply, first-approved basis. Selected team members will receive confirmation letters by email. Do not make travel arrangements without a confirmation letter from the Clinical Support Center indicating you were selected to attend. Register on line at http://www.csc.ihs.gov "Event Calendar."

For more information, please contact: Bret Benally Thompson, MD at Bret.BenallyThompson@ihs.gov

ACCREDITATION
The Indian Health Service (IHS) Clinical Support Center is accredited by the Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians.

The IHS Clinical Support Center is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

POSITION VACANCIES

Editor's note: As a service to our readers, The IHS Provider *will publish notices of clinical positions available. Indian health program employers should send brief announcements as attachments by e-mail to* john.saari@ihs.gov. *Please include an e-mail address in the item so that there is a contact for the announcement. If there is more than one position, please combine them into one announcement per location. Submissions will be run for four months and then will be dropped, without notification,, but may be renewed as many times as necessary. Tribal organizations that have taken their tribal "shares" of the CSC budget will need to reimburse CSC for the expense of this service ($100 for four months). The Indian Health Service assumes no responsibility for the accuracy of the information in such announcements.*

WIC Coordinator
Southeast Alaska Regional Health Consortium (SEARHC); Juneau, Alaska

SEARHC invites registered dietitians to apply for a community dietitian opening on the SEARHC health promotion team. The baseline qualifications are a BS in community nutrition/dietetics or a nutrition related field. Four years clinical nutrition and/or community nutrition work experience with progressive experiences in maternal/child nutrition, outpatient medical nutrition therapy, and program planning and administration. Must be a registered dietitian and eligible for dietetic licensure in the State of Alaska.

The WIC Coordinator/RD works as a member of the SEARHC health promotion team to assess for, plan, implement, administer, and evaluate nutrition and health education programming that responds to Goals 8 and 9 in SEARHC's strategic plan. The WIC Coordinator also works to ensure high quality WIC services are provided to eligible women, infants, and children throughout southeast Alaska. Additionally, the WIC Coordinator partners with organizations working with the WIC population to make appropriate referrals and to enhance the WIC program.

SEARHC is a nonprofit tribal health consortium of 18 Native communities, which serves the health interests of the Tlingit, Haida, Tsimshian, and other Native people of southeast Alaska. Residents of southeast Alaska towns share a strong sense of community. Residents take full advantage of the excellent opportunities for fishing, boating, skiing, hiking, and other outdoor activities. Applications are available online at *www.searhc.org*, or contact our Human Resources Office at (907) 966-8311 or send an e-mail to *hr-web@searhc.org*. (06/11)

Family Nurse Practitioner
Family Practice Physician
Physician Assistant
Pharmacist
Dentist
Clinical Social Worker (3)
School Social Worker
Behavioral Coordinator
Child Adolescent BHS Coordinator
Substance Abuse Treatment Coordinator
Alamo Navajo School Board, Inc.; Alamo, New Mexico

The Alamo Navajo Health Services is seeking applicants to fill numerous positions. Our organization requires background investigation as required by law. ANSB, Inc. offers a benefits package including medical, dental, vision, life, and disability insurance, and a 403B retirement plan. ANSB, Inc. gives Navajo/Indian Preference to qualified applicants. For information about qualifications and requirements, and to request for a position description or application, please call the Personnel Office at (575) 854-2543 ext. 1309 or 1304; or e-mail *rkelly@ansbi.org*. (5/11)

Clinical Director
Confederated Tribes of the Umatilla Indian Reservation; Pendleton, Oregon

Yellowhawk Tribal Health Center houses a fully accredited, primary care medical facility located on the Confederated Tribes of the Umatilla Indian Reservation. We are looking for a highly motivated, dedicated clinical director to join our already established two-provider practice. We offer excellent hours in a team environment, a well-funded and well-equipped clinic, a competitive salary, and an outstanding benefits package with relocation assistance, and signing bonus. Yellowhawk is located 10 minutes from Pendleton, Oregon, in the foothills of the beautiful Blue Mountains. Come and experience our culture and a rewarding practice where the focus is on quality patient care. Please contact Janyce Quaempts at YTHC, PO Box 160, Pendleton, Oregon 97801; telephone (541) 278-7549; e-mail *janycequaempts@yellowhawk.org*; or see our website at Yellowhawk.org. (5/11)

Hospital Quality Manager
Community Health Services Quality Manager
Safety and Infection Control Officer
Data Specialist
SouthEast Alaska Regional Health Consortium (SEARHC); Sitka, Alaska

Are you passionate about quality improvement and patient satisfaction? Do you enjoy applying new approaches to difficult problems? Do you have a positive attitude and desire to succeed? If so, an exciting opportunity awaits you in scenic Sitka, Alaska. SEARHC recently created a Performance Improvement Division and is recruiting for the following positions:

- Performance Improvement Director: a new position responsible for management of all aspects of the program including customer service, accreditation, infection prevention and control, and patient safety. Position reports directly to the COO and works closely with other division directors in managing and directing the health programs of SEARHC.
- Hospital Quality Manager: responsible for infection control, patient safety activities, patient satisfaction, risk management, hospital accreditation through the Joint Commission, and data management.
- Community Health Services Quality Manager: responsible for infection control, patient safety activities, patient satisfaction, risk management, accreditation through AAAHC, and data management.
- Safety and Infection Control Officer: responsible for infection control, emergency preparedness, risk assessments, and safety surveys.
- Data Specialist: part-time position responsible for data management, analysis, and reporting used to improved quality of care and customer satisfaction.

Native American preference applies. Apply online at www.searhc.org. For more information e-mail Connie Goldhahn at *connieg@searhc.org*; telephone (907) 966-8629. (4/11)

Family Practice PA-C
Family Nurse Practitioners
Family Practice Physicians
Fort Thompson Health Center; Fort Thompson, South Dakota

The Ft. Thompson Health Center in Ft. Thompson, South Dakota is seeking board eligible/board certified physicians and mid-levels with at least 1 - 2 years post-residency experience. We are also in need of family practice physician assistants and family nurse practitioners. Ft. Thompson is located in rural south central South Dakota, east of the Missouri River on the Crow Creek Indian Reservation, and is approximately 80 miles from the Nebraska border. We are a busy clinic that offers the following services: family practice, ob/gyn, pediatrics, optometry, dentistry, dietary counseling, and behavioral health. Our staff is dedicated and devoted to providing quality patient care. The beautiful Black Hills, Badlands, Custer State Park, Mount Rushmore, and Crazy Horse Memorial are just 2 - 3 hours away. South Dakota is an outdoorsman's paradise with plenty of sites for skiing, hiking, hunting, fishing, boating, and horseback riding. Steeped in western folklore, Sioux cultural history, and land of such famous movies as "Dances with Wolves" and "Into the West," there is plenty for the history buff to explore. If you are interested in applying for a position, please contact Mr. Robert Douville, Clinical Services Administrator at (605)245-1514; e-mail him at *robert.douville@ihs.gov*; or Diana Rodriguez, MD, Medical Director at (605) 245-1516; e-mail her at *diana.rodriguez@ihs.gov*. (4/11)

Internist
Family Practice Physician
Family Practice Nurse Practitioner
Internal Medicine Nurse Practitioner
Oklahoma City Indian Clinic; Oklahoma City, Oklahoma

The Oklahoma City Indian Clinic is a comprehensive ambulatory health care facility located in the Oklahoma City metropolitan area. The clinic is a non-profit Urban Indian health facility. From its beginning in 1974 as a volunteer, after hours clinic, it has grown to serve over 16,000 patients. Clinical services offered on-site include Family Medicine, Internal Medicine, Podiatry, Pediatrics, Dental, Optometry, Radiology, Public Health, Behavioral Health and WIC. The clinic also has a Laboratory and Pharmacy.

The full-time medical staff includes two family physicians, a pediatrician, two physician assistants and a pediatric nurse practitioner. We are currently recruiting for a board certified/board eligible family medicine physician and an internal medicine physician for our growing clinic. Operating hours for the clinic are 8:00 am – 5:00 pm Monday through Friday; no nights, weekends, or on-call. The clinic offers competitive salary, excellent benefits, retirement, and holidays off. The clinic pays 100% of premiums for medical and dental insurance for employee and family. The clinic also pays for licensures, liability insurance, and CME.

The Oklahoma City Indian Clinic is located in the heart of Oklahoma City and offers limitless entertainment, cultural, and recreational opportunities. Enjoy shopping, fine dining, downtown night life, museums, NBA basketball, Division 1 college football, professional baseball, and hockey. There are also major universities and colleges close by for continuing education opportunities. Oklahoma City's economy continues to grow. As reported in USA Today and Newsweek, Oklahoma

City has proven to be one of the most recession-proof places to live in the United States.

For more information, inquiries, or if interested, please contact Dr. Mark James, Medical Director, at (405) 948-4900 ext. 238 or by e-mail at *mark.j@okcic.com*; or Monica Tippit, Director of Human Resources at (405) 948-4900 ext. 214 or by e-mail at *monica.t@okcic.com*. (4/11)

Family Practice Physician
Social Worker
Consolidated Tribal Health Project; Redwood Valley, California

The Consolidated Tribal Health Project in Redwood Valley, California is recruiting for a family practice physician and a social worker. These positions are full-time with benefits; salary DOE. All applicants will be considered; Native American preference applies. Visit *www.cthp.org* for an application and job description. Send application and resume to HR Department by fax at (707) 485-7837. ADA/EEO. (3/11)

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MEETINGS OF INTEREST

Advancements in Diabetes Seminars
Monthly; WebEx

Join us monthly for a series of one-hour WebEx seminars for health care program professionals who work with patients who have diabetes or are at risk for diabetes. Presented by experts in the field, these seminars will discuss what's new, update your knowledge and skills, and describe practical tools you can use to improve the care for people with diabetes. No registration is necessary. The accredited sponsors are the IHS Clinical Support Center and IHS Nutrition and Dietetics Training Program.

For information on upcoming seminars and/or previous seminars, including the recordings and handouts, click on this link and see Diabetes Seminar Resources: *http://www.diabetes.ihs.gov/index.cfm?module=trainingSeminars*

Available EHR Courses

EHR is the Indian Health Service's Electronic Health Record software that is based on the Resource and Patient Management System (RPMS) clinical information system. For more information about any of these courses described below, please visit the EHR website at *http://www.ihs.gov/CIO/EHR/index.cfm?module=rpms_ehr_training*. To see registration information for any of these courses, go to *http://www.ihs.gov/Cio/RPMS/index.cfm?module=Training&option=index*.

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Indian Health Service
Clinical Support Center
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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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Opinions expressed in articles are those of the authors and do not necessarily reflect those of the Indian Health Service or the Editors.

Circulation: The PROVIDER (ISSN 1063-4398) is distributed to more than 6,000 health care providers working for the IHS and tribal health programs, to medical schools throughout the country, and to health professionals working with or interested in American Indian and Alaska Native health care. If you would like to receive a copy, send your name, address, professional title, and place of employment to the address listed below.

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