



THE IHS PRIMARY CARE PROVIDER

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



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Editor's Note: In commemoration of American Heart Month and consistent with the Department of Health and Human Services' plan to designate the February issue of The Provider as the annual issue devoted to heart health, we present the following articles devoted to this topic.

Hormone Replacement Therapy and Cardiovascular Disease

Beth R. Malasky, MD, FACC, The Native American Cardiology Program, Tucson, Arizona

Hormone replacement therapy has recently come into the spotlight in both the lay and medical press. The long held belief that hormone replacement therapy had significant cardioprotective effects for postmenopausal women was based primarily on observational studies and prospective trials assessing intermediate end-points. Estrogen replacement therapy had favorable effects on lipid profiles, angioplasty results, and outcomes after bypass surgery. Cohort studies, mainly the Nurse's Health Study, showed significantly lower rates of myocardial infarction and stroke among the women on combination hormone replacement therapy (HRT). Estrogen improves endothelial function, decreases low density lipoprotein (LDL), inhibits oxidation of LDL, increases high density lipoprotein, and decreases Lp(a) and fibrinogen. While progesterone ameliorates some of the positive effects of estrogen therapy on lipids, the Nurse's Health Study found reductions in coronary heart disease among women taking combination therapy. Since women experience a ten year lag in the onset of coronary artery disease compared with men, and this delay was thought to be due to the hormonal milieu prior to menopause, it made perfect sense to try to recreate that hormonal environment and stave off the 30-fold rise in coronary heart disease that occurs with menopause.

The average age of menopause in the US is 51 years. Approximately one million women each year undergo menopause. With a life expectancy of 80 years, one-half to one-third of a woman's life may be spent in a postmenopausal state. Menopause is defined as the end of ovarian function and generally occurs over 2-8 years. During that time there is a decline in estrogen and progesterone levels, along with increasing

levels of follicular stimulating hormone (FSH).

The clinical definition includes 12 months without menses, elevation of FSH to greater than 50 IU/ml and estradiol levels below 50 pg/ml. These hormonal changes result in distressing clinical symptoms in the majority of women. Hot flashes, with their associated flushing, vasodilation, and perspiration, occur in 50% to 80% of women and can last from 5 years to 15 years. The intensity and severity of hot flashes vary among women. Insomnia also increases after menopause and may result in decreased mental acuity, irritability, depression, and increased fatigue.

In this Issue...

- 21 Hormone Replacement Therapy and Cardiovascular Disease
- 25 Clinical Cardiology Services within the Indian Health System
- 27 Cardiovascular Prevention Activities within Indian Health: A Status Report
- 29 The Indian Health Service Integrated Diabetes Education Recognition Program: A System to Assure Quality Diabetes Services in I/T/U Facilities
- 34 Reviewers Needed for IHS Integrated Diabetes Education Recognition Program
- 35 Recording Health Factors in the RPMS System
- 38 The Indian Health Services 16th Annual IHS Research Conference
- 42 Position Vacancies
- 44 Meetings of Interest

Urogenital changes include vaginal wall thinning and degeneration, decreased elasticity, decreased lubrication, dyspareunia, pelvic laxity with prolapse, increased urinary tract infections, and incontinence. Osteoporosis is a major health concern for women and increases significantly after menopause, affecting 50-68% of women over the age of 50. Bone loss accelerates at the time of menopause, increasing from 0.3%/year to 3%/year for approximately five years. By 5 to 7 years after menopause, women have lost approximately 20% of their bone mass.

Menopause and aging are associated with increases in body mass index, hypertension, diabetes, and the metabolic syndrome. Since cardiovascular disease is the leading cause of mortality among women, and because one out of every two women will die of heart disease or stroke, this postmenopausal increase in risk factors is important. The protective effects of hormones were believed to delay the onset of heart disease, and the postmenopausal increase in heart disease was presumed to be due to a deficit of these hormones, so it seemed logical that hormone replacement was the correct course of action.

The Heart and Estrogen/Progesterone Replacement Trial (HERS)

The Heart and Estrogen/Progesterone Replacement Trial (HERS) was the first trial that undermined this thinking. The HERS trial was the first large-scale, double-blinded, randomized, prospective trial to assess the effects of hormone replacement on risk of coronary heart disease, looking at hard clinical events such as myocardial infarction or death from cardiovascular causes. In this study, 2,763 postmenopausal women, average age of 67 years, with known coronary artery disease or coronary artery disease equivalents were randomized to conjugated equine estrogen (CEE) 0.625 mg and medroxyprogesterone (2.5 mg) or placebo. Initial follow-up was 4.1 years. In the first year of therapy, there was a 50% increase in cardiac events. By the end of the trial, there was no significant difference in nonfatal myocardial infarction or cardiac mortality.

Given concern that the positive effects of HRT were being missed because follow-up was too short to see the benefits, an open-label follow-up study extended to 6.8 years, HERS II, was proposed. Even with longer follow-up, there was no difference in cardiovascular event rates or mortality for the HRT arm compared to placebo. There was a significant increase in deep venous thrombosis, pulmonary emboli, and gallbladder disease among the HRT patients. There was a nonsignificant increase in breast cancer rates and overall cancer rates among the HRT group. Interestingly, there was no significant difference in the overall fracture rate between HRT and placebo, calling into question a primary indication for use of hormone therapy.

Women's Health Initiative (WHI)

Given the results of HERS and HERS II, the benefits of HRT were called into question. Since these trials were performed

to assess benefits of HRT in secondary prevention, it was unknown whether HRT might be cardioprotective as a primary prevention measure. The Women's Health Initiative (WHI) sought to answer this question. In this study, 16,608 healthy, postmenopausal women, mean age of 63 years, were randomized to combination therapy with CEE and medroxyprogesterone or placebo and were to be followed for 5.2 years. An arm of the trial evaluated CEE alone versus placebo in women who had undergone a hysterectomy.

The combination treatment arm was stopped early secondary to excess rates of breast cancer. Outcome analysis again revealed a significant increase in coronary heart disease rates among women treated with HRT compared to those on placebo (hazard ratio of 1.29). Results confirmed an almost 2-fold rise in cardiovascular events during the first year of therapy. For every 10,000 patient years of treatment, there would be 7 additional cardiac events in the treatment arm above event rates in the placebo arm. There was also an increase in breast cancer rates of borderline significance with a hazard ratio of 1.26 but with confidence intervals touching 1.0. For every 10,000 patients years of treatment, there would be 8 extra breast cancer cases in the treatment arm. Venous thromboembolism rates were significantly higher and, in fact, doubled in the treatment arm. While there was a significant decrease in the overall fracture rate for women in the HRT arm, there was no significant difference in hip fracture rates between the HRT and placebo.

Where did we go wrong? First, the bulk of the data prior to these trials was observational rather than randomized. Since observational trials cannot correct for other factors that may alter risk, the strength of the data is limited at best. Given a standard benefit from placebo in many trials, any results from therapy not assessed against a placebo cannot prove therapeutic benefit above placebo. In other words, all benefit seen might be placebo effect and the same results might have been achieved with a placebo. The scientific soundness of double-blind trials results in controlling behavioral alterations on the part of both the patient and physician that might occur depending on the therapy. Lastly, many of our assumptions regarding the benefits of HRT were based on trials assessing intermediate end-points such as lipid profiles, endothelial function, or plaque burden rather than clinical events. It may seem logical to assume that if a therapy improves lipid profiles and people with better lipid profiles have fewer coronary events, then the therapy that improves lipid profiles will decrease coronary event rates. Scientific study, however, has clearly shown that intermediate endpoints are not surrogates of clinical endpoints.

What are some of the limitations of these trials? The mean age of the women in these trials was significantly older than the mean age of menopause, suggesting that the population in the trials does not represent the typical perimenopausal patient presenting to her physician for consideration of hormone therapy. Subgroup analysis of the HERS trial showed a similar increase in the cardiac event rates among all the age groups.

The estrogen used in almost all US trials is CEE while

worldwide 75% of HRT has 17 β -estradiol as the estrogen component. Almost all US trials use medroxyprogesterone as the progestin, so there is no data regarding clinical effects of different progestins on clinical endpoints. There are clear data that different progestins as well as different dosing regimens have different side effect profiles and different pharmacologic effects on lipid profiles. We do not have data to determine if different agents, different delivery systems, or different dosing regimens might result in different outcomes. We also do not have data to determine if estrogen without a progestin may have cardioprotective effects, though the remaining arm of the WHI may answer that question. Much lower doses of estrogen improve bone density, and it is possible that lower doses may result in improved cardiovascular outcomes, though this is speculative.

On the other hand, approximately 50% of women stop HRT in the first year due to unacceptable side effects, and by three years, approximately 70% to 80% of women have stopped HRT. The main reasons for stopping HRT are vaginal bleeding and breast pain. Other less common side effects include headache, weight gain, depression, and bloating. Side effects vary depending on the type of progestin. Often the type of HRT may be guided by a woman's tolerance of oral contraceptive prior to menopause. Notably, the concentration of hormones in HRT is much lower than the concentrations in oral contraceptives.

What can we offer our patients?

Hormone replacement therapy is the most effective treatment for the symptoms of menopause. HRT is 75-90% effective in treating hot flashes and sleep disturbances associated with menopause in the majority of women. Megestrol, clonidine, and methyldopa are effective for decreasing hot flashes but have significant side effects as well as medication interactions that limit their utility. Phytoestrogens may decrease the intensity but not frequency of hot flashes; in a controlled trial rhythmic deep breathing decreased hot flashes by 39%; black cohosh may decrease sleep disturbances; and selective serotonin reuptake inhibitors may diminish hot flashes and sleep disturbances, although the data are relatively limited at this time.

Practical suggestions include maintaining cool ambient temperatures; avoiding hot or spicy foods, alcohol, and caffeine; regular exercise; and dressing in layered clothing. Atrophic vaginitis with urinary tract infections may be treated with local estrogen creams. Pelvic floor laxity can be treated with pelvic floor exercises, urethral sphincter collagen injections, pessaries, biofeedback, and electrical stimulation. The benefits of estrogen for stress incontinence are unclear. Lubrication locally can be very effective for minimizing dyspareunia.

HRT increases bone density and may decrease fracture rates. Proven alternative treatments include increased calcium intake, isoflavones, weight-bearing exercise, bisphosphonates, and selective estrogen receptor modifiers (SERMS). Ultimately, the decision must be based on a thoughtful evaluation of the risks and benefits of HRT in each individual woman. If

the woman is taking HRT solely for osteoporosis, there are clearly effective and safe alternatives. If the symptoms of menopause are refractory to other therapies and quality of life is significantly compromised, HRT may be the only option.

If a woman has been on HRT for reduction of cardiovascular risk, it seems clear that this is not an appropriate therapeutic choice, and she should be tapered off the therapy. There are many proven ways to decrease cardiovascular risk, such as regular exercise, smoking cessation, dietary modification and weight loss, and lipid-lowering therapy, if indicated. Women who choose to stop HRT after many years may be plagued with the same menopausal symptoms that led them to take HRT in the first place. Alternative treatment of symptoms may be tried but approximately 25% of those who stop HRT will restart it due to recurrence of intolerable symptoms. It is unknown whether women who resume HRT after stopping suffer the same increased risk of cardiovascular events as those first starting therapy.

Conclusions

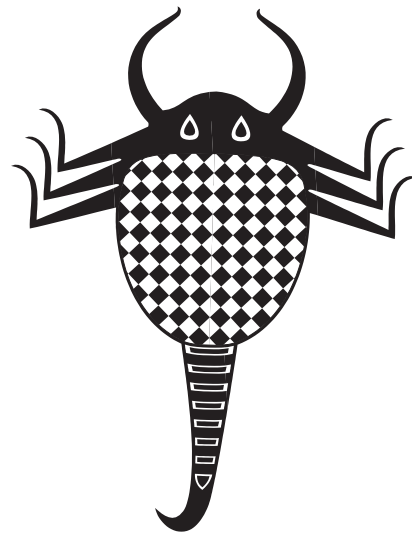
- In both primary and secondary prevention trials, HRT was associated with an increase in cardiovascular events, primarily during the first year of therapy.
- HRT is the most effective treatment for symptoms of menopause, such as hot flashes and insomnia.
- While osteoporosis increases at menopause and HRT improves bone mineral density, very safe and effective treatment alternatives are available.
- Urogenital symptoms may be effectively treated with local therapies.
- Data regarding the risks and benefits of estrogen without progesterone or very low dose preparations is not yet available.
- Conclusions regarding the studied combination of conjugated equine estrogen and medroxyprogesterone cannot be applied to all formulations without trials to study these other compounds.
- Cardiovascular disease increases in women significantly after menopause.
- Cardiovascular risk prevention with proven medical therapies and lifestyle modification is essential in the fight against coronary disease.

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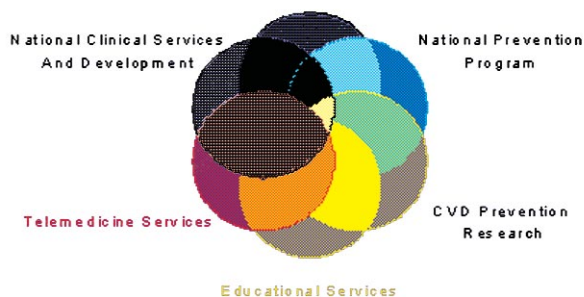
Clinical Cardiology Services within the Indian Health System

James M. Galloway, MD, FACP, FACC, Director; Eric A. Brody, MD, FACC, Associate Director; Beth Malasky, MD, FACC; Neil Freund, MD, FACC; M. Ynes Brueckner, MD, all from the Native American Cardiology Program, Tucson, Arizona

The Native American Cardiology Program (NACP) was started in 1993 as a collaboration between the Phoenix and Tucson Areas of the Indian Health Service; the Tucson Veterans Administration Medical Center; and the University of Arizona in Tucson, Arizona. As the IHS Cardiovascular Center of Excellence, the NACP was developed as a clinical cardiology program, providing services in Tucson as well as in the rural IHS hospitals and clinics of the southwest. Due to the increasing rates of cardiovascular disease (CVD), the program has grown and, under the direction and guidance of our tribes and service units, has expanded its services in a number of arenas. The NACP offers a comprehensive array of sophisticated clinical care and preventive services; in addition, the program emphasizes the provision of educational services, development and expansion of clinical cardiology programs, prevention research activities, and the increasing use of telemedicine and related technologies for clinical care and provider education.

The Native American Cardiology Program

Phoenix, Navajo and Tucson Area Direct Clinical Services



In the southwest, in partnership with our communities and service units, additional services are available via advanced

telecommunication technology. These “telecardiology” services include clinical and preventative consultation, immediate and routine echocardiography interpretation and Holter monitoring and event recording interpretation and coordination. Within the resource limitations of our program, the program is pleased to collaborate with and offer these services to other Indian health sites across the nation. The following three major NACP services could be considered as potentially available to your clinic or hospital site.

Echocardiography (Cardiac Ultrasound) Interpretation

The availability of echocardiography is very important for the diagnosis and treatment of patients with known or suspected heart disease, and, in acute situations, a well-performed and promptly reviewed echocardiogram can be life saving. Indeed, the assessment of wall motion abnormalities in the emergency setting provides significant guidance in the difficult decision related to the administration of thrombolytics and the appropriate transfer for acute intervention.

Generally, an echocardiogram is performed by a trained technician (sonographer) using an appropriate echocardiogram machine (although the NACP, in conjunction with the University of Arizona, has trained a number of physicians in the acquisition of echocardiographic images as well as the basic interpretation of echocardiograms). In ideal situations, the sonographer records the video on videotape or as a digital file, and a cardiologist at that site then reviews the study. However, in most Indian health facilities, this level of expertise is often not available. Therefore, the study may be interpreted by another trained physician, skilled in echocardiography interpretation or, alternatively, the study may be physically transported to another center for delayed review. Many IHS or tribal facilities do not have any capacity for echocardiography, in part because a sonographer may not be available and/or prompt interpretation by a cardiologist is not available. The lack of prompt interpretation may result in the possibility of a delayed diagnosis or inappropriate therapy.

In the southwest, the NACP has developed a service offering traveling contracted sonographers to various sites, along with the availability of immediate echocardiographic interpretation, as well as prompt reviews for non-urgent studies. This service, based on secure information technology methodology, uses an “encoder” to convert echocardiograms to digitally compressed files that can then be immediately (within minutes) transmitted to our IHS server in Tucson. The study can then be accessed

by an IHS cardiologist for emergent or prompt review. Rapid study transmission times and automated notifications to cardiologists allow for a prompt review of studies and an enhanced level of care.

Clearly, the potential benefits are significant for rural Indian health hospitals and clinics. Delays in diagnosis and treatment can be reduced, resulting in a dramatic increase in quality of cardiovascular care across the entire Indian health system.

Holter Monitor And Event Recorder Program

Due to discoveries of suboptimal Holter and event monitor systems for the diagnosis of arrhythmias by some of the sites we serve, the NACP has also developed a centralized capability for Holter monitor and event recording interpretation. This system utilizes a company that provides the necessary equipment (at a reasonable rate) for the rural placement of this equipment at the ordering site with direct connectivity to the NACP. This is coupled with rapid study transmission to NACP for reading, allowing for 48-72 hour availability of faxed results to the ordering provider and urgent/emergent phone call notification about more serious results and concerns. This system allows for an integrated and uniform approach to cardiac rhythm disturbances for our patients.

Telemedicine Services

The NACP, in collaboration with the Arizona Telemedicine Program and the University of Arizona, has established telemedicine services that are potentially available to any IHS or tribal site across the nation with telemedicine equipment and appropriate connectivity. These opportunities for collaboration include the monthly IHS Cardiology Grand Rounds (CME), scheduled clinical evaluations of patients for cardiovascular disease at a distance, and the use of real time telemedicine for emergency echocardiography. In addition, based on work done to date at the Tuba City Regional Health Care Corporation, on-site dobutamine stress echocardiography can be offered for those facilities with sonographers (or physicians trained in image acquisition) and physicians with dobutamine stress testing expertise and training. These services may offer greater convenience, decreased transportation needs, and cost savings for those served at your clinical site.

If your hospital or clinical site is interested in developing a collaboration with the Native American Cardiology Program related to any of these services, please call Dr. Galloway at (928) 214-3920.

The authors would like to acknowledge the expertise and assistance of Dr. Mark Carroll, Chief Medical Officer, Tuba City Regional Health Care Corporation, for his generous efforts related to this article, as well as his continued outstanding guidance in the development and optimal use of appropriate, leading edge technology within the NACP.



Cardiovascular Prevention Activities within Indian Health: A Status Report

James M. Galloway, MD, FACP, FACC, Director, The Native American Cardiology Program, Tucson, Arizona

In the past, the rates of risk factors for atherosclerosis and cardiovascular disease (CVD) as well as the manifestations of coronary heart disease, stroke, and peripheral vascular disease in Native Americans appears to have been quite low compared to the general US population. However, over the past several decades the rates of cardiovascular risk factors among American Indians and Alaska Natives have markedly increased, with the concomitant development of a significant and alarming rise in the manifestations of atherosclerosis and cardiovascular disease.

Indeed, since 1968, the age adjusted CVD mortality rates within the general U.S. population have declined by more than 50%.¹ During this same period, however, among American Indians and Alaska Natives (AI/AN), the incidence of CVD has dramatically increased with CVD incidence rates now at almost double that of the general U.S. population.² Indeed, CVD has become the leading cause of death for American Indians. CVD has also become a major source of disability, hospitalization, and both inpatient and outpatient procedures. As a result, a need for effective and aggressive primordial, primary, secondary, and tertiary prevention activities has become widely recognized by Indian communities as well as by those working within the Indian health system.

Within the past year or so, due to the dedicated efforts of many outstanding individuals within Indian communities as well as in private and federal agencies, there have been multiple, significant successes in this arena. We would like to take this opportunity to celebrate the successes of our team, our colleagues, our neighbors, and our partners in these CVD prevention efforts and would like to share their successes with you.

A major success has been the entry of the Indian Health Service into the Healthy People 2010 CVD Prevention Partnership with the American Heart Association, the Centers for Disease Control and Prevention (CDC), the National Heart, Lung, and Blood Institute (NHLBI), Centers for Medicare and Medicaid (CMS), and the Office of Disease Prevention and Health Promotion (ODPHP), developing the ability to focus significant national expertise and resources on the prevention of CVD and its consequences within American Indian communities. Currently, this partnership is involved with a number of the projects described below.

The establishment of a National AI/AN CVD Prevention

Committee, involving staff from IHS and the National Heart, Lung and Blood Institute, has fostered the development of focused CVD activities. This committee's goals have been to further coordinate and enhance current and future CVD prevention activities within Indian communities, as well as to provide oversight to some of the activities described below.

A successful National Roundtable on CVD Prevention among American Indians and Alaska Natives was held in Washington, DC on September 25 and 26, 2003. Experts in CVD prevention (including the American Heart Association, the American Diabetes Association, the American College of Cardiology, National Institutes of Health, Centers for Disease Control, leaders of academic CVD Prevention programs, and others) were brought in to assist tribal leaders in developing a strategic plan for the prevention of CVD within Indian communities.

A collaboration between the Indian Health Service and the National Heart, Lung, and Blood Institute led to the development and funding of a national Strengthening The Heartbeat of American Indians and Alaska Natives "Train the Trainers" CVD Prevention Conference in Phoenix in December, 2003. This week-long program began with a one-day tribal leaders meeting for education and the development of successful collaborations for the prevention of heart disease among American Indians and Alaska Natives. The ensuing meeting provided training for community leaders and faculty for a planned series of regional train-the-trainer CVD prevention conferences throughout the US in 2004-2005 with subsequent community dissemination.

These plans include developing prevention efforts and trainings for more than 200 tribes and urban Indian communities. The training manual for this course, the Native American-specific Heart Healthy Manual, was developed by NHLBI in conjunction with IHS and three tribal communities who received NIH funding for the development of prevention programs within their communities: the Ponca Tribe in Oklahoma, the Bristol Bay Corporation in Dillingham, Alaska and the Laguna Pueblo in New Mexico. Other sites that are initiating new or expanding current CV Prevention projects with support from IHS include the Santa Fe Indian Hospital, in New Mexico; the Clinton Service Unit, in Oklahoma; Crow Agency, Montana; and the Northern Cheyenne Service Unit, Lame Deer, Montana.

A national Indian health provider CVD prevention and treatment education program has been completed recently, incorporating regional seminars throughout the country, along with the broad distribution of educational guidelines and

materials through multiple mechanisms. A number of trainings for public health nurses and community health representatives on this topic have been held as well.

The Indian Health Service is participating with NHLBI in a “Stop Atherosclerosis in Native Diabetics” (SANDS) project, a five year, multi-center scientific evaluation of the benefit of more aggressive secondary prevention of CVD among those at the highest risk: those individuals with diabetes mellitus.

Members of the prevention committee have participated in the American Diabetes Association/American College of Cardiology collaboration entitled the “Make The Link,” which promotes community and provider education focusing on the link between diabetes and heart disease.

There are plans for a national “Prevention of CVD and DM Among Native Americans” conference to be held in spring 2005 in Phoenix, in conjunction with the Joslin Diabetes Clinic and multiple other partners (including the American Heart Association, the American College of Cardiology, the American Diabetes Association, National Institutes of Health, Centers for Disease Control and Prevention, the University of Arizona, and others). This conference will focus on cutting edge clinical and community prevention knowledge and expertise.

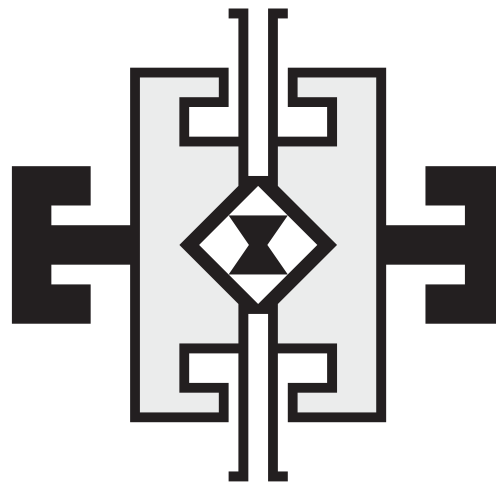
In addition, a number of efforts have been focused on the development of clinical reminders, registries, and other mechanisms to ensure appropriate CVD prevention interventions during clinic visits, including lipid and blood pressure control, as well as educational reminders for patients, as an option integrated within the PCC+ system.

Finally, the Indian Health Service and tribal communities, with support from the American Heart Association, are working on an initial trial of the national “Get With The Guidelines” program to ensure that appropriate secondary prevention efforts are made at the time of hospital discharge for patients with coronary artery disease. We are beginning efforts to implement this within our clinics for outpatient use as well.

All of these prevention efforts are the result of the collaboration between dedicated individuals from tribes and Indian communities, private, non-profit organizations, and federal agencies. While showing significant promise and initial success, these efforts are just beginning to have the impact of a significant and coordinated prevention effort. If you are interested in being a part of the team, those of us focused on the prevention of CVD among American Indians and Alaska Natives welcome your assistance and future participation.

Author’s Note: This article is written on behalf of the numerous individuals within Indian Health who are focused on the prevention of CVD among American Indians and Alaska Natives.

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The Indian Health Service Integrated Diabetes Education Recognition Program: A System to Assure Quality Diabetes Services in I/T/U Facilities

Tammy L. Brown, RD, MPH, BC-ADM, CDE, Nutrition Consultant, IHS National Diabetes Program, Albuquerque, New Mexico; Lorraine Valdez, RN, MPA, CDE, Nurse Educator Consultant, IHS National Diabetes Program, Albuquerque, New Mexico; Cecelia Shorty, Administrative Coordinator, Integrated Diabetes Education Recognition Program, Albuquerque, New Mexico; and JoAnne Lafley, MSN, CRNP, CDE, Review Coordinator, IHS Integrated Diabetes Education Recognition Program, Newfield, Maine

Introduction

In March 2002 the Centers for Medicare and Medicaid Services (CMS) approved the Indian Health Service (IHS) as a national accreditation organization for outpatient diabetes self-management education (DSME) services. With this approval, diabetes self-management training programs accredited by the IHS are able to receive “deemed” status under the Medicare program and are allowed to seek Medicare reimbursement of DSME services for Medicare Part B-eligible beneficiaries.

Achieving CMS approval as one of the two national accreditation organizations for outpatient diabetes self-management education (the American Diabetes Association is the other) is a culmination of the IHS’s history as a leader in setting standards for quality diabetes education and care. The IHS is a member of the consortium that developed and revised the *National Standards for Diabetes Self-Management Education*. Since 1986, the *IHS Integrated Diabetes Education and Care Standards* have been used by IHS, tribal, and urban (I/T/U) health care facilities to guide and improve diabetes education and care (See Figure 1 in opposite column).

The Integrated Diabetes Education Recognition Program (IDERP) — the IHS accreditation program approved by CMS — builds on this history by enabling I/T/U facilities, serving American Indians and Alaska Natives (AI/AN) and meeting the *National Standards for Diabetes Self-Management Education*, to seek recognition for quality diabetes education and care services. IHS Recognition has other benefits in addition to acknowledging the quality of the diabetes services, including:

- Medicare reimbursement of DSME.
- enhanced marketing of quality diabetes services to the community and providers.
- improved clinical and behavioral outcomes for participating patients with diabetes.

Further, there is no application cost for IHS recognition.

Figure 1. Timeline of events leading to the IDERP

| Timeline |
|--|
| 2002: IHS approved by CMS as national accreditation organization for DSME services |
| 1988: ADA Diabetes Care Standards developed |
| 1986: IHS Integrated Diabetes Education and Care Standards developed |
| 1986: National Certification Board for Diabetes Educators (CDE exam) |
| 1986: IHS Clinical Standards of Diabetes Care Developed |
| 1984: <i>National Standards for Diabetes Self-Management Education</i> developed (revised 1995 and 2000) |

IDERP is also the only national accreditation program that provides the flexibility of a three-stage approach to meeting standards and recognizes program integration of educational, clinical, and public health standards. Programs at Level 1, or the developmental stage, are beginning to work on developing a quality program. Programs that complete Level 2, or the educational stage, have a quality diabetes education service in place. Completion of Level 3, or the integrated stage, means that a facility is offering the best in diabetes care and education practices by integrating community-wide prevention programs, diabetes clinical systems, and educational programs for people with diabetes and their families.

Eligibility

The IHS IDERP is available only to I/T/U programs that serve American Indians and Alaska Natives. Programs need to have provided diabetes education services for at least six months and have a minimum of six months of educational and clinical outcome data before applying for IHS Recognition. They need to

submit application within three months of the end of the data period used.

Frequency of Accreditation

Full accreditation is awarded for three years. Recognized programs need to maintain the IDERP standards and requirements during the three-year recognition period. Programs seeking continuation of their diabetes education program recognition must reapply three months before the date recognition expires.

Application and Review Process

The Indian Health Service National Diabetes Program (IHS NDP) encourages collaboration in those sites with tribal and IHS diabetes education programs in order to submit one application for the site. It would be a duplication of effort to have two diabetes education programs operating within one community.

However, if programs offer their diabetes education services at more than one site (more than one community), each site needs to submit a separate application. Some of the information will be the same for each application, but each site will have some unique information in their application, such as site-specific team meetings, performance improvement data, consumer satisfaction surveys, and/or consumer advisory members. Programs are encouraged to seek clarification from the IHS NDP, before applying for IHS recognition, concerning whether the requirement for separate applications applies to them.

Figure 2 below depicts an applicant checklist to guide programs through the application process. Programs need to prepare and submit four copies of a complete Recognition Application to the IHS NDP. The IHS NDP logs in the application and distributes it to a review coordinator, who assigns review of the application to two reviewers (different professional disciplines). Reviewers complete their review with a Reviewer Checklist, following standard instructions and scoring criteria. They are required to send their review documentation to the review coordinator within six weeks. The review coordinator contacts reviewers to discuss reviewer

findings, tabulates review findings, and prepares a summary for IHS NDP. After the IHS NDP reviews the summary from the review coordinator and reviewers, it makes the final decision regarding accreditation status. The IHS NDP notifies applicants of the accreditation decision within 12 weeks following receipt of the application. See Figure 3 for a list of successful applicants.

Figure 3. List of recognized IDERP Types of Accreditation

| IHS Recognized Programs (November 2003) |
|---|
| * Albuquerque Service Unit Diabetes Program, Albuquerque, NM |
| Diabetes Education Path to Health (DEPTH), Phoenix Indian Medical Center, Phoenix, AZ |
| Educating Partners in Care, Sapulpa, OK |
| Educating Partners in Care, Okemah, OK |
| Educating Partners in Care, Okmulgee, OK |
| Educating Partners in Care, Eufaula, OK |
| *New Patient Diabetes Education Program, Claremore, OK |
| SEARHC (Southeast Alaska Regional Health Consortium) Diabetes Program, Juneau, AK |
| SEARHC Diabetes Program, Sitka, AK |
| STAR (Start Taking an Active Role) Diabetes Self-Care Education Program, Shawnee, OK |
| Wagner IHS Diabetes Program, Wagner, SD |
| *Also ADA Recognized |

The Indian Health Service National Diabetes Program awards **full accreditation** to applicants who document evidence that all review criteria are met (See Figure 4 next page). **Provisional accreditation** is a six month conditional award given to programs

Figure 2. Applicant Checklist

| Applicant Checklist |
|--|
| <ul style="list-style-type: none">· Team obtains (from IHS NDP) and studies the <i>IHS Recognition Program Standards and Review Criteria Manual, Sample Materials for Developing Quality Diabetes Education Programs</i> and <i>Recognition Application</i>· Team uses the <i>Reviewer Checklist</i> in the <i>Recognition Program Manual</i> to complete a self-assessment of their diabetes education program· Team chooses type of Recognition to apply for· Team requests technical assistance from NDP as needed to meet Recognition requirements· When team determines that the diabetes education program is meeting all required IHS Recognition Program standards and review criteria, coordinator completes Recognition Application and sends four copies to IHS NDP |

with a maximum of three incomplete review criteria. In this case, programs need to provide documentation of evidence addressing deficiencies cited by reviewers within six months. When all review criteria are met, the program is awarded full accreditation as of that date. Applications receive a **denial** when there is inadequate documentation of four or more review criteria. Programs must be fully recognized to seek Medicare reimbursement.

Each program fully accredited by the IHS IDERP needs to maintain the Recognition Program standards during the entire three-year recognition period. They are required to follow monthly and annual reporting requirements and need to be prepared for a possible site audit. Applications for continuing accreditation after three years need to show documentation of ongoing activities that assure continuity of IDERP standards and review criteria.

Figure 4. IDERP Standards Application Documentation

1. Organizational structure, mission statement, goals, and support for DSME are in place.
2. Target population and educational needs are identified and resources are available.
3. Advisory body participates in planning and review.
4. Coordinator oversees program planning, implementation, and evaluation.
5. Instructional team is collectively qualified to teach content and includes RN and RD minimum.
6. Instructors obtain regular continuing education.
7. Written curriculum with criteria for successful learning outcomes is used; assessed need of individual determines content delivered.
8. Individualized assessment, educational plan, and periodic reassessment directs selection of educational materials and interventions.
9. Documentation of individual's assessment, education plan, intervention, evaluation and follow-up is in medical record.
10. Continuous quality improvement process is used.

The documentation that programs send with their recognition application is critical to the review team. Each reviewer uses this documentation to assess whether the applicant meets the IDERP standards and review criteria. When preparing an application, programs need to select documentation that best supports the quality of their diabetes education program. Applicants are encouraged to study the standards, review criteria, and instructions outlined in the *IHS Recognition Program Standards and Review Criteria Manual* and Recognition Application to assure that the documentation they provide with their application is pertinent and complete. Although it is not within the scope of this article to address all the review criteria and requirements for each standard, answers to some of the common questions follow.

Frequently Asked Questions

Our diabetes education program serves several different tribal communities — do we need a letter of support from every tribe?

Yes. Your application needs to show support from all tribal communities your education program serves. This support can be documented in various ways, such as letters of support from each tribe, tribal resolutions, letter of support from tribal

health board(s), etc. You may submit one letter from a local health board if the board contains representation from each community served.

Our program (policy) manual is not complete—can we still apply for Recognition?

Yes. However, each program needs to have an operational diabetes education program (policy) manual in place before applying for recognition. Your policy manual needs to document the structure and process of your diabetes education program, including organizational structure, mission, goals, staffing, annual plan and evaluation, description of educational process, follow-up, documentation, and other components. You do not need to submit the manual with your application.

Do we have to follow a special format for our meeting (team and advisory body) minutes?

No. Use a format that best suits your committee documentation needs. However, reviewers are looking for evidence of meeting standards and review criteria in your minutes, including committee composition, meeting dates, member attendance, interactive discussion of diabetes education issues, etc. For example, if your program serves more than one community, your advisory body needs to include a consumer representative from each community, and your minutes should reflect this.

Do we need to include position descriptions with our application?

No. You do not need to submit position descriptions with your recognition application. The application requires completion of a brief diabetes team member role and responsibility checklist.

Is there a credential or a continuing education requirement for the coordinator and instructors?

Yes. The coordinator needs to demonstrate education and experience in chronic disease management and is required to obtain 12 hours of relevant continuing education every two years. The coordinator does not have to be a certified diabetes educator (CDE) or licensed professional. For example, the coordinator could be a community health representative or administrator.

Instructors need to have recent didactic and experiential preparation in diabetes management and educational issues and be familiar with diabetes in AI/AN communities. Beginning in February 2004, at least one instructor must be a CDE. Instructors are required to obtain 12 hours of relevant continuing education every two years.

Do we need to include an actual patient record with our application?

No. You will need to provide copies of the diabetes education forms you use to document the education process — educational needs assessment, education plan, education intervention, and periodic follow-up.

Our hospital completes a consumer satisfaction survey every year — is this an acceptable method to assess diabetes education needs in our community?

No. If there are specific questions related to the diabetes

education program in this survey, it meets the requirement for consumer satisfaction, not for a needs assessment. Needs assessments look at the education needs of your community. The consumer satisfaction survey gathers feedback about the diabetes education program and services you provide.

We cannot always get everyone on our diabetes team together at team meetings — does everyone need to be at every meeting?

No, but minutes need to reflect the teamwork of core members — RN, RD, and primary care provider — at most meetings. Reviewers use the minutes to assess team composition, member attendance, and the team approach to diabetes education. Minutes need to document discussion, tracking, and recommendations related to diabetes education issues, as well as coordination with other departments.

Our coordinator and instructors have other responsibilities in our facility besides diabetes education — how much time is required for them to be working in the education program?

There is no minimum time (FTE) requirement for the coordinator and instructors. Reviewers assess whether the time involvement shown on the Coordinator and Instructor Profiles in the application is sufficient to meet the needs of the community served.

Does the Indian Health Service have a curriculum we can use?

Yes. The Indian Health Service's *Balancing Your Life and Diabetes* curriculum is an approved curriculum and is available from the IHS NDP. It can be ordered on line at www.ihs.gov/medicalprograms/diabetes. There are several other approved curricula listed in the Recognition Application. Programs using any of these approved curricula do not need to submit the curriculum with their application. If you are not using an approved curriculum, you will need to submit the entire curriculum with your application for review.

Not everyone who starts our diabetes education program finishes it — do we need to show that a minimum number (or percent) of participants complete the education program in order to apply for Recognition?

No. There is variability with program completion rates and reviewers do not consider them as a marker for quality diabetes education programming. Completion rates will vary according to the number of people with diabetes in your community, community/seasonal events, diabetes education program cycles, etc.

Programs need to set up a tracking system to identify participant movement through the diabetes education program. The tracking system will help you provide annual participant counts and profiles. It will also help your program with participant follow-up and program evaluation efforts. Tracking data may show that you need to rethink your program structure and process, especially if less than 50% of your participants are completing the critical elements of your diabetes education program — needs assessment, individualized educational plan, educational intervention, and periodic follow-up.

We have a program plan, including goals, objectives, and process/outcome measures, in our Diabetes Grant Plan. Does this meet the program plan requirement for IHS Recognition?

No. The goals, objectives, and process/outcome measures for your diabetes education program need to be specific to the diabetes education program services. The diabetes grant plan is usually too broad, applying to the entire diabetes community rather than only to participants in the diabetes education program.

We evaluate A1c and SBGM behavior each year through our IHS Diabetes Audit — does this meet the requirement for clinical and behavioral CQI reporting?

Yes. But, the general diabetes program audit results are minimally acceptable on an initial Recognition Application. Diabetes education program audit results specific to the education program and its participants are preferred. Programs might use the general diabetes audit in the early stages of education program development, but as the program evolves, program performance measures and evaluation data need to be more specific to those who have completed the education program. The continuous quality improvement process evaluates the diabetes education program effectiveness in order to identify opportunities for improvement. This process needs to include evaluation of a minimum of one behavioral and two clinical indicators. For example, SBGM behavior can be used as a behavioral indicator, and A1c can be used as one of the two required clinical indicators.

Site Audits

The IHS NDP performs random site audits of fully accredited programs to certify program compliance with IHS Integrated Diabetes Education Recognition Program standards and review criteria. The minimum number of site audits each year will be five percent of accredited programs within each IHS region (or one per region if there are less than ten). Programs will be asked to allow auditors access to the registry, policy and procedure manuals, meeting minutes, position descriptions, patient medical records, and other evidence of compliance with standards and review criteria. Programs will be notified of the date of their site audit about one month ahead of the visit.

Reimbursement

Programs that are fully accredited by the IHS IDERP are eligible to bill Medicare for reimbursement of diabetes self-management education. When IHS NDP awards IHS Program Recognition, they will provide the program with information about meeting CMS requirements, such as how to notify CMS of recognition status and how to assure consumer complaints are reported. Diabetes teams need to work closely with their facility's patient billing office (PBO) to coordinate the billing process and assure policies are in place to address consumer complaints. Programs may also check with their state's Diabetes Control Program, local American Diabetes Association, local diabetes educators' association, or IHS Area Diabetes Consultant for information about reimbursement for

Medicaid and private insurance. For more information on reimbursement contact:

- Tammy Brown, Co-Chair, IHS Integrated Diabetes Care and Review Board; e-mail tammy.brown@na.ihs.gov.
- IHS National Diabetes Program website: www.ihs.gov/medicalprograms/diabetes.
- Trailblazer Health Enterprises, LLC (National Medicare carrier for Indian Health) www.trailblazerhealth.com.
- American Association of Diabetes Educators — Government Relations, www.diabeteseducator.org.
- Centers for Medicare and Medicaid Services, www.cms.gov.

the IHS NDP if you have questions.

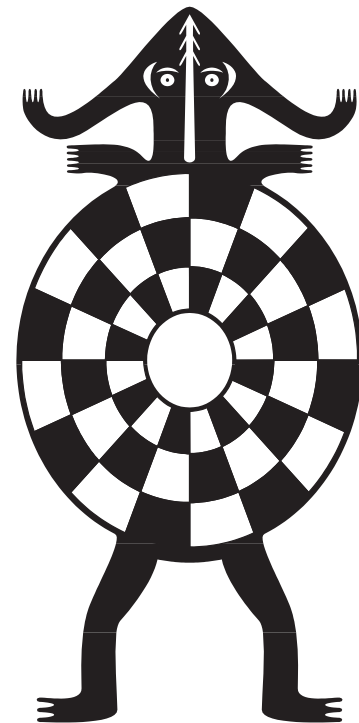
Technical Assistance and Information

Technical assistance is available on request from the IHS NDP to help programs meet IDERP standards and review criteria and prepare an application for IHS Recognition. Current information, manuals, and application materials are available from the IHS NDP website at www.ihs.gov/medicalprograms/diabetes (See Figure 5)

Programs may also contact Cecelia (Sea) Shorty at the IHS NDP, telephone (505) 248-4182, or e-mail diabetesprogram@mail.ihs.gov for Recognition Program information and resources.

Figure 5. IHS Integrated Diabetes Education Recognition Program Resources

- FAQ Sheets
- Recognition Application
- Standards and Review Criteria Manual
- Sample Materials for Development of Quality Diabetes Education Programs
- Reviewer Checklist



Conclusion

The Indian Health Service Integrated Diabetes Education Recognition Program benefits tribal communities by guiding and supporting the development of quality diabetes education programs, enhancing the marketing of their services, and improving outcomes for patients who participate in them. It also enables programs that receive IHS Recognition to seek Medicare reimbursement for diabetes self-management education. This article provides a brief overview of the IHS Recognition Program. We applaud your commitment to quality diabetes education in your community. Please do not hesitate to contact

Recording Health Factors in the RPMS System

Scott Hamstra, MD, Health Factor Task Group, Clinical Information and Technology Advisory Group (CIMTAC), Whiteriver, Arizona

The Indian Health Service utilizes a robust Resource and Patient Management System (RPMS) electronic database that is added to on a daily basis as we record our patient encounters using paper Patient Care Component (PCC) forms. Historically, data entry clerks have grabbed a defined portion of the information documented on the encounter form and entered these data bits into the local RPMS database. This database is used to facilitate a number of processes. These data elements include Measurements, Purposes of Visit, Diagnoses, Problem Lists, Plans, and Procedures. Some information is integrated into the patient's electronic record directly if your site is using specific clinical applications, e.g., Laboratory and Immunization packages. This patient and visit information is available for a number of uses, including display on the health summary for individual patient care as well as review for performance improvement across the service unit population, e.g., as GPRA indicators.

While the use of ICD-9 and CPT codes often provide valuable information, some additional health information that would be valuable and helpful for both care of the patient and for GPRA measures is not easy to capture via these traditional methods. Due to this limitation, the Health Factors application was created. Health factor fields enable RPMS to record and track certain important health parameters. Initially, four categories were created, as follows:

1. Diabetes mellitus
2. Alcohol use or abuse
3. TB status
4. Tobacco use

Using the Tobacco Health Factor in patient clinic encounters as an example, I hope to illustrate the practical aspects of Health Factors, and show how the use of Health Factors helps address our unique data needs.

Andy, our first patient, arrives in primary clinic for follow-up of his hypertension. The provider asks Andy if he uses tobacco. He responds, Yes, he smokes cigarettes but doesn't chew tobacco. The provider would like to document this information in the medical record.

There are at least two options available to capture and record this information.

Method 1: The provider can document tobacco use as a secondary Purpose of Visit and add it to the Problem List. Data entry then captures the POV

Provider Narrative as an ICD-9 Code (choosing from four options):

1. Unspecified 305.10
2. Continuous 305.11
3. Episodic 305.12
4. In Remission 305.13

Note that the ICD9 coding does NOT distinguish between smoke and smokeless tobacco, even though clinically these are very different and have very different impacts on the patient.

Method 2: The other option is to for the provider to document tobacco use as a Health Factor; as seen below, this method provides more detail and specificity than the use of the ICD-9 codes. See Table 1.

Table 1. Options (12) for recording Tobacco as a Health Factor

| Health Factors (Circle all that apply) | Definition |
|---|---|
| TO - Non User | Never used cigarettes or chewing tobacco |
| Current Smoker | Uses regularly |
| Current Smokeless | Uses regularly |
| Current Smoker & Smokeless | Actively trying to quit < 6 months smoke free |
| Cessation Smoker | Actively trying to quit < 6 months smoke free |
| Cessation Smokeless | Actively trying to quit < 6 months smokeless free |
| Previous Smoker | Quit: Smoke free for > 6 months |
| Previous Smokeless | Quit: Smokeless free for > 6 months |
| Smoker in Home | Exposure to Smoke (household) |
| Smoke Free Home | Smoke Free Home |
| TO - ETS | Exposure to Environmental Tobacco Smoke (work) |
| TO - Ceremonial | Ceremonial Use Only |

In the case of Andy, using the first method, the provider records on the Purpose of Visit, as follows:

| A/I/R | # | Purpose of Visit | Health Factors |
|-------|---|------------------|----------------|
| | | Hypertension | |
| A | 2 | Tobacco use | |

The data entry clerk will capture these data elements, which are then searchable data bits in the RPMS database, and the information is displayed on the Health Summary as follows:

Problem List

- PL1 Hypertension
- PL2 Tobacco Use 305.11

Alternatively, using method 2, the provider records as follows at the end of the artical as follows:

| A/I/R | # | Purpose of Visit | Health Factors |
|-------|---|------------------|----------------|
| | | Hypertension | Current Smoker |
| | | | |

Here, the data entry clerk will capture these data elements, which are then searchable data bits in the RPMS database, and the information is displayed on the Health Summary as follows:

Health Factors
Current Smoker

Which documentation is quicker and easier? In this case, the methods are arguably about the same. However, which form of documentation provides the most valuable data? The Health Factor actually allows more specific documentation — smoking vs. smokeless — that ICD-9 coding does not.

Convinced? No? Let's try another example.

Susan, our second patient, arrives in primary clinic for prenatal care. The provider asks this 18-year old if she uses Tobacco. She responds, No, I have never smoked cigarettes or chewed tobacco and neither does anyone else in my home. The provider would like to document this information in the medical record.

How? There is no ICD-9 code to document the absence of diseases. After all, ICD-9 codes were created to document reasons why people die. How can the provider document the absence of smoking, get credit for asking the question, and help us demonstrate how many in a population are Tobacco Non-Users? The answer is, of course, to use the Health Factors method — the new data field that provides this ability! In this case, for Susan, the provider records as follows:

| A/I/R | # | Purpose of Visit | Health Factors |
|-------|---|---------------------------|-----------------|
| | | Prenatal Visit - 12 weeks | TO - Non User |
| | | | Smoke Free Home |

The data entry clerk will capture these data elements. When entered into the database, this allows you can find how many prenatal patients do not use tobacco, and displays the information in the Health Summary as follows:

Health Factors
Tobacco Non-User
Smoke Free Home

One more example, a bit different and more complex, may be more convincing.

Our third patient, Tom, arrives in primary care clinic for a Bus Driver Physical. The provider asks Tom if the patient uses tobacco. He responds, Yes, he chews tobacco daily, but quit smoking a couple of years ago. The provider would like to document this information in the medical record or chart.

How? Using method 1, above, there are two options. First, the provider could use POV and ICD-9 codes to document both the active problem of using smokeless tobacco and the history of smoking; there is a V code (V15.82) for History of Tobacco use. Alternatively, the provider could use the Health Factor tobacco codes to document both elements of the history. In this case then, for Tom, the provider records as follows:

| A/I/R | # | Purpose of Visit | Health Factors |
|-------|---|--------------------------|----------------|
| | | Bus Driver Physical Exam | |
| A | 1 | Tobacco use | |
| MHX | | History of Tobacco Use | |

The data entry clerk will capture these data elements, and the information displays on the Health Summary as follows:

Problem List
PL1 305.11 Tobacco Use
Past Medical History
History of Tobacco Use

Using the second, Health Factors, method, however, the provider records as follows:

| A/I/R | # | Purpose of Visit | Health Factors |
|-------|---|--------------------------|-------------------|
| | | Bus Driver Physical Exam | Current Smokeless |
| | | | Previous Smoker |

The data entry clerk will capture these data elements. Once entered in the database, you can find how many men use smokeless tobacco, or even how many men use smokeless tobacco but are previous smokers. The information displays on the Health Summary as follows:

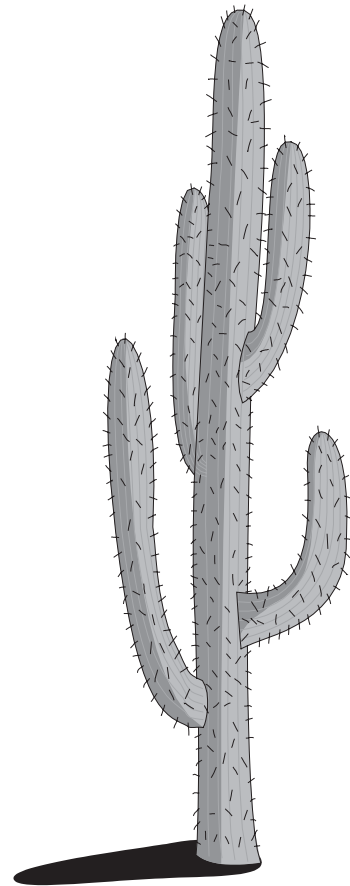
Health Factors
Current Smokeless
Previous Smoker

As can be seen above, the use of the ICD-9 codes can be confusing since it does not distinguish between Smoking and Smokeless. It is simply both easier and clearer to use the Health Factors method. These three examples demonstrate how **Health Factors** facilitate our asking every patient about tobacco use and facilitate **documentation** of more detailed information for all patient encounters, compared to using ICD-9 codes. We now also have a clear mechanism to document **Tobacco Non Users, Smoke Free Home, Smoker in Home, Exposure to Environmental Tobacco Smoke, and Ceremonial Use**, as well as to distinguish between the

kind of tobacco use — Smoker vs. Smokeless.

In future articles, we will explore in more detail other Health Factors that are currently available and the process by which other Health Factors can be added.

Special thanks to Caroline Renner, who has been championing tobacco issues in Alaska and helping to further develop this area.





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THE IHS PRIMARY CARE PROVIDER



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Indian Health Service
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Two Renaissance Square, Suite 780
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