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# An EMTALA Update for Indian Country

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## Introduction

The Emergency Treatment and Active Labor Act (EMTALA) was passed into law as a few pages of the mammoth Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985. EMTALA is an antidiscrimination law focused on emergency medical care. It became enforceable in 1986 but did not emerge as a major force in the health care industry until the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA), released the first version of the EMTALA regulations and Interpretive Guidelines in 1994. These were revised in 1995 and 1998; they were modified by the Outpatient Payment System (OPPS) issuance of 2000; and after many delays, were updated again in September 2003. CMS issued the latest regulations and Interpretive Guidelines in May 2004.

Statutes and regulations have the full force and enforceability of law. Interpretive Guidelines do not have the force of law and cannot be directly cited against, but they reveal CMS's position on given regulations and instruct surveyors on what to look for and what regulatory language to cite evidence against. The prudent facility will take the content of the Interpretive Guidelines to heart.

Federally and tribally operated IHS facilities became Medicare/Medicaid participants with the passage of the Indian Health Care Improvement Act (IHCIA) in 1976. The monies from this Medicare and Medicaid (M&M) participation are received in addition to federally budgeted funds. Third party billings, including M&M, are critical for the provision of services to Indian people. The stipulation for continued M&M participation by IHS facilities is that they meet "all of the requirements" for continued participation,[1] which includes EMTALA for hospitals and critical access hospitals (CAHs).

EMTALA first hit Indian country in September 1997, when an IHS hospital became the subject of an EMTALA complaint investigation and corrective action activities over a number of months.[2] Since then, EMTALA investigations have spread to a number of IHS hospitals in many parts of the country.

## Disclaimers and Definitions

This article is written in July 2004, from the author's perspective of having served as CMS Region 9's lead EMTALA officer from 1994 – 1998, and having continuing EMTALA involvement since that time. This article is not legal advice, but is intended to assist IHS facilities in achieving practical regulatory compliance and protecting M&M participation. Due to the complexity of many EMTALA situations, this article should be taken only as a summary of important update information and not an all-inclusive treatment of the subject. Facilities may purchase an excellent EMTALA reference book[3] from the American College of Emergency Physicians (ACEP), in which I have no vested interest. The opinions expressed in this article are those of the author and do not necessarily reflect the views of the IHS.

## In this Issue...

Italics used denote either formal titles or my own added emphasis. "JCAHO" refers to the Joint Commission on Accreditation of Healthcare Organizations. "AOA" refers to the American Osteopathic Association. "OIG" refers to the U.S. Department of Health and Human Services (DHHS) Office of Inspector General. The word "hospital" in this article includes both Medicare-participating hospitals and CAHs. The words "investigation" and "survey" are used interchangeably. Issues are organized using the CMS "data tag" numbers for reference. The EMTALA Interpretive Guidelines are Appendix V of the State Operations Manual (SOM) and are available on the CMS website.[4]

### Today's IHS Hospital Compliance Hierarchy

Prior to the IHCIA of 1976, IHS compliance functions were primarily internal in nature, and were generally governed by the Indian Health Manual (IHM) as the highest authority. Medicare and Medicaid participation changed this. Since 1976, an IHS hospital's regulatory compliance hierarchy has evolved to look like this:

1. EMTALA – because it applies directly against a hospital's Medicare Provider Agreement, and can negatively affect participation in the M&M programs regardless of any of items (2) through (6);
2. Direct CMS Medicare certification *or* JCAHO (or AOA) accreditation – as alternate pathways to Medicare certification of the whole hospital;
3. CLIA, OSHA, HIPAA, etc. – as important requirements that affect significant parts of the facility's operations, but don't directly bear on Third Party revenues;
4. The Indian Health Manual – for issues not superceded by anything in (1), (2) or (3);
5. IHS Headquarters and Area Offices; and finally,
6. The facility's administration itself.

While JCAHO and AOA have deeming authority to determine hospital compliance with the Medicare *Conditions of Participation* (CoPs), they do not have the authority to determine compliance with EMTALA. EMTALA is not contained in the CoPs and is reserved to CMS.[5] It is theoretically possible for a hospital to be fully compliant with the Medicare CoPs or JCAHO or AOA Standards, and still be terminated from M&M participation by CMS due to an uncorrected EMTALA violation.

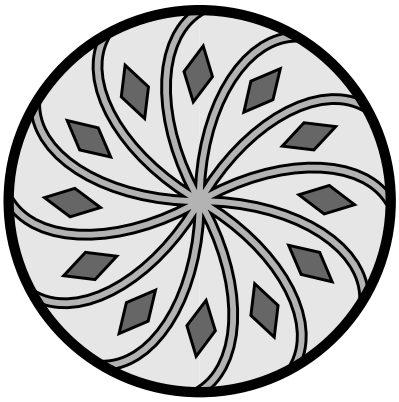
Some parts of the IHM have not been updated for many years. However, in 2000 there was language added to the IHM to broadly require EMTALA compliance.[6] In a parallel development, hospitals are now required by the OIG to have an overall facility Compliance Plan in effect, which has many elements and includes EMTALA compliance.[7] Tribally operated facilities may have some different relationships to the IHM and the IHS, but their relationship to compliance hierarchy items (1), (2), (3), and (6) is not diminished.

In EMTALA as in all areas of facility operations, it is imperative that the facility has current policies and procedures (P&Ps) in place that are written in compliance with all applicable laws, regulations, and directives; that satisfy a variety of outside auditors, including accrediting, certifying, and financial entities; and that describe what the facility actually does on a day to day basis. It is vitally important that the facility actually operates in accordance with its own P&Ps once it writes them, and that it reviews and revises them as it says it will. For those issues where there is not a mandate by a higher authority, the facility's own P&Ps become the survey standard.

### EMTALA Requirements and Survey Comments

There are twelve EMTALA regulations in the Code of Federal Regulations (CFR); the first six are found at 42 CFR §489.20, and the second six are found at 42 CFR §489.24. The latter (§489.24) contains the six specific EMTALA requirements added in 1985, which are frequently referred to as "the EMTALA statute." Violations cited in the first six regulations (A400 – A405) are *generally* issues that will earn a hospital a "slow track," 90-day Medicare termination action if that's all that is found; violations cited in the second six regulations (A406-A411) will *generally* lead to the hospital facing a "fast track" 23-day termination action. This description of possible termination actions is not comprehensive, as CMS makes its compliance and termination decisions based on the total findings of each individual investigation.

It is important for facilities to understand that once a surveyor enters the facility on any routine or complaint-based Federal survey, anything that they find can be used to extend both the scope and duration of the survey. In the case of an EMTALA investigation that is complaint-based and focused on the provision of emergency care and the formal Emergency Department (ED) if one exists, if a surveyor sees things that lead him to believe that the hospital is not meeting at least one of the 16 mandatory or the 11 applicable optional/special CoPs, then the EMTALA investigators can be authorized by the CMS Regional Office to expand the survey to include the suspect CoPs. This is true even if no EMTALA violations are



ultimately cited, and survey expansion can happen more than once. Thus, what began as an ED-based investigation of a single patient complaint can mushroom into a "whole house" survey with few limits, done by investigators who cannot be denied access to any unredacted document that they need to see in order to make compliance decisions, or to photocopy as evidence

The "state survey agency" is a state's Department of Health Services (or similar agency) that performs Medicare compliance surveys in that state as a contractor to CMS. State agency surveyors may perform Federal surveys in Indian facilities on tribal lands, although they may not enforce state law where it otherwise doesn't apply in Indian Country. CMS now directs that the identity of the complainant (*no change*) and the index patient case (*this is new*) be kept confidential unless CMS has obtained written consent to reveal them to the hospital being investigated.

Statutory citations follow the text in the titles of each following requirement. The OIG has jurisdiction over anything with a §489.24 citation, and has a seven-year window to initiate separate investigative and punitive actions against the hospital and individual physicians.

### Data Tag A400 – Basic Compliance (§489.20)

Here, the hospital agrees that if it meets the definition of a hospital found in 42 CFR §489.24(b), then it agrees to comply with the requirements of 42 CFR §489.24. In terms of documenting investigatory findings, this is a "bonus violation" if the hospital has findings cited at Data Tags A404 or A406 through A411. A citation at A400 requires a separate corrective action plan statement, and the OIG can assess a separate fine ("civil monetary penalty") for it.

### Data Tag A401 – Mandatory Reporting (§489.20(m))

This regulation requires that a hospital that receives an "unstable" patient ("unstable" being a legal definition in this case, not a clinical description) in an inappropriate transfer is required to report receiving that patient to CMS, or to the state survey agency on CMS's behalf. This is a *positive* duty to report in a timely manner, and does not require that the receiving hospital conduct an exhaustive internal investigation and have final findings before reporting. The actual language is that the reporting hospital "has reason to believe it *may* have received an individual . . . in an unstable emergency medical condition from another hospital in violation of §489.24(d)."

There is a long-standing EMTALA myth that this report must be made within 72 hours, but this has never been a part of the requirements. While not binding, "72 hours" is still useful as rule of thumb guidance for hospitals

The four transfer requirements of §489.24(d) are contained in Data Tag A409, and must be met for a transfer to be judged appropriate.

### Data Tag A402 – Required Signage (§489.20(q))

The hospital must conspicuously post this sign in all hospital areas where patients enter, await treatment, and receive medical screening examinations and treatment for emergency medical conditions. The signs need to be clearly visible and readable in the space, and should be legible at a distance of 20 feet from where a patient would be seated, etc. Smaller spaces may have smaller signs, as long as visibility and legibility are maintained. There is CMS-required content, which at a minimum is:

> IF YOU HAVE A MEDICAL EMERGENCY OR ARE IN LABOR, YOU HAVE THE RIGHT TO RECEIVE, WITHIN THE CAPABILITIES OF THIS HOSPITAL'S STAFF AND FACILTIES, AN APPROPRIATE MEDICAL SCREENING EXAMINATION; NECESSARY STABILIZING TREATMENT, INCLUDING TREATMENT FOR AN UNBORN CHILD; AND IF NECESSARY, AN APPROPRIATE TRANSFER TO ANOTHER FACILITY EVEN IF YOU CANNOT PAY OR DO NOT HAVE MEDICAL INSURANCE OR YOU ARE NOT ENTITLED TO MEDICARE OR MEDICAID. THIS HOSPITAL DOES (OR DOES NOT) PARTICIPATE IN THE MEDICAID PROGRAM.

The Interpretive Guidelines note that the wording of the sign must be clear, and in simple terms and language that are understandable by the population served by the hospital. Having only the common English and Spanish versions posted may not adequately meet this requirement in Indian Country, or in any area of the country with residents who do not read either English or Spanish. Signs may be produced internally or purchased from commercial sources.

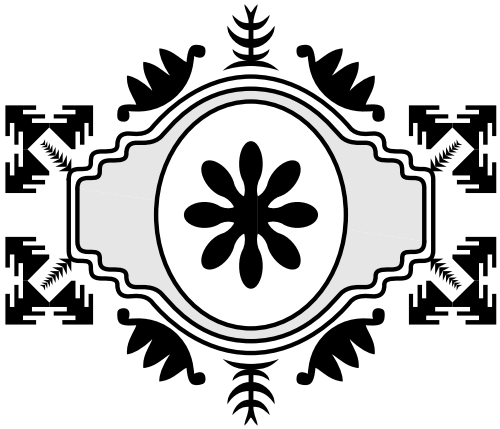
### Data Tag A403 – Medical Records (§489.24(r))

Transferring and receiving hospitals must maintain "medical and other records related to individuals transferred to or from the hospital for a period of five years from the date of the transfer." The records may be maintained in the original hard copy or any legally reproducible form such as microfilm, computer discs and systems, etc. In many cases, medical records are maintained for longer periods of time, anyway; you are encouraged to consult your medical records professional to learn your facility's policy.

I cannot stress too much that the core of the EMTALA investigation, or any federally driven survey for that matter, is the patient's medical record. While the survey team will review masses of organizational information, the medical record is where the facility really lives or dies. It is critical that the record exists, be safeguarded, be quickly retrievable, and contain information consistent with the information found in the Central Log. Medical records selected by the surveyor usually need to be available early on the first day of the investigation, and hospitals should factor this in to any plans

for archiving medical records offsite. For regulatory and other purposes, it is critical that the record be completed in accordance with applicable outside requirements and hospital P&Ps, be legible, contain complete information, reflect appropriate patient observations, be signed-off and countersigned as needed; and for internal data and Third Party revenue purposes, be accurately coded and billed.

In my experience, an EMTALA complaint filed with CMS is usually about an alleged incident that occurred within the three years preceding the surveyor's arrival. However, there is no "statute of limitations" for the filing of an EMTALA complaint with CMS, and additional time may have passed.



**Data Tag A404 – On-call Physicians (§489.20(r)(2); §489.24(j))**

Since EMTALA's inception, this has been one of the more controversial requirements – made even more so in parts of the country with significant penetration of the healthcare market by managed care organizations (MCOs). EMTALA was written without consideration for health maintenance organizations (HMOs) and all the other MCO variants that have evolved. It is safe to say that when it passed EMTALA, Congress assumed that most hospitals provided a full menu of general and specialty services, that inpatient care was the dominant model, that physicians were dependent on having hospital privileges for financial security, and that hospitals exerted complete control over the activity of their medical staff through the medical staff membership and privileging processes.

The American medical marketplace has changed since EMTALA emerged, in too many ways to explore in this article. Suffice it to say here that market forces have resulted in a shortage of medical and surgical specialties available to Emergency Departments in many locations, and that meeting this on-call requirement has become challenging for many hospitals where medical staff members are not facility employees.

The statutory requirement contained in this part of the regulation is that the hospital must maintain "a list of physicians who are on call for duty after the initial examination, to provide further evaluation and/or treatment necessary to stabilize an individual with an emergency medical condition (EMC)"; and that it do so in a manner which "best meets the needs of the hospital's patients" who are receiving services under EMTALA. This core requirement has never changed. The specialties available on-call need to appropriately reflect the types of patient services that the hospital holds out to the community. CMS has softened some earlier positions on this, presenting the hospital with the double-edged sword of having "maximum flexibility" in meeting its EMTALA on-call obligations but little in the way of firm guidelines on how to do it in a predictably compliant manner.

The on-call specialist must respond to the ED in a timely manner, this being determined by hospital policy and the judgment of the ED provider who is evaluating the patient. The on-call specialist is expected to respond to the ED to see the patient, and there are few circumstances where CMS would likely judge it in the "EMTALA-unstable" patient's best interest to leave the hospital to go to the specialist's office – although in some specialties such as ophthalmology, for example, this may be the case if the patient's only unstabilized EMC is their eye problem. A specialist can be on-call at more than one hospital at a time; can schedule patients and surgery during his/her on-call tour; and the hospital must have a plan in place to provide the specialty care, including through transfers, if the on-call specialist is not available.

CAHs are different in this regard in that their on-call emergency practitioners are required to be available 24 hours a day, to respond immediately by phone or radio, and be on-site within 30 minutes (or 60 minutes in some frontier areas).[8] CMS has methodologies to pay for the practitioner's on-call services to the CAH, so the practitioner may not be on-call simultaneously at more than one facility.[9]

Dispelling another EMTALA myth, CMS states that there is no "rule of three," which would require that a hospital with three specialists in a given specialty must provide 24/7 on-call ED coverage in that specialty. This has actually *never* been an EMTALA statutory or administrative requirement, although risk-averse hospitals may have embraced it because CMS, in practice, has found this "rule" to meet its test for "reasonable coverage."[10] "Reasonable coverage' is mandated, based on the assets of the hospital's medical staff, but not specifically required to be provided on a 24/7/365 basis. Hospitals that must have a state license may be required to meet state on-call (or other) requirements that are more stringent than Federal requirements.

In the case of making an EMTALA compliance decision, CMS will be determining a hospital's on-call coverage status retrospectively. This is not a change in itself, but is complicated by lack of firm guidance as to what CMS might find acceptable. In Indian country where the physicians are actual employees or contractors of the hospital, this is not quite the critical issue that it is in the general hospital industry.

### Data Tag A405 – Central Log (§489.20(r)(3))

The hospital must enter into the central log a certain minimum amount of information about each individual "who comes to the emergency department as defined in §489.24(b) seeking assistance and whether he or she refused treatment, was refused treatment, or whether or not he or she was transferred, admitted and treated, stabilized and transferred, or discharged." In reality, the hospital's central log usually contains more information than this, and that's fine – just make sure that you are following your hospital's P&P, and that at least the minimum required information is captured.

The central log is the document that the surveyors will request first, and they will expect to have it in about 20 minutes. The surveyors will draw the universe of patient records from the log, which will generally contain 20 to 50 records drawn from "at least" a six-month period and will include the complaint case "regardless of when it occurred." Records will be selected to allow the surveyor to look for indications of discrimination in the provision of EMTALA-mandated care to individuals. You can expect gender, ethnicity, surnames, residence location, ZIP code, tribal membership, insurance status, patient disposition, and IHS beneficiary status to all be factors in record selection, in addition to similarities between the complaint case and others. Even if the complaint case itself results in no violations found, any other violations found in the universe of records or organizational documents can be cited.

The central log includes separate logs kept in other places in the hospital where specific Medical Screening Exams (MSE) might be performed, such as Labor and Delivery/OB Triage or other locations not in the Emergency Department; these logs must also be delivered to the surveyor. The log needs to be complete, accurate, and free of missing information and a lot of late entries. If the log is kept on paper, there should be no use of liquid correction fluid, blank stickers covering an entry, heavily inked-out entries, etc. The condition of the central log can positively or negatively affect the tone of the survey, in addition to generating violations itself.

### Data Tag A406 – Medical Screening Examination (§489.24(a) and (c))

The anti-discrimination nature of EMTALA manifests here, with the core statutory language and requirement that "*if any individual* comes … to the emergency department … and a request is made … *for examination or treatment of a medical condition,*" then the hospital is obligated to provide an appropriate Medical Screening Examination (MSE). The key words are "any individual." This requirement of EMTALA is really unchanged by any of the revisions that have been made, although CMS has changed its application somewhat by introducing the notion of the "dedicated emergency department (DED)." A DED is any department of the hospital, on or off of the main campus, that meets at least one of these definitions: 1) that the department is state-licensed as an emergency department; 2) is held out to the public as providing emergency care on an unscheduled basis; or 3) a review of the preceding calendar year's patient visits determines that the facility provides at least 1/3 of all outpatient visits on an unscheduled, urgent basis. However, if a patient comes to a part of a hospital that is *not* a DED, *and* requests examination or treatment of a *possible* emergency medical condition (EMC), then the hospital's EMTALA obligation to provide an MSE is also triggered.

The purpose of the MSE is to determine the presence or absence of an EMC, which has this legal (*not clinical*) definition: "Acute symptoms, reasonably expected to seriously jeopardize the health of the individual or the unborn child; seriously impair any bodily function; cause serious dysfunction of any organ or body part; or if there is inadequate time to safely transfer a pregnant woman who is having contractions."

The MSE is provided by an *appropriately privileged physician* (MD, DO, DDS, OD, DC) *or qualified medical person (PA, APN, "RN with specialized training")* as defined in the medical staff bylaws. While it is technically possible to have an "RN with specialized training" perform some level of an MSE, my advice is to not do this. The original intent of this language has been stretched in the past to legitimize many other practices – usually having to do with a physician not seeing a patient after-hours and an RN sending that patient home to return the next working day – that are both high-risk and EMTALA violations.

The MSE is defined as "the process required to reach with reasonable clinical confidence . . . (the determination) that a medical emergency does or does not exist." The MSE, therefore, is a patient-driven spectrum of activities ranging from a focused examination and history-taking at the low end; through extensive lab, imaging, and invasive diagnostics at the high end. There is no minimum set of activities.

CMS has added specific language to the guidelines discussing the performance of a "labor check" MSE by a "QMP other than a physician (Registered Nurse, Physician's Assistant. etc.)" – that language being that "if (the) QMP determines a woman to be in false labor, a physician must certify the diagnosis. How the physician certifies (telephone consultation, or actually examines the patient) the diagnosis of false labor is determined by the hospital and its medical staff." This is the clearest statement on this that CMS has made to date, even though "false labor" is an archaic term itself and nowhere in EMTALA are the onset or stages of labor clearly defined. Note the earlier stipulation that this QMP should be "appropriately privileged" via the usual medical staff process. An RN's licensure requires compliance with the issuing state's Nurse Practice Act; thus the RN's ability to perform certain MSE tasks varies widely by issuing state. The IHS recognizes variation in state Nurse Practice Acts in Part 3, Chapter 4 of the IHM; but the IHM does not contain guidance on how to align RN practice within the IHS with that of the state where the IHS

facility is located. The infrastructure that must be in place to support the "RN with specialized training" to do MSEs can be prohibitive to operate on a practical basis. In most non-labor situations, if a staff RN performs a patient assessment and then consults with a physician by telephone, and the patient leaves the hospital without the physician actually examining the patient, then CMS will find that the MSE was never provided. Patient triage by an RN does not equal the performance of an MSE. Triage by an RN, including the movement of a patient to different appropriate places in the hospital in order to have their MSE performed in a timely manner by a privileged provider *on the same day,* is allowed.

A hospital owned and operated ambulance is defined as being "the hospital," for EMTALA purposes, that the patient has come to requesting care. However, if the hospital-owned ambulance is operating under the direction of local emergency medical services (EMS) dispatch and medical control, that ambulance may take the patient directly to a different hospital without creating an EMTALA violation for the owning hospital. Also, the transfer of a patient from one ambulance to another (air or ground), which occurs on hospital property but without a request for medical care assistance made of the hospital staff by the ambulance crew, does not create an EMTALA obligation for the hospital.

**Data Tag A407 – Stabilizing Treatment (§489.24(d)(3))**

If a patient who requests care at the hospital is found to have an EMC as defined by EMTALA, then the hospital is required to provide – within its capability – further examination and treatment as needed to stabilize the EMC, or to appropriately transfer the patient to another facility if it cannot provide stabilizing treatment.

The Interpretive Guidelines at this data tag is where the whole discussion of patient stability, stability for transfer, and stability for discharge has resided. This discussion has been framed in an expanded discussion format. There is a return to the §489.24(b) definition of "stabilized," resting on the notion that stabilization is indicated by the provider's determination that – within reasonable medical probability – the patient's condition will not deteriorate during a necessary transfer.

The Guidelines state that the hospital's EMTALA obligation ends when one of these actions occurs: 1) The physician or QMP has determined that the EMC did not exist or has been resolved (the patient might be a candidate for discharge in this instance); 2) The patient is admitted to the hospital for continued care (which might be thought of as care necessary to maintain the patient's new "stabilized" status); or 3) the patient has been appropriately transferred to another facility. The surveyor is instructed to assess whether or not the patient was stable, and if not, was an appropriate transfer arranged. Once again, the surveyor will be relying heavily on the medical record to make this retrospective determination.

CMS states in this section that a hospital's EMTALA obligation ends when a patient is admitted "in good faith" – and frankly, this has traditionally been CMS's position. There is some ongoing legal discussion as to whether or not this means that EMTALA actually ceases to cover a patient who is admitted before their EMC becomes stabilized.[11-13] For practical regulatory compliance purposes, I believe that hospitals are well served by operating with the understanding that a good faith patient admission turns EMTALA off. We can expect ongoing debate of this topic.

It is also important to note here that CMS, for the first time in EMTALA history, directly references the Medicare CoPs as protecting all inpatients whether admitted emergently or electively, and providing for the emergency needs of inpatients. The surveyor is instructed to consider this, and the Guidelines list which conditions to consider as a starting point. I believe that this signals a new willingness on CMS's part to launch CoP-based, whole-hospital surveys, based on what the EMTALA surveyor finds on-site.

In this section, the patient's right to refuse screening, further examination, and treatment is noted; as is a warning to hospitals against coercing patients into making decisions "not in their best interest" such as leaving without treatment, due to financial pressure.

**Data Tag A408 – No Delay in Examination or Treatment (§489.24(d)(4) and (5))**

The requirement that a Medicare-participating hospital not delay the provision of an MSE and necessary stabilizing treatment due to financial inquiry is unchanged. Medicare-participating hospitals in Indian Country need to note that this reflects the anti-discriminatory foundation that EMTALA is built upon. Medicare-participating hospitals in Indian Country must provide EMTALA-mandated services to *any* person who requests it, without delaying the MSE due to excessive questioning about finances or insurance. An individual's status as an Indian person is irrelevant under EMTALA, as is American citizenship itself.

New in this section is the CMS statement that this requirement applies to both the sending hospital and the *receiving* hospital in an EMTALA transfer situation – that being where the patient is not stabilized within the meaning of EMTALA, and the receiving hospital cannot delay acceptance of the transfer in order to ferret out or verify financial or insurance information on the patient.

Needed services under EMTALA must be provided without regard to a person's health insurance or financial condition; and in the case of HMO insurance coverage, needed

services must be provided regardless of any prior authorization requirement. Note that this doesn't mean that EMTALA mandates the insurer has to pay, though.

From a practical standpoint, it is prudent for a hospital to consider any patient who requires hospitalization or transfer in order to achieve clinical stability to have an EMC as defined by EMTALA; to most likely be "unstable" under EMTALA's legal definition; and as one who should be managed and described as an "EMTALA-unstable" patient.

### Data Tag A409 – Appropriate Transfer (§489.24(e)(1) and (2))

The issue of appropriate transfers under EMTALA is huge. The initial ("sending") hospital is required to not transfer the patient until the patient's EMC is stabilized; or if the EMC has not been stabilized, the transfer of the patient must be an appropriate one. In addition, the patient must request the transfer, and the documentation must reflect this. The patient also has the right to refuse to be transferred, even if the patient absolutely needs it to preserve life, limb, or function. There must also be written certification by the transferring physician (as defined in Section 1861(r)(1) of the Social Security Act (SSA)) that the medical benefits of the transfer outweigh the risks, based on what is known at the time of transfer. Section 1861 of the SSA defines a physician as a doctor of medicine or osteopathy, who can delegate tasks to other qualified health care personnel in accordance with state law or regulation; and states that if a physician is not present at the time of transfer, then a QMP (PA, APN, or "RN with specialized training") may sign the transfer certification *only after* consultation with a physician who later countersigns the medical record in accordance with the hospital's policies and procedures. The date and time of signature of the transfer certification itself should closely match the date and time of transfer.

The stipulated hallmarks of an appropriate transfer are 1) that the sending hospital has done all that it can, within its capacity, to minimize risks to the individual's health or to that of the unborn child in the case of a pregnant woman; 2) that the receiving facility has agreed *in advance of the patient transport* to accept the patient and has the space and personnel that the patient requires; 3) that the sending hospital sends all EMC-related medical information that is available at the time of transport; and 4) that the transfer is done using appropriate transportation equipment and skill level of attendant. This sounds simple enough, but this is where the challenges really begin in many cases.

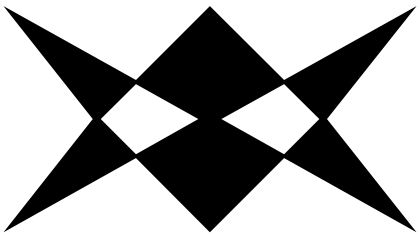
If an EMTALA-unstable patient requires transfer to another facility ("Hospital B"), then Hospital B cannot refuse the transfer if it has the services available that the patient requires, and the sending hospital ("Hospital A") cannot provide those services. If a patient is being transferred to Hospital B for diagnostic testing and/or treatment, even if the patient is expected to return to Hospital A afterwards, then an EMTALA-compliant transfer process must still be done between Hospitals A and B. Hospital B has grounds to refuse a patient in an EMTALA transfer if Hospital A can provide the same services that are being requested of Hospital B, even if the patient has requested the transfer to Hospital B; or if Hospital B does not have the appropriate space and staff available.

The determinations of what transportation vehicle, skill level of attendants, and enroute treatments are necessary are made by the ED provider at Hospital A. Hospital B cannot condition its acceptance of an EMTALA-covered patient transfer on financial guarantees by Hospital A or anybody else, or that Hospital A must accept transportation that Hospital B may insist upon. CMS holds that the opinion of the ED provider at Hospital A is the best opinion of what the patient needs for transfer, regardless of opinions expressed by other specialists who haven't examined the patient. Regardless of how elegant a medically necessary, EMTALA-covered transfer plan may be, the patient still has the right to refuse to be transferred, and Hospital A may have to admit the patient in that case and do the best it can. All of this requires complete and clear documentation, of course. In Indian country, all of this may involve the emergency treatment of a non-beneficiary by the Indian hospital; and may result in admission to, definitive treatment by, and ultimate discharge of the non-beneficiary patient from, the Indian hospital.

CMS reserves the right to second-guess any decision by Hospital B to refuse a transfer based on the unavailability of the needed bed, specialty care unit, or hospital staff – although these deficiencies are common issues in these days of nursing staff and other relevant shortages, and bear significantly on patient safety – and can focus on how the hospital usually operates to cover episodic patient overloads.

### A410 – Whistleblower Protection (§489.24(e)(3))

This requirement has never been modified. A Medicare-participating hospital may not take any adverse action against one of its physicians or QMPs who was trying to *prevent* the hospital from committing an EMTALA violation by inappropriately transferring an EMTALA-unstable patient. The classic illustration of this is Hospital A's financial officer trying to force the medical staff (ED and admitting physicians) to transfer an uninsured patient rather than admit him or her to Hospital A, when Hospital A can provide what the patient needs. The hospital may not take any adverse action against a hospital employee because the employee reports an EMTALA violation that occurred at the hospital. These become Medicare-termination tracks separate from any other the hospital may (or may not) already be facing.



### A411 – Duty to Accept Transfers (§489.24(f))

This requirement has never been modified. Simply put, if a Medicare-certified Indian hospital (whether Federally or tribally operated) becomes Hospital B in an EMTALA-covered transfer request; and even if Hospital A is a non-Indian facility and the patient is not an IHS beneficiary – then the Indian hospital *may not refuse* to accept the patient in transfer if it can provide the bed and services that the patient needs and that the requesting Hospital A cannot. The Indian hospital may refuse an EMTALA-covered transfer request only as discussed under Data Tag A409, as could any other Medicare-participating hospital.

### Conclusion

EMTALA, in one form or another, is here to stay. An EMTALA investigation is a complaint-driven process, and the likelihood of a complaint diminishes when both good care and good customer service are provided in an EMTALA-friendly manner. I welcome questions from anywhere in Indian country, and can be reached by phone at (602) 364-5045 or by e-mail at *ken.simpson@ihs.gov*.

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# Cancer Mortality among Wisconsin American Indians, 1996-2000

*From the Spirit of EAGLES Project, University of Wisconsin Comprehensive Cancer Center, Madison, Wisconsin (Monica Monteon, MS, Project Assistant; Patrick Remington, MD, MPH, Co-Principal Investigator; Rick Strickland, MA, Project Coordinator); the Great Lakes Inter-Tribal Council, Lac du Flambeau, Wisconsin (Nancy Miller-Korth, RN, MSN, Epidemiology Center Director; Kimmine Pierce, MS, Staff Epidemiologist); the Peter Christiansen, Sr., Health Center (Adrienne Laverdure, MD, Medical Director and Principal Investigator, Great Lakes Native American Research Centers for Health); and Spirit of EAGLES, Mayo Clinic Cancer Center, Rochester, Minnesota (Judith S. Kaur, MD, Principal Investigator)*

## Abstract

The purpose of this study is to compare cancer mortality rates among American Indians living in Wisconsin with the overall state population, during the five-year period from 1996-2000. Age-specific rates and indirect adjustments are used to examine the cancer burden for Wisconsin American Indians. Cancer mortality rates for the Wisconsin population (total and American Indian) were obtained from death certificates available from the Wisconsin State Vital Records Section, Bureau of Heath Information. Age- and sex-specific mortality rates were calculated based on 2000 census estimates of the Wisconsin American Indian and total Wisconsin populations. Chi-square tests were used to test for significant differences. Wisconsin American Indians have higher cancer mortality rates (219 per 100,000) compared to the Wisconsin total, U.S. total, and the U.S. American Indian populations. The number of deaths among Wisconsin American Indians was 13% higher than expected compared to the general Wisconsin population. The ratio of mortality rates (Indians versus Wisconsin) varied markedly by age and gender. Mortality rates from lung, colorectal, and cervical cancers were all significantly higher among American Indians living in Wisconsin.

The cancer burden among Indians living in Wisconsin, compared to the general population of Wisconsin, demonstrates marked variation, by age, gender, and specific cancer. When such discrepancies exist, reports should present age-specific rates for the population under study, rather than using summary age adjusted rates

## Introduction

Nationwide, cancer remains the second leading cause of death among American Indians.[1] Concern about cancer in the Wisconsin American Indian population is evident from previous studies investigating potential cancer clusters in three Wisconsin Indian reservations.[2-4] Recent research indicates that national cancer mortality rates are declining overall; however, American Indians are experiencing increased mortality in lung, colorectal, and breast cancer.[5,6] Furthermore, recent studies suggest that American Indian cancer rates in the Northern Plains are higher than the national averages for both the total population and the total American Indian population.[7,8]

Previous literature presents an inconsistent picture of the Wisconsin American Indian cancer burden.[9,10] Cancer was the second leading cause of death in the Wisconsin American Indian population from 1994-1998 (24% of all deaths).[9] Reeves, et al[11] found that Wisconsin American Indian cancer mortality rates were similar, or even slightly lower compared with the white population for breast, lung, colorectal, and prostate cancer. The American Indian cervical cancer mortality rate was elevated, however. Observations by Tavris[12] indicated that cancer deaths were not a major cause of the overall excess mortality found in the Wisconsin American Indian population. Dellinger[13] reported that the overall cancer rate in American Indians was less than expected. A 2002 report by the Great Lakes Inter-Tribal Council stated that the age-adjusted lung cancer mortality rates of American Indians were lower than those of the total Wisconsin population; however, the mortality rates for all cancers combined were higher.[10]

The objective of the current study is to examine methods

that can be used to compare current rates of cancer mortality among Wisconsin American Indians and the overall state population. Cancer mortality data for lung, colorectal, breast, cervical, prostate, and all-cause cancers between 1996 and 2000 were analyzed. In addition to a traditional analysis comparing Wisconsin American Indian rates with Wisconsin's overall population, age-specific and indirect adjustment were used to examine the effect of using different approaches to assess the cancer burden for Wisconsin American Indians.

## Methods

*Population:* Total Wisconsin American Indian population (including Alaskan Natives) and the total Wisconsin population from 1996-2000.

*Data Sources:* The cancer mortality rates for the Wisconsin population (total and American Indian) were obtained from death certificates from the Wisconsin State Vital Records Section, Bureau of Heath Information. Additionally, cancer mortality rates in Indian Health Service (IHS) area populations are used for comparative purposes. The IHS population includes the American Indians that used IHS services at least once in the five-year period 1994 - 1998.[14,15] Vital events statistics are provided yearly by the National Center for Health Statistics to the IHS.

The International Classification of Diseases (ICD) was used to classify cancers. Mortality data were obtained on American Indians (as identified on death certificates) and the total population residing in Wisconsin between January 1996 and December 2000 for the following cancers: lung and bronchus (ICD-9 codes 162 - 162.9, ICD-10 code C34); breast (ICD-9 codes 174 - 174.9, ICD-10 code C50); cervix (ICD-9 codes 180 - 180.9, ICD-10 code C53); colorectal (ICD-9 codes 153 - 154.1, ICD-10 codes C18 - C20); prostate (ICD-9 codes 185, ICD-10 code C61); and all malignant cancers (ICD-9 codes 140 - 208, ICD-10 codes C00 - C97).

*Analysis:* Age- and sex-specific mortality rates were calculated based on the 2000 census estimates of the Wisconsin American Indian and total Wisconsin populations. All rates are per 100,000 persons. Indirect age-adjustment to the American Indian population was used for calculation of expected cases. The observed and expected numbers of cases are presented for each type of cancer and all cancers combined. Chi-square tests were used to determine significant differences between observed and expected cases stratified by age and sex ($\alpha = 0.05$).

## Results

Cancer mortality rates for Wisconsin American Indians and the total state population are compared to the US American Indian and total US population, adjusted to the US 2000 population standard (Table 1). The Wisconsin American Indians have the highest cancer mortality rates, 219 per 100,000, among all four population groups. In addition, results from a recent Centers for Disease Control study[6] are presented in Table 1 to allow for comparisons to American Indians in other areas of the United States. American Indians in the Northern Plains region (which includes Wisconsin) have the

**Table 1. Cancer Mortality Rates of Different Populations**

| Population | Years | Deaths | Population | Rate* |
|---|---|---|---|---|
| Wisconsin American Indian | 1996-2000 | 225 | 46,446 | 219 |
| Wisconsin All | 1996-2000 | 51,906 | 5,296,087 | 192 |
| **IHS Region†** | | | | |
| Northern Plains | 1994-98 | 1,383 | | 292 |
| Alaska | 1994-98 | 593 | | 249 |
| East | 1994-98 | 1,602 | | 140 |
| Pacific Coast | 1994-98 | 970 | | 134 |
| Southwest | 1994-98 | 1,404 | | 128 |
| US all | 1994-98 | | | 206 |
| American Indian all | 1994-98 | | | 161 |

* per 100,000, age adjusted to US 2000 population

†Alaska; Northern Plains = Indiana, Iowa, Michigan, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wisconsin, and Wyoming; East = Alabama, Connecticut, Florida, Kansas, Louisiana, Massachusetts, Maine, Mississippi, New York, North Carolina, Oklahoma, Pennsylvania, Rhode Island, South Carolina, Tennessee, and Texas; Pacific Coast = California, Idaho Oregon, and Washington; Southwest = Arizona, Colorado, Nevada, New Mexico, and Utah.

highest cancer mortality rates in the US.

Next, we examined mortality rates by age and gender for all cancers combined (Table 2). Overall, the number of deaths among American Indians was 13% higher than in comparison to the Wisconsin population. American Indian males had increased differences at ages 45 - 74 years compared to the Wisconsin population. For example, there was a 46% higher mortality rate for males 45 - 54 years of age. The greatest difference among female American Indians was at 55 - 64 years of age: 32% higher than the Wisconsin population. Figure 2 presents the risk of death by age for American Indians relative to the Wisconsin population. The risk peaks at 55 - 64 years of age. None of these age-specific differences in total cancer mortality was statistically significant.

American Indian cancer mortality rates for 1996 - 2000 differ by cancer type and gender (Table 3). The five most prevalent cancers were analyzed: lung, colorectal, breast, cervical, and prostate. Lung, colorectal, and cervical cancers all had statistically significant higher overall rates, 38%, 44%, and 233%, respectively. For lung cancer, this was driven by higher than expected rates among American Indian females (51% higher than expected), while for colorectal cancer men experienced the higher rates (71% higher). Breast cancer cases were 47% less than the expected rate, also a statistically significant difference.

## Discussion

American Indians in Wisconsin appear to face overall higher cancer mortality compared to the general Wisconsin population, and there are marked differences by age, gender, and specific cancer. While the age-specific differences were not statistically significant, the similarities seen in females and males suggest a pattern. American Indians have noticeably higher rates between 55 - 74 years of age. After 75 years, the differences are less marked.

The reason for the lower rate in the under 45 category may be the result of miscoding on death certificates (see discussion below). Significant differences may not show due to the small American Indian population. American Indian females have a lower mortality from breast cancer compared to the Wisconsin general population, a result consistent with previous studies showing higher rates in whites.[8,10,17]

There are several possible reasons for the higher mortality rates that Wisconsin American Indians experience in the age

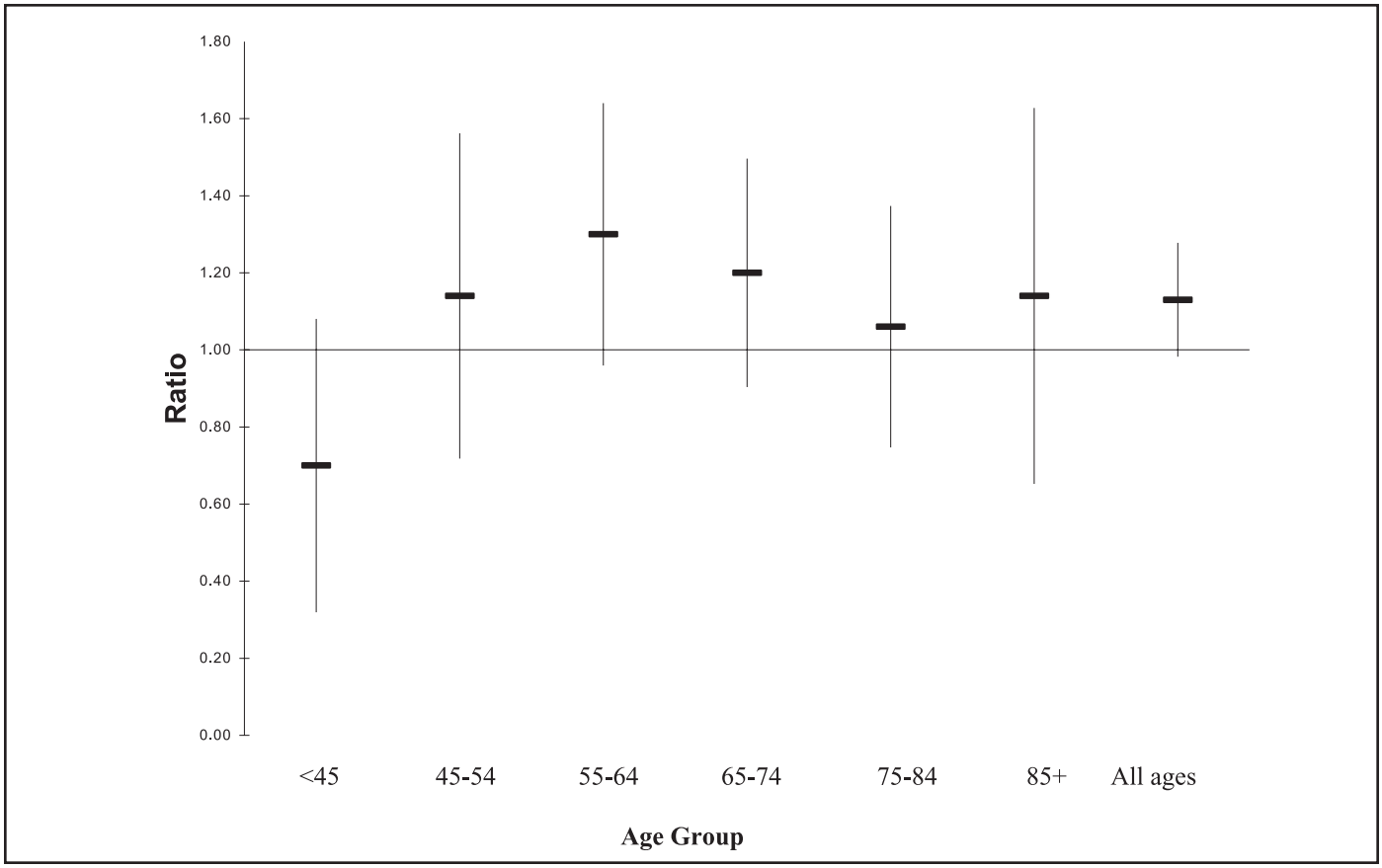
**Table 2. American Indian All Sites Cancer Mortality by Age and Sex, 1996-2000**

| | Age-specific Wisconsin Rate 1996-2000 | American Indian Population 1996-2000 | Expected # Deaths [1] | Observed # Deaths [2] | Difference | Ratio |
|---|---|---|---|---|---|---|
| | | | | | | |
| **Males** | | | | | | |
| All Ages | | 115534 | 101 | 119 | 18 | 1.18 |
| <45 | 10.58 | 94808 | 8 | 3 | -5 | 0.36 |
| 45-54 | 116.61 | 10552 | 12 | 18 | 6 | 1.46 |
| 55-64 | 390.22 | 5794 | 23 | 29 | 6 | 1.28 |
| 65-74 | 987.47 | 2840 | 28 | 37 | 9 | 1.32 |
| 75-84 | 1715.442 | 1246 | 21 | 24 | 3 | 1.12 |
| 85+ | 2688.06 | 294 | 8 | 8 | 0 | 1.01 |
| **Females** | | | | | | |
| All Ages | | 116698 | 97 | 106 | 9 | 1.09 |
| <45 | 13.25 | 92727 | 10 | 10 | 0 | 0.98 |
| 45-54 | 110.94 | 11076 | 12 | 10 | -2 | 0.81 |
| 55-64 | 312.61 | 6518 | 20 | 27 | 7 | 1.32 |
| 65-74 | 650.11 | 3678 | 24 | 26 | 2 | 1.09 |
| 75-84 | 1006.22 | 1963 | 20 | 20 | 0 | 1.01 |
| 85+ | 1416.26 | 736 | 10 | 13 | 3 | 1.25 |
| **Both Sexes** | | | | | | |
| All Ages | | 232232 | 198 | 225 | 27 | 1.13 |
| <45 | 11.91 | 187535 | 19 | 13 | -6 | 0.70 |
| 45-54 | 113.76 | 21628 | 25 | 28 | 3 | 1.14 |
| 55-64 | 350.50 | 12312 | 43 | 56 | 13 | 1.30 |
| 65-74 | 805.36 | 6518 | 52 | 63 | 11 | 1.20 |
| 75-84 | 1287.65 | 3209 | 41 | 44 | 3 | 1.06 |
| 85+ | 1782.04 | 1030 | 18 | 21 | 3 | 1.14 |

* None were significantly different than expected (chi-square test). Numbers may not add due to rounding.

1. Expected number is determined by multiplying the calculated WI age specific rates by the AI population.
2. Number of deaths, 1996-2000.

**Figure 1. Ratio of American Indian Cancer Deaths to Expected Deaths.**




cohorts of 45 - 74 for males and 55 - 64 for females. First, Wisconsin American Indians may have a higher rate of cancer incidence, for example as a result of higher smoking rates or poor diets. Second, screenings for cancer may not be utilized at the recommended frequencies or age. This would result in a diagnosis of cancer at a later stage and delayed treatment, resulting in a lower chance of survival. Third, inadequate access to appropriate treatment, poor treatment, or the choice to not obtain treatment could result in an early death from cancer.

Higher rates of smoking among Americans Indians in Wisconsin have been suggested as the cause for some cancers. A recent Great Lakes Inter-Tribal Council Youth Tobacco Study found current tobacco use of Wisconsin American Indians in middle school to be 57% in 8th grade. The rate of tobacco use among all middle school children in the state was found to be 23% by the Wisconsin Youth Tobacco Survey.[18]

In this report, the total Wisconsin population was used as a referent population, as would be customary. The use of a different referent population would have resulted in a change in the cancer-specific table. Comparisons to different populations provide insight into how interpretation of the burden of disease can vary. On the other hand, use of indirect age adjustment is useful when comparing age strata to understand where the burden of disease exists for the study population compared to the referent populations. Also, the use of expected and observed deaths allows for more intuitive comparisons.

The Wisconsin American Indians observed six more deaths from all cancers than Wisconsin's total population; however, if a different standard were used, such as the US American Indian population, the results would be different. The expected number of deaths would be 153, yet the observed is 225. Thus, Wisconsin American Indians have 72 more deaths than expected relative to the national cancer mortality of American Indians. Direct age-standardization may have been inappropriate to use in this population because the general population and the American Indian populations have different patterns in age-specific cancer mortality and a summary measure would have been misleading.[19]

A major goal of Healthy People 2010 and the Department of Health and Human Services[14,20] is to eliminate disparities in health. If the 2000 US American Indian rate is used, American Indians would be regarded as having lower cancer mortality rates (161 for all IHS areas or 127 for the total US Indian population[16]); however, this report suggests that such broad assumptions can lead to conclusions that are misleading or erroneous. The rates among Wisconsin American Indians are much higher than the total US American Indian population. In addition, cancer mortality rates in the different IHS regions show great variation. Assumptions based on generalized statistics can have damaging

impacts on the health of subgroups since they do not account for subgroup differences.

An assumption that American Indians have lower cancer mortality rates than the general population has important policy implications, and the health care system must realize that there is considerable geographic variation in American Indian cancer mortality rates. While low rates of cancer are found in southwestern American Indians, this is not the case in the Northern Plains and Alaska.[5] Wisconsin American Indians were shown to have higher rates of cancer than those of the Wisconsin and US general populations, the total US American Indian population, and all of the IHS regions. It will be important to monitor the cancer mortality rates of Wisconsin American Indians in the future and to identify reasons for these higher rates and develop strategies for lowering cancer mortality.

There are some limitations to this study. Death certificates were used to determine American Indian cancer deaths. It has been widely reported that racial misclassification occurs on death certificates, as discussed in further detail below. Due to the racial misclassification of American Indians on death certificates, our results could subsequently underreport the true number of cancer deaths in American Indians. In addition, there were often low numbers of cancer deaths when examining data on Wisconsin American Indians. For this reason, a five-year period was considered for current rates rather than a single year. Another limitation of this study would be that IHS populations were used to determine the regional rates for American Indians. IHS populations only include American Indians who sought service through IHS supported facilities, and our analysis included all American Indians in the state of Wisconsin.

Underreporting of race on death certificates has been reported in several publications, with estimates varying among populations.[21-24] It is reasonable to assume that some underreporting of race has occurred on Wisconsin death certificates. The extent to which this occurs could have dramatic effects on the calculation of cancer mortality rates for Wisconsin American Indians due to small populations. It has been reported that blood quantum level,[22,24] year of analysis,[24] cause of death,[22] age at death[24] and tribal size[22] are all related to the extent of racial misclassification among American Indians. If misclassification is corrected, the rates of cancer mortality are likely to be higher still; however, it is impossible to determine where the effects would be seen. Some inferences can be drawn from the adjusted rates provided by IHS.[25] Nonetheless, it is impossible to know the exact rate of miscoding in Wisconsin without further studies to determine age-specific underreporting of American Indian classification in Wisconsin.

This study shows marked variation in Wisconsin American Indian cancer burden, compared with the Wisconsin general population, by age, gender, and specific cancer. We recommend that age adjustment is not appropriate when discrepancies vary by age. All reports should present age-specific rates for the population under study when such discrepancies exist. The use of indirect age adjustment better accounts for burden, since it reflects the distribution to the population under study.[26]

**Table 3. Total Cancer Mortality in American Indians by Sex, 1996-2000**

| Primary Cancer Site | Sex | Expected* | Observed | Difference | Ratio** | $\chi^2$ |
|---|---|---|---|---|---|---|
| All sites | Both sexes | 198 | 225 | 27 | 1.13 | 3.57 |
| | Male | 101 | 119 | 18 | 1.18 | 3.37 |
| | Female | 97 | 106 | 9 | 1.09 | 0.85 |
| Lung | Both sexes | 50 | 69 | 19 | 1.38 | 7.15 |
| | Male | 28 | 37 | 9 | 1.30 | 2.58 |
| | Female | 21 | 32 | 11 | 1.51 | 5.49 |
| Colorectal | Both sexes | 20 | 29 | 9 | 1.44 | 3.87 |
| | Male | 11 | 18 | 8 | 1.71 | 5.36 |
| | Female | 10 | 11 | 1 | 1.15 | 0.22 |
| Breast | Female | 17 | 9 | -8 | 0.53 | 3.74 |
| Cervix | Female | 2 | 6 | 4 | 3.33 | 9.80 |
| Prostate | Male | 10 | 13 | 3 | 1.32 | 1.02 |

* Based on rate in Wisconsin for 1996-2000

** Rates are indirectly age adjusted to the 2000 Wisconsin American Indian population estimated by the US Census Bureau

† Statistically significant at $\propto = 0.05$

†† Statistically significant at $\propto < 0.0001$, Fisher Exact Test used

## Acknowledgments

This report presents the results of a collaborative effort to improve cancer surveillance practices among Wisconsin tribal and urban program Indian clinics. Participating partners were the Wisconsin Tribal Health Directors Association, the Great Lakes Inter-Tribal Council, the Wisconsin Cancer Reporting System, Mayo Clinic Cancer Center, University of Wisconsin Comprehensive Cancer Center, and Spirit of EAGLES: American Indian/Alaska Native Leadership Initiative on Cancer. This project was supported through the Spirit of EAGLES: An AI/AN Leadership Initiative on Cancer (Grant Number: UO1 CA86098) and the Great Lakes Native American Research Centers for Health (Grant Number: 1 U26 94 00014-01).

The authors would like to thank Dr. Paul Peppard for his input and assistance in the preparation of the cancer mortality data.

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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

"*If I ever see the word 'rat' or 'dog' in a paper I cross it out*" — Sir Francis Avery Jones, explaining his success as the editor of *Gut.*

## Articles of Interest

Impact of childhood vaccination on racial disparities in invasive *Streptococcus pneumoniae* infections. *JAMA*. 2004 May 12;291(18):2197-203. *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=pubmed*.

- The pneumococcal conjugate vaccine (PCV7) was licensed in 2000 and has decreased rates of invasive pneumococcal disease (IPD). The decline in IPD has been especially dramatic in blacks. In the prevaccine era, black children had rates of IPD three times higher than the US population. The rates of IPD for black children now approach those of whites.

Updated Recommendations for Use of Pneumococcal Conjugate Vaccine. *MMWR*. July 9, 2004 53(26):589-90.

Effective immediately, CDC . . . recommends that providers administer three doses of vaccine. The fourth dose should still be deferred for healthy children until further production and supply data demonstrate that a 4-dose schedule can be sustained. **Alaska Native children and American Indian children who live in Alaska, Arizona, or New Mexico, and Navajo children who live in Colorado and Utah have a risk for invasive pneumococcal disease more than twice the national average. These children should receive the standard 4-dose PCV7 series despite the shortage.** *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5326a7.htm*.

- The recurrent shortages of the PCV7 have been troubling to those of us caring for AI/AN children because of the perceived higher risk of IPD. Recent analysis of hospital discharge data for IPD from the Indian Health Service shows that the burden of this disease does not fall equally on all AI/AN children. AI/AN children in Alaska and the Southwest had hospitalization rates of IPD three times the US average. Rates in other IHS areas were equivalent to the overall US rates.
- This change in policy makes the full four dose series of the pneumococcal vaccine available to AI/AN children even in times of vaccine shortage. Providers in Alaska and the Southwest should request increased vaccine to provide four doses of the pneumococcal vaccine to their patients. They should provide catch up doses to those who have received fewer than four doses of the pneumococcal vaccine.
- Additional data show that rates of IPD have declined almost 60% in AI/AN children in Alaska and the Southwest, but this decline is less than that seen in the US as a whole and far less than that seen in black children as noted above. The relative incidence of IPD has actually increased in AI/AN children since the introduction of the PCV7 vaccine in 2000.
- The reason for the continued disparity in IPD rates in Alaska and the Southwest is unclear. There is no evidence that AI/AN children respond less well to a two-dose vaccine schedule than other children. It is known that Alaskan and Southwest AI/AN have earlier nasopharyngeal carriage and higher colonization rates. Four doses of PCV7 may provide more lasting protection, decreased colonization, and better herd immunity.

Validity of self-reported dietary intake at school meals by American Indian children: the Pathways Study. *J Am Diet Assoc*. 2004 May;104(5):746-52. *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15127059*.

- You may not like the answers you get when you ask your patients what they eat, but this study suggests that their answers are valid.

## Meetings of Interest for Child Health

Join the American Academy of Pediatrics and the Canadian Paediatric Society, in cooperation with the Indian Health Service, for the first International Meeting on Inuit and Native American Child Health, April 29 - May 1, 2005 in Seattle, Washington. Pediatricians, family physicians, residents, other health care professionals, clinical researchers, state and federal public health employees, child advocates, and other professionals and family representatives dedicated to working with First Nations, Inuit, and American Indian/Alaska Native (AI/AN) children should attend. Participants will have the opportunity to share ideas on culturally effective health care delivery models, present research findings, and dialogue about strategies to improve the health of First Nations, Inuit, and AI/AN children and communities.

This is the first international meeting on Indian/Inuit health with sponsorship by both country's pediatric societies. It should be an excellent forum for education and sharing of ideas. Go to *http://www.aap.org/nach/InternationalMeeting.htm* to learn more.

*Editor's Note: The following is a digest of the monthly Obstetrics and Gynecology Chief Clinical Consultant's Newsletter (Volume 2, No. 7, July 2004) available on the Internet at* http://www.ihs.gov/MedicalPrograms/MCH/M/OBGYN01.cfm. *We wanted to make our readers aware of this resource, and encourage those who are interested to use it on a regular basis. You may also subscribe to a listserv to receive reminders about this service. If you have any questions, please contact Dr. Neil Murphy, Chief Clinical Consultant in Obstetrics and Gynecology, at* nmurphy@anmc.org**.**

# OB/GYN Chief Clinical Consultant's Corner Digest

***Abstract of the Month***

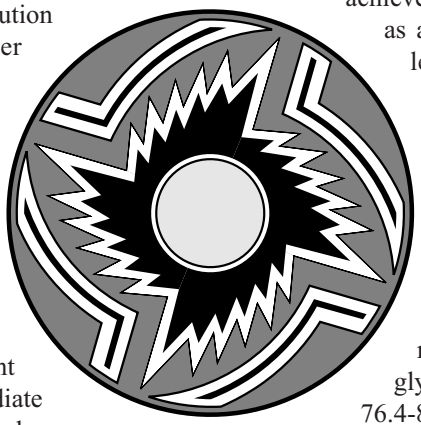
Lidocaine Plus Naproxen for Endometrial Sampling Pain: POEM (Patient-Oriented Evidence that Matters).

*Clinical Question*: Do intrauterine lidocaine, oral naproxen, or both, lead to better pain control for endometrial sampling?

*Setting*: Outpatient (primary care)

*Study Design*: Randomized controlled trial (double-blinded)

*Synopsis*: Oral analgesia is recommended frequently to decrease the pain of endometrial sampling in the medical office. Intrauterine anesthesia also is promising. In this study, 120 women undergoing pipelle aspiration for endometrial sampling were randomized to one of four groups: 1) local lidocaine plus oral naproxen; 2) lidocaine with placebo oral analgesia; 3) placebo anesthesia (sterile saline) with oral naproxen; or 4) both treatment placebos. Local lidocaine in a dose of 5 mL of 2 percent solution was given via an 18-gauge angiocatheter sheath. Syringe and sheath were left in place for three minutes and then withdrawn. Naproxen sodium was given as a single 550 mg oral dose one hour before the procedure.



Women rated their pain during the procedure on a visual analog scale. Mean pain scores were lower in the lidocaine plus naproxen group than in the placebo group (4.6 versus 7.1, $P < .05$), a clinically relevant difference. Mean pain scores were intermediate and not statistically different from placebo or combined treatment in the lidocaine only and naproxen only groups (5.9 and 5.8, respectively).

*Bottom Line*: The combination of intrauterine lidocaine plus oral naproxen sodium significantly decreases pain associated with endometrial sampling in the medical office (Level of Evidence: 1b). Go to *http://www.aafp.org/afp/20040615/tips/13.html*.

*OB/GYN CCC Editorial comment*: Patients experience intense cramps/discomfort as the endometrial device traverses the cervical canal. Any effort we can make to alleviate that discomfort will serve our patients well, as this is can be one of the more uncomfortable outpatient procedures we perform. AI /AN facilities should explore ways to implement the above procedures into their day to day practice guidelines.

**From your colleagues**
**From George Gilson, Anchorage**

*Eighty percent of patients with gestational diabetes can be treated effectively with glyburide.*

*Objective*: This study was undertaken to evaluate the effectiveness of glyburide in patients with gestational diabetes who failed diet therapy.

*Methods*: Patients who were beyond the first trimester and who failed to achieve satisfactory glucose control with diet therapy were treated with glyburide, at a starting dose of 2.5 mg daily. The dose was increased in increments to a maximum of 20 mg/day. The main treatment outcome was achievement of satisfactory glucose control, defined as a mean plasma fasting glucose 90 mg % or less and mean 1-hour postprandial plasma glucose determinations 135 mg % or less. Patients who failed to achieve satisfactory control were treated with twice-daily doses of insulin.

*Results*: During the period July 2001 through December 2002, we managed 197 patients with gestational diabetes. One-hundred twenty-four patients responded to diet alone; 73 were treated with glyburide. Of the 73 patients, 59 (81%, 95% CI 76.4-85.6) achieved satisfactory glucose control with glyburide; 44 women required 7.5 mg/day or less. Eleven of the 59 women (19%) had macrosomic infants. Eight patients (11%) experienced noticeable side effects related to glyburide; only 1 patient discontinued treatment.

*Conclusion*: Approximately 80% of patients with gestational diabetes who fail to respond to diet therapy can be treated effectively with glyburide.

*Reference*: Kremer CJ, Duff P. Glyburide for the treatment of gestational diabetes. *Am J Obstet Gynecol*. 2004 May;190(5):1438-9. *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15167862*

**From Jennifer Retsinas, Anchorage**

*Do you use e-mail with your patients? If so, you may want a few style points for caution*.

"Phones seem antagonistic these days, [and] I'm not sure I can process health stuff that quickly. With e-mail I can address issues when I have the mental space. I have time to think and shape the question and keep a file. And my doctor. . . helps me think things through. He has really gotten to know me and my evolving circumstance. — A patient in our practice.

Alexander Graham Bell invented the telephone in 1876, and within decades it was impossible to imagine society without it. E-mail emerged in the early 1970s, and today about 100 million Americans . . .."

Delbanco T, Sands DZ. Electrons in flight — e-mail between doctors and patients. *N Engl J Med*. 2004 Apr 22;350(17):1705-7. *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=retrieve&db=pubmed&list_uids=15102994&dopt=Abstract*.

Here is a second resource from MIEC, Liability Insurer: When using e-mail to communicate with patients: What physicians should consider. Request Special Report 24A, revised January 2004 for a Sample agreement. *http://www.miec.com*.

## Hot Topics

### Obstetrics

*Aberdeen Area Infant Mortality Study (AAIMS) available on the MCH web page*.

Leslie Randall, et al, present an audio and Powerpoint conference on infant mortality data from the Aberdeen Area. *http://www.ihs.gov/MedicalPrograms/MCH/M/Pr01.cfm#AAIMS*.

*Acyclovir Can Reduce Genital Herpes Recurrence at Delivery*. Prophylactic acyclovir therapy from the 36th week of pregnancy reduces the risks of clinical HSV in the mother at delivery or cesarean delivery, and asymptomatic viral shedding at delivery. Similar results were noticed regardless of type of HSV disease and dosage of acyclovir. Sheffield JS, et al. Acyclovir prophylaxis to prevent herpes simplex virus recurrence at delivery: a systematic review. *Obstet Gynecol*. December 2003;102:1396-403. *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=14662233*.

### Gynecology

*Polycystic Ovary Syndrome More Prevalent in US Than Had Been Thought*. The prevalence rates of PCOS for Black and White women were 8.0 and 4.8%, respectively, not significantly different. These data from a large, representative, unselected population support the concept that PCOS is the most common endocrine abnormality of reproductive-aged women in the United States. Azziz R, et al. The prevalence and features of the polycystic ovary syndrome in an unselected population. *J Clin Endocrinol Metab*. 2004 Jun;89(6):2745-9. *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15181052*.

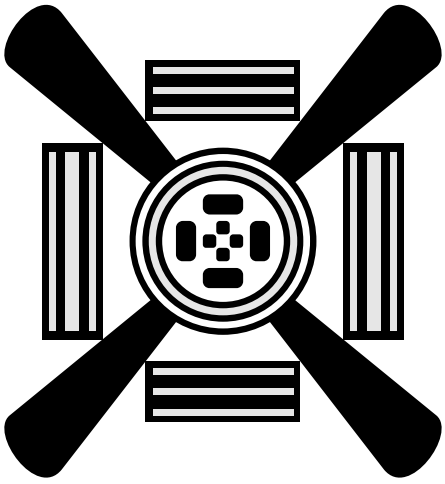
### Child Health

*Emergency Contraception to Adolescents*. A position paper published by the Society for Adolescent Medicine in the July 2004 issue of the *Journal of Adolescent Health*. In this paper, "emergency contraception" refers to the use of estrogen- and progestin-containing pills (combination emergency contraceptive pills, or ECPs) or levonorgestrel-only pills (progestin-only ECPs) that are taken after unprotected or underprotected intercourse to prevent pregnancy. The paper presents background information on ECPs and adolescents and discusses ECP provision, accessibility, and advocacy.

Gold M, Sucato GS, Conard LE, et al. 2004. Provision of emergency contraception to adolescents. Position Paper of the Society for Adolescent Medicine. *American Journal of Adolescent Health*. 35(1):66-70. *http://www.adolescenthealth.org/html/publications.html*.

*Motivational Counseling improves dental caries in children*. "Motivational interviewing, a brief form of counseling, presents promise in working with parents of young children to prevent caries in those children, especially children at high risk for developing the disease." The MI approach used for this study focused on establishing rapport and need, discussing options, and using strategies that structure and reinforce change. After one year, children in the experimental group had .71 carious surfaces while those in the control group had 1.91 carious surfaces. The authors conclude that "results of the study, at this time the only clinical dental study using MI counseling, suggest that MI counseling has an effect on children's health that is greater than the effect of traditional health education."

Weinstein P, Harrison R, Benton T. Motivating parents to prevent caries in their young children: One-year findings. *Journal of the American Dental Association*. 2004; 156(6):731-738. *http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=15270155*.



## Features

*Vaginal Birth After Previous Cesarean Delivery*. ACOG Practice Bulletin, Number 54, July 2004.

*Summary of Recommendations*

***The following recommendations are based on good and consistent scientific evidence (Level A):***

- Most women with one previous cesarean delivery with a low-transverse incision are candidates for VBAC and should be counseled about VBAC and offered a trial of labor.
- Epidural anesthesia may be used for VBAC.

***The following recommendations are based on limited or inconsistent scientific evidence (Level B):***

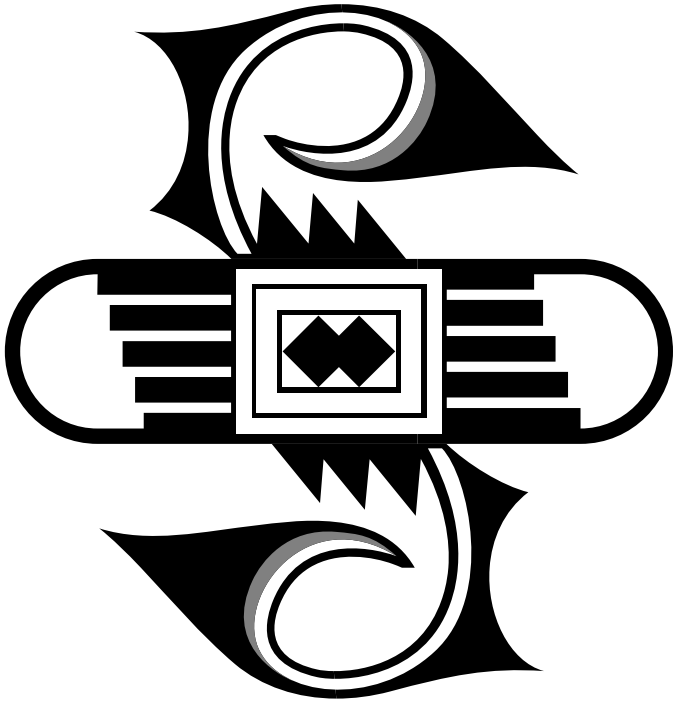
- Women with a vertical incision within the lower uterine segment that does not extend into the fundus are candidates for VBAC.
- The use of prostaglandins for cervical ripening or induction of labor in most women with a previous cesarean delivery should be discouraged.

***The following recommendations are based primarily on consensus and expert opinion (Level C):***

- Because uterine rupture may be catastrophic, VBAC should be attempted in institutions equipped to respond to emergencies with physicians immediately available to provide emergency care.
- After thorough counseling that weighs the individual benefits and risks of VBAC, the ultimate decision to attempt this procedure or undergo a repeat cesarean delivery should be made by the patient and her physician. This discussion should be documented in the medical record.
- Vaginal birth after a previous cesarean delivery is contraindicated in women with a previous classical uterine incision or extensive transfundal uterine surgery.

*First-Trimester Screening for Fetal Aneuploidy*. Committee Opinion Number 296, July 2004.

*Abstract*: First-trimester screening for chromosomal abnormalities offers potential advantages over second-trimester screening. Studies in the 1990s demonstrated an association between chromosomal abnormalities and the ultrasonographic finding of abnormally increased nuchal translucency (an echo-free area at the back of the fetal neck) between 10 and 14 weeks of gestation. First-trimester screening using nuchal translucency, free ß-hCG, and pregnancy-associated plasma protein-A has comparable detection rates and positive screening rates for Down syndrome as second-trimester screening using four serum markers (alpha-fetoprotein, ß-hCG, unconjugated estriol, and inhibin-A). Although first-trimester screening for Down syndrome and trisomy 18 is an option, it should be offered only if certain criteria can be met.*https://www.acog.com/from_home/publications/press_releases/nr06-30-04.cfm*



*Pain Relief During Labor*. Committee Opinion, Number 295, July 2004.

*Abstract*: Pain management should be provided whenever medically indicated. The American Society of Anesthesiologists (ASA) and the American College of Obstetricians and Gynecologists (ACOG) believe that women requesting epidural analgesia during labor should not be deprived of this service based on their insurance or inadequate nursing participation in the management of regional analgesic modalities. Furthermore, in an effort to allow the maximum number of patients to benefit from neuraxial analgesia, ASA and ACOG believe that labor nurses should not be restricted from participating in the management of pain relief during labor.

*The National Breastfeeding Campaign, Babies Were Born to Be Breastfed,* aims to promote breastfeeding among first-time parents (mothers and fathers) who would not typically breastfeed their infants. The overall goal is to increase the proportion of mothers who breastfeed their babies in the early postpartum period to 75% and during the 6-month period following delivery to 50% by the year 2010. More information: *http://www.4woman.gov/breastfeeding.*

*Therapeutic Foster Care for the Prevention of Violence*. To assess the effectiveness of therapeutic foster care programs in preventing violent behavior among youths who are unable to live at home, the Task Force on Community Preventive Services reviewed the scientific literature concerning two

interventions. First, they looked at therapeutic foster care for reduction of violence by children with severe emotional disturbance. This intervention involved programs in which clusters of foster-parent families cooperated in the care of such children. The Task Force found insufficient evidence to determine the effectiveness of this intervention. Second, they looked at therapeutic foster care for the reduction of violence by chronically delinquent adolescents. This intervention involved short-term programs in which program personnel collaborated closely and daily with foster families caring for such adolescents. The Task Force recommends this intervention as effective. The report briefly describes how the reviews were conducted, provides additional information about the findings, and provides information that might help communities in applying the intervention locally. *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5310a1.htm*.

*Calcium Supplementation in Postmenopausal Women: Cochrane Abstract*. Calcium supplementation has a beneficial effect on bone density and may reduce vertebral fractures. It has no clear effect on nonvertebral fractures, although the number of patients studied may be too small to predict this outcome. *http://www.aafp.org/afp/20040615/cochrane.html*.

*Strontium Reduces Risk of Vertebral Fracture: POEM.*

*Clinical Question*: Does strontium ranelate improve clinical outcomes in patients with postmenopausal osteoporosis and at least one previous vertebral fracture?

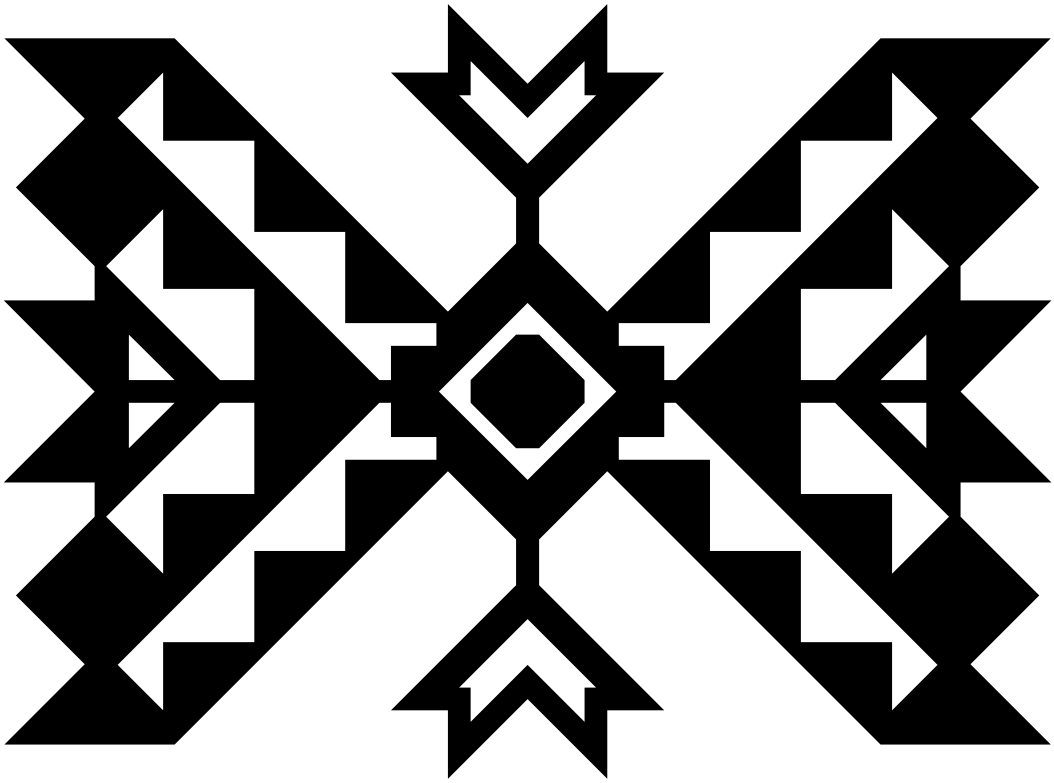
*Bottom Line*: The use of strontium ranelate prevents one symptomatic vertebral fracture for every 17 postmenopausal women with a history of vertebral fracture who take it for three years. (Level of Evidence: 1b). *http://www.aafp.org/afp/20040615/tips/12.html*.

## Primary Care Discussion Forum

*November 1, 2004: Violence against Native women.* Moderator: Terry Cullen.

This discussion will include the scope of violence against Native women, tools for patient evaluation, best practice policies and procedures, plus ideas about available resources. To subscribe to the **Primary Care Discussion Forum**, please go the site below and click the word 'subscribe' in the first paragraph, *www.ihs.gov/MedicalPrograms/MCH/M/MCHdiscuss.asp*, or contact me, *nmurphy@anmc.org*.

The past CCC Corners are archived at: *http://www.ihs.gov/MedicalPrograms/MCH/M/OBGYN01.cfm#top*.



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

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