

# THE IHS PRIMARY CARE PROVIDER



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

November 1997

Published by the IHS Clinical Support Center

Volume 22, Number 11

## Out-of-Hospital Medical Direction

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### Introduction

Two respected national organizations in emergency medical services, the National Association of State EMS Directors and the National Association of EMS Physicians, have jointly defined Emergency Medical Services (EMS) as “the provision of services to a patient with medical emergencies<sup>1</sup>. A medical emergency is defined as “a sudden and/or unanticipated medical event which requires immediate assistance”<sup>1</sup>. An emergency medical service system is described as “a comprehensive, coordinated arrangement of resources and functions which are organized to respond in a timely, staged manner to targeted medical emergencies, regardless of their cause and patients’ ability to pay, and to minimize their physical and emotional impact.”<sup>1</sup>. The staged EMS response mentioned above involves the steps listed in Table 1. Steps 1 through 7 involve medical care provided prior to arrival at the health care facility. This is termed prehospital medical care. Out-of-hospital care is prehospital care plus step 9, interfacility transport. Out-of-hospital care is the phase of EMS that will be addressed in the following overview.

Medical direction for out-of-hospital emergency medical services is provided on two levels. Direct Medical Control, On-

line Medical Control, or Immediate Medical Control, are all terms that describe the physician on the radio or telephone who gives concurrent medical direction to the out-of-hospital providers. Indirect or Off-line Medical Control or Direction for out-of-hospital emergency services refers to the physician who has the overall responsibility for the medical aspects of out-of-hospital care. The focus of this review is on the Indirect or Off-Line Medical Director.

### Responsibilities of the EMS Medical Director

Responsibilities of the Indirect or Off-line Medical Director include, but are not limited to the items listed in Table 2.

**Table 2. Responsibilities of the EMS Medical Director.**

1. Training
2. Quality Improvement
3. Dispatch
4. Communication
5. Protocol Development and/or Review
6. Continuing Medical Education
7. Direct Medical Control
8. Critical Incident Stress Debriefing
9. Involvement in State and National EMS Organizations
10. Research

**Table 1. The steps of a staged EMS response.**

1. Prevention
2. Detection
3. Notification
4. Dispatch
5. Pre-arrival
6. On-scene
7. Transport and Facility Notification
8. Emergency Department/Receiving Facility
9. Interfacility Transport
10. Critical Care
11. Inpatient Care
12. Rehabilitation
13. Follow-up

### In This Issue...

- 169 Out-of-Hospital Medical Direction
- 171 Call For Papers — 10th Annual IHS Research Conference
- 173 Investigating Cancer Clusters
- 176 Treatment of Hypertriglyceridemia
- 178 Meetings of Interest
- 179 Native American Medical Literature

In 1992, the National Association of EMS Physicians and Fitch & Associates surveyed Out-of-Hospital Medical Directors from across the United States<sup>2</sup>. This survey revealed that 60% of the physicians who provided medical direction were emergency physicians, 25% were family physicians, and the remaining 15% a mix of other specialties. A 1993 survey of Indian Health Service (IHS) EMS Medical Direction revealed that the majority of physicians performing as Medical Directors were family physicians, internists, or general practitioners; very few were emergency medicine physicians. Family physicians, general practitioners and internists do not receive training for medical direction of emergency medical services in their internships or residencies. The majority of IHS physicians assigned EMS duties receive no training to support this assignment.

Knowledgeable Indirect (Off-Line) Medical Direction is particularly important in the generally rural medical practice setting of most Indian Health Service facilities. The Special Report on Rural Emergency Medical Services from November 1989<sup>3</sup>, which was based on the National Rural EMS Needs Workshop held in March 1989, provides pertinent information on this issue. This report presents evidence of higher death rates from blunt trauma in rural areas, and a higher incidence of medical illnesses such as cardiovascular problems, respiratory disease, and diabetes. To complicate the problem for rural areas, there are shortages of out-of-hospital providers and a lower level of out-of-hospital care than found in metropolitan areas. Additionally, according to the report, rural EMS Medical Direction is generally lacking.

The need for providing knowledgeable physician medical direction in the IHS is further supported by the recent changes in skills performed by the basic emergency medical technician (EMT-B). There are currently four levels of Emergency Medical Technician described and recognized by the National Highway Traffic Safety Administration, which is the agency responsible for developing National Standard Curricula for out-of-hospital providers. The basic emergency medical technician or EMT-B, receives 100 hours of classroom instructions and 10 hours of clinical experience. Once training and testing are completed successfully, the EMT-B can then provide basic patient assessment, application of military anti-shock trousers, cervical spine stabilization, cardiopulmonary resuscitation, basic vehicle extrication, oxygen administration, use of an oxygen powered and flow restricted ventilating device, fracture stabilization, bandaging, basic radio communication, patient transport, use of an automatic external defibrillator (AED), and administration or assistance with certain medications. The EMT-B is the most common level of out-of-hospital provider in the field. Advanced levels include EMT-Defibrillation (EMT-D), EMT-Intermediate (EMT-I), and EMT-Paramedic (EMT-P). Advancement to the EMT-D level requires certification as an EMT-B and 12-16 hours of additional training depending on whether an automatic or manual defibrillator is to be used. An EMT-I must also be an EMT-B who then undergoes an additional 40-55 hours of classroom instruction covering advanced patient assessment, advanced medical communication, intravenous fluid therapy, and advanced airway management. The most advanced category is the EMT-Paramedic, which includes training as an EMT-B and an additional minimum

of 212 hours of didactic instruction, 232 hours of clinical experience and 100 hours of field experience. An EMT-P performs all functions of an EMT-B, EMT-D, and EMT-I. In addition, an EMT-P can utilize advanced cardiac life support skills, perform advanced airway management skills including cricothyroidotomy and needle thoracentesis, and administer medications to treat various medical problems.

Medical direction is required of EMTs who practice advanced level skills; until recently this meant the EMT-D, EMT-I, and EMT-P. However, the EMT-B National Standard Curriculum<sup>4</sup> was revised in 1994 and now medical direction has become a requirement with the addition of the AED, administration or assistance with medications, and the optional advanced airway management technique of endotracheal intubation. Therefore, all levels of EMTs now require physician medical direction.

Out-of-hospital medical practice is receiving increased attention from the Joint Commission on Accreditation of Health Care Organizations (JCAHO) and from the Consolidated Omnibus Budget Reconciliation Act (COBRA). JCAHO has trauma indicators in place that include an evaluation of prehospital trauma scene times and is in the process of developing other indicators that deal with out-of-hospital care. In the COBRA legislation, although patient transfer is but a small element, it does mandate appropriate and safe interfacility transports. This includes the appropriate choice of transport vehicle and level of provider<sup>5</sup>. This impacts the out-of-hospital emergency medical system and its medical direction, especially in rural areas that require relatively more frequent interfacility transports due to limited local capabilities.

## Conclusions

It is obvious from the preceding discussion that knowledgeable Indirect (Off-Line) Medical Direction can no longer be an option in an emergency medical services system, especially in rural or frontier areas. Training is offered by some state EMS offices; you are encouraged to call to find out what is available in your state. The Indian Health Service offers a two-day basic medical directors course annually. For information about this, contact Dr. Jim Upchurch at the PHS Indian Hospital, Crow Agency, MT 59022; the phone number is 406-638-3309. The National Association of EMS Physicians holds a three-day advanced medical direction course once or twice a year; information about this can be obtained by calling them at 412-578-3222. Participation in any of these training opportunities will allow you to become a more knowledgeable and effective EMS medical director. Your ambulance service and your patients will benefit. □

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# Investigating Cancer Clusters

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## **Abstract:**

*A cluster is a mini-epidemic of a rare disease. Clusters may give clues to the etiology of disease, or may signal a hazardous exposure. Unfortunately, cluster investigations seldom are conclusive, for several reasons. Statistically significant clusters can occur by chance. The probability of finding chance cancer clusters is calculated for the 200 Alaska Native villages. The problem of selection bias is explained, and other limitations of epidemiology are described. A logical, stepwise protocol for investigating clusters is presented.*

## **Cancer Clusters**

Clusters of non-infectious diseases, especially cancer, can cause great anxiety in communities, and headaches for epidemiologists. In this article I will define what we mean by a cluster, and describe the ways that clusters might be useful or important. I will then demonstrate how some clusters might occur by chance, and explain some of the limitations of epidemiology in studying clusters. A logical, stepwise approach to the investigation of reported clusters is essential, and I will describe such an approach. I will use cancer examples because that is the most common type of reported cluster, but the same methods apply to any non-infectious disease process.

The term cluster does not have a precise meaning. Generally it is used to mean a mini-epidemic of some condition so rare that even a handful of cases begs an explanation.<sup>1</sup> If the disease is more common, or the number of cases is larger, it might be called an epidemic.

How are clusters useful? In some situations, a handful of cancer cases can give valuable clues to the cause of cancer. For example, a rare type of liver cancer among chemical workers led to the discovery of the connection between exposure to vinyl chloride and angiosarcoma of the liver.<sup>2</sup> This type of cluster is sometimes called a time-cohort cluster, because the disease occurs in a group of people (cohort) that is defined by their exposure (chemical workers in this case) rather than by where they live.

In cases where the cause of a rare cancer is already known, a cluster can indicate a harmful exposure. For example, three cases of malignant mesothelioma in a northern New Mexico

pueblo alerted health workers to a probable asbestos exposure. An investigation turned up the source: asbestos boiler insulation from trains had been thrown beside the tracks, and local residents were using the white material to whiten their ceremonial buckskins.<sup>3</sup>

So why don't health departments like clusters? Quite frequently, the alert citizen who reports a possible cluster of cancers in his community is greeted with skepticism and disinterest at the county or state health department. This is because, unfortunately, most clusters turn out to be not so useful. There are a number of problems that can turn a promising cluster investigation into an unsolvable mess:

- 1) The putative cluster turns out to be a mixed collection of cancers with different causes.
- 2) Some of the key cases recently moved to the area from elsewhere. This is a problem in cancer investigation because it usually takes years after the exposure for the cancer to develop.
- 3) Clusters can happen by chance, even if the disease occurs in a completely random fashion in the population.

## **Probability of a Random Cluster**

Let's calculate the probability that a statistically significant cluster of cancer cases might happen just through the random occurrence of events, without any particular cancer-causing exposure. First, some basic statistical terms. By convention, when we say that a statistic is "significant," we mean that the event has only a 5% probability of being a chance occurrence, or that we are 95% sure that the event was due to something other than chance (such as exposure to a chemical carcinogen or ionizing radiation). When you see this in scientific papers, the probability is usually referred to as the "p" value. The statement " $p < .05$ " means that the probability is less than 5% (one in twenty) that the event was random. When we wish to be more certain, we often talk about even smaller p values. For example,  $p < .0001$  implies that there is only one chance out of 10,000 that the event occurred by chance alone. This is a very convincing level of statistical certainty.

There are about 200 Alaska Native villages. For diseases with an average expectation of five or more cases per time period of interest, we can say the following (note that you would have to observe for several years to see even one case of some rare cancers):

If we survey the 200 villages for an excess of any one type of cancer, we would expect to see  $(.05 \times 200) = 10$  villages with significantly elevated rates of that cancer at the  $p < .05$  level, by chance alone. If we insist on the more stringent level of  $p < .01$ , we would still expect to see  $(.01 \times 200) = 2$  villages with elevated rates of that kind of cancer.

This calculation assumes that you were setting out to look for an excess of one type of cancer. In real life, it more commonly happens the other way around: someone in the village reports an excess of cancer cases, and requests an investigation. There are about 80 different types of cancers, more or less, each with a distinct set of causes and risk factors. What are the chances that a town could escape having a cluster of each and every one of the 80 major types of cancer? The probability of escaping a cluster of each type is .95, so the probability of escaping them all is  $(.95) \times (.95) \times (.95) \dots$  eighty times, or  $(.95)$  to the eightieth power, which equals .0165. This means that the probability of having at least one cancer cluster in your town is  $1 - .0165 = .9835$ ; so there is a 98% probability that any given town will have at least one type of cancer cluster at the  $p = .05$  level.

Following the same logic, the chance of a significant cluster at the  $p < .01$  level is  $(.01)$  to the eightieth power = .55, or 55%, and the chance of a cluster at the  $p < .0001$  level is 0.8%. Out of 200 villages, we can expect to see  $(.008) \times 200 = 1.6$ . So we should not be surprised to find one or two village clusters with this extreme level of statistical significance, just by chance alone.

### Selection Bias

Another potential pitfall in the investigation of clusters is in how the study area is selected. To illustrate this, consider that statistical significance is like a score in marksmanship; you get more points for hitting closer to the center of the target, and it is not by chance that a skillful sharpshooter gets most of his bullets on target. One of the basic rules of shooting competition is that the target is in place before the shooting begins, and it remains in the same place during your turn. Is this rule observed in “cluster shooting”? Consider the following scenario.

Joe’s aunt dies of brain cancer. He is talking with a neighbor, who points out that several people in the neighborhood have had cancer recently. They bring in the local health officer, who studies the problem. He finds out who has had brain cancer in the last few years, and where they live. He then draws a circle around the area where the cases occurred, determines the population of that small area, calculates the cancer rate (cases per population) and does a test of significance. The rate is significantly greater than expected. Well, if you will let me

draw the target after I have fired my shot, I bet I could hit the bullseye every time! Sometimes this is called “Texas sharpshooting.” Epidemiologists call it selection bias. Note that the target can be constructed both in time and in space.

### A Stepwise Approach

Are these twin problems, clusters happening by chance, and selection bias, unsurmountable? No, but you have to be careful. There are some things to look for when investigating a cluster that may indicate a “real” exposure-related disease.

Epidemiologic investigation should follow a well-defined sequence of stages. Each stage depends on the results of the last, and the investigation should not proceed to the next stage unless the results of the previous one so indicate. Here are the stages:

- 1. Collect basic information and decide whether to proceed.** If the initial indication is that there are: a) unusual numbers of rare conditions; b) the presence of biologically plausible exposures; or c) intense community concern, further study is probably warranted. If none of these three criteria is met, an investigation is unlikely to be fruitful. Note, however, that even when all the initial evidence is against a “real” cluster, political realities may require an investigation. Nothing upsets a community more than to think that their legitimate concerns are being ignored or covered up by their public officials.
- 2. Verify index cases and exposure reports, and make a case definition.** This might involve reviewing hospital records, death certificates, or other medical documents. The point is to be sure that there actually is a disease of concern. Exposure records might be from agency or company files, public monitoring sources, or any of a wide variety of records indicating a possible exposure. If case reports cannot be verified, or if (for example) the disease began before the exposure, there is no point in going further. If there is no plausible source for exposure, that also may be reason to stop the investigation.
- 3. Full case ascertainment and analysis of data.** Obtain a complete count of confirmed cases in the area of interest. This is a tedious procedure, involving extensive review of medical records, interviews, etc., as well as obtaining population and comparison illness data (to protect against selection bias). The investigation

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may be ended at this point if no excess is found with full case ascertainment. If a small excess is found, but it is of low statistical significance or biologic plausibility, it may be most reasonable to carry out targeted surveillance over the next few years to chart whether cases are increasing over time.

4. **Special studies.** If the results of full ascertainment are highly suggestive, a special study may be the next step. This could involve case interviews, a case control study, a population-based survey, or an exposure field survey. Special studies require considerable resources in expertise, money, and time. Sometimes it will be cheaper to clean up a known source of exposure (like a toxic waste dump) than to prove that human disease is actually being caused by that source. On the other hand, many expensive cleanup operations have been undertaken without any evidence of a threat to human health.

Let me illustrate the stages with an example. Suppose you are walking outdoors and you see something gleaming on the ground. Your first stage of investigation is to walk back to the place and look again, more carefully, but still standing up. If you don't see anything, you might walk away. If you still see the gleam, you might scuff with your shoe at the object. If you can see that it is a bottlecap, you leave it in place. If it appears to be a coin, or you can't tell what it is, you bend over and dig with your hands to expose the object. If you saw a characteristic flash that makes you think it might be a diamond, you will search long and hard. At any stage, you may obtain enough information to discontinue the search, or you may be encour-

aged to keep after it. In exactly the same way, the epidemiologist looks into cluster concerns.

### The Limitations of Epidemiology

There are also some other important limitations of epidemiology that I have not mentioned here. It follows from our discussion of probability and statistical significance that it is difficult to prove beyond any doubt that there is a cause and effect relationship between any given exposure and disease. The tobacco companies frequently remind us of this fact. Another problem is that when studying small populations (under 10,000 people), there is a high degree of uncertainty associated with any calculated rate. In other words, we might calculate and report a rate of 20 deaths per 100,000 population, but a mathematically correct interpretation of the data might be that we can only say that the rate is between 10 and 30 deaths per 100,000. The larger the population is, the more precise our estimate can be.

In summary, it is important to remember that clusters sometimes can occur by chance; to be aware of selection bias when studying clusters; to investigate reported clusters in a logical, stepwise manner; and to know the limitations of epidemiology. □

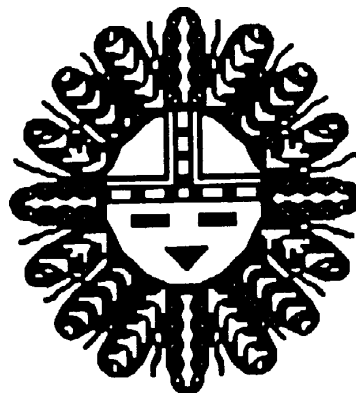
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# Treatment of Hypertriglyceridemia

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## Introduction and Pathophysiology

Triglycerides are composed of fatty acids esterified to glycerol. The glycerol backbone of the triglyceride molecule may be used as fuel for gluconeogenesis, and the fatty acids are utilized directly as an energy source for ATP production. Dietary triglyceride is absorbed through the gut, transported through blood by lipoprotein carriers and stored primarily in adipose tissue as a concentrated reservoir of metabolic energy. Normal triglyceride levels are less than 200 mg/dL.

Triglyceride levels of 200-400 mg/dL may play a role in the progression of atherosclerosis, especially if there is evidence of elevated concentrations of VLDL and intermediate-density lipoproteins.<sup>1</sup> Hypertriglyceridemia in patients with chronic renal disease, diabetes mellitus, and nephrotic syndrome is associated with increased cardiovascular risk.<sup>2</sup> Triglyceride levels greater than 1000 mg/dL lead to an increased risk of pancreatitis, hepatomegaly, splenomegaly, or hepatic steatosis.<sup>3</sup>

## Management of Hypertriglyceridemia

The primary treatment for hypertriglyceridemia is change in lifestyle and habits: weight control, dietary modification, regular exercise, smoking cessation, and restriction of alcohol use. Identification and management of secondary causes such as hypothyroidism, diabetes, or certain medication (e.g., estrogens, thiazides, and beta blockers) are also indicated.

Drug therapy should be considered in patients who have triglyceride levels of 400-1000 mg/dL, especially if these patients present with established atherosclerotic disease, a family history of premature coronary artery disease (CAD), or concomitant elevated total cholesterol and low HDL levels. Because of the increased risk of pancreatitis, drug therapy should be initiated in patients with triglyceride levels greater than 1000

mg/dL.<sup>4</sup> In this group of patients, therapy is considered to be successful if the triglyceride levels fall below 500 mg/dL.<sup>4</sup> The pharmacotherapeutic mainstays for treating hypertriglyceridemia are niacin and gemfibrozil.

Niacin (1.5-3 gm/day) has been shown to lower triglycerides by 30-60%, elevate HDL by 20-35%, and decrease LDL levels by 15-25%.<sup>2,3,5,6</sup> Niacin has limited use in diabetics because of its potential to increase plasma glucose levels. Niacin can also elevate serum uric acid and should be avoided in patients with gout. It should not be used in patients with liver disease, active peptic ulcer disease, or in those who abuse alcohol. Niacin is associated with gastrointestinal distress and

flushing sensations that can be minimized by taking each dose immediately after a large meal and by taking 325 mg of non-enteric coated aspirin 60 minutes before each dose. Compliance is a major problem with niacin; in a retrospective cohort study, it was reported that approximately 46% of patients were shown to have

stopped taking niacin within the first year of therapy.<sup>7</sup>

Gemfibrozil, in doses of 1200 mg/day, can reduce triglyceride levels up to 70-90% in patients with severe hypertriglyceridemia (>975 mg/dL).<sup>8</sup> It can elevate HDL by 10-30%, and has little effect on LDL.<sup>3</sup> Its use should be avoided in patients with coronary artery disease<sup>9</sup>, gallbladder disease, biliary cirrhosis, or severe hepatic or renal dysfunction.

The combination of gemfibrozil and niacin was reviewed by Spencer et al in a retrospective study of 161 patients with mean triglyceride levels averaging 275 mg/dL. Treatment for 6-12 months with doses of niacin between 1-1.5 gm/day and 1200 mg daily of gemfibrozil decreased triglycerides by up to 52% (P < 0.001).<sup>10</sup> Those patients with triglycerides > 250 mg/dL benefitted the most from combination therapy. While 281 patients began treatment, only 57% of patient chart data were included in the study because of compliance problems.

HMG-CoA reductase inhibitors (the so-called "statins") have not been advocated for use in patients with pure hypertriglyceridemia.<sup>11</sup> Little information is available evaluat-

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## Amerisource VA Contract Costs For Triglyceride Lowering Agents (September 1997)

| Drug                  | Strength      | Cost Per Day               |
|-----------------------|---------------|----------------------------|
| Niacin (generic)      | 500 mg tablet | \$0.09 - 0.18 (1.5 - 3 gm) |
| Gemfibrozil (generic) | 600 mg tablet | \$0.17 (1.2 gm)            |
| Atorvastatin          | 20 mg tablet  | \$1.78 (20 mg)             |

ing the use of statins in patients with triglyceride levels above 400 mg/dL. Fluvastatin, lovastatin, pravastatin, and simvastatin have not been studied in patients with primary hypertriglyceridemia. These drugs have been shown to lower triglycerides by 5-15% in patients with mixed hyperlipidemia.<sup>3,12</sup> Because of this, statins may be useful in lowering elevated triglycerides in patients with mixed hyperlipidemia and diabetic hypertriglyceridemia.<sup>12</sup>

Atorvastatin, released in February, 1993 is the only statin that has been shown to produce a substantial reduction in triglyceride levels. Bakker-Arkema et al studied the use of this agent in a double blind study of 56 patients with primary hypertriglyceridemia (mean baseline triglyceride level of 603.3 mg/dL and mean LDL-C of 118.8 mg/dL). Patients were treated for 4 weeks with either placebo or atorvastatin (5 mg, 20 mg, or 80 mg daily). All patients were placed on an ADA Step I diet. At the end of four weeks, the placebo group showed a drop in triglyceride levels of 8.9%. In the atorvastatin groups, triglycerides were reduced by 26.5%, 32.4%, and 45.8% ( $P < 0.05$ ) in the 5 mg, 20 mg and 80 mg treatment groups, respectively.<sup>14</sup>

Atorvastatin, like other statins, is contraindicated in patients with active liver disease. Rhabdomyolysis with acute renal failure secondary to myoglobinuria has been associated with all statins. The risk of myopathy is increased when statins are given concurrently with niacin or gemfibrozil.

### Conclusion

In conclusion, niacin and gemfibrozil are the mainstays of therapy for primary hypertriglyceridemia. They can be given together to reduce triglycerides. Atorvastatin, a potent HMG-CoA reductase inhibitor, offers another treatment option for lowering triglycerides. At doses of 20 mg a day or greater (daily dose range 10-80 mg), atorvastatin is the only statin shown to have substantial ( $> 30\%$ ) triglyceride lowering potential.<sup>14</sup> Atorvastatin, like niacin and gemfibrozil, is more effective in lowering triglycerides in patients with high to very high triglycerides ( $> 400$  mg/dL). For pharmacoeconomic reasons, atorvastatin should be reserved for patients who are unable to tolerate niacin and/or gemfibrozil, or who have contraindications to their use. □

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Special thanks for help with editing this manuscript to Cath Heyneman, Pharm.D., Assistant Professor of Pharmacy Practice, Idaho State College of Pharmacy, Pocatello, Idaho

The following is an updated MEDLINE search on Native American medical literature. This computer search is published regularly as a service to our readers, so that you can be aware of what is being published about the health and health care of American Indians and Alaska Natives.

The Clinical Support Center cannot furnish the articles listed in this section of The Provider. For those of you who may wish to obtain a copy of a specific article, this can be facilitated by giving the librarian nearest you the unique identifying number (UI number), found at the end of each cited article.

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