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## The IHS National Core Drug Formulary: A New Quality of Care Tool for the IHS

*Howard Hays, MD, MSPH, Acting Chair, IHS National Pharmacy and Therapeutics Committee, Phoenix, Arizona*

### Introduction

In February 2000 and again in May 2001, the Indian Health Service (IHS) National Pharmacy Council presented the national core formulary concept to the IHS Executive Leadership Group (ELG), recommending the consideration of a national core drug formulary for the Indian health care system. While this was not the first call for action on this issue, these presentations raised several key and timely points that gave the issue new momentum: 1) the inexorable rise in pharmaceutical costs experienced across the country; 2) the use of formulary restrictions by some facilities as a cost management tool; and 3) the leadership and positive experience of the Veterans Health Administration (VHA) and Department of Defense (DoD) in developing and implementing their own national formulary systems.

The ELG authorized the formation of a work group comprised of physicians and pharmacists representing the spectrum of federal and tribally operated hospitals and clinics. The ELG charged the group with exploring the possibility of a national formulary for the IHS/Tribal/Urban (I/T/U) health care system, and with making recommendations for the content of that formulary. The group was also asked to recommend a process for implementing and maintaining the formulary throughout the system. After consultation with formulary experts from the VHA and DoD, as well as presentations to and feedback from IHS leaders and clinical practitioners across the country, the National Core Formulary Workgroup (or National Formulary Group – NFG) made its final recommendations to IHS leadership in fall 2002.

In February 2004, IHS Director ADM Charles Grim approved the implementation of the National Core Formulary

(NCF) and chartered the establishment of the IHS National Pharmacy and Therapeutics Committee (NPTC) to develop and maintain it. This paper will discuss the rationale for a national formulary, describe the activities of the original NFG, and introduce I/T/U readers to the new NPTC.

### Why a National Core Formulary?

The National Formulary Group made a number of observations and adopted a number of philosophies that guided its work:

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- Drug costs are increasing at a rate several times that of the core rate of inflation.
- IHS appropriations are not increasing, and cannot be expected to increase, at a rate that matches inflation for health care costs in general, much less that of pharmaceuticals.
- The I/T/U system has a mission to provide high quality medical care to American Indian and Alaska Native (AI/AN) patients, in a context of rising user numbers, increasing complexity of medical conditions in an aging population, exploding health care costs, and flat appropriations.
- Elimination of standard-of-care drugs from local formularies is not a rational or appropriate strategy for managing costs.
- No attempt to manage drug costs can or should be made without establishing the core level of service that must be maintained in order to remain true to our mission. A core drug formulary is part of the foundation of any attempt to manage rising pharmaceutical costs.
- Most patient care activities, client morbidity and mortality, and drug costs in I/T/U facilities occur as a result of a limited number of chronic medical conditions. Systematic efforts to improve and standardize clinical practice should begin by targeting these conditions.
- Numerous evidence-based guidelines for medical practice and drug utilization exist. Neither the resources nor the expertise are present in I/T/U facilities to duplicate this work. The Indian health care system has a responsibility to ensure that this information is made available to providers in a manner that facilitates application at the point of care.
- Providing quality care and managing costs are not optional. Both are essential to the success of the I/T/U mission. Providers must be given appropriate tools, but should also be presented with clear expectations about the use of those tools. Implementation of and compliance with the provisions of a core drug formulary should be compulsory for Federal facilities.
- Medical knowledge changes rapidly, and with it standards for clinical practice. If I/T/U leaders and patients expect care consistent with evolving standards, commitment must be made to a process for perpetual review and dissemination of new information.
- If health professionals are expected to comply with a national formulary, they deserve an active voice in a formulary development process that is transparent and responsive. A National Pharmacy and Therapeutics Committee, consisting of practicing physicians and pharmacists, should have the responsibility of updating and publishing the national core formulary, and of interacting with the field on its content.

### **Benefits of a National Core Formulary**

The advantages of a national core formulary can be appreciated in the context of a number of factors that are important to I/T/U staff and patients: parity, portability, quality, safety, convenience, and cost.

### **Parity**

One of the characteristics of the Indian health care system is its diversity. As each tribe is geographically and culturally unique, so are the health care facilities that serve them. These range from small, rural clinics with one or two contract providers to multiple-specialty hospitals, and everything in between. About half of the system is under the direct administration of the Federal government, and tribes or tribal consortia operate the remainder.

No defined package of benefits, pharmaceutical or otherwise, has been established for AI/AN patients using I/T/U facilities. As a consequence, patients across the country have access to different sets of services depending on where they live and choose to receive care. Surgery, obstetrics, podiatry, physical therapy, and mental health are among the obvious examples of services that are available to patients at some locations but are either limited or inaccessible at others.

There is a similar disparity in access to pharmacy services. Some facilities have no pharmacy service at all; patients must depend on sample medications or purchase their drugs on the open market. For facilities with pharmacies, local formularies range from highly restrictive to broadly inclusive, depending on budgets, third party reimbursements, local precedent, and a variety of other factors. Decentralization and the reduction of Area and national consultative support have increased local autonomy, but at the expense of consistency in pharmacy services.

Variability in pharmacy services has consequences at both ends of the spectrum. A few facilities have restricted formularies so much that patients do not have access to important standard-of-care medications. Other formularies are so broad that the facility expends considerable financial and staff resources in purchasing, stocking, and supplying medications that would be a luxury at other locations, or for which cheaper and equally effective alternatives are available. In some places, patients who cannot get a medication they want or need at one facility will travel to another to get it there. This is neither desirable nor appropriate from a patient care standpoint.

A national core formulary, while not restricting a facility's ability to supply a broad variety of medications (except in certain closed classes), ensures that basic core drugs are available to all patients using I/T/U pharmacies. It levels the playing field to some extent, by establishing a floor that is common to all participants. This floor then becomes a starting point for parity among facilities for all patients.

### **Portability**

While most patients receive most or all of their care at one location, I/T/U facilities serve a mobile population. Whether it

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is a “snowbird” who lives in the north but winters in the south, a person traveling the powwow circuit, or simply someone whose access to transportation is inconsistent and cannot always get to the same facility, all pharmacies routinely see patients who need to be continued on medications prescribed at another location. While it is impossible to ensure that every drug a patient may be taking is available wherever he or she goes, a national core formulary will maximize the probability that patients on a typical medical regimen will be able to have their needs met at any facility in the system, without the inconvenience and risk of switching drugs.

### **Quality**

One of the consequences of decentralized administration of health care facilities is that each facility creates its own formulary. In what other system does a group of six or seven busy doctors and pharmacists with limited resources have the responsibility for researching and creating an entire drug formulary? The VHA and DoD each employ national committees with substantial research budgets, solicit input from expert panels, and continuously revise and update their formularies according to evolving knowledge and indications. Large health plans and state Medicaid systems have comparable mechanisms. Private offices and hospitals have little need for formulary management, because although they generate the demand for drugs, they do not have to pay for them. The I/T/U system is unique in expecting average doctors and pharmacists to have the time and expertise to create evidence-based formularies, and to keep them up to date.

The scene is familiar for IHS pharmacy staff. One doctor leaves and the next one comes with a list of drugs that he or she likes and must have on the formulary. A pharmaceutical representative makes a presentation, complete with lunch and pens, and suddenly new demand is created. A nearby consultant sends several patients back on a new medication, and now the P&T committee has to consider adding it. However, they typically do not have the time and expertise to research and make informed decisions on these issues.

The intent of the IHS National Core Drug Formulary is that it will be based upon the most current medical practice and evidence. It will rely heavily on work done by the VHA, both to critically evaluate drugs and drug classes, and to establish guidelines for drug use and nonformulary prescribing. Other sources of information include guidelines published by the National Institutes of Health as well as other national and international resources. The national core formulary process also requires consultation and review by subject matter experts from within the Indian health care system. While most of this information is readily available to local facilities through electronic and print media, the national core formulary process will ensure that new information is evaluated in a timely manner and distributed consistently to all participants. Local formularies will be up to date, at least in those areas covered by the core formulary, and P&T committees will be able to focus on issues more important than adding or deleting drugs.

### **Safety**

Patient safety has always been of paramount importance, but nationally publicized reports of the prevalence of serious medical errors have brought this issue to the forefront. Accrediting agencies require organizations to continually monitor for errors, and to have mechanisms in place for correcting them and for improving performance. A national core formulary can play an important role in the effort to improve safety.

As indicated above, if all facilities have the same core of medications for common conditions, chances are that a patient transferring care from another location will not have to switch medications. This will obviate the need for the additional monitoring and follow-up often necessitated by such changes. If use of a core formulary encourages providers to use a relatively small set of drugs for most prescriptions, then increased familiarity with these medications on the part of both prescribers and pharmacists should improve safety. In addition, the consistent utilization of disease state management guidelines will promote appropriate drug use and reduce the likelihood of errors.

### **Convenience**

Pharmacy and Therapeutics committees have multiple responsibilities over and above the routine addition and deletion of drugs from the formulary list. Ideally, these committees will spend the majority of their time in activities relating to quality of care such as drug utilization evaluations and training on practice guidelines and standards of care. One intent of the national formulary process is to relieve P&T committees of some of the routine formulary management. Their energies can then be productively directed toward more important quality improvement responsibilities.

The National Pharmacy and Therapeutics Committee will act as a resource to local P&T committees by researching and providing recommendations and documents for standard drug utilization reviews (DUR). The Committee will collaborate with IHS subject matter experts, including the Council of Chief Clinical Consultants and the National Diabetes Program, to supply and update relevant disease state management guidelines as they become available. Members of the Committee will assist Areas in educating staff on core formulary use and compliance. These efforts, undertaken by one group at a national level, will obviate the need for duplicative efforts by multiple groups across the country.

### **Cost**

A core formulary will not, by itself, produce substantial cost savings. Indian health care facilities, after all, already have access to the best possible drug prices through Federal Supply Schedule and VHA National Standardization Contracts. The intent of the core formulary is to ensure availability of standard-of-care medications for key medical conditions. Facilities with overly restrictive formularies may actually see increased drug costs because of the need to comply

with the requirements of the core formulary. On the other hand, since drugs recommended by the formulary tend to be well established and less expensive, preferential use of formulary drugs is likely to support cost management efforts.

In certain cases, cost differences between formulary drugs and others in the same class are substantial, and the NPTC may determine that these classes should be closed. Conscientious efforts to use the formulary drug in these and certain other classes have the potential to create savings both locally and nationally. For example, at current contract prices, cost advantages of preferentially using simvastatin for cholesterol management, or omeprazole for gastroesophageal reflux, would result in many hundreds of thousands of dollars saved nationwide.

Although cost management is not the principal purpose of the National Core Formulary, the NPTC believes that the two are inseparable. A core formulary ensures that other efforts toward cost reduction are not taken at the expense of quality of care for priority health conditions. As such, this effort is the first step toward implementation of any comprehensive cost management strategy.

### The Formulary Development Process

The first version of the National Core Formulary was developed through a collaborative process involving members of the NFG and IHS subject matter experts (specifically in diabetes, cardiology, and psychiatry). Other resources included the VHA National Formulary, the Department of Defense Basic Core Formulary, other documents published by the VHA and DOD (including drug class reviews and prescribing guidelines), guidelines published by other national bodies, and the Institute of Medicine's 2001 report on quality in health care.

Determining the content of a core that has relevance throughout the I/T/U system requires consideration of the similarities that allow us to think of ourselves as a system of health care. The vast majority of drugs prescribed in the I/T/U are provided to outpatients, and most of these patients are being treated for limited number of diagnoses. It thus makes sense to define a set of conditions treated in the ambulatory setting that constitute the source of the core formulary. The Institute of Medicine report on health care quality recommended that efforts to address quality deficiencies should focus on those health conditions that have the greatest impact in terms of morbidity, mortality, and cost. The work group agreed that the National Core Formulary should address a top priority set of conditions, specifically diabetes, hypertension and cardiovascular disease, asthma and chronic lung disease, stomach ulcers and related disorders, arthritis, and depression and anxiety disorders. Thirty of the top fifty drugs purchased through the Prime Vendor system are in these diagnostic categories, so a formulary that addresses them will cover a preponderance of prescriptions and pharmacy costs at Indian health care facilities. As experience and confidence with the national formulary grow, future iterations should include additional classes of drugs addressing other priority conditions.

In selecting drugs for the first edition of the IHS National Core Formulary, work group members posed three questions (see box). Affirmative answers to all three led to inclusion of the drug in the core formulary.

Certainly, Agency-wide agreement on the appropriate content for a core formulary will be difficult to achieve. For

#### Core Formulary Questions

Is this a drug that can be expected to be used by a substantial proportion of patients?

Is this drug a core component of current standards of care? (Conversely: Can a provider in IHS deliver appropriate medical care to a significant majority of patients without using this medication?)

Will the availability of this medication at all I/T/U facilities substantially enhance the portability of the pharmacy care benefit?

this reason, the NFG agreed to start with a fairly straightforward list that the overwhelming majority of I/T/U providers should readily accept as core to the treatment of the six specified disease categories. Certain drugs or drug classes may be notable by their absence from the first edition of the NCF. These will no doubt be addressed in future versions as the formulary is adopted into general use.

Considering the wide variety of drugs that are available for treatment of the selected priority health conditions, the National Formulary Group concluded its work believing it had selected a reasonable and effective set of medications for the National Core Formulary. Providers or facilities that have recommendations for changes or additions to the NCF should make their requests known to the National Pharmacy and Therapeutics Committee. The NPTC intends for the process of revising and updating the NCF to be as careful, scientific, and responsive as the process for developing the first edition has been.

#### An Explanation of Closed Classes

The principal purpose of a core formulary is to ensure the availability of those drugs that are needed in order to provide basic standards of care for health conditions that cause the greatest morbidity and mortality in the service population. Another purpose, however, is to promote practices that produce the greatest efficiencies in pharmacy cost management without sacrificing quality of care. For certain medical conditions, the best (standard of care) treatment includes use of fairly costly, innovator drugs for which no generic substitutes are available. However, often there are several different drugs available, which are essentially equivalent in their efficacy and side effect profiles. If one of these drugs offers a significant cost advantage, all other factors being equal, it makes sense to preferentially prescribe this drug.

The VHA Pharmacy Benefits Management program periodically performs systematic evaluations of particular drug

classes to identify those drugs that offer the greatest therapeutic benefit to patients and should therefore be used preferentially in patient care. From time to time the VHA will identify a class of drugs with comparable efficacy profiles and will decide to solicit a National Standardization Contract for a particular drug or drugs. The manufacturer is guaranteed virtually exclusive access to all VHA facilities for distribution of their product, in exchange for a substantial discount on cost, for a period of up to five years. The drug class in question becomes “closed,” meaning that all VHA prescribers must use the contract drug(s) as their first-line choice for the relevant condition. If intolerance, ineffectiveness, or adverse effects are demonstrated, there is a facilitated process to obtain an alternative non-formulary drug for the patient.

Presently, there are five closed drug classes in the VHA National Formulary (see box). Studies of the VHA National Formulary system have demonstrated that enforcing a system of closed drug classes has contributed to many millions of dollars in savings for VHA hospitals, without compromising the quality of care.

The IHS National Core Drug Formulary, in its first edition, contains two closed drug classes: HMG Co-A Reductase inhibitors (statins) and proton pump inhibitors (PPI). **Facilities are required to keep only one high-potency statin drug (simvastatin) on their formularies, and to utilize this drug preferentially for treatment of hyperlipidemia when a high-potency statin is indicated.** (Lovastatin and fluvastatin are approved for those facilities wishing to keep a lower cost statin available for patients who do not require a high potency drug.) **Similarly, omeprazole is the only PPI that may be included in local formularies.** Patients already on other drugs should be switched to the closed class drug in a timely manner, if there are no medical contraindications. **Each facility must have policies**

**facilitating requests for non-formulary alternatives for patients who cannot tolerate or who do not achieve desired therapeutic results with the formulary drugs.**

Purchases of drugs in closed classes through the Prime Vendor are monitored, and from time to time the NPTC will provide information to facility and Area leadership about drug acquisition and cost patterns, so that opportunities for additional cost avoidance can be identified.

#### VA National Formulary Closed Classes

HMG Co-A Reductase inhibitors (statins):

Simvastatin  
Lovastatin  
Fluvastatin

Triptans:

Zolmitriptan

Ophthalmic prostaglandins:

Travoprost

5Ht3 Receptor Antagonist:

Ondansetron

Leuteinizing hormone

releasing hormone (LHRH)

Goserelin

#### The Statin Issue

Emerging information from a number of clinical studies suggests that LDL cholesterol targets for certain high-risk patients should be revised downward to 70 mg/dl or below. Many of these patients, and others with extremely high baseline LDL levels, will require the highest approved dose of atorvastatin (80 mg/day) to reach these targets, because no other single drug currently marketed has been shown to have comparable potency. The question has been raised as to whether it is appropriate to have a closed class that excludes this drug when it is clear that it will be medically indicated for a certain proportion of patients.

As noted above, any closed class designation will be subject to exceptions because a certain number of patients will not respond to or will not tolerate the formulary drug. It is important to keep in mind that simvastatin is considered a high potency statin, and at current pricing levels can be acquired at about one-third the cost of equally potent dosages of atorvastatin. Considering that atorvastatin and simvastatin are the second and seventh highest cost drugs purchased in IHS (totaling over \$12 million annually), the potential for cost savings with preferential use of simvastatin, **when appropriate**, is substantial. To date, the VHA and DoD have continued to close the statin class, but expect providers to follow national recommendations and initiate non-formulary requests for atorvastatin 80 mg when necessary. This issue is scheduled to be discussed at the June 2005 NPTC meeting.

#### Formulary Implementation Requirements

In authorizing the National Core Drug Formulary and the formation of the National Pharmacy and Therapeutics Committee, IHS leadership has approved the following implementation parameters:

- Implementation of the National Core Drug Formulary is mandatory for all Federally-operated IHS hospitals and clinics. IHS facilities are expected to be in compliance by October 1, 2005. Implementation is urged for tribally operated facilities.
- Implementation consists of two components: 1) commitment to making all core drugs available to patients; 2) commitment to observing closed class restrictions.
- Although preferable from a cost standpoint, addition of all core drugs to local formularies is not required. National Core Formulary participation only mandates that facilities make all core drugs available to patients, through whatever means the facility selects.
- Normal P&T processes should continue to be used to complete the local formulary for disease categories not covered by the core formulary and, if desired, to add non-core drugs for treatment of priority conditions (except in closed classes).

- Cost advantages and portability of the drug benefit will be maximized if core drugs are used preferentially for all patients, with non-core drugs prescribed only when there is a clear clinical indication to do so.
- For closed classes, only those drugs specified on the National Core Formulary may be listed on facility formularies. Closed class drugs are to be prescribed as first line agents when a drug in the class is indicated.
- Every facility must have expedited processes for providing access to non-formulary drugs in closed classes when the formulary drug is contraindicated by reason of ineffectiveness or adverse effect.
- For patients already on non-formulary drugs in closed classes, facilities must develop procedures for transitioning them to the formulary drug, unless a contraindication to the formulary drug is present.

### The National P&T Committee and the Future of the National Core Formulary

The charge to the National Formulary Work Group was to evaluate the need for and feasibility of a national formulary, and to develop a formulary and recommendations for its implementation. One of the earliest NFG recommendations was that no attempt should be made to initiate a national formulary system without a process in place for keeping it up to date. The NFG recommended that a permanent committee be chartered, with the responsibility of maintaining the National Core Formulary and providing ongoing therapeutics and cost management support to I/T/U facilities. This committee will function as a National Pharmacy and Therapeutics Committee.

The composition of the National Pharmacy and Therapeutics Committee (NPTC) is a field membership of twelve practicing physicians and pharmacists representing the full spectrum of geographic and practice settings in Indian country. Physicians must be in the majority on this committee; NFG members felt that credibility and acceptance of NPTC recommendations by I/T/U providers would be at risk if practicing physicians were not the majority participants.

Leadership of the NPTC resides in a physician Chairperson and a pharmacist Vice-Chair. These individuals will be permanently assigned to the NPTC with salary support (up to 25% for the Chair and 100% for the Vice-Chair) from IHS Headquarters. The majority of the research work and travel associated with NPTC membership will fall to these individuals by virtue of their salary support.

The NPTC meets semi-annually – its inaugural meeting took place December 16 - 17, 2004. The purpose of NPTC meetings is to discuss evolving research and practice guidelines for conditions addressed by the NCF, to review the status of national contracts and other pharmacoeconomic data, to consult with subject matter experts on formulary and guidelines issues, and to modify the National Core Formulary as needed. Interim business between meetings is conducted via e-mail and conference calls.

The NPTC will be governed by certain rules and ethical standards, including the following:

- NPTC members are required to certify that they have no conflicts of interest involving pharmaceutical products or companies.
- NPTC members are volunteers, and the time they spend on NPTC business is not compensated. They have committed to being responsive to their Area facilities and to the NPTC, but are not to be contacted directly by drug companies or their representatives.
- The NPTC agenda is derived through input from the field and from evolving medical knowledge and practice guidelines. Drug manufacturers may not request items to be added to the agenda, and are not permitted to make presentations to NPTC.
- NPTC will not add drugs to the National Core Formulary in exchange for incentive agreements or other concessions.

The NPTC will develop processes for field input to the Committee, both requests for information and research, and requests for modifications to the National Core Formulary. These processes will include requirements for a threshold level of consensus from the field before NCF changes are considered. NPTC members (see inset) are expected to be a resource to medical staffs and facilities in their Areas on pharmacy and therapeutics issues, and to represent and interpret actions of the Committee to the field. Many providers and pharmacists will wish to bring issues before the NPTC, and are encouraged to do so. However, in order to protect NPTC members from having to deal with multiple sources of input, facilities should develop a single point of contact (such as the Clinical Director or Chief Pharmacist) for their Area representative. NPTC officers may be contacted directly by e-mail at [NPTC@ihs.gov](mailto:NPTC@ihs.gov). An NPTC website is under construction, and may be active by the time this article goes to press.

#### IHS National Pharmacy and Therapeutics Committee

##### Chair (acting)

Howard Hays, MD, MSPH

##### Vice-Chair (acting)

Robert Pittman, RPh, MPH

##### Pharmacoeconomics Consultant

Michael Contos, PharmD

**Aberdeen** – John E. Jones, RPh (Rapid City)

**Alaska** – Robert H. Carlson, MD (SEARHC, Sitka)

**Albuquerque** – Matthew A. Clark, MD (Southern Ute, Ignacio)

**Bemidji** – Patrick Rock, MD (Indian Health Board, MPLS)

**Billings** – JoEllen Maurer, RPh (Fort Peck)

**California** – Daniel J. Calac, MD (Indian Health Council)

**Nashville** – Jonathan Dando, RPh (Cherokee)

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**Oklahoma** – Travis E. Watts, PharmD (Claremore)

**Phoenix** – Mark Caspi, PharmD (PIMC)

**Portland** – S. Miles Rudd, MD (Warm Springs)

**Tucson** – James Olson, MD (Sells)

## The Vocabulary of Pharmaceutical Purchasing

The language of pharmaceutical procurement in the IHS can be confusing. The purpose of this section is to acquaint the reader with the various terms that are used when discussing these issues.

Presently in the IHS, most drug purchases are made through the **Pharmaceutical Prime Vendor (PPV)**. IHS and tribally operated facilities are permitted to purchase drugs through the PPV by virtue of a 1996 interagency agreement between IHS and the Veterans Health Administration (VHA). This agreement enables Indian health care facilities to utilize the contracts and/or contracting expertise of the VHA for Prime Vendor distribution of pharmaceuticals, medical-surgical supplies, and other health care items.

The national PPV program is managed by the VHA, and is a pharmaceutical distribution contract with one or more drug wholesalers. The current contract is with McKesson and expires in 2009. The PPV contractor is required to maintain a supply of and distribute pharmaceuticals, and a variety of other items with therapeutic uses, that are dispensed through pharmacy services. The PPV program utilizes state-of-the-art software and payment capabilities to achieve just-in-time acquisition services for participating facilities. The PPV is required to offer products at the lowest price available through the four pricing schemes listed below. McKesson further discounts this price by 4.5% as part of its agreement to be the PPV. This results in the best possible drug pricing for IHS and tribal facilities.

The maximum price that the PPV can charge for drug products is defined by the **Federal Ceiling Price**, which can be no greater than 76% of the Non-Federal Average Manufacturer Price. All prices obtained through the other three pricing schemes will be at or below the Federal Ceiling Price.

**Federal Supply Schedule** contracts are solicited, awarded, and administered by the VHA's Federal Supply Schedule Program. Vendors contract with the VHA (and through the VHA with all other Federal agencies) for discounted prices on drugs or other items, without a specific agreement on volumes or amounts that will be purchased. FSS prices for drugs are at least 24%, and often as much as 60%, lower than Average Wholesale Price (AWP), and total FSS purchases by all Federal agencies exceed \$2 billion annually. The vast majority of drugs purchased through the PPV program are bought at FSS prices.

**Blanket Purchase Agreements** are occasionally signed between a drug manufacturer and an IHS Area, IHS nationally, or VHA (with or without IHS participation). These are not binding contracts, but are incentive agreements that offer the participating entity a graduated discount in drug pricing that depends on the market share of the manufacturer's product in comparison to specific competitor products in the same drug class. For example, IHS has recently signed a national BPA with the manufacturer of pioglitazone (currently the top drug IHS-wide in terms of cost), which is expected to produce between \$2 million and \$4 million in savings over the coming year. BPA can offer considerable opportunities for cost savings, but historically some manufacturers have been reluctant to offer them to IHS in the absence of a national formulary. The advent of the IHS National Core Formulary opens up the possibility for additional new system-wide incentive agreements.

**National Standardization Contracts** are managed by the Special Contracts Team of the VHA Pharmaceutical Products

Division. These are a mandatory source for VHA healthcare facilities, and the VHA is committed to procuring all its requirements of the contracted items from the identified contractors. IHS facilities may also utilize these contracts, but must provide projected purchase quantities and sign a commitment agreement. The PPV makes the specified item(s) available and restricts the ordering facility's ability to purchase equivalent items from other manufacturers, unless specifically overridden. The occurrence of frequent overrides is monitored and reported to VHA and IHS as a potential variation from contract provisions.

National contract prices are very competitive because of the volume commitment and the VHA's ability to enforce compliance with the contracts at its facilities. The product prices under these contracts are generally considerably lower than FSS prices for the same or similar product. The contract period is typically for one base year plus 1 to 4 one-year renewal option periods. All national contract items are distributed exclusively through the VHA PPV program.

National contracts serve two major roles. Most commonly, a national contract is solicited when several brand or generic options exist for a particular high-volume drug. The VHA contracts with a single manufacturer to purchase that manufacturer's version of the drug, guaranteeing a certain volume of business for a specified time frame (up to five years). Participating facilities must select this manufacturer's product when purchasing from the PPV, for the duration of the contract. IHS facilities are routinely invited to participate in these contracts.

Less commonly, the VHA may elect to solicit a national standardization contract from a manufacturer of a particular innovator drug (still under patent) in a drug class with several competitors, each of comparable therapeutic efficacy. This will usually be a high-volume and high-cost drug category, and by executing an agreement to preferentially utilize a particular drug product, the VHA can obtain sharply discounted pricing and substantially reduce its costs for the drug class in question. On the VHA formulary, this type of national contract results in a "closed class," that is, a drug class with only one product (sometimes two) on the formulary. See the previous discussion on closed classes.

It is appropriate to remind readers that certain rules and restrictions apply to organizations that purchase drug products through any Federal pricing program, including the PPV. All products so acquired must be used for direct service to Federal government beneficiaries. They may not be resold, or diverted to non-beneficiaries (i.e., non-Indian patients other than certain other defined beneficiaries such as Commissioned Officers and their families). Access to the PPV is a privilege, because the VHA is under no obligation to permit IHS to participate in its contracts. If the VHA receives validated complaints from drug companies that their products are being sold or otherwise provided to non-beneficiaries, it can elect to exclude IHS from current and future contracts.

The ability to utilize the Pharmaceutical Prime Vendor and to take advantage of Blanket Purchase Agreements, Federal Supply Schedule, and National Standardization Contracts works to the great advantage of IHS and tribal health care facilities. The problem of rising pharmaceutical costs would be even more critical if we were not afforded this privilege. Facilities that are not maximizing their use of these pricing schedules are missing an opportunity for substantial cost avoidance. Moreover, maintaining a close partnership with the VHA on national contracts puts IHS in a position to have a voice in their future contracting decisions.

## Additional Reading

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National Asthma Education and Prevention Program, NAEPP Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma – Update on Selected Topics 2002 (web-based document): <http://www.nhlbi.nih.gov/guidelines/asthma/execsumm.pdf>

## IHS National Core Drug Formulary (version 1.2, revised 12/2004)

Disease Category	Therapeutic Class	Pharmacologic Class	Drug Name	Comment	
Cardiovascular	Antiplatelet		Aspirin		
			Clopidogrel		
	Anticoagulants	Coumarins	Warfarin		
	Diuretics	Loop diuretics	Furosemide		
		Thiazides	Hydrochlorothiazide		
		Potassium-sparing diuretics	Spirolactone		
	Inotropics	Digitalis glycosides	Digoxin		
	Antianginals	Nitrates	Nitroglycerine 0.4 mg tab		
			Isosorbide dinitrate	Mononitrates are not excluded	
	Antihypertensives	Alpha blockers	Terazosin or Doxazosin	Either alpha blocker formulation is acceptable but sites must carry at least one.	
		Beta blockers, selective	Atenolol		
			Metoprolol	Extended release metoprolol preparations are not required as part of the core formulary.	
		Calcium Channel Blockers			
		All calcium channel blockers (CCB) specified by the National Core Formulary are extended release preparations. Immediate-release CCBs are associated with higher rates of side effects and complications.			
		Phenylalkylamine	Verapamil		
		Benzenothiazepine	Diltiazem		
		Dihydropyridine	Nifedipine		
		ACE Inhibitors	Captopril		
			Lisinopril		
		Angiotensin Receptor Blockers (ARB)	Any drug in the ARB class is acceptable, but facilities must make at least 1 ARB available to patients.		
	Lipid Management	Statins	Simvastatin	Closed Class: Sites are required to carry simvastatin and may carry lovastatin or fluvastatin as lower cost alternatives. Other statins are specifically excluded.	
			Lovastatin or Fluvastatin		
		Fibrates	Gemfibrozil		
Water-soluble vitamins		Niacin			

IHS National Core Drug Formulary (version 1.2, revised 12/2004) (continued)

Disease Category	Therapeutic Class	Pharmacologic Class	Drug Name	Comment	
<b>Diabetes Mellitus and other Endocrine</b>	Hypoglycemic	Sulfonylureas	Glipizide	Both of these common drugs must be available to promote portability of the drug benefit.	
			Glyburide		
		Biguanides	Metformin		
		Thiazolidinediones	Pioglitazone		
		Insulins (human recombinant)	Short-acting (Regular)		
			Intermediate-acting (NPH)		
	Combination (70/30)				
	Although multiple insulin formulations and regimens are available, the majority of patients requiring insulin can be appropriately treated with those listed.				
	Renal protective	ACE Inhibitors	Captopril		
			Lisinopril		
	ARBs	Any ARB (see comment under antihypertensives above)			
Thyroid	Thyroid replacement	Levothyroxine			
<b>Depression &amp; Anxiety</b>	Antidepressants	Tricyclic	Amitriptyline		
			Imipramine		
			Nortriptyline		
		Tetracyclic	Trazodone		
		SSRI	Fluoxetine		
	Anxiolytics	Benzodiazepine	Clonazepam		
			Lorazepam		
<b>Asthma &amp; Chronic Lung Disease</b>	Bronchodilators	Beta Agonists	Albuterol	The NPTC expects that facilities will carry three preparations of Albuterol: albuterol for inhalation (MDI), albuterol solution for inhalation, and albuterol solution for oral use.	
			Salmeterol		
		Anticholinergics	Ipratropium MDI		
	Anti-inflammatory agents	Steroids	Any inhaled steroid		
			Prednisone (oral)		
Recommendations for asthma treatment are drawn from the 2002 updated NAEPP Expert Panel Report. Note that current recommendations of the NAEPP, and an FDA "black box" warning for salmeterol, emphasize that this drug should not be used as sole treatment for asthma.					
<b>GE Reflux &amp; Peptic Ulcer Disease</b>	Anti-acid agents	Histamine-2 Blockers	Ranitidine 150 mg tablets		
		Proton Pump Inhibitors	Omeprazole 20 mg tablet	Closed Class	
<b>Arthritis</b>	Pain relievers		Acetaminophen	Acetaminophen is considered a first-line agent for treatment of osteoarthritis.	
	Anti-inflammatory agents	NSAIDS	Aspirin	Already part of the formulary for cardiovascular disease, aspirin remains a valuable and inexpensive solution for management of arthritic conditions.	
			Ibuprofen		
			Naproxen		
			Sulindac		
	Multiple NSAID agents are available, and facilities may choose to include several on their formularies. However, the above agents represent well-established and commonly used drugs from a variety of chemical classes. In the interest of consistency among facilities, these core drugs should be available to patients at all facilities.				
	Disease-modifying anti-rheumatic drugs (DMARD)	Steroids	Prednisone		
Antimetabolites			Methotrexate		
			Sulfasalazine		
Certain other commonly used disease-modifying antirheumatic drugs, specifically hydroxychloroquine and azathioprine, are not on the IHS core formulary.					

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# IHS Rural Prophylaxis Mass Clinic Planning Committee Shares Lessons Learned in Partnering with their LEPC and the Utilization of Community Volunteers

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*CDR Kimberlae Houk, RN, MSN, Public Health Nurse, Shiprock Agency, Northern Navajo Medical Center, Shiprock, New Mexico; and Dr. Lynn Sweeney, MD, Shiprock Agency; Northern Navajo Medical Center*

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## **Motivation**

Because of increased national awareness of infectious disease, both as a weapon of mass destruction and as an emerging potential epidemic, the need was identified to be able to administer vaccinations or prophylactic medications to large populations in a brief period of time using currently available resources.

Local history demonstrates the ability for hospitals on the Navajo Nation to react to small community epidemics, such as meningitis, measles, Hanta virus, and plague. In 1991, 60,000 individuals were vaccinated against measles across the Navajo Nation over a 30 to 60 day period, thereby averting a potential epidemic. In the mid 1990s, several thousand exposed persons were given meningitis prophylaxis after several Meningococcal deaths. In both of these situations, community clinics were established at community Chapter Houses. These community clinics were staffed entirely with public health personnel.

Current concerns were triggered by the use of *Bacillus anthrax* in 2001, the potential use of smallpox as a bioweapon, and the emergence of severe acute respiratory syndrome (SARS). The need to be able to vaccinate or otherwise give prophylaxis to a large number of community members in a very brief period of time could overwhelm the resources of any public health department. If the need for prophylaxis were local only, additional staff could be requested from other health departments and federal agencies. In a large state or national situation, outside resources may not be readily available. Additional staff could be recruited from local hospitals and clinics, but would be limited due to the need to continue routine medical care. Potential additional staff may need to be discovered from local sources to supplement public health staff.

## **Problem Statement**

The Shiprock Service Unit (SRSU) consists of a small, comprehensive, acute care medical facility, the Northern Navajo Medical Center (NNMC), and a public health clinic. The SRSU is tasked with responding to the medical needs of a population of 50,500 community members. NNMC is the sole Indian Health Service hospital resource for a large geographic area covering a significant portion of San Juan County, New Mexico, along with small areas in eastern Arizona and southern Utah. This service area is divided into 22 community units called "Chapters." San Juan Regional Medical Center (SJRMC) in Farmington provides hospital care for the remainder of the approximately 150,000 population in San Juan County. The New Mexico Department of Health maintains an office in San Juan County with a small staff.

In an infectious disease emergency, these three agencies would face the challenge of designing and staffing a prophylactic care/vaccination clinic for 150,000 persons, possibly using only the personnel resources available within the county. The solution? Ask the community for help.

## **Approach**

Historically hospitals, county health departments, and other medical entities within San Juan County (SJC) have not had a close working relationship, and communication has been poor. San Juan County has a strong Local Emergency Planning Committee (LEPC), although it is heavily involved with hazardous material issues due to the large number of oil and gas companies in the area. The LEPC has always solicited membership from all potential emergency response agencies. The SJC LEPC monthly business meeting was the catalyst for representatives from the two different departments of public health to meet and realize the need for collaboration, which resulted in a LEPC Public Health Committee (LEPC PHC).

The LEPC PHC began meeting just a few months prior to September 11, 2001. The committee became a drawing power, bringing together representatives from both hospitals, state and Indian Health Service (IHS) public health departments, local school districts, mental health providers, numerous smaller

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medical entities, and the county emergency manager, providing a forum for communication and exchange of ideas and a collaborative force for change.

After the anthrax-by-mail attacks on the east coast in 2001, this committee was informed of state plans to start developing mass prophylaxis clinics, should New Mexico (NM) be targeted for a similar attack. The NM state's plans emphasized the use of large, centrally located prophylaxis clinics, which in San Juan County would require some of the population to drive more than two hours to receive care. Because the SRSU had a proven history of having provided prophylactic care, and having the need to serve a large rural population, the county health department representative agreed to allow SRSU to design several smaller rural clinics to work in conjunction with the larger county department of health clinic systems. This would also benefit the county department of health as SRSU's clinics would serve about one-third of the county's population using their own (SRSU) personnel.

### **Shiprock Service Unit**

With the charge to develop rural clinics, a small design team was established at SRSU with the charge of creating a clinic design, patient flow pattern, and potential staffing patterns. Adjustments were made to allow for language and cultural issues, matters important to the IHS philosophy. Calculations based on the number of available health care professional personnel showed that we could not staff 22 simultaneous chapter house clinics. The committee decided that five clinics, strategically located to cover the entire service area, proved more feasible for medical staffing capabilities. There were not, however, enough hospital personnel to provide the required number of nonmedical staff. The decision was made to go to the communities and ask for help, requesting volunteers to staff the nonhealth care positions.

Other considerations unique to the development of a rural clinic system included the lack of electricity and refrigeration in some of the more remote communities. Road signs and addresses are not found in many service areas. Persons unfamiliar with the area locale would not be able to effectively locate many homes in the area. Community members who are familiar with the area, however, would be able to easily locate these and help other community members requiring special assistance.

Navajo culture warns against the discussion of disaster and disease processes. The clinics discussed through this paper are prophylaxis clinics, meaning clinics "to keep well people well." This was an essential part of community education as "disaster" to a taboo topic among the Navajo people. It was noted that there are numerous ways that the Navajo people prophylactically care for themselves every day. Brushing teeth and wearing seat belts were connected to disease prevention and the use of mass prophylactic community clinics.

### **Community Involvement**

Community prophylaxis clinics could be placed in schools, community buildings, bingo parlors, or churches. Navajo community buildings, called chapter houses, were selected as sites for clinics. Chapter houses are the social, political, and often geographical center of Navajo communities. They are natural gathering places and a logical choice for any emergency meeting or service. As a community owned public building, access to chapter houses can be granted by the community itself.

Valid questions were raised concerning the use of hospitals for the prophylaxis clinics, rather than community sites, but hospitals resources need to be conserved for the sick. Hospitals have and will continue to assist in prophylactic care as able, but to depend on a single facility to meet the full community need in a large scale event was deemed unfeasible. An additional consideration is the fact that hospitals can become a quarantine site, leaving a community without prophylactic clinic plans.

The use of volunteers is essential in the operations of community clinics, as the SRSU is not able to field enough personnel to completely staff community clinics and maintain essential hospital medical services. Volunteers can function as runners, writers, and interpreters. For example, a community member serving as a "Greeter" (triage) will be provided a card listing several questions (designed by the medical staff) to ask community members arriving to the clinic. If an individual answers positively to the listed questions then he/she will be sent to a separate, outside clinic, for evaluation of acute disease. If the individual answers negatively, then he/she will be allowed into the chapter clinic for prophylaxis care. This simple triage position is an example of one of the many clinic roles that community members can perform with minimal instruction and no need for prior training (other than the day of the clinic).

For a community clinic with the capacity to serve 1000 individuals per day, working 10-hour days, with the intention of serving 10,000 community members in ten days, six clinic stations were identified, using approximately 13 medical staff and 21 community volunteers. Station #1 is tasked to triage (greeter) community members by asking several predesigned questions, and would be staffed with three volunteer interviewers and one volunteer runner. Station #2, an isolation station for community members identified as possibly having an infectious condition, would require one physician or nurse practitioner, one PHN (for community communicable disease follow-up), and one nurse aid.

Most of the community population will progress from station #1 to station #3 where registration information is recorded by six volunteer community members. Station #4 provides education using a videotape or a script read to small groups to teach the reason for the clinic and the need for prophylactic measures; it is staffed with two medical educators

and one community volunteer. Even with education materials prepared ahead of time, this station will need to be staffed by medical educators due to the need to be able to answer questions from the public accurately. Station #5 may be a single station for screening and treatment, or it may be split into two stations, depending on the disease of concern. This station is staffed with five nurses, pharmacists or other health care providers, yet also needs a compliment of seven volunteers to act as scribes and runners. Station #6 is a medical station for compromised community members who may need more in-depth evaluation prior to prophylaxis and is mostly staffed with medical personnel. Additional clinic staff needs include a supervisor, a mental health worker, and possibly a security officer.

It is acknowledged that some disease concerns may need a more rapid response than ten days. This community plan can be expanded for more rapid processing at the direction of the clinical director, if warranted and if staff levels permit.

### Community Education and Response

It is imperative to utilize the existing Navajo Nation legal systems to gain permission to utilize community buildings. SRSU serves 22 identified communities, called “Chapters,” each of which has a community building and a legal system of response called “Resolutions.” Each chapter was approached at a community chapter meeting, provided education on “prophylaxis” and prophylaxis clinics, and presented a draft resolution to vote on. Educators taught that SRSU did not have the personnel to assist with a potential 22 simultaneous sites, but felt that there was adequate medical staff to assist with five sites if chapter communities would volunteer to help other chapter communities. Chapter houses responded to community education with the passing of legal resolutions agreeing to “plan, prepare, and facilitate a clinic at their chapter house as a primary site”; or “being willing to support a primary site at another location and for their chapter house to serve as a secondary site as needed.”

### Results

Traditionally, NNMC and the Shiprock community have created their own individual disaster drills and have rarely sat at a table and conversed with county health departments or the other hospital within the county. Through LEPC activities, SRSU started to participate in county-wide drills, and a Memorandum of Understanding was facilitated between NNMC and San Juan Regional Medical Center, in which both facilities agreed to work together to expedite the transfer of disaster victims.

San Juan County has a county-wide emergency plan, which has never included medical concerns. An amendment to the plan was written to include the SRSU mass prophylaxis community clinic plan. This was additionally reviewed by the NM State Department of Health with the plan that it would be

added to their overall response plan and Strategic National Stockpile Plan.

Chapters with no history of collaborating with each other or with other agencies have now done so to create a plan to provide prophylactic care to their own community members and have created resolutions to that end. The SRSU has responded by adding mass community clinics as an addition to the hospital epidemiologic response plan. Signed policies have been returned to each chapter to also act as Memoranda of Agreement.

### Conclusion: Volunteer Recruitment Works

A drill was created to test the ability of the SRSU to recruit, train, and utilize volunteers. This functional drill utilized a SARS outbreak/flu vaccine model, with 200 community members coming to this drill/clinic for flu vaccine. The team needed to recruit 21 volunteers and had an actual 31 community volunteers on site. The day started with training, which included clinic design, explanation of prophylaxis care, and evaluation system. Volunteers were highly motivated to learn their respective jobs, innovative in finding ways to accommodate community needs, and actively participated in the evaluation of the clinic process.

Historically, the community population has always anticipated that the medical facility would be there to meet any medical need. With education, community members learned about prophylactic care and how they could help. Twenty-one individual community chapter houses voted and passed legal resolutions agreeing to “plan, prepare, and facilitate” mass prophylactic clinics and to provide primary or secondary facilities for these clinics. Instead of expecting the small rural hospital to come to the community; the community is now asking how they can help.



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# Feasibility and Acceptability of An Intervention to Reduce The Prevalence of Risk Factors for Otitis Media In a Minnesota American Indian Population: The Little Ears Study

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*Phyllis L. Pirie, PhD, at the time of the study, Professor, University of Minnesota, Division of Epidemiology, School of Public Health, Minneapolis, Minnesota; currently at the Division of Health Behavior and Health Promotion, School of Public Health, Ohio State University, Columbus, Ohio; Kristine Rhodes, MPH, Coordinator, University of Minnesota, Division of Epidemiology, School of Public Health; Kathleen Daly, PhD, Associate Professor, University of Minnesota, School of Medicine, Department of Otolaryngology; Cynthia Davey, MS, Research Fellow, University of Minnesota, School of Public Health, Division of Biostatistics*

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Although common among children of all ethnic groups, otitis media has been shown to be more prevalent in American Indian children,<sup>1</sup> for reasons that are not well understood. While some have postulated a variable genetic susceptibility to these ear infections,<sup>2</sup> it is likely that differential exposure to established risk factors also plays a role.

Established environmental risk factors for otitis media include exposure to cigarette smoke,<sup>3</sup> lack of breastfeeding, and exposure to large-group day care settings.<sup>4</sup> Daly *et al*<sup>5</sup> have recently demonstrated higher prevalence of several of these risk factors in American Indian populations in Minnesota, including greater rates of exposure to cigarette smoke and low rates of breastfeeding; exposure to other children in day care was not elevated in the population studied.

Based on concern about the higher rates of otitis media in their communities and the concomitant danger to the health and development of their children, tribal officials from the communities involved in an ongoing epidemiology study (the Little Ears study<sup>5</sup>) requested that an intervention be developed to address the problem of increased risk of otitis media.

Discussions were held with community advisory board members from the involved communities (three reservations in northern Minnesota and an urban American Indian health clinic in Minneapolis, Minnesota). On the basis of these discussions, the decision was made to develop an intervention program focused on reducing cigarette smoke exposure and increasing breastfeeding. Community advisors felt that these were important risk factors to address, both because they are

well established as risk factors for otitis media and because they are known to have health implications for other important childhood diseases as well.

Additional discussions with community advisors concerned the type of program to conduct. While a community-wide public health approach had considerable appeal, a clinic-based program was endorsed due to feasibility of implementing it with limited resources and the increased likelihood that a clinic-based approach could be continued after the end of this funding. Paying attention to sustainability of projects is an important aspect of community participatory research.<sup>6</sup> Furthermore, in keeping with this model, ongoing discussions and review of materials with members of the community advisory board were undertaken to ensure that the program would be culturally appropriate.

The purpose of this manuscript is to describe the feasibility, acceptability, and preliminary findings pertaining to the pilot intervention.

## Study Design

Following completion of an epidemiologic study of risk factors for and prevalence of otitis media in the involved communities, women were recruited to participate in this pilot intervention program. Participating women were late in their pregnancies, and individualized intervention sessions were held in late pregnancy, 2 weeks postpartum, 2 - 3 months postpartum, and 6 months postpartum. Baseline data on knowledge and risk characteristics were collected prior to the first intervention session; follow-up data were collected at the 2 week postpartum intervention and the 6 month postpartum intervention sessions. Evaluation of the intervention program involved two strategies: direct questioning of the program participants about what they had learned and what changes they had made, and comparison of behaviors between the women participating in the intervention study and those participating in the related epidemiology study.

Tribal officials from all sites had given permission for the epidemiology and intervention studies, and study procedures were approved by both the University of Minnesota and Indian Health Service Institutional Review Boards.

## Recruitment

Women were recruited to the intervention program in the waiting room of prenatal clinics and/or Women, Infant and Children (WIC) Program clinics in each location by study nurses. The choice of recruitment location was based on the preference of the local health care agencies. Recruitment began August 15, 2001 and ended October 1, 2002.

## Eligibility

Eligible women were at least 16 years of age, in the second or third trimester of pregnancy, and did not have another infant currently participating in the Little Ears study.

## Intervention

Because pregnant and postpartum women are frequent visitors to health care settings, the majority of intervention programs targeting this group make use of a health care setting for program delivery, rather than other methods of outreach. The Little Ears intervention program also followed this model, making initial contact with participants in prenatal and WIC clinics and continuing follow-up by study nurses in clinic settings or by home visits as needed. The program was delivered one-on-one by nurses who had worked for Little Ears or the local site for several years and were familiar to local residents.

The decision to offer individual rather than group meetings was made because the participants living on reservations are widely dispersed over a considerable geographic area and would have found it difficult to make extra trips to the clinic site for intervention purposes. The sessions consisted of discussions and presentation of information about breastfeeding, smoke exposure, and general strategies for infection control, individually tailored to focus on the issues raised by each study participant. The session content was designed based on principles of brief, patient-centered counseling,<sup>7</sup> beginning with an assessment of interest on the part of the participant in adopting the particular behavior (breastfeeding, control of smoke exposure, infection control practices) and proceeding to a discussion of barriers and self-generated strategies for overcoming barriers, as dictated by the participant's interests and willingness to engage in discussions.

The smoke exposure intervention was not targeted toward smoking cessation of the individual mother, but toward strategies to avoid exposing the infant to passive cigarette smoke. There were several reasons for this choice: first, because of the high prevalence of cigarette smoking in this population, even the babies of non-smoking mothers had a high probability of being exposed to smoke regularly; and second, the investigators were concerned that too much focus on smoking cessation might alienate mothers who would otherwise participate. For these reasons, the decision was made to focus on avoiding smoke exposure for the infant, and on helping women identify strategies to protect their infants from smoke exposure.

At each intervention session, participating women were given written materials appropriate to the topics discussed, as outlined in Table 1. Whenever possible, materials targeted to American Indian populations were used; for example, specifically targeted materials on breastfeeding and on the ceremonial use of tobacco were incorporated. In addition to the written materials, women were given small gifts (baby clothes, tote bags, refrigerator magnets) at each session, also as described in Table 1. Several of the gift items were designed specifically for the study and carried the Little Ears logo, created by an artist from one of the participating communities. The items also carried slogans endorsing breast feeding or avoiding smoke exposure. These gifts were intended both to thank the participants for their participation, and to remind them of the intervention messages between visits.

**Table 1. Intervention program schedule and materials**

Visit number	Education topics	Written materials	Gifts
1: prenatal	Breastfeeding	Q & A sheet: breastfeeding Pamphlets: breastfeeding Busy Moms Encouragement Embarrassment Your new life	Hand massager and batteries  \$5 cash
2: early postpartum (average 4 weeks)	Reinforcement of Continued breastfeeding  Smoke exposure	Working and breastfeeding booklet  Smoke Free family materials  Passive smoke brochure	"Onesie" t-shirt (breastfeeding slogan) Water bottle (breastfeeding slogan) Tote bag (smoke exposure slogan) Visor, doorknob and table tent signs (smoke exposure slogan) Magnet (smoke exposure slogan) \$5 cash
3: 2 - 3 months postpartum	Reinforcement of continued breastfeeding  Smoke exposure  Infection control	Long term breastfeeding video; to lend as needed  Infection control handout	Magnet to share (smoke exposure slogan) "Onesie" t-shirt (smoke exposure slogan) Baby bib (smoke exposure slogan) \$5 cash
4: 6 months postpartum	Any of above, as appropriate		Sippee cup (Little Ears logo)  \$10 cash

The goal of the breastfeeding intervention was to encourage increased initiation and duration of breastfeeding. The goal of the smoke exposure intervention was to decrease the exposure of the baby to cigarette smoke. Discussion of both topics was focused on identification of barriers to performing the behavior, and discussion of potential coping strategies.

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## Data Collection

Prior to beginning any study activities, potential participants were told about the study, and if they were interested, they were asked to sign a consent statement. Before the first intervention meeting, the study nurse arranged a phone call to a data collection center at the University of Minnesota. During this call, participants answered questions about family demographic variables and their beliefs and attitudes concerning breast feeding and smoke exposure. Placing a phone call to a distant location for data collection was the method chosen to separate the data collection and program activities and to provide participants with a sense of privacy about answering study-related questions.

Data collection at subsequent intervention visits was conducted in the same way, with a data collection telephone call preceding the intervention discussion. The exception was the intervention visit scheduled about 2 - 3 months postpartum, which did not involve any data collection. At 4 weeks and 6 months, mothers were asked about hours of smoke exposure of the baby from various sources, infant feeding practices, use of day care, and frequency of the baby's contact with other children. At 6 months, mothers were asked about what they felt they had learned and the acceptability of the intervention overall.

## Data Analysis

Behaviors were compared between intervention study and epidemiologic study participants using chi-square tests for nominal and t-test for continuous data; two-factor ANOVA tests were used to compare continuous variables in the two groups over time.

## Results

*Recruitment and retention of study participants.* For the intervention portion of the study, 103 women were recruited to participate; of those, 81 provided data at the early postpartum follow-up, and 63 provided data at the six month postpartum follow-up. Overall retention in the study by 6 months (61%) was nearly identical to retention in the epidemiologic study (217 of 380 participants, or 57%). Those lost to follow-up in the intervention study group differed from those retained by having been less likely to be working or going to school at baseline (25% vs. 48%,  $p=.055$ ). Those lost to follow-up did not differ from those retained in terms of standard demographic variables such as education, age, or marital status. Those lost to follow-up were also not significantly more likely to be smokers than those retained in the follow-up study (54% vs. 46%, n.s.).

*Intervention delivery.* As noted above, intervention visits were targeted to occur at baseline (prenatal), early postpartum, 2 - 3 months postpartum, and 6 months postpartum. Since the baseline intervention visit was concomitant with the baseline data collection in most cases, nearly all women (97%) who provided

baseline data also received the prenatal intervention. Participation in the early postpartum visit was 83%; at 2 - 3 months postpartum, it was 45%; and at six months it was 63%. Smoke exposure was heavily emphasized in the intervention visits, being discussed in 98% of the early postpartum visits, 96% of the 2 - 3 month visits, and 92% of the 6 month postpartum visits. Breastfeeding was discussed at 99% of the prepartum visits but only 60% of the early postpartum, 26% of 2 - 3 month postpartum, and 20% of the 6 month postpartum visits.

*Comparison of behaviors in intervention and epidemiologic study mothers.* Comparisons were made between mothers who participated in the intervention study and those who participated in the epidemiologic study (data collection only). To be included in the comparisons, a woman had to have provided data at baseline, early postpartum, and at the six-month follow-up visit. This included 63 mothers in the intervention study and 217 in the epidemiologic study.

Despite similar recruitment strategies, differences were noted between the intervention and epidemiologic study groups at baseline, with the intervention group being more likely to have favorable baseline attitudes toward breastfeeding.

At the early postpartum follow-up visit (approximately 4 weeks postpartum), mothers in both groups were asked whether they had ever breastfed their baby and whether they were currently breastfeeding. There were no significant differences demonstrated between the two groups, with 59% in the epidemiologic group and 69% in the intervention group ever breastfeeding and 38% in the epidemiology and 34% in the intervention group currently breastfeeding.

Mothers in both groups reported a significant amount of cigarette smoking, with 49% of epidemiologic group mothers and 56% of intervention group mothers smoking at the time of the early postpartum interview, and similar percentages smoking among those who completed the 6 month interview (54% in the epidemiologic group, 65% in the intervention group).

At the early postpartum visit, about 28% of mothers in both the epidemiologic and intervention groups lived with a significant other who smoked. At the 6 month visit, about 41% of epidemiology group mothers and 36% of intervention group mothers lived with a significant other who smoked. For babies in households with a significant other who smoked at both interviews, 15% of babies of epidemiologic group mothers were exposed to cigarette smoke one hour or more per day in early postpartum, and 34% were exposed to smoke one hour or more per day at six months. In the intervention study group, 6% of babies were exposed to cigarette smoke one hour or more per day in early postpartum, and 28% were exposed to cigarette smoke one hour or more per day at six months. While intervention group babies were less exposed to cigarette smoke than epidemiologic group babies, it is possible that this reflects a preexisting difference between the groups rather than a result of the intervention. Significant others of intervention group mothers smoked significantly fewer cigarettes per day than the significant others of epidemiologic group mothers.

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In addition, about 28% of the epidemiologic group mothers and 26% of the intervention group mothers lived with other household members who smoked (that is, other than the spouse) at the time when the babies were 4 weeks old, and 29% of epidemiologic group and 27% of intervention group mothers lived with other household members who smoked at the time of the 6 month interview. For those babies living in households with smokers at both interviews, the hours of smoke exposure per day of the baby went up over time in both the intervention and epidemiologic groups, but the groups were similar to each other.

### **Perceived Knowledge and Behavior Change**

At the end of the study, mothers who participated in the intervention were asked the open-ended question, "What was the most important thing you learned in the Little Ears study?" Overwhelmingly, the most common response was that "smoking around children should be avoided," which was mentioned by 32 of the 63 mothers responding to the item; the next most common response, the benefits of breastfeeding, was mentioned by only 4 of the mothers.

When asked an open-ended question about whether they had made any changes as a result of the Little Ears study, 25 of the 63 mothers reported they were trying to limit cigarette smoke exposure of the infant, and 6 said they were trying to quit or cut down on cigarettes themselves. Six mentioned that they avoided propping bottles or feeding the baby while s/he was lying flat. Only 3 mentioned breastfeeding.

Participants were also asked whether they had asked someone not to smoke in the same room with the baby, and 95% said they had done so. When asked if they had asked someone not to smoke in the car with the baby, 93% said they had done so. Participants were also asked whether with the Little Ears program they had breastfed longer than they might otherwise have done, and 29% (18 women) agreed.

### **Program Acceptability**

The intervention program was well liked by the mothers who completed the 6 month postpartum interview. There was universal agreement that the gift items were useful, that the meetings with study nurses were interesting, and that they would advise other mothers to take part. Only 13% felt the meetings with study nurses were too long. While 56% felt they already knew most of the information in the program, 97% felt they had learned at least some new things. There is also evidence that the program was shared among community members; 73% indicated they had shared the study gifts, 79% had talked with other women about what they had learned, and 86% had talked with family members about what they had learned.

### **Discussion**

Although loss to follow-up between the baseline and six-month interviews was substantial, it did not differ in the

intervention group from what was seen in the epidemiologic study group. Follow-up was also not markedly worse than follow-up of patients in several recent studies of smoking cessation in pregnancy. Several features of the program may have enhanced follow-up: personalized follow-up by a consistent study nurse, the use of monetary incentives and gifts, and the focus on protecting the baby rather than on maternal smoking. Overall, the follow-up rate suggests that the intervention topics, including extensive focus on infant smoke exposure, did not alienate mothers or discourage them from participating.

While evaluation of this pilot intervention provided little hard evidence to suggest behavior change as a result of the program, there are several promising indications. Babies of intervention study mothers may have been somewhat less exposed to cigarette smoke than babies of epidemiologic study mothers. Also noteworthy is the high percentage who spontaneously reported learning from the intervention the importance of keeping the baby away from cigarette smoke. Given the high prevalence of smoking in the population, the message to protect the infant from smoke exposure may have been relatively novel. Most interventions to date have focused on urging new mothers to quit smoking; the current effort was focused on protecting the infant from smoke even for mothers who did not smoke themselves. Although mothers in the intervention reported attempting to keep their babies away from smoke, the data on smoke exposure suggest at best a modest effect. There are several possible explanations, including the difficulty of protecting the baby in an environment containing numerous smokers and relatively weak measures of outcome concerning smoke exposure.

Little effect was noted concerning breastfeeding, and very few mothers reported that the breastfeeding information was influential. This is perhaps not unexpected, since health care providers and WIC staff have begun strenuous efforts to encourage breastfeeding. In addition, the Little Ears intervention began rather late in pregnancy, when the decision about breastfeeding may have already been made.

Despite frequent calls on the part of researchers for the development of culturally appropriate programs to address the problem of cigarette smoking in the American Indian population, little progress has been made. Although the program described here was not directly targeted to smoking cessation, it did address the related issue of passive smoke exposure. The evidence presented here suggests that the described approach was both feasible and acceptable, and seems to have demonstrated some impact on awareness of the problem of smoke exposure in infants. An encouraging finding was the high percentage of participants who shared the intervention gifts with others and discussed the intervention content with others. These findings suggest that the use of targeted baby items as vehicles for the intervention message may inspire broader community awareness of the message.

## Limitations

The main limitation of this study was that the group recruited to participate was small (only 103 eligible mothers with data at baseline and only 63 with data at the six month interview) and was somewhat different from the epidemiologic group mothers, making comparisons difficult. The counseling approach to intervention was well-received, but a public health approach involving broad community support might have had more impact. The positive comments about the intervention program itself may have been in part due to the fact that only about two-thirds of those who began the intervention program were interviewed after six months.

## Summary and Conclusions

An intervention program targeted toward increasing breastfeeding rates and decreasing smoke exposure of the infant was well-received by participating mothers in four Minnesota sites (three reservations and an urban Indian health clinic). Participating women reported taking steps to protect their infants from smoke exposure; no effect was noted on breastfeeding frequency or duration. The study methods and materials – one-on-one counseling and the use of gifts and take-home materials to remind the mother of the study messages – were well received and readily adaptable to a clinic situation.

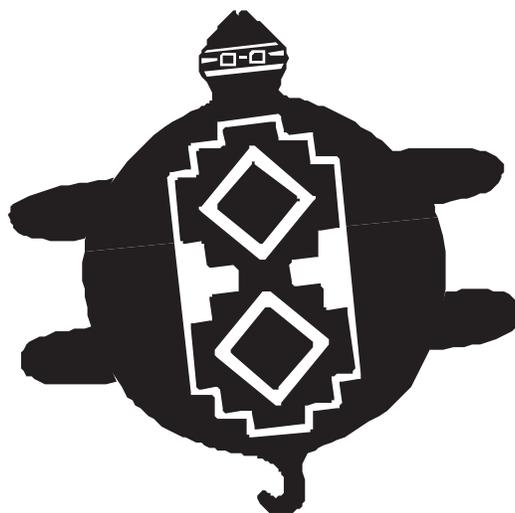
## Acknowledgements

We are grateful for the assistance of the women who participated in this study, and to the tribal and urban American Indian health clinics and communities that worked with us on this study. The research nurses – Lois Anderson, Carol Bennett, Marilyn Bowstring, Pat Butler, Carol Clay, Connie Schroeder, Ronda Stock and Sue Walline – were central to the success of the study, and their help is gratefully acknowledged.

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# Breastfeeding Duration and Prevalence of Overweight Among 4- to 5-Year Olds

Sara Lee Thomas, MS, RD, and Diane Cook, RD, Nutrition Department, Warm Springs Health and Wellness Center, Warm Springs, Oregon

## Introduction:

A growing number of scientists believe that early nutritional experiences before and after birth can have a strong and lasting influence on metabolism (“metabolic imprinting”) and the risk for obesity, diabetes, hypertension, and cardiovascular disease later in life.<sup>1</sup> For instance, research has found that infants who gain weight too fast between birth and four months of age may be prone to obesity later in life.<sup>2</sup> This period of rapid weight gain is more common in formula fed than breastfed infants, which could be one explanation for why breastfeeding has a protective effect against childhood obesity in some, but not all, research studies.<sup>3,4,5,6</sup>

In one large U.S. study of 177,304 children, there were 30% fewer overweight individuals among low-income white children who were breastfed (ever), but no difference in black and Hispanic children.<sup>3</sup> This indicates that there could be some important differences between ethnic groups. Research in the Pima Indian population found a faster rate of growth between 1 and 6 months of age compared to the general population.<sup>7</sup>

This could mean that Native Americans, at least those similar to the Pimas, might get more (or less) obesity protection from breastfeeding than other ethnic groups. They could get more protection if breastfeeding significantly slows early weight gain, and less protection if the rate of early weight gain is inherently faster in this population regardless of feeding method.

At present there are almost no published studies on breastfeeding and obesity in Native Americans. A longitudinal study in Pima Indians found 59% less risk for type 2 diabetes and significantly lower mean sex- and age-adjusted relative weight in the breastfeeding group compared to the formula fed group (139% vs. 146%).<sup>8</sup> In addition, a case-control study found that in Native Americans, less obesity and diabetes type 2 was found in Pima Indians and Canadian Natives who were breastfed 2 or more months after birth.<sup>8</sup> Canadian Natives breastfed 12 or more months had 76% lower risk of having type 2 diabetes by age 18; however, this study did not report any obesity data.<sup>9</sup> In unpublished data, Suzan Murphy, Breastfeeding Promotion Specialist at Phoenix Indian Medical Center’s Diabetes Center of Excellence, compared the weight at age 3 - 4 by feeding status at 6 months, and found only 23% overweight in the breastfeeding group in contrast to 64% in the formula fed group.<sup>10</sup>

## Subjects and Methods:

Subject characteristics are found in Table 1. We selected patients at the Warm Springs Health and Wellness Center who were 4 to 5 years of age as of June 1, 2003 (n=288) who had current BMI data (n=144) and infant feeding data (n=81). Overall average Indian quantum was 56%. About two-thirds of the subjects were members of the Warm Springs Confederated Tribes, which comprises the Piute, Wasco, and Warm Springs Tribes. Quantum and tribal membership were generated using Patient General Retrieval (PGEN) to look at overall numbers in all 4- to 5-year olds (n=288).

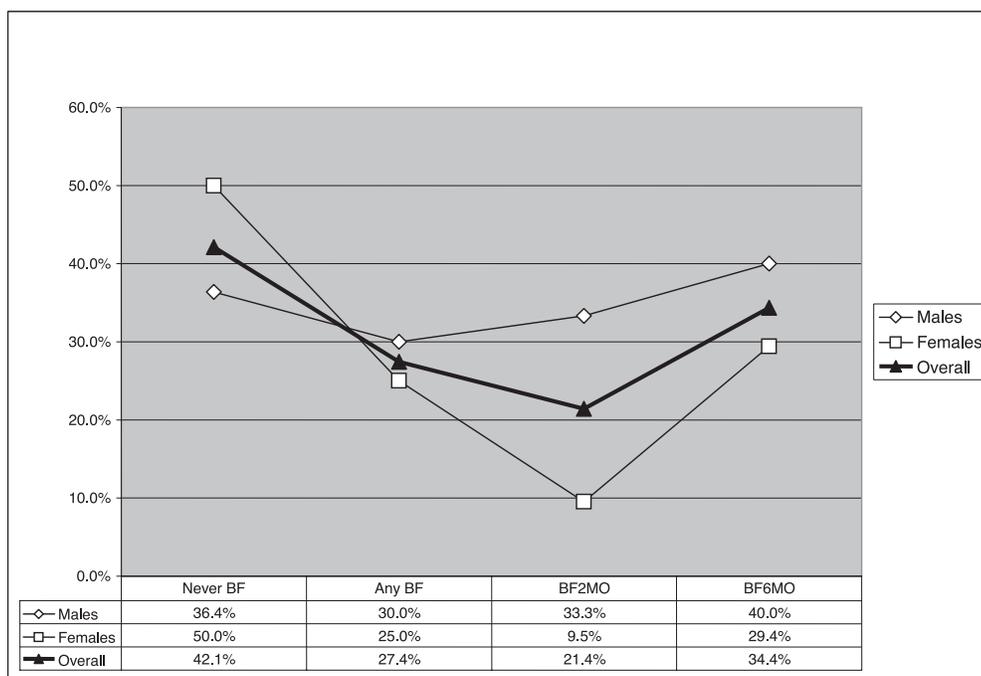
Table 1. Characteristics of subjects in the study

Number (%)	Male	Female	Overall
Subjects	41 (50.6%)	40 (49.4%)	81 (100%)
Never Breastfed	11 (26.8%)	8 (20.0%)	19 (23.5%)
Breastfed, any	30 (73.2%)	32 (80.0%)	62 (76.5%)
Breastfed >=2 months	21 (51.2%)	21 (52.5%)	42 (51.9%)
Breastfed >=6 months	15 (36.6%)	17 (42.5%)	32 (39.5%)
Overweight (BMI>=95 <sup>th</sup> tile)	13 (31.7%)	12 (30.0%)	25 (30.9%)

Obesity data were generated by running the Body Mass Index (BMI) Obesity Report in RPMS (Resource Patient Management System) PCC (Patient Care Component). The results were limited to 4- to 5-year old American Indian/Alaska Native (AI/AN) beneficiaries with height and weight measurements recorded on the same day within the past year. Overweight was defined as BMI  $\geq$ 95<sup>th</sup> percentile for age based on standards from the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics.

The report yielded 144 subjects with BMI data. Infant feeding data came from the local Quality Improvement Microsoft Excel spreadsheets kept on *Prenatal Patients and Births* that were recorded in 1998 and 1999. The combined data sets resulted in 81 subjects with both infant feeding and BMI data. The rate of overweight in the BMI data set (n=144) was 29%, which was comparable to the rate of overweight (31%) among the combined data group (n=81) and very similar to the rate of overweight found in Native American schoolchildren in the seven Indian communities that participated in the Pathways study on Native American schoolchildren (average age 7.6 years old), which found that 30.5% of girls and 26.8% of boys were overweight ( $\geq$ 95<sup>th</sup> percentile).<sup>11</sup>

**Figure 1. Percentage overweight at ages 4 – 5 compared to breastfeeding duration**



**Strengths of the Study**

Our infant feeding data were unbiased by outcome, being recorded in 1998 and 1999 rather than retrospectively. Warm Springs’ 76.5% rate of breastfeeding in 1998-9 was excellent, and not only exceeded the national rate of 64% in 1998 but also met the *Healthy People 2000* goal of 75% breastfeeding. It also exceeds the 44% rate reported for low-income Native Americans by the 1994 CDC Pediatric Nutrition Surveillance System.<sup>12</sup> The only downside of this for our review is that this high rate of breastfeeding meant that there were few formula only children (n=19) for comparison.

**Limitations**

Statistical analysis was very limited, as we did not have statistical software other than Microsoft Excel. Also, as mentioned, there were very small numbers in the never breastfed categories (11 males, 8 females). In addition the RPMS BMI report indicated overweight status only by a Y(es) or N(o), and did not report relative weights. Representing overweight as a binary variable (0, 1) failed to show any statistically significant difference between ever and never breastfed groups. We also did not adjust or control for important confounding variables such as socioeconomic status, birth weight, maternal diabetes, and parental obesity. However other studies have nevertheless found significant relationships even after adjusting for these factors.<sup>3,5,6</sup> Despite these limitations, we feel that this review is still a useful contribution, given the scarcity of studies on this subject in AI/AN populations.

**Results**

Our data showed 35% fewer overweight children in the group who were breastfed for any duration compared to the children who were never breastfed (27% vs. 42% overweight) (See Table 2). When broken down by sex, the girls seemed to benefit most from breastfeeding. Breastfeeding seems to have little impact on overweight status in 4- to 5-year old boys, whereas there were 81% fewer overweight girls among those breastfed 2 to 5 months compared to the group never breastfed (50.0% vs. 9.5% overweight). Girls breastfed ≥6 months still had a 41% relative decrease in overweight compared with the group never breastfed (29.4% vs. 50%). While there seem to be pronounced sex differences in our population, the overall decrease of 35% is consistent with other research that has found a benefit of breastfeeding on childhood obesity. These studies also compared ever vs. never breastfed children, and found about 30% less overweight children in Germany (n=9,206),<sup>13</sup> Scotland (n=32,200),<sup>14</sup> and in low-income white children in the U.S (total n=177,304).<sup>4</sup>

**Table 2. Percent overweight**

Overweight, BMI>=95 <sup>th</sup> tile	Never Breastfed	Breastfed, any	Breastfed >=2 months	Breastfed >=6 months
Males	4/11 (36.4%)	9/30 (30.0%)	7/21 (33.3%)	6/15 (40.0%)
Females	4/8 (50.0%)	8/32 (25.0%)	2/21 (9.5%)	5/17 (29.4%)
Overall	8/19 (42.1%)	17/62 (27.4%)	9/42 (21.4%)	11/32 (34.4%)

All of these studies showed a continuous, dose-related, inverse linear drop in obesity with increased breastfeeding duration. For instance, in the U.S. study, the children ever breastfed had 30% less overweight, but the group breastfed 6-12 months benefited even more with 51% fewer overweight children compared to the formula only group.<sup>4</sup> In contrast, our data shows a 'U' shaped pattern with percent overweight lowest with 2 to 5 months of breastfeeding (See Figure 1). Interestingly, this 'U' shaped relationship was also found in a recent study in Brazil in 18 year old males (n=2,155) that also found 3 - 5 months of breastfeeding to be optimal to reduce the risk of obesity, finding over 50% less obesity with 3 - 5 months breastfeeding than *either* shorter *or* longer breastfeeding durations.<sup>15</sup> This provides some additional support for the theory that a rapid rate of weight gain during the first four months of life, which is associated with formula use, increases the risk for becoming obese.<sup>2</sup> In contrast, the natural rate of early weight gain seen with breastfeeding may offer protection against obesity.

## Conclusion

Any amount of breastfeeding in infancy may help reduce the number of overweight Native American children. Breastfeeding 2 to 5 months may be the optimal duration for reducing childhood obesity in Native Americans, but longer durations appear to be better for diabetes prevention.<sup>8, 9</sup> Additional research is needed to see if these relationships hold true for all other Native American tribal groups.

While the relationship between breastfeeding and obesity remains open for debate, the other benefits of breastfeeding are well proven and include multiple health and cost advantages to the mother, child, and the healthcare system.<sup>16, 17</sup> Therefore, breastfeeding should be promoted regardless of how the breastfeeding-obesity question finally resolves itself.

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*Editor's Note: The following is a digest of the monthly Obstetrics and Gynecology Chief Clinical Consultant's Newsletter (Volume 3, No. 3, March 2005) available on the Internet at <http://www.ihs.gov/MedicalPrograms/MCH/M/OBGYN01.cfm>. We want 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](mailto:nmurphy@anmc.org).*

## OB/GYN Chief Clinical Consultant's Corner Digest

### Abstracts of the Month

Use of "opt out" HIV screening methods during pregnancy in Indian Country routine population-wide HIV screening may be cost-effective.

*Conclusions:* In all but the lowest-risk populations, routine, voluntary screening for HIV once every three to five years is justified on both clinical and cost-effectiveness grounds. One-time screening in the general population may also be cost-effective.

Paltiel AD et al. Expanded screening for HIV in the United States — an analysis of cost-effectiveness. *N Engl J Med.* 2005 Feb 10;352(6):586-95.

*Conclusions:* The cost-effectiveness of routine HIV screening in health care settings, even in relatively low-prevalence populations, is similar to that of commonly accepted interventions, and such programs should be expanded.

Sanders GD et al. Cost-effectiveness of screening for HIV in the era of highly active antiretroviral therapy. *N Engl J Med.* 2005 Feb 10;352(6):570-85.

*Editorial:* Bozzette SA. Routine screening for HIV infection — timely and cost-effective. *N Engl J Med.* 2005 Feb 10;352(6):620-1.

### OB/GYN CCC Editorial Comment:

While the articles above discuss the cost effectiveness of future population based HIV screening in the general population, the use of universal screening for HIV has already been a reality in pregnancy since 2001. Here are excerpts from the Frequently Asked Questions that are on the MCH website.

*Q. What is the Indian Health policy for HIV screening in pregnancy?*

A. Our goal is to maximize our care by using 'opt out' HIV screening. In Indian health we follow the PHS, CDC, ACOG, and Institute of Medicine (see Resources below) recommended "opt out" system that minimizes barriers to universal screening for HIV in pregnancy. "Opt out" screening includes elements of prenatal education for our patients, teaching that universal HIV screening significantly decreases perinatal HIV transmission. By screening, we may save her infant's life and improve her own maternal health status. We should further inform all pregnant patients that they will be screened for HIV unless the patient otherwise declines HIV screening.

Initial HIV screening should occur during the early prenatal education and intake process. Screening should be repeated in high risk groups and upon admission to labor and delivery, if screening has not occurred previously. Our goal is the highest attainable health status for our AI/AN patients. If an IHS facility is in a state that has additional screening requirements, then those requirements should be considered.

*Q. Does there have to be a separate, specific consent, in writing, during pregnancy?*

A. No, staff does not need a specific separate signed informed consent for HIV screening in pregnancy; that is, the written consent can be part of a "bundled consent." This written consent may be handled differently in pregnancy compared to the non-pregnant state in some facilities.

*From the 2001 Revised CDC guidelines, "... Information regarding consent may be presented separately from or combined with other consent procedures for health services (e.g., as part of a package of tests or care for certain conditions). However, if consent for HIV testing is combined with consent for other tests or procedures, the inclusion of HIV testing should be specifically discussed with the client. For a discussion of HIV testing in pregnant women, consult the guidelines for HIV screening of pregnant women.*

The IHS uses the IOM, ACOG and CDC as best practices benchmarks, and Chapter 13 of the IHS Manual does not require an additional, separate written consent for HIV screening in pregnancy. Those benchmarks call for "opt out testing." The idea with "opt out" testing is to remove barriers to what constitutes life saving therapy for fetuses. The specifics of "opt out" testing require that the patient be informed about HIV and its consequences, and that the patient will be screened unless she specifically declines screening. There is no longer a need to complete the two-sided IHS-509, 8/93, HIV Screening form for each patient. Most centers that have successfully implemented "opt out" have done so by informing the patient in her initial prenatal teaching session about HIV (and that she will be screened as a course of her routine care) along with the standard compliment of important prenatal teaching content.

The rest of the Frequently Asked Questions information is continued, with many other resources, on the MCH web page.

## Second Abstract

Early epidural provided shorter labor and did not increase cesarean delivery.

*Conclusions:* Neuraxial analgesia in early labor did not increase the rate of cesarean delivery, and it provided better analgesia and resulted in a shorter duration of labor than systemic analgesia.

Wong CA et al. The risk of cesarean delivery with neuraxial analgesia given early versus late in labor. *N Engl J Med.* 2005 Feb 17;352(7):655-65.

Camann W. Pain relief during labor. *N Engl J Med.* 2005 Feb 17;352(7):718-20.

## OB/GYN CCC Editorial Comment:

This was a randomized trial of 750 nulliparous women at term who were in spontaneous labor or had spontaneous rupture of the membranes and who had a cervical dilatation of less than 4.0 cm. Neuraxial analgesia in early labor did not increase the rate of cesarean delivery. As epidural analgesia is both safe and effective, it may deserve a larger role in the care of AI/AN women.

AI/AN birth rates have been steadily declining over the last decade. The reasons for the decreasing birth rate are myriad, but include demographic, educational, and socioeconomic factors, among others. One other factor is that some AI/AN patients choose to deliver outside the Indian health system because epidural or intrathecal analgesia is not available. In many cases there is a loss of patient continuity or a loss of the patient and her family to another health system for future care, as many times these patients function as the health care gatekeepers for the extended family. In that latter process, there is also a loss of alternate funding resources that could be helpful for the whole system. Please also review Dr. Diane Pond's comments below. Dr. Pond is the Anesthesia Chief Clinical Consultant for the IHS.

## Anesthesia CCC Editorial Comment (Diane Pond, MD, PIMC):

In the earlier days of epidural analgesia for labor and delivery, it was common practice to utilize more concentrated doses of local anesthetics. Infusions consisted of 1/8%, and 1/4% bupivacaine with or without narcotics. At this concentration it was common to see mild to moderate motor blockade in addition to sensory blockade. Excessive motor block has been related to difficulty with the pushing phase of labor. Lack of ability to effectively push can, intuitively, lead to an increase in cesarean rate. Since then, further studies with more dilute solutions have shown effective analgesia can be achieved with minimal motor blockade. Solutions as dilute as 1/16% with 1 - 2 mcg of fentanyl have been shown to be effective. The phrase "walking epidural" has been coined to describe the possibilities now available to patients with the dilute solutions, and intrathecal techniques.

There is also evidence that effective analgesia can actually result in a shorter duration of labor. The mechanism that has

been postulated to explain this is a reduction in maternal systemic catecholamines. By reducing the sympathetic system response to a pain challenge, delivery outcome can actually be improved.

Bottom line: the advantages far outweigh the risks and include the following:

- Safe method
- Effective pain relief
- Minimize depressive effects on infants
- Method provides a rapid means of inducing surgical anesthesia if needed in emergent situations.

It is my opinion that relief of pain during childbirth should be a medically indicated human right.

## From your Colleagues:

### Scott Sunde, Albuquerque

What is the significance of the latest *NEJM* article on trial of labor after cesarean (TOLAC)?

*Conclusions:* A trial of labor after prior cesarean delivery is associated with a greater perinatal risk than is elective repeated cesarean delivery without labor, although absolute risks are low. This information is relevant for counseling women about their choices after a cesarean section.

Landon MB et al. Maternal and perinatal outcomes associated with a trial of labor after prior cesarean delivery. *N Engl J Med.* 2004 Dec 16;351(25):2581-9.

*Editorial:* Greene MF. Vaginal birth after cesarean revisited. *N Engl J Med.* 2004 Dec 16;351(25):2647-9.

## OB/GYN CCC Editorial Comment:

"Risk, like beauty, is in the eye of the beholder."

This article is significant both for what it says, and what it doesn't say. This is a large observational 4-year prospective study at 19 academic institutions. It showed a small increased risk of hypoxic-ischemic encephalopathy, endometritis, and blood transfusion among the vaginal delivery group. As the editorial points out, it would take approximately 588 cesarean deliveries to prevent a single adverse perinatal outcome. Due to the timing of this study and its observational nature, approximately half of the symptomatic uterine ruptures were involved with prostaglandin administration, so even the 1/588 risk number may be overstated by a large factor.

As this is not a RCT, we can't know with certainty the exact risk, but this study confirms previous studies that the risk of adverse outcome is very small. It is reasonable to follow the tenets described at the August 2004 Indian Women's Health Conference (see the lecture notes from Michelle Lauria):

- minimize risk by assuring the entire L/D unit functions as a cohesive team
- perform periodic emergency delivery drills on L/D as a team
- carefully triage TOLAC patients: low, medium, and high risk
- be especially mindful of a lack of timely intrapartum labor progress

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## Obstetrics

A single dose of intravaginal misoprostol decreases oxytocin use compared with intracervical dinoprostone, largely due to labor within the ripening period. Level Of Evidence: II-1.

Meyer M, Pflum J, Howard D. Outpatient misoprostol compared with dinoprostone gel for preinduction cervical ripening: a randomized controlled trial. *Obstet Gynecol.* 2005 Mar;105(3):466-72.

## Gynecology

Vaginal pH for diagnosing status of menopause. A vaginal pH greater than 4.5 indicates menopause in women who are without vaginitis and are not receiving estrogen therapy. They add that vaginal pH is similar to FSH levels in establishing the diagnosis of low estrogen levels or menopause, and that a vaginal pH of 4.5 or less can be used to monitor adequate response to estrogen replacement therapy.

Roy S, et al. Vaginal pH is similar to follicle-stimulating hormone for menopause diagnosis. *Am J Obstet Gynecol.* May 2004;190:1272-7.

## Child Health

Pregnancy and birth rates decline for teenagers aged 15 - 17 years, 1976-2003. Since 1990, pregnancy rates have declined substantially for teenagers aged 15 - 17 years. From 1990 to 2000, the pregnancy rate decreased 33%, from 80.3 per 1,000 females to 53.5, a record low. The birth rate declined 42%, from its peak of 38.6 in 1991 to 22.4 in 2003. The induced abortion rate peaked in 1983 at 30.7 and decreased by more than half to 14.5 by 2000.

## Chronic Disease and Illness

Low-dose aspirin can prevent cardiovascular disease in older women.

Conclusions: In this large, primary prevention trial among women, aspirin lowered the risk of stroke without affecting the risk of myocardial infarction or death from cardiovascular causes, leading to a non-significant finding with respect to the primary end point.

Ridker PM et al. A randomized trial of low-dose aspirin in the primary prevention of cardiovascular disease in women. *N Engl J Med.* 2005 Mar 31.

## Ask a Librarian: Diane Cooper, MSLS/NIH

Salmonella from pet turtles – again. Although banned by the FDA, pet turtles have emerged as a source of salmonella disease in children in Wisconsin and Wyoming recently. In some cases, the turtles were given away with purchases in a souvenir shop. Apparently the shop owner thought the FDA ban applied only to selling, but that's not a loophole. In another case, the turtle was sold "for educational purposes," again, not a loophole. Health departments can issue orders to stop distribution in both cases. "Salmonella infections usually (are)

mild but can lead to . . . septicemia or meningitis (especially in infants and immunocompromised persons)" the CDC warns.

*MMWR* March 11, 2005;54:9.

## Midwives Corner: Marsha Tahquechi, CNM, GMC

Emergency OB drills: The Phoenix Indian Medical Center experience. After attending the American Native Women's Health and Maternity Care Conference in Albuquerque last August, the Phoenix Indian Medical Center Midwifery Services created an Emergency OB Drill team, which includes CNMs and RNs from the obstetrical services. The team has been holding emergency OB drills focusing on emergency cesarean section and post-partum hemorrhage, with future plans to add eclamptic events and shoulder dystocia. The drills have been quite successful with participation from the OB/GYN providers, CNMs, RNs, and most ancillary services, such as, anesthesia, laboratory, radiology, and respiratory therapy. They have been instrumental in discovering areas to improve and are well received by staff.

## OB/GYN CCC Editorial Comment:

Thanks very much to Tami McBride, RNC, and Karen Carey, CNM, of PIMC for that posting. This is exactly what we all need to continue to do to keep up our skills as a team.

## Other Midwives Corner Items:

Concern over rising cesarean delivery rate: ACNM approaches Congress. The American College of Nurse Midwives in February sent a letter to Congress expressing concern over the rising cesarean delivery rate (27% in 2003) and the declining VBAC rate (10.6% in 2003) in this country. They have asked Congress to explore these issues from a public health perspective.

## Ice Massage for the Reduction of Labor Pain

Two recent studies have explored the use of ice massage for the reduction of pain in early labor. This technique may be added to the armamentarium of providers for some patients seeking pain relief in early labor.

## Alternative Medicines' Popularity Prompts Concern

Use of alternative and complementary remedies on the rise. Midwives and Ob-Gyn providers are not strangers to the use of traditional and alternative medicine in native populations. The Center for Complementary and Alternative Medicine at NIH released a survey in May 2004 demonstrating the widespread use of CAM across the nation. The need for careful screening of ob-gyn patients in the use of CAM at entry into care is essential for safely and effectively treating patients. The "WHO Guidelines: Developing Information on Proper Use of Traditional, Complementary and Alternative Medicine" can be found online.

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# Emergency Department Internship Program

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*Mark L. Wilson, RN, BSN, CEN, Nurse Educator, Emergency Department, Gallup Indian Medical Center, Gallup, New Mexico, and David J. Hodgins, RN, MSN, CEN, Supervisory Clinical Nurse, Emergency Department, Northern Navajo Medical Center, Shiprock, New Mexico*

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## Introduction

In its 2002 Emergency Department Survey, the Centers for Disease Control and Prevention (CDC) reported that during that year an estimated 110.2 million visits were made to hospital emergency departments. This equates to approximately, 38.9 visits per one hundred persons, an increase of 9 percent from the 1992 data. Combine this information with the Joint Commission report of an overall nurse vacancy rate of 13% and it is easy to predict gloom for those patients seeking emergency health care. It is estimated that by the year 2020, there will be at least 400,000 fewer nurses available to provide care than are needed. The demand is expected to continue to rise as the first of the baby boomer generation reach retirement age.

## IHS Vacancy Rate

Recent statistics from the office of the Indian Health Service (IHS) principal nurse consultant report an overall nurse vacancy rate of 16 percent (IHS only) with a 24 percent vacancy rate for emergency nurses. This shortfall is being felt daily by IHS hospitals in the Navajo Area. The emergency departments of Northern Navajo Medical Center (NNMC) and Gallup Indian Medical Center (GIMC) presently report vacancy rates of 40% and 15% respectively. At present, NNMC has six vacant positions filled by contract nursing. While contract nurses temporarily alleviated the shortage, their salaries tend to be higher than permanent employees, and the mobile nature of their employment increases the amount of time spent in orientation.

## Retention Strategies

During a major nursing shortage in the early 1980s, the American Academy of Nursing (AAN) conducted extensive research to identify hospitals that were successful in recruiting and retaining nurses. An aggregated ranking and scoring process yielded a total of 41 hospitals across the country that exhibited exceptional organizational characteristics supporting professional nursing. The selection method predicted that these 41 hospitals shared general organizational characteristics. The key characteristics of magnet status hospitals identified by the AAN task force were grouped under

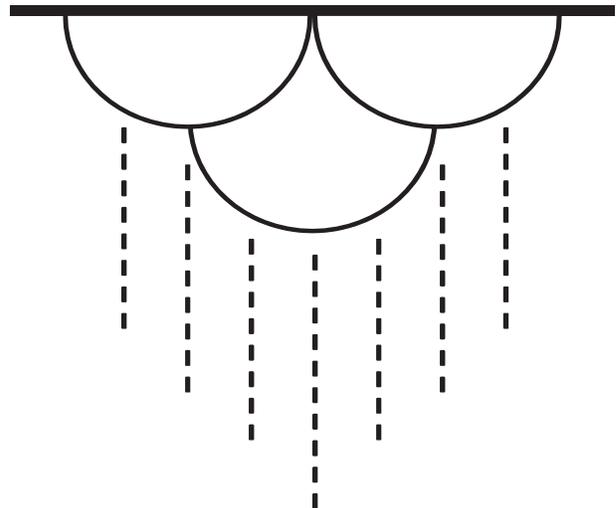
three heading: administration, professional practice, and professional development.

## GIMC Internship Program

In an effort to combat the shortage of emergency nurses across the Navajo Area, the supervisory clinical nurse from GIMC, in conjunction with the Dine Nursing Partnership Council, proposed initiating an emergency nurse internship program. Following the guidelines of professional development identified in magnet status research, the program was designed to take registered nurses with little critical care experience and support their transition into the role of emergency department nurse. Based on the premise that learning takes place as individuals interact with their environment and incorporate new information or experiences with what they already know or have learned, the course was designed to allow immediate clinical application of lecture content in a relatively safe environment. Course content included a brief review of physiology, an extensive review of emergency pathologies, and critical thinking processes required when dealing with patients whose conditions change rapidly.

The program consisted of the following:

- An average of 96 hours of guided clinical experience with a three to one preceptor ratio.
- Fifteen lecture sessions that followed the outline contained in the text on Emergency Nursing published by the Emergency Nurses Association.
- A self-study program consisting of 31 modules published by the ENA.



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The curriculum, previously developed in 2000 by the nursing education staff of NNMC as part of a course presented at San Juan College, was updated using the text, *Sheehy's Emergency Nursing, Principles and Practices*, 5<sup>th</sup> edition. The self-study modules provided a comprehensive curriculum that included further readings and the completion of a question/answer booklet on each subject. Lecture sessions were held each Monday and Tuesday morning with six hours of clinical time each afternoon. The class consisted of five registered nurses, one from each of the following hospitals: GIMC; NNMC, Winslow Health Center; Crownpoint Indian Hospital, and Acoma-Cannoncito-Laguna Hospital (Albuquerque Area).

### Results

All of the participants successfully complete the program. Evaluation noted the need for additional administrative support with travel and per diem. In addition, the need for more visual aides and the use of more case presentations was identified.

A major goal for the instructors was to assist the students with the development of critical thinking. Providing lecture content, which was then applied in the clinical setting as soon as possible, approached this. It was hoped that the immediate application of knowledge, including discussion regarding pathology, medicines, and expected clinical outcomes, would assist the student in the development of this necessary skill.

Future courses will include patient care simulations that will require students to review assessment parameters related to various emergency situations and to make clinical decisions regarding nursing care. Immediate feedback will allow students to relate signs and symptoms to pathology and to discuss the impact of care.

### Summary

The need for professional nursing to move forward in support of residency programs has arrived. New graduates and experienced nurses seeking to practice in different areas are faced with higher acuity patients with increasingly complex needs. The detailed knowledge required in nursing practice in today's acute care settings has increased the need for residency programs. We can no longer afford to allow the risk of new graduates or inexperienced nurses learning as care is provided. Residency programs provide a unique opportunities for nurses to acquire new skills and a new knowledge base and apply them in settings supervised by experience nurses. In addition, discussion and review of cases allow the development of the critical thinking skills vital to providing care to patients whose physical condition changes at a rapid pace.

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## Guidelines for STD Screening in Tribal Jails Available

Developed by the IHS National STD Program in conjunction with the CDC Division of STD Prevention, the guidelines describe action steps and special considerations for IHS/tribal health providers and detention facility staff to collaboratively implement STD screening in tribal jails. The STD Program can provide technical assistance to implement the guidelines in your community. For additional information, or for a copy of the guidelines (available in PDF or a limited number of hard copies), please contact Lori de Ravello, telephone (505) 248-4202; e-mail [lori.deravello@ihs.gov](mailto:lori.deravello@ihs.gov).



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