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Management of Dyslipidemias Establishing a Clinic Run by Clinical Pharmacy Specialists

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Introduction

This article will describe how one facility, the Santa Fe Indian Hospital, examined its patients' risk for coronary artery disease (CAD) and its usual practices with regard to management of dyslipidemias. It will then discuss how a lipid clinic managed by clinical pharmacy specialists was designed and established to address their findings.

Background

Heart disease is the leading cause of death in American Indians over age 45 (see *The IHS Provider*, January and September 1997 issues). However, information about the incidence and prevalence of coronary heart disease in this population is limited. A number of recently published studies have shown that elevated cholesterol is directly related to the development of CAD.^{1,2,3,4} Lowering cholesterol is fundamental in reducing the morbidity and mortality from CAD in patients with documented atherosclerotic disease (secondary prevention), as well as in those without documented disease who are at high risk (primary prevention).^{1,2,3,4}

In the past, the incidence of cardiac deaths in American Indians was lower, but recently it has been showing an upward trend. A total of 65 cardiac-related deaths were reported in the Santa Fe Service Unit from 1989-95. We suspect that

the numbers of cardiac-related deaths in the Santa Fe Service Unit are underreported.

Of the approximately 7378 patients over 19 years old who have visited the Santa Fe Indian Hospital (SFIH) one or more times between October 1995 and October 1996, 249 have been diagnosed as having CAD. Data on expenditures for cardiology services during this time period could only be obtained for the 72 patients (29% of the total number of this secondary prevention cohort) who were Contract Health Care eligible. Approximately \$450,000 has been spent on this group. Obviously the total dollar figure for all 249 patients is much higher. Among the potential primary prevention patients at SFIH, hundreds are at high risk (having two or more risk factors) for the development of CAD.

In This Issue...

- 17 Management of Dyslipidemias – Establishing a Clinic Run by Clinical Pharmacy Specialists
- 20 New National Women's Health Information Center Now Open for Testing
- 21 Gestational Diabetes is a Herald of NIDDM (Type 2 Diabetes) in Navajo Women
- 21 The Annual Elders Issue
- 22 CSC Receives Four-Year Accreditation from ACCME
- 23 National Standards for Transmission of Health Care Transactions
- 24 Meetings of Interest
- 26 Position Vacancies
- 27 NCME Videotapes Available
- 27 Erratum

As of October 1996, 27 SFIH primary and secondary prevention patients were being treated to lower their cholesterol. In a drug utilization review of these patients, we concluded that dietary and pharmacotherapeutic goals could not be determined due to the absence of low density lipoprotein (LDL) cholesterol assays or documentation of dietary intervention. All 27 patients were receiving the HMG-CoA reductase inhibitor lovastatin during at the time of the review, but were not being managed according to the National Cholesterol Education Program (NCEP II)⁵ guidelines. Appropriate laboratory monitoring for lovastatin use, such as periodic liver function testing, was not being performed in the majority of patients. Other than these 27 patients, the majority of the potentially treatable SFIH primary and secondary prevention patients were not being managed with diet or pharmacotherapy for hypercholesterolemia. Of the 249 potential secondary prevention patients, only 21 (8.5%) were on lipid lowering medication. Given what we know, it is possible that some heart attacks, coronary artery bypass grafts (CABGs), and angioplasties could have been delayed or prevented by aggressively treating all secondary and high risk primary prevention patients with dietary/pharmacotherapeutic regimens and working with the patients to modify/control other CAD risk factors (smoking, diabetes, and hypertension).

The Lipid Clinic

The findings above reflect the unmet needs of our patients and correlate well with the concerns of the Strong Heart Study authors expressed when they stated "Prevention programs tailored toward decreasing the prevalence of risk factors are recommended for long-term reduction of cardiovascular disease rates in American Indian communities."⁶

Prompted by the realization that our high risk patients were being undermanaged, we developed and implemented the first Indian Health Service pharmacist-managed lipid clinic. The SFIH Lipid Clinic was established with the following purposes: decrease CAD mortality, delay/prevent cardiac occurrences, and optimize drug therapy in Native American primary and secondary CAD prevention patients. It was designed to augment physician efforts to diminish/delay complications of CAD.

The clinic is set up as follows. The clinical pharmacy specialist screens for secondary causes of hyperlipidemia, evaluates patients' cardiovascular risk factors, works with the patients to modify risks, enhances patient compliance through education, orders the appropriate drug(s) and laboratory tests, and, through careful dose titration, monitors and reduces adverse drug effects, all while achieving lipid lowering treatment goals in a timely manner.

After completing specialized training in lipid management at Veterans Affairs Medical Centers, three pharmacists were credentialed by the SFIH Medical Staff as clinical pharmacy specialist primary care providers. Two of the pharma-

cists hold post-BS PharmD degrees; the third is completing a post-BS non-traditional PharmD degree.

Prescribing guidelines concordant with the NCEP II guidelines⁵ for dietary and therapeutic interventions were developed. The Pharmacy and Therapeutics Committee added additional lipid lowering medications to the formulary and incorporated their use into prescribing guidelines for practitioners. These guidelines also included laboratory monitoring recommendations for lipid and medication monitoring. The guidelines were derived primarily from the 1993 Adult Treatment Panel II guidelines of the National Education Program Expert Panel,⁵ the Management of Hyperlipidemia PEC UPDATE,⁷ and the Department of Veterans Affairs Management of Hyperlipidemia.⁸ The protocol also utilized the Long Beach and Oklahoma City VAMCs' Lipid Clinic Protocols.

Patients are enrolled in the Lipid Clinic by pharmacists or are referred by IHS physicians and/or the New Mexico Heart Institute Cardiology group, whose physicians provide cardiology consultation for the SFIH. All patients must be seen by the Lipid Clinic dietitian at least twice, once for initiation, and once for follow-up on an American Heart Association (AHA) Step I diet.

Scope of Practice and Review

All clinical pharmacy specialists must request a Lipid Clinic scope of practice and are credentialed by the medical staff as providers of care. These pharmacist clinicians fall under the supervision of the Outpatient Medical Director when practicing in the Lipid Clinic.

The scope of practice includes the following:

1. Order indicated laboratory tests required for screening and monitoring of antilipidemic drug therapy
2. Request appropriate return appointments to clinics as necessary
3. Document clinic visits in the medical records
4. Prescribe medication
5. Evaluate the patient on a regular basis for diet, exercise, and medication compliance, as well as medication side effects

Prescriptive authority is based on a directive from Michael H. Trujillo, MD, MPH, Director, IHS, dated October 18, 1996. This memo refers to Sections 401 and 402 (25 USC 1641 and 1642) of Title IV, Public Law 94-427. It designates specially trained pharmacists as clinical pharmacy specialists, or primary care providers with prescriptive authority.

Clinical pharmacy specialists follow prescribing and management guidelines for initiation and titration of diet and

drug therapy for the patients seen in the Lipid Clinic. Prescriptions may be written and signed by the clinical pharmacy specialist for drugs needed in the management of hyperlipidemic patients. All medications prescribed by a clinical pharmacy specialist that are not covered in the scope of practice require a physician countersignature.

Expansion of the Lipid Clinic

In October 1997, the SFIH Lipid Clinic received a \$25,000 grant from the McCune Charitable Foundation to fully establish and expand the clinic. The money is being used to build two clinic rooms in the pharmacy department, purchase computers for data collection and tracking, purchase office equipment, and support additional staff training in lipid management.

Evaluation Project

In October 1997, a proposal by the SFIH was selected as a FY 1998 IHS Research and Evaluation Project, which provided funding in the amount of \$111,000. The project was entitled *Hyperlipidemia and Coronary Heart Disease in Native Americans: Evaluation of lipid control through a pharmacy practitioner managed lipid clinic*. The project will evaluate the results of lipid clinic CAD risk management, counseling, aggressive medical nutrition therapy, and pharmacotherapeutic treatment of hypercholesterolemia in high risk primary and secondary SFIH patients. We hope to demonstrate a favorable impact on morbidity and mortality within 3 to 4 years in secondary prevention patients. Primary prevention patients will probably need to be evaluated for at least 5 to 6 years to demonstrate favorable outcomes. If the findings of this evaluation show that the lipid clinic is successful in decreasing morbidity and mortality in our population, this clinic could serve as a prototype for other IHS facilities. We will depend on annual IHS funding to continue this evaluation project, although other sources of income such as local grants or billing for the cognitive services provided by the pharmacists could support day-to-day clinic staffing in the future.

We will evaluate:

1. **Reduction in risk factors reported** The following risk factors will be assessed: decrease in smoking behavior, change in diet, and compliance with medications as reported by the patients. For each patient, we will follow blood pressure, weight, glycemic control, total cholesterol, LDL cholesterol, and triglycerides. These items are monitored regularly in patients attending the Lipid Clinic. For the “usual treatment” patients (that is, patients followed in general clinics other than the Lipid Clinic), nurses routinely ask about smoking at each patient visit, as well as check blood pressure. If indicated, the physician

will order a blood test to follow the lipid parameters. We will compare the changes in lipid levels over time for Lipid Clinic patients and “usual care” patients.

2. **Reduction in morbidity from CAD** We will track all hospitalizations for CAD related diagnoses (angina, myocardial infarction, hypertension, stroke, etc.). We will compare the rate of hospitalizations for these conditions between Lipid Clinic patients and usual care.
3. **Reduction in mortality from CAD** We will track all deaths due to CAD for both clinic patients and usual care. It may take several years to obtain enough mortality data among primary prevention patients to achieve meaningful comparisons.
4. **Costs incurred by patients** The cost of medications for patients enrolled in the Lipid Clinic will be compared to costs of medications for those not in the clinic. In addition, and even more importantly, we will examine the cost of cardiology referrals for patients enrolled in the clinic and compare those to the costs for patients not enrolled.

We hope to answer the following questions by conducting this evaluation:

1. Can we enhance the impact we have in CAD risk reduction by means of an intensive lipid clinic managed by clinical pharmacy specialists supported by a dietitian?
2. Can we increase adherence to lipid lowering medications through this clinic?
3. Is such a clinic cost-effective?
4. Can the Lipid Clinic contribute to a reduction in morbidity and mortality from CAD for the population of the SFIH?

Healthy People 2010

This approach to management of dyslipidemias fits in well with the proposed Objectives for Healthy People 2010. These goals include “reducing the mean serum cholesterol level among adults to no more than 200 mg/dL, reducing the prevalence of blood cholesterol levels of 240 mg/dL or greater to no more than 20% among adults, and increasing to at least 60% the proportion of adults with high blood cholesterol who are aware of their condition and taking action to reduce their blood cholesterol to recommended levels” (sections 15.6-15.8).

The 1997 summary list of objectives also includes “increasing to at least 75% the proportion of primary care providers who initiate diet, and if necessary, drug therapy at levels of blood cholesterol consistent with current management guidelines for patients with high blood cholesterol” (section 15.15, referring to NCEP guidelines). Reduction of coronary heart disease deaths is one of the main objectives of the SFIH Lipid Clinic, which corresponds well to the Healthy People 2010 objective of “reducing CAD deaths to no more than 100 per 100,000 people” (section 15.1).

Summary

In the IHS and VA health care systems, pharmacists have a long history of providing primary care services. There are a number of well-run pharmacist-managed specialty clinics (e.g. warfarin) within the IHS. As pharmacists become credentialed as clinical pharmacy specialists, management of chronically ill patients will certainly fall into their scope of practice. The lipid clinic described is one example of this. It is our hypothesis that aggressive dietary, pharmacologic, and risk reduction practices through such a clinic will result in diminished cardiovascular complications. This will not only improve the outcomes in terms of morbidity and mortality, but will have certain pharmacoeconomic advantages as well. □

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New National Women's Health Information Center Now Open for Testing

The U.S. Public Health Service's Office on Women's Health (PHS OWH) invites you to test its new National Women's Health Information Center (NWHIC) during the month of February. Through a toll-free phone number and the Internet, the NWHIC acts as a federal “Woman's Health Central” for the public, health care professionals, educators, researchers, and women in the military. By organizing the vast array of health information for women to a single point of entry, the PHS OWH hopes that women will have easier access to information from Federal Health Clearinghouses within the DHHS, and hundreds of private sector organizations.

If you have a question about women's health in general or about a specific program, concern, or disease, you can call 1-800-994-WOMAN. Specially trained health information specialists will be happy to provide the information to you. You can also access the website at <http://www.4woman.org>.

Once you have made the connection with the new service, your feedback would be appreciated. Were the specialists

helpful? Were you able to get your questions answered? Is the website user friendly? Do you have any suggestions on how the service can be improved? You can give feedback by e-mailing via the FEEDBACK option on the website, or by calling the PHS OWH office at 202-260-9275. This pretest period is intended to give the PHS OWH the information it needs to make this a truly useful service for women, as well as help assess the impact of the service on other federal health agencies.

The OWH would like to officially launch this new service in March/April. Please help them reach that goal by testing it and letting them know how it works.

The National Women's Health Information Center (NWHIC) is a joint project of the U.S. Public Health Service's Office on Women's Health, within the Department of Health and Human Services, and the Department of Defense Women's Health Research Program. Please give it a try and let them hear from you. □

Gestational Diabetes is a Herald of NIDDM (Type 2 Diabetes) in Navajo Women

The following abstract (and the associated article) appeared in the June issue of Diabetes Care (June, 1997, Volume 20, Number 6, pages 943-947). The editors believe that this information is important enough that we should reproduce the abstract here in The Provider. The italicized text in the abstract reflects either changes that are warranted by the new ADA classification (see "New Recommendations for the Classification of Diabetes Mellitus," The Provider, Volume 22, Number 8, pages 121-122 and page 124), or clarification of the original text.

Jonathan R. Steinhart, MD, Northern Navajo Medical Center, Shiprock, New Mexico; and Jonathan R. Sugarman, MD and Fred A. Connell, MD, both of the University of Washington School of Public Health and Community Medicine, Seattle Washington.

Objective: To estimate the rate of deterioration of glucose tolerance and evaluate risk factors for development of type 2 diabetes in Navajo women with a history of gestational diabetes mellitus (GDM).

Research Design and Methods: A retrospective analysis of 111 GDM deliveries over a 4-year period, 1983-1987, was conducted in 1994 to determine glucose tolerance status. Patients who had not developed type 2 diabetes were recalled for a 2-hour glucose tolerance test (GTT). Tested and non-tested patients were compared, an esti-

mate of conversion to type 2 diabetes was calculated, and risk factors for type 2 diabetes were evaluated. A life-table analysis was developed to estimate the probability of type 2 diabetes after GDM.

Results: At the time of the chart review, 32 patients (29%) had already been diagnosed with type 2 diabetes. Of the remaining patients, all 79 were offered GTT testing, and 56 (71%) returned for follow-up. Of the 56 patients tested, 15 were diagnosed with type 2 diabetes, 17 with impaired glucose tolerance (IGT), and 4 with impaired fasting glucose (IFG). At the conclusion of the study, 47 (42%) of the original 111 GDM patients had developed type 2 diabetes; 64 (58%) had developed either type 2 diabetes or IGT; and 68 (61%) had developed type 2 diabetes or IGT or IFG. Patients who developed type 2 diabetes had greater body mass indexes (BMIs), parity, and infant weights. Fasting blood glucose more than 5.83 mmol/L (105 mg/dl), GTT (total of all values) more than 41.63 mmol/L (750mg/dl), and recurrence of GDM were associated with later type 2 diabetes. A life-table analysis estimated a 53% likelihood of having type 2 diabetes at an 11-year follow-up; a second model, based only on patients with known type 2 diabetes status, predicted a 70% rate of type 2 diabetes at an 11-year follow-up.

Conclusions: A high proportion of Navajo women with GDM progressed to type 2 diabetes. Postpartum counseling and periodic GTTs are recommended. □

The Annual Elders Issue

May is National Elders Month. In recognition of this, for the past two years, *The Provider* has dedicated its May issue to articles related to the health and health care of Indian elders. We would like to invite our readers to submit articles for this issue as soon as possible. In addition to clinical or descriptive articles, we would welcome submissions from elders themselves who are willing to share their viewpoints

about the status of health care for Indian elders and their perceptions of future needs. If you would like to submit an article, please send it to:

Editor
The Provider
1616 East Indian School Road, Suite 375
Phoenix, AZ 85016

CSC Receives Four-Year Accreditation from ACCME

One New Change Instituted

The IHS Clinical Support Center is pleased to report that, following a site survey this past summer by the Accreditation Council for Continuing Medical Education (the ACCME), we have received a full four-year accreditation by that organization. The ACCME seeks to assure both physicians and the patients they care for that continuing medical education activities sponsored by the CSC meet the high standards of the Essentials and Standards for Accreditation as specified by the ACCME. The ACCME rigorously evaluates the overall continuing medical education programs of institutions according to standards adopted by all seven sponsoring organizations of the ACCME. These are the American Board of Medical Specialties, the American Hospital Association, the American Medical Association, the Association for Hospital Medical Education, the Association of American Medical Colleges, the Council of Medical Specialty Societies, and the Federation of State Medical Boards.

One concern raised by the survey was that we need to do a better job with regard to one facet of our activities. All accredited sponsors are obligated to have all speakers or faculty members complete and sign a "Disclosure of Commercial Support." The purpose of this is to find out if there are any relationships between that presenter and any commercial entity. It is not that such relationships are wrong, but simply that they must be made known to the audience. Sometimes these relationships would not surface unless the question is asked; that's why we complete the form.

The second step in the process is to communicate to the

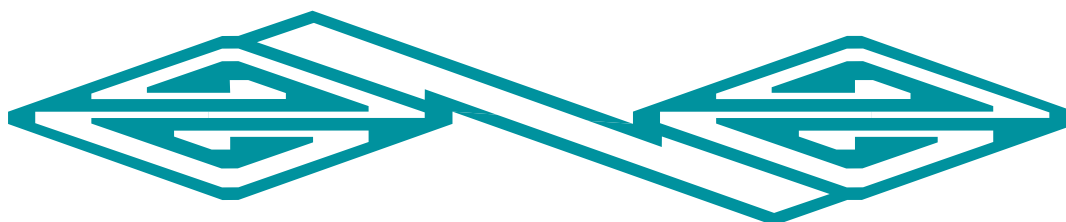
participants whether or not such relationships exist. When there is advanced, written publicity, such disclosure should be included in the brochure in the information about the speaker and topic. At the time when a speaker is introduced to the audience, again it is proper, and required, to make a verbal announcement if there is a relationship.

Simple enough so far, you say. As always, however, if we can't show some documentation, there is no proof that this is being done. Therefore, we propose that we will add a box on the Disclosure Form that you can mark to show that disclosure was made at the time of the introduction. It will look something like this:

- Any possible conflict of interest listed above was included in the preconference publicity and/or was disclosed at the time the speaker was introduced.

As well, we will look to make sure that any information discovered in the routine completion of the Disclosure Forms is included in the written brochures. One clear implication of this is that the Disclosure forms must be completed and returned before the brochure is written.

As always, we are interested in hearing your suggestions about how to accomplish this or any other step in the sponsorship process in an easier fashion; if you have a better way, let us hear it. In the meantime, look for a new Disclosure Form to arrive soon, and be sure to complete the new box as described above. □



National Standards for Transmission of Health Care Transactions

What impact does the Health Insurance Portability and Accountability Act of 1996 have on you? More than you may have realized.

The Administrative Simplification provisions of the Act mandate that the Secretary of Health and Human Services adopts national standards for the electronic transmission of health care transactions. **All** health plans and clearinghouses and those providers who use electronic data interchange must meet these standards. That's right – not just the Medicare and Medicaid programs but **all** health plans. The provisions also require national standards for medical code sets; standard identifiers for providers, health plans, employers, and individuals; and security and privacy standards.

A wide range of organizations and individuals will be affected, including those that:

- Pay health care claims or coordinate benefits across payers
- Submit claims to health plans
- Submit medical encounter data to managed care plans
- Enroll employees in health plans
- Pay premiums to health plans
- Conduct authorized referrals
- Provide prior authorization for services
- File first reports of injury for worker's compensation
- Query insurance eligibility or claim status

The standards for these health care transactions, code sets, identifiers, and security are scheduled to go into effect two years after they are adopted by the Secretary. At that time, organizations will need to be able to accept standard electronic transactions from their customers. In addition, the Secretary has made recommendations to Congress for privacy legislation to protect individually identifiable health information. Standards for claims attachments will also be adopted. These will be proposed in the next year.

There will be clear benefits to those who use electronic transactions. With a national standard, the same claim can be sent to any insurance company for payment, greatly simplifying claims submission for providers. And payers will know exactly what a claim from any provider will look like – it will be the same as claims from other providers.

The Department of Health and Human Services (DHHS) and other Federal and state agencies have been hard at work since the passage of the Act in August 1996. After extensive consultation with technical and professional organizations, a series of standards is ready to be proposed. The standards to

be adopted will build on the voluntary consensus standards already developed by the private sector.

We have received extensive industry input to date but are continuing to look for important comments on these standards. The official Notices of Proposed Rule Making (NPRMs), the first official publications of the proposed standards, are expected to be published in the *Federal Register* shortly. In addition, the NPRMs will be available from the Department's Administrative Simplification World Wide Web site at:

<http://aspe.os.dhhs.gov/admsimp/>

Because you will be directly affected by these standards, we urge you to carefully read the proposed rules and give us your comments. These comments will be critical in determining the final set of standards to be adopted. We ask that associations work with their members to provide input to us.

DHHS has arranged for the implementation guides for proposed standards to be available on the World Wide Web. The guides can be downloaded free of charge from the Washington Publishing Company Web site at:

<http://www.wpc-edi.com/hipaa>

Additionally, now is the time for you to begin planning for implementation of these new standards. This is an opportunity to move from paper transactions to electronic transactions, to move from proprietary systems to open systems – to move to national standards.

We urge you and your members to begin the process of implementation by discussing these transactions with your business partners and with the vendors that provide these services.

So watch the *Federal Register*, watch the Web site, and start the implementation process. Now is the time.

For more information, contact either of the co-chairs of the HHS Data Council, Committee on Health Data Standards:

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Health care professionals employed by Indian health programs may borrow videotapes produced by the Network for Continuing Medical Education (NCME) by contacting the IHS Clinical Support Center, 1616 East Indian School Road, Suite 375, Phoenix, Arizona 85016.

These tapes offer Category 1 or Category 2 credit towards the AMA Physician's Recognition Award. These CME credits can be earned by viewing the tape(s) and submitting the appropriate documentation directly to the NCME.

To increase awareness of this service, new tapes are listed in *The Provider* on a regular basis.

NCME #725

Domestic Violence: Recognizing and Treating Abused Patients (60 minutes) Practitioners nationwide are increasingly faced with the need to identify, manage, and/or refer victims of domestic violence. Within the context of selected case histories, this program addresses the prevalence and forms of domestic abuse in the United States, and discusses how best to assess and manage patients. Emphasis is given to prompt and

accurate diagnosis and treatment based on the latest assessment and management tools. Cases include standard presentations of domestic violence in the emergency room, as well as outpatient or in-hospital presentations that may at **first** appear to have a primarily organic or psychiatric basis, but in fact may indicate unreported domestic abuse.

NCME #726

Managing Diabetes in the Primary Care Setting: A Team Approach (60 minutes) Approximately 16 million Americans have diabetes. Of these, 90% to 95% have type II, or noninsulin dependent diabetes (NIDDM). In this video, Dr. Ellsweig explores current issues in diagnosis, tight glucose control, lifestyle modification and pharmacologic therapy to illustrate the primary care physician's role in the team approach to managing diabetes. "The primary care physician must be able to take the information provided to us by patients, by consultants, by the tests we have done and by whatever therapeutic intervention we have initiated, and coordinate it, collate it, and give the patient back the information so that he or she can manage his or her own care."

Erratum

The listing of authors was inadvertently omitted from the articles published in the January issue of *The Provider*. We apologize to the authors and our readers. The authors are as follows:

Controlling Sexually Transmitted Diseases: An IHS Perspective

Darcy K. Hunt, MPH, Staff Epidemiologist; James Cheek, MD, MPH, Principal Consultant; and Laura K. Shelby, BA, STD Program Coordinator, all from the Epidemiology Branch, IHS Headquarters West, Albuquerque, New Mexico

Taking a Sexual History: Communicating Prevention

Laura K. Shelby, BA, STD, Program Coordinator; and James Cheek, MD, MPH, Principal Consultant, both from the Epidemiology Branch, IHS Headquarters West, Albuquerque, New Mexico.

STD Prevention and Control in the IHS: An Emphasis on Chlamydia

Darcy K. Hunt, MPH, Staff Epidemiologist; James Cheek,

MD, MPH, Principal Consultant; and Laura K. Shelby, BA, STD Program Coordinator, all from the Epidemiology Branch, IHS Headquarters West, Albuquerque, New Mexico

Chlamydia Rates in the IHS

Darcy K. Hunt, MPH, Staff Epidemiologist; James Cheek, MD, MPH, Principal Consultant; and Laura K. Shelby, BA, STD Program Coordinator, all from the Epidemiology Branch, IHS Headquarters West, Albuquerque, New Mexico

Screening and Treatment of Chlamydial Infections: Recommendations by the Centers for Disease Control and Prevention

Darcy K. Hunt, MPH, Staff Epidemiologist; James Cheek, MD, MPH, Principal Consultant; and Laura K. Shelby, BA, STD Program Coordinator, all from the Epidemiology Branch, IHS Headquarters West, Albuquerque, New Mexico

Institute of Medicine Releases Report on Sexually Transmitted Diseases

The Institute of Medicine, National Academy of Sciences

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

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Publication of articles: Manuscripts, comments, and letters to the editor are welcome. Items submitted for publication should be no longer than 3000 words in length, typed, double-spaced, and conform to manuscript standards. PC-compatible word processor files are preferred. Manuscripts may be received via the IHS Banyan electronic mail system.

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