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The Future of Clinical Pharmacy Services in the IHS

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Changes in the Environment of Pharmacy Practice

Pharmaceutical care is defined as “the determination of the drug needs for a given individual and the provision not only of the drug required but also the necessary services (before, during, or after treatment) to assure optimally safe and effective therapy.” Although “pharmacists are moving away from their traditional role as drug dispensers to a new role as full-fledged members of the health care team providing direct, patient-focused care,” the Centers for Medicare and Medicaid Services (CMS) do not recognize pharmacists as approved providers as they recognize physicians, physician assistants, nurse practitioners, nurse midwives, clinical psychologists, and clinical social workers. Pharmacists are currently recognized as a provider only for the provision of immunization services. Despite the transition in the types of services provided by the pharmacist, lack of reimbursement for the pharmacists’ patient care services is impeding the development of new, expanded practice roles.³

To promote pharmaceutical care, pharmacy education has engaged in widespread curricular change to better prepare graduates to assume increased responsibility for patient care.⁴ In addition to a degree conferred by a college or university, the Council on Credentialing in Pharmacy has defined two other basic types of pharmacist credentials: 1) licensure, to demonstrate that the pharmacist has met the minimum requirements needed to practice pharmacy in a given state, and 2) certification or post-graduate degrees.⁵ Advanced certification programs require advanced training, documented experience in the area of practice, expertise in the area of practice as demonstrated by passing examinations or evaluations, and constant continuing education or passing of examinations to maintain certification.

- The American Pharmaceutical Association (APhA) developed the first certification board called the Board of Pharmaceutical Specialists (BPS) in 1976. They developed a program that would: 1) recognize specialties in pharmacy practice, 2) set standards for certification and recertification, 3) objectively evaluate individuals seeking certification and recertification, and 4) serve as a source of information and coordinating agency for pharmacy specialties. Five specialty practice areas are recognized by the BPS: 1) nuclear pharmacy (BCNP), recognized in 1978, 2) nutrition support pharmacy (BCNSP), recognized in 1988, 3) pharmacotherapy (BCPS), recognized in 1988, 4) psychiatric pharmacy (BCPP), recognized in

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1992, and 5) oncology pharmacy (BCOP), recognized in 1996. Board Certification provides standardized credentials for pharmacists who practice within a realm of medicine.

- The American Society of Consultant Pharmacists (ASCP) established the Commission for Certification in Geriatric Pharmacy (CCGP) in 1997. This certifying body was created to credential pharmacists practicing geriatric pharmacy as a Certified Geriatric Pharmacist (CGP).
- The National Institute for Standards in Pharmacist Credentialing (NISPC) provides an alternative method to credential pharmacists to provide focused disease state management (DSM) services. The NISPC was established in 1998 by the American Pharmaceutical Association (APhA), the National Association of Boards of Pharmacy (NABP), the National Association of Chain Drug Stores (NACDS), and the National Community Pharmacists Association (NCPA). The goal of the NISPC is to provide documentation of a pharmacist's competency in the areas of diabetes, asthma, dyslipidemia, and anticoagulation.
- In addition to pharmacy-specific certification, pharmacists may be credentialed through other programs including: 1) the National Certification Board for Diabetes Educators (NBCDE) as a Certified Diabetes Educator (CDE), 2) the NBCDE's Board Certified Advanced Diabetes Management (BCADM), 3) the American Academy of Pain Management (AAPM), 4) American Academy of Wound Management (AAWM) as a Certified Wound Specialist (CWS), 5) the Certification Board of Infection Control and Epidemiology (CBIC) as an Infection Control Professional (ICP) using the CIC (Certified in Infection Control) signature, 6) the National Association of Healthcare Quality (NAHQ) as a Certified Professional in Healthcare Quality (CPHQ), and 7) the Healthcare Information and Management Systems Society (HIMSS) as a Certified Professional in Healthcare Information and Management Systems (CPHIMS), among others.

In 1996, the scope of pharmacy practice in the IHS was broadened to include prescriptive authority when Dr. Trujillo, the previous IHS Director, recognized IHS pharmacists as primary care providers in his October 18, 1996 memorandum:

“Clinical Pharmacy Specialists will be included in the IHS definition of a primary care provider for the purposes of workload reporting, program planning, and reimbursement from all third party payers. An appropriate primary provider code will be assigned to CPS.”

Representatives from the IHS pharmacy program and leaders from CMS discussed recognition of pharmacists as primary care providers. A recommendation was made by CMS to develop a credentialing program to assure consistency and quality of care for patients treated or managed by IHS pharmacists. This and other factors led to the development of the National Clinical Pharmacy Credentialing Committee (NCPSCC) in 1997. Since that time, more than fifty-four IHS pharmacists have become certified by the NCPSCC and are participating in at least one of eight different collaborative disease state management practices including: anticoagulation, dyslipidemia, coronary artery disease, diabetes, asthma, hypertension, end-stage renal disease, pain management, and tobacco cessation. NCPS certified pharmacists are providing disease state management and patient education based upon national interdisciplinary protocols, medication education and evaluation, and a review of the patient's medical record to ensure medication safety with every patient visit.

Pharmacists Are Gaining the Opportunity and Privileges to Engage in Pharmaceutical Care Services Including Medication Therapy Management Services

The number of midlevel practitioners such as physician assistants (PA), nurse practitioners (NP), and clinical pharmacy specialists (CPS) has been increasing,⁶ and states have passed laws expanding the scope of practice for non-physician providers.⁷ Many states now recognize pharmacy collaborative practice agreements and collaborative drug therapy management (CDTM). A collaborative practice agreement is a voluntary agreement among health care professionals of multiple disciplines, including prescribers and pharmacists, that define cooperative practice procedures for the management of disease states. CDTM is defined as a voluntary practice in which prescribers authorize pharmacists



to perform specific tasks, including evaluating, initiating, or adjusting drug therapy. These activities vary based on the definitions of the collaborative practice agreement and state law concerning collaborative practice agreements.⁸ State legislation concerning CDTM may assist pharmacists in obtaining reimbursement for cognitive services, especially from programs such as Medicaid.⁹

Many states have statutes regarding CDTM. Alaska, Idaho, Oregon, and Vermont have regulations concerning CDTM, but no specific legislation.¹⁰ The Tennessee Board of Pharmacy recognizes pharmacists' CDTM authority; however, there are no statutes or regulations concerning it.¹¹ Most state Boards of Pharmacy encourage expanded pharmacy practices; Alabama, Delaware, Massachusetts, Missouri, New Hampshire, New York, Oklahoma, West Virginia, and the District of Columbia are the only states that do not allow some form of collaborative practice, and legislation or regulations allowing the practice are pending in Alabama, Massachusetts, and New York.¹⁰

Methods Pharmacists Currently Use for Billing and How IHS Pharmacists Can Use Them

Reimbursement for services can change the future practice of pharmacy and further enable pharmaceutical care practices, MTMS, and CDTM. Pharmacists are currently utilizing a number of methods to obtain reimbursement for provided services. Since pharmacists are not recognized by CMS as providers, many of these billing methods utilize a “back door” approach and may not be applicable or feasible to the practice of pharmacy within the IHS. Pharmacists have documented successful billing through inpatient consultations, outpatient services utilizing the “incident to physician services” regulations, (also known as the “incident to” rule), through direct billing, through salaried collaborative practice agreements in a physician’s office, in which physicians pay the pharmacist a fee to provide CDTM service to their established patients, as mass immunizers, for procedures performed (point-of-care testing services), or through the provision of diabetes self-management.¹²

Rather than describe each of these methods of reimbursement, it is important to recognize some of the key elements required and the limitations of billing within the IHS. Documentation remains the key to pharmacy billing, and pharmacists must have a keen understanding of the third party requirements for documentation in order to bill successfully. Documentation requirements will depend upon the insurance and services for which reimbursement is being requested.

Although most outpatient services are using an outpatient prospective payment system (PPS) to bill for outpatient services as required by the *Balanced Budget Act of 1997*, the IHS has received a waiver from CMS to bill utilizing a “flat rate,” also called the “all inclusive rate.” Any service performed by a CMS-recognized provider in the IHS receives the same amount of payment whether that service is placing a cast on a patient’s leg after an accident or providing a

comprehensive diabetes examination.

This decision was made after a successful petition to the CMS filed by the IHS demonstrating that a number of IHS facilities did not have an adequate number of certified coders and that coding requirements could prevent some IHS facilities from receiving adequate reimbursement to remain operational. The flat rate waiver has prohibited the use of the “incident to” rule as well as the use of alternative billing mechanisms that are available to pharmacists in other outpatient institutions and settings.

The “incident to” rule enables nonrecognized health care providers, such as pharmacists and nurses, to provide services under the supervision (being in the same office or clinic) of the CMS-recognized provider, such as a physician, PA, or nurse practitioner. To use the “incident to” rule and receive reimbursement, 1) the patient must be initially worked up by the provider, and the provider must refer the patient to your service, 2) the provider must work for the same employer as you, and 3) you must be available if needed (within the office or clinic during the incident to visit).^{13,14} In addition, as most IHS facilities are classified as hospitals, even though the outpatient workload may be much greater than the inpatient, this negates the ability to bill through many outpatient modalities. The prohibition of pharmacy practice standards has resulted from the inability of IHS pharmacists to bill for cognitive services.

Some methods have demonstrated success within the IHS pharmacy program. In certain states in which the legislature recognizes the pharmacist as a provider, pharmacists can bill for and receive reimbursement from Medicaid and some private insurance. Another process to legally enable reimbursement for pharmacy services is to incorporate a physician visit face-to-face with the patient to evaluate and review the pharmacist’s assessment and plan. The physician can then assign an appropriate Evaluation and Management (E&M) code to the visit, which is used for billing purposes. While this method can result in increased collections, it is somewhat impractical and cumbersome for the physician, the pharmacist, and the patient. Other billing modalities have been tried, and there may exist other success stories, albeit with limited experience.

Since the CMS recognizes pharmacists as providers of immunizations, many pharmacists have embraced this role as a first step in obtaining provider recognition. Immunization services are encouraged by the American Pharmaceutical Association (APhA), the ASHP, the American College of Physicians (ACP), and the American Society of Internal Medicine (ASIM).^{15,16,17} To bill for immunization services, pharmacists should complete an application form (Form 855) through their CMS carrier. Since the IHS utilizes Trailblazers as their fiscal intermediary and carrier, applications should be submitted to Trailblazers; however, recent conversation has suggested that pharmacists can utilize the facility Medicare number to bill for immunization services. The ability to

provide immunization services is determined by the pharmacist's state regulations and the local medical staff bylaws, even though they can be recognized and reimbursed, as immunization providers, just like physicians and other CMS-recognized providers.

Medication Therapy Management Services

The American Society of Health System Pharmacists (ASHP) conducted a survey among 1,004 adults nationwide. Eighty-three percent of respondents said they would be interested in having a pharmacist work closely with them and their physician to monitor how well their medication is working. The vast majority (93 percent) of respondents who were interested in having a pharmacist monitor their medication said they would support this as a new Medicare benefit.¹⁸ Legislation entitled the *Medicare Pharmacist Services Coverage Act of 2001* was developed to amend title XVII (Medicare) of the *Social Security Act (SSA)*, as amended by the *Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000*. Although this act was unsuccessful, the *Medicare Prescription Drug Improvement, and Modernization Act (MMA) of 2003* provides Medicare coverage of Medication Therapy Management Services (MTMS) for beneficiaries who choose to participate in the new Prescription Drug Plan (PDP) that will be added to Medicare Part D in 2006. The provisions of MTMS specify a pharmacist as a health professional who may deliver these services to the beneficiaries. Only recently, through this legislation, were pharmacists added to the Medicare health system.²⁰ MTMS identifies a pharmacist as a healthcare professional to provide improved therapeutic outcomes services, which gives *de facto* privileges allowing the pharmacist to assume provider status.²⁰

In July 2004 the CMS released regulations from the *Health Insurance Portability and Accountability Act 1996*, to assign a National Provider Identifier (NPI) to health care providers. Pharmacists, included in their regulation, are eligible to acquire an NPI.²¹ This provider status definition and the ability to obtain an NPI serve as stepping stones to enable the pharmacist to work towards the potential for billing and compensation for cognitive services.

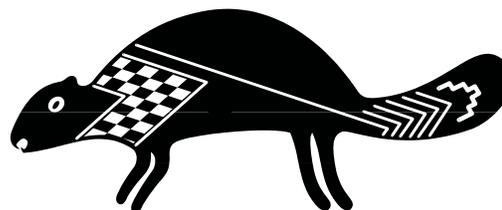
A Pharmacy Practice Activity Classification (PPAC), was developed in 1998 by the major nationally recognized pharmacy organizations to assign fees for the various services that pharmacist performs.²² These services have been divided into four domains of pharmaceutical activity: 1) ensuring appropriate therapy and outcomes, 2) dispensing medications and devices, 3) health promotion and disease prevention, and 4) health systems management; these activities may be used by pharmacists for obtaining compensation for services similarly to the method by which "V" codes are used. In May 2004, the Pharmacy Profession Stakeholders Conference adopted this classification system as a building block for the creation of a definition and program criteria outline of MTMS.²⁰ Since the components of this system are designed to cover a broad range

of pharmacist services, it is appropriate to use it as a billing mechanism. As individual pharmacists begin the practice of billing, the PPAC will prove to be helpful in defining what services pharmacists have provided and how these services should be billed. When establishing fees for therapeutic services, PDPs will be required to account for resources and time of services. This requirement within the PDP helps establish professional fees for pharmacist MTMS and CDTM.

IHS Pharmacy and the Future

One of the many components of pharmaceutical care is the "responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life."²³ Through the NCPSCC, the IHS Pharmacy program is making every effort to ensure that IHS pharmacists will be ready for provider recognition and the ability to bill for cognitive services. To ensure a proactive stance on this issue, the NCPSCC has performed a focused evaluation of the necessary steps that will be required to gain provider recognition when available. These steps include: 1) development of a recognized certification body to evaluate collaborative practice agreements (policies and procedures) and pharmacists, 2) utilization or development of a standardized set of national outcomes for the disease state management services provided, 3) design of a tool to easily collect outcomes data, and 3) publication of reports (local and national) regarding outcomes data to evaluate the effect of pharmacist collaborative practices.

As previously described, the NCPSCC established a national system for credentialing IHS, tribal, and urban (I/T/U) pharmacists in an effort to promote enhanced patient outcomes. The standardization of outcomes data is underway. The CMS defines outcomes data as "data that measure the health status of people enrolled in managed care resulting from specific medical and health interventions." Outcomes data help to ensure that programs accredited by the NCPSCC are continuously evaluating their programs for aspects that are working well or that may be improved. They may also be used as tools to demonstrate the efficacy of pharmacist managed programs. National IHS standards for anticoagulation have been approved, and additional disease states will continue to be evaluated. Michael Pike, a programmer working at the Shiprock Service Unit in New Mexico has been developing a tool to enable the appropriate collection of outcomes data that will easily integrate or adapt to current workflow processes. Completion of this project is expected in early 2005 and will enable outcomes data to be securely sent to a central database



where it can be collected and evaluated. Individual site data will only be available to the specific site, and no personal health information or patient identifiers will be transferred. Finally, with the cooperation of pharmacists and I/T/U sites, the IHS will be able to develop and provide reports on a national level that can potentially be used to strengthen the case for pharmacist recognition as a provider and enhanced opportunities to bill for clinical pharmacy services.

The ability of pharmacists to gain provider recognition is the most vital factor in determining the future of pharmacy practice. The ability of pharmacists in the IHS to bill for the cognitive services provided, (pharmaceutical care practices, MTMS, or CDTM), is severely hindered by the current billing structures, although some sites may receive reimbursement by state and private insurances. The potential for CMS provider recognition exists for the profession of pharmacy with the release of the MMA. To achieve this goal, national pharmacy organizations are developing a billing structure to enable pharmacists to bill for various cognitive services. With all of these efforts, the IHS is establishing a performance improvement and quality assurance program to establish a necessary framework for pharmaceutical care.

If you are a pharmacist providing pharmaceutical care services, MTMS, or CDTM, be sure to become a member of the National Clinical Pharmacy Specialist (NCPS) program and provide your support for the future practice of pharmacy. NCPS applications can be obtained at <http://home.pharmacy.ihs.gov>.

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The Beers Criteria

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Approximately 40% of people over the age of 65 years receive at least five medications, and 12% receive ten or more, accounting for nearly one-third of all drug prescriptions in the United States.¹ Polypharmacy and the effects of aging (altered pharmacokinetics and pharmacodynamics), contribute to an increased incidence of adverse drug reactions within this population.² Adverse drug events (ADEs) are associated with approximately 30% of hospitalizations in the elderly³; 38% of these ADEs are classified as life-threatening or fatal, and 28% are identified as being preventable.⁴ One tool that is used to reduce the risk of ADEs in the elderly is the Beers Criteria.

In 1991, Dr. Beers and colleagues developed the first guidelines, (termed the Beers Criteria), for the use of medications in nursing home patients.⁵ These criteria identify and discourage the use of medications associated with an increased risk of adverse effects when used in patients residing in nursing homes. Medication selection for inclusion in the Beers Criteria is based upon an evaluation of the medical literature and expert opinions in various fields, e.g., pharmacology, geriatrics, and long term care.

In 1997, the Beers Criteria were expanded⁶ to provide guidelines for evaluating the appropriateness of medication regimens in all geriatric patients, regardless of their level of care. The Beers Criteria were updated once more in 2003,⁷ to reflect new knowledge of the pharmacologic changes associated with the aging process, such as up-regulation and down-regulation of receptors⁸ and the general decline in the body's ability to maintain cardiovascular stability, pulmonary function, renal function, and bone mineral density.⁹ These changes make elderly patients more susceptible to the adverse effects of medications, and the risk of an ADE increases with the number of medications patients are receiving.

For the past ten years, the Beers Criteria have been the most widely used guidelines for evaluating medication use in the elderly. The criteria serve regulators as a drug utilization review tool,¹⁰ as an assessment tool in many studies,¹¹ and they have been adopted by the Centers for Medicare and Medicaid Services in July 1999 for nursing home regulations. While the Beers criteria have been criticized as "too simplistic and limiting the freedom of physicians to prescribe,"¹² they remain the most well developed and studied explicit criteria for prescribing for the elderly.

The practice of using explicit, evidence-based criteria for evaluating the appropriateness of medication prescribing has achieved widespread acceptance.⁶ Nonetheless, many older patients are still prescribed medications found on the Beers list. Studies have indicated that 14% to 40.3% of elderly patients in various settings receive a medication appearing on the Beers list.⁹

The importance of appropriate medication use in the elderly is uncontested. In 2011, the first of the "baby boomers" will turn 65 years of age. Without appropriate utilization of medications, the number of adverse drug events will continue to increase. Healthy People 2010, a national initiative to improve the health of all Americans, calls for regular medication reviews in older patients. Explicit, evidence-based criteria, as exemplified by the Beers criteria, are critical for ensuring appropriate prescribing for the elderly. Safer treatment alternatives are available for each medication appearing on the Beers Criteria; increased utilization of these safer treatments remains a goal of geriatric medicine.

The latest revision of the Beers criteria can be accessed at <http://archinte.ama-assn.org/cgi/reprint/163/22/2716.pdf>. A PDA version of the Beers Criteria is located at <http://www.freewarepalm.com/medical/beers/list.shtml>.

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Evaluation of Medication Use in the Elderly at the Cherokee Indian Hospital Using the Beers Criteria

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Background

Approximately 10% (n=1,007) of the user population at the Cherokee Indian Hospital is greater than 65 years of age (defined as patients age 65 or older with at least two visits to the Cherokee Indian Hospital within the past three years). Chronic diseases such as diabetes, heart disease, arthritis, and pulmonary disorders are highly prevalent among this age group and necessitate increased evaluation of pharmacotherapy. The Beers Criteria provide a tool to assess the safety of medications prescribed to elderly patients.

Methods

The most recent version of the Beers Criteria was compared to the Cherokee Indian Hospital (CIH) formulary. Formulary medications that appear on the Beers Criteria were identified and a retrospective search of the Resource Patient Management System (RPMS) was conducted to search for patients age 65 or greater who had been prescribed such medications during the time period December 1, 2003 and December 1, 2004.

Example

Q-man search:
 Living patients
 Age greater than 64 years

Rx: atropine

Select from the pharmacy system list of medications in the RPMS

Condition: between dates 12/1/03 and 12/1/04

Print results...

Results

A total of 319 patients (31.7% of patients age greater than 64 years) were prescribed 553 medications that appeared in the Beers Criteria during the 1-year study period. The number of medications prescribed appears in Table 1. The most commonly prescribed medications were diphenhydramine, naproxen, and propoxyphene.

Table 1. Number of patients prescribed medications from the Beers Criteria.

Number of Medications	Number of Patients	Percent of Patients
1	176	17.5
2	79	7.8
3	43	4.3
4	17	1.7
5+	4	0.2
Total	319	31.7

Discussion

The results of this retrospective evaluation reveal that 31.7 percent of patients age 65 years or older are prescribed at least one medication that appears in the Beers Criteria. These results are consistent with results elsewhere in the medical literature, in which 14 to 40% of elderly patients in various settings were prescribed at least one of these medications. The importance of recognizing medications for which safer alternatives may exist was the primary goal of this review; the impact of prescribing practices on adverse events is beyond the scope of this review. It is important to note that for most of the

medications on the Beers list, there are alternative medications or dosing strategies with a lower risk of adverse effects. This is particularly true for those Beers Criteria medications most commonly prescribed at CIH, such as diphenhydramine, propoxyphene, and amitriptyline.

Having identified commonly prescribed medications on the Beers Criteria through this medication review, the Cherokee Indian Hospital is developing a performance improvement process, including education and a formulary review, to encourage the use of therapeutic alternatives to medications appearing on the Beers Criteria.

Table 2. Most commonly prescribed medications on the Beers Criteria at CIH

Medication	Number of Patients	Reason to Avoid in Elderly	Severity Rating
Diphenhydramine	76	May cause confusion and sedation; should not be used as a hypnotic	High
Naproxen	75	Potential for GI bleed, renal failure, high blood pressure, and heart failure	High
Propoxyphene	63	Offers few analgesic advantages over acetaminophen, yet has the adverse effects of other narcotic drugs.	High
Amitriptyline	31	Anticholinergic and sedative effects	High
Clonidine	29	Orthostatic hypotension, CNS adverse effects	Low
Promethazine	28	Poorly tolerated in elderly, due to anticholinergic adverse effects, sedation, and weakness	High
Cyclobenzaprine	28	Potent anticholinergic effects	High
Ketorolac	24	High incidence of adverse GI effects	High
Oral estrogen	23	Potentially carcinogenic, lacks cardioprotective effects in older women	Low
Hydroxyzine	21	Potent anticholinergic effects	High
Ferrous sulfate > 325mg/day	18	Increase incidence of constipation, but no increase in amount absorbed	Low
Oxybutynin	17	Poorly tolerated in elderly, due to anticholinergic adverse effects, sedation, and weakness	High
Methocarbamol	17		High
Indomethacin	15	Most CNS adverse effects of all the NSAIDS	High
Nitrofurantoin	14	Potential renal failure	High
Piroxicam	11	Potential for GI bleed, renal failure, high blood pressure, and heart failure	High
Digoxin > 0.125mg/d	10	Decreased renal clearance may lead to increase risk of toxic effects	Low
Lorazepam > 3mg/d	9	Highly anticholinergic, questionable effectiveness	High
Hyoscyamine	9	Increased sensitivity seen in elderly patients, smaller doses are desired	High
Meperidine	6	Oral dosing not effective, potential for CNS adverse effects, safer alternatives	High

Adapted from Table 1, *Arch Inter Med.* 2003;163:2719-20

Editor's Note: The following is a digest of the monthly Obstetrics and Gynecology Chief Clinical Consultant's Newsletter (Volume 2, No. 12, December 2004) available on the Internet at <http://www.ihs.gov/MedicalPrograms/MCH/M/OBGYN01.cfm>. We wanted to make our readers aware of this resource, and encourage those who are interested to use it on a regular basis. You may also subscribe to a listserv to receive reminders about this service. If you have any questions, please contact Dr. Neil Murphy, Chief Clinical Consultant in Obstetrics and Gynecology, at nmurphy@anmc.org.

OB/GYN Chief Clinical Consultant's Corner Digest

News Flashes

The IHS Advanced Colposcopy course/Refresher Workshop will be held March 30 - April 1, 2005 in Albuquerque, New Mexico (see Dr. Waxman's comments, below).

The IHS/ACOG Postgraduate Course: Obstetric, Neonatal, and Gynecologic Care will be held June 19 - 23, 2005 in Denver, Colorado. For more information, contact Yvonne Malloy at ymalloy@acog.org or call (202) 863-2580.

Abstract of the Month

Tension-Free Vaginal Tape Procedure Effective Long-Term for Urinary Incontinence.

Objective: To evaluate the long-term cure rates and late complication rates after treatment of female urinary stress incontinence with the minimally invasive tension-free vaginal tape operation.

Methods: Prospective observational, three-center cohort study originally of 90 women requiring surgical treatment for primary urinary stress incontinence. Assessment variables included a 24-hour pad weighing test, a stress test, visual analog scale for assessing the degree of bother, and a questionnaire assessing the subjective perception of the women on their continence status.

Results: The follow-up time was a mean of 91 months (range 78 - 100 months). Both objective and subjective cure rates were 81.3% for the 80 women available for follow-up. Asymptomatic pelvic organ prolapse was found in 7.8%, de novo urge symptoms in 6.3%, and recurrent urinary tract infection in 7.5% of the women. No other long term adverse effects of the procedure were detected.

Conclusion: The tension-free vaginal tape procedure for treatment of female urinary stress incontinence is effective over a period of seven years. Level of evidence: II-3.

Nilsson CG, Falconer C, Rezapour M. Seven-year follow-up of the tension-free vaginal tape procedure for treatment of urinary incontinence. *Obstet Gynecol.* 2004 Dec;104(6):1259-62.

OB/GYN CCC Editorial Comment:

The "green journal," *Obstetrics and Gynecology*, also presented four other articles (see below) on tension free

vaginal tape (TVT) this month as this procedure is "coming of age." The abstract above describes the seven-year success rate in a prospective three-center study in two Nordic countries. The results were comparable to the Burch procedure. One other article describes a comparison with the laparoscopic Burch procedure. Of special note are the three articles on complications associated with the TVT procedure. This procedure has a distinct learning curve. I suggest that providers seeking to add this procedure to their therapeutic armamentarium do so with a mentor, and follow their initial results in a departmental quality assurance project.

There are other tape-related incontinence procedures that a provider might want to explore. ANMC had been an early adapter to TVT in Indian health and has experience with other helpful new methods. Please contact me directly for questions on the ANMC experience. Here are the other related articles.

Laparoscopic Burch colposuspension versus TVT: a randomized trial.

Conclusion: The TVT procedure results in greater objective and subjective cure rates for urodynamic stress incontinence than does laparoscopic Burch colposuspension. Level of evidence: I. Paraiso MF, et al. Laparoscopic Burch colposuspension versus tension-free vaginal tape: a randomized trial. *Obstet Gynecol.* 2004 Dec;104(6):1249-58.

Prevalence of persistent and de novo overactive bladder symptoms after the TVT.

Conclusion: The proportion of patients in whom de novo overactive bladder or urge incontinence symptoms developed postoperatively is low, and approximately 57% of patients with preoperative overactive bladder symptoms can expect resolution of these symptoms after a TVT. Segal JL, et al. Prevalence of persistent and de novo overactive bladder symptoms after the tension-free vaginal tape. *Obstet Gynecol.* 2004 Dec;104(6):1263-9.

Lateral excision of TVT for the treatment of iatrogenic urethral obstruction.

Conclusion: Urethral obstruction after TVT is a relatively uncommon condition. It can be effectively treated with transvaginal lateral excision of the tape. Recurrent stress incontinence seems to be less likely to occur when the takedown procedure occurs beyond 14 days after the initial TVT operation. Level of evidence: III. Long CY, et al. Lateral

excision of tension-free vaginal tape for the treatment of iatrogenic urethral obstruction. *Obstet Gynecol.* 2004 Dec;104(6):1270-4.

Necrotizing surgical site infection after tension-free vaginal tape.

Conclusion: This is the first case of necrotizing surgical site infection after TVT placement. Infectious morbidity risks need to be considered in these procedures. Connolly TP. Necrotizing surgical site infection after tension-free vaginal tape. *Obstet Gynecol.* 2004 Dec;104(6):1275-6.

From Your Colleagues:

Alan Waxman, Retired IHS OB/GYN CCC

This year we are offering a review and update for OB/GYNs, FPs and APNs currently doing colposcopy or in their preceptorships March 30 - April 1, 2005 in Albuquerque, New Mexico.

Regarding colposcopy “certification” for the non-OB/GYN provider, one might ask, How many colposcopies in a year does a non-OB/GYN provider need to perform to maintain their “certification”? Are there standards established, or are there criteria with regards to credentials? If not, how would you recommend verification of a non-OB/GYN provider’s continued competency in this procedure?

First there is no “certification” for colposcopy. The IHS has recommendations for initial colposcopy privileges the completion of 50 supervised exams, and the ASCCP’s Mentorship program requires 25 exams (at least three high grade) with written examination. The ASCCP program is a training program that many practices use as de facto certification. No one has established criteria for maintenance of privileges. When we set up the IHS program, we established 60 exams a year as a “reasonable” number to stay competent. Some providers can do fewer and remain competent, some would need to do more, but an average of five a month sounded reasonable.

There are no data to support one volume of experience over another. Because many I/T/U settings have a low volume of abnormal Paps, but geographic isolation justifies an on-site colposcopist, the IHS epidemiology program, with support from the CDE, has established a program of annual continuing colposcopy education with emphasis on small group case reviews and lots of images of high grade lesions. I’d suggest that if there is a question of competence with any non-OB/GYN provider, he/she should plan to come to the IHS Refresher course this year and at least every other year. That’s a good way to document that he/she has maintained his or her competence.

In consecutive years there are Basic IHS Colposcopy Workshops alternating with IHS Advanced Colposcopy course/Refresher Workshops. These occur in March or April of each year. Check on the MCH Conference webpage for more information.

Hot Topics

Obstetrics

IHS prenatal assessment form: alcohol, tobacco, substance abuse, domestic violence, other home issues. This IHS form (for identifying potentially “at risk” women of childbearing age) is far superior to any form that is currently being used (e.g., CAGE) for this purpose. Aberdeen Area is implementing the form Area-wide. This may be a good activity for an FAS/D initiative – to go with the new GPRA indicator 11.

Child Health

Parents believe that they are not completely in control of their children’s television. If this is correct, parents would both welcome and benefit from tools and strategies that would help them exert more control over their children’s television habits and reduce their hours of viewing. Christakis DA, Ebel BE, Rivara FP, et al. Television, video, and computer game usage in children under 11 years of age. *Journal of Pediatrics.* 2004;145(5):652-656.

Exposure to even one cigarette raised the odds of future smoking. Relatively small increases in the number of cigarettes consumed during childhood are associated with significantly higher odds of current, established, and daily smoking in adolescence. Jackson C, Dickinson D. Cigarette consumption during childhood and persistence of smoking through adolescence. *Archives of Pediatrics and Adolescent Medicine.* 2004;158(11):1050-1056.

Teen contraceptive use has become more effective since 1995. Adolescents in 2002 delayed first intercourse for longer than adolescents in 1995. Adolescents in 2002 used contraceptives more often than adolescents in 1995. Trends in sexual activity and contraceptive use as measured from 1995 through 2002 are consistent with the downward trend in pregnancies and births to adolescents that has been observed since 1991. NCHS Fact sheets available

Features:

ACOG

Informed Refusal. ACOG Committee Opinion Number 306, December 2004.

Abstract: Informed refusal is a fundamental component of the informed consent process. Informed consent laws have evolved to the “materiality or patient viewpoint” standard. A physician must disclose to the patient the risks, benefits, and alternatives that a reasonable person in the patient’s position would want to know to make an informed decision. Throughout this process, the patient’s autonomy, level of health literacy, and cultural background should be respected. The subsequent election by the patient to forgo an intervention that has been recommended by the physician constitutes informed refusal. Documentation of the informed refusal process is essential. It should include a notation that the need for the intervention, as well as risks, benefits, and alternatives

to the intervention, and possible consequences of refusal, have been explained. The patient's reason for refusal also should be documented. Informed refusal. ACOG Committee Opinion No. 306. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2004;104:1465–6.

OB/GYN CCC Editorial comment:

Every IHS and tribal facility should have a vigorous program to document informed refusal with their patients. The document above outlines excellent basic tenets.

Ultrasonography in Pregnancy

Number 58, December 2004. ACOG Practice Bulletin

Conclusions:

- Ultrasound examination is an accurate method of determining gestational age, fetal number, viability, and placental location. Gestational age is most accurately determined in the first half of pregnancy.
- The ability of ultrasonography to diagnose major fetal anomalies is well established.
- The diagnosis of fetal growth abnormalities with ultrasonography is not precise.
- Ultrasonography is safe for the fetus when used appropriately.
- Specific indications are the best basis for the use of ultrasonography in pregnancy.
- The optimal timing for a single ultrasound examination in the absence of specific indications for a first-trimester examination is at 16–20 weeks of gestation.

Summary of Recommendations

The following recommendation is based on limited or inconsistent scientific evidence (Level B):

- Serial ultrasonograms to determine the rate of growth should be obtained approximately every 2–4 weeks.

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

- Casual use of ultrasonography, especially during pregnancy, should be avoided.

- Before an ultrasound examination is performed, patients should be counseled about the limitations of ultrasonography for diagnosis.

Ultrasonography in pregnancy. ACOG Practice Bulletin No. 58. American College of Obstetricians and Gynecologists. *Obstet Gynecol.* 2004;104:1449–58.

**Ask the Librarian Clinical Informationist, Diane Cooper
Children Having Children**

The birth rate of 10 - 14 year-old American Indian girls has decreased again according to the National Center for Health Statistics. For the latest recorded year, 2002, the rate was 2.1 per 1,000 females in that age group. In 2000, it was 2.7, and in 1999, it was 4.1. These rates are lower than for Hispanics (3.6 in 2002) and non-Hispanic blacks (4.7 in 2002). For all races the 2002 rate was 1.7. "American Indian" includes Aleuts and Eskimos. (*National Vital Statistics Reports November 15, 2004*). Contact your Clinical Informationist - IHS, Diane Cooper at cooperd@mail.nih.gov.

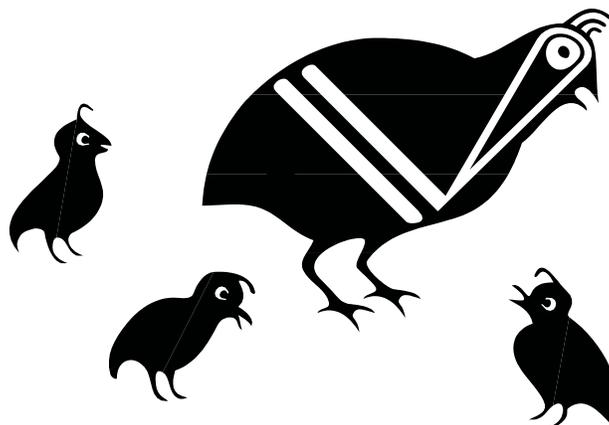
Family Planning

Do Combination Contraceptives Cause Weight Gain?

Conclusion: Available evidence is insufficient to determine the effect of combination contraceptives on weight, but no large effect is evident. Gallo MF, Grimes DA, Schulz KF, Helmerhorst FM. Combination estrogen-progestin contraceptives and body weight: systematic review of randomized controlled trials. *Obstet Gynecol.* 2004 Feb;103 (2):359-73.

OB/GYN CCC Editorial comment:

The worry about possible significant weight gain with combination oral contraceptives (OCP) use is a commonly articulated reason for patients not to use OCPs. The results can be associated with subsequent unintended pregnancy. Please share the above information from systematic review of randomized controlled trials with your patients.

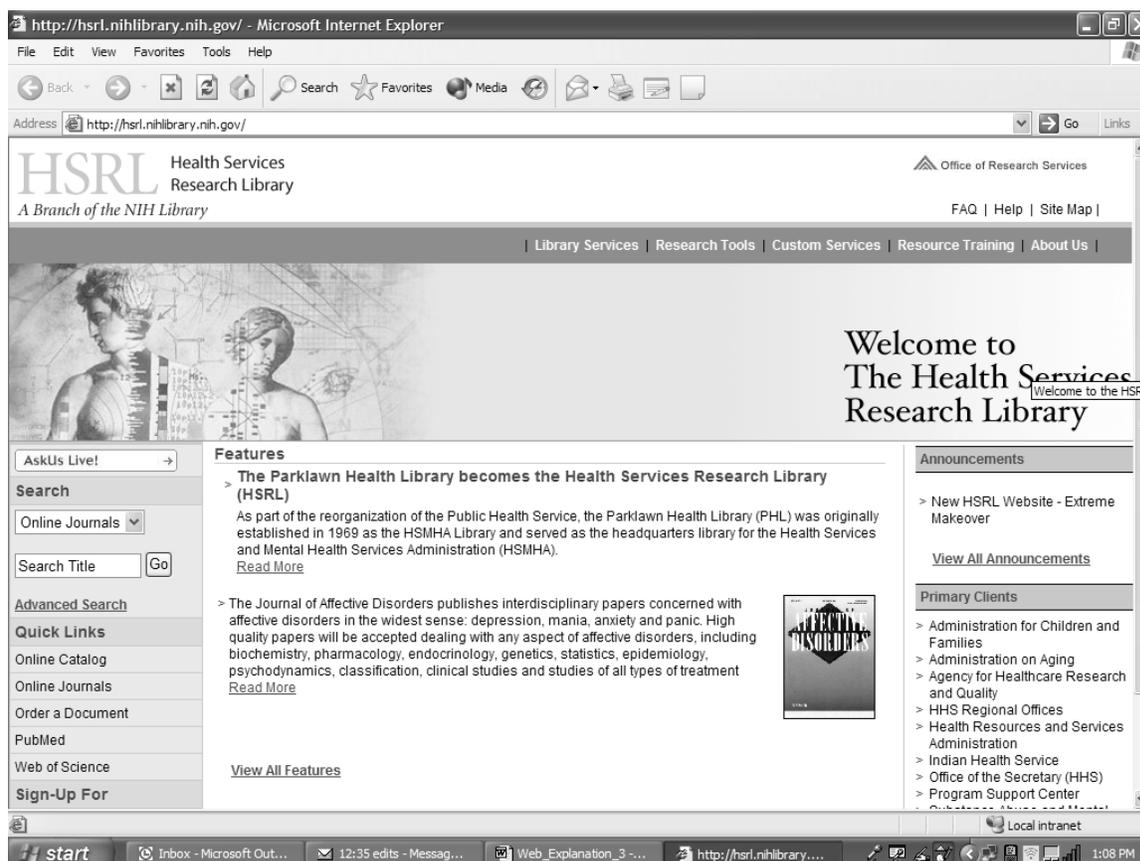


Your “New” Library

You have a new library on your desk, “you” being the Indian Health Service, the Administration on Aging, the HHS Regional Offices, the Health Services and Resources Agency, and several other PHS agencies, and “library” being a virtual library that can deliver electronic and hard copies of articles, books, and reports. Your library-on-a-desk is provided by the Health Services and Research Library (HSRL), a branch of the National Institutes of Health Library.

In this issue, we introduce you to the library website. Future columns will provide more information. First, go to the website, <http://hsrl.nihlibrary.nih.gov>.

Looking at the home page, below, you may marvel at the artistic embellishments and pleasant colors. Or not. You may just want to use the site to get your job done, and that’s what we are helping with today. To begin with, focus your attention on the frame on the left. Here’s an explanation of that list.



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2005 Native American Child Health Advocacy Award

The American Academy of Pediatrics (AAP) Committee on Native American Child Health will be accepting nominations for the **2005 Native American Child Health Advocacy Award** through March 31, 2005. The award will be presented at the 2005 AAP National Conference and Exhibition in Washington, DC to recognize an individual who has made a major contribution to promoting Native American child health. If you know of a physician or non-physician who merits this recognition, please submit a letter of nomination, along with the candidate’s CV to:

Committee on Native American Child Health
American Academy of Pediatrics
141 Northwest Point Blvd.
Elk Grove Village, IL 60007
Fax (847) 434-8729
E-mail indianhealth@aap.org

For more information, please contact Sunnah Kim by

telephone at (800) 433-9016, ext. 4729, or e-mail skim@aap.org.

Call for Nominations to the AAP Committee on Native American Child Health

We are currently soliciting nominations to fill three member vacancies to the AAP Committee on Native American Child Health for a term beginning July 1, 2005. You must be an AAP member in good standing to qualify. The deadline for nominations is **March 1, 2005**. Nominees need a letter of nomination and must submit a completed fact sheet and *curriculum vitae* to their AAP Chapter President and to the Central Office in Elk Grove Village, IL, attention Department of Committees and Sections.

A copy of the fact sheet (which includes additional information and instructions) is available at www.aap.org/nach. For additional information, please contact Sunnah Kim at (800) 433-9016, ext 4729, or e-mail skim@aap.org.



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