



Are all aromatase inhibitors alike?

The anti-estrogen tamoxifen was the gold-standard adjuvant therapy for hormone-receptor-positive (HR+) early breast cancer for several decades, but has recently been displaced by the third-generation aromatase inhibitors (AIs). Three AIs are commercially available: letrozole, anastrozole and exemestane. All are more effective and at least as well tolerated as tamoxifen as adjuvant therapy for HR+ breast cancer in postmenopausal women. Despite the wealth of data comparing AIs with tamoxifen, it is unclear whether the three AIs are clinically equivalent, owing to the lack of head-to-head trials directly comparing them. Preclinical and small clinical studies suggest that letrozole is the most potent inhibitor of aromatase, reducing circulating estrogen levels to a greater degree than the other agents. However, whether this greater activity translates into superior clinical efficacy remains to be determined. In the absence of direct comparative data, cross-trial comparisons have been used to gain insights into any safety or efficacy differences. All three AIs have been compared directly with tamoxifen, and efficacy relative to tamoxifen has been compared across trials, although such analyses are complicated by differences in treatment schedules, patient populations and trial designs. Definitive conclusions cannot yet be drawn, but some important differences are coming to light, with upfront letrozole appearing particularly effective at preventing early distant metastasis, an event strongly associated with breast-cancer-related death. No safety differences between the AIs have yet been identified. This article explores the pharmacologic and clinical differences between the AIs, based on data from clinical and preclinical studies.

Blackwell KL. *Are all aromatase inhibitors alike?* *Breast Cancer Res Treat.* 2008 Dec 20. [Epub ahead of print]

www.ncbi.nlm.nih.gov/pubmed/19101793

Hormone Therapy in Breast Cancer SERMs—Selective Estrogen Receptor Modulators and AIs—Aromatase Inhibitors

Laura Tillman, MD & Shannon Myers, FNP
Hormone therapy is a form of systemic therapy for breast cancer. It can be used as adjuvant therapy to reduce risk of recurrence but may also be used for treatment in more advanced breast cancers. Selective Estrogen Receptor Modulators (SERMs) and Aromatase Inhibitors (AIs) are two main classes of hormonal drugs used for breast cancer. Both SERMs and AIs are used to treat estrogen receptor positive (ER+) breast cancer.

SERMs are selective estrogen-receptor modulators, or drugs that block the naturally circulating estrogen in breast tissues and other estrogen-sensitive tissues in your body. SERMs are called “selective” because they bind to particular estrogen receptors. This selective binding action is sometimes called estrogen inhibition, or estrogen suppression. SERMs do not prevent the production of estrogen, but they help to slow or stop the growth of estrogen-sensitive cancer cells by starving them of a full dose of natural estrogen.

Tamoxifen was the first SERM produced, and has been in use for over 30 years. Initially, it was used in metastatic disease, but we now know that it is effective in reducing recurrence of primary breast cancer and improving overall survival in both postmenopausal and premenopausal women. It has also been shown to reduce the incidence of recurrence of breast cancer in the contralateral breast. Tamoxifen is prescribed for 5 years and there are now studies looking at the use of tamoxifen for even longer periods of time. More recently, tamoxifen has been approved in the United States as a prevention strategy for women at high risk for developing breast

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THIS MONTH

Guest Editorialists

We are fortunate to have guest editorialists for the *Abstract of the Month* for this issue who are experts in the treatment of breast cancer. Laura Tillman, MD and Shannon Myers, FNP lead a Breast Clinic at Phoenix Indian Medical Center that is a model practice within the IHS. They have provided the accompanying overview of Hormone Therapy in Breast Cancer for your consideration. They will also be presenting a session on Breast Health and leading a roundtable discussion about the PIMC Breast Clinic at the First International Meeting on Indigenous Women's Health on March 4th. For more information about the conference, please see page 16

Also on-line....

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Jean E Howe, MD, MPH

Jean Howe, MD, MPH
Ob/Gyn—
Chief Clinical Consultant (C.C.C.)

Hot Topics

Obstetrics

Excess gestational weight gain: modifying fetal macrosomia risk associated with maternal glucose

OBJECTIVE: To estimate how maternal weight gain and maternal glucose relate to fetal macrosomia risk (greater than 4,000 g) among a population universally screened for gestational diabetes mellitus (GDM).

METHODS: Between 1995 and 2003, 41,540 pregnant women in two regions (Northwest/Hawaii) of a large U.S. health plan had GDM screening using the 50-g glucose challenge test; 6,397 also underwent a 3-hour, 100-g oral glucose tolerance test. We assessed the relationship between level of maternal glucose with glucose screening and fetal macrosomia risk after adjustment for potential confounders, including maternal age, parity, and ethnicity and sex of the newborn. We stratified by maternal weight gain (40 lb or fewer compared with more than 40 lb) because excessive maternal weight gain modified results.

RESULTS: Among women with both normal and abnormal GDM screenings, increasing level of maternal glucose was linearly related to macrosomia risk ($P < .001$ for trend in all groups). Women with excessive weight gain (more than 40 lb) had nearly double the risk of fetal macrosomia for each level of maternal glucose compared with those with gestational weight gain of 40 lb or fewer. For example, among women with normal post-glucose challenge test glucose levels (less than 95 mg/dL) and excessive weight gain, 16.5% had macrosomic newborns compared with 9.3% of women who gained 40 lb or fewer. Moreover, nearly one third of women (29.3%) with GDM who gained more than 40 lb had a macrosomic newborn compared with only 13.5% of women with GDM who gained 40 lb or fewer during pregnancy ($P = .018$).

CONCLUSION: Excessive pregnancy weight gain nearly doubles the risk of fetal macrosomia with each increasing level of maternal glucose, even among women with GDM.

Hillier TA, Pedula KL, Vesco KK, Schmidt MM, Mullen JA, LeBlanc ES, Pettitt DJ. Excess gestational weight gain: modifying fetal macrosomia risk associated with maternal glucose. *Obstet Gynecol*. 2008 Nov;112(5):1007-14.

www.ncbi.nlm.nih.gov/pubmed/18978099

Pregnancy and fertility following bariatric surgery: a systematic review

CONTEXT: Use of bariatric surgery has increased dramatically during the past 10 years, particularly among women of reproductive age.

OBJECTIVES: To estimate bariatric surgery rates among women aged 18 to 45 years and to assess the published literature on pregnancy outcomes and fertility after surgery.

EVIDENCE ACQUISITION: Search of the Nationwide Inpatient Sample (1998–2005) and multiple electronic databases (Medline, EMBASE, Controlled Clinical Trials Register Database, and the Cochrane Database of Reviews of Effectiveness) to identify articles published between 1985 and February 2008 on bariatric surgery among women of reproductive age. Search terms included bariatric procedures, fertility, contraception, pregnancy, and nutritional deficiencies. Information was abstracted about study design, fertility, and nutritional, neonatal, and pregnancy outcomes after surgery.

EVIDENCE SYNTHESIS: Of 260 screened articles, 75 were included. Women aged 18 to 45 years accounted for 49% of all patients undergoing bariatric surgery (>50,000 cases annually for the 3 most recent years). Three matched cohort studies showed lower maternal complication rates after bariatric surgery than in obese women without bariatric surgery, or rates approaching those of nonobese controls. In 1 matched cohort study that compared maternal complication rates in women after laparoscopic adjustable gastric band surgery with obese women without surgery, rates of gestational diabetes (0% vs. 22.1%, $P < .05$) and pre-eclampsia (0% vs. 3.1%, $P < .05$) were lower in the bariatric surgery group. Findings were supported by 13 other bariatric cohort studies. Neonatal outcomes were similar or better after surgery compared with obese women without laparoscopic adjustable gastric band surgery (7.7% vs. 7.1% for premature delivery; 7.7% vs. 10.6% for low birth weight, $P < .05$; 7.7% vs. 14.6% for macrosomia, $P < .05$). No differences in neonatal outcomes were found after gastric bypass compared with nonobese controls (26.3%–26.9% vs. 22.4%–20.2% for premature delivery, $P =$ not reported [1 study] and $P = .43$ [1 study]; 7.7% vs. 9.0% for low birth weight, $P =$ not reported [1 study]; and 0% vs. 2.6%–4.3% for macrosomia, $P =$ not reported [1 study] and $P = .28$ [1 study]). Findings were supported by 10 other studies. Studies regarding nutrition, fertility, cesarean delivery, and contraception were limited.

CONCLUSION: Rates of many adverse maternal and neonatal outcomes may be lower in women who become pregnant after having had bariatric surgery compared with rates in pregnant women who are obese; however, further data are needed from rigorously designed studies.

Maggard MA, Yermilov I, Li Z, Maglione M, Newberry S, Suttorp M, Hilton L, Santry HP, Morton JM, Livingston EH, Shekelle PG.

Pregnancy and fertility following bariatric surgery: a systematic review. *JAMA*. 2008 Nov 19;300(19):2286-96.

www.ncbi.nlm.nih.gov/pubmed/19017915

Gynecology

Clinical practice guidelines on vaginal graft use from the society of gynecologic surgeons

OBJECTIVE: To develop guidelines regarding whether graft or native tissue repair should be done in transvaginal repair of anterior, posterior, or apical pelvic organ prolapse.

METHODS: The Society of Gynecologic Surgeons formed a work group to develop evidence-based guidelines. Published data from 1950 to November 27, 2007, from the companion systematic review were reviewed to develop guidelines on biologic and synthetic graft use compared with native tissue repair in vaginal prolapse repair. The work group formulated guidelines based on its overall assessment of the evidence. The approach to grading the quality of evidence and the strength of recommendations was based on a modification of the Grades for Recommendation Assessment, Development, and Evaluation system.

RESULTS: It is suggested that native tissue repair remains appropriate when compared with biologic graft use. Nonabsorbable synthetic graft use may improve anatomic outcomes of anterior vaginal wall repair, but there are trade-offs in regard to additional risks. The group suggests issues that should be included in the preoperative counseling of patients in whom clinicians propose to use a vaginally placed graft.

CONCLUSION: Based on the overall low quality of evidence, only weak recommendations could be provided. This highlights the need for practitioners to fully explain the relative merits of each alternative and carefully consider patients' values and preferences to arrive at an appropriate decision. Future research is likely to change the estimates in the net benefit and risk and the confidence around these assessments.

Murphy M; Society of Gynecologic Surgeons Systematic Review Group. Clinical practice guidelines on vaginal graft use from the society of gynecologic surgeons. *Obstet Gynecol.* 2008 Nov;112(5):1123-30.

www.ncbi.nlm.nih.gov/pubmed/18978115

FDA Public Health Notification:

Serious Complications Associated with Transvaginal Placement of Surgical Mesh in Repair of Pelvic Organ Prolapse and Stress Urinary Incontinence
www.fda.gov/cdrh/safety/102008-surgicalmesh.html

Child Health

Increased Risk of Adverse Neurological Development for Late Preterm Infants

OBJECTIVE: To assess the risks of moderate prematurity for cerebral palsy (CP), developmental delay/mental retardation (DD/MR), and seizure disorders in early childhood.

STUDY DESIGN: Retrospective cohort study using hospitalization and outpatient databases from the Northern California Kaiser Permanente Medical Care Program. Data covered 141 321 children ≥ 30 weeks born between Jan 1, 2000, and June 30, 2004, with follow-up through Jun 30, 2005. Presence of CP, DD/MR, and seizures was based on International Classification of Diseases, Ninth Revision codes identified in the encounter data. Separate Cox proportional hazard models were used for each of the outcomes, with crude and adjusted hazard ratios calculated for each gestational age group.

RESULTS: Decreasing gestational age was associated with increased incidence of CP and DD/MR, even for those born at 34 to 36 weeks gestation. Children born late preterm were >3 times as likely (hazard ratio, 3.39; 95% CI, 2.54-4.52) as children born at term to be diagnosed with CP. A modest association with DD/MR was found for children born at 34 to 36 weeks (hazard ratio, 1.25; 95% CI, 1.01-1.54), but not for children in whom seizures were diagnosed. **CONCLUSIONS:** Prematurity is associated with long-term neurodevelopmental consequences, with risks increasing as gestation decreases, even in infants born at 34 to 36 weeks.

Petrini JR, Dias T, McCormick MC, Massolo ML, Green NS, Escobar GJ. Increased Risk of Adverse Neurological Development for Late Preterm Infants. *J Pediatr.* 2008 Dec 8. [Epub ahead of print]
www.ncbi.nlm.nih.gov/pubmed/19081113

Risk factors for unintentional injuries in children: are grandparents protective?

OBJECTIVE: We sought to identify sociodemographic and familial correlates of injury in children aged 2 to 3 years.

METHODS: The Healthy Steps data set describes 5565 infants who were enrolled at birth in 15 US cities in 1996-1997 and had follow-up until they were 30 to 33 months of age. Data were linked to medical claims reporting children's medically attended office visits by age 30 to 33 months. Each claim was accompanied by a reason for the visit. An analytical

From Your Colleagues

Scott Giberson, HQE Indian Health Service HIV Testing Guidance and Resources are now available on-line

The IHS HIV Program is now able to provide guidance as well as other resources and templates for use by health care clinics to move forward in advancing HIV services toward more universal HIV testing. Many questions often arise about guidance from IHS regarding HIV testing. As we begin to develop more sites and clinics with successful HIV testing practices, we are able to formulate guidance to assist with implementation, advocacy and awareness. Please refer to the following url within the IHS HIV Website:

www.ihs.gov/MedicalPrograms/HIV/AIDS/index.cfm?module=testing&option=ihsGuidance

Once you have clicked on this page, additional resources can be found by navigating through the top box which lists: "More HIV Testing and Guidance Information".

From Your Colleagues

Myra Tucker, CDC Maternal and Child Health Journal Issue Dedicated to AI/AN Mothers and Children

The first Maternal and Child Health Journal issue dedicated to AI/AN—Research for Maternal and Child Health Practice in American Indian and Alaska Native Communities—was published recently. “It has been the realization of a dream to bring this journal issue to fruition,” explains Myra Tucker, BSN, MPH (CAPT USPHS), and tribal liaison in the Division of Reproductive Health (DRH). Working with journal editors and authors to produce this special issue has been a natural partnership for DRH, which conducts a broad range of surveillance, research, and programmatic activities to develop the evidence base for improving maternal and infant health in the US.

Questions? Contact Ms. Tucker at mjt2@cdc.gov.

sample of 3449 was derived from the children who could be effectively followed up and linked to medical charts. Missing data were imputed by using multiple imputation with chained equations. The analytical sample showed no systematic evidence of sample selection bias. Multivariate logistic regression was used to determine the odds ratios of injury events.

RESULTS: Odds of medically attended injuries were decreased for children who received care from grandparents. Odds were increased for children who lived where fathers did not co-reside or in households where the parents never married. Statistical results were robust to the addition of a variety of covariates such as income, education, age, gender, and race.

CONCLUSIONS: Children are at higher risk for medically attended injury when their parents are unmarried. Having grandparents as caregivers seems to be protective. Household composition seems to play a key role in placing children at risk for medically attended injuries.

Bishai D, Trevitt JL, Zhang Y, McKenzie LB, Leventhal T, Gielen AC, Guyer B. Risk factors for unintentional injuries in children: are grandparents protective? Pediatrics. 2008 Nov;122(5):e980-7. www.ncbi.nlm.nih.gov/pubmed/18977965

Chronic disease and illness Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States

CONTEXT: Despite concerns about drug safety, current information on older adults’ use of prescription and over-the-counter medications and dietary supplements is limited.

OBJECTIVE: To estimate the prevalence and patterns of medication use among older adults (including concurrent use), and potential major drug-drug interactions.

DESIGN, SETTING, AND PARTICIPANTS: Three thousand five community-residing individuals, aged 57 through 85 years, were drawn from a cross-sectional, nationally representative probability sample of the United States. In-home interviews, including medication logs, were administered between June 2005 and March 2006. Medication use was defined as prescription, over-the-counter, and dietary supplements used “on a regular schedule, like every

day or every week.” Concurrent use was defined as the regular use of at least 2 medications.

MAIN OUTCOME MEASURE: Population estimates of the prevalence of medication use, concurrent use, and potential major drug-drug interactions, stratified by age group and gender. **RESULTS:** The unweighted survey response rate was 74.8% (weighted response rate, 75.5%). Eighty-one percent (95% confidence interval [CI], 79.4%–83.5%) used at least 1 prescription medication, 42% (95% CI, 39.7%–44.8%) used at least 1 over-the-counter medication, and 49% (95% CI, 46.2%–52.7%) used a dietary supplement. Twenty-nine percent (95% CI, 26.6%–30.6%) used at least 5 prescription medications concurrently; this was highest among men (37.1%; 95% CI, 31.7%–42.4%) and women (36.0%; 95% CI, 30.2%–41.9%) aged 75 to 85 years. Among prescription medication users, concurrent use of over-the-counter medications was 46% (95% CI, 43.4%–49.1%) and concurrent use of dietary supplements was 52% (95% CI, 48.8%–55.5%). Overall, 4% of individuals were potentially at risk of having a major drug-drug interaction; half of these involved the use of nonprescription medications. These regimens were most prevalent among men in the oldest age group (10%; 95% CI, 6.4%–13.7%) and nearly half involved anticoagulants. No contraindicated concurrent drug use was identified.

CONCLUSIONS: In this sample of community-dwelling older adults, prescription and nonprescription medications were commonly used together, with nearly 1 in 25 individuals potentially at risk for a major drug-drug interaction.

Qato DM, Alexander GC, Conti RM, Johnson M, Schumm P, Lindau ST. Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. JAMA. 2008 Dec 24;300(24):2867-78. http://www.ncbi.nlm.nih.gov/pubmed/19109115

Features

ACOG American College of Obstetricians and Gynecologists ACOG Committee Opinion No. 420, Hormone Therapy and Heart Disease

ABSTRACT: The effect of menopausal hormone therapy on coronary heart disease has been the subject of much concern. The Heart and Estrogen/Progestin Replacement Study (HERS) and Women's Health Initiative studies found an increased risk of cardiovascular events with conjugated equine estrogen and medroxyprogesterone acetate use. However, recent evidence suggests that women in early menopause who are in good cardiovascular health are at low risk of adverse cardiovascular outcomes and as such should be considered candidates for the use of conjugated equine estrogen or conjugated equine estrogen and medroxyprogesterone acetate for relief of menopausal vasomotor symptoms. Hormone therapy use should be limited to the treatment of menopausal symptoms at the lowest effective dosage over the shortest duration possible, and continued use should be reevaluated on a periodic basis.

American College of Obstetricians and Gynecologists, ACOG Committee Opinion No. 420, November 2008: hormone therapy and heart disease. Obstet Gynecol. 2008 Nov;112(5):1189-92. www.ncbi.nlm.nih.gov/pubmed/18978127

ACOG Committee Opinion No. 421, Antibiotic Prophylaxis for Infective Endocarditis

ABSTRACT: The recommendations for endocarditis prophylaxis from the American Heart Association have changed for three main reasons: 1) most cases of endocarditis are not attributable to an invasive procedure but rather are the result of randomly occurring bacteremia from routine daily activities; 2) prophylaxis may only prevent a small number of cases of infective endocarditis in women undergoing genitourinary procedures; and 3) the risk of antibiotic associated adverse events exceeds the benefit, if any, from prophylactic antibiotic therapy. The specific changes pertinent to the obstetrician-gynecologist are discussed.

American College of Obstetricians and Gynecologists, ACOG Committee Opinion No. 421, November 2008: antibiotic prophylaxis for infective endocarditis. Obstet Gynecol. 2008 Nov;112(5):1193-4. www.ncbi.nlm.nih.gov/pubmed/18978128

ACOG Committee Opinion No. 422: At-risk drinking and illicit drug use: ethical issues in obstetric and gynecologic practice

ABSTRACT: Drug and alcohol abuse is a major health problem for American women regardless of their socioeconomic status, race, ethnicity, and age. It is costly to individuals and to society. Obstetrician-gynecologists have an ethical obligation to learn and use a protocol for universal screening questions, brief intervention, and referral to treatment in order to provide patients

and their families with medical care that is state-of-the-art, comprehensive, and effective. In this Committee Opinion, the American College of Obstetricians and Gynecologists' Committee on Ethics proposes an ethical rationale for this protocol in both obstetric and gynecologic practice, offers a practical aid for incorporating such care, and provides guidelines for resolving common ethical dilemmas related to drug and alcohol use that arise in the clinical setting.

American College of Obstetricians and Gynecologists. ACOG Committee Opinion No. 422: at-risk drinking and illicit drug use: ethical issues in obstetric and gynecologic practice. Obstet Gynecol. 2008 Dec;112(6):1449-60.

www.ncbi.nlm.nih.gov/pubmed/19037056

ACOG Practice Bulletin No. 99, Management of Abnormal Cervical Cytology and Histology

Summary of Recommendations

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

- Premenopausal women 21 years and older with ASC-US cytology results may undergo immediate colposcopy or may undergo triage testing to determine which of them should be referred to colposcopy. Triage testing may be performed by a single test for high-risk (oncogenic) types of HPV or by repeat cytology screening at 6 months and 12 months. When the index cytology test specimen was obtained by liquid-based cytology or when an HPV specimen was co-collected, "reflex" HPV testing is the preferred approach.
- Colposcopy is recommended in premenopausal women 21 years and older with ASC-US who are HPV positive, those with two consecutive ASC-US cytology results or with LSIL, or women of any age with ASC-H
- For premenopausal women 21 years and older with an HPV-positive ASC-US, or ASC-H or LSIL cytology result in whom CIN 2,3 is not identified, follow-up without treatment is recommended using either repeat cervical cytology tests at 6 months and 12 months or an HPV test at 12 month-intervals; a repeat colposcopy is indicated for a cytology result of ASC-US or higher-grade abnormality or a positive high-risk HPV test result. After two consecutive negative cytology results or one negative HPV result women can return to routine screening.
- In women 21 years and older with HSIL cytology results, immediate loop electrosurgical excision or colposcopy with endocervical assessment are both acceptable management options. In adolescents and pregnant women with HSIL cytology results, colposcopy is recommended. Immediate excision is not acceptable in adolescents and pregnant women. A diagnostic excisional procedure is recommended for all nonpregnant women with HSIL when colposcopy is unsatisfactory or when CIN of any grade is identified on endocervical assessment.
- Posttreatment management options for women 21 years and older who have CIN 2,3 include a single HPV DNA test at 6–12 months, cytology alone at 6-month intervals or a combination

of cytology and colposcopy at 6-month intervals. For adolescents who have undergone treatment, cytology follow-up is preferred. Colposcopy with endocervical sampling is recommended for women who are HPV DNA positive or have a result of ASC-US or greater on repeat cytology. If the HPV DNA test is negative or if two consecutive repeat cytology test results are negative, routine screening commencing at 12 months is recommended for at least 20 years.

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

- Women 21 years or older with ASC-US who test negative for HPV, or whose HPV status is unknown and who test negative for abnormalities using colposcopy, should have a repeat cytology test in 1 year. Women with ASC-US who have two negative results on repeat cytology at 6-month intervals can return to routine screening.
- In adolescents (before age 21 years) with ASC-US or LSIL cytology results, or CIN 1 histology results preceded by ASC-US or LSIL or AGC-NOS cytology results, follow-up is recommended at 12-month intervals. At the first follow-up visit (at 12 months), only adolescents with HSIL or greater on the repeat cytology should be referred to colposcopy. At the 24-month follow-up, those with an ASC-US or greater result should be referred to colposcopy. Human papillomavirus DNA testing is unacceptable for adolescents. If HPV testing is inadvertently performed, a positive result should not influence management.
- In nonpregnant women with ASC and LSIL cytology results who are undergoing colposcopy, endocervical sampling using a brush or curette is preferred for women in whom no lesions are identified and those with an unsatisfactory colposcopy results. Endocervical sampling is acceptable for women with satisfactory colposcopy results and a lesion identified in the transformation zone. Endo-cervical assessment either with colposcopy or by sampling is recommended for all nonpregnant women with HSIL cytology results. Endocervical curettage is unacceptable in pregnant women.
- The recommended management of pregnant women with a histology diagnosis of CIN 1 is follow-up without treatment. Treatment of pregnant women for CIN 1 is unacceptable.
- In a woman 21 years and older with CIN 1 that has persisted for at least 2 years, either continued follow-up or treatment is acceptable. If treatment is selected and the colposcopy result is satisfactory, either excision or ablation is acceptable. If treatment is selected and the colposcopy examination is unsatisfactory, the ECC is positive, or the woman has been previously treated, excision is recommended and ablative procedures are unacceptable.
- Pregnant women with biopsy-proven CIN 2 or CIN 3 in whom there is no suspicion of invasive cancer may postpone re-evaluation with cytology and colposcopy to no sooner than 6 weeks postpartum. Treatment during pregnancy is unacceptable unless invasion is suspected. When invasion is suspected, a diagnostic excisional procedure is recommended.
- For women 21 years and older, the preferred management of CIN 2,3 identified at the margins of a diagnostic excisional

procedure or in an endocervical sample obtained at the end of the procedure is reassessment using cytology with endocervical sampling at 4–6 months following treatment. Performing a repeat diagnostic excisional procedure is acceptable, as is a hysterectomy if a repeat diagnostic procedure is not feasible and for women with a histology diagnosis of recurrent or persistent CIN 2,3

- In nonpregnant women 21 years and older, both excision and ablation are acceptable treatment modalities in the presence of histology diagnoses of CIN 2,3 and satisfactory colposcopy results. Ablation is unacceptable when colposcopy has not been performed, the endocervical sampling is positive for any grade of CIN, the colposcopy result is unsatisfactory, or a woman has recurrent CIN 2,3.
- Colposcopy with endocervical sampling is recommended and HPV DNA testing is preferred for women with all subcategories of AGC and AIS. In addition, endometrial sampling is recommended in women 35 years and older and in women younger than 35 years with clinical indications suggesting they may be at risk of neoplastic endometrial lesions (e.g., unexplained vaginal bleeding, chronic anovulation, or atypical endometrial cells). Colposcopy can be performed either at the initial evaluation or after the results are known. If no endometrial pathology is identified, colposcopy is recommended. Endometrial and endocervical sampling are unacceptable in pregnant women.
- Women 21 years and older with either atypical endocervical, endometrial, or glandular cells NOS who do not have CIN or glandular neoplasia identified histologically should receive repeat cytology testing combined with HPV DNA testing at 6 months if they are HPV DNA positive and at 12 months if they are HPV DNA negative. Referral to colposcopy is recommended for women who subsequently test positive for high-risk HPV DNA or who are found to have ASC-US or greater on their repeat cytology tests. If both tests are negative, women can return to routine cytology testing.
- Women with AGC, favors neoplasia or AIS cytology results should undergo a diagnostic excisional procedure unless invasive disease is identified during the initial colposcopy workup. The diagnostic excisional procedure used in this setting should provide an intact specimen with interpretable margins. Concomitant endocervical sampling is preferred, except in pregnant women.
- Hysterectomy is unacceptable as the primary therapy for CIN.
- Diagnostic ablation or excision is unacceptable as the initial management for ASC or LSIL.

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

For the Class C recommendations, please refer to the online issue of the CCC Corner at

www.ihs.gov/MedicalPrograms/MCH/M/ob.cfm

or to the full length document available from ACOG.

American College of Obstetricians and Gynecologists. ACOG practice bulletin no. 99: management of abnormal cervical cytology and histology. Obstet Gynecol. 2008 Dec;112(6):1419-44. www.ncbi.nlm.nih.gov/pubmed/19037054

ACOG Technology Assessment No. 5, Sonohysterography

ABSTRACT: The goal of sonohysterography is to visualize the endometrial cavity in more detail than is possible with routine transvaginal ultrasound. The procedure consists of the manual injection of sterile fluid under real-time ultrasonographic imaging. The most common indication for sonohysterography is abnormal uterine bleeding. The procedure should not be performed in a woman who is pregnant or who could be pregnant, or who has a pelvic infection or unexplained pelvic tenderness. Physicians who perform or supervise diagnostic sonohysterography should be skilled in vaginal ultrasonography and transcervical placement of catheters; should have training, experience, and demonstrated competence in gynecologic ultrasonography and sonohysterography; and should keep careful records. Portions of this document were developed jointly with the American College of Radiology and the American Institute of Ultrasound in Medicine.

American College of Obstetricians and Gynecologists. ACOG Technology Assessment No. 5. Sonohysterography. Obstet Gynecol 2008;112: 1467–9.
www.ncbi.nlm.nih.gov/pubmed/19037058

Behavioral Health Insights

Peter Stuart, IHS Psychiatry CCC

Suicide and Antiepileptics—Real Concerns?

FDA ALERT [1/31/2008, Updated 12/16/2008] - The FDA has completed its analysis of reports of suicidality (suicidal behavior or ideation [thoughts]) from placebo-controlled clinical trials of drugs used to treat epilepsy, psychiatric disorders, and other conditions. Based on the outcome of this review, FDA is requiring, under the authorities granted under the Food and Drug Administration Amendments Act (FDAAA) of 2007, that all manufacturers of drugs in this class include a Warning in their labeling and develop a Medication Guide to be provided to patients prescribed these drugs to inform them of the risks of suicidal thoughts or actions.

The drugs affected by these safety labeling changes are commonly referred to as antiepileptic or anticonvulsant drugs (see the list below). FDA’s pooled analyses of 199 clinical trials of eleven antiepileptic drugs used as mono- and adjunctive therapies showed that patients who were randomized to receive one of the antiepileptic drugs had almost twice the risk of suicidal behavior or ideation (0.43%) compared to patients randomized to receive placebo (0.24%). This increase in the risk of suicidal thoughts or behavior represents the occurrence of approximately one additional case of suicidal thinking or behavior for every 530 patients treated with an antiepileptic drug.

The risk of suicidal thoughts or behavior was generally consistent among the eleven drugs analyzed and was observed in patients who were treated for epilepsy, psychiatric disorders, and other conditions. The relative risk for suicidal thoughts or behavior was higher in the clinical trials for epilepsy compared to

trials for psychiatric or other conditions. However, the absolute risk differences were similar in the clinical trials for epilepsy and psychiatric indications.

The increased risk was observed as early as one week after starting antiepileptic drug treatment and throughout the observed duration of treatment. The increased risk of suicidal thoughts or behavior was generally consistent among the eleven drugs with varying mechanisms of action and across a range of indications. This observation suggests that the risk applies to all antiepileptic drugs used for any indication.

All patients who are currently taking or starting on any antiepileptic drug for any indication should be monitored for notable changes in behavior that could indicate the emergence or worsening of suicidal thoughts or behavior or depression.

Psychiatry CCC Editorial Comment: This advisory is part of a larger concern about adverse consequences of medications used to treat neuropsychiatric conditions. The actual event numbers involved were quite small (4 suicides in a population ~27,000 for a rate of 16/100,000—lower than the background rate of suicides in our populations) and this was a post-hoc analysis of drug company reporting data thus reducing the power of the analysis to clearly identify causation. The FDA chose to keep the concern at an advisory level and not add a black box warning after extensive hearings.

Unfortunately, similar discussions and reviews related to antidepressants resulted in black box warnings. Recent data suggests that with the black box warnings there has been a reduction in the use of antidepressants particularly in adolescents—now followed by increases in suicide rates that may or may not be linked to the reduction.

The bottom line—treating neuropsychiatric conditions whether they are classically “psychiatric” or not require attention to the mood and emotional status of a person. This includes doing a basic assessment of propensity for self or other injury, mood and substance abuse history, and impulsivity, and incorporating the findings into the treatment plan. If there is a 1) a reasonable indication, 2) appropriate treatment targets and 3) reasonable alignment between the provider and the patient on treatment and treatment risks providers should continue to assertively treat such disorders. They remain some of the biggest contributors to mortality and morbidity in our populations and major sources of distress and suffering.

www.fda.gov/cder/drug/InfoSheets/HCP/antiepilepticsHCP.htm

Breastfeeding

Suzan Murphy, PIMC

We are very fortunate to have Dr. Frank Nice as a guest writer. He is highly respected in many arenas including the use of medications during breastfeeding. He is considered by many lactation professionals to be THE expert on the use of herbs during lactation. He holds numerous degrees in pharmacological sciences and administration and currently serves as a pharmacist at the National Institutes of Health. He retired from USPHS after 30 years of service, has published numerous articles about

breastfeeding, medication, and herbs and continues to tirelessly contribute to the betterment of public health. Please welcome Frank J. Nice RPh, DPA, CPHP

Herbal Galactogogues

As with prescription drugs and over the counter (OTC) medications, consumers use herbals to treat a variety of ailments and to maintain health. In fact, lactation consultants recommend, and breastfeeding mothers take, herbals called galactogogues, to help increase milk supply, usually by initiating the breast milk letdown reflex, but also sometimes by aiding in breast milk ejection. Commonly used galactogogues include blessed thistle, chaste tree fruit, fennel, fenugreek, garlic, goat’s rue, and milk thistle. Herbs, among others, that may also act as galactogogues include alfalfa, anise, borage, caraway, coriander, dandelion, dill, hops, marshmallow root, nettle, oat straw, red clover, red raspberry, and vervain.

Blessed thistle, chaste tree fruit, fennel, fenugreek, garlic, goat’s rue, and milk thistle are considered major galactogogues in that they are the primary herbs used as galactogogues and are commonly used alone. Alfalfa, anise, borage, caraway, coriander, dandelion, dill, hops, marshmallow, nettle, oat straw, red clover, red raspberry, and vervain are considered minor galactogogues because they are not as commonly used and commonly are used in combination with each other, often in homeopathic preparations. If one looks at the list of minor galactogogues, along with some of the major galactogogues, it is apparent that many of these herbs find use as food products, especially within particular ethnic groups.

Common daily doses for the major galactogogues are: blessed thistle: 2-6 grams; chaste tree fruit: 30-40 mg; fennel: equivalent to 100-600mg; fenugreek: 6 grams; garlic: 4-9 grams; goat’s rue: 1-2 ml of tincture; milk thistle: 12-15 grams daily. Dosage forms may include oral capsules, alcoholic extracts, tinctures, oils, seeds, and infusions.

Common daily doses for the minor galactogogues are: alfalfa: up to 60 grams; anise: 10-42 grams; borage: 1-2 grams; caraway: 1.5-6 grams; coriander: 3 grams; dandelion: 15 grams; dill: 3 grams; hops: 500 mg or one bottle of stout beer; marshmallow root: 3 grams; nettle: 1.8 grams; oat straw: 100 grams; red clover: 40-80 mg; red raspberry: 2.7 grams; vervain: 30-50 grams. Dosage forms are the same as for the major galactogogues and also include teas and beer (hops).

Interesting facts about the major galactogogues include: blessed and milk thistle: these are two distinct herbs, other thistles are also used as galactogogues; chaste tree fruit: also known as chasteberry and vitex, if used in higher doses for breast pain, may negatively affect nursing performance; fennel: may also aid in milk ejection; fenugreek: the most commonly used herbal galactogogue, do not use if allergic to peanuts or legumes; mother and baby may smell like maple syrup; garlic: increases nursing time because baby likes smell of garlic, but if baby does not, opposite may occur; goat’s rue: contains galegin, a precursor of metformin, which also shows galactogogue properties, increases milk production in goats, sheep, and cattle.

Interesting facts about some of the minor galactogogues: alfalfa: do not use if allergic to peanuts or legumes or in mothers with systemic lupus erythematosus; anise: has mild estrogenic properties, which may aid in milk ejection; borage: potential blood thinner in large amounts; caraway: avoid volatile oil form; coriander; also known as cilantro, avoid if allergic to celery; dandelion: contraindicated in bile duct blockage and bowel obstruction; dill: acts as diuretic to reduce postpartum edema; hops: aids milk letdown; marshmallow root: not the Kraft variety, acts as diuretic; nettle: acts as diuretic; oat straw: yes, regular oat meal; red clover: avoid fermented type, potential blood thinner; red raspberry: may aid in milk ejection, may decrease milk supply after two weeks use; vervain: contraindicated in pregnancy due to oxytocic properties.

For more information, please contact Dr. Nice at Frank.Nice@nih.hhs.gov

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**Indian Child Health Notes Steve Holve,
 Pediatrics Chief Clinical Consultant
 December 2008**

Quote of the month

“The trouble with the world is that the ignorant are cocksure and the intelligent are full of doubt”—Anonymous

Etiquette-Based Medicine

“Patients ideally deserve to have a compassionate doctor, but might they be satisfied with one who is simply well-behaved? When I hear patients complain about doctors, their criticism often has nothing to do with not feeling understood or empathized with. Instead, they object that “he just stared at his computer screen,” “she never smiles,” or “I had no idea who I was talking to.” During my own recent hospitalization, I found the Old World manners of my European-born surgeon—and my reaction to them—revealing in this regard.”

This is the opening paragraph from a thought provoking essay recently published in the NEJM. The author reviews how much effort has been expended in the past few decades to teach medical students to be more humane and compassionate. He believes there has been no similar effort to teach clinicians “good manners”.

He uses an analogy with the recent decrease in ICU infections with the use of strict checklist protocols. Rather than a “sophisticated” approach such as developing new antibiotics, success was achieved by strictly following simple hygiene rules. Changing attitudes is hard... changing behavior is much easier. He makes the argument that we might do as well by patients with developing a checklist of better behaviors that we can teach medical students.

Editorial Comment

At first glance it seems wrong to value form over content. Yet, the author makes a compelling case that patient satisfaction

might be better served. It is an especially interesting concept since for most of us our work in Indian Health involves a cross cultural component. The author is a psychiatrist and feels that training students to be empathic is laudable but difficult. As he summarizes, “I’m not sure I teach students to see things through the patient’s eye, or to tolerate suffering. I think I can, however, train them to shake a patient’s hand, sit down during a conversation, and pay attention.

Read the whole post at no charge at the link below:

Kahn, MW. *Etiquette-Based Medicine*. *N Eng J Med*. 2008 May 8;358(19):1988-9

<http://content.nejm.org/cgi/content/full/358/19/1988>

Infectious Disease Updates

Rosalyn Singleton, MD

Changes to the Pneumococcal Polysaccharide Vaccination (PPV23) Recommendation

The Advisory Committee on Immunization Practices (ACIP) met on Oct. 22nd, 2008, and reviewed and expanded the recommendation for the use of the 23-valent pneumococcal polysaccharide vaccine (PPV23). Persons 19–64 years of age with asthma as well as persons 19–64 years of age who are current smokers were added to the recommendation, and should routinely receive PPV23.

In addition, the ACIP pneumococcal working group, which included representatives from IHS and tribal health programs, presented information related to the routine use of PPV23 in American Indian/Alaska Native (AI/AN) populations. Based on this information, the ACIP voted to make the following changes to the recommendation for the use of PPV23 in AI/AN children and adults.

1. Previously, the ACIP recommendation stated that routine use of PPV23 after receipt of pneumococcal conjugate vaccine “could be considered” for AI/AN children.¹ In addition to being confusing for providers, the working group found that there are limited data on the effectiveness of this strategy in reducing invasive pneumococcal disease, and noted limited data that suggest that PPV23 vaccination after receipt of pneumococcal conjugate vaccine could cause hyporesponsiveness, although the clinical implications of this finding are not known. Based on this information the ACIP approved the following change to the recommendation re: the use of PPV23 for AI/AN children. The new recommendation reads:

Routine use of PPV23 after PCV7 is not recommended for Alaska Native or American Indian children aged 24-59 months. However, in special situations, public health authorities may consider recommending the use of PPV23 after PCV7 for Alaska Native or American Indian children aged 24-59 months who are living in areas where the risk of invasive pneumococcal disease is increased.

2. The previous ACIP pneumococcal recommendation stated that “Persons aged 2–64 years who are living in environments or social settings in which the risk for invasive pneumococcal

disease or its complications is increased (e.g., Alaskan Natives and certain American Indian populations) should be vaccinated.”²The working group found that there was no data to support such a broad recommendation, and expressed concern that the recommendation was confusing for providers and offensive to some AI/AN people. Based on this information, the ACIP voted to approve the following change to this recommendation:

Routine use of PPV23 is not recommended for Alaska Native or American Indian persons younger than 65 years old unless they have underlying medical conditions that are PPV23 indications. However, public health authorities may consider recommending PPV23 for Alaska Natives and certain American Indians aged 50-64 years who are living in areas where the risk of invasive pneumococcal disease is increased.

In summary, routine use of PPV23 is still indicated for people, including AI/AN people, who (bold indicates new risk groups):

- Are 65 years and older
- Have a chronic health condition (e.g. chronic cardiovascular disease chronic pulmonary disease (**including asthma**), diabetes mellitus, alcoholism, and chronic liver disease (cirrhosis), or CSF leaks.
- **Are a current smoker**
- Have functional or anatomic asplenia (e.g., sickle cell disease or splenectomy)

¹*Preventing Pneumococcal Disease Among Infants and Young Children. Recommendations of the Advisory Committee on Immunization Practices (ACIP). October 06, 2000 / 49(RR09):1-38*

²*Ibid*

Recent literature on American Indian/Alaskan Native Health

Michael L. Bartholomew, MD

Results of a Collaborative School-Based Oral Health Program in a Remote First Nations Community

Dental caries continues to be a significant infectious disease afflicting American Indians and Alaska Native children. Multiple programs addressing oral health have been implemented with varying success. Dr. Steve Holve presented the current state of oral health in AI/AN communities in the October 2006 edition of the IHS Primary Care Provider.¹ Concerns about oral health of native or aboriginal children extend across national boundaries. Aboriginal children of Canada appear to have an increase prevalence of poor oral health, often 2–3 times poorer than other populations in Canada. Dental decay rates in Canada have been cited to be 3 to 5 times greater in aboriginal children than in non-aboriginal children. Causes for this increase have been bottle caries, high sugar diets, limited access to dental health care and oral hygiene.

This cross-sectional study reports the results of a collaborative school-based oral health program in a remote First Nations community over the past three years. The Pediatric Residency Program at the University of British Columbia established a partnership with the people of Hartley Bay. After meeting

with the community and its elders, oral health was identified as a problem. Four possible interventions addressing oral health were presented. The community chose a school based intervention consisting of supervised, daily school-based brush-ins after lunch, weekly fluoride rinse, and fluoride varnish applications for those under 9 years of age, dental health anticipatory guidance, and classroom presentations on oral health. All the children in the community participated. Fifty-eight children were enrolled into the study of which 26 students were given pre-enrollment complete dental examinations. 18 children who were initially enrolled were lost to follow-up. Therefore only 40 students completed the study. Thirteen students had both pre and post intervention evaluations. Each participant was given a Decayed, Missing, and Filled Surfaces (DMFS) score for primary or permanent teeth, cavity free status and an oral health habits questionnaire.

Over the three-year period, the children evaluated pre and post intervention had significant improvement in DMFS scores. Improvement in cavity free status and oral health habits were also seen. The success of this study underscores the importance of collaboration and community input in the design of public health interventions.

Macnab AJ, Rozmus J, Benton D, Gagnon, FA. 3-Year Results of a Collaborative School-Based Oral Health Program in a Remote First Nations Community. Rural and Remote Health 8:882. 2008.

www.ncbi.nlm.nih.gov/pubmed/18444770

Reference:

Holve S. Fluoride Varnish Applied at Well Child Care Visits Can Reduce Early Childhood Caries. IHS Primary Care Provider 2006. 31(10):243-245.

January 2009

Editor's Comment from Steve Holve, CCC Pediatrics
The recent death of Dr. Roger Gollub was an unexpected tragedy. I am using this editorial space to reprint a tribute to Dr. Gollub from Robert McSwain, Director of the Indian Health Service. I would urge you to contribute to the memorial fund listed in the last paragraph.

It is my sad duty to inform you that Dr. Roger Gollub, who recently retired from the U.S. Public Health Service Commissioned Corps, died unexpectedly on November 19, 2008, in Kotzebue, Alaska. Dr. Gollub had retired in September after serving in the USPHS for over 24 years. During his career, he devoted himself to working with American Indians and Alaska Natives in their communities.

Dr. Gollub was a brilliant and committed scientist and pediatrician. He began his career as a staff pediatrician at the Gallup Indian Medical Center in Gallup, New Mexico. After two years in the Epidemiology Intelligence Service of the Centers for Disease Control in an assignment with the Colorado Department of Health, he subsequently served for 11 years as the epidemiologist for the IHS Albuquerque Area. During that time, Dr. Gollub was pediatric advisor to the National IHS Head Start Program and collaborated with other pediatricians on a five-year Healthy Tomorrows grant to serve children with special needs.

For the past seven years, he served as a full-time pediatrician in the South central Foundation Primary Care Clinic at the Alaska Native Medical Center in Anchorage. His clinical services included outreach to rural Alaska villages. Dr. Gollub was in Kotzebue providing a pediatric clinic on the day of his death.

He loved the adventure of living in Alaska, and frequently shared his resulting photographs and stories with friends. Dr. Gollub chose to retire from the Corps in September so he could also pursue his dream and commitment to research and working with the Alaska Native Head Start program, while continuing his clinical services part-time.

He lived his life serving others. His tragic and untimely death has highlighted some of the public health issues facing the communities he served and his commitment to prevention. Although Dr. Gollub's co-workers were always amazed at his vast knowledge and teachings, he believed those around him were his greatest teachers, and that he was their student.

Dr. Gollub was born in University City, Missouri. Not surprisingly, he was the valedictorian of his high school class. He attended Yale University, obtained his medical degree from John Hopkins University, and completed his pediatric residency at Case Western Reserve University.

Dr. Gollub is survived by his wife, Diane Abrahams-Gollub; two daughters, Anna and Sarah, his mother, Sheila Gollub; brother, David, and numerous co-workers and friends. His family has established a memorial fund in Dr. Gollub's name to benefit the Head Start program for Alaska Native children. Contributions can be sent to the Alaska USA Federal Credit Union, Account # 1429780 and Routing # 325272021. The address of the bank is P.O. Box 196613 Anchorage, AK 99508-6613. Further information is available at www.drrogergollubcommunity.org

International Health Update

Claire Wendland, Madison, WI

Warfare and neglected diseases

Last year The Lancet ran a series of research articles looking at the implications of understanding health as a human right. In the third article in the series, Chris Beyrer and colleagues explore the intersection of so-called "neglected diseases" and civil conflict. Using detailed case studies from Burma and Colombia, they make a convincing argument that conflict can drive substantial increases in the rates of these diseases.

"Neglected diseases" is a blanket term that covers various tropical infections, many resulting from protozoans or helminths. They are neglected because they are unprofitable to treat, even though by most estimates they collectively account for about a fourth of the global burden of disease (above better-known infections like malaria or tuberculosis). These diseases afflict the poorest people in poor countries. In the wealthy world, then, there is little motivation to research these diseases or provide therapy for them; in the poor countries in which they are found, there is little infrastructure to do either.

Burma is ruled by a military junta with one of the worst

human rights records in the world; over forty percent of state expenditure goes to the military, and less than three percent is directed to health. Neighboring Thailand has nearly eliminated *Wuchereria bancrofti*, the cause of the disabling chronic disease lymphatic filariasis, by mass chemotherapy in affected zones using diethylcarbamazine. Burma's rulers, in contrast, provide neither the drugs nor the community health workers to deliver them. Filariasis affects roughly 10% of Burma's population, and some 40% show signs of exposure. Not only are Burma's citizens affected, but fleeing refugees are threatening *W. bancrofti* control in nearby countries. In Colombia, Beyrer and colleagues document increases in leishmaniasis, yellow fever, and *Trypanosoma cruzi* (the cause of Chagas' disease, a progressive cardiomyopathy) in the most violent rural areas. Neither treatment nor preventive measures can be effectively applied in guerrilla-controlled areas; in fact, vaccines and drugs have even been hijacked.

Conflict allows neglected diseases to burgeon in many ways. It restricts disease surveillance, limits access to diagnostic and curative services, and disables preventive measures like control of disease-bearing insects or distribution of vaccines. In addition, affected patients may present at very late stages because of difficulty in accessing care, and infections may spread rapidly as displaced people move beyond previous community boundaries. Donors and researchers may be (understandably) reluctant to investigate or treat outbreaks in unsafe conditions. The diversion of money from health care to the military clearly also plays a role in many conflicts.

The authors do not offer much in the way of strategies to improve health in conflict settings. In addition, they do not draw the obvious connections with other kinds of health problems exacerbated by warfare. We know, for instance, that maternal morbidity and mortality suffer when access to care is lost, and childhood deaths rise as community infrastructure breaks down and safe food and water can no longer be assured. The focus on neglected infectious diseases seems narrow. But their conclusion is right: "resolving these health problems cannot be better done than with peace, reconciliation, and the end of chronic conflicts."

Beyrer C et al. Neglected diseases, civil conflicts, and the right to health. The Lancet 370(9587):619-627, 2007 <http://www.ncbi.nlm.nih.gov/pubmed/17707757>

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MCH Alert

Curriculum Aims to Decrease Incidence and Improve Care of Diabetes among American Indians and Alaska Natives

Diabetes Education in Tribal Schools: Health is Life in Balance is a K-12 curriculum designed to enhance the understanding and appreciation of the problems of diabetes in American Indian and Alaska Native (AI/AN) communities, to empower students to make healthy lifestyle choices, and to stimulate general student interest in diabetes-based science careers. The Diabetes Education in Tribal Schools (DETS) curriculum was developed by the

National Institute of Diabetes and Digestive and Kidney Diseases in collaboration with the Indian Health Service Division of Diabetes Treatment and Prevention, the Centers for Disease Control and Prevention Native Diabetes Wellness Program, eight tribal colleges and universities, and the National Institutes of Health Office of Science Education. The curriculum comprises multidisciplinary units with lessons that incorporate National Science Education Standards and AI/AN cultural and community knowledge. The DETS Web site contains information on the curriculum's background, mission, instructional content, federal agencies and contributing partners, tribal colleges and universities, and participating schools. A press release about the DETS national launch, answers to frequently asked questions, and the 2008 DETS implementation test evaluation research summary are also provided.

The curriculum is available at:

www3.niddk.nih.gov/fund/other/dets/index.htm.

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MCH Headlines

Judy Thierry HQE

Project Making Medicine; Specialized training in the treatment of child physical and sexual abuse

From Dee Big Foot: "I am pleased to announce that we have received a grant from Indian Health Service and the Children's Bureau to provide specialized training in the treatment of child physical and sexual abuse. This funding will allow the Indian Country Child Trauma Center at the University of Oklahoma Health Sciences Center to offer 4 regional trainings with 45 training slots available at each regional location.

If you are interested in attending the training in your region, please check out our website at www.icctc.org for information about the application process. A limited amount of travel funds are available for applicants who successful apply; I strongly encourage two or more applicants from each site to allow for carpooling or other creative ways to get the most out of the limited funds.

Please share this information with your colleagues or other mental health or wellness providers in your area. I do not have current email information for many of our past training participants and I would greatly appreciate if you could help disseminate this announcement as widely as possible.

Location and Dates:

- Phoenix, AZ — February 17-19, 2009
- Portland, OR — March 10-12, 2009
- Minneapolis, MN — April 13-15, 2009
- Anchorage, AK — June 2-5, 2009

If you have questions, please contact me at dee-bigfoot@ouhsc.edu or Janie Braden at Janie-braden@ouhsc.edu. You may also call 405-271-8858.

2009 Childhood Obesity Conference: Creating Healthy Places for All Children

The 5th biennial Childhood Obesity Conference is the largest gathering of professionals focused on the prevention of pediatric overweight in the nation with over 1,800 in attendance. The conference is devoted to providing the most pressing and innovative issues related to childhood obesity. Showcased will be presentations focused on issues, strategies and programs as they relate to the environmental, organizational, media advocacy and policy, nutrition and physical activity education, and family and clinical approaches to childhood obesity.

Goals

- Showcase evidenced-based prevention interventions to reduce overweight and obesity in high risk and low income communities.
- Feature community efforts to implement environmental and policy strategies that promote and sustain healthy eating and activity behaviors.
- Accelerate the obesity prevention movement to promote health equities and reduce disparities at the local, state and national levels.
- Promote collaboration among diverse stakeholders to ensure access to healthy foods and physical activity for all children.

Registration

To register, sponsor, exhibit, or apply for a poster session, visit www.childhood-obesity.net or call (800) 858-7743.

- Early Registration (on or before May 8th) \$350
- Late Registration (after May 8th) \$400

Location

Westin Bonaventure Hotel
404 South Figueroa Street, Los Angeles, CA 90071

Breastfeeding Initiation DVD Resource

These DVD's are a must for all hospitals, nurseries, rooming-in programs and delivery units, even for sites that send their mom's out for delivery. This is the most explicit documentation and visual/audio education that I have seen on breastfeeding initiation.

1. Making Enough Milk, The Key to Successful Breastfeeding...Planning for Day One
2. A Premie Needs His Mother. First Steps to Breastfeeding Your Premature Baby
3. Breastfeeding, A Guide to Getting Started
4. Breastfeeding Management, Educational Tools for Physicians and Other Professionals

Breastmilk Solutions has 4 DVD's @ 65\$ each or \$225 for the set of four—bulk orders may be priced lower.

www.breastmilkolutions.com/order.html

Medical Mystery Tour

Neil Murphy, ANMC, Southcentral Foundation

Test your knowledge on Polycystic Ovarian Syndrome (PCOS); The Answers:

1. Menstrual cycles become more irregular in women with polycystic ovarian syndrome (PCOS) as they approach menopause? True/False

Answer - False

Actually perimenopause may cause women with PCO to have a little more regular menstrual spacing. This change may be related to the elevation, or relative normalization, of the FSH levels as the woman ages. This change in the LH / FSH ratio seems to revert the ovarian function towards normal in this population.

Having said that, it does not imply that the basic PCO metabolic abnormalities have dissipated with age. The patient is still at risk for dyslipidemia, etc.... so the patient should still aggressively manage her Metabolic Syndrome with weight loss and optimizing her health status.

2. Medical management of adolescents with PCOS is most appropriately directed towards:

- a. Maximizing fertility
- b. Preventing excessive weight gain
- c. Arresting the progression of hirsutism
- d. Decreasing insulin levels

Answer - b. Preventing excessive weight gain

While PCO is associated with insulin resistance in 75% of cases, and one key to its management is controlling the insulin resistance, it is the control of excess body weight that is the most direct management for the overall syndrome.

As was shown in the Diabetes Prevention Program, intense lifestyle changes and weight loss can decrease the onset of diabetes in 60%, while treatment with metformin can decrease the subsequent onset of diabetes by 30%.

Though it is not easy, exercise and weight loss should predate oral contraceptive use and metformin use. As this is a lifelong syndrome, we also do not know the lifelong effects of agents like metformin on 12 -13 year old girls. In addition, we do not know the lifetime effect of early treatment with oral contraceptive agents which are begun before the maximum skeletal peak bone accrual.

At first it is reasonable to initiate a work up for a proinflammatory milieu and hyperinsulinemia. One could consider a C-reactive protein (CRP) and a provoked insulin challenge (integrated insulin level >150 uIU/mL).

Then one should obtain a detailed nutritional history with the help of a nutritionist. This step can be especially important in adolescents as it can reveal particularly unique dietary indiscretions that are amenable to counseling.

Next, a physical activity regimen should be recommended. As the magnitude of weight loss can be overwhelming, reachable goals should be set and frequent follow-up scheduled to provide positive feedback. Many of the benefits can be seen after they lose only 10% of their body weight. It is much easier to lose 20 lbs. than 75 lbs., hence short term goals should be realistic to be of benefit.

Next, if metformin is used, then a very gradual increase is suggested to allay the anticipated gastrointestinal side effects. Start at 500 mg and increase no quicker than 500 mg per week until the usual maintenance dose of 1500 mg /day is achieved. Remember, there is no hurry, this is a lifelong syndrome and metformin is currently the only agent of its kind in our armamentarium at this juncture.

There is some evidence in patients with a BMI > 30 that 2000 mg / day may be a better option, though again the gastrointestinal side effects are often the rate limiting factor.

3. Intrauterine growth retardation is associated with an increased risk of PCOS in offspring? True/False

Answer - True

It seems that PCO, like many other disorders in the reproductive lifespan, does have an in utero initiation. Mothers with obesity, GDM, macrosomic infants, IUGR infants, or SGA infants are associated with the stigmata of the PCOS phenotype when the offspring are followed through menarche.

PCOS mothers showed a significantly higher prevalence of SGA newborns which cannot be completely attributed to pregnancy complications, and seems to be more related to the PCOS condition of the mother.

Though genetics are clearly important, there may be epigenetic programming that put the mother herself at risk for insulin resistance. Evidence in non-human primates reveal that fetal exposure to elevated levels of androgens can result in elevated levels of luteinizing hormone (LH) later in life.

There may be a sequence in the associations between reduced fetal growth and components of the postnatal endocrine system; minor fetal growth reduction appears to be associated with amplified adrenarche, whereas more pronounced prenatal growth restriction seem to precede functional ovarian hyperandrogenism and hyperinsulinemia during adolescence. In conclusion, these findings corroborate the hypothesis that the frequent concurrence of precocious pubarche (with pronounced adrenarche), functional ovarian hyperandrogenism, and hyperinsulinemia in girls may result from a common early origin (low birth weight serving as a marker), rather than from a direct interrelationship later in life.

There is evidence that if children have early adrenarche, an elevated BMI, and/or have acanthosis nigricans, they should be followed closely for PCO, as early as 6 years old.

4. Brothers of women with PCOS are at greater risk for which of the following conditions?

- Decrease sperm counts
- Type 2 diabetes
- Hirsutism
- Increased pregnancy wastage

Answer - b. Type 2 diabetes

Sons of PCOS women exhibit higher body weight from early infancy. In addition, insulin resistance became evident as the subjects got older, which may place them at risk for the development of type 2 diabetes and cardiovascular disease.

Unfortunately, in the early family history studies, the fathers of PCOS patients could not be found in the kindreds. The males had severe metabolic syndrome and fatal myocardial infarctions and were not available to be studied.

It may be that the female family members may actually be protected by the presence of estrogen earlier in life. Often the family history obtained in the office will identify multiple sisters and multiple cousins with PCOS, rather just sporadically throughout the pedigree. Most likely there is polygenic pattern that we are far from understanding.

5. The most appropriate first line modality for ovulation induction in women with PCOS is

- Ovarian drilling
- Clomiphene citrate
- Metformin
- Exogenous gonadotropins

Answer - b. Clomiphene citrate

Clomiphene is superior to metformin in achieving live birth in infertile women with the polycystic ovary syndrome, although multiple birth is a complication.

‘Having said that, it is not unreasonable to treat a PCO patient who is open to pregnancy with metformin. For those couples in whom an immediate pregnancy is not perceived to be absolutely necessary, metformin does increase the rate of live birth and it allows the couple to pursue a more normal lifestyle without the need for precisely timed coitus, etc...

Another related approach is to use metformin to optimize the metabolic milieu so that she is healthier when she does achieve pregnancy. In this longer term scenario, then clomiphene does become a second line agent after the patient has lost some weight and improved her lipid profile. If the patient is young enough, one can use the prospect of a future pregnancy as a motivator over a 3 - 6 month period to encourage weight loss so that perhaps the patient could pursue pregnancy in a non-medicated state.

In fact weight loss should be really considered as a first option for women who are infertile and overweight. It has been demonstrated that weight loss can improve the fertility of obese women through the recovery of spontaneous ovulation, whereas others will have improved response to ovarian stimulation in infertility treatment. Therefore, it is proposed that following the initial as-

assessment of infertility and body mass index or other measurement of obesity, various weight management interventions, including diet, exercise or pharmacotherapeutic approaches, should be considered for overweight and obese infertile women.

Many helpful resources and links are included with the on-line version of this article, available at www.ihs.gov/MedicalPrograms/MCH/M/ob.cfm

Correction from last issue:

There was an error in the description of Category III fetal heart rate tracings.

The correct description of Category III is:

- Absent baseline FHR variability and any of the following:
 - Recurrent late decelerations
 - Recurrent variable decelerations
 - Bradycardia
- Sinusoidal pattern

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Midwives Corner

Lisa Allee, CNM, Chinle

Midwifery care unequivocally supported and recommended by Cochrane Review

Okay, first the bottom line—Cochrane Review loves midwifery care. Check out these two direct quotes: “Midwife-led care confers benefits for pregnant women and their babies and is recommended.” and “Authors’ conclusions: All women should be offered midwife-led models of care and women should be encouraged to ask for this option.” Wow, wow, and wow. As midwives we certainly knew this, but this is some awesome confirmation of the value of the midwifery model of care.

Here are the statistical results: “We included 11 trials (12,276 women). Women who had midwife-led models of care were less likely to experience antenatal hospitalisation, risk ratio (RR) 0.90, 95% confidence interval (CI) 0.81 to 0.99), the use of regional analgesia (RR 0.81, 95% CI 0.73 to 0.91), episiotomy (RR 0.82, 95% CI 0.77 to 0.88), and instrumental delivery (RR 0.86, 95% CI 0.78 to 0.96) and were more likely to experience no intrapartum analgesia/anaesthesia (RR 1.16, 95% CI 1.05 to 1.29), spontaneous vaginal birth (RR 1.04, 95% CI 1.02 to 1.06), to feel in control during labour and childbirth (RR 1.74, 95% CI 1.32 to 2.30), attendance at birth by a known midwife (RR 7.84, 95% CI 4.15 to 14.81) and initiate breastfeeding (RR 1.35, 95% CI 1.03 to 1.76). In addition, women who were randomized to receive midwife-led care were less likely to experience fetal loss before 24 weeks’ gestation (RR 0.79, 95% CI 0.65 to 0.97), and their babies were more likely to have a shorter length of hospital stay

(mean difference -2.00, 95% CI -2.15 to -1.85). There were no statistically significant differences between groups for overall fetal loss/neonatal death (RR 0.83, 95% CI 0.70 to 1.00), or fetal loss/neonatal death of at least 24 weeks (RR 1.01, 95% CI 0.67 to 1.53).”

These are some fabulous numbers that all midwives can feel very proud of and can share with whoever needs to be educated on the value of what we do. The authors also do a good job of describing the midwifery model of care. For example: “The midwife-led model of care is based on the premise that pregnancy and birth are normal life events and is woman-centered. The midwife-led model of care includes: continuity of care; monitoring the physical, psychological, spiritual and social wellbeing of the woman and family throughout the childbearing cycle; providing the woman with individualized education, counseling and antenatal care; continuous attendance during labor, birth and the immediate postpartum period; ongoing support during the postnatal period; minimizing technological interventions; and identifying and referring women who require obstetric or other specialist attention.”

Overall, this Cochrane review is a document midwives and others in IHS can use if they are needing support to establish, or re-establish, a midwifery service; or to expand the number of midwives so all women in a service unit have the opportunity to be attended by a midwife; or, at some sites, to just remind ourselves, other providers, and the women and families we serve how blessed we are in IHS to have midwifery care as the standard of care. Enjoy.

If you are having trouble getting a copy of this landmark document please contact me at lisa.allee@ihs.gov and I will send you a copy electronically or via snail mail!

Hatem M, Sandall J, Devane D, Soltani H, Gates S. Midwife-led versus other models of care for childbearing women. Cochrane Database of Systematic Reviews 2008, Issue 4. Art. No.: CD004667. DOI: 10.1002/14651858.CD004667.pub2. <http://mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD004667/frame.html> www.ncbi.nlm.nih.gov/pubmed/18843666

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Nurses Corner

Sandra Haldane, HQE

Registered nurses are key to detecting, correcting, and preventing medical errors during critical care

Since registered nurses (RNs) play a pivotal role in preventing or reducing the impact of medical errors during critical care, interventions should build on

2008 Edition of Women’s Health Data Book Released

Women’s Health USA 2008, the seventh edition of the data book, selectively highlights emerging issues and trends in women’s health using a variety of data sources. The data book, developed by the Health Resources and Services Administration, includes information and data on population characteristics, health status, and health services utilization. New topics in the 2008 edition include occupational injury, maternal mortality, digestive disorders, oral health, eye health, and urologic disorders. Racial and ethnic, sex and gender, and socioeconomic disparities in women’s health are also highlighted. The data book is intended to be a concise reference for policymakers and program managers at the federal, state, and local levels to identify and clarify issues affecting the health of women.

It is available at <http://mchb.hrsa.gov/whusa08/>.

factors that enhance their effectiveness in preventing, intercepting, or correcting these errors, suggests a new study.

Using entries in daily logbooks maintained by a random sample of 502 critical care nurses over a 28-day period, Ann E. Rogers, Ph.D., R.N., of the University of Pennsylvania School of Nursing, and colleagues examined the type and frequency of medical errors detected by critical care nurses. They found 367 errors identified by 184 of the nurse participants during the data-gathering period. Errors in medication administration (most commonly, wrong drug, wrong dosage, or dose not given) were the most frequent problems. They accounted for 163 of the errors—43 percent of which involve giving the wrong dosage of a prescribed medication. Procedural errors were the next most common (115 errors reported), followed by charting errors (55 instances), and transcription errors (55 instances).

The nurses caught only 43 of the 367 errors—mostly medication errors or overlooked allergies—before they reached the patient. Yet, nurses were particularly effective at discovering and correcting errors that had been made by other nurses and other

members of the health care team. The incredibly busy pace of critical care units may play a role in errors, with an average of 187 activities performed for each patient each day. Heavy workloads and fatigue are also factors that may affect the ability of RNs to intercept or correct errors, note the researchers. Their results did not show differences in error types or rates based on the size of the critical care unit or of the hospital.

Because procedures for administering medications and other health care procedures are similar across health care institutions despite how they are organized or their size, the researchers suggest that future studies should focus on system- and process-related factors. Their study was funded in part by a grant from the Agency for Healthcare Research and Quality (HS11963).

More details are in "Role of registered nurses in error prevention, discovery and correction," by Dr. Rogers, Grace E. Dean, Ph.D., R.N., Wei-Ting Hwang, Ph.D., and Linda D. Scott, Ph.D., R.N., in the *April 2008 Quality and Safety in Health Care* 17(2), pp.117-121.

www.ahrq.gov/research/sep08/0908RA2.htm

(influenza immunization ..., continued from page 1)

cancer. However, it does have side effects. The most serious side effects are blood clots, stroke, uterine cancer and cataracts. The most common side effects are hot flashes and vaginal dryness.

Aromatase Inhibitors have a different mechanism of action than SERMs. AIs prevent estrogen production instead of blocking estrogen receptors the way SERMs do. AIs reduce the amount of estrogen in the body. AIs do not block estrogen production by the ovaries, but they can block other tissues from making this hormone. That is why AIs are used in women who are in menopause, when the ovaries are no longer producing estrogen. AIs may be used as a first-line therapy or after treatment with tamoxifen. Currently, there are three AIs approved by the U.S. Food and Drug Administration: anastrozole (Arimidex), exemestane (Aromasin) and letrozole (Femara). The most serious side effect is bone thinning (osteoporosis). The most common side effects are hot flashes and body aches.

For more information about the use of SERMs and AIs and about breast cancer in American Indian and Alaska Native women, please consult the articles below or contact Dr. Tillman or Ms. Myers at Phoenix Indian Medical Center.

Laura.Tillman@ihs.gov; Shannon.Myers@ihs.gov.

Carpenter R. Choosing early adjuvant therapy for postmenopausal women with hormone-sensitive breast cancer: aromatase inhibitors versus tamoxifen. *Eur J Surg Oncol*. 2008 Jul;34(7):746-55. Epub 2008 Mar 4.

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Flum DR, Stuart S, Wilcox M. Processes and outcomes of care among Navajo women with breast cancer. *JAMA*. 2003 Oct 15;290(15):1996-7. <http://www.ncbi.nlm.nih.gov/pubmed/14559952>
Free Full Text:

jama.ama-assn.org/cgi/content/full/290/15/1996-a

MedScape CME: Comprehensive Breast Care: An Update for the Menopause Practitioner

www.medscape.com/viewprogram/17686

Save the Dates

Telluride Midwinter Conference on Maternal and Child Health

- January 30th–February 1st, 2009
- Fun and inexpensive CME
- Telluride, Colorado
- www.ihs.gov/MedicalPrograms/MCH/F/CN01.cfm?module=09&option=1#top
scroll down to date

First International Meeting on Indigenous Women's Health/Third International Meeting on Indigenous Child Health Conference; Many Voices into One Song

- Women's Health March 4–6, 2009
- Child Health March 6–8, 2009
- Albuquerque, NM
- Joint conference of Women's Health and Children's Health Providers from Canada and the United States
- www.ihs.gov/MedicalPrograms/MCH/F/CN01.cfm?module=09&option=3#top

IHS Colposcopy Update & Refresher Course

- April 1–3, 2009
- Albuquerque, NM
- Contact: AWaxman@salud.unm.edu

Advances in Indian Health Conference

- April 21–24, 2009 in Albuquerque, NM
- Indian Health's conference for primary care providers and nurses
- 28 hours of CME/CE credit
- Optional Diabetes track
- Contact the Course Director, Dr. Ann Bullock, at annbull@nc-chokeee.com for more information.

Indian Health Summit

- July 7–9, 2009, Hyatt Regency Hotel, Denver, Colorado
- The Health Summit will be a national gathering of Indian Health professionals and administrative leadership, community health advocates and activists, and Tribal leadership. We will join together to build skills and share ideas and innovations
- <http://conferences.thehillgroup.com/healthsummit/index.html>

Many Voices into One Song

First International Meeting on Indigenous Women's Health (March 4–6, 2009) + Third International Meeting on Indigenous Child Health (March 6–8, 2009)

These paired conferences are simply the biggest events on the horizon for both Women's Health and Child Health teams working in IHS, Tribal and Urban programs. They each offer:

- Extensive clinical updates focused on the major issues affecting American Indian and Alaska Native Health.
- A variety of formats (plenary sessions, breakouts, roundtables, poster presentations, etc.).
- Nationally known speakers, most with a background in Indigenous Health.
- Opportunities to learn about and share programs and innovations that work.
- Many occasions to network and socialize with others working on similar issues from across the country and around the globe.

Please join us in sunny Albuquerque, New Mexico in March! Better yet, bring an entire team from your facility!!

For more information please visit:

<http://hsc.unm.edu/cme/2009Web/IndigenousWomensHealth/IndigenousWomensHealthIndex.shtml>

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