



FDA Approves OTC Access for Plan B for 18 and Older:

A 'Catch-22' for AI/AN patients? *Prescription Remains Required for Those 17 and Under*

The U.S. Food and Drug Administration (FDA) announced approval of Plan B, a contraceptive drug, as an over-the-counter (OTC) option for women aged 18 and older. Plan B is often referred to as emergency contraception or the "morning after pill." It contains an ingredient used in prescription birth control pills—only in the case of Plan B, each pill contains a higher dose and the product has a different dosing regimen. Like other birth control pills, Plan B has been available to all women as a prescription drug. When used as directed, Plan B effectively and safely prevents pregnancy. Plan B will remain available as a prescription-only product for women age 17 and under.

Duramed, a subsidiary of Barr Pharmaceuticals, will make Plan B available with a rigorous labeling, packaging, education, distribution and monitoring program. In the CARE (Convenient Access, Responsible Education) program Duramed commits to:

- Provide consumers and healthcare professionals with labeling and education about the appropriate use of prescription and OTC Plan B, including an informational toll-free number for questions about Plan B;
- Ensure that distribution of Plan B will only be through licensed drug wholesalers, retail operations with pharmacy services, and clinics with licensed healthcare practitioners, and not through convenience stores or other retail outlets where it could be made available to younger women without a prescription;
- Packaging designed to hold both OTC and

prescription Plan B. Plan B will be stocked by pharmacies behind the counter because it cannot be dispensed without a prescription or proof of age; and

- Monitor the effectiveness of the age restriction and the safe distribution of OTC Plan B to consumers 18 and above and prescription Plan B to women under 18.

This action concludes an extensive process that included obtaining expert advice from a joint meeting of two FDA advisory committees and providing an opportunity for public comment on issues regarding the scientific and policy questions associated with the application to switch Plan B to OTC use. Duramed's application raised novel issues regarding simultaneously marketing both prescription and non-prescription Plan B for emergency contraception, but for different populations, in a single package.

The agency remains committed to a careful and rigorous scientific process for resolving novel issues in order to fulfill its responsibility to protect the health of all Americans.

www.fda.gov/cder/drug/infopage/planB/default.htm

OB/GYN CCC Editorial

Let's make sure that it is not a 'Catch-22' for AI/AN patients

While this is long overdue good news for women over 18 yo, we need to be sure it is not a 'Catch-22' for our AI/AN patients.

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Solstice

The Bighorn Medicine Wheel west of Sheridan, WY is perhaps the most famous of the 40 or more similar "wheels" on the high plains area of the Rocky Mountains. Mostly are located in Canada. At Bighorn, the center of a small cairn, that is external to the main wheel, lines up with the center of the wheel and the sun rising at the summer equinox. Another similar sighting cairn provides a sighting for three dawn-rising stars: Aldebaran, Rigel and Sirius. A third cairn lines up with fourth star: Fomalhaut. The term "medicine wheel" was coined by Europeans; it was a term used to describe anything native that white people didn't understand.

Also on-line....

Subscribe to the listserv and receive reminders about this service. If you have any questions, please contact me at nmurphy@scf.cc.

Neil J. Murphy

Dr. Neil Murphy
Ob/Gyn Chief
Clinical Consultant (C.C.C.)

IHS Child Health Notes

Sept 2006

"Never eat more than you can lift"

—Miss Piggy

Articles of Interest

Intake of sugar-sweetened beverages and weight gain: a systematic review.

Am J Clin Nutr. 2006 Aug;84(2):274-88.

The authors reviewed English language articles from 1966–2005 on the relationship of consumption of sugar sweetened beverages and the risk of weight gain. Findings from large cross-sectional studies with long periods of follow-up show a positive association with greater intake of sugar sweetened beverages and weight gain in both children and adults. Short-term feeding trials in adults also support an induction of positive energy balance and weight gain with sugar sweetened sodas. The authors believe the weight of epidemiological and experimental evidence supports the need for public health strategies to discourage consumption of sugary drinks.

Obesity—the new frontier of public health law.

N Engl J Med. 2006 Jun 15;354(24):2601-10

The law can be a powerful instrument of public health. The authors mention decreased lead exposure, improved workplace safety, the mandate of seatbelts and airbags and even increased immunization rates as the result of legislation and litigation. One of the newest targets of public health law is obesity.

Increased regulation or taxing of food raises issues about the appropriate balance between personal freedoms and the potential public health benefits. The authors do an excellent job of pointing out that such regulations were rejected in the past. They go on to show that restrictions on food advertising now are far more likely to be accepted given the documented increase in obesity. Various pending legislation and litigation around food advertising, distribution and taxation are discussed.

Editorial Comment

These two articles complement one another: Identification of a problem and a set of possible solutions. Beyond one-on-one counseling of patients (which appears to be fairly ineffective) what public health strategies involving courts or legislatures might work? An interesting angle is that tribes are sovereign nations and have the power to set their own laws and taxes. A Navajo Nation tax on soda pop? A Hopi Nation tax on any soda > 12 ounces? An Apache ban Twinkies®? Or would this lead to bootlegging of Big Gulps® and Twinkies®? There are lots of intriguing possibilities. Read the articles and dream.

"It doesn't matter if the cat is black or white as long as it catches mice."

—Deng Hsaio P'ing 1904–1997

Infectious Disease Updates.

Rosalyn Singleton, MD, MPH

Outpatient visits associated with otitis media and Tympanostomy tube placement among young American Indian and Alaska Native children in the age of Pneumococcal conjugate vaccine

Rosalyn J. Singleton, Robert C. Holman, Krista L. Yorita, James E. Cheek.

Outpatient visit rates with otitis media (OM) and with tympanostomy (PE) tube placement were evaluated in American Indian and Alaska Native (AI/AN) children.

METHODS: Records for all outpatient visits with OM listed as one of the diagnoses and with myringotomy and insertion of tube listed as a procedure for AI/AN children <5 years of age were obtained from the Indian Health Service National Patient Information Reporting system for 2000–2004. Rates for OM visits were obtained for the general population of US children by using the National Ambulatory Medical Care Survey.

RESULTS: Outpatient visit rates associated with otitis media for AI/AN children <5 years old (97/100/year) in 2000–2004 were less than those previously reported for 1994–1996 (138); however, the rate remained higher than that for the US population in 2000–2004 (71, 95% confidence interval 64–77). The OM visits rate for AI/AN infants <1 year of age (204) were more than twice as high as that for US infants (93). The OM visit rate in AI/AN children varied by region, and was highest for the Alaska region (157 for children < 5 years of age) and lowest for the Oregon and Washington Areas (76 for children < 5 years of age). The PE tube placement rate for AI/AN children <5 years of age also varied by region; the rate was highest for the Alaska region (23/1,000/year) and low (0.5 to 2.2) for each of the other regions.

COMMENT: The OM outpatient visit rate in AI/AN children, as well the rate for the general population of US children, has decreased since routine Pneumococcal conjugate vaccination. The rate of OM and PE tube placement for AI/AN children varied widely by region; the PE tube placement rate may be affected by the OM rates, as well as availability of and referrals to otolaryngologists.

I. Curns AT, Holman RC, Shay DK, et al. Outpatient and hospital visits associated with otitis media among American Indian and Alaska Native children younger than 5 years. Pediatrics 2002;109:e41

Special thanks to Bob Holman, statistician from CDC Division of Viral and Rickettsial Disease, Atlanta, GA.

Recent literature on American Indian/ Alaskan Native Health

Doug Esposito, MD

Cancer in 15- to 29-year-olds by primary site.

Oncologist. 2006 Jun;11(6):590-601.

This report represents an adaptation of a larger, more detailed 205 page document (<http://seer.cancer.gov/publications/aya/>). According to the authors, this is the first report detailing cancer epidemiology specifically in the 15-29 year-old age group.

Cancer incidence and survival rates reported by the authors derive from data collected through the Surveillance, Epidemiology, and End Result (SEER) program of the National Cancer Institute. Population estimates are from U.S. Census data. SEER collects data on all invasive malignancies occurring in defined geographic areas. Although these areas represent a relatively small portion of the entire U.S. population (approximately 13%), they are chosen to be representative of the nation as a whole with regard to ethnic/racial make-up. The data is then generalized to the rest of the country. Mortality rates are derived from analysis of data provided by the CDC's National Center for Health Statistics (NCHS). A more detailed description of the statistical manipulations of the data is beyond the scope of this review. For a full description of methods, the interested reader should refer to the full monograph referenced above.

Cancer in the 15-29 year-old population comprises only 2% of all malignancies in the U.S. An estimated 21,400 cancer diagnoses occurred in the year 2000 in this age group. By way of comparison, only 0.75% of all malignancies occur prior to age 15. Due to the fact that cancer incidence increases exponentially with age, half of all cancers in the 15-29 year age group actually occur in 25-29 year-olds. SEER reports cancer incidence to be lowest for AI/ANs at all ages, and highest for non-Hispanic whites in the first 40 years. African Americans/blacks have the highest cancer incidence over age 40.

The distribution of cancer type in the 15-29 year-old age group is unique and changes over time so that the distribution of cancer type seen at age 15 years is very different from that seen by age 30. The five most frequent invasive malignancies in 15-29 year-olds are lymphomas (20%), invasive skin cancers (15%, with 76% of these being melanoma), male genital system cancers (11%), endocrine system cancers (11%, with 96% of these being thyroid), and female genital system cancers (9%). These cancers account for 66% of all malignancies in this age group. CNS cancers and leukemias account for only 6% each. Significant gender differences exist. For females, genital system cancers account for 18%, while lymphomas and thyroid cancers account for 17% each, melanoma 15%, and breast cancer 7% of all malignancies (representing 74% of all female cancers in this age group). For males, genital system cancers account for 22%, lymphomas 21%, melanoma 17%, CNS cancers 8%, and leukemias 8% (representing 76% of all male malignancies in this age group).

Perhaps of more interest to us pediatricians, for 15-19 year-olds, the five most frequent malignancies are lymphomas (26%), leukemias (12%), CNS cancers (10%), endocrine system cancers (9%, with 87% of these being thyroid), and invasive skin cancers (8%, with 84% of these being melanoma). These five account for 65% of all malignancies in this age group.

Cancer incidence increased in all age groups younger than 45 years between 1975 and 2000. However, it appears that this rise has leveled off for 15-24 year-olds, with a decrease in incidence for 25-29 year-olds over the last five years.

With regard to mortality, the authors conclude that age-dependent cancer death rates generally reflect the incidence profile; i.e. the more patients diagnosed with cancer the higher the expected death rate. As such, Native Americans are reported to have the lowest death rate from cancer for all age groups. Trends in mortality have been positive over time. Between 1975 and 2000, mortality due to invasive cancers has declined in all age groups younger than 45 years. However, the rate of reduction in mortality for African Americans/blacks was reported to be significantly lower than the reduction observed in other racial groups.

The authors report cancer survival to be best for non-Hispanic whites and worst for African Americans/blacks in the 15-29 year-old age group. AI/ANs had intermediate survival rates. However, AI/ANs had a more rapid death rate in the first two years following diagnosis than non-Hispanic whites, Hispanics, and Asians/Pacific Islanders. This high death rate in the first two years following diagnosis was then followed by a unique and unexplained plateau or leveling off not seen in any other ethnic or racial group. During the 1990s, 15-29 year-old AI/ANs experienced more than twice the death rate of non-Hispanic whites. For the age group <15 years, AI/AN survival was worse than any other ethnic/racial group until approximately 3.5 years after diagnosis, at which point the survival rate met and subsequently paralleled the rate for African Americans/blacks. Overall, AI/ANs appear to experience the second worst cancer survival rates below 45 years of age.

Progress toward improving 1 and 5 year survival rates for 15-29 year-old cancer patients over time has occurred, but only fractionally as compared to older and younger age groups. Males fared far worse than females overall.

Finally, the authors contend that the patterns and trends observed in cancer incidence suggest the sporadic nature of cancer in 15-29 year-olds: "In general, there are relatively scant data to support either an environmental causation or an inherited predisposition to cancer in this age group. The vast majority of cases of cancer diagnosed before age 30 appear to be spontaneous and unrelated to either carcinogens in the environment or family cancer syndromes."

Editorial Comment

Fortunately, invasive malignancies are relatively rare in the pediatric age group. That being said, they are obviously among the most devastating set of conditions for our patients and their families. This report affords a valuable perspective on cancer epidemiology

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Hot Topics

Obstetrics

Cesarean delivery: Increased risk of postpartum maternal death versus vaginal delivery

RESULTS: After adjustment for potential confounders, the risk of postpartum death was 3.6 times higher after cesarean than after vaginal delivery (odds ratio 3.64 95% confidence interval 2.15–6.19). Both prepartum and intra-partum cesarean delivery were associated with a significantly increased risk. Cesarean delivery was associated with a significantly increased risk of maternal death from complications of anesthesia, puerperal infection, and venous thromboembolism. The risk of death from postpartum hemorrhage did not differ significantly between vaginal and cesarean deliveries.

CONCLUSION: Cesarean delivery is associated with an increased risk of postpartum maternal death. Knowledge of the causes of death associated with this excess risk informs contemporary discussion about cesarean delivery on request and should inform preventive strategies.

Deneux-Tharaux C, et al Postpartum Maternal Mortality and Cesarean Delivery. Obstet Gynecol. 2006 Sep;108(3):541-548.

Cesarean delivery in the first delivery is associated with increased cumulative costs

RESULTS: A total of 27,613 pregnancies satisfied inclusion and exclusion criteria. When cumulative costs by type of labor at first delivery were considered, induction of labor (\$7,220) was more costly than spontaneous onset of labor (\$6,919, $P=.006$). The cumulative costs of assisted vaginal delivery at first delivery (\$7,288) and cesarean delivery in labor at first delivery (\$9,524) were similar in magnitude and were higher than spontaneous vaginal delivery at first delivery ($P<.001$). Cesarean delivery in labor in the first delivery was the most costly type of delivery (\$9,524), and the differences in cost increased with increasing number of deliveries ($P<.05$).

CONCLUSION: Cesarean delivery in labor in the first delivery is associated with increased cumulative costs compared with other methods of delivery, regardless of the number or type of subsequent deliveries.

Allen VM et al Cumulative economic implications of initial method of delivery. Obstet Gynecol. 2006 Sep;108(3):549-55.

OB/GYN CCC Editorial

Deneux-Tharaux C, et al and Allen VM et al above have joined the expanding literature that has documented the downside of the now nearly 30 percent cesarean delivery rate. Here are recent additions to that growing body of literature. In the meantime, please continue to be an advocate for vaginal delivery in your AI/AN patients when possible.

Here is an excerpt from a recent ACOG Press Release on this topic:

Cesarean Delivery Associated with Increased Risk of Maternal Death from Blood Clots, Infection, Anesthesia

‘...Many developed countries, including the US and France, have seen a considerable rise in the number of cesareans performed each year (28% and 20% in 2003, respectively). Women today may view cesarean delivery as a relatively low-risk procedure and to request it for themselves, even though it may not be medically necessary. Though rates of maternal death in most developed countries are relatively low—US women have a 1 in 3,500 chance of pregnancy-related death—incidences of maternal mortality have not significantly decreased in the last two decades. These study results suggest that mode of delivery may be a modifiable risk factor, and in some cases, choosing vaginal delivery over non-medically indicated cesarean delivery could help lower maternal mortality rates....’

Gynecology

See and treat: HPV positive, HSIL cytology, and a high-grade impression at 2nd colposcopy

CONCLUSION: In the ALTS population, after the first colposcopic diagnosis of <CIN₂, clear risk stratification for CIN₃ outcomes was obtained among women with a subsequent HPV-positive test. Because absolute risk for histologic CIN₃ outcomes was high for women with HPV positive tests, HSIL cytology, and a high-grade impression at second colposcopy, it is worth considering whether this combination of findings might warrant immediate excisional therapy in some circumstances.

From Your Colleagues

Burt Attico, Phoenix

Congenital Anomalies Linked to NSAID Use in First Trimester

BACKGROUND: Many women take non-steroidal anti-inflammatory drugs (NSAIDs) during pregnancy but the risks for the infant remain controversial. We carried out a study to quantify the association between those women prescribed NSAIDs in early pregnancy and congenital anomalies.

CONCLUSIONS: Our study suggests that women prescribed NSAIDs during early pregnancy may be at a greater risk of having children with congenital anomalies, specifically cardiac septal defects

Ofori B, et al Risk of congenital anomalies in pregnant users of non-steroidal anti-inflammatory drugs: a nested case-control study. Birth Defects Res B Dev Reprod Toxicol. 2006 Aug 23

Walker JL, et al Predicting absolute risk of CIN3 during post-colposcopic follow-up: Results from the ASCUS-LSIL Triage Study (ALTS) *Am J Obstet Gynecol*. 2006 Aug;195(2):341-8

Activity Restriction After Pelvic Floor Surgery?

After having pelvic floor surgery, most women are advised not to lift more than 10 lb (4.5 kg) and to avoid exercise or heavy work. Weir and colleagues found little evidence in the research literature that such activity restrictions are associated with improved outcomes. They conducted experiments to assess the intra-abdominal pressures associated with lifting and other common activities in women differing in age, body habitus, and grip strength.

The researchers conclude that many activities that commonly are restricted following surgery have no greater effect on intra-abdominal pressure than normal daily activities. They call for additional research to clarify guidance given to patients after surgery. Weir LF, et al. *Postoperative activity restrictions. Any evidence? Obstet Gynecol February 2006;107:305-9.*

Child Health

Metformin Useful for Treating PCOS in Adolescents

Polycystic ovary syndrome (PCOS) is a common hormonal disorder in women that is characterized by excessive androgen and menstrual dysfunction. Originally believed to be a cosmetic and fertility problem, PCOS can increase risk of cardiovascular disease and diabetes mellitus. The cause of PCOS is not fully understood, but insulin resistance and hyperinsulinemia can increase androgen production in the ovaries and adrenal glands. Studies have found that weight loss and the use of insulin-sensitizing agents have improved clinical status and hyperinsulinemia, and reduced excessive androgens in women with the syndrome. However, these studies do not address PCOS in adolescents. Bridger and colleagues evaluated insulin-sensitizer (metformin [Glucophage]) use with healthy lifestyle counseling in adolescents with the disorder.

The authors conclude that metformin lowers testosterone levels and improves menstrual regularity in adolescent women with PCOS. They also note an improvement in HDL cholesterol but none in other lipid parameters. There is a trend toward improvement in insulin sensitivity in the metformin group, but long-term follow-up studies need to be performed to determine if it is significant.

Bridger T, et al. *Randomized placebo-controlled trial of metformin for adolescents with polycystic ovary syndrome. Arch Pediatr Adolesc Med March 2006;160:241-6.*

Chronic disease and Illness

Varenicline was significantly more efficacious for smoking cessation

CONTEXT: The alpha₄beta₂ nicotinic acetylcholine receptors (nAChRs) are linked to the reinforcing effects of nicotine and maintaining smoking behavior. Varenicline, a novel alpha₄beta₂

nAChR partial agonist, may be beneficial for smoking cessation.

CONCLUSION: Varenicline was significantly more efficacious than placebo for smoking cessation at all time points and significantly more efficacious than bupropion SR at the end of 12 weeks of drug treatment and at 24 weeks.

Gonzales D et al *Varenicline, an alpha₄beta₂ nicotinic acetylcholine receptor partial agonist, vs sustained-release bupropion and placebo for smoking cessation: a randomized controlled trial. JAMA. 2006 Jul 5;296(1):47-55.*

OB/GYN CCC Editorial

Varenicline for smoking cessation: Deterrent effect—definite promise, but no panacea

Varenicline has just been released to the public and may signify an advance as it both decreases the desire for nicotine and provides a deterrent effect.

First, by partially activating the α₂ nAChR, craving and withdrawal symptoms may be mitigated following abrupt cessation or reduction of nicotine consumption. Second, by occupying part of the receptors and blocking nicotine binding, a partial agonist may also act as a partial antagonist to reduce smoking satisfaction prior to quitting or following a slip or relapse.

In the above issue of JAMA, Gonzales and colleagues, Jorenby and colleagues, and Tonstad and colleagues report the results of 3 randomized trials on the efficacy of the nicotinic acetylcholine receptor partial agonist varenicline for achieving smoking cessation.

The JAMA Editorial points out: “It is important for clinicians to moderate some of the potential enthusiasm that is likely to occur as the result of the publication of these trials, FDA approval of the drug, and promotion by this manufacturer. On the one hand, these studies¹⁻³ demonstrate that varenicline is associated with higher smoking cessation rates than placebo and may produce better cessation rates than bupropion, a first-line-approved smoking cessation drug. Importantly, varenicline represents a third class of drug with probably a different mechanism of action than either nicotine replacement therapy or bupropion. On the other hand, varenicline definitely is not a panacea for smoking cessation. Many participants in these trials experienced adverse events, stopped taking their study medication before they should have, and discontinued participation in the studies. Importantly, the majority of participants in these 3 studies did not quit smoking even with varenicline.”

Treatobacco.net is another resource for those working on the treatment of tobacco dependence throughout the world. It presents authoritative evidence-based information about the treatment of tobacco dependence, under five headings:

Efficacy • Safety • Demographics and Health Effects
Policy • Health Economics

<http://www.treatobacco.net/home/home.cfm>

Klesges RC, et al *Varenicline for smoking cessation: definite promise, but no panacea. JAMA. 2006 Jul 5;296(1):94-5.*

Features

American Family Physician** Patient-Oriented Evidence that Matters (POEMS)*

Acupressure vs. Physical Therapy for Low Back Pain

CLINICAL QUESTION: Is acupressure more effective than physical therapy for chronic low back pain?

STUDY DESIGN: Randomized controlled trial (single-blinded)

SYNOPSIS: The Taiwanese researchers conducting this study enrolled 129 patients who attended an orthopedic clinic for low back pain for at least one month. Physical therapy could include pelvic manual traction, spinal manipulation, thermotherapy, infrared light therapy, electrical stimulation, or exercise therapy as directed by a physical therapist. Acupressure is significantly more effective than standard physical therapy modalities and

exercise at decreasing disability scores and pain in patients with chronic low back pain.

BOTTOM LINE: Acupressure is significantly more effective than standard physical therapy modalities and exercise at decreasing disability scores and pain in patients with chronic low back pain. (Level of Evidence: 1b)

Study Reference: Hsieh LL, et al. Treatment of low back pain by acupressure and physical therapy: randomized controlled trial. BMJ March 25, 2006;332:696-700.

American Family Physician. Kansas City: Aug 15, 2006. Vol. 74, Iss. 4; pg. 651

Menopause Management

Clonidine and Gabapentin Effective for Hot Flashes

STUDY QUESTION: Which nonhormonal therapies are effective in the management of menopausal hot flashes?

STUDY DESIGN: Meta-analysis (randomized controlled trials)

SYNOPSIS: Recent concerns about the adverse effects of hormonal therapy have increased interest in alternative treatments of menopausal hot flashes.

BOTTOM LINE: Evidence supports the nonhormonal treatment of menopausal hot flashes with paroxetine, clonidine, gabapentin, and soy isoflavone extract. The overall effect size of all nonhormonal treatments is less than that of estrogen. Treatment should be individualized according to symptom severity and risk profiles.

(Level of Evidence: 1a-)

Nelson HD, et al. Nonhormonal therapies for menopausal hot flashes: systematic review and meta-analysis. JAMA May 3, 2006;295:2057-71.

Estrogen Alone Does Not Increase Breast Cancer Risk

CLINICAL QUESTION: Does unopposed estrogen therapy in postmenopausal women with hysterectomy increase the risk of breast cancer?

STUDY DESIGN: Randomized controlled trial (double-blinded)

SYNOPSIS: Hormone therapy with estrogen and progesterone increases the risk of invasive breast cancer. The risk in postmenopausal women with hysterectomy who have been treated with estrogen alone is uncertain. As part of the Women's Health Initiative, investigators randomized (concealed allocation

assignment) 10,739 postmenopausal women, 50 to 79 years of age, who had undergone hysterectomy. The women received 0.625 mg per day of conjugated equine estrogen or placebo. Persons assessing outcomes remained blinded to treatment group assignment. Follow-up occurred for nearly 95 percent of the participants for a mean of 7.1 years.

Using intention-to-treat analysis, investigators observed non-significant reductions in invasive breast cancer and total breast cancer in women receiving conjugated equine estrogen. Significantly more women in this group had questionably abnormal mammography results (36.2 versus 28.1 percent in the placebo group over seven years), requiring further short-term evaluation.

BOTTOM LINE: Estrogen therapy alone does not increase the risk of breast cancer in postmenopausal women who have had a hysterectomy. Women receiving estrogen are more likely to require further testing because of questionably abnormal mammography results, which could lead to heightened anxiety and a reduced quality of life. The decision to use estrogen in postmenopausal women after hysterectomy should be individualized based on overall potential risks and benefits. Women most likely to benefit from estrogen therapy include those with disabling hot flashes and an increased risk of osteoporotic fractures. Treatment should be limited, whenever possible, to within the first five years after menopause. (Level of Evidence: 1b)

Stefanick ML, et al., for the WHI Investigators. Effects of conjugated equine estrogens on breast cancer and mammography screening in postmenopausal women with hysterectomy. JAMA April 12, 2006;295:1647-57.

American Family Physician. Kansas City: Aug 15, 2006. Vol. 74, Iss. 4; pg. 651,

Breastfeeding

Suzan Murphy, PIMC

Engorgement—

It only feels like it is going to last forever

New mothers might forget the pain of childbirth, but they usually do not forget the discomfort of engorgement. New moms describe engorgement as “having rock hard, huge breasts,” “being so full that the baby can’t latch,” “having pain all over, even into the back,” and generally a frustrating and difficult problem.

If engorgement occurs, it will be 2-5 days after birth. As hormones shift to support the new phase of lactation, colostrum transitions to mature milk, and the milk supply increases. If the baby is not drawing the milk off the breast every 2-3, the breasts can become congested. The congestion usually lasts a long 24-48 hours. Some moms will experience a low-grade fever (100 degrees).

Treatment for engorgement is:

- Re-assurance that the engorgement/swelling/congestion will calm down in 24-48 hours.
- Apply cold compresses to the breasts between feedings. Some moms report relief with applying cold, washed cabbage leaves to the breast, replacing them as they wilt. Research has not found clinical difference when cabbage is compared to other treatments such as cold packs. However, no harm has been found and cabbage may be more accessible to families.
- Use gentle heat while nursing. Warm packs are soothing and allow more milk to be released.
- If latching is not possible, hand express or use a pump to gently

express enough milk for the areola to soften and the baby to latch. If a hospital grade pump is available, use it. Using a department store pump or vigorously hand pumping can damage the nipple, aggravating an already difficult situation.

- Sometimes with the arrival of the mature milk, babies will change how they suck. This could be because the shape of the breast and/or nipple have changed – but it can mean a dysfunctional latch, sore nipples, and an unhappy dyad. So ask the mom, watch and help her make the sure the latch is still okay.
- Stress to the mom that breastfeeding or expressing milk about every 2 hours for the next 24 hours will help. Assure the mom that it will get better.
- Motrin/ibuprofen as an anti-inflammatory treatment helps also. It is generally considered safe to use with lactation.

Prevention will help. To keep engorgement from happening, encourage new families to breastfeed 8-12 times in 24 hours—that is about every 2-3 hours. Caution new families that letting the baby or mom sleep through feedings in the first 2-5 days can have miserable results.

Once the new family is past the first 5 days, profound engorgement goes away. The mom may notice that her breasts become softer as the weeks progress. Sometimes moms will fear that their milk supply is dwindling. It helps to assure the mom that her milk is still there, her body is becoming accustomed to it being there.

References: *Online*

Family Planning

Adolescent perception of sexual abstinence

Findings of confusion around the definition of sexual abstinence underscore the need for a clear operational definition of abstinence in research and programs. Sexual abstinence is an important component of adolescent sexually transmitted infection and pregnancy prevention. Despite high levels of public investment in “abstinence only” interventions, research is needed to more clearly define sexual abstinence, as well as the factors that influence adolescent decision-making around abstinence.

The authors found that

- Participants knew that abstinence had something to do with sex, but many were unsure of its exact meaning. However, although the term “abstinence” was misunderstood, the concept of choosing not to have sex was clear and relevant.
- Participants viewed abstinence as a natural stage of development: people are abstinent for some time during their lives and then transition to sexual activity when they feel “ready.” According

to participants, readiness was influenced by individual characteristics; relationship characteristics; and a balance of health, family, and social risks and benefits.

- Participants considered the transition from abstinence to sexual activity as an irreversible, life-changing decision.
- Age and sexual experience influenced how participants determined readiness for sexual activity.

Adolescents are likely to be best served by placing abstinence back within the framework of broader sexuality education. This would provide adolescents with the information and decision-making skills to evaluate relationships, develop communication within relationships, and accurately assess their own level of readiness.

Ott MA, Pfeiffer EJ, Fortenberry D. 2006. Perceptions of sexual abstinence among high-risk early and middle adolescents. Journal of Adolescent Health 39(2):192-197. Abstract available at

Midwives Corner

Lisa Allee, CNM

Postpartum Care: Still the neglected stepchild of perinatal services?

Borders, N, *After the Afterbirth: A Critical Review of Postpartum Health Relative to Method of Delivery Journal of Midwifery & Women's Health Vol 51 No 4 July/August 2006*

Noelle Borders, CNM, a recent UNM graduate did a mega-analysis of the literature on postpartum health, experience, and care. What she found overall was a dearth of good studies especially in this country, but in those available, mainly from the UK, Australia, New Zealand, and Scandinavia, she did find intriguing information about women's experience of postpartum. The vast majority (87-94%) of postpartum women report at least one health problem in the immediate (birth to 3 months) postpartum period. These include: backache, urinary stress incontinence, fecal incontinence, urinary frequency, depression and anxiety, hemorrhoids, extreme tiredness, frequent headaches, migraines, perineal pain, constipation, increased sweating, acne, hand numbness or tingling, dizziness, hot flashes, dyspareunia, decreased libido, and breast discomforts (lactating or not!). Many of these problems slowly resolve with time, but some worsen and new ones become identified. One fascinating trend is that perineal pain is reported at 25-30% at 0-3 months, 11% at 3-6 months and 21% at greater than 6 months. Two small studies tried to assess functional status at 6 weeks (when we conventionally call the postpartum over and done with?!!) and found that none of the mothers had resumed full functional status per

self reports. Another very important finding was that "women experience an array of symptoms, the majority of which they may never report to health care providers." Borders then looks at the effect of delivery method on postpartum health. The literature shows that women with a cesarean or assisted vaginal birth fare significantly worse than women who had a spontaneous vaginal birth. For example, women with an assisted vaginal birth had more perineal pain, constipation, hemorrhoids, break down of stitches, sexual problems, and fecal incontinence, although the last was not associated with vacuum assists. After cesarean section women had more bodily pain, backaches, and greatly increased risk of readmission for problems such as hemorrhage, uterine infection, wound complications, cardio-pulmonary and thromboembolic conditions, pelvic injury, genitourinary problems, etc. The much-touted-of-late protective effects of cesarean birth on urinary and fecal incontinence were not borne out. Fecal incontinence was less after cesarean births but did happen and the urinary incontinence protection was only in the immediate postpartum, was negated entirely if it was C-section number three or more and, actually, women who had cesareans were more likely to report other urinary problems by 6 months postpartum. Interestingly headaches and tiredness were not related to mode of delivery and, contrary to common beliefs, neither was depression. However, maternal satisfaction, fulfillment and distress/sense of feeling cheated were related to delivery mode. Spontaneous vaginal birth gave women the highest sense of fulfillment and satisfaction and the lowest lev-

Midwives Corner

Midwives applaud new false labor EMTALA regulations

Silver Spring, MD—The American College of Nurse-Midwives (ACNM), the nation's oldest women's health organization, commends the Centers for Medicare and Medicaid Services (CMS) for changes it makes today, to regulations governing the Emergency Medical Treatment and Labor Act (EMTALA), that highlight the important role of certified nurse-midwives (CNM) and certified midwives (CM), and helps to improve hospital efficiency with respect to discharging women who are not yet in labor.

Today, the CMS published its final rule (link below) addressing changes to the hospital inpatient payment rates for fiscal year 2007. As part of this final rule, it also addresses

the definition of 'labor' within the regulations that govern the EMTALA. The final rule changes existing regulations to revise the definition of 'labor' in §489.24(b) to state that:

"a woman experiencing contractions is in true labor unless a physician, certified nurse-midwife, or other qualified medical person acting within his or her scope of practice as defined in hospital medical staff bylaws and State law, certifies that, after a reasonable time of observation, the woman is in false labor."

The current regulation requires a physician to certify when a woman is in false labor. While not specifically named in the new regulation, CMs would also be covered by this new definition in that it identifies that other qualified personnel acting within their scope of practice may certify when a woman is in false labor. →

els of distress or sense of being cheated, while assisted vaginal births and C-sections were the exact opposite and these findings persisted after six months. From the literature, Borders makes it clear that the gold standard for optimal postpartum health is a spontaneous vaginal birth. Borders next tackles research and care—both are greatly lacking, especially in the United States. She calls for more research quoting the results of a study using focus groups where participants voluntarily asked “What is normal postpartum recovery?” and no one knew the answer. She also very nicely points out that just doing research is not enough—the information then needs to be shared with women so they better know what to expect postpartum and to clinicians so they can provide better care. As for care, she points out how abysmal the US standard of one visit at 6 weeks really is. She reports an amazing standard in England of 6-7 home visits by a midwife in the first 2 weeks, other visits as needed, and a check up at 6 to 8 weeks. Other models include: the WHO’s recommendation of visits at times of greatest need, i.e., 6 hours, 6 days, 6 weeks and 6 months; a study looked at customizing care to each woman’s response on a symptoms checklist and found lower rates of depression and higher satisfaction with care; but another study found no difference with simply adding a 1-week visit to the 6-week visit model. Borders calls for all of us “to improve postpartum care by experimenting with flexible ways of meeting women’s needs after the birth of a baby” and reminds us of the tremendously far reaching effects this improvement in postpartum care can have.

Editorial Comment: Lisa Allee, CNM

When I was in midwifery school more than 10 years ago the poor state of postpartum care in this country was decried and we were encouraged to do better! I read this article and realized not much has changed in the ensuing years. I felt a bit personally reassured that I had for a time fulfilled our postpartum professor’s dream when I had my own homebirth practice and I was able to provide home visits at 24 hours and 3-5 days and office visits at 2 and 6 weeks and frequently stayed in touch with women beyond that. The reality for us in IHS is drastically different, but I have reason for hope! Here at Chinle we have started offering 2 week postpartum visits and the response has been encouraging. Another big source of encouragement is Centering Pregnancy, which is sweeping through IHS. Many non-IHS Centering sites have found that women and families want to continue the groups past birth and so postpartum visits have been added and Centering Parenting (for the whole first year) has been born! As we embrace Centering in IHS let’s be sure to remember the neglected stepchild and include postpartum care! If you are not doing Centering and for the women not electing to do Centering, we also need to heed Borders call for innovative, flexible change in how we do postpartum care and support—home visits, phone calls, support group—dream big!

Link to article abstract:

www.ncbi.nlm.nih.gov/entrez/query.fcgi?CMD=search&DB=pubmed

Link to full article:

<http://linkinghub.elsevier.com/retrieve/pii/S1526952305005660>

➔ CMS states in the rule that the effect of this change would be to have a single, uniform policy on the personnel who are authorized to make a determination as to whether an individual has an emergency medical condition. The final rule takes effect October 1, 2006.

“This change demonstrates that the bureaucratic process can work,” stated Katherine Camacho Carr, CNM, PhD, president of the ACNM. “ACNM has been working with an EMTALA Technical Advisory Group and CMS officials for more than a year and a half to get this regulation modified. ACNM appreciates the thoughtful work CMS and the EMTALA TAG put into making this modification that will benefit the women CNMs and CMs serve.”

ACNM also wishes to express its appreciation to the American College of Obstetricians and Gynecologists for its support during the process. August 18, 2006

<http://a257.g.akamai.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/pdf/06-6692.pdf>

OB/GYN CCC Editorial

The changes above represent a major shift in the regulation on how ‘false labor’ can be triaged.

Kudos to ACNM and ACOG for their hard work on this. Each facility should re-evaluate their triage policies and procedures based on the new regulations.

Medical Mystery Tour

First trimester screening: How would you counsel this patient?

Let's review last week's case....

Ms. L. is a 40 y/o G1P0 at 9 weeks gestation (by a 6 week ultrasound) and is aware of her age-related risks for fetal aneuploidy. She inquires about the possibility of early screening.

Which ONE of the statements below is the most accurate way to counsel her:

- A Ultrasonic measurement of fetal nuchal translucency combined with biochemical tests between 11 and 13 weeks may detect close to 90% of chromosomally abnormal fetuses
- B Early trimester screening has a better detection rate, but a higher false positive rate, than Mid-trimester screening
- C Women who have first trimester screening that is negative will not need further testing

Answer

- A Ultrasonographic measurement of the fetal nuchal translucency combined with biochemical tests between 11 and 13 weeks may detect close to 90% of chromosomally abnormal fetuses Ms L. is likewise 40 years old and has the same age-related risks as Ms Walks Alone. First trimester screening between 11 and 13 weeks may be an option for her if you are able to refer her to a site where she can have nuchal translucency (NT) performed by a certified sonographer, and have free beta HCG and PAPP-A determinations done. Studies to date demonstrate that such testing will have an 85-89 % detection rate for fetal aneuploidy, if the NT is reliably measured. These detection rates and false positive rates are comparable, or better, than a second trimester strategy utilizing the 'quad screen' and high resolution ultrasound, and much better than 'triple testing'. Remember that second trimester screening for neural tube defects is still necessary since that issue will not be addressed by this testing. The important logistic issue is whether you have the resources available to provide accurate testing and appropriate follow up. If so, and if the patient requests it, this is certainly an appropriate strategy for this patient.

References Online

MFM Editorial—George Gilson, MFM, ANMC Do We Need to do MSAFP Testing after First Trimester Down Syndrome Screening?

A recent Fetal Medicine Foundation newsletter (Vol.2, Issue 3, July 2006)* discussed this topic and reached some interesting conclusions that may be pertinent to our practices. The current standard of care in the United States has been in place since the early 1980's, and is to offer maternal serum alpha fetoprotein (MSAFP) testing to all pregnant women in order to screen for fetal open neural tube defects (ONTD), including anencephaly and meningomyelocele. Other important abnormalities suggested by an elevated MSAFP are the abdominal wall defects, including gastroschisis and omphalocele. Most MSAFP determinations are done between 15 and 20 weeks gestation, and are now part of either the "triple" or "quad" screens, which are also done to

screen for fetal Down syndrome (DS). Unfortunately, MSAFP has less than optimal sensitivity and specificity for ONTD, with a detection rate of about 80% (MSAFP >2.5 MoM) at a fixed false positive rate of 5%.

Second trimester ultrasound on the other hand has sensitivity and specificity for ONTD that are >95%. The diagnosis of anencephaly is usually immediate. The diagnosis of spinal defects is also excellent. In addition to vertebral column defects, the cranial findings of an abnormal cerebellum, the "banana" sign (Chiari type II malformation), and the resultant cranial deformity of the "lemon" sign, have been well described for several decades. Fetal abdominal wall defects are usually also easily diagnosed with ultrasound. The more rare fetal problems, such as the genitourinary abnormalities, bowel obstruction, and teratomas, which are also associated with elevated MSAFP, are also usually apparent on ultrasound.

If your patient has chosen first trimester "combined" screening for Down syndrome (measurement of the fetal nuchal translucency (NT) and determinations of pregnancy associated plasma protein A [PAPP-A] and free beta HCG between 11 and 13 weeks), does she also need to undergo MSAFP screening in the second trimester? Does she need a second trimester anatomic survey to look for the abnormalities detailed above? Ultrasound at 11-13 weeks should easily be able to diagnose anencephaly, as well as abdominal wall defects. At the present time however, there are no studies that have looked at the accuracy of screening for spinal defects at this gestational age.

In our system in Alaska, those women who have had negative first trimester screening for fetal DS receive a second trimester sonographic anatomic survey, and are thus screened for ONTD with the modality with the best detection rate. If a woman has had a negative first trimester screen, we have elected not to do "integrated" DS screening with a quad screen in the second trimester, and thus we do not get an MSAFP. Women who present after 13 weeks can elect multiple marker screening, with MSAFP, and may also require second trimester ultrasound as indicated. However, this scheme may not be most cost-effective in your setting, especially if "level II" ultrasound services are not readily available. Likewise, remember that ACOG guidelines continue to recommend MSAFP screening for women who have had first trimester screening, despite the above evidence. As this is a continuously evolving field, remember to "stay tuned for further details...."

References online

OB/GYN CCC Editorial

For more background on this and other Prenatal genetic screening questions, please go to this free CME module which is also just a great resource

Prenatal genetic screening: Serum and ultrasound

www.ihs.gov/MedicalPrograms/MCH/M/TM01.cfm

ACOG

Human Papillomavirus Vaccination

ABSTRACT: The U.S. Food and Drug Administration recently approved a quadrivalent human papillomavirus (HPV) vaccine for females aged 9–26 years. The American College of Obstetricians and Gynecologists recommends the vaccination of females in this age group. The Advisory Committee on Immunization Practices has recommended that the vaccination routinely be given to girls when they are 11 or 12 years old. Although obstetrician–gynecologists are not likely to care for many girls in this initial vaccination target group, they are critical to the widespread use of the vaccine for females aged 13–26 years. The quadrivalent HPV vaccine is most effective if given before any exposure to HPV infection, but sexually active women can receive and benefit from the vaccination. Vaccination with the quadrivalent HPV vaccine is not recommended for pregnant women. It can be provided to women who are breastfeeding. The need for booster vaccination after 5 years has not been established. (see Harper et al below) Health care providers are encouraged to discuss with their patients the benefits and limitations of the quadrivalent HPV vaccine and the need for continued routine cervical cytology screening.

Human papillomavirus vaccination. ACOG Committee Opinion

No. 344. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2006;108:699–705.

HPV Vaccine Shows Promise, at Least in Short Term

Initial studies of vaccines against HPV 16 and 18 indicate that 90 percent of infections can be prevented, but long-term immunogenicity is required to prevent malignant change. Harper and colleagues studied participants in a randomized controlled trial of HPV vaccines to determine the long-term effectiveness and safety of these vaccines.

The authors conclude that the immunization provided effective protection against HPV-16 and HPV-18 infections. The degree of protection exceeded expectations and may be attributed to additional protection against other oncogenic HPV types such as HPV-45 and HPV-31. The vaccine protection appears to last for four to five years.

Harper DM, et al. Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomised control trial. Lancet April 15, 2006;367:1247-55.

International Health Update

Claire Wendland, Madison, WI

Health care and indigenous peoples: the other side of the planet

New Zealand's indigenous minority people, the Maori, have substantially worse health indicators than the majority population, mostly descendants of British colonizers or later migrants. The authors of this article questioned whether part of the problem might be a lesser quality of hospital care for Maori patients. (New Zealand's health system is publicly funded; hospital care is both free of charge and reasonably evenly geographically distributed; 90% of the population lives within an hour's drive of a hospital).

A team of research assistants reviewed records of nearly 6000 admissions randomly selected from a stratified sample of six tertiary care hospitals, four secondary hospitals with 300 beds or more, and four secondary hospitals with less than 300 beds. Outpatient, psychiatric, and rehabilitation admissions were excluded. They identified adverse events (any unintended injury resulting in disability that could be considered at least in part iatrogenic) and used multiple logistic regression to assess the likelihood of an adverse event against gender, socioeconomic status, indigeneity status, and age. Age-adjusted rates of preventable adverse events were found to be significantly higher for Maori patients, especially for those who were over 45 or hospital-

ized for a musculoskeletal or digestive problem. (Interestingly, Maori patients had a significantly *lower* risk of adverse outcomes related to surgery or obstetrical admissions, data the authors present in tables but do not discuss.) Socioeconomic status did not affect adverse events.

Though the authors concluded that a higher likelihood of suboptimal care might contribute to the poor health indicators of New Zealand's Maori population, their study raises more questions than it answers. The utility of chart audits for assessing quality of care has been questioned, for instance; as the authors acknowledge, preventable adverse events are only one small measure of overall health system access and process issues that may be important in indigenous health. Nonetheless, the study is an interesting contribution to a surprisingly small body of research on health systems issues for indigenous people.

Davis P. et al. Quality of hospital care for Maori patients in New Zealand: retrospective cross-sectional assessment. The Lancet 367:1920-5, June 10, 2006

Editorial Note:

You can access both of these articles at www.thelancet.com (requires free registration)

Navajo News

Jean Howe, Chinle

Implanon-A single rod contraceptive implant...

On July 17, 2006 the FDA approved a new single rod contraceptive implant for use in the United States. Implanon consists of a 40 x 2.0 mm (about the size of a matchstick) rod of ethylene vinyl acetate (EVA) and etonogestrel (ENG). The total dose of 68mg of ENG is initially released at a rate of 60 micrograms per day, gradually declining to 30 micrograms per day over 3 years of use. Implanon has been sold in over 30 countries worldwide and has been used by more than 2.5 million women since 1998. This is the first contraceptive implant to be marketed in the U.S. since Norplant, a six-rod system, was withdrawn from the market in 2000. Because it is a single rod system, insertion and removal are simplified; one study (Zheng) comparing Implanon and Norplant demonstrated insertion times of 0.61 minutes vs. 3.90 minutes and removal times of 2.18 minutes vs. 11.25 minutes respectively.

Contraceptive efficacy is achieved primarily by suppression of ovulation by the effect of etonogestrel on the hypothalamic-pituitary-ovarian axis. A secondary effect is thickening of the cervical mucus, making it less penetrable to sperm. Additionally, the endometrial lining is rendered less favorable for implantation. Overall efficacy is cited as >99%, with most failures in study populations occurring at the time of insertion or removal. The U.S. study populations did not include women over 130% of their ideal weight; it is unclear if efficacy is reduced in obese women.

As with most hormonal contraception, changes in bleeding patterns are likely and are the most frequent reason for patient dissatisfaction and for requests for early removal. There is no single bleeding pattern to be anticipated and some women experience amenorrhea while others have more frequent bleeding. One U.S. study (Funk, et al.) followed 330 women using Implanon for 474 women-years of exposure. Amenorrhea rates from month 4 onwards ranged from 14 to 20%. Of women enrolled in the study population, withdrawal was attributed to the following

side effects: bleeding pattern changes (13%), emotional lability (6.1%), weight increase (3.3%), depression (2.4%), and acne (1.5%). To improve patient tolerance, extensive counseling prior to selection of this method will be essential.

Organon, the manufacturer of Implanon, is sponsoring trainings for clinicians on insertion and removal techniques. Implanon will not be dispensed to providers who have not completed the training. Training sessions can be arranged by calling 1-877-IMPLANON and are expected to start this fall. Organon states that Implanon will be available in the fourth quarter of this year; no pricing has been established yet but an Organon representative states that the price will be "no more than the cost of a 3 year supply of combined oral contraceptive pills". Similarly, information on federal pricing has not yet been released.

Implanon is likely to be a useful addition to the contraceptive options available in the United States. Women selecting this method must be carefully counseled about bleeding irregularities to improve tolerance. Addition to the formulary at Indian Health Service facilities is likely to be influenced by cost; availability of federal pricing will be important in making this method widely available throughout IHS.

The manufacturer's website:

www.IMPLANON-USA.com

The patient information:

www.implanon-usa.com/authfiles/images/543_174732.pdf

The prescribing information:

www.implanon-usa.com/authfiles/images/543_174733.pdf

Funk S, et al. Safety and efficacy of Implanon, a single-rod implantable contraceptive containing etonogestrel. Contraception. 2005. 71;319-326.

Zheng SR, et al. A randomized multicenter study comparing the efficacy and bleeding pattern of a single-rod (Implanon) and a six-capsule (Norplant) hormonal contraceptive implant. Contraception. 1999. 60;1-8.

Osteoporosis

Calcium during pregnancy: Higher maternal Vitamin D/folate and newborn Weight/mineralization

RESULTS: All mothers were similar in weight, height, and BP. Mothers in the orange juice plus calcium and dairy groups had higher intakes of Ca (1,472 mg and 1,771 mg) than controls (862 mg). One half of the mothers in the orange juice plus calcium group required Ca tablets. Mothers in the dairy group had higher intakes of P, D, and Mg, higher serum folate and D, and higher cord D levels. Mothers in the orange juice plus calcium group had higher serum P but lower serum folate and D. Infants (3,517±273 g) in the dairy group were heavier than infants in the

control (3,277±177 g) and orange juice plus calcium (3,292±165 g) groups. Infants in the dairy group had higher total body calcium than control infants.

CONCLUSION: Calcium diet supplemented with dairy products during adolescent pregnancy resulted in higher maternal vitamin D and folate serum levels and higher newborn weight and bone mineralization compared with controls.

Chan GM, et al Effects of dietary calcium intervention on adolescent mothers and newborns: a randomized controlled trial. Obstet Gynecol. 2006 Sep;108(3):565-71.

STD Corner

Lori de Ravello, National IHS STD Program

Sexual Education/HIV Education and youth in the developing world

Here are three reports from a recent WHO series on Sexual Education / HIV Education and youth in the developing world. I think much of it is relevant for reservation communities. All three reports (and more) can be downloaded from the full WHO report at this site below.*

Effectiveness of sex education and HIV education interventions in schools

CONCLUSIONS: A large majority of school-based sex education and HIV education interventions reduced reported risky sexual behaviours in developing countries. The curriculum-based interventions having the characteristics of effective interventions in the developed and developing world should be implemented more widely. All types of school-based interventions need additional rigorous evaluation, and more rigorous evaluations of peer-led and non-curriculum-based interventions are necessary before they can be widely recommended.

Kirby D, Obasi A, Laris BA. The effectiveness of sex education and HIV education interventions in schools in developing countries. World Health Organ Tech Rep Ser. 2006;938:103-50; discussion 317-41

Effectiveness of community interventions targeting HIV and AIDS prevention at youth

CONCLUSIONS: Considerable creativity, ingenuity and commitment is demonstrated in designing and delivering HIV interventions but there is a paucity of adequate evidence of their effectiveness. This precludes identification of the types of interventions that actually produce the targeted changes. It is essential that governments and donor agencies invest in high quality process and outcome evaluations and cost-benefit analyses so that effective interventions can be identified and promoted.

Maticka-Tyndale E, Brouillard-Coyle C. The effectiveness of community interventions targeting HIV and AIDS prevention at young people in developing countries. World Health Organ Tech Rep Ser. 2006;938:243-85; discussion 317-41

Effectiveness of mass media in changing HIV/AIDS-related behaviour among youth

CONCLUSIONS: We found that mass media programmes can influence HIV-related outcomes among young people, although not on every variable or in every campaign. Campaigns that include television require the highest threshold of evidence, yet they also yield the strongest evidence of effects. This suggests that comprehensive mass media programmes are valuable.

Bertrand JT, Anhang R. The effectiveness of mass media in changing HIV/AIDS-related behaviour among young people in developing countries. World Health Organ Tech Rep Ser. 2006;938:205-41; discussion 317-41

*Full WHO report

www.who.int/child-adolescent-health/New_Publications/ADH/TRS/ISBN_92_4_120938_0.pdf

Other Sexually Transmitted Diseases Treatment Guidelines, 2006

These guidelines for the treatment of patients who have STDs were developed by CDC after consultation with a group of professionals knowledgeable in the field of STDs. Physicians and other health-care providers play a critical role in preventing and treating STDs, and these guidelines are intended to assist with that effort.

www.cdc.gov/mmwr/preview/mmwrhtml/rr5511a1.htm

MCH Alert

Adolescents' Use of Contraception

Trends and Recent Estimates: Contraceptive Use Among U.S. Teens focuses on trends and characteristics of contraceptive use among adolescents in the United States, including contraceptive use at first sex and most recent sex, as well as specific method used. The research brief, published by Child Trends, presents an analysis of recently released nationally representative data from a survey of never-married adolescents ages 15-19. Patterns of adolescent contraceptive use are examined by gender, race and ethnicity, and age. A summary and a discussion of policy implications are also included.

www.childtrends.org/Files/ContraceptivesRB.pdf

Perinatology Picks

George Gilson, MFM, ANMC

How important is maternal intrapartum glucose to neonatal hypoglycemia?

Review of the Literature and Summary of the Evidence

SUMMARY: 6 of the 7 studies of maternal intra-partum glycemic control (total N=660) demonstrate a lower incidence of neonatal hypoglycemia in women who were euglycemic during labor. Surprisingly, neonatal hypoglycemia was not necessarily correlated with maternal antepartum glycemic control.

1 Anderson O, et al. Influence of maternal plasma glucose concentration at delivery on the risk of hypoglycaemia in infants of insulin-dependent diabetic mothers. *Acta Paediatr Scand* 1985; 74:268-73.

N=53 infants of diabetic mothers. 20.8% incidence of neonatal hypoglycemia. None of the IDMs became hypoglycemic if the maternal glucose at delivery was <7.1 mmol/L (128 mg/dL). Infants with hypoglycemia had elevated cord blood insulin levels. **CONCLUSION:** A major factor in neonatal hypoglycemia in IDM is the maternal plasma glucose concentration at the time of delivery.

2 Lean ME et al. Insulin management during labour and delivery in mothers with diabetes. *Diab Med* 1990; 7: 162-4.

N=25 insulin dependent diabetic women. Blood glucose attempted to be maintained at <6.0 mmol/L (113 mg/dL) for 24 h prior to delivery. Neonatal hypoglycemia (<2.0 mmol/L [<36 mg/dL]) occurred in 1 infant (4%).

CONCLUSION: Neonatal blood sugar correlated with maternal blood glucose at delivery.

3 Njenga E et al. Five year audit of peripartum blood glucose control in type 1 diabetic patients. *Diab Med* 1992; 9:567-70.

N=37 type 1 diabetic women. Glucose-insulin drip was instituted the morning labor was induced; target glucose of 3-6 mmol/L (54-108 mg/dL). There was a 19% incidence of neonatal hypoglycemia (<2.2 mmol/L [<40 mg/dL]), but 4 of these infants' mothers had been given dextrose boluses for maternal hypoglycemia.

CONCLUSION: Less stringent intra-partum blood glucose control may be appropriate.

4 Curet LB et al. Effect of antepartum and intrapartum maternal blood glucose levels on incidence of neonatal hypoglycemia. *J Perinatol* 1997; 17: 113-5.

*(this is the UNM study, of which I am a co-author, and which has the largest "n"...)

N=233 pregnant insulin-requiring diabetic women. Intra-partum glucose and insulin drips were begun at the time of induction of labor to try to maintain plasma glucose <100 mg/dL. The incidence of neonatal hypoglycemia was 10% in women who achieved this goal (mean IP glucose 84 mg/dL), and 43% in those women who didn't (mean IP glucose 107 mg/dL, $p<.05$), even if antepartum control had been suboptimal.

CONCLUSION: Even in the presence of poor antepartum diabetic control, tight regulation of the intrapartum plasma glucose levels will significantly reduce the incidence of neonatal hypoglycemia.

5 Carron-Brown S, et al. Effect of management policy upon 120 type 1 diabetic pregnancies: Policy decisions in practice. *Diab Med* 1999; 16:573-8.

N=80 type 1 pregnant diabetic women in period 1 (tight control) compared to 40 women in period 2 (less stringent control). In the "less stringent" study period, there was a 47% incidence of neonatal hypoglycemia. However, if the maternal blood glucose was maintained between 4-7 mmol/L (72-126 mg/dL) during labor, there was only 1 infant who had hypoglycemia. **CONCLUSION:** Control of hyperglycemia during labor results in reduced newborn hypoglycemia.

6 Balsells M, et al. Gestational diabetes mellitus: Metabolic control during labor. *Diab Nutr Metab* 2000; 13:257-62.

N=85 women with GDM, 54 on insulin, who received intrapartum glucose and insulin infusions. Target capillary blood glucose (CBG) of 2.8-6.9 mmol/L (50-124 mg/dL) was obtained in 83%. In several logistic regression models, CBG during labor was predictive of neonatal hypoglycemia.

CONCLUSION: Insulin requirements during labor are unrelated to therapy during pregnancy, and high CBG during labor increases the risk of neonatal hypoglycemia.

7 Taylor R, et al. Clinical outcomes of pregnancy in women with type 1 diabetes. *Obstet Gynecol* 2002; 99:537-41.

N=107 type 1 diabetic women who received glucose and insulin infusions during induction of labor. Mean maternal blood glucose in labor was 6.3 mmol/L (113 mg/dL, range 72-153 mg/dL). Neonatal hypoglycemia (<2.5 mmol/L [<45 mg/dL]) occurred in 17% of infants, all of whose mothers had a mean glucose >144 mg/dL. There was no correlation between neonatal blood glucose and maternal glycemic control during pregnancy as assessed by HbA1C.

U Neonatal hypoglycemia correlates with maternal hyperglycemia in labor.

(There is no Cochrane review of this topic.)

(Plan B, continued from page 1)

Why a 'Catch-22'?

As drugs develops 'over the counter' status many Indian Health pharmacies have been known to drop the drug from their formulary for cost and space reasons. So if it had been a complete change to OTC status, many of our more cash strapped patients would actually have less access to Plan B as it may have been removed from the formulary and that particular

patient may not have had the funds to buy it OTC.

Ironically, the fact that a prescription is still required for this particular product for women less than 18 yo will actually preserve Plan B's place on your facility's formulary. I would urge you to remind your P / T Committee of that requirement, so that Plan B stays on formulary at your facility.

(IHS Child Health Notes, continued from page 3)

in young adults.

The authors report incidence rates for invasive malignancies among 15-29 year-old AI/ANs to be the lowest of any ethnic/racial group. On the one hand, that American Indian/Native Alaska young adults as a group seem to be somehow protected from malignancy is encouraging. However, I don't buy it! It is well known and has been amply reported that racial misclassification occurs frequently among individuals of AI/AN heritage. This racial misclassification often results in an underestimate of disease burden. The methods employed by the authors of this report are highly susceptible to such errors in racial classification. In fact, SEER data and other disease registries have been extensively criticized on this point. Additional inaccuracies arise when trying to lump together a highly diverse ethnic/racial group such as AI/AN.

This report also suggests that AI/AN groups tend to have worse cancer survival as compared to other ethnic/racial categories. True disparities in cancer survival for AI/AN populations do appear to exist, and have been reported in a number of studies employing a variety of research methodologies. I cannot definitively say that I understand the exact cause of these disparities, but I would wager a guess that it has something to do with the source of most of the health disparities afflicting vulnerable populations the world over: socially imposed inequities and injustices in exposure and in access to resources. And so, the struggle continues.

Additional Reading

Measuring the health status gap for American Indians/Alaska Natives: getting closer to the truth. *Am J Public Health.* 2005 May;95(5):838-43.
Childhood cancer among Alaska Natives.

Pediatrics. 2003 Nov;112(5):e396.

Improving American Indian Cancer Data in the Washington State Cancer Registry using linkages with the Indian Health Service and Tribal Records. *Cancer.* 1996 Oct 1;78(7 Suppl):1564-8.

Announcements from the AAP Indian Health Special Interest Group—Sunnah Kim, MS

AAP Committee on Native American Child Health Receives Contribution

The AAP Committee on Native American Child Health (CONACH) recently received notification of a financial contribution from the estate of Demaree Low Jackson. Little is known about Ms Jackson, other than the fact that she was born in Nevada, and that her father worked very hard on behalf of Native American populations in Nevada many years ago, particularly related to education for children.

The CONACH will receive approximately \$100,000 from Ms Jackson's estate. Members of the CONACH will be meeting in September 2006 to discuss plans for utilizing these funds. The CONACH hopes to maximize these funds to make a significant impact on the health of American Indian and Alaskan Native (AI/AN) children.

We welcome your suggestions on programs that could be set up by the CONACH. Please submit your ideas to indianhealth@aap.org.

Your Opinion Matters!

We are very interested in hearing your opinions about the Indian Health Special Interest Group. Please take a moment to complete a brief on-line survey:

www.surveymonkey.com/s.asp?u=339182157349

We greatly appreciate your help!

Alaska State Diabetes Program Barbara Stillwater

Weight Loss Should be the Primary Intervention for Risk of Diabetes

In a randomized trial with 1079 participants, for over 3 years it was found that for every 2 pounds of weight loss there was a 16% reduction in risk.

With the increasing prevalence of overweight and adoption of a Western lifestyle, many populations are at risk of developing diabetes and may be reasonable candidates for a prevention intervention like that of the DPP. Weight loss, largely determined by changes in diet and exercise, is the primary factor resulting in reduced diabetes incidence among those in the ILS group. An increase in physical activity helps sustain weight loss and independently reduces diabetes risk among those who do not lose weight. Interventions to reduce the incidence of diabetes should aim at weight loss as the primary determinant of success.

Hamman RF, et al Effect of weight loss with lifestyle intervention on risk of diabetes. *Diabetes Care* 29: 2102-2107.

SAVE THE DATES

Best Practices and GPRA Tracking

- Nov 1–2, 2006
- Sacramento, CA
- California IHS Area Office, Contact:
Elaine.brinn@ihs.gov
- www.ihs.gov/MedicalPrograms/MCH/F/documents/BestPracticesFlyer1.pdf

22nd Annual Midwinter Indian Health OB/PEDS Conference

- For providers caring for Native women and children
- January 26–26, 2007
- Telluride, CO
- Contact Alan Waxman at:
awaxman@salud.unm.edu

2nd International Meeting on Indigenous Child Health

- April 20–22, 2007
- Montreal, Quebec, Canada
- Solutions, not Problems
- Joint meeting of IHS, AAP-CONACH, First Nations and several other stakeholders
- www.aap.org/nach/2InternationalMeeting.htm

2007 Indian Health MCH and Women's Health National Conference

- August 15–17, 2007
- Albuquerque, NM
- THE place to be for anyone involved in care of AI/AN women, children
- Internationally recognized speakers
- Save the dates. Details to follow
- 11 months away and counting
- Want a topic discussed? Contact:
nmurphy@scf.cc

Abstract of the Month

- FDA Approves OTC Access for Plan B for 18 and Older:
- A 'Catch-22' for AI/AN patients?

IHS Child Health Notes

- Intake of sugar-sweetened beverages and weight gain: a systematic review.
- Obesity—the new frontier of public health law.
- Cancer in 15- to 29-year-olds by primary site.

Hot Topics

- Obstetrics—Cesarean delivery: Increased risk of postpartum maternal death versus vaginal delivery; increased cumulative costs; increased Risk of Maternal Death from Blood Clots, Infection, Anesthesia
- Gynecology—See and treat: HPV positive, HSIL cytology, and a high-grade impression at 2nd colposcopy
- Child Health—Metformin Useful for Treating PCOS in Adolescents
- Chronic disease and Illness—Varenicline was significantly more efficacious for smoking cessation

Features

- American Family Physician—Acupressure vs. Physical Therapy for Low Back Pain
- ACOG—Human Papillomavirus Vaccination
- Breastfeeding—Engorgement, It only feels like it is going to last forever
- Family Planning—Adolescent perception of sexual abstinence
- MCH Alert—Adolescents' Use of Contraception
- Medical Mystery Tour—First trimester screening: How would you counsel this patient?
- Menopause Management—Clonidine and Gabapentin Effective for Hot Flashes
- Midwives Corner —Postpartum Care: Still the neglected stepchild of perinatal services?
- Osteoporosis—Calcium during pregnancy: Higher maternal Vitamin D/folate and newborn Weight/mineralization
- Perinatology Picks —How important is maternal intratpartum glucose to neonatal hypoglycemia?
- STD Corner—Sexual Education/HIV Education and youth in the developing world

Neil Murphy, MD
PCC-WH
4320 Diplomacy Drive
Anchorage, AK 99508

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